

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 2600 E

Product name(s): PENSHUI

Chemical active substances:

Pendimethalin, 455 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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Version history

When	What
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March 2022	Applicant update
April 2022	Final version after Commenting period process

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPS

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I**	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	CEU	Winter cereals (wheat, barley, rye, oats, triticale)	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-400									
2	CEU	Winter cereals (wheat, barley, rye, oats, triticale)	F	Broadleaved and grass weeds	Spray	Post emergence BBCH 10-13	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-400									
3	CEU	Maize	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-600									
4	CEU	Maize	F	Broadleaved and grass weeds	Spray	Post emergence BBCH 10-13	a) 1 b) 1	NA	a) 2.5-3.5 b) 2.5-3.5	a) 1.137-1.59 b) 1.137-1.59	200-600									
5	CEU	Pome fruits (apple, pear)	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09 applications between rows	a) 1 b) 1	NA	a) 3.5 b) 2.5	a) 1.59 b) 1.59	200-600		After harvest and before emergence next season							
6	CEU	Stone fruits (peach, apricot, plum, nectarine, cherry)	F	Broadleaved and grass weeds	Spray	Pre emergence BBCH 00-09 applications between rows	a) 1 b) 1	NA	a) 3.5 b) 3.5	a) 1.59 b) 1.59	200-600		After harvest and before emergence next season							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
Minor uses according to Article 51 (zonal uses)																				
Minor uses according to Article 51 (interzonal uses)																				

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

- | | | |
|-----------------------|--|--|
| Remarks table: | <p>(1) Numeration necessary to allow references</p> <p>(2) Use official codes/nomenclatures of EU</p> <p>(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application</p> <p>(5) Scientific names <u>and</u> EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named</p> <p>(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</p> | <p>(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(8) The maximum number of application possible under practical conditions of use must be provided</p> <p>(9) Minimum interval (in days) between applications of the same product.</p> <p>(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products</p> <p>(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</p> <p>(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.</p> <p>(13) PHI - minimum pre-harvest interval</p> <p>(14) Remarks may include: Extent of use/economic importance/restrictions</p> |
|-----------------------|--|--|

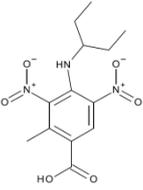
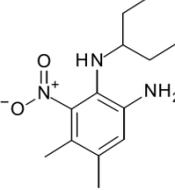
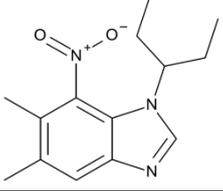
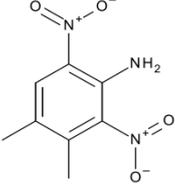
9.1.1 Overall conclusions

zRMS comments:

This document is based on the information provided by Applicant and reflects the Applicant's opinion. Clarifications and conclusions of the zRMS are presented in the commenting boxes Amendments/corrections by zRMS are marked in blue.

The zRMS has focused the review on the elements which are crucial for the risk assessment and decision-making; hence, minor errors of no importance for the overall conclusion, or the specific phrasing of the text may not have been commented upon.

9.1.1.1 Table 9.1-3 Metabolites of Pendimethalin

9.1.1.2 Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
M455H001	311.1		Soil: 6.9 % Water/sediment: 0.00001 %	Yes, for soil and water
P48 (M455H033)	251.3		Soil: 25.9 % Water/sediment: 12.1 %	Yes, for soil and water
P36 (M455H029; M12)	261.3		Soil: 0.00001% Water/sediment: 23.4 %	Yes, for water
2,6-dinitro-3,4-dimethylaniline (aqueous photolysis metabolite) (M455H032)	211.2		Soil: 0.00001% Water/sediment: 14.2 %	Yes, for water

9.1.1.3 Effects on birds (KCP 10.1.1), The risk assessment shows that there is no acute risk for birds after exposure to Pendimethalin 45.5% CS.

Most of the crops failed at Tier I for long-term exposure. The refinement of the chronic endpoint showed an acceptable long-term risk for birds except for cereals, maize, pulses and leafy vegetables. Further refinement of foliar DT₅₀ showed an acceptable long-term risk for birds.

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating birds. The risk of secondary poisoning to earthworm eating birds was found acceptable after refinement.

9.1.1.4 Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

The risk assessment shows that there is no acute risk for birds after exposure to Pendimethalin 45.5% CS. Most of the crops failed at Tier I for long-term exposure. The refinement of the chronic endpoint showed an acceptable long-term risk for birds except for cereals, maize, pulses and leafy vegetables. Further refinement of foliar DT₅₀ showed an acceptable long-term risk for birds.

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating birds. The risk of secondary poisoning to earthworm eating birds was found acceptable after refinement.

The risk assessment shows that there is no acute risk for mammals after exposure to Pendimethalin 45.5% CS. No long-term risk was observed for mammals in bare soil and legume forage whereas for all the crops risk was observed and further assessment was needed. After the refinement of the chronic endpoint there was still risk for vole in maize, orchards, bush and cane fruit, vineyard and fruiting vegetables and vineyard, but further refinement of foliar DT₅₀ an acceptable long-term risk for mammals was obtained.

~~If no refinement of the BB-agreed endpoint is done, The refinement of other parameters (e.g. foliar DT₅₀ (dicot plants, PT, PD and weight of evidence) showed and acceptable long-term risk for mammals – unacceptable long-term risk for mammals for rabbit for cereals, for brown hare in maize (post emergence) and for vole in orchards, bush and cane fruits and vineyards. Further refinement is needed.~~

For wood mouse the TER_{LT} values were slight below 5 (4.57) indicating needs for further refinement.

In zRMS's opinion taking into account that the default values of PT and DT₅₀ = 10 days were used and considering that trigger value is only slight below trigger of 5 the risk can be considered as an acceptable for this species. Additionally, it should be noted that DT₅₀ for pendimethalin seems to be less than 10 days for winter cereals/weeds.

However, there are not sufficiently data to provided quantitative risk assessment and WoE approach may be used at MSs level, if relevant.

~~For only pre-emergence application (BBCH<10) for arable crops the risk is considered as acceptable.~~

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating mammals. The risk of secondary poisoning to earthworm eating mammals was found acceptable after refinement.

9.1.1.5 Effects on aquatic organisms (KCP 10.2)

For the intended uses, calculated PEC/RAC ratios for metabolites showed an acceptable risk for aquatic organisms after Step 1-3 scenarios.

Calculated PEC/RAC ratios for the formulation PENSHUI did indicate an acceptable risk for aquatic organisms when the following risk mitigation measures are considered: 5 m no spray buffer zone or no spray buffer zone + 50% drift reducing nozzles.

Calculated PEC/RAC ratios for Pendimethalin did indicate and acceptable risk for aquatic organisms when the following risk mitigation measures are considered:

If the RAC of 0.93 µg a.s./L is considered acceptable for the higher tier refinement, PEC/RAC ratios for Pendimethalin did indicate an acceptable risk for aquatic organisms when the following risk mitigation measures are considered:

- Winter oilseed rape (455 g/ha): 10m no spray buffer zone + 10m vegetative strip or 5m no spray

buffer zone + 5m vegetative strip + 50% nozzle reduction

- Sunflower, soybean, lupine, strawberry, winter cereals (post-emergence 1 x 1137 g/ha), beans (1x1137 g/ha), carrots, parsley, parsnip and fennel (1x1137 g/ha), maize (1x1137 g/ha post-emergence): 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction
- Winter cereals (pre-emergence 1 x 1590 g/ha), maize (post-emergence 1 x 1590 g/ha), beans: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction
- Winter cereals (post-emergence 1 x 1590 g/ha): 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction
- Winter cereals (pre-emergence 1x1137 g/ha), maize (pre-emergence 1x1137 g/ha, post-emergence 1x1137 g/ha): 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction
- Maize (pre-emergence 1 x 1590 g/ha): 20m no spray buffer zone + 20m vegetative strip or 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
- Pome/stone fruits, strawberry (1x 1137 g/ha), raspberry, currants, grapevine, winter oilseed rape (1x1137 g/ha), potato (1x1137 g/ha), clover, alfalfa: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction
- Asparagus, brassicas, leek, lettuce, endive and artichoke (1x1590 g/ha pre-emergence): 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction.
- Maize, beans (1x1590 g/ha), carrot, parsley, parsnip and fennel (1x1590 g/ha), asparagus, brassicas, leek, lettuce, endive and artichoke (1x1590 g/ha post-emergence), ornamentals, cucurbits, potato (1x1590 g/ha): 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction
- Bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1 x 1590 g/ha pre-emergence and post-emergence), strawberry (1x1590 g/ha): 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction
- Bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1x 1137 g/ha pre-emergence and post-emergence): 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

Winter oilseed rape (455 g/ha) – SPe 3: To protect aquatic organisms respect an unsprayed buffer zone of 10m + 10m vegetative strip or unsprayed buffer zone of 5m + 5m vegetative strip + 50% nozzle reduction to surface water bodies

Sunflower, soybean, lupine, strawberry, winter cereals (post-emergence 1 x 1137 g/ha), beans (1 x 1137 g/ha), carrots, parsley, parsnip and fennel (1 x 1137 g/ha), maize (post-emergence 1 x 1137 g/ha) – SPe 3: To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip or unsprayed buffer zone of 10m + 10m vegetative strip + 50% nozzle reduction to surface water bodies

Winter cereals (pre-emergence 1 x 1590 g/ha), maize (post-emergence 1 x 1590 g/ha), beans – SPe 3: To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction

Winter cereals (post-emergence 1 x 1590 g/ha) – SPe 3: To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip + 50% nozzle reduction to surface water bodies

Winter cereals (pre-emergence 1x1137 g/ha), maize (pre- and post-emergence 1x1137 g/ha 1x1137 g/ha) – SPe 3: To protect aquatic organisms respect an unsprayed buffer zone of 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction to surface water bodies

Maize (pre-emergence 1 x 1590 g/ha) – SPe 3: To protect aquatic organisms respect and unsprayed buffer zone of 20m no spray buffer zone + 20m vegetative strip or 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction of 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction to surface water bodies

Pome/stone fruits, strawberry (1 x 1137 g/ha), raspberry, currants, grapevine, winter oilseed rape (1 x 910 g/ha), potato (1 x 1137 g/ha), clover, alfalfa – SPe 3: To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip or unsprayed buffer zone of 10m + 10m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 5m + 5m vegetative strip + 75% nozzle reduction to surface water bodies.

Asparagus, brassicas, leek, lettuce, endive and artichoke (pre-emergence 1 x 1590 g/ha) – SPe 3: To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction to surface water bodies.

Maize, Beans (1 x 1590 g/ha), carrot, parsley, parsnip and fennel (1 x 1590 g/ha), asparagus, brassicas, leek, lettuce, endive and artichoke (post-emergence 1 x 1590 g/ha) ornamentals, cucurbits, potato (1 x 1590 g/ha) – SPe 3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip or unsprayed buffer zone of 10m + 10m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 5m + 5m vegetative strip + 75% nozzle reduction to surface water bodies

Bulb vegetables (onion, garlic, shallot, spring onion and ornamentals pre-and post-emergence 1 x 1590 g/ha), strawberry (1 x 1590 g/ha) – SPe 3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 5m + 5m vegetative strip + 75% nozzle reduction to surface water bodies.

Bulb vegetables (onion, garlic, shallot, spring onion and ornamentals pre- and post-emergence 1x 1137 g/ha) – SPe 3: To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip or unsprayed buffer zone of 10m + 10m vegetative strip + 50% nozzle reduction to surface water bodies.

In the case that the RAC of 0.93 µg a.s./L will be considered for the higher tier refinement, PEC/RAC ratios for Pendimethalin did indicate an acceptable risk for aquatic organisms when the following risk mitigation measures and restrictions are considered:

Mitigation measures:

- Winter cereals (pre-emergence 1 x 1590 g/ha): 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction
- Winter cereals (post-emergence 1 x 1590 g/ha), maize (pre-emergence and post-emergence 1x1590 g/ha), bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1x1590 g/ha post-emergence), asparagus, brassicas, leek, lettuce, endive and artichoke (1x1590 g/ha pre-emergence and post-emergence): 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction
- Winter cereals (pre-emergence 1 x 1137 g/ha, post-emergence 1 x 1137 g/ha), maize (pre-emergence 1x1137 g/ha, post-emergence 1x1137 g/ha), potato (1x1590 g/ha and 1x1137 g/ha), ornamentals, clover, alfalfa: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
- Pome/stone fruits, sunflower, soybean, bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1x1590 g/ha pre-emergence): 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
- Beans (1x 1590 g/ha), carrots, parsley, parsnip and fennel (1x1590 g/ha), lupine, winter oilseed rape (1x910 g/ha), strawberry (1x1590 g/ha), cucurbits: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction
- Bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1x1137 g/ha pre-emergence and post-emergence), Carrot, parsley, parsnip and fennel (1x1137 g/ha), strawberry (1x1137 g/ha), currants, grapevine: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
- Beans (1x1137 g/ha): 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction
- Winter oilseed rape (1x455 g/ha): 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction
- Raspberry: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

Winter cereals (pre-emergence 1 x 1590 g/ha) – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 50% nozzle reduction to surface water bodies

Winter cereals (post-emergence 1 x 1590 g/ha), maize (pre- and post-emergence 1x1590 g/ha), bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1x1590 g/ha post-emergence), asparagus, brassicas, leek, lettuce, endive and artichoke (pre-and post-emergence 1x1590 g/ha) – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip +

90% nozzle reduction to surface water bodies

Winter cereals (pre- and post-emergence 1 x 1137 g/ha), maize (pre- and postemergence 1x1137 g/ha, potato (1x1590 g/ha and 1x1137 g/ha), ornamentals, clover, alfalfa – SPe3: To protect aquatic organisms respect and unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies

Pome/stone fruits, sunflower, soybean, bulb vegetables (onion, garlic, shallot, spring onion and ornamentals pre-emergence 1x1590 g/ha) – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies

Beans (1x 1590 g/ha), carrots, parsley, parsnip and fennel (1 x 1590 g/ha), lupine, winter oilseed rape (1 x 910 g/ha), strawberry (1 x 1590 g/ha), cucurbits – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction to surface water bodies

Bulb vegetables (onion, garlic, shallot, spring onion and ornamentals pre- and post-emergence 1x1137 g/ha), carrot, parsley, parsnip and fennel (1 x 1137 g/ha), strawberry (1 x 1137 g/ha), currants, grapevine – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies

Beans (1 x 1137 g/ha) – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 90% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction to surface water bodies

Winter oilseed rape (1 x 455 g/ha) – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction to surface water bodies

Raspberry – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 5m + 5m vegetative strip + 90% nozzle reduction to surface water bodies

Restrictions:

Winter cereals (1 x 1590 g/ha pre-emergence, 1 x 1137 g/ha pre-emergence), Bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1 x 1590 g/ha pre-emergence), Beans (1 x 1590 g/ha), carrots, parsley, parsnip and fennel (1 x 1590 g/ha), cucurbits (1 x 1590 g/ha)- SPe2: To protect aquatic organisms do not apply on terraced clay soils with a slope greater than 10%.

Sunflower (1 x 1183 g/ha), Bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1 x 1590 g/ha pre-emergence and post-emergence and 1x 1137 g/ha pre-emergence and post-emergence), Beans (1 x 1590 g/ha and 1 x 1137 g/ha) – SPe2: To protect aquatic organisms do not apply on silty soils with a slope greater than 3%.

In the case that the RAC of 0.48 µg a.i./L will be considered acceptable for the higher tier refinement, PEC/RAC ratios for Pendimethalin did indicate an acceptable risk for aquatic organisms when the following risk mitigation measures are considered:

- Winter cereals (pre-emergence 1 x 1590 g/ha): 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction
- Winter cereals (post-emergence 1 x 1590 g/ha, post-emergence 1 x 1137 g/ha), maize (pre- and

post-emergence 1 x 1590 g/ha, pre- and post-emergence 1 x 1137 g/ha), sunflower, soybean, bulb vegetables (pre- and post-emergence 1 x 1590 g/ha, pre- and post-emergence 1 x 1137 g/ha), beans (1 x 1590 g/ha, 1 x 1137 g/ha), carrots, parsley, parsnip and fennel (1 x 1590 g/ha, 1 x 1137 g/ha), lupine, leafy vegetables (asparagus, brassicas, leek, lettuce, endive and artichoke pre- and post-emergence 1 x 1590 g/ha), strawberry (1 x 1590 g/ha, 1 x 1137 g/ha), potato (1 x 1590 g/ha, 1 x 1137 g/ha), cucurbits (1 x 1590 g/ha): 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Winter cereals (pre-emergence 1 x 1137 g/ha): 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

Pome/stone fruits (1 x 1590 between rows), raspberry, currants and grapevine (1 x 1590 g/ha), clover and alfalfa (1 x 1000 g/ha): 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

Winter oilseed rape (1 x 455 g/ha): 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

Winter oilseed rape (1 x 910 g/ha): 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

Ornamentals (1 x 1590 g/ha): 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

Winter cereals (pre-emergence 1 x 1590 g/ha) – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction to surface water bodies

Winter cereals (post-emergence 1 x 1590 g/ha, post-emergence 1 x 1137 g/ha), maize (pre- and post-emergence 1 x 1590 g/ha, pre- and post-emergence 1 x 1137 g/ha), sunflower, soybean, bulb vegetables (pre- and post-emergence 1 x 1590 g/ha, pre- and post-emergence 1 x 1137 g/ha), beans (1 x 1590 g/ha, 1 x 1137 g/ha), carrots, parsley, parsnip and fennel (1 x 1590 g/ha, 1 x 1137 g/ha), lupine, leafy vegetables (asparagus, brassicas, leek, lettuce, endive and artichoke pre- and post-emergence 1 x 1590 g/ha), strawberry (1 x 1590 g/ha, 1 x 1137 g/ha), potato (1 x 1590 g/ha, 1 x 1137 g/ha), cucurbits (1 x 1590 g/ha) – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies

Winter cereals (pre-emergence 1 x 1137 g/ha) – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction to surface water bodies

Pome/stone fruits (1 x 1590 between rows), raspberry, currants and grapevine (1 x 1590 g/ha), clover and alfalfa (1 x 1000 g/ha) – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip or unsprayed buffer zone of 10m + 10m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 5m + 5m vegetative strip + 75% nozzle reduction to surface water bodies

Winter oilseed rape (1 x 455 g/ha) – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip or unsprayed buffer zone of 10m + 10m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 5m + 5m vegetative strip + 75% nozzle reduction to surface

water bodies

Winter oilseed rape (1 x 910 g/ha) – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction to surface water bodies

Ornamentals (1 x 1590 g/ha) – SPe3: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 15m + 15m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 5m + 5m vegetative strip + 90% nozzle reduction to surface water bodies

Based on lowest value of **RAC of 0.23 µg a.s./L for aquatic organism agreed at EU level** an acceptable risk for aquatic organisms is considered when the following risk mitigation measures and restrictions are applied:

Winter cereals 1 x 1590 g a.s./ha, pre-emergence application

PEC/RAC ratios in winter cereals in pre-emergence are <1 when risk mitigation options are considered:

D1 ditch: 20m no spray buffer zone + 90% nozzle reduction

D1 stream, D3 ditch, D5 stream: 15m no spray buffer zone + 90% nozzle reduction

D2 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzles reduction

D4 pond, D5 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5 m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction.

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzles reduction or 10m no spray buffer zone + 10m vegetative strip + 50% nozzles reduction

For scenarios D2 ditch, D4 stream and D6 ditch PEC/RAC ratios are >1 even considering the mitigation. However, scenarios D2 and D6 are not relevant for CEU countries.

For scenario R3 stream the PEC/RAC ratios are > 1 even considering mitigation measures and a restriction will have to be included (do not apply on terraced clay soils with a slope greater than 10%).

Winter cereals, 1 x 1590 g a.s./ha, post emergence application

PEC/RAC ratios in winter cereals in post-emergence (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D1 ditch, D1 stream: 10m no spray buffer zone + 90% nozzle reduction

D2 stream, D3 ditch, D5 stream: 15m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D2 ditch, D4 stream and D6 ditch PEC/RAC ratios are >1 even considering the maximum mitigation measures. However, scenarios D2 and D6 are not relevant for CEU countries.

Winter cereals 1 x 1137 g a.s./ha, pre-emergence application

PEC/RAC ratios in winter cereals in pre-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D1 ditch, D1 stream, D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15 no spray buffer

zone + 90% nozzle reduction

D2 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D3 ditch, D4 stream, D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However scenario D6 is not relevant in CEU countries.

For scenario R3 stream PEC/RAC ratios are > 1 even considering the maximum mitigation measures and a restriction will have to be included (do not apply on terraced clay soils with a slope greater than 10%)

Winter cereals 1 x 1137 g a.s./ha, post emergence application

PEC/RAC ratios in winter cereals in post-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D1 ditch: 10m no spray buffer zone + 90% nozzle reduction

D1 stream, D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15 no spray buffer zone + 90% nozzle reduction

D2 stream, D3 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 stream, D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation. However, scenario D6 is not relevant in CEU countries

Maize, 1 x 1590 g a.s./ha, pre emergence application

PEC/RAC ratios in maize pre-emergence (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D5 stream: 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However scenario D6 is not relevant in CEU countries.

Maize 1 x 1590 g a.s./ha, post emergence

PEC/RAC ratios in maize post-emergence (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 10m no spray buffer zone + 90% nozzle reduction

D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzles

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However, scenario D6 is not relevant in CEU countries.

Maize 1 x 1137 g a.s./ha, pre emergence

PEC/RAC ratios in maize pre-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However, scenario D6 is not relevant in CEU countries.

Maize 1 x 1137 g a.s./ha, post emergence application

PEC/RAC ratios in maize post-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However scenario D6 is not relevant in CEU countries.

Orchards 1590 g a.s./ha, early application

PEC/RAC ratios in pome/stone fruits (early application 1 x 1590 g/ha between rows) are <1 when risk

mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Sunflower 1 x 1183 g a.s /ha

PEC/RAC ratios in sunflower (1 x 1183 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenario R1 stream the PEC/RAC ratios are > 1 even with risk mitigation measures and then a restriction have to be considered (do not apply on silty soils with a slope greater than 3%).

Soybean 1 x 1183 g a.s./ha

PEC/RAC ratios in soybean (1 x 1183 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 150m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Bulb vegetables 1590 g a.s./ha, pre emergence application

PEC/RAC ratios in bulb vegetables (pre-emergence 1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream: 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with mitigation measures. Scenario D6 is not relevant for CEU countries.

For scenario R1 stream and R3 stream the PEC/RAC ratios are below the trigger with mitigation

measures and restriction sentences have to be consider (do not apply on silty soils with a slope greater than 3% and do not apply on terraced clay soils with a slope greater than 10% respectively).

Bulb vegetables 1 x 1590 g a.s./ha, post emergence application

PEC/RAC ratios in bulb vegetables (post-emergence 1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

R2 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with mitigation measures. Scenario D6 is not relevant in CEU countries.

For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures and restriction sentences will have to be considered (do not apply on silty soils with a slope greater than 3%).

Bulb vegetables 1 x 1137 g a.s./ha, pre-emergence application

PEC/RAC ratios in bulb vegetables (pre-emergence 1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with risk mitigation measures. However, scenario D6 is not relevant for CEU countries.

For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures and a restriction will be considered (do not apply on silty soils with a slope greater than 3%).

Bulb vegetables 1 x 1137 g a.s./ha, post –emergence application

PEC/RAC ratios in bulb vegetables (post-emergence 1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with mitigation measures. However, scenario D6 is not relevant for CEU countries.

For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures and a restriction has to be considered (do not apply on silty soils with a slope greater than 3%)

Beans 1 x 1590 g a.s./ha

PEC/RAC ratios in beans (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D2 stream, D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 20m no spray buffer zone or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D2 ditch, D6 ditch 1st and D6 ditch 2nd the PEC/RAC ratios are below the trigger with mitigation measures. However D2 and D6 are not relevant in CEU countries.

For scenario R1 stream, R3 stream, the PEC/RAC ratios are below the trigger even considering risk mitigation measures and restrictions will be needed (do not apply on silty soils with a slope greater than 3% and do not apply on terraced clay soils with a slope greater than 10% respectively)

Beans 1 x 1137 g a.s./ha

PEC/RAC ratios in beans (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

D2 stream, D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

For scenarios D6 ditch 1st and D6 ditch 2nd the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries.

For scenario R1 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures and a restriction will have to be considered (do not apply on silty soils with a slope greater than 3%).

Carrots, parsley, parsnip and fennel 1 x 1590 g a.s./ha

PEC/RAC ratios in carrots, parsley, parsnip and fennel (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream 1st, R2 stream 2nd: 15m no spray buffer zone + 15m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. Scenario D6 is not relevant for CEU countries.

For scenario R3 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures and a restriction will have to be considered (do not apply on terraced clay soils with a slope greater than 10%).

Carrots, parsley, parsnip and fennel 1 x 1137 g a.s./ha

PEC/RAC ratios in carrots, parsley, parsnip and fennel (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D6 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Lupine (legume) 1183 g a.s./ha

PEC/RAC ratios in lupine (1 x 1183 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries.

Winter oilseed rape 455 g a.s./ha

PEC/RAC ratios in winter oilseed rape (1 x 455 g/ha) are <1 when risk mitigation options are considered:

D2 ditch: 20 m no spray buffer zone or 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D2 stream, D4 stream: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D3 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

D5 stream: 15m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

Winter oilseed rape 910 g a.s./ha

PEC/RAC ratios in winter oilseed rape (1 x 910 g/ha) are <1 when risk mitigation options are considered:

D2 ditch, D3 ditch, D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D2 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction
R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

Asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop in pre emergence (leafy vegetables 1st and 2nd crop 1 x 1590 g a.s./ha)

PEC/RAC ratios in asparagus, brassicas, leek, lettuce, endive and artichoke (1 x 1590 g/ha pre-emergence) are <1 when risk mitigation options are considered:

D3 1st ditch: 15m no spray buffer zone + 90% nozzle reduction

D3 2nd ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond 1st: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R1 pond 2nd: 15m no spray buffer zone + 15m vegetative strip

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. Scenario D6 is not relevant for CEU countries.

Asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop in post emergence (leafy vegetables 1st and 2nd crop 1 x 1590 g a.s./ha)

PEC/RAC ratios in asparagus, brassicas, leek, lettuce, endive and artichoke (1 x 1590 g/ha post-emergence) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch the PEC/RAC ratios are below the trigger even considering mitigation measures. Scenario D6 is not relevant for CEU countries.

Strawberry 1 x 1590 g a.s./ha

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenario D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries

Strawberry 1137 g a.s./ha

PEC/RAC ratios in strawberry (1 x 1137 g/ha between rows) are <1 when risk mitigation options are con-

sidered:

D3 ditch: 20m no spray buffer zone + 50% nozzle reduction or 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 50% nozzle reduction

D4 stream, D6 ditch: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Raspberry 1 x 1365 g a.s./ha

PEC/RAC ratios in raspberry (1 x 1365 g/ha between rows) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D6 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Currants and grapevine (vines early application 1 x 1590 g a.s./ha between rows)

PEC/RAC ratios in currants and grapevines (1 x 1590 g/ha between rows) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D6 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R4 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Potato 1 x 1590 g a.s./ha

PEC/RAC ratios in potato (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 90% nozzle reduction
R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction
R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle

For scenarios D4 stream and D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries

Potato 1 x 1137 g a.s./ha

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction
D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction
R1 stream, R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries

Ornamentals (vines, early application 1 x 1590 g a.s./ha)

PEC/RAC ratios in ornamentals (1 x 1590 g/ha) are <1 when risk mitigation options are considered:
D3 ditch, D6 ditch: 20m no spray buffer zone + 90% nozzle reduction
D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction
D4 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction
R1 stream, R2 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
R3 stream: 15m no spray buffer zone + 15m vegetative strip + 90% nozzle reduction

Clover and alfalfa (grass 1 x 1000 g a.s./ha)

PEC/RAC ratios in clover, alfalfa (1 x 1000 g/ha) are <1 when risk mitigation options are considered:
D1 ditch, D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction
D1 stream, D3 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
D2 stream, D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction
R1 stream, R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Cucurbits (fruiting vegetables 1 x 1590 g a.s./ha)

PEC/RAC ratios in cucurbits (1 x 1590 g/ha) are <1 when risk mitigation options are considered:
D3 ditch: 15m no spray buffer zone + 90% nozzle reduction
D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction
R1 pond: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative

strip + 50% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D4 stream, D6 ditch, and R3 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures. Scenario D6 is not relevant for CEU countries.

For scenario R3 restriction will be needed (do not apply on terraced clay soils with a slope greater than 10% respectively)

The final risk mitigation measures to aquatic organism should be considered at MSs level.

9.1.1.6 Effects on bees

No risk for bees is expected following the application of PENSHUI at the proposed rates.

9.1.1.7 Effects on arthropods other than bees (KCP 10.3.2)

~~In field HQ values were higher than the trigger after the first step of the assessment for *T. pyri* and *Aphidius*.~~

Data from higher tier studies showed that the effects on the two indicator species were < 50% on mortality and reproduction even at higher doses than the maximum rate proposed in GAP. Data on additional non-target arthropod species showed no risk at a rates higher than the maximum rate proposed in the GAP.

No off-field risk is expected for non-target arthropods after the application of Pendimethalin 45.5% CS according to the proposed GAP.

Therefore, the application of Pendimethalin 45.5% CS in accordance to the GAP poses no unacceptable risk to non-target arthropods.

9.1.1.8 Effects on non-target soil meso- and macrofauna (KCP 10.4), The long-term TER values are above the respective trigger indicating no long-term risk to earthworms and soil macrofauna after the application of PENSHUI according to the proposed GAP.

9.1.1.9 Effects on soil microbial activity (KCP 10.5)

The long-term TER values are above the respective trigger indicating no long-term risk to earthworms and soil macrofauna after the application of PENSHUI according to the proposed GAP.

No risk to soil microorganisms is expected following the application of Pendimethalin 45.5% CS at the proposed rates in the GAP.

9.1.1.10

9.1.1.11 No risk to soil microorganisms is expected following the application of Pendimethalin 45.5% CS at the proposed rates in the GAP.

9.1.1.12 Effects on non-target terrestrial plants (KCP 10.6)

No risk to non-target plants located outside the treated area after application of PENSUI is expected in winter oilseed rape, clover and alfalfa. For the other crops, no risk is expected when risk mitigation measures are considered:

~~Winter cereals, maize, pome fruits, stone fruits, bulb vegetables, bean, pea, broad bean, field bean, carrot, parsley, asparagus, brassica vegetables, strawberry, currants, leek, parsnip, lettuce, endive, potato, grapevine, ornamentals, artichoke, fennel, cucurbits, sunflower, soybean, lupine and raspberry~~ **SPe3:** To protect non-target plants respect an unsprayed buffer zone of 5 m or no spray buffer zone with 50% drift reducing nozzles to non-agricultural land.

No risk to non-target plants located outside the treated area is expected in any of the crops after the application of PENSUI

9.1.1.13 No risk to non-target plants located outside the treated area after application of PENSUI is expected in winter oilseed rape, clover and alfalfa. For the other crops, no risk is expected when risk mitigation measures are considered:

~~Winter cereals, maize, pome fruits, stone fruits, bulb vegetables, bean, pea, broad bean, field bean, carrot, parsley, asparagus, brassica vegetables, strawberry, currants, leek, parsnip, lettuce, endive, potato, grapevine, ornamentals, artichoke, fennel, cucurbits, sunflower, soybean, lupine and raspberry~~ **SPe3:** To protect non-target plants respect an unsprayed buffer zone of 5 m or no spray buffer zone with 50% drift reducing nozzles to non-agricultural land

No risk to non-target plants located outside the treated area is expected in any of the crops after the application of PENSUI.

zRMS comment:

The risk assessment for to non-target plants located outside the treated area is considered as acceptable after the application of PENSUI.

9.1.1.14 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

No data on other non-target species is required.

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk enve-

lope approach (according to SANCO/11244/2011).

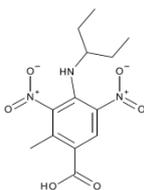
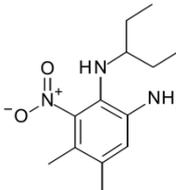
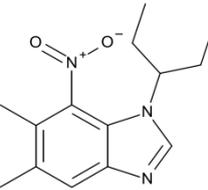
Table 9.1-2: Critical use pattern of Sharpen–Penshui 45.5% CS grouped according to criterion

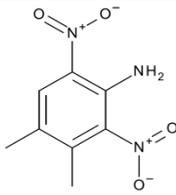
Grouping according to criterion			
Group	Intended uses	relevant use parameters for grouping	relevant parameter or value for sorting
Bare soil	All crops	Pre-emergence or pre-transplant BBCH 00-09	1 x 3.5 L f.p./ha (equivalent to 1 x 1590 g a.s./ha)
Cereals	Winter cereals	Post-emergence BBCH 10-13	1 x 3.5 L f.p./ha (equivalent to 1 x 1590 g a.s./ha)
Maize	Maize	Post-emergence BBCH 10-13	1 x 3.5 L f.p./ha (equivalent to 1 x 1590 g a.s./ha)
Bulb vegetables	Onion, garlic, shallot, spring onion, leek	Post-emergence BBCH 10-13	1 x 3.5 L f.p./ha (equivalent to 1 x 1590 g a.s./ha)
Oilseed rape	Winter oilseed rape	Post-emergence BBCH 10-16	1 x 2.0 L f.p./ha (equivalent to 1 x 910 g a.s./ha)
Legume forage	Clover, alfalfa	Post-emergence BBCH 13-18	1 x 2.2 L f.p./ha (equivalent to 1 x 1000 g a.s./ha)

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of PENSUI is indicated in the table.

Table 9.1-3 Metabolites of Pendimethalin

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
M455H001	311.1		Soil: 6.9 % Water/sediment: 0.00001 %	Yes, for soil and water
P48 (M455H033)	251.3		Soil: 25.9 % Water/sediment: 12.1%	Yes, for soil and water
P36 (M455H029; M12)	261.3		Soil: 0.00001% Water/sediment: 23.4%	Yes, for water

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
2,6-dinitro-3,4-dimethylaniline (aqueous photolysis metabolite) (M455H032)	211.2		Soil: 0.00001% Water/sediment: 14.2 %	Yes, for water

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with pendimethalin and its relevant metabolites. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on birds of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of pendimethalin. However, the provision of further data on the formulation is not considered essential because birds are typically exposed to dry residues on their food items following the dilution and spraying of the formulated product. During these processes, much of the formulation constituents are likely to be lost by volatilisation. Since oral exposure is the main route of exposure, toxicity data for the active substance are therefore used in preference to data from tests with the formulated product.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
<i>Anas platyrhynchos</i>	pendimethalin	Oral Acute	LD ₅₀ = 1421 mg/kg bw	EFSA Journal 2016;14(3):4420
<i>Anas platyrhynchos</i>	Pendimethalin	Dietary Short-term	LC ₅₀ = >4640 ppm	EFSA Journal 2016;14(3):4420
<i>Colinus virginianus</i>	pendimethalin	Dietary Short-term	LC ₅₀ = 4187 ppm	EFSA Journal 2016;14(3):4420
<i>Anas platyrhynchos</i>	pendimethalin	Dietary Reproductive toxicity	NOEC = 141 ppm NOEL = 17.5 mg/kg bw per day	EFSA Journal 2016;14(3):4420
<i>Colinus virginianus</i>	Pendimethalin	Dietary Reproductive toxicity	NOEC = 1410 ppm NOEL = 141 mg/kg bw per day	EFSA Journal 2016;14(3):4420

9.2.1.1 Justification for new endpoints

The EU agreed endpoints are used for the risk assessment.

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in bare soil

Intended use		Bare soil				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		1421				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Bare soil	“Indicator species for screening”	25.3	1	40.23	35.32	
Reprod. toxicity (mg/kg bw/d)		17.5				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Bare soil	“Indicator species for screening”	11.4	1 x 0.53	9.61	1.82	
Bare soils BBCH<10	Small granivorous bird “finch”	11.4	1 x 0.53	9.61	1.82	
Bare soils BBCH<10	Small omnivorous bird “lark”	8.2	1 x 0.53	6.91	2.53	
Bare soils BBCH<10	Small insectivorous bird “wagtail”	5.9	1 x 0.53	4.97	3.52	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in Cereals

Intended use		Cereals				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		1421				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	

Cereals	“Indicator species for screening”	158.8	1	252.49	5.63
Cereals Early (shoots) au- tumn-winter BBCH 10-29	Large herbivorous bird "goose"	30.5	1	48.50	29.30
Cereals BBCH 10 - 29	Small omnivorous bird “lark”	24	1	38.16	41.67
Reprod. toxicity (mg/kg bw/d)		17.5			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
Cereals	“Indicator species for screening”	64.8	1 x 0.53	54.61	0.32
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird “goose”	16.2	1 x 0.53	13.65	1.28
Cereals BBCH 10-29	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	1.90

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in Maize

Intended use	maize				
Active substance/product	pendimethalin				
Application rate (g/ha)	1 × 1590				
Acute toxicity (mg/kg bw)	1421				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Maize	“Indicator species for screening”	158.8	1	252.49	5.63
Maize BBCH 10-29	Medium granivorous bird "gamebird"	6.6	1	10.49	135.46
Maize Leaf development BBCH 10 to 19	Small insectivorous/worm feeding species “thrush”	10.5	1	16.70	85.09
Maize BBCH 10-29	Small omnivorous bird “lark”	24	1	38.16	37.24
Maize BBCH 10-29	medium herbivorous/grani vorous bird "pigeon"	55.6	1	87.70	16.20
Reprod. toxicity (mg/kg bw/d)		17.5			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
Maize	“Indicator species for screening”	64.8	1 x 0.53	54.61	0.32

Maize BBCH 10-29	Medium granivorous bird "gamebird"	3	1 x 0.53	2.53	6.92
Maize Leaf development BBCH 10 to 19	Small insectivorous/worm feeding species "thrush"	5.7	1 x 0.53	4.80	3.65
Maize BBCH 10-29	Small omnivorous bird "lark"	10.9	1 x 0.53	9.19	1.90
Maize BBCH 10-29	medium herbivorous/granivorous bird "pigeon"	22.7	1 x 0.53	19.13	0.91

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-5: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in Orchards

Intended use		Orchards				
Active substance/product		pendimethalin				
2.28		1 × 1590				
Acute toxicity (mg/kg bw)		1421				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a	
Growth stage						
Orchard Not crop directed, application all season	Small insectivorous/worm feeding species "thrush"	7.4	1	11.77	120.73	
Orchard Not crop directed, application all season	Small granivorous bird "finch"	27.4	1	43.57	32.61	
Reprod. toxicity (mg/kg bw/d)		17.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Growth stage						
Orchard Not crop directed, application all season	Small insectivorous/worm feeding species "thrush"	2.7	1 x 0.53	2.28	7.68	
Orchard Not crop directed, application all season	Small granivorous bird "finch"	12.6	1 x 0.53	10.62	1.65	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-6: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in sunflower

Intended use		Sunflower
Active substance/product		pendimethalin
Application rate (g/ha)		1 × 1183
Acute toxicity (mg/kg bw)		1421

TER criterion		10			
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Sunflower	“Indicator species for screening”	158.8	1	187.86	7.56
Sunflower Early germination/leaf development BBCH 00-19	Small omnivorous bird “lark”	24.0	1	28.39	50.05
Reprod. toxicity (mg/kg bw/d)		17.5			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Sunflower	“Indicator species for screening”	64.8	1 x 0.53	40.63	0.43
Sunflower Early germination/leaf development BBCH 00-19	Small omnivorous bird “lark”	10.9	1 x 0.53	6.83	2.56

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-7: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in Bulbs and onion like crops,

Intended use		Bulbs and onion like crops			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Acute toxicity (mg/kg bw)		1421			
TER criterion		10			
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Bulbs and onion like crops	“Indicator species for screening”	158.8	1	252.49	5.63
Bulbs and onion like crops BBCH 10-39	Small granivorous bird “finch”	24.7	1	39.27	36.19
Bulbs and onion like crops BBCH 10-39	Small omnivorous bird “lark”	24	1	38.16	37.24
Bulbs and onion like crops BBCH 10-19	Small insectivorous bird “wagtail”	26.8	1	42.61	33.35
Reprod. toxicity (mg/kg bw/d)		17.5			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Bulbs and onion like crops	“Indicator species for screening”	64.8	1 x 0.53	54.61	0.32
Bulbs and onion like crops	Small granivorous bird “finch”	11.4	1 x 0.53	9.61	1.82

crops BBCH 10-39					
Bulbs and onion like crops BBCH 10-39	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	1.90
Bulbs and onion like crops BBCH 10-19	Small insectivorous bird “wagtail”	11.3	1 x 0.53	9.52	1.84

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-8: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in pulses

Intended use		Pulses				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		1421				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Pulses	“Indicator species for screening”	158.8	1	252.49	5.63	
Pulses BBCH 10-49	Small granivorous bird “finch”	24.7	1	39.27	36.18	
Pulses BBCH 10-49	Small omnivorous bird “lark”	24	1	38.16	37.24	
Pulses Leaf development, BBCH 10-19	Medium herbivorous/granivorous bird “pigeon”	55.6	1	88.40	16.07	
Reprod. toxicity (mg/kg bw/d)		17.5				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{tt}	
Pulses	“Indicator species for screening”	64.8	1 x 0.53	54.61	0.32	
Pulses BBCH 10-49	Small granivorous bird “finch”	11.4	1 x 0.53	9.61	1.82	
Pulses BBCH 10-49	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	1.90	
Pulses Leaf development, BBCH 10-19	Medium herbivorous/granivorous bird “pigeon”	22.7	1 x 0.53	19.13	0.91	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-9: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in Legume forage

Intended use		Legume forage				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1183				
Acute toxicity (mg/kg bw)		1421				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Legume forage	“Indicator species for screening”	158.8	1	187.86	7.56	
Legume forage BBCH 10-49	Small granivorous bird “finch”	24.7	1	29.22	48.63	
Legume forage BBCH 10-49	Small omnivorous bird “lark”	24	1	28.39	50.05	
Legume forage BBCH 10-19	Small insectivorous bird “wag-tail”	26.8	1	31.70	44.83	
Reprod. toxicity (mg/kg bw/d)		17.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Legume forage	“Indicator species for screening”	64.8	1 x 0.53	40.63	0.43	
Legume forage BBCH 10-49	Small granivorous bird “finch”	11.4	1 x 0.53	7.15	2.45	
Legume forage BBCH 10-49	Small omnivorous bird “lark”	10.9	1 x 0.53	6.83	2.56	
Legume forage BBCH 10-19	Small insectivorous bird “wagtail”	11.3	1 x 0.53	7.08	2.47	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-10: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in winter oilseed rape

Intended use		Winter oilseed rape				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 910				
Acute toxicity (mg/kg bw)		1421				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Oilseed rape	“Indicator species for screening”	158.8	1	144.51	9.83	
Oilseed rape Early (shoots) BBCH 10-19	Large herbivorous bird “goose”	39.0	1	35.49	40.04	
Oilseed rape	Small omnivorous bird “lark”	24.0	1	26.37	53.89	

BBCH 10-29					
Oilseed rape BBCH 10-19	Medium herbivorous/granivorous bird “pigeon”	55.6	1	50.60	28.08
Oilseed rape BBCH 10-19	Small insectivorous bird “wag-tail”	10.9	1	9.92	143.26
Reprod. toxicity (mg/kg bw/d)	17.5				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Oilseed rape	“Indicator species for screening”	64.8	1 x 0.53	31.25	0.56
Oilseed rape Early (shoots) BBCH 10-19	Large herbivorous bird “goose”	15.9	1 x 0.53	7.67	2.28
Oilseed rape BBCH 10-29	Small omnivorous bird “lark”	10.9	1 x 0.53	5.26	3.33
Oilseed rape BBCH 10-19	Medium herbivorous/granivorous bird “pigeon”	22.7	1 x 0.53	10.95	1.60
Oilseed rape BBCH 10-19	Small insectivorous bird “wagtail”	5.9	1 x 0.53	2.85	6.14

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-11: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in Leafy vegetables

Intended use	Leafy vegetables				
Active substance/product	pendimethalin				
Application rate (g/ha)	1 × 1590				
Acute toxicity (mg/kg bw)	1421				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Leafy vegetables BBCH 10-49	Small granivorous bird “finch”	27.4	1	43.57	32.61
Leafy vegetables BBCH 10-49	Small omnivorous bird “lark”	24	1	38.16	37.24
Leafy vegetables Leaf development, BBCH 10-19	Medium herbivorous/granivorous bird “pigeon”	55.5	1	88.25	16.10
Reprod. toxicity (mg/kg bw/d)	17.5				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Leafy vegetables BBCH 10-49	Small granivorous bird “finch”	12.6	1 x 0.53	10.62	1.65
Leafy vegetables BBCH 10-49	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	1.90

Leafy vegetables Leaf development BBCH 10-19	Medium herbivorous/granivorous bird “pigeon”	26.7 22.7	1 x 0.53	22.50 19.13	0.78 0.91
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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-12: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in strawberry

Intended use		strawberry				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		1421				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a	
Strawberry BBCH 10-39	Small omnivorous bird “lark”	24.0	1	38.16	37.24	
Reprod. toxicity (mg/kg bw/d)		17.5				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Strawberry BBCH 10-39	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	1.90	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-13: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in potatoes

Intended use		Potatoes				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		1421				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a	
Potatoes BBCH 10-39	Small omnivorous bird “lark”	24.0	1	38.16	37.24	
Reprod. toxicity (mg/kg bw/d)		17.5				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Potatoes BBCH 10-39	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	1.90	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-14: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in Vineyard

Intended use		Vineyard				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		1421				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Vineyard BBCH 10-19	Small granivorous bird “finch”	14.8	1	23.53	60.39	
Vineyard BBCH 10-19	Small omnivorous bird “lark”	14.4	1	22.90	62.05	
Reprod. toxicity (mg/kg bw/d)		17.5				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Vineyard BBCH 10-19	Small granivorous bird “finch”	6.9	1 x 0.53	5.81	3.01	
Vineyard BBCH 10-19	Small omnivorous bird “lark”	6.5	1 x 0.53	5.48	3.19	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-15: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 40% SC in Fruiting vegetables

Intended use		Fruiting vegetables				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		1421				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Fruiting vegetables BBCH 10 – 49	Small granivorous bird “finch”	24.7	1	39.27	36.19	
Fruiting vegetables BBCH 10-49	Small omnivorous bird “lark”	24.0	1	38.16	37.24	
Reprod. toxicity (mg/kg bw/d)		17.5				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Fruiting vegetables BBCH 10-49	Small granivorous bird “finch”	11.4	1 x 0.53	9.61	1.82	
Fruiting vegetables	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	1.90	

BBCH 10-49					
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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

After the First-tier assessment, no acute risk was observed for birds in any of the crops, whereas long-term risk was observed in most of the crops and further assessment will be needed.

zRMS comment:

We agree with Tier 1 risk assessment provided by the applicant.
 No acute risk was observed for birds in any of the crops, whereas long-term risk was observed in most of the crops and further assessment was needed.

9.2.2.2 Higher-tier risk assessment

Refinement of toxicity endpoint

The value of 17.5 mg/kg bw/d is based on a 10% reduced bodyweight of 14-d old survivors and that this effect was only seen for one of the species and their hatchling weight did not differ from the controls (*Anas platyrhynchos* and not *Colinus virginianus*). Moreover, no other effects on mortality in ovo, egg shell strength, development, fertilisation rate and fecundity, were seen in the next treatment group of 181 mg/kg bw/d. Since growth of chicks is dependent on a variety of factors besides food, it is assumed that a dose of 181 mg/kg bw/d does not adversely affect population development. Therefore, it became evident that the long-term EU-agreed endpoint of 141 ppm (=17.5 mg/kg bw/d) is apparently not ecotoxicologically relevant and, as such, use of this endpoint leads to too conservative and overestimating assessment. In the EFSA Journal 2016;14(3):4420, EFSA agreed with the refinement of the long-term endpoint for birds by using a BMDL₅ of 61.5 mg/kg bw/d.

Therefore, the reproductive risk was refined using the NOEL of 61.5 mg as/kg bw/d for birds.

The resulting TER values are given in Tables below.

Table 9.2-16: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in bare soil – refined parameters (*) are further described and justified in the text

Intended use		Bare soil			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 x 1590			
Reprod. toxicity (mg/kg bw/d)		61.5*			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _t
Bare soils BBCH<10	Small granivorous bird “finch”	11.4	1 x 0.53	9.61	6.40
Bare soils BBCH<10	Small omnivorous bird “lark”	8.2	1 x 0.53	6.91	8.90
Bare soils	Small insectivorous bird	5.9	1 x 0.53	4.97	12.37

BBCH<10	“wagtail”				
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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-17: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in cereals – refined parameters (*) are further described and justified in the text

Intended use		Cereals				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		61.5*				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}	
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird “goose”	16.2	1 x 0.53	13.65	4.51	
Cereals BBCH 10-29	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	6.69	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-18: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in maize – refined parameters (*) are further described and justified in the text

Intended use		maize				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		61.5*				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}	
Maize Leaf development BBCH 10 to 19	Small insectivorous/worm feeding species “thrush”	5.7	1 x 0.53	4.80	12.81	
Maize BBCH 10-29	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	6.69	
Maize BBCH 10-29	medium herbivorous/granivorous bird "pigeon"	22.7	1 x 0.53	19.13	3.21	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-19: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in orchards – refined parameters (*) are further described and justified in the text

Intended use		Orchards				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		61.5*				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Growth stage						
Orchard Not crop directed, application all season	Small granivorous bird “finch”	12.6	1 x 0.53	10.62	5.79	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-20: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in sunflower – refined parameters (*) are further described and justified in the text

Intended use		sunflower				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1183				
Reprod. toxicity (mg/kg bw/d)		61.5*				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Growth stage						
Sunflower Early germination/leaf development BBCH 00-19	Small omnivorous bird “lark”	10.9	1 x 0.53	6.83	9.00	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-21: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in bulbs and onion like crops – refined parameters (*) are further described and justified in the text

Intended use		Bulbs and onion like crops				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		61.5*				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Growth stage						
Bulbs and onion like crops	Small granivorous bird “finch”	11.4	1 x 0.53	9.61	6.40	

BBCH 10-39					
Bulbs and onion like crops BBCH 10-39	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	6.69
Bulbs and onion like crops BBCH 10-19	Small insectivorous bird “wagtail”	11.3	1 x 0.53	9.52	6.46

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-22: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in pulses – refined parameters (*) are further described and justified in the text

Intended use		pulses			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		61.5*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
Pulses BBCH 10-49	Small granivorous bird "finch"	11.4	1 x 0.53	9.61	6.40
Pulses BBCH 10-49	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	6.69
Pulses Leaf development BBCH 10-19	Medium herbivorous/granivorous bird “pigeon”	22.7	1 x 0.53	19.13	3.21

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-23: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in Legume forage – refined parameters (*) are further described and justified in the text

Intended use		Legume forage			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1183			
Reprod. toxicity (mg/kg bw/d)		61.5*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
Legume forage BBCH 10-49	Small granivorous bird “finch”	11.4	1 x 0.53	7.15	8.60
Legume forage BBCH 10-49	Small omnivorous bird “lark”	10.9	1 x 0.53	6.83	9.00
Legume forage BBCH 10-19	Small insectivorous bird “wagtail”	11.3	1 x 0.53	7.08	8.69

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: tox-

icity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-24: Higher-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in winter oilseed rape – refined parameters (*) are further described and justified in the text

Intended use		Winter oilseed rape				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 910				
Reprod. toxicity (mg/kg bw/d)		61.5*				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Oilseed rape Early (shoots) BBCH 10-19	Large herbivorous bird “goose”	15.9	1 x 0.53	7.67	8.02	
Oilseed rape BBCH 10-29	Small omnivorous bird “lark”	10.9	1 x 0.53	5.26	11.69	
Oilseed rape BBCH 10-19	Medium herbivorous/granivorous bird “pigeon”	22.7	1 x 0.53	10.95	5.62	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-25: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in leafy vegetables – refined parameters (*) are further described and justified in the text

Intended use		Leafy vegetables				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		61.5*				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Leafy vegetables BBCH 10-49	Small granivorous bird “finch”	12.6	1 x 0.53	10.62	5.79	
Leafy vegetables BBCH 10-49	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	6.69	
Leafy vegetables Leaf development BBCH 10-19	Medium herbivorous/granivorous bird “pigeon”	26.7 22.7	1 x 0.53	22.50 19.13	2.73 3.21	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-26: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in strawberry – refined parameters (*) are further described and justified in the text

Intended use		strawberry				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		61.5*				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Strawberry BBCH 10-39	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	6.69	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-27: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in potatoes – refined parameters (*) are further described and justified in the text

Intended use		Potatoes				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		61.5*				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Potatoes BBCH 10-39	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	6.69	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-28: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in vineyard – refined parameters (*) are further described and justified in the text

Intended use		Vineyard				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		61.5*				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Vineyard BBCH 10-19	Small granivorous bird “finch”	6.9	1 x 0.53	5.81	10.59	
Vineyard BBCH 10-19	Small omnivorous bird “lark”	6.5	1 x 0.53	5.48	11.22	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: tox-

icity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-29: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in fruiting vegetables – refined parameters (*) are further described and justified in the text

Intended use		Fruiting vegetables				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		61.5*				
TER criterion		5				
Crop scenario	Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Fruiting vegetables	BBCH 10-49	Small granivorous bird “finch”	11.4	1 x 0.53	9.61	6.40
Fruiting vegetables	BBCH 10-49	Small omnivorous bird “lark”	10.9	1 x 0.53	9.19	6.69

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

The TER_{it} value is below the trigger of 5 for the following scenarios and species:

Cereals: Early shoots autumn-winter (BBCH 10-29) large herbivorous “goose”

Maize: (BBCH 10-29) medium herbivorous/granivorous “pigeon”

Pulses: (leaf development BBCH 10-19) medium herbivorous/granivorous “pigeon”

Leafy vegetables: (leaf development BBCH 10-19) medium herbivorous/granivorous “pigeon”

Therefore, a further refinement will be needed.

zRMS comment:

The risk assessment for scenario bare soil was considered as acceptable.

Based on the risk assessment provided above the TER_{LT} value is below the trigger of 5 for the following scenarios and species:

- Cereals: Early shoots autumn-winter (BBCH 10-29) large herbivorous “goose”
- Maize: (BBCH 10-29) medium herbivorous/granivorous “pigeon”
- Pulses: (leaf development BBCH 10-19) medium herbivorous/granivorous “pigeon”
- Leafy vegetables: (leaf development BBCH 10-19) medium herbivorous/granivorous “pigeon”

Therefore, a further refinement was provided by the applicant below.

DT₅₀ and twa

In the first tier risk assessment a default foliar DT₅₀ value of 10 days was considered. Sharda has conducted residue decline studies in wheat in CEU countries to refine the DT₅₀ value. The below table summarize the information of the trials as well as the calculated foliar DT₅₀ values.

Crop	Trial	BBCH	Application rate	Analyzed	Residues (mg /kg)	Days	DT ₅₀ (days)
Wheat	SHRU10-2017-034HR (Hungary)	BBCH 30	1650 g a.s./ha	Whole plant	146.48	0	2.48
					102.99	1	
					90.25	2	
					83.17	3	
					27.51	4	

					17.14	5	
					27.56	6	
					26.83	7	
					16.54	8	
					31.34	9	
					13.47	10	
					11.03	12	
					2.91	14	
Wheat	CT17-1-47DE1 (Germany)	BBCH 30	1498.6 g a.s./ha	Whole plant	5.81	0	2.50
					3.69	1	
					3.42	2	
					1.39	3	
					1.19	4	
					1.21	5	
					0.31	6	
					0.34	7	
					0.21	8	
					0.03	9	
					0.19	10	
					0.07	12	
0.12	14						
Wheat	BPL17-010-03 (Poland)	BBCH 25-30	1498 g a.s./ha	Whole plant	6.79	0	4.48
					2.8	1	
					3.19	2	
					2.68	3	
					1.19	4	
					1.16	5	
					1.15	6	
					1.22	7	
					1.34	8	
					1.49	9	
					1.49	10	
					0.68	13	
0.78	14						

The DT₅₀ values have been calculated according to the formula given in Appendix H of the EFSA Journal 2009; 7(12):1438:

$$DT_{50} = - (t \times \ln 2) / \ln (C_{\text{final}}/C_{\text{max}})$$

Being:

t = time interval between sampling dates

C_{max}: maximum residue level

C_{final}: last measured residue level

The resulting DT₅₀ values were 2.48, 2.50 and 4.48 days. Based on those values, the geometric mean DT₅₀ resulted to be 3.03 days and this value will be used to refine the ftwa value and the resulting MAFxTwa value was 0.21 which was used in the refined risk assessment below.

The kinetic evaluation of the residue decline studies, as requested by the zRMS, is provided in a separate report (XXX J.J. 2021)

No residue decline data are available for dicotyledoneous plants. From the data obtained in the trials of wheat, the DT₅₀ value is clearly below the default DT₅₀ value of 10 days used in the Tier I risk assessment. In the EFSA conclusions the DT₅₀ values determined for peas and wheat from decline residue trials are practically the same (3 days vs. 2.73 days respectively). The data obtained by the applicant in the residue decline trials in wheat show that values are very similar to that given in the EFSA conclusions. There-

fore, taking into account all this, it was considered appropriate to refine the DT_{50} of dicotyledoneous plants considering as a surrogate the same geomean DT_{50} value of 3.03 days obtained for wheat. This value was used to refine the f_{TWA} and the resulting MAF_{XTWA} value was 0.21 and was used in the refined risk assessment below.

zRMS comments:

Higher Tier assessment: DT_{50} estimation in

Considering the EU agreed refinement of f_{TWA} (DT_{50} for wheat = 2.73; Jene, 2014), it is stated in the EFSA conclusion on pendimethalin that the available residue decline studies can be applied for spring cereals (north and south Europe) and winter cereals (south Europe only). Furthermore, it is stated that ‘*as dissipation was measured for residues on plants surface and not for residues within plant tissues, such refinement was not considered suitable for pre-emergence applications*’. As Pehnsui is intended for a use in central Europe and for a growth stage of winter cereals including pre-emergence and post emergence application (BBCH 00-13), the refinement based on DT_{50} of 2.73 d is only applicable for post-emergence applications (BBCH 10-29) but only **in spring cereals** for Central Zone.

No spring cereals are included in the GAP table.

The new DT_{50} of 3.03 d (geomean from three sites) are provided by the applicant.

This value was not accepted by zRMS –PL. It should be noted that only trials from two sites Germany and Hungary were taken into account to estimate DT_{50} value. The DT_{50} values from tested site were- Germany (DT_{50} =1.81 d) , Hungary (DT_{50} =2.74 d) were estimated.

For a detailed evaluation of the new residue decline trials submitted by the applicant and estimation of DT_{50} values, reference is made to Appendix 2. In all of the referenced studies residues of pendimethalin were measured following post - emergence applications on cereals. However, the zRMS identified several shortcomings in the studies that are summarised in the following. For two study sites, applications were carried out in spring for spring cereals on April or May trials from Poland and Germany and BBCH from 25-30 and in spring for **winter cereals** from Hungary (BBCH-30), which reduces the data set for a refinement of the intended Pehnsui use in winter cereals/weeds.

In addition during evaluation of the dissipation kinetics of pendimethalin the sites from Poland were excluded from the kinetic analysis (please see in Appendix 2).

Finally, only one site from Germany (DT_{50} =1.8 d) and one site from Hungary (2.54 d) were taken into account to estimate DT_{50} value in plants for a.s.

Therefore, the geomean value of DT_{50} of 3.03 d for winter cereals proposed by the applicant from three sites are not used in the risk assessment.

The minimum requirement in order to have a reliable refinement of the dissipation as defined by the EFSA (four sites per regulatory zone) is also not fulfilled.

Summarizing the above, the presented studies are not suitable to derive a DT_{50} for pendimethalin that is applicable for the intended uses of Pehnsui in the central zone for winter cereals post- emergence.

For winter cereals new decline studies is recommended with application in autumn to confirm the new DT_{50} for a.s.-pendimethalin.

In conclusion:

The default value of DT_{50} for winter cereals/weeds should be used. However, it should be noted that DT_{50} seems to be less than 10 days.

For non-grass herbs the DT_{50} of 3 days (from dicot plants, EFSA Conclusion) was used by zRMS in the risk assessment.

Table 9.2-30: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in cereals – refined parameters (*) are further described and justified in the text

Intended use		Cereals				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		61.5*				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird “goose”	16.2	1 x 0.21* 1 x 0.53	5.40 13.65	11.39 4.50	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

zRMS comment :

The risk for wood pigone needs further refinement.

zRMS used the PT of 0.10 value (90th percentile) for consumer only in cereal from literature data by Prosser 2010.

Intended use		Cereals				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		61.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{lt}
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird “goose”	16.2	1 x 0.53	0.1	1.365	45

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

The TER_{LT} value are above trigger indicating acceptable risk to large herbivorous bird „goose”.

Table 9.2-31: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in pulses – refined parameters (*) are further described and justified in the text

Intended use	pulses
Active substance/product	pendimethalin

Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		61.5*			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
Growth stage					
Pulses Leaf development BBCH 10-19 (non-grass herb)	Medium herbivorous/granivorous bird “pigeon”	22.7	1 × 0.21* 1 × 0.20	7.58 7.57	8.11 8.10

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-32: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in leafy vegetables – refined parameters (*) are further described and justified in the text

Intended use		Leafy vegetables			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		61.5*			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
Growth stage					
Leafy vegetables Leaf development BBCH 10-19 (non-grass herbs)	Medium herbivorous/granivorous bird “pigeon”	26.7 22.7	1 × 0.21* 1 × 0.20	8.92 8.91 7.22	6.89 6.88 8.52

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comment:

According to EFSA GD for B&M, DT₅₀ of 3 d and f_{twa}=0.20 obtained from dicot plants was considered in the risk assessment for non-grass herbs by zRMS.
 The risk is considered as acceptable for pigeon.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

Leaf scenario

Since Pendimethalin 45.5% CS is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

With a $K(f)_{oc}$ of 13792 (EFSA Journal 2016;14(3):4420), pendimethalin belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use bare soil also covers the risk for birds from all other intended uses (see 9.1.2).

Effective application rate (g/ha) =	1590		
Acute toxicity (mg/kg bw) =	1421	quotient =	1.12
Reprod. toxicity (mg/kg bw/d) =	17.5	quotient =	90.86

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 3000 a quantitative risk assessment (calculation of TER values) is not necessary.

zRMS comment:

We agree that since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 3000 a quantitative risk assessment (calculation of TER values) is not necessary.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of pendimethalin amounts to 5.4 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil also covers the risk for birds from all other intended uses (see 9.1.2)

Table 9.2-33: Assessment of the risk for earthworm-eating birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) for the intended use in bare soil

Parameter	pendimethalin	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	1.961	Section 8, Chapter 8.7.2
$\log P_{ow} / P_{ow}$	5.4	EFSA Journal 2016;14(3):4420
K_{oc}	13792	EFSA Journal 2016;14(3):4420
foc	0.02	Default
BCF_{worm}	6.9	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$

Parameter	pendimethalin	comments
		$= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	13.53	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	14.21	DDD = PEC _{worm} × 1.05
NOEL (mg/kg bw/d)	17.5	EFSA Journal 2016;14(3):4420
TER _{It}	1.23	Risk (TER _{It} <5)

TER values shown in bold fall below the relevant trigger.

Since the TER is below the trigger, further assessment with refined BMDL₅ value of 61.5 mg/kg bw/d was conducted

Table 9.2-34: Assessment of the risk for earthworm-eating birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) for the intended use in bare soil

Parameter	pendimethalin	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	1.961	Section 8, Chapter 8.7.2
log P _{ow} / P _{ow}	5.4	EFSA Journal 2016;14(3):4420
Koc	13792	EFSA Journal 2016;14(3):4420
foc	0.02	Default
BCF _{worm}	6.9	BCF _{worm/soil} = (PEC _{worm,ww} /PEC _{soil,dw}) = $(0.84 + 0.12 \times P_{ow}) / foc \times Koc$
PEC _{worm}	13.53	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	14.21	DDD = PEC _{worm} × 1.05
BMDL ₅ (mg/kg bw/d)	61.5	EFSA Journal 2016;14(3):4420
TER _{It}	4.33	Risk (TER _{It} <5)

TER values shown in bold fall below the relevant trigger.

Since the TER is below the trigger, further assessment is needed. A mean BCF of 0.81 is used in the refined risk assessment for earthworm-eating mammals, based on the study *Bioaccumulation in earthworms (laboratory study)* (Garret, 2000) (*Data from old dossier (Addendum B-8 Ecotoxicology, February 2002)*). According to the *Conclusions of the peer review of the pesticide risk assessment of the active substance pendimethalin* (EFSA Journal 2016;14(3):4420), the BCF is derived from the most reliable study and EFSA agrees on the use of this endpoint in the refinement.

Table 9.2-35: Assessment of the risk for earthworm-eating birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) for the intended use in bare soil

Parameter	pendimethalin	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	1.961	Section 8, Chapter 8.7.2
log P _{ow} / P _{ow}	5.4	EFSA Journal 2016;14(3):4420
Koc	13792	EFSA Journal 2016;14(3):4420
foc	0.02	Default
BCF _{worm}	0.81	Study from RAR of bioaccumulation on earthworms (Garret, 2000)

Parameter	pendimethalin	comments
PEC _{worm}	1.59	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	1.67	DDD = PEC _{worm} × 1.05
BMDL ₅ (mg/kg bw/d)	61.5	EFSA Journal 2016;14(3):4420
TER _{lt}	36.83	No risk, TER _{lt} >5

TER values shown in bold fall below the relevant trigger

Since the TER_{lt} is above the trigger, the long-term risk of secondary poisoning to earthworm eating birds from the use of Pendimethalin 45.5% CS is acceptable.

zRMS comment:

zRMS verified the risk for earthworm-eating birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) taking into account the highest available BAF applied as a refined worst-case approach and PEC_{Saccum}.

Parameter	Pendimethalin	Comments
PEC _{soil} accumulation, (mg/kg soil)	2.305	PEC _{soil} accumulation (PEC _{act} + PEC _{soil} plateau)
log Pow; Pow	5.4*; 251188	-
K _{OC}	13792	Arithmetic mean (n = 9)
f _{OC}	0.02	Default
BAF _{worm}	0.81*	
PEC _{worm}	1.86 x 0.81=1.51	PEC _{worm} = PEC _{soil} × BAF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	1.51 x 1.05=1.58	DDD = PEC _{worm} × 1.05
NOEL (mg/kg bw/d)	61.5	Refined endpoint: BMDL5
TER _{LT}	38.60	TER _{LT} = NOEL / DDD

TER values shown in bold fall below the relevant trigger.

* EFSA Journal 2016;14(3):4420

The risk for earthworm-eating birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) is considered as acceptable with BAF =0.81.

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

Table 9.2-36: Assessment of the risk for fish-eating birds due to exposure to pendimethalin via bioaccumulation in fish (secondary poisoning) for the intended use

Parameter	pendimethalin	comments
PEC _{sw} (twa = 21 d) (mg/L)	0.00959	Section 8, point 8.9.2 (PEC _{sw} twa 21d, step 2; appln.hand crop < 50cm)
BCF _{fish}	931	EFSA Journal 2016;14(3):4420 (most reliable)

Parameter	pendimethalin	comments
		endpoint)
BMF	<p>CT₅₀=5.1 days, 1.34 d ; 2.5 – 4.4 d CT₉₀: 87% depuration in 14 d; -; 96-97% clearance within 21 d (CT₉₀ 8.3-15 d) Two outdoor mesocosm studies with a.s. pendimethalin targeted at bioconcentration are available: <i>Lepomis macrochirus</i>, BMF_{KGL}= 0.1054 <i>Oncorhynchus mykiss</i> BMF_{KGL}= 0.0402 BMF_{KGL}= 0.0423 Outdoor mesocosms <i>Leuciscus idus melanotus</i> mean BCF_{actual conc} = 199 aquatic community in outdoor mesocosms including fish No evidence of biomagnification of either pendimethalin, its metabolites or equivalent radioactivity within the aquatic food chain. NOEC fish: 0.0050 mg a.s./L</p>	<p>biomagnification factor (relevant for BCF ≥ 2000) EFSA Journal 2016;14(3):4420</p>
PEC _{fish}	8.93	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	1.42	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	17.5	EFSA Journal 2016;14(3):4420
TER _{It}	12.32	No risk, TER > 5

TER values shown in bold fall below the relevant trigger.

The TER is above the trigger, showing no risk for birds of secondary poisoning via fish.

zRMS comment:

zRMS verified the risk for fish-eating birds due to exposure to pendimethalin via bioaccumulation in fish (secondary poisoning) taking into account the lowest and the highest available BCF values applied as a refined worst-case approach and max PEC_{sw} (Step 2).

Parameter	Pendimethalin	Comments
PEC _{sw} (mg/L)	0.001246	FOCUS Step 2, max PEC _{sw}
BCF _{Fish}	931 / 3300*	Lowest and highest available BCF values
PEC _{Fish}	1.16/4.11	PEC _{fish} = PEC _{water} × BCF _{fish}

Daily dietary dose (mg/kg bw/d)	0.18/0.65	DDD = $PEC_{\text{fish}} \times 0.159$
NOEL (mg/kg bw/d)	61.5	Refined endpoint: BMDL5
TER _{LT}	341.6/94.61	TER _{LT} = NOEL / DDD

TER values shown in bold fall below the relevant trigger.

* Highest and lowest BCF values available from EFSA Journal 2016;14(3):4420

The risk for fish -eating birds due to exposure to pendimethalin via bioaccumulation in fish (secondary poisoning) is considered as acceptable.

9.2.2.5 Biomagnification in terrestrial food chains

According to *Peer review of the pesticide risk assessment of the active substance pendimethalin* (EFSA Journal 2016;14(3):4420): “studies on three different species were available for assessing the bioconcentration factor (BCF) of pendimethalin in fish. The kinetic BCF ranged from 931 L/kg to 3,300 L/kg. The study providing the lowest BCF value was considered reliable, while the other two had some methodological flaws. However, the large difference between BCFs indicated that the bioconcentration of pendimethalin might be species-dependent, with higher bioconcentration for bluegill sunfish. This is consistent with the finding of the two available biomagnification (BMF) studies. These BMF studies were very much comparable (same protocol, author, laboratory, year, and tested batch) and showed that the BMF calculated for rainbow trout was less than a half of the BMF calculated for bluegill sunfish”

zRMS comment:

please see above.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant. Pendimethalin 45.5% CS is not intended for use as a bait, it is not a pellet, granule or prill, nor is it used for seed treatment.

9.2.4 Overall conclusions

The risk assessment shows that there is no acute risk for birds after exposure to Pendimethalin 45.5% CS. Most of the crops failed at Tier I for long-term exposure. The refinement of the chronic endpoint showed an acceptable long-term risk for birds except for cereals, maize, pulses and leafy vegetables. Further refinement of foliar DT₅₀ showed an acceptable long-term risk for birds.

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating birds. The risk of secondary poisoning to earthworm eating birds was found acceptable after refinement.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with Pendimethalin. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on mammals of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of Pendimethalin. However, the provision of further data on the formulation is not considered essential because mammals are typically exposed to dry residues on their food items following the dilution and spraying of the formulated product. During these processes, much of the formulation constituents are likely to be lost by volatilisation. Since oral exposure is the main route of exposure, toxicity data for the active substance are therefore used in preference to data from tests with the formulated product

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Mouse	Pendimethalin	Acute	LD ₅₀ (male) = 3399 mg/kg bw LD ₅₀ (female) = 2899 mg/kg bw LD ₅₀ (combined) = 3189 mg/kg bw	EFSA Journal 2016;14(3):4420
Rat	Pendimethalin	Acute	LD ₅₀ (male) > 5000 mg/kg bw/d LD ₅₀ (female) > 5000 mg/kg bw/d LD ₅₀ (combined) > 5000 mg/kg bw/d	EFSA Journal 2016;14(3):4420
Rat	Pendimethalin	Acute	LD ₅₀ (male) = 4665 mg/kg bw/d LD ₅₀ (female) = 5000 mg/kg bw/d LD ₅₀ (combined) = 4830 mg/kg bw/d	EFSA Journal 2016;14(3):4420
	Pendimethalin	Acute	Overall geomean LD ₅₀ = 3927 mg/kg bw/d	EFSA Journal 2016;14(3):4420
Rat	Pendimethalin	Long-term 2-generation	NOAEL (parental and pup effects) = 30 mg/kg bw/d	EFSA Journal 2016;14(3):4420
Rat	Pendimethalin	Long-term Developmental	NOAEL _{developmental} = 500 mg/kg bw/d	EFSA Journal 2016;14(3):4420
Rabbit	Pendimethalin	Long-term Developmental	NOAEL _{developmental} = 30 mg/kg bw/d	EFSA Journal 2016;14(3):4420

9.3.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in bare soil

Intended use		Bare soil				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		3927				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a	
Bare soil	“Indicator species for screening”	14.4	1	22.90	171.48	
Reprod. toxicity (mg/kg bw/d)		30				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Bare soil	“Indicator species for screening”	6.6	1 x 0.53	5.56	5.40	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in Cereals

150*		Cereals				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		3927				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a	
Cereals	“Indicator species for screening”	118.4	1	188.26	20.86	
Reprod. toxicity (mg/kg bw/d)		30				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Cereals	“Indicator species for screening”	48.3	1 x 0.53	40.70	0.74	

Cereals BBCH 10-19	Small insectivorous mammal “shrew”	4.2	1 x 0.53	3.54	8.47
Cereals Early (shoots)	Large herbivorous mammal “lagomorph”	22.3	1 x 0.53	18.79	1.60
Cereals BBCH 10-29	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in maize

Intended use		Maize				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		3927				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a	
Maize	“Indicator species for screening”	136.4	1	216.88	18.11	
Reprod. toxicity (mg/kg bw/d)		30				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Maize	“indicator species for screening”	72.3	1 x 0.53	60.93	0.49	
Maize BBCH 10-19	Small insectivorous mammal “shrew”	4.2	1 x 0.53	3.54	8.47	
Maize BBCH 10-29	Small herbivorous mammal “vole”	72.3	1 x 0.53	60.93	0.49	
Maize BBCH 10-19	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-5: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% SC in Orchards

Intended use		Orchards				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		3927				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a	
Orchards Application crop directed BBCH<10 or not crop directed	Small herbivorous mammal “vole”	136.4	1	216.88	18.11	

Orchards Application crop directed BBCH<10 or not crop directed	Large herbivorous mammal “lagomorph”	35.1	1	55.81	70.36
Orchards Application crop directed BBCH<10 or not crop directed	Small omnivorous mammal “mouse”	17.2	1	14.50	270.83
Reprod. toxicity (mg/kg bw/d)	30				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal “vole”	72.3	1 x 0.53	60.93	0.49
Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	12.05	2.49
Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-6: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in sunflower

Intended use	Sunflower				
Active substance/product	pendimethalin				
Application rate (g/ha)	1 x 1183				
Acute toxicity (mg/kg bw)	3927				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Sunflower BBCH 10-19	Large herbivorous mammal “lagomorph”	35.1	1	41.52	94.58
Sunflower BBCH 10-19	Small omnivorous mammal “mouse”	17.2	1	27.35	143.58
Reprod. toxicity (mg/kg bw/d)	30				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
Sunflower BBCH 10-19	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	8.97	3.34
Oilseed rape BBCH 10-29	Small omnivorous mammal “mouse”	7.8	1 x 0.53	4.89	6.13

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: tox-

icity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-7: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in Bulbs and onion like crops

Intended use		Bulbs and onion like crops				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		3927				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a	
Growth stage						
Bulbs and onion like crops	“Indicator species for screening”	118.4	1	188.26	20.86	
Reprod. toxicity (mg/kg bw/d)		30				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Growth stage						
Bulbs and onion like crops	“indicator species for screening”	48.3	1 x 0.53	40.70	0.74	
Bulbs and onion like crops BBCH 10-19	Small insectivorous mammal “shrew”	4.2	1 x 0.53	3.54	8.47	
Bulbs and onion like crops BBCH 10-39	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-8: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in pulses

Intended use		Pulses				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		3927				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a	
Growth stage						
Pulses BBCH 10-49	Large herbivorous mammal “lagomorph”	35.1	1	55.81	70.36	
Pulses BBCH 10-49	Small omnivorous mammal “mouse”	17.2	1	27.35	143.58	
Reprod. toxicity (mg/kg bw/d)		30				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Growth stage						

Pulses BBCH 10-49	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	12.05	2.49
Pulses BBCH 10-39	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-9: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in legume forage

Intended use	Legume forage				
Active substance/product	pendimethalin				
Application rate (g/ha)	1 × 1183				
Acute toxicity (mg/kg bw)	3927				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Legume forage BBCH 10-19	Small insectivorous mammal “shrew”	7.6	1	8.99	436.82
Legume forage BBCH 10-49	Small omnivorous mammal “mouse”	17.2	1	20.35	192.97
Reprod. toxicity (mg/kg bw/d)	30				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Legume forage BBCH 10-19	Small insectivorous mammal “shrew”	4.2	1 x 0.53	2.63	11.41
Legume forage BBCH 10-49	Small omnivorous mammal “mouse”	7.8	1 x 0.53	4.89	6.13

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-10: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in winter oilseed rape

Intended use		Winter oilseed rape				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 910				
Acute toxicity (mg/kg bw)		3927				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a	
Oilseed rape BBCH 10-19	Small insectivorous mammal “shrew”	7.6	1	6.92	567.49	
Oilseed rape All season	Large herbivorous mammal “lagomorph”	35.1	1	31.94	122.95	
Oilseed rape BBCH 10-29	Small omnivorous mammal “mouse”	17.2	1	15.65	250.93	
Reprod. toxicity (mg/kg bw/d)		30				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}	
Oilseed rape BBCH 10-19	Small insectivorous mammal “shrew”	4.2	1 x 0.53	2.03	14.78	
Oilseed rape All season	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	6.90	4.35	
Oilseed rape BBCH 10-29	Small omnivorous mammal “mouse”	7.8	1 x 0.53	3.76	7.98	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-11: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in leafy vegetables

Intended use		Leafy vegetables				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		3927				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a	
Leafy vegetables All season	Large herbivorous mammal “lagomorph”	35.1	1	55.81	70.36	
Leafy vegetables BBCH 10-49	Small omnivorous mammal “mouse”	17.2	1	27.35	143.58	
Reprod. toxicity (mg/kg bw/d)		30				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m ×	DDD_m	TER_{lt}	

Growth stage			TWA	(mg/kg bw/d)	
Leafy vegetables All season	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	12.05	2.49
Leafy vegetables BBCH 10-49	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-12: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in strawberry

Intended use		Strawberry				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Acute toxicity (mg/kg bw)		3927				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Strawberries BBCH 10-39	Large herbivorous mammal “lagomorph”	35.1	1	55.81	70.36	
Strawberries BBCH 10-39	Small omnivorous mammal “mouse”	17.2	1	27.35	143.58	
Reprod. toxicity (mg/kg bw/d)		30				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}	
Strawberries BBCH 10-39	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	12.05	2.49	
Strawberries BBCH 10-39	Small omnivorous mammals “mouse”	7.8	1 x 0.53	6.57	4.57	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-13: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in bush and cane fruit

Intended use		Bush and cane fruit			
Active substance/product		Pendimethalin			
Application rate (g/ha)		1 × 1590			
Acute toxicity (mg/kg bw)		3927			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Bush and cane fruit BBCH 10-19	Small herbivorous mammal "vole"	81.9	1	130.22	30.16
Bush and cane fruit BBCH 10-19	Small omnivorous mammal "mouse"	10.3	1	16.38	239.74
Reprod. toxicity (mg/kg bw/d)		30			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Fruiting vegetables Bush and cane fruit BBCH 10-49	Small herbivorous mammal "vole"	43.4	1 x 0.53	36.57	0.82
Bush and cane fruit BBCH 10-19	Small omnivorous mammal "mouse"	4.7	1 x 0.53	3.96	7.58

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-14: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in potatoes

Intended use		Potatoes			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Acute toxicity (mg/kg bw)		3927			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Potatoes BBCH 10-40	Large herbivorous mammal "lagomorph"	35.1	1	55.81	70.36
Potatoes BBCH 10-39	Small omnivorous mammal "mouse"	17.2	1	27.35	143.58
Reprod. toxicity (mg/kg bw/d)		30			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Potatoes BBCH 10-40	Large herbivorous mammal "lagomorph"	14.3	1 x 0.53	12.05	2.49
Potatoes	Small omnivorous mammal	7.8	1 x 0.53	6.57	4.57

BBCH 10-39	“mouse”				
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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-15: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in vineyard

Intended use		Vineyard			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Acute toxicity (mg/kg bw)		3927			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Vineyard Application ground directed	Large herbivorous mammal “lagomorph”	27.2	1	43.25	90.79
Vineyard Application ground directed	Small herbivorous mammal “vole”	136.4	1	216.88	18.11
Vineyard Application ground directed	Small omnivorous mammal “mouse”	17.2	1	27.35	143.58
Reprod. toxicity (mg/kg bw/d)		30			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Vineyard Application ground directed	Large herbivorous mammal “lagomorph”	11.1	1 x 0.53	9.35	3.21
Vineyard Application ground directed	Small herbivorous mammal “vole”	72.3	1 x 0.53	60.93	0.49
Vineyard Application ground directed	Small omnivorous mammals “mouse”	7.8	1 x 0.53	6.57	4.57

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-16: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in ornamentals

Intended use		Ornamentals			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Acute toxicity (mg/kg bw)		3927			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Ornamentals Application crop directed BBCH 10-49	Small omnivorous mammal “mouse”	17.2	1	27.35	143.58
Reprod. toxicity (mg/kg bw/d)		30			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Ornamentals Application crop directed BBCH 10-49	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-17: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in fruiting vegetables

Intended use		Fruiting vegetables			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Acute toxicity (mg/kg bw)		3927			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Fruiting vegetables BBCH 10-49	Small herbivorous mammal “vole”	136.4	1	216.88	18.11
Fruiting vegetables BBCH 10-49	Small omnivorous mammal “mouse”	17.2	1	27.35	143.58
Reprod. toxicity (mg/kg bw/d)		30			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Fruiting vegetables BBCH 10-49	Small herbivorous mammal “vole”	72.3	1 x 0.53	60.93	0.49
Fruiting vegetables BBCH 10-49	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

After the first-tier risk assessment, no acute risk was observed for mammals in any of the crops. No long-term risk was observed for mammals in bare soil and legume forage, whereas for the other crops long-term risk was observed in some scenarios and then further assessment will be needed.

zRMS comment:

After the first-tier risk assessment, the acute risk for mammals is considered as acceptable.

The acceptable long-term risk was observed for mammals in bare soil (BBCH<10) and legume forage, whereas for the other crops long-term risk was observed in some scenarios and then further assessment was needed for scenarios summarised in the Table below:

Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
Cereals Early (shoots)	Large herbivorous mammal “lagomorph”	22.3	1 x 0.53	18.79	1.60
Cereals BBCH 10-29	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57
Maize BBCH 10-29	Small herbivorous mammal “vole”	72.3	1 x 0.53	60.93	0.49
Maize BBCH 10-19	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57
Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal “vole”	72.3	1 x 0.53	60.93	0.49
Orchards Application crop directed BBCH < 10 or not crop directed	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	12.05	2.49
Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57
Sunflower BBCH 10-19	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	8.97	3.34
Bulbs and onion like crops BBCH 10-39	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57
Pulses BBCH 10-49	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	12.05	2.49
Pulses BBCH 10-39	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57
Oilseed rape All season	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	6.90	4.35
Leafy vegetables All season	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	12.05	2.49
Leafy vegetables BBCH 10-49	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	4.57

Strawberries BBCH 10-39	Large herbivorous mammal "lagomorph"	14.3	1 x 0.53	12.05	2.49
Strawberries BBCH 10-39	Small omnivorous mammals "mouse"	7.8	1 x 0.53	6.57	4.57
Bush and cane fruit BBCH 10-49	Small herbivorous mammal "vole"	43.4	1 x 0.53	36.57	0.82
Potatoes BBCH 10-40	Large herbivorous mammal "lagomorph"	14.3	1 x 0.53	12.05	2.49
Potatoes BBCH 10-39	Small omnivorous mammal "mouse"	7.8	1 x 0.53	6.57	4.57
Vineyard Application ground directed	Large herbivorous mammal "lagomorph"	11.1	1 x 0.53	9.35	3.21
Vineyard Application ground directed	Small herbivorous mammal "vole"	72.3	1 x 0.53	60.93	0.49
Vineyard Application ground directed	Small omnivorous mammals "mouse"	7.8	1 x 0.53	6.57	4.57
Ornamentals Application crop directed BBCH 10-49	Small omnivorous mammal "mouse"	7.8	1 x 0.53	6.57	4.57
Fruiting vegetables BBCH 10-49	Small herbivorous mammal "vole"	72.3	1 x 0.53	60.93	0.49
Fruiting vegetables BBCH 10-49	Small omnivorous mammal "mouse"	7.8	1 x 0.53	6.57	4.57

9.3.2.2 Higher-tier risk assessment

Refinement of toxicity endpoint

The refinement of the toxicity endpoint was done considering the conclusions of the evaluation of products containing Pendimethalin in national evaluations, where an endpoint more relevant than the EU agreed endpoint of 30 mg/kg bw/d was considered for the refinement of the long-term risk for mammals.

Considering the publicly available conclusions of the national evaluation of the product Stomp, conducted by the Dutch Competent Authority, CTGB, for the purpose of authorizing Stomp in the Netherlands, it became evident that the long-term EU-agreed endpoint of 500 ppm (=30 mg/kg bw/d) is apparently not ecotoxicologically relevant and, as such, use of this endpoint leads to too conservative and overestimating assessment.

Citing the comments made by the Dutch Authority:

Summaries of the reproduction studies are available in the DAR. The endpoint given in the LoE comes from the two-generation study toxicity/reproduction study in rat. Information from the DAR:

“For two generations the animals were fed AC 92,553 (92.6 % content) in the diet at concentrations 0, 500, 2500, and 5000 ppm, which correspond to 30, 150, 296 mg/kg bw/day for males (M) and 39, 195, 388 mg/kg bw/day for females (F). There were no significant mortalities either in the P1 and F1 generation related to treatment. Discoloured yellow urine was observed in all treated animals. Yellow fur staining was also observed, mainly in the F1 generation animals in the 296(M)-388(F) mg/kg bw/day dose level (fed 5000 ppm), and to a lesser degree in those of the 150(M)-195(F) mg/kg bw/day dose level (fed 2500 ppm).

Lower body weight gain was statistically significant in the animals fed 5000 ppm [296(M)-388(F) mg/kg bw/day], and to a lesser degree in those of 2500 ppm group [150(M)-195(F) mg/kg bw/day]. Food reduction consumption was also related to dose level, being more remarkable in the 5000 ppm group than in the 2500 ppm dose level. There were no significant adverse effect at any dose level on vaginal smear pattern, time- course of mating, performance of mating (males and females), fecundity and fertility in either generation, neither on gestation duration, or outcome of pregnancy; there was only a slight decrease of the number of pups in the group administered 5000 ppm in both litters of both generations, as compared to the control.

Conclusions:

There was parental toxicity at 296(M)-388(F) mg/kg bw/day dose level and, to a lesser degree, at 150(M)-195(F) mg/kg bw/day when AC 92,553 was administered over two successive generations.

Parental toxicity manifested as a lower body weight, lower body weight gain during lactation and lower food consumption. There was no other treatment related effect than skin and or urine discoloration at necropsy, as far as histopathological abnormalities, clinical condition and abnormalities of the pups are concerned. Fertility, fecundity, gestation, pregnancies and other reproductive characteristics were unaltered by treatment as compared to controls. Based on all these findings, NOAEL is set 30(M)-39(F) mg/kg bw/day as there was no association of adverse effect on offspring and parental toxicity at this level and below.”

Germany also has considered a higher endpoint relevant, with the following argumentation.

“2-generation study with rats: dosing with 0, 500, 2500 and 5000 ppm. In the first generation, lower body weight, lower body-weight gain during lactation and lower food consumption were recorded at 5000 ppm (296 (m)-388 (f) mg/kg bw/d) and to a lesser extent also at 2500 ppm (150 (m) - 195 (f) mg/kg bw/d). Except from colour changes of urine and skin, no effects regarding the offspring, fertility, fecundity or pregnancy or regarding other adverse effects on reproduction were seen. It may be thus assumed that even a dose of 2500 ppm (150(m) -195 (f) mg/kg KG/d) does not adversely affect population development. In the context of the refined risk assessment, thus the NOAEL = 195 mg/kg KG/d is used.”

Note that several other MS have for national authorisation used a different endpoint than the one given in the Final LoEP. Germany used a NOAEL of 195 mg/kg bw/d (2500 ppm, females). Denmark used a NOAEL of 150 mg/kg bw/d. France agreed to use a NOAEL of 296 mg/kg bw/d (5000 ppm, males) for the refined risk assessment since it was considered that the effects observed at this dose does not appear relevant as part of an assessment of the long-term impact of pendimethalin on mammalian reproduction. All these endpoints are derived from the same study.

From all the values considered at MS level for national authorisations, the lowest value of 150 mg/kg bw/d was considered appropriate to be used in the higher tier risk assessment.

Table 9.3-18: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in cereals – refined parameters (*) are further described and justified in the text

Intended use		Cereals			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Cereals Early (shoots)	Large herbivorous mammal “lagomorph”	22.3	1 x 0.53	18.79	7.98
Cereals BBCH 10-29	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	22.83

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-19: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in maize – refined parameters (*) are further described and justified in the text

Intended use		Maize			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Maize BBCH 10-29	Small herbivorous mammal “vole”	72.3	1 x 0.53	60.93	2.46
Maize BBCH 10-19	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	22.83

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-20: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in orchards – refined parameters (*) are further described and justified in the text

Intended use		Orchards			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Orchards Application crop directed BBCH < 10 or not crop directed	Small herbivorous mammal “vole”	72.3	1 x 0.53	60.93	2.46
Orchards Application crop	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	12.05	12.45

directed BBCH < 10 or not crop directed					
Orchards Application crop directed BBCH < 10 or not crop directed	Small omnivorous mammal "mouse"	7.8	1 x 0.53	6.57	22.83

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-21: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in sunflower – refined parameters (*) are further described and justified in the text

Intended use		Sunflower			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1183			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{tt}
Sunflower BBCH 10-19	Large herbivorous mammal "lagomorph"	14.3	1 x 0.53	8.97	16.72

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-22: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in Bulbs and onion like crops – refined parameters (*) are further described and justified in the text

Intended use		Bulbs and onion like crops			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{tt}
Bulbs and onion like crops BBCH 10-39	Small omnivorous mammal "mouse"	7.8	1 x 0.53	6.57	22.83

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-23: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in pulses – refined parameters (*) are further described and justified in the text

Intended use		Pulses			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			

Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{It}
Pulses BBCH 10-49	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	12.05	12.45
Pulses BBCH 10-39	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	22.83

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-24: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in winter oilseed rape – refined parameters (*) are further described and justified in the text

Intended use	Winter oilseed rape				
Active substance/product	pendimethalin				
Application rate (g/ha)	1 × 910				
Reprod. toxicity (mg/kg bw/d)	150*				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{It}
Oilseed rape All season	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	6.90	21.74

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-25: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in leafy vegetables – refined parameters (*) are further described and justified in the text

Intended use	Leafy vegetables				
Active substance/product	pendimethalin				
Application rate (g/ha)	1 × 1590				
Reprod. toxicity (mg/kg bw/d)	150*				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{It}
Leafy vegetables All season	Large herbivorous mammal “lagomorph”	14.3	1 x 0.53	12.05	12.45
Leafy vegetables BBCH 10-49	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	22.83

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-26: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in strawberry – refined parameters (*) are further described and justified in the text

Intended use	Strawberry
Active substance/product	pendimethalin

Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Strawberries BBCH 10-39	Large herbivorous mammal "lagomorph"	14.3	1 x 0.53	12.05	12.45
Strawberries BBCH 10-39	Small omnivorous mammals "mouse"	7.8	1 x 0.53	6.57	22.83

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-27: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in bush and cane fruit – refined parameters (*) are further described and justified in the text

Intended use		Bush and cane fruit			
Active substance/product		Pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Bush and cane fruit BBCH 10-49	Small herbivorous mammal "vole"	43.4	1 x 0.53	36.57	4.10

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-28: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in potatoes – refined parameters (*) are further described and justified in the text

Intended use		Potatoes			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Potatoes BBCH 10-40	Large herbivorous mammal "lagomorph"	14.3	1 x 0.53	12.05	12.45
Potatoes BBCH 10-39	Small omnivorous mammal "mouse"	7.8	1 x 0.53	6.57	22.83

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-29: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in vineyard – refined parameters (*) are further described and justified in the text

Intended use		Vineyard			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Vineyard Application ground directed	Large herbivorous mammal “lagomorph”	11.1	1 x 0.53	9.35	16.04
Vineyard Application ground directed	Small herbivorous mammal “vole”	72.3	1 x 0.53	60.93	2.46
Vineyard Application ground directed	Small omnivorous mammals “mouse”	7.8	1 x 0.53	6.57	22.83

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-30: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in ornamentals

Intended use		Ornamentals			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Ornamentals Application crop directed BBCH 10-49	Small omnivorous mammal “mouse”	7.8	1 x 0.53	6.57	22.83

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-31: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in fruiting vegetables – refined parameters (*) are further described and justified in the text

Intended use		Fruiting vegetables			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}

Fruiting vegetables BBCH 10-49	Small herbivorous mammal "vole	72.3	1 x 0.53	60.93	2.46
Fruiting vegetables BBCH 10-49	Small omnivorous mammal "mouse"	7.8	1 x 0.53	6.57	22.83

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

After the refinement of the endpoint, there is still long-term risk for small herbivorous mammal "vole" in the following crops:

Maize (BBCH 10-29)
 Orchards (application not crop directed)
 Bush and cane fruit (BBCH 10-49)
 Vineyard (application ground directed)
 Fruiting vegetables (BBCH 10-49)

Therefore, further refinement will be needed.

DT₅₀ and twa

In the first tier risk assessment a default foliar DT₅₀ value of 10 days was considered. Sharda has conducted residue decline studies in wheat in CEU countries to refine the DT₅₀ value. The below table summarize the information of the trials as well as the calculated foliar DT₅₀ values.

Crop	Trial	BBCH	Application rate	Analyzed	Residues (mg /kg)	Days	DT ₅₀ (days)
Wheat	SHRU10-2017-034HR (Hungary)	BBCH 30	1650 g a.s./ha	Whole plant	146.48	0	2.48
					102.99	1	
					90.25	2	
					83.17	3	
					27.51	4	
					17.14	5	
					27.56	6	
					26.83	7	
					16.54	8	
					31.34	9	
					13.47	10	
					11.03	12	
2.91	14						
Wheat	CT17-1-47DE1 (Germany)	BBCH 30	1498.6 g a.s./ha	Whole plant	5.81	0	2.50
					3.69	1	
					3.42	2	
					1.39	3	
					1.19	4	
					1.21	5	
					0.31	6	
					0.34	7	
					0.21	8	
					0.03	9	
					0.19	10	
					0.07	12	
0.12	14						
Wheat	BPL17-010-03 (Poland)	BBCH 25-30	1498 g a.s./ha	Whole plant	6.79	0	4.48
					2.8	1	
					3.19	2	
					2.68	3	
					1.19	4	

					1.16	5	
					1.15	6	
					1.22	7	
					1.34	8	
					1.49	9	
					1.49	10	
					0.68	13	
					0.78	14	

The DT₅₀ values have been calculated according to the formula given in Appendix H of the EFSA Journal 2009; 7(12):1438:

$$DT_{50} = - (t \times \ln 2) / \ln (C_{\text{final}}/C_{\text{max}})$$

Being:

t = time interval between sampling dates

C_{max}: maximum residue level

C_{final}: last measured residue level

The resulting DT₅₀ values were 2.48, 2.50 and 4.48 days. Based on those values, the geometric mean DT₅₀ resulted to be 3.03 days and this value will be used to refine the ftwa value and the resulting MAFxTwa value was 0.21 which was used in the refined risk assessment below.

The kinetic evaluation of the residue decline studies, as requested by the zRMS, is provided in a separate report (XXX J.J. 2021)

Table 9.3-32: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in maize – refined parameters (*) are further described and justified in the text

Intended use		Maize				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		150*				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}	
Maize BBCH 10-29	Small herbivorous mammal “vole”	72.3	1 x 0.21*	24.14	6.21	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-33: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in orchards – refined parameters (*) are further described and justified in the text

Intended use		Orchards				
Active substance/product		pendimethalin				
Application rate (g/ha)		1 × 1590				
Reprod. toxicity (mg/kg bw/d)		150*				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}	
Orchards Application crop	Small herbivorous mammal “vole”	72.3	1 x 0.21*	24.14	6.21	

directed, BBCH < 10 or not crop directed					
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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-34: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in bush and cane fruit – refined parameters (*) are further described and justified in the text

Intended use		Bush and cane fruit			
Active substance/product		Pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Bush and cane fruit BBCH 10-49	Small herbivorous mammal "vole"	43.4	1 x 0.21*	14.49	10.35

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-35: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in vineyard – refined parameters (*) are further described and justified in the text

Intended use		Vineyard			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Vineyard Application ground directed	Small herbivorous mammal "vole"	72.3	1 x 0.21*	24.14	6.21

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-36: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in fruiting vegetables – refined parameters (*) are further described and justified in the text

Intended use		Fruiting vegetables			
Active substance/product		pendimethalin			
Application rate (g/ha)		1 × 1590			
Reprod. toxicity (mg/kg bw/d)		150*			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}

Fruiting vegetables BBCH 10-49	Small herbivorous mammal "vole	72.3	1 x 0.21*	24.14	6.21
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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

The TER_{it} values are above the trigger, showing no chronic risk to mammals after the exposure to Pendimethalin 45.5% CS.

Applicant update September 2021

zRMS informed applicant that in the case of mammals, the only endpoint that is considered is 30 mg a.s./kg bw/d and that the long-term refinements for mammals has to be done considering only this endpoint. Therefore, applicant has updated the risk assessment considering the endpoint of 30 mg a.s./kg bw/d.

DT₅₀ and ftwa

Applicant presented above several residue decline studies to refine the foliar DT₅₀ value. From the residues decline studies on wheat, a geomean DT₅₀ value of 3.03 days was used to refine the ftwa obtaining a value of 0.21 that is used in the risk assessment for the refinement of twa for grass/cereals diet.

No residue decline data are available for dicotyledoneous plants. From the data obtained in the trials of wheat, the DT₅₀ value is clearly below the default DT₅₀ value of 10 days used in the Tier I risk assessment. In the ESFA conclusions the DT₅₀ values determined for peas and wheat from decline residue trials are practically the same, 3 days and 2.73 days respectively. The data obtained by the applicant in the residue decline trials in wheat show that values are very similar to that given in the EFSA conclusions. Therefore, taking this into account, it was considered appropriate to refine the DT₅₀ of dicotyledoneous plants considering as a surrogate the same geomean DT₅₀ value of 3.03 days obtained for wheat. This value was used to refine the FTWA and the resulting MAF_xTWA value was 0.21 and was used in the refined risk assessment below.

zRMS comment:

The new value of DT₅₀ = 3.03 d was not considered by zRMS-PL for using in refined risk assessment for birds and mammals for winter cereals/weeds.

Cereals

Table 9.3-37: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in cereals – refined parameters (*) are further described and justified in the text

Intended use		Cereals					
Active substance/product		pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Rabbit (<i>Oryctolagus cuniculus</i>)	Grass + cereals 100% cereal shoots	0.41	54.2 x 1	1 x 0.21*	1	7.42	4.0

Wood mouse (<i>Apodemus sylvaticus</i>)	25% weeds	0.27	28.7 x 1	1 x 0.21*	1	0.65	
	50% weed seeds		40.2 x 1	1 x 0.53	1	4.57	
	25% ground arthropods		3.5 ^a x 1	1 x 0.53	1	0.20	
	Whole diet					5.42	5.5

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

^a According to Appendix A from EFSA (2009), RUD values for arthropods with interception are relevant to cereals at BBCH 10-29

The risk for rabbit after the TWA refinement is still unacceptable. However, it is close to the trigger and in has to be considered that for calculations, no refinement of PT value is done and as worst case a PT of 1 is used, assuming that rabbit will obtain all the food in the cereal field. Therefore, under this worst case assumption the risk to rabbit could be considered as acceptable.

A further refinement option for rabbit in cereals is presented for those countries where the risk will be considered as unacceptable. According to GAP, the application of PENSHUI comprises a range from 1137 to 1590 g a.s./ha. Below table shows the risk assessment for rabbit when the lower application rate of the interval is considered.

Table 9.3-38: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in cereals – refined parameters (*) are further described and justified in the text (1137 g/ha)

Intended use		Cereals					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 1137					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Rabbit (<i>Oryctolagus cuniculus</i>)	Grass + cereals 100% cereal shoots	0.41	54.2 x 1	1 x 0.21*	1	5.31	5.7

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The TER is above the trigger showing no risk to hare when the application rate of 1137 g a.s./ha is considered.

Applicant update February 2022

The refinement of the twa was not found acceptable by the zRMS and therefore further refinements are needed for cereals.

PD

The initial risk assessment for cereals assumes that the rabbit is consuming 100% crop leaves. Applicant wish to refer here to refinement applied and accepted on Fluazifop formulations at EU as well as national level in CZ. As per the revised LoEP (Sep 2014) for Fluazifop, with regard to modification of PD, EFSA

experts agreed that less than 54% crop leaves or less than 72% of non-crop leaves are uptaken from the treated area:

According to **Harris and Yalden (2008)** [Harris, S. and Yalden, D.W. (2008) Lagomorphs. In: The Handbook of British Mammals (third edition). Published for the Mammal Society, Blackwell Scientific Publications, London], *rabbits prefer to feed on plants growing close to their burrows or other cover. The most suitable habitats for rabbits are areas of short grass or closely grazed agricultural pasture. Further requirements are secure refuges such as hedgerows or scrubland close to the feeding grounds.*

It is therefore reasonable to assume the PD for a large herbivorous lagomorph, which will range over a significant area, to be less than one. The proportion of diet obtained from the treated area could be as high as 54% (crop leaves) to 72% (non-crop leaves) to demonstrate an acceptable risk to large herbivorous mammals [...].

Zoerner (1989) [Zoerner, H. (1989): *Lepus europaeus* (Pallas), 286-321. In: Stubble, M. Buch der Hege Band 1 Haarwild. Deutscher Landwirtschaftsverlag, Berlin] *summarises data from a study by Oderscheka, et al., (1981) looking at hare diet from analysis of botanical composition of stomach contents (366 hares in 8 regions of Austria). This study showed that the average percentage stomach content of beet ranged from 0.0 to 9.1% and that cereals and grasses dominate the diet of hares (about 50% to 70%) which is supplemented by beets, alfalfa, red clover and various plants that often occur only individually. In spring, the portion of wild brasses and herbs constitutes around 48% of the total diet; while in the summer, they can comprise up to 65% of the diet.*

*In a study by Reitz & Léonard (1994) [Reitz, F., Leonard, Y. (1994) characteristics of European hare *Lepus europaeus* use of space in a French agricultural region of intensive farming. Acta Theriologica 39 (2): 143-157] French hares were monitored for at least one month by radio-tracking in an intensely farmed landscape. The mean home range size was about 100 ha and the associated crops within the monitored area were wheat (47% of the area), sugar beet (19%), peas (11%), maize (5%) and potatoes (4%).*

According to above, it is considered that the same approach is adequate to assess the risk following application to cereals: the proportion of diet obtained from the treated area could be as high as 54% (crop leaves) to 72% (non-crop leaves).

A generic PD value for rabbit should be 0.5 for non-grass herbs and 0.5 of grasses. However, as data is available on cereals and grasses in study Zoerner (1989), the Applicant considers more relevant the use of a PD of 0.7 as a worst case value. Therefore, the use of PD value of 0.7 for cereals and grasses and 0.3 for non-grass herbs, were considered in the refinement.

Food intake rate

The FIR/bw for rabbit was calculated by the applicant considering a body weight of 1543 g as indicated in the EFSA (2009) and considering that rabbit will feed on non-grass herbs, cereals and grasses, as indicated above. Calculation is presented below. The FIR/bw was calculated using the equation provided in Appendix G of the Guidance Document.

$$\text{FIR} = \left(\frac{\text{DEE}}{\text{FE} * \left(1 - \frac{\text{MC}}{100} \right) * \left(\frac{\text{AE}}{100} \right)} \right) \quad [\text{g fresh weight/d}]$$

In which:

$$\log \text{DEE} = \log a + b \times \log \text{bw}$$

Calculation of FIR/bw for rabbit

Food type	PD	DEE	bw (g)	FE (kJ/dry g)	MC (%)	AE (%)	FEitem (kJ/g)	FEtotal (kJ/g)	FIR (g/day)	FIR/bw
Cereals and grasses	70%	1240.742	1543	17.6 ^a	76.4 ^a	47 ^b	1.37	1.85	670.86	0.43
Non-grass herbs	30%			17.8 ^a	88.1 ^a	76 ^b	0.48			

DEE: Daily energy expenditure; FE: food energy; MC: moisture content; AE: assimilation efficiency; FIR: food intake rate.

^a From table 3 of Appendix G in EFSA (2009)

^b From table 4 of Appendix G in EFSA (2009)

Dissipation and ftwa refinement

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb¹: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH.

Further, zRMS used for non-grass herbs the DT₅₀ of 3 days (from dicot plants, EFSA Conclusion) in the risk assessment, giving an ftwa of 0.2, which was also used in the higher tier refinement. The DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

PT

According to the EFSA GD (2009), the focal species to use in the tier I risk assessment should be the rabbit (*Oryctolagus cuniculus*). This species feeds mainly on grass and cereals. According to Prosser, 2010², a 90th %ile PT of 0.87 is relevant for Brown hare for the consumers only in cereal crops in winter. The Applicant is the opinion that the focal species Brown Hare (*Lepus europaeus*) presents a similar diet and behaviour than rabbit, therefore the use of the refined PT from Prosser would be justified.

A new higher-tier assessment of the long-term/reproductive risk for large herbivorous “lagomorph” with the use of the more appropriate PD, the previously discussed ftwa and the PT obtained from Prosser 2010, is proposed by the applicant:

Table 9.3-38bis: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in cereals – refined parameters (*) are further described and justified in the text (1137 g/ha)

Intended use	Winter cereals, BBCH 10-13
Active substance/product	Pendimethalin
Application rate (g/ha)	1 × 1137
Reprod. toxicity (mg/kg bw/d)	30
TER criterion	5

¹ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

² Consolidation of bird and mammal PT data for use in risk assessment. Food and Environment Research Agency (March 2010). Prosser, P.

Focal species	Food category, % in diet	FIR/bw*	RUD _m × DF (mg/kg food)	MAF _m × TWA*	PT*	PD*	DDD _m (mg/kg bw/d)	TER _{It}
Rabbit (<i>Oryctolagus cuniculus</i>)	Cereals and grasses	0.43	54.2 x 1	0.29	0.87	0.7	4.68	5.54
	Non-grass herbs	0.43	28.7 x 1	0.2	0.87	0.3	0.73	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Weight of evidence

Additionally to the refinements presented above for lagomorphs, the Applicant wishes to argue the following points:

- Lagomorphs are mobile species and therefore they do not spend more time in one crop. Therefore, from the point of view of the long-term assessment, it is not expected they are exposed to treated crops for a long period.
- Pendimethalin is selective to gramineae (grasses) which means that after treatment grasses won't be available anymore and then, the weeds are assumed to be less attractive and palatable for large herbivorous mammals. Thus, the crop is less attractive for rabbit.
- The considered value of NOEL of 30 mg/kg bw/d is more conservative than the value of 150 mg/kg bw/d (or even higher in some cases), which was used for the risk assessment and accepted by several other MS for national authorization.

zRMS comments:

The risk assessment was verified by zRMS. The default values of MAF and ftwa were considered by zRMS. PT value from Prosser, March 2011 for wood mouse (PT= 0.81, 90th percentile, consumers only) was used by zRMS to refine the risk assessment for this species for post-emergence application.

Intended use	Winter cereals (10-13 BBCH)							
Active substance/product	Pendimethalin							
Application rate (g/ha)	1 × 1590							
Reprod. toxicity (mg/kg bw/d)	30							
TER criterion	5							
Focal species	Food category, % in diet	FIR/bw	RUD _m × DF (mg/kg food)	MAF _m × TWA*	PT	DDD _m (mg/kg bw/d)	TER _{It}	
Wood mouse (<i>Apodemus sylvaticus</i>)	25% weeds	0.27	28.7 x 1	1 x 0.53	0.81	1.32		
	50% weed seeds		40.2 x 1	1 x 0.53	0.81	3.7		
	25% ground arthropods		3.5 ^a x 1	1 x 0.53	0.81	0.16		
	Whole diet					5.18	5.8	
Focal species	Food category, % in diet	FIR/bw	RUD _m × DF (mg/kg food)	MAF _m × TWA*	PT	DDD _m (mg/kg bw/d)	TER _{It}	
Rabbit (<i>Oryctolagus cuniculus</i>)	Grass + cereals 100% cereal shoots	0.41	54.2 x 1	1x 0.53	1	18.72	1.60	

Intended use		Winter cereals, BBCH 10-13					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 1137					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{It}
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{It}
Rabbit (<i>Oryctolagus cuniculus</i>)	Grass + cereals 100% cereal shoots	0.41	54.2 x 1	1x 0.53	1	13.39	2.24

In conclusion:

The risk for rabbit needs further refinement.

For the second species wood mouse the risk is considered as acceptable.

Further refinement was provided for rabbit.

During Commenting period the applicant referred to ftwa parameter evaluated by zRMS :

Dissipation and ftwa refinement- applicant approach:

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb³: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH.

Further, zRMS used for non-grass herbs the DT₅₀ of 3 days (from dicot plants, EFSA Conclusion) in the risk assessment, giving an ftwa of 0.2, which was also used in the higher tier refinement. The DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

zRMS still doesn't agree with ftwa 0.29 parameter in quantitative risk assessment. It should be noted the DT₅₀ value 4.48 d is obtained from the study in Poland which was excluded from kinetic analysis by the applicant and it was confirmed by zRMS previously.

Therefore, for refinement risk assessment for cereals the PD 50/50 % value by Zoerner (1989) and FIR/bw=0.45 were considered by zRMS.

Table 9.3-38bis_{corr}: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in cereals – (1137 g/ha)

Intended use	Winter cereals, BBCH 10-13
Active substance/product	Pendimethalin
Application rate (g/ha)	1 × 1137
Reprod. toxicity (mg/kg bw/d)	30
TER criterion	5

³ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

Focal species	Food category, % in diet	FIR/bw*	RUD _m × DF (mg/kg food)	MAF _m × TWA	PT	PD	DDD _m (mg/kg bw/d)	TER _{It}
Rabbit (<i>Oryctolagus cuniculus</i>)	Cereals and grasses	0.45	54.2 x 1	0.53	1	0.5	7.34	3.5
	Non-grass herbs	0.45	28.7 x 1	0.2	1	0.5	1.29	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

TER_{LT} is below the trigger of 5 when default value of DT₅₀ = 10 d for grasses/cereals is taken into consideration as the most conservative approach in case of pendimethalin.

For further refinement PT value by Prosser, 2010 for brownhare was proposed by the applicant. zRMS is in the opinion that PT= 0.69 value, 90th percentile by Prosser 2010 for brown hare (consumer only) is more appropriate to use in the risk assessment and may be considered at MSs level, if relevant.

Maize

Identification of relevant focal mammal species in early maize (BBCH 10-13)

There are many reasons why the risk assessment for vole is considered to be covered through the assessment of other small mammalian species:

- High fecundity and population recuperation of the vole.
- Primary source of food outside crops fields for the vole.
- Necessity of population control measures since the vole is considered a crop pest when high population levels are reached.
- Other agricultural techniques being also means of population control

Also, according to Pesticides Peer Review 111 Experts' Meeting on Ecotoxicology (3 -7 February 2014), it was concluded, based on literature data, that common voles do not inhabit maize fields at early growth stages. Therefore, it is not a relevant species (reference: BENI, Bentazone 87% SG (SHA 0900 C))

In addition, based in generic studies and literatura data, the Wood mouse (*Apodemus sylvaticus*) and the European hare (*Lepus europaeus*) were identified as suitable focal species in maize fields at early BBCH stages (please refer to the *Peer review of the pesticide risk assessment of the active substance mesotrione*).

Therefore, the risk assessment for long-term exposure in maize fields will be focused in the small omnivorous mammal "mouse" (*A. sylvaticus*) and in large herbivorous mammal "hare" (*L. europaeus*). In order to refine the risk assessment, the below refined parameters were considered.

PT refinement

In order to refine the PT value, applicant refers to the following field monitoring study.

Wood mouse

XXX T., Dietzen C & von Blanckenhagen F (2013): Generic field study on small mammals focal species and wood mouse (*Apodemus sylvaticus*) PT in maize fields in Germany, Report P12225 [Applicant has access to this study and LoA is provided].

From this study, conducted in Germany in early stages of maiz fields, a PT of 0.139 for the omnivorous wood mouse was agreed at EU level. Therefore the PT of 0.139 will be used in the higher tier risk assessment for wood mouse

PD refinement

Wood mouse

For the higher tier risk assessment, the default diet as indicated in EFSA (2009) will be considered: 25% weeds, 50% weed seeds and 25% ground arthropods

Brown hare

In the higher tier risk assessment it will be considered that hares will feed exclusively on maize shoots available in the field as worst case assumption.

Food intake rate

Brown hare

The FIR/bw for hare was calculated by the applicant considering a body weight of 3800 g as indicated in the EFSA (2009) and considering that hare will feed exclusively on maize shoots. Calculation is presented below. The FIR/bw was calculated using the equation provided in Appendix G of the Guidance Document.

$$\text{FIR} = \left(\frac{\text{DEE}}{\text{FE} * \left(1 - \frac{\text{MC}}{100}\right) * \left(\frac{\text{AE}}{100}\right)} \right) \quad [\text{g fresh weight/d}]$$

In which

$$\log \text{DEE} = \log a + b \times \log \text{bw}$$

Table 9.3-39: Calculation of FIR/bw for hare

Food type	Daily energy expenditure (DEE)	bw (g)	Food energy (kJ/dry g)	Moisture content (%)	Assimilation efficiency (%)	FIR (g/day)	FIR/bw
Monocots (maize shoots)	2363.444	3800	17.6 ^a	76.4 ^a	47 ^b	1210.66	0.32

^a From table 3 of Appendix G in EFSA (2009)

^b From table 4 of Appendix G in EFSA (2009)

Refined calculations for wood mouse and hare are presented in the tables below.

Table 9.3-40: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in maize – refined parameters (*) are further described and justified in the text

Intended use		Maize					
Active substance/product		pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_h

Brown hare (<i>Lepus europaeus</i>)	All maize shoots	0.32	54.2 x 1	1 x 0.21* 1 x 0.53	1	5.79 14.61	5.2 2.05
Wood mouse (<i>Apodemus sylvaticus</i>) BBCH 10-29	25% (plant material – maize)	0.27	54.2 x 1	1 x 0.21* 1 x 0.53	0.139	0.17 1.71	
	50% weed seeds		40.2 x 1	1 x 0.53	0.139	0.64	
	25% ground arthropods		3.5 ^a x 1	1 x 0.53	0.139	0.03	
	Total					0.84 2.38	35.7 12.6

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

^a According to Appendix A from EFSA (2009), RUD values for arthropods with interception are relevant to cereals at BBCH 10-29

The TER values for both species were above the trigger showing no risk after the application of Penschui according to the proposed GAP.

Applicant update February 2022

The refinement of the twa was not found acceptable by the zRMS and therefore further refinements are needed for maize.

PD

The initial risk assessment for cereals assumes that the hare is consuming 100% grass and cereals. However, applicant wishes to refer that the brown hare diet relevant for maize is indicated in the Northern Zone Guidance Document. The derived PD values were based on published data from studies carried out in Sweden (Frylestam 1980a), England (Tapper and Barnes 1986), France (Chapuis 1990) and Denmark (Olesen & Asferg 2006; Hansen 1990). Following PD values are recommended:

Crop	Growth stage	Season	PD (fresh weight)		
			Monocotyledons (cereals, grasses)	Dicotyledons (leafy crops, non-grass weeds)	Bush berry plants (buds, leaves)
Maize	BBCH 10-19	Spring	0.84	0.16	-
	BBCH 10-39	Summer	0.72	0.28	-

The above values were based on results obtained from studies in all EU zones, including Central Zone. In fact, all publications were already assessed, validated and agreed by the ecotoxicology experts of the Northern Zone.

Moreover, it is highly unlikely that the brown hare would feed exclusively on maize shoots, which is confirmed by various publications. Zörner (1989) summarised data from a study by Onderschecka et al. (1981) which investigated hare diet from analysis of botanical composition of stomach contents (366 hares in 8 regions of Austria). Below table is shared as supportive information that the brown hare feed on dicotyledonous plants and that the diet composition as proposed by the Northern Zone Guidance Document is relevant.

Number of stomachs	16	33	32	16	57	70	84	58
Territory	Wiener Neustadt	Theresienfeld	Weikersdorf	Sollenau	Zurndorf Süd	Zurndorf Nord	Schrems	Meires
Cultivated plants								
Barley	7.3	11.8	7.6	13.1	6.1	5.2	2.7	10.4

Wheat	2.4	1	1.1	0	16.2	15.5	0	8.4
Oats	1.9	2	3.1	1.4	0.2	0	3.2	8.9
Rye	17.1	21.5	19	18.3	0.6	3.3	23.7	11.4
Maize	11.6	14.2	11.5	13.6	4.8	9.2	0	0
Beet	4.9	-	9.1	5.7	-	3.7	0	0
Alfalfa	5.1	3.7	6.1	2.8	1	0.2	-	-
Canola	-	0	0	0	2.3	-	1	0
Soybeans	-	-	-	-	1.2	0.3	-	-
Red clover	-	-	-	-	-	-	12.5	16.6
Potatoes	-	-	-	-	-	-	0.1	0.1
Total	50.3	53.2	57.5	54.9	32.4	37.4	43.2	55.8
<i>Non-cultivated plants</i>								
Grasses	11.8	13.8	10	9.9	21.6	26	39.7	29.1
Faboidea	11.3	6	9.4	7.8	1.5	0.3	2	4.3
Asteraceae	2.7	4.5	1.8	5.6	4	3.2	5.4	4.2
Brassicaceae	2.3	4.2	1.8	0.4	1.2	0	0	0.2
Plantain	2.4	2.1	3.7	5	2.2	1.7	0.7	0
Other	7.4	8.7	6.3	5.3	16.9	13.3	4.5	3.1
Total	37.9	39.3	33	34	47.4	44.5	52.3	40.9
<i>Supplemental food</i>								
Cabbage	-	-	-	-	1.2	2.6	-	-
Carrots	-	-	-	-	5.1	1.5	-	-
Not determined	10.5	5.5	5.1	8.1	13.6	12.5	3.8	2.5
Animal hair	1.3	2	4.4	3	0.3	1.5	0.7	0.8

Based on above data, seems clear that brown hare feeds on dicotyledonous plants, that monocots represent the major part of their diet and that maize is not their preferred food. Taking this into account, PD values of 0.84 and 0.16 for monocots and dicots, respectively, as proposed by the Northern Zone Guidance Document, are proposed to be used also in evaluation.

Food intake rate

The FIR/bw for hare was calculated by the applicant considering a body weight of 3800 g as indicated in the EFSA (2009) and considering that hare will feed on non-grass herbs, cereals and grasses, as indicated above. Calculation is presented below. The FIR/bw was calculated using the equation provided in Appendix G of the Guidance Document. For further detail, refer to refinements in winter cereals.

Calculation of FIR/bw for hare

Food type	PD	DEE	bw (g)	FE (kJ/dry g)	MC (%)	AE (%)	FEitem (kJ/g)	FEtotal (kJ/g)	FIR (g/day)	FIR/bw
Cereals and grasses	84%	2363.444	3800	17.6 ^a	76.4 ^a	47 ^b	1.64	1.90	1245.61	0.33
Non-grass herbs	16%			17.8 ^a	88.1 ^a	76 ^b	0.26			

DEE: Daily energy expenditure; FE: food energy; MC: moisture content; AE: assimilation efficiency; FIR: food intake rate.

^a From table 3 of Appendix G in EFSA (2009)

^b From table 4 of Appendix G in EFSA (2009)

Dissipation and ftwa refinement

Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH. Moreover, the DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the higher DT₅₀ of 4.48 days from residue decline data from our trials, giving an ftwa of 0.29, was used in the refined risk assessment. Furthermore, as was done by the zRMS for non-grass herbs, the DT₅₀ of 3 days (from dicot plants, EFSA Conclusions), giving an ftwa of 0.2, was also used. For further detail, please, refer to new proposed refinements in win-

ter cereals.

PT

Further refinement was performed with consideration of the new field monitoring study (XXX & Katzchner (2019)) for which Sharda has a Letter of Access. On the basis of its results the PT value could be refined. A 90th percentile PT of 0.62 was used in the risk assessment for brown hare.

A new higher-tier assessment of the long-term/reproductive risk for large herbivorous “lagomorph” with the use of the more appropriate PD, the previously discussed ftwa and the PT obtained from XXX & Katzchner (2019), is proposed by the applicant:

Table 9.3-40bis: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in maize – refined parameters (*) are further described and justified in the text (1137 g/ha)

Intended use		Maize							
Active substance/product		pendimethalin							
Application rate (g/ha)		1 × 1137							
Reprod. toxicity (mg/kg bw/d)		30							
TER criterion		5							
Focal species	Food category, % in diet	FIR/bw*	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT*	PD*	DDD_m (mg/kg bw/d)		TER_{tr}
Brown hare (<i>Lepus europaeus</i>)	Cereals and grasses	0.33	54.2 × 1	0.29	0.62	0.84	3.07	3.29	9.13
	Non-grass herbs	0.33	28.7 × 1	0.2	0.62	0.16	0.21		

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Weight of evidence

Additionally to the refinements presented above for lagomorphs, the Applicant wishes to argue the following points:

- Lagomorphs are mobile species and therefore they do not spend more time in one crop. Therefore, from the point of view of the long-term assessment, it is not expected they are exposed to treated crops for a long period.
- Pendimethalin is selective to gramineae (grasses) which means that after treatment grasses won't be available anymore and then, the weeds are assumed to be less attractive and palatable for large herbivorous mammals. Thus, the crop is less attractive for rabbit.
- The considered value of NOEL of 30 mg/kg bw/d is more conservative than the value of 150 mg/kg bw/d (or even higher in some cases), which was used for the risk assessment and accepted by several other MS for national authorization.

zRMS comment:

The refined risk for wood mouse and brown hare in maize was verified by zRMS with consideration default values of MAF and ftwa. The applicant used PT = 0.139 for wood mouse (LoA to field study, by XXX, 2013) to refine the risk for this species. We agree that vole is less relevant species in maize and therefore the risk for wood mouse is sufficient for risk assessment for small mammals.

In conclusion:

The risk for brown hare needs further refinement for use in maize.

In the same time the risk for wood mouse is considered acceptable.

During Commenting period the applicant referred to ftwa parameter evaluated by zRMS .

Dissipation and ftwa refinement- applicant approach:

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb⁴: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH.

Further, zRMS used for non-grass herbs the DT₅₀ of 3 days (from dicot plants, EFSA Conclusion) in the risk assessment, giving an ftwa of 0.2, which was also used in the higher tier refinement. The DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach

zRM still doesn't agree with ftwa 0.29 parameter in quantitative risk assessment.

It should be noted the DT₅₀ value 4.48 d is obtained from the study in Poland which was excluded from kinetic analysis by the applicant and it was confirmed by zRMS previously.

It should be noted that to support of this submission the applicant provided the LoA to study by XXX & XXX (2019) monitoring brown hares in two Central Zone countries (Germany and Hungary).

As 21 individuals were found to be crop consumers, it was agreed by the zRMS-PL for that the overall 90th percentile PT value is sufficiently robust for purposes of the risk refinement. This study was evaluated by zRMS-PL previously in the other ppps (please see in Appendix 2).

Table 9.3-40bis_{corr}: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in maize – refined parameters (1137 g/ha)

Intended use		Maize							
Active substance/product		pendimethalin							
Application rate (g/ha)		1 × 1137							
Reprod. toxicity (mg/kg bw/d)		30							
TER criterion		5							
Focal species	Food category, % in diet	FIR/bw*	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT*	PD*	DDD_m (mg/kg bw/d)		TER_{tt}
Brown hare (<i>Lepus europaeus</i>)	Cereals and grasses	0.33	54.2 x 1	0.53	0.62	0.84	5.49	5.70	5.26
	Non-grass herbs	0.33	28.7 x 1	0.2	0.62	0.16	0.21		

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Orchards

Table 9.3-41: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in orchards – refined parameters (*) are further described and justified in the text

Intended use	Orchards
Active substance/product	pendimethalin
Application rate (g/ha)	1 × 1590

⁴ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals.	1.33	54.2 x 1	1 x 0.21*	1	24.07	1.3
	100% grass.			1 x 0.53		60.74	
Rabbit (<i>Oryctolagus cuniculus</i>)	100% non-grass herbs.	0.50	28.7 x 1	1 x 0.21*	1	4.79	6.3
				1 x 0.2		4.56	
Wood mouse (<i>Apodemus sylvaticus</i>)	25% weeds	0.27	28.7 x 1	1 x 0.21*	1	0.65	
				1 x 0.53		1.63	
	50% weed seeds			1 x 0.53		4.57	
	25% ground arthropods			1 x 0.53		0.43	
Total						5.65	5.3
						6.63	4.52

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The risk for vole after the TWA refinement is still below the trigger. Hence, further refinement is needed for long-term exposure in orchards.

Applications between rows

In assessing the potential risk to mammals it has been assumed as worst case that the animals obtain 100% of their diet within the treated area. It is possible to refine the PD (proportion of an animal's daily diet obtained within the treated area) to obtain a more accurate reflection of the actual exposure of mammals to residues of pendimethalin.

For permanent crop habitats like orchards (i.e. orchards) where the application is done between rows to create a weed free area with very low forage and cover for small herbivorous mammals. The strip along the crop line is left as untreated.

Predicted environmental concentrations (in soil, surface water and ground water) were calculated based on the assumption that as worst case, 75% of the total area is treated. As only 75% area is treated, it is reasonable to assume that, for a small herbivorous vole which will range over a significant area of orchard, only approximately 75% of its diet will be taken from the treated area. A maximum PD value of 0.75 could be considered to further refine the risk assessment for orchards.

Below is risk assessment considering the mentioned refinement.

Table 9.3-42: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in orchards – refined parameters (*) are further described and justified in the text

Intended use		Orchards					
Active substance/product		pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PD*	DDD_m (mg/kg bw/d)	TER_{it}

Common vole (<i>Microtus arvalis</i>)	Grass + cereals. 100% grass.	1.33	54.2 x 1	1 x 0.21*	0.75	18.05	1.66
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FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The TER value is still below the trigger and therefore there would be risk. However, it has to be considered that Pendimethalin is a herbicide and the application will directly have an impact on the attractiveness and availability of the food for herbivores mammal; effects on the grass are rapid and the vegetation would be unpalatable, further reducing the probability that can serve as voles forage. In addition, orchards are intensively managed crops, besides the use of pesticides particularly mechanical husbandry activities such as mowing, mulching and pruning take place. Based in generic studies and literature data, intensively managed orchards by mowing, mulching and herbicidal weeding pose adverse habitat conditions for the common vole and are therefore considered only as secondary habitats for this species. Orchards are mulched regularly during the vegetation season reducing the vegetation height which increases the predation risk being orchards are a secondary habitat for voles. All this may be taken as a weight of evidence approach to consider that there will be no a long-term exposure of small herbivorous vole and that the risk is acceptable.

As a further approach for vole, and considering that the vegetation treated between rows will be not attractive and available for vole due to the rapid effects of pendimethalin, it is more realistic to assume that vole will feed on the vegetation below the trees line which are untreated. The untreated area below the trees line would be 25% of the total area. Assuming that voles will feed on this, then it can be assumed that only a 25% of its diet will be taken from the untreated area and hence a maximum PD or 0.25 could be considered to further refine the risk assessment for orchards.

Table 9.3-43: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in orchards – refined parameters (*) are further described and justified in the text

Intended use		Orchards					
Active substance/product		pendimethalin					
Application rate (g/ha)		1 x 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PD*	DDD_m (mg/kg bw/d)	TER_{it}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals. 100% grass.	1.33	54.2 x 1	1 x 0.21*	0.25	6.02	5.0

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

When considering that vole will feed on the vegetation below the trees rows untreated, which would be a more realistic scenario to assess the long-term risk for vole, the TER_{it} value is 5 showing that the risk would be acceptable.

Weight of evidence

There are many reasons why the risk assessment for vole is considered to be covered through the assessment of other small mammalian species:

- High fecundity and population recuperation of the vole.
- Primary source of food outside crops fields for the vole.
- Necessity of population control measures since the vole is considered a crop pest when high population levels are reached.
- Other agricultural techniques being also means of population control.

In addition, orchards are intensively managed crops, besides the use of pesticides particularly mechanical husbandry activities such as mowing, mulching and pruning take place. Based in generic studies and literature data, intensively managed orchards by mowing, mulching and herbicidal weeding pose adverse habitat conditions for the common vole and are therefore considered only as secondary habitats for this species. Orchards are mulched regularly during the vegetation season reducing the vegetation height which increases the predation risk being orchards are a secondary habitat for voles.

Therefore, the exposure of common voles to plant protection products within orchards is not ecologically relevant for the persistence of the populations. Since the exposure of common voles to plant protection products in orchards is not ecologically relevant for the survival and reproduction of the populations, the Wood mouse (*Apodemus sylvaticus*) and the European hare (*Lepus europaeus*) were identified as suitable focal species in pome fruits. Same findings were reported in studies already evaluated by EFSA (*EFSA Journal 2010;8(11):1904*).

Applicant update February 2022

The refinement of the PD and twa was not found acceptable by the zRMS and therefore further refinements are needed for orchards.

Dissipation and ftwa refinement

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb⁵: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH.

Further, the DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

Table 9.3-44bis: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in orchards – refined parameters (*) are further described and justified in the text

Intended use		Orchards					
Active substance/product		pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals, 100% grass.	1.33	54.2 × 1	1 × 0.29	1	33.24	0.90
Wood mouse	25% weeds	0.27	28.7 × 1	1 × 0.29	1	0.89	

⁵ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

<i>Apodemus sylvaticus</i>	50% weed seeds		40.2 x 1	1 x 0.53	1	4.57	
	25% ground arthropods		7.5 x 1	1 x 0.53	1	0.43	
	Total					5.89	5.09

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Weight of evidence

Besides the reasonings stated above, the applicant wishes to point out further evidences by which the risk for small herbivorous mammals “vole” is considered acceptable.

First, pendimethalin is an herbicide, application will directly have an impact on the attractiveness and availability of the food for herbivores (EFSA Journal 2015; 13(4):4077).

Also, the common vole in the crops is almost not represented, due to the fact that they require a thick vegetation layer (e.g. established hedges where there is a dense understory) as protection from predators. Voles are very unlikely to spend much time on sparsely covered ground and the application of the product is intended to be done at pre- and early post-emergence, where the ground is barely covered. As, the risk for small omnivorous mammals and large herbivorous mammals has been demonstrated to be acceptable, the risk assessment for “vole” is assumed to be covered by the assessment of the other mammalian species.

The considered value of NOEL of 30 mg/kg bw/d is more conservative than the value of 150 mg/kg bw/d (or even higher in some cases), which was used for the risk assessment and accepted by several other MS for national authorization.

Furthermore, in cases where the relevant model species for the risk assessment is a mouse or a vole, the TER acceptability criterion according to Annex VI of Directive 91/414/EEC may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europe’s middle zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a TER \geq 5 in the acute exposure scenario and a TER \geq 2 in the long-term exposure scenario may be accepted as sufficient.

zRMS comments:

The refined risk for vole, wood mouse and rabbit in orchards was verified by zRMS. The default values of MAF and ftwa were used by zRMS. The argumentation provided by the applicant for vole as WoE approach should be considered further at MSs level. In zRMS’s opinion the PD values of 0.75 or 0.25 for vole was not recommended for use.

In case of wood mouse taking into account that the default values of PT and DT₅₀ = 10 days were used and considering that trigger value is only slight below trigger of 5 the risk can be considered as an acceptable. It should be noted that DT₅₀ for pendimethalin seems to be less than 10 days for winter cereals/weeds. The DT₅₀ for spring cereals is 2.73 day.

However, there are not sufficiently data to provide the quantitative risk assessment and WoE approach may be used at MSs level, if relevant.

The risk for vole the risk needs further refinement at MSs level depend on their own requirements concerned on this species.

During Commenting period the applicant referred to ftwa parameter evaluated by zRMS :

Dissipation and ftwa refinement- applicant approach:

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb⁶: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH. Further, zRMS used for non-grass herbs the DT₅₀ of 3 days (from dicot plants, EFSA Conclusion) in the risk assessment, giving an ftwa of 0.2, which was also used in the higher tier refinement. The DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

zRMS till doesn't agree with ftwa 0.29 parameter in quantitative risk assessment. It should be noted the DT₅₀ value 4.48 d is obtained from the study in Poland which was excluded from kinetic analysis before by the applicant and it was confirmed by zRMS previously.

Sunflower

Table 9.3-45: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in sunflower – refined parameters (*) are further described and justified in the text

Intended use		Sunflower					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 1183					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Rabbit (<i>Oryctolagus cuniculus</i>)	100% non-grass herbs.	0.50	28.7 x 1	1 x 0.21* 1 x 0.20	1	3.56 3.55	8.4 8.5

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The TER is above the trigger showing no risk after the application of Panshui.

zRMS comment:

The long-term risk is considered as acceptable for rabbit in sunflower.

⁶ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

Bulbs and onion like crops

Table 9.3-46: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in Bulbs and onion like crops – refined parameters (*) are further described and justified in the text

Intended use		Bulbs and onion like crops					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Wood mouse (<i>Apodemus sylvaticus</i>)	25% weeds	0.27	28.7 x 1	1 x 0.21* 1 x 0.53	1	0.65 1.63	
	50% weed seeds		40.2 x 1	1 x 0.53	1	4.57	
	25% ground arthropods		7.5 x 1	1 x 0.53	1	0.43	
	Total					5.65 6.63	5.3 4.52

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The TER is above the trigger showing no risk after the application of Peshui.

Applicant update February 2022

The refinement of the twa was not found acceptable by the zRMS and therefore further refinements might be needed for bulbs and onion like crops.

Dissipation and ftwa refinement

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb⁷: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH.

Further, the DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

Table 9.3-47bis: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in Bulbs and onion like crops – refined parameters (*) are further described and justified in the text

Intended use	Bulbs and onion like crops
Active substance/product	Pendimethalin

⁷ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

Application rate (g/ha)*		1 × 1137					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Wood mouse (Apodemus sylvaticus)	25% weeds	0.27	28.7 × 1	1 × 0.29	1	0.64	
	50% weed seeds		40.2 × 1	1 × 0.53	1	3.27	
	25% ground arthropods		7.5 × 1	1 × 0.53	1	0.31	
	Total					4.21	7.12

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Weight of evidence

Besides the reasonings stated above, the applicant wishes to point out further evidences by which the risk for small omnivorous mammals is considered acceptable.

The considered value of NOEL of 30 mg/kg bw/d is more conservative than the value of 150 mg/kg bw/d (or even higher in some cases), which was used for the risk assessment and accepted by several other MS for national authorization.

Furthermore, in cases where the relevant model species for the risk assessment is a mouse or a vole, the TER acceptability criterion according to Annex VI of Directive 91/414/EEC may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europe’s middle zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a TER ≥ 5 in the acute exposure scenario and a TER ≥ 2 in the long-term exposure scenario may be accepted as sufficient.

zRMS comments:

The long-term risk was verified by zRMS and as consequence of this further refinement was needed for wood mouse for post-emergence application.

In zRMS opinion taking into account that the default values of PT and DT₅₀ = 10 days were used and considering that trigger value is only slight below trigger of 5 the risk can be considered as an acceptable. It should be noted that DT₅₀ for pendimethalin seems to be less than 10 days for winter cereals/weeds. The DT₅₀ for spring cereals is 2.73 day.

However, there are not sufficiently data to provide the quantitative risk assessment and WoE approach may be used at MSs level, if relevant.

During Commenting period the applicant referred to ftwa parameter evaluated by zRMS :

Dissipation and ftwa refinement- applicant approach:

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb⁸: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH. Further, zRMS used for non-grass herbs the DT₅₀ of 3 days (from dicot plants, EFSA Conclusion) in

⁸ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

the risk assessment, giving an ftwa of 0.2, which was also used in the higher tier refinement. The DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

RMS still doesn't agree with ftwa 0.29 parameter in quantitative risk assessment. It should be noted the DT₅₀ value 4.48 d is obtained from the study in Poland which was excluded from kinetic analysis before by the applicant and it was confirmed by zRMS previously.

Pulses

Table 9.3-48: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in pulses – refined parameters (*) are further described and justified in the text

Intended use		Pulses							
Active substance/product		Pendimethalin							
Application rate (g/ha)		1 × 1590							
Reprod. toxicity (mg/kg bw/d)		30							
TER criterion		5							
Focal species	Food category, % in diet	FIR/bw	RUD _m × DF (mg/kg food)	MAF _m × TWA*	PT	DDD _m (mg/kg bw/d)	TER _{it}		
Rabbit (<i>Oryctolagus cuniculus</i>)	100% non-grass herbs	0.50	28.7 x 1	1 x 0.21*	1	4.79	6.3		
				1 x 0.20		4.56	6.57		
Wood mouse (<i>Apodemus sylvaticus</i>)	25% weeds	0.27	28.7 x 1	1 x 0.21*	1	0.65			
				1 x 0.53		1.63			
	50% weed seeds			40.2 x 1		1 x 0.53	1	4.57	
	25% ground arthropods			7.5 x 1		1 x 0.53	1	0.43	
	Total					5.65 6.63	5.3 4.52		

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The TER is above the trigger showing no risk after the application of Peshui.

Applicant update February 2022

The refinement of the twa was not found acceptable by the zRMS and therefore further refinements are needed for pulses.

Dissipation and ftwa refinement

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb⁹: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH.

Further, the DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

Table 9.3-49bis: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in pulses – refined parameters (*) are further described and justified in the text

Intended use		Pulses					
Active substance/product		Pendimethalin					
Application rate (g/ha)*		1 × 1183					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD _m × DF (mg/kg food)	MAF _m × TWA*	PT	DDD _m (mg/kg bw/d)	TER _{it}
Wood mouse (<i>Apodemus sylvaticus</i>)	25% weeds	0.27	28.7 x 1	1 x 0.29	1	0.66	
	50% weed seeds		40.2 x 1	1 x 0.53	1	3.40	
	25% ground arthropods		7.5 x 1	1 x 0.53	1	0.32	
	Total					4.38	6.84

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Weight of evidence

Besides the reasonings stated above, the applicant wishes to point out further evidences by which the risk for small omnivorous mammals is considered acceptable.

The considered value of NOEL of 30 mg/kg bw/d is more conservative than the value of 150 mg/kg bw/d (or even higher in some cases), which was used for the risk assessment and accepted by several other MS for national authorization.

Furthermore, in cases where the relevant model species for the risk assessment is a mouse or a vole, the TER acceptability criterion according to Annex VI of Directive 91/414/EEC may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in

⁹ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

Europe's middle zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a TER ≥ 5 in the acute exposure scenario and a TER ≥ 2 in the long-term exposure scenario may be accepted as sufficient.

zRMS comments:

The long-term risk was verified by zRMS and as consequence of this further refinement for wood mouse was needed.

In zRMS opinion taking into account that the default values of PT and DT₅₀ = 10 days were used and considering that trigger value is only slight below trigger of 5 the risk can be considered as an acceptable. It should be noted that DT₅₀ for pendimethalin seems to be less than 10 days for winter cereals/weeds. The DT₅₀ for spring cereals is 2.73 day.

However, there are not sufficiently data to provide the quantitative risk assessment and WoE approach may be used at MSs level, if relevant.

During Commenting period the applicant referred to ftwa parameter evaluated by zRMS :

Dissipation and ftwa refinement- applicant approach:

Applicant wishes to offer the reference to the document "Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009" from ctgb¹⁰: "...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor". Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH.

Further, zRMS used for non-grass herbs the DT₅₀ of 3 days (from dicot plants, EFSA Conclusion) in the risk assessment, giving an ftwa of 0.2, which was also used in the higher tier refinement. The DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

zRMS still doesn't agree with ftwa 0.29 parameter in quantitative risk assessment.

It should be noted the DT₅₀ value 4.48 d is obtained from the study in Poland which was excluded from kinetic analysis before by the applicant and it was confirmed by zRMS previously.

Winter oilseed rape

Table 9.3-50: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in winter oilseed rape – refined parameters (*) are further described and justified in the text

Intended use		Winter oilseed rape					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 910					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Rabbit (<i>Oryctolagus cuniculus</i>)	100% non-grass herbs.	0.50	28.7 x 1	1 x 0.21* 1 x 0.20	1	2.74 2.61	10.9 11.5

¹⁰ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The TER is above the trigger showing no risk after the application of Penschui.

zRMS comments:

The long-term risk is considered as acceptable for rabbit in winter oilseed rape.

Leafy vegetables

Table 9.3-51: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in leafy vegetables – refined parameters (*) are further described and justified in the text

Intended use		Leafy vegetables					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Rabbit (<i>Oryctolagus cuniculus</i>)	100% non-grass herbs.	0.50	28.7 x 1	1 x 0.21* 1 x 0.20	1	4.79 4.56	6.3 6.57
Wood mouse (<i>Apodemus sylvaticus</i>)	25% weeds	0.27	28.7 x 1	1 x 0.21* 1 x 0.53	1	0.65 1.63	
	50% weed seeds		40.2 x 1	1 x 0.53	1	4.57	
	25% ground arthropods		7.5 x 1	1 x 0.53	1	0.43	
	Total					5.65 6.63	5.3 4.52

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The TER is above the trigger showing no risk after the application of Penschui.

Applicant update February 2022

The refinement of the PD and twa was not found acceptable by the zRMS and therefore further refinements are needed for leafy vegetables.

Dissipation and twa refinement

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of

plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb¹¹: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH.

Further, the DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

Table 9.3-52bis: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in leafy vegetables – refined parameters (*) are further described and justified in the text

Intended use		Leafy vegetables					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Wood mouse (<i>Apodemus sylvaticus</i>)	25% weeds	0.27	28.7 x 1	1 x 0.29	1	0.89	
	50% weed seeds		40.2 x 1	1 x 0.53	1	4.57	
	25% ground arthropods		7.5 x 1	1 x 0.53	1	0.43	
	Total					5.89	5.09

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Weight of evidence

Besides the reasoning stated above, the applicant wishes to point out further evidences by which the risk for small omnivorous mammals is considered acceptable.

The considered value of NOEL of 30 mg/kg bw/d is more conservative than the value of 150 mg/kg bw/d (or even higher in some cases), which was used for the risk assessment and accepted by several other MS for national authorization.

Furthermore, in cases where the relevant model species for the risk assessment is a mouse or a vole, the TER acceptability criterion according to Annex VI of Directive 91/414/EEC may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europe’s middle zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a TER ≥ 5 in the acute exposure scenario and a TER ≥ 2 in the long-term exposure scenario may be accepted as sufficient.

zRMS comments:

The long-term risk was verified by zRMS and as consequence of this further refinement for wood

¹¹ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

mouse was needed.

In zRMS opinion taking into account that the default values of PT and DT₅₀ = 10 days were used and considering that trigger value is only slight below trigger of 5 the risk can be considered as an acceptable. It should be noted that DT₅₀ for pendimethalin seems to be less than 10 days for winter cereals/weeds.

However, there are not sufficiently data to provide the quantitative risk assessment and WoE approach may be used at MSs level, if relevant.

During Commenting period the applicant referred to ftwa parameter evaluated by zRMS :

Dissipation and ftwa refinement- applicant approach:

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb¹²: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH. Further, zRMS used for non-grass herbs the DT₅₀ of 3 days (from dicot plants, EFSA Conclusion) in the risk assessment, giving an ftwa of 0.2, which was also used in the higher tier refinement. The DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

RMS still doesn't agree with ftwa 0.29 parameter in quantitative risk assessment.

It should be noted the DT₅₀ value 4.48 d is obtained from the study in Poland which was excluded from kinetic analysis by the applicant and it was confirmed by zRMS previously.

Strawberry

Table 9.3.53: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% GS in strawberry—refined parameters⁽¹²⁾ are further described and justified in the text

Intended use		Strawberry					
Active substance/product		pendimethalin					
Application rate (g/ha)		1 x 1500					
Reprod. toxicity (mg/kg bw/d)		25					
TER criterion		5					
Focal species	Food category (% in diet)	FTWA ₅₀	RED ₅₀ × DT ₅₀ (mg/kg food)	MAF ₅₀ × TWA ₅₀	PT	BDD ₅₀ (mg/kg bw/d)	TER ₅₀
Rabbit (<i>Oryctolagus cuniculus</i>) 10-20	100% non-grass herbs	0.50	18.7 x 1	1 x 0.213	1	4.70	6.5
Wood mouse (<i>Apodemus sylvaticus</i>) 10-20	25% weeds	0.29	18.7 x 1	1 x 0.213	1	9.65	
	50% weed seeds		40.2 x 1	1 x 0.53	1	4.50	
	25% ground arthropods		1.5 x 1	1 x 0.53	1	9.43	

¹² Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

	Total	5.65	5.65
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FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple-application factor; DDD: daily dietary dose; TER: toxicity-to-exposure ratio; TER values shown in bold fall below the relevant trigger

The TER is above the trigger showing no risk after the application of Pendshot.

Bush and cane fruit

Table 9.3-54: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in bush and cane fruit – refined parameters (*) are further described and justified in the text

Intended use		Bush and cane fruit					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals. 100% grass.	1.33	54.2 x 1	1 x 0.21* 1x 0.53	1	24.07 60.74	1.3 0.49

The risk for vole after the TWA refinement is still unacceptable. Hence, further refinement is needed for long-term exposure in bush and cane fruits.

Applications between rows

According to the GAP specifications, the application in bush and cane fruits, would follow the same procedure as for orchards (application between rows). Hence, the same approach is selected here as a refinement.

The first approach of refinement is considering a PD value of 0.75.

Table 9.3-55: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in bush and cane fruit – refined parameters (*) are further described and justified in the text

Intended use		Bush and cane fruit					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PD	DDD_m (mg/kg bw/d)	TER_{it}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals. 100% grass.	1.33	54.2 x 1	1 x 0.21*	0.75 [§]	18.05	1.66

The TER value is still below the trigger and therefore there would be risk. However, it has to be considered that Pendimethalin is a herbicide and the application will directly have an impact on the attractiveness and availability of the food for herbivores mammal; effects on the grass are rapid and the vegetation

would be unpalatable, further reducing the probability that can serve as voles forage. In addition, bush and cane fruit are intensively managed crops, besides the use of pesticides particularly mechanical husbandry activities such as mowing, mulching and pruning take place. Based in generic studies and literature data, intensively managed bush and cane fruit by mowing, mulching and herbicidal weeding pose adverse habitat conditions for the common vole and are therefore considered only as secondary habitats for this species. Bush and cane fruits are mulched regularly during the vegetation season reducing the vegetation height which increases the predation risk being orchards are a secondary habitat for voles. All this may be taken as a weight of evidence approach to consider that there will be no a long-term exposure of small herbivorous vole and that the risk is acceptable.

As a further approach for vole, and considering that the vegetation treated between rows will be not attractive and available for vole due to the rapid effects of pendimethalin, it is more realistic to assume that vole will feed on the vegetation below the crop lines which are untreated. The untreated area below the crop lines would be 25% of the total area. Assuming that voles will feed on this, then it can be assumed that only a 25% of its diet will be taken from the untreated area and hence a maximum PD or 0.25 could be considered to further refine the risk assessment for bush and cane fruit.

Table 9.3-56: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in bush and cane fruit – refined parameters (*) are further described and justified in the text

Intended use		Bush and cane fruit					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PD*	DDD_m (mg/kg bw/d)	TER_{it}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals. 100% grass.	1.33	54.2 x 1	1 x 0.21*	0.25*	6.02	5.0

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

When considering that vole will feed on the vegetation below the crop rows which are untreated, which would be a more realistic scenario to assess the long-term risk for vole, the TER_{it} value is 5 showing that the risk would be acceptable.

Weight of evidence

There are many reasons why the risk assessment for vole is considered to be covered through the assessment of other small mammalian species:

- High fecundity and population recuperation of the vole.
- Primary source of food outside crops fields for the vole.
- Necessity of population control measures since the vole is considered a crop pest when high population levels are reached.
- Other agricultural techniques being also means of population control.

In addition, bush and cane fruits are intensively managed crops, besides the use of pesticides particularly mechanical husbandry activities such as mowing, mulching and pruning take place which pose adverse

habitat conditions for the common vole and are therefore considered only as secondary habitats for this species.

Therefore, the exposure of common voles to plant protection products within bush and cane fruits is not ecologically relevant for the persistence of the populations. Since the exposure of common voles to plant protection products in bush and cane fruits is not ecologically relevant for the survival and reproduction of the populations, the small omnivorous mouse would be the suitable focal species.

Applicant update February 2022

The refinement of the PD and twa was not found acceptable by the zRMS and therefore further refinements are needed for bush and cane fruit.

Dissipation and ftwa refinement

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb¹³: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH.

Further, the DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

Table 9.3-57bis: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in bush and cane fruit – refined parameters (*) are further described and justified in the text

Intended use		Bush and cane fruit					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PD	DDD_m (mg/kg bw/d)	TER_n
Common vole (<i>Microtus arvalis</i>)	Grass + cereals, 100% grass.	1.33	54.2 × 1	1 × 0.29	1	33.24	0.90

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Weight of evidence

Besides the reasonings stated above, the applicant wishes to point out further evidences by which the risk for small herbivorous mammals “vole” is considered acceptable.

First, pendimethalin is an herbicide, application will directly have an impact on the attractiveness and availability of the food for herbivores (EFSA Journal 2015; 13(4):4077).

¹³ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

Also, the common vole in the crops is almost not represented, due to the fact that they require a thick vegetation layer (e.g. established hedges where there is a dense understory) as protection from predators. Voles are very unlikely to spend much time on sparsely covered ground and the application of the product is intended to be done at pre- and early post-emergence, where the ground is barely covered. As, the risk for small omnivorous mammals and large herbivorous mammals has been demonstrated to be acceptable, the risk assessment for “vole” is assumed to be covered by the assessment of the other mammalian species.

The considered value of NOEL of 30 mg/kg bw/d is more conservative than the value of 150 mg/kg bw/d (or even higher in some cases), which was used for the risk assessment and accepted by several other MS for national authorization.

Furthermore, in cases where the relevant model species for the risk assessment is a mouse or a vole, the TER acceptability criterion according to Annex VI of Directive 91/414/EEC may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europe’s middle zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a $TER \geq 5$ in the acute exposure scenario and a $TER \geq 2$ in the long-term exposure scenario may be accepted as sufficient.

zRMS comment:

The applicant proposed the risk assessment based on the same approach as for orchards. In B&M GD, 2009 this scenario is not included.

The refined risk for vole in orchards was verified by zRMS with consideration default values of MAF and ftwa. The argumentation provided by the applicant for vole as WoE approach should be considered at MSs level. In zRMS’s opinion the PD values of 0.75 or 0.25 for vole was not recommended for use to quantitative risk assessment.

In conclusion:

The risk for vole the risk needs further refinement at MSs level depend on their own requirements concerned on vole species.

During Commenting period the applicant referred to ftwa parameter evaluated by zRMS :

Dissipation and ftwa refinement- applicant approach:

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb¹⁴: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH. Further, zRMS used for non-grass herbs the DT₅₀ of 3 days (from dicot plants, EFSA Conclusion) in the risk assessment, giving an ftwa of 0.2, which was also used in the higher tier refinement. The DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

RMS still doesn’t agree with ftwa 0.29 parameter in quantitative risk assessment.

It should be noted the DT₅₀ value 4.48 d is obtained from the study in Poland which was excluded from kinetic analysis before by the applicant and it was confirmed by zRMS previously.

¹⁴ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

Potato

Table 9.3-58: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in potatoes – refined parameters (*) are further described and justified in the text

Intended use		Potatoes					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Rabbit (<i>Oryctolagus cuniculus</i>)	100% non-grass herbs	0.50	28.7 x 1	1 x 0.21* 1 x 0.20	1	4.79 4.56	6.3 6.57
Wood mouse (<i>Apodemus sylvaticus</i>)	25% weeds	0.27	28.7 x 1	1 x 0.21* 1 x 0.53	1	0.65 1.63	
	50% weed seeds		40.2 x 1	1 x 0.53	1	4.57	
	25% ground arthropods		7.5 x 1	1 x 0.53	1	0.43	
	Total						5.65 6.63

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The TER is above the trigger showing no risk after the application of Penschui.

Applicant update February 2022

The refinement of the twa was not found acceptable by the zRMS and therefore further refinements are needed for potatoes.

Dissipation and ftwa refinement

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb¹⁵: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH.

Further, the DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

¹⁵ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

Table 9.3-59bis: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in potatoes – refined parameters (*) are further described and justified in the text

Intended use		Potatoes					
Active substance/product		pendimethalin					
Application rate (g/ha)*		1 × 1137					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals, 100% grass.	1.33	54.2 x 1	1 x 0.29	1	23.77	1.26
Wood mouse (<i>Apodemus sylvaticus</i>)	25% weeds	0.27	28.7 x 1	1 x 0.29	1	0.64	
	50% weed seeds		40.2 x 1	1 x 0.53	1	3.27	
	25% ground arthropods		7.5 x 1	1 x 0.53	1	0.31	
	Total					4.21	7.12

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Weight of evidence

Besides the reasonings stated above, the applicant wishes to point out further evidences by which the risk for small herbivorous mammals “vole” is considered acceptable.

First, pendimethalin is an herbicide, application will directly have an impact on the attractiveness and availability of the food for herbivores (EFSA Journal 2015; 13(4):4077).

Also, the common vole in the crops is almost not represented, due to the fact that they require a thick vegetation layer (e.g. established hedges where there is a dense understory) as protection from predators. Voles are very unlikely to spend much time on sparsely covered ground and the application of the product is intended to be done at pre- and early post-emergence, where the ground is barely covered. As, the risk for small omnivorous mammals and large herbivorous mammals has been demonstrated to be acceptable, the risk assessment for “vole” is assumed to be covered by the assessment of the other mammalian species.

The considered value of NOEL of 30 mg/kg bw/d is more conservative than the value of 150 mg/kg bw/d (or even higher in some cases), which was used for the risk assessment and accepted by several other MS for national authorization.

Furthermore, in cases where the relevant model species for the risk assessment is a mouse or a vole, the TER acceptability criterion according to Annex VI of Directive 91/414/EEC may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europe’s middle zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a TER ≥ 5 in the acute exposure scenario and a TER ≥ 2 in the long-term exposure scenario may be accepted as sufficient.

zRMS comments:

The long-term risk was verified by zRMS and as consequence of this further refinement for wood mouse was needed. In zRMS opinion taking into account that the default values of PT and DT₅₀ = 10

days were used and considering that trigger value is only slight below trigger of 5 the risk can be considered as an acceptable. It should be noted that DT₅₀ for pendimethalin seems to be less than 10 days for winter cereals/weeds.

However, there are not sufficiently data to provide the quantitative risk assessment and WoE approach may be used at MSs level, if relevant.

The risk for vole needs further refinement.

zRMS comments:

The long-term risk was verified by zRMS and as consequence of this further refinement for wood mouse was needed. In zRMS opinion taking into account that the default values of PT and DT₅₀ = 10 days were used and considering that trigger value is only slight below trigger of 5 the risk can be considered as an acceptable. It should be noted that DT₅₀ for pendimethalin seems to be less than 10 days for winter cereals/weeds.

However, there are not sufficiently data to provide the quantitative risk assessment and WoE approach may be used at MSs level, if relevant.

Vineyard

Table 9.3-60: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in vineyard – refined parameters (*) are further described and justified in the text

Intended use		Vineyard					
Active substance/product		pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Brown hare (<i>Lepus europaeus</i>)	100% plant matter. Non-grass herbs.	0.39	28.7 x 1	1 x 0.21* 1 x 0.20	1	3.74 3.73	8.0 8.04
Common vole (<i>Microtus arvalis</i>)	Grass + cereals. 100% grass.	1.33	54.2 x 1	1 x 0.21* 1 x 0.53	1	24.07 60.74	1.3 0.50
Wood mouse (<i>Apodemus sylvaticus</i>)	25% weeds	0.27	28.7 x 1	1 x 0.21* 1 x 0.53	1	0.65 1.63	
	50% weed seeds		40.2 x 1	1 x 0.53	1	4.57	
	25% ground arthropods		7.5 x 1	1 x 0.53	1	0.43	
	Total						5.65 6.63

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by

the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The risk for vole after the TWA refinement is still unacceptable. Hence, further refinement is needed for long-term exposure in vineyards.

Applications between rows

According to the GAP specifications, the application in vineyards, would follow the same procedure as for orchards (application between rows). Hence, the same approach is selected here as a refinement.

The first approach of refinement is considering a PD value of 0.75.

Table 9.3-61: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in vineyard – refined parameters (*) are further described and justified in the text

Intended use		Vineyard					
Active substance/product		Pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PD*	DDD_m (mg/kg bw/d)	TER_{it}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals, 100% grass.	1.33	54.2 x 1	1 x 0.21*	0.75*	18.05	1.66

The TER value is still below the trigger and therefore there would be risk. However, it has to be considered that Pendimethalin is a herbicide and the application will directly have an impact on the attractiveness and availability of the food for herbivores mammal; effects on the grass are rapid and the vegetation would be unpalatable, further reducing the probability that can serve as voles forage. In addition, vineyard are intensively managed crops, besides the use of pesticides particularly mechanical husbandry activities such as mowing, mulching and pruning take place. Based in generic studies and literature data, intensively managed vineyards by mowing, mulching and herbicidal weeding pose adverse habitat conditions for the common vole and are therefore considered only as secondary habitats for this species. Vineyards are mulched regularly during the vegetation season reducing the vegetation height which increases the predation risk being orchards are a secondary habitat for voles. All this may be taken as a weight of evidence approach to consider that there will be no a long-term exposure of small herbivorous vole and that the risk is acceptable.

As a further approach for vole, and considering that the vegetation treated between rows will be not attractive and available for vole due to the rapid effects of pendimethalin, it is more realistic to assume that vole will feed on the vegetation below the crop lines which are untreated. The untreated area below the crop lines would be 25% of the total area. Assuming that voles will feed on this, then it can be assumed that only a 25% of its diet will be taken from the untreated area and hence a maximum PD or 0.25 could be considered to further refine the risk assessment for vineyard.

Table 9.3-62: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in vineyard – refined parameters (*) are further described and justified in the text

Intended use	Vineyard
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Active substance/product		pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PD*	DDD_m (mg/kg bw/d)	TER_{it}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals, 100% grass.	1.33	54.2 x 1	1 x 0.21*	0.25*	6.02	5.0

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

When considering that vole will feed on the vegetation below the crop rows which are untreated, which would be a more realistic scenario to assess the long-term risk for vole, the TER_{it} value is 5 showing that the risk would be acceptable.

Weight of evidence

There are many reasons why the risk assessment for vole is considered to be covered through the assessment of other small mammalian species:

- High fecundity and population recuperation of the vole.
- Primary source of food outside crops fields for the vole.
- Necessity of population control measures since the vole is considered a crop pest when high population levels are reached.
- Other agricultural techniques being also means of population control.

In addition, vineyard are intensively managed crops, besides the use of pesticides particularly mechanical husbandry activities such as mowing, mulching and pruning take place. Intensively managed vineyard by mowing, mulching and herbicidal weeding pose adverse habitat conditions for the common vole and are therefore considered only as secondary habitats for this species.

Therefore, the exposure of common voles to plant protection products within vineyard is not ecologically relevant for the persistence of the populations. Since the exposure of common voles to plant protection products in vineyard is not ecologically relevant for the survival and reproduction of the populations, the small omnivorous mouse and the large herbivorous lagomorph would be more suitable focal species in vineyard.

Applicant update February 2022

The refinement of the twa was not found acceptable by the zRMS and therefore further refinements are needed for vineyards.

Dissipation and ftwa refinement

Applicant wishes to offer the reference to the document “Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009” from ctgb¹⁶: “...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor”. Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH.

Further, the DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined

¹⁶ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

Table 9.3-63bis: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in vineyard – refined parameters (*) are further described and justified in the text

Intended use		Vineyard					
Active substance/product		pendimethalin					
Application rate (g/ha)		1 × 1590					
Reprod. toxicity (mg/kg bw/d)		30					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF (mg/kg food)	MAF_m × TWA*	PT	DDD_m (mg/kg bw/d)	TER_{it}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals, 100% grass	1.33	54.2 x 1	1 x 0.29	1	33.24	0.90
Wood mouse (<i>Apodemus sylvaticus</i>)	25% weeds	0.27	28.7 x 1	1 x 0.29	1	0.89	
	50% weed seeds		40.2 x 1	1 x 0.53	1	4.57	
	25% ground arthropods		7.5 x 1	1 x 0.53	1	0.43	
	Total					5.89	5.09

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Weight of evidence

Besides the reasonings stated above, the applicant wishes to point out further evidences by which the risk for small herbivorous mammals “vole” is considered acceptable.

First, pendimethalin is an herbicide, application will directly have an impact on the attractiveness and availability of the food for herbivores (EFSA Journal 2015; 13(4):4077).

Also, the common vole in the crops is almost not represented, due to the fact that they require a thick vegetation layer (e.g. established hedges where there is a dense understory) as protection from predators. Voles are very unlikely to spend much time on sparsely covered ground and the application of the product is intended to be done at pre- and early post-emergence, where the ground is barely covered. As, the risk for small omnivorous mammals and large herbivorous mammals has been demonstrated to be acceptable, the risk assessment for “vole” is assumed to be covered by the assessment of the other mammalian species.

The considered value of NOEL of 30 mg/kg bw/d is more conservative than the value of 150 mg/kg bw/d (or even higher in some cases), which was used for the risk assessment and accepted by several other MS for national authorization.

Furthermore, in cases where the relevant model species for the risk assessment is a mouse or a vole, the TER acceptability criterion according to Annex VI of Directive 91/414/EEC may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europe’s middle zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a TER ≥ 5 in the acute exposure scenario and a TER ≥ 2 in the long-term exposure scenario may be accepted as sufficient.

zRMS comments:

The refined risk for vole in orchards was verified by zRMS with consideration default values of MAF and ftwa. The argumentation provided by the applicant for vole as WoE approach should be considered at MSs level. In zRMS's opinion the PD values of 0.75 or 0.25 for vole was not recommended for use.

In conclusion:

The risk for vole the risk needs further refinement at MSs level depend on their own requirements concerned on vole species.

During Commenting period the applicant referred to ftwa parameter evaluated by zRMS :

Dissipation and ftwa refinement- applicant approach:

Applicant wishes to offer the reference to the document "Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009" from ctgb¹⁷: "...However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor". Therefore, the Applicant is the opinion that an ftwa refinement with residue data at higher BBCH is a conservative approach since the dissipation of the residue would be slower than that at early BBCH, despite the fact that weeds can grow faster at early BBCH. Further, zRMS used for non-grass herbs the DT₅₀ of 3 days (from dicot plants, EFSA Conclusion) in the risk assessment, giving an ftwa of 0.2, which was also used in the higher tier refinement. The DT₅₀ for winter cereals seems to be less than the default value of 10 days, as stated by the zRMS. Therefore, the Applicant considers that the use of the higher DT₅₀ value of 4.48 days determined in one of the residue trials performed by the applicant, and the resulting value of ftwa of 0.29, is fully justified as conservative approach.

RMS still doesn't agree with ftwa 0.29 parameter in quantitative risk assessment.

It should be noted the DT₅₀ value 4.48 d is obtained from the study in Poland which was excluded from kinetic analysis by the applicant and it was confirmed by zRMS previously.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 13792 (EFSA Journal 2016;14(3):4420), pendimethalin belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil also covers the risk for mammals from all other intended uses (see 9.1.2).

Effective application rate (g/ha)=	1590			
Acute toxicity (mg/kg bw) =	3927	quotient	=	0.40
Reprod. toxicity (mg/kg bw/d) =	30	quotient	=	53.00

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 3000 a quantitative risk assessment (calculation of TER values) is not necessary.

¹⁷ Evaluation Manual for the Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009. Chapter 7 Ecotoxicology: terrestrial; birds and mammal. version 2.1; October 2016.

zRMS comments:

We agree that since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 3000 a quantitative risk assessment (calculation of TER values) is not necessary.

9.3.2.4 Effects of secondary poisoning

The log Pow of pendimethalin amounts to 5.4 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cotton also covers the risk for mammals from all other intended uses (see 9.1.2).

Table 9.3-64: Assessment of the risk for earthworm-eating mammals due to exposure to Pendimethalin via bioaccumulation in earthworms (secondary poisoning) for the intended use in bare soil

Parameter	Pendimethalin	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	1.961	Section 8, Chapter 8.7.2
log P _{ow} / P _{ow}	5.4	EFSA Journal 2009;7(12):1438
Koc	13792	Mean
foc	0.02	Default
BCF _{worm}	6.9	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	13.53	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	17.32	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	30	EFSA Journal 2009;7(12):1438
TER _{lt}	1.73	Risk, TER _{lt} <5

TER values shown in bold fall below the relevant trigger.

Since the TER is below the trigger value, a mean BCF of 0.81 is used in the refined risk assessment for earthworm-eating mammals, based on the study *Bioaccumulation in earthworms (laboratory study)* (Garret, 2000) (*Data from old dossier (Addendum B-8 Ecotoxicology, February 2002)*). According to the *Conclusions of the peer review of the pesticide risk assessment of the active substance pendimethalin* (EFSA Journal 2016;14(3):4420), it is derived from the most reliable study and EFSA agrees on the use of this endpoint in the refinement.

Table 9.3-65: Assessment of the risk for earthworm-eating mammals due to exposure to Pendimethalin via bioaccumulation in earthworms (secondary poisoning) for the intended use in bare soil

Parameter	Pendimethalin	comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	1.961	Section 8, Chapter 8.7.2
log P _{ow} / P _{ow}	5.4	EFSA Journal 2016;14(3):4420
K _{oc}	13792	EFSA Journal 2016;14(3):4420
f _{oc}	0.02	Default
BCF _{worm}	0.81	Study from RAR of bioaccumulation on earthworms (Garret, 2000)
PEC _{worm}	1.59	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	2.04	DDD = PEC _{worm} × 1.28
NOEL (mg/kg bw/d)	30	EFSA Journal 2016;14(3):4420
TER _{lt}	14.71	No risk, TER _{lt} >5

TER values shown in bold fall below the relevant trigger.

Since the TER_{lt} is above the trigger, the long-term risk of secondary poisoning to earthworm eating mammals from the use of Pendimethalin 45.5% CS is acceptable.

zRMS comment:

zRMS verified the risk for earthworm-eating mammals due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) taking into account the highest available BAF applied as a refined worst-case approach and PEC_{saccum}

Parameter	Pendimethalin	Comments
PEC _{soil} accumulation, (mg/kg soil)	2.305	PEC _{soil} accumulation (PEC _{act} + PEC _{soil} plateau)
log P _{OW} ; P _{OW}	5.4*; 251188	-
K _{OC}	13792	Arithmetic mean (n = 9)
f _{OC}	0.02	Default
BAF _{worm}	0.81	Refined BAF; worst-case approach
PEC _{worm}	1.86 x 0.81 =1.5	PEC _{worm} = PEC _{soil} × BAF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	1.5 x 1.28 = 1.92	DDD = PEC _{worm} × 1.28
NOEL (mg/kg bw/d)	30	Refined endpoint: BMDL5
TER _{LT}	15.62	TER _{LT} = NOEL / DDD

TER values shown in bold fall below the relevant trigger.

* EFSA Journal 2016;14(3):4420

The risk for earthworm-eating mammals due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) is considered as acceptable.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g

body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

Table 9.3-66: Assessment of the risk for fish-eating mammals due to exposure to Pendimethalin via bioaccumulation in fish (secondary poisoning) for the intended use

Parameter	Pendimethalin	comments
PEC _{sw} (twa = 21 d) (mg/L)	0.00959	Section 8, point 8.9.2 (PEC _{sw} twa 21d, step 2; appln.hand crop < 50cm)
BCF _{fish}	931	EFSA Journal 2016;14(3):4420 (most reliable endpoint)
BMF	<p>CT₅₀=5.1 days, 1.34 d ; 2.5 – 4.4 d CT₉₀: 87% depuration in 14 d; -; 96-97% clearance within 21 d (CT₉₀ 8.3-15 d) Two outdoor mesocosm studies with a.s. pendimethalin targeted at bioconcentration are available: <i>Lepomis macrochirus</i>, BMF_{KGL}= 0.1054 <i>Oncorhynchus mykiss</i> BMF_{KGL}= 0.0402 BMF_{KGL}= 0.0423</p> <p>Outdoor mesocosms</p> <p><i>Leuciscus idus melanotus</i> mean BCF_{actual conc} = 199</p> <p>aquatic community in outdoor mesocosms including fish No evidence of biomagnification of either pendimethalin, its metabolites or equivalent radioactivity within the aquatic food chain. NOEC fish: 0.0050 mg a.s./L</p>	<p>biomagnification factor (relevant for BCF ≥ 2000) EFSA Journal 2016;14(3):4420</p>
PEC _{fish}	8.93	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	1.27	DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	30	EFSA Journal 2016;14(3):4420
TER _{lt}	23.62	No risk, TER > 5

TER values shown in bold fall below the relevant trigger.

The TER is above the trigger, showing no risk for mammals of secondary poisoning by fish.

zRMS comment:

zRMS verified the risk for fish-eating birds due to exposure to pendimethalin via bioaccumulation in fish (secondary poisoning) taking into account the lowest and the highest available

BCF values applied as a refined worst-case approach and max PEC_{sw} (Step 2).

Parameter	Pendimethalin	Comments
PEC _{sw} (mg/L)	0.001246	FOCUS Step 2, max PEC _{sw}
BCF _{Fish}	931 / 3300*	Lowest and highest available BCF values
PEC _{Fish}	1.16/4.11	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.16/0.58	DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	30	Refined endpoint: BMDL5
TER _{LT}	187.5/51.72	TER _{LT} = NOEL / DDD

TER values shown in bold fall below the relevant trigger.

* Highest and lowest BCF values available from EFSA Journal 2016;14(3):4420

The risk for fish -eating birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) is considered as acceptable.

9.3.2.5 Biomagnification in terrestrial food chains

According to *Peer review of the pesticide risk assessment of the active substance pendimethalin* (EFSA Journal 2016;14(3):4420): “studies on three different species were available for assessing the bioconcentration factor (BCF) of pendimethalin in fish. The kinetic BCF ranged from 931 L/kg to 3,300 L/kg. The study providing the lowest BCF value was considered reliable, while the other two had some methodological flaws. However, the large difference between BCFs indicated that the bioconcentration of pendimethalin might be species-dependent, with higher bioconcentration for bluegill sunfish. This is consistent with the finding of the two available biomagnification (BMF) studies. These BMF studies were very much comparable (same protocol, author, laboratory, year, and tested batch) and showed that the BMF calculated for rainbow trout was less than a half of the BMF calculated for bluegill sunfish”.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant. Pendimethalin 45.5% CS is not a granule, nor is it intended for use as a bait or as seed treatment

9.3.4 Overall conclusions

The risk assessment shows that there is no acute risk for mammals after exposure to Pendimethalin 45.5% CS. No long-term risk was observed for mammals in bare soil and legume forage whereas for all the crops risk was observed and further assessment was needed. After the refinement of the chronic endpoint there was still risk for vole in maize, orchards, bush and cane fruit, vineyard and fruiting vegetables and vineyard, but further refinement of foliar DT₅₀ an acceptable long-term risk for mammals was obtained.

If no refinement of the EU agreed endpoint is done, The refinement of other parameters (e.g. foliar DT50 (dicot plants, PT, PD and weight of evidence) showed and acceptable long-term risk for mammals – unacceptable long-term risk for mammals for rabbit for cereals (post -emergence), for brown hare in maize (post- emergence) and for vole in orchards, bush and cane fruits and vineyards. Further refinement is needed.

For wood mouse the TER_{LT} values were slight below 5 (4.52) indicating needs for further refinement.

In zRMS's opinion taking into account that the default values of PT and DT₅₀ = 10 days were used and considering that trigger value is only slight below trigger of 5 the risk can be considered as an acceptable for this species. Additionally, it should be noted that DT₅₀ for pendimethalin seems to be less than 10 days for winter cereals/weeds.

However, there are not sufficiently data to provided quantitative risk assessment and WoE approach may be used at MSs level, if relevant.

For pre-emergence application (BBCH<10) for arable crops the risk is considered as acceptable.

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating mammals. The risk of secondary poisoning to earthworm eating mammals was found acceptable after refinement.

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating mammals. The risk of secondary poisoning to earthworm eating mammals was found acceptable after refinement.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

According to EFSA Journal 2016;14(3):4420 for Pendimethalin: “Based on information from the public literature, RMS concludes that the available data indicate that the risk for amphibians and reptiles is covered by the risk assessments for birds and mammals and aquatic organisms.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with Pendimethalin and its relevant metabolites. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on aquatic organisms of Pendimethalin 45.5% SC were not evaluated as part of the EU assessment of Pendimethalin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms regarding Pendimethalin and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Fish				
<i>Oncorhynchus mykiss</i>	Pendimethalin	Acute 96 hr (static, with and without sediment)	Without sediment: LC ₅₀ = 0.196 mg a.s./L _{mm} LC ₅₀ = 0.283 mg a.s./L _{mm}	EFSA Journal 2016;14(3):4420
<i>Pimephales promelas</i>	Pendimethalin	Acute 96 hr (flow-through)	LC ₅₀ > 0.240 mg a.s./L _{mm}	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	BAS 455 48 H	Acute 96 hr (static)	LC ₅₀ = 8.427 mg prep./L (3.263 mg a.s./L _(mm))	EFSA Journal 2016;14(3):4420
<i>Cyprinus carpio</i>	BAS 455 48 H	Acute 96 hr (static)	LC ₅₀ = 27.8 mg prep./L (10.6 mg a.s./L _(mm))	EFSA Journal 2016;14(3):4420
<i>Oncorhynchus mykiss</i>	AG-P4-400-SC	Acute 96 hr (semi-static)	LC ₅₀ = 41.1 mg prep./L (14.7 mg a.s./L _(mm))	EFSA Journal 2016;14(3):4420
<i>Oncorhynchus mykiss</i>	M455H001 (P44)	Acute 96 hr (static)	LC ₅₀ = 8.28 mg/L(nom)	EFSA Journal 2016;14(3):4420
<i>Danio rerio</i>	Pendimethalin	Chronic (ELS) (static, in presence of sediment*)	NOEC (growth) = 0.108 mg a.s./L(nom) NOEAEC (35 d) = 0.300 mg a.s./L(nom)	EFSA Journal 2016;14(3):4420
<i>Pimephales promelas</i>	Pendimethalin	Chronic (FFLC) (flow-through)	Reproduction NOEC = 0.0063 mg a.s./L(mm) BCF = 1810 L/Kg	EFSA Journal 2016;14(3):4420
<i>Danio rerio</i>	Pendimethalin	Chronic (FFLC) (static, with sediment – exposure profile considered realistic to worst case)	NOEC (survival) = 20 µg a.s./L (nom)	EFSA Journal 2016;14(3):4420
<i>Danio rerio</i>	Pendimethalin	Chronic (FFLC) (static, with sediment – exposure profile considered realistic to worst case)	NOEC (highest test concentration) = 50 µg a.s./L (nom)	EFSA Journal 2016;14(3):4420
			Geomean <i>D. rerio</i> FFLC: 32 µg a.s./L (nom)* * nominal endpoint applicable for single peak exposure scenario's only	EFSA Journal 2016;14(3):4420
Aquatic invertebrates				
<i>Daphnia magna</i>	Pendimethalin	48 h, s	EC ₅₀ = 0.147 mg a.s./L _{mm}	EFSA Journal 2016;14(3):4420
<i>Daphnia magna</i>	Pendimethalin	48 h (static, with and without sediment*)	Without sediment: EC ₅₀ > 1.0 mg a.s./L (nom) / 0.701 (mm) With sediment : EC ₅₀ > 1.0 mg a.s./L (nom) / 0.606 (mm)	EFSA Journal 2016;14(3):4420
<i>Daphnia magna</i>	BAS 455 48 H	48 h, s	EC ₅₀ > 41.6 mg prep./L (> 16.1 mg a.s./L (mm))	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
<i>Daphnia magna</i>	AG-P4-400-SC	48 h (semi-static)	EC ₅₀ = 6.55 mg prep./L (2.33 mg a.s./L _(mm))	EFSA Journal 2016;14(3):4420
<i>Daphnia magna</i>	M455H033 (P48)	48 h, s	EC ₅₀ = 0.613 mg/L(mm)	EFSA Journal 2016;14(3):4420
<i>Daphnia magna</i>	M455H001 (P44)	48 h, s	EC ₅₀ = 7.73 mg/L(nom)	EFSA Journal 2016;14(3):4420
<i>Daphnia magna</i>	Pendimethalin	21 d, f	NOEC _(reproduction) = 0.0145 mg a.s./L_{nom}	EFSA Journal 2016;14(3):4420
<i>Daphnia magna</i>	Pendimethalin	21 d (semi-static)	NOEC _(reproduction) = 0.0173 mg a.s./L _{nom}	EFSA Journal 2016;14(3):4420
Sediment-dwelling organisms				
<i>Chironomus riparius</i>	Pendimethalin	30 d, s, spiked water	NOEC = 0.082 mg a.s./l (219 mg a.s./kg sed dw _(mm))	EFSA Journal 2016;14(3):4420
<i>Chironomus riparius</i>	Pendimethalin	28 d (static, spiked water)	NOEC ≥ 0.0011 mg a.s./L _(mm)	EFSA Journal 2016;14(3):4420
<i>Chironomus riparius</i>	Pendimethalin	28 d (static, spiked sediment)	NOEC = 227.3 mg a.s./kg dry sediment (im) (0.1099 mg a.s./L (im). 0.080 mg a.s./L _(mm))	EFSA Journal 2016;14(3):4420
Algae				
<i>Selenastrum capricornutum</i> (syn. <i>Pseudokirchneriella subcapitata</i>) (freshwater green algae)	Pendimethalin	72 h (static)	E _b C ₅₀ = 0.0041 mg a.s./L (mm) E _r C ₅₀ = 0.0093 mg a.s./L (mm) E _y C ₅₀ = 0.0038 mg a.s./L (mm)	EFSA Journal 2016;14(3):4420
	Pendimethalin	72 h (static)	E _r C ₅₀ > 0.055 mg a.s./L (mm) E _y C ₅₀ = 0.0043 mg a.s./L (mm)	EFSA Journal 2016;14(3):4420
	Pendimethalin	72 h (static)	E _r C ₅₀ = 0.0243 mg a.s./L (mm) E _y C ₅₀ = 0.0127 mg a.s./L (mm) 72 h + 7 d recovery period NOEC = > 0.050 (nom)	EFSA Journal 2016;14(3):4420
<i>Anabaena flos-aquae</i> (blue green algae)	Pendimethalin	120 h (static)	E _y C ₅₀ > 0.174 (mm)	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
<i>Pseudokirchneriella subcapitata</i>	BAS 455 48 H	72 h (static)	E _r C ₅₀ = 1.13 mg prep./L (0.438 mg a.s./L _(mm)) E _y C ₅₀ = 0.164 mg prep./L (0.0635 mg a.s./L _(mm))	EFSA Journal 2016;14(3):4420
<i>Pseudokirchneriella subcapitata</i>	AG-P4-400-SC	72 h (static)	E _r C ₅₀ = 0.120 mg prep./L (0.0429 mg a.s./L _(mm)) E _y C ₅₀ = 0.0256 mg prep./L (0.00915 mg a.s./L _(mm))	EFSA Journal 2016;14(3):4420
	M455H033 (P48)	72 h (static)	E _r C ₅₀ > 1.45 mg/L _(mm) E _y C ₅₀ = 0.498 mg/L _(mm)	EFSA Journal 2016;14(3):4420
	M455H001 (P44)	72 h (static)	E _r C ₅₀ > 2.5 mg/L _(nom) E _y C ₅₀ > 2.5 mg/L _(nom)	EFSA Journal 2016;14(3):4420
	M455H032	72 h (static)	E _r C ₅₀ = 1.48 mg/L _(nom) E _b C ₅₀ = 0.90 mg/L _(nom)	EFSA Journal 2016;14(3):4420
Higher plant				
<i>Lemna gibba</i>	Pendimethalin	14 d, s	Fronnd number E _r C ₅₀ = 0.022 mg a.s./L _(mm) E _y C ₅₀ = 0.0084 mg a.s./L _(mm)	EFSA Journal 2016;14(3):4420
<i>Lemna gibba</i>	Pendimethalin	7 d, s	Fronnd number E _r C ₅₀ = 0.0156 mg a.s./L (im)/ 0.012 mg a.s./L _(mm) E _y C ₅₀ = 0.0064 mg a.s./L (im) / 0.0049 mg a.s./L_(mm)	EFSA Journal 2016;14(3):4420
<i>Lemna gibba</i>	BAS 455 48 H	7 d, ss	Fronnd number E _r C ₅₀ = 7.55 mg a.s./L (nom) E _y C ₅₀ = 1.74 mg a.s./L _(nom) Dry weight E _r C ₅₀ >39.2 mg a.s./L (nom) E _y C ₅₀ = 23.2 mg a.s./L _(nom)	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
<i>Lemna gibba</i>	AG-P4-400-SC	7 d, ss	Frond number $E_rC_{50} = 0.0366$ mg a.s./L (nom) $E_yC_{50} = 0.0122$ mg a.s./L (nom) Dry weight $E_rC_{50} > 0.263$ mg a.s./L (nom) $E_yC_{50} = 0.0366$ mg a.s./L (nom)	EFSA Journal 2016;14(3):4420
Further testing on aquatic organisms				
<p>In total 4 mesocosms are available. Since the representative formulations from both notifiers do not indicate a higher toxicity than the a.s. and the mesocosms show consistent results, it is considered acceptable to combine all mesocosms for the current risk assessment. However, it is noted that the study of Kubitzka (2004) used a formulation containing pendimethalin together with picolinafen and therefore this study is considered as supportive information (agreement TC123).</p> <p>In the study with Pendimethalin 330 EC the NOEAEC was determined in a range from 4 to 16 µg a.s./L (within the most sensitive groups phytoplankton and zooplankton). Taking into account however that the number of endpoints showing a class 3A effect was considerably lower in the 4 µg a.s./L treatment than in the 16 µg a.s./L treatment, and that in the study with the formulation BAS 455 48 H there were clear effects at 8.5 and 18.5 µg a.s./L, including class 5A effects, RMS derived an overall NOEAC for all available mesocosms of 5 µg a.s./L.</p> <p>In TC 123 it was discussed if NOEAEC values can be used for risk assessment, since the applications may be in autumn, while all studies have been performed in spring/summer. If effects occur as result of the applications in autumn, then recovery may not be possible because of different climatic and ecological circumstances. Therefore it was agreed by the participants of the TC to use the NOEC values from the mesocosm studies for risk assessment.</p> <p>Furthermore it was not agreed by the TC participants to take a geomean of the available mesocosm endpoints given that they are not equivalent endpoints and based on different ecological thresholds. It was agreed to take the lowest NOEC value of the studies and to lower the safety factor to take into account that several mesocosm studies are available.</p> <p>Hence, based on all available information and the agreements from TC123 the NOEC of 0.23 µg as/L from the study of Ebke (2001) together with a safety factor of 1 should be used for risk assessment. This endpoint covers the higher tier risk assessment for all aquatic organisms groups, including sediment dwellers, except fish.</p> <p>The exposure profiles in the mesocosms were checked by RMS and the use of nominal concentrations was considered acceptable.</p>				
Aquatic community in outdoor mesocosms; single treatment. Endpoints: Impact on pelagic and benthic species, phytoplankton and periphyton, macrophytes.	BAS 455 24 H (400 g/L pendimethalin SC)	128 d	NOEC = 0.00023 mg a.s./L (nom) NOEAEC = 0.0011 mg a.s./L (nom)	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
Aquatic community in outdoor mesocosms; single treatment. Endpoints: -macrophytes -phytoplankton -periphyton -zooplankton -functional parameters (only supportive information)	BAS 701 00H (320 g/L pendimethalin + 16 g/L picolinafen)	70 d	NOEC _{pop} = 0.0012 mg a.s./L (nom) NOEC _{com} = 0.0012 mg a.s./L (nom) NOEAEC = 0.005 mg a.s./L (nom)	EFSA Journal 2016;14(3):4420
Aquatic community in outdoor mesocosms; single treatment. Endpoints: macrophytes; phytoplankton periphyton; zooplankton; macorzoobenthos.	Pendimethalin 330 EC	84 d	NOEC _{pop} = 0.001 mg a.s./L (nom) NOEC _{com} = 0.001 mg a.s./L (nom) NOEAEC = 0.004 to 0.016 mg a.s./L (nom)	EFSA Journal 2016;14(3):4420
Aquatic community in outdoor mesocosms; single treatment. Endpoints: -macrophytes -phytoplankton -periphyton -zooplankton -functional parameters	BAS 455 48 H	140 d	NOEC = 0.0038 mg a.s./L NOEAEC = 0.0038 mg a.s./L	EFSA Journal 2016;14(3):4420

Potential endocrine disrupting properties (Annex Part A, point 8.2.3)

Fish full life cycle (FFLC) testing with zebrafish suggest a weak estrogenic or anti-androgenic effects. Adult male zebrafish exposed to pendimethalin at levels <10µ/L showed increased vitellogenin and decreased 11-keto-testosterone levels. Adult male fish are most sensitive to this category of substances and changes in these two biomarkers are commonly used to indicate substances which may interact with the estrogen receptor. In vitro assays and one modified uterotrophic assay from the literature, along with data from ToxCast indicate a potential interaction with ER α and/or ER β . No effects upon reproduction (number, quality or survival of offspring) were seen in either the FFLCs nor the mammalian toxicology section that would indicate an ecological relevance of this potential interaction.

The results taken together indicate that pendimethalin interacts with the endocrine system in fish. In order to determine if this interaction leads to adverse effects on the population level, effects on population relevant endocrine related parameters need to be considered (i.e. growth, reproduction, sex ratio). The lowest concentration where such effects were observed in the two higher tier FFLC tests with *D. rerio* was: 80 µg/L (F1 single fish weight group A). This endpoint is higher than the lowest endpoint used in the long-term risk assessment for fish (i.e. NOEC 20 µg/L, based on day 28 F1 survival group B), indicating that toxicity is driving the aquatic risk assessment.

(nom) nominal concentration; (mm) mean measured concentration; prep: preparation; a.s.: active substance

* Exposure profile in the study in presence of sediment was not considered realistic to worst case by RMS and therefore the use of the endpoint based nominal concentration as included in the study report is not justified. The study report contains analytical measurements, which can be used for a higher tier endpoint based on geometric mean measured concentrations if necessary at member state level.

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Pendimethalin 45.5% CS

Species	Substance	Exposure System	Results	Reference
<i>Desmodosmus subspicatus</i>	Pendimethalin 40% SC	72 h	ErC ₅₀ = 1.16 mg f.p./L EyC ₅₀ = 0.40 mg a.s./L	KCP 10.2.1-01 XXX, E. 2017 17-99-131-ES
<i>Lemna minor</i>	Pendimethalin 40% SC	7d,	ErC ₅₀ = 0.318 mg f.p./L EyC ₅₀ = 0.131 mg f.p./L	KCP 10.2.1-02 XXX, E. 2017 17-99-134-ES
<i>Oncorhynchus mykiss</i>	Pendimethalin 45.5% CS	96 h, s	LC ₅₀ = 9.24 mg f.p./L	KCP 10.2.1-03 XXX, K. 2020 7887/2020
<i>Daphnia magna</i>	Pendimethalin 45.5% CS	48 h, s	EC ₅₀ = 47.16 mg f.p./L	KCP 10.2.1-04 XXX, S. 2021 9010/2021
<i>Raphidocelis subcapitata</i>	Pendimethalin 45.5% CS	72 h, s	ErC ₅₀ = 1.233 mg f.p./L EyC ₅₀ = 0.386 mg f.p./L	KCP 10.2.1-05 XXX, S. 2021 9008/2021
<i>Lemna gibba</i>	Pendimethalin 45.5% CS	7d, s	Frond number ErC ₅₀ = 19.271 mg f.p./L EyC ₅₀ = 9.407 mg f.p./L Dry weight ErC ₅₀ > 100 mg f.p./L EyC ₅₀ = 62.501 mg f.p./L	KCP 10.2.1-06 XXX, S. 2021 9009/2021
Higher-tier studies (micro- or mesocosm studies)				
None				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

Except for the formulation, the used endpoints are the EU agreed ones. However, for algae and aquatic macrophytes, the endpoints considered for the risk assessment were the ErC₅₀ instead of EyC₅₀, since according to the EFSA Journal 2013;11(/):3290, for algae and macrophytes, *growth rate is the preferred endpoint to be used.*

In addition, Sharda has conducted studies on aquatic organisms with the formulation Pendimethalin 40% SC, which is a similar formulation to Pendimethalin 45.5% CS. Similarity of both formulation has been done by comparing the acute oral and contact toxicity endpoints with both formulations to bees.

Pendimethalin 45.5% CS showed that the acute oral and contact toxicity to bees was LD_{50e} > 110.83 µg a.s./bee and LD_{50e} > 100 µg a.s./bee respectively and the acute oral and contact toxicity to bees with the formulation Pendimethalin 40% SC was LD_{50e} > 100 µg a.s./bee and the LD_{50e} > 100 µg a.s./bee respectively. As it can be observed from the results, the toxicity values observed on bees with both formulations are practically the same. Therefore, it was considered appropriate to refer to studies conducted with the formulation Pendimethalin 40% SC to do the risk assessment for aquatic organisms.

Aquatic studies with the formulation were conducted only with algae and aquatic macrophytes (*Lemna*) since both species are the most sensitive to technical pendimethalin (more than a factor of 10 compared to fish and daphnia).

Applicant has conducted studies with the formulation Pendimethalin 45.5% CS and the endpoints of these

studies were also used in the risk assessment.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{sw} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the tables below.

In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PEC_{SED}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter cereals in pre-emergence (1 x 1590 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dweller prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D1 ditch	10.07	5.14	15.98	3.15	6.85	6.94	10.83	1.23	8.39	14.53	0.00064
D1 stream	8.809	4.49	13.98	2.75	5.99	6.08	9.47	1.07	7.34	4.816	0.00021
D2 ditch	10.08	5.14	16.00	3.15	6.86	6.95	10.84	1.23	8.40	15.29	0.00067
D2 stream	8.969	4.58	14.24	2.80	6.10	6.19	9.64	1.09	7.47	13.61	0.00060
D3 ditch	9.930	5.07	15.76	3.10	6.76	6.85	10.68	1.21	8.28	5.180	0.00023
D4 pond	0.343	0.18	0.54	0.11	0.23	0.24	0.37	0.04	0.29	1.185	0.00005

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er pro-longed
D4 stream	8.608	4.39	13.66	2.69	5.86	5.94	9.26	1.05	7.17	1.778	0.00008
D5 pond	0.343	0.18	0.54	0.11	0.23	0.24	0.37	0.04	0.29	1.542	0.00007
D5 stream	9.287	4.74	14.74	2.90	6.32	6.40	9.99	1.13	7.74	2.519	0.00011
D6 ditch	10.04	5.12	15.94	3.14	6.83	6.92	10.80	1.22	8.37	16.05	0.00071
R1 pond	0.346	0.18	0.55	0.11	0.24	0.24	0.37	0.04	0.29	3.177	0.00014
R1 stream	6.543	3.34	10.39	2.04	4.45	4.51	7.04	0.80	5.45	13.50	0.0006
R3 stream	9.085	4.64	14.42	2.84	6.18	6.27	9.77	1.11	7.57	481.4	0.0212
R4 stream	6.583	3.36	10.45	2.06	4.48	4.54	7.08	0.80	5.49	4.900	0.0002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses winter cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-4: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals

Intended use		Winter cereals							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re-duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D1 ditch	2.729	1.455	1.003	0.763	-	-	-	-
50%		1.418	0.805	0.565	-	-	-	-	-

75%		0.839	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D1 stream	3.222	1.709	1.168	0.888	-	-	-	-
50%		1.613	0.856	0.585	-	-	-	-	-
75%		0.809	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D2 ditch	2.731	1.462	1.008	0.768	-	-	-	-
50%		1.425	0.814	0.572	-	-	-	-	-
75%		0.849	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D2 stream	3.281	1.741	1.189	0.904	-	-	-	-
50%		1.642	0.872	0.596	-	-	-	-	-
75%		0.824	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D3 ditch	2.690	1.426	0.974	0.741	-	-	-	-
50%		1.344	0.738	0.513	-	-	-	-	-
75%		0.740	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.150	1.672	1.142	0.869	-	-	-	-
50%		1.578	0.857	0.591	-	-	-	-	-
75%		0.838	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	3.397	1.803	1.231	0.936	-	-	-	-
50%		1.701	0.915	0.631	0.480	-	-	-	-

None	D6 ditch	2.92	1.58	1.09	0.83	-	-	-	-
50%		1.54	0.89	0.62	-	-	-	-	-
75%		0.92	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.65	1.43	0.98	-
50%		-	-	-	-	1.38	0.87	-	-
75%		-	-	-	-	1.25	-	-	-
90%		-	-	-	-	1.25	-	-	-
None	R3 stream	-	-	-	-	3.65	1.97	1.35	1.03
50%		-	-	-	-	1.89	1.03	0.71	0.54
75%		-	-	-	-	1.21	0.84	-	-
90%		-	-	-	-	1.21	-	-	-
None	R4 stream	-	-	-	-	2.65	1.43	0.98	-
50%		-	-	-	-	1.53	1.06	-	-
75%		-	-	-	-	1.53	1.06	-	-
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter cereals are <1 when risk mitigation options are considered:

D1 ditch, D1 stream, D2 ditch, D2 stream, D3 ditch, D4 stream and D6 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzles or 5 m no spray buffer zone + 75% nozzle reduction

D5 stream: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction.

R1 stream and R4 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

In addition, PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-5: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in pre emergence

Intended use		Winter cereals pre emergence							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D1 ditch	2.729	1.455	1.003	0.763	-	-	-	-
50%		1.418	0.805	0.565	0.431	-	-	-	-
75%		0.839	0.514	0.372	0.280	-	-	-	-
90%		0.534	0.359	0.267	0.202	-	-	-	-
None	D1 stream	3.222	1.709	1.168	0.888	-	-	-	-
50%		1.613	0.856	0.585	0.445	-	-	-	-
75%		0.809	0.441	0.313	0.239	-	-	-	-
90%		0.440	0.304	0.222	0.169	-	-	-	-
None	D2 ditch	2.731	1.462	1.008	0.768	-	-	-	-
50%		1.425	0.814	0.572	0.435	-	-	-	-
75%		0.849	0.519	0.372	0.315	-	-	-	-
90%		0.544	0.365	0.315	0.315	-	-	-	-
None	D2 stream	3.281	1.741	1.189	0.904	-	-	-	-
50%		1.642	0.872	0.596	0.453	-	-	-	-
75%		0.824	0.438	0.299	0.228	-	-	-	-
90%		0.338	0.207	0.204	-	-	-	-	-

None	D3 ditch	2.690	1.426	0.974	0.741	-	-	-	-
50%		1.344	0.738	0.513	0.396	-	-	-	-
75%		0.740	0.437	0.311	0.237	-	-	-	-
90%		0.441	0.291	0.213	0.162	-	-	-	-
None	D4 Pond	0.324	0.235	0.186	-	-	-	-	-
50%		0.192	0.141	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.150	1.672	1.142	0.869	-	-	-	-
50%		1.578	0.857	0.591	0.450	-	-	-	-
75%		0.838	0.469	0.326	0.258	-	-	-	-
90%		0.421	0.258	0.258	0.258	-	-	-	-
None	D5 pond	0.332	0.241	0.191	-	-	-	-	-
50%		0.198	0.145	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	3.397	1.803	1.231	0.936	-	-	-	-
50%		1.701	0.915	0.631	0.480	-	-	-	-
75%		0.894	0.506	0.355	0.271	-	-	-	-
90%		0.463	0.294	0.210	0.160	-	-	-	-
None	D6 ditch	2.720	1.467	1.011	0.770	-	-	-	-
50%		1.429	0.824	0.579	0.445	-	-	-	-
75%		0.860	0.526	0.445	0.445	-	-	-	-
90%		0.557	0.445	0.455	-	-	-	-	-

None	R1 pond	-	-	-	-	0.340	0.247	0.195	-
50%		-	-	-	-	0.203	0.148	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.464	1.328	0.912	0.694
50%		-	-	-	-	1.279	0.811	0.631	0.425
75%		-	-	-	-	1.165	0.811	0.622	0.425
90%		-	-	-	-	1.165	-	0.622	-
None	R3 stream	-	-	-	-	3.393	1.828	1.255	0.955
50%		-	-	-	-	1.758	0.961	0.663	0.505
75%		-	-	-	-	1.124	0.784	0.602	0.417
90%		-	-	-	-	1.124	0.784	0.602	0.411
None	R4 stream	-	-	-	-	2.462	1.332	0.916	0.698
50%		-	-	-	-	1.424	0.990	0.758	0.517
75%		-	-	-	-	1.424	0.990	0.758	0.517
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D1 ditch	11.865	6.326	4.361	3.317	-	-	-	-
50%		6.165	3.500	2.457	1.874	-	-	-	-
75%		3.648	2.235	1.617	1.217	-	-	-	-
90%		2.322	1.561	1.161	0.878	-	-	-	-
None	D1 stream	14.009	7.430	5.078	3.861	-	-	-	-
50%		7.013	3.722	2.543	1.935	-	-	-	-

75%		3.517	1.917	1.361	1.04	-	-	-	-
90%		1.913	1.322	0.965	0.735	-	-	-	-
None	D2 ditch	11.874	6.357	4.383	3.339	-	-	-	-
50%		6.196	3.539	2.487	1.891	-	-	-	-
75%		3.691	2.257	1.617	1.370	-	-	-	-
90%		2.365	1.587	1.370	1.370	-	-	-	-
None		D2 stream	14.265	7.570	5.170	3.930	-	-	-
50%	7.139		3.791	2.591	1.970	-	-	-	-
75%	3.583		1.904	1.300	0.991	-	-	-	-
90%	1.470		0.900	0.887	-	-	-	-	-
None	D3 ditch	11.696	6.200	4.235	3.222	-	-	-	-
50%		5.843	3.209	2.230	1.722	-	-	-	-
75%		3.217	1.900	1.352	1.030	-	-	-	-
90%		1.917	1.265	0.926	0.704	-	-	-	-
None	D4 Pond	1.409	1.022	0.809	-	-	-	-	-
50%		0.835	0.613	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	13.696	7.270	4.965	3.778	-	-	-	-
50%		6.861	3.726	2.570	1.957	-	-	-	-
75%		3.643	2.039	1.417	1.122	-	-	-	-
90%		1.830	1.122	1.122	1.122	-	-	-	-
None	D5 pond	1.443	1.048	0.830	-	-	-	-	-
50%		0.861	0.630	-	-	-	-	-	-

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	14.770	7.839	5.352	4.070	-	-	-	-
50%		7.396	3.978	2.743	2.087	-	-	-	-
75%		3.887	2.200	1.543	1.178	-	-	-	-
90%		2.013	1.278	0.913	0.696	-	-	-	-
None		D6 ditch	11.826	6.378	4.396	3.348	-	-	-
50%	6.213		3.583	2.517	1.935	-	-	-	-
75%	3.739		2.287	1.935	1.935	-	-	-	-
90%	2.422		1.935	1.978	-	-	-	-	-
None	R1 pond	-	-	-	-	1.478	1.074	0.848	-
50%		-	-	-	-	0.883	0.643	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	10.713	5.774	3.967	3.017
50%		-	-	-	-	5.561	3.527	2.743	1.848
75%		-	-	-	-	5.065	3.526	2.704	1.848
90%		-	-	-	-	5.065	-	2.704	-
None	R3 stream	-	-	-	-	14.752	7.948	5.457	4.152
50%		-	-	-	-	7.643	4.178	2.883	2.196
75%		-	-	-	-	4.887	3.409	2.617	1.813
90%		-	-	-	-	4.887	3.409	2.617	1.787
None	R4 stream	-	-	-	-	10.704	5.791	3.983	3.035
50%		-	-	-	-	6.191	4.304	3.296	2.248

75%	-	-	-	-	-	6.191	4.304	3.296	2.248
90%	-	-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-6: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in pre emergence

Intended use		Winter cereals pre emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.213
90%		0.215	-
75%	R3 stream	-	0.392
90%		0.620	0.392
75%	R4 stream	-	0.213
90%		0.218	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.93
90%		0.93	-
75%	R3 stream	-	1.70
90%		2.70	1.70

75%	R4 stream	-	0.93
90%		0.95	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter cereals in pre-emergence are <1 when risk mitigation options are considered:

D1 ditch: 20m no spray buffer zone + 90% nozzle reduction

D1 stream, D3 ditch, D5 stream: 15m no spray buffer zone + 90% nozzle reduction

D2 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzles reduction

D4 pond, D5 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5 m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction.

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzles reduction or 10m no spray buffer zone + 10m vegetative strip + 50% nozzles reduction

For scenarios D2 ditch, D4 stream and D6 ditch PEC/RAC ratios are >1 even considering the mitigation. However, scenarios D2 and D6 are not relevant for CEU countries. For scenario R3 stream the PEC/RAC ratios are > 1 even considering mitigation measures and a restriction will have to be included (do not apply on terraced clay soils with a slope greater than 10%).

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter cereals in post emergence (1 x 1590 g/ha)

Group	Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
Test species	<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)	LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
AF	196	6.3	32	147	14.5	9.3	82	12		227300
	100	10	10	100	10	10	10	10		10

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D1 ditch	10.07	5.14	15.98	3.15	6.85	6.94	10.83	1.23	8.39	26.14	0.00115
D1 stream	8.809	4.49	13.98	2.75	5.99	6.08	9.47	1.07	7.34	5.326	0.00023
D2 ditch	10.01	5.11	15.89	3.13	6.81	6.90	10.76	1.22	8.34	16.40	0.00072
D2 stream	8.126	4.15	12.90	2.54	5.53	5.60	8.74	0.99	6.77	0.567	0.00002
D3 ditch	9.921	5.06	15.75	3.10	6.75	6.84	10.67	1.21	8.27	5.095	0.00022
D4 pond	0.343	0.18	0.54	0.11	0.23	0.24	0.37	0.04	0.29	1.760	0.00008
D4 stream	8.608	4.39	13.66	2.69	5.86	5.94	9.26	1.05	7.17	1.822	0.00008
D5 pond	0.343	0.18	0.54	0.11	0.23	0.24	0.37	0.04	0.29	2.021	0.00009
D5 stream	9.287	4.74	14.74	2.90	6.32	6.40	9.99	1.13	7.74	2.580	0.00011
D6 ditch	10.04	5.12	15.94	3.14	6.83	6.92	10.80	1.22	8.37	20.94	0.00092
R1 pond	0.351	0.18	0.56	0.11	0.24	0.24	0.38	0.04	0.29	4.267	0.00019
R1 stream	6.543	3.34	10.39	2.04	4.45	4.51	7.04	0.80	5.45	13.51	0.00059
R3 stream	9.180	4.68	14.57	2.87	6.24	6.33	9.87	1.12	7.65	4.578	0.00020
R4 stream	6.489	3.31	10.30	2.03	4.41	4.48	6.98	0.79	5.41	6.400	0.00028

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses winter cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-8: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in post emergence

Intended use		Winter cereals post emergence							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D1 ditch	2.782	1.532	1.063	0.809	-	-	-	-
50%		1.530	0.886	0.629	0.478	-	-	-	-
75%		0.945	0.591	0.428	0.325	-	-	-	-
90%		0.613	0.416	0.309	0.234	-	-	-	-
None	D1 stream	3.222	1.709	1.168	0.888	-	-	-	-
50%		1.613	0.856	0.585	0.445	-	-	-	-
75%		0.834	0.495	0.353	0.269	-	-	-	-
90%		0.502	0.346	0.256	0.195	-	-	-	-
None	D2 ditch	2.713	1.470	1.013	0.771	-	-	-	-
50%		1.444	0.836	0.588	0.447	-	-	-	-
75%		0.872	0.546	0.396	0.300	-	-	-	-
90%		0.569	0.387	0.290	0.290	-	-	-	-
None	D2 stream	3.036	1.626	1.114	0.848	-	-	-	-
50%		1.552	0.839	0.577	0.439	-	-	-	-
75%		0.810	0.446	0.309	0.235	-	-	-	-

90%		0.373	0.219	0.188	0.188	-	-	-	-
None	D3 ditch	2.688	1.425	0.973	0.740	-	-	-	-
50%		1.343	0.746	0.519	0.395	-	-	-	-
75%		0.748	0.444	0.316	0.241	-	-	-	-
90%		0.439	0.294	0.215	0.164	-	-	-	-
None	D4 Pond	0.336	0.244	0.193	-	-	-	-	-
50%		0.200	0.146	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.150	1.675	1.163	0.873	-	-	-	-
50%		1.600	0.874	0.603	0.459	-	-	-	-
75%		0.854	0.478	0.335	0.255	-	-	-	-
90%		0.426	0.265	0.248	0.248	-	-	-	-
None	D5 pond	0.342	0.249	0.196	-	-	-	-	-
50%		0.204	0.149	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	3.397	1.803	1.231	0.937	-	-	-	-
50%		1.710	0.932	0.642	0.489	-	-	-	-
75%		0.910	0.518	0.363	0.277	-	-	-	-
90%		0.469	0.298	0.216	0.165	-	-	-	-
None	D6 ditch	2.756	1.506	1.045	0.795	-	-	-	-
50%		1.504	0.870	0.612	0.465	-	-	-	-
75%		0.920	0.576	0.449	0.449	-	-	-	-

90%		0.598	0.449	0.449	0.449	-	-	-	-
None	R1 pond	-	-	-	-	0.348	0.253	0.200	-
50%		-	-	-	-	0.214	0.152	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.470	1.332	0.915	0.696
50%		-	-	-	-	1.282	0.813	0.624	0.426
75%		-	-	-	-	1.168	0.813	0.624	0.426
90%		-	-	-	-	1.168	-	-	-
None	R3 stream	-	-	-	-	3.430	1.852	1.273	0.969
50%		-	-	-	-	1.786	0.980	0.677	0.516
75%		-	-	-	-	1.025	0.713	0.546	0.372
90%		-	-	-	-	1.025	0.713	0.546	0.372
None	R4 stream	-	-	-	-	2.452	1.323	0.909	0.692
50%		-	-	-	-	1.514	1.052	0.806	0.549
75%		-	-	-	-	1.514	1.052	0.806	0.549
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D1 ditch	2.99	1.65	1.14	0.87	-	-	-	-
50%		1.65	0.95	0.68	0.51	-	-	-	-
75%		1.02	0.64	0.46	0.35	-	-	-	-
90%		0.66	0.45	0.33	0.25	-	-	-	-
None	D1 stream	3.46	1.84	1.26	0.95	-	-	-	-

50%		1.73	0.92	0.63	0.48	-	-	-	-
75%		0.90	0.53	0.38	0.29	-	-	-	-
90%		0.54	0.37	0.28	0.21	-	-	-	-
None	D2 ditch	2.92	1.58	1.09	0.83	-	-	-	-
50%		1.55	0.90	0.63	0.48	-	-	-	-
75%		0.94	0.59	0.43	0.32	-	-	-	-
90%		0.61	0.42	0.31	0.31	-	-	-	-
None	D2 stream	3.26	1.75	1.20	0.91	-	-	-	-
50%		1.67	0.90	0.62	0.47	-	-	-	-
75%		0.87	0.48	0.33	0.25	-	-	-	-
90%		0.40	0.24	0.20	0.20	-	-	-	-
None	D3 ditch	2.89	1.53	1.05	0.80	-	-	-	-
50%		1.44	0.80	0.56	0.42	-	-	-	-
75%		0.80	0.48	0.34	0.26	-	-	-	-
90%		0.47	0.32	0.23	0.18	-	-	-	-
None	D4 Pond	0.36	0.26	0.21	-	-	-	-	-
50%		0.22	0.16	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.39	1.80	1.25	0.94	-	-	-	-
50%		1.72	0.94	0.65	0.49	-	-	-	-
75%		0.92	0.51	0.36	0.27	-	-	-	-
90%		0.46	0.28	0.27	0.27	-	-	-	-
None	D5 pond	0.37	0.27	0.21	-	-	-	-	-

50%		0.22	0.16	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	3.65	1.94	1.32	1.01	-	-	-	-
50%		1.84	1.00	0.69	0.53	-	-	-	-
75%		0.98	0.56	0.39	0.30	-	-	-	-
90%		0.50	0.32	0.23	0.18	-	-	-	-
None	D6 ditch	2.96	1.62	1.12	0.85	-	-	-	-
50%		1.62	0.94	0.66	0.50	-	-	-	-
75%		0.99	0.62	0.48	0.48	-	-	-	-
90%		0.64	0.48	0.48	0.48	-	-	-	-
None	R1 pond	-	-	-	-	0.37	0.27	0.22	-
50%		-	-	-	-	0.23	0.16	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.66	1.43	0.98	0.75
50%		-	-	-	-	1.38	0.87	0.67	0.46
75%		-	-	-	-	1.26	0.87	0.67	0.46
90%		-	-	-	-	1.26	-	-	-
None	R3 stream	-	-	-	-	3.69	1.99	1.37	1.04
50%		-	-	-	-	1.92	1.05	0.73	0.55
75%		-	-	-	-	1.10	0.77	0.59	0.40
90%		-	-	-	-	1.10	0.77	0.59	0.40
None	R4 stream	-	-	-	-	2.64	1.42	0.98	0.74

50%		!	!	!	!	1.63	1.13	0.87	0.59
75%		!	!	!	!	1.63	1.13	0.87	0.59
90%		!	!	!	!	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter cereals (post-emergence 1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D1 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D1 stream, D2 ditch, D2 stream, D3 ditch, D4 stream and D6 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzles or 5 m no spray buffer zone + 75% nozzle reduction

D5 stream: 15m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction.

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction

In addition, PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenrios, with the exception of R1 pond scenario.

Table 9.5-9: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in post emergence

Intended use		Winter cereals post emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D1 ditch	2.782	1.532	1.063	0.809	-	-	-	-
50%		1.530	0.886	0.629	0.478	-	-	-	-
75%		0.945	0.591	0.428	0.325	-	-	-	-

90%		0.613	0.416	0.309	0.234	-	-	-	-
None	D1 stream	3.222	1.709	1.168	0.888	-	-	-	-
50%		1.613	0.856	0.585	0.445	-	-	-	-
75%		0.834	0.495	0.353	0.269	-	-	-	-
90%		0.502	0.346	0.256	0.195	-	-	-	-
None	D2 ditch	2.713	1.470	1.013	0.771	-	-	-	-
50%		1.444	0.836	0.588	0.447	-	-	-	-
75%		0.872	0.546	0.396	0.300	-	-	-	-
90%		0.569	0.387	0.290	0.290	-	-	-	-
None	D2 stream	3.036	1.626	1.114	0.848	-	-	-	-
50%		1.552	0.839	0.577	0.439	-	-	-	-
75%		0.810	0.446	0.309	0.235	-	-	-	-
90%		0.373	0.219	0.188	0.188	-	-	-	-
None	D3 ditch	2.688	1.425	0.973	0.740	-	-	-	-
50%		1.343	0.746	0.519	0.395	-	-	-	-
75%		0.748	0.444	0.316	0.241	-	-	-	-
90%		0.439	0.294	0.215	0.164	-	-	-	-
None	D4 Pond	0.336	0.244	0.193	-	-	-	-	-
50%		0.200	0.146	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.150	1.675	1.163	0.873	-	-	-	-
50%		1.600	0.874	0.603	0.459	-	-	-	-
75%		0.854	0.478	0.335	0.255	-	-	-	-

90%		0.426	0.265	0.248	0.248	-	-	-	-
None	D5 pond	0.342	0.249	0.196	-	-	-	-	-
50%		0.204	0.149	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	3.397	1.803	1.231	0.937	-	-	-	-
50%		1.710	0.932	0.642	0.489	-	-	-	-
75%		0.910	0.518	0.363	0.277	-	-	-	-
90%		0.469	0.298	0.216	0.165	-	-	-	-
None	D6 ditch	2.756	1.506	1.045	0.795	-	-	-	-
50%		1.504	0.870	0.612	0.465	-	-	-	-
75%		0.920	0.576	0.449	0.449	-	-	-	-
90%		0.598	0.449	0.449	0.449	-	-	-	-
None	R1 pond	-	-	-	-	0.348	0.253	0.200	-
50%		-	-	-	-	0.214	0.152	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.470	1.332	0.915	0.696
50%		-	-	-	-	1.282	0.813	0.624	0.426
75%		-	-	-	-	1.168	0.813	0.624	0.426
90%		-	-	-	-	1.168	-	-	-
None	R3 stream	-	-	-	-	3.430	1.852	1.273	0.969
50%		-	-	-	-	1.786	0.980	0.677	0.516
75%		-	-	-	-	1.025	0.713	0.546	0.372

90%		-	-	-	-	1.025	0.713	0.546	0.372
None	R4 stream	-	-	-	-	2.452	1.323	0.909	0.692
50%		-	-	-	-	1.514	1.052	0.806	0.549
75%		-	-	-	-	1.514	1.052	0.806	0.549
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D1 ditch	12.096	6.661	4.622	3.517	-	-	-	-
50%		6.652	3.852	2.735	2.078	-	-	-	-
75%		4.109	2.570	1.861	1.413	-	-	-	-
90%		2.665	1.809	1.343	1.017	-	-	-	-
None	D1 stream	14.009	7.430	5.078	3.861	-	-	-	-
50%		7.013	3.722	2.543	1.935	-	-	-	-
75%		3.626	2.152	1.535	1.170	-	-	-	-
90%		2.183	1.504	1.113	0.848	-	-	-	-
None	D2 ditch	11.796	6.391	4.404	3.352	-	-	-	-
50%		6.278	3.635	2.557	1.943	-	-	-	-
75%		3.791	2.374	1.722	1.304	-	-	-	-
90%		2.474	1.683	1.261	1.261	-	-	-	-
None	D2 stream	13.200	7.070	4.843	3.687	-	-	-	-
50%		6.748	3.648	2.509	1.909	-	-	-	-
75%		3.522	1.939	1.343	1.022	-	-	-	-
90%		1.622	0.952	0.817	0.817	-	-	-	-
None	D3 ditch	11.687	6.196	4.230	3.217	-	-	-	-

50%		5.839	3.243	2.257	1.717	-	-	-	-
75%		3.252	1.930	1.374	1.048	-	-	-	-
90%		1.909	1.278	0.935	0.713	-	-	-	-
None	D4 Pond	1.461	1.061	0.839	-	-	-	-	-
50%		0.870	0.635	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	13.696	7.283	5.057	3.796	-	-	-	-
50%		6.957	3.800	2.622	1.996	-	-	-	-
75%		3.713	2.078	1.457	1.109	-	-	-	-
90%		1.852	1.152	1.078	1.078	-	-	-	-
None	D5 pond	1.487	1.083	0.852	-	-	-	-	-
50%		0.887	0.648	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	14.770	7.839	5.352	4.074	-	-	-	-
50%		7.435	4.052	2.791	2.126	-	-	-	-
75%		3.957	2.252	1.578	1.204	-	-	-	-
90%		2.039	1.296	0.939	0.717	-	-	-	-
None	D6 ditch	11.983	6.548	4.543	3.457	-	-	-	-
50%		6.539	3.783	2.661	2.022	-	-	-	-
75%		4.000	2.504	1.952	1.952	-	-	-	-
90%		2.600	1.952	1.952	1.952	-	-	-	-
None	R1 pond	-	-	-	-	1.513	1.100	0.870	-

50%		-	-	-	-	0.930	0.661	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	10.739	5.791	3.978	3.026
50%		-	-	-	-	5.574	3.535	2.713	1.852
75%		-	-	-	-	5.078	3.535	2.713	1.852
90%		-	-	-	-	5.078	-	-	-
None	R3 stream	-	-	-	-	14.913	8.052	5.535	4.213
50%		-	-	-	-	7.765	4.261	2.943	2.243
75%		-	-	-	-	4.457	3.100	2.374	1.617
90%		-	-	-	-	4.457	3.100	2.374	1.617
None	R4 stream	-	-	-	-	10.661	5.752	3.952	3.009
50%		-	-	-	-	6.583	4.574	3.504	2.387
75%		-	-	-	-	6.583	4.574	3.504	2.387
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-10: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in post-emergence

Intended use		Winter cereals post-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20

	No-spray buffer (m)	10	20
75%	R1 stream	-	0.214
90%		0.216	-
75%	R3 stream	-	0.296
90%		0.306	0.168
75%	R4 stream	-	0.206
90%		0.201	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.93
90%		1.06	-
75%	R3 stream	-	1.29
90%		1.33	0.73
75%	R4 stream	-	0.90
90%		0.87	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter cereals in post-emergence (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D1 ditch, D1 stream: 10m no spray buffer zone + 90% nozzle reduction

D2 stream, D3 ditch, D5 stream: 15m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D2 ditch, D4 stream and D6 ditch PEC/RAC ratios are >1 even considering the maximum mitigation measures. However, scenarios D2 and D6 are not relevant for CEU countries.

Table 9.5-11 Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter cereals in pre emergence (1 x 1137 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D1 ditch	7.201	3.67	11.43	2.25	4.90	4.97	7.74	0.88	6.00	14.88	0.00065
D1 stream	6.298	3.21	10.00	1.97	4.28	4.34	6.77	0.77	5.25	3.687	0.00016
D2 ditch	7.208	3.68	11.44	2.25	4.90	4.97	7.75	0.88	6.01	15.41	0.00068
D2 stream	6.413	3.27	10.18	2.00	4.36	4.42	6.90	0.78	5.34	13.72	0.00060
D3 ditch	7.099	3.62	11.27	2.22	4.83	4.90	7.63	0.87	5.92	3.890	0.00017
D4 pond	0.245	0.13	0.39	0.08	0.17	0.17	0.26	0.03	0.20	1.146	0.00005
D4 stream	6.154	3.14	9.77	1.92	4.19	4.24	6.62	0.75	5.13	1.303	0.00006
D5 pond	0.245	0.13	0.39	0.08	0.17	0.17	0.26	0.03	0.20	1.449	0.00006

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
D5 stream	6.640	3.39	10.54	2.08	4.52	4.58	7.14	0.81	5.53	1.845	0.00008
D6 ditch	7.177	3.66	11.39	2.24	4.88	4.95	7.72	0.88	5.98	15.01	0.00066
R1 pond	0.249	0.13	0.40	0.08	0.17	0.17	0.27	0.03	0.21	3.052	0.00013
R1 stream	4.678	2.39	7.43	1.46	3.18	3.23	5.03	0.57	3.90	9.833	0.00043
R3 stream	6.495	3.31	10.31	2.03	4.42	4.48	6.98	0.79	5.41	346.3	0.01524
R4 stream	4.707	2.40	7.47	1.47	3.20	3.25	5.06	0.57	3.92	3.625	0.00016

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses winter cereals (pre-emergence, 1 x 1137 g/ha), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-12: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in pre emergence

Intended use		Winter cereals pre emergence									
Active substance		pendimethalin									
Application rate (g/ha)		1 x 1137									
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20		
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20		
None	D1 ditch	1.966	1.070	0.741	0.562	-	-	-	-		
50%		1.064	0.615	0.433	0.328	-	-	-	-		
75%		0.645	0.402	0.292	0.221	-	-	-	-		

90%		0.420	0.284	0.210	-	-	-	-	-
None	D1 stream	2.303	1.222	0.835	0.635	-	-	-	-
50%		1.153	0.612	0.418	0.318	-	-	-	-
75%		0.580	0.342	0.244	0.185	-	-	-	-
90%		0.346	0.237	0.176	-	-	-	-	-
None	D2 ditch	1.973	1.074	0.746	0.566	-	-	-	-
50%		1.071	0.619	0.436	0.330	-	-	-	-
75%		0.652	0.407	0.295	0.223	-	-	-	-
90%		0.424	0.286	0.213	-	-	-	-	-
None	D2 stream	2.345	1.244	0.850	0.646	-	-	-	-
50%		1.174	0.623	0.426	0.324	-	-	-	-
75%		0.589	0.313	0.217	0.163	-	-	-	-
90%		0.238	0.131	-	-	-	-	-	-
None	D3 ditch	1.923	1.019	0.696	0.530	-	-	-	-
50%		0.964	0.537	0.373	0.284	-	-	-	-
75%		0.540	0.323	0.231	0.175	-	-	-	-
90%		0.323	0.215	0.159	-	-	-	-	-
None	D4 Pond	0.240	0.175	-	-	-	-	-	-
50%		0.143	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.252	1.197	0.820	0.623	-	-	-	-
50%		1.144	0.625	0.431	0.328	-	-	-	-
75%		0.611	0.342	0.239	0.182	-	-	-	-

90%		0.305	0.189	0.178	-	-	-	-	-
None	D5 pond	0.245	0.178	-	-	-	-	-	-
50%		0.146	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.429	1.288	0.880	0.669	-	-	-	-
50%		1.223	0.666	0.459	0.349	-	-	-	-
75%		0.651	0.370	0.260	0.197	-	-	-	-
90%		0.336	0.213	0.155	-	-	-	-	-
None	D6 ditch	1.971	1.077	0.749	0.568	-	-	-	-
50%		1.076	0.621	0.438	0.332	-	-	-	-
75%		0.659	0.411	0.305	0.305	-	-	-	-
90%		0.429	0.305	0.305	0.305	-	-	-	-
None	R1 pond	-	-	-	-	0.249	0.180	-	-
50%		-	-	-	-	0.151	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.766	0.952	0.654	0.497
50%		-	-	-	-	0.917	0.576	0.441	0.301
75%		-	-	-	-	0.826	0.576	0.441	0.301
90%		-	-	-	-	0.826	-	-	-
None	R3 stream	-	-	-	-	2.438	1.313	0.902	0.685
50%		-	-	-	-	1.263	0.691	0.478	0.363
75%		-	-	-	-	0.794	0.554	0.425	0.290

90%		-	-	-	-	0.794	0.554	0.425	0.290
None	R4 stream	-	-	-	-	1.773	0.959	0.660	0.502
50%		-	-	-	-	1.012	0.703	0.539	0.367
75%		-	-	-	-	1.012	0.703	0.539	0.367
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D1 ditch	2.11	1.15	0.80	0.60	-	-	-	-
50%		1.14	0.66	0.47	0.35	-	-	-	-
75%		0.69	0.43	0.31	0.24	-	-	-	-
90%		0.45	0.31	0.23	-	-	-	-	-
None	D1 stream	2.48	1.31	0.90	0.68	-	-	-	-
50%		1.24	0.66	0.45	0.34	-	-	-	-
75%		0.62	0.37	0.26	0.20	-	-	-	-
90%		0.37	0.25	0.19	-	-	-	-	-
None	D2 ditch	2.12	1.15	0.80	0.61	-	-	-	-
50%		1.15	0.67	0.47	0.35	-	-	-	-
75%		0.70	0.44	0.32	0.24	-	-	-	-
90%		0.46	0.31	0.23	-	-	-	-	-
None	D2 stream	2.52	1.34	0.91	0.69	-	-	-	-
50%		1.26	0.67	0.46	0.35	-	-	-	-
75%		0.63	0.34	0.23	0.18	-	-	-	-
90%		0.26	0.14	-	-	-	-	-	-
None	D3 ditch	2.07	1.10	0.75	0.57	-	-	-	-

50%		1.04	0.58	0.40	0.31	-	-	-	-
75%		0.58	0.35	0.25	0.19	-	-	-	-
90%		0.35	0.23	0.17	-	-	-	-	-
None	D4 Pond	0.26	0.19	-	-	-	-	-	-
50%		0.15	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.42	1.29	0.88	0.67	-	-	-	-
50%		1.23	0.67	0.46	0.35	-	-	-	-
75%		0.66	0.37	0.26	0.20	-	-	-	-
90%		0.33	0.20	0.19	-	-	-	-	-
None	D5 pond	0.26	0.19	-	-	-	-	-	-
50%		0.16	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.61	1.38	0.95	0.72	-	-	-	-
50%		1.32	0.72	0.49	0.38	-	-	-	-
75%		0.70	0.40	0.28	0.21	-	-	-	-
90%		0.36	0.23	0.17	-	-	-	-	-
None	D6 ditch	2.12	1.16	0.81	0.61	-	-	-	-
50%		1.16	0.67	0.47	0.36	-	-	-	-
75%		0.71	0.44	0.33	0.33	-	-	-	-
90%		0.46	0.33	0.33	0.33	-	-	-	-
None	R1 pond	-	-	-	-	0.27	0.19	-	-

50%		-	-	-	-	0.16	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.90	1.02	0.70	0.53
50%		-	-	-	-	0.99	0.62	0.47	0.32
75%		-	-	-	-	0.89	0.62	0.47	0.32
90%		-	-	-	-	0.89	-	-	-
None	R3 stream	-	-	-	-	2.62	1.41	0.97	0.74
50%		-	-	-	-	1.36	0.74	0.51	0.39
75%		-	-	-	-	0.85	0.60	0.46	0.31
90%		-	-	-	-	0.85	0.60	0.46	0.31
None	R4 stream	-	-	-	-	1.91	1.03	0.71	0.54
50%		-	-	-	-	1.09	0.76	0.58	0.39
75%		-	-	-	-	1.09	0.76	0.58	0.39
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter cereals (pre-emergence 1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D1 ditch, D1 stream, D2 ditch, D2 stream, D3 ditch, D4 stream, D5 stream, D6 ditch: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-13: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in pre emergence

Intended use		Winter cereals pre emergence							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1137							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D1 ditch	1.966	1.070	0.741	0.562	-	-	-	-
50%		1.064	0.615	0.433	0.328	-	-	-	-
75%		0.645	0.402	0.292	0.221	-	-	-	-
90%		0.420	0.284	0.210	-	-	-	-	-
None	D1 stream	2.303	1.222	0.835	0.635	-	-	-	-
50%		1.153	0.612	0.418	0.318	-	-	-	-
75%		0.580	0.342	0.244	0.185	-	-	-	-
90%		0.346	0.237	0.176	-	-	-	-	-
None	D2 ditch	1.973	1.074	0.746	0.566	-	-	-	-
50%		1.071	0.619	0.436	0.330	-	-	-	-
75%		0.652	0.407	0.295	0.223	-	-	-	-
90%		0.424	0.286	0.213	-	-	-	-	-
None	D2 stream	2.345	1.244	0.850	0.646	-	-	-	-
50%		1.174	0.623	0.426	0.324	-	-	-	-
75%		0.589	0.313	0.217	0.163	-	-	-	-

90%		0.238	0.131	-	-	-	-	-	-
None	D3 ditch	1.923	1.019	0.696	0.530	-	-	-	-
50%		0.964	0.537	0.373	0.284	-	-	-	-
75%		0.540	0.323	0.231	0.175	-	-	-	-
90%		0.323	0.215	0.159	-	-	-	-	-
None	D4 Pond	0.240	0.175	-	-	-	-	-	-
50%		0.143	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.252	1.197	0.820	0.623	-	-	-	-
50%		1.144	0.625	0.431	0.328	-	-	-	-
75%		0.611	0.342	0.239	0.182	-	-	-	-
90%		0.305	0.189	0.178	-	-	-	-	-
None	D5 pond	0.245	0.178	-	-	-	-	-	-
50%		0.146	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.429	1.288	0.880	0.669	-	-	-	-
50%		1.223	0.666	0.459	0.349	-	-	-	-
75%		0.651	0.370	0.260	0.197	-	-	-	-
90%		0.336	0.213	0.155	-	-	-	-	-
None	D6 ditch	1.971	1.077	0.749	0.568	-	-	-	-
50%		1.076	0.621	0.438	0.332	-	-	-	-
75%		0.659	0.411	0.305	0.305	-	-	-	-

90%		0.429	0.305	0.305	0.305	-	-	-	-
None	R1 pond	-	-	-	-	0.249	0.180	-	-
50%		-	-	-	-	0.151	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.766	0.952	0.654	0.497
50%		-	-	-	-	0.917	0.576	0.441	0.301
75%		-	-	-	-	0.826	0.576	0.441	0.301
90%		-	-	-	-	0.826	-	-	-
None	R3 stream	-	-	-	-	2.438	1.313	0.902	0.685
50%		-	-	-	-	1.263	0.691	0.478	0.363
75%		-	-	-	-	0.794	0.554	0.425	0.290
90%		-	-	-	-	0.794	0.554	0.425	0.290
None	R4 stream	-	-	-	-	1.773	0.959	0.660	0.502
50%		-	-	-	-	1.012	0.703	0.539	0.367
75%		-	-	-	-	1.012	0.703	0.539	0.367
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D1 ditch	8.548	4.652	3.222	2.443	-	-	-	-
50%		4.626	2.674	1.883	1.426	-	-	-	-
75%		2.804	1.748	1.270	0.961	-	-	-	-
90%		1.826	1.235	0.913	-	-	-	-	-
None	D1 stream	10.013	5.313	3.630	2.761	-	-	-	-

50%		5.013	2.661	1.817	1.383	-	-	-	-
75%		2.522	1.487	1.061	0.804	-	-	-	-
90%		1.504	1.030	0.765	-	-	-	-	-
None	D2 ditch	8.578	4.670	3.243	2.461	-	-	-	-
50%		4.657	2.691	1.896	1.435	-	-	-	-
75%		2.835	1.770	1.283	0.970	-	-	-	-
90%		1.843	1.243	0.926	-	-	-	-	-
None	D2 stream	10.196	5.409	3.696	2.809	-	-	-	-
50%		5.104	2.709	1.852	1.409	-	-	-	-
75%		2.561	1.361	0.943	0.709	-	-	-	-
90%		1.035	0.570	-	-	-	-	-	-
None	D3 ditch	8.361	4.430	3.026	2.304	-	-	-	-
50%		4.191	2.335	1.622	1.235	-	-	-	-
75%		2.348	1.404	1.004	0.761	-	-	-	-
90%		1.404	0.935	0.691	-	-	-	-	-
None	D4 Pond	1.043	0.761	-	-	-	-	-	-
50%		0.622	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	9.791	5.204	3.565	2.709	-	-	-	-
50%		4.974	2.717	1.874	1.426	-	-	-	-
75%		2.657	1.487	1.039	0.791	-	-	-	-
90%		1.326	0.822	0.774	-	-	-	-	-
None	D5 pond	1.065	0.774	-	-	-	-	-	-

50%		0.635	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	10.561	5.600	3.826	2.909	-	-	-	-
50%		5.317	2.896	1.996	1.517	-	-	-	-
75%		2.830	1.609	1.130	0.857	-	-	-	-
90%		1.461	0.926	0.674	-	-	-	-	-
None	D6 ditch	8.570	4.683	3.257	2.470	-	-	-	-
50%		4.678	2.700	1.904	1.443	-	-	-	-
75%		2.865	1.787	1.326	1.326	-	-	-	-
90%		1.865	1.326	1.326	1.326	-	-	-	-
None	R1 pond	-	-	-	-	1.083	0.783	-	-
50%		-	-	-	-	0.657	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	7.678	4.139	2.843	2.161
50%		-	-	-	-	3.987	2.504	1.917	1.309
75%		-	-	-	-	3.591	2.504	1.917	1.309
90%		-	-	-	-	3.591	-	-	-
None	R3 stream	-	-	-	-	10.600	5.709	3.922	2.978
50%		-	-	-	-	5.491	3.004	2.078	1.578
75%		-	-	-	-	3.452	2.409	1.848	1.261
90%		-	-	-	-	3.452	2.409	1.848	1.261
None	R4 stream	-	-	-	-	7.709	4.170	2.870	2.183

50%		-	-	-	-	4.400	3.057	2.343	1.596
75%		-	-	-	-	4.400	3.057	2.343	1.596
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-14: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in pre-emergence

Intended use		Winter cereals pre-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	0.286	0.152
90%		0.154	-
75%	R3 stream	0.438	0.277
90%		0.438	-
75%	R4 stream	0.288	0.153
90%		0.158	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	1.24	0.66
90%		0.67	-
75%	R3 stream	1.90	1.20

90%		1.90	-
75%	R4 stream	1.25	0.67
90%		0.69	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter cereals in pre-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D1 ditch, D1 stream, D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15 no spray buffer zone + 90% nozzle reduction

D2 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D3 ditch, D4 stream, D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However scenario D6 is not relevant in CEU countries.

For scenario R3 stream PEC/RAC ratios are > 1 even considering the maximum mitigation measures and a restriction will have to be included (do not apply on terraced clay soils with a slope greater than 10%)

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter cereals in post emergence (1 x 1137 g/ha)

Group	Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dweller prolonged
Test species	<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)	LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
AF	196	6.3	32	147	14.5	9.3	82	12		227300
	100	10	10	100	10	10	10	10		10

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D1 ditch	7.201	3.67	11.43	2.25	4.90	4.97	7.74	0.88	6.00	18.75	0.00082
D1 stream	6.298	3.21	10.00	1.97	4.28	4.34	6.77	0.77	5.25	3.810	0.00017
D2 ditch	7.160	3.65	11.37	2.24	4.87	4.94	7.70	0.87	5.97	11.73	0.00052
D2 stream	5.810	2.96	9.22	1.82	3.95	4.01	6.25	0.71	4.84	0.404	0.00002
D3 ditch	7.093	3.62	11.26	2.22	4.83	4.89	7.63	0.87	5.91	3.645	0.00016
D4 pond	0.245	0.13	0.39	0.08	0.17	0.17	0.26	0.03	0.20	1.264	0.00006
D4 stream	6.154	3.14	9.77	1.92	4.19	4.24	6.62	0.75	5.13	1.303	0.00006
D5 pond	0.245	0.13	0.39	0.08	0.17	0.17	0.26	0.03	0.20	1.451	0.00006
D5 stream	6.640	3.39	10.54	2.08	4.52	4.58	7.14	0.81	5.53	1.845	0.00008
D6 ditch	7.177	3.66	11.39	2.24	4.88	4.95	7.72	0.88	5.98	15.00	0.00066
R1 pond	0.249	0.13	0.40	0.08	0.17	0.17	0.27	0.03	0.21	3.047	0.00013
R1 stream	4.678	2.39	7.43	1.46	3.18	3.23	5.03	0.57	3.90	9.780	0.00043
R3 stream	6.564	3.35	10.42	2.05	4.47	4.53	7.06	0.80	5.47	3.281	0.00014
R4 stream	4.640	2.37	7.37	1.45	3.16	3.20	4.99	0.57	3.87	4.612	0.00020

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses winter cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-16: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in post emergence

Intended use		Winter cereals post emergence							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1137							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D1 ditch	1.989	1.095	0.761	0.577	-	-	-	-
50%		1.095	0.632	0.449	0.340	-	-	-	-
75%		0.677	0.422	0.305	0.231	-	-	-	-
90%		0.440	0.296	0.220	0.166	-	-	-	-
None	D1 stream	2.303	1.222	0.832	0.635	-	-	-	-
50%		1.153	0.612	0.418	0.318	-	-	-	-
75%		0.597	0.354	0.253	0.191	-	-	-	-
90%		0.360	0.247	0.184	-	-	-	-	-
None	D2 ditch	1.940	1.051	0.724	0.551	-	-	-	-
50%		1.034	0.597	0.421	0.319	-	-	-	-
75%		0.624	0.390	0.283	0.214	-	-	-	-
90%		0.408	0.276	0.205	-	-	-	-	-
None	D2 stream	2.171	1.162	0.796	0.606	-	-	-	-
50%		1.110	0.600	0.412	0.313	-	-	-	-
75%		0.579	0.319	0.221	0.168	-	-	-	-
90%		0.267	0.156	-	-	-	-	-	-

None	D3 ditch	1.922	1.019	0.696	0.529	-	-	-	-
50%		0.960	0.533	0.371	0.282	-	-	-	-
75%		0.535	0.317	0.227	0.171	-	-	-	-
90%		0.315	0.210	-	-	-	-	-	-
None	D4 Pond	0.240	0.175	-	-	-	-	-	-
50%		0.143	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.252	1.197	0.820	0.623	-	-	-	-
50%		1.144	0.625	0.431	0.328	-	-	-	-
75%		0.611	0.342	0.239	0.182	-	-	-	-
90%		0.305	0.189	0.172	-	-	-	-	-
None	D5 pond	0.245	0.178	-	-	-	-	-	-
50%		0.146	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.429	1.288	0.880	0.669	-	-	-	-
50%		1.223	0.666	0.459	0.349	-	-	-	-
75%		0.651	0.370	0.260	0.197	-	-	-	-
90%		0.336	0.213	0.155	-	-	-	-	-
None	D6 ditch	1.971	1.077	0.749	0.568	-	-	-	-
50%		1.076	0.621	0.438	0.332	-	-	-	-
75%		0.659	0.411	0.306	0.306	-	-	-	-
90%		0.429	0.306	0.306	-	-	-	-	-

None	R1 pond	-	-	-	-	0.249	0.180	-	-
50%		-	-	-	-	0.151	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.766	0.952	0.654	0.497
50%		-	-	-	-	0.917	0.574	0.440	0.300
75%		-	-	-	-	0.824	0.574	0.440	0.300
90%		-	-	-	-	0.824	-	-	-
None	R3 stream	-	-	-	-	2.453	1.324	0.910	0.692
50%		-	-	-	-	1.277	0.701	0.484	0.368
75%		-	-	-	-	0.721	0.501	0.384	0.262
90%		-	-	-	-	0.721	0.501	0.384	0.262
None	R4 stream	-	-	-	-	1.753	0.946	0.650	0.494
50%		-	-	-	-	1.067	0.742	0.568	0.387
75%		-	-	-	-	1.067	0.742	0.568	0.387
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D1 ditch	2.14	1.18	0.82	0.62	-	-	-	-
50%		1.18	0.68	0.48	0.37	-	-	-	-
75%		0.73	0.45	0.33	0.25	-	-	-	-
90%		0.47	0.32	0.24	0.18	-	-	-	-
None	D1 stream	2.48	1.31	0.89	0.68	-	-	-	-
50%		1.24	0.66	0.45	0.34	-	-	-	-

75%		0.64	0.38	0.27	0.21	-	-	-	-
90%		0.39	0.27	0.20	-	-	-	-	-
None	D2 ditch	2.09	1.13	0.78	0.59	-	-	-	-
50%		1.11	0.64	0.45	0.34	-	-	-	-
75%		0.67	0.42	0.30	0.23	-	-	-	-
90%		0.44	0.30	0.22	-	-	-	-	-
None	D2 stream	2.33	1.25	0.86	0.65	-	-	-	-
50%		1.19	0.65	0.44	0.34	-	-	-	-
75%		0.62	0.34	0.24	0.18	-	-	-	-
90%		0.29	0.17	-	-	-	-	-	-
None	D3 ditch	2.07	1.10	0.75	0.57	-	-	-	-
50%		1.03	0.57	0.40	0.30	-	-	-	-
75%		0.58	0.34	0.24	0.18	-	-	-	-
90%		0.34	0.23	-	-	-	-	-	-
None	D4 Pond	0.26	0.19			-	-	-	-
50%		0.15	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.42	1.29	0.88	0.67	-	-	-	-
50%		1.23	0.67	0.46	0.35	-	-	-	-
75%		0.66	0.37	0.26	0.20	-	-	-	-
90%		0.33	0.20	0.18	-	-	-	-	-
None	D5 pond	0.26	0.19	-	-	-	-	-	-
50%		0.16	-	-	-	-	-	-	-

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.61	1.38	0.95	0.72	-	-	-	-
50%		1.32	0.72	0.49	0.38	-	-	-	-
75%		0.70	0.40	0.28	0.21	-	-	-	-
90%		0.36	0.23	0.17	-	-	-	-	-
None	D6 ditch	2.12	1.16	0.81	0.61	-	-	-	-
50%		1.16	0.67	0.47	0.36	-	-	-	-
75%		0.71	0.44	0.33	0.33	-	-	-	-
90%		0.46	0.33	0.33	-	-	-	-	-
None	R1 pond	-	-	-	-	0.27	0.19	-	-
50%		-	-	-	-	0.16	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.90	1.02	0.70	0.53
50%		-	-	-	-	0.99	0.62	0.47	0.32
75%		-	-	-	-	0.89	0.62	0.47	0.32
90%		-	-	-	-	0.89	-	-	-
None	R3 stream	-	-	-	-	2.64	1.42	0.98	0.74
50%		-	-	-	-	1.37	0.75	0.52	0.40
75%		-	-	-	-	0.78	0.54	0.41	0.28
90%		-	-	-	-	0.78	0.54	0.41	0.28
None	R4 stream	-	-	-	-	1.88	1.02	0.70	0.53
50%		-	-	-	-	1.15	0.80	0.61	0.42

75%		-	-	-	-	1.15	0.80	0.61	0.42
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter cereals (post-emergence 1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D1 ditch, D1 stream, D2 ditch, D2 stream, D3 ditch, D4 stream, D5 stream, D6 ditch: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-17: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in post emergence

Intended use		Winter cereals post emergence							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D1 ditch	1.989	1.095	0.761	0.577	-	-	-	-
50%		1.095	0.632	0.449	0.340	-	-	-	-
75%		0.677	0.422	0.305	0.231	-	-	-	-
90%		0.440	0.296	0.220	0.166	-	-	-	-
None	D1 stream	2.303	1.222	0.832	0.635	-	-	-	-

50%		1.153	0.612	0.418	0.318	-	-	-	-
75%		0.597	0.354	0.253	0.191	-	-	-	-
90%		0.360	0.247	0.184	-	-	-	-	-
None	D2 ditch	1.940	1.051	0.724	0.551	-	-	-	-
50%		1.034	0.597	0.421	0.319	-	-	-	-
75%		0.624	0.390	0.283	0.214	-	-	-	-
90%		0.408	0.276	0.205	-	-	-	-	-
None	D2 stream	2.171	1.162	0.796	0.606	-	-	-	-
50%		1.110	0.600	0.412	0.313	-	-	-	-
75%		0.579	0.319	0.221	0.168	-	-	-	-
90%		0.267	0.156	-	-	-	-	-	-
None	D3 ditch	1.922	1.019	0.696	0.529	-	-	-	-
50%		0.960	0.533	0.371	0.282	-	-	-	-
75%		0.535	0.317	0.227	0.171	-	-	-	-
90%		0.315	0.210	-	-	-	-	-	-
None	D4 Pond	0.240	0.175	-	-	-	-	-	-
50%		0.143	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.252	1.197	0.820	0.623	-	-	-	-
50%		1.144	0.625	0.431	0.328	-	-	-	-
75%		0.611	0.342	0.239	0.182	-	-	-	-
90%		0.305	0.189	0.172	-	-	-	-	-
None	D5 pond	0.245	0.178	-	-	-	-	-	-

50%		0.146	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.429	1.288	0.880	0.669	-	-	-	-
50%		1.223	0.666	0.459	0.349	-	-	-	-
75%		0.651	0.370	0.260	0.197	-	-	-	-
90%		0.336	0.213	0.155	-	-	-	-	-
None	D6 ditch	1.971	1.077	0.749	0.568	-	-	-	-
50%		1.076	0.621	0.438	0.332	-	-	-	-
75%		0.659	0.411	0.306	0.306	-	-	-	-
90%		0.429	0.306	0.306	-	-	-	-	-
None	R1 pond	-	-	-	-	0.249	0.180	-	-
50%		-	-	-	-	0.151	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.766	0.952	0.654	0.497
50%		-	-	-	-	0.917	0.574	0.440	0.300
75%		-	-	-	-	0.824	0.574	0.440	0.300
90%		-	-	-	-	0.824	-	-	-
None	R3 stream	-	-	-	-	2.453	1.324	0.910	0.692
50%		-	-	-	-	1.277	0.701	0.484	0.368
75%		-	-	-	-	0.721	0.501	0.384	0.262
90%		-	-	-	-	0.721	0.501	0.384	0.262
None	R4 stream	-	-	-	-	1.753	0.946	0.650	0.494

50%		-	-	-	-	1.067	0.742	0.568	0.387
75%		-	-	-	-	1.067	0.742	0.568	0.387
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D1 ditch	8.648	4.761	3.309	2.509	-	-	-	-
50%		4.761	2.748	1.952	1.478	-	-	-	-
75%		2.943	1.835	1.326	1.004	-	-	-	-
90%		1.913	1.287	0.957	0.722	-	-	-	-
None	D1 stream	10.013	5.313	3.617	2.761	-	-	-	-
50%		5.013	2.661	1.817	1.383	-	-	-	-
75%		2.596	1.539	1.100	0.830	-	-	-	-
90%		1.565	1.074	0.800	-	-	-	-	-
None	D2 ditch	8.435	4.570	3.148	2.396	-	-	-	-
50%		4.496	2.596	1.830	1.387	-	-	-	-
75%		2.713	1.696	1.230	0.930	-	-	-	-
90%		1.774	1.200	0.891	-	-	-	-	-
None	D2 stream	9.439	5.052	3.461	2.635	-	-	-	-
50%		4.826	2.609	1.791	1.361	-	-	-	-
75%		2.517	1.387	0.961	0.730	-	-	-	-
90%		1.161	0.678	-	-	-	-	-	-
None	D3 ditch	8.357	4.430	3.026	2.300	-	-	-	-
50%		4.174	2.317	1.613	1.226	-	-	-	-
75%		2.326	1.378	0.987	0.743	-	-	-	-

90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	7.678	4.139	2.843	2.161
50%		-	-	-	-	3.987	2.496	1.913	1.304
75%		-	-	-	-	3.583	2.496	1.913	1.304
90%		-	-	-	-	3.583	-	-	-
None	R3 stream	-	-	-	-	10.665	5.757	3.957	3.009
50%		-	-	-	-	5.552	3.048	2.104	1.600
75%		-	-	-	-	3.135	2.178	1.670	1.139
90%		-	-	-	-	3.135	2.178	1.670	1.139
None	R4 stream	-	-	-	-	7.622	4.113	2.826	2.148
50%		-	-	-	-	4.639	3.226	2.470	1.683
75%		-	-	-	-	4.639	3.226	2.470	1.683
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-18: Aquatic organisms: PEC calculation and acceptability of risk ($PEC/RAC < 1$) for pendimethalin based on FOCUS VFSSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in post-emergence

Intended use		Winter cereals post-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20

75%	R1 stream	-	0.152
90%		0.154	-
75%	R3 stream	-	0.210
90%		0.219	-
75%	R4 stream	-	0.147
90%		0.143	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.66
90%		0.67	-
75%	R3 stream	-	0.91
90%		0.95	-
75%	R4 stream	-	0.64
90%		0.62	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter cereals in post-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D1 ditch: 10m no spray buffer zone + 90% nozzle reduction

D1 stream, D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15 no spray buffer zone + 90% nozzle reduction

D2 stream, D3 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 stream, D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation. However, scenario D6 is not relevant in CEU countries

Table 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Pendimethalin 45.5% CS in maize in pre emergence (1 x 1590 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	E _r C ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)										PEC _{gl-max} (µg/kg)
Step 3											
D3 ditch	8.232	4.20	13.07	2.57	5.60	5.68	8.85	1.00	6.86	5.110	0.00022
D4 pond	0.332	0.17	0.53	0.10	0.23	0.23	0.36	0.04	0.28	1.445	0.00006
D4 stream	6.788	3.46	10.77	2.12	4.62	4.68	7.30	0.83	5.66	0.309	0.00001
D5 pond	0.332	0.17	0.53	0.10	0.23	0.23	0.36	0.04	0.28	1.242	0.00005
D5 stream	7.339	3.74	11.65	2.29	4.99	5.06	7.89	0.90	6.12	0.350	0.00002
D6 ditch	8.233	4.20	13.07	2.57	5.60	5.68	8.85	1.00	6.86	5.109	0.00022
R1 pond	0.346	0.18	0.55	0.11	0.24	0.24	0.37	0.04	0.29	2.845	0.00013
R1 stream	5.691	2.90	9.03	1.78	3.87	3.92	6.12	0.69	4.74	7.921	0.00035

Group		Fish acute	Fish pro- longed	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell- er pro- longed
R2 stream	7.567	3.86	12.01	2.36	5.15	5.22	8.14	0.92	6.31	16.21	0.00071
R3 stream	8.054	4.11	12.78	2.52	5.48	5.55	8.66	0.98	6.71	2.740	0.00012
R4 stream	5.690	2.90	9.03	1.78	3.87	3.92	6.12	0.69	4.74	9.896	0.00044

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses maize (pre-emergence 1 x 1590 g/ha), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-20: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize pre-emergence (1 x 1590 g/ha)

Intended-use		Maize									
Active substance		pendimethalin									
Application rate (g/ha)		1 x 1590									
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20		
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20		
None	D3 ditch	2.696	1.429	0.976	0.742	-	-	-	-		
50%		1.347	0.748	0.520	-	-	-	-	-		
75%		0.750	-	-	-	-	-	-	-		
90%		-	-	-	-	-	-	-	-		
None	D4 stream	2.914	1.558	1.067	0.812	-	-	-	-		
50%		1.485	0.801	0.550	-	-	-	-	-		

75%		0.771	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	3.152	1.686	1.155	0.879	-	-	-	-
50%		1.607	0.867	0.595	-	-	-	-	-
75%		0.835	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None		D6 ditch	2.697	1.429	0.976	0.743	-	-	-
50%	1.348		0.733	0.510	-	-	-	-	-
75%	0.736		-	-	-	-	-	-	-
90%	-		-	-	-	-	-	-	-
None	R1 stream		-	-	-	-	2.460	1.325	0.911
50%		-	-	-	-	1.281	0.754	-	-
75%		-	-	-	-	1.083	-	-	-
90%		-	-	-	-	1.083	-	-	-
None		R2 stream	-	-	-	-	3.277	1.759	1.206
50%	-		-	-	-	1.684	0.914	0.629	-
75%	-		-	-	-	0.888	-	-	-
90%	-		-	-	-	-	-	-	-
None	R3 stream		-	-	-	-	3.402	1.807	1.235
50%		-	-	-	-	1.724	0.943	0.653	0.497
75%		-	-	-	-	0.935	0.612	-	-
90%		-	-	-	-	0.882	-	-	-
None		R4 stream	-	-	-	-	2.452	1.321	0.907
50%	-		-	-	-	1.610	1.122	-	-

75%		-	-	-	-	1.610	1.122	-	-
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (P. subcapitata)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.56	-	-	-	-	-
75%		0.81	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.13	1.68	1.15	0.87	-	-	-	-
50%		1.60	0.86	0.59	-	-	-	-	-
75%		0.83	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	3.39	1.81	1.24	0.95	-	-	-	-
50%		1.73	0.93	0.64	-	-	-	-	-
75%		0.90	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.79	0.55	-	-	-	-	-
75%		0.79	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.65	1.42	0.98	-
50%		-	-	-	-	1.38	0.81	-	-
75%		-	-	-	-	1.16	-	-	-
90%		-	-	-	-	1.16	-	-	-

None	R2 stream	-	-	-	-	3.52	1.89	1.30	0.99
50%		-	-	-	-	1.81	0.98	0.68	-
75%		-	-	-	-	0.95	-	-	-
90%		-	-	-	-	-	-	-	-
None	R3 stream	-	-	-	-	3.66	1.94	1.33	1.01
50%		-	-	-	-	1.85	1.01	0.70	0.53
75%		-	-	-	-	1.01	0.66	-	-
90%		-	-	-	-	0.95	-	-	-
None	R4 stream	-	-	-	-	2.64	1.42	0.98	-
50%		-	-	-	-	1.73	1.21	-	-
75%		-	-	-	-	1.73	1.21	-	-
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Maize in pre emergence							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.696	1.429	0.976	0.742	-	-	-	-
50%		1.347	0.748	0.520	0.396	-	-	-	-
75%		0.750	0.455	0.325	0.248	-	-	-	-
90%		0.456	0.305	0.223	0.170	-	-	-	-
None	D4 pond	0.337	0.245	0.194	-	-	-	-	-
50%		0.201	0.147	-	-	-	-	-	-

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.914	1.558	1.067	0.812	-	-	-	-
50%		1.485	0.801	0.550	0.418	-	-	-	-
75%		0.771	0.422	0.291	0.222	-	-	-	-
90%		0.342	0.195	0.187	-	-	-	-	-
None	D5 pond	0.331	0.240	0.190	-	-	-	-	-
50%		0.197	0.144	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	3.152	1.686	1.155	0.879	-	-	-	-
50%		1.607	0.867	0.595	0.453	-	-	-	-
75%		0.835	0.458	0.316	0.241	-	-	-	-
90%		0.372	0.212	0.148	0.113	-	-	-	-
None	D6 ditch	2.697	1.429	0.976	0.743	-	-	-	-
50%		1.348	0.733	0.510	0.449	-	-	-	-
75%		0.736	0.449	0.449	0.449	-	-	-	-
90%		0.449	0.449	0.449	-	-	-	-	-
None	R1 pond	-	-	-	-	0.340	0.246	0.195	-
50%		-	-	-	-	0.205	0.150	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.460	1.325	0.911	0.693
50%		-	-	-	-	1.281	0.754	0.578	0.394

75%		-	-	-	-	1.083	0.754	0.578	0.394
90%		-	-	-	-	1.083	-	-	-
None	R1 stream	-	-	-	-	3.277	1.759	1.206	0.918
50%		-	-	-	-	1.684	0.914	0.629	0.479
75%		-	-	-	-	0.888	0.492	0.341	0.260
90%		-	-	-	-	0.410	0.239	0.168	0.129
None	R2 stream	-	-	-	-	3.402	1.807	1.235	0.939
50%		-	-	-	-	1.724	0.943	0.653	0.497
75%		-	-	-	-	0.935	0.612	0.469	0.320
90%		-	-	-	-	0.882	0.612	0.469	0.320
None	R3 stream	-	-	-	-	2.452	1.321	0.907	0.690
50%		-	-	-	-	1.610	1.122	0.861	0.588
75%		-	-	-	-	1.610	1.122	0.861	0.588
90%		-	-	-	-	-	-	-	-
None	R4 stream	-	-	-	-	0.340	0.246	0.195	-
50%		-	-	-	-	0.205	0.150	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.56	0.43	-	-	-	-
75%		0.81	0.49	0.35	0.27	-	-	-	-
90%		0.49	0.33	0.24	0.18	-	-	-	-

None	R1 stream	-	-	-	-	2.65	1.42	0.98	0.75
50%		-	-	-	-	1.38	0.81	0.62	0.42
75%		-	-	-	-	1.16	0.81	0.62	0.42
90%		-	-	-	-	1.16	-	-	-
None	R2 stream	-	-	-	-	3.52	1.89	1.30	0.99
50%		-	-	-	-	1.81	0.98	0.68	0.52
75%		-	-	-	-	0.95	0.53	0.37	0.28
90%		-	-	-	-	0.44	0.26	0.18	0.14
None	R3 stream	-	-	-	-	3.66	1.94	1.33	1.01
50%		-	-	-	-	1.85	1.01	0.70	0.53
75%		-	-	-	-	1.01	0.66	0.50	0.34
90%		-	-	-	-	0.95	0.66	0.50	0.34
None	R4 stream	-	-	-	-	2.64	1.42	0.98	0.74
50%		-	-	-	-	1.73	1.21	0.93	0.63
75%		-	-	-	-	1.73	1.21	0.93	0.63
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in maize (pre-emergence 1x1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D5 stream, D6 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 stream: **20m no spray buffer zone + 20m vegetative strip or** 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction of 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip

R2 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-21: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize in pre emergence

Intended use		Maize in pre emergence							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.696	1.429	0.976	0.742	-	-	-	-
50%		1.347	0.748	0.520	0.396	-	-	-	-
75%		0.750	0.455	0.325	0.248	-	-	-	-
90%		0.456	0.305	0.223	0.170	-	-	-	-
None	D4 pond	0.337	0.245	0.194	-	-	-	-	-
50%		0.201	0.147	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.914	1.558	1.067	0.812	-	-	-	-
50%		1.485	0.801	0.550	0.418	-	-	-	-
75%		0.771	0.422	0.291	0.222	-	-	-	-
90%		0.342	0.195	0.187	-	-	-	-	-
None	D5 pond	0.331	0.240	0.190	-	-	-	-	-
50%		0.197	0.144	-	-	-	-	-	-

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	3.152	1.686	1.155	0.879	-	-	-	-
50%		1.607	0.867	0.595	0.453	-	-	-	-
75%		0.835	0.458	0.316	0.241	-	-	-	-
90%		0.372	0.212	0.148	0.113	-	-	-	-
None	D6 ditch	2.697	1.429	0.976	0.743	-	-	-	-
50%		1.348	0.733	0.510	0.449	-	-	-	-
75%		0.736	0.449	0.449	0.449	-	-	-	-
90%		0.449	0.449	0.449	-	-	-	-	-
None	R1 pond	-	-	-	-	0.340	0.246	0.195	-
50%		-	-	-	-	0.205	0.150	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.460	1.325	0.911	0.693
50%		-	-	-	-	1.281	0.754	0.578	0.394
75%		-	-	-	-	1.083	0.754	0.578	0.394
90%		-	-	-	-	1.083	-	-	-
None	R1 stream	-	-	-	-	3.277	1.759	1.206	0.918
50%		-	-	-	-	1.684	0.914	0.629	0.479
75%		-	-	-	-	0.888	0.492	0.341	0.260
90%		-	-	-	-	0.410	0.239	0.168	0.129
None	R2 stream	-	-	-	-	3.402	1.807	1.235	0.939
50%		-	-	-	-	1.724	0.943	0.653	0.497

75%		-	-	-	-	0.935	0.612	0.469	0.320
90%		-	-	-	-	0.882	0.612	0.469	0.320
None	R3 stream	-	-	-	-	2.452	1.321	0.907	0.690
50%		-	-	-	-	1.610	1.122	0.861	0.588
75%		-	-	-	-	1.610	1.122	0.861	0.588
90%		-	-	-	-	-	-	-	-
None	R4 stream	-	-	-	-	0.340	0.246	0.195	-
50%		-	-	-	-	0.205	0.150	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	11.722	6.213	4.243	3.226	-	-	-	-
50%		5.857	3.252	2.261	1.722	-	-	-	-
75%		3.261	1.978	1.413	1.078	-	-	-	-
90%		1.983	1.326	0.970	0.739	-	-	-	-
None	D4 pond	1.465	1.065	0.843	-	-	-	-	-
50%		0.874	0.639	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	12.670	6.774	4.639	3.530	-	-	-	-
50%		6.457	3.483	2.391	1.817	-	-	-	-
75%		3.352	1.835	1.265	0.965	-	-	-	-
90%		1.487	0.848	0.813	-	-	-	-	-

None	D5 pond	1.439	1.043	0.826	-	-	-	-	-
50%		0.857	0.626	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	13.704	7.330	5.022	3.822	-	-	-	-
50%		6.987	3.770	2.587	1.970	-	-	-	-
75%		3.630	1.991	1.374	1.048	-	-	-	-
90%		1.617	0.922	0.643	0.491	-	-	-	-
None	D6 ditch	11.726	6.213	4.243	3.230	-	-	-	-
50%		5.861	3.187	2.217	1.952	-	-	-	-
75%		3.200	1.952	1.952	1.952	-	-	-	-
90%		1.952	1.952	1.952	-	-	-	-	-
None	R1 pond	-	-	-	-	1.478	1.070	0.848	-
50%		-	-	-	-	0.891	0.652	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	10.696	5.761	3.961	3.013
50%		-	-	-	-	5.570	3.278	2.513	1.713
75%		-	-	-	-	4.709	3.278	2.513	1.713
90%		-	-	-	-	4.709	-	-	-
None	R2 stream	-	-	-	-	14.248	7.648	5.243	3.991
50%		-	-	-	-	7.322	3.974	2.735	2.083
75%		-	-	-	-	3.861	2.139	1.483	1.130
90%		-	-	-	-	1.783	1.039	0.730	0.561

None	R3 stream	-	-	-	-	14.791	7.857	5.370	4.083
50%		-	-	-	-	7.496	4.100	2.839	2.161
75%		-	-	-	-	4.065	2.661	2.039	1.391
90%		-	-	-	-	3.835	2.661	2.039	1.391
None	R4 stream	-	-	-	-	10.661	5.743	3.943	3.000
50%		-	-	-	-	7.000	4.878	3.743	2.557
75%		-	-	-	-	7.000	4.878	3.743	2.557
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-22: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize pre-emergence

Intended use		Maize pre-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.216
90%		0.215	-
75%	R2 stream	-	0.260
90%		0.239	0.129
75%	R3 stream	-	0.285
90%		0.305	0.168

75%	R4 stream	-	0.212
90%		0.275	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.94
90%		0.93	-
75%	R2 stream	-	1.13
90%		1.04	0.56
75%	R3 stream	-	1.24
90%		1.33	0.73
75%	R4 stream	-	0.92
90%		1.20	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in maize pre-emergence (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D5 stream: 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However scenario D6 is not relevant in CEU countries.

Table 9.5-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Pendimethalin 45.5% CS in maize in post emergence (1 x 1590 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell. er prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	E _r C ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	8.239	4.20	13.08	2.57	5.60	5.68	8.86	1.00	6.87	5.436	0.00024
D4 pond	0.332	0.17	0.53	0.10	0.23	0.23	0.36	0.04	0.28	1.450	0.00006
D4 stream	7.055	3.60	11.20	2.20	4.80	4.87	7.59	0.86	5.88	0.483	0.00002
D5 pond	0.332	0.17	0.53	0.10	0.23	0.23	0.36	0.04	0.28	1.449	0.00006
D5 stream	7.030	3.59	11.16	2.20	4.78	4.85	7.56	0.86	5.86	0.233	0.00001
D6 ditch	8.239	4.20	13.08	2.57	5.60	5.68	8.86	1.00	6.87	5.359	0.00024
R1 pond	0.346	0.18	0.55	0.11	0.24	0.24	0.37	0.04	0.29	4.036	0.00018
R1 stream	5.599	2.86	8.89	1.75	3.81	3.86	6.02	0.68	4.67	15.21	0.00067
R2 stream	7.636	3.90	12.12	2.39	5.19	5.27	8.21	0.93	6.36	17.18	0.00076

None	D4 stream	3.036	1.625	1.114	0.847	-	-	-	-
50%		1.551	0.838	0.576	0.438	-	-	-	-
75%		0.809	0.445	0.308	0.235	-	-	-	-
90%		0.372	0.218	0.182	0.182	-	-	-	-
None	D5 pond	0.333	0.242	0.192	-	-	-	-	-
50%		0.198	0.145	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	3.004	1.603	1.097	0.835	-	-	-	-
50%		1.524	0.818	0.561	0.427	-	-	-	-
75%		0.784	0.427	0.294	0.224	-	-	-	-
90%		0.341	0.191	0.133	-	-	-	-	-
None	D6 ditch	2.699	1.430	0.977	0.743	-	-	-	-
50%		1.365	0.762	0.529	0.456	-	-	-	-
75%		0.773	0.473	0.456	0.456	-	-	-	-
90%		0.473	0.456	0.456	-	-	-	-	-
None	R1 pond	-	-	-	-	0.345	0.251	0.198	-
50%		-	-	-	-	0.209	0.152	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.432	1.311	0.900	0.685
50%		-	-	-	-	1.262	0.801	0.614	0.419
75%		-	-	-	-	1.151	0.801	0.614	0.419
90%		-	-	-	-	1.151	-	-	-

None	R2 stream	-	-	-	-	3.313	1.780	1.221	0.929
50%		-	-	-	-	1.706	0.928	0.639	0.487
75%		-	-	-	-	0.903	0.502	0.348	0.265
90%		-	-	-	-	0.424	0.251	0.177	0.136
None	R3 stream	-	-	-	-	3.394	1.819	1.248	0.950
50%		-	-	-	-	1.751	0.965	0.667	0.508
75%		-	-	-	-	0.956	0.665	0.510	0.348
90%		-	-	-	-	0.956	0.665	0.510	0.348
None	R4 stream	-	-	-	-	2.464	1.328	0.914	0.695
50%		-	-	-	-	1.628	1.134	0.870	0.594
75%		-	-	-	-	1.628	1.134	0.870	0.594
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.81	0.56	0.43	-	-	-	-
75%		0.81	0.50	0.36	0.27	-	-	-	-
90%		0.50	0.33	0.24	0.19	-	-	-	-
None	D4 pond	0.36	0.26	0.21	-	-	-	-	-
50%		0.22	0.16	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.26	1.75	1.20	0.91	-	-	-	-
50%		1.67	0.90	0.62	0.47	-	-	-	-

75%		0.87	0.48	0.33	0.25	-	-	-	-
90%		0.40	0.23	0.20	0.20	-	-	-	-
None	D5 pond	0.36	0.26	0.21		-	-	-	-
50%		0.21	0.16	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	3.23	1.72	1.18	0.90	-	-	-	-
50%		1.64	0.88	0.60	0.46	-	-	-	-
75%		0.84	0.46	0.32	0.24	-	-	-	-
90%		0.37	0.21	0.14		-	-	-	-
None	D6 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.47	0.82	0.57	0.49	-	-	-	-
75%		0.83	0.51	0.49	0.49	-	-	-	-
90%		0.51	0.49	0.49		-	-	-	-
None	R1 pond	-	-	-	-	0.37	0.27	0.21	-
50%		-	-	-	-	0.22	0.16	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.62	1.41	0.97	0.74
50%		-	-	-	-	1.36	0.86	0.66	0.45
75%		-	-	-	-	1.24	0.86	0.66	0.45
90%		-	-	-	-	1.24	-	-	-
None	R2 stream	-	-	-	-	3.56	1.91	1.31	1.00
50%		-	-	-	-	1.83	1.00	0.69	0.52

75%		-	-	-	-	0.97	0.54	0.37	0.28
90%		-	-	-	-	0.46	0.27	0.19	0.15
None	R3 stream	-	-	-	-	3.65	1.96	1.34	1.02
50%		-	-	-	-	1.88	1.04	0.72	0.55
75%		-	-	-	-	1.03	0.72	0.55	0.37
90%		-	-	-	-	1.03	0.72	0.55	0.37
None	R4 stream	-	-	-	-	2.65	1.43	0.98	0.75
50%		-	-	-	-	1.75	1.22	0.94	0.64
75%		-	-	-	-	1.75	1.22	0.94	0.64
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in maize (post-emergence 1x1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D5 stream, D6 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

None	D5 stream	3.004	1.603	1.097	0.835	-	-	-	-
50%		1.524	0.818	0.561	0.427	-	-	-	-
75%		0.784	0.427	0.294	0.224	-	-	-	-
90%		0.341	0.191	0.133	-	-	-	-	-
None	D6 ditch	2.699	1.430	0.977	0.743	-	-	-	-
50%		1.365	0.762	0.529	0.456	-	-	-	-
75%		0.773	0.473	0.456	0.456	-	-	-	-
90%		0.473	0.456	0.456	-	-	-	-	-
None	R1 pond	-	-	-	-	0.345	0.251	0.198	-
50%		-	-	-	-	0.209	0.152	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.432	1.311	0.900	0.685
50%		-	-	-	-	1.262	0.801	0.614	0.419
75%		-	-	-	-	1.151	0.801	0.614	0.419
90%		-	-	-	-	1.151	-	-	-
None	R2 stream	-	-	-	-	3.313	1.780	1.221	0.929
50%		-	-	-	-	1.706	0.928	0.639	0.487
75%		-	-	-	-	0.903	0.502	0.348	0.265
90%		-	-	-	-	0.424	0.251	0.177	0.136
None	R3 stream	-	-	-	-	3.394	1.819	1.248	0.950
50%		-	-	-	-	1.751	0.965	0.667	0.508
75%		-	-	-	-	0.956	0.665	0.510	0.348
90%		-	-	-	-	0.956	0.665	0.510	0.348

None	R4 stream	-	-	-	-	2.464	1.328	0.914	0.695
50%		-	-	-	-	1.628	1.134	0.870	0.594
75%		-	-	-	-	1.628	1.134	0.870	0.594
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	11.735	6.217	4.248	3.230	-	-	-	-
50%		5.870	3.270	2.274	1.730	-	-	-	-
75%		3.291	2.013	1.439	1.096	-	-	-	-
90%		2.017	1.348	0.987	0.752	-	-	-	-
None	D4 pond	1.470	1.070	0.843	-	-	-	-	-
50%		0.874	0.639	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	13.200	7.065	4.843	3.683	-	-	-	-
50%		6.743	3.643	2.504	1.904	-	-	-	-
75%		3.517	1.935	1.339	1.022	-	-	-	-
90%		1.617	0.948	0.791	0.791	-	-	-	-
None	D5 pond	1.448	1.052	0.835	-	-	-	-	-
50%		0.861	0.630	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	13.061	6.970	4.770	3.630	-	-	-	-
50%		6.626	3.557	2.439	1.857	-	-	-	-

75%		3.409	1.857	1.278	0.974	-	-	-	-
90%		1.483	0.830	0.578	-	-	-	-	-
None	D6 ditch	11.735	6.217	4.248	3.230	-	-	-	-
50%		5.935	3.313	2.300	1.983	-	-	-	-
75%		3.361	2.057	1.983	1.983	-	-	-	-
90%		2.057	1.983	1.983	-	-	-	-	-
None	R1 pond	-	-	-	-	1.500	1.091	0.861	-
50%		-	-	-	-	0.909	0.661	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	10.574	5.700	3.913	2.978
50%		-	-	-	-	5.487	3.483	2.670	1.822
75%		-	-	-	-	5.004	3.483	2.670	1.822
90%		-	-	-	-	5.004	-	-	-
None	R2 stream	-	-	-	-	14.404	7.739	5.309	4.039
50%		-	-	-	-	7.417	4.035	2.778	2.117
75%		-	-	-	-	3.926	2.183	1.513	1.152
90%		-	-	-	-	1.843	1.091	0.770	0.591
None	R3 stream	-	-	-	-	14.757	7.909	5.426	4.130
50%		-	-	-	-	7.613	4.196	2.900	2.209
75%		-	-	-	-	4.157	2.891	2.217	1.513
90%		-	-	-	-	4.157	2.891	2.217	1.513
None	R4 stream	-	-	-	-	10.713	5.774	3.974	3.022
50%		-	-	-	-	7.078	4.930	3.783	2.583

75%		-	-	-	-	7.078	4.930	3.783	2.583
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-26: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize post-emergence

Intended use		Maize post-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.203
90%		0.197	-
75%	R2 stream	-	0.265
90%		0.251	0.136
75%	R3 stream	-	0.289
90%		0.306	0.168
75%	R4 stream	-	0.214
90%		0.273	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.88
90%		0.86	-

75%	R2 stream	-	1.15
90%		1.09	0.59
75%	R3 stream	-	1.26
90%		1.33	0.73
75%	R4 stream	-	0.93
90%		1.19	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in maize post-emergence (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 10m no spray buffer zone + 90% nozzle reduction

D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzles

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However, scenario D6 is not relevant in CEU countries.

Table 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Pendimethalin 45.5% CS in maize in pre emergence (1 x 1137 g/ha)

Group	Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. Prolonged	Higher plant		Sed. dwell-er prolonged
Test species	<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>		<i>Chironomus riparius</i>
Endpoint	LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. Prolonged	Higher plant		Sed. dwell-er prolonged
(µg/L)		196	6.3	32	147	14.5	9.3	82	12		227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	5.886	3.00	9.34	1.84	4.00	4.06	6.33	0.72	4.91	3.918	0.00017
D4 pond	0.237	0.12	0.38	0.07	0.16	0.16	0.25	0.03	0.20	1.296	0.00006
D4 stream	4.853	2.48	7.70	1.52	3.30	3.35	5.22	0.59	4.04	0.221	0.00001
D5 pond	0.237	0.12	0.38	0.07	0.16	0.16	0.25	0.03	0.20	1.143	0.00005
D5 stream	5.247	2.68	8.33	1.64	3.57	3.62	5.64	0.64	4.37	0.252	0.00001
D6 ditch	5.886	3.00	9.34	1.84	4.00	4.06	6.33	0.72	4.91	4.129	0.00018
R1 pond	0.255	0.13	0.40	0.08	0.17	0.18	0.27	0.03	0.21	2.796	0.00012
R1 stream	4.069	2.08	6.46	1.27	2.77	2.81	4.38	0.50	3.39	5.782	0.00025
R2 stream	5.410	2.76	8.59	1.69	3.68	3.73	5.82	0.66	4.51	11.87	0.00052
R3 stream	5.758	2.94	9.14	1.80	3.92	3.97	6.19	0.70	4.80	2.010	0.00009
R4 stream	4.068	2.08	6.46	1.27	2.77	2.81	4.37	0.50	3.39	7.137	0.00031

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses maize (pre-emergence 1 x 1137 g/ha), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

None	D5 stream	2.254	1.205	0.826	0.628	-	-	-	-
50%		1.149	0.620	0.426	0.324	-	-	-	-
75%		0.597	0.327	0.226	0.172	-	-	-	-
90%		0.266	0.152	-	-	-	-	-	-
None	D6 ditch	1.928	1.022	0.698	0.531	-	-	-	-
50%		0.973	0.543	0.377	0.310	-	-	-	-
75%		0.554	0.338	0.310	0.310	-	-	-	-
90%		0.340	0.310	0.310	-	-	-	-	-
None	R1 pond	-	-	-	-	0.254	0.184	-	-
50%		-	-	-	-	0.156	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.765	0.953	0.656	0.498
50%		-	-	-	-	0.923	0.533	0.409	0.279
75%		-	-	-	-	0.766	0.533	0.409	0.279
90%		-	-	-	-	0.766	-	-	-
None	R2 stream	-	-	-	-	2.344	1.258	0.863	0.656
50%		-	-	-	-	1.205	0.654	0.451	0.342
75%		-	-	-	-	0.636	0.353	0.245	0.189
90%		-	-	-	-	0.294	0.172	0.121	-
None	R3 stream	-	-	-	-	2.433	1.305	0.896	0.681
50%		-	-	-	-	1.255	0.690	0.478	0.363
75%		-	-	-	-	0.685	0.435	0.333	0.227
90%		-	-	-	-	0.625	0.435	0.333	-

None	R4 stream	-	-	-	-	1.762	0.949	0.653	0.496
50%		-	-	-	-	1.137	0.792	0.608	0.415
75%		-	-	-	-	1.137	0.792	0.608	0.415
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.07	1.10	0.75	0.57	-	-	-	-
50%		1.05	0.59	0.41	0.31	-	-	-	-
75%		0.60	0.37	0.26	0.20	-	-	-	-
90%		0.37	0.24	0.18	-	-	-	-	-
None	D4 pond	0.26	0.19	-	-	-	-	-	-
50%		0.16	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.24	1.20	0.82	0.62	-	-	-	-
50%		1.14	0.62	0.42	0.32	-	-	-	-
75%		0.59	0.32	0.22	0.17	-	-	-	-
90%		0.26	0.15	-	-	-	-	-	-
None	D5 pond	0.26	0.19	-	-	-	-	-	-
50%		0.16	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.42	1.30	0.89	0.68	-	-	-	-
50%		1.24	0.67	0.46	0.35	-	-	-	-

75%		0.64	0.35	0.24	0.18	-	-	-	-
90%		0.29	0.16	-	-	-	-	-	-
None	D6 ditch	2.07	1.10	0.75	0.57	-	-	-	-
50%		1.05	0.58	0.41	0.33	-	-	-	-
75%		0.60	0.36	0.33	0.33	-	-	-	-
90%		0.37	0.33	0.33	-	-	-	-	-
None		R1 pond	-	-	-	-	0.27	0.20	-
50%	-		-	-	-	0.17	-	-	-
75%	-		-	-	-	-	-	-	-
90%	-		-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.90	1.02	0.71	0.54
50%		-	-	-	-	0.99	0.57	0.44	0.30
75%		-	-	-	-	0.82	0.57	0.44	0.30
90%		-	-	-	-	0.82	-	-	-
None	R2 stream	-	-	-	-	2.52	1.35	0.93	0.71
50%		-	-	-	-	1.30	0.70	0.48	0.37
75%		-	-	-	-	0.68	0.38	0.26	0.20
90%		-	-	-	-	0.32	0.18	0.13	-
None	R3 stream	-	-	-	-	2.62	1.40	0.96	0.73
50%		-	-	-	-	1.35	0.74	0.51	0.39
75%		-	-	-	-	0.74	0.47	0.36	0.24
90%		-	-	-	-	0.67	0.47	0.36	-
None	R4 stream	-	-	-	-	1.89	1.02	0.70	0.53
50%		-	-	-	-	1.22	0.85	0.65	0.45

75%		-	-	-	-	1.22	0.85	0.65	0.45
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in maize (pre-emergence 1x1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D5 stream, D6 ditch: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-29: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize in pre emergence

Intended use		Maize in pre emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 × 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	1.928	1.022	0.698	0.531	-	-	-	-
50%		0.979	0.546	0.379	0.288	-	-	-	-
75%		0.557	0.340	0.244	0.184	-	-	-	-
90%		0.341	0.227	0.168	-	-	-	-	-
None	D4 pond	0.246	0.179	-	-	-	-	-	-

50%		0.147	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.084	1.114	0.763	0.580	-	-	-	-
50%		1.062	0.572	0.393	0.299	-	-	-	-
75%		0.551	0.302	0.208	0.158	-	-	-	-
90%		0.245	0.139	-	-	-	-	-	-
None	D5 pond	0.244	0.177	-	-	-	-	-	-
50%		0.145	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.254	1.205	0.826	0.628	-	-	-	-
50%		1.149	0.620	0.426	0.324	-	-	-	-
75%		0.597	0.327	0.226	0.172	-	-	-	-
90%		0.266	0.152	-	-	-	-	-	-
None	D6 ditch	1.928	1.022	0.698	0.531	-	-	-	-
50%		0.973	0.543	0.377	0.310	-	-	-	-
75%		0.554	0.338	0.310	0.310	-	-	-	-
90%		0.340	0.310	0.310	-	-	-	-	-
None	R1 pond	-	-	-	-	0.254	0.184	-	-
50%		-	-	-	-	0.156	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.765	0.953	0.656	0.498

90%		-	-	-	-	-	-	-	-
None	D4 stream	9.061	4.843	3.317	2.522	-	-	-	-
50%		4.617	2.487	1.709	1.300	-	-	-	-
75%		2.396	1.313	0.904	0.687	-	-	-	-
90%		1.065	0.604	-	-	-	-	-	-
None	D5 pond	1.061	0.770	-	-	-	-	-	-
50%		0.630	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	9.800	5.239	3.591	2.730	-	-	-	-
50%		4.996	2.696	1.852	1.409	-	-	-	-
75%		2.596	1.422	0.983	0.748	-	-	-	-
90%		1.157	0.661	-	-	-	-	-	-
None	D6 ditch	8.383	4.443	3.035	2.309	-	-	-	-
50%		4.230	2.361	1.639	1.348	-	-	-	-
75%		2.409	1.470	1.348	1.348	-	-	-	-
90%		1.478	1.348	1.348	-	-	-	-	-
None	R1 pond	-	-	-	-	1.104	0.800	-	-
50%		-	-	-	-	0.678	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	7.674	4.143	2.852	2.165
50%		-	-	-	-	4.013	2.317	1.778	1.213
75%		-	-	-	-	3.330	2.317	1.778	1.213

90%		-	-	-	-	3.330	-	-	-
None	R2 stream	-	-	-	-	10.191	5.470	3.752	2.852
50%		-	-	-	-	5.239	2.843	1.961	1.487
75%		-	-	-	-	2.765	1.535	1.065	0.822
90%		-	-	-	-	1.278	0.748	0.526	-
None	R3 stream	-	-	-	-	10.578	5.674	3.896	2.961
50%		-	-	-	-	5.457	3.000	2.078	1.578
75%		-	-	-	-	2.978	1.891	1.448	0.987
90%		-	-	-	-	2.717	1.891	1.448	-
None	R4 stream	-	-	-	-	7.661	4.126	2.839	2.157
50%		-	-	-	-	4.943	3.443	2.643	1.804
75%		-	-	-	-	4.943	3.443	2.643	1.804
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-30: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize pre-emergence

Intended use		Maize pre-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.153

90%		0.155	-
75%	R2 stream	-	0.186
90%		0.172	-
75%	R3 stream	-	0.208
90%		0.225	-
75%	R4 stream	-	0.152
90%		0.196	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.67
90%		0.67	-
75%	R2 stream	-	0.81
90%		0.75	-
75%	R3 stream	-	0.90
90%		0.98	-
75%	R4 stream	-	0.66
90%		0.85	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in maize pre-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However, scenario D6 is not relevant in CEU countries.

Table 9.5-31: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Pendimethalin 45.5% CS in maize in post emergence (1 x 1137 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell. er prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	5.891	3.01	9.35	1.84	4.01	4.06	6.33	0.72	4.91	3.890	0.00017
D4 pond	0.237	0.12	0.38	0.07	0.16	0.16	0.25	0.03	0.20	1.041	0.00005
D4 stream	5.044	2.57	8.01	1.58	3.43	3.48	5.42	0.62	4.20	0.345	0.00002
D5 pond	0.237	0.12	0.38	0.07	0.16	0.16	0.25	0.03	0.20	1.040	0.00005
D5 stream	5.026	2.56	7.98	1.57	3.42	3.47	5.40	0.61	4.19	0.167	0.00001
D6 ditch	5.891	3.01	9.35	1.84	4.01	4.06	6.33	0.72	4.91	3.834	0.00017
R1 pond	0.247	0.13	0.39	0.08	0.17	0.17	0.27	0.03	0.21	2.875	0.00013
R1 stream	4.003	2.04	6.35	1.25	2.72	2.76	4.30	0.49	3.34	11.03	0.00049

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.171	1.162	0.796	0.605	-	-	-	-
50%		1.109	0.599	0.412	0.313	-	-	-	-
75%		0.579	0.318	0.220	0.167	-	-	-	-
90%		0.266	0.156	-	-	-	-	-	-
None	D5 pond	0.238	0.173	-	-	-	-	-	-
50%		0.142	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.148	1.146	0.784	0.596	-	-	-	-
50%		1.090	0.585	0.401	0.305	-	-	-	-
75%		0.561	0.305	0.210	0.160	-	-	-	-
90%		0.244	0.137	-	-	-	-	-	-
None	D6 ditch	1.929	1.023	0.699	0.531	-	-	-	-
50%		0.976	0.544	0.378	0.314	-	-	-	-
75%		0.554	0.338	0.314	0.314	-	-	-	-
90%		0.339	0.314	0.314	-	-	-	-	-
None	R1 pond	-	-	-	-	0.247	0.179	-	-
50%		-	-	-	-	0.150	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.739	0.937	0.644	0.489
50%		-	-	-	-	0.903	0.565	0.433	0.295

None	D4 stream	2.33	1.25	0.86	0.65	-	-	-	-
50%		1.19	0.64	0.44	0.34	-	-	-	-
75%		0.62	0.34	0.24	0.18	-	-	-	-
90%		0.29	0.17	-	-	-	-	-	-
None	D5 pond	0.26	0.19	-	-	-	-	-	-
50%		0.15	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.31	1.23	0.84	0.64	-	-	-	-
50%		1.17	0.63	0.43	0.33	-	-	-	-
75%		0.60	0.33	0.23	0.17	-	-	-	-
90%		0.26	0.15	-	-	-	-	-	-
None	D6 ditch	2.07	1.10	0.75	0.57	-	-	-	-
50%		1.05	0.58	0.41	0.34	-	-	-	-
75%		0.60	0.36	0.34	0.34	-	-	-	-
90%		0.36	0.34	0.34	-	-	-	-	-
None	R1 pond	-	-	-	-	0.27	0.19	-	-
50%		-	-	-	-	0.16	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.87	1.01	0.69	0.53
50%		-	-	-	-	0.97	0.61	0.47	0.32
75%		-	-	-	-	0.87	0.61	0.47	0.32
90%		-	-	-	-	0.87	-	-	-

None	R2 stream	-	-	-	-	2.55	1.37	0.94	0.71
50%		-	-	-	-	1.31	0.71	0.49	0.37
75%		-	-	-	-	0.69	0.39	0.27	0.20
90%		-	-	-	-	0.33	0.19	0.14	-
None	R3 stream	-	-	-	-	2.61	1.40	0.96	0.73
50%		-	-	-	-	1.35	0.74	0.51	0.39
75%		-	-	-	-	0.73	0.50	0.39	0.26
90%		-	-	-	-	0.72	0.50	0.39	0.26
None	R4 stream	-	-	-	-	1.89	1.02	0.70	0.53
50%		-	-	-	-	1.23	0.86	0.66	0.45
75%		-	-	-	-	1.23	0.86	0.66	0.45
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in maize (post-emergence 1x1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D5 stream, D6 ditch: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

None	D5 stream	2.148	1.146	0.784	0.596	-	-	-	-
50%		1.090	0.585	0.401	0.305	-	-	-	-
75%		0.561	0.305	0.210	0.160	-	-	-	-
90%		0.244	0.137	-	-	-	-	-	-
None	D6 ditch	1.929	1.023	0.699	0.531	-	-	-	-
50%		0.976	0.544	0.378	0.314	-	-	-	-
75%		0.554	0.338	0.314	0.314	-	-	-	-
90%		0.339	0.314	0.314	-	-	-	-	-
None	R1 pond	-	-	-	-	0.247	0.179	-	-
50%		-	-	-	-	0.150	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.739	0.937	0.644	0.489
50%		-	-	-	-	0.903	0.565	0.433	0.295
75%		-	-	-	-	0.812	0.565	0.433	0.295
90%		-	-	-	-	0.812	-	-	-
None	R2 stream	-	-	-	-	2.369	1.272	0.873	0.664
50%		-	-	-	-	1.220	0.663	0.457	0.347
75%		-	-	-	-	0.646	0.359	0.249	0.189
90%		-	-	-	-	0.304	0.179	0.127	-
None	R3 stream	-	-	-	-	2.427	1.300	0.892	0.678
50%		-	-	-	-	1.252	0.690	0.477	0.363
75%		-	-	-	-	0.682	0.468	0.359	0.245
90%		-	-	-	-	0.674	0.468	0.359	0.245

None	R4 stream	-	-	-	-	1.762	0.949	0.653	0.496
50%		-	-	-	-	1.147	0.800	0.614	0.419
75%		-	-	-	-	1.147	0.800	0.614	0.419
90%		-	-	-	-	-	-	--	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	8.387	4.448	3.039	2.309	-	-	-	-
50%		4.200	2.339	1.626	1.235	-	-	-	-
75%		2.357	1.439	1.035	0.778	-	-	-	-
90%		1.443	0.961	0.709	-	-	-	-	-
None	D4 pond	1.052	0.765	-	-	-	-	-	-
50%		0.626	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	9.439	5.052	3.461	2.630	-	-	-	-
50%		4.822	2.604	1.791	1.361	-	-	-	-
75%		2.517	1.383	0.957	0.726	-	-	-	-
90%		1.157	0.678	-	-	-	-	-	-
None	D5 pond	1.035	0.752	-	-	-	-	-	-
50%		0.617	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	9.339	4.983	3.409	2.591	-	-	-	-
50%		4.739	2.543	1.743	1.326	-	-	-	-

75%		2.439	1.326	0.913	0.696	-	-	-	-
90%		1.061	0.596	-	-	-	-	-	-
None	D6 ditch	8.387	4.448	3.039	2.309	-	-	-	-
50%		4.243	2.365	1.643	1.365	-	-	-	-
75%		2.409	1.470	1.365	1.365	-	-	-	-
90%		1.474	1.365	1.365	-	-	-	-	-
None		R1 pond	-	-	-	-	1.074	0.778	-
50%	-		-	-	-	0.652	-	-	-
75%	-		-	-	-	-	-	-	-
90%	-		-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	7.561	4.074	2.800	2.126
50%		-	-	-	-	3.926	2.457	1.883	1.283
75%		-	-	-	-	3.530	2.457	1.883	1.283
90%		-	-	-	-	3.530	-	-	-
None	R2 stream	-	-	-	-	10.300	5.530	3.796	2.887
50%		-	-	-	-	5.304	2.883	1.987	1.509
75%		-	-	-	-	2.809	1.561	1.083	0.822
90%		-	-	-	-	1.322	0.778	0.552	-
None	R3 stream	-	-	-	-	10.552	5.652	3.878	2.948
50%		-	-	-	-	5.443	3.000	2.074	1.578
75%		-	-	-	-	2.965	2.035	1.561	1.065
90%		-	-	-	-	2.930	2.035	1.561	1.065
None	R4 stream	-	-	-	-	7.661	4.126	2.839	2.157
50%		-	-	-	-	4.987	3.478	2.670	1.822

75%		-	-	-	-	4.987	3.478	2.670	1.822
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-33: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize post-emergence

Intended use		Maize post-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.145
90%		0.140	-
75%	R2 stream	-	0.189
90%		0.179	-
75%	R3 stream	-	0.206
90%		0.219	-
75%	R4 stream	-	0.152
90%		0.194	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.63
90%		0.61	-

75%	R2 stream	-	0.82
90%		0.78	-
75%	R3 stream	-	0.90
90%		0.95	-
75%	R4 stream	-	0.66
90%		0.84	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in maize post-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However scenario D6 is not relevant in CEU countries.

Table 9.5-344: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in pome/stone fruits (early application 1 x 1590 g/ha, between rows)

Group	Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
Test species	<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)	LC ₅₀ 196	NOEC 6.3	NOEC geomean 32	EC ₅₀ 147	NOEC 14.5	E _r C ₅₀ 9.3	NOEC 82	ErC ₅₀ 12		NOEC 227300

Group		Fish acute	Fish pro- longed	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell- er pro- longed
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	7.468	3.81	11.85	2.33	5.08	5.15	8.03	0.91	6.22	4.714	0.00021
D4 pond	0.257	0.13	0.41	0.08	0.17	0.18	0.28	0.03	0.21	1.263	0.00006
D4 stream	5.697	2.91	9.04	1.78	3.88	3.93	6.13	0.69	4.75	0.206	0.00001
D5 pond	0.257	0.13	0.41	0.08	0.17	0.18	0.28	0.03	0.21	1.101	0.00005
D5 stream	6.013	3.07	9.54	1.88	4.09	4.15	6.47	0.73	5.01	0.185	0.00001
R1 pond	0.257	0.13	0.41	0.08	0.17	0.18	0.28	0.03	0.21	1.014	0.00004
R1 stream	4.901	2.50	7.78	1.53	3.33	3.38	5.27	0.60	4.08	0.626	0.00003
R2 stream	6.493	3.31	10.31	2.03	4.42	4.48	6.98	0.79	5.41	0.401	0.00002
R3 stream	6.902	3.52	10.96	2.16	4.70	4.76	7.42	0.84	5.75	1.360	0.00006
R4 stream	4.902	2.50	7.78	1.53	3.33	3.38	5.27	0.60	4.09	0.630	0.00003

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses pome/stone fruits (early application 1 x 1590 g/ha between rows), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-5: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in pome/stone fruits

Intended use		pome/stone fruits					
Active substance		pendimethalin					
Application rate (g/ha)		1 × 1590					
Nozzle reduction	No-spray buffer (m)	5	10	20	5	10	15
	Vegetated filter strip (m)	None	None	None	5	10	15
None	D3 ditch	2.023	1.073	0.782	-	-	-
50%		1.011	0.561	-	-	-	-
75%		0.563	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	1.768	0.945	0.690	-	-	-
50%		0.901	0.486	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	D5 stream	1.861	0.994	0.725	-	-	-
50%		0.946	0.508	-	-	-	-
75%		0.488	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.548	0.837	-
50%		-	-	-	0.810	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-

None	R2 stream	-	-		2.040	1.097	0.801
50%		-	-		1.052	0.573	-
75%		-	-		0.558	-	-
90%		-	-		-	-	-
None	R3 stream	-	-		2.132	1.152	0.843
50%		-	-		1.113	0.613	-
75%		-	-		0.615	-	-
90%		-	-		-	-	-
None	R4 stream	-	-		1.548	0.837	-
50%		-	-		0.810	-	-
75%		-	-		-	-	-
90%		-	-		-	-	-
RAC (µg/L)							
0.93 (P. subcapitata)		PEC/RAC ratio					
None	D3 ditch	2.18	1.15	0.84	-	-	-
50%		1.09	0.60	-	-	-	-
75%		0.61	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	1.90	1.02	0.74	-	-	-
50%		0.97	0.52	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	D5 stream	2.00	1.07	0.78	-	-	-
50%		1.02	0.55	-	-	-	-

75%		0.52	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-		1.66	0.90	-
50%		-	-		0.87	-	-
75%		-	-		-	-	-
90%		-	-		-	-	-
None			-	-		2.19	1.18
50%	R2 stream	-	-		1.13	0.62	-
75%		-	-		0.60	-	-
90%		-	-		-	-	-
None			-	-		2.29	1.24
50%	R3 stream	-	-		1.20	0.66	-
75%		-	-		0.66	-	-
90%		-	-		-	-	-
None			-	-		1.66	0.90
50%	R4 stream	-	-		0.87	-	-
75%		-	-		-	-	-
90%		-	-		-	-	-
None			-	-		-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-35: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in pome/stone fruits

Intended use	pome/stone fruits (early between rows)
Active substance	pendimethalin
Application rate (g/ha)	1 × 1590

Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.023	1.073	0.782	0.557	-	-		
50%		1.011	0.561	0.412	0.296	-	-		
75%		0.563	0.343	0.255	0.186	-	-		
90%		0.343	0.2298	0.173	-	-	-		
None	D4 Pond	0.253	0.184	-	-	-	-		
50%		0.150	-	-	-	-	-		
75%		-	-	-	-	-	-		
90%		-	-	-	-	-	-		
None	D4 stream	1.768	0.945	0.690	0.492	-	-		
50%		0.901	0.486	0.355	0.254	-	-		
75%		0.467	0.256	0.190	0.134	-	-		
90%		0.208	0.118	-	-	-	-		
None	D5 Pond	0.248	0.180	-	-	-	-		
50%		0.148	-	-	-	-	-		
75%		-	-	-	-	-	-		
90%		-	-	-	-	-	-		
None	D5 stream	1.861	0.994	0.725	0.517	-	-		
50%		0.946	0.508	0.372	0.265	-	-		
75%		0.488	0.266	0.195	0.139	-	-		
90%		0.214	0.121	-	-	-	-		
None	R1 Pond	-	-	-	-	0.249	0.181	-	-
50%		-	-	-	-	0.148	-	-	-

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.548	0.837	0.612	0.438
50%		-	-	-	-	0.810	0.446	0.327	0.235
75%		-	-	-	-	0.445	0.257	0.190	0.137
90%		-	-	-	-	0.232	0.143	-	-
None	R2 stream	-	-	-	-	2.040	1.097	0.801	0.572
50%		-	-	-	-	1.052	0.573	0.419	0.300
75%		-	-	-	-	0.558	0.311	0.228	0.164
90%		-	-	-	-	0.262	0.154	-	-
None	R3 stream	-	-	-	-	2.132	1.152	0.843	0.602
50%		-	-	-	-	1.113	0.613	0.450	0.324
75%		-	-	-	-	0.615	0.356	0.263	0.190
90%		-	-	-	-	0.324	0.204	0.153	-
None	R4 stream	-	-	-	-	1.548	0.837	0.613	0.438
50%		-	-	-	-	0.810	0.446	0.328	0.236
75%		-	-	-	-	0.446	0.257	0.190	0.137
90%		-	-	-	-	0.232	0.144	-	-
RAC (µg/L)		PEC/RAC ratio							
0.93 (algae)									
None	D3 ditch	2.18	1.15	0.84	0.60	-	-	-	-
50%		1.09	0.60	0.44	0.32	-	-	-	-
75%		0.61	0.37	0.27	0.20	-	-	-	-
90%		0.37	0.25	0.19	-	-	-	-	-

None	D4 Pond	0.27	0.20	-	-	-	-	-	-
50%		0.16	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	1.90	1.02	0.74	0.53	-	-	-	-
50%		0.97	0.52	0.38	0.27	-	-	-	-
75%		0.50	0.28	0.20	0.14	-	-	-	-
90%		0.22	0.13	-	-	-	-	-	-
None	D5 Pond	0.27	0.19	-	-	-	-	-	-
50%		0.16	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.00	1.07	0.78	0.56	-	-	-	-
50%		1.02	0.55	0.40	0.28	-	-	-	-
75%		0.52	0.29	0.21	0.15	-	-	-	-
90%		0.23	0.13	-	-	-	-	-	-
None	R1 Pond	-	-	-	-	0.27	0.19	-	-
50%		-	-	-	-	0.16	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.66	0.90	0.66	0.47
50%		-	-	-	-	0.87	0.48	0.35	0.25
75%		-	-	-	-	0.48	0.28	0.20	0.15
90%		-	-	-	-	0.25	0.15	-	-

None	R2 stream	-	-	-	-	2.19	1.18	0.86	0.62
50%		-	-	-	-	1.13	0.62	0.45	0.32
75%		-	-	-	-	0.60	0.33	0.25	0.18
90%		-	-	-	-	0.28	0.17	-	-
None	R3 stream	-	-	-	-	2.29	1.24	0.91	0.65
50%		-	-	-	-	1.20	0.66	0.48	0.35
75%		-	-	-	-	0.66	0.38	0.28	0.20
90%		-	-	-	-	0.35	0.22	0.16	-
None	R4 stream	-	-	-	-	1.66	0.90	0.66	0.47
50%		-	-	-	-	0.87	0.48	0.35	0.25
75%		-	-	-	-	0.48	0.28	0.20	0.15
90%		-	-	-	-	0.25	0.15	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in pome/stone fruits (early application 1 x 1590 between rows) are <1 when risk mitigation options are considered:

D3 ditch, D5 stream: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

D4 stream: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 stream, R4 stream: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5 m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-36: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in pome/stone fruits (early between rows)

Intended use		pome/stone fruits (early between rows)							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.023	1.073	0.782	0.557	-	-		
50%		1.011	0.561	0.412	0.296	-	-		
75%		0.563	0.343	0.255	0.186	-	-		
90%		0.343	0.2298	0.173	-	-	-		
None	D4 Pond	0.253	0.184	-	-	-	-		
50%		0.150	-	-	-	-	-		
75%		-	-	-	-	-	-		
90%		-	-	-	-	-	-		
None	D4 stream	1.768	0.945	0.690	0.492	-	-		
50%		0.901	0.486	0.355	0.254	-	-		
75%		0.467	0.256	0.190	0.134	-	-		
90%		0.208	0.118	-	-	-	-		
None	D5 Pond	0.248	0.180	-	-	-	-		
50%		0.148	-	-	-	-	-		
75%		-	-	-	-	-	-		
90%		-	-	-	-	-	-		
None	D5 stream	1.861	0.994	0.725	0.517	-	-		

50%		0.946	0.508	0.372	0.265	-	-		
75%		0.488	0.266	0.195	0.139	-	-		
90%		0.214	0.121	-	-	-	-		
None	R1 Pond	-	-	-	-	0.249	0.181	-	-
50%		-	-	-	-	0.148	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.548	0.837	0.612	0.438
50%		-	-	-	-	0.810	0.446	0.327	0.235
75%		-	-	-	-	0.445	0.257	0.190	0.137
90%		-	-	-	-	0.232	0.143	-	-
None	R2 stream	-	-	-	-	2.040	1.097	0.801	0.572
50%		-	-	-	-	1.052	0.573	0.419	0.300
75%		-	-	-	-	0.558	0.311	0.228	0.164
90%		-	-	-	-	0.262	0.154	-	-
None	R3 stream	-	-	-	-	2.132	1.152	0.843	0.602
50%		-	-	-	-	1.113	0.613	0.450	0.324
75%		-	-	-	-	0.615	0.356	0.263	0.190
90%		-	-	-	-	0.324	0.204	0.153	-
None	R4 stream	-	-	-	-	1.548	0.837	0.613	0.438
50%		-	-	-	-	0.810	0.446	0.328	0.236
75%		-	-	-	-	0.446	0.257	0.190	0.137
90%		-	-	-	-	0.232	0.144	-	-
RAC (µg/L)		PEC/RAC ratio							

90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	6.730	3.639	2.661	1.904
50%		-	-	-	-	3.522	1.939	1.422	1.022
75%		-	-	-	-	1.935	1.117	0.826	0.596
90%		-	-	-	-	1.009	0.622	-	-
None	R2 stream	-	-	-	-	8.870	4.770	3.483	2.487
50%		-	-	-	-	4.574	2.491	1.822	1.304
75%		-	-	-	-	2.426	1.352	0.991	0.713
90%		-	-	-	-	1.139	0.670	-	-
None	R3 stream	-	-	-	-	9.270	5.009	3.665	2.617
50%		-	-	-	-	4.839	2.665	1.957	1.409
75%		-	-	-	-	2.674	1.548	1.143	0.826
90%		-	-	-	-	1.409	0.887	0.665	-
None	R4 stream	-	-	-	-	6.730	3.639	2.665	1.904
50%		-	-	-	-	3.522	1.939	1.426	1.026
75%		-	-	-	-	1.939	1.117	0.826	0.596
90%		-	-	-	-	1.009	0.626	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-37: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in pome/stone fruits (early application between rows)

Intended use	Pome/stone fruits (early application between rows)
Active substance	pendimethalin
Application rate (g/ha)	1 × 1137

Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.137
90%		0.143	-
75%	R2 stream	-	0.164
90%		0.154	-
75%	R3 stream	-	0.190
90%		0.204	-
75%	R4 stream	-	0.137
90%		0.144	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.60
90%		0.62	-
75%	R2 stream	-	0.71
90%		0.67	-
75%	R3 stream	-	0.83
90%		0.89	-
75%	R4 stream	-	0.60
90%		0.63	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in pome/stone fruits (early application 1 x 1590 g/ha between rows) are <1 when risk mitigation options are considered:
 D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
 D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction
 R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction
 R1 stream, R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-386: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in sunflower (1 x 1183 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell. er prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC ^{gl-max} (µg/L)										PEC ^{gl-max} (µg/kg)
Step 3											
D3 ditch	7.387	3.77	11.73	2.31	5.03	5.09	7.94	0.90	6.16	3.855	0.00017
D4 pond	0.255	0.13	0.40	0.08	0.17	0.18	0.27	0.03	0.21	0.884	0.00004
D4 stream	6.403	3.27	10.16	2.00	4.36	4.42	6.88	0.78	5.34	1.323	0.00006
D5 pond	0.247	0.13	0.39	0.08	0.17	0.17	0.27	0.03	0.21	0.997	0.00004
D5 stream	5.538	2.83	8.79	1.73	3.77	3.82	5.95	0.68	4.62	0.305	0.00001

Group		Fish acute	Fish pro- longed	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell- er pro- longed
R1 pond	0.257	0.13	0.41	0.08	0.17	0.18	0.28	0.03	0.21	2.163	0.00010
R1 stream	4.230	2.16	6.71	1.32	2.88	2.92	4.55	0.52	3.53	6.702	0.00029
R3 stream	5.975	3.05	9.48	1.87	4.06	4.12	6.42	0.73	4.98	5.114	0.00022
R4 stream	4.242	2.16	6.73	1.33	2.89	2.93	4.56	0.52	3.54	6.890	0.00030

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses in sunflower, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-7: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in sunflower (1 x 1183 g/ha)

Intended use		Sunflower							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1183							
Nozzle re- duction	No spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.001	1.061	0.725	-	-	-	-	-
50 %		1.000	0.549	-	-	-	-	-	-
75 %		0.550	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream	2.343	1.243	0.850	-	-	-	-	-
50 %		1.174	0.638	-	-	-	-	-	-

None	D4 stream	2.52	1.34	0.91	-	-	-	-	-
50%		1.26	0.69	-	-	-	-	-	-
75%		0.67	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.56	1.38	0.94	-	-	-	-	-
50%		1.31	0.71	-	-	-	-	-	-
75%		0.68	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.97	1.08	0.73	-
50%		-	-	-	-	1.02	0.59	-	-
75%		-	-	-	-	0.85	-	-	-
90%		-	-	-	-	-	-	-	-
None	R3 stream	-	-	-	-	2.72	1.46	0.99	-
50%		-	-	-	-	1.39	0.76	-	-
75%		-	-	-	-	0.81	-	-	-
90%		-	-	-	-	-	-	-	-
None	R4 stream	-	-	-	-	1.96	1.08	0.73	-
50%		-	-	-	-	1.19	0.83	-	-
75%		-	-	-	-	1.19	-	-	-
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-39: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in sunflower (1 x 1183 g/ha)

Intended use	Sunflower
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Active substance		pendimethalin							
Application rate (g/ha)		1 × 1183							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.001	1.061	0.725	0.551	-	-	-	-
50 %		1.000	0.549	0.381	0.290	-	-	-	-
75 %		0.550	0.325	0.232	0.176	-	-	-	-
90 %		0.324	0.215	0.159	-	-	-	-	-
None	D4 Pond	0.241	0.175	-	-	-	-	-	-
50 %		0.142	-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream	2.343	1.243	0.850	0.646	-	-	-	-
50%		1.174	0.638	0.440	0.335	-	-	-	-
75%		0.623	0.349	0.243	0.186	-	-	-	-
90%		0.309	0.191	0.186	-	-	-	-	-
None	D5 pond	0.246	0.179	-	-	-	-	-	-
50%		0.147	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.382	1.287	0.874	-	-	-	-	-
50%		1.216	0.657	0.451	-	-	-	-	-
75%		0.634	0.348	0.241	-	-	-	-	-
90%		0.284	0.163	-	-	-	-	-	-

None	R1 pond	-	-	-	-	0.253	0.183	-	-
50%		-	-	-	-	0.153	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.830	1.002	0.677	-
50%		-	-	-	-	0.950	0.553	0.424	-
75%		-	-	-	-	0.795	0.553	0.424	-
90%		-	-	-	-	0.795	-	-	-
None	R3 stream	-	-	-	-	2.527	1.362	0.920	-
50%		-	-	-	-	1.290	0.709	0.489	-
75%		-	-	-	-	0.752	0.524	0.402	-
90%		-	-	-	-	0.752	0.524	-	-
None	R4 stream	-	-	-	-	1.824	1.003	0.676	-
50%		-	-	-	-	1.106	0.771	0.591	-
75%		-	-	-	-	1.106	0.771	0.591	-
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.15	1.14	0.78	0.59	-	-	-	-
50%		1.08	0.59	0.41	0.31	-	-	-	-
75%		0.59	0.35	0.25	0.19	-	-	-	-
90%		0.35	0.23	0.17	-	-	-	-	-
None	D4 Pond	0.26	0.19	-	-	-	-	-	-
50%		0.15	-	-	-	-	-	-	-

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.52	1.34	0.91	0.69	-	-	-	-
50%		1.26	0.69	0.47	0.36	-	-	-	-
75%		0.67	0.38	0.26	0.20	-	-	-	-
90%		0.33	0.21	0.20	-	-	-	-	-
None	D5 pond	0.26	0.19	-	-	-	-	-	-
50%		0.16	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.56	1.38	0.94	-	-	-	-	-
50%		1.31	0.71	0.48	-	-	-	-	-
75%		0.68	0.37	0.26	-	-	-	-	-
90%		0.31	0.18	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.27	0.20	-	-
50%		-	-	-	-	0.16	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.97	1.08	0.73	-
50%		-	-	-	-	1.02	0.59	0.46	-
75%		-	-	-	-	0.85	0.59	0.46	-
90%		-	-	-	-	0.85	-	-	-
None	R3 stream	-	-	-	-	2.72	1.46	0.99	-
50%		-	-	-	-	1.39	0.76	0.53	-

75%		-	-	-	-	0.81	0.56	0.43	-
90%		-	-	-	-	0.81	0.56	-	-
None	R4 stream	-	-	-	-	1.96	1.08	0.73	-
50%		-	-	-	-	1.19	0.83	0.64	-
75%		-	-	-	-	1.19	0.83	0.64	-
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in sunflower are <1 when risk mitigation options are considered:

D3 ditch, D4 stream and D5 stream: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream and R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-40: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in sunflower (1 x 1183 g/ha)

Intended use		Sunflower							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1183							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.001	1.061	0.725	0.551	-	-	-	-

50 %		1.000	0.549	0.381	0.290	-	-	-	-
75 %		0.550	0.325	0.232	0.176	-	-	-	-
90 %		0.324	0.215	0.159	-	-	-	-	-
None	D4 Pond	0.241	0.175	-	-	-	-	-	-
50 %		0.142	-	-	-	-	-	-	-
75 %		-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream	2.343	1.243	0.850	0.646	-	-	-	-
50%		1.174	0.638	0.440	0.335	-	-	-	-
75%		0.623	0.349	0.243	0.186	-	-	-	-
90%		0.309	0.191	0.186	-	-	-	-	-
None	D5 pond	0.246	0.179	-	-	-	-	-	-
50%		0.147	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.382	1.287	0.874	0.665	-	-	-	-
50%		1.216	0.657	0.451	0.344	-	-	-	-
75%		0.634	0.348	0.241	0.183	-	-	-	-
90%		0.284	0.163	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.253	0.183	-	-
50%		-	-	-	-	0.153	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.830	1.002	0.677	0.515

50%		-	-	-	-	0.950	0.553	0.424	0.289
75%		-	-	-	-	0.795	0.553	0.424	0.289
90%		-	-	-	-	0.795	-	-	-
None	R3 stream	-	-	-	-	2.527	1.362	0.920	0.700
50%		-	-	-	-	1.290	0.709	0.489	0.372
75%		-	-	-	-	0.752	0.524	0.402	0.275
90%		-	-	-	-	0.752	0.524	-	0.275
None	R4 stream	-	-	-	-	1.824	1.003	0.676	0.515
50%		-	-	-	-	1.106	0.771	0.591	0.404
75%		-	-	-	-	1.106	0.771	0.591	0.404
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	8.700	4.613	3.152	2.396	-	-	-	-
50%		4.348	2.387	1.657	1.261	-	-	-	-
75%		2.391	1.413	1.009	0.765	-	-	-	-
90%		1.409	0.935	0.691	-	-	-	-	-
None	D4 Pond	1.048	0.761	-	-	-	-	-	-
50%		0.617	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	10.187	5.404	3.696	2.809	-	-	-	-
50%		5.104	2.774	1.913	1.457	-	-	-	-
75%		2.709	1.517	1.057	0.809	-	-	-	-

90%		1.343	0.830	0.809	-	-	-	-	-
None	D5 pond	1.070	0.778	-	-	-	-	-	-
50%		0.639	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	10.357	5.596	3.800	2.809	-	-	-	-
50%		5.287	2.857	1.961	1.456	-	-	-	-
75%		2.757	1.513	1.048	0.809	-	-	-	-
90%		1.235	0.709	-	-	-	-	-	-
None	R1 pond	-	-	-	-	1.100	0.796	-	-
50%		-	-	-	-	0.665	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	7.957	4.357	2.943	2.24
50%		-	-	-	-	4.130	2.404	1.843	1.26
75%		-	-	-	-	3.457	2.404	1.843	1.26
90%		-	-	-	-	3.457	-	-	-
None	R3 stream	-	-	-	-	10.987	5.922	4.000	3.04
50%		-	-	-	-	5.609	3.083	2.126	1.62
75%		-	-	-	-	3.270	2.278	1.748	1.20
90%		-	-	-	-	3.270	2.278	-	1.20
None	R4 stream	-	-	-	-	7.930	4.361	2.939	2.24
50%		-	-	-	-	4.809	3.352	2.570	1.76
75%		-	-	-	-	4.809	3.352	2.570	1.76

90%		-	-	-	-	-	-	-	-
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PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-40: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in sunflower (1 x 1183 g/ha)

Intended use		Sunflower	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1183	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.484
90%		0.484	0.484
75%	R3 stream	-	0.217
90%		0.228	-
75%	R4 stream	-	0.160
90%		0.200	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	2.10
90%		2.10	2.10
75%	R3 stream	-	0.94
90%		0.99	-
75%	R4 stream	-	0.70

90%		0.87	-
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PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in sunflower (1 x 1183 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenario R1 stream the PEC/RAC ratios are > 1 even with risk mitigation measures and then a restriction have to be considered (do not apply on silty soils with a slope greater than 3%)

Table 9.5-418: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in soybean (1 x 1183 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
Test species		<i>O. mykiss</i>	<i>P. promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12		227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	

Group		Fish acute	Fish pro- longed	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell- er pro- longed
Step 3											
D3 ditch	6.118	3.12	9.71	1.91	4.16	4.22	6.58	0.75	5.10	3.544	0.00016
D4 pond	0.247	0.13	0.39	0.08	0.17	0.17	0.27	0.03	0.21	1.214	0.00005
D4 stream	4.902	2.50	7.78	1.53	3.33	3.38	5.27	0.60	4.09	0.177	0.00001
R1 pond	0.255	0.13	0.40	0.08	0.17	0.18	0.27	0.03	0.21	1.872	0.00008
R1 stream	4.235	2.16	6.72	1.32	2.88	2.92	4.55	0.52	3.53	3.507	0.00015
R3 stream	5.991	3.06	9.51	1.87	4.08	4.13	6.44	0.73	4.99	2.563	0.00011
R4 stream	4.212	2.15	6.69	1.32	2.87	2.90	4.53	0.51	3.51	9.538	0.00042

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses soybeans, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-9: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in soybean

Intended use		Soybean									
Active substance		pendimethalin									
Application rate (g/ha)		1 × 1183									
Nozzle reduction	No spray buffer (m)	5	10	15	10	15	20				
	Vegetated filter strip (m)	None	None	None	10	15	20				
None	D3 ditch	2.004	1.062	0.726	-	-	-				

50%		1.001	0.553	-	-	-	-
75%		0.554	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	2.097	1.120	0.767	-	-	-
50%		1.065	0.573	-	-	-	-
75%		0.549	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.830	0.986	0.678
50%		-	-	-	0.954	0.527	-
75%		-	-	-	0.697	-	-
90%		-	-	-	-	-	-
None	R3 stream	-	-	-	2.531	1.344	0.919
50%		-	-	-	1.282	0.701	-
75%		-	-	-	0.720	-	-
90%		-	-	-	-	-	-
None	R4 stream	-	-	-	1.825	0.985	0.676
50%		-	-	-	1.247	0.869	-
75%		-	-	-	1.247	-	-
90%		-	-	-	-	-	-
RAC (µg/L)							
0.93 (P. subcapitata)		PEC/RAC ratio					
None	D3 ditch	2.15	1.14	0.78	-	-	-
50%		1.08	0.59	-	-	-	-
75%		0.60	-	-	-	-	-

90%		-	-	-	-	-	-
None	D4 stream	2.25	1.20	0.82	-	-	-
50%		1.15	0.62	-	-	-	-
75%		0.59	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.97	1.06	0.73
50%		-	-	-	1.03	0.57	-
75%		-	-	-	0.75	-	-
90%		-	-	-	-	-	-
None	R3 stream	-	-	-	2.72	1.45	0.99
50%		-	-	-	1.38	0.75	-
75%		-	-	-	0.77	-	-
90%		-	-	-	-	-	-
None	R4 stream	-	-	-	1.96	1.06	0.73
50%		-	-	-	1.34	0.93	-
75%		-	-	-	1.34	-	-
90%		-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-42: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in soybean

Intended use	Soybean
Active substance	Pendimethalin
Application rate (g/ha)	1 x 1183

Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.004	1.062	0.726	0.560	-	-	-	-
50%		1.001	0.553	0.389	0.296	-	-	-	-
75%		0.554	0.336	0.242	0.184	-	-	-	-
90%		0.338	0.225	0.167	-	-	-	-	-
None	D4 pond	0.254	0.185	-	-	-	-	-	-
50%		0.152	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.097	1.120	0.767	0.591	-	-	-	-
50%		1.065	0.573	0.399	0.303	-	-	-	-
75%		0.549	0.304	0.209	0.205	-	-	-	-
90%		0.244	0.205	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.255	0.185	-	-
50%		-	-	-	-	0.154	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.830	0.986	0.678	0.523
50%		-	-	-	-	0.954	0.527	0.376	0.281
75%		-	-	-	-	0.697	0.490	0.376	0.256
90%		-	-	-	-	0.697	0.490	0.376	0.256

None	R3 stream	-	-	-	-	2.531	1.344	0.919	0.709
50%		-	-	-	-	1.282	0.701	0.492	0.375
75%		-	-	-	-	0.720	0.507	0.389	0.265
90%		-	-	-	-	0.720	0.507	0.389	0.265
None	R4 stream	-	-	-	-	1.825	0.985	0.676	0.522
50%		-	-	-	-	1.247	0.869	0.676	0.462
75%		-	-	-	-	1.247	0.869	0.676	0.462
90%		-	-	-	-	1.247	0.869	-	-
RAC (µg/L)		PEC/RAC ratio							
0.93 (mesocosm)									
None	D3 ditch	2.15	1.14	0.78	0.60	-	-	-	-
50%		1.08	0.59	0.42	0.32	-	-	-	-
75%		0.60	0.36	0.26	0.20	-	-	-	-
90%		0.36	0.24	0.18	-	-	-	-	-
None	D4 pond	0.27	0.20	-	-	-	-	-	-
50%		0.16	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.25	1.20	0.82	0.64	-	-	-	-
50%		1.15	0.62	0.43	0.33	-	-	-	-
75%		0.59	0.33	0.22	0.22	-	-	-	-
90%		0.26	0.22	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.27	0.20	-	-
50%		-	-	-	-	0.17	-	-	-

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.97	1.06	0.73	0.56
50%		-	-	-	-	1.03	0.57	0.40	0.30
75%		-	-	-	-	0.75	0.53	0.40	0.28
90%		-	-	-	-	0.75	0.53	0.40	0.28
None	R3 stream	-	-	-	-	2.72	1.45	0.99	0.76
50%		-	-	-	-	1.38	0.75	0.53	0.40
75%		-	-	-	-	0.77	0.55	0.42	0.28
90%		-	-	-	-	0.77	0.55	0.42	0.28
None	R4 stream	-	-	-	-	1.96	1.06	0.73	0.56
50%		-	-	-	-	1.34	0.93	0.73	0.50
75%		-	-	-	-	1.34	0.93	0.73	0.50
90%		-	-	-	-	1.34	0.93	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in soybeans are <1 when risk mitigation options are considered:

D3 ditch and D4 stream: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream and R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.830	0.986	0.678	0.523
50%		-	-	-	-	0.954	0.527	0.376	0.281
75%		-	-	-	-	0.697	0.490	0.376	0.256
90%		-	-	-	-	0.697	0.490	0.376	0.256
None	R3 stream	-	-	-	-	2.531	1.344	0.919	0.709
50%		-	-	-	-	1.282	0.701	0.492	0.375
75%		-	-	-	-	0.720	0.507	0.389	0.265
90%		-	-	-	-	0.720	0.507	0.389	0.265
None	R4 stream	-	-	-	-	1.825	0.985	0.676	0.522
50%		-	-	-	-	1.247	0.869	0.676	0.462
75%		-	-	-	-	1.247	0.869	0.676	0.462
90%		-	-	-	-	1.247	0.869	-	-
RAC (µg/L)		PEC/RAC ratio							
0.23 (mesocosm)									
None	D3 ditch	8.713	4.617	3.157	2.435	-	-	-	-
50%		4.352	2.404	1.691	1.287	-	-	-	-
75%		2.409	1.461	1.052	0.800	-	-	-	-
90%		1.470	0.978	0.726	-	-	-	-	-
None	D4 pond	1.104	0.804	-	-	-	-	-	-
50%		0.661	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	9.117	4.870	3.335	2.570	-	-	-	-

50%		4.630	2.491	1.735	1.317	-	-	-	-
75%		2.387	1.322	0.909	0.891	-	-	-	-
90%		1.061	0.891	-	-	-	-	-	-
None	R1 pond	-	-	-	-	1.109	0.804	-	-
50%		-	-	-	-	0.670	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	7.957	4.287	2.948	2.274
50%		-	-	-	-	4.148	2.291	1.635	1.222
75%		-	-	-	-	3.030	2.130	1.635	1.113
90%		-	-	-	-	3.030	2.130	1.635	1.113
None	R3 stream	-	-	-	-	11.004	5.843	3.996	3.083
50%		-	-	-	-	5.574	3.048	2.139	1.630
75%		-	-	-	-	3.130	2.204	1.691	1.152
90%		-	-	-	-	3.130	2.204	1.691	1.152
None	R4 stream	-	-	-	-	7.935	4.283	2.939	2.270
50%		-	-	-	-	5.422	3.778	2.939	2.009
75%		-	-	-	-	5.422	3.778	2.939	2.009
90%		-	-	-	-	5.422	3.778	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-44: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in soybean (1 x 1183 g/ha)

Intended use	Soybean
Active substance	pendimethalin

Application rate (g/ha)		1 × 1183	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.161
90%		0.162	-
75%	R3 stream	-	0.215
90%		0.230	-
75%	R4 stream	-	0.157
90%		0.200	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.7
90%		0.70	-
75%	R3 stream	-	0.93
90%		1.00	-
75%	R4 stream	-	0.68
90%		0.87	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in soybean (1 x 1183 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 150m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-4510: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in bulb vegetables **in pre emergence** (1 x 1590 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dweller prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	E _r C ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)										PEC _{gl-max} (µg/kg)
Step 3											
D3 ditch	9.944	5.07	15.78	3.11	6.76	6.86	10.69	1.21	8.29	5.753	0.00025
D4 pond	0.343	0.18	0.54	0.11	0.23	0.24	0.37	0.04	0.29	1.679	0.00007
D4 stream	7.595	3.88	12.06	2.37	5.17	5.24	8.17	0.93	6.33	0.274	0.00001
D6 1 st ditch	9.800	5.00	15.56	3.06	6.67	6.76	10.54	1.20	8.17	2.349	0.00010
D6 2 nd ditch	10.04	5.12	15.94	3.14	6.83	6.92	10.80	1.22	8.37	9.701	0.00043
R1 pond	0.355	0.18	0.56	0.11	0.24	0.24	0.38	0.04	0.30	2.694	0.00012
R1 stream	6.557	3.35	10.41	2.05	4.46	4.52	7.05	0.80	5.46	8.792	0.00039

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er pro-longed
R2 stream	8.602	4.39	13.65	2.69	5.85	5.93	9.25	1.05	7.17	26.90	0.00118
R3 stream	9.280	4.73	14.73	2.90	6.31	6.40	9.98	1.13	7.73	2.964	0.00013
R4 stream	6.583	3.36	10.45	2.06	4.48	4.54	7.08	0.80	5.49	14.35	0.00063

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses bulb vegetables (**pre-emergence**, 1 x 1590 g/ha), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-11: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables

Intended use		Bulb vegetables									
Active substance		Pendimethalin									
Application rate (g/ha)		1 x 1590									
Nozzle re-duction	No-spray buffer (m)	5	10	15	20	5	10	15	20		
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20		
None	D3 ditch	2.694	1.428	0.975	0.742	-	-	-	-		
50%		1.346	0.743	0.516	-	-	-	-	-		
75%		0.745	-	-	-	-	-	-	-		
90%		-	-	-	-	-	-	-	-		
None	D4 stream	2.819	1.505	1.030	0.784	-	-	-	-		
50%		1.432	0.770	0.528	-	-	-	-	-		

75%		0.739	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 1 st ditch	2.655	1.407	0.961	0.731	-	-	-	-
50%		1.327	0.704	0.532	-	-	-	-	-
75%		0.663	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 2 nd ditch	2.720	1.442	1.060	1.060	-	-	-	-
50%		1.359	1.060	1.060	1.060	-	-	-	-
75%		1.060	1.060	-	-	-	-	-	-
90%		1.060	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.460	1.325	0.910	-
50%		-	-	-	-	1.280	0.713	-	-
75%		-	-	-	-	1.024	-	-	-
90%		-	-	-	-	1.024	-	-	-
None	R2 stream	-	-	-	-	3.222	1.727	1.184	0.901
50%		-	-	-	-	1.651	0.894	0.615	-
75%		-	-	-	-	0.866	-	-	-
90%		-	-	-	-	-	-	-	-
None	R3 stream	-	-	-	-	3.402	1.824	1.253	0.953
50%		-	-	-	-	1.754	0.964	0.668	0.509
75%		-	-	-	-	0.957	0.643	-	-
90%		-	-	-	-	0.929	-	-	-
None	R4 stream	-	-	-	-	2.459	1.331	0.915	-
50%		-	-	-	-	1.625	1.132	-	-

75%		-	-	-		1.625	1.132	-	-
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.93 (P. subcapitata)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.55	-	-	-	-	-
75%		0.80	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.03	1.62	1.11	0.84	-	-	-	-
50%		1.54	0.83	0.57	-	-	-	-	-
75%		0.79	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 1 st ditch	2.85	1.51	1.03	0.79	-	-	-	-
50%		1.43	0.76	0.57	-	-	-	-	-
75%		0.71	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 2 nd ditch	2.92	1.55	1.14	1.14	-	-	-	-
50%		1.46	1.14	1.14	1.14	-	-	-	-
75%		1.14	1.14	-	-	-	-	-	-
90%		1.14	-	-	-	-	-	-	-
None	R1 stream	-	-	-		2.65	1.42	0.98	-
50%		-	-	-		1.38	0.77	-	-
75%		-	-	-		1.10	-	-	-
90%		-	-	-		1.10	-	-	-

None	R2 stream	-	-	-		3.46	1.86	1.27	0.97
50%		-	-	-		1.78	0.96	0.66	-
75%		-	-	-		0.93	-	-	-
90%		-	-	-		-	-	-	-
None	R3 stream	-	-	-		3.66	1.96	1.35	1.02
50%		-	-	-		1.89	1.04	0.72	0.55
75%		-	-	-		1.03	0.69	-	-
90%		-	-	-		1.00	-	-	-
None	R4 stream	-	-	-		2.64	1.43	0.98	-
50%		-	-	-		1.75	1.22	-	-
75%		-	-	-		1.75	1.22	-	-
90%		-	-	-		-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-46: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables in pre emergence

Intended use		Bulb vegetables in pre emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.694	1.428	0.975	0.742	!	!	!	!
50%		1.346	0.743	0.516	0.399	!	!	!	!
75%		0.745	0.453	0.324	0.245	!	!	!	!

90%		0.453	0.304	0.223	0.170	-	-	-	-
None	D4 pond	0.342	0.248	0.196	-	-	-	-	-
50%		0.203	0.149	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.819	1.505	1.030	0.784	-	-	-	-
50%		1.432	0.770	0.528	0.408	-	-	-	-
75%		0.739	0.408	0.308	0.308	-	-	-	-
90%		0.328	0.308	0.308	0.308	-	-	-	-
None	D6 ditch 1 st	2.655	1.407	0.961	0.731	-	-	-	-
50%		1.327	0.704	0.540	0.540	-	-	-	-
75%		0.663	0.540	0.540	0.540	-	-	-	-
90%		0.540	0.540	-	-	-	-	-	-
None	D6 ditch 2 nd	2.720	1.442	1.060	1.060	-	-	-	-
50%		1.359	1.060	1.060	1.060	-	-	-	-
75%		1.060	1.060	-	-	-	-	-	-
90%		1.060	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.344	0.250	0.197	-
50%		-	-	-	-	0.208	0.152	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.460	1.325	0.910	0.702
50%		-	-	-	-	1.280	0.713	0.554	0.378
75%		-	-	-	-	1.024	0.713	0.554	0.378

90%		-	-	-		1.024	0.713	-	-
None	R2 stream	-	-	-		3.222	1.727	1.184	0.901
50%		-	-	-		1.651	0.894	0.615	0.475
75%		-	-	-		0.866	0.485	0.336	0.256
90%		-	-	-		0.400	0.232	0.163	0.124
None	R3 stream	-	-	-		3.402	1.824	1.253	0.953
50%		-	-	-		1.754	0.964	0.668	0.509
75%		-	-	-		0.957	0.643	0.449	0.339
90%		-	-	-		0.929	0.643	0.449	0.339
None	R4 stream	-	-	-		2.459	1.331	0.915	0.707
50%		-	-	-		1.625	1.132	0.915	0.601
75%		-	-	-		1.625	1.132	0.915	0.601
90%		-	-	-		1.625	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.55	0.43	-	-	-	-
75%		0.80	0.49	0.35	0.26	-	-	-	-
90%		0.49	0.33	0.24	0.18	-	-	-	-
None	D4 pond	0.37	0.27	0.21	-	-	-	-	-
50%		0.22	0.16	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.03	1.62	1.11	0.84	-	-	-	-

50%		1.54	0.83	0.57	0.44	-	-	-	-
75%		0.79	0.44	0.33	0.33	-	-	-	-
90%		0.35	0.33	0.33	0.33	-	-	-	-
None	D6 ditch 1 st	2.85	1.51	1.03	0.79	-	-	-	-
50%		1.43	0.76	0.58	0.58	-	-	-	-
75%		0.71	0.58	0.58	0.58	-	-	-	-
90%		0.58	0.58	-	-	-	-	-	-
None	D6 ditch 2 nd	2.92	1.55	1.14	1.14	-	-	-	-
50%		1.46	1.14	1.14	1.14	-	-	-	-
75%		1.14	1.14	-	-	-	-	-	-
90%		1.14	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.37	0.27	0.21	-
50%		-	-	-	-	0.22	0.16	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.65	1.42	0.98	0.75
50%		-	-	-	-	1.38	0.77	0.60	0.41
75%		-	-	-	-	1.10	0.77	0.60	0.41
90%		-	-	-	-	1.10	0.77	-	-
None	R2 stream	-	-	-	-	3.46	1.86	1.27	0.97
50%		-	-	-	-	1.78	0.96	0.66	0.51
75%		-	-	-	-	0.93	0.52	0.36	0.28
90%		-	-	-	-	0.43	0.25	0.18	0.13
None	R3 stream	-	-	-	-	3.66	1.96	1.35	1.02

50%		-	-	-	-	1.89	1.04	0.72	0.55
75%		-	-	-	-	1.03	0.69	0.48	0.36
90%		-	-	-	-	1.00	0.69	0.48	0.36
None	R4 stream	-	-	-	-	2.64	1.43	0.98	0.76
50%		-	-	-	-	1.75	1.22	0.98	0.65
75%		-	-	-	-	1.75	1.22	0.98	0.65
90%		-	-	-	-	1.75	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in bulb vegetables are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 1st ditch : 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

For scenario D6 2nd ditch the PEC is above RAC even with risk mitigation measures. However, scenario D6 is not relevant in CEU countries.

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or ~~5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction~~

R4 stream: 15m no spray buffer zone + 15 vegetative strip

R2 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R3 stream: ~~20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction~~ 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-47: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables in pre emergence

Intended use		Bulb vegetables in pre emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.694	1.428	0.975	0.742	-	-	-	-
50%		1.346	0.743	0.516	0.399	-	-	-	-
75%		0.745	0.453	0.324	0.245	-	-	-	-
90%		0.453	0.304	0.223	0.170	-	-	-	-
None	D4 pond	0.342	0.248	0.196	-	-	-	-	-
50%		0.203	0.149	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.819	1.505	1.030	0.784	-	-	-	-
50%		1.432	0.770	0.528	0.408	-	-	-	-
75%		0.739	0.408	0.308	0.308	-	-	-	-
90%		0.328	0.308	0.308	0.308	-	-	-	-
None	D6 ditch 1 st	2.655	1.407	0.961	0.731	-	-	-	-
50%		1.327	0.704	0.540	0.540	-	-	-	-
75%		0.663	0.540	0.540	0.540	-	-	-	-
90%		0.540	0.540	-	-	-	-	-	-

None	D6 ditch 2 nd	2.720	1.442	1.060	1.060	-	-	-	-
50%		1.359	1.060	1.060	1.060	-	-	-	-
75%		1.060	1.060	-	-	-	-	-	-
90%		1.060	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.344	0.250	0.197	-
50%		-	-	-	-	0.208	0.152	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.460	1.325	0.910	0.702
50%		-	-	-	-	1.280	0.713	0.554	0.378
75%		-	-	-	-	1.024	0.713	0.554	0.378
90%		-	-	-	-	1.024	0.713	-	-
None	R2 stream	-	-	-	-	3.222	1.727	1.184	0.901
50%		-	-	-	-	1.651	0.894	0.615	0.475
75%		-	-	-	-	0.866	0.485	0.336	0.256
90%		-	-	-	-	0.400	0.232	0.163	0.124
None	R3 stream	-	-	-	-	3.402	1.824	1.253	0.953
50%		-	-	-	-	1.754	0.964	0.668	0.509
75%		-	-	-	-	0.957	0.643	0.449	0.339
90%		-	-	-	-	0.929	0.643	0.449	0.339
None	R4 stream	-	-	-	-	2.459	1.331	0.915	0.707
50%		-	-	-	-	1.625	1.132	0.915	0.601
75%		-	-	-	-	1.625	1.132	0.915	0.601
90%		-	-	-	-	1.625	-	-	-

RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	11.713	6.209	4.239	3.226	-	-	-	-
50%		5.852	3.230	2.243	1.735	-	-	-	-
75%		3.239	1.970	1.409	1.065	-	-	-	-
90%		1.970	1.322	0.970	0.739	-	-	-	-
None	D4 pond	1.487	1.078	0.852	-	-	-	-	-
50%		0.883	0.648	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	12.257	6.543	4.478	3.409	-	-	-	-
50%		6.226	3.348	2.296	1.774	-	-	-	-
75%		3.213	1.774	1.339	1.339	-	-	-	-
90%		1.426	1.339	1.339	1.339	-	-	-	-
None	D6 ditch 1 st	11.543	6.117	4.178	3.178	-	-	-	-
50%		5.770	3.061	2.348	2.348	-	-	-	-
75%		2.883	2.348	2.348	2.348	-	-	-	-
90%		2.348	2.348	-	-	-	-	-	-
None	D6 ditch 2 nd	11.826	6.270	4.609	4.609	-	-	-	-
50%		5.909	4.609	4.609	4.609	-	-	-	-
75%		4.609	4.609	-	-	-	-	-	-
90%		4.609	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	1.496	1.087	0.857	-
50%		-	-	-	-	0.904	0.661	-	-

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	10.696	5.761	3.957	3.052
50%		-	-	-	-	5.565	3.100	2.409	1.643
75%		-	-	-	-	4.452	3.100	2.409	1.643
90%		-	-	-	-	4.452	3.100	-	-
None	R2 stream	-	-	-	-	14.009	7.509	5.148	3.917
50%		-	-	-	-	7.178	3.887	2.674	2.065
75%		-	-	-	-	3.765	2.109	1.461	1.113
90%		-	-	-	-	1.739	1.009	0.709	0.539
None	R3 stream	-	-	-	-	14.791	7.930	5.448	4.143
50%		-	-	-	-	7.626	4.191	2.904	2.213
75%		-	-	-	-	4.161	2.796	1.952	1.474
90%		-	-	-	-	4.039	2.796	1.952	1.474
None	R4 stream	-	-	-	-	10.691	5.787	3.978	3.074
50%		-	-	-	-	7.065	4.922	3.978	2.613
75%		-	-	-	-	7.065	4.922	3.978	2.613
90%		-	-	-	-	7.065	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-48: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables (pre-emergence, 1 x 1590 g/ha)

Intended use	Bulb vegetables (pre-emergence)
Active substance	pendimethalin
Application rate (g/ha)	1 x 1590

Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.591
90%		0.591	-
75%	R2 stream	-	0.241
90%		0.228	-
75%	R3 stream	-	0.270
90%		0.314	-
75%	R4 stream	-	0.197
90%		0.218	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	2.57
90%		2.57	-
75%	R2 stream	-	1.05
90%		0.99	-
75%	R3 stream	-	1.17
90%		1.37	-
75%	R4 stream	-	0.86
90%		0.95	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in bulb vegetables (pre-emergence 1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream: 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with mitigation measures. Scenario D6 is not relevant for CEU countries.

For scenario R1 stream and R3 stream the PEC/RAC ratios are below the trigger with mitigation measures and restriction sentences have to be consider (do not apply on silty soils with a slope greater than 3% and do not apply on terraced clay soils with a slope greater than 10% respectively).

Table 9.5-49: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in bulb vegetables in post emergence (1 x 1590 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dweller prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	9.959	5.08	15.81	3.11	6.77	6.87	10.71	1.21	8.30	0.449	0.00002
D4 pond	0.343	0.18	0.54	0.11	0.23	0.24	0.37	0.04	0.29	0.174	0.00001
D4 stream	7.641	3.90	12.13	2.39	5.20	5.27	8.22	0.93	6.37	0.018	0.00000

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
D6 1 st ditch	9.958	5.08	15.81	3.11	6.77	6.87	10.71	1.21	8.30	0.473	0.00002
D6 2 nd ditch	10.04	5.12	15.94	3.14	6.83	6.92	10.80	1.22	8.37	1.161	0.00005
R1 pond	0.365	0.19	0.58	0.11	0.25	0.25	0.39	0.04	0.30	0.192	0.00001
R1 stream	6.557	3.35	10.41	2.05	4.46	4.52	7.05	0.80	5.46	0.122	0.00001
R2 stream	8.670	4.42	13.76	2.71	5.90	5.98	9.32	1.06	7.23	0.070	0.00000
R3 stream	9.212	4.70	14.62	2.88	6.27	6.35	9.91	1.12	7.68	0.205	0.00001
R4 stream	6.466	3.30	10.26	2.02	4.40	4.46	6.95	0.79	5.39	0.349	0.00002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses bulb vegetables (post-emergence, 1 x 1590 g/ha), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-50: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables in post emergence

Intended use		Bulb vegetables in post emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1590							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.698	1.430	0.977	0.743	-	-	-	-
50%		1.349	0.752	0.522	0.398	-	-	-	-
75%		0.756	0.462	0.330	0.251	-	-	-	-

90%		0.462	0.309	0.226	0.172	-	-	-	-
None	D4 pond	0.338	0.245	0.194	-	-	-	-	-
50%		0.201	0.147	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.838	1.516	1.038	0.790	-	-	-	-
50%		1.443	0.776	0.533	0.405	-	-	-	-
75%		0.745	0.406	0.315	0.315	-	-	-	-
90%		0.327	0.315	0.315	-	-	-	-	-
None	D6 ditch 1 st	2.698	1.430	0.977	0.743	-	-	-	-
50%		1.348	0.748	0.520	0.487	-	-	-	-
75%		0.750	0.487	0.487	0.487	-	-	-	-
90%		0.487	0.487	0.487	-	-	-	-	-
None	D6 ditch 2 nd	2.720	1.456	1.051	1.051	-	-	-	-
50%		1.418	1.051	1.051	-	-	-	-	-
75%		1.051	1.051	-	-	-	-	-	-
90%		1.051	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.354	0.257	0.202	-
50%		-	-	-	-	0.216	0.157	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.468	1.331	0.916	0.697
50%		-	-	-	-	1.289	0.713	0.547	0.375
75%		-	-	-	-	1.025	0.713	0.547	0.373

90%		-	-	-	-	1.025	-	-	-
None	R2 stream	-	-	-	-	3.254	1.746	1.197	0.911
50%		-	-	-	-	1.671	0.906	0.624	0.475
75%		-	-	-	-	0.879	0.487	0.337	0.257
90%		-	-	-	-	0.405	0.235	0.169	0.126
None	R3 stream	-	-	-	-	3.418	1.841	1.264	0.962
50%		-	-	-	-	1.770	0.976	0.676	0.515
75%		-	-	-	-	1.001	0.696	0.534	0.364
90%		-	-	-	-	1.001	0.696	0.534	0.364
None	R4 stream	-	-	-	-	2.440	1.317	0.904	0.688
50%		-	-	-	-	1.642	1.144	0.877	0.598
75%		-	-	-	-	1.642	1.144	0.877	0.598
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.81	0.56	0.43	-	-	-	-
75%		0.81	0.50	0.35	0.27	-	-	-	-
90%		0.50	0.33	0.24	0.18	-	-	-	-
None	D4 pond	0.36	0.26	0.21	-	-	-	-	-
50%		0.22	0.16	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.05	1.63	1.12	0.85	-	-	-	-

50%		1.55	0.83	0.57	0.44	-	-	-	-
75%		0.80	0.44	0.34	0.34	-	-	-	-
90%		0.35	0.34	0.34	-	-	-	-	-
None	D6 ditch 1 st	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.56	0.52	-	-	-	-
75%		0.81	0.52	0.52	0.52	-	-	-	-
90%		0.52	0.52	0.52	-	-	-	-	-
None	D6 ditch 2 nd	2.92	1.57	1.13	1.13	-	-	-	-
50%		1.52	1.13	1.13	-	-	-	-	-
75%		1.13	1.13	-	-	-	-	-	-
90%		1.13	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.38	0.28	0.22	-
50%		-	-	-	-	0.23	0.17	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.65	1.43	0.98	0.75
50%		-	-	-	-	1.39	0.77	0.59	0.40
75%		-	-	-	-	1.10	0.77	0.59	0.40
90%		-	-	-	-	1.10	-	-	-
None	R2 stream	-	-	-	-	3.50	1.88	1.29	0.98
50%		-	-	-	-	1.80	0.97	0.67	0.51
75%		-	-	-	-	0.95	0.52	0.36	0.28
90%		-	-	-	-	0.44	0.25	0.18	0.14
None	R3 stream	-	-	-	-	3.68	1.98	1.36	1.03

50%		↓	↓	↓	↓	1.90	1.05	0.73	0.55
75%		↓	↓	↓	↓	1.08	0.75	0.57	0.39
90%		↓	↓	↓	↓	1.08	0.75	0.57	0.39
None	R4 stream	↓	↓	↓	↓	2.62	1.42	0.97	0.74
50%		↓	↓	↓	↓	1.77	1.23	0.94	0.64
75%		↓	↓	↓	↓	1.77	1.23	0.94	0.64
90%		↓	↓	↓	↓	↓	↓	↓	↓

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in bulb vegetables (post-emergence 1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 1st ditch : 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

For scenario D6 2nd ditch the PEC is above RAC even with risk mitigation measures. However, scenario D6 is not relevant in CEU countries.

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R4 stream: 15m no spray buffer zone + 15 vegetative strip

R2 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-51: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables in post emergence

Intended use	Bulb vegetables in post emergence
Active substance	Pendimethalin
Application rate (g/ha)	1 × 1590

Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.698	1.430	0.977	0.743	-	-	-	-
50%		1.349	0.752	0.522	0.398	-	-	-	-
75%		0.756	0.462	0.330	0.251	-	-	-	-
90%		0.462	0.309	0.226	0.172	-	-	-	-
None	D4 pond	0.338	0.245	0.194	-	-	-	-	-
50%		0.201	0.147	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.838	1.516	1.038	0.790	-	-	-	-
50%		1.443	0.776	0.533	0.405	-	-	-	-
75%		0.745	0.406	0.315	0.315	-	-	-	-
90%		0.327	0.315	0.315	-	-	-	-	-
None	D6 ditch 1 st	2.698	1.430	0.977	0.743	-	-	-	-
50%		1.348	0.748	0.520	0.487	-	-	-	-
75%		0.750	0.487	0.487	0.487	-	-	-	-
90%		0.487	0.487	0.487	-	-	-	-	-
None	D6 ditch 2 nd	2.720	1.456	1.051	1.051	-	-	-	-
50%		1.418	1.051	1.051	-	-	-	-	-
75%		1.051	1.051	-	-	-	-	-	-
90%		1.051	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.354	0.257	0.202	-
50%		-	-	-	-	0.216	0.157	-	-

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.468	1.331	0.916	0.697
50%		-	-	-	-	1.289	0.713	0.547	0.375
75%		-	-	-	-	1.025	0.713	0.547	0.373
90%		-	-	-	-	1.025	-	-	-
None	R2 stream	-	-	-	-	3.254	1.746	1.197	0.911
50%		-	-	-	-	1.671	0.906	0.624	0.475
75%		-	-	-	-	0.879	0.487	0.337	0.257
90%		-	-	-	-	0.405	0.235	0.169	0.126
None	R3 stream	-	-	-	-	3.418	1.841	1.264	0.962
50%		-	-	-	-	1.770	0.976	0.676	0.515
75%		-	-	-	-	1.001	0.696	0.534	0.364
90%		-	-	-	-	1.001	0.696	0.534	0.364
None	R4 stream	-	-	-	-	2.440	1.317	0.904	0.688
50%		-	-	-	-	1.642	1.144	0.877	0.598
75%		-	-	-	-	1.642	1.144	0.877	0.598
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	11.730	6.217	4.248	3.230	-	-	-	-
50%		5.865	3.270	2.270	1.730	-	-	-	-
75%		3.287	2.009	1.435	1.091	-	-	-	-
90%		2.009	1.343	0.983	0.748	-	-	-	-

None	D4 pond	1.470	1.065	0.843	-	-	-	-	-
50%		0.874	0.639	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	12.339	6.591	4.513	3.435	-	-	-	-
50%		6.274	3.374	2.317	1.761	-	-	-	-
75%		3.239	1.765	1.370	1.370	-	-	-	-
90%		1.422	1.370	1.370	-	-	-	-	-
None	D6 ditch 1 st	11.730	6.217	4.248	3.230	-	-	-	-
50%		5.861	3.252	2.261	2.117	-	-	-	-
75%		3.261	2.117	2.117	2.117	-	-	-	-
90%		2.117	2.117	2.117	-	-	-	-	-
None	D6 ditch 2 nd	11.826	6.330	4.570	4.570	-	-	-	-
50%		6.165	4.570	4.570	-	-	-	-	-
75%		4.570	4.570	-	-	-	-	-	-
90%		4.570	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	1.539	1.117	0.878	-
50%		-	-	-	-	0.939	0.683	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	10.730	5.787	3.983	3.030
50%		-	-	-	-	5.604	3.100	2.378	1.630
75%		-	-	-	-	4.457	3.100	2.378	1.622
90%		-	-	-	-	4.457	-	-	-

None	R2 stream	-	-	-	-	14.148	7.591	5.204	3.961
50%		-	-	-	-	7.265	3.939	2.713	2.065
75%		-	-	-	-	3.822	2.117	1.465	1.117
90%		-	-	-	-	1.761	1.022	0.735	0.548
None	R3 stream	-	-	-	-	14.861	8.004	5.496	4.183
50%		-	-	-	-	7.696	4.243	2.939	2.239
75%		-	-	-	-	4.352	3.026	2.322	1.583
90%		-	-	-	-	4.352	3.026	2.322	1.583
None	R4 stream	-	-	-	-	10.609	5.726	3.930	2.991
50%		-	-	-	-	7.139	4.974	3.813	2.600
75%		-	-	-	-	7.139	4.974	3.813	2.600
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-52: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables (post-emergence, 1 x 1590 g/ha)

Intended use		Bulb vegetables (post-emergence)	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.593
90%		0.593	-

75%	R2 stream	-	0.257
90%		0.235	0.126
75%	R3 stream	-	0.296
90%		0.309	0.170
75%	R4 stream	-	0.204
90%		0.243	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	2.58
90%		2.58	-
75%	R2 stream	-	1.12
90%		1.02	0.55
75%	R3 stream	-	1.29
90%		1.34	0.74
75%	R4 stream	-	0.89
90%		1.06	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in bulb vegetables (post-emergence 1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

R2 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with mitigation measures. Scenario D6 is not relevant in CEU countries.

For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures and restriction sentences will have to be considered (do not apply on

silty soils with a slope greater than 3%).

Table 9.5-53: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in bulb vegetables in pre emergence (1 x 1137 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dweller prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	7.109	3.63	11.28	2.22	4.84	4.90	7.64	0.87	5.92	4.379	0.00019
D4 pond	0.245	0.13	0.39	0.08	0.17	0.17	0.26	0.03	0.20	1.462	0.00006
D4 stream	5.430	2.77	8.62	1.70	3.69	3.74	5.84	0.66	4.53	0.197	0.00001
D6 1 st ditch	7.007	3.58	11.12	2.19	4.77	4.83	7.53	0.85	5.84	1.775	0.00008
D6 2 nd ditch	7.179	3.66	11.40	2.24	4.88	4.95	7.72	0.88	5.98	10.18	0.00045
R1 pond	0.261	0.13	0.41	0.08	0.18	0.18	0.28	0.03	0.22	2.737	0.00012
R1 stream	4.688	2.39	7.44	1.47	3.19	3.23	5.04	0.57	3.91	6.521	0.00029

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.016	1.076	0.737	0.560	-	-	-	-
50%		1.024	0.550	0.378	0.287	-	-	-	-
75%		0.528	0.288	0.211	0.211	-	-	-	-
90%		0.231	0.211	-	-	-	-	-	-
None	D6 ditch 1 st	1.898	1.006	0.687	0.523	-	-	-	-
50%		0.949	0.503	0.367	0.367	-	-	-	-
75%		0.474	0.367	0.367	-	-	-	-	-
90%		0.367	0.367	-	-	-	-	-	-
None	D6 ditch 2 nd	1.945	1.041	0.733	0.733	-	-	-	-
50%		1.015	0.733	0.733	-	-	-	-	-
75%		0.733	0.733	-	-	-	-	-	-
90%		0.733	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.253	0.183	-	-
50%		-	-	-	-	0.155	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.765	0.952	0.655	0.498
50%		-	-	-	-	0.922	0.515	0.395	0.269
75%		-	-	-	-	0.741	0.515	0.395	0.269
90%		-	-	-	-	0.741	-	-	-
None	R2 stream	-	-	-	-	2.304	1.235	0.847	0.644
50%		-	-	-	-	1.181	0.640	0.440	0.335

75%		-	-	-	-	0.620	0.342	0.237	0.180
90%		-	-	-	-	0.283	0.164	0.115	-
None	R3 stream	-	-	-	-	2.446	1.317	0.904	0.688
50%		-	-	-	-	1.267	0.698	0.484	0.368
75%		-	-	-	-	0.694	0.457	0.394	0.238
90%		-	-	-	-	0.659	0.457	0.394	0.238
None	R4 stream	-	-	-	-	1.722	0.959	0.659	0.501
50%		-	-	-	-	1.147	0.799	0.613	0.418
75%		-	-	-	-	1.147	0.799	0.613	0.418
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.07	1.10	0.75	0.57	-	-	-	-
50%		1.05	0.58	0.36	0.31	-	-	-	-
75%		0.59	0.36	0.26	0.19	-	-	-	-
90%		0.36	0.24	0.18	-	-	-	-	-
None	D4 pond	0.26	0.19	-	-	-	-	-	-
50%		0.16	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.17	1.16	0.79	0.60	-	-	-	-
50%		1.10	0.59	0.41	0.31	-	-	-	-
75%		0.57	0.31	0.23	0.23	-	-	-	-
90%		0.25	0.23	-	-	-	-	-	-

None	D6 ditch 1 st	2.04	1.08	0.74	0.56	-	-	-	-
50%		1.02	0.54	0.39	0.39	-	-	-	-
75%		0.51	0.39	0.39	-	-	-	-	-
90%		0.39	0.39	-	-	-	-	-	-
None	D6 ditch 2 nd	2.09	1.12	0.79	0.79	-	-	-	-
50%		1.09	0.79	0.79	-	-	-	-	-
75%		0.79	0.79	-	-	-	-	-	-
90%		0.79	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.27	0.20	-	-
50%		-	-	-	-	0.17	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.90	1.02	0.70	0.54
50%		-	-	-	-	0.99	0.55	0.42	0.29
75%		-	-	-	-	0.80	0.55	0.42	0.29
90%		-	-	-	-	0.80	-	-	-
None	R2 stream	-	-	-	-	2.48	1.33	0.91	0.69
50%		-	-	-	-	1.27	0.69	0.47	0.36
75%		-	-	-	-	0.67	0.37	0.25	0.19
90%		-	-	-	-	0.30	0.18	0.12	-
None	R3 stream	-	-	-	-	2.63	1.42	0.97	0.74
50%		-	-	-	-	1.36	0.75	0.52	0.40
75%		-	-	-	-	0.75	0.49	0.42	0.26
90%		-	-	-	-	0.71	0.49	0.42	0.26

None	R4 stream	-	-	-	-	1.85	1.03	0.71	0.54
50%		-	-	-	-	1.23	0.86	0.66	0.45
75%		-	-	-	-	1.23	0.86	0.66	0.45
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in bulb vegetables (pre-emergence 1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 1st ditch, D6 2nd ditch : 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-55: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables in pre emergence

Intended use		Bulb vegetables in pre emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 × 1137							
Nozzle re-duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	1.926	1.021	0.697	0.530	-	-	-	-
50%		0.972	0.542	0.337	0.286	-	-	-	-

75%		0.549	0.333	0.240	0.181	-	-	-	-
90%		0.334	0.223	0.164	-	-	-	-	-
None	D4 pond	0.246	0.179	-	-	-	-	-	-
50%		0.147	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.016	1.076	0.737	0.560	-	-	-	-
50%		1.024	0.550	0.378	0.287	-	-	-	-
75%		0.528	0.288	0.211	0.211	-	-	-	-
90%		0.231	0.211	-	-	-	-	-	-
None	D6 ditch 1 st	1.898	1.006	0.687	0.523	-	-	-	-
50%		0.949	0.503	0.367	0.367	-	-	-	-
75%		0.474	0.367	0.367	-	-	-	-	-
90%		0.367	0.367	-	-	-	-	-	-
None	D6 ditch 2 nd	1.945	1.041	0.733	0.733	-	-	-	-
50%		1.015	0.733	0.733	-	-	-	-	-
75%		0.733	0.733	-	-	-	-	-	-
90%		0.733	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.253	0.183	-	-
50%		-	-	-	-	0.155	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.765	0.952	0.655	0.498
50%		-	-	-	-	0.922	0.515	0.395	0.269

None	D4 stream	8.765	4.678	3.204	2.435	-	-	-	-
50%		4.452	2.391	1.643	1.248	-	-	-	-
75%		2.296	1.252	0.917	0.917	-	-	-	-
90%		1.004	0.917	-	-	-	-	-	-
None	D6 ditch 1 st	8.252	4.374	2.987	2.274	-	-	-	-
50%		4.126	2.187	1.596	1.596	-	-	-	-
75%		2.061	1.596	1.596	-	-	-	-	-
90%		1.596	1.596	-	-	-	-	-	-
None	D6 ditch 2 nd	8.457	4.526	3.187	3.187	-	-	-	-
50%		4.413	3.187	3.187	-	-	-	-	-
75%		3.187	3.187	-	-	-	-	-	-
90%		3.187	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	1.100	0.796	-	-
50%		-	-	-	-	0.674	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	7.674	4.139	2.848	2.165
50%		-	-	-	-	4.009	2.239	1.717	1.170
75%		-	-	-	-	3.222	2.239	1.717	1.170
90%		-	-	-	-	3.222	-	-	-
None	R2 stream	-	-	-	-	10.017	5.370	3.683	2.800
50%		-	-	-	-	5.135	2.783	1.913	1.457
75%		-	-	-	-	2.696	1.487	1.030	0.783
90%		-	-	-	-	1.230	0.713	0.500	-

None	R3 stream	-	-	-	-	10.635	5.726	3.930	2.991
50%		-	-	-	-	5.509	3.035	2.104	1.600
75%		-	-	-	-	3.017	1.987	1.713	1.035
90%		-	-	-	-	2.865	1.987	1.713	1.035
None	R4 stream	-	-	-	-	7.487	4.170	2.865	2.178
50%		-	-	-	-	4.987	3.474	2.665	1.817
75%		-	-	-	-	4.987	3.474	2.665	1.817
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-56: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables (pre-emergence, 1 x 1137 g/ha)

Intended use		Bulb vegetables (pre-emergence)	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	-
90%		0.429	-
75%	R2 stream	-	0.180
90%		0.164	-
75%	R3 stream	-	0.211
90%		0.228	-

75%	R4 stream	-	0.153
90%		0.158	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	-
90%		1.87	-
75%	R2 stream	-	0.78
90%		0.71	-
75%	R3 stream	-	0.92
90%		0.99	-
75%	R4 stream	-	0.53
90%		0.69	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in bulb vegetables (pre-emergence 1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with risk mitigation measures. However, scenario D6 is not relevant for CEU countries.

For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures and a restriction will be considered (do not apply on silty soils with a slope greater than 3%).

Table 9.5-57: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in bulb vegetables in post emergence (1 x 1137 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell. er prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 196	NOEC 6.3	NOEC geomean 32	EC ₅₀ 147	NOEC 14.5	E _r C ₅₀ 9.3	NOEC 82	ErC ₅₀ 12		NOEC 227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	7.121	3.63	11.30	2.23	4.84	4.91	7.66	0.87	5.93	4.653	0.00020
D4 pond	0.245	0.13	0.39	0.08	0.17	0.17	0.26	0.03	0.20	1.233	0.00005
D4 stream	5.463	2.79	8.67	1.71	3.72	3.77	5.87	0.67	4.55	0.206	0.00001
D6 1 st ditch	7.120	3.63	11.30	2.23	4.84	4.91	7.66	0.87	5.93	4.776	0.00021
D6 2 nd ditch	7.179	3.66	11.40	2.24	4.88	4.95	7.72	0.88	5.98	10.18	0.00045
R1 pond	0.261	0.13	0.41	0.08	0.18	0.18	0.28	0.03	0.22	2.680	0.00012
R1 stream	4.688	2.39	7.44	1.47	3.19	3.23	5.04	0.57	3.91	6.414	0.00028
R2 stream	6.199	3.16	9.84	1.94	4.22	4.28	6.67	0.76	5.17	20.18	0.00089
R3 stream	6.587	3.36	10.46	2.06	4.48	4.54	7.08	0.80	5.49	3.625	0.00016

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
R4 stream	4.623	2.36	7.34	1.44	3.14	3.19	4.97	0.56	3.85	7.289	0.00032

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses bulb vegetables (post-emergence, 1 x 1137 g/ha), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-58: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables in post emergence

Intended use		Bulb vegetables in post emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	1.929	1.023	0.698	0.531	-	-	-	-
50%		0.965	0.537	0.373	0.283	-	-	-	-
75%		0.541	0.330	0.237	0.179	-	-	-	-
90%		0.331	0.221	0.163	-	-	-	-	-
None	D4 pond	0.242	0.175	-	-	-	-	-	-
50%		0.144	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.029	1.084	0.742	0.564	-	-	-	-

50%		1.032	0.555	0.381	0.289	-	-	-	-
75%		0.533	0.290	0.218	0.218	-	-	-	-
90%		0.234	0.218	-	-	-	-	-	-
None	D6 ditch 1 st	1.929	1.022	0.698	0.531	-	-	-	-
50%		0.964	0.534	0.372	0.335	-	-	-	-
75%		0.537	0.335	0.335	0.335	-	-	-	-
90%		0.335	0.335	0.335	-	-	-	-	-
None	D6 ditch 2 nd	1.945	1.041	0.724	0.724	-	-	-	-
50%		1.015	0.724	0.724	0.724	-	-	-	-
75%		0.724	0.724	-	-	-	-	-	-
90%		0.724	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.253	0.183	-	-
50%		-	-	-	-	0.155	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.765	0.951	0.655	0.498
50%		-	-	-	-	0.922	0.509	0.386	0.268
75%		-	-	-	-	0.724	0.504	0.386	0.263
90%		-	-	-	-	0.724	0.504	-	-
None	R2 stream	-	-	-	-	2.327	1.248	0.856	0.651
50%		-	-	-	-	1.195	0.648	0.446	0.339
75%		-	-	-	-	0.629	0.348	0.241	0.183
90%		-	-	-	-	0.290	0.168	0.119	-
None	R3 stream	-	-	-	-	2.444	1.316	0.904	0.687

50%		-	-	-	-	1.266	0.697	0.483	0.367
75%		-	-	-	-	0.705	0.490	0.375	0.256
90%		-	-	-	-	0.705	0.490	0.375	0.256
None	R4 stream	-	-	-	-	1.745	0.941	0.647	0.491
50%		-	-	-	-	1.157	0.806	0.618	0.421
75%		-	-	-	-	1.157	0.806	0.618	0.421
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.07	1.10	0.75	0.57	-	-	-	-
50%		1.04	0.58	0.40	0.30	-	-	-	-
75%		0.58	0.35	0.25	0.19	-	-	-	-
90%		0.36	0.24	0.18	-	-	-	-	-
None	D4 pond	0.26	0.19	-	-	-	-	-	-
50%		0.15	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.18	1.17	0.80	0.61	-	-	-	-
50%		1.11	0.60	0.41	0.31	-	-	-	-
75%		0.57	0.31	0.23	0.23	-	-	-	-
90%		0.25	0.23	-	-	-	-	-	-
None	D6 ditch 1 st	2.07	1.10	0.75	0.57	-	-	-	-
50%		1.04	0.57	0.40	0.36	-	-	-	-
75%		0.58	0.36	0.36	0.36	-	-	-	-

90%		0.36	0.36	0.36	-	-	-	-	-
None	D6 ditch 2 nd	2.09	1.12	0.78	0.78	-	-	-	-
50%		1.09	0.78	0.78	0.78	-	-	-	-
75%		0.78	0.78	-	-	-	-	-	-
90%		0.78	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.27	0.20	-	-
50%		-	-	-	-	0.17	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.90	1.02	0.70	0.54
50%		-	-	-	-	0.99	0.55	0.42	0.29
75%		-	-	-	-	0.78	0.54	0.42	0.28
90%		-	-	-	-	0.78	0.54	-	-
None	R2 stream	-	-	-	-	2.50	1.34	0.92	0.70
50%		-	-	-	-	1.28	0.70	0.48	0.36
75%		-	-	-	-	0.68	0.37	0.26	0.20
90%		-	-	-	-	0.31	0.18	0.13	
None	R3 stream	-	-	-	-	2.63	1.42	0.97	0.74
50%		-	-	-	-	1.36	0.75	0.52	0.39
75%		-	-	-	-	0.76	0.53	0.40	0.28
90%		-	-	-	-	0.76	0.53	0.40	0.28
None	R4 stream	-	-	-	-	1.88	1.01	0.70	0.53
50%		-	-	-	-	1.24	0.87	0.66	0.45
75%		-	-	-	-	1.24	0.87	0.66	0.45

90%		-	-	-	-	-	-	-	-
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PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in bulb vegetables (post-emergence 1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 1st ditch, D6 2nd ditch: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R4 stream: 15m no spray buffer zone + 15 vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario and R2 stream scenario.

Table 9.5-59: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables in post emergence

Intended use		Bulb vegetables in post emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	1.929	1.023	0.698	0.531	-	-	-	-
50%		0.965	0.537	0.373	0.283	-	-	-	-
75%		0.541	0.330	0.237	0.179	-	-	-	-
90%		0.331	0.221	0.163	-	-	-	-	-

None	D4 pond	0.242	0.175	-	-	-	-	-	-
50%		0.144	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.029	1.084	0.742	0.564	-	-	-	-
50%		1.032	0.555	0.381	0.289	-	-	-	-
75%		0.533	0.290	0.218	0.218	-	-	-	-
90%		0.234	0.218	-	-	-	-	-	-
None	D6 ditch 1 st	1.929	1.022	0.698	0.531	-	-	-	-
50%		0.964	0.534	0.372	0.335	-	-	-	-
75%		0.537	0.335	0.335	0.335	-	-	-	-
90%		0.335	0.335	0.335	-	-	-	-	-
None	D6 ditch 2 nd	1.945	1.041	0.724	0.724	-	-	-	-
50%		1.015	0.724	0.724	0.724	-	-	-	-
75%		0.724	0.724	-	-	-	-	-	-
90%		0.724	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.253	0.183	-	-
50%		-	-	-	-	0.155	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.765	0.951	0.655	0.498
50%		-	-	-	-	0.922	0.509	0.386	0.268
75%		-	-	-	-	0.724	0.504	0.386	0.263
90%		-	-	-	-	0.724	0.504	-	-

None	R2 stream	-	-	-	-	2.327	1.248	0.856	0.651
50%		-	-	-	-	1.195	0.648	0.446	0.339
75%		-	-	-	-	0.629	0.348	0.241	0.183
90%		-	-	-	-	0.290	0.168	0.119	-
None	R3 stream	-	-	-	-	2.444	1.316	0.904	0.687
50%		-	-	-	-	1.266	0.697	0.483	0.367
75%		-	-	-	-	0.705	0.490	0.375	0.256
90%		-	-	-	-	0.705	0.490	0.375	0.256
None	R4 stream	-	-	-	-	1.745	0.941	0.647	0.491
50%		-	-	-	-	1.157	0.806	0.618	0.421
75%		-	-	-	-	1.157	0.806	0.618	0.421
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	8.387	4.448	3.035	2.309	-	-	-	-
50%		4.196	2.335	1.622	1.230	-	-	-	-
75%		2.352	1.435	1.030	0.778	-	-	-	-
90%		1.439	0.961	0.709	-	-	-	-	-
None	D4 pond	1.052	0.761	-	-	-	-	-	-
50%		0.626	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	8.822	4.713	3.226	2.452	-	-	-	-
50%		4.487	2.413	1.657	1.257	-	-	-	-

75%		2.317	1.261	0.948	0.948	-	-	-	-
90%		1.017	0.948	-	-	-	-	-	-
None	D6 ditch 1 st	8.387	4.443	3.035	2.309	-	-	-	-
50%		4.191	2.322	1.617	1.457	-	-	-	-
75%		2.335	1.457	1.457	1.457	-	-	-	-
90%		1.457	1.457	1.457	-	-	-	-	-
None	D6 ditch 2 nd	8.457	4.526	3.148	3.148	-	-	-	-
50%		4.413	3.148	3.148	3.148	-	-	-	-
75%		3.148	3.148	-	-	-	-	-	-
90%		3.148	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	1.100	0.796	-	-
50%		-	-	-	-	0.674	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	7.674	4.135	2.848	2.165
50%		-	-	-	-	4.009	2.213	1.678	1.165
75%		-	-	-	-	3.148	2.191	1.678	1.143
90%		-	-	-	-	3.148	2.191	-	-
None	R2 stream	-	-	-	-	10.117	5.426	3.722	2.830
50%		-	-	-	-	5.196	2.817	1.939	1.474
75%		-	-	-	-	2.735	1.513	1.048	0.796
90%		-	-	-	-	1.261	0.730	0.517	-
None	R3 stream	-	-	-	-	10.626	5.722	3.930	2.987
50%		-	-	-	-	5.504	3.030	2.100	1.596

75%		-	-	-	-	3.065	2.130	1.630	1.113
90%		-	-	-	-	3.065	2.130	1.630	1.113
None	R4 stream	-	-	-	-	7.587	4.091	2.813	2.135
50%		-	-	-	-	5.030	3.504	2.687	1.830
75%		-	-	-	-	5.030	3.504	2.687	1.830
90%		-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-52: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables (post-emergence, 1 x 1137 g/ha)

Intended use		Bulb vegetables (post-emergence)	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.420
90%		0.420	-
75%	R3 stream	-	0.210
90%		0.220	-
75%	R4 stream	-	0.146
90%		0.172	-
RAC (µg/L)			
0.23		PEC/RAC ratio	

75%	R1 stream	-	1.83
90%		1.83	-
75%	R3 stream	-	0.91
90%		0.96	-
75%	R4 stream	-	0.63
90%		0.75	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in bulb vegetables (post-emergence 1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with mitigation measures. However, scenario D6 is not relevant for CEU countries.

For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures and a restriction has to be considered (do not apply on silty soils with a slope greater than 3%)

Table 9.5-5312: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in beans (1 x 1590 g/ha)

Group	Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
Test species	<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>		<i>Chironomus riparius</i>

Group		Fish acute	Fish pro- longed	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell- er pro- longed
Endpoint		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	E _r C ₅₀	NOEC	ErC ₅₀		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12		227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D2 ditch	8.307	4.24	13.19	2.60	5.65	5.73	8.93	1.01	6.92	12.66	0.00056
D2 stream	7.354	3.75	11.67	2.30	5.00	5.07	7.91	0.90	6.13	0.931	0.00004
D3 ditch	8.233	4.20	13.07	2.57	5.60	5.68	8.85	1.00	6.86	5.181	0.00023
D4 pond	0.332	0.17	0.53	0.10	0.23	0.23	0.36	0.04	0.28	1.627	0.00007
D4 stream	6.589	3.36	10.46	2.06	4.48	4.54	7.08	0.80	5.49	0.238	0.00001
D6 1 st ditch	8.146	4.16	12.93	2.55	5.54	5.62	8.76	0.99	6.79	2.561	0.00011
D6 2 nd ditch	8.305	4.24	13.18	2.60	5.65	5.73	8.93	1.01	6.92	5.900	0.00026
R1 pond	0.339	0.17	0.54	0.11	0.23	0.23	0.36	0.04	0.28	2.745	0.00012
R1 stream	5.684	2.90	9.02	1.78	3.87	3.92	6.11	0.69	4.74	8.685	0.00038
R2 stream	7.484	3.82	11.88	2.34	5.09	5.16	8.05	0.91	6.24	26.92	0.00118
R3 stream	8.008	4.09	12.71	2.50	5.45	5.52	8.61	0.98	6.67	6.098	0.00027
R4 stream	5.695	2.91	9.04	1.78	3.87	3.93	6.12	0.69	4.75	9.924	0.0004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses field beans, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-50: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in beans (1 x 1137 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dweller prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)										PEC _{gl-max} (µg/kg)
Step 3											
D2 ditch	5.939	3.03	9.43	1.86	4.04	4.10	6.39	0.72	4.95	10.74	0.00047
D2 stream	5.258	2.68	8.35	1.64	3.58	3.63	5.65	0.64	4.38	0.671	0.00003
D3 ditch	5.886	3.00	9.34	1.84	4.00	4.06	6.33	0.72	4.91	3.969	0.00017
D4 pond	0.237	0.12	0.38	0.07	0.16	0.16	0.25	0.03	0.20	1.417	0.00006
D4 stream	4.711	2.40	7.48	1.47	3.20	3.25	5.07	0.57	3.93	0.171	0.00001
D6 1 st ditch	5.824	2.97	9.24	1.82	3.96	4.02	6.26	0.71	4.85	1.932	0.00008

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell. prolonged
D6 2 nd ditch	5.938	3.03	9.43	1.86	4.04	4.10	6.38	0.72	4.95	6.375	0.00028
R1 pond	0.247	0.13	0.39	0.08	0.17	0.17	0.27	0.03	0.21	2.852	0.00013
R1 stream	4.064	2.07	6.45	1.27	2.76	2.80	4.37	0.50	3.39	6.733	0.00030
R2 stream	5.351	2.73	8.49	1.67	3.64	3.69	5.75	0.65	4.46	19.65	0.00086
R3 stream	5.726	2.92	9.09	1.79	3.90	3.95	6.16	0.70	4.77	4.443	0.00020
R4 stream	4.072	2.08	6.46	1.27	2.77	2.81	4.38	0.50	3.39	7.321	0.00032

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-5113: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in beans

Intended use		Beans							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D2 ditch	2.721	1.461	1.007	0.767	-	-	-	
50%		1.424	0.817	0.575	-	-	-		
75%		0.853	-	-	-	-	-		
90%		-	-	-	-	-	-		
None	D2 stream	3.117	1.668	1.143	0.870	-	-	-	
50%		1.591	0.861	0.595	-	-	-		

75%		0.847	-	-	-	-	-	-	
90%		-	-	-	-	-	-	-	
None	D3 ditch	2.697	1.429	0.976	0.743	-	-	-	
50%		1.348	0.748	0.520	-	-	-	-	
75%		0.750	-	-	-	-	-	-	
90%		-	-	-	-	-	-	-	
None			2.819	1.505	1.030	0.784	-	-	-
50%	D4 stream	1.432	0.770	0.528	-	-	-	-	
75%		0.739	-	-	-	-	-	-	
90%		-	-	-	-	-	-	-	
None	D6 1 st ditch	2.668	1.414	0.966	0.735	-	-	-	
50%		1.333	0.707	0.483	-	-	-	-	
75%		0.675	-	-	-	-	-	-	
90%		-	-	-	-	-	-	-	
None	D6 2 nd ditch	2.720	1.442	0.985	0.749	-	-	-	
50%		1.359	0.722	0.579	-	-	-	-	
75%		0.723	-	-	-	-	-	-	
90%		-	-	-	-	-	-	-	
None	R1 stream	-	-	-		2.459	1.325	0.910	-
50%		-	-	-		1.276	0.724	-	-
75%		-	-	-		1.040	-	-	-
90%		-	-	-		1.040	-	-	-
None	R2 stream	-	-	-		3.233	1.734	1.188	-
50%		-	-	-		1.657	0.898	0.618	-

None	D4 stream	3.03	1.62	1.11	0.84	-	-	-	-
50%		1.54	0.83	0.57	-	-	-	-	-
75%		0.79	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 1 st ditch	2.87	1.52	1.04	0.79	-	-	-	-
50%		1.43	0.76	0.52	-	-	-	-	-
75%		0.73	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 2 nd ditch	2.92	1.55	1.06	0.81	-	-	-	-
50%		1.46	0.78	0.62	-	-	-	-	-
75%		0.78	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-		2.64	1.42	0.98	-
50%		-	-	-		1.37	0.78	-	-
75%		-	-	-		1.12	-	-	-
90%		-	-	-		1.12	-	-	-
None	R2 stream	-	-	-		3.48	1.86	1.28	-
50%		-	-	-		1.78	0.97	0.66	-
75%		-	-	-		0.94	-	-	-
90%		-	-	-		-	-	-	-
None	R3 stream	-	-	-		3.65	1.95	1.34	1.02
50%		-	-	-		1.88	1.04	0.97	0.55
75%		-	-	-		1.02	0.71	-	-
90%		-	-	-		1.02	-	-	-

None	R4 stream	-	-	-		2.64	1.42	0.98	-
50%		-	-	-		1.67	1.16	-	-
75%		-	-	-		1.67	1.16	-	-
90%		-	-	-		-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Beans							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D2 ditch	2.721	1.461	1.007	0.767	-	-	-	
50%		1.424	0.817	0.575	0.444	-	-	-	
75%		0.853	0.530	0.385	0.292	-	-	-	
90%		0.554	0.377	0.280	0.249	-	-	-	
None	D2 stream	3.117	1.668	1.143	0.870	-	-	-	
50%		1.591	0.861	0.595	0.460	-	-	-	
75%		0.847	0.485	0.338	0.258	-	-	-	
90%		0.420	0.252	0.179	0.162	-	-	-	
None	D3 ditch	2.697	1.429	0.976	0.743	-	-	-	
50%		1.348	0.748	0.520	0.402	-	-	-	
75%		0.750	0.463	0.331	0.252	-	-	-	
90%		0.464	0.310	0.227	0.173	-	-	-	
None	D4 pond	0.342	0.248	0.196	-	-	-	-	
50%		0.203	0.149	-	-	-	-	-	

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.819	1.505	1.030	0.784	-	-	-	-
50%		1.432	0.770	0.528	0.408	-	-	-	-
75%		0.739	0.408	0.281	0.214	-	-	-	-
90%		0.328	0.189	0.189	-	-	-	-	-
None	D6 1 st ditch	2.668	1.414	0.966	0.735	-	-	-	-
50%		1.333	0.707	0.483	0.452	-	-	-	-
75%		0.675	0.452	0.452	0.452	-	-	-	-
90%		0.452	0.452	0.452	-	-	-	-	-
None	D6 2 nd ditch	2.720	1.442	0.985	0.749	-	-	-	-
50%		1.359	0.722	0.588	0.588	-	-	-	-
75%		0.723	0.588	0.588	0.588	-	-	-	-
90%		0.588	0.588	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.341	0.247	0.196	-
50%		-	-	-	-	0.204	0.149	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.459	1.325	0.910	0.703
50%		-	-	-	-	1.276	0.724	0.563	0.384
75%		-	-	-	-	1.040	0.724	0.563	0.384
90%		-	-	-	-	1.040	-	-	-
None	R2 stream	-	-	-	-	3.233	1.734	1.188	0.917
50%		-	-	-	-	1.657	0.898	0.618	0.477

75%		-	-	-		0.870	0.488	0.338	0.257
90%		-	-	-		0.404	0.234	0.173	0.126
None	R3 stream	-	-	-		3.393	1.818	1.248	0.949
50%		-	-	-		1.745	0.963	0.904	0.508
75%		-	-	-		0.952	0.661	0.515	0.352
90%		-	-	-		0.947	0.661	0.515	0.352
None	R4 stream	-	-	-		2.452	1.321	0.907	0.700
50%		-	-	-		1.550	1.080	0.840	0.574
75%		-	-	-		1.550	1.080	0.840	0.574
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D2 ditch	2.93	1.57	1.08	0.82	-	-	-	-
50%		1.53	0.88	0.62	0.48	-	-	-	-
75%		0.92	0.57	0.41	0.31	-	-	-	-
90%		0.60	0.41	0.30	0.27	-	-	-	-
None	D2 stream	3.35	1.79	1.23	0.94	-	-	-	-
50%		1.71	0.93	0.64	0.49	-	-	-	-
75%		0.91	0.52	0.36	0.28	-	-	-	-
90%		0.45	0.27	0.19	0.17	-	-	-	-
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.56	0.43	-	-	-	-
75%		0.81	0.50	0.36	0.27	-	-	-	-
90%		0.50	0.33	0.24	0.19	-	-	-	-

None	D4 pond	0.37	0.27	0.21	-	-	-	-	-
50%		0.22	0.16	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.03	1.62	1.11	0.84	-	-	-	-
50%		1.54	0.83	0.57	0.44	-	-	-	-
75%		0.79	0.44	0.30	0.23	-	-	-	-
90%		0.35	0.20	0.20	-	-	-	-	-
None	D6 1 st ditch	2.87	1.52	1.04	0.79	-	-	-	-
50%		1.43	0.76	0.52	0.49	-	-	-	-
75%		0.73	0.49	0.49	0.49	-	-	-	-
90%		0.49	0.49	0.49	-	-	-	-	-
None	D6 2 nd ditch	2.92	1.55	1.06	0.81	-	-	-	-
50%		1.46	0.78	0.63	0.63	-	-	-	-
75%		0.78	0.63	0.63	0.63	-	-	-	-
90%		0.63	0.63	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.37	0.27	0.21	-
50%		-	-	-	-	0.22	0.16	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.64	1.42	0.98	0.76
50%		-	-	-	-	1.37	0.78	0.61	0.41
75%		-	-	-	-	1.12	0.78	0.61	0.41
90%		-	-	-	-	1.12	-	-	-

None	R2 stream	-	-	-	-	3.48	1.86	1.28	0.99
50%		-	-	-	-	1.78	0.97	0.66	0.51
75%		-	-	-	-	0.94	0.52	0.36	0.28
90%		-	-	-	-	0.43	0.25	0.19	0.14
None	R3 stream	-	-	-	-	3.65	1.95	1.34	1.02
50%		-	-	-	-	1.88	1.04	0.97	0.55
75%		-	-	-	-	1.02	0.71	0.55	0.38
90%		-	-	-	-	1.02	0.71	0.55	0.38
None	R4 stream	-	-	-	-	2.64	1.42	0.98	0.75
50%		-	-	-	-	1.67	1.16	0.90	0.62
75%		-	-	-	-	1.67	1.16	0.90	0.62
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in beans (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D2 ditch, D2 stream, D3 ditch, D4 stream, D6 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R2 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip

R3 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

None	D4 stream	2.819	1.505	1.030	0.784	-	-	-	
50%		1.432	0.770	0.528	0.408	-	-	-	
75%		0.739	0.408	0.281	0.214	-	-	-	
90%		0.328	0.189	0.189	-	-	-	-	
None	D6 1 st ditch	2.668	1.414	0.966	0.735	-	-	-	
50%		1.333	0.707	0.483	0.452	-	-	-	
75%		0.675	0.452	0.452	0.452	-	-	-	
90%		0.452	0.452	0.452	-	-	-	-	
None	D6 2 nd ditch	2.720	1.442	0.985	0.749	-	-	-	
50%		1.359	0.722	0.588	0.588	-	-	-	
75%		0.723	0.588	0.588	0.588	-	-	-	
90%		0.588	0.588	-	-	-	-	-	
None	R1 pond	-	-	-		0.341	0.247	0.196	-
50%		-	-	-		0.204	0.149	-	-
75%		-	-	-		-	-	-	-
90%		-	-	-		-	-	-	-
None	R1 stream	-	-	-		2.459	1.325	0.910	0.703
50%		-	-	-		1.276	0.724	0.563	0.384
75%		-	-	-		1.040	0.724	0.563	0.384
90%		-	-	-		1.040	-	-	-
None	R2 stream	-	-	-		3.233	1.734	1.188	0.917
50%		-	-	-		1.657	0.898	0.618	0.477
75%		-	-	-		0.870	0.488	0.338	0.257
90%		-	-	-		0.404	0.234	0.173	0.126

None	R3 stream	-	-	-		3.393	1.818	1.248	0.949
50%		-	-	-		1.745	0.963	0.904	0.508
75%		-	-	-		0.952	0.661	0.515	0.352
90%		-	-	-		0.947	0.661	0.515	0.352
None	R4 stream	-	-	-		2.452	1.321	0.907	0.700
50%		-	-	-		1.550	1.080	0.840	0.574
75%		-	-	-		1.550	1.080	0.840	0.574
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D2 ditch	11.830	6.352	4.378	3.335	-	-	-	-
50%		6.191	3.552	2.500	1.930	-	-	-	-
75%		3.709	2.304	1.674	1.270	-	-	-	-
90%		2.409	1.639	1.217	1.083	-	-	-	-
None	D2 stream	13.552	7.252	4.970	3.783	-	-	-	-
50%		6.917	3.743	2.587	2.000	-	-	-	-
75%		3.683	2.109	1.470	1.122	-	-	-	-
90%		1.826	1.096	0.778	0.704	-	-	-	-
None	D3 ditch	11.726	6.213	4.243	3.230	-	-	-	-
50%		5.861	3.252	2.261	1.748	-	-	-	-
75%		3.261	2.013	1.439	1.096	-	-	-	-
90%		2.017	1.348	0.987	0.752	-	-	-	-
None	D4 pond	1.487	1.078	0.852	-	-	-	-	-
50%		0.883	0.648	-	-	-	-	-	-

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	12.257	6.543	4.478	3.409	-	-	-	-
50%		6.226	3.348	2.296	1.774	-	-	-	-
75%		3.213	1.774	1.222	0.930	-	-	-	-
90%		1.426	0.822	0.822	-	-	-	-	-
None	D6 1 st ditch	11.600	6.148	4.200	3.196	-	-	-	-
50%		5.796	3.074	2.100	1.965	-	-	-	-
75%		2.935	1.965	1.965	1.965	-	-	-	-
90%		1.965	1.965	1.965	-	-	-	-	-
None	D6 2 nd ditch	11.826	6.270	4.283	3.257	-	-	-	-
50%		5.909	3.139	2.557	2.557	-	-	-	-
75%		3.143	2.557	2.557	2.557	-	-	-	-
90%		2.557	2.557	-	-	-	-	-	-
None	R1 pond	-	-	-	-	1.483	1.074	0.852	-
50%		-	-	-	-	0.887	0.648	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	10.691	5.761	3.957	3.057
50%		-	-	-	-	5.548	3.148	2.448	1.670
75%		-	-	-	-	4.522	3.148	2.448	1.670
90%		-	-	-	-	4.522	-	-	-
None	R2 stream	-	-	-	-	14.057	7.539	5.165	3.987
50%		-	-	-	-	7.204	3.904	2.687	2.074

75%		-	-	-	-	3.783	2.122	1.470	1.117
90%		-	-	-	-	1.757	1.017	0.752	0.548
None	R3 stream	-	-	-	-	14.752	7.904	5.426	4.126
50%		-	-	-	-	7.587	4.187	3.930	2.209
75%		-	-	-	-	4.139	2.874	2.239	1.530
90%		-	-	-	-	4.117	2.874	2.239	1.530
None	R4 stream	-	-	-	-	10.661	5.743	3.943	3.043
50%		-	-	-	-	6.739	4.696	3.652	2.496
75%		-	-	-	-	6.739	4.696	3.652	2.496
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-53: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in beans (1 x 1590 g/ha)

Intended use		beans	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.609
90%		0.610	-
75%	R2 stream	-	0.254
90%		0.230	-

75%	R3 stream	-	0.289
90%		0.305	-
75%	R4 stream	-	0.212
90%		0.263	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	2.65
90%		2.65	-
75%	R2 stream	-	1.10
90%		1	-
75%	R3 stream	-	1.26
90%		1.33	-
75%	R4 stream	-	0.92
90%		1.14	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in beans (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D2 stream, D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 20m no spray buffer zone or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D2 ditch, D6 ditch 1st and D6 ditch 2nd the PEC/RAC ratios are below the trigger with mitigation measures. However D2 and D6 are not relevant in CEU countries.

For scenario R1 stream, R3 stream, the PEC/RAC ratios are below the trigger even considering risk mitigation measures and restrictions will be needed (do not apply on silty soils with a slope greater than 3% and do not apply on terraced clay soils with a slope greater than 10% respectively)

Table 9.5-50: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in beans (1 x 1137 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell. er prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	E _r C ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
FOCUS Scenario	PEC _{gl-max} (µg/L)	1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
Step 3											
D2 ditch	5.939	3.03	9.43	1.86	4.04	4.10	6.39	0.72	4.95	10.74	0.00047
D2 stream	5.258	2.68	8.35	1.64	3.58	3.63	5.65	0.64	4.38	0.671	0.00003
D3 ditch	5.886	3.00	9.34	1.84	4.00	4.06	6.33	0.72	4.91	3.969	0.00017
D4 pond	0.237	0.12	0.38	0.07	0.16	0.16	0.25	0.03	0.20	1.417	0.00006
D4 stream	4.711	2.40	7.48	1.47	3.20	3.25	5.07	0.57	3.93	0.171	0.00001
D6 1 st ditch	5.824	2.97	9.24	1.82	3.96	4.02	6.26	0.71	4.85	1.932	0.00008
D6 2 nd ditch	5.938	3.03	9.43	1.86	4.04	4.10	6.38	0.72	4.95	6.375	0.00028
R1 pond	0.247	0.13	0.39	0.08	0.17	0.17	0.27	0.03	0.21	2.852	0.00013
R1 stream	4.064	2.07	6.45	1.27	2.76	2.80	4.37	0.50	3.39	6.733	0.00030

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell. prolonged
R2 stream	5.351	2.73	8.49	1.67	3.64	3.69	5.75	0.65	4.46	19.65	0.00086
R3 stream	5.726	2.92	9.09	1.79	3.90	3.95	6.16	0.70	4.77	4.443	0.00020
R4 stream	4.072	2.08	6.46	1.27	2.77	2.81	4.38	0.50	3.39	7.321	0.00032

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-51: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in beans (1 x 1137 g/ha)

Intended use		Beans							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D2 ditch	1.957	1.065	0.737	0.559	-	-	-	
50%		1.059	0.612	0.432	0.327	-	-	-	
75%		0.640	0.403	0.292	0.221	-	-	-	
90%		0.421	0.285	0.211	-	-	-	-	
None	D2 stream	2.238	1.197	0.820	0.624	-	-	-	
50%		1.142	0.621	0.429	0.326	-	-	-	
75%		0.611	0.345	0.241	0.183	-	-	-	
90%		0.299	0.179	0.128	-	-	-	-	
None	D3 ditch	1.928	1.022	0.698	0.531	-	-	-	

50%		0.979	0.546	0.380	0.288	-	-	-	
75%		0.559	0.341	0.245	0.185	-	-	-	
90%		0.342	0.228	0.168	-	-	-	-	
None	D4 pond	0.246	0.179	-	-	-	-	-	
50%		0.147	-	-	-	-	-	-	
75%		-	-	-	-	-	-	-	
90%		-	-	-	-	-	-	-	
None	D4 stream	2.016	1.076	0.737	0.560	-	-	-	
50%		1.024	0.550	0.378	0.287	-	-	-	
75%		0.528	0.288	0.198	0.151	-	-	-	
90%		0.231	0.130	-	-	-	-	-	
None	D6 1 st ditch	1.908	1.011	0.691	0.525	-	-	-	
50%		0.953	0.505	0.346	0.308	-	-	-	
75%		0.496	0.308	0.308	0.308	-	-	-	
90%		0.308	0.308	0.308	-	-	-	-	
None	D6 2 nd ditch	1.945	1.031	0.704	0.536	-	-	-	
50%		0.986	0.550	0.399	0.399	-	-	-	
75%		0.565	0.399	0.399	0.399	-	-	-	
90%		0.399	0.399	-	-	-	-	-	
None	R1 pond	-	-	-		0.250	0.181	-	-
50%		-	-	-		0.151	-	-	-
75%		-	-	-		-	-	-	-
90%		-	-	-		-	-	-	-
None	R1 stream	-	-	-		1.765	0.951	0.653	0.496

50%		-	-	-		0.919	0.539	0.414	0.282
75%		-	-	-		0.775	0.539	0.414	0.282
90%		-	-	-		0.775	-	-	-
None	R2 stream	-	-	-		2.312	1.240	0.850	0.646
50%		-	-	-		1.186	0.643	0.442	0.336
75%		-	-	-		0.623	0.344	0.238	0.181
90%		-	-	-		0.285	0.165	0.120	-
None	R3 stream	-	-	-		2.441	1.313	0.901	0.685
50%		-	-	-		1.267	0.699	0.484	0.368
75%		-	-	-		0.692	0.466	0.358	0.244
90%		-	-	-		0.667	0.466	0.358	0.244
None	R4 stream	-	-	-		1.762	0.951	0.655	0.498
50%		-	-	-		1.145	0.798	0.612	0.418
75%		-	-	-		1.145	0.798	0.612	0.418
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D2 ditch	2.10	1.15	0.79	0.60	-	-	-	-
50%		1.14	0.66	0.46	0.35	-	-	-	-
75%		0.69	0.43	0.31	0.24	-	-	-	-
90%		0.45	0.31	0.23	-	-	-	-	-
None	D2 stream	2.41	1.29	0.88	0.67	-	-	-	-
50%		1.23	0.67	0.46	0.35	-	-	-	-
75%		0.66	0.37	0.26	0.20	-	-	-	-

90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.90	1.02	0.70	0.53
50%		-	-	-	-	0.99	0.58	0.45	0.30
75%		-	-	-	-	0.83	0.58	0.45	0.30
90%		-	-	-	-	0.83	-	-	-
None	R2 stream	-	-	-	-	2.49	1.33	0.91	0.69
50%		-	-	-	-	1.28	0.69	0.48	0.36
75%		-	-	-	-	0.67	0.37	0.26	0.19
90%		-	-	-	-	0.31	0.18	0.13	-
None	R3 stream	-	-	-	-	2.62	1.41	0.97	0.74
50%		-	-	-	-	1.36	0.75	0.52	0.40
75%		-	-	-	-	0.74	0.50	0.38	0.26
90%		-	-	-	-	0.72	0.50	0.38	0.26
None	R4 stream	-	-	-	-	1.89	1.02	0.70	0.54
50%		-	-	-	-	1.23	0.86	0.66	0.45
75%		-	-	-	-	1.23	0.86	0.66	0.45
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in beans (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D2 ditch, D2 stream, D3 ditch, D4 stream, D6 ditch: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-52: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in beans

Intended use		Beans							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D2 ditch	1.957	1.065	0.737	0.559	-	-	-	
50%		1.059	0.612	0.432	0.327	-	-	-	
75%		0.640	0.403	0.292	0.221	-	-	-	
90%		0.421	0.285	0.211	-	-	-	-	
None	D2 stream	2.238	1.197	0.820	0.624	-	-	-	
50%		1.142	0.621	0.429	0.326	-	-	-	
75%		0.611	0.345	0.241	0.183	-	-	-	
90%		0.299	0.179	0.128	-	-	-	-	
None	D3 ditch	1.928	1.022	0.698	0.531	-	-	-	
50%		0.979	0.546	0.380	0.288	-	-	-	
75%		0.559	0.341	0.245	0.185	-	-	-	
90%		0.342	0.228	0.168	-	-	-	-	
None	D4 pond	0.246	0.179	-	-	-	-	-	

50%		0.147	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.016	1.076	0.737	0.560	-	-	-	-
50%		1.024	0.550	0.378	0.287	-	-	-	-
75%		0.528	0.288	0.198	0.151	-	-	-	-
90%		0.231	0.130	-	-	-	-	-	-
None	D6 1 st ditch	1.908	1.011	0.691	0.525	-	-	-	-
50%		0.953	0.505	0.346	0.308	-	-	-	-
75%		0.496	0.308	0.308	0.308	-	-	-	-
90%		0.308	0.308	0.308	-	-	-	-	-
None	D6 2 nd ditch	1.945	1.031	0.704	0.536	-	-	-	-
50%		0.986	0.550	0.399	0.399	-	-	-	-
75%		0.565	0.399	0.399	0.399	-	-	-	-
90%		0.399	0.399	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.250	0.181	-	-
50%		-	-	-	-	0.151	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.765	0.951	0.653	0.496
50%		-	-	-	-	0.919	0.539	0.414	0.282
75%		-	-	-	-	0.775	0.539	0.414	0.282
90%		-	-	-	-	0.775	-	-	-
None	R2 stream	-	-	-	-	2.312	1.240	0.850	0.646

50%		-	-	-		1.186	0.643	0.442	0.336
75%		-	-	-		0.623	0.344	0.238	0.181
90%		-	-	-		0.285	0.165	0.120	-
None	R3 stream	-	-	-		2.441	1.313	0.901	0.685
50%		-	-	-		1.267	0.699	0.484	0.368
75%		-	-	-		0.692	0.466	0.358	0.244
90%		-	-	-		0.667	0.466	0.358	0.244
None	R4 stream	-	-	-		1.762	0.951	0.655	0.498
50%		-	-	-		1.145	0.798	0.612	0.418
75%		-	-	-		1.145	0.798	0.612	0.418
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D2 ditch	8.51	4.63	3.20	2.43	-	-	-	-
50%		4.60	2.66	1.88	1.42	-	-	-	-
75%		2.78	1.75	1.27	0.96	-	-	-	-
90%		1.83	1.24	0.92	-	-	-	-	-
None	D2 stream	9.73	5.20	3.57	2.71	-	-	-	-
50%		4.97	2.70	1.87	1.42	-	-	-	-
75%		2.66	1.50	1.05	0.80	-	-	-	-
90%		1.30	0.78	0.56	-	-	-	-	-
None	D3 ditch	8.38	4.44	3.03	2.31	-	-	-	-
50%		4.26	2.37	1.65	1.25	-	-	-	-
75%		2.43	1.48	1.07	0.80	-	-	-	-

90%		1.49	0.99	0.73	-	-	-	-	-
None	D4 pond	1.07	0.78	-	-	-	-	-	-
50%		0.64	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	8.77	4.68	3.20	2.43	-	-	-	-
50%		4.45	2.39	1.64	1.25	-	-	-	-
75%		2.30	1.25	0.86	0.66	-	-	-	-
90%		1.00	0.57	-	-	-	-	-	-
None	D6 1 st ditch	8.30	4.40	3.00	2.28	-	-	-	-
50%		4.14	2.20	1.50	1.34	-	-	-	-
75%		2.16	1.34	1.34	1.34	-	-	-	-
90%		1.34	1.34	1.34	-	-	-	-	-
None	D6 2 nd ditch	8.46	4.48	3.06	2.33	-	-	-	-
50%		4.29	2.39	1.73	1.73	-	-	-	-
75%		2.46	1.73	1.73	1.73	-	-	-	-
90%		1.73	1.73	-	-	-	-	-	-
None	R1 pond	-	-	-	-	1.09	0.79	-	-
50%		-	-	-	-	0.66	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	7.67	4.13	2.84	2.16
50%		-	-	-	-	4.00	2.34	1.80	1.23
75%		-	-	-	-	3.37	2.34	1.80	1.23

90%		-	-	-	-	3.37	-	-	-
None	R2 stream	-	-	-	-	10.05	5.39	3.70	2.81
50%		-	-	-	-	5.16	2.80	1.92	1.46
75%		-	-	-	-	2.71	1.50	1.03	0.79
90%		-	-	-	-	1.24	0.72	0.52	
None	R3 stream	-	-	-	-	10.61	5.71	3.92	2.98
50%		-	-	-	-	5.51	3.04	2.10	1.60
75%		-	-	-	-	3.01	2.03	1.56	1.06
90%		-	-	-	-	2.90	2.03	1.56	1.06
None	R4 stream	-	-	-	-	7.66	4.13	2.85	2.17
50%		-	-	-	-	4.98	3.47	2.66	1.82
75%		-	-	-	-	4.98	3.47	2.66	1.82
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-53: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in beans (1 x 1137 g/ha)

Intended use		beans	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.454

90%		0.454	-
75%	R2 stream	-	0.181
90%		0.165	-
75%	R3 stream	-	0.209
90%		0.223	-
75%	R4 stream	-	0.152
90%		0.193	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	1.97
90%		1.97	-
75%	R2 stream	-	0.79
90%		0.72	-
75%	R3 stream	-	0.91
90%		0.97	-
75%	R4 stream	-	0.66
90%		0.84	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in beans (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

D2 stream, D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

For scenarios D6 ditch 1st and D6 ditch 2nd the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not

relevant for CEU countries.

For scenario R1 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures and a restriction will have to be considered (do not apply on silty soils with a slope greater than 3%).

Table 9.5-5414: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Step 3 calculations for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel (root vegetables 1 x 1590 g/ha)

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er pro-longed
Test species		<i>O. mykiss</i>	<i>P. promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 196	NOEC 6.3	NOEC geomean 32	EC ₅₀ 147	NOEC 14.5	ErC ₅₀ 9.3	NOEC 82	ErC ₅₀ 12		NOEC 227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)										PEC _{gl-max} (µg/kg)
Step 3											
D3 ditch	9.944	5.07	15.78	3.11	6.76	6.86	10.69	1.21	8.29	5.753	0.00025
D4 pond	0.343	0.18	0.54	0.11	0.23	0.24	0.37	0.04	0.29	1.311	0.00006
D4 stream	7.805	3.98	12.39	2.44	5.31	5.38	8.39	0.95	6.50	0.346	0.00002
D6 ditch	9.835	5.02	15.61	3.07	6.69	6.78	10.58	1.20	8.20	2.990	0.00013
R1 pond	0.358	0.18	0.57	0.11	0.24	0.25	0.38	0.04	0.30	2.576	0.00011

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er pro-longed
R1 stream	6.561	3.35	10.41	2.05	4.46	4.52	7.05	0.80	5.47	15.01	0.00066
R2 1 st stream	8.606	4.39	13.66	2.69	5.85	5.94	9.25	1.05	7.17	27.23	0.00120
R2 2 nd stream	8.826	4.50	14.01	2.76	6.00	6.09	9.49	1.08	7.36	69.25	0.00305
R3 stream	9.281	4.74	14.73	2.90	6.31	6.40	9.98	1.13	7.73	4.367	0.00019
R4 stream	6.583	3.36	10.45	2.06	4.48	4.54	7.08	0.80	5.49	14.35	0.00063

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended use carrots, parsley, parsnip and fennel, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-5515: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel

Intended use		Carrots, parsley, parsnip and fennel									
Active substance		pendimethalin									
Application rate (g/ha)		1 × 1590									
Nozzle reduction	No spray buffer (m)	5	10	15	20	5	10	15	20		
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20		
None	D3 ditch	2.694	1.428	0.975	0.742	-	-	-			
50%		1.346	0.743	0.516	-	-	-	-			
75%		0.745	-	-	-	-	-	-			
90%		-	-	-	-	-	-	-			
None	D4 stream	2.906	1.554	1.064	0.811						

50%		1.480	0.798	0.548	-				
75%		0.768	-	-	-				
90%		-	-	-	-				
None	D6 ditch	2.664	1.412	0.965	0.734	-	-	-	
50%		1.331	0.706	0.482	-	-	-	-	
75%		0.679	-	-	-	-	-	-	
90%		-	-	-	-	-	-	-	
None	R1 stream	-	-	-		2.460	1.325	0.911	-
50%		-	-	-		1.282	0.728	-	-
75%		-	-	-		1.046	-	-	-
90%		-	-	-		1.046	-	-	-
None	R2 1 st stream	-	-	-		3.224	1.728	1.185	0.901
50%		-	-	-		1.652	0.895	0.615	-
75%		-	-	-		0.866	-	-	-
90%		-	-	-		-	-	-	-
None	R2 2 nd stream	-	-	-		3.320	1.783	1.223	0.931
50%		-	-	-		1.708	0.928	0.639	0.487
75%		-	-	-		0.902	-	-	-
90%		-	-	-		-	-	-	-
None	R3 stream	-	-	-		3.402	1.824	1.252	0.953
50%		-	-	-		1.753	0.964	0.668	0.509
75%		-	-	-		0.956	0.630	-	-
90%		-	-	-		0.910	-	-	-
None	R4 stream	-	-	-		2.459	1.331	0.915	0.697

50%		-	-	-		1.628	0.906	0.870	-
75%		-	-	-		1.628	-	-	-
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.93 (P. subcapitata)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.55	-	-	-	-	-
75%		0.80	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.12	1.67	1.14	0.87	-	-	-	-
50%		1.59	0.86	0.59	-	-	-	-	-
75%		0.83	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 ditch	2.86	1.52	1.04	0.79	-	-	-	-
50%		1.43	0.76	0.52	-	-	-	-	-
75%		0.73	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-		2.65	1.42	0.98	-
50%		-	-	-		1.38	0.78	-	-
75%		-	-	-		1.12	-	-	-
90%		-	-	-		1.12	-	-	-
None	R2-1 st stream	-	-	-		3.47	1.86	1.27	0.97
50%		-	-	-		1.78	0.96	0.66	-
75%		-	-	-		0.93	-	-	-

90%		-	-	-		-	-	-	-
None	R2 2 nd stream	-	-	-		3.57	1.92	1.32	1.00
50%		-	-	-		1.84	1.00	0.69	0.52
75%		-	-	-		0.97	-	-	-
90%		-	-	-		-	-	-	-
None	R3 stream	-	-	-		3.66	1.96	1.35	1.02
50%		-	-	-		1.88	1.04	0.72	0.55
75%		-	-	-		1.03	0.68	-	-
90%		-	-	-		0.98	-	-	-
None	R4 stream	-	-	-		2.64	1.43	0.98	0.75
50%		-	-	-		1.75	0.97	0.94	--
75%		-	-	-		1.75	-	-	-
90%		-	-	-		-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Carrots, parsley, parsnip and fennel							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.694	1.428	0.975	0.742	-	-	-	-
50%		1.346	0.743	0.516	0.399	-	-	-	-
75%		0.745	0.453	0.324	0.247	-	-	-	-
90%		0.453	0.304	0.223	0.170	-	-	-	-
None	D4 pond	0.331	0.241	0.190	-	-	-	-	-

50%		0.197	0.144	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.906	1.554	1.064	0.810	-	-	-	-
50%		1.480	0.798	0.548	0.423	-	-	-	-
75%		0.768	0.426	0.307	0.307	-	-	-	-
90%		0.346	0.307	0.307	0.307	-	-	-	-
None	D6 ditch	2.664	1.412	0.965	0.734	-	-	-	-
50%		1.331	0.706	0.482	0.372	-	-	-	-
75%		0.679	0.398	0.290	0.290	-	-	-	-
90%		0.366	0.290	0.290	0.290	-	-	-	-
None	R1 pond	-	-	-	-	0.345	0.251	0.198	-
50%		-	-	-	-	0.209	0.153	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.460	1.325	0.911	0.704
50%		-	-	-	-	1.282	0.728	0.566	0.386
75%		-	-	-	-	1.046	0.728	0.566	0.386
90%		-	-	-	-	1.046	-	-	-
None	R2 stream 1 st	-	-	-	-	3.224	1.728	1.185	0.901
50%		-	-	-	-	1.652	0.895	0.615	0.475
75%		-	-	-	-	0.866	0.485	0.336	0.256
90%		-	-	-	-	0.401	0.232	0.163	0.125
None	R2 stream 2 nd	-	-	-	-	3.320	1.783	1.223	0.931

50%		-	-	-	-	1.708	0.928	0.639	0.487
75%		-	-	-	-	0.902	0.508	0.353	0.269
90%		-	-	-	-	0.425	0.251	0.178	0.136
None	R3 stream	-	-	-	-	3.402	1.824	1.252	0.953
50%		-	-	-	-	1.753	0.964	0.668	0.509
75%		-	-	-	-	0.956	0.630	0.489	0.332
90%		-	-	-	-	0.910	0.630	0.489	0.332
None	R4 stream	-	-	-	-	2.459	1.331	0.915	0.697
50%		-	-	-	-	1.628	1.149	0.870	0.602
75%		-	-	-	-	1.628	1.149	0.870	0.602
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.55	0.43	-	-	-	-
75%		0.80	0.49	0.35	0.27	-	-	-	-
90%		0.49	0.33	0.24	0.18	-	-	-	-
None	D4 pond	0.36	0.26	0.20	-	-	-	-	-
50%		0.21	0.15	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.12	1.67	1.14	0.87	-	-	-	-
50%		1.59	0.86	0.59	0.45	-	-	-	-
75%		0.83	0.46	0.33	0.33	-	-	-	-

90%		0.37	0.33	0.33	0.33	-	-	-	-
None	D6 ditch	2.86	1.52	1.04	0.79	-	-	-	-
50%		1.43	0.76	0.52	0.40	-	-	-	-
75%		0.73	0.43	0.31	0.31	-	-	-	-
90%		0.39	0.31	0.31	0.31	-	-	-	-
None	R1 pond	-	-	-	-	0.37	0.27	0.21	-
50%		-	-	-	-	0.22	0.16	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.65	1.42	0.98	0.76
50%		-	-	-	-	1.38	0.78	0.61	0.42
75%		-	-	-	-	1.12	0.78	0.61	0.42
90%		-	-	-	-	1.12	-	-	-
None	R2 stream 1 st	-	-	-	-	3.47	1.86	1.27	0.97
50%		-	-	-	-	1.78	0.96	0.66	0.51
75%		-	-	-	-	0.93	0.52	0.36	0.28
90%		-	-	-	-	0.43	0.25	0.18	0.13
None	R2 stream 2 nd	-	-	-	-	3.57	1.92	1.32	1.00
50%		-	-	-	-	1.84	1.00	0.69	0.52
75%		-	-	-	-	0.97	0.55	0.38	0.29
90%		-	-	-	-	0.46	0.27	0.19	0.15
None	R3 stream	-	-	-	-	3.66	1.96	1.35	1.02
50%		-	-	-	-	1.88	1.04	0.72	0.55
75%		-	-	-	-	1.03	0.68	0.53	0.36

90%		-	-	-	-	0.98	0.68	0.53	0.36
None	R4 stream	-	-	-	-	2.64	1.43	0.98	0.75
50%		-	-	-	-	1.75	1.24	0.94	0.65
75%		-	-	-	-	1.75	1.24	0.94	0.65
90%		-	-	-	-	-	-	-	-

PEC/RAC ratios in carrot, parsley, parsnip and fennel are <1 when risk mitigation options are considered:

D3 ditch, D4 stream and D6 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream and R4 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction of 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction + 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R2 2nd stream: 15m no spray buffer zone + 15m vegetative strip +50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R2 1st stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario and R2 stream scenario.

Table 9.5-56: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel

Intended use		Carrots, parsley, parsnip and fennel							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.694	1.428	0.975	0.742	-	-	-	-

50%		1.346	0.743	0.516	0.399	-	-	-	-
75%		0.745	0.453	0.324	0.247	-	-	-	-
90%		0.453	0.304	0.223	0.170	-	-	-	-
None	D4 pond	0.331	0.241	0.190	-	-	-	-	-
50%		0.197	0.144	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.906	1.554	1.064	0.810	-	-	-	-
50%		1.480	0.798	0.548	0.423	-	-	-	-
75%		0.768	0.426	0.307	0.307	-	-	-	-
90%		0.346	0.307	0.307	0.307	-	-	-	-
None	D6 ditch	2.664	1.412	0.965	0.734	-	-	-	-
50%		1.331	0.706	0.482	0.372	-	-	-	-
75%		0.679	0.398	0.290	0.290	-	-	-	-
90%		0.366	0.290	0.290	0.290	-	-	-	-
None	R1 pond	-	-	-	-	0.345	0.251	0.198	-
50%		-	-	-	-	0.209	0.153	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.460	1.325	0.911	0.704
50%		-	-	-	-	1.282	0.728	0.566	0.386
75%		-	-	-	-	1.046	0.728	0.566	0.386
90%		-	-	-	-	1.046	-	-	-
None	R2 stream 1 st	-	-	-	-	3.224	1.728	1.185	0.901

90%		-	-	-	-	-	-	-	-
None	D4 stream	12.635	6.757	4.626	3.522	-	-	-	-
50%		6.435	3.470	2.383	1.839	-	-	-	-
75%		3.339	1.852	1.335	1.335	-	-	-	-
90%		1.504	1.335	1.335	1.335	-	-	-	-
None	D6 ditch	11.583	6.139	4.196	3.191	-	-	-	-
50%		5.787	3.070	2.096	1.617	-	-	-	-
75%		2.952	1.730	1.261	1.261	-	-	-	-
90%		1.591	1.261	1.261	1.261	-	-	-	-
None	R1 pond	-	-	-	-	1.500	1.091	0.861	-
50%		-	-	-	-	0.909	0.665	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	10.696	5.761	3.961	3.061
50%		-	-	-	-	5.574	3.165	2.461	1.678
75%		-	-	-	-	4.548	3.165	2.461	1.678
90%		-	-	-	-	4.548	-	-	-
None	R2 stream 1 st	-	-	-	-	14.017	7.513	5.152	3.917
50%		-	-	-	-	7.183	3.891	2.674	2.065
75%		-	-	-	-	3.765	2.109	1.461	1.113
90%		-	-	-	-	1.743	1.009	0.709	0.543
None	R2 stream 2 nd	-	-	-	-	14.435	7.752	5.317	4.048
50%		-	-	-	-	7.426	4.035	2.778	2.117
75%		-	-	-	-	3.922	2.209	1.535	1.170

90%		-	-	-	-	1.848	1.091	0.774	0.591
None	R3 stream	-	-	-	-	14.791	7.930	5.443	4.143
50%		-	-	-	-	7.622	4.191	2.904	2.213
75%		-	-	-	-	4.157	2.739	2.126	1.443
90%		-	-	-	-	3.957	2.739	2.126	1.443
None	R4 stream	-	-	-	-	10.691	5.787	3.978	3.030
50%		-	-	-	-	7.078	4.996	3.783	2.617
75%		-	-	-	-	7.078	4.996	3.783	2.617
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-57: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel (root vegetables 1 x 1590 g/ha)

Intended use		Carrots, parsley, parsnip and fennel	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.213
90%		0.215	-
75%	R3 stream	-	0.292
90%		0.314	-
75%	R4 stream	-	0.212

90%		0.218	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.93
90%		0.93	-
75%	R3 stream	-	1.27
90%		1.37	-
75%	R4 stream	-	0.92
90%		0.95	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in carrots, parsley, parsnip and fennel (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream 1st, R2 stream 2nd: 15m no spray buffer zone + 15m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. Scenario D6 is not relevant for CEU countries.

For scenario R3 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures and a restriction will have to be considered (do not apply on terraced clay soils with a slope greater than 10%).

Table 9.5-58: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Step 3 calculations for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel (root vegetables 1 x 1137 g/ha)

Group	Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
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Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er pro-longed
Test species		<i>O. mykiss</i>	<i>P. promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	E _r C ₅₀	NOEC	ErC ₅₀		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12		227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	7.109	3.63	11.28	2.22	4.84	4.90	7.64	0.87	5.92	4.379	0.00019
D4 pond	0.245	0.13	0.39	0.08	0.17	0.17	0.26	0.03	0.20	1.224	0.00005
D4 stream	5.581	2.85	8.86	1.74	3.80	3.85	6.00	0.68	4.65	0.248	0.00001
D6 ditch	7.032	3.59	11.16	2.20	4.78	4.85	7.56	0.86	5.86	2.214	0.00010
R1 pond	0.263	0.13	0.42	0.08	0.18	0.18	0.28	0.03	0.22	2.605	0.00011
R1 stream	4.691	2.39	7.45	1.47	3.19	3.24	5.04	0.57	3.91	11.13	0.00049
R2 1 st stream	6.153	3.14	9.77	1.92	4.19	4.24	6.62	0.75	5.13	20.44	0.00090
R2 2 nd stream	6.310	3.22	10.02	1.97	4.29	4.35	6.78	0.77	5.26	50.68	0.00223
R3 stream	6.636	3.39	10.53	2.07	4.51	4.58	7.14	0.81	5.53	3.180	0.00014
R4 stream	4.706	2.40	7.47	1.47	3.20	3.25	5.06	0.57	3.92	10.47	0.00046

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses carrots, parsley, parsnip and fennel (1 x 1137 g/ha), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-59: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel

Intended use		Carrots, parsley, parsnip and fennel							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1137							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	1.926	1.021	0.697	0.530	-	-	-	-
50%		0.972	0.542	0.377	0.286	-	-	-	-
75%		0.549	0.333	0.240	0.181	-	-	-	-
90%		0.334	0.223	0.164	-	-	-	-	-
None	D4 pond	0.242	0.176	-	-	-	-	-	-
50%		0.144	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.078	1.111	0.761	0.579	-	-	-	-
50%		1.059	0.571	0.392	0.298	-	-	-	-
75%		0.594	0.301	0.210	0.210	-	-	-	-
90%		0.244	0.210	-	-	-	-	-	-
None	D6 ditch	1.905	1.010	0.690	0.525	-	-	-	-
50%		0.952	0.505	0.345	0.262	-	-	-	-

75%		0.495	0.287	0.202	0.196	-	-	-	-
90%		0.264	0.196	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.254	0.184	-	-
50%		-	-	-	-	0.156	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.765	0.953	0.656	0.499
50%		-	-	-	-	0.923	0.527	0.404	0.275
75%		-	-	-	-	0.758	0.527	0.404	0.275
90%		-	-	-	-	0.758	0.527	-	-
None	R2 stream 1 st	-	-	-	-	2.306	1.236	0.847	0.664
50%		-	-	-	-	1.182	0.640	0.440	0.335
75%		-	-	-	-	0.602	0.342	0.237	0.180
90%		-	-	-	-	0.283	0.164	0.115	-
None	R2 stream 2 nd	-	-	-	-	2.376	1.276	0.875	0.666
50%		-	-	-	-	1.223	0.665	0.458	0.348
75%		-	-	-	-	0.647	0.360	0.250	0.190
90%		-	-	-	-	0.305	0.180	0.128	-
None	R3 stream	-	-	-	-	2.446	1.317	0.904	0.687
50%		-	-	-	-	1.266	0.698	0.484	0.373
75%		-	-	-	-	0.694	0.449	0.343	0.233
90%		-	-	-	-	0.648	0.449	0.343	0.233
None	R4 stream	-	-	-	-	1.772	0.959	0.659	0.501
50%		-	-	-	-	1.161	0.808	0.620	0.423

None	R1 stream	-	-	-	-	1.90	1.02	0.71	0.54
50%		-	-	-	-	0.99	0.57	0.43	0.30
75%		-	-	-	-	0.82	0.57	0.43	0.30
90%		-	-	-	-	0.82	0.57	-	-
None	R2 stream 1 st	-	-	-	-	2.48	1.33	0.91	0.71
50%		-	-	-	-	1.27	0.69	0.47	0.36
75%		-	-	-	-	0.65	0.37	0.25	0.19
90%		-	-	-	-	0.30	0.18	0.12	-
None	R2 stream 2 nd	-	-	-	-	2.55	1.37	0.94	0.72
50%		-	-	-	-	1.32	0.72	0.49	0.37
75%		-	-	-	-	0.70	0.39	0.27	0.20
90%		-	-	-	-	0.33	0.19	0.14	-
None	R3 stream	-	-	-	-	2.63	1.42	0.97	0.74
50%		-	-	-	-	1.36	0.75	0.52	0.40
75%		-	-	-	-	0.75	0.48	0.37	0.25
90%		-	-	-	-	0.70	0.48	0.37	0.25
None	R4 stream	-	-	-	-	1.91	1.03	0.71	0.54
50%		-	-	-	-	1.25	0.87	0.67	0.45
75%		-	-	-	-	1.25	0.87	0.67	0.45
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios ab-ove the relevant trigger of 1 are shown in bold

PEC/RAC ratios in carrots, parsley, parnsnip and fennel (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 ditch: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream 1st, R2 stream 2nd, R3 stream: 15m no spray buffer zone + 15 m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle re-

duction + 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R4 stream: 15m no spray buffer zone + 15 vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario and R2 stream.

Table 9.5-60: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel

Intended use		Carrots, parsley, parsnip and fennel							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	1.926	1.021	0.697	0.530	-	-	-	-
50%		0.972	0.542	0.377	0.286	-	-	-	-
75%		0.549	0.333	0.240	0.181	-	-	-	-
90%		0.334	0.223	0.164	-	-	-	-	-
None	D4 pond	0.242	0.176	-	-	-	-	-	-
50%		0.144	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.078	1.111	0.761	0.579	-	-	-	-
50%		1.059	0.571	0.392	0.298	-	-	-	-

75%		0.594	0.301	0.210	0.210	-	-	-	-
90%		0.244	0.210	-	-	-	-	-	-
None	D6 ditch	1.905	1.010	0.690	0.525	-	-	-	-
50%		0.952	0.505	0.345	0.262	-	-	-	-
75%		0.495	0.287	0.202	0.196	-	-	-	-
90%		0.264	0.196	-	-	-	-	-	-
None		R1 pond	-	-	-	-	0.254	0.184	-
50%	-		-	-	-	0.156	-	-	-
75%	-		-	-	-	-	-	-	-
90%	-		-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.765	0.953	0.656	0.499
50%		-	-	-	-	0.923	0.527	0.404	0.275
75%		-	-	-	-	0.758	0.527	0.404	0.275
90%		-	-	-	-	0.758	0.527	-	-
None	R2 stream 1 st	-	-	-	-	2.306	1.236	0.847	0.664
50%		-	-	-	-	1.182	0.640	0.440	0.335
75%		-	-	-	-	0.602	0.342	0.237	0.180
90%		-	-	-	-	0.283	0.164	0.115	-
None	R2 stream 2 nd	-	-	-	-	2.376	1.276	0.875	0.666
50%		-	-	-	-	1.223	0.665	0.458	0.348
75%		-	-	-	-	0.647	0.360	0.250	0.190
90%		-	-	-	-	0.305	0.180	0.128	-
None	R3 stream	-	-	-	-	2.446	1.317	0.904	0.687
50%		-	-	-	-	1.266	0.698	0.484	0.373

75%		-	-	-	-	0.694	0.449	0.343	0.233
90%		-	-	-	-	0.648	0.449	0.343	0.233
None	R4 stream	-	-	-	-	1.772	0.959	0.659	0.501
50%		-	-	-	-	1.161	0.808	0.620	0.423
75%		-	-	-	-	1.161	0.808	0.620	0.423
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	8.374	4.439	3.030	2.304	-	-	-	-
50%		4.226	2.357	1.639	1.243	-	-	-	-
75%		2.387	1.448	1.043	0.787	-	-	-	-
90%		1.452	0.970	0.713	-	-	-	-	-
None	D4 pond	1.052	0.765	-	-	-	-	-	-
50%		0.626	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	9.035	4.830	3.309	2.517	-	-	-	-
50%		4.604	2.483	1.704	1.296	-	-	-	-
75%		2.583	1.309	0.913	0.913	-	-	-	-
90%		1.061	0.913	-	-	-	-	-	-
None	D6 ditch	8.283	4.391	3.000	2.283	-	-	-	-
50%		4.139	2.196	1.500	1.139	-	-	-	-
75%		2.152	1.248	0.878	0.852	-	-	-	-
90%		1.148	0.852	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-61: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel (1 x 1137 g/ha)

Intended use		Carrots, parsley, parsnip and fennel	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.153
90%		0.155	-
75%	R3 stream	-	0.212
90%		0.229	-
75%	R4 stream	-	0.153
90%		0.158	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.67
90%		0.67	-
75%	R3 stream	-	0.92
90%		0.99	-
75%	R4 stream	-	0.67
90%		0.69	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in carrots, parsley, parsnip and fennel (1 x 1137 g/ha) are <1 when risk mitigation options are considered:
 D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
 D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction
 D4 stream, D6 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
 R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction
 R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-6216: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in lupine (legumes 1 x 1183 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Pimephales promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Chironomus riparius</i>	<i>Lemna gibba</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 196	NOEC 6.3	NOEC geomean 32	EC ₅₀ 147	NOEC 14.5	ErC ₅₀ 9.3	NOEC 82	ErC ₅₀ 12		NOEC 227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	6.118	3.12	9.71	1.91	4.16	4.22	6.58	0.75	5.10	3.544	0.00016
D4 pond	0.247	0.13	0.39	0.08	0.17	0.17	0.27	0.03	0.21	1.214	0.00005

Group		Fish acute	Fish pro- longed	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell- er pro- longed
D4 stream	4.902	2.50	7.78	1.53	3.33	3.38	5.27	0.60	4.09	0.177	0.00001
D5 pond	0.247	0.13	0.39	0.08	0.17	0.17	0.27	0.03	0.21	1.067	0.00005
D5 stream	5.091	2.60	8.08	1.59	3.46	3.51	5.47	0.62	4.24	0.142	0.00001
D6 ditch	6.124	3.12	9.72	1.91	4.17	4.22	6.58	0.75	5.10	3.801	0.00017
R1 pond	0.255	0.13	0.40	0.08	0.17	0.18	0.27	0.03	0.21	1.872	0.00008
R1 stream	4.235	2.16	6.72	1.32	2.88	2.92	4.55	0.52	3.53	3.507	0.00015
R2 stream	5.630	2.87	8.94	1.76	3.83	3.88	6.05	0.69	4.69	9.312	0.00041
R3 stream	5.991	3.06	9.51	1.87	4.08	4.13	6.44	0.73	4.99	63.81	0.00281
R4 stream	4.230	2.16	6.71	1.32	2.88	2.92	4.55	0.52	3.53	28.17	0.00124

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended use lupine, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-6317: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in lupine

Intended use		Lupine					
Active substance		pendimethalin					
Application rate (g/ha)		1 × 1183					
Nozzle re- duction	No spray buffer (m)	5	10	15	5	10	15
	Vegetated filter strip (m)	None	None	None	5	10	15
None	D3 ditch	2.004	1.062	0.726	-	-	-

50%		1.001	0.553	-	-	-	-
75%		0.554	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	2.097	1.120	0.767	-	-	-
50%		1.065	0.573	-	-	-	-
75%		0.549	-	-	-	-	-
90%		-	-	-	-	-	-
None	D5 stream	2.170	1.157	0.792	-	-	-
50%		1.098	0.5889	-	-	-	-
75%		0.5626	-	-	-	-	-
90%		-	-	-	-	-	-
None	D6 ditch	2.006	1.063	0.726	-	-	-
50%		1.002	0.546	-	-	-	-
75%		0.547	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.830	0.986	0.678
50%		-	-	-	0.954	0.527	-
75%		-	-	-	0.697	-	-
90%		-	-	-	-	-	-
None	R2 stream	-	-	-	2.438	1.308	0.897
50%		-	-	-	1.252	0.680	-
75%		-	-	-	0.660	-	-
90%		-	-	-	-	-	-
None	R3 stream	-	-	-	2.531	1.344	0.918

50%		-	-	-	1.282	0.701	-
75%		-	-	-	0.730	-	-
90%		-	-	-	-	-	-
None	R4 stream	-	-	-	1.824	0.983	0.675
50%		-	-	-	1.198	0.836	-
75%		-	-	-	1.198	-	-
90%		-	-	-	-	-	-
RAC (µg/L)							
0.93 (P. subcapitata)		PEC/RAC ratio					
None	D3 ditch	2.15	1.14	0.78	-	-	-
50%		1.08	0.59	-	-	-	-
75%		0.60	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	2.25	1.20	0.82	-	-	-
50%		1.15	0.62	-	-	-	-
75%		0.59	-	-	-	-	-
90%		-	-	-	-	-	-
None	D5 stream	2.33	1.24	0.85	-	-	-
50%		1.18	0.63	-	-	-	-
75%		0.60	-	-	-	-	-
90%		-	-	-	-	-	-
None	D6 ditch	2.16	1.14	0.78	-	-	-
50%		1.08	0.59	-	-	-	-
75%		0.59	-	-	-	-	-

90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.97	1.06	0.73
50%		-	-	-	1.03	0.57	-
75%		-	-	-	0.75	-	-
90%		-	-	-	-	-	-
None	R2 stream	-	-	-	2.62	1.41	0.96
50%		-	-	-	1.35	0.73	-
75%		-	-	-	0.71	-	-
90%		-	-	-	-	-	-
None	R3 stream	-	-	-	2.72	1.45	0.99
50%		-	-	-	1.38	0.75	-
75%		-	-	-	0.78	-	-
90%		-	-	-	-	-	-
None	R4 stream	-	-	-	1.96	1.06	0.73
50%		-	-	-	1.29	0.90	-
75%		-	-	-	1.29	-	-
90%		-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Lupine							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1183							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.004	1.062	0.726	0.560	-	-	-	-

50%		1.001	0.553	0.389	0.296	-	-	-	-
75%		0.554	0.336	0.242	0.184	-	-	-	-
90%		0.338	0.225	0.167	-	-	-	-	-
None	D4 pond	0.254	0.185	-	-	-	-	-	-
50%		0.152	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.097	1.120	0.767	0.591	-	-	-	-
50%		1.065	0.573	0.399	0.303	-	-	-	-
75%		0.549	0.304	0.209	0.205	-	-	-	-
90%		0.244	0.205	-	-	-	-	-	-
None	D5 pond	0.250	0.181	-	-	-	-	-	-
50%		0.149	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.170	1.157	0.792	0.611	-	-	-	-
50%		1.098	0.5889	0.409	0.312	-	-	-	-
75%		0.5626	0.309	0.213	0.162	-	-	-	-
90%		0.245	0.137	-	-	-	-	-	-
None	D6 ditch	2.006	1.063	0.726	0.560	-	-	-	-
50%		1.002	0.546	0.384	0.293	-	-	-	-
75%		0.547	0.331	0.257	0.257	-	-	-	-
90%		0.334	0.257	0.257	0.257	-	-	-	-
None	R1 pond	-	-	-	-	0.255	0.185	-	-

50%		-	-	-	-	0.154	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.830	0.986	0.678	0.523
50%		-	-	-	-	0.954	0.527	0.376	0.281
75%		-	-	-	-	0.697	0.490	0.376	0.256
90%		-	-	-	-	0.697	0.490	0.376	0.256
None	R2 stream	-	-	-	-	2.438	1.308	0.897	0.692
50%		-	-	-	-	1.252	0.680	0.475	0.362
75%		-	-	-	-	0.660	0.372	0.258	0.196
90%		-	-	-	-	0.310	0.181	0.127	-
None	R3 stream	-	-	-	-	2.531	1.344	0.918	0.708
50%		-	-	-	-	1.282	0.701	0.492	0.375
75%		-	-	-	-	0.730	0.517	0.397	0.271
90%		-	-	-	-	0.730	0.517	0.397	0.271
None	R4 stream	-	-	-	-	1.824	0.983	0.675	0.521
50%		-	-	-	-	1.198	0.836	0.651	0.445
75%		-	-	-	-	1.198	0.836	0.651	0.445
90%		-	-	-	-	1.198	0.836	0.651	0.445
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.15	1.14	0.78	0.60	-	-	-	-
50%		1.08	0.59	0.42	0.32	-	-	-	-
75%		0.60	0.36	0.26	0.20	-	-	-	-

90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.97	1.06	0.73	0.56
50%		-	-	-	-	1.03	0.57	0.40	0.30
75%		-	-	-	-	0.75	0.53	0.40	0.28
90%		-	-	-	-	0.75	0.53	0.40	0.28
None	R2 stream	-	-	-	-	2.62	1.41	0.96	0.74
50%		-	-	-	-	1.35	0.73	0.51	0.39
75%		-	-	-	-	0.71	0.40	0.28	0.21
90%		-	-	-	-	0.33	0.19	0.14	-
None	R3 stream	-	-	-	-	2.72	1.45	0.99	0.76
50%		-	-	-	-	1.38	0.75	0.53	0.40
75%		-	-	-	-	0.78	0.56	0.43	0.29
90%		-	-	-	-	0.78	0.56	0.43	0.29
None	R4 stream	-	-	-	-	1.96	1.06	0.73	0.56
50%		-	-	-	-	1.29	0.90	0.70	0.48
75%		-	-	-	-	1.29	0.90	0.70	0.48
90%		-	-	-	-	1.29	0.90	0.70	0.48

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in lupine (**1 x 1183 g/ha**) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D5 stream and D6 ditch: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream, R2 stream and R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction.

R4 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L

(mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-64: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in lupine

Intended use		Lupine							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1183							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.004	1.062	0.726	0.560	-	-	-	-
50%		1.001	0.553	0.389	0.296	-	-	-	-
75%		0.554	0.336	0.242	0.184	-	-	-	-
90%		0.338	0.225	0.167	-	-	-	-	-
None	D4 pond	0.254	0.185	-	-	-	-	-	-
50%		0.152	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.097	1.120	0.767	0.591	-	-	-	-
50%		1.065	0.573	0.399	0.303	-	-	-	-
75%		0.549	0.304	0.209	0.205	-	-	-	-
90%		0.244	0.205	-	-	-	-	-	-
None	D5 pond	0.250	0.181	-	-	-	-	-	-
50%		0.149	-	-	-	-	-	-	-

75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.170	1.157	0.792	0.611	-	-	-	-
50%		1.098	0.5889	0.409	0.312	-	-	-	-
75%		0.5626	0.309	0.213	0.162	-	-	-	-
90%		0.245	0.137	-	-	-	-	-	-
None	D6 ditch	2.006	1.063	0.726	0.560	-	-	-	-
50%		1.002	0.546	0.384	0.293	-	-	-	-
75%		0.547	0.331	0.257	0.257	-	-	-	-
90%		0.334	0.257	0.257	0.257	-	-	-	-
None	R1 pond	-	-	-	-	0.255	0.185	-	-
50%		-	-	-	-	0.154	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.830	0.986	0.678	0.523
50%		-	-	-	-	0.954	0.527	0.376	0.281
75%		-	-	-	-	0.697	0.490	0.376	0.256
90%		-	-	-	-	0.697	0.490	0.376	0.256
None	R2 stream	-	-	-	-	2.438	1.308	0.897	0.692
50%		-	-	-	-	1.252	0.680	0.475	0.362
75%		-	-	-	-	0.660	0.372	0.258	0.196
90%		-	-	-	-	0.310	0.181	0.127	-
None	R3 stream	-	-	-	-	2.531	1.344	0.918	0.708
50%		-	-	-	-	1.282	0.701	0.492	0.375

None	D5 stream	9.435	5.030	3.443	2.657	-	-	-	-
50%		4.774	2.560	1.778	1.357	-	-	-	-
75%		2.446	1.343	0.926	0.704	-	-	-	-
90%		1.065	0.596	-	-	-	-	-	-
None	D6 ditch	8.722	4.622	3.157	2.435	-	-	-	-
50%		4.357	2.374	1.670	1.274	-	-	-	-
75%		2.378	1.439	1.117	1.117	-	-	-	-
90%		1.452	1.117	1.117	1.117	-	-	-	-
None	R1 pond	-	-	-	-	1.109	0.804	-	-
50%		-	-	-	-	0.670	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	7.957	4.287	2.948	2.274
50%		-	-	-	-	4.148	2.291	1.635	1.222
75%		-	-	-	-	3.030	2.130	1.635	1.113
90%		-	-	-	-	3.030	2.130	1.635	1.113
None	R2 stream	-	-	-	-	10.600	5.687	3.900	3.009
50%		-	-	-	-	5.443	2.957	2.065	1.574
75%		-	-	-	-	2.870	1.617	1.122	0.852
90%		-	-	-	-	1.348	0.787	0.552	-
None	R3 stream	-	-	-	-	11.004	5.843	3.991	3.078
50%		-	-	-	-	5.574	3.048	2.139	1.630
75%		-	-	-	-	3.174	2.248	1.726	1.178
90%		-	-	-	-	3.174	2.248	1.726	1.178

None	R4 stream	-	-	-	-	7.930	4.274	2.935	2.265
50%		-	-	-	-	5.209	3.635	2.830	1.935
75%		-	-	-	-	5.209	3.635	2.830	1.935
90%		-	-	-	-	5.209	3.635	2.830	1.935

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-65: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in lupine (1 x 1183 g/ha)

Intended use		Lupine	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1183	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.161
90%		0.162	-
75%	R2 stream	-	0.196
90%		0.181	-
75%	R3 stream	-	0.215
90%		0.324	-
75%	R4 stream	-	0.159
90%		0.180	-
RAC (µg/L)			
0.23		PEC/RAC ratio	

75%	R1 stream	-	0.7
90%		0.70	-
75%	R2 stream	-	0.85
90%		0.79	-
75%	R3 stream	-	0.93
90%		1.41	-
75%	R4 stream	-	0.69
90%		0.78	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in lupine (1 x1183 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone+ 10m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries.

Table 9.5-6618: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 455 g/ha)

Group	Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell. prolonged
Test species	<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
Endpoint		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	E _r C ₅₀	NOEC	ErC ₅₀		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12		227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D2 ditch	2.883	1.47	4.58	0.90	1.96	1.99	3.10	0.35	2.40	4.308	0.00019
D2 stream	2.565	1.31	4.07	0.80	1.74	1.77	2.76	0.31	2.14	3.837	0.00017
D3 ditch	2.878	1.47	4.57	0.90	1.96	1.98	3.09	0.35	2.40	2.610	0.00011
D4 pond	0.098	0.05	0.16	0.03	0.07	0.07	0.11	0.01	0.08	0.302	0.00001
D4 stream	2.461	1.26	3.91	0.77	1.67	1.70	2.65	0.30	2.05	0.498	0.00002
D5 pond	0.098	0.05	0.16	0.03	0.07	0.07	0.11	0.01	0.08	0.281	0.00001
D5 stream	2.656	1.36	4.22	0.83	1.81	1.83	2.86	0.32	2.21	0.682	0.00003
R1 pond	0.099	0.05	0.16	0.03	0.07	0.07	0.11	0.01	0.08	0.456	0.00002
R1 stream	1.882	0.96	2.99	0.59	1.28	1.30	2.02	0.23	1.57	0.664	0.00003
R3 stream	2.646	1.35	4.20	0.83	1.80	1.82	2.85	0.32	2.21	1.743	0.00008

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses winter oilseed rape (1 x 455 g/ha), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-19: Aquatic organisms: PEC calculation and acceptability of risk ($PEC/RAC < 1$) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape

Intended use		Winter oilseed rape			
Active substance		pendimethalin			
Application rate (g/ha)		1 × 455			
Nozzle reduction	No spray buffer (m)	5	10	5	10
	Vegetated filter strip (m)	None	None	5	10
None	D2 ditch	0.781	-		
50%		-	-		
75%		-	-		
90%		-	-		
None	D2 stream	0.938	0.498		
50%		0.470	-		
75%		-	-		
90%		-	-		
None	D3 ditch	0.780	-	-	-
50%		-	-	-	-
75%		-	-	-	-
90%		-	-	-	-
None	D4 stream	0.901	-	-	-
50%		-	-	-	-
75%		-	-	-	-

90%		-	-	-	-
None	D5 stream	0.972	0.515	-	-
50%		0.486	-	-	-
75%		-	-	-	-
90%		-	-	-	-
None	R1 stream	-	-	0.698	-
50%		-	-	-	-
75%		-	-	-	-
90%		-	-	-	-
None	R3 stream	-	-	0.971	0.516
50%		-	-	0.488	-
75%		-	-	-	-
90%		-	-	-	-
RAC (µg/L)					
0.93 (<i>P. subcapitata</i>)		PEC/RAC ratio			
None	D2 ditch	0.84	-	-	-
50%		-	-	-	-
75%		-	-	-	-
90%		-	-	-	-
None	D2 stream	1.01	0.54	-	-
50%		0.51	-	-	-
75%		-	-	-	-
90%		-	-	-	-
None	D3 ditch	0.84	-	-	-

50%		-	-	-	-
75%		-	-	-	-
90%		-	-	-	-
None	D4 stream	0.97	-	-	-
50%		-	-	-	-
75%		-	-	-	-
90%		-	-	-	-
None	D5 stream	1.05	0.55	-	-
50%		0.52	-	-	-
75%		-	-	-	-
90%		-	-	-	-
None	R1 stream	-	-	0.75	-
50%		-	-	-	-
75%		-	-	-	-
90%		-	-	-	-
None	R3 stream	-	-	1.04	0.55
50%		-	-	0.52	-
75%		-	-	-	-
90%		-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-67: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape

Intended use	Winter oil seed rape
Active substance	pendimethalin

Application rate (g/ha)		1 × 455							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D2 ditch	0.781	0.424	0.292	0.222	-	-	-	-
50%		0.413	0.235	0.166	-	-	-	-	-
75%		0.245	0.150	-	-	-	-	-	-
90%		0.154	-	-	-	-	-	-	-
None	D2 stream	0.938	0.498	0.345	0.262	-	-	-	-
50%		0.470	0.253	0.173	0.132	-	-	-	-
75%		0.239	0.127	-	-	-	-	-	-
90%		0.097	-	-	-	-	-	-	-
None	D3 ditch	0.780	0.419	0.286	0.218	-	-	-	-
50%		0.395	0.217	0.151	-	-	-	-	-
75%		0.218	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	0.901	0.485	0.331	0.252	-	-	-	-
50%		0.458	0.245	0.169	0.128	-	-	-	-
75%		0.240	0.134	-	-	-	-	-	-
90%		0.119	-	-	-	-	-	-	-
None	D5 stream	0.972	0.515	0.357	0.272	-	-	-	-
50%		0.486	0.262	0.179	0.136	-	-	-	-
75%		0.249	-	-	-	-	-	-	-
90%		0.125	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	0.698	0.381	0.262	0.199

50%		-	-	-	-	0.368	0.203	0.140	-
75%		-	-	-	-	0.242	-	-	-
90%		-	-	-	-	0.242	-	-	-
None	R3 stream	-	-	-	-	0.971	0.516	0.358	0.272
50%		-	-	-	-	0.488	0.264	0.180	0.137
75%		-	-	-	-	0.257	-	-	-
90%		-	-	-	-	0.199	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D2 ditch	0.84	0.46	0.31	0.24	-	-	-	-
50%		0.44	0.25	0.18	-	-	-	-	-
75%		0.26	0.16	-	-	-	-	-	-
90%		0.17	-	-	-	-	-	-	-
None	D2 stream	1.01	0.54	0.37	0.28	-	-	-	-
50%		0.51	0.27	0.19	0.14	-	-	-	-
75%		0.26	0.14	-	-	-	-	-	-
90%		0.10	-	-	-	-	-	-	-
None	D3 ditch	0.84	0.45	0.31	0.23	-	-	-	-
50%		0.42	0.23	0.16	-	-	-	-	-
75%		0.23	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	0.97	0.52	0.36	0.27	-	-	-	-
50%		0.49	0.26	0.18	0.14	-	-	-	-
75%		0.26	0.14	-	-	-	-	-	-

90%		0.13	-	-	-	-	-	-	-
None	D5 stream	1.05	0.55	0.38	0.29	-	-	-	-
50%		0.52	0.28	0.19	0.15	-	-	-	-
75%		0.27	-	-	-	-	-	-	-
90%		0.13	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	0.75	0.41	0.28	0.21
50%		-	-	-	-	0.40	0.22	0.15	-
75%		-	-	-	-	0.26	-	-	-
90%		-	-	-	-	0.26	-	-	-
None	R3 stream	-	-	-	-	1.04	0.55	0.38	0.29
50%		-	-	-	-	0.52	0.28	0.19	0.15
75%		-	-	-	-	0.28	-	-	-
90%		-	-	-	-	0.21	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter oilseed rape (1 x 455 g/ha) are <1 when risk mitigation options are considered:

D2 ditch, D3 ditch and D4 stream: 5m no spray buffer zone

D2 stream and D5 stream: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 stream: 5m no spray buffer zone + 5m vegetative strip

R3 stream: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction.

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios.

Table 9.5-68: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape

Intended use		Winter oil seed rape							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 455							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D2 ditch	0.781	0.424	0.292	0.222	-	-	-	-
50%		0.413	0.235	0.166	-	-	-	-	-
75%		0.245	0.150	-	-	-	-	-	-
90%		0.154	-	-	-	-	-	-	-
None	D2 stream	0.938	0.498	0.345	0.262	-	-	-	-
50%		0.470	0.253	0.173	0.132	-	-	-	-
75%		0.239	0.127	-	-	-	-	-	-
90%		0.097	-	-	-	-	-	-	-
None	D3 ditch	0.780	0.419	0.286	0.218	-	-	-	-
50%		0.395	0.217	0.151	-	-	-	-	-
75%		0.218	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	0.901	0.485	0.331	0.252	-	-	-	-
50%		0.458	0.245	0.169	0.128	-	-	-	-
75%		0.240	0.134	-	-	-	-	-	-
90%		0.119	-	-	-	-	-	-	-

None	D5 stream	0.972	0.515	0.357	0.272	-	-	-	-
50%		0.486	0.262	0.179	0.136	-	-	-	-
75%		0.249	-	-	-	-	-	-	-
90%		0.125	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	0.698	0.381	0.262	0.199
50%		-	-	-	-	0.368	0.203	0.140	-
75%		-	-	-	-	0.242	-	-	-
90%		-	-	-	-	0.242	-	-	-
None	R3 stream	-	-	-	-	0.971	0.516	0.358	0.272
50%		-	-	-	-	0.488	0.264	0.180	0.137
75%		-	-	-	-	0.257	-	-	-
90%		-	-	-	-	0.199	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D2 ditch	3.396	1.843	1.270	0.965	-	-	-	-
50%		1.796	1.022	0.722	-	-	-	-	-
75%		1.065	0.652	-	-	-	-	-	-
90%		0.670	-	-	-	-	-	-	-
None	D2 stream	4.078	2.165	1.500	1.139	-	-	-	-
50%		2.043	1.100	0.752	0.574	-	-	-	-
75%		1.039	0.552	-	-	-	-	-	-
90%		0.422	-	-	-	-	-	-	-
None	D3 ditch	3.391	1.822	1.243	0.948	-	-	-	-
50%		1.717	0.943	0.657	-	-	-	-	-

75%		0.948	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.917	2.109	1.439	1.096	-	-	-	-
50%		1.991	1.065	0.735	0.557	-	-	-	-
75%		1.043	0.583	-	-	-	-	-	-
90%		0.517	-	-	-	-	-	-	-
None	D5 stream	4.226	2.239	1.552	1.183	-	-	-	-
50%		2.113	1.139	0.778	0.591	-	-	-	-
75%		1.083	-	-	-	-	-	-	-
90%		0.543	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	3.035	1.657	1.139	0.865
50%		-	-	-	-	1.600	0.883	0.609	-
75%		-	-	-	-	1.052	-	-	-
90%		-	-	-	-	1.052	-	-	-
None	R3 stream	-	-	-	-	4.222	2.243	1.557	1.183
50%		-	-	-	-	2.122	1.148	0.783	0.596
75%		-	-	-	-	1.117	-	-	-
90%		-	-	-	-	0.865	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-69: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 455 g/ha)

Intended use	Winter oilseed rape
Active substance	pendimethalin
Application rate (g/ha)	1 × 455

Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
None	R1 stream	0.381	0.199
50 %		0.203	-
None	R3 stream	0.523	0.272
50 %		0.264	0.137
75 %		0.145	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
None	R1 stream	1.66	0.87
50 %		0.88	-
None	R3 stream	2.27	1.18
50 %		1.15	0.60
75 %		0.63	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter oilseed rape (1 x 455 g/ha) are <1 when risk mitigation options are considered:

D2 ditch: 20 m no spray buffer zone or 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D2 stream, D4 stream: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D3 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

D5 stream: 15m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

Table 9.5-7020: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 910 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dweller prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 196	NOEC 6.3	NOEC geomean 32	EC ₅₀ 147	NOEC 14.5	ErC ₅₀ 9.3	NOEC 82	ErC ₅₀ 12		NOEC 227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D2 ditch	5.769	2.94	9.16	1.80	3.92	3.98	6.20	0.70	4.81	8.779	0.00039
D2 stream	5.132	2.62	8.15	1.60	3.49	3.54	5.52	0.63	4.28	7.820	0.00034
D3 ditch	5.719	2.92	9.08	1.79	3.89	3.94	6.15	0.70	4.77	4.368	0.00019
D4 pond	0.196	0.10	0.31	0.06	0.13	0.14	0.21	0.02	0.16	0.682	0.00003
D4 stream	4.925	2.51	7.82	1.54	3.35	3.40	5.30	0.60	4.10	1.018	0.00004
D5 pond	0.196	0.10	0.31	0.06	0.13	0.14	0.21	0.02	0.16	0.566	0.00002
D5 stream	5.314	2.71	8.43	1.66	3.61	3.66	5.71	0.65	4.43	1.365	0.00006
R1 pond	0.197	0.10	0.31	0.06	0.13	0.14	0.21	0.02	0.16	1.119	0.00005
R1 stream	3.765	1.92	5.98	1.18	2.56	2.60	4.05	0.46	3.14	2.614	0.00012

Group		Fish acute	Fish pro- longed	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell- er pro- longed
R3 stream	5.265	2.69	8.36	1.65	3.58	3.63	5.66	0.64	4.39	26.45	0.00116

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses winter oilseed rape (1 x 910 g/ha), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-21: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 910 g/ha)

Intended use		Winter oilseed rape						
Active substance		pendimethalin						
Application rate (g/ha)		1 x 910						
Nozzle re- duction	No-spray buffer (m)	5	10	15	5	10	15	
	Vegetated filter strip (m)	None	None	None	5	10	15	
None	D2 ditch	1.563	0.837	-	-	-	-	
50%		0.815	-	-	-	-	-	
75%		-	-	-	-	-	-	
90%		-	-	-	-	-	-	
None	D2 stream	1.877	0.996	0.680	-	-	-	
50%		0.940	0.499	-	-	-	-	
75%		0.471	-	-	-	-	-	
90%		-	-	-	-	-	-	
None	D3 ditch	1.549	0.821	-	-	-	-	

50%		0.774	-	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	1.802	0.956	0.653	-	-	-
50%		0.903	0.490	-	-	-	-
75%		0.491	-	-	-	-	-
90%		-	-	-	-	-	-
None	D5 stream	1.944	1.031	-	-	-	-
50%		0.973	0.517	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.400	0.755	-
50%		-	-	-	0.730	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	R3 stream	-	-	-	1.940	1.033	0.708
50%		-	-	-	0.991	0.542	-
75%		-	-	-	0.876	-	-
90%		-	-	-	-	-	-
RAC (µg/L)							
0.93 (<i>P. subcapitata</i>)		PEC/RAC ratio					
None	D2 ditch	1.68	0.90	-	-	-	-
50%		0.88	-	-	-	-	-
75%		-	-	-	-	-	-

90%		-	-	-	-	-	-
None	D2 stream	2.02	1.07	0.73	-	-	-
50%		1.01	0.54	-	-	-	-
75%		0.51	-	-	-	-	-
90%		-	-	-	-	-	-
None	D3 ditch	1.67	0.88	-	-	-	-
50%		0.83	-	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	1.94	1.03	0.70	-	-	-
50%		0.97	0.53	-	-	-	-
75%		0.53	-	-	-	-	-
90%		-	-	-	-	-	-
None	D5 stream	2.09	1.11	-	-	-	-
50%		1.05	0.56	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.51	0.81	-
50%		-	-	-	0.78	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	R3 stream	-	-	-	2.09	1.11	0.76
50%		-	-	-	1.07	0.58	-
75%		-	-	-	0.94	-	-

90%		-	-	-	-	-	-
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PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-71: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape

Intended use		Winter oil seed rape							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 910							
Nozzle re-duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D2 ditch	1.563	0.837	0.586	0.445	-	-	-	-
50%		0.815	0.472	0.332	0.252	-	-	-	-
75%		0.493	0.301	0.217	0.163	-	-	-	-
90%		0.311	0.213	-	-	-	-	-	-
None	D2 stream	1.877	0.996	0.680	0.525	-	-	-	-
50%		0.940	0.499	0.346	0.263	-	-	-	-
75%		0.471	0.254	0.174	0.132	-	-	-	-
90%		0.193	0.103	-	-	-	-	-	-
None	D3 ditch	1.549	0.821	0.569	0.433	-	-	-	-
50%		0.774	0.431	0.301	0.228	-	-	-	-
75%		0.433	0.262	0.188	-	-	-	-	-
90%		0.264	0.176	-	-	-	-	-	-
None	D4 stream	1.802	0.956	0.653	0.504	-	-	-	-
50%		0.903	0.490	0.344	0.261	-	-	-	-

75%		0.491	0.272	0.190	-	-	-	-	-
90%		0.241	0.149	-	-	-	-	-	-
None	D5 stream	1.944	1.031	0.715	0.543	-	-	-	-
50%		0.973	0.517	0.358	0.272	-	-	-	-
75%		0.498	0.279	0.196	0.149	-	-	-	-
90%		0.249	0.158	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.400	0.755	0.527	0.400
50%		-	-	-	-	0.730	0.408	0.296	0.215
75%		-	-	-	-	0.730	0.386	0.296	-
90%		-	-	-	-	0.554	0.386	-	-
None	R3 stream	-	-	-	-	1.940	1.033	0.708	0.546
50%		-	-	-	-	0.991	0.542	0.380	0.288
75%		-	-	-	-	0.876	0.404	0.310	0.212
90%		-	-	-	-	0.580	0.404	0.310	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D2 ditch	1.68	0.90	0.63	0.48	-	-	-	-
50%		0.88	0.51	0.36	0.27	-	-	-	-
75%		0.53	0.32	0.23	0.18	-	-	-	-
90%		0.33	0.23	-	-	-	-	-	-
None	D2 stream	2.02	1.07	0.73	0.56	-	-	-	-
50%		1.01	0.54	0.37	0.28	-	-	-	-
75%		0.51	0.27	0.19	0.14	-	-	-	-
90%		0.21	0.11	-	-	-	-	-	-

None	D3 ditch	1.67	0.88	0.61	0.47	-	-	-	-
50%		0.83	0.46	0.32	0.25	-	-	-	-
75%		0.47	0.28	0.20	-	-	-	-	-
90%		0.28	0.19	-	-	-	-	-	-
None	D4 stream	1.94	1.03	0.70	0.54	-	-	-	-
50%		0.97	0.53	0.37	0.28	-	-	-	-
75%		0.53	0.29	0.20	-	-	-	-	-
90%		0.26	0.16	-	-	-	-	-	-
None	D5 stream	2.09	1.11	0.77	0.58	-	-	-	-
50%		1.05	0.56	0.38	0.29	-	-	-	-
75%		0.54	0.30	0.21	0.16	-	-	-	-
90%		0.27	0.17	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.51	0.81	0.57	0.43
50%		-	-	-	-	0.78	0.44	0.32	0.23
75%		-	-	-	-	0.78	0.42	0.32	-
90%		-	-	-	-	0.60	0.42	-	-
None	R3 stream	-	-	-	-	2.09	1.11	0.76	0.59
50%		-	-	-	-	1.07	0.58	0.41	0.31
75%		-	-	-	-	0.94	0.43	0.33	0.23
90%		-	-	-	-	0.62	0.43	0.33	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios ab-ove the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter oilseed rape (1 x 910 g/ha) are <1 when risk mitigation options are considered:

D2 ditch, D3 ditch: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reaction

D2 stream, **D5 stream**: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

D4 stream: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D5 stream: 10m no spray buffer zone + 50% nozzles reduction

R1 stream: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone +5m vegetative strip + 50% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios.

Table 9.5-72: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape

Intended use		Winter oil seed rape							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 910							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D2 ditch	1.563	0.837	0.586	0.445	-	-	-	-
50%		0.815	0.472	0.332	0.252	-	-	-	-
75%		0.493	0.301	0.217	0.163	-	-	-	-
90%		0.311	0.213	-	-	-	-	-	-
None	D2 stream	1.877	0.996	0.680	0.525	-	-	-	-
50%		0.940	0.499	0.346	0.263	-	-	-	-
75%		0.471	0.254	0.174	0.132	-	-	-	-
90%		0.193	0.103	-	-	-	-	-	-
None	D3 ditch	1.549	0.821	0.569	0.433	-	-	-	-
50%		0.774	0.431	0.301	0.228	-	-	-	-

75%		0.433	0.262	0.188	-	-	-	-	-
90%		0.264	0.176	-	-	-	-	-	-
None	D4 stream	1.802	0.956	0.653	0.504	-	-	-	-
50%		0.903	0.490	0.344	0.261	-	-	-	-
75%		0.491	0.272	0.190	-	-	-	-	-
90%		0.241	0.149	-	-	-	-	-	-
None	D5 stream	1.944	1.031	0.715	0.543	-	-	-	-
50%		0.973	0.517	0.358	0.272	-	-	-	-
75%		0.498	0.279	0.196	0.149	-	-	-	-
90%		0.249	0.158	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.400	0.755	0.527	0.400
50%		-	-	-	-	0.730	0.408	0.296	0.215
75%		-	-	-	-	0.730	0.386	0.296	-
90%		-	-	-	-	0.554	0.386	-	-
None	R3 stream	-	-	-	-	1.940	1.033	0.708	0.546
50%		-	-	-	-	0.991	0.542	0.380	0.288
75%		-	-	-	-	0.876	0.404	0.310	0.212
90%		-	-	-	-	0.580	0.404	0.310	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D2 ditch	6.796	3.639	2.548	1.935	-	-	-	-
50%		3.543	2.052	1.443	1.096	-	-	-	-
75%		2.143	1.309	0.943	0.709	-	-	-	-
90%		1.352	0.926	-	-	-	-	-	-

None	D2 stream	8.161	4.330	2.957	2.283	-	-	-	-
50%		4.087	2.170	1.504	1.143	-	-	-	-
75%		2.048	1.104	0.757	0.574	-	-	-	-
90%		0.839	0.448	-	-	-	-	-	-
None	D3 ditch	6.735	3.570	2.474	1.883	-	-	-	-
50%		3.365	1.874	1.309	0.991	-	-	-	-
75%		1.883	1.139	0.817	-	-	-	-	-
90%		1.148	0.765	-	-	-	-	-	-
None	D4 stream	7.835	4.157	2.839	2.191	-	-	-	-
50%		3.926	2.130	1.496	1.135	-	-	-	-
75%		2.135	1.183	0.826	-	-	-	-	-
90%		1.048	0.648	-	-	-	-	-	-
None	D5 stream	8.452	4.483	3.109	2.361	-	-	-	-
50%		4.230	2.248	1.557	1.183	-	-	-	-
75%		2.165	1.213	0.852	0.648	-	-	-	-
90%		1.083	0.687	-	-	-	-	-	-
None	R1 stream	-	-	-	-	6.087	3.283	2.291	1.739
50%		-	-	-	-	3.174	1.774	1.287	0.935
75%		-	-	-	-	3.174	1.678	1.287	-
90%		-	-	-	-	2.409	1.678	-	-
None	R3 stream	-	-	-	-	8.435	4.491	3.078	2.374
50%		-	-	-	-	4.309	2.357	1.652	1.252
75%		-	-	-	-	3.809	1.757	1.348	0.922
90%		-	-	-	-	2.522	1.757	1.348	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-73: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 910 g/ha)

Intended use		Winter oilseed rape	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 910	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
None	R1 stream	-	0.212
50 %		0.226	-
None	R3 stream	-	-
50 %		-	0.284
75 %		0.305	0.162
RAC (µg/L)			
0.23		PEC/RAC ratio	
None	R1 stream	-	0.92
50 %		0.98	-
None	R3 stream	-	-
50 %		-	1.23
75 %		1.33	0.70

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter oilseed rape (1 x 910 g/ha) are <1 when risk mitigation options are considered:

D2 ditch, D3 ditch, D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
 D2 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction
 R1 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction
 R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

Table 9.5-7422: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop **in pre emergence** (leafy vegetables 1st and 2nd crop 1 x 1590 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
Test species		<i>O.mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P.subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 1 st ditch	9.944	5.07	15.78	3.11	6.76	6.86	10.69	1.21	8.29	5.752	0.00025
D3 2 nd ditch	9.969	5.09	15.82	3.12	6.78	6.88	10.72	1.22	8.31	5.635	0.00025
D4 pond	0.343	0.18	0.54	0.11	0.23	0.24	0.37	0.04	0.29	1.311	0.00006
D4 stream	7.805	3.98	12.39	2.44	5.31	5.38	8.39	0.95	6.50	0.346	0.00002
D6 ditch	10.04	5.12	15.94	3.14	6.83	6.92	10.80	1.22	8.37	6.119	0.00027

Group		Fish acute	Fish pro- longed	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell- er pro- longed
R1 1 st pond	0.415	0.21	0.66	0.13	0.28	0.29	0.45	0.05	0.35	2.980	0.00013
R1 2 nd pond	0.598	0.31	0.95	0.19	0.41	0.41	0.64	0.07	0.50	5.482	0.00024
R1 1 st stream	6.562	3.35	10.42	2.05	4.46	4.53	7.06	0.80	5.47	30.35	0.00134
R1 1 st stream	6.506	3.32	10.33	2.03	4.43	4.49	7.00	0.79	5.42	9.660	0.00042
R2 1 st stream	8.606	4.39	13.66	2.69	5.85	5.94	9.25	1.05	7.17	26.24	0.00115
R2 2 nd stream	8.826	4.50	14.01	2.76	6.00	6.09	9.49	1.08	7.36	44.99	0.00198
R3 1 st stream	9.281	4.74	14.73	2.90	6.31	6.40	9.98	1.13	7.73	6.615	0.0003
R3 2 nd stream	9.253	4.72	14.69	2.89	6.29	6.38	9.95	1.13	7.71	6.746	0.0003
R4 1 st stream	6.461	3.30	10.26	2.02	4.40	4.46	6.95	0.79	5.38	14.40	0.0006
R4 2 nd stream	6.521	3.33	10.35	2.04	4.44	4.50	7.01	0.80	5.43	21.74	0.0010

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses asparagus, brassicas, leek, lettuce, endive and artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop 1 x 1590 g/ha), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5 23: ~~Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in asparagus, brassicas, leek, lettuce, endive and artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop 1 x 1590 g/ha)~~

Intended use	Asparagus, brassicas, leek, lettuce, endive and artichoke									
Active substance	pendimethalin									
Application rate (g/ha)	1 x 1590									
Nozzle re-	No spray buffer (m)	5	10	15	20	5	10	15	20	

duction	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 1 st ditch	2.694	1.428	0.975	0.742	-	-	-	-
50%		1.346	0.743	0.516	-	-	-	-	-
75%		0.745	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D3 2 nd ditch	2.701	1.432	0.978	0.744	-	-	-	-
50%		1.350	0.716	0.494	-	-	-	-	-
75%		0.713	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.906	1.554	1.064	0.810	-	-	-	-
50%		1.480	0.798	0.548	-	-	-	-	-
75%		0.768	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 ditch	2.720	1.442	0.985	0.750	-	-	-	-
50%		1.359	0.750	0.750	-	-	-	-	-
75%		0.750	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 1 st stream	-	-	-	-	2.460	1.325	0.912	-
50%		-	-	-	-	1.282	0.708	-	-
75%		-	-	-	-	0.984	-	-	-
90%		-	-	-	-	0.984	-	-	-
None	R1 2 nd stream	-	-	-	-	2.441	1.310	0.900	-
50%		-	-	-	-	1.262	0.692	-	-
75%		-	-	-	-	0.932	-	-	-

90%		-	-	-		0.932	-	-	-
None	R2 1 st -stream	-	-	-		3.224	1.728	1.185	0.902
50%		-	-	-		1.652	0.895	0.616	-
75%		-	-	-		0.866	-	-	-
90%		-	-	-		-	-	-	-
None	R2 2 nd -stream	-	-	-		3.320	1.783	1.223	0.931
50%		-	-	-		1.708	0.928	0.639	0.487
75%		-	-	-		0.902	-	-	-
90%		-	-	-		-	-	-	-
None	R3 1 st -stream	-	-	-		3.402	1.824	1.252	0.953
50%		-	-	-		1.753	0.964	0.668	0.509
75%		-	-	-		0.956	0.639	-	-
90%		-	-	-		0.924	-	-	-
None	R3 2 nd -stream	-	-	-		3.396	1.804	1.233	0.938
50%		-	-	-		1.706	0.909	0.628	0.478
75%		-	-	-		0.893	-	-	-
90%		-	-	-		-	-	-	-
None	R4 1 st -stream	-	-	-		2.433	1.309	0.900	-
50%		-	-	-		1.554	1.081	-	-
75%		-	-	-		1.554	1.081	-	-
90%		-	-	-		-	-	-	-
None	R4 2 nd -stream	-	-	-		2.441	1.308	0.899	-
50%		-	-	-		1.538	1.072	-	-
75%		-	-	-		1.538	1.072	-	-

90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.93 (P. subcapitata)		PEC/RAC ratio							
None	D3 1 st ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.55	-	-	-	-	-
75%		0.80	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D3 2 nd ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.77	0.53	-	-	-	-	-
75%		0.77	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.12	1.67	1.14	0.87	-	-	-	-
50%		1.59	0.86	0.59	-	-	-	-	-
75%		0.83	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 ditch	2.92	1.55	1.06	0.81	-	-	-	-
50%		1.46	0.81	0.81	-	-	-	-	-
75%		0.81	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 1 st stream	-	-	-		2.65	1.42	0.98	-
50%		-	-	-		1.38	0.76	-	-
75%		-	-	-		1.06	-	-	-
90%		-	-	-		1.06	-	-	-
None	R1 2 nd stream	-	-	-		2.62	1.41	0.97	-

50%		-	-	-		1.36	0.74	-	-
75%		-	-	-		1.00	-	-	-
90%		-	-	-		1.00	-	-	-
None	R2 1 st -stream	-	-	-		3.47	1.86	1.27	0.97
50%		-	-	-		1.78	0.96	0.66	-
75%		-	-	-		0.93	-	-	-
90%		-	-	-		-	-	-	-
None	R2 2 nd -stream	-	-	-		3.57	1.92	1.32	1.00
50%		-	-	-		1.84	1.00	0.69	0.52
75%		-	-	-		0.97	-	-	-
90%		-	-	-		-	-	-	-
None	R3 1 st -stream	-	-	-		3.66	1.96	1.35	1.02
50%		-	-	-		1.88	1.04	0.72	0.55
75%		-	-	-		1.03	0.69	-	-
90%		-	-	-		0.99	-	-	-
None	R3 2 nd -stream	-	-	-		3.65	1.94	1.33	1.01
50%		-	-	-		1.83	0.98	0.68	0.51
75%		-	-	-		0.96	-	-	-
90%		-	-	-		-	-	-	-
None	R4 1 st -stream	-	-	-		2.62	1.41	0.97	-
50%		-	-	-		1.67	1.16	-	-
75%		-	-	-		1.67	1.16	-	-
90%		-	-	-		-	-	-	-
None	R4 2 nd -stream	-	-	-		2.62	1.41	0.97	-

50%		-	-	-		1.65	1.15	-	-
75%		-	-	-		1.65	1.15	-	-
90%		-	-	-		-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-75: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in asparagus, brassicas, leek, lettuce, endive and artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop 1 x 1590 g/ha pre-emergence)

Intended use		Asparagus, brassicas, leek, lettuce, endive and artichoke (pre-emergence)							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1590							
Nozzle re-duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 1 st ditch	2.694	1.428	0.975	0.742	-	-	-	-
50%		1.346	0.743	0.516	0.399	-	-	-	-
75%		0.745	0.453	0.324	0.247	-	-	-	-
90%		0.453	0.304	0.223	0.170	-	-	-	-
None	D3 2 nd ditch	2.701	1.432	0.978	0.744	-	-	-	-
50%		1.350	0.716	0.494	0.382	-	-	-	-
75%		0.713	0.421	0.299	0.228	-	-	-	-
90%		0.419	0.282	0.207	-	-	-	-	-
None	D4 pond	0.331	0.241	0.190	-	-	-	-	-
50%		0.197	0.144	-	-	-	-	-	-
None	D4 stream	2.906	1.554	1.064	0.810	-	-	-	-

50%		1.480	0.798	0.548	0.423	-	-	-	-
75%		0.768	0.426	0.307	0.307	-	-	-	-
90%		0.346	0.307	0.307	0.307	-	-	-	-
None	D6 ditch	2.720	1.442	0.985	0.750	-	-	-	-
50%		1.359	0.750	0.750	0.750	-	-	-	-
75%		0.750	0.750	0.750	-	-	-	-	-
90%		0.750	-	-	-	-	-	-	-
None		-	-	-	-	0.343	0.249	0.197	-
50%	R1 1 st pond	-	-	-	-	0.257	0.173	-	-
75%		-	-	-	-	0.257	-	-	-
90%		-	-	-	-	0.373	0.251	0.196	-
None		-	-	-	-	0.373	0.251	-	-
50%	R1 2 nd pond	-	-	-	-	2.460	1.325	0.912	0.704
75%		-	-	-	-	1.282	0.708	0.533	0.379
90%		-	-	-	-	0.984	0.694	0.533	0.363
None		-	-	-	-	0.984	0.694	0.533	0.363
50%	R1 1 st stream	-	-	-	-	2.441	1.310	0.900	0.695
75%		-	-	-	-	1.262	0.692	0.505	0.369
90%		-	-	-	-	0.932	0.659	0.505	0.345
None		-	-	-	-	0.932	0.659	0.505	0.345
50%	R1 2 nd stream	-	-	-	-	3.224	1.728	1.185	0.902
75%		-	-	-	-	1.652	0.895	0.616	0.475
90%		-	-	-	-	0.945	0.486	0.336	0.256
None		-	-	-	-	0.945	0.232	0.163	0.125

50%	R2 1 st stream	-	-	-	3.320	1.783	1.223	0.931
75%		-	-	-	1.708	0.928	0.639	0.487
90%		-	-	-	0.902	0.508	0.353	0.269
None	R2 2 nd stream	-	-	-	0.401	0.251	0.178	0.136
50%		-	-	-	3.402	1.824	1.252	0.953
75%		-	-	-	1.753	0.964	0.668	0.509
90%		-	-	-	0.956	0.639	0.496	0.337
None	R3 1 st stream	-	-	-	0.924	0.639	0.496	0.337
50%		-	-	-	3.396	1.804	1.233	0.938
75%		-	-	-	1.706	0.909	0.628	0.478
90%		-	-	-	0.893	0.540	0.415	0.283
None	R3 2 nd stream	-	-	-	0.774	0.540	0.415	0.283
50%		-	-	-	2.433	1.309	0.900	0.694
75%		-	-	-	1.554	1.081	0.841	0.574
90%		-	-	-	1.554	1.081	0.841	0.574
None	R4 1 st stream	-	-	-	-	-	-	-
50%		-	-	-	2.441	1.308	0.899	0.694
75%		-	-	-	1.538	1.072	0.835	0.571
90%		-	-	-	1.538	1.072	0.835	0.571
None	R4 2 nd stream	-	-	-	-	-	-	-
50%		-	-	-	0.343	0.249	0.197	-
75%		-	-	-	0.257	0.173	-	-
90%		-	-	-	0.257	-	-	-
RAC (µg/L)								

0.93 (algae)		PEC/RAC ratio							
None	D3 1 st ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.55	0.43	-	-	-	-
75%		0.80	0.49	0.35	0.27	-	-	-	-
90%		0.49	0.33	0.24	0.18	-	-	-	-
None	D3 2 nd ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.77	0.53	0.41	-	-	-	-
75%		0.77	0.45	0.32	0.25	-	-	-	-
90%		0.45	0.30	0.22	-	-	-	-	-
None	D4 pond	0.36	0.26	0.20	-	-	-	-	-
50%		0.21	0.15	-	-	-	-	-	-
None	D4 stream	3.12	1.67	1.14	0.87	-	-	-	-
50%		1.59	0.86	0.59	0.45	-	-	-	-
75%		0.83	0.46	0.33	0.33	-	-	-	-
90%		0.37	0.33	0.33	0.33	-	-	-	-
None	D6 ditch	2.92	1.55	1.06	0.81	-	-	-	-
50%		1.46	0.81	0.81	0.81	-	-	-	-
75%		0.81	0.81	0.81	-	-	-	-	-
90%		0.81	-	-	-	-	-	-	-
None	R1 1 st pond	-	-	-	-	0.37	0.27	0.21	-
50%		-	-	-	-	0.28	0.19	-	-
75%		-	-	-	-	0.28	-	-	-
None	R1 2 nd pond	-	-	-	-	0.40	0.27	0.21	-
50%		-	-	-	-	0.40	0.27	-	-

None	R1 1 st stream	-	-	-	-	2.65	1.42	0.98	0.76
50%		-	-	-	-	1.38	0.76	0.57	0.41
75%		-	-	-	-	1.06	0.75	0.57	0.39
90%		-	-	-	-	1.06	0.75	0.57	0.39
None	R1 2 nd stream	-	-	-	-	2.62	1.41	0.97	0.75
50%		-	-	-	-	1.36	0.74	0.54	0.40
75%		-	-	-	-	1.00	0.71	0.54	0.37
90%		-	-	-	-	1.00	0.71	0.54	0.37
None	R2 1 st stream	-	-	-	-	3.47	1.86	1.27	0.97
50%		-	-	-	-	1.78	0.96	0.66	0.51
75%		-	-	-	-	1.02	0.52	0.36	0.28
90%		-	-	-	-	1.02	0.25	0.18	0.13
None	R2 2 nd stream	-	-	-	-	3.57	1.92	1.32	1.00
50%		-	-	-	-	1.84	1.00	0.69	0.52
75%		-	-	-	-	0.97	0.55	0.38	0.29
90%		-	-	-	-	0.43	0.27	0.19	0.15
None	R3 1 st stream	-	-	-	-	3.66	1.96	1.35	1.02
50%		-	-	-	-	1.88	1.04	0.72	0.55
75%		-	-	-	-	1.03	0.69	0.53	0.36
90%		-	-	-	-	0.99	0.69	0.53	0.36
None	R3 2 nd stream	-	-	-	-	3.65	1.94	1.33	1.01
50%		-	-	-	-	1.83	0.98	0.68	0.51
75%		-	-	-	-	0.96	0.58	0.45	0.30
90%		-	-	-	-	0.83	0.58	0.45	0.30

None	R4 1 st stream	-	-	-	-	2.62	1.41	0.97	0.75
50%		-	-	-	-	1.67	1.16	0.90	0.62
75%		-	-	-	-	1.67	1.16	0.90	0.62
90%		-	-	-	-	-	-	-	-
None	R4 2 nd stream	-	-	-	-	2.62	1.41	0.97	0.75
50%		-	-	-	-	1.65	1.15	0.90	0.61
75%		-	-	-	-	1.65	1.15	0.90	0.61
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in asparagus, brassicas, leek, lettuce, endive and artichoke (1 x 1590 g/ha pre-emergence) are <1 when risk mitigation options are considered:
 D3 ditch, D4 stream and D6 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R2 1st stream and R3 2nd stream: **20m no spray buffer zone + 20m vegetative strip or** 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction ~~or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction~~

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 1st stream: 15m no spray buffer zone + 15m vegetative strip + **50% nozzle reduction** or 10 no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R3 2nd stream: 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip

R2 2nd stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-76: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in asparagus, brassicas, leek, lettuce, endive and artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop 1 x 1590 g/ha pre-emergence)

Intended use		Asparagus, brassicas, leek, lettuce, endive and artichoke (pre-emergence)							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 1 st ditch	2.694	1.428	0.975	0.742	-	-	-	-
50%		1.346	0.743	0.516	0.399	-	-	-	-
75%		0.745	0.453	0.324	0.247	-	-	-	-
90%		0.453	0.304	0.223	0.170	-	-	-	-
None	D3 2 nd ditch	2.701	1.432	0.978	0.744	-	-	-	-
50%		1.350	0.716	0.494	0.382	-	-	-	-
75%		0.713	0.421	0.299	0.228	-	-	-	-
90%		0.419	0.282	0.207	-	-	-	-	-
None	D4 pond	0.331	0.241	0.190	-	-	-	-	-
50%		0.197	0.144	-	-	-	-	-	-
None	D4 stream	2.906	1.554	1.064	0.810	-	-	-	-
50%		1.480	0.798	0.548	0.423	-	-	-	-
75%		0.768	0.426	0.307	0.307	-	-	-	-
90%		0.346	0.307	0.307	0.307	-	-	-	-
None	D6 ditch	2.720	1.442	0.985	0.750	-	-	-	-
50%		1.359	0.750	0.750	0.750	-	-	-	-

75%		0.750	0.750	0.750	-	-	-	-	-
90%		0.750	-	-	-	-	-	-	-
None	R1 1 st pond	-	-	-		0.343	0.249	0.197	-
50%		-	-	-		0.257	0.173	-	-
75%		-	-	-		0.257	-	-	-
None	R1 2 nd pond	-	-	-		0.373	0.251	0.196	-
50%		-	-	-		0.373	0.251	-	-
None	R1 1 st stream	-	-	-		2.460	1.325	0.912	0.704
50%		-	-	-		1.282	0.708	0.533	0.379
75%		-	-	-		0.984	0.694	0.533	0.363
90%		-	-	-		0.984	0.694	0.533	0.363
None	R1 2 nd stream	-	-	-		2.441	1.310	0.900	0.695
50%		-	-	-		1.262	0.692	0.505	0.369
75%		-	-	-		0.932	0.659	0.505	0.345
90%		-	-	-		0.932	0.659	0.505	0.345
None	R2 1 st stream	-	-	-		3.224	1.728	1.185	0.902
50%		-	-	-		1.652	0.895	0.616	0.475
75%		-	-	-		0.945	0.486	0.336	0.256
90%		-	-	-		0.945	0.232	0.163	0.125
None	R2 2 nd stream	-	-	-		3.320	1.783	1.223	0.931
50%		-	-	-		1.708	0.928	0.639	0.487
75%		-	-	-		0.902	0.508	0.353	0.269
90%		-	-	-		0.401	0.251	0.178	0.136
None		-	-	-		3.402	1.824	1.252	0.953

50%	R3 1 st stream	-	-	-		1.753	0.964	0.668	0.509
75%		-	-	-		0.956	0.639	0.496	0.337
90%		-	-	-		0.924	0.639	0.496	0.337
None	R3 2 nd stream	-	-	-		3.396	1.804	1.233	0.938
50%		-	-	-		1.706	0.909	0.628	0.478
75%		-	-	-		0.893	0.540	0.415	0.283
90%		-	-	-		0.774	0.540	0.415	0.283
None	R4 1 st stream	-	-	-		2.433	1.309	0.900	0.694
50%		-	-	-		1.554	1.081	0.841	0.574
75%		-	-	-		1.554	1.081	0.841	0.574
90%		-	-	-		-	-	-	-
None	R4 2 nd stream	-	-	-		2.441	1.308	0.899	0.694
50%		-	-	-		1.538	1.072	0.835	0.571
75%		-	-	-		1.538	1.072	0.835	0.571
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 1 st ditch	11.713	6.209	4.239	3.226	-	-	-	-
50%		5.852	3.230	2.243	1.735	-	-	-	-
75%		3.239	1.970	1.409	1.074	-	-	-	-
90%		1.970	1.322	0.970	0.739	-	-	-	-
None	D3 2 nd ditch	11.743	6.226	4.252	3.235	-	-	-	-
50%		5.870	3.113	2.148	1.661	-	-	-	-
75%		3.100	1.830	1.300	0.991	-	-	-	-

90%		1.822	1.226	0.900	-	-	-	-	-
None	D4 pond	1.439	1.048	0.826	-	-	-	-	-
50%		0.857	0.626	-	-	-	-	-	-
None	D4 stream	12.635	6.757	4.626	3.522	-	-	-	-
50%		6.435	3.470	2.383	1.839	-	-	-	-
75%		3.339	1.852	1.335	1.335	-	-	-	-
90%		1.504	1.335	1.335	1.335	-	-	-	-
None	D6 ditch	11.826	6.270	4.283	3.261	-	-	-	-
50%		5.909	3.261	3.261	3.261	-	-	-	-
75%		3.261	3.261	3.261	-	-	-	-	-
90%		3.261	-	-	-	-	-	-	-
None	R1 1 st pond	-	-	-	-	1.49	1.08	0.86	-
50%		-	-	-	-	1.12	0.75	-	-
75%		-	-	-	-	1.12	-	-	-
None	R1 2 nd pond	-	-	-	-	1.62	1.09	0.85	-
50%		-	-	-	-	1.62	1.09	-	-
None	R1 1 st stream	-	-	-	-	10.70	5.76	3.97	3.06
50%		-	-	-	-	5.57	3.08	2.32	1.65
75%		-	-	-	-	4.28	3.02	2.32	1.58
90%		-	-	-	-	4.28	3.02	2.32	1.58
None	R1 2 nd stream	-	-	-	-	10.61	5.70	3.91	3.02
50%		-	-	-	-	5.49	3.01	2.20	1.60
75%		-	-	-	-	4.05	2.87	2.20	1.50
90%		-	-	-	-	4.05	2.87	2.20	1.50

None	R2 1 st stream	-	-	-	-	14.02	7.51	5.15	3.92
50%		-	-	-	-	7.18	3.89	2.68	2.07
75%		-	-	-	-	4.11	2.11	1.46	1.11
90%		-	-	-	-	4.11	1.01	0.71	0.54
None	R2 2 nd stream	-	-	-	-	14.43	7.75	5.32	4.05
50%		-	-	-	-	7.43	4.03	2.78	2.12
75%		-	-	-	-	3.92	2.21	1.53	1.17
90%		-	-	-	-	1.74	1.09	0.77	0.59
None	R3 1 st stream	-	-	-	-	14.79	7.93	5.44	4.14
50%		-	-	-	-	7.62	4.19	2.90	2.21
75%		-	-	-	-	4.16	2.78	2.16	1.47
90%		-	-	-	-	4.02	2.78	2.16	1.47
None	R3 2 nd stream	-	-	-	-	14.77	7.84	5.36	4.08
50%		-	-	-	-	7.42	3.95	2.73	2.08
75%		-	-	-	-	3.88	2.35	1.80	1.23
90%		-	-	-	-	3.37	2.35	1.80	1.23
None	R4 1 st stream	-	-	-	-	10.58	5.69	3.91	3.02
50%		-	-	-	-	6.76	4.70	3.66	2.50
75%		-	-	-	-	6.76	4.70	3.66	2.50
90%		-	-	-	-	-	-	-	-
None	R4 2 nd stream	-	-	-	-	10.61	5.69	3.91	3.02
50%		-	-	-	-	6.69	4.66	3.63	2.48
75%		-	-	-	-	6.69	4.66	3.63	2.48
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-77: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop, 1 x 1590 g/ha) in pre emergence

Intended use		Asparagus, brassicas, leek, lettuce, endive, artichoke 1 st and 2 nd crop (pre-emergence)	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream 1 st	-	0.216
90%		0.218	-
75%	R1 stream 2 nd	-	0.206
90%		0.203	-
75%	R2 stream 1 st	-	0.256
90%		0.232	0.125
75%	R2 stream 2 nd	-	0.269
90%		0.251	0.134
75%	R3 stream 1 st	-	0.297
90%		0.319	0.176
75%	R3 stream 2 nd	-	0.273
90%		0.284	0.156
75%	R4 stream 1 st	-	0.206

90%		0.200	-
75%	R4 stream 2nd	-	0.205
90%		0.206	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream 1 st	-	0.94
90%		0.95	-
75%	R1 stream 2 nd	-	0.90
90%		0.88	-
75%	R2 stream 1 st	-	1.11
90%		1.01	0.54
75%	R2 stream 2 nd	-	1.17
90%		1.09	0.58
75%	R3 stream 1 st	-	1.29
90%		1.39	0.77
75%	R3 stream 2 nd	-	1.19
90%		1.23	0.68
75%	R4 stream 1 st	-	0.90
90%		0.87	-
75%	R4 stream 2 nd	-	0.89
90%		0.90	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in asparagus, brassicas, leek, lettuce, endive and artichoke (1 x 1590 g/ha pre-emergence) are <1 when risk mitigation options are considered:

D3 1st ditch: 15m no spray buffer zone + 90% nozzle reduction

D3 2nd ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond 1st: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R1 pond 2nd: 15m no spray buffer zone + 15m vegetative strip

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. Scenario D6 is not relevant for CEU countries.

Table 9.5-78: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop in post emergence (leafy vegetables 1st and 2nd crop 1 x 1590 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell. er prolonged
Test species		<i>O.mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P.subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 196	NOEC 6.3	NOEC geomean 32	EC ₅₀ 147	NOEC 14.5	ErC ₅₀ 9.3	NOEC 82	ErC ₅₀ 12		NOEC 227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 1 st ditch	9.959	5.08	15.81	3.11	6.77	6.87	10.71	1.21	8.30	0.445	0.00002

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
D3 2 nd ditch	9.969	5.09	15.82	3.12	6.78	6.88	10.72	1.22	8.31	0.458	0.00002
D4 pond	0.343	0.18	0.54	0.11	0.23	0.24	0.37	0.04	0.29	0.174	0.00001
D4 stream	7.805	3.98	12.39	2.44	5.31	5.38	8.39	0.95	6.50	0.021	0.00000
D6 ditch	9.743	4.97	15.47	3.04	6.63	6.72	10.48	1.19	8.12	0.116	0.00001
R1 1 st pond	0.438	0.22	0.70	0.14	0.30	0.30	0.47	0.05	0.37	0.209	0.00001
R1 2 nd pond	0.571	0.29	0.91	0.18	0.39	0.39	0.61	0.07	0.48	0.363	0.00002
R1 1 st stream	6.562	3.35	10.42	2.05	4.46	4.53	7.06	0.80	5.47	0.135	0.00001
R1 1 st stream	6.584	3.36	10.45	2.06	4.48	4.54	7.08	0.80	5.49	0.121	0.00001
R2 1 st stream	8.674	4.43	13.77	2.71	5.90	5.98	9.33	1.06	7.23	0.070	0.00000
R2 2 nd stream	8.826	4.50	14.01	2.76	6.00	6.09	9.49	1.08	7.36	0.083	0.00000
R3 1 st stream	9.220	4.70	14.63	2.88	6.27	6.36	9.91	1.12	7.68	0.209	0.00001
R3 2 nd stream	9.253	4.72	14.69	2.89	6.29	6.38	9.95	1.13	7.71	0.220	0.00001
R4 1 st stream	6.553	3.34	10.40	2.05	4.46	4.52	7.05	0.80	5.46	0.302	0.00001
R4 2 nd stream	6.521	3.33	10.35	2.04	4.44	4.50	7.01	0.80	5.43	0.281	0.00001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-79: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in asparagus, brassicas, leek, lettuce, endive and artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop 1 x 1590 g/ha post-emergence)

Intended use	Asparagus, brassicas, leek, lettuce, endive and artichoke (post-emergence)
Active substance	pendimethalin
Application rate (g/ha)	1 x 1590

Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 1 st ditch	2.698	1.430	0.977	0.743	-	-	-	-
50%		1.348	0.751	0.522	0.398	-	-	-	-
75%		0.755	0.461	0.329	0.251	-	-	-	-
90%		0.462	0.309	0.226	0.172	-	-	-	-
None	D3 2 nd ditch	2.701	1.432	0.978	0.744	-	-	-	-
50%		1.350	0.747	0.519	0.395	-	-	-	-
75%		0.748	0.456	0.326	0.248	-	-	-	-
90%		0.457	0.306	0.224	0.170	-	-	-	-
None	D4 pond	0.338	0.246	0.194	-	-	-	-	-
50%		0.201	0.147	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.906	1.554	1.064	0.810	-	-	-	-
50%		1.481	0.798	0.548	0.417	-	-	-	-
75%		0.768	0.421	0.306	0.306	-	-	-	-
90%		0.341	0.306	0.306	0.306	-	-	-	-
None	D6 ditch	2.640	1.399	0.956	0.727	-	-	-	-
50%		1.319	0.699	0.657	0.657	-	-	-	-
75%		0.659	0.657	0.657	-	-	-	-	-
90%		0.657	0.657	-	-	-	-	-	-
None						0.353	0.256	0.202	-
50%						0.268	0.180	-	-

75%	R1 1 st pond	-	-	-	0.268	-	-	-
90%		-	-	-	-	-	-	-
None	R1 2 nd pond	-	-	-	0.352	0.248	0.195	-
50%		-	-	-	0.351	0.237	-	-
75%		-	-	-	0.350	-	-	-
90%		-	-	-	-	-	-	-
None	R1 1 st stream	-	-	-	2.468	1.334	0.918	0.699
50%		-	-	-	1.291	0.713	0.524	0.376
75%		-	-	-	0.981	0.683	0.524	0.357
90%		-	-	-	0.981	0.683	-	0.357
None	R1 2 nd stream	-	-	-	2.459	1.331	0.915	0.697
50%		-	-	-	1.287	0.709	0.491	0.374
75%		-	-	-	0.843	0.587	0.451	0.308
90%		-	-	-	0.843	0.587	0.451	0.308
None	R2 1 st stream	-	-	-	3.256	1.747	1.198	0.912
50%		-	-	-	1.672	0.907	0.624	0.475
75%		-	-	-	0.880	0.488	0.338	0.257
90%		-	-	-	0.405	0.236	0.167	0.127
None	R2 2 nd stream	-	-	-	3.322	1.785	1.224	0.932
50%		-	-	-	1.710	0.930	0.641	0.488
75%		-	-	-	0.905	0.503	0.349	0.266
90%		-	-	-	0.425	0.252	0.178	0.136
None	R3 1 st stream	-	-	-	3.416	1.839	1.262	0.961
50%		-	-	-	1.768	0.977	0.677	0.515

75%		-	-	-		0.992	0.690	0.528	0.360
90%		-	-	-		0.992	0.690	0.528	0.360
None	R3 2 nd stream	-	-	-		3.396	1.805	1.233	0.938
50%		-	-	-		1.720	0.945	0.659	0.497
75%		-	-	-		0.930	0.531	0.385	0.284
90%		-	-	-		0.720	0.502	0.385	0.263
None	R4 1 st stream	-	-	-		2.468	1.330	0.914	0.696
50%		-	-	-		1.362	0.949	0.728	0.497
75%		-	-	-		1.362	0.949	0.728	0.497
90%		-	-	-		-	-	-	-
None	R4 2 nd stream	-	-	-		2.447	1.320	0.907	0.690
50%		-	-	-		1.438	1.001	0.768	0.524
75%		-	-	-		1.438	1.001	0.768	0.524
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 1 st ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.81	0.56	0.43	-	-	-	-
75%		0.81	0.50	0.35	0.27	-	-	-	-
90%		0.50	0.33	0.24	0.18	-	-	-	-
None	D3 2 nd ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.56	0.42	-	-	-	-
75%		0.80	0.49	0.35	0.27	-	-	-	-
90%		0.49	0.33	0.24	0.18	-	-	-	-

None	D4 pond	0.36	0.26	0.21	-	-	-	-	-
50%		0.22	0.16	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.12	1.67	1.14	0.87	-	-	-	-
50%		1.59	0.86	0.59	0.45	-	-	-	-
75%		0.83	0.45	0.33	0.33	-	-	-	-
90%		0.37	0.33	0.33	0.33	-	-	-	-
None	D6 ditch	2.84	1.50	1.03	0.78	-	-	-	-
50%		1.42	0.75	0.71	0.71	-	-	-	-
75%		0.71	0.71	0.71	-	-	-	-	-
90%		0.71	0.71	-	-	-	-	-	-
None	R1 1 st pond	-	-	-	-	0.38	0.28	0.22	-
50%		-	-	-	-	0.29	0.19	-	-
75%		-	-	-	-	0.29	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 2 nd pond	-	-	-	-	0.38	0.27	0.21	-
50%		-	-	-	-	0.38	0.25	-	-
75%		-	-	-	-	0.38	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 1 st stream	-	-	-	-	2.65	1.43	0.99	0.75
50%		-	-	-	-	1.39	0.77	0.56	0.40
75%		-	-	-	-	1.05	0.73	0.56	0.38
90%		-	-	-	-	1.05	0.73	-	0.38

None	R4 2 nd stream	-	-	-	-	2.63	1.42	0.98	0.74
50%		-	-	-	-	1.55	1.08	0.83	0.56
75%		-	-	-	-	1.55	1.08	0.83	0.56
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in asparagus, brassicas, leek, lettuce, endive and artichoke (1 x 1590 g/ha post-emergence) are <1 when risk mitigation options are considered: D3 ditch, D4 stream and D6 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream 1st: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R1 stream 2nd: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R2 1st stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R2 2nd stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R3 1st stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

R3 2nd stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R4: 15m no spray buffer zone + 15m vegetative strip

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-80: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in asparagus, brassicas, leek, lettuce, endive and artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop 1 x 1590 g/ha post-emergence)

Intended use	Asparagus, brassicas, leek, lettuce, endive and artichoke (post-emergence)
Active substance	pendimethalin

Application rate (g/ha)		1 × 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 1 st ditch	2.698	1.430	0.977	0.743	-	-	-	-
50%		1.348	0.751	0.522	0.398	-	-	-	-
75%		0.755	0.461	0.329	0.251	-	-	-	-
90%		0.462	0.309	0.226	0.172	-	-	-	-
None	D3 2 nd ditch	2.701	1.432	0.978	0.744	-	-	-	-
50%		1.350	0.747	0.519	0.395	-	-	-	-
75%		0.748	0.456	0.326	0.248	-	-	-	-
90%		0.457	0.306	0.224	0.170	-	-	-	-
None	D4 pond	0.338	0.246	0.194	-	-	-	-	-
50%		0.201	0.147	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.906	1.554	1.064	0.810	-	-	-	-
50%		1.481	0.798	0.548	0.417	-	-	-	-
75%		0.768	0.421	0.306	0.306	-	-	-	-
90%		0.341	0.306	0.306	0.306	-	-	-	-
None	D6 ditch	2.640	1.399	0.956	0.727	-	-	-	-
50%		1.319	0.699	0.657	0.657	-	-	-	-
75%		0.659	0.657	0.657	-	-	-	-	-
90%		0.657	0.657	-	-	-	-	-	-
None						0.353	0.256	0.202	-

50%	R1 1 st pond					0.268	0.180	-	-
75%		-	-	-		0.268	-	-	-
90%		-	-	-		-		-	-
None	R1 2 nd pond	-	-	-		0.352	0.248	0.195	-
50%		-	-	-		0.351	0.237	-	-
75%		-	-	-		0.350	-	-	-
90%		-	-	-		-	-	-	-
None	R1 1 st stream	-	-	-		2.468	1.334	0.918	0.699
50%		-	-	-		1.291	0.713	0.524	0.376
75%		-	-	-		0.981	0.683	0.524	0.357
90%		-	-	-		0.981	0.683	-	0.357
None	R1 2 nd stream	-	-	-		2.459	1.331	0.915	0.697
50%		-	-	-		1.287	0.709	0.491	0.374
75%		-	-	-		0.843	0.587	0.451	0.308
90%		-	-	-		0.843	0.587	0.451	0.308
None	R2 1 st stream	-	-	-		3.256	1.747	1.198	0.912
50%		-	-	-		1.672	0.907	0.624	0.475
75%		-	-	-		0.880	0.488	0.338	0.257
90%		-	-	-		0.405	0.236	0.167	0.127
None	R2 2 nd stream	-	-	-		3.322	1.785	1.224	0.932
50%		-	-	-		1.710	0.930	0.641	0.488
75%		-	-	-		0.905	0.503	0.349	0.266
90%		-	-	-		0.425	0.252	0.178	0.136
None		-	-	-		3.416	1.839	1.262	0.961

50%	R3 1 st stream	-	-	-		1.768	0.977	0.677	0.515
75%		-	-	-		0.992	0.690	0.528	0.360
90%		-	-	-		0.992	0.690	0.528	0.360
None	R3 2 nd stream	-	-	-		3.396	1.805	1.233	0.938
50%		-	-	-		1.720	0.945	0.659	0.497
75%		-	-	-		0.930	0.531	0.385	0.284
90%		-	-	-		0.720	0.502	0.385	0.263
None	R4 1 st stream	-	-	-		2.468	1.330	0.914	0.696
50%		-	-	-		1.362	0.949	0.728	0.497
75%		-	-	-		1.362	0.949	0.728	0.497
90%		-	-	-		-	-	-	-
None	R4 2 nd stream	-	-	-		2.447	1.320	0.907	0.690
50%		-	-	-		1.438	1.001	0.768	0.524
75%		-	-	-		1.438	1.001	0.768	0.524
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 1 st ditch	11.73	6.22	4.25	3.23	-	-	-	-
50%		5.86	3.27	2.27	1.73	-	-	-	-
75%		3.28	2.00	1.43	1.09	-	-	-	-
90%		2.01	1.34	0.98	0.75	-	-	-	-
None	D3 2 nd ditch	11.74	6.23	4.25	3.23	-	-	-	-
50%		5.87	3.25	2.26	1.72	-	-	-	-
75%		3.25	1.98	1.42	1.08	-	-	-	-

90%		1.99	1.33	0.97	0.74	-	-	-	-
None	D4 pond	1.47	1.07	0.84	-	-	-	-	-
50%		0.87	0.64	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	12.63	6.76	4.63	3.52	-	-	-	-
50%		6.44	3.47	2.38	1.81	-	-	-	-
75%		3.34	1.83	1.33	1.33	-	-	-	-
90%		1.48	1.33	1.33	1.33	-	-	-	-
None	D6 ditch	11.48	6.08	4.16	3.16	-	-	-	-
50%		5.73	3.04	2.86	2.86	-	-	-	-
75%		2.87	2.86	2.86	-	-	-	-	-
90%		2.86	2.86	-	-	-	-	-	-
None	R1 1 st pond	-	-	-	-	1.53	1.11	0.88	-
50%		-	-	-	-	1.17	0.78	-	-
75%		-	-	-	-	1.17	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 2 nd pond	-	-	-	-	1.53	1.08	0.85	-
50%		-	-	-	-	1.53	1.03	-	-
75%		-	-	-	-	1.52	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 1 st stream	-	-	-	-	10.73	5.80	3.99	3.04
50%		-	-	-	-	5.61	3.10	2.28	1.63
75%		-	-	-	-	4.27	2.97	2.28	1.55

90%		-	-	-	-	4.27	2.97	-	1.55
None	R1 2 nd stream	-	-	-	-	10.69	5.79	3.98	3.03
50%		-	-	-	-	5.60	3.08	2.13	1.63
75%		-	-	-	-	3.67	2.55	1.96	1.34
90%		-	-	-	-	3.67	2.55	1.96	1.34
None	R2 1 st stream	-	-	-	-	14.16	7.60	5.21	3.97
50%		-	-	-	-	7.27	3.94	2.71	2.07
75%		-	-	-	-	3.83	2.12	1.47	1.12
90%		-	-	-	-	1.76	1.03	0.73	0.55
None	R2 2 nd stream	-	-	-	-	14.44	7.76	5.32	4.05
50%		-	-	-	-	7.43	4.04	2.79	2.12
75%		-	-	-	-	3.93	2.19	1.52	1.16
90%		-	-	-	-	1.85	1.10	0.77	0.59
None	R3 1 st stream	-	-	-	-	14.85	8.00	5.49	4.18
50%		-	-	-	-	7.69	4.25	2.94	2.24
75%		-	-	-	-	4.31	3.00	2.30	1.57
90%		-	-	-	-	4.31	3.00	2.30	1.57
None	R3 2 nd stream	-	-	-	-	14.77	7.85	5.36	4.08
50%		-	-	-	-	7.48	4.11	2.87	2.16
75%		-	-	-	-	4.04	2.31	1.67	1.23
90%		-	-	-	-	3.13	2.18	1.67	1.14
None	R4 1 st stream	-	-	-	-	10.73	5.78	3.97	3.03
50%		-	-	-	-	5.92	4.13	3.17	2.16
75%		-	-	-	-	5.92	4.13	3.17	2.16

90%		-	-	-	-	-	-	-	-
None	R4 2 nd stream	-	-	-	-	10.64	5.74	3.94	3.00
50%		-	-	-	-	6.25	4.35	3.34	2.28
75%		-	-	-	-	6.25	4.35	3.34	2.28
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-81: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop, 1 x 1590 g/ha) in pre emergence

Intended use		Asparagus, brassicas, leek, lettuce, endive, artichoke 1 st and 2 nd crop (pre-emergence) vegetables (post-emergence)	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream 1 st	-	0.215
90%		0.217	-
75%	R1 stream 2 nd	-	0.212
90%		0.218	-
75%	R2 stream 1 st	-	0.257
90%		0.236	0.127
75%	R2 stream 2 nd	-	0.266

90%		0.252	0.136
75%	R3 stream 1 st	-	0.295
90%		0.310	0.171
75%	R3 stream 2 nd	-	0.284
90%		0.297	0.164
75%	R4 stream 1 st	-	0.214
90%		0.223	-
75%	R4 stream 2 nd	-	0.206
90%		0.208	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream 1 st	-	0.93
90%		0.94	-
75%	R1 stream 2 nd	-	0.92
90%		0.95	-
75%	R2 stream 1 st	-	1.12
90%		1.03	0.55
75%	R2 stream 2 nd	-	1.16
90%		1.10	0.59
75%	R3 stream 1 st	-	1.28
90%		1.35	0.74
75%	R3 stream 2 nd	-	1.23
90%		1.29	0.71
75%	R4 stream 1 st	-	0.90

90%		0.97	-
75%	R4 stream 2nd	-	0.90
90%		0.90	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in asparagus, brassicas, leek, lettuce, endive and artichoke (1 x 1590 g/ha post-emergence) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch the PEC/RAC ratios are below the trigger even considering mitigation measures. Scenario D6 is not relevant for CEU countries.

Table 9.5-8224: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in strawberry (fruiting vegetables 1 x 1590 g/ha, between rows)

Group	Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
Test species	<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint	LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	E _r C ₅₀	NOEC	ErC ₅₀		NOEC
(µg/L)	196	6.3	32	147	14.5	9.3	82	12		227300
AF	100	10	10	100	10	10	10	10		10
RAC (µg/L)	1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730

Group		Fish acute	Fish pro- longed	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell- er pro- longed
FOCUS Scenario	PEC ^{gl-max} (µg/L)									PEC ^{gl-max} (µg/kg)	
Step 3											
D3 ditch	7.460	3.81	11.84	2.33	5.07	5.14	8.02	0.91	6.22	4.318	0.00019
D4 pond	0.257	0.13	0.41	0.08	0.17	0.18	0.28	0.03	0.21	0.987	0.00004
D4 stream	5.856	2.99	9.30	1.83	3.98	4.04	6.30	0.71	4.88	0.260	0.00001
D6 ditch	7.407	3.78	11.76	2.31	5.04	5.11	7.96	0.90	6.17	2.672	0.00012
R1 pond	0.308	0.16	0.49	0.10	0.21	0.21	0.33	0.04	0.26	2.240	0.00010
R1 stream	4.923	2.51	7.81	1.54	3.35	3.40	5.29	0.60	4.10	23.13	0.00102
R2 stream	6.518	3.33	10.35	2.04	4.43	4.50	7.01	0.79	5.43	97.70	0.00430
R3 stream	6.963	3.55	11.05	2.18	4.74	4.80	7.49	0.85	5.80	2.730	0.00012
R4 stream	4.925	2.51	7.82	1.54	3.35	3.40	5.30	0.60	4.10	28.48	0.00125

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses strawberry, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5 25: ~~Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in strawberry~~

Intended use	Strawberry
Active substance	pendimethalin
Application rate (g/ha)	1 × 1590

Nozzle re- duction	No-spray buffer (m)	5	10	15	5	10	15
	Vegetated filter strip (m)	None	None	None	5	10	15
None	D3 ditch	2.021	1.072	0.732	-	-	-
50%		1.010	0.557	-	-	-	-
75%		0.559	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	2.180	1.165	0.798	-	-	-
50%		1.111	0.598	-	-	-	-
75%		0.576	-	-	-	-	-
90%		-	-	-	-	-	-
None	D6 ditch	2.007	1.064	0.727	-	-	-
50%		1.003	0.532	-	-	-	-
75%		0.517	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.845	0.994	0.684
50%		-	-	-	0.962	0.531	-
75%		-	-	-	0.730	-	-
90%		-	-	-	-	-	-
None	R2 stream	-	-	-	2.447	1.313	0.901
50%		-	-	-	1.257	0.681	-
75%		-	-	-	0.662	-	-
90%		-	-	-	-	-	-
None	R3 stream	-	-	-	2.552	1.355	0.926
50%		-	-	-	1.293	0.706	-

75%		-	-	-	0.718	-	-
90%		-	-	-	-	-	-
None	R4 stream	-	-	-	1.840	0.990	0.681
50%		-	-	-	1.220	0.852	-
75%		-	-	-	1.220	-	-
90%		-	-	-	-	-	-
RAC (µg/L)							
0.93 (P. subcapitata)		PEC/RAC ratio					
None	D3 ditch	2.17	1.15	0.79	-	-	-
50%		1.09	0.60	-	-	-	-
75%		0.60	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	2.34	1.25	0.86	-	-	-
50%		1.19	0.64	-	-	-	-
75%		0.62	-	-	-	-	-
90%		-	-	-	-	-	-
None	D6 ditch	2.16	1.14	0.78	-	-	-
50%		1.08	0.57	-	-	-	-
75%		0.56	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.98	1.07	0.74
50%		-	-	-	1.03	0.57	-
75%		-	-	-	0.78	-	-
90%		-	-	-	-	-	-

None	R2 stream	-	-	-	2.63	1.41	0.97
50%		-	-	-	1.35	0.73	-
75%		-	-	-	0.71	-	-
90%		-	-	-	-	-	-
None	R3 stream	-	-	-	2.74	1.46	1.00
50%		-	-	-	1.39	0.76	-
75%		-	-	-	0.77	-	-
90%		-	-	-	-	-	-
None	R4 stream	-	-	-	1.98	1.06	0.73
50%		-	-	-	1.31	0.92	-
75%		-	-	-	1.31	-	-
90%		-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-83: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in strawberry

Intended use	Strawberry (between rows)								
Active substance	pendimethalin								
Application rate (g/ha)	1 × 1590								
Nozzle re-duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.021	1.072	0.732	0.564	!	!	!	!
50%		1.010	0.557	0.393	0.298	!	!	!	!
75%		0.559	0.340	0.240	0.184	!	!	!	!

90%		0.340	0.228	0.168	-	-	-	-	-
None	D4 pond	0.249	0.181	-	-	-	-	-	-
50%		0.148	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.180	1.165	0.798	0.616	-	-	-	-
50%		1.111	0.598	0.417	0.317	-	-	-	-
75%		0.576	0.320	0.225	0.225	-	-	-	-
90%		0.259	0.225	-	-	-	-	-	-
None	D6 ditch	2.007	1.064	0.727	0.560	-	-	-	-
50%		1.003	0.532	0.368	0.330	-	-	-	-
75%		0.517	0.330	0.330	0.330	-	-	-	-
90%		0.330	0.330	0.330	-	-	-	-	-
None	R1 pond	-	-	-	-	0.258	0.187	-	-
50%		-	-	-	-	0.191	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.845	0.994	0.684	0.527
50%		-	-	-	-	0.962	0.531	0.396	0.283
75%		-	-	-	-	0.730	0.516	0.396	0.270
90%		-	-	-	-	0.730	0.516	0.396	0.270
None	R2 stream	-	-	-	-	2.447	1.313	0.901	0.694
50%		-	-	-	-	1.257	0.681	0.477	0.362
75%		-	-	-	-	0.662	0.371	0.258	0.196

90%		-	-	-	-	0.309	0.187	0.144	-
None	R3 stream	-	-	-	-	2.552	1.355	0.926	0.714
50%		-	-	-	-	1.293	0.706	0.498	0.377
75%		-	-	-	-	0.718	0.506	0.387	0.264
90%		-	-	-	-	0.718	0.506	0.387	0.264
None	R4 stream	-	-	-	-	1.840	0.990	0.681	0.518
50%		-	-	-	-	1.220	0.852	0.663	0.453
75%		-	-	-	-	1.220	0.852	0.663	0.453
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.17	1.15	0.79	0.61	-	-	-	-
50%		1.09	0.60	0.42	0.32	-	-	-	-
75%		0.60	0.37	0.26	0.20	-	-	-	-
90%		0.37	0.25	0.18	-	-	-	-	-
None	D4 pond	0.27	0.19	-	-	-	-	-	-
50%		0.16	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.34	1.25	0.86	0.66	-	-	-	-
50%		1.19	0.64	0.45	0.34	-	-	-	-
75%		0.62	0.34	0.24	0.24	-	-	-	-
90%		0.28	0.24	-	-	-	-	-	-
None	D6 ditch	2.16	1.14	0.78	0.60	-	-	-	-

50%		1.08	0.57	0.40	0.35	-	-	-	-
75%		0.56	0.35	0.35	0.35	-	-	-	-
90%		0.35	0.35	0.35	-	-	-	-	-
None	R1 pond	-	-	-	-	0.28	0.20	-	-
50%		-	-	-	-	0.21	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.98	1.07	0.74	0.57
50%		-	-	-	-	1.03	0.57	0.43	0.30
75%		-	-	-	-	0.78	0.55	0.43	0.29
90%		-	-	-	-	0.78	0.55	0.43	0.29
None	R2 stream	-	-	-	-	2.63	1.41	0.97	0.75
50%		-	-	-	-	1.35	0.73	0.51	0.39
75%		-	-	-	-	0.71	0.40	0.28	0.21
90%		-	-	-	-	0.33	0.20	0.15	-
None	R3 stream	-	-	-	-	2.74	1.46	1.00	0.77
50%		-	-	-	-	1.39	0.76	0.54	0.41
75%		-	-	-	-	0.77	0.54	0.42	0.28
90%		-	-	-	-	0.77	0.54	0.42	0.28
None	R4 stream	-	-	-	-	1.98	1.06	0.73	0.56
50%		-	-	-	-	1.31	0.92	0.71	0.49
75%		-	-	-	-	1.31	0.92	0.71	0.49
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

90%		-	-	-	-	-	-	-	-
None	D4 stream	2.180	1.165	0.798	0.616	-	-	-	-
50%		1.111	0.598	0.417	0.317	-	-	-	-
75%		0.576	0.320	0.225	0.225	-	-	-	-
90%		0.259	0.225	-	-	-	-	-	-
None	D6 ditch	2.007	1.064	0.727	0.560	-	-	-	-
50%		1.003	0.532	0.368	0.330	-	-	-	-
75%		0.517	0.330	0.330	0.330	-	-	-	-
90%		0.330	0.330	0.330	-	-	-	-	-
None	R1 pond	-	-	-	-	0.258	0.187	-	-
50%		-	-	-	-	0.191	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.845	0.994	0.684	0.527
50%		-	-	-	-	0.962	0.531	0.396	0.283
75%		-	-	-	-	0.730	0.516	0.396	0.270
90%		-	-	-	-	0.730	0.516	0.396	0.270
None	R2 stream	-	-	-	-	2.447	1.313	0.901	0.694
50%		-	-	-	-	1.257	0.681	0.477	0.362
75%		-	-	-	-	0.662	0.371	0.258	0.196
90%		-	-	-	-	0.309	0.187	0.144	-
None	R3 stream	-	-	-	-	2.552	1.355	0.926	0.714
50%		-	-	-	-	1.293	0.706	0.498	0.377
75%		-	-	-	-	0.718	0.506	0.387	0.264

90%		-	-	-		0.718	0.506	0.387	0.264
None	R4 stream	-	-	-		1.840	0.990	0.681	0.518
50%		-	-	-		1.220	0.852	0.663	0.453
75%		-	-	-		1.220	0.852	0.663	0.453
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	8.787	4.661	3.183	2.452	-	-	-	-
50%		4.391	2.422	1.709	1.296	-	-	-	-
75%		2.430	1.478	1.043	0.800	-	-	-	-
90%		1.478	0.991	0.730	-	-	-	-	-
None	D4 pond	1.083	0.787	-	-	-	-	-	-
50%		0.643	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	9.478	5.065	3.470	2.678	-	-	-	-
50%		4.830	2.600	1.813	1.378	-	-	-	-
75%		2.504	1.391	0.978	0.978	-	-	-	-
90%		1.126	0.978	-	-	-	-	-	-
None	D6 ditch	8.726	4.626	3.161	2.435	-	-	-	-
50%		4.361	2.313	1.600	1.435	-	-	-	-
75%		2.248	1.435	1.435	1.435	-	-	-	-
90%		1.435	1.435	1.435	-	-	-	-	-
None	R1 pond	-	-	-	-	1.122	0.813	-	-

50%		-	-	-	-	0.830	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	8.022	4.322	2.974	2.291
50%		-	-	-	-	4.183	2.309	1.722	1.230
75%		-	-	-	-	3.174	2.243	1.722	1.174
90%		-	-	-	-	3.174	2.243	1.722	1.174
None	R2 stream	-	-	-	-	10.639	5.709	3.917	3.017
50%		-	-	-	-	5.465	2.961	2.074	1.574
75%		-	-	-	-	2.878	1.613	1.122	0.852
90%		-	-	-	-	1.343	0.813	0.626	-
None	R3 stream	-	-	-	-	11.096	5.891	4.026	3.104
50%		-	-	-	-	5.622	3.070	2.165	1.639
75%		-	-	-	-	3.122	2.200	1.683	1.148
90%		-	-	-	-	3.122	2.200	1.683	1.148
None	R4 stream	-	-	-	-	8.000	4.304	2.961	2.252
50%		-	-	-	-	5.304	3.704	2.883	1.970
75%		-	-	-	-	5.304	3.704	2.883	1.970
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-85: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in strawberry (1 x 1590 g/ha between rows)

Intended use	Strawberry (between rows)
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Active substance		pendimethalin	
Application rate (g/ha)		1 × 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.162
90%		0.163	-
75%	R2 stream	-	0.196
90%		0.180	-
75%	R3 stream	-	0.216
90%		0.231	-
75%	R4 stream	-	0.161
90%		0.202	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.70
90%		0.71	-
75%	R2 stream	-	0.85
90%		0.78	-
75%	R3 stream	-	0.94
90%		1.00	-
75%	R4 stream	-	0.7
90%		0.88	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in strawberry (1 x 1590 g/ha between rows) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone +75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenario D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries

Table 9.5-8673: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in strawberry (fruiting vegetables 1 x 1137 g/ha, between rows)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell. er prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12		227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
D3 ditch	5.333	2.72	8.47	1.67	3.63	3.68	5.73	0.65	4.44	3.286	0.00014
D4 pond	0.184	0.09	0.29	0.06	0.13	0.13	0.20	0.02	0.15	0.921	0.00004
D4 stream	4.186	2.14	6.64	1.31	2.85	2.89	4.50	0.51	3.49	0.186	0.00001
D6 ditch	5.295	2.70	8.40	1.65	3.60	3.65	5.69	0.65	4.41	2.035	0.00009
R1 pond	0.244	0.12	0.39	0.08	0.17	0.17	0.26	0.03	0.20	2.384	0.00010
R1 stream	3.519	1.80	5.59	1.10	2.39	2.43	3.78	0.43	2.93	18.42	0.00081
R2 stream	4.659	2.38	7.40	1.46	3.17	3.21	5.01	0.57	3.88	70.45	0.00310
R3 stream	4.978	2.54	7.90	1.56	3.39	3.43	5.35	0.61	4.15	2.001	0.00009
R4 stream	3.521	1.80	5.59	1.10	2.40	2.43	3.79	0.43	2.93	20.79	0.00091

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses strawberry (1 x 1137 g/ha between rows), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-87: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in strawberry (between rows)

Intended use		Strawberry (between rows)									
Active substance		pendimethalin									
Application rate (g/ha)		1 x 1137									
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20		
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20		
None	D3 ditch	1.445	0.766	0.523	0.398	-	-	-	-		

50%		0.729	0.406	0.283	0.215	-	-	-	-
75%		0.411	0.249	0.179	-	-	-	-	-
90%		0.250	0.166	-	-	-	-	-	-
None	D4 pond	0.181	-	-	-	-	-	-	-
50%		-	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	1.559	0.833	0.571	0.434	-	-	-	-
50%		0.794	0.428	0.294	0.224	-	-	-	-
75%		0.412	0.225	0.156	-	-	-	-	-
90%		0.183	-	-	-	-	-	-	-
None	D6 ditch	1.434	0.760	0.519	0.395	-	-	-	-
50%		0.717	0.381	0.265	0.226	-	-	-	-
75%		0.382	0.226	0.226	-	-	-	-	-
90%		0.226	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.189	-	-	-
50%		-	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.324	0.715	0.492	0.347
50%		-	-	-	-	0.693	0.382	0.293	0.201
75%		-	-	-	-	0.548	0.381	0.293	-
90%		-	-	-	-	0.548	-	-	-
None	R2 stream	-	-	-	-	1.750	0.939	0.644	0.490

50%		-	-	-	-	0.899	0.487	0.336	0.256
75%		-	-	-	-	0.474	0.262	0.182	0.138
90%		-	-	-	-	0.219	0.130	-	-
None	R3 stream	-	-	-	-	1.825	0.978	0.672	0.511
50%		-	-	-	-	0.941	0.517	0.359	0.272
75%		-	-	-	-	0.514	0.353	0.270	0.184
90%		-	-	-	-	0.508	0.353	0.270	-
None	R4 stream	-	-	-	-	1.322	0.714	0.491	0.374
50%		-	-	-	-	0.861	0.600	0.461	0.315
75%		-	-	-	-	0.861	0.600	0.461	0.315
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	1.55	0.82	0.56	0.43	-	-	-	-
50%		0.78	0.44	0.30	0.23	-	-	-	-
75%		0.44	0.27	0.19	-	-	-	-	-
90%		0.27	0.18	-	-	-	-	-	-
None	D4 pond	0.19	-	-	-	-	-	-	-
50%		-	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	1.68	0.90	0.61	0.47	-	-	-	-
50%		0.85	0.46	0.32	0.24	-	-	-	-
75%		0.44	0.24	0.17	-	-	-	-	-

90%		0.20	-	-	-	-	-	-	-
None	D6 ditch	1.54	0.82	0.56	0.42	-	-	-	-
50%		0.77	0.41	0.28	0.24	-	-	-	-
75%		0.41	0.24	0.24		-	-	-	-
90%		0.24				-	-	-	-
None	R1 pond	-	-	-	-	0.20	-	-	-
50%		-	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.42	0.77	0.53	0.37
50%		-	-	-	-	0.75	0.41	0.32	0.22
75%		-	-	-	-	0.59	0.41	0.32	-
90%		-	-	-	-	0.59	-	-	-
None	R2 stream	-	-	-	-	1.88	1.01	0.69	0.53
50%		-	-	-	-	0.97	0.52	0.36	0.28
75%		-	-	-	-	0.51	0.28	0.20	0.15
90%		-	-	-	-	0.24	0.14	-	-
None	R3 stream	-	-	-	-	1.96	1.05	0.72	0.55
50%		-	-	-	-	1.01	0.56	0.39	0.29
75%		-	-	-	-	0.55	0.38	0.29	0.20
90%		-	-	-	-	0.55	0.38	0.29	-
None	R4 stream	-	-	-	-	1.42	0.77	0.53	0.40
50%		-	-	-	-	0.93	0.65	0.50	0.34
75%		-	-	-	-	0.93	0.65	0.50	0.34

90%		!	!	!	!	!	!	!	!
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PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in strawberry (1 x 1137 g/ha between rows) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 ditch: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 stream, R4 stream: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-88: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in strawberry (between rows)

Intended use		Strawberry (between rows)							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1137							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	1.445	0.766	0.523	0.398	!	!	!	!
50%		0.729	0.406	0.283	0.215	!	!	!	!
75%		0.411	0.249	0.179	!	!	!	!	!
90%		0.250	0.166	!	!	!	!	!	!
None	D4 pond	0.181	!	!	!	!	!	!	!

50%		-	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	1.559	0.833	0.571	0.434	-	-	-	-
50%		0.794	0.428	0.294	0.224	-	-	-	-
75%		0.412	0.225	0.156	-	-	-	-	-
90%		0.183	-	-	-	-	-	-	-
None	D6 ditch	1.434	0.760	0.519	0.395	-	-	-	-
50%		0.717	0.381	0.265	0.226	-	-	-	-
75%		0.382	0.226	0.226	-	-	-	-	-
90%		0.226	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.189	-	-	-
50%		-	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.324	0.715	0.492	0.347
50%		-	-	-	-	0.693	0.382	0.293	0.201
75%		-	-	-	-	0.548	0.381	0.293	-
90%		-	-	-	-	0.548	-	-	-
None	R2 stream	-	-	-	-	1.750	0.939	0.644	0.490
50%		-	-	-	-	0.899	0.487	0.336	0.256
75%		-	-	-	-	0.474	0.262	0.182	0.138
90%		-	-	-	-	0.219	0.130	-	-
None	R3 stream	-	-	-	-	1.825	0.978	0.672	0.511

50%		-	-	-	-	0.941	0.517	0.359	0.272
75%		-	-	-	-	0.514	0.353	0.270	0.184
90%		-	-	-	-	0.508	0.353	0.270	-
None	R4 stream	-	-	-	-	1.322	0.714	0.491	0.374
50%		-	-	-	-	0.861	0.600	0.461	0.315
75%		-	-	-	-	0.861	0.600	0.461	0.315
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	6.28	3.33	2.27	1.73	-	-	-	-
50%		3.17	1.77	1.23	0.93	-	-	-	-
75%		1.79	1.08	0.78	-	-	-	-	-
90%		1.09	0.72	-	-	-	-	-	-
None	D4 pond	0.79	-	-	-	-	-	-	-
50%		-	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	6.78	3.62	2.48	1.89	-	-	-	-
50%		3.45	1.86	1.28	0.97	-	-	-	-
75%		1.79	0.98	0.68	-	-	-	-	-
90%		0.80	-	-	-	-	-	-	-
None	D6 ditch	6.23	3.30	2.26	1.72	-	-	-	-
50%		3.12	1.66	1.15	0.98	-	-	-	-
75%		1.66	0.98	0.98	-	-	-	-	-

90%		0.98	-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.82	-	-	-
50%		-	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	5.76	3.11	2.14	1.51
50%		-	-	-	-	3.01	1.66	1.27	0.87
75%		-	-	-	-	2.38	1.66	1.27	-
90%		-	-	-	-	2.38	-	-	-
None	R2 stream	-	-	-	-	7.61	4.08	2.80	2.13
50%		-	-	-	-	3.91	2.12	1.46	1.11
75%		-	-	-	-	2.06	1.14	0.79	0.60
90%		-	-	-	-	0.95	0.57	-	-
None	R3 stream	-	-	-	-	7.93	4.25	2.92	2.22
50%		-	-	-	-	4.09	2.25	1.56	1.18
75%		-	-	-	-	2.23	1.53	1.17	0.80
90%		-	-	-	-	2.21	1.53	1.17	-
None	R4 stream	-	-	-	-	5.75	3.10	2.13	1.63
50%		-	-	-	-	3.74	2.61	2.00	1.37
75%		-	-	-	-	3.74	2.61	2.00	1.37
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-89: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in strawberry (1 x 1137 g/ha between rows)

Intended use		Strawberry (between rows)	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
50%	R1 stream	-	0.211
75%		-	-
90%		0.116	-
50%	R2 stream	-	0.255
75%		-	0.138
90%		0.127	-
50%	R3 stream	-	0.272
75%		-	0.156
90%		0.168	-
50%	R4 stream	-	0.201
75%		-	-
90%		0.141	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
50%	R1 stream	-	0.92
75%		-	-

90%		0.50	-
50%	R2 stream	-	1.11
75%		-	0.6
90%		0.55	-
50%	R3 stream	-	1.18
75%		-	0.68
90%		0.55	-
50%	R4 stream	-	0.87
75%		-	-
90%		0.61	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in strawberry (1 x 1137 g/ha between rows) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 50% nozzle reduction or 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 50% nozzle reduction

D4 stream, D6 ditch: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-9026: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in raspberry (1 x 1365 g/ha, between rows)

Group	Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
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Group		Fish acute	Fish pro- longed	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell- er pro- longed
Test spe- cies		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 196	NOEC 6.3	NOEC geomean 32	EC ₅₀ 147	NOEC 14.5	E _r C ₅₀ 9.3	NOEC 82	ErC ₅₀ 12		NOEC 227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	6.421	3.28	10.19	2.01	4.37	4.43	6.90	0.78	5.35	4.274	0.00019
D4 pond	0.221	0.11	0.35	0.07	0.15	0.15	0.24	0.03	0.18	1.212	0.00005
D4 stream	4.899	2.50	7.78	1.53	3.33	3.38	5.27	0.60	4.08	0.177	0.00001
D6 ditch	6.477	3.30	10.28	2.02	4.41	4.47	6.96	0.79	5.40	12.66	0.00056
R1 pond	0.221	0.11	0.35	0.07	0.15	0.15	0.24	0.03	0.18	1.028	0.00005
R1 stream	4.208	2.15	6.68	1.32	2.86	2.90	4.52	0.51	3.51	0.517	0.00002
R2 stream	5.578	2.85	8.85	1.74	3.79	3.85	6.00	0.68	4.65	0.341	0.00002
R3 stream	5.926	3.02	9.41	1.85	4.03	4.09	6.37	0.72	4.94	1.130	0.00005
R4 stream	4.195	2.14	6.66	1.31	2.85	2.89	4.51	0.51	3.50	0.480	0.00002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses raspberry, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FO-

CUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-27: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in raspberry

Intended use		Raspberry					
Active substance		pendimethalin					
Application rate (g/ha)		1 × 1365					
Nozzle reduction	No-spray buffer (m)	5	10	15	5	10	15
	Vegetated filter strip (m)	None	None	None	5	10	15
None	D3 ditch	1.741	0.923	-	-	-	-
50%		0.885	-	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 ditch	1.521	0.814	-	-	-	-
50%		0.776	-	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	D6 ditch	1.777	0.967	0.711	-	-	-
50%		0.967	0.558	-	-	-	-
75%		0.591	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.335	0.723	-
50%		-	-	-	0.700	-	-

75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	R2 stream	-	-	-	1.754	0.943	0.689
50%		-	-	-	0.905	0.493	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None		R3 stream	-	-	-	1.853	1.003
50%	-		-	-	0.971	0.536	-
75%	-		-	-	0.536	-	-
90%	-		-	-	-	-	-
None	R4 stream		-	-	-	1.332	0.721
50%		-	-	-	0.698	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
RAC (µg/L)							
0.93 (P. subcapitata)		PEC/RAC ratio					
None	D3 ditch	1.87	0.99	-	-	-	-
50%		0.95	-	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	1.64	0.88	-	-	-	-
50%		0.83	-	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-

None	D6 ditch	1.91	1.04	0.76	-	-	-
50%		1.04	0.60	-	-	-	-
75%		0.64	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.44	0.78	-
50%		-	-	-	0.75	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	R2 stream	-	-	-	1.89	1.01	0.74
50%		-	-	-	0.97	0.53	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	R3 stream	-	-	-	1.99	1.08	0.79
50%		-	-	-	1.04	0.58	-
75%		-	-	-	0.58	-	-
90%		-	-	-	-	-	-
None	R4 stream	-	-	-	1.43	0.78	-
50%		-	-	-	0.75	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-91: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in raspberry

Intended use	Raspberry (between rows)
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Active substance		Pendimethalin							
Application rate (g/ha)		1 × 1365							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	1.741	0.923	0.673	0.480	-	-	-	-
50%		0.885	0.493	0.363	0.261	-	-	-	-
75%		0.504	0.307	0.209	0.167	-	-	-	-
90%		0.309	0.205	-	-	-	-	-	-
None	D4 stream	1.521	0.814	0.594	0.424	-	-	-	-
50%		0.776	0.418	0.306	0.218	-	-	-	-
75%		0.403	0.220	0.161	-	-	-	-	-
90%		0.179	-	-	-	-	-	-	-
None	D6 ditch	1.777	0.967	0.711	0.510	-	-	-	-
50%		0.967	0.558	0.413	0.298	-	-	-	-
75%		0.591	0.370	0.276	0.202	-	-	-	-
90%		0.385	0.261	0.196	-	-	-	-	-
None	R1 stream	-	-	-	-	1.335	0.723	0.529	0.378
50%		-	-	-	-	0.700	0.386	0.283	0.203
75%		-	-	-	-	0.383	0.220	0.163	-
90%		-	-	-	-	0.199	-	-	-
None	R2 stream	-	-	-	-	1.754	0.943	0.689	0.492
50%		-	-	-	-	0.905	0.493	0.361	0.258
75%		-	-	-	-	0.480	0.268	0.196	0.141
90%		-	-	-	-	0.226	0.132	-	-

None	R3 stream	-	-	-		1.853	1.003	0.734	0.525
50%		-	-	-		0.971	0.536	0.393	0.282
75%		-	-	-		0.536	0.311	0.2298	0.166
90%		-	-	-		0.285	0.178	-	-
None	R4 stream	-	-	-		1.332	0.721	0.527	0.377
50%		-	-	-		0.698	0.385	0.282	0.203
75%		-	-	-		0.381	0.217	0.160	-
90%		-	-	-		0.196	-	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	1.87	0.99	0.72	0.52	-	-	-	-
50%		0.95	0.53	0.39	0.28	-	-	-	-
75%		0.54	0.33	0.22	0.18	-	-	-	-
90%		0.33	0.22	-	-	-	-	-	-
None	D4 stream	1.64	0.88	0.64	0.46	-	-	-	-
50%		0.83	0.45	0.33	0.23	-	-	-	-
75%		0.43	0.24	0.17	-	-	-	-	-
90%		0.19	-	-	-	-	-	-	-
None	D6 ditch	1.91	1.04	0.76	0.55	-	-	-	-
50%		1.04	0.60	0.44	0.32	-	-	-	-
75%		0.64	0.40	0.30	0.22	-	-	-	-
90%		0.41	0.28	0.21	-	-	-	-	-
None	R1 stream	-	-	-	-	1.44	0.78	0.57	0.41
50%		-	-	-	-	0.75	0.42	0.30	0.22

75%		-	-	-	-	0.41	0.24	0.18	-
90%		-	-	-	-	0.21	-	-	-
None	R2 stream	-	-	-	-	1.89	1.01	0.74	0.53
50%		-	-	-	-	0.97	0.53	0.39	0.28
75%		-	-	-	-	0.52	0.29	0.21	0.15
90%		-	-	-	-	0.24	0.14	-	-
None	R3 stream	-	-	-	-	1.99	1.08	0.79	0.56
50%		-	-	-	-	1.04	0.58	0.42	0.30
75%		-	-	-	-	0.58	0.33	0.25	0.18
90%		-	-	-	-	0.31	0.19	-	-
None	R4 stream	-	-	-	-	1.43	0.78	0.57	0.41
50%		-	-	-	-	0.75	0.41	0.30	0.22
75%		-	-	-	-	0.41	0.23	0.17	-
90%		-	-	-	-	0.21	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in raspberry are <1 when risk mitigation options are considered:

D3 ditch and D4 stream: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D6 ditch: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream and R4 stream: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction.

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios.

Table 9.5-92: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in raspberry

Intended use		Raspberry							
Active substance		Pendimethalin							
Application rate (g/ha)		1 × 1365							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	1.741	0.923	0.673	0.480	-	-	-	-
50%		0.885	0.493	0.363	0.261	-	-	-	-
75%		0.504	0.307	0.209	0.167	-	-	-	-
90%		0.309	0.205	-	-	-	-	-	-
None	D4 stream	1.521	0.814	0.594	0.424	-	-	-	-
50%		0.776	0.418	0.306	0.218	-	-	-	-
75%		0.403	0.220	0.161	-	-	-	-	-
90%		0.179	-	-	-	-	-	-	-
None	D6 ditch	1.777	0.967	0.711	0.510	-	-	-	-
50%		0.967	0.558	0.413	0.298	-	-	-	-
75%		0.591	0.370	0.276	0.202	-	-	-	-
90%		0.385	0.261	0.196	-	-	-	-	-
None	R1 stream	-	-	-	-	1.335	0.723	0.529	0.378
50%		-	-	-	-	0.700	0.386	0.283	0.203
75%		-	-	-	-	0.383	0.220	0.163	-

90%		-	-	-		0.199	-	-	-
None	R2 stream	-	-	-		1.754	0.943	0.689	0.492
50%		-	-	-		0.905	0.493	0.361	0.258
75%		-	-	-		0.480	0.268	0.196	0.141
90%		-	-	-		0.226	0.132	-	-
None	R3 stream	-	-	-		1.853	1.003	0.734	0.525
50%		-	-	-		0.971	0.536	0.393	0.282
75%		-	-	-		0.536	0.311	0.2298	0.166
90%		-	-	-		0.285	0.178	-	-
None	R4 stream	-	-	-		1.332	0.721	0.527	0.377
50%		-	-	-		0.698	0.385	0.282	0.203
75%		-	-	-		0.381	0.217	0.160	-
90%		-	-	-		0.196	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	7.570	4.013	2.926	2.087	-	-	-	-
50%		3.848	2.143	1.578	1.135	-	-	-	-
75%		2.191	1.335	0.909	0.726	-	-	-	-
90%		1.343	0.891	-	-	-	-	-	-
None	D4 stream	6.613	3.539	2.583	1.843	-	-	-	-
50%		3.374	1.817	1.330	0.948	-	-	-	-
75%		1.752	0.957	0.700	-	-	-	-	-
90%		0.778	-	-	-	-	-	-	-
None	D6 ditch	7.726	4.204	3.091	2.217	-	-	-	-

50%		4.204	2.426	1.796	1.296	-	-	-	-
75%		2.570	1.609	1.200	0.878	-	-	-	-
90%		1.674	1.135	0.852	-	-	-	-	-
None	R1 stream	-	-	-	-	5.804	3.143	2.300	1.643
50%		-	-	-	-	3.043	1.678	1.230	0.883
75%		-	-	-	-	1.665	0.957	0.709	-
90%		-	-	-	-	0.865	-	-	-
None	R2 stream	-	-	-	-	7.626	4.100	2.996	2.139
50%		-	-	-	-	3.935	2.143	1.570	1.122
75%		-	-	-	-	2.087	1.165	0.852	0.613
90%		-	-	-	-	0.983	0.574	-	-
None	R3 stream	-	-	-	-	8.057	4.361	3.191	2.283
50%		-	-	-	-	4.222	2.330	1.709	1.226
75%		-	-	-	-	2.330	1.352	0.999	0.722
90%		-	-	-	-	1.239	0.774	-	-
None	R4 stream	-	-	-	-	5.791	3.135	2.291	1.639
50%		-	-	-	-	3.035	1.674	1.226	0.883
75%		-	-	-	-	1.657	0.943	0.696	-
90%		-	-	-	-	0.852	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-93: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in raspberry (1 x 1365 g/ha between rows)

Intended use	Raspberry (between rows)
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Active substance		pendimethalin	
Application rate (g/ha)		1 × 1365	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.118
90%		0.123	-
75%	R2 stream	-	0.141
90%		0.132	-
75%	R3 stream	-	0.166
90%		0.178	-
75%	R4 stream	-	0.115
90%		0.120	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.51
90%		0.53	-
75%	R2 stream	-	0.61
90%		0.57	-
75%	R3 stream	-	0.72
90%		0.77	-
75%	R4 stream	-	0.5
90%		0.52	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in raspberry (1 x 1365 g/ha between rows) are <1 when risk mitigation options are considered:
 D3 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
 D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction
 D6 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction
 R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
 R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
 R3 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-9428: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in currants and grapevine (vines early application 1 x 1590 g/ha between rows)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dweller prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 196	NOEC 6.3	NOEC geomean 32	EC ₅₀ 147	NOEC 14.5	ErC ₅₀ 9.3	NOEC 82	ErC ₅₀ 12		NOEC 227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	7.468	3.81	11.85	2.33	5.08	5.15	8.03	0.91	6.22	4.714	0.00021

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er pro-longed
D4 pond	0.257	0.13	0.41	0.08	0.17	0.18	0.28	0.03	0.21	1.263	0.00006
D4 stream	5.697	2.91	9.04	1.78	3.88	3.93	6.13	0.69	4.75	0.206	0.00001
D6 ditch	7.533	3.84	11.96	2.35	5.12	5.20	8.10	0.92	6.28	11.46	0.00050
R1 pond	0.257	0.13	0.41	0.08	0.17	0.18	0.28	0.03	0.21	1.014	0.00004
R1 stream	4.893	2.50	7.77	1.53	3.33	3.37	5.26	0.60	4.08	0.599	0.00003
R2 stream	6.486	3.31	10.30	2.03	4.41	4.47	6.97	0.79	5.41	0.395	0.00002
R3 stream	6.891	3.52	10.94	2.15	4.69	4.75	7.41	0.84	5.74	1.299	0.00006
R4 stream	4.878	2.49	7.74	1.52	3.32	3.36	5.25	0.59	4.07	0.556	0.00002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses currants and grapevine (early application, 1 x 1590 between rows), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-29: ~~Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in currants and grapevine~~

Intended use		Currants and grapevine					
Active substance		pendimethalin					
Application rate (g/ha)		1 x 1590					
Nozzle reduction	No-spray buffer (m)	5	10	15	5	10	15
	Vegetated filter strip (m)	None	None	None	5	10	15
None	D3 ditch	2.023	1.073	0.782	-	-	-
50%		1.011	0.561	-	-	-	-

75%		0.563	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	1.768	0.945	0.690	-	-	-
50%		0.901	0.486	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None		D6 ditch	1.777	0.967	0.711	-	-
50%	0.967		0.558	-	-	-	-
75%	0.591		-	-	-	-	-
90%	-		-	-	-	-	-
None	R1 stream		-	-	-	1.335	0.723
50%		-	-	-	0.700	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None		R2 stream	-	-	-	1.754	0.943
50%	-		-	-	0.905	0.493	-
75%	-		-	-	-	-	-
90%	-		-	-	-	-	-
None	R3 stream		-	-	-	1.853	1.003
50%		-	-	-	0.971	0.536	-
75%		-	-	-	0.536	-	-
90%		-	-	-	-	-	-
None		R4 stream	-	-	-	1.332	0.721
50%	-		-	-	0.698	-	-

75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
RAC (µg/L)							
0.93 (<i>P. subcapitata</i>)		PEC/RAC ratio					
None	D3 ditch	2.18	1.15	0.84	-	-	-
50%		1.09	0.60	-	-	-	-
75%		0.61	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	1.90	1.02	0.74	-	-	-
50%		0.97	0.52	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	D6 ditch	1.91	1.04	0.76	-	-	-
50%		1.04	0.60	-	-	-	-
75%		0.64	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.44	0.78	-
50%		-	-	-	0.75	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	R2 stream	-	-	-	1.89	1.01	0.74
50%		-	-	-	0.97	0.53	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-

90%		-	-	-	-	-	-	-	-
None	D4 stream	1.768	0.945	0.690	0.492	-	-	-	-
50%		0.901	0.486	0.355	0.254	-	-	-	-
75%		0.467	0.256	0.187	0.134	-	-	-	-
90%		0.208	0.118	-	-	-	-	-	-
None	D6 ditch	2.041	1.096	0.802	0.574	-	-	-	-
50%		1.068	0.612	0.452	0.327	-	-	-	-
75%		0.638	0.391	0.290	0.214	-	-	-	-
90%		0.405	0.276	0.209	-	-	-	-	-
None	R1 pond	-	-	-	-	0.249	0.181	-	-
50%		-	-	-	-	0.148	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.546	0.837	0.612	0.437
50%		-	-	-	-	0.809	0.446	0.327	0.235
75%		-	-	-	-	0.441	0.254	0.187	0.135
90%		-	-	-	-	0.229	0.142	-	-
None	R2 stream	-	-	-	-	2.037	1.095	0.800	0.571
50%		-	-	-	-	1.050	0.572	0.418	0.299
75%		-	-	-	-	0.557	0.310	0.228	0.164
90%		-	-	-	-	0.261	0.153	-	-
None	R3 stream	-	-	-	-	2.132	1.154	0.844	0.603
50%		-	-	-	-	1.117	0.615	0.458	0.329
75%		-	-	-	-	0.612	0.355	0.263	0.190

90%		-	-	-	-	0.325	0.203	0.152	-
None	R4 stream	-	-	-	-	1.541	0.834	0.618	0.436
50%		-	-	-	-	0.807	0.445	0.327	0.234
75%		-	-	-	-	0.440	0.251	0.185	0.133
90%		-	-	-	-	0.222	0.137	-	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.18	1.15	0.84	0.60	-	-	-	-
50%		1.09	0.60	0.44	0.32	-	-	-	-
75%		0.61	0.37	0.27	0.20	-	-	-	-
90%		0.37	0.25	0.19	-	-	-	-	-
None	D4 pond	0.27	0.20	-	-	-	-	-	-
50%		0.16	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	1.90	1.02	0.74	0.53	-	-	-	-
50%		0.97	0.52	0.38	0.27	-	-	-	-
75%		0.50	0.28	0.20	0.14	-	-	-	-
90%		0.22	0.13	-	-	-	-	-	-
None	D6 ditch	2.19	1.18	0.86	0.62	-	-	-	-
50%		1.15	0.66	0.49	0.35	-	-	-	-
75%		0.69	0.42	0.31	0.23	-	-	-	-
90%		0.44	0.30	0.22	-	-	-	-	-
None	R1 pond	-	-	-	-	0.27	0.19	-	-

50%		-	-	-	-	0.16	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.66	0.90	0.66	0.47
50%		-	-	-	-	0.87	0.48	0.35	0.25
75%		-	-	-	-	0.47	0.27	0.20	0.15
90%		-	-	-	-	0.25	0.15	-	-
None	R2 stream	-	-	-	-	2.19	1.18	0.86	0.61
50%		-	-	-	-	1.13	0.62	0.45	0.32
75%		-	-	-	-	0.60	0.33	0.25	0.18
90%		-	-	-	-	0.28	0.16	-	-
None	R3 stream	-	-	-	-	2.29	1.24	0.91	0.65
50%		-	-	-	-	1.20	0.66	0.49	0.35
75%		-	-	-	-	0.66	0.38	0.28	0.20
90%		-	-	-	-	0.35	0.22	0.16	-
None	R4 stream	-	-	-	-	1.66	0.90	0.66	0.47
50%		-	-	-	-	0.87	0.48	0.35	0.25
75%		-	-	-	-	0.47	0.27	0.20	0.14
90%		-	-	-	-	0.24	0.15	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in currants and grapevine (1 x 1590 g/ha between rows) are <1 when risk mitigation options are considered:

D3 ditch and D6 ditch: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

D4 stream: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 stream and R4 stream: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip or **10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction**

R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-96: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in currants and grapevine between rows

Intended use		Currants and grapevine between rows							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re-duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.023	1.073	0.782	0.557	-	-	-	-
50%		1.011	0.561	0.412	0.296	-	-	-	-
75%		0.563	0.343	0.255	0.186	-	-	-	-
90%		0.343	0.2298	0.173	-	-	-	-	-
None	D4 pond	0.253	0.184	-	-	-	-	-	-
50%		0.150	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	1.768	0.945	0.690	0.492	-	-	-	-
50%		0.901	0.486	0.355	0.254	-	-	-	-
75%		0.467	0.256	0.187	0.134	-	-	-	-

90%		0.208	0.118	-	-	-	-	-	-
None	D6 ditch	2.041	1.096	0.802	0.574	-	-	-	-
50%		1.068	0.612	0.452	0.327	-	-	-	-
75%		0.638	0.391	0.290	0.214	-	-	-	-
90%		0.405	0.276	0.209	-	-	-	-	-
None	R1 pond	-	-	-	-	0.249	0.181	-	-
50%		-	-	-	-	0.148	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.546	0.837	0.612	0.437
50%		-	-	-	-	0.809	0.446	0.327	0.235
75%		-	-	-	-	0.441	0.254	0.187	0.135
90%		-	-	-	-	0.229	0.142	-	-
None	R2 stream	-	-	-	-	2.037	1.095	0.800	0.571
50%		-	-	-	-	1.050	0.572	0.418	0.299
75%		-	-	-	-	0.557	0.310	0.228	0.164
90%		-	-	-	-	0.261	0.153	-	-
None	R3 stream	-	-	-	-	2.132	1.154	0.844	0.603
50%		-	-	-	-	1.117	0.615	0.458	0.329
75%		-	-	-	-	0.612	0.355	0.263	0.190
90%		-	-	-	-	0.325	0.203	0.152	-
None	R4 stream	-	-	-	-	1.541	0.834	0.618	0.436
50%		-	-	-	-	0.807	0.445	0.327	0.234
75%		-	-	-	-	0.440	0.251	0.185	0.133

90%		-	-	-	-	0.222	0.137	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	8.796	4.665	3.400	2.422	-	-	-	-
50%		4.396	2.439	1.791	1.287	-	-	-	-
75%		2.448	1.491	1.109	0.809	-	-	-	-
90%		1.491	0.999	0.752	-	-	-	-	-
None	D4 pond	1.100	0.800	-	-	-	-	-	-
50%		0.652	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	7.687	4.109	3.000	2.139	-	-	-	-
50%		3.917	2.113	1.543	1.104	-	-	-	-
75%		2.030	1.113	0.813	0.583	-	-	-	-
90%		0.904	0.513	-	-	-	-	-	-
None	D6 ditch	8.874	4.765	3.487	2.496	-	-	-	-
50%		4.643	2.661	1.965	1.422	-	-	-	-
75%		2.774	1.700	1.261	0.930	-	-	-	-
90%		1.761	1.200	0.909	-	-	-	-	-
None	R1 pond	-	-	-	-	1.083	0.787	-	-
50%		-	-	-	-	0.643	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	6.722	3.639	2.661	1.900

50%		-	-	-	-	3.517	1.939	1.422	1.022
75%		-	-	-	-	1.917	1.104	0.813	0.587
90%		-	-	-	-	0.996	0.617	-	-
None	R2 stream	-	-	-	-	8.857	4.761	3.478	2.483
50%		-	-	-	-	4.565	2.487	1.817	1.300
75%		-	-	-	-	2.422	1.348	0.991	0.713
90%		-	-	-	-	1.135	0.665	-	-
None	R3 stream	-	-	-	-	9.270	5.017	3.670	2.622
50%		-	-	-	-	4.857	2.674	1.991	1.430
75%		-	-	-	-	2.661	1.543	1.143	0.826
90%		-	-	-	-	1.413	0.883	0.661	-
None	R4 stream	-	-	-	-	6.700	3.626	2.687	1.896
50%		-	-	-	-	3.509	1.935	1.422	1.017
75%		-	-	-	-	1.913	1.091	0.804	0.578
90%		-	-	-	-	0.965	0.596	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-97: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in currants and grapevines (1 x 1590 g/ha, between rows)

Intended use		Currants and grapevines between rows	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20

	No-spray buffer (m)	10	20
75%	R1 stream	-	0.135
90%		0.142	-
75%	R2 stream	-	0.164
90%		0.153	-
75%	R3 stream	-	0.190
90%		0.203	-
75%	R4 stream	-	0.132
90%		0.137	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.59
90%		0.62	-
75%	R2 stream	-	0.71
90%		0.67	-
75%	R3 stream	-	0.83
90%		0.88	-
75%	R4 stream	-	0.57
90%		0.60	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in currants and grapevines (1 x 1590 g/ha between rows) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D6 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction
 R1 stream, R4 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
 R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
 R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-9830: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in potato (1 x 1590 g/ha)

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er pro-longed
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	E _r C ₅₀	NOEC	ErC ₅₀		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12		227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	8.238	4.20	13.08	2.57	5.60	5.68	8.86	1.00	6.87	4.756	0.00021
D4 pond	0.332	0.17	0.53	0.10	0.23	0.23	0.36	0.04	0.28	1.271	0.00006
D4 stream	6.799	3.47	10.79	2.12	4.63	4.69	7.31	0.83	5.67	0.312	0.00001
D6 1 st ditch	8.146	4.16	12.93	2.55	5.54	5.62	8.76	0.99	6.79	2.566	0.00011
D6 2 nd ditch	8.280	4.22	13.14	2.59	5.63	5.71	8.90	1.01	6.90	5.079	0.00022

Group		Fish acute	Fish pro- longed	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell- er pro- longed
R1 pond	0.345	0.18	0.55	0.11	0.23	0.24	0.37	0.04	0.29	2.777	0.00012
R1 stream	5.691	2.90	9.03	1.78	3.87	3.92	6.12	0.69	4.74	7.480	0.00033
R2 stream	7.537	3.85	11.96	2.36	5.13	5.20	8.10	0.92	6.28	130.5	0.00574
R3 stream	8.012	4.09	12.72	2.50	5.45	5.53	8.62	0.98	6.68	8.458	0.00037

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses potato, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-31: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in potato

Intended-use		Potato									
Active substance		pendimethalin									
Application rate (g/ha)		1 × 1590									
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20		
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20		
None	D3 ditch	2.698	1.430	0.977	0.743	-	-	-	-		
50%		1.348	0.724	0.503	-	-	-	-	-		
75%		0.726	-	-	-	-	-	-	-		
90%		-	-	-	-	-	-	-	-		
None	D4 stream	2.919	1.561	1.069	0.813	-	-	-	-		

0.93 (P. subcapitata)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.78	0.54	-	-	-	-	-
75%		0.78	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.14	1.68	1.15	0.87	-	-	-	-
50%		1.60	0.86	0.59	-	-	-	-	-
75%		0.83	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 1 st ditch	2.87	1.52	1.04	0.79	-	-	-	-
50%		1.43	0.76	0.60	-	-	-	-	-
75%		0.73	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 2 nd ditch	2.92	1.55	1.06	0.80	-	-	-	-
50%		1.46	0.77	0.77	-	-	-	-	-
75%		0.77	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.65	1.42	0.98	-
50%		-	-	-	-	1.38	0.79	-	-
75%		-	-	-	-	1.13	-	-	-
90%		-	-	-	-	1.13	-	-	-
None	R2 stream	-	-	-	-	3.51	1.88	1.29	0.98
50%		-	-	-	-	1.80	0.98	0.67	-
75%		-	-	-	-	0.95	-	-	-

90%		-	-	-	-	-	-	-	-
None	R3 stream	-	-	-	-	3.65	1.95	1.34	1.02
50%		-	-	-	-	1.88	1.04	0.72	0.55
75%		-	-	-	-	1.20	0.84	-	-
90%		-	-	-	-	1.20	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-99: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in potato

Intended use		Potato							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re-duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.698	1.430	0.977	0.743	-	-	-	-
50%		1.348	0.724	0.503	0.389	-	-	-	-
75%		0.726	0.433	0.310	0.236	-	-	-	-
90%		0.434	0.291	0.214	0.163	-	-	-	-
None	D4 pond	0.331	0.241	0.190	-	-	-	-	-
50%		0.197	0.144	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.919	1.561	1.069	0.813	-	-	-	-
50%		1.487	0.802	0.551	0.425	-	-	-	-

75%		0.772	0.429	0.322	0.322	-	-	-	-
90%		0.348	0.178	0.322	0.322	-	-	-	-
None	D6 ditch 1 st	2.668	1.414	0.966	0.735	-	-	-	-
50%		1.333	0.707	0.558	0.566	-	-	-	-
75%		0.675	0.566	0.566	0.566	-	-	-	-
90%		0.566	0.566	0.566	-	-	-	-	-
None		D6 ditch 2 nd	2.712	1.438	0.982	0.747	-	-	-
50%	1.355		0.718	0.718	0.718	-	-	-	-
75%	0.718		0.718	0.718	0.718	-	-	-	-
90%	0.718		-	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.344	0.250	0.197	-
50%		-	-	-	-	0.208	0.152	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.460	1.325	0.911	0.703
50%		-	-	-	-	1.281	0.731	0.568	0.387
75%		-	-	-	-	1.050	0.731	0.568	0.387
90%		-	-	-	-	1.050	-	-	-
None	R2 stream	-	-	-	-	3.261	1.750	1.200	0.913
50%		-	-	-	-	1.674	0.909	0.625	0.483
75%		-	-	-	-	0.881	0.495	0.343	0.262
90%		-	-	-	-	0.412	0.240	0.184	0.129
None	R3 stream	-	-	-	-	3.394	1.816	1.246	0.948
50%		-	-	-	-	1.746	0.963	0.666	0.507

75%		-	-	-	-	1.113	0.777	0.605	0.413
90%		-	-	-	-	1.113	0.777	0.605	0.413
RAC (µg/L)									
0.93 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.78	0.54	0.42	-	-	-	-
75%		0.78	0.47	0.33	0.25	-	-	-	-
90%		0.47	0.31	0.23	0.18	-	-	-	-
None	D4 pond	0.36	0.26	0.20	-	-	-	-	-
50%		0.21	0.15	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.14	1.68	1.15	0.87	-	-	-	-
50%		1.60	0.86	0.59	0.46	-	-	-	-
75%		0.83	0.46	0.35	0.35	-	-	-	-
90%		0.37	0.19	0.35	0.35	-	-	-	-
None	D6 ditch 1 st	2.87	1.52	1.04	0.79	-	-	-	-
50%		1.43	0.76	0.60	0.61	-	-	-	-
75%		0.73	0.61	0.61	0.61	-	-	-	-
90%		0.61	0.61	0.61	-	-	-	-	-
None	D6 ditch 2 nd	2.92	1.55	1.06	0.80	-	-	-	-
50%		1.46	0.77	0.77	0.77	-	-	-	-
75%		0.77	0.77	0.77	0.77	-	-	-	-
90%		0.77	-	-	-	-	-	-	-

None	R1 pond	-	-	-	-	0.37	0.27	0.21	-
50%		-	-	-	-	0.22	0.16	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.65	1.42	0.98	0.76
50%		-	-	-	-	1.38	0.79	0.61	0.42
75%		-	-	-	-	1.13	0.79	0.61	0.42
90%		-	-	-	-	1.13	-	-	-
None	R2 stream	-	-	-	-	3.51	1.88	1.29	0.98
50%		-	-	-	-	1.80	0.98	0.67	0.52
75%		-	-	-	-	0.95	0.53	0.37	0.28
90%		-	-	-	-	0.44	0.26	0.20	0.14
None	R3 stream	-	-	-	-	3.65	1.95	1.34	1.02
50%		-	-	-	-	1.88	1.04	0.72	0.55
75%		-	-	-	-	1.20	0.84	0.65	0.44
90%		-	-	-	-	1.20	0.84	0.65	0.44

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in potato are <1 when risk mitigation options are considered:

D3ditch, D4 stream and D6 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

R2 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction.

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L

(mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-100: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in potato

Intended use		Potato							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.698	1.430	0.977	0.743	-	-	-	-
50%		1.348	0.724	0.503	0.389	-	-	-	-
75%		0.726	0.433	0.310	0.236	-	-	-	-
90%		0.434	0.291	0.214	0.163	-	-	-	-
None	D4 pond	0.331	0.241	0.190	-	-	-	-	-
50%		0.197	0.144	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.919	1.561	1.069	0.813	-	-	-	-
50%		1.487	0.802	0.551	0.425	-	-	-	-
75%		0.772	0.429	0.322	0.322	-	-	-	-
90%		0.348	0.322	0.322	0.322	-	-	-	-
None	D6 ditch 1 st	2.668	1.414	0.966	0.735	-	-	-	-
50%		1.333	0.707	0.558	0.566	-	-	-	-

75%		0.675	0.566	0.566	0.566	-	-	-	-
90%		0.566	0.566	0.566	-	-	-	-	-
None	D6 ditch 2 nd	2.712	1.438	0.982	0.747	-	-	-	-
50%		1.355	0.718	0.718	0.718	-	-	-	-
75%		0.718	0.718	0.718	0.718	-	-	-	-
90%		0.718	-	-	-	-	-	-	-
None		R1 pond	-	-	-	-	0.344	0.250	0.197
50%	-		-	-	-	0.208	0.152	-	-
75%	-		-	-	-	-	-	-	-
90%	-		-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.460	1.325	0.911	0.703
50%		-	-	-	-	1.281	0.731	0.568	0.387
75%		-	-	-	-	1.050	0.731	0.568	0.387
90%		-	-	-	-	1.050	-	-	-
None	R2 stream	-	-	-	-	3.261	1.750	1.200	0.913
50%		-	-	-	-	1.674	0.909	0.625	0.483
75%		-	-	-	-	0.881	0.495	0.343	0.262
90%		-	-	-	-	0.412	0.240	0.184	0.129
None	R3 stream	-	-	-	-	3.394	1.816	1.246	0.948
50%		-	-	-	-	1.746	0.963	0.666	0.507
75%		-	-	-	-	1.113	0.777	0.605	0.413
90%		-	-	-	-	1.113	0.777	0.605	0.413
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							

None	R1 stream	-	-	-	-	10.696	5.761	3.961	3.057
50%		-	-	-	-	5.570	3.178	2.470	1.683
75%		-	-	-	-	4.565	3.178	2.470	1.683
90%		-	-	-	-	4.565	-	-	-
None	R2 stream	-	-	-	-	14.178	7.609	5.217	3.970
50%		-	-	-	-	7.278	3.952	2.717	2.100
75%		-	-	-	-	3.830	2.152	1.491	1.139
90%		-	-	-	-	1.791	1.043	0.800	0.561
None	R3 stream	-	-	-	-	14.757	7.896	5.417	4.122
50%		-	-	-	-	7.591	4.187	2.896	2.204
75%		-	-	-	-	4.839	3.378	2.630	1.796
90%		-	-	-	-	4.839	3.378	2.630	1.796

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-101: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in potato (1 x 1590 g/ha)

Intended use		Potato	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.117
90%		0.215	-

75%	R2 stream	-	0.127
90%		0.236	-
75%	R3 stream	-	0.167
90%		0.305	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.51
90%		0.93	-
75%	R2 stream	-	0.55
90%		1.03	-
75%	R3 stream	-	0.73
90%		1.33	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in potato (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 90% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle

For scenarios D4 stream and D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries

Table 9.5-102: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in potato (1 x 1137 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell. er prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 196	NOEC 6.3	NOEC geomean 32	EC ₅₀ 147	NOEC 14.5	ErC ₅₀ 9.3	NOEC 82	ErC ₅₀ 12		NOEC 227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	5.890	3.01	9.35	1.84	4.01	4.06	6.33	0.72	4.91	3.849	0.00017
D4 pond	0.237	0.12	0.38	0.07	0.16	0.16	0.25	0.03	0.20	1.180	0.00005
D4 stream	4.861	2.48	7.72	1.52	3.31	3.35	5.23	0.59	4.05	0.224	0.00001
D6 1 st ditch	5.824	2.97	9.24	1.82	3.96	4.02	6.26	0.71	4.85	1.936	0.00009
D6 2 nd ditch	5.920	3.02	9.40	1.85	4.03	4.08	6.37	0.72	4.93	5.172	0.00023
R1 pond	0.254	0.13	0.40	0.08	0.17	0.18	0.27	0.03	0.21	2.763	0.00012
R1 stream	4.069	2.08	6.46	1.27	2.77	2.81	4.38	0.50	3.39	5.462	0.00024
R2 stream	5.389	2.75	8.55	1.68	3.67	3.72	5.79	0.66	4.49	94.02	0.00414
R3 stream	5.729	2.92	9.09	1.79	3.90	3.95	6.16	0.70	4.77	6.135	0.00027

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses potato (1 x 1137 g/ha), calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-103: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in potato

Intended use		Potato							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1137							
Nozzle re-duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	1.929	1.023	0.698	0.531	-	-	-	-
50%		0.965	0.537	0.373	0.284	-	-	-	-
75%		0.541	0.330	0.237	0.179	-	-	-	-
90%		0.332	0.221	0.163	-	-	-	-	-
None	D4 pond	0.242	0.176	-	-	-	-	-	-
50%		0.144	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.087	1.116	0.765	0.581	-	-	-	-
50%		1.064	0.574	0.394	0.300	-	-	-	-
75%		0.553	0.302	0.220	0.220	-	-	-	-
90%		0.246	0.220	-	-	-	-	-	-

None	D6 ditch 1 st	1.908	1.011	0.691	0.525	-	-	-	-
50%		0.953	0.505	0.386	0.386	-	-	-	-
75%		0.496	0.386	0.386	0.386	-	-	-	-
90%		0.386	0.386	-	-	-	-	-	-
None	D6 ditch 2 nd	1.939	1.028	0.702	0.534	-	-	-	-
50%		0.969	0.537	0.495	0.495	-	-	-	-
75%		0.540	0.495	0.495	0.495	-	-	-	-
90%		0.495	0.495	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.254	0.183	-	-
50%		-	-	-	-	0.155	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.765	0.953	0.656	0.498
50%		-	-	-	-	0.923	0.517	0.396	0.270
75%		-	-	-	-	0.742	0.517	0.396	0.270
90%		-	-	-	-	0.742	-	-	-
None	R2 stream	-	-	-	-	2.332	1.251	0.858	0.652
50%		-	-	-	-	1.198	0.650	0.448	0.340
75%		-	-	-	-	0.631	0.350	0.242	0.184
90%		-	-	-	-	0.291	0.169	0.128	-
None	R3 stream	-	-	-	-	2.440	1.331	0.901	0.685
50%		-	-	-	-	1.268	0.699	0.484	0.368
75%		-	-	-	-	0.785	0.548	0.421	0.287
90%		-	-	-	-	0.785	0.548	0.421	0.287

RAC (µg/L)		PEC/RAC ratio							
0.93 (mesocosm)									
None	D3 ditch	2.07	1.10	0.75	0.57	-	-	-	-
50%		1.04	0.58	0.40	0.31	-	-	-	-
75%		0.58	0.35	0.25	0.19	-	-	-	-
90%		0.36	0.24	0.18		-	-	-	-
None	D4 pond	0.26	0.19			-	-	-	-
50%		0.15				-	-	-	-
75%						-	-	-	-
90%						-	-	-	-
None	D4 stream	2.24	1.20	0.82	0.62	-	-	-	-
50%		1.14	0.62	0.42	0.32	-	-	-	-
75%		0.59	0.32	0.24	0.24	-	-	-	-
90%		0.26	0.24			-	-	-	-
None	D6 ditch 1 st	2.05	1.09	0.74	0.56	-	-	-	-
50%		1.02	0.54	0.42	0.42	-	-	-	-
75%		0.53	0.42	0.42	0.42	-	-	-	-
90%		0.42	0.42			-	-	-	-
None	D6 ditch 2 nd	2.08	1.11	0.75	0.57	-	-	-	-
50%		1.04	0.58	0.53	0.53	-	-	-	-
75%		0.58	0.53	0.53	0.53	-	-	-	-
90%		0.53	0.53			-	-	-	-
None	R1 pond	-	-	-	-	0.27	0.20		
50%		-	-	-	-	0.17			

75%									
90%									
None	R1 stream					1.90	1.02	0.71	0.54
50%						0.99	0.56	0.43	0.29
75%						0.80	0.56	0.43	0.29
90%						0.80			
None	R2 stream					2.51	1.35	0.92	0.70
50%						1.29	0.70	0.48	0.37
75%						0.68	0.38	0.26	0.20
90%						0.31	0.18	0.14	
None	R3 stream					2.62	1.43	0.97	0.74
50%						1.36	0.75	0.52	0.40
75%						0.84	0.59	0.45	0.31
90%						0.84	0.59	0.45	0.31

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in potato (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3ditch, D4 stream and D6 ditch: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-104: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in potato

Intended use		Potato							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1137							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	1.929	1.023	0.698	0.531	-	-	-	-
50%		0.965	0.537	0.373	0.284	-	-	-	-
75%		0.541	0.330	0.237	0.179	-	-	-	-
90%		0.332	0.221	0.163	-	-	-	-	-
None	D4 pond	0.242	0.176	-	-	-	-	-	-
50%		0.144	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.087	1.116	0.765	0.581	-	-	-	-
50%		1.064	0.574	0.394	0.300	-	-	-	-
75%		0.553	0.302	0.220	0.220	-	-	-	-
90%		0.246	0.220	-	-	-	-	-	-
None	D6 ditch 1 st	1.908	1.011	0.691	0.525	-	-	-	-
50%		0.953	0.505	0.386	0.386	-	-	-	-
75%		0.496	0.386	0.386	0.386	-	-	-	-

90%		0.386	0.386	-	-	-	-	-	-
None	D6 ditch 2 nd	1.939	1.028	0.702	0.534	-	-	-	-
50%		0.969	0.537	0.495	0.495	-	-	-	-
75%		0.540	0.495	0.495	0.495	-	-	-	-
90%		0.495	0.495	-	-	-	-	-	-
None	R1 pond	-	-	-	-	0.254	0.183	-	-
50%		-	-	-	-	0.155	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.765	0.953	0.656	0.498
50%		-	-	-	-	0.923	0.517	0.396	0.270
75%		-	-	-	-	0.742	0.517	0.396	0.270
90%		-	-	-	-	0.742	-	-	-
None	R2 stream	-	-	-	-	2.332	1.251	0.858	0.652
50%		-	-	-	-	1.198	0.650	0.448	0.340
75%		-	-	-	-	0.631	0.350	0.242	0.184
90%		-	-	-	-	0.291	0.169	0.128	-
None	R3 stream	-	-	-	-	2.440	1.331	0.901	0.685
50%		-	-	-	-	1.268	0.699	0.484	0.368
75%		-	-	-	-	0.785	0.548	0.421	0.287
90%		-	-	-	-	0.785	0.548	0.421	0.287
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	8.39	4.45	3.03	2.31	-	-	-	-

50%		4.20	2.33	1.62	1.23	-	-	-	-
75%		2.35	1.43	1.03	0.78	-	-	-	-
90%		1.44	0.96	0.71	-	-	-	-	-
None	D4 pond	1.05	0.77	-	-	-	-	-	-
50%		0.63	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	9.07	4.85	3.33	2.53	-	-	-	-
50%		4.63	2.50	1.71	1.30	-	-	-	-
75%		2.40	1.31	0.96	0.96	-	-	-	-
90%		1.07	0.96	-	-	-	-	-	-
None	D6 ditch 1 st	8.30	4.40	3.00	2.28	-	-	-	-
50%		4.14	2.20	1.68	1.68	-	-	-	-
75%		2.16	1.68	1.68	1.68	-	-	-	-
90%		1.68	1.68	-	-	-	-	-	-
None	D6 ditch 2 nd	8.43	4.47	3.05	2.32	-	-	-	-
50%		4.21	2.33	2.15	2.15	-	-	-	-
75%		2.35	2.15	2.15	2.15	-	-	-	-
90%		2.15	2.15	-	-	-	-	-	-
None	R1 pond	-	-	-	-	1.10	0.80	-	-
50%		-	-	-	-	0.67	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	7.67	4.14	2.85	2.17

50%		-	-	-	-	4.01	2.25	1.72	1.17
75%		-	-	-	-	3.23	2.25	1.72	1.17
90%		-	-	-	-	3.23	-	-	-
None	R2 stream	-	-	-	-	10.14	5.44	3.73	2.83
50%		-	-	-	-	5.21	2.83	1.95	1.48
75%		-	-	-	-	2.74	1.52	1.05	0.80
90%		-	-	-	-	1.27	0.73	0.56	-
None	R3 stream	-	-	-	-	10.61	5.79	3.92	2.98
50%		-	-	-	-	5.51	3.04	2.10	1.60
75%		-	-	-	-	3.41	2.38	1.83	1.25
90%		-	-	-	-	3.41	2.38	1.83	1.25

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-105: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in potato (1 x 1137 g/ha)

Intended use		Potato	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.153
90%		0.155	-
75%	R2 stream	-	0.184

90%		0.169	-
75%	R3 stream	-	0.209
90%		0.223	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.67
90%		0.67	-
75%	R2 stream	-	0.8
90%		0.73	-
75%	R3 stream	-	0.91
90%		0.97	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in potato (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries

Table 9.5-10632: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in ornamentals (vines, early application 1 x 1590 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dweller prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
AF		196	6.3	32	147	14.5	9.3	82	12		227300
RAC (µg/L)		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D3 ditch	9.955	5.08	15.80	3.11	6.77	6.87	10.70	1.21	8.30	6.279	0.00028
D4 pond	0.343	0.18	0.54	0.11	0.23	0.24	0.37	0.04	0.29	1.678	0.00007
D4 stream	7.595	3.88	12.06	2.37	5.17	5.24	8.17	0.93	6.33	0.274	0.00001
D6 ditch	10.04	5.12	15.94	3.14	6.83	6.92	10.80	1.22	8.37	15.25	0.00067
R1 pond	0.343	0.18	0.54	0.11	0.23	0.24	0.37	0.04	0.29	1.347	0.00006
R1 stream	6.522	3.33	10.35	2.04	4.44	4.50	7.01	0.80	5.44	0.799	0.00004
R2 stream	8.646	4.41	13.72	2.70	5.88	5.96	9.30	1.05	7.21	0.527	0.00002
R3 stream	9.186	4.69	14.58	2.87	6.25	6.34	9.88	1.12	7.66	1.731	0.00008
R4 stream	6.502	3.32	10.32	2.03	4.42	4.48	6.99	0.79	5.42	0.741	0.00003

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses ornamentals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-33: ~~Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in ornamentals~~

Intended use		Ornamentals							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle reduction	No spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.697	1.430	1.042	0.743	-	-	-	
50%		1.348	0.749	0.549	-	-	-	-	
75%		0.751	-	-	-	-	-	-	
90%		-	-	-	-	-	-	-	
None	D4 stream	2.357	1.260	0.919	-	-	-	-	
50%		1.201	0.647	-	-	-	-	-	
75%		0.623	-	-	-	-	-	-	
90%		-	-	-	-	-	-	-	
None	D6 ditch	2.720	1.461	1.068	0.767	-	-	-	
50%		1.424	0.816	0.600	-	-	-	-	
75%		0.851	-	-	-	-	-	-	
90%		-	-	-	-	-	-	-	
None	R1 stream	-	-	-		2.061	1.115	0.8151	-

50%		-	-	-		1.079	0.595	-	-
75%		-	-	-		0.588	-	-	-
90%		-	-	-		-	-	-	-
None	R2 stream	-	-	-		2.716	1.460	1.066	0.7622
50%		-	-	-		1.400	0.762	0.5573	-
75%		-	-	-		0.742	-	-	-
90%		-	-	-		-	-	-	-
None	R3 stream	-	-	-		2.842	1.538	1.124	0.8055
50%		-	-	-		1.488	0.821	0.6010	-
75%		-	-	-		0.815	-	-	-
90%		-	-	-		-	-	-	-
None	R4 stream	-	-	-		2.055	1.112	0.8129	-
50%		-	-	-		1.076	0.594	-	-
75%		-	-	-		0.587	-	-	-
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.93 (P. subcapitata)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.12	0.80	-	-	-	-
50%		1.45	0.81	0.59	-	-	-	-	-
75%		0.81	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.53	1.35	0.99	-	-	-	-	-
50%		1.29	0.70	-	-	-	-	-	-
75%		0.67	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-107: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in ornamentals (1 x 1590 g/ha)

Intended use		Ornamentals							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.697	1.430	1.042	0.743	-	-	-	
50%		1.348	0.749	0.549	0.402	-	-	-	
75%		0.751	0.464	0.343	0.253	-	-	-	
90%		0.464	0.311	0.232	0.173	-	-	-	
None	D4 pond	0.342	0.248	0.203	-	-	-	-	
50%		0.203	0.149	-	-	-	-	-	
75%		-	-	-	-	-	-	-	
90%		-	-	-	-	-	-	-	
None	D4 stream	2.357	1.260	0.919	0.666	-	-	-	
50%		1.201	0.647	0.480	0.344	-	-	-	
75%		0.623	0.346	0.253	0.182	-	-	-	
90%		0.281	0.160	0.117	-	-	-	-	
None	D6 ditch	2.720	1.461	1.068	0.767	-	-	-	
50%		1.424	0.816	0.600	0.443	-	-	-	
75%		0.851	0.528	0.392	0.288	-	-	-	

90%		0.548	0.373	0.282	0.210	-	-	-	
None	R1 pond	-	-	-		0.337	0.245	0.200	-
50%		-	-	-		0.200	0.147	-	-
75%		-	-	-		-	-	-	-
90%		-	-	-		-	-	-	-
None	R1 stream	-	-	-		2.061	1.115	0.8151	0.592
50%		-	-	-		1.079	0.595	0.442	0.318
75%		-	-	-		0.588	0.344	0.253	0.184
90%		-	-	-		0.309	0.192	0.142	-
None	R2 stream	-	-	-		2.716	1.460	1.066	0.7622
50%		-	-	-		1.400	0.762	0.5573	0.406
75%		-	-	-		0.742	0.419	0.308	0.222
90%		-	-	-		0.353	0.207	0.153	-
None	R3 stream	-	-	-		2.842	1.538	1.124	0.8055
50%		-	-	-		1.488	0.821	0.6010	0.439
75%		-	-	-		0.815	0.481	0.354	0.259
90%		-	-	-		0.439	0.275	0.204	0.152
None	R4 stream	-	-	-		2.055	1.112	0.8129	0.591
50%		-	-	-		1.076	0.594	0.441	0.318
75%		-	-	-		0.587	0.339	0.249	0.181
90%		-	-	-		0.300	0.186	0.138	-
RAC (µg/L) 0.93 (algae)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.12	0.80	-	-	-	-

50%		1.45	0.81	0.59	0.43	-	-	-	-
75%		0.81	0.50	0.37	0.27	-	-	-	-
90%		0.50	0.33	0.25	0.19	-	-	-	-
None	D4 pond	0.37	0.27	0.22	-	-	-	-	-
50%		0.22	0.16	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.53	1.35	0.99	0.72	-	-	-	-
50%		1.29	0.70	0.52	0.37	-	-	-	-
75%		0.67	0.37	0.27	0.20	-	-	-	-
90%		0.30	0.17	0.13	-	-	-	-	-
None	D6 ditch	2.92	1.57	1.15	0.82	-	-	-	-
50%		1.53	0.88	0.65	0.48	-	-	-	-
75%		0.92	0.57	0.42	0.31	-	-	-	-
90%		0.59	0.40	0.30	0.23	-	-	-	-
None	R1 pond	-	-	-	-	0.36	0.26	0.22	-
50%		-	-	-	-	0.22	0.16	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.22	1.20	0.88	0.64
50%		-	-	-	-	1.16	0.64	0.48	0.34
75%		-	-	-	-	0.63	0.37	0.27	0.20
90%		-	-	-	-	0.33	0.21	0.15	-
None	R2 stream	-	-	-	-	2.92	1.57	1.15	0.82

50%						1.51	0.82	0.60	0.44
75%						0.80	0.45	0.33	0.24
90%						0.38	0.22	0.16	-
None						3.06	1.65	1.21	0.87
50%	R3 stream					1.60	0.88	0.65	0.47
75%						0.88	0.52	0.38	0.28
90%						0.47	0.30	0.22	0.16
None						2.21	1.20	0.87	0.64
50%	R4 stream					1.16	0.64	0.47	0.34
75%						0.63	0.36	0.27	0.19
90%						0.32	0.20	0.15	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in ornamentals are <1 when risk mitigation options are considered

D4 stream: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

D3 ditch and D6 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream and R4 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R2 stream and R3 stream: 20 m no spray buffer zone + 20 m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-108: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in ornamentals

Intended use		Ornamentals							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re- reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.697	1.430	1.042	0.743	-	-	-	-
50%		1.348	0.749	0.549	0.402	-	-	-	-
75%		0.751	0.464	0.343	0.253	-	-	-	-
90%		0.464	0.311	0.232	0.173	-	-	-	-
None	D4 pond	0.342	0.248	0.203	-	-	-	-	-
50%		0.203	0.149	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.357	1.260	0.919	0.666	-	-	-	-
50%		1.201	0.647	0.480	0.344	-	-	-	-
75%		0.623	0.346	0.253	0.182	-	-	-	-
90%		0.281	0.160	0.117	-	-	-	-	-
None	D6 ditch	2.720	1.461	1.068	0.767	-	-	-	-
50%		1.424	0.816	0.600	0.443	-	-	-	-
75%		0.851	0.528	0.392	0.288	-	-	-	-
90%		0.548	0.373	0.282	0.210	-	-	-	-

None	R1 pond	-	-	-	-	0.337	0.245	0.200	-
50%		-	-	-	-	0.200	0.147	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.061	1.115	0.8151	0.592
50%		-	-	-	-	1.079	0.595	0.442	0.318
75%		-	-	-	-	0.588	0.344	0.253	0.184
90%		-	-	-	-	0.309	0.192	0.142	-
None	R2 stream	-	-	-	-	2.716	1.460	1.066	0.7622
50%		-	-	-	-	1.400	0.762	0.5573	0.406
75%		-	-	-	-	0.742	0.419	0.308	0.222
90%		-	-	-	-	0.353	0.207	0.153	-
None	R3 stream	-	-	-	-	2.842	1.538	1.124	0.8055
50%		-	-	-	-	1.488	0.821	0.6010	0.439
75%		-	-	-	-	0.815	0.481	0.354	0.259
90%		-	-	-	-	0.439	0.275	0.204	0.152
None	R4 stream	-	-	-	-	2.055	1.112	0.8129	0.591
50%		-	-	-	-	1.076	0.594	0.441	0.318
75%		-	-	-	-	0.587	0.339	0.249	0.181
90%		-	-	-	-	0.300	0.186	0.138	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	11.726	6.217	4.530	3.230	-	-	-	-
50%		5.861	3.257	2.387	1.748	-	-	-	-

75%		3.265	2.017	1.491	1.100	-	-	-	-
90%		2.017	1.352	1.009	0.752	-	-	-	-
None	D4 pond	1.487	1.078	0.883	-	-	-	-	-
50%		0.883	0.648	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None		D4 stream	10.248	5.478	3.996	2.896	-	-	-
50%	5.222		2.813	2.087	1.496	-	-	-	-
75%	2.709		1.504	1.100	0.791	-	-	-	-
90%	1.222		0.696	0.509	-	-	-	-	-
None	D6 ditch	11.826	6.352	4.643	3.335	-	-	-	-
50%		6.191	3.548	2.609	1.926	-	-	-	-
75%		3.700	2.296	1.704	1.252	-	-	-	-
90%		2.383	1.622	1.226	0.913	-	-	-	-
None	R1 pond	-	-	-	-	1.465	1.065	0.870	-
50%		-	-	-	-	0.870	0.639	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	8.961	4.848	3.544	2.574
50%		-	-	-	-	4.691	2.587	1.922	1.383
75%		-	-	-	-	2.557	1.496	1.100	0.800
90%		-	-	-	-	1.343	0.835	0.617	-
None	R2 stream	-	-	-	-	11.809	6.348	4.635	3.314
50%		-	-	-	-	6.087	3.313	2.423	1.765

75%		-	-	-	-	3.226	1.822	1.339	0.965
90%		-	-	-	-	1.535	0.900	0.665	-
None		-	-	-	-	12.357	6.687	4.887	3.502
50%	R3 stream	-	-	-	-	6.470	3.570	2.613	1.909
75%		-	-	-	-	3.543	2.091	1.539	1.126
90%		-	-	-	-	1.909	1.196	0.887	0.661
None		-	-	-	-	8.935	4.835	3.534	2.570
50%	R4 stream	-	-	-	-	4.678	2.583	1.917	1.383
75%		-	-	-	-	2.552	1.474	1.083	0.787
90%		-	-	-	-	1.304	0.809	0.600	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-109: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in ornamentals (1 x 1590 g/ha)

Intended use		Ornamentals	
Active substance		pendimethalin	
Application rate (g/ha)		1 × 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.182
90%		0.189	-
75%	R2 stream	-	0.219
90%		0.204	-

75%	R3 stream	-	0.255
90%		0.271	0.149
75%	R4 stream	-	0.178
90%		0.183	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.79
90%		0.82	-
75%	R2 stream	-	0.95
90%		0.87	-
75%	R3 stream	-	1.11
90%		1.18	0.65
75%	R4 stream	-	0.77
90%		0.80	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in ornamentals (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D6 ditch: 20m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip + 90% nozzle reduction

Table 9.5-11034: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in clover and alfalfa (grass 1 x 1000 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell. er prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 196	NOEC 6.3	NOEC geomean 32	EC ₅₀ 147	NOEC 14.5	ErC ₅₀ 9.3	NOEC 82	ErC ₅₀ 12		NOEC 227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	
Step 3											
D1 ditch	6.294	3.21	9.99	1.97	4.28	4.34	6.77	0.77	5.25	8.934	0.00039
D1 stream	5.077	2.59	8.06	1.59	3.45	3.50	5.46	0.62	4.23	0.320	0.00001
D2 ditch	6.337	3.23	10.06	1.98	4.31	4.37	6.81	0.77	5.28	12.29	0.00054
D2 stream	5.599	2.86	8.89	1.75	3.81	3.86	6.02	0.68	4.67	10.75	0.00047
D3 ditch	6.266	3.20	9.95	1.96	4.26	4.32	6.74	0.76	5.22	4.380	0.00019
D4 pond	0.216	0.11	0.34	0.07	0.15	0.15	0.23	0.03	0.18	1.066	0.00005
D4 stream	4.817	2.46	7.65	1.51	3.28	3.32	5.18	0.59	4.01	0.185	0.00001
D5 pond	0.216	0.11	0.34	0.07	0.15	0.15	0.23	0.03	0.18	0.930	0.00004
D5 stream	5.164	2.63	8.20	1.61	3.51	3.56	5.55	0.63	4.30	0.190	0.00001

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er pro-longed
R1 pond	0.216	0.11	0.34	0.07	0.15	0.15	0.23	0.03	0.18	0.016	0.00000
R1 stream	4.121	2.10	6.54	1.29	2.80	2.84	4.43	0.50	3.43	3.915	0.00017
R2 stream	5.454	2.78	8.66	1.70	3.71	3.76	5.86	0.67	4.55	0.357	0.0000
R3 stream	5.828	2.97	9.25	1.82	3.96	4.02	6.27	0.71	4.86	1.453	0.0001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses clover and alfalfa, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L.

Table 9.5-35: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in clover and alfalfa

Intended use		Clover and alfalfa					
Active substance		pendimethalin					
Application rate (g/ha)		1 × 1000					
Nozzle reduction	No spray buffer (m)	5	10	15	5	10	15
	Vegetated filter strip (m)	None	None	None	5	10	15
None	D1 ditch	1.706	0.933	0.644			
50%		0.925	0.543	-			
75%		-	-	-			
90%		-	-	-			
None	D1 stream	1.904	1.021	0.700			
50%		0.977	0.530	-			

75%		0.514	-	-			
90%		-	-	-			
None	D2 ditch	1.745	0.959	0.668			
50%		0.966	0.566	-			
75%		0.605	-	-			
90%		-	-	-			
None	D2 stream	2.048	1.087	0.742			
50%		1.026	0.545	-			
75%		0.515	-	-			
90%		-	-	-			
None	D3 ditch	1.697	0.900	-	-	-	-
50%		0.871	-	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	1.796	0.961	0.658	-	-	-
50%		0.916	0.494	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	D5 stream	1.924	1.029	0.705	-	-	-
50%		0.981	0.529	-	-	-	-
75%		0.509	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.558	0.840	-
50%		-	-	-	0.819	-	-

75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	R2 stream	-	-	-	2.058	1.106	0.759
50%		-	-	-	1.062	0.578	-
75%		-	-	-	0.564	-	-
90%		-	-	-	-	-	-
None	R3 stream	-	-	-	2.139	1.142	0.785
50%		-	-	-	1.104	0.608	-
75%		-	-	-	0.610	-	-
90%		-	-	-	-	-	-
RAC (µg/L)							
0.93 (P. subcapitata)		PEC/RAC ratio					
None	D1 ditch	1.83	1.00	0.69			
50%		0.99	0.58	-			
75%		-	-	-			
90%		-	-	-			
None	D1 stream	2.05	1.10	0.75			
50%		1.05	0.57	-			
75%		0.55	-	-			
90%		-	-	-			
None	D2 ditch	1.88	1.03	0.72			
50%		1.04	0.61	-			
75%		0.65	-	-			
90%		-	-	-			

None	D2 stream	2.20	1.17	0.80			
50%		1.10	0.59	-			
75%		0.55	-	-			
90%		-	-	-			
None	D3 ditch	1.82	0.97	-	-	-	-
50%		0.94	-	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	D4 stream	1.93	1.03	0.71	-	-	-
50%		0.98	0.53	-	-	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	D5 stream	2.07	1.11	0.76	-	-	-
50%		1.05	0.57	-	-	-	-
75%		0.55	-	-	-	-	-
90%		-	-	-	-	-	-
None	R1 stream	-	-	-	1.68	0.90	-
50%		-	-	-	0.88	-	-
75%		-	-	-	-	-	-
90%		-	-	-	-	-	-
None	R2 stream	-	-	-	2.21	1.19	0.82
50%		-	-	-	1.14	0.62	-
75%		-	-	-	0.61	-	-
90%		-	-	-	-	-	-

None	R3 stream	-	-	-	2.30	1.23	0.84
50%		-	-	-	1.19	0.65	-
75%		-	-	-	0.66	-	-
90%		-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-111: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in clover and alfalfa

Intended use		Clover and alfalfa							
Active substance		Pendimethalin							
Application rate (g/ha)		1 × 1000							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D1 ditch	1.706	0.933	0.644	0.488	-	-	-	-
50%		0.925	0.543	0.367	0.280	-	-	-	-
75%		0.582	0.333	0.240	0.184	-	-	-	-
90%		0.345	0.235	0.175	-	-	-	-	-
None	D1 stream	1.904	1.021	0.700	0.537	-	-	-	-
50%		0.977	0.530	0.365	0.278	-	-	-	-
75%		0.514	0.281	0.195	0.149	-	-	-	-
90%		0.231	0.133	-	-	-	-	-	-
None	D2 ditch	1.745	0.959	0.668	0.500	-	-	-	-
50%		0.966	0.566	0.383	0.293	-	-	-	-
75%		0.605	0.355	0.258	0.197	-	-	-	-

90%		0.369	0.251	0.187	-	-	-	-	-
None	D2 stream	2.048	1.087	0.742	0.573	-	-	-	-
50%		1.026	0.545	0.378	0.287	-	-	-	-
75%		0.515	0.277	0.190	0.144	-	-	-	-
90%		0.211	0.113	-	-	-	-	-	-
None	D3 ditch	1.697	0.900	0.624	0.474	-	-	-	-
50%		0.871	0.497	0.335	0.255	-	-	-	-
75%		0.520	0.298	0.213	0.163	-	-	-	-
90%		0.298	0.199	-	-	-	-	-	-
None	D4 stream	1.796	0.961	0.658	0.505	-	-	-	-
50%		0.916	0.494	0.341	0.260	-	-	-	-
75%		0.483	0.260	0.180	0.137	-	-	-	-
90%		0.210	0.118	-	-	-	-	-	-
None	D5 stream	1.924	1.029	0.705	0.541	-	-	-	-
50%		0.981	0.529	0.365	0.278	-	-	-	-
75%		0.509	0.278	0.192	0.146	-	-	-	-
90%		0.223	0.126	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.558	0.840	0.588	0.442
50%		-	-	-	-	0.819	0.462	0.312	0.238
75%		-	-	-	-	0.461	0.312	0.239	0.163
90%		-	-	-	-	0.447	0.312	0.239	-
None	R2 stream	-	-	-	-	2.058	1.106	0.759	0.581
50%		-	-	-	-	1.062	0.578	0.398	0.303
75%		-	-	-	-	0.564	0.310	0.215	0.164

90%		-	-	-	-	0.258	0.149	-	-
None	R3 stream	-	-	-	-	2.139	1.142	0.785	0.599
50%		-	-	-	-	1.104	0.608	0.418	0.318
75%		-	-	-	-	0.610	0.342	0.241	0.184
90%		-	-	-	-	0.384	0.267	0.204	-
RAC (µg/L)									
0.93 (algae)		PEC/RAC ratio							
None	D1 ditch	1.83	1.00	0.69	0.52	-	-	-	-
50%		0.99	0.58	0.39	0.30	-	-	-	-
75%		0.63	0.36	0.26	0.20	-	-	-	-
90%		0.37	0.25	0.19	-	-	-	-	-
None	D1 stream	2.05	1.10	0.75	0.58	-	-	-	-
50%		1.05	0.57	0.39	0.30	-	-	-	-
75%		0.55	0.30	0.21	0.16	-	-	-	-
90%		0.25	0.14	-	-	-	-	-	-
None	D2 ditch	1.88	1.03	0.72	0.54	-	-	-	-
50%		1.04	0.61	0.41	0.32	-	-	-	-
75%		0.65	0.38	0.28	0.21	-	-	-	-
90%		0.40	0.27	0.20	-	-	-	-	-
None	D2 stream	2.20	1.17	0.80	0.62	-	-	-	-
50%		1.10	0.59	0.41	0.31	-	-	-	-
75%		0.55	0.30	0.20	0.15	-	-	-	-
90%		0.23	0.12	-	-	-	-	-	-
None	D3 ditch	1.82	0.97	0.67	0.51	-	-	-	-

50%		0.94	0.53	0.36	0.27	-	-	-	-
75%		0.56	0.32	0.23	0.18	-	-	-	-
90%		0.32	0.21	-	-	-	-	-	-
None	D4 stream	1.93	1.03	0.71	0.54	-	-	-	-
50%		0.98	0.53	0.37	0.28	-	-	-	-
75%		0.52	0.28	0.19	0.15	-	-	-	-
90%		0.23	0.13	-	-	-	-	-	-
None	D5 stream	2.07	1.11	0.76	0.58	-	-	-	-
50%		1.05	0.57	0.39	0.30	-	-	-	-
75%		0.55	0.30	0.21	0.16	-	-	-	-
90%		0.24	0.14	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.68	0.90	0.63	0.48
50%		-	-	-	-	0.88	0.50	0.34	0.26
75%		-	-	-	-	0.50	0.34	0.26	0.18
90%		-	-	-	-	0.48	0.34	0.26	-
None	R2 stream	-	-	-	-	2.21	1.19	0.82	0.62
50%		-	-	-	-	1.14	0.62	0.43	0.33
75%		-	-	-	-	0.61	0.33	0.23	0.18
90%		-	-	-	-	0.28	0.16	-	-
None	R3 stream	-	-	-	-	2.30	1.23	0.84	0.64
50%		-	-	-	-	1.19	0.65	0.45	0.34
75%		-	-	-	-	0.66	0.37	0.26	0.20
90%		-	-	-	-	0.41	0.29	0.22	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in clover and alfalfa are <1 when risk mitigation options are considered:

D3 ditch: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D1 ditch, D4 stream: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D1 stream, D2 ditch, D2 stream, D5 stream: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream: 15 m no spray buffer zone + 15 m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios.

Table 9.5-112: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in clover and alfalfa

Intended use		Clover and alfalfa							
Active substance		Pendimethalin							
Application rate (g/ha)		1 × 1000							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D1 ditch	1.706	0.933	0.644	0.488	-	-	-	-
50%		0.925	0.543	0.367	0.280	-	-	-	-
75%		0.582	0.333	0.240	0.184	-	-	-	-
90%		0.345	0.235	0.175	-	-	-	-	-
None	D1 stream	1.904	1.021	0.700	0.537	-	-	-	-
50%		0.977	0.530	0.365	0.278	-	-	-	-

75%		0.514	0.281	0.195	0.149	-	-	-	-
90%		0.231	0.133	-	-	-	-	-	-
None	D2 ditch	1.745	0.959	0.668	0.500	-	-	-	-
50%		0.966	0.566	0.383	0.293	-	-	-	-
75%		0.605	0.355	0.258	0.197	-	-	-	-
90%		0.369	0.251	0.187	-	-	-	-	-
None	D2 stream	2.048	1.087	0.742	0.573	-	-	-	-
50%		1.026	0.545	0.378	0.287	-	-	-	-
75%		0.515	0.277	0.190	0.144	-	-	-	-
90%		0.211	0.113	-	-	-	-	-	-
None	D3 ditch	1.697	0.900	0.624	0.474	-	-	-	-
50%		0.871	0.497	0.335	0.255	-	-	-	-
75%		0.520	0.298	0.213	0.163	-	-	-	-
90%		0.298	0.199	-	-	-	-	-	-
None	D4 stream	1.796	0.961	0.658	0.505	-	-	-	-
50%		0.916	0.494	0.341	0.260	-	-	-	-
75%		0.483	0.260	0.180	0.137	-	-	-	-
90%		0.210	0.118	-	-	-	-	-	-
None	D5 stream	1.924	1.029	0.705	0.541	-	-	-	-
50%		0.981	0.529	0.365	0.278	-	-	-	-
75%		0.509	0.278	0.192	0.146	-	-	-	-
90%		0.223	0.126	-	-	-	-	-	-
None	R1 stream	-	-	-	-	1.558	0.840	0.588	0.442
50%		-	-	-	-	0.819	0.462	0.312	0.238

75%		-	-	-	-	0.461	0.312	0.239	0.163
90%		-	-	-	-	0.447	0.312	0.239	-
None	R2 stream	-	-	-	-	2.058	1.106	0.759	0.581
50%		-	-	-	-	1.062	0.578	0.398	0.303
75%		-	-	-	-	0.564	0.310	0.215	0.164
90%		-	-	-	-	0.258	0.149	-	-
None	R3 stream	-	-	-	-	2.139	1.142	0.785	0.599
50%		-	-	-	-	1.104	0.608	0.418	0.318
75%		-	-	-	-	0.610	0.342	0.241	0.184
90%		-	-	-	-	0.384	0.267	0.204	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D1 ditch	7.417	4.057	2.800	2.122	-	-	-	-
50%		4.022	2.361	1.596	1.217	-	-	-	-
75%		2.530	1.448	1.043	0.800	-	-	-	-
90%		1.500	1.022	0.761	-	-	-	-	-
None	D1 stream	8.278	4.439	3.043	2.335	-	-	-	-
50%		4.248	2.304	1.587	1.209	-	-	-	-
75%		2.235	1.222	0.848	0.648	-	-	-	-
90%		1.004	0.578	-	-	-	-	-	-
None	D2 ditch	7.587	4.170	2.904	2.174	-	-	-	-
50%		4.200	2.461	1.665	1.274	-	-	-	-
75%		2.630	1.543	1.122	0.857	-	-	-	-
90%		1.604	1.091	0.813	-	-	-	-	-

None	D2 stream	8.904	4.726	3.226	2.491	-	-	-	-
50%		4.461	2.370	1.643	1.248	-	-	-	-
75%		2.239	1.204	0.826	0.626	-	-	-	-
90%		0.917	0.491	-	-	-	-	-	-
None	D3 ditch	7.378	3.913	2.713	2.061	-	-	-	-
50%		3.787	2.161	1.457	1.109	-	-	-	-
75%		2.261	1.296	0.926	0.709	-	-	-	-
90%		1.296	0.865	-	-	-	-	-	-
None	D4 stream	7.809	4.178	2.861	2.196	-	-	-	-
50%		3.983	2.148	1.483	1.130	-	-	-	-
75%		2.100	1.130	0.783	0.596	-	-	-	-
90%		0.913	0.513	-	-	-	-	-	-
None	D5 stream	8.365	4.474	3.065	2.352	-	-	-	-
50%		4.265	2.300	1.587	1.209	-	-	-	-
75%		2.213	1.209	0.835	0.635	-	-	-	-
90%		0.970	0.548	-	-	-	-	-	-
None	R1 stream	-	-	-	-	6.774	3.652	2.557	1.922
50%		-	-	-	-	3.561	2.009	1.357	1.035
75%		-	-	-	-	2.004	1.357	1.039	0.709
90%		-	-	-	-	1.943	1.357	1.039	-
None	R2 stream	-	-	-	-	8.948	4.809	3.300	2.526
50%		-	-	-	-	4.617	2.513	1.730	1.317
75%		-	-	-	-	2.452	1.348	0.935	0.713
90%		-	-	-	-	1.122	0.648	-	-

None	R3 stream	-	-	-	-	9.300	4.965	3.413	2.604
50%		-	-	-	-	4.800	2.643	1.817	1.383
75%		-	-	-	-	2.652	1.487	1.048	0.800
90%		-	-	-	-	1.670	1.161	0.887	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-113: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in clover, alfalfa (1 x 1000 g/ha)

Intended use		Clover, alfalfa	
Active substance		Pendimethalin	
Application rate (g/ha)		1 x 1000	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.140
90%		0.146	-
75%	R2 stream	-	0.173
90%		0.156	-
75%	R3 stream	-	0.201
90%		0.212	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.61
90%		0.63	-

75%	R2 stream	-	0.75
90%		0.68	-
75%	R3 stream	-	0.87
90%		0.92	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in clover, alfalfa (1 x 1000 g/ha) are <1 when risk mitigation options are considered:

D1 ditch, D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

D1 stream, D3 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D2 stream, D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-11436: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in cucurbits (fruiting vegetables 1 x 1590 g/ha)

Group		Fish acute	Fish prolonged	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell-er prolonged
Test species		<i>O. mykiss</i>	<i>P.promelas</i>	<i>Danio rerio</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>	<i>Lemna gibba</i>		<i>C. riparius</i>
Endpoint		LC ₅₀	NOEC	NOEC geomean	EC ₅₀	NOEC	ErC ₅₀	NOEC	ErC ₅₀		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12		227300
AF		100	10	10	100	10	10	10	10		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2		22730
FOCUS Scenario	PEC _{gl-max} (µg/L)									PEC _{gl-max} (µg/kg)	

Group		Fish acute	Fish pro- longed	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant		Sed. dwell- er pro- longed
Step 3											
D3 ditch	9.944	5.07	15.78	3.11	6.76	6.86	10.69	1.21	8.29	5.752	0.00025
D4 pond	0.343	0.18	0.54	0.11	0.23	0.24	0.37	0.04	0.29	1.311	0.00006
D4 stream	7.805	3.98	12.39	2.44	5.31	5.38	8.39	0.95	6.50	0.346	0.00002
D6 ditch	9.873	5.04	15.67	3.09	6.72	6.81	10.62	1.20	8.23	3.560	0.00016
R1 pond	0.415	0.21	0.66	0.13	0.28	0.29	0.45	0.05	0.35	2.980	0.00013
R1 stream	6.562	3.35	10.42	2.05	4.46	4.53	7.06	0.80	5.47	30.35	0.00134
R2 stream	8.689	4.43	13.79	2.72	5.91	5.99	9.34	1.06	7.24	129.4	0.00569
R3 stream	9.282	4.74	14.73	2.90	6.31	6.40	9.98	1.13	7.74	3.613	0.00016
R4 stream	6.565	3.35	10.42	2.05	4.47	4.53	7.06	0.80	5.47	37.29	0.00164

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses cucurbits, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the most sensitive endpoint, RAC = 0.93 µg a.s./L (algae).

Table 9.5-37: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in cucurbits

Intended use		Cucurbits									
Active substance		pendimethalin									
Application rate (g/ha)		1 × 1590									
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20		
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20		

None	D3 ditch	2.694	1.428	0.975	0.742	-	-	-	-
50%		1.346	0.743	0.511	-	-	-	-	-
75%		0.745	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.906	1.554	1.064	0.810	-	-	-	-
50%		1.480	0.798	0.548	-	-	-	-	-
75%		0.768	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 ditch	2.675	1.418	0.968	0.737	-	-	-	-
50%		1.337	0.709	0.484	-	-	-	-	-
75%		0.689	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.460	1.325	0.912	-
50%		-	-	-	-	1.282	0.708	-	-
75%		-	-	-	-	0.984	-	-	-
90%		-	-	-	-	0.984	-	-	-
None	R2 stream	-	-	-	-	3.262	1.750	1.200	0.913
50%		-	-	-	-	1.675	0.909	0.626	-
75%		-	-	-	-	0.882	-	-	-
90%		-	-	-	-	-	-	-	-
None	R3 stream	-	-	-	-	3.402	1.807	1.235	0.939
50%		-	-	-	-	1.723	0.942	0.653	-
75%		-	-	-	-	0.969	0.673	-	-
90%		-	-	-	-	0.969	-	-	-

None	R4 stream	-	-	-	-	2.452	1.320	0.907	-
50%		-	-	-	-	1.646	1.148	-	-
75%		-	-	-	-	1.646	1.148	-	-
90%		-	-	-	-	-	-	-	-
RAC (µg/L)									
0.93 (P. subcapitata)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.55	-	-	-	-	-
75%		0.80	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.12	1.67	1.14	0.87	-	-	-	-
50%		1.59	0.86	0.59	-	-	-	-	-
75%		0.83	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D6 ditch	2.88	1.52	1.04	0.79	-	-	-	-
50%		1.44	0.76	0.52	-	-	-	-	-
75%		0.74	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.65	1.42	0.98	-
50%		-	-	-	-	1.38	0.76	-	-
75%		-	-	-	-	1.06	-	-	-
90%		-	-	-	-	1.06	-	-	-
None	R2 stream	-	-	-	-	3.51	1.88	1.29	0.98
50%		-	-	-	-	1.80	0.98	0.67	-

75%		-	-	-	-	0.95	-	-	-
90%		-	-	-	-	-	-	-	-
None	R3-stream	-	-	-	-	3.66	1.94	1.33	1.01
50%		-	-	-	-	1.85	1.01	0.70	-
75%		-	-	-	-	1.04	0.72	-	-
90%		-	-	-	-	1.04	-	-	-
None	R4-stream	-	-	-	-	2.64	1.42	0.98	-
50%		-	-	-	-	1.77	1.23	-	-
75%		-	-	-	-	1.77	1.23	-	-
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-115: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in curcubits

Intended use		Curcubits							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.694	1.428	0.975	0.742	-	-	-	-
50%		1.346	0.743	0.511	0.399	-	-	-	-
75%		0.745	0.453	0.324	0.247	-	-	-	-
90%		0.453	0.304	0.223	0.170	-	-	-	-
None	D4 pond	0.331	0.241	0.190	-	-	-	-	-

50%		0.197	0.144	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.906	1.554	1.064	0.810	-	-	-	-
50%		1.480	0.798	0.548	0.423	-	-	-	-
75%		0.768	0.426	0.307	0.307	-	-	-	-
90%		0.346	0.307	0.307	0.307	-	-	-	-
None	D6 ditch	2.675	1.418	0.968	0.737	-	-	-	-
50%		1.337	0.709	0.484	0.459	-	-	-	-
75%		0.689	0.459	0.459	0.459	-	-	-	-
90%		0.459	0.459	0.459	-	-	-	-	-
None	R1 pond 1 st	-	-	-	-	0.343	0.249	0.197	-
50%		-	-	-	-	0.257	0.173	-	-
75%		-	-	-	-	0.257	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.460	1.325	0.912	0.704
50%		-	-	-	-	1.282	0.708	0.533	0.379
75%		-	-	-	-	0.984	0.694	0.533	0.363
90%		-	-	-	-	0.984	0.694	0.533	0.363
None	R2 stream	-	-	-	-	3.262	1.750	1.200	0.913
50%		-	-	-	-	1.675	0.909	0.626	0.483
75%		-	-	-	-	0.882	0.496	0.343	0.262
90%		-	-	-	-	0.412	0.252	0.194	0.132
None	R3 stream	-	-	-	-	3.402	1.807	1.235	0.939

50%		-	-	-		1.723	0.942	0.653	0.504
75%		-	-	-		0.969	0.673	0.523	0.356
90%		-	-	-		0.969	0.673	0.523	0.356
None	R4 stream	-	-	-		2.452	1.320	0.907	0.691
50%		-	-	-		1.646	1.148	0.894	0.611
75%		-	-	-		1.646	1.148	0.894	0.611
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	2.90	1.54	1.05	0.80	-	-	-	-
50%		1.45	0.80	0.55	0.43	-	-	-	-
75%		0.80	0.49	0.35	0.27	-	-	-	-
90%		0.49	0.33	0.24	0.18	-	-	-	-
None	D4 pond	0.36	0.26	0.20	-	-	-	-	-
50%		0.21	0.15	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	3.12	1.67	1.14	0.87	-	-	-	-
50%		1.59	0.86	0.59	0.45	-	-	-	-
75%		0.83	0.46	0.33	0.33	-	-	-	-
90%		0.37	0.33	0.33	0.33	-	-	-	-
None	D6 ditch	2.88	1.52	1.04	0.79	-	-	-	-
50%		1.44	0.76	0.52	0.49	-	-	-	-
75%		0.74	0.49	0.49	0.49	-	-	-	-

90%		0.49	0.49	0.49	-	-	-	-	-
None	R1 pond 1 st	-	-	-	-	0.37	0.27	0.21	-
50%		-	-	-	-	0.28	0.19	-	-
75%		-	-	-	-	0.28	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.65	1.42	0.98	0.76
50%		-	-	-	-	1.38	0.76	0.57	0.41
75%		-	-	-	-	1.06	0.75	0.57	0.39
90%		-	-	-	-	1.06	0.75	0.57	0.39
None	R2 stream	-	-	-	-	3.51	1.88	1.29	0.98
50%		-	-	-	-	1.80	0.98	0.67	0.52
75%		-	-	-	-	0.95	0.53	0.37	0.28
90%		-	-	-	-	0.44	0.27	0.21	0.14
None	R3 stream	-	-	-	-	3.66	1.94	1.33	1.01
50%		-	-	-	-	1.85	1.01	0.70	0.54
75%		-	-	-	-	1.04	0.72	0.56	0.38
90%		-	-	-	-	1.04	0.72	0.56	0.38
None	R4 stream	-	-	-	-	2.64	1.42	0.98	0.74
50%		-	-	-	-	1.77	1.23	0.96	0.66
75%		-	-	-	-	1.77	1.23	0.96	0.66
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in cucurbits are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R4 stream: 15m no spray buffer zone + 15m vegetative strip

R1 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

R2 stream: 20m no spray buffer zone + 20 m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

PEC/RAC ratios were also calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies and the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L. Furthermore, VFSSMOD calculation have been done as refinement for all R scenarios, with the exception of R1 pond scenario.

Table 9.5-116: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in cucurbits

Intended use		Cucurbits							
Active substance		pendimethalin							
Application rate (g/ha)		1 × 1590							
Nozzle re- duction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.694	1.428	0.975	0.742	-	-	-	-
50%		1.346	0.743	0.511	0.399	-	-	-	-
75%		0.745	0.453	0.324	0.247	-	-	-	-
90%		0.453	0.304	0.223	0.170	-	-	-	-
None	D4 pond	0.331	0.241	0.190	-	-	-	-	-
50%		0.197	0.144	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.906	1.554	1.064	0.810	-	-	-	-

50%		1.480	0.798	0.548	0.423	-	-	-	-
75%		0.768	0.426	0.307	0.307	-	-	-	-
90%		0.346	0.307	0.307	0.307	-	-	-	-
None	D6 ditch	2.675	1.418	0.968	0.737	-	-	-	-
50%		1.337	0.709	0.484	0.459	-	-	-	-
75%		0.689	0.459	0.459	0.459	-	-	-	-
90%		0.459	0.459	0.459	-	-	-	-	-
None	R1 pond 1 st	-	-	-	-	0.343	0.249	0.197	-
50%		-	-	-	-	0.257	0.173	-	-
75%		-	-	-	-	0.257	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	2.460	1.325	0.912	0.704
50%		-	-	-	-	1.282	0.708	0.533	0.379
75%		-	-	-	-	0.984	0.694	0.533	0.363
90%		-	-	-	-	0.984	0.694	0.533	0.363
None	R2 stream	-	-	-	-	3.262	1.750	1.200	0.913
50%		-	-	-	-	1.675	0.909	0.626	0.483
75%		-	-	-	-	0.882	0.496	0.343	0.262
90%		-	-	-	-	0.412	0.252	0.194	0.132
None	R3 stream	-	-	-	-	3.402	1.807	1.235	0.939
50%		-	-	-	-	1.723	0.942	0.653	0.504
75%		-	-	-	-	0.969	0.673	0.523	0.356
90%		-	-	-	-	0.969	0.673	0.523	0.356
None	R4 stream	-	-	-	-	2.452	1.320	0.907	0.691

50%		-	-	-		1.646	1.148	0.894	0.611
75%		-	-	-		1.646	1.148	0.894	0.611
90%		-	-	-		-	-	-	-
RAC (µg/L)									
0.23 (mesocosm)		PEC/RAC ratio							
None	D3 ditch	11.713	6.209	4.239	3.226	-	-	-	-
50%		5.852	3.230	2.222	1.735	-	-	-	-
75%		3.239	1.970	1.409	1.074	-	-	-	-
90%		1.970	1.322	0.970	0.739	-	-	-	-
None	D4 pond	1.439	1.048	0.826	-	-	-	-	-
50%		0.857	0.626	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	12.635	6.757	4.626	3.522	-	-	-	-
50%		6.435	3.470	2.383	1.839	-	-	-	-
75%		3.339	1.852	1.335	1.335	-	-	-	-
90%		1.504	1.335	1.335	1.335	-	-	-	-
None	D6 ditch	11.630	6.165	4.209	3.204	-	-	-	-
50%		5.813	3.083	2.104	1.996	-	-	-	-
75%		2.996	1.996	1.996	1.996	-	-	-	-
90%		1.996	1.996	1.996	-	-	-	-	-
None	R1 pond 1 st	-	-	-	-	1.491	1.083	0.857	-
50%		-	-	-	-	1.117	0.752	-	-
75%		-	-	-	-	1.117	-	-	-

90%		-	-	-	-	-	-	-	-
None	R1 stream	-	-	-	-	10.696	5.761	3.965	3.061
50%		-	-	-	-	5.574	3.078	2.317	1.648
75%		-	-	-	-	4.278	3.017	2.317	1.578
90%		-	-	-	-	4.278	3.017	2.317	1.578
None	R2 stream	-	-	-	-	14.183	7.609	5.217	3.970
50%		-	-	-	-	7.283	3.952	2.722	2.100
75%		-	-	-	-	3.835	2.157	1.491	1.139
90%		-	-	-	-	1.791	1.096	0.843	0.574
None	R3 stream	-	-	-	-	14.791	7.857	5.370	4.083
50%		-	-	-	-	7.491	4.096	2.839	2.191
75%		-	-	-	-	4.213	2.926	2.274	1.548
90%		-	-	-	-	4.213	2.926	2.274	1.548
None	R4 stream	-	-	-	-	10.661	5.739	3.943	3.004
50%		-	-	-	-	7.157	4.991	3.887	2.657
75%		-	-	-	-	7.157	4.991	3.887	2.657
90%		-	-	-	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-117: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in cucurbits (1 x 1590 g/ha)

Intended use	Cucurbits
Active substance	pendimethalin
Application rate (g/ha)	1 x 1590

Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	-	0.213
90%		0.215	-
75%	R3 stream	-	0.285
90%		0.305	-
75%	R4 stream	-	0.212
90%		0.267	-
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream	-	0.93
90%		0.93	-
75%	R3 stream	-	1.24
90%		1.33	-
75%	R4 stream	-	0.92
90%		1.16	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in cucurbits (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D4 stream, D6 ditch, and R3 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures. Scenario D6 is not relevant for CEU countries.

For scenario R3 restriction will be needed (do not apply on terraced clay soils with a slope greater than 10% respectively)

Further refinement

As as further refinement of the aquatic risk assessment, applicant wishes to propose an alternative approach by using the suggestion of the RMS (NL) during the pendimethalin EU peer review. The RMS proposed a higher tier risk assessment based on a geomen NOEC = 0.96 µg a.s./L (three validated mesocosm) with an assessment factor (AF) = 2 resulting to an ETO-RAC = 0.48 µg a.s./L. This approach is accepted by France as zRMS, since considers that the ETO-RAC = 0.48 µg a.s./L is still conservative and reliable for the higher tier risk assessment. Calculations for all crops, step 4, considering the RAC of 0.48 µg/L are shown below. VFSMOD calculation have been done as refinement for R scenarios.

zRMS comments:

Four different mesocosms were available to address the risk to algae, macrophytes, aquatic invertebrates, and sediment-dwelling organisms. All mesocosm studies resulted in consistent NOEC (0.23–3.8 µg a.s./L) and NOEAEC (1.1–5 µg a.s./L), confirming algae as the most sensitive group. During the Peer Review Experts' Teleconference it was agreed that the use of the NOEAEC (recovery approach) was not a suitable option, since recovery after autumn applications of

pendimethalin might be slower than what is observed in the mesocosms, all carried out in spring/summer. Hence, it was agreed to use the most conservative NOEC value (0.23 µg a.s./L), together with an assessment factor of 1. Such low assessment factor was agreed due to the consistency between the results of the mesocosm studies. In the final commenting round of the present conclusion the RMS disagreed on this approach, which was nevertheless deemed as appropriate during the Peer Review Experts' Teleconference. The opinion of RMS was that a geometric mean across NOEC from the different mesocosms should have been used in the risk assessment. It must be noted that the use of the geometric mean was considered during the Peer Review Experts' Teleconference and considered not appropriate.

Therefore the risk was based on the NOEC of 0.23 microgram/L

Table 9.5-118: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in pre emergence

Intended use		Winter cereals pre emergence							
Active substance		pendimethalin							
Application rate (g/ha)		1 > 1390							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D1 ditch	0.729	1.455	1.005	0.765				
50%		1.415	0.805	0.565	0.431				
75%		0.839	0.515	0.372	0.280				
90%		0.534	0.339	0.267	0.202				
None	D1 stream	0.222	1.209	1.068	0.888				
50%		1.015	0.836	0.588	0.455				
75%		0.609	0.441	0.318	0.259				
90%		0.440	0.304	0.222	0.169				
None	D2 ditch	0.731	1.462	1.008	0.768				
50%		1.425	0.815	0.572	0.435				
75%		0.849	0.519	0.372	0.315				

90%		0.394	0.365	0.316	0.313				
None	D3 stream	0.281	0.241	0.189	0.303				
90%		0.640	0.572	0.596	0.453				
75%		0.534	0.435	0.399	0.225				
90%		0.338	0.207	0.204					
None	D3 ditch	0.691	0.426	0.574	0.291				
90%		0.344	0.235	0.515	0.396				
75%		0.240	0.137	0.511	0.257				
90%		0.141	0.091	0.215	0.162				
None	D4 Pond	0.324	0.245	0.186					
90%		0.192	0.141						
75%									
90%									
None	D4 stream	0.150	0.372	0.142	0.369				
90%		0.575	0.857	0.591	0.430				
75%		0.335	0.469	0.326	0.258				
90%		0.121	0.258	0.258	0.258				
None	D5 pond	0.232	0.241	0.191					
90%		0.196	0.145						
75%									
90%									
None	D5 stream	0.397	0.803	0.231	0.236				
90%		0.701	0.915	0.671	0.480				
75%		0.694	0.506	0.555	0.271				

90%		0.123	0.290	0.210	0.160				
None	D6 ditch	0.210	0.467	0.010	0.270				
90%		0.130	0.330	0.570	0.465				
75%		0.560	0.526	0.045	0.465				
90%		0.557	0.445	0.455					
None	R1 pond					0.540	0.217	0.095	
90%						0.208	0.165		
75%									
90%									
None	R1 stream					0.564	0.326	0.912	0.624
90%						0.272	0.181	0.630	0.465
75%						0.165	0.181	0.622	0.465
90%						0.165	0.181	0.622	0.465
None	R1 stream					0.536	0.326	0.255	0.265
90%						0.255	0.091	0.668	0.505
75%						0.124	0.264	0.602	0.417
90%						0.124	0.264	0.602	0.417
None	R4 stream					0.462	0.332	0.916	0.672
90%						0.224	0.290	0.758	0.517
75%						0.224	0.290	0.758	0.517
90%									
RAC (mg/L)									
L48 (geometric mean/cm)		TEC/RAC ratio							
None	D1 ditch	5.69	1.05	3.09	1.59				

80%		135	168	178	130				
75%		175	107	178	138				
90%		111	173	156	141				
None	D2 stream	671	156	143	135				
80%		136	178	132	131				
75%		169	122	135					
90%		152	131	146	135				
None	D2 ditch	569	105	110	100				
80%		197	170	119	131				
75%		177	108	173	136				
90%		145	126	136	136				
None	D2 stream	634	163	148	138				
80%		542	132	124	121				
75%		172	121	132	143				
90%		171	143	143					
None	D3 ditch	568	197	103	154				
80%		130	154	107	131				
75%		154	121	135	141				
90%		132	161	144	141				
None	D4 Road	163	147	139					
80%		140	129						
75%									
90%									
None	D4 stream	656	143	146	131				

80%		173	179	183	194				
75%		175	198	178	193				
90%		188	152	154	193				
None	D5 pond	163	180	180					
80%		181	180						
75%									
90%									
None	D5 stream	208	176	156	195				
80%		154	191	181	190				
75%		196	105	182	196				
90%		197	161	180	193				
None	D6 ditch	167	106	111	190				
80%		158	172	121	193				
75%		179	110	195	193				
90%		146	193	195					
None	E1 pond					181	181	181	
80%						182	181		
75%									
90%									
None	E1 stream					183	177	180	185
80%						186	169	181	180
75%						183	169	180	180
90%						183	169	180	180
None	E5 stream					207	181	161	198

80%						376	200	138	0.05
75%						354	153	125	0.37
90%						354	153	125	0.36
None						515	273	191	0.15
80%	R4 stream					337	206	158	0.05
75%						337	206	158	0.05
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-119: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in pre emergence

Intended use		Winter cereals pre emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1 < 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream		0.21
90%		0.215	
75%	R2 stream		0.802
90%		0.620	0.802
75%	R4 stream		0.21
90%		0.215	
RAC (µg/L)			

PEC		PEC/RAC ratio	
75%	R1 stream		0.44
90%		0.53	
75%	R3 stream		0.82
90%		1.29	
75%	R4 stream		0.44
90%		0.53	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter cereals in pre-emergence are <1 when risk mitigation options are considered:

D1 ditch, D2 ditch: 20m no spray buffer zone + 50% nozzle reduction or 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D1 stream, D2 stream, D3 ditch, D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

Table 9.5-120: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in post emergence

Intended use		Winter cereals post emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 < 1391							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20

None	D1 stream	0.150	0.675	0.165	0.374				
50%		0.600	0.870	0.405	0.459				
75%		0.850	0.475	0.335	0.355				
90%		0.136	0.265	0.248	0.205				
None	D3 pond	0.340	0.240	0.196					
50%		0.200	0.100						
75%									
90%									
None	D5 stream	0.597	0.801	0.251	0.267				
50%		0.710	0.230	0.602	0.089				
75%		0.910	0.510	0.365	0.277				
90%		0.402	0.225	0.216	0.165				
None	D6 ditch	0.536	0.500	0.015	0.295				
50%		0.500	0.870	0.602	0.165				
75%		0.920	0.570	0.449	0.449				
90%		0.595	0.440	0.449	0.449				
None	R1 pond					0.345	0.252	0.200	
50%						0.210	0.152		
75%									
90%									
None	R1 stream					0.470	0.302	0.015	0.006
50%						0.202	0.160	0.625	0.426
75%						0.165	0.160	0.625	0.426
90%						0.165			

None	R1 stream					0.331	0.332	0.333	0.333
50%						0.336	0.330	0.332	0.332
75%						0.335	0.333	0.336	0.332
90%						0.335	0.333	0.336	0.332
None	R4 stream					0.352	0.325	0.309	0.302
50%						0.310	0.332	0.305	0.333
75%						0.310	0.332	0.305	0.333
90%									
RAC (µg/L)									
1:48 (mesosom isomer)		FEORAC ratio							
None	D1 ditch	5.80	3.19	3.21	1.69				
50%		3.19	1.85	1.51	1.00				
75%		1.97	1.23	0.99	0.68				
90%		1.28	0.87	0.64	0.49				
None	D1 stream	6.71	3.56	3.46	1.85				
50%		3.56	1.98	1.72	1.22				
75%		1.74	1.03	0.74	0.56				
90%		1.05	0.72	0.53	0.41				
None	D2 ditch	5.05	3.06	3.11	1.61				
50%		3.01	1.74	1.23	0.92				
75%		1.82	1.14	0.85	0.63				
90%		1.16	0.81	0.60	0.46				
None	D2 stream	6.33	3.34	3.33	1.77				
50%		3.33	1.75	1.26	0.91				

75%		169	192	174	199				
90%		173	196	179	203				
Name	D3 Road	570	597	583	634				
80%		230	253	238	263				
75%		156	192	176	230				
90%		191	231	215	266				
Name	D4 Road	167	151	180					
80%		162	180						
75%									
90%									
Name	D4 stream	654	692	642	732				
80%		315	332	326	376				
75%		178	200	190	231				
90%		269	288	282	323				
Name	D5 pond	671	652	691					
80%		343	331						
75%									
90%									
Name	D5 stream	708	676	656	728				
80%		356	334	324	372				
75%		198	188	176	238				
90%		298	282	275	338				
Name	D6 ditch	574	514	518	466				
80%		313	281	286	232				

75%		137	137	137	137				
90%		135	135	135	135				
None	R1 pond					153	153	153	
80%						155	152		
75%									
90%									
None	R1 stream					515	478	151	145
80%						377	162	150	139
75%						243	162	150	139
90%						243			
None	R2 stream					715	686	205	202
80%						592	204	151	150
75%						243	132	114	113
90%						243	132	114	113
None	R4 stream					511	276	139	144
80%						515	219	168	143
75%						515	219	168	143
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-121: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in post-emergence

Intended use	Winter cereals post-emergence
Active substance	pendimethalin

Application rate (g/ha)		15 x 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	D1 stream		0.21
90%		0.216	
75%	R3 stream		0.27
90%		0.306	0.168
75%	R4 stream		0.20
90%		0.201	
PEC (µg/L)			
0.48		PEC/RAC ratio	
75%	D1 stream		0.45
90%		0.45	
75%	R3 stream		0.6
90%		0.64	
75%	R4 stream		0.45
90%		0.42	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter cereals in post-emergence (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D1 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D1 stream, D2 ditch, D6 ditch: 20m no spray buffer zone + 90% nozzle reduction or 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D2 stream, D3 ditch: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle

reduction

D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-122: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in pre emergence

Intended use		Winter cereals pre emergence							
Active substance		pendimethalin							
Application rate (g/ha)		1 < 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D1 ditch	1.966	1.070	0.741	0.562				
50%		1.064	0.615	0.435	0.328				
75%		0.645	0.402	0.292	0.221				
90%		0.420	0.254	0.210					
None	D1 stream	3.307	1.222	0.875	0.634				
50%		1.157	0.612	0.419	0.319				
75%		0.580	0.342	0.248	0.185				
90%		0.346	0.237	0.172					
None	D2 ditch	1.973	1.074	0.742	0.562				
50%		1.071	0.619	0.437	0.330				
75%		0.652	0.407	0.292	0.222				
90%		0.424	0.256	0.213					

None	D3 stream	0.35	0.24	0.551	0.536				
80%		0.174	0.531	0.026	0.327				
75%		0.589	0.311	0.212	0.163				
90%		0.238	0.181						
None	D3 ditch	0.924	1.019	0.796	0.530				
80%		0.964	0.537	0.578	0.234				
75%		0.540	0.328	0.251	0.175				
90%		0.224	0.215	0.159					
None	D4 Pond	0.240	0.176						
80%		0.148							
75%									
90%									
None	D4 stream	0.252	1.197	0.324	0.623				
80%		0.146	0.625	0.431	0.326				
75%		0.011	0.344	0.235	0.132				
90%		0.305	0.139	0.178					
None	D5 pond	0.245	0.176						
80%		0.146							
75%									
90%									
None	D5 stream	0.429	1.248	0.384	0.669				
80%		0.223	0.668	0.459	0.349				
75%		0.651	0.370	0.261	0.192				
90%		0.256	0.215	0.155					

None	D1 ditch	0.571	0.027	0.544	0.568				
50%		0.676	0.531	0.658	0.658				
75%		0.659	0.411	0.505	0.605				
90%		0.639	0.305	0.505	0.605				
None	R1 pond					0.249	0.130		
50%						0.151			
75%									
90%									
None	R1 stream					0.766	0.958	0.658	0.197
50%						0.917	0.576	0.401	0.301
75%						0.926	0.576	0.401	0.301
90%						0.926			
None	R1 stream					0.333	0.313	0.902	0.665
50%						0.268	0.621	0.428	0.365
75%						0.794	0.594	0.425	0.291
90%						0.794	0.594	0.425	0.291
None	R4 stream					0.775	0.958	0.660	0.502
50%						0.012	0.703	0.589	0.367
75%						0.012	0.703	0.589	0.367
90%									
RAC (ng/L)									
148 (metoclopramid german)		TEO/RAC ratio							
None	D1 ditch	0.16	0.22	0.54	0.17				
50%		0.22	0.23	0.50	0.58				

75%		134	134	131	136				
90%		133	130	134					
None	D1 stream	130	153	174	131				
90%		140	120	137	136				
75%		121	121	131	139				
90%		122	139	137					
None	D2 ditch	111	124	155	113				
90%		123	120	131	139				
75%		126	135	131	136				
90%		133	130	134					
None	D2 stream	139	152	177	135				
90%		145	130	139	138				
75%		123	133	135	135				
90%		131	127						
None	D3 ditch	101	112	146	110				
90%		101	112	133	139				
75%		113	107	146	136				
90%		107	143	145					
None	D4 Pond	130	136						
90%		130							
75%									
90%									
None	D4 stream	139	149	171	130				
90%		146	130	130	138				

75%		157	171	150	138				
90%		174	139	157					
None	D5 pond	151	132						
80%		151							
75%									
90%									
None	D5 stream	506	268	133	139				
80%		255	139	136	121				
75%		137	177	152	141				
90%		171	142	152					
None	D6 ditch	111	124	156	143				
80%		122	129	131	131				
75%		137	136	131	134				
90%		132	132	131	134				
None	R1 pond					152	138		
80%						131			
75%									
90%									
None	R1 stream					506	128	130	134
80%						151	120	132	135
75%						172	120	132	135
90%						172			
None	R2 stream					506	272	168	173
80%						263	144	160	176

75%						0.65	0.13	0.80	0.30
90%						0.65	0.13	0.80	0.30
Name	R1 stream					3.69	2.00	1.39	0.05
75%						3.11	1.46	1.12	0.26
90%						3.11	1.46	1.12	0.26
75%									
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-123: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in pre-emergence

Intended use		Winter cereals pre-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1.2-1.37	
Nozzle reduc- tion	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	0.286	0.152
90%		0.154	
75%	R2 stream	0.431	0.237
90%		0.237	
75%	R4 stream	0.286	0.152
90%		0.154	
RAC (µg/L)			
0.33		PEC/RAC ratio	

75%	R1 stream	0.61	0.32
90%			
75%	R3 stream	0.91	0.58
90%			
75%	R4 stream	0.6	0.32
90%			

PEC: Predicted environmental concentration, RAC: Regulatory acceptable concentration, PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter cereals in pre-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered.

D1 ditch, D1 stream, D2 ditch, D2 stream, D3 ditch, D4 stream, D5 stream, D6 ditch: 15m no spray buffer zone+ 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

Table 9.5-L24: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in post emergence

Intended use		Winter cereals post emergence							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D1 ditch	0.989	0.095	0.763	0.577				
50%		0.095	0.432	0.449	0.330				
75%		0.677	0.432	0.305	0.331				
90%		0.140	0.296	0.224	0.166				

None	D1 stream	0.303	0.330	0.533	0.533				
50%		0.153	0.161	0.408	0.416				
75%		0.597	0.330	0.253	0.191				
90%		0.360	0.247	0.184					
None	D2 ditch	0.940	0.051	0.724	0.551				
50%		0.034	0.597	0.424	0.319				
75%		0.634	0.590	0.283	0.214				
90%		0.408	0.276	0.205					
None	D3 stream	0.171	0.164	0.796	0.806				
50%		0.111	0.600	0.412	0.313				
75%		0.579	0.419	0.224	0.168				
90%		0.267	0.136						
None	D3 ditch	0.322	0.019	0.696	0.539				
50%		0.360	0.533	0.371	0.283				
75%		0.533	0.317	0.222	0.171				
90%		0.315	0.210						
None	D4 Pond	0.240	0.175						
50%		0.146							
75%									
90%									
None	D4 stream	0.252	0.197	0.824	0.625				
50%		0.144	0.625	0.461	0.328				
75%		0.611	0.344	0.259	0.182				
90%		0.306	0.189	0.172					

None	D5 pond	0.235	0.123						
80%		0.126							
75%									
90%									
None	D5 stream	0.229	0.285	0.380	0.369				
80%		0.223	0.306	0.459	0.439				
75%		0.651	0.320	0.260	0.197				
90%		0.336	0.216	0.155					
None	D6 pond	0.971	0.027	0.829	0.368				
80%		0.076	0.621	0.455	0.333				
75%		0.659	0.411	0.506	0.306				
90%		0.429	0.806	0.506					
None	R1 pond					0.229	0.130		
80%						0.151			
75%									
90%									
None	R1 stream					0.760	0.252	0.652	0.497
80%						0.917	0.572	0.440	0.300
75%						0.824	0.572	0.440	0.300
90%						0.824			
None	R2 stream					0.453	0.322	0.916	0.602
80%						0.277	0.701	0.482	0.363
75%						0.721	0.501	0.582	0.362
90%						0.721	0.501	0.582	0.362

None	R1 stream					1753	1976	1653	1709
50%						1059	1219	1568	1357
75%						1059	1219	1568	1357
90%									
RAC (µg/L)									
148 (mixture of isomers)		TEORAC ratio							
None	D1 ditch	414	228	159	120				
50%		228	132	120	72				
75%		141	88	120	72				
90%		82	62	126	75				
None	D1 stream	420	255	173	132				
50%		240	138	127	78				
75%		124	92	135	74				
90%		85	61	138					
None	D2 ditch	404	219	151	115				
50%		215	124	128	78				
75%		126	83	139	74				
90%		85	63	143					
None	D2 stream	452	242	166	126				
50%		251	125	136	78				
75%		151	86	146	78				
90%		102	62						
None	D3 ditch	408	213	146	110				
50%		208	111	127	72				

F302		131	132	133	134				
P002		134	134						
N002	DE Road	133	132						
P002		133							
F302									
P002									
N002	DE stream	133	133	131	130				
P002		133	130	130	133				
F302		137	131	130	133				
P002		134	132	136					
N002	DE road	131	133						
P002		131							
F302									
P002									
N002	DE stream	136	133	133	133				
P002		135	132	136	137				
F302		136	131	134	131				
P002		137	134	132					
N002	DE ditch	131	134	136	138				
P002		134	132	131	133				
F302		137	136	134	134				
P002		132	134	134					
N002	R1 pond					132	133		
P002						131			

75%									
90%									
None	R1 stream					378	1.98	1.36	0.01
80%						131	1.20	0.92	0.35
75%						172	1.20	0.92	0.35
90%						172			
None	R1 stream					511	2.76	1.91	0.14
80%						376	1.46	1.01	0.27
75%						151	1.04	0.81	0.35
90%						151	1.04	0.81	0.35
None	R1 stream					965	1.97	1.55	0.03
80%						222	1.55	1.19	0.31
75%						222	1.55	1.19	0.31
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-125: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals in post-emergence

Intended use		Winter cereals post-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1.5-1157	
Nozzle reduction	Vegetated filter strip (m)	0	20
	No-spray buffer (m)	0	20

75%	R1 stream		0.152
90%		0.154	
75%	R3 stream		0.270
90%		0.279	
75%	R4 stream		0.147
90%		0.148	
RAC (µg/L)			
0.33		PEC/RAC ratio	
75%	R1 stream		0.32
90%		0.32	
75%	R3 stream		0.42
90%		0.46	
75%	R4 stream		0.33
90%		0.30	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter cereals in post-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered.

D1 ditch, D1 stream, D2 ditch, D2 stream, D3 ditch, D4 stream, D5 stream, D6 ditch: 15m no spray buffer zone+ 50% nozzle reduction or 10m no spray buffer zone+ 75% nozzle reduction or 5m no spray buffer zone+ 90% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-126: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize in pre emergence

Intended use	Maize in pre emergence
Active substance	pendimethalin

Application rate (g/ha)		15-1391							
Nozzle re- fraction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	0.696	1.429	0.976	0.733				
50%		0.347	0.714	0.520	0.396				
75%		0.231	0.435	0.325	0.243				
90%		0.156	0.305	0.225	0.170				
None	D4 pond	0.337	0.245	0.192					
50%		0.201	0.147						
75%									
90%									
None	D4 stream	0.914	1.558	1.062	0.812				
50%		0.485	0.801	0.551	0.418				
75%		0.271	0.422	0.291	0.222				
90%		0.242	0.192	0.162					
None	D5 pond	0.231	0.240	0.198					
50%		0.167	0.144						
75%									
90%									
None	D5 stream	0.152	1.698	1.155	0.879				
50%		0.607	0.867	0.595	0.452				
75%		0.405	0.458	0.316	0.231				
90%		0.372	0.312	0.148	0.115				
None	D6 ditch	1.697	1.430	0.976	0.733				

80%		0.30	0.33	0.37	0.40				
75%		0.26	0.30	0.34	0.38				
90%		0.40	0.43	0.49					
None	R1 pond					0.30	0.26	0.05	
80%						0.25	0.30		
75%									
90%									
None	R1 stream					0.30	0.25	0.01	0.02
80%						0.20	0.20	0.57	0.34
75%						0.05	0.20	0.57	0.34
90%						0.05			
None	R1 stream					0.22	0.20	0.05	0.23
80%						0.24	0.11	0.22	0.12
75%						0.35	0.22	0.30	0.10
90%						0.10	0.20	0.05	0.12
None	R2 stream					0.30	0.30	0.35	0.29
80%						0.24	0.13	0.55	0.17
75%						0.35	0.12	0.40	0.20
90%						0.30	0.12	0.40	0.20
None	R3 stream					0.52	0.21	0.02	0.00
80%						0.10	0.22	0.60	0.33
75%						0.10	0.22	0.60	0.33
90%									
None	R4 stream					0.30	0.26	0.05	

10%						0.205	0.150		
75%									
90%									
RAC (µg/L)									
148 (maximum amount)		PEC/RAC ratio							
None	D1 pond	5.02	0.98	2.03	0.55				
10%		2.91	0.56	1.08	0.31				
75%		1.50	0.28	0.58	0.16				
90%		0.95	0.18	0.36	0.10				
None	D4 pond	0.70	0.13	0.30					
10%		0.42	0.07						
75%									
90%									
None	D4 stream	6.07	0.25	2.22	0.69				
10%		3.02	0.07	1.15	0.37				
75%		1.61	0.38	0.61	0.18				
90%		0.71	0.41	0.59					
None	D5 pond	0.69	0.50	0.40					
10%		0.41	0.30						
75%									
90%									
None	D5 stream	6.57	0.51	2.41	0.73				
10%		3.35	0.31	1.24	0.38				
75%		1.74	0.35	0.66	0.20				

90%		153	144	153	134				
None	D6 dust	575	498	303	155				
90%		231	153	106	134				
75%		153	134	152	134				
90%		152	134	152					
None	R1 nord					191	151	191	
90%						195	191		
75%									
90%									
None	R1 stream					515	476	190	144
90%						407	157	140	133
75%						420	157	140	133
90%						420			
None	R2 stream					633	366	251	191
90%						351	190	151	100
75%						195	103	171	154
90%						195	150	195	147
None	R3 stream					710	376	257	196
90%						350	196	150	104
75%						195	128	198	167
90%						194	128	198	167
None	R4 stream					511	275	169	124
90%						335	194	179	141
75%						335	194	179	141

90%									
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PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the risk-in trigger of 1 are shown in bold

Table 9.5-127: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize pre-emergence

Intended use		Maize pre-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1 < 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	 	0.216
90%		0.216	
75%	R2 stream	 	0.240
90%		0.250	0.120
75%	R3 stream	 	0.243
90%		0.205	0.168
75%	R4 stream	 	0.213
90%		0.275	
RAC (µg/L)			
0.33		PEC/RAC ratio	
75%	R1 stream	 	0.65
90%		0.65	
75%	R2 stream	 	0.72

90%		0.30	
75%	R3 stream		0.59
90%		0.64	
75%	R4 stream		0.44
90%		0.57	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in maize pre-emergence (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D5 stream, D6 ditch: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

Table 9.5-128: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize in post emergence

Intended use		Maize in post emergence								
Active substance		pendimethalin								
Application rate (g/ha)		1 x 1590								
Nozzle reduction	No-spray buffer (m)	5	10	15	20		5	10	15	20
	Vegetated filter strip (m)	None	None	None	None		5	10	15	20
None	D3 ditch	2.699	1.430	0.979	0.743					
50%		1.250	0.752	0.525	0.398					
75%		0.757	0.465	0.331	0.252					
90%		0.464	0.310	0.225	0.172					

Nome	D1 sand	0338	0336	0339					
80%		0301	0347						
75%									
90%									
Nome	D1 stream	0336	0325	0334	0357				
80%		0351	0338	0376	0338				
75%		0309	0345	0308	0255				
90%		0372	0215	0332	0138				
Nome	D3 sand	0333	0241	0392					
80%		0398	0145						
75%									
90%									
Nome	D3 stream	0304	0301	0392	0335				
80%		0324	0313	0336	0427				
75%		0324	0427	0292	0223				
90%		0341	0191	0135					
Nome	D6 ditch	0399	0430	0372	0243				
80%		0365	0362	0329	0456				
75%		0373	0472	0456	0456				
90%		0473	0456	0456					
Nome	R1 pond					0235	0251	0108	
80%						0202	0152		
75%									
90%									

None	R1 stream					0.53	0.31	0.90	0.55
50%						0.26	0.80	0.48	0.19
75%						0.51	0.80	0.48	0.19
90%						0.51			
None	R2 stream					0.38	0.20	0.91	0.23
50%						0.26	0.25	0.39	0.17
75%						0.38	0.50	0.48	0.25
90%						0.24	0.51	0.72	0.16
None	R3 stream					0.94	0.39	0.46	0.21
50%						0.21	0.65	0.62	0.30
75%						0.26	0.65	0.50	0.33
90%						0.26	0.65	0.50	0.33
None	R4 stream					0.34	0.32	0.91	0.25
50%						0.23	0.14	0.20	0.24
75%						0.23	0.14	0.20	0.24
90%									
RAC (mg/L)									
D48 (mesocosm, geotank)		PEC/RAC ratio							
None	D3 ditch	0.62	0.98	0.04	0.55				
50%		0.61	0.57	0.09	0.23				
75%		0.58	0.96	0.69	0.25				
90%		0.97	0.65	0.87	0.26				
None	D4 pond	0.70	0.51	0.40					
50%		0.42	0.31						

75%									
90%									
None	D1 stream	633	139	339	176				
80%		323	173	120	191				
75%		169	192	174	149				
90%		128	145	158	138				
None	D3 pond	165	150	140					
80%		141	150						
75%									
90%									
None	D3 stream	626	334	229	174				
80%		318	170	117	139				
75%		165	182	161	141				
90%		121	140	128					
None	D6 ditch	562	298	204	155				
80%		284	159	110	128				
75%		141	129	125	128				
90%		122	125	125					
None	R1 pond					192	162	141	
80%						142	132		
75%									
90%									
None	R1 stream					507	278	168	143
80%						263	167	126	137

75%						270	152	183	133
90%						270			
None	RI stream					690	371	354	130
80%						355	193	133	101
75%						158	105	125	135
90%						158	152	152	125
None	RI stream					707	322	270	135
80%						375	201	139	106
75%						159	132	106	124
90%						159	132	106	124
None	RI stream					515	277	190	115
80%						339	236	181	124
75%						339	236	181	124
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-129: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize post-emergence

Intended use		Maize post-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1 < 1500	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20

75%	R1 stream		0.80
90%		0.92	
75%	R2 stream		0.65
90%		0.51	0.56
75%	R3 stream		0.90
90%		0.96	1.05
75%	R4 stream		0.41
90%		0.28	
RAC (µg/L)			
0.3		PEC/RAC ratio	
75%	R1 stream		0.42
90%		0.41	
75%	R2 stream		0.53
90%		0.52	
75%	R3 stream		0.68
90%		0.64	
75%	R4 stream		0.45
90%		0.57	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in maize post-emergence (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D5 stream, D6 ditch: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

None	D5 stream	0.354	0.305	0.306	0.325				
80%		0.449	0.530	0.406	0.327				
75%		0.597	0.337	0.306	0.173				
90%		0.376	0.153						
None	D6 ditch	0.928	0.021	0.798	0.531				
80%		0.973	0.541	0.572	0.310				
75%		0.554	0.335	0.510	0.310				
90%		0.340	0.310	0.510					
None	E1 pond					0.854	0.034		
80%						0.856			
75%									
90%									
None	E1 stream					0.625	0.251	0.656	0.393
80%						0.923	0.533	0.402	0.373
75%						0.760	0.533	0.402	0.373
90%						0.760			
None	E2 stream					0.344	0.256	0.365	0.650
80%						0.205	0.634	0.451	0.342
75%						0.630	0.552	0.245	0.319
90%						0.294	0.172	0.121	
None	E3 stream					0.433	0.305	0.596	0.601
80%						0.255	0.690	0.473	0.365
75%						0.665	0.435	0.535	0.227
90%						0.625	0.435	0.535	

None	E3 stream					1763	1939	1658	1796
50%						1853	1992	1708	1815
75%						1853	1992	1708	1815
90%									
RAC (µg/L)									
148 (injection isomeric)		FEORAC ratio							
None	D3 pond	402	243	135	311				
50%		203	113	129	230				
75%		146	101	151	238				
90%		87	147	155					
None	D4 pond	0.1	0.2						
50%		0.1							
75%									
90%									
None	D4 stream	434	232	159	221				
50%		221	119	132	192				
75%		145	103	143	233				
90%		85	129						
None	D5 pond	0.1	0.2						
50%		0.2							
75%									
90%									
None	D5 stream	470	251	172	231				
50%		230	123	139	193				

732		124	138	129	136				
902		133	132						
None	R6 pond	103	213	125	111				
802		203	113	129	135				
732		115	120	133	135				
902		121	132	133					
None	R1 pond					153	132		
802						153			
732									
902									
None	R3 stream					303	122	152	104
802						132	111	133	131
732						110	111	133	131
902						110			
None	R2 stream					433	262	130	127
802						251	136	122	121
732						133	122	151	131
902						131	136	123	
None	R3 stream					307	272	137	123
802						261	144	160	126
732						143	122	162	124
902						136	122	162	
None	R4 stream					367	198	136	103
802						257	165	127	136

75%						0.37	0.5	0.27	0.36
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-131: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize pre-emergence

Intended use		Maize pre-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		12-1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream		0.152
90%		0.155	
75%	R2 stream		0.186
90%		0.192	
75%	R3 stream		0.206
90%		0.215	
75%	R4 stream		0.152
90%		0.156	
RAC (µg/L)			
0.3		PEC/RAC ratio	
75%	R1 stream		0.52
90%		0.53	

75%	R3 stream		0.30
90%		0.36	
75%	R3 stream		0.43
90%		0.47	
75%	R4 stream		0.32
90%		0.40	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in maize pre-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered

D3 ditch, D4 stream, D5 stream, D6 ditch: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-132: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize in post emergence

Intended use		Maize post emergence							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	1.929	1.024	0.699	0.531				
90%		0.960	0.530	0.379	0.284				

75%		0.530	0.331	0.538	0.139				
90%		0.530	0.331	0.163					
None	D1 pond	0.230	0.126						
80%		0.124							
75%									
90%									
None	D4 stream	0.171	0.161	0.296	0.305				
80%		0.109	0.592	0.412	0.311				
75%		0.579	0.313	0.221	0.167				
90%		0.235	0.136						
None	D5 pond	0.250	0.124						
80%		0.142							
75%									
90%									
None	D5 stream	0.146	0.146	0.784	0.526				
80%		0.090	0.533	0.401	0.305				
75%		0.561	0.302	0.211	0.160				
90%		0.244	0.137						
None	D6 ditch	0.929	0.022	0.692	0.531				
80%		0.976	0.544	0.974	0.314				
75%		0.554	0.336	0.814	0.314				
90%		0.230	0.314	0.814					
None	R1 pond					0.237	0.122		
80%						0.150			

73%									
90%									
None	R1 stream					0.730	0.937	0.636	0.759
80%						0.918	0.805	0.833	0.805
73%						0.918	0.805	0.833	0.805
90%						0.918			
None	R3 stream					0.760	0.927	0.876	0.709
80%						0.820	0.663	0.852	0.817
73%						0.816	0.859	0.819	0.819
90%						0.918	0.179	0.192	
None	R4 stream					0.892	0.800	0.892	0.673
80%						0.852	0.690	0.872	0.805
73%						0.852	0.808	0.892	0.815
90%						0.874	0.808	0.892	0.815
None	R4 stream					0.702	0.949	0.658	0.816
80%						0.847	0.800	0.618	0.819
73%						0.847	0.800	0.618	0.819
90%									
RAC (mg/L)									
D48 (mesocosm, geotitan)		TEC/RAC ratio							
None	D2 ditch	0.02	0.13	0.46	0.11				
80%		0.01	0.12	0.78	0.59				
73%		0.03	0.69	0.50	0.37				
90%		0.69	0.46	0.50					

None	R1 stream					372	1.98	1.34	0.02
80%						138	1.13	0.91	0.31
75%						169	1.13	0.91	0.31
90%						169			
None	R2 stream					434	2.58	1.52	0.35
80%						354	1.31	0.95	0.27
75%						435	0.92	0.52	0.30
90%						0.23	0.32	0.22	
None	R3 stream					506	2.71	1.36	0.41
80%						201	1.41	0.99	0.27
75%						132	0.98	0.75	0.31
90%						130	0.98	0.75	0.31
None	R4 stream					307	1.98	1.36	0.04
80%						239	1.67	1.23	0.37
75%						239	1.67	1.23	0.37
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-133: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in maize post-emergence

Intended use		Maize post-emergence	
Active substance		pendimethalin	
Application rate (g/ha)		1.5 = 1137	
Nozzle reduction	Vegetated filter strip (m)	X	30

	No-spray buffer (m)	0	0
75%	R1 stream		0.15
90%		0.141	
75%	R2 stream		0.09
90%		0.079	
75%	R3 stream		0.20
90%		0.19	
75%	R4 stream		0.13
90%		0.124	
RAC (µg/L)			
0.48		PEC/RAC ratio	
75%	R1 stream		0.30
90%		0.29	
75%	R2 stream		0.39
90%		0.37	
75%	R3 stream		0.43
90%		0.46	
75%	R4 stream		0.32
90%		0.40	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in maize post-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D5 stream, D6 stream: 15m no spray buffer zone+ 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R2 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-134: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in pome/stone fruits (early between rows)

Intended use		pome/stone fruits (early between rows)							
Active substance		pendimethalin							
Application rate (g/ha)		1 < 1500							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	0.023	0.072	0.282	0.557				
50%		0.011	0.361	0.112	0.296				
75%		0.566	0.342	0.255	0.186				
90%		0.343	0.2208	0.177					
None	D4 Pond	0.253	0.184						
50%		0.150							
75%									
90%									
None	D4 stream	0.768	0.945	0.600	0.492				
50%		0.901	0.436	0.355	0.252				
75%		0.469	0.236	0.150	0.132				
90%		0.208	0.113						
None	D5 Pond	0.248	0.130						
50%		0.248							

75%									
90%									
None	D5 stream	0.861	0.930	0.735	0.512				
80%		0.946	0.805	0.572	0.253				
75%		0.485	0.206	0.125	0.132				
90%		0.212	0.121						
None	R1 Pond					0.259	0.151		
80%						0.135			
75%									
90%									
None	R1 stream					0.333	0.337	0.612	0.433
80%						0.311	0.316	0.527	0.245
75%						0.145	0.157	0.180	0.137
90%						0.232	0.133		
None	R2 stream					0.040	0.097	0.601	0.572
80%						0.052	0.573	0.412	0.300
75%						0.556	0.311	0.223	0.164
90%						0.262	0.154		
None	R3 stream					0.132	0.152	0.343	0.602
80%						0.113	0.613	0.450	0.324
75%						0.615	0.356	0.263	0.190
90%						0.224	0.204	0.153	
None	R4 stream					0.543	0.337	0.613	0.433
80%						0.310	0.346	0.323	0.236

75%						0.050	0.250	0.100	0.500
90%						0.050	0.100		
RAC (µg/L)		PEC/RAC ratio							
1.48 (maximum groundwater)									
None	D3 Pond	1.21	1.24	0.75	1.16				
90%		1.11	1.17	0.97	1.02				
75%		1.17	0.91	0.53	0.99				
90%		0.71	0.48	0.97					
None	D4 Pond	0.53	0.91						
90%		0.91							
75%									
90%									
None	D4 stream	3.08	1.97	1.44	1.08				
90%		1.88	1.01	0.74	0.58				
75%		1.97	0.51	0.40	0.28				
90%		0.45	0.25						
None	D5 Pond	0.52	0.91						
90%		0.91							
75%									
90%									
None	D5 stream	3.08	2.07	1.51	1.08				
90%		1.97	1.06	0.78	0.58				
75%		1.02	0.51	0.41	0.29				
90%		0.45	0.25						

None	R1 stream					0.50	0.33		
50%						0.51			
75%									
90%									
None	R1 stream					0.25	0.74	0.28	0.91
50%						0.69	0.95	0.68	0.49
75%						0.92	0.54	0.40	0.29
90%						0.48	0.50		
None	R2 stream					0.25	0.40	0.62	0.10
50%						0.19	0.10	0.82	0.35
75%						0.16	0.35	0.48	0.49
90%						0.55	0.82		
None	R3 stream					0.14	0.10	0.76	0.25
50%						0.32	0.25	0.95	0.35
75%						0.25	0.74	0.55	0.40
90%						0.68	0.43	0.82	
None	R4 stream					0.25	0.74	0.28	0.91
50%						0.69	0.95	0.68	0.49
75%						0.92	0.54	0.40	0.29
90%						0.48	0.50		

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-135: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in pome/stone fruits (early application between rows)

Intended use	Pome/stone fruits (early application between rows)
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Active substance		resmethalin	
Application rate (g/ha)		15-117	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream		0.137
90%		0.145	
75%	R2 stream		0.164
90%		0.154	
75%	R3 stream		0.190
90%		0.204	
75%	R4 stream		0.137
90%		0.144	
RAC (µg/L)			
0.3		PEO/RAC ratio	
75%	R1 stream		0.20
90%		0.20	
75%	R2 stream		0.23
90%		0.23	
75%	R3 stream		0.30
90%		0.23	
75%	R4 stream		0.20
90%		0.23	

PEO: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEO/RAC ratio above the relevant critical value shown in bold

PEC/RAC ratios in pome/stone fruits (early application 1 x 1590 g/ha between rows) are <1 when risk mitigation options are considered:
 D3 ditch, D5 stream: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction
 D4 stream: 15m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction
 R1 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction
 R2 stream, R3 stream, R4 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

Table 9.5-136: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in sunflower (1 x 1183 g/ha)

Intended use		Sunflower							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1183							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	2.01	1.061	0.725	0.551				
50%		1.01	0.530	0.361	0.290				
75%		0.531	0.274	0.182	0.126				
90%		0.274	0.121	0.082					
None	D4 Pond	0.241	0.124						
50%		0.122							
75%									
90%									
None	D4 stream	2.34	1.24	0.851	0.646				

80%		0.174	0.133	0.041	0.333				
75%		0.754	0.310	0.243	0.136				
90%		0.309	0.191	0.186					
None	DS pond	0.236	0.129						
80%		0.147							
75%									
90%									
None	DS stream	0.392	0.287	0.074					
80%		0.216	0.337	0.051					
75%		0.634	0.348	0.241					
90%		0.284	0.163						
None	R1 pond					0.253	0.133		
80%						0.153			
75%									
90%									
None	R1 stream					0.331	0.002	0.672	0.315
80%						0.251	0.532	0.422	0.219
75%						0.795	0.532	0.422	0.219
90%						0.795			
None	R2 stream					0.529	0.302	0.920	0.700
80%						0.230	0.709	0.469	0.272
75%						0.752	0.524	0.402	0.272
90%						0.752	0.524		0.272
None	R4 stream					0.824	0.002	0.674	0.315

80%						18106	1827	18391	18709
75%						18106	1827	18391	18709
90%									
RAC (µg/L)									
148 (maximum amount)		PEC/RAC ratio							
None	D1 pond	47	221	151	215				
80%		208	114	189	230				
75%		115	168	148	237				
90%		168	145	155					
None	D4 Pond	0.9	186						
80%		0.9							
75%									
90%									
None	D4 stream	4.8	259	177	235				
80%		245	133	192	270				
75%		120	228	151	230				
90%		220	240	159					
None	D5 pond	0.1	23						
80%		0.1							
75%									
90%									
None	D5 stream	4.6	268	182	240				
80%		243	137	191	272				
75%		122	222	150	232				

90%		0.33	0.32						
None	R1 pond					0.53	0.53		
90%						0.53			
75%									
90%									
None	R1 stream					0.91	2.02	1.41	0.07
90%						0.38	0.15	0.38	0.00
75%						0.66	0.15	0.38	0.00
90%						0.66			
None	R1 stream					5.26	2.84	1.92	0.06
90%						2.09	0.98	1.02	0.01
75%						1.57	1.02	0.84	0.57
90%						1.57	1.02		0.57
None	R1 stream					0.30	2.02	1.41	0.07
90%						2.30	0.61	1.23	0.34
75%						2.30	0.61	1.23	0.34
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-137: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in sunflower (1 x 1183 g/ha)

Intended use	Sunflower
Active substance	pendimethalin
Application rate (g/ha)	1 x 1183

Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R3 stream	1	0.23
90%		0.23	1
75%	R4 stream	1	0.10
90%		0.10	1
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R3 stream	1	0.45
90%		0.45	1
75%	R4 stream	1	0.35
90%		0.42	1

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in sunflower (1 x 1183 g/ha) are <1 when risk mitigation options are considered.

D3 ditch, D4 stream, D5 stream: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction

R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-138: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in soybean

Intended use	Soybean
Active substance	Pendimethalin

Application rate (g/ha)		Lx, LSS							
Nozzle reduc- tion	No-spray buffer (m)	5	11	15	21	5	11	15	21
	Vegetated filter strip (m)	None	None	None	None	5	11	15	21
None	D3 ditch	2.002	1.062	0.736	0.591				
50%		1.001	0.531	0.368	0.296				
75%		0.552	0.306	0.212	0.134				
90%		0.338	0.225	0.167					
None	D4 pond	0.252	0.185						
50%		0.152							
75%									
90%									
None	D4 stream	2.092	1.121	0.767	0.591				
50%		1.062	0.572	0.399	0.302				
75%		0.540	0.304	0.209	0.202				
90%		0.244	0.205						
None	R1 pond					0.535	0.115		
50%						0.154			
75%									
90%									
None	R1 stream					0.631	0.336	0.672	0.322
50%						0.354	0.157	0.372	0.231
75%						0.692	0.400	0.372	0.356

90%						0.398	0.400	0.376	0.350
None	R3 stream					0.531	0.311	0.219	0.209
90%						0.589	0.301	0.202	0.175
75%						0.721	0.507	0.339	0.265
90%						0.721	0.507	0.339	0.265
None	R4 stream					0.725	0.915	0.376	0.322
90%						0.229	0.869	0.376	0.172
75%						0.229	0.869	0.376	0.172
90%						0.229	0.869		
RAC (µg/L)		PEC/RAC ratio							
0.48 (mesocosm)									
0.48 (common)									
None	D3 pond	4.16	2.21	0.51	0.17				
90%		2.09	0.15	0.31	0.02				
75%		1.15	0.70	0.50	0.38				
90%		0.71	0.47	0.35					
None	D4 pond	0.55	0.32						
90%		0.32							
75%									
90%									
None	D4 stream	4.37	2.33	0.60	0.23				
90%		2.22	0.16	0.35	0.05				
75%		1.14	0.65	0.44	0.45				
90%		0.51	0.43						
None	R1 pond					0.55	0.39		

80%						0.33			
75%									
90%									
None	R3 stream					3.71	2.05	1.81	0.09
80%						1.39	0.10	0.25	0.39
75%						1.45	0.02	0.25	0.35
90%						1.45	0.02	0.25	0.35
None	R3 stream					5.27	2.80	1.81	0.15
80%						2.07	0.16	0.31	0.25
75%						1.50	0.06	0.31	0.35
90%						1.50	0.06	0.31	0.35
None	R4 stream					5.30	2.05	1.81	0.09
80%						2.00	1.81	1.81	0.20
75%						2.00	1.81	1.81	0.20
90%						2.00	1.81		

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-139: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in soybean (1 x 1183 g/ha)

Intended use		Soybean	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1183	
Nozzle reduction	Vegetated filter strip	15	20

	No-spray buffer (m)	0	0
75%	R1 stream		0.16
90%		0.17	
75%	R3 stream		0.25
90%		0.25	
75%	R4 stream		0.15
90%		0.20	
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream		0.32
90%		0.32	
75%	R3 stream		0.45
90%		0.46	
75%	R4 stream		0.33
90%		0.42	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in soybean (1 x 1183 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-140: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables in pre emergence

Intended use		Bulb vegetables in pre emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 < 1590							
Nozzle reduction	No-spray buffer (m)	5	10	15	30	5	10	15	30
	Vegetated filter strip (m)	None	None	None	None	5	10	15	30
None	0.3 ditch	0.04	0.43	0.075	0.23				
80%		0.36	0.24	0.316	0.39				
75%		0.25	0.43	0.32	0.25				
90%		0.55	0.30	0.23	0.20				
None	0.3 pond	0.42	0.24	0.196					
80%		0.03	0.19						
75%									
90%									
None	0.3 stream	0.19	0.50	0.131	0.23				
80%		0.32	0.70	0.23	0.30				
75%		0.29	0.60	0.30	0.30				
90%		0.28	0.30	0.30	0.30				
None	0.3 ditch 1'	0.55	0.40	0.261	0.231				
80%		0.27	0.20	0.50	0.50				
75%		0.63	0.50	0.50	0.50				
90%		0.50	0.50						

None	D6 stream	0.720	0.442	0.060	0.060				
80%		0.359	0.000	0.060	0.060				
75%		0.060	0.000						
90%		0.060							
None	R1 pond					0.028	0.250	0.027	
80%						0.028	0.152		
75%									
90%									
None	R1 stream					0.060	0.025	0.010	0.012
80%						0.030	0.015	0.005	0.005
75%						0.024	0.015	0.005	0.005
90%						0.024	0.015		
None	R2 stream					0.022	0.027	0.012	0.011
80%						0.001	0.004	0.015	0.005
75%						0.006	0.005	0.006	0.006
90%						0.001	0.002	0.003	0.004
None	R3 stream					0.002	0.004	0.002	0.002
80%						0.004	0.004	0.003	0.002
75%						0.002	0.003	0.002	0.002
90%						0.002	0.003	0.002	0.002
None	R4 stream					0.050	0.001	0.015	0.007
80%						0.025	0.001	0.015	0.001
75%						0.025	0.001	0.015	0.001
90%						0.025			

RAC (µg/L)		PEC/RAC ratio							
148 (mesocosm pond)									
None	D3 ditch	5.71	2.98	3.03	1.55				
50%		2.91	1.55	1.08	0.83				
75%		1.55	0.92	1.38	0.81				
90%		0.92	0.63	1.36	0.83				
None	D4 pond	1.71	0.52	1.31					
50%		0.52	0.31						
75%									
90%									
None	D4 stream	5.57	3.13	2.15	1.63				
50%		2.98	1.60	1.10	0.83				
75%		1.54	0.83	0.64	0.64				
90%		0.63	0.63	0.64	0.64				
None	D6 ditch 1'	5.53	2.93	2.00	1.52				
50%		2.76	1.47	1.13	0.73				
75%		1.48	0.73	1.13	0.73				
90%		0.73	0.73						
None	D6 ditch 2'	5.57	3.00	2.21	2.21				
50%		2.83	2.21	2.21	2.21				
75%		2.21	2.21						
90%		2.21							
None	E1 pond					0.52	0.52	1.31	
50%						0.63	0.63		

75%									
90%									
None	R1 stream					513	376	190	146
80%						267	149	115	122
75%						213	149	115	122
90%						213	149		
None	R2 stream					671	370	242	153
80%						344	176	128	137
75%						180	101	100	123
90%						183	115	133	126
None	R3 stream					709	330	201	122
80%						365	201	132	106
75%						192	134	133	121
90%						194	134	133	121
None	R4 stream					512	277	191	127
80%						339	236	191	125
75%						339	236	191	125
90%						339			

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevance trigger of 1 are shown in bold

Table 9.5-141: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables (pre-emergence, 1 x 1590 g/ha)

Intended use	Bulb vegetables (pre-emergence)
Active substance	pendimethalin
Application rate (g/ha)	1 x 1590

Nozzle reduction	Vegetated filter strip (m)	0	0
	No-spray buffer (m)	0	0
75%	R2 stream	1	0.21
90%		0.25	1
75%	R3 stream	1	0.20
90%		0.14	1
75%	R4 stream	1	0.27
90%		0.18	1
RAC (µg/L)			
0.48		PEC/RAC ratio	
75%	R2 stream	1	0.50
90%		0.48	1
75%	R3 stream	1	0.50
90%		0.65	1
75%	R4 stream	1	0.41
90%		0.45	1

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in bulb vegetables (pre-emergence 1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction

R2 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenario D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with mitigation measures. However, scenario D6 is not relevant for CEU countries.

Table 9.5-142: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables in post emergence

Intended use		Bulb vegetables in post emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 > 1590							
Nozzle reduction	No-spray buffer (m)	5	10	15	30	5	10	15	30
	Vegetated filter strip (m)	None	None	None	None	5	10	15	30
None	D3 ditch	0.008	0.430	0.072	0.243				
80%		0.349	0.352	0.522	0.398				
75%		0.756	0.462	0.331	0.331				
90%		0.163	0.309	0.206	0.172				
None	D4 pond	0.338	0.245	0.194					
80%		0.011	0.117						
75%									
90%									
None	D4 stream	0.558	0.516	0.158	0.290				
80%		0.445	0.276	0.553	0.005				
75%		0.245	0.006	0.915	0.315				
90%		0.327	0.315	0.915					
None	D6 ditch 1 st	0.008	0.430	0.072	0.243				
80%		0.349	0.243	0.521	0.397				

75%		0.750	0.437	0.087	0.437					
90%		0.837	0.437	0.087						
None	R6 ditch 20	0.730	0.436	0.051	0.051					
80%		0.018	0.031	0.051						
75%		0.031	0.031							
90%		0.031								
None	R1 pond					0.559	0.257	0.002		
80%						0.213	0.157			
75%										
90%										
None	R1 stream					0.468	0.331	0.016	0.027	
80%						0.232	0.213	0.547	0.475	
75%						0.028	0.213	0.547	0.475	
90%						0.028				
None	R2 stream					0.258	0.216	0.127	0.211	
80%						0.671	0.906	0.624	0.475	
75%						0.072	0.487	0.337	0.257	
90%						0.408	0.235	0.162	0.126	
None	R3 stream					0.418	0.341	0.264	0.362	
80%						0.270	0.276	0.676	0.515	
75%						0.001	0.006	0.534	0.364	
90%						0.001	0.006	0.534	0.364	
None	R4 stream					0.446	0.317	0.904	0.658	
80%						0.642	0.164	0.877	0.508	

75%						1.648	0.779	1.372	0.395
90%									
RAC (µg/L)			PEC/RAC ratio						
1.48 (mesocosm experiment)									
None	D3 ditch	5.72	2.98	2.04	1.55				
50%		2.51	1.56	1.01	0.81				
75%		1.56	1.01	1.01	0.81				
90%		1.01	1.01	1.01	0.81				
None	D4 pond	0.71	0.51	0.30					
50%		0.32	0.31						
75%									
90%									
None	D4 stream	5.91	3.16	2.16	1.65				
50%		3.01	1.62	1.01	0.81				
75%		1.55	0.85	0.66	0.66				
90%		0.66	0.66	0.66					
None	D6 ditch 1'	5.62	2.98	2.04	1.55				
50%		2.51	1.56	1.01	0.81				
75%		1.56	1.01	1.01	0.81				
90%		1.01	1.01	1.01					
None	D6 ditch 2'	5.67	3.03	2.19	2.19				
50%		2.95	2.19	2.19					
75%		2.19	2.19						
90%		2.19							

None	R1 pond					0.24	0.30	0.28	
80%						0.25	0.33		
75%									
90%									
None	R1 stream					5.04	2.27	0.91	0.25
80%						2.69	0.49	0.13	0.23
75%						2.14	0.49	0.13	0.23
90%						2.14			
None	R2 stream					6.73	3.60	2.49	0.90
80%						3.43	0.39	0.30	0.99
75%						1.83	0.01	0.00	0.23
90%						0.84	0.03	0.35	0.23
None	R3 stream					7.12	3.34	2.68	2.00
80%						3.69	2.03	1.41	1.07
75%						2.09	0.45	1.11	0.76
90%						2.09	0.45	1.11	0.76
None	R4 stream					5.06	2.74	1.68	1.43
80%						3.42	2.38	1.68	1.25
75%						3.42	2.38	1.68	1.25
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-143: Aquatic organisms: PEC calculation and acceptability of risk ($PEC/RAC < 1$) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables (post-emergence, 1 x 1590 g/ha)

Intended use	Bulb vegetables (post-emergence)
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Active substance		penidmethalin	
Application rate (g/ha)		1 x 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R2 stream	1	0.257
90%		0.235	0.126
75%	R3 stream	1	0.296
90%		0.302	0.170
75%	R4 stream	1	0.204
90%		0.245	1
PEC (µg/L)		PEC/RAC ratio	
0.32			
75%	R2 stream	1	0.52
90%		0.49	1
75%	R3 stream	1	0.65
90%		0.64	1
75%	R4 stream	1	0.42
90%		0.51	1

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in bulb vegetables (post-emergence 1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction

R2 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenario D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with mitigation measures. However, scenario D6 is not relevant in CEU countries.

Table 9.5-144: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables in pre emergence

Intended use		Bulb vegetables pre emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 = 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	0.926	1.021	0.697	0.530				
50%		0.972	0.543	0.537	0.236				
75%		0.549	0.332	0.240	0.181				
90%		0.334	0.222	0.164					
None	D4 pond	0.346	0.179						
50%		0.347							
75%									
90%									
None	D3 stream	0.016	0.076	0.577	0.560				
50%		0.024	0.530	0.578	0.387				
75%		0.528	0.238	0.521	0.311				
90%		0.231	0.311						

None	D6 ditch 1	0.308	1.007	0.689	0.524				
50%		0.309	0.503	0.767	0.367				
75%		0.374	0.357	0.767					
90%		0.367	0.357						
None	D6 ditch 2	0.295	1.001	0.753	0.235				
50%		0.015	0.235	0.753					
75%		0.753	0.235						
90%		0.753							
None	R1 pond					0.258	0.135		
50%						0.058			
75%									
90%									
None	R1 stream					0.768	0.292	0.653	0.198
50%						0.922	0.515	0.925	0.209
75%						0.741	0.515	0.925	0.209
90%						0.741			
None	R2 stream					0.308	0.235	0.047	0.644
50%						1.101	0.640	0.440	0.235
75%						0.620	0.242	0.237	0.180
90%						0.238	0.164	0.115	
None	R3 stream					0.446	0.217	0.904	0.650
50%						1.267	0.608	0.484	0.260
75%						0.694	0.257	0.894	0.280
90%						0.650	0.257	0.894	0.280

None	R1 stream					1702	1702	1769	1801
50%						1702	1702	1769	1801
75%						1702	1702	1769	1801
90%									
RAC (µg/L)									
123 (mg/kg)		PEC/RAC ratio							
None	D3 pond	0.01	0.13	1.35	1.70				
50%		0.03	0.43	4.20	0.38				
75%		0.14	0.62	6.50	0.38				
90%		0.70	0.93	9.50					
None	D4 pond	0.51	0.37						
50%		0.51							
75%									
90%									
None	D4 stream	0.20	0.24	1.54	1.17				
50%		0.13	0.15	0.79	0.68				
75%		0.10	0.62	0.44	0.44				
90%		0.43	0.44						
None	D6 ditch 1	0.95	0.10	1.43	1.09				
50%		1.98	1.05	0.76	0.76				
75%		0.99	0.76	0.76					
90%		0.76	0.76						
None	D6 ditch 2	0.65	0.17	1.53	1.53				
50%		0.11	1.53	1.53					

75%		153	153						
90%		153							
None	R1 pond					153	135		
80%						153			
75%									
90%									
None	R1 stream					173	155	136	113
80%						192	167	132	117
75%						154	107	132	117
90%						154			
None	R2 stream					180	257	176	143
80%						240	143	132	110
75%						129	171	132	113
90%						152	144	124	
None	R3 stream					510	274	188	143
80%						264	145	101	117
75%						145	128	132	110
90%						137	128	132	110
None	R4 stream					359	206	137	104
80%						239	166	128	117
75%						239	166	128	117
90%									

R1C: Dissolved environmental concentration (L/CC) Regulatory guideline Concentration; R2: RAC ratios above the risk level (R1C) are shown in bold

Table 9.5-145: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables (pre-emergence, 1 x 1137 g/ha)

Intended use		Bulb vegetables (pre-emergence)	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1137	
Nozzle reduction	Vegetated filter strip (m)	0	0
	No-spray buffer (m)	0	0
75%	R1 stream		
90%		0.029	
75%	R2 stream		0.030
90%		0.029	
75%	R3 stream		0.21
90%		0.25	
75%	R4 stream		0.153
90%		0.153	
RAC (µg/L)			
0.3		PEC/RAC ratio	
75%	R1 stream		
90%		0.09	
75%	R2 stream		0.58
90%		0.34	
75%	R3 stream		0.44
90%		0.46	

75%	R4 stream		0.32
90%		0.33	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in bulb vegetables (pre-emergence 1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 ditch 1st: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream: 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenario D6 ditch 2nd the PEC/RAC ratios are below the trigger with risk mitigation measures. However, scenario D6 is not relevant for CEU countries.

Table 9.5-146: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables in post emergence

Intended use		Bulb vegetables post emergence							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	30	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	0.929	0.703	0.698	0.531				
		0.965	0.517	0.373	0.283				
		0.541	0.310	0.257	0.179				
		0.331	0.221	0.163					
None	D4 pond	0.242	0.125						

80%		0.00							
75%									
90%									
None	D3 stream	0.039	0.084	0.743	0.364				
80%		0.039	0.555	0.581	0.239				
75%		0.555	0.290	0.216	0.216				
90%		0.54	0.216						
None	D6 ditch 1	0.929	0.024	0.995	0.531				
80%		0.974	0.534	0.572	0.335				
75%		0.537	0.335	0.555	0.335				
90%		0.335	0.335	0.555					
None	D6 ditch 2	0.935	0.041	0.924	0.723				
80%		0.035	0.722	0.924	0.723				
75%		0.724	0.722						
90%		0.724							
None	R1 pond					0.258	0.133		
80%						0.158			
75%									
90%									
None	R1 stream					0.768	0.501	0.659	0.490
80%						0.922	0.509	0.336	0.260
75%						0.724	0.504	0.336	0.263
90%						0.724	0.504		
None	R2 stream					0.529	0.248	0.356	0.651

80%						1.005	1.345	1.242	1.339
75%						1.689	1.345	1.341	1.335
90%						1.603	1.165	1.119	
None	R3 stream					2.449	1.314	1.009	1.687
80%						1.266	1.097	1.081	1.377
75%						1.205	1.191	1.325	1.256
90%						1.205	1.191	1.325	1.256
None	R4 stream					1.745	1.311	1.697	1.431
80%						1.152	1.305	1.613	1.421
75%						1.152	1.305	1.613	1.421
90%									
RAC (µg/L)									
D-48 (mesocosm geomant)		PEC/RAC ratio							
None	D3 ditch	0.02	0.13	1.45	0.11				
80%		0.01	1.12	0.73	0.59				
75%		1.13	0.69	0.49	0.37				
90%		0.69	0.45	0.34					
None	D4 pond	0.50	0.36						
80%		0.50							
75%									
90%									
None	D4 stream	0.23	0.26	1.55	0.18				
80%		0.15	1.16	0.70	0.60				
75%		0.11	0.58	0.45	0.45				

90%		109	113						
None	D6 ditch 1	113	113	115	111				
90%		111	111	118	120				
75%		111	120	120	120				
90%		120	120	120					
None	D6 ditch 2	105	112	151	151				
90%		111	151	151	151				
75%		151	151						
90%		151							
None	R1 pond					153	135		
90%						152			
75%									
90%									
None	R1 stream					305	138	136	103
90%						192	106	100	156
75%						151	105	100	155
90%						151	105		
None	R2 stream					185	200	178	136
90%						249	135	138	171
75%						151	122	150	153
90%						160	125	125	
None	R3 stream					509	274	188	143
90%						264	145	101	176
75%						147	102	178	153

90%						1.47	0.02	0.38	0.33
None	R1 stream					3.64	0.06	1.35	0.09
90%						2.41	0.05	1.39	0.38
75%						2.41	0.05	1.39	0.38
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-147: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in bulb vegetables (post-emergence, 1 x 1137 g/ha)

Intended use		Bulb vegetables (post-emergence)	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream		0.430
90%		0.420	
75%	R5 stream		0.210
90%		0.220	
75%	R4 stream		0.146
90%		0.172	
RAC (µg/L)			
0.38		PEC/RAC ratio	
75%	R1 stream		0.38

90%		0.38	
75%	R3 stream		0.44
90%		0.36	
75%	R4 stream		0.30
90%		0.36	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in bulb vegetables (post-emergence 1 x 1137 g/ha) are <1 when risk mitigation options are considered

D3 ditch, D4 stream, D6 ditch 1st: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R2 stream: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenario D6 ditch 2nd the PEC/RAC ratios are below the trigger with mitigation measures. However, scenario D6 is not relevant for CEU countries

Table 9.5-148: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in beans

Intended use		Beans								
Active substances		pendimethalin								
Application rate (g/ha)		1 x 1390								
Nozzle reduction	No-spray buffer (m)	5	10	15	20		5	10	15	20
	Vegetated filter strip (m)	None	None	None	None		5	10	15	20
None	D2 ditch	0.221	0.461	0.691	0.921					
90%		0.424	0.847	1.270	1.694					

75%		1.353	1.530	1.335	1.592				
90%		1.354	1.537	1.330	1.599				
None	D2 stream	1.147	1.668	1.143	1.870				
80%		1.391	1.861	1.595	1.430				
75%		1.347	1.485	1.338	1.238				
90%		1.120	1.252	1.129	1.161				
None	D3 ditch	1.697	1.429	1.976	1.241				
80%		1.148	1.748	1.520	1.401				
75%		1.731	1.465	1.631	1.251				
90%		1.164	1.510	1.227	1.171				
None	D4 sord	1.342	1.248	1.196					
80%		1.305	1.152						
75%									
90%									
None	D4 stream	2.319	1.505	1.030	1.734				
80%		1.432	1.770	1.528	1.408				
75%		1.739	1.408	1.281	1.211				
90%		1.321	1.189	1.189					
None	D6 1 st ditch	1.668	1.411	1.966	1.735				
80%		1.533	1.707	1.483	1.452				
75%		1.675	1.452	1.452	1.452				
90%		1.452	1.452	1.452					
None	D6 2 nd ditch	1.720	1.441	1.985	1.749				
80%		1.559	1.721	1.586	1.598				

75%		1.323	0.538	0.538	0.538				
90%		1.338	0.538						
None	R1 pond					0.831	0.817	0.026	
80%						0.804	0.810		
75%									
90%									
None	R1 stream					0.859	0.825	0.010	0.015
80%						0.876	0.824	0.568	0.881
75%						0.880	0.824	0.568	0.881
90%						0.880			
None	R2 stream					0.855	0.844	0.088	0.017
80%						0.852	0.826	0.618	0.872
75%						0.870	0.838	0.538	0.857
90%						0.884	0.844	0.028	0.026
None	R3 stream					0.896	0.815	0.248	0.249
80%						0.845	0.803	0.908	0.808
75%						0.852	0.661	0.515	0.852
90%						0.847	0.661	0.515	0.852
None	R4 stream					0.852	0.821	0.902	0.700
80%						0.850	0.800	0.640	0.874
75%						0.850	0.800	0.640	0.874
90%									
RAC (ng/L)									
148 (mesocosm german)		PEC/RAC ratio							

None	D3 stream	5.67	3.04	3.10	1.60				
80%		3.97	1.70	1.70	0.92				
75%		1.76	1.10	0.90	0.61				
90%		1.15	0.79	0.53	0.52				
None	D3 stream	6.49	3.48	2.93	1.91				
80%		3.31	1.79	1.24	0.96				
75%		1.76	1.01	0.70	0.52				
90%		1.05	0.55	0.37	0.32				
None	D3 stream	5.62	2.98	2.03	1.55				
80%		2.31	1.56	1.08	0.82				
75%		1.56	0.96	0.69	0.52				
90%		0.97	0.65	0.37	0.36				
None	D4 pond	0.71	0.52	0.31					
80%		0.33	0.31						
75%									
90%									
None	D4 stream	5.57	3.14	2.15	1.63				
80%		2.98	1.60	1.10	0.85				
75%		1.54	0.85	0.59	0.45				
90%		0.98	0.59	0.39					
None	D6 15' ditch	5.56	2.95	2.01	1.55				
80%		2.78	1.47	1.01	0.82				
75%		1.41	0.98	0.64	0.52				
90%		0.94	0.64	0.34					

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-149: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in beans (1 x 1590 g/ha)

Intended use		beans	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1590	
Nozzle reduc- tion	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R2 stream	1	0.254
90%		0.250	1
75%	R3 stream	1	0.249
90%		0.205	1
75%	R4 stream	1	0.232
90%		0.266	1
RAC (µg/L)			
0.39		PEC/RAC ratio	
75%	R2 stream	1	0.52
90%		0.248	1
75%	R3 stream	1	0.60
90%		0.24	1
75%	R4 stream	1	0.44
90%		0.55	1

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in beans (1 x 1590 g/ha) are <1 when risk mitigation options are considered:
 D2 ditch: 20m no spray buffer zone + 50% nozzle reduction or 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
 D2 stream, D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction
 D3 ditch, D6 ditch 1st: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction
 R1 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction
 R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenario D6 ditch 2nd the PEC/RAC ratios are below the trigger with mitigation measures. However scenario D6 is not relevant in CEU countries.

Table 9.5-150: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in beans

Intended use		Beans							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D2 ditch	0.957	1.065	0.737	0.559				
50%		0.059	0.613	0.432	0.327				
75%		0.640	0.403	0.292	0.221				
90%		0.421	0.285	0.211					
None	D2 stream	0.338	1.197	0.820	0.623				
50%		0.142	0.621	0.439	0.326				

75%		0.511	0.335	0.201	0.134				
90%		0.299	0.170	0.128					
None	D3 pond	0.928	0.022	0.698	0.531				
80%		0.929	0.592	0.380	0.238				
75%		0.359	0.347	0.245	0.185				
90%		0.342	0.226	0.168					
None	D4 pond	0.206	0.020						
80%		0.147							
75%									
90%									
None	D4 stream	0.016	0.026	0.237	0.580				
80%		0.024	0.550	0.378	0.287				
75%		0.328	0.288	0.192	0.131				
90%		0.241	0.180						
None	D6 1 st ditch	0.908	0.011	0.691	0.525				
80%		0.983	0.802	0.346	0.808				
75%		0.406	0.808	0.308	0.808				
90%		0.308	0.808	0.308					
None	D6 2 nd ditch	0.945	0.031	0.704	0.536				
80%		0.986	0.558	0.399	0.899				
75%		0.565	0.899	0.399	0.899				
90%		0.899	0.899						
None	R1 pond					0.250	0.181		
80%						0.151			

75%									
90%									
None	R1 stream					1765	1931	0253	0196
80%						1810	1839	0414	0239
75%						1875	1839	0414	0239
90%						1875			
None	R2 stream					1519	1220	0350	0246
80%						1186	1643	0402	0336
75%						1224	1814	0253	0181
90%						1265	0165	0120	
None	R3 stream					2441	1313	0901	0685
80%						1267	1629	0484	0368
75%						1392	1406	0358	0244
90%						1392	1406	0358	0244
None	R4 stream					1769	1951	0355	0493
80%						1145	0798	0612	0413
75%						1145	0798	0612	0413
90%									
RAC (mg/L)									
D48 (mesocosm, germination)		PFC/RAC ratio							
None	D2 ditch	4.08	3.22	1.54	1.16				
80%		3.21	1.28	0.96	0.68				
75%		3.32	1.88	0.61	0.46				
90%		3.38	1.59	0.44					

None	D3 stream	0.60	2.40	0.71	0.30				
80%		0.35	1.39	0.59	0.58				
75%		0.27	0.72	0.51	0.58				
90%		0.65	0.37	0.27					
None	D3 ditch	0.02	2.13	0.45	0.11				
80%		2.04	0.14	0.59	0.60				
75%		0.16	0.71	0.51	0.59				
90%		0.71	0.08	0.55					
None	D4 pond	0.31	0.52						
80%		0.31							
75%									
90%									
None	D4 stream	0.30	2.24	0.71	0.17				
80%		2.13	0.15	0.79	0.60				
75%		0.10	0.69	0.71	0.51				
90%		0.16	0.22						
None	D6 1° ditch	0.98	2.11	0.44	0.72				
80%		0.98	0.65	0.72	0.62				
75%		0.03	0.65	0.54	0.62				
90%		0.64	0.62	0.54					
None	D6 2° ditch	0.05	2.15	0.47	0.12				
80%		2.05	0.15	0.55	0.55				
75%		0.18	0.65	0.55	0.55				
90%		0.45	0.65						

None	R1 pond					0.59	0.58		
80%						0.50			
75%									
90%									
None	R1 stream					3.68	1.98	1.56	0.03
80%						1.90	0.42	0.86	0.59
75%						0.70	0.42	0.86	0.59
90%						0.70			
None	R2 stream					0.92	2.58	1.72	0.85
80%						2.37	0.90	0.92	0.70
75%						1.80	0.72	0.80	0.83
90%						0.89	0.62	0.65	
None	R3 stream					5.09	2.74	1.80	1.43
80%						2.64	1.46	1.01	0.77
75%						1.44	0.97	0.75	0.50
90%						1.39	0.97	0.75	0.50
None	R4 stream					3.67	1.98	1.36	1.04
80%						2.39	1.66	1.28	0.97
75%						2.39	1.66	1.28	0.97
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-151: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in beans (1 x 1137 g/ha)

Intended use	beans
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Active substance		resmethalin	
Application rate (g/ha)		15-117	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream		0.434
90%		0.454	
75%	R2 stream		0.181
90%		0.165	
75%	R3 stream		0.207
90%		0.228	
75%	R4 stream		0.162
90%		0.183	
RAC (µg/L)			
0.38		PEO/RAC ratio	
75%	R1 stream		0.93
90%		0.93	
75%	R2 stream		0.93
90%		0.93	
75%	R3 stream		0.93
90%		0.93	
75%	R4 stream		0.93
90%		0.93	

PEO: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEO/RAC ratio above the relevant critical value shown in bold

PEC/RAC ratios in beans (1 x 1137 g/ha) are <1 when risk mitigation options are considered:
 D2 ditch, D2 stream, D3 ditch, D4 stream, D6 ditch: 15m no spray buffer zone +50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction
 R2 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone+ 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
 R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-152: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel

Intended use		Carrots, parsley, parsnip and fennel							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1590							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	0.924	1.428	0.975	0.743				
50%		0.346	0.743	0.516	0.329				
75%		0.745	0.453	0.324	0.247				
90%		0.453	0.304	0.225	0.170				
None	D4 pond	0.331	0.247	0.190					
50%		0.197	0.144						
75%									
90%									
None	D4 stream	2.906	1.554	1.064	0.810				
50%		0.480	0.794	0.546	0.423				

75%		1.768	1.892	1.307	1.807				
90%		1.346	1.807	1.307	1.807				
None	R6 dikes	1.664	1.812	1.965	1.738				
80%		1.331	1.806	1.889	1.872				
75%		1.679	1.898	1.891	1.890				
90%		1.765	1.890	1.891	1.890				
None	R1 pond					1.835	1.831	0.098	
80%						1.809	1.833		
75%									
90%									
None	R1 stream					1.861	1.834	0.911	1.811
80%						1.822	1.833	0.863	1.835
75%						1.816	1.833	0.863	1.835
90%						1.816			
None	R2 stream 1'					1.824	1.833	1.185	1.801
80%						1.852	1.825	0.615	1.875
75%						1.860	1.835	0.836	1.856
90%						1.801	1.822	0.168	1.825
None	R2 stream 2'					1.820	1.833	1.228	1.821
80%						1.808	1.824	0.639	1.832
75%						1.802	1.808	0.853	1.869
90%						1.825	1.831	0.178	1.836
None	R3 stream					1.802	1.834	1.252	1.853
80%						1.853	1.864	0.668	1.809

75%						0.556	0.530	0.489	0.530
90%						0.500	0.530	0.489	0.530
None	R1 stream					0.550	0.331	0.415	0.607
90%						0.728	0.149	0.500	0.610
75%						0.728	0.149	0.500	0.610
90%									
RAC (µg/L)									
1,48 (mosses)an isomer		PIC/RAC ratio							
None	D1 ditch	5.01	2.98	2.03	0.55				
90%		2.30	1.55	1.08	0.53				
75%		0.55	0.95	0.68	0.51				
90%		0.34	0.65	0.46	0.55				
None	D4 pond	0.99	0.50	0.40					
90%		0.41	0.30						
75%									
90%									
None	D6 stream	0.05	3.24	2.22	0.60				
90%		3.08	1.66	1.14	0.58				
75%		1.60	0.89	0.64	0.62				
90%		0.72	0.62	0.54	0.62				
None	D6 ditch	5.55	2.94	2.01	0.53				
90%		2.77	1.47	1.00	0.52				
75%		0.41	0.85	0.60	0.62				
90%		0.76	0.60	0.60	0.62				

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

Table 9.5-133: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel (root vegetables 1 x 1590 g/ha)

Intended use		Carrots, parsley, parsnip and fennel	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream	1	0.21
90%		0.216	1
75%	R2 stream	1	0.202
90%		0.214	1
75%	R3 stream	1	0.21
90%		0.216	1
RAC (µg/L)			
0.33		PEC/RAC ratio	
75%	R1 stream	1	0.44
90%		0.45	1
75%	R2 stream	1	0.33
90%		0.35	1
75%	R3 stream	1	0.44
90%		0.45	1

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

PEC/RAC ratios in carrots, parsley, parsnip and fennel (1 x 1590 g/ha) are <1 when risk mitigation options are considered:
 D3 ditch, D4 stream, D6 ditch: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction
 R2 stream 1st: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
 R2 stream 2nd: 15m no spray buffer zone + 15m vegetative strip+ 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
 R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-154: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel

Intended use		Carrots, parsley, parsnip and fennel							
Active substances		pendimethalin							
Application rate (g/ha)		1 x 1137							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	0.936	1.021	0.697	0.530				
80%		0.972	0.542	0.377	0.286				
75%		1.349	0.332	0.240	0.181				
90%		1.354	0.222	0.164					
None	D4 pond	0.242	0.176						
80%		0.144							
75%									
90%									
None	D4 stream	0.978	1.111	0.761	0.579				

80%		0.059	0.577	0.397	0.598				
75%		0.304	0.307	0.210	0.270				
90%		0.274	0.210						
None	R6 dock	0.905	1.010	0.690	0.525				
80%		0.952	0.506	0.345	0.263				
75%		0.495	0.287	0.302	0.196				
90%		0.264	0.195						
None	R1 road					0.251	0.134		
80%						0.156			
75%									
90%									
None	R1 stream					0.658	0.253	0.656	0.129
80%						0.223	0.527	0.405	0.275
75%						0.255	0.527	0.405	0.275
90%						0.255	0.527		
None	R2 stream 1'					0.300	0.216	0.347	0.664
80%						0.182	0.610	0.440	0.335
75%						0.602	0.312	0.267	0.180
90%						0.205	0.164	0.115	
None	R2 stream 2'					0.276	0.276	0.275	0.666
80%						0.223	0.665	0.455	0.348
75%						0.647	0.300	0.250	0.190
90%						0.505	0.180	0.125	
None	R3 stream					0.446	0.317	0.204	0.657

80%						18766	18905	18934	18735
75%						18794	18910	18949	18755
90%						18748	18910	18949	18755
None	R1 stream					18778	18939	18959	18701
80%						18761	18905	18901	18755
75%						18761	18905	18901	18755
90%									
RAC (µg/L)									
148 (mesosoma isomer)		PEC/RAC ratio							
None	D1 ditch	0.01	0.18	0.45	0.10				
80%		0.03	0.18	0.79	0.60				
75%		0.14	0.02	0.51	0.58				
90%		0.70	0.46	0.24					
None	D4 pond	0.50	0.32						
80%		0.30							
75%									
90%									
None	D4 stream	0.53	0.51	0.50	0.24				
80%		0.21	0.19	0.72	0.62				
75%		0.24	0.62	0.24	0.44				
90%		0.51	0.46						
None	D6 ditch	0.92	0.10	0.44	0.09				
80%		0.08	0.05	0.72	0.55				
75%		0.02	0.60	0.52	0.41				

90%		133	120						
None	R1 pond					153	153		
90%						153			
75%									
90%									
None	R1 stream					378	192	157	104
90%						152	110	150	157
75%						153	110	150	157
90%						153	110		
None	R2 stream 1					190	258	170	153
90%						240	153	192	170
75%						125	171	129	153
90%						152	152	124	
None	R2 stream 2					195	266	182	159
90%						245	152	195	173
75%						135	175	152	150
90%						161	158	127	
None	R3 stream					510	274	188	143
90%						274	145	161	172
75%						145	192	171	159
90%						155	192	171	159
None	R4 stream					370	200	157	104
90%						142	168	129	153
75%						142	168	129	153

90%									
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PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-155: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel (1 x 1137 g/ha)

Intended use		Carrots, parsley, parsnip and fennel	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	81 stream		0.152
90%		0.155	
75%	83 stream		0.229
90%		0.229	
75%	84 stream		0.152
90%		0.151	
RAC (µg/L)			
1.31		PEC/RAC ratio	
75%	81 stream		0.112
90%		0.113	
75%	83 stream		0.174
90%		0.174	
75%	84 stream		0.112

None	D1 stream	0.007	0.130	0.075	0.590				
80%		0.065	0.573	0.300	0.502				
75%		0.510	0.368	0.200	0.005				
90%		0.214	0.265						
None	D5 pond	0.230	0.180						
80%		0.139							
75%									
90%									
None	D5 stream	0.170	0.157	0.092	0.611				
80%		0.008	0.589	0.000	0.512				
75%		0.5636	0.302	0.213	0.062				
90%		0.215	0.137						
None	D6 pond	0.000	0.065	0.220	0.560				
80%		0.002	0.546	0.534	0.233				
75%		0.547	0.331	0.257	0.257				
90%		0.334	0.257	0.257	0.257				
None	R1 pond					0.255	0.165		
80%						0.152			
75%									
90%									
None	R1 stream					0.680	0.286	0.078	0.524
80%						0.052	0.227	0.376	0.280
75%						0.697	0.496	0.376	0.256
90%						0.697	0.496	0.376	0.256

None	R2 stream					1452	1305	1397	1692
50%						1452	1350	1425	1572
75%						1650	1372	1335	1407
90%						1310	1151	1127	
None	R3 stream					1531	1422	1215	1202
50%						1282	1201	1492	1525
75%						1780	1517	1397	1221
90%						1780	1517	1397	1221
None	R4 stream					1521	1232	1375	1521
50%						1428	1330	1351	1445
75%						1428	1330	1351	1445
90%						1428	1330	1351	1445
RAC (µg/L)									
D4S (mesocosm geomant)		PEC/RAC ratio							
None	D3 ditch	1.18	2.21	1.51	1.17				
50%		2.09	1.15	0.81	0.62				
75%		1.15	0.70	0.50	0.38				
90%		0.70	0.47	0.35					
None	D4 pond	0.55	0.59						
50%		0.32							
75%									
90%									
None	D4 stream	1.37	1.12	1.64	1.22				
50%		1.22	1.10	1.15	0.65				

75%		114	133	144	155				
90%		131	151						
None	D5 pond	152	138						
80%		131							
75%									
90%									
None	D5 stream	152	141	155	127				
80%		129	124	135	165				
75%		117	151	142	153				
90%		151	139						
None	D6 pond	118	121	151	117				
80%		109	114	130	161				
75%		114	139	152	152				
90%		170	154	152	152				
None	R1 pond					158	139		
80%						152			
75%									
90%									
None	R1 stream					161	105	141	109
80%						139	110	128	152
75%						145	102	128	153
90%						145	102	128	153
None	R2 stream					168	122	137	144
80%						161	112	122	125

75%						1.38	0.23	0.52	0.44
90%						1.65	0.33	0.20	
None	R3 stream					5.27	2.30	1.91	1.48
80%						2.67	1.46	1.03	0.78
75%						1.52	1.03	0.83	0.56
90%						1.52	1.03	0.83	0.56
None	R4 stream					3.80	2.05	1.41	1.09
80%						2.50	1.24	1.36	0.95
75%						2.50	1.24	1.36	0.95
90%						2.50	1.24	1.36	0.95

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-157: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in lupine (1 x 1183 g/ha)

Intended use		Lupine	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1183	
Nozzle refuges: Run	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream		0.161
90%		0.163	
75%	R2 stream		0.190
90%		0.181	

75%	R3 stream		0.15
90%		0.32	
75%	R4 stream		0.19
90%		0.30	
RAC (µg/L)			
0.3		PEC/RAC ratio	
75%	R1 stream		0.3
90%		0.3	
75%	R2 stream		0.4
90%		0.3	
75%	R3 stream		0.4
90%		0.6	
75%	R4 stream		0.3
90%		0.3	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in lupine (1 x1183 g/ha) are <1 when risk mitigation options are considered.

D3 ditch, D4 stream, D5 stream, D6 ditch: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip+ 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-158: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape

Intended use		Winter oil seed rape							
Active substance		pendimethalin							
Application rate (g/ha)		1 > 455							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D2 disk	0.781	0.492	0.391	0.291				
		0.02	0.413	0.333	0.166				
		75%	0.215	0.180					
		90%	0.134						
None	D3 stream	0.938	0.498	0.345	0.261				
		0.02	0.470	0.253	0.173				
		75%	0.239	0.127					
		90%	0.097						
None	D3 disk	0.791	0.419	0.386	0.213				
		0.02	0.395	0.217	0.151				
		75%	0.218						
		90%							
None	D4 stream	0.901	0.483	0.331	0.252				
		0.02	0.453	0.245	0.169				
		75%	0.240	0.132					
		90%	0.119						

None	D5 stream	0.974	0.514	0.357	0.974				
50%		1.154	0.262	0.179	0.136				
75%		1.219							
90%		1.135							
None	E1 stream					0.798	0.511	0.262	0.159
50%						0.365	0.201	0.100	
75%						0.219			
90%						0.219			
None	E8 stream					0.971	0.516	0.355	0.472
50%						0.385	0.261	0.139	0.157
75%						0.252			
90%						0.199			
RAC (µg/L)									
D-48 (mesocosm geometric)		PEC/RAC ratio							
None	D2 ditch	0.93	0.88	0.61	0.45				
50%		0.96	0.49	0.35					
75%		0.51	0.31						
90%		0.12							
None	D2 stream	0.95	1.04	0.72	0.55				
50%		0.98	0.55	0.36	0.23				
75%		0.50	0.26						
90%		0.20							
None	D3 ditch	0.62	0.87	0.60	0.45				
50%		0.32	0.45	0.31					

75%		1.35							
90%									
None	D1 stream	1.38	1.01	1.69	1.52				
80%		1.26	1.51	1.35	1.27				
75%		1.30	1.28						
90%		1.25							
None	D5 stream	1.03	1.02	1.24	1.52				
80%		1.01	1.55	1.37	1.28				
75%		1.32							
90%		1.26							
None	R1 stream					1.45	1.02	1.55	1.11
80%						1.37	1.42	1.29	
75%						1.50			
90%						1.50			
None	R2 stream					1.02	1.08	1.75	1.57
80%						1.02	1.55	1.38	1.29
75%						1.54			
90%						1.41			

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-159: Aquatic organisms: PEC calculation and acceptability of risk ($PEC/RAC < 1$) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 455 g/ha)

Intended use	Winter oilseed rape
Active substance	pendimethalin
Application rate (g/ha)	1 x 455

Nozzle reduction	Vegetated filter strip (m)	0	0
	No-spray buffer (m)	0	0
None	R1 stream	0.81	1.09
50%		0.20	
75%		0.15	
None	R3 stream	0.24	0.27
50%		0.24	0.13
75%		0.15	
RAC (µg/L)			
0.24		PEC/RAC ratio	
None	R1 stream	0.72	0.4
50%			
None	R3 stream	1.09	0.5
50%		0.55	
75%			

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter oilseed rape (1 x 455 g/ha) are <1 when risk mitigation options are considered:

D2 ditch, D3 ditch: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D2 stream, D4 stream: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D5 stream: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

Table 9.5-160: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape

Intended use		Winter oil seed rape								
Active substance		pendimethalin								
Application rate (g/ha)		1 > 910								
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20	
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20	
None	D2 ditch	0%	0.563	0.837	0.586	0.445				
		50%	0.315	0.472	0.332	0.252				
		75%	0.193	0.301	0.217	0.163				
		90%	0.311	0.212						
None	D3 stream	0%	0.377	0.596	0.680	0.525				
		50%	0.240	0.399	0.446	0.283				
		75%	0.171	0.252	0.274	0.182				
		90%	0.193	0.176						
None	D4 ditch	0%	0.549	0.821	0.569	0.433				
		50%	0.274	0.431	0.311	0.228				
		75%	0.133	0.262	0.188					
		90%	0.264	0.176						
None	D4 stream	0%	0.302	0.456	0.655	0.501				
		50%	0.203	0.296	0.344	0.221				
		75%	0.131	0.222	0.190					
		90%	0.241	0.152						

None	D5 stream	0.04	1.031	0.15	0.54				
50%		0.03	0.512	0.58	0.22				
75%		0.08	0.229	0.32	0.10				
90%		0.20	0.158						
None	R1 stream					0.00	0.25	0.52	0.00
50%						0.20	0.05	0.25	0.15
75%						0.20	0.07	0.25	
90%						0.50	0.07		
None	R8 stream					0.00	0.03	0.05	0.26
50%						0.29	0.12	0.30	0.33
75%						0.27	0.03	0.10	0.12
90%						0.50	0.03	0.10	
RAC (µg/L)									
D48 (mesocosm geometric)		PEC/RAC ratio							
None	D2 ditch	0.26	1.74	0.22	0.2				
50%		0.70	0.98	0.69	0.5				
75%		0.03	0.65	0.15	0.3				
90%		0.65	0.4						
None	D2 stream	0.91	2.08	0.42	1.09				
50%		0.96	1.04	0.72	0.5				
75%		0.98	0.53	0.76	0.2				
90%		0.40	0.21						
None	D3 ditch	0.21	1.71	0.10	0.38				
50%		0.61	0.96	0.63	0.4				

75%		1.90	1.55	1.20					
90%		1.35	1.32						
None	D1 stream	3.75	1.99	1.36	1.06				
80%		1.35	1.02	1.72	1.52				
75%		1.02	1.52	1.01					
90%		1.30	1.31						
None	D5 stream	1.05	2.15	1.47	1.13				
80%		2.03	1.08	1.75	1.52				
75%		1.04	1.53	1.11	1.31				
90%		1.32	1.33						
None	R1 stream					2.92	1.57	1.10	1.33
80%						1.52	1.33	1.32	1.33
75%						1.52	1.32	1.32	
90%						1.35	1.32		
None	R2 stream					4.04	2.15	1.36	1.34
80%						2.06	1.13	0.72	0.69
75%						1.83	1.34	0.65	0.44
90%						1.21	1.34	0.65	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-161: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 910 g/ha)

Intended use	Winter oilseed rape
Active substance	pendimethalin
Application rate (g/ha)	1 x 910

Nozzle reduction	Vegetated filter strip (m)	0	0
	No-spray buffer (m)	0	0
None	R1 stream		0.21
50%		0.26	
None		R3 stream	
50%			0.33
75%	0.35		0.63
RAC (µg/L)			
0.48		PEC/RAC ratio	
None	R1 stream		0.43
50%		0.47	
None	R3 stream		
50%			0.59
75%		0.64	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in winter oilseed rape (1 x 910 g/ha) are <1 when risk mitigation options are considered:

D2 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D2 stream: 15m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

D3 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

Table 9.5-162: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in asparagus, brassicas, leek, lettuce, endive and artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop 1 x 1500 g/ha pre-emergence)

Intended use		Asparagus, brassicas, leek, lettuce, endive and artichoke (pre-emergence)							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1500							
Nozzle reduction	No-spray buffer (m)	5	10	15	30	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 1 st crop	0.604	0.428	0.375	0.343				
80%		0.346	0.243	0.216	0.200				
75%		0.245	0.158	0.134	0.127				
60%		0.158	0.104	0.088	0.080				
None	D3 2 nd crop	0.701	0.492	0.378	0.343				
80%		0.350	0.216	0.164	0.158				
75%		0.215	0.131	0.100	0.092				
60%		0.119	0.082	0.060					
None	D4 pond	0.331	0.241	0.191					
80%		0.197	0.144						
None	D4 stream	2.916	1.554	1.064	0.810				
80%		0.481	0.298	0.208	0.165				
75%		0.268	0.126	0.080	0.060				
60%		0.146	0.067	0.040	0.030				
None	D6 pond	2.220	1.442	0.985	0.750				
80%		0.359	0.230	0.151	0.110				

75%		0.750	0.630	0.751					
90%		0.750							
None	R1 1 st pond					0.646	0.679	0.192	
80%						0.659	0.673		
75%						0.659			
None	R1 2 nd pond					0.678	0.651	0.193	
80%						0.678	0.651		
None	R1 1 st stream					0.660	0.635	0.192	0.191
80%						0.659	0.708	0.533	0.479
75%						0.938	0.694	0.533	0.363
90%						0.938	0.694	0.533	0.363
None	R1 2 nd stream					0.441	0.311	0.900	0.695
80%						0.462	0.692	0.506	0.369
75%						0.932	0.659	0.506	0.345
90%						0.932	0.659	0.506	0.345
None	R2 1 st stream					0.224	0.273	0.188	0.902
80%						0.652	0.895	0.616	0.475
75%						0.948	0.486	0.886	0.256
90%						0.948	0.482	0.168	0.125
None	R2 2 nd stream					0.820	0.778	0.228	0.921
80%						0.708	0.928	0.669	0.452
75%						0.902	0.503	0.853	0.269
90%						0.401	0.251	0.198	0.186
None						0.402	0.324	0.259	0.953

80%	R3 1 st stream					1758	1309	1658	1519
75%						1953	1332	1496	1537
90%						1998	1332	1496	1537
None	R3 2 nd stream					3506	1309	1831	1535
80%						1708	1303	1620	1475
75%						1808	1301	1415	1435
90%					1728	1301	1415	1435	
None	R4 1 st stream					2438	1303	1970	1750
80%						1558	1031	1347	1470
75%						1558	1031	1347	1470
90%									
None	R4 2 nd stream					2441	1308	1822	1620
80%						1538	1072	1335	1471
75%						1538	1072	1335	1471
90%									
RAC (ng/L)									
D-48 (mesocosm, geometric)		PEC/RAC ratio							
None	D3 1 st ditch	561	296	203	156				
50%		250	155	106	78				
75%		155	94	66	51				
90%		94	63	46	36				
None	D3 2 nd ditch	563	296	204	156				
50%		251	149	103	78				
75%		149	98	67	51				

90%		137	159	183					
None	DA pond	139	150	180					
90%		141	130						
None	DA stream	105	124	152	139				
90%		108	136	114	138				
75%		120	139	139	134				
90%		122	129	139	134				
None	DA ditch	107	100	105	136				
90%		133	156	156	136				
75%		156	156	156					
90%		156							
None						171	152	141	
90%	RI 1 st pond					159	137		
75%						159			
None						176	152	141	
90%	RI 2 nd pond					176	152		
None						513	276	190	187
90%	RI 1 st stream					267	143	111	172
75%						205	145	111	176
90%						205	145	111	176
None						500	272	188	185
90%	RI 2 nd stream					263	144	108	177
75%						194	147	108	172
90%						194	147	108	172

None	R3 1 st stream					672	370	179	133
80%						334	136	125	133
75%						197	101	130	133
90%						197	115	139	137
None	R3 2 nd stream					692	371	255	133
80%						356	193	133	101
75%						188	106	128	137
90%						188	132	132	135
None	R3 1 st stream					709	330	261	139
80%						365	201	139	106
75%						192	133	108	120
90%						193	133	108	120
None	R3 2 nd stream					708	376	252	135
80%						355	199	131	100
75%						180	113	106	139
90%						161	113	106	139
None	R4 1 st stream					507	273	168	145
80%						324	225	175	120
75%						324	225	175	120
90%									
None	R4 2 nd stream					509	273	167	145
80%						320	225	174	119
75%						320	225	174	119
90%									

PEC: Pesticides environmental concentration; PAC: Regulatory acceptable concentration; PRO: RAC ratios above the release trigger (RAC) are shown in bold

Table 9.5-163: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop, 1 x 1590 g/ha) in pre emergence

Intended use		Asparagus, brassicas, leek, lettuce, endive, artichoke 1 st and 2 nd crop (pre-emergence)	
Active substance		Pendimethalin	
Application rate (g/ha)		1 x 1590	
Nozzle reduction	Vegetated filter strip (m)	0	0
	No-spray buffer (m)	0	0
75%	R1 stream 1st		0.217
90%		0.218	
75%	R1 stream 2nd		0.207
90%		0.208	
75%	R2 stream 1st		0.237
90%		0.232	0.125
75%	R2 stream 2nd		0.267
90%		0.251	0.134
75%	R3 stream 1st		0.297
90%		0.319	0.176
75%	R3 stream 2nd		0.273
90%		0.284	0.156
75%	R4 stream 1st		0.206

90%		0.201	
75%	R1 stream 2nd		0.805
90%		0.206	
RAC (µg/L)			
1.0		PEC/RAC ratio	
75%	R1 stream 1st		0.45
90%		0.5	
75%	R1 stream 2nd		0.43
90%		0.42	
75%	R2 stream 1st		0.53
90%		0.43	
75%	R2 stream 2nd		0.56
90%		0.52	
75%	R3 stream 1st		0.62
90%		0.66	
75%	R3 stream 2nd		0.57
90%		0.59	
75%	R4 stream 1st		0.43
90%		0.42	
75%	R4 stream 2nd		0.43
90%		0.43	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in asparagus, brassicas, leek, lettuce, endive and artichoke (1 x 1590 g/ha pre-emergence) are <1 when risk mitigation options are considered: D3 ditch, D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone +90% nozzle reduction

90%									
None	D3 stream	0.916	0.534	0.024	0.810				
80%		0.831	0.398	0.548	0.817				
75%		0.768	0.431	0.506	0.806				
90%		0.841	0.806	0.506	0.806				
None	D6 ditch	0.640	0.329	0.556	0.227				
80%		0.319	0.629	0.652	0.652				
75%		0.659	0.652	0.652					
90%		0.652	0.652						
None	R1 1 st pond					0.558	0.446	0.202	
80%						0.268	0.731		
75%						0.268			
90%									
None	R1 2 nd pond					0.552	0.448	0.125	
80%						0.351	0.247		
75%						0.351			
90%									
None	R1 1 st stream					0.468	0.534	0.018	0.692
80%						0.291	0.718	0.524	0.576
75%						0.901	0.665	0.524	0.552
90%						0.901	0.665	0.524	0.552
None	R1 2 nd stream					0.452	0.548	0.015	0.692
80%						0.287	0.709	0.491	0.574
75%						0.648	0.367	0.451	0.508

90%						1848	1337	1451	1319
None	R2 1 st stream					1855	1377	1498	1319
90%						1679	1307	1692	1475
75%						1880	1438	1338	1457
90%						1405	1336	1157	1397
None	R2 2 nd stream					1522	1255	1221	1329
90%						1711	1391	1691	1488
75%						1905	1505	1399	1476
90%						1425	1249	1173	1436
None	R2 1 st stream					1413	1339	1269	1361
90%						1768	1377	1697	1415
75%						1902	1601	1528	1361
90%						1902	1601	1528	1361
None	R2 2 nd stream					1596	1305	1288	1328
90%						1721	1345	1682	1497
75%						1901	1581	1388	1394
90%						1721	1502	1388	1363
None	R4 1 st stream					2468	1931	1912	1696
90%						1362	1349	1728	1497
75%						1362	1349	1728	1497
90%									
None	R4 2 nd stream					2447	1920	1907	1690
90%						1436	1301	1768	1524
75%						1436	1301	1768	1524

90%									
RAC (µg/L)									
148 (insecticide psulmetan)		PEC/RAC ratio							
None	D3 15' canal	572	298	204	155				
90%		291	156	109	83				
75%		157	83	59	45				
90%		83	43	30	23				
None	D3 20' canal	563	298	204	155				
90%		291	156	108	83				
75%		156	83	58	45				
90%		82	43	30	23				
None	D4 pond	670	351	240					
90%		342	181						
75%									
90%									
None	D4 stream	605	324	222	169				
90%		309	166	114	87				
75%		160	83	56	43				
90%		81	43	30	23				
None	D6 ditch	550	291	199	151				
90%		275	146	100	76				
75%		137	73	50					
90%		69	37						
None	R1 15' pond					074	052	040	

80%						157	133		
75%						157			
90%									
None	R1 2 nd pond					173	133	141	
80%						173	130		
75%						173			
90%									
None	R1 1 st stream					514	275	191	136
80%						269	149	109	123
75%						204	142	109	124
90%						204	142	109	124
None	R1 2 nd stream					512	272	191	135
80%						268	148	109	123
75%						176	142	108	124
90%						176	142	108	124
None	R2 1 st stream					673	364	250	190
80%						343	189	130	122
75%						183	102	100	123
90%						184	103	105	123
None	R2 2 nd stream					692	372	255	194
80%						350	194	134	102
75%						189	105	108	125
90%						189	105	109	125
None						712	388	268	200

80%	R1 1 st stream					3.68	3.00	1.23	0.67
75%						2.07	1.40	1.48	0.73
90%						2.07	1.40	1.48	0.73
None	R1 2 nd stream					7.08	3.76	1.88	1.35
80%						3.58	1.97	1.82	1.03
75%						1.94	1.11	1.80	0.59
90%					1.50	1.05	1.80	0.55	
None	R1 3 rd stream					5.14	2.77	1.90	1.35
80%						2.84	1.98	1.52	1.03
75%						2.84	1.98	1.52	1.03
90%									
None	R1 2 nd stream					5.10	2.75	1.89	1.33
80%						3.00	2.09	1.40	1.09
75%						3.00	2.09	1.40	1.09
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-165: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop, 1 x 1590 g/ha) in pre emergence

Intended use	Asparagus, brassicas, leek, lettuce, endive, artichoke 1 st and 2 nd crop (pre-emergence) vegetables (post-emergence)
Active substance	Pendimethalin
Application rate (g/ha)	1 x 1590

75%	Vegetated filter strip (m)	0	0
90%	No-spray buffer (m)	0	0
75%	R1 stream 1 ^m		0215
90%		0217	
75%	R1 stream 2 ^m		0218
90%		0219	
75%	R2 stream 1 ^m		0251
90%		0253	0127
75%	R2 stream 2 ^m		0200
90%		0252	0130
75%	R3 stream 1 ^m		0295
90%		0310	0127
75%	R3 stream 2 ^m		0294
90%		0292	0164
75%	R4 stream 1 ^m		0218
90%		0223	
75%	R4 stream 2 ^m		0204
90%		0203	
RAC (µg/L)			
0.38		TEC/RAC ratio	
75%	R1 stream 1 ^m		043
90%		043	
75%	R1 stream 2 ^m		044

90%		0.5	
75%	R3 stream 1m		0.5
90%		0.9	
75%	R3 stream 2m		0.5
90%		0.5	
75%	R3 stream 1m		0.3
90%		0.5	
75%	R3 stream 2m		0.5
90%		0.2	
75%	R4 stream 1m		0.3
90%		0.6	
75%	R4 stream 2m		0.3
90%		0.5	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in asparagus, brassicas, leek, lettuce, endive and artichoke (1 x 1590 g/ha post-emergence) are <1 when risk mitigation options are considered: D3 ditch, D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5v no spray buffer zone + 90% nozzle reduction

R1 stream, R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenario D6 ditch the PEC/RAC ratios are below the trigger even considering mitigation measures. However, scenario D6 is not relevant for CEU countries

Table 9.5-166: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in strawberry (between rows)

Intended use	Strawberry (between rows)
--------------	---------------------------

None	R1 stream					18245	13099	17682	15347
50%						19769	13531	13396	18235
75%						19730	13312	13396	18270
90%						19730	13312	13396	18270
None	R2 stream					24949	18115	19001	17624
50%						12552	17091	14927	18372
75%						12669	18171	12558	18326
90%						12502	18157	11149	
None	R3 stream					25552	18355	19226	18719
50%						12498	17006	14928	18377
75%						12718	17506	13587	18261
90%						12718	17506	13587	18261
None	R4 stream					12841	12991	17681	18118
50%						12201	13352	17633	18453
75%						12201	13352	17633	18453
90%									
RAC (mg/L)									
1-48 (mesocosm, geotitan)		PEC/RAC ratio							
None	D3 ditch	021	023	153	118				
50%		210	116	182	269				
75%		116	171	150	238				
90%		171	148	153					
None	D4 pond	152	158						
50%		151							

75%									
90%									
None	D1 stream	154	243	166	138				
90%		251	125	187	168				
75%		120	167	187	141				
90%		154	147						
None	D3 ditch	418	222	151	141				
90%		209	141	187	189				
75%		108	182	189	189				
90%		169	182	189					
None	R1 pond					054	039		
90%						041			
75%									
90%									
None	R1 stream					334	207	148	141
90%						200	141	088	059
75%						152	008	088	056
90%						152	008	088	056
None	R2 stream					510	274	188	145
90%						262	143	092	078
75%						138	077	054	041
90%						064	039	080	
None	R3 stream					582	242	198	149
90%						260	147	104	079

75%						150	0.05	0.80	0.55
90%						150	0.05	0.80	0.55
None	R1 stream					383	3.06	1.42	0.08
90%						254	0.75	1.38	0.59
75%						254	0.75	1.38	0.59
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-167: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in strawberry (1 x 1590 g/ha between rows)

Intended use		Strawberry (between rows)	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream		0.162
90%		0.162	
75%	R2 stream		0.196
90%		0.180	
75%	R3 stream		0.216
90%		0.201	
75%	R4 stream		0.161
90%		0.202	

fraction	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	0.45	0.76	0.53	0.98				
50%		0.29	0.96	0.88	0.15				
75%		0.11	0.29	0.79					
90%		0.50	0.18						
None	D4 pond	0.81							
50%									
75%									
90%									
None	D4 stream	0.59	0.83	0.51	0.33				
50%		0.24	0.42	0.29	0.23				
75%		0.12	0.22	0.15					
90%		0.35							
None	D6 ditch	0.34	0.70	0.50	0.25				
50%		0.17	0.89	0.26	0.26				
75%		0.02	0.23	0.26					
90%		0.26							
None	R1 pond					0.18			
50%									
75%									
90%									
None	R1 stream					0.52	0.25	0.49	0.27
50%						0.69	0.32	0.29	0.50
75%						0.54	0.31	0.29	

90%						0538			
None	R3 stream					0450	0389	0691	0480
90%						0809	0457	0330	0456
75%						0478	0273	0182	0438
90%						0219	0130		
None	R3 stream					0825	0375	0692	0411
90%						0901	0317	0359	0479
75%						0518	0135	0290	0459
90%						0508	0135	0290	
None	R3 stream					0822	0213	0491	0474
90%						0861	0301	0461	0415
75%						0861	0301	0461	0415
90%									
RAC (µg/L)									
D48 (mesocosm geomim)		PEC/RAC ratio							
None	D3 ditch	001	160	109	038				
90%		052	038	059	045				
75%		006	052	057					
90%		052	038						
None	D4 pond	008							
90%									
75%									
90%									
None	D4 stream	025	074	010	001				

80%		175	189	181	181				
75%		186	192	183					
90%		183							
None	R6 road	239	158	108	138				
80%		149	129	155	141				
75%		151	142	147					
90%		147							
None	R1 road					159			
80%									
75%									
90%									
None	R1 stream					270	149	108	172
80%						144	130	161	182
75%						144	129	161	
90%						144			
None	R2 stream					365	196	134	102
80%						187	101	170	153
75%						192	155	138	129
90%						186	127		
None	R3 stream					360	204	140	106
80%						196	108	175	157
75%						187	128	156	133
90%						186	128	156	
None	R4 stream					275	149	102	178

50%						1.79	0.25	0.0%	0.66
75%						1.79	0.25	0.0%	0.66
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-169: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in strawberry (1 x 1137 g/ha between rows)

Intended use		Strawberry (between rows)	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1137	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
50%	81 stream		0.24
75%			
90%		0.16	
50%	82 stream		0.33
75%			0.19
90%		0.27	
50%	83 stream		0.27
75%			0.15
90%		0.16	
50%	84 stream		0.20
75%			

PEC		PEC/RAC	
50%		0.141	
RAC (µg/L)			
10%		PEC/RAC ratio	
50%	R1 stream		0.44
75%			
90%		0.24	
50%	R2 stream		0.53
75%			
90%		0.26	
50%	R3 stream		0.57
75%			
90%		0.35	
50%	R4 stream		0.43
75%			
90%		0.29	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in strawberry (1 x 1137 g/ha between rows) are < 1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Table 9.5-170: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in raspberry

Intended use		Raspberry							
Active substance		Pendimethalin							
Application rate (g/ha)		1 < 1365							
Nozzle reduction	No-spray buffer (m)	5	10	15	30	5	10	15	30
	Vegetated filter strip (m)	None	None	None	None	5	10	15	30
None	0.5 ditch	0.241	0.321	0.673	0.430				
80%		0.335	0.491	0.763	0.361				
75%		0.504	0.307	0.300	0.167				
90%		0.309	0.203						
None	0.5 stream	0.524	0.814	0.594	0.424				
80%		0.776	0.413	0.506	0.213				
75%		0.403	0.220	0.161					
90%		0.179							
None	0.5 ditch	0.277	0.267	0.211	0.510				
80%		0.367	0.533	0.313	0.298				
75%		0.391	0.370	0.276	0.203				
90%		0.385	0.281	0.196					
None	0.1 stream					0.538	0.273	0.522	0.373
80%						0.701	0.356	0.283	0.213
75%						0.538	0.221	0.133	
90%						0.192			

None	R3 stream					1654	1305	1689	1690
50%						1905	1393	1331	1655
75%						1480	1265	1196	1491
90%						1626	1159		
None	R3 stream					1558	1303	1739	1525
50%						1921	1336	1321	1632
75%						1536	1111	12205	1476
90%						1285	1175		
None	R4 stream					1532	1221	1527	1477
50%						1698	1335	1282	1416
75%						1531	1217	1160	
90%						1193			
RAC (µg/L)									
D48 (mesocosm geometric)		PEC/RAC ratio							
None	D3 ditch	0.63	1.92	1.40	1.00				
50%		1.34	1.03	0.76	0.58				
75%		1.05	0.62	0.44	0.35				
90%		0.64	0.43						
None	D4 stream	3.17	1.70	1.24	0.88				
50%		1.62	0.81	0.61	0.45				
75%		0.94	0.46	0.34					
90%		0.57							
None	D6 ditch	3.70	2.01	1.48	1.06				
50%		2.01	1.16	0.86	0.62				

75%		0.3	0.7	0.38	0.49				
90%		0.30	0.52	0.30					
None	R1 stream					2.78	0.51	0.10	0.79
80%						1.46	0.30	0.59	0.19
75%						0.80	0.76	0.39	
90%						0.91			
None	R2 stream					3.25	0.26	0.48	0.03
80%						1.89	0.03	0.75	0.59
75%						1.00	0.56	0.01	0.49
90%						0.97	0.25		
None	R3 stream					5.86	0.09	0.58	0.09
80%						2.02	0.12	0.82	0.59
75%						1.12	0.35	0.38	0.35
90%						0.89	0.37		
None	R4 stream					2.76	0.50	0.10	0.79
80%						1.45	0.30	0.52	0.12
75%						0.79	0.45	0.38	
90%						0.91			

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-171: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in raspberry (1 x 1365 g/ha between rows)

Intended use	Raspberry (between rows)
Active substance	pendimethalin

Application rate (g/ha)		1 x 1365	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream		0.113
90%		0.123	
75%	R2 stream		0.141
90%		0.152	
75%	R3 stream		0.160
90%		0.178	
75%	R4 stream		0.115
90%		0.120	
PEC (ng/L)			
0.48		PEC/RAC ratio	
75%	R1 stream		0.23
90%		0.26	
75%	R2 stream		0.29
90%		0.33	
75%	R3 stream		0.33
90%		0.37	
75%	R4 stream		0.24
90%		0.25	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in raspberry (1 x 1365 g/ha between rows) are <1 when risk mitigation options are considered

D3 ditch: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D4 stream: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

D6 ditch: 20m no spray buffer zone or 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R2 stream, R3 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

Table 9.5-172: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in currants and grapevine between rows

Intended use		Currants and grapevine between rows							
Active substance		pendimethalin							
Application rate (g/ha)		1 x 1590							
Nozzle reduction	No-spray buffer (m)	5	10	15	30	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	0.025	0.021	0.018	0.017				
80%		0.014	0.011	0.010	0.009				
75%		0.005	0.004	0.003	0.003				
90%		0.003	0.002	0.002					
None	D4 pond	0.25	0.18						
80%		0.15							
75%									
90%									
None	D4 stream	0.26	0.14	0.09	0.02				

80%		0301	0436	0555	0334				
75%		0167	0336	0187	0134				
90%		0308	0116						
None	R6 road	0091	0096	0302	0327				
80%		0068	0612	0452	0327				
75%		0758	0391	0291	0214				
90%		0405	0226	0209					
None	R1 road					0229	0151		
80%						0108			
75%									
90%									
None	R1 stream					0546	0337	0612	0437
80%						0302	0416	0327	0255
75%						0441	0254	0187	0155
90%						0222	0112		
None	R2 stream					0032	0025	0600	0571
80%						0051	0372	0418	0299
75%						0552	0311	0228	0164
90%						0261	0153		
None	R3 stream					0132	0154	0384	0603
80%						0112	0315	0458	0220
75%						0612	0255	0268	0190
90%						0328	0203	0152	
None	R4 stream					0541	0354	0618	0456

90%									
None	R1 stream					3.92	0.27	1.45	0.51
90%						1.69	0.91	1.68	0.49
75%						0.98	1.55	1.39	0.33
90%						0.88	1.30		
None	R2 stream					4.24	2.25	1.62	1.49
90%						2.19	1.19	1.52	0.79
75%						1.16	1.65	1.08	0.54
90%						0.59	1.32		
None	R3 stream					4.44	2.10	1.76	1.26
90%						2.53	1.28	1.58	0.69
75%						1.28	1.74	1.58	0.40
90%						0.65	1.48	1.32	
None	R4 stream					3.21	1.74	1.29	0.91
90%						1.69	1.26	1.68	0.49
75%						0.92	1.52	1.39	0.33
90%						0.46	1.29		

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-173: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in currants and grapevines (1 x 1590 g/ha, between rows)

Intended use	Currants and grapevines between rows
Active substance	pendimethalin
Application rate (g/ha)	1 x 1590

Nozzle reduction	Vegetated filter strip (m)	0	0
	No-spray buffer (m)	0	0
75%	R1 stream		0.15
90%		0.12	
75%	R2 stream		0.16
90%		0.13	
75%	R3 stream		0.20
90%		0.16	
75%	R4 stream		0.13
90%		0.12	
RAC (µg/L)			
0.4		PEC/RAC ratio	
75%	R1 stream		0.28
90%		0.20	
75%	R2 stream		0.34
90%		0.22	
75%	R3 stream		0.40
90%		0.22	
75%	R4 stream		0.28
90%		0.20	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in currants and grapevines (1 x 1590 g/ha between rows) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 ditch: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R2 stream, R3 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

Table 9.5-174: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in potato

Intended use		Potato							
Active substance		pendimethalin							
Application rate (g/ha)		1 = 1590							
Nozzle reduction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	0.3 ditch	0.698	0.436	0.977	0.743				
50%		0.348	0.222	0.503	0.389				
75%		0.226	0.143	0.310	0.236				
90%		0.154	0.097	0.214	0.162				
None	0.3 pond	0.531	0.331	0.740					
50%		0.267	0.164						
75%									
90%									
None	0.3 stream	0.919	0.561	0.669	0.813				
50%		0.457	0.282	0.551	0.425				
75%		0.273	0.169	0.332	0.322				
90%		0.148	0.092	0.172	0.162				

None	D6 direct 1	0.668	0.418	0.566	0.233				
80%		0.533	0.207	0.558	0.566				
75%		0.675	0.566	0.566	0.566				
90%		0.566	0.566	0.566					
None	D6 direct 2	0.718	0.438	0.588	0.243				
80%		0.555	0.218	0.578	0.218				
75%		0.718	0.218	0.578	0.218				
90%		0.718							
None	R1 pond					0.508	0.241	0.127	
80%						0.408	0.132		
75%									
90%									
None	R1 stream					0.468	0.325	0.171	0.218
80%						0.288	0.271	0.538	0.337
75%						0.058	0.271	0.538	0.337
90%						0.058			
None	R2 stream					0.268	0.250	0.200	0.218
80%						0.672	0.909	0.625	0.488
75%						0.688	0.495	0.345	0.262
90%						0.412	0.240	0.184	0.129
None	R3 stream					0.392	0.316	0.245	0.348
80%						0.742	0.368	0.668	0.507
75%						0.418	0.277	0.268	0.218
90%						0.418	0.277	0.268	0.218

RAC (µg/L)		PEC/RAC ratio							
148 (mesocosm groundwater)									
None	D3 ditch	572	298	304	155				
50%		291	151	105	031				
75%		151	090	035	009				
90%		091	031	035	034				
None	D4 ponds	069	050	030					
50%		031	030						
75%									
90%									
None	D4 stream	608	325	323	169				
50%		310	167	105	039				
75%		161	082	067	037				
90%		073	037	067	037				
None	D6 ditch 1'	556	295	301	153				
50%		278	147	106	046				
75%		141	048	008	016				
90%		048	048	008					
None	D6 ditch 2'	565	300	305	156				
50%		282	150	150	050				
75%		150	050	050	050				
90%		050							
None	E1 ponds					052	052	040	
50%						005	052		

P50									
P05									
N05	R1 stream					513	376	130	0.36
R05						267	152	118	0.31
P50						219	152	118	0.31
P05						219			
N05	R2 stream					679	375	250	0.30
R05						349	119	130	0.01
P50						134	103	171	0.35
P05						086	130	138	0.37
N05	R3 stream					702	378	200	0.38
R05						304	201	132	0.06
P50						252	162	126	0.36
P05						252	162	126	0.36

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-175: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on POCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in potato (1 x 1590 g/ha)

Intended use		Potato	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1590	
Nozzle reduc- tion	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20

75%	R1 stream		0.17
90%		0.35	
75%	R2 stream		0.18
90%		0.36	
75%	R3 stream		0.16
90%		0.33	
RAC (µg/L)			
0.3		PEC/RAC ratio	
75%	R1 stream		0.22
90%		0.5	
75%	R2 stream		0.26
90%		0.49	
75%	R3 stream		0.33
90%		0.64	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in potato (1 x 1390 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R1 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenario D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries

Table 9.5-176: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in potato

Intended use		Potato							
Active substance		pendimethalin							
Application rate (g/ha)		1.5-1337							
Nozzle reduction	No-spray buffer (m)	5	10	15	30	5	10	15	30
	Vegetated filter strip (m)	None	None	None	None	5	10	15	30
None	Dr ditch	0.939	1.027	0.698	0.531				
		0.965	0.537	0.373	0.284				
		0.541	0.330	0.237	0.179				
		0.339	0.231	0.163					
None	Dr road	0.249	0.126						
		0.144							
None	Dr stream	2.087	1.116	0.765	0.531				
		1.064	0.574	0.394	0.300				
		0.555	0.304	0.221	0.220				
		0.246	0.220						
None	Dr ditch 1'	0.908	1.011	0.691	0.525				
		0.925	0.505	0.381	0.306				
		0.496	0.386	0.286	0.306				
		0.386	0.386						

Nome	D3 stream	0339	0338	0338	0337				
80%		0389	0337	0395	0395				
75%		0390	0395	0395	0395				
90%		0385	0395						
Nome	R1 pond					0359	0355		
80%						0355			
75%									
90%									
Nome	R1 stream					0365	0365	0366	0395
80%						0328	0317	0326	0370
75%						0342	0317	0326	0370
90%						0342			
Nome	R2 stream					0332	0341	0353	0352
80%						0398	0390	0443	0340
75%						0391	0390	0342	0384
90%						0391	0367	0323	
Nome	R2 stream					0340	0341	0391	0355
80%						0365	0399	0454	0360
75%						0385	0345	0421	0367
90%						0385	0345	0421	0367
RAC (µg/L)									
1.48 (mesocosm geometric)		PEC/RAC ratio							
Nome	D3 stream	033	033	035	031				
80%		031	032	038	039				

75%		1.1	1.29	1.29	1.37				
90%		1.37	1.45	1.54					
None	D3 pond	1.51	1.57						
80%		1.51							
75%									
90%									
None	D4 stream	1.55	1.63	1.59	1.61				
80%		1.62	1.60	1.62	1.63				
75%		1.65	1.65	1.66	1.66				
90%		1.71	1.68						
None	D6 ditch 1	1.98	2.11	1.94	1.99				
80%		1.97	1.95	1.91	1.91				
75%		1.93	1.89	1.91	1.91				
90%		1.91	1.89						
None	D6 ditch 2	1.94	2.14	1.96	1.91				
80%		2.02	1.92	1.93	1.93				
75%		1.93	1.93	1.93	1.93				
90%		1.93	1.93						
None	R1 pond					1.55	1.57		
80%						1.52			
75%									
90%									
None	R1 stream					1.68	1.69	1.57	1.64
80%						1.62	1.68	1.68	1.56

75%	R1 stream					155	0.05	0.38	0.36
90%						155			
75%						186	0.61	1.79	0.36
90%						250	0.85	2.38	0.71
75%	R2 stream					151	0.76	1.50	0.33
90%						220	0.85	1.22	
75%						508	2.27	1.88	0.43
90%						264	0.76	1.01	0.77
75%						164	0.13	0.88	0.01
90%						164	0.13	0.88	0.01

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration. PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-177: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in potato (1 x 1137 g/ha)

Intended use		Potato	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1137	
Nozzle reduc- tion	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream		0.152
90%		0.155	
75%	R2 stream		0.154
90%		0.160	

75%	R3 stream		0.809
90%		0.233	
RAC (µg/L)			
0.38		PEC/RAC ratio	
75%	R1 stream		0.32
90%		0.52	
75%	R2 stream		0.58
90%		0.35	
75%	R3 stream		0.42
90%		0.36	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in potato (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 ditch 1st: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R1 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch 2nd the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries

Table 9.5-178: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in ornamentals

Intended use	Ornamental
Active substance	pendimethalin

Application rate (g/ha)		1.5-1.890							
Nozzle re- fraction	No-spray buffer (m)	5	10	15	20	5	10	15	20
	Vegetated filter strip (m)	None	None	None	None	5	10	15	20
None	D3 ditch	0.697	1.488	1.032	0.745				
50%		0.438	0.732	0.549	0.402				
75%		0.251	0.468	0.345	0.253				
90%		0.164	0.311	0.232	0.172				
None	D3 pond	0.342	0.248	0.215					
50%		0.303	0.192						
75%									
90%									
None	D3 stream	0.357	1.268	0.919	0.668				
50%		0.201	0.694	0.488	0.344				
75%		0.028	0.348	0.253	0.182				
90%		0.281	0.168	0.112					
None	D3 ditch	0.720	1.461	1.068	0.767				
50%		0.428	0.816	0.600	0.443				
75%		0.351	0.628	0.392	0.288				
90%		0.348	0.575	0.282	0.210				
None	E1 pond					0.857	0.245	0.208	
50%						0.500	0.137		
75%									
90%									
None	E1 stream					0.661	0.115	0.0151	0.332

90%									
None	D4 stream	1.91	2.63	1.91	1.39				
90%		1.30	1.35	1.01	1.72				
75%		1.30	1.72	1.53	1.38				
90%		1.39	1.35	1.24					
None	D6 ditch	5.67	3.04	2.25	1.60				
90%		1.97	1.70	1.25	1.92				
75%		1.27	1.10	1.52	1.30				
90%		1.13	1.78	1.29	1.22				
None	R1 pond					1.90	1.51	1.32	
90%						1.32	1.51		
75%									
90%									
None	R1 stream					1.29	2.32	1.70	1.23
90%						2.25	1.24	1.92	1.68
75%						1.23	1.72	1.53	1.38
90%						1.60	1.40	1.30	
None	R2 stream					3.66	3.04	2.22	1.59
90%						2.92	1.59	1.16	1.65
75%						1.55	1.67	1.64	1.26
90%						1.74	1.25	1.32	
None	R3 stream					3.92	3.20	2.34	1.63
90%						3.10	1.71	1.25	1.91
75%						1.50	1.00	0.74	0.52

90%						0.50	0.52	0.48	0.53
None	R4 stream					0.28	0.32	0.49	0.53
90%						0.24	0.24	0.50	0.56
75%						0.22	0.21	0.50	0.53
90%						0.25	0.32	0.29	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-179: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in ornamentals (1 x 1590 g/ha)

Intended use		Ornamentals	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1590	
Nozzle reduction	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream		0.182
90%		0.180	
75%	R2 stream		0.210
90%		0.204	
75%	R3 stream		0.235
90%		0.231	0.109
75%	R4 stream		0.175
90%		0.182	
RAC (µg/L)			

PEC		PEC/RAC ratio	
75%	R1 stream	1	0.38
90%		0.39	1
75%	R2 stream	1	0.36
90%		0.35	1
75%	R3 stream	1	0.53
90%		0.56	1
75%	R4 stream	1	0.37
90%		0.38	1

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in ornamentals (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D6 ditch: 20m no spray buffer zone + 50% nozzle reduction or 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 stream, R4 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R2 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

Table 9.5-180: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in clover and alfalfa

Intended use	Clover and alfalfa
Active substance	Pendimethalin

Application rate (g/ha)		I > 1000							
Nozzle reduction	No-spray buffer (m)	I	II	IS	SO	S	II	IS	SO
	Vegetated filter strip (m)	None	None	None	None	S	II	IS	SO
None	D1 ditch	1.706	0.983	0.644	0.488	I	I	I	I
50%		0.924	0.543	0.367	0.280	I	I	I	I
75%		0.582	0.333	0.240	0.184	I	I	I	I
90%		0.345	0.235	0.174	I	I	I	I	I
None	D1 stream	1.904	1.091	0.700	0.532	I	I	I	I
50%		0.977	0.530	0.365	0.278	I	I	I	I
75%		0.514	0.281	0.195	0.149	I	I	I	I
90%		0.241	0.133	I	I	I	I	I	I
None	D2 ditch	1.745	0.959	0.668	0.508	I	I	I	I
50%		0.906	0.566	0.383	0.293	I	I	I	I
75%		0.605	0.355	0.258	0.197	I	I	I	I
90%		0.369	0.251	0.187	I	I	I	I	I
None	D2 stream	2.048	1.087	0.742	0.573	I	I	I	I
50%		1.026	0.545	0.378	0.287	I	I	I	I
75%		0.513	0.277	0.190	0.144	I	I	I	I
90%		0.241	0.133	I	I	I	I	I	I
None	D3 ditch	1.697	0.960	0.634	0.474	I	I	I	I
50%		0.871	0.497	0.331	0.255	I	I	I	I
75%		0.520	0.308	0.213	0.163	I	I	I	I
90%		0.298	0.199	I	I	I	I	I	I
None	D4 stream	1.706	0.983	0.644	0.488	I	I	I	I

80%		0316	0394	0341	0326				
75%		0433	0294	0100	0139				
90%		0310	0118						
None	R5 stream	0924	0039	0305	0541				
80%		0931	0529	0305	0323				
75%		0809	0328	0192	0185				
90%		0225	0126						
None	R1 stream					0553	0390	0533	0442
80%						0310	0162	0312	0233
75%						0167	0312	0239	0163
90%						0147	0312	0239	
None	R2 stream					0053	0106	0252	0331
80%						0162	0372	0323	0303
75%						0302	0310	0215	0162
90%						0253	0149		
None	R3 stream					0132	0142	0233	0392
80%						0102	0606	0413	0313
75%						0100	0342	0241	0162
90%						0332	0267	0204	
RAC (mg/L)									
0-48 (mesocosm, geomean)		PEC/RAC ratio							
None	D1 ditch	056	004	034	002				
50%		092	011	032	053				
75%		021	009	050	053				

90%		0.72	0.39	0.52					
None	D1 stream	0.97	0.13	0.42	0.12				
90%		0.04	0.10	0.52	0.58				
75%		0.07	0.39	0.41	0.51				
90%		0.48	0.25						
None	D2 (0.03)	0.84	0.00	0.39	0.04				
90%		0.01	0.15	0.80	0.61				
75%		0.26	0.24	0.52	0.41				
90%		0.07	0.39	0.52					
None	D2 stream	0.27	0.26	0.55	0.19				
90%		0.14	0.14	0.02	0.61				
75%		0.07	0.38	0.40	0.51				
90%		0.11	0.23						
None	D3 (0.01)	0.84	0.58	0.30	0.92				
90%		0.81	0.04	0.70	0.55				
75%		0.08	0.02	0.42	0.32				
90%		0.02	0.41						
None	D4 stream	0.74	0.00	0.37	0.05				
90%		0.91	0.03	0.21	0.52				
75%		0.01	0.54	0.58	0.29				
90%		0.44	0.25						
None	D5 stream	0.01	0.14	0.47	0.18				
90%		0.04	0.10	0.52	0.58				
75%		0.06	0.38	0.40	0.51				

90%		0.46	1.27						
None	R1 stream					1.35	1.76	1.21	0.92
90%						1.71	1.96	1.35	1.51
75%						1.06	1.35	1.50	1.34
90%						1.08	1.35	1.50	
None	R2 stream					1.29	2.00	1.58	1.21
90%						2.21	1.20	1.31	1.68
75%						1.18	1.35	1.45	1.34
90%						1.53	1.31		
None	R3 stream					1.46	2.08	1.61	1.25
90%						2.30	1.27	1.37	1.66
75%						1.22	1.21	1.50	1.38
90%						1.30	1.36	1.43	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-181: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VPSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in clover, alfalfa (1 x 1000 g/ha)

Intended use		Clover, alfalfa	
Active substance		Pendimethalin	
Application rate (g/ha)		1 x 1000	
Nozzle reduce-Run	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream		0.110

90%		0.176	
75%	R3 stream		0.176
90%		0.156	
75%	R3 stream		0.301
90%		0.218	
RAC (µg/L)			
0.23		PEC/RAC ratio	
75%	R1 stream		0.22
90%		0.30	
75%	R2 stream		0.36
90%		0.35	
75%	R3 stream		0.43
90%		0.44	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in clover, alfalfa (1 x 1000 g/ha) are <1 when risk mitigation options are considered.

D1 ditch, D1 stream, D2 ditch, D2 stream, D3 ditch, D4 stream, D5 stream: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

R2 stream, R3 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

Table 9.5-182: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in cucurbits

Intended use	Cucurbits
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None	R1 stream					0.763	0.355	0.012	0.004
50%						1.639	1.708	1.531	0.579
75%						1.939	1.609	1.531	0.373
90%						1.939	1.609	1.531	0.373
None	R2 stream					3.269	0.751	1.800	0.915
50%						1.675	1.903	1.626	0.435
75%						0.839	1.196	1.341	0.279
90%						0.812	1.252	1.121	0.152
None	R3 stream					3.412	0.107	1.285	0.939
50%						1.728	0.912	1.653	0.911
75%						0.962	0.673	1.528	0.356
90%						0.962	0.673	1.528	0.356
None	R4 stream					0.452	0.321	0.917	0.621
50%						1.646	0.113	0.894	0.011
75%						1.646	0.113	0.894	0.011
90%									
RAC (mg/L)									
1.48 (metocoum, pomegran)		PEC/RAC ratio							
None	D3 ditch	5.61	2.96	2.03	1.55				
50%		2.80	1.55	1.06	0.83				
75%		1.55	0.94	0.66	0.51				
90%		0.94	0.65	0.46	0.36				
None	D4 pond	0.65	0.58	0.40					
50%		0.41	0.38						

75%									
90%									
None	D1 stream	605	124	332	109				
80%		308	166	114	138				
75%		160	189	174	158				
90%		172	179	174	158				
None	D6 ditch	557	295	302	154				
80%		279	148	101	126				
75%		134	126	126	126				
90%		136	126	126					
None	R1 non-01E					101	132	111	
80%						154	136		
75%						154			
90%									
None	R1 stream					513	276	190	127
80%						267	148	111	112
75%						205	145	111	116
90%						205	145	111	116
None	R2 stream					600	365	250	150
80%						349	188	130	101
75%						164	103	124	125
90%						166	128	140	128
None	R3 stream					700	376	257	156
80%						350	196	136	105

75%	R1 stream					2.02	0.70	1.09	0.74
90%						2.02	0.70	1.09	0.74
75%						5.11	3.75	1.89	0.44
90%						3.43	2.19	1.86	0.27
75%						3.43	2.19	1.86	0.27
90%									

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-183: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS VFSMOD Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in cucurbitis (1 x 1590 g/ha)

Intended use		Cucurbitis	
Active substance		pendimethalin	
Application rate (g/ha)		1 x 1590	
Nozzle reduc- tion	Vegetated filter strip (m)	10	20
	No-spray buffer (m)	10	20
75%	R1 stream		0.23
90%		0.31	
75%	R2 stream		0.23
90%		0.31	
75%	R3 stream		0.31
90%		0.30	
75%	R4 stream		0.23
90%		0.26	

RAC (µg/L)			
PEC		PEC/RAC ratio	
75%	R1 stream	1	144
90%		0.5	1
75%	R2 stream	1	154
90%		0.9	1
75%	R3 stream	1	152
90%		0.6	1
75%	R4 stream	1	144
90%		0.5	1

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

PEC/RAC ratios in cucurbits (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 ditch: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Pendimethalin metabolites

Table 9.5-18438: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H001 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of Pendimethalin 45.5% CS in appln. Hand (crop < 50cm)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	-
Endpoint (µg/L)		LC ₅₀ 8280	EC ₅₀ 7730	E _r C ₅₀ > 2500
AF		100	100	10
RAC (µg/L)		82.8	77.3	> 250
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	31.19	0.38	0.40	0.12
Step 2				
N-Europe	14.55	0.18	0.19	0.06
S-Europe	11.64	0.14	0.15	0.05

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-18539: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Pendimethalin 45.5% CS in appln.hand (crop< 50cm)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 1			
	35.98	5.87	0.25
Step 2			
N-Europe	11.22	1.83	0.08
S-Europe	9.05	1.48	0.06

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-18643: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter cereals (1 x 1590 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC ^{gl-max} (µg/L)		
Step 3			
D1 ditch	0.014	0.00228	0.00010
D1 stream	<0.001	0.00016	0.00001
D2 ditch	0.013	0.00212	0.00009
D2 stream	0.008	0.00131	0.00006
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.002	0.00033	0.00001
D4 stream	0.010	0.00163	0.00007
D5 pond	0.001	0.00016	0.00001
D5 stream	0.002	0.00033	0.00001
D6 ditch	0.025	0.00408	0.00017

Group		Inverteb. acute	Algae
R1 pond	0.006	0.00098	0.00004
R1 stream	0.030	0.00489	0.00021
R3 stream	0.023	0.00375	0.00016
R4 stream	0.041	0.00669	0.00028

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-18744: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in maize (1 x 1590 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001

Group		Inverteb. acute	Algae
D4 pond	0.002	0.00033	0.00001
D4 stream	0.007	0.00114	0.00005
D5 pond	0.001	0.00016	0.00001
D5 stream	0.002	0.00033	0.00001
D6 ditch	0.017	0.00277	0.00012
R1 pond	0.011	0.00179	0.00008
R1 stream	0.031	0.00506	0.00021
R2 stream	0.010	0.00163	0.00007
R3 stream	0.027	0.00440	0.00019
R4 stream	0.039	0.00636	0.00027

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-188 45: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in pome/stone fruits (early application 1 x 1590 between rows)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC ^{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.001	0.00016	0.00001
D4stream	0.001	0.00016	0.00001
D5 pond	0.001	0.00016	0.00001
D5 stream	<0.001	0.00016	0.00001
R1 Pond	0.001	0.00016	0.00001
R1 stream	<0.001	0.00016	0.00001
R2 stream	<0.001	0.00016	0.00001
R3 stream	<0.001	0.00016	0.00001
R4 stream	<0.001	0.00016	0.00001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-189 46: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in sunflower (1 x 1183 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.002	0.00033	0.00001
D4 stream	0.007	0.00114	0.00005
D5 pond	0.001	0.00016	0.00001
D5 stream	0.001	0.00016	0.00001
R1 pond	0.008	0.00131	0.00006
R1 stream	0.023	0.00375	0.00016
R3 stream	0.020	0.00326	0.00014

Group		Inverteb. acute	Algae
R4 stream	0.027	0.00440	0.00019

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-190 47: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in soybeans (1 x 1183 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.002	0.00033	0.00001
D4 stream	0.007	0.00114	0.00005
R1 pond	0.007	0.00114	0.00005
R1 stream	0.021	0.00343	0.00014

Group		Inverteb. acute	Algae
R3 stream	0.019	0.00310	0.00013
R4 stream	0.031	0.00506	0.00021

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-191 48: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in bulb vegetables (1 x 1590 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC ^{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.002	0.00033	0.00001
D4 stream	0.010	0.00163	0.00007
D6 1 st ditch	0.021	0.00343	0.00014
D6 2 nd ditch	0.041	0.00669	0.00028
R1 Pond	0.011	0.00179	0.00008
R1 stream	0.029	0.00473	0.00020
R2 stream	0.010	0.00163	0.00007
R3 stream	0.027	0.00440	0.00019
R4 stream	0.037	0.00604	0.00026

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-192 49: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in beans (1 x 1590 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 3			
D2 ditch	0.011	0.00179	0.00008
D2 stream	0.007	0.00114	0.00005
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.002	0.00033	0.00001
D4 stream	0.007	0.00114	0.00005
D6 1 st ditch	0.017	0.00277	0.00012
D6 2 nd ditch	0.023	0.00375	0.00016
R1 pond	0.011	0.00179	0.00008

Group		Inverteb. acute	Algae
R1 stream	0.029	0.00473	0.00020
R2 stream	0.011	0.00179	0.00008
R3 stream	0.027	0.00440	0.00019
R4 stream	0.037	0.00604	0.00026

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-193 50: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel (root vegetables 1 x 1590 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.002	0.00033	0.00001
D4 stream	0.010	0.00163	0.00007
D6 ditch	0.013	0.00212	0.00009
R1 pond	0.010	0.00163	0.00007
R1 stream	0.028	0.00457	0.00019
R2 1 st stream	0.010	0.00163	0.00007
R2 2 nd stream	0.008	0.00131	0.00006
R3 stream	0.028	0.00457	0.00019
R4 stream	0.037	0.00604	0.00026

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-194 51: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in lupine (legumes, 1 x 1183 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.002	0.00033	0.00001
D4 stream	0.007	0.00114	0.00005
D5 pond	0.001	0.00016	0.00001
D5 stream	0.001	0.00016	0.00001
D6 ditch	0.011	0.00179	0.00008
R1 pond	0.007	0.00114	0.00005
R1 stream	0.021	0.00343	0.00014

Group		Inverteb. acute	Algae
R2 stream	0.007	0.00114	0.00005
R3 stream	0.016	0.00261	0.00011
R4 stream	0.027	0.00440	0.00019

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-195 52: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 455 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC ^{gl-max} (µg/L)		
Step 3			
D2 ditch	0.004	0.00065	0.00003
D2 stream	0.003	0.00049	0.00002
D3 ditch	0.003	0.00049	0.00002

Group		Inverteb. acute	Algae
D4 pond	0.001	0.00016	0.00001
D4 stream	0.003	0.00049	0.00002
D5 pond	<0.001	0.00016	0.00001
D5 stream	0.001	0.00016	0.00001
R1 pond	0.002	0.00033	0.00001
R1 stream	0.008	0.00131	0.00006
R3 stream	0.006	0.00098	0.00004

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-196 53: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 910 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC ^{gl-max} (µg/L)		
Step 3			
D2 ditch	0.006	0.00098	0.00004
D2 stream	0.004	0.00065	0.00003
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.001	0.00016	0.00001
D4 stream	0.006	0.00098	0.00004
D5 pond	<0.001	0.00016	0.00001
D5 stream	0.001	0.00016	0.00001
R1 pond	0.004	0.00065	0.00003
R1 stream	0.018	0.00294	0.00012
R3 stream	0.014	0.00228	0.00010

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-197 54: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop, 1 x 1590 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC ^{gl-max} (µg/L)		
Step 3			
D3 1 st ditch	<0.001	0.00016	0.00001
D3 2 nd ditch	0.001	0.00016	0.00001
D4 pond	0.002	0.00033	0.00001
D4 stream	0.010	0.00163	0.00007
D6 ditch	0.029	0.00473	0.00020
R1 1 st pond	0.017	0.00277	0.00012
R1 2 nd pond	0.018	0.00294	0.00012

Group		Inverteb. acute	Algae
R1 1 st stream	0.028	0.00457	0.00019
R1 2 nd stream	0.029	0.00473	0.00020
R2 1 st stream	0.010	0.00163	0.00007
R2 2 nd stream	0.008	0.00131	0.00006
R3 1 st stream	0.027	0.00440	0.00019
R3 2 nd stream	0.020	0.00326	0.00014
R4 1 st stream	0.036	0.00587	0.00025
R4 2 nd stream	0.039	0.00636	0.00027

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-198 55: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in strawberry (fruiting vegetables 1 x 1590 g/ha between rows)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC ^{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.002	0.00033	0.00001
D4 stream	0.008	0.00131	0.00006
D6 ditch	0.013	0.00212	0.00009
R1 pond	0.013	0.00212	0.00009
R1 stream	0.021	0.00343	0.00014
R2 stream	0.008	0.00131	0.00006
R3 stream	0.019	0.00310	0.00013
R4 stream	0.029	0.00473	0.00020

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-199 56: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in raspberry (1 x 1365 g/ha between rows)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	ErC ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.001	0.00016	0.00001
D4 stream	0.001	0.00016	0.00001
D6 ditch	0.004	0.00065	0.00003
R1 pond	0.001	0.00016	0.00001
R1 stream	<0.001	0.00016	0.00001
R2 stream	<0.001	0.00016	0.00001
R3 stream	<0.001	0.00016	0.00001

Group		Inverteb. acute	Algae
R4 stream	<0.001	0.00016	0.00001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-200 57: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in currants and grapevine (vines early application 1 x 1590 g/ha between rows)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC ^{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.001	0.00016	0.00001
D4 stream	0.001	0.00016	0.00001
D6 ditch	0.004	0.00065	0.00003
R1 Pond	0.001	0.00016	0.00001

Group		Inverteb. acute	Algae
R1 stream	<0.001	0.00016	0.00001
R2 stream	<0.001	0.00016	0.00001
R3 stream	<0.001	0.00016	0.00001
R4 stream	<0.001	0.00016	0.00001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-201 58: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in potato (1 x 1590 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC ^{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.002	0.00033	0.00001
D4 stream	0.011	0.00179	0.00008
D6 1 st ditch	0.020	0.00326	0.00014
D6 2 nd ditch	0.027	0.00440	0.00019
R1 pond	0.011	0.00179	0.00008
R1 stream	0.030	0.00489	0.00021
R2 stream	0.010	0.00163	0.00007
R3 stream	0.028	0.00457	0.00019

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-202 59: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in ornamentals (vines early application 1 x 1590 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	ErC ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC _{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.001	0.00016	0.00001
D4stream	0.001	0.00016	0.00001
D6 ditch	0.005	0.00082	0.00003
R1 Pond	0.001	0.00016	0.00001
R1 stream	<0.001	0.00016	0.00001
R2 stream	<0.001	0.00016	0.00001
R3 stream	<0.001	0.00016	0.00001

Group		Inverteb. acute	Algae
R4 stream	<0.001	0.00016	0.00001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-203 60: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in clover, alfalfa (grass 1 x 1000 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC ^{gl-max} (µg/L)		
Step 3			
D1 ditch	0.004	0.00065	0.00003
D1 stream	<0.001	0.00016	0.00001
D2 ditch	0.006	0.00098	0.00004
D2 stream	0.004	0.00065	0.00003

Group		Inverteb. acute	Algae
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.001	0.00016	0.00001
D4 stream	<0.001	0.00016	0.00001
D5 pond	0.001	0.00016	0.00001
D5 stream	<0.001	0.00016	0.00001
R1 Pond	0.003	0.00049	0.00002
R1 stream	0.013	0.00212	0.00009
R2 stream	0.003	0.00049	0.00002
R3 stream	0.008	0.00131	0.00006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-204 61: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in cucurbits (fruiting vegetables 1 x 1590 g/ha)

Group		Inverteb. acute	Algae
Test species		<i>Daphnia magna</i>	-
Endpoint (µg/L)		EC ₅₀ 613	E _r C ₅₀ >1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	PEC ^{gl-max} (µg/L)		
Step 3			
D3 ditch	<0.001	0.00016	0.00001
D4 pond	0.002	0.00033	0.00001
D4 stream	0.010	0.00163	0.00007
D6 ditch	0.017	0.00277	0.00012
R1 Pond	0.017	0.00277	0.00012
R1 stream	0.028	0.00457	0.00019
R2 stream	0.011	0.00179	0.00008
R3 stream	0.026	0.00424	0.00018
R4 stream	0.039	0.00636	0.00027

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

According to *Peer review of the pesticide risk assessment of the active substance pendimethalin* (EFSA Journal 2016;14(3):4420), as for the two metabolites 2,6-dinitro-3,4-dimethylaniline (M455H032) and P36 (M455H029) no experimental data were available, a screening risk assessment was performed considering the metabolites 10 times more toxic than the parent.

Table 9.5-205 62: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of Pendimethalin 45.5% CS in appln.hand (crop < 50 cm)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	58.06	296.22	394.97	624.30
Step 2				
N-Europe	28.85	147.19	196.26	310.22
S-Europe	23.29	118.83	158.44	250.43

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-206 63: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter cereals (1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D1 ditch	0.001	0.00510	0.00680	0.01075
D1 stream	0.001	0.00510	0.00680	0.01075
D2 ditch	0.001	0.00510	0.00680	0.01075
D2 stream	0.001	0.00510	0.00680	0.01075
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
D5 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-207 64: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of Pendimethalin 45.5% CS in maize (1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC gl-max (µg/L)			

Group		Fish acute	Inverteb. acute	Algae
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-208 65: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in pome/stone fruits (early application 1 x 1590 g/ha between rows)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀

Group		Fish acute	Inverteb. acute	Algae
(µg/L)		19.6	14.7	0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC_{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
R1 Pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-209 66: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of Pendimethalin 45.5% CS in sunflower (1 x 1183 g/ha)

Group		Fish acute	Inverteb. acute	Algae
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Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-210 67: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in soybeans (1 x 1183 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₄ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-211 68: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in bulb vegetables (1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₄ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4stream	<0.001	0.00510	0.00680	0.01075
D6 1 st ditch	<0.001	0.00510	0.00680	0.01075
D6 2 nd ditch	0.001	0.00510	0.00680	0.01075
R1 Pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-212 69: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in beans (1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D2 ditch	<0.001	0.00510	0.00680	0.01075
D2 stream	0.001	0.00510	0.00680	0.01075
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 1 st ditch	<0.001	0.00510	0.00680	0.01075
D6 2 nd ditch	0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-213 70: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel (root vegetables 1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 1 st stream	<0.001	0.00510	0.00680	0.01075
R2 2 nd stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 sream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-214 74: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in lupine (legumes, 1 x 1183 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₁ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-215 72: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 455 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₄ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D2 ditch	<0.001	0.00510	0.00680	0.01075
D2 stream	<0.001	0.00510	0.00680	0.01075
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-216 73: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 910 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			

Group		Fish acute	Inverteb. acute	Algae
Step 3				
D2 ditch	<0.001	0.00510	0.00680	0.01075
D2 stream	0.001	0.00510	0.00680	0.01075
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-217 74: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop, 1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93

Group		Fish acute	Inverteb. acute	Algae
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC_{gl-max} (µg/L)			
Step 3				
D3 1 st ditch	<0.001	0.00016	0.00001	0.00016
D3 2 nd ditch	<0.001	0.00016	0.00001	0.00016
D4 pond	<0.001	0.00016	0.00001	0.00016
D4 stream	<0.001	0.00016	0.00001	0.00016
D6 ditch	0.001	0.00016	0.00001	0.00016
R1 1 st pond	<0.001	0.00016	0.00001	0.00016
R1 2 nd pond	<0.001	0.00016	0.00001	0.00016
R1 1 st stream	<0.001	0.00016	0.00001	0.00016
R1 2 nd stream	<0.001	0.00016	0.00001	0.00016
R2 1 st stream	<0.001	0.00016	0.00001	0.00016
R2 2 nd stream	<0.001	0.00016	0.00001	0.00016
R3 1 st stream	<0.001	0.00016	0.00001	0.00016
R3 2 nd stream	<0.001	0.00016	0.00001	0.00016
R4 1 st stream	<0.001	0.00016	0.00001	0.00016
R4 2 nd stream	<0.001	0.00016	0.00001	0.00016

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-218 75: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in strawberry (fruiting vegetables 1 x 1590 g/ha between rows)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-219 76: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in raspberry (vines early application 1 x 1365 g/ha between rows)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₁ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-220 77: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in currants and grapevine (vines early application 1 x 1590 g/ha between rows)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	<0.001	0.00510	0.00680	0.01075
R1 Pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-221 78: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in potato (1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₄ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 1 st ditch	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
D6 2 nd ditch	0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-222 79: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in ornamentals (vines early application 1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₁ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-223 80: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in clover, alfalfa (grass 1 x 1000 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D1 ditch	<0.001	0.00510	0.00680	0.01075
D1 stream	<0.001	0.00510	0.00680	0.01075
D2 ditch	<0.001	0.00510	0.00680	0.01075
D2 stream	0.001	0.00510	0.00680	0.01075
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
D5 stream	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-224 81: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in cucurbits (fruiting vegetables 1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
(µg/L)		19.6	14.7	0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				

Group		Fish acute	Inverteb. acute	Algae
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	0.001	0.00510	0.00680	0.01075
R4 stream	0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-225 82: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 1, 2 calculations for the use of Pendimethalin 45.5% CS in appln.hand (crop < 50cm)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₄ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	11.22	57.14	76.19	120.43
Step 2				
N-Europe	4.21	21.63	28.84	45.59
S-Europe	3.42	17.45	23.27	36.77

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-226 83: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter cereals (1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₁ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D1 ditch	0.009	0.04592	0.06122	0.09677
D1 stream	<0.001	0.00510	0.00680	0.01075
D2 ditch	0.003	0.01531	0.02041	0.03226
D2 stream	0.003	0.01531	0.02041	0.03226
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	0.004	0.02041	0.02721	0.04301

Group		Fish acute	Inverteb. acute	Algae
R1 pond	0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-227 84: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in maize (1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	0.001	0.00510	0.00680	0.01075
R1 pond	0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-228 85: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in pome/stone fruits (early application 1 x 1590 g/ha between rows)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₄ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	0.001	0.00510	0.00680	0.01075
D4stream	<0.001	0.00510	0.00680	0.01075
D5 pond	0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
R1 Pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-229 86: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in sunflower (1 x 1183 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
R1 pond	0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-230 87: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in soybeans (1 x 1183 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint		LC ₅₀	EC ₅₀	E _t C ₅₀
(µg/L)		19.6	14.7	0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D4 stream	<0.001			
R1 pond	0.001			
R1 stream	<0.001			
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-231 88: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in bulb vegetables (1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	0.001	0.00510	0.00680	0.01075
D4stream	<0.001	0.00510	0.00680	0.01075
D6 1 st ditch	<0.001	0.00510	0.00680	0.01075
D6 2 nd ditch	0.004	0.02041	0.02721	0.04301
R1 Pond	0.001	0.01020	0.01361	0.02151
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-232 89: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in beans (1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₄ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D2 ditch	0.001	0.00510	0.00680	0.01075
D2 stream	<0.001	0.00510	0.00680	0.01075
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 1 st ditch	<0.001	0.00510	0.00680	0.01075
D6 2 nd ditch	0.003	0.01531	0.02041	0.03226
R1 pond	0.001	0.01020	0.01361	0.02151
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-233 90: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in carrots, parsley, parsnip and fennel (root vegetables 1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
R1 pond	0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 1 st pond	<0.001	0.00510	0.00680	0.01075
R2 2 nd stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-234 94: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in lupine (legumes, 1 x 1183 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				

Group		Fish acute	Inverteb. acute	Algae
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	0.001	0.00510	0.00680	0.01075
R1 pond	0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-235 92: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 455 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₄ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D2 ditch	0.003	0.01531	0.02041	0.03226
D2 stream	0.002	0.01020	0.01361	0.02151
D3 ditch	0.002	0.01020	0.01361	0.02151
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-236 93: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 910 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D2 ditch	0.003	0.01531	0.02041	0.03226
D2 stream	0.002	0.01020	0.01361	0.02151
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075
D5 stream	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
R1 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-237 94: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop (leafy vegetables 1st and 2nd crop, 1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 1 st ditch	<0.001	0.00510	0.00680	0.01075
D3 2 nd ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
D4stream	<0.001	0.03061	0.04082	0.06452
D6 ditch	0.003	0.01531	0.02041	0.03226
R1 1 st pond	0.001	0.01020	0.01361	0.02151
R1 2 nd pond	0.002	0.01020	0.01361	0.02151
R1 1 st stream	<0.001	0.00510	0.00680	0.01075
R1 2 nd stream	<0.001	0.00510	0.00680	0.01075
R2 1 st stream	<0.001	0.00510	0.00680	0.01075
R2 2 nd stream	<0.001	0.00510	0.00680	0.01075
R3 1 st stream	<0.001	0.00510	0.00680	0.01075
R3 2 nd stream	<0.001	0.00510	0.00680	0.01075
R4 1 st stream	<0.001	0.00510	0.00680	0.01075
R4 2 nd stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-238 95: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in strawberry (fruiting vegetables 1 x 1590 g/ha between rows)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₁ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	<0.001	0.00510	0.00680	0.01075
R1 pond	0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-239 96: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in raspberry (vine early application 1 x 1365 g/ha between rows)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	0.004	0.02041	0.02721	0.04301
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-240 97: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in currants and grapevine (vines early application 1 x 1590 g/ha between rows)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _t C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	0.003	0.01531	0.02041	0.03226
R1 Pond	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-241 98: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in potato (1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 1 st ditch	<0.001	0.01020	0.01361	0.02151
D6 2 nd ditch	0.002	0.01020	0.01361	0.02151
R1 pond	0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-242 99: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in ornamentals (vines early application 1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₁ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	0.001	0.00510	0.00680	0.01075
D4stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	0.005	0.02551	0.03401	0.05376
R1 pond	<.001	0.01020	0.01361	0.02151
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-243 100: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in clover, alfalfa (grass 1 x 1000 g/ha between rows)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E _r C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D1 ditch	0.003	0.01531	0.02041	0.03226
D1 stream	<0.001	0.00510	0.00680	0.01075
D2 ditch	0.004	0.02041	0.02721	0.04301
D2 stream	0.003	0.01531	0.02041	0.03226
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	<0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D5 pond	<0.001	0.00510	0.00680	0.01075

Group		Fish acute	Inverteb. acute	Algae
D5 stream	<0.001	0.00510	0.00680	0.01075
R1 pond	<0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-244 401: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 3 calculations for the use of Pendimethalin 45.5% CS in cucurbits (fruiting vegetables 1 x 1590 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 19.6	EC ₅₀ 14.7	E ₁ C ₅₀ 0.93
AF		100	100	10
RAC (µg/L)		0.196	0.147	0.093
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 3				
D3 ditch	<0.001	0.00510	0.00680	0.01075
D4 pond	0.001	0.00510	0.00680	0.01075
D4 stream	<0.001	0.00510	0.00680	0.01075
D6 ditch	<0.001	0.00510	0.00680	0.01075
R1 pond	0.001	0.00510	0.00680	0.01075
R1 stream	<0.001	0.00510	0.00680	0.01075
R2 stream	<0.001	0.00510	0.00680	0.01075
R3 stream	<0.001	0.00510	0.00680	0.01075
R4 stream	<0.001	0.00510	0.00680	0.01075

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary for metabolites.

zRMS comments:

For the intended uses, calculated PEC/RAC ratios for metabolites of a.s. did indicate an acceptable risk for the most sensitive group of aquatic organisms in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary for metabolites.

Formulation

Table 9.5-245 402: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin 45.5% SC for each organism group for the use of PENSUI in single application to different crops

Group			Fish	Inverteb. acute	Algae	Algae	Higher plant	Higher plant
Test species			<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Desmodesmus subspicatus</i>	<i>Raphidocelis subcapitata</i>	<i>Lemna gibba</i>	<i>Lemna gibba</i>
Endpoint (µg/L)			LC ₅₀ 9240	EC ₅₀ 47160	E _r C ₅₀ 1160	E _r C ₅₀ 1233	E _r C ₅₀ 318	E _r C ₅₀ 19271
AF			100	100	10	10	10	10
RAC (µg/L)			92.40	471.6	116	123.3	31.8	1927.1
Nozzles	Distance (m)	PEC _{gl-max} (µg/L)						
None	1	37.827	0.41		0.33		1.19	
50%		18.914	0.20		-		0.59	
None	5	7.784	0.08		-		0.24	

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

For the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms after exposure to the formulation when risk mitigations are considered: 5 m no-spray buffer zone or no-spray buffer zone + 50% drift reducing nozzles.

zRMS comments:

For the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms after exposure to the formulation when risk mitigations are considered: 5 m no-spray buffer zone or no-spray buffer zone + 50% drift reducing nozzles.

9.5.3 Overall conclusions

For the intended uses, calculated PEC/RAC ratios for metabolites showed an acceptable risk for aquatic organisms after Step 1-3 scenarios.

Calculated PEC/RAC ratios for the formulation PENSUI did indicate an acceptable risk for aquatic organisms when the following risk mitigation measures are considered: 5 m no spray buffer zone or no spray buffer zone + 50% drift reducing nozzles.

~~Calculated PEC/RAC ratios for Pendimethalin did indicate an acceptable risk for aquatic organisms when the following risk mitigation measures are considered:~~

~~If the RAC of 0.93 µg a.s./L is considered acceptable for the higher tier refinement, PEC/RAC ratios for Pendimethalin did indicate an acceptable risk for aquatic organisms when the following risk mitigation measures are considered:~~

- Winter oilseed rape (455 g/ha): 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction
- Sunflower, soybean, lupine, strawberry, winter cereals (post-emergence 1 x 1137 g/ha), beans (1x1137 g/ha), carrots, parsley, parsnip and fennel (1x1137 g/ha), maize (1x1137 g/ha post-emergence): 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction
- Winter cereals (pre-emergence 1 x 1590 g/ha), maize (post-emergence 1 x 1590 g/ha), beans: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction
- Winter cereals (post-emergence 1 x 1590 g/ha): 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction
- Winter cereals (pre-emergence 1x1137 g/ha), maize (pre-emergence 1x1137 g/ha, post-emergence 1x1137 g/ha): 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction
- Maize (pre-emergence 1 x 1590 g/ha): 20m no spray buffer zone + 20m vegetative strip or 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
- Pome/stone fruits, strawberry (1x 1137 g/ha), raspberry, currants, grapevine, winter oilseed rape (1x910 g/ha), potato (1x1137 g/ha), clover, alfalfa: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction
- Asparagus, brassicas, leek, lettuce, endive and artichoke (1x1590 g/ha pre-emergence): 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
- Maize, beans (1x1590 g/ha), carrot, parsley, parsnip and fennel (1x1590 g/ha), asparagus, brassicas, leek, lettuce, endive and artichoke (1x1590 g/ha post-emergence), ornamentals, cucurbits, potato (1x1590 g/ha): 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer

zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

- Bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1 x 1590 g/ha pre-emergence and post-emergence), strawberry (1x1590 g/ha): 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction

- Bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1x 1137 g/ha pre-emergence and post-emergence): 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

In the case that the RAC of 0.23 µg a.s./L will be considered for the higher tier refinement, PEC/RAC ratios for Pendimethalin did indicate an acceptable risk for aquatic organisms when the following risk mitigation measures and restrictions are considered.

Mitigation measures:

- Winter cereals (pre-emergence 1 x 1590 g/ha): 20m no spray buffer zone + 20m vegetative strip + 75% nozzles reduction or 10m no spray buffer zone + 10m vegetative strip + 50% nozzles reduction
- Winter cereals (post-emergence 1 x 1590 g/ha), maize (pre-emergence and post-emergence 1x1590 g/ha), bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1x1590 g/ha post-emergence), leafy vegetables (asparagus, brassicas, leek, lettuce, endive and artichoke (1x1590 g/ha pre-emergence and post-emergence): 20m no spray buffer zone + 20m vegetative strip + 90% nozzles reduction
- Winter cereals (pre-emergence 1 x 1137 g/ha, post-emergence 1 x 1137 g/ha), maize (pre-emergence 1x1137 g/ha, post-emergence 1x1137 g/ha), potato (1x1590 g/ha and 1x1137 g/ha), ornamentals, clover, alfalfa: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
- Pome/stone fruits, sunflower, soybean, bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1x1590 g/ha pre-emergence): 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
- Beans (1x 1590 g/ha), carrots, parsley, parsnip and fennel (1x1590 g/ha), lupine, winter oilseed rape (1x910 g/ha), strawberry (1x1590 g/ha), cucurbits: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction
- Bulb vegetables (onion, garlic, shallot, spring onion and ornamentals 1x1137 g/ha pre-emergence and post-emergence). Carrot, parsley, parsnip and fennel (1x1137 g/ha), strawberry (1x1137 g/ha), currants, grapevine: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
- Beans (1x1137 g/ha): 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction
- Winter oilseed rape (1x455 g/ha): 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

- Raspberry: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

Restrictions:

Winter cereals (pre-emergence 1 x 1590 g/ha, pre-emergence 1 x 1137 g/ha), bulb vegetables (onion, garlic, shallot, spring onion and ornamentals pre-emergence 1 x 1590 g/ha), beans (1 x 1590 g/ha), carrots, parsley, parsnip and fennel (1 x 1590 g/ha), cucurbits (1 x 1590 g/ha)- SPe2: To protect aquatic organisms do not apply on terraced clay soils with a slope greater than 10%.

Sunflower (1 x 1183 g/ha), Bulb vegetables (onion, garlic, shallot, spring onion and ornamentals pre- and post-emergence 1 x 1590 g/ha, pre- and post-emergence 1x 1137 g/ha), beans (1 x 1590 g/ha and 1 x 1137 g/ha) – SPe2: To protect aquatic organisms do not apply on silty soils with a slope greater than 3%.

Leafy vegetables (pre- and post-emergence 1 x 1590 g a.s./ha) and Cucurbits (fruiting vegetables 1 x 1590 g a.s./ha) – SPe2: To protect aquatic organisms do not apply to drainage loam soils with slope below 2%

In the case that the RAC of 0.48 µg a.s./L will be considered acceptable for the higher tier refinement, PEC/RAC ratios for Pendimethalin did indicate an acceptable risk for aquatic organisms when the following risk mitigation measures are considered:

- Winter cereals (pre-emergence 1 x 1590 g/ha): 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction
- Winter cereals (post-emergence 1 x 1590 g/ha, post-emergence 1 x 1137 g/ha), maize (pre- and post-emergence 1 x 1590 g/ha, pre- and post-emergence 1 x 1137 g/ha), sunflower, soybean, bulb vegetables (pre- and post-emergence 1 x 1590 g/ha, pre- and post-emergence 1 x 1137 g/ha), beans (1 x 1590 g/ha, 1 x 1137 g/ha), carrots, parsley, parsnip and fennel (1 x 1590 g/ha, 1 x 1137 g/ha), lupine, leafy vegetables (asparagus, brassicas, leek, lettuce, endive and artichoke pre- and post-emergence 1 x 1590 g/ha), strawberry (1 x 1590 g/ha, 1 x 1137 g/ha), potato (1 x 1590 g/ha, 1 x 1137 g/ha), cucurbits (1 x 1590 g/ha): 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
- Winter cereals (pre-emergence 1 x 1137 g/ha): 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction
- Pomo/stone fruits (1 x 1590 between rows), raspberry, currants and grapevine (1 x 1590 g/ha), clover and alfalfa (1 x 1000 g/ha): 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction
- Winter oilseed rape (1 x 455 g/ha): 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction
- Winter oilseed rape (1 x 910 g/ha): 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

Ornamentals (1 x 1590 g/ha): 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction

zRMS comments:

Based on lowest **RAC of 0.23 µg a.s./L agreed at EU level** an acceptable risk for aquatic organisms is considered when the following risk mitigation measures and restrictions are applied:

Winter cereals 1 x 1590 g a.s./ha, pre-emergence application

PEC/RAC ratios in winter cereals in pre-emergence are <1 when risk mitigation options are considered:

D1 ditch: 20m no spray buffer zone + 90% nozzle reduction

D1 stream, D3 ditch, D5 stream: 15m no spray buffer zone + 90% nozzle reduction

D2 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzles reduction

D4 pond, D5 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5 m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction.

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzles reduction or 10m no spray buffer zone + 10m vegetative strip + 50% nozzles reduction

For scenarios D2 ditch, D4 stream and D6 ditch PEC/RAC ratios are >1 even considering the mitigation. However, scenarios D2 and D6 are not relevant for CEU countries. For scenario R3 stream the PEC/RAC ratios are > 1 even considering mitigation measures and a restriction will have to be included (do not apply on terraced clay soils with a slope greater than 10%).

Winter cereals, 1 x 1590 g a.s./ha, post emergence application

PEC/RAC ratios in winter cereals in post-emergence (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D1 ditch, D1 stream: 10m no spray buffer zone + 90% nozzle reduction

D2 stream, D3 ditch, D5 stream: 15m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D2 ditch, D4 stream and D6 ditch PEC/RAC ratios are >1 even considering the maximum mitigation measures. However, scenarios D2 and D6 are not relevant for CEU countries.

Winter cereals 1 x 1137 g a.s./ha, pre-emergence application

PEC/RAC ratios in winter cereals in pre-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D1 ditch, D1 stream, D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15 no spray buffer

zone + 90% nozzle reduction
D2 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
D3 ditch, D4 stream, D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction
R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction
R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However scenario D6 is not relevant in CEU countries.

For scenario R3 stream PEC/RAC ratios are > 1 even considering the maximum mitigation measures and a restriction will have to be included (do not apply on terraced clay soils with a slope greater than 10%)

Winter cereals 1 x 1137 g a.s./ha, post emergence application

PEC/RAC ratios in winter cereals in post-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D1 ditch: 10m no spray buffer zone + 90% nozzle reduction
D1 stream, D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15 no spray buffer zone + 90% nozzle reduction
D2 stream, D3 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
D4 stream, D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction
R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction
R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation. However, scenario D6 is not relevant in CEU countries

Maize, 1 x 1590 g a.s./ha, pre emergence application

PEC/RAC ratios in maize pre-emergence (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction
D4 pond, D5 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction
D4 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
D5 stream: 10m no spray buffer zone + 90% nozzle reduction
R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction
R1 stream: 20m no spray buffer zone + 20m vegetative strip 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction
R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However

scenario D6 is not relevant in CEU countries.

Maize 1 x 1590 g a.s./ha, post emergence application

PEC/RAC ratios in maize post-emergence (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 10m no spray buffer zone + 90% nozzle reduction

D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzles

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However, scenario D6 is not relevant in CEU countries.

Maize 1 x 1137 g a.s./ha, pre emergence application

PEC/RAC ratios in maize pre-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However, scenario D6 is not relevant in CEU countries.

Maize 1 x 1137 g a.s./ha, post emergence application

PEC/RAC ratios in maize post-emergence (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch PEC/RAC ratios are >1 even considering mitigation measures. However scenario D6 is not relevant in CEU countries.

Orchards 1590 g a.s./ha, early application

PEC/RAC ratios in pome/stone fruits (early application 1 x 1590 g/ha between rows) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Sunflower 1 x 1183 g a.s /ha

PEC/RAC ratios in sunflower (1 x 1183 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenario R1 stream the PEC/RAC ratios are > 1 even with risk mitigation measures and then a restriction have to be considered (do not apply on silty soils with a slope greater than 3%).

Soybean 1 x 1183 g a.s./ha

PEC/RAC ratios in soybean (1 x 1183 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 150m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Bulb vegetables 1590 g a.s./ha, pre emergence application

PEC/RAC ratios in bulb vegetables (pre-emergence 1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream: 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with mitigation measures. Scenario D6 is not relevant for CEU countries.

For scenario R1 stream and R3 stream the PEC/RAC ratios are below the trigger with mitigation measures and restriction sentences have to be consider (do not apply on silty soils with a slope greater than 3% and do not apply on terraced clay soils with a slope greater than 10% respectively).

Bulb vegetables 1 x 1590 g a.s./ha, post emergence application

PEC/RAC ratios in bulb vegetables (post-emergence 1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

R2 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with mitigation measures. Scenario D6 is not relevant in CEU countries.

For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures and restriction sentences will have to be considered (do not apply on silty soils with a slope greater than 3%).

Bulb vegetables 1 x 1137 g a.s./ha, pre-emergence application

PEC/RAC ratios in bulb vegetables (pre-emergence 1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with risk mitigation measures. However, scenario D6 is not relevant for CEU countries.

For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures and a restriction will be considered (do not apply on silty soils with a slope greater than 3%).

Bulb vegetables 1 x 1137 g a.s./ha, post – emergence application

PEC/RAC ratios in bulb vegetables (post-emergence 1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch 1st and 2nd the PEC/RAC ratios are below the trigger with mitigation measures. However, scenario D6 is not relevant for CEU countries.

For scenario R1 stream the PEC/RAC ratios are below the trigger with mitigation measures and a restriction has to be considered (do not apply on silty soils with a slope greater than 3%)

Beans 1 x 1590 g a.s./ha

PEC/RAC ratios in beans (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D2 stream, D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 20m no spray buffer zone or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D2 ditch, D6 ditch 1st and D6 ditch 2nd the PEC/RAC ratios are below the trigger with mitigation measures. However D2 and D6 are not relevant in CEU countries.

For scenario R1 stream, R3 stream, the PEC/RAC ratios are below the trigger even considering risk mitigation measures and restrictions will be needed (do not apply on silty soils with a slope greater than 3% and do not apply on terraced clay soils with a slope greater than 10% respectively)

Beans 1 x 1137 g a.s./ha

PEC/RAC ratios in beans (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

D2 stream, D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R2 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction

For scenarios D6 ditch 1st and D6 ditch 2nd the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries.

For scenario R1 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures and a restriction will have to be considered (do not apply on silty soils with a slope greater than 3%).

Carrots, parsley, parsnip and fennel 1 x 1590 g a.s./ha

PEC/RAC ratios in carrots, parsley, parsnip and fennel (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R2 stream 1st, R2 stream 2nd: 15m no spray buffer zone + 15m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. Scenario D6 is not relevant for CEU countries.

For scenario R3 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures and a restriction will have to be considered (do not apply on terraced clay soils with a slope greater than 10%).

Carrots, parsley, parsnip and fennel 1 x 1137 g a.s./ha

PEC/RAC ratios in carrots, parsley, parsnip and fennel (1 x 1137 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D6 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R3 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Lupine (legume) 1x 1183 g a.s./ha

PEC/RAC ratios in lupine (1 x 1183 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries.

Winter oilseed rape 455 g a.s./ha

PEC/RAC ratios in winter oilseed rape (1 x 455 g/ha) are <1 when risk mitigation options are considered:

D2 ditch: 20 m no spray buffer zone or 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D2 stream, D4 stream: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

D3 ditch: 20m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction

D5 stream: 15m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray

buffer zone + 10m vegetative strip + 75% nozzle reduction

Winter oilseed rape 910 g a.s./ha

PEC/RAC ratios in winter oilseed rape (1 x 910 g/ha) are <1 when risk mitigation options are considered:

D2 ditch, D3 ditch, D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D2 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

Asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop in pre emergence (leafy vegetables 1st and 2nd crop 1 x 1590 g a.s/ha)

PEC/RAC ratios in asparagus, brassicas, leek, lettuce, endive and artichoke (1 x 1590 g/ha pre-emergence) are <1 when risk mitigation options are considered:

D3 1st ditch: 15m no spray buffer zone + 90% nozzle reduction

D3 2nd ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond 1st: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R1 pond 2nd: 15m no spray buffer zone + 15m vegetative strip

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. Scenario D6 is not relevant for CEU countries.

Asparagus, brassicas, leek, lettuce, endive, artichoke 1st and 2nd crop in post emergence (leafy vegetables 1st and 2nd crop 1 x 1590 g a.s./ha)

PEC/RAC ratios in asparagus, brassicas, leek, lettuce, endive and artichoke (1 x 1590 g/ha post-emergence) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 90% nozzle reduction

For scenarios D4 stream and D6 ditch the PEC/RAC ratios are below the trigger even considering mitigation measures. Scenario D6 is not relevant for CEU countries.

Strawberry 1 x 1590 g a.s./ha

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction
R1 stream, R2 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenario D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries.

Strawberry 1x 1137 g a.s./ha

PEC/RAC ratios in strawberry (1 x 1137 g/ha between rows) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 50% nozzle reduction or 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 50% nozzle reduction
D4 stream, D6 ditch: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction
R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Raspberry 1 x 1365 g a.s./ha

PEC/RAC ratios in raspberry (1 x 1365 g/ha between rows) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction
D6 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction
R1 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 50% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
R3 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Currants and grapevine (vines early application 1 x 1590 g a.s./ha between rows)

PEC/RAC ratios in currants and grapevines (1 x 1590 g/ha between rows) are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction
D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction
D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction
D6 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction
R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R4 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 90% nozzle reduction
R2 stream: 15m no spray buffer zone + 15m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction
R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Potato 1 x 1590 g a.s./ha

PEC/RAC ratios in potato (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 90% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle

For scenarios D4 stream and D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries

Potato 1 x 1137 g a.s./ha

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

For scenarios D6 ditch the PEC/RAC ratios are below the trigger even considering risk mitigation measures. However, scenario D6 is not relevant for CEU countries

Ornamentals (vines, early application 1 x 1590 g a.s./ha)

PEC/RAC ratios in ornamentals (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D6 ditch: 20m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

D4 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction

R1 stream, R2 stream, R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R3 stream: 15m no spray buffer zone + 15m vegetative strip + 90% nozzle reduction

Clover and alfalfa (grass 1 x 1000 g a.s./ha)

PEC/RAC ratios in clover, alfalfa (1 x 1000 g/ha) are <1 when risk mitigation options are considered:

D1 ditch, D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction

D1 stream, D3 ditch: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction

D2 stream, D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle recution or 5m no spray buffer zone + 90% nozzle reduction

R1 stream, R2 stream, R3 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

Cucurbits (fruiting vegetables 1 x 1590 g a.s./ha)

PEC/RAC ratios in cucurbits (1 x 1590 g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction

R1 pond: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction

R2 stream: 15m no spray buffer zone + 15m vegetative strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction or 10m no spray buffer zone + 10m vegetative strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone + 20m vegetative strip + 75% nozzle reduction

For scenarios D4 stream, D6 ditch, and R3 stream the PEC/RAC ratios are below the trigger even considering risk mitigation measures. Scenario D6 is not relevant for CEU countries.

For scenario R3 restriction will be needed (do not apply on terraced clay soils with a slope greater than 10% respectively)

The final risk mitigation measures should be considered at MSs level.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Pendimethalin. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on bees of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of Pendimethalin. New data submitted with this application are listed in **Błąd! Nie można odnaleźć źródła odwołania.** and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	Pendimethalin	Acute oral	LD ₅₀ > 101.2 µg a.s./bee	EFSA Journal 2016;14(3):4420
<i>Apis mellifera</i>	BAS 455 48 H	Acute oral	LD ₅₀ > 120 µg a.s./bee	EFSA Journal 2016;14(3):4420
<i>Apis mellifera</i>	AG-P4-400-SC	Acute oral	LD ₅₀ > 198.5 µg a.s./bee	EFSA Journal 2016;14(3):4420
<i>Apis mellifera</i>	Pendimethalin	Acute Contact	LD ₅₀ = 100 µg a.s./bee	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	BAS 455 48 H	Acute oral	LD ₅₀ > 100 µg a.s./bee	EFSA Journal 2016;14(3):4420
<i>Apis mellifera</i>	AG-P4-400-SC	Acute contact	LD ₅₀ > 200 µg a.s./bee	EFSA Journal 2016;14(3):4420
<i>Apis mellifera</i>	BAS 455 48 H	Chronic	10 d-LDD ₅₀ > 96.5 µg a.s./bee/day	EFSA Journal 2016;14(3):4420
<i>Apis mellifera</i>	AG-P4-400 SC	Chronic	10 d-LDD ₅₀ > 88.2 µg a.s./bee/day	EFSA Journal 2016;14(3):4420
<i>Apis mellifera</i>	BAS 455 48 H	Honeybee larvae study	72 h NOED larvae > > 105.6 µg a.s./larva	EFSA Journal 2016;14(3):4420
<i>Apis mellifera</i>	AG-P4-400 SC	Honeybee larvae study	72 h NOED larvae > > 100 µg a.s./larva	EFSA Journal 2016;14(3):4420
<i>Apis mellifera</i>	Pentimethalin 45.5% CS	Acute oral	LD ₅₀ > 110.83 µg a.s./bee	KCP 10.3.1.1.1 XXX, K. 2019 18-212-G
<i>Apis mellifera</i>	Pentimethalin 45.5% CS	Acute contact	LD ₅₀ > 100 µg a.s./bee	KCP 10.3.1.1.2 XXX, K. 2019 18-211-G
<i>Apis mellifera</i>	Pendimethalin	Chronic 10d	LDD ₅₀ = 56.58 µg a.s./bee/day NOEDD = 25.8 µg a.s./bee/day	KCP 10.3.1.2 XXX, A. 2017 B/107/17
<i>Apis mellifera</i>	Pendimethalin	Honeybee larvae study 22d	NOED larvae > > 0.64 µg a.s./µg/larva	KCP 10.3.1.3 Keebaum, K. 2017 17 48 BLC 0083
Higher-tier studies (tunnel test, field studies)				
None				

9.6.1.1 Justification for new endpoints

There is no deviation to the EU agreed endpoints. In addition, new acute toxicity studies were performed with the formulation PENSHUI and therefore the resulting endpoints are used in the risk assessment of the product.

Chronic studies on adult bees and larvae were performed. According to the EFSA Guidance for bees (EFSA Journal 2013;11(7):3295), *if there is indication from the acute oral study that the formulation is more toxic than the active substance, then the formulation should be tested... if the difference is less than a factor of 5, then the adult chronic toxicity and larval study should only be carried out on the active substance.* The acute oral toxicity of the formulation Pendimethalin 45.5% CS (expressed in terms of active substance) is not more toxic by a factor of 5 than the acute oral endpoint with the active substance (in fact toxicities are very similar), and therefore chronic studies should only be carried out on the active substance. Therefore, chronic studies to adults and larvae studies with the formulation are not needed and are presented with the technical active substance.

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guid-

ance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil also covers the risk for birds from all other intended uses (see 9.1.2).

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of Pendimethalin 40% SC in bare soil

Intended use	Bare soil		
Active substance	Pendimethalin		
Application rate (g/ha)	1 x 1590 ga a.s./ha		
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	>101.2	1590	<15.71
Contact toxicity	100		15.90
Product	Pendimethalin 45.5% CS		
Application rate (g/ha)	1 x 1590 g a.s./ha		
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	>110.83	1590	< 14.35
Contact toxicity	>100		< 15.90

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

The EPPO Standard PP 3/10(3) propose define a **bee brood-feeding test**. Effects on brood may be assessed qualitatively or quantitatively depending on the test that is performed. A larvae bees study has been performed by the Applicant and effects were assessed quantitatively. According to EPPO Standard PP 3/10(3), a calculation of the ratio (TER) between the no observed effect level (NOEL) and exposure should be performed. Exposure is assessed by estimating the amount of residues that may be ingested by a bee in 1 day. Since residues in plant material are not available, a generic worst-case value of 1 mg a.s./kg plant matrix was proposed. This value is deduced from a compilation of the data generated in various plant species treated with systemic insecticides.

The oral NOED is measured in µg active substance per bee and residues in plant parts are expressed in mg/kg. Therefore, a conversion of residue data is necessary to express exposure as an amount of residue ingested. This conversion may be done by multiplying the residue concentration (mg a.s./kg plant part) by the daily food ingestion that reflects the dietary need in sugar for a larvae bee. The maximum food ingestion may be estimated from Rortais et al., 2005 at 59.4 mg sugar/larvae for five days for workers. The data set provided by Rortais et al. (2005) is considered to satisfyingly represent food consumption estimates of the different categories of bees. Considering the maximum amount of sugar a worker larvae bee consumes per day (11.88 mg/larva/day) and the amount of sugar in nectar of 15% (worst-case sugar content based on the available scientific literature (Maccagnani et al., 2003; Monzon et al., 2004; Nicolson, 2009)), adults consume an amount of nectar of 79.2 mg/larva/day (thus will be exposed to 0.0792 µg a.s./larva/day). The relevant calculations are presented below.

- 1 kg (=1000000 mg) of plant matrix contains 1 mg of a.s. (=1000 µg a.s.) → 1 mg plant matrix (=nectar) contain 0.001 µg a.s.
- Consumption of 11.88 mg sugar/larva/day and 15% sugar content in nectar → 79.2 mg nectar/larva/day → 79.2*0.001 µg a.s. = 0.0792 µg a.s.

In addition, according to Rortais et al. (2005) a worker larvae might consume up to 5.4 mg of pollen in 5 days which corresponds to 1.08 mg pollen/larva/day.

Tier-1 calculations based on consumption of both nectar and pollen are presented below:

Table 9.6-3: Risk assessment of the risk for larvae bees due to the use of Pendimethalin

Test design	NOED (lab.) ($\mu\text{g a.s./larva}$)	Consumption ($\mu\text{g a.s./larva}$)		TER criterion: $\text{TER} \geq 1$
		Nectar	Pollen	
Larvae	0.64 (Pendimethalin)	0.0792	0.00108	7.97

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

Applicability of such approach is justified following the risk assessment scheme for Identification of potential risks to larvae according to *EPPO Standard PP 3/10(3)*.

Question	EPPO Standard PP 3/10 provisions	Option	Justification	Outcome
4	Can effects on growth or development of bees be excluded (risk assessment for bee brood triggered)?	No		Go to 5
5	Conduct a bee brood-feeding test (see Note 8). Effects on brood may be assessed qualitatively or quantitatively depending on the test that is performed. In the case where effects are assessed quantitatively, calculate the ratio (TER) between the no observed effect level (NOEL) and exposure. Exposure is assessed by estimating the amount of residues that may be ingested by a bee in 1 day.	Ratio ≥ 1		Go to 11
11	Categorize as low risk to bees	Yes		Low risk demonstrated

The EPPO 2010 scheme does not recommend a **chronic assessment for adults** for foliar spray applications. However, as an approach is proposed as an assessment refinement for seed coatings/soil treatments (point 7, on the scheme), this approach can be adapted to provide a worst-case assessment for foliar sprays.

A worst-case of potential exposure via residues in pollen and nectar can be estimated, as before, based on the default worst-case value of 1 mg a.s./kg proposed in the EPPO 2010 scheme (see Note 6), based on a database of measured values from aerial plant parts as a surrogate for nectar and pollen.

The default residues can then be combined with a measure of consumption in order to estimate the exposure. Worst case data from Rortais et al., 2005, as proposed in the EPPO 2010 scheme, have been used to estimate the consumption by bee foragers: 898.8 mg sugar/bee for seven days (worst case for nectar foragers). Considering the maximum amount of sugar a nectar foragers bee consumes per day (128.4 mg/bee/day) and the amount of sugar in nectar of 15% (worst-case sugar content based on the available scientific literature (Maccagnani et al., 2003; Monzon et al., 2004; Nicolson, 2009)), adults consume an amount of nectar of 856 mg/bee/day (thus will be exposed to 0.856 $\mu\text{g a.s./bee/day}$). The relevant calculations are presented below.

- 1 kg (=1000000 mg) of plant matrix contains 1 mg of a.s. (=1000 $\mu\text{g a.s.}$) → 1 mg plant matrix (=nectar) contain 0.001 $\mu\text{g a.s.}$

- Consumption of 128.4 mg sugar/bee/day and 15% sugar content in nectar → 856 mg nectar/bee/day → $856 \times 0.001 \mu\text{g a.s.} = 0.856 \mu\text{g a.s.}$

In addition, according to Rortais et al. (2005) honeybees might consume several milligrams of pollen per day. Then as a worst case scenario, the nurses pollen consumption was considered, which might be up to 65 mg of pollen in 10 days, which corresponds to 6.5 mg pollen/bee/day.

Tier-1 calculations based on consumption of both nectar and pollen are presented below:

Table 9.6-4: Risk assessment of the risk for adult bees due to the use of Pendimethalin

Test design	NOED (lab.) ($\mu\text{g a.s./bee}$)	Consumption ($\mu\text{g a.s./bee}$)		TER criterion: $\text{TER} \geq 1$
		Nectar	Pollen	
Foraging bees (nectar foragers)	25.8 (Pendimethalin)	0.856	0.0065	29.91

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

According to the trigger proposed by the EPPO 2010 scheme it is clear that with above TER values there is a wide safety margin, indicating that the proposed uses of Pendimethalin pose an acceptable chronic risk to adult and larvae bees.

zRMS comments:

The HQ values are below trigger of 50 indicating an acceptable risk for adult bees for a.s. and formulation Penshui.

Chronic studies for a.s. on adult bees and larvae were performed. According to the EFSA Guidance for bees (EFSA Journal 2013;11(7):3295), *if there is indication from the acute oral study that the formulation is more toxic than the active substance, then the formulation should be tested... if the difference is less than a factor of 5, then the adult chronic toxicity and larval study should only be carried out on the active substance.* The acute oral toxicity of the formulation Pendimethalin 45.5% CS (expressed in terms of active substance) is not more toxic by a factor of 5 than the acute oral endpoint with the active substance (in fact toxicities are very similar), and therefore chronic studies should only be carried out on the active substance.

In addition, the chronic risk assessment according to EPPO 2010 guidance was provided.

According to the trigger proposed by the EPPO 2010 scheme it is clear that with above TER values there is a wide safety margin, indicating that the proposed uses of Pendimethalin pose an acceptable chronic risk to adult and larvae bees.

Therefore, chronic studies to adults and larvae studies with the formulation are not needed and are presented with the technical active substance.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

Not relevant.

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

No risk for bees is expected following the application of PENSUI at the proposed rates.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with Pendimethalin. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on non-target arthropods of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of Pendimethalin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
<i>Aphidius rhopalosiphi</i> (protonymphs)	BAS 455 48 H	Tier I laboratory test	Corrected mortality: 2.50% at 0.1024 kg a.s./ha 2.50% at 0.256 kg a.s./ha 20.00% at 0.64 kg a.s./ha 80.00% at 1.6 kg a.s./ha 80.00% at 4.0 kg a.s./ha Sublethal effects: n.d. LR ₅₀ = 1.20 kg a.s./ha (2.637 L formulation/ha)	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i> (adults)	BAS 455 48 H	Tier I laboratory test	<p>Corrected mortality: 2.78% at 0.1024 kg a.s./ha 16.67% at 0.256 kg a.s./ha 16.67% at 0.64 kg a.s./ha 25.35% at 1.6 kg a.s./ha 30.56% at 4.0 kg a.s./ha</p> <p>Sublethal effects: n.d.</p> <p>LR₅₀ >4.0 kg a.s./ha (> 8791 mL formulation /ha)</p>	EFSA Journal 2016;14(3):4420
<i>Aphidius rhopalosiphi</i> (adults)	BAS 455 48 H	Extended laboratory test: Dry residues on barley seedlings (3D-test)	<p>Corrected mortality: 0.00% at 0.25 kg a.s./ha 0.00% at 0.5 kg a.s./ha 0.00% at 1.0 kg a.s./ha 0.00% at 2.0 kg a.s./ha 0.0% at 4.0 kg a.s./ha</p> <p>Sublethal effects: -- at 0.25 kg a.s./ha -- at 0.5 kg a.s./ha 2.2% at 1.0 kg a.s./ha 4.4% at 2.0 kg a.s./ha 3.3% at 4.0 kg a.s./ha</p> <p>LR₅₀ and ER₅₀ > 4.0 kg a.s./ha (> 8791 mL formulation /ha)</p>	EFSA Journal 2016;14(3):4420
<i>Chrysoperla carnea</i> (adults)	BAS 455 48 H	Extended laboratory test: Dry residues on bean leaves (2D-test)	<p>Corrected mortality: 2.1% at 0.25 kg a.s./ha 0.00% at 0.5 kg a.s./ha 0.00% at 1.0 kg a.s./ha 0.00% at 2.0 kg a.s./ha -2.1% at 4.0 kg a.s./ha</p> <p>Sublethal effects: no effects on reproduction at all test rates</p> <p>LR₅₀ and ER₅₀ > 4.0 kg a.s./ha (> 8791 mL formulation /ha)</p>	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
<i>Aphidius rhopalosiphi</i> (adults)	AG-P4-400 SC (= FSG 01100 H)	Extended laboratory test: Dry residues on barley seedlings (3D-test)	<p>Corrected mortality: 0.0% at 0.024 kg a.s./ha 3.3% at 0.073 kg a.s./ha 6.7% at 0.22 kg a.s./ha 0.0% at 0.661 kg a.s./ha 13.3% at 1.983 kg a.s./ha</p> <p>Sublethal effects: -- at 0.024 kg a.s./ha -- at 0.073 kg a.s./ha 20.4% at 0.22 kg a.s./ha 13.5% at 0.661 kg a.s./ha 12.9% at 1.983 kg a.s./ha</p> <p>LR₅₀ and ER₅₀ > 1.983 kg a.s./ha (> 5000 mL formulation /ha)</p>	EFSA Journal 2016;14(3):4420
<i>Typhlodromus pyri</i> (protonymphs)	AG-P4-400 SC (= FSG 01100 H)	Extended laboratory test: Dry residues on bean leaf discs (2D-test)	<p>Corrected mortality: 12.4% at 0.024 kg a.s./ha 0.0% at 0.073 kg a.s./ha 3.5% at 0.22 kg a.s./ha 6.2% at 0.661 kg a.s./ha 5.4% at 1.983 kg a.s./ha</p> <p>Sublethal effects: -- at 0.024 kg a.s./ha -- at 0.073 kg a.s./ha 1.0% at 0.22 kg a.s./ha 4.0% at 0.661 kg a.s./ha 25.0% at 1.983 kg a.s./ha</p> <p>LR₅₀ and ER₅₀ > 1.983 kg a.s./ha (> 5000 mL formulation /ha)</p>	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
<i>Pardosa</i>	STOMP SC (400 g/L pendimethalin SC)	Tier I laboratory test	Corrected mortality: 3% at 0.12 kg a.s./ha 0% at 0.16 kg a.s./ha 6% at 2.4 kg a.s./ha 6% at 3.2 kg a.s./ha Sublethal effects: no effects on feeding activity for all test rates	EFSA Journal 2016;14(3):4420
<i>Aleochara bilineata</i> (adult)	STOMP SC (400 g/L pendimethalin SC)	Tier I laboratory test	Corrected mortality: 0% at 0.12 kg a.s./ha 0% at 0.16 kg a.s./ha 0% at 2.4 kg a.s./ha 9% at 3.2 kg a.s./ha Sublethal effects: +0.56% at 0.12 kg a.s./ha +6.5% at 0.16 kg a.s./ha 10% at 2.4 kg a.s./ha 11% at 3.2 kg a.s./ha	EFSA Journal 2016;14(3):4420
<i>Aleochara. bilineata</i>	STOMP SC (400 g/L pendimethalin SC)	Laboratory test	17% total parasitization at 2 kg a.s./ha 13% life parasitization at 2 kg a.s./ha*	EFSA Journal 2016;14(3):4420
<i>Poecilus cupreus</i> (adult)	STOMP SC (400 g/L pendimethalin SC)	Laboratory test	3.3% corrected mortality at 2.4 kg a.s./ha LR ₅₀ > 2.4 kg a.s./ha (> 6 L Stomp 400 SC/ha)	EFSA Journal 2016;14(3):4420
<i>Typhlodromus pyri</i>	Pendimethalin 40% SC	Laboratory test	LR ₅₀ = 0.43 kg a.s./ha	KCP 10.3.2.1 01 XXX, L. 2009 C33732
<i>Aphidius rhopalosiphi</i>	Pendimethalin 40% SC	Laboratory test	LR ₅₀ = 0.58 kg a.s./ha	KCP 10.3.2.1 02 XXX, L. 2009 C33721
<i>Aphidius rhopalosiphi</i>	Pendimethalin 40% SC	Extended laboratory test barley plants (3D)	LR ₅₀ > 8000 g a.s./ha ER ₅₀ > 8000 g a.s./ha	KCP 10.3.2.2 01 XXX, S. 2018 S18-05327

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i>	Pendimethalin 40% SC	Aged-residue test	Corrected mortality at 2000 g a.s./ha: 1.11% at 0 DAT 13.10 % at 7 DAT 8.99% at 14 DAT Corrected mortality at 2480 g a.s./ha: 16.67% at 0 DAT 2.38% at 7 DAT 2.25% at 14 DAT Red. of reproduction at 2000 g a.s./ha: -38.08% at 0 DAT -5.34% at 7 DAT -14.51% at 14 DAT Red. of reproduction at 2480 g a.s./ha: -13.59% at 0 DAT -0.89% at 7 DAT 15.96% at 14 DAT	KCP 10.3.2.2-02 XXX, S. 2018 S18-05605
<i>Aphidius rhopalosiphi</i>	Pendimethalin 45.5% CS	Extended laboratory test barley plants (3D)	LR ₅₀ = 13.32 L f.p./ha (6.07 kg a.s./ha) ER ₅₀ = 14.31 L f.p./ha (6.53 kg a.s./ha)	KCP 10.3.2.2-03 XXX, K. 2021 9006/2021
<i>Typhlodromus pyri</i>	Pendimethalin 45.5% CS	Extended laboratory test on bean leaves (2D)	LR ₅₀ = 9.51 L f.p./ha (4.3 kg a.s./ha) ER ₅₀ = 9.02 L f.p./ha (4.1 kg a.s./ha)	KCP 10.3.2.2-04 XXX, V. 2021 9007/2021
<i>Aleochara bilineata</i>	Pendimethalin 45.5% CS	Extended laboratory test on standard soil	LR ₅₀ = 9.14 L f.p./ha (4.17 kg a.s./ha) ER ₅₀ = 9.44 L f.p./ha (4.30 kg a.s./ha)	KCP 10.3.2.2-05 XXX, V. 2021 8923/2021
<i>Chrysoperla carnea</i>	Pendimethalin 45.5% CS	Extended laboratory test on bean leaves (2D)	LR ₅₀ = 9.46 L f.p./ha (4.31 kg a.s./ha) ER ₅₀ = 9.24 L f.p./ha (4.21 kg a.s./ha)	KCP 10.3.2.2-06 XXX, K. 2021 8924/2021

n.d. = not determined

Effects reported as adverse effects, which means:

x % effect on mortality = x % increase of mortality compared to control

y % effect on a sublethal parameter = y % decrease of sublethal parameter compared to control

(sublethal parameters are e.g. reproduction, parasitism, food consumption)

When effects are favourable for the test organisms, a + sign is used for the sublethal effect percentages (i.e. increase of e.g. reproduction) and a - sign for mortality effect percentages (i.e. decrease of mortality).

* The percentages of hatched beetles at test termination termed life parasitization, and the percentages of all parasitized *Delia* puparia termed total parasitization.

9.7.1.1 Justification for new endpoints

~~Sharda has conducted studies on non target arthropods with the formulation Pendimethalin 40% SC, which is a similar formulation to Pendimethalin 45.5% CS. Similarity of both formulation has been done~~

by comparing the acute oral and contact toxicity endpoints with both formulations to bees. Pendimethalin 45.5% CS showed that the acute oral and contact toxicity to bees was $LD_{50e} > 110.83 \mu\text{g a.s./bee}$ and $LD_{50e} > 100 \mu\text{g a.s./bee}$ respectively and the acute oral and contact toxicity to bees with the formulation Pendimethalin 40% SC was $LD_{50e} > 100 \mu\text{g a.s./bee}$ and the $LD_{50e} > 100 \mu\text{g a.s./bee}$ respectively. As it can be observed from the results, the toxicity values observed on bees with both formulations are practically the same. Therefore, it was considered appropriate to refer to studies conducted with the formulation Pendimethalin 40% SC to do the risk assessment for non target arthropods.

Studies with both indicator species and with two additional species have been carried out with the formulation Pendimethalin 45.5% CS and the endpoints were used in the risk assessment.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil also covers the risk for non-target arthropods from all other intended uses (see 9.1.2).

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of Pendimethalin 45.5% CS in bare soil

Intended use	Bare soil		
Active substance/product	Pendimethalin 45.5% CS		
Application rate (g/ha)	1 × 1590 g a.s./ha		
MAF	1.0		
Test species Tier I	LR₅₀ (lab.) (g/ha)	PER_{in-field} (g/ha)	HQ_{in-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	430	1590	3.70
<i>Aphidius rhopalosiphi</i>	580		2.74
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	PER_{in-field} (g/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Aphidius rhopalosiphi</i>	≥8000	1590	yes
<i>Aphidius rhopalosiphi</i>	6070		yes
<i>Typhlodromus pyri</i>	4100		yes
<i>Aleochara bilineata</i>	4170		yes
<i>Chrysoperla carnea</i>	4210		yes
Test species Higher-tier	Rate with ≤ 50 % effect (g/ha) at 0 DALT	PER_{in-field} (g/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	2480 (0 DALT)	1590	yes

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

* If an LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

The HQ values for T.pyri and A. rhopalosiphi were above the trigger after first assessment considering

~~the endpoints from laboratory studies. An extended laboratory study was done with Pendimethalin 40% SC on *A. rhopalosiphi*, and the PER_{in-field} was below the LR₅₀/ER₅₀ determined in the study (> 8000 g a.s./ha), showing no risk. For *T. pyri* an aged residue study was conducted with Pendimethalin 40% SC, and the results showed that at a rate of 2480 g a.s./ha (higher than the maximum PER_{in field} of 1590 g a.s./ha) the effects on mortality and reproduction were < 50% at time ODAT (after exposure to fresh residues), showing no risk.~~

~~With regard to data on additional species, applicant wishes to refer to the unprotected old Tier I studies on *Pardosa* sp, *Aleochara bilineata* and *Poecilus cupreus* with the formulation Stomp 400 SC. Reference to that data was considered appropriate since longer term effects are clearly active substance related and not affected by rapidly dissipating other components of the formulation. Results of laboratory tests are given below.~~

<i>Test species</i>	Application	Status	Effects
<i>Poecilus cupreus</i>	2.4 kg a.s./ha	adults	3.3% Corrected mortality LR ₅₀ > 2.4 kg a.s./ha
<i>Aleochara bilineata</i>	2 kg a.s./ha	adults	17% Total parasitization 13% Life parasitization
<i>Aleochara bilineata</i>	3.2 kg a.s./ha	adults	9% Corrected mortality 11% Sublethal effects
<i>Pardosa spec.</i>	3.2 kg a.s./ha	adults	6% Corrected mortality No effects on feeding activity

~~At rates from 2-3.2 kg a.s./ha, the effects on mortality and sublethal effects on additional non-target arthropod species were low or even in some cases were not observed. Then, considering that Pendimethalin 45.5% CS will be applied at a maximum rate of 1590 g a.s./ha, lower than the rates tested in the studies where none or low effects were found, the application of Pendimethalin 45.5% CS in accordance to the GAP would pose no unacceptable risk to additional non-target arthropod species.~~

~~Therefore, it can be concluded that the application of Pendimethalin 45.5% CS in accordance to the GAP poses no unacceptable risk to non-target arthropods.~~

The results of the extended laboratory studies performed with the formulation Pendimethalin 45.5% CS showed that the effects on the two indicator species and the additional species were < 50% on mortality and reproduction at higher doses than the maximum rate proposed in GAP. The PER_{in-field} were below the rates with ≤ 50 % effects. Therefore, no in-field risk is expected for non-target arthropods after the application of Pendimethalin 45.5% CS according to the proposed GAP.

zRMS comment:

The results of the extended laboratory studies performed with the formulation Pendimethalin 45.5% CS showed that the effects on the two indicator species and the additional species were < 50% on mortality and reproduction at higher doses than the maximum rate proposed in GAP. The PER_{in-field} were below the rates with ≤ 50 % effects. Therefore, no in-field risk is expected for non-target arthropods after the application of Pendimethalin 45.5% CS according to the proposed GAP.

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil also cover the risk for non-target arthropods from all other intended uses (see 9.1.2).

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Pendimethalin 45.5% CS in bare soil

Intended use		Bare soil			
Active substance/product		Pendimethalin 45.5% CS			
Application rate (g/ha)		1 x 1590 (g a.s./ha)			
MAF		1.0			
vdf		10 (2D) / 1 (3D)			
Test species Tier I	LR₅₀ (lab.) (g/ha)	Drift rate	PER_{off-field} (g/ha)	CF	HQ_{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	430	2.77	4.40	10	0.10
<i>Aphidius rhopalosiphi</i>	580				0.08
Test species Higher-tier	Rate with ≤ 50 % effect* (g f.p./ha)	Drift rate	PER_{off-field} (g/ha)	CF	corr. PER_{off-field} below rate with ≤ 50 % effect?
<i>Aphidius rhopalosiphi</i>	6070	2.77	44.04	5	yes
<i>Typhlodromus pyri</i>	4100		4.40		yes
<i>Aleochara bilineata</i>	4170		4.40		yes
<i>Chrysoperla carnea</i>	4210		4.40		yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

HQ values fall below the trigger values, indicating that Pendimethalin 45.5% CS does not pose an unacceptable risk to non-target arthropods in off-field areas.

The results of the extended laboratory studies performed with the formulation Pendimethalin 45.5% CS showed that the effects on the two indicator species and the additional species were < 50% on mortality and reproduction at higher doses than the maximum rate proposed in GAP. The corrected PER_{off-field} values were below the rate with effects ≤ 50%. Therefore, no off-field risk is expected for non-target arthropods after the application of Pendimethalin 45.5% CS according to the proposed GAP.

zRMS comment:

The results of the extended laboratory studies performed with the formulation Pendimethalin 45.5% CS showed that the effects on the two indicator species and the additional species were < 50% on mortality and reproduction at higher doses than the maximum rate proposed in GAP. The corrected PER_{off-field} values were below the rate with effects ≤ 50%. Therefore, no off-field risk is expected for non-target arthropods after the application of Pendimethalin 45.5% CS according to the proposed GAP.

9.7.2.3 Additional higher-tier risk assessment

Not required.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

~~In field HQ values were higher than the trigger after the first step of the assessment for *T. pyri* and *Aphidius*.~~ Data from higher tier studies showed that the effects on the two indicator species were < 50% on mortality and reproduction even at higher doses than the maximum rate proposed in GAP. Data on additional non-target arthropod species showed no risk at a rates higher than the maximum rate proposed in the GAP.

No off-field risk is expected for non-target arthropods after the application of Pendimethalin 45.5% CS according to the proposed GAP.

Therefore, the application of Pendimethalin 45.5% CS in accordance to the GAP poses no unacceptable risk to non-target arthropods.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with Pendimethalin and its relevant metabolites. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of Pendimethalin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	Pendimethalin	28d, chronic Mixed through soil 10% peat	NOEC = 33.45 mg a.s./kg dw soil NOECcorr = 16.73 mg a.s./kg dw soil EC ₁₀ = 49 mg a.s./kg d.w.soil dw EC _{10 corr} = 24.5 mg a.s./kg d.w.soil dw	EFSA Journal 2016;14(3):4420
<i>Eisenia fetida</i>	M455H001	Chronic, Mixed through soil 5% peat	NOEC= 32 mg/kg soil dw NOEC _{corr} = 16 mg/kg soil dw EC ₁₀ = 24 mg/kg d.w.soil dw EC_{10corr} = 12 mg/kg d.w.soil dw	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	M455H033	Chronic, Mixed through soil 10% peat	NOEC= 25 mg/kg soil dw NOEC _{corr} = 12.5 mg/kg soil dw EC ₁₀ = 14.9 mg/kg d.w.soil dw EC_{10corr} = 7.5 mg/kg d.w.soil dw	EFSA Journal 2016;14(3):4420
<i>Folsomia candida</i>	BAS455 48 H	Chronic, Mixed through soil 5% peat	NOEC=193 mg/kg soil dw NOEC _{corr} =96.5 mg/kg soil dw EC ₁₀ = 561 mg/kg d.w.soil dw EC _{10corr} = 280.5 mg/kg soil dw	EFSA Journal 2016;14(3):4420
<i>Folsomia candida</i>	AG-P4-400-SC	Chronic, Mixed through soil 5% peat	NOEC= 78.22 mg a.s./kg soil dw NOEC_{corr} = 39.1 mg a.s./kg soil dw	EFSA Journal 2016;14(3):4420
<i>Hypoaspis aculeifer</i>	BAS455 48 H	Chronic, Mixed through soil 5% peat	NOEC= 385 mg a.s./kg soil dw EC ₁₀ = 257 mg a.s./kg d.w.soil dw EC_{10corr} = 128.5 mg a.s./kg d.w.soil dw	EFSA Journal 2016;14(3):4420
<i>Hypoaspis aculeifer</i>	AG-P4-400-SC	Chronic, Mixed through soil 5% peat	NOEC= 381.5 mg a.s./kg soil dw NOEC _{corr} = 190.75 mg a.s./kg d.w.soil dw	EFSA Journal 2016;14(3):4420
<i>Eisenia fetida</i>	Pendimethalin 40% SC	56 d, chronic	NOEC = 168.2 mg fp/kg dw soil NOEC_{corr} = 84.1 mg fp/kg dw soil	KCP 10.4.1.1-01 XXX, E. 2017 17-99-135 ES
<i>Eisenia fetida</i>	Pendimethalin 45.5% CS	56 d, chronic	NOEC = 95.00 mg f.p./kg dw soil NOEC_{corr} = 47.50 mg f.p./kg dw soil EC ₁₀ = 58.94 mg f.p./kg dw soil EC_{10corr} = 29.47 mg f.p./kg dw soil	KCP 10.4.1.1-02 XXX, T. 2021 EMI/4/40/2019
<i>Folsomia candida</i>	Pendimethalin 40% SC	28 d, chronic	NOEC = 97 mg f.p./kg dw soil NOEC_{corr} = 48.5 mg fp/kg dw soil	KCP 10.4.2.1-01 XXX, E., 2019 17-99-128 ES

Species	Substance	Exposure System	Results	Reference
<i>Hypoaspis aculeifer</i>	Pendimethalin 40% SC	14 d, chronic	NOEC = 1010 mg f.p./kg dw soil NOEC _{corr} = 505 mg f.p./kg dw soil	KCP 10.4.2.1-02 XXX E., 2019 17-99-129 ES
<i>Folsomia candida</i>	Pendimethalin 45.5% CS	28 d, chronic	NOEC = 171.47 mg f.p./kg dw soil NOEC _{corr} = 85.74 mg f.p./kg dw soil EC ₁₀ = 225.12 mg f.p./kg dw soil EC _{10corr} = 112.56 mg f.p./kg dw soil	KCP 10.4.2.1-03 XXX, D., 2021 EMI/4/17/2020
<i>Hypoaspis aculeifer</i>	Pendimethalin 45.5% CS	14 d, chronic	NOEC = 1000 mg f.p./kg dw soil NOEC _{corr} = 500 mg f.p./kg dw soil EC ₁₀ > 1000 mg f.p./kg dw soil EC _{10corr} > 500 mg f.p./kg dw soil	KCP 10.4.2.1-04 XXX, V., 2021 8925/2021
Field studies				
Two earthworm field studies with BAS 455 48 H: - No effect after spring application on bare soil in Germany at 11323 g a.s./ha (soil with 0.77% OC) - After spring application on bare soil in Southern France: LOEC 2265 g a.s./ha based on reduced number of tanilobous juveniles (soil with 0.63% OC). No NOEC could be established.				

9.8.1.1 Justification for new endpoints

Sharda has conducted studies on non target soil meso and macrofauna with the formulation Pendimethalin 40% SC, which is a similar formulation to Pendimethalin 45.5% CS. Similarity of both formulation has been done by comparing the acute oral and contact toxicity endpoints with both formulations to bees. Pendimethalin 45.5% CS showed that the acute oral and contact toxicity to bees was LD_{50e} > 110.83 µg a.s./bee and LD_{50e} > 100 µg a.s./bee respectively and the acute oral and contact toxicity to bees with the formulation Pendimethalin 40% SC was LD_{50e} > 100 µg a.s./bee and the LD_{50e} > 100 µg a.s./bee respectively. As it can be observed from the results, the toxicity values observed on bees with both formulations are practically the same. Therefore, it was considered appropriate to refer to studies conducted with the formulation Pendimethalin 40% SC to do the risk assessment for non target soil meso and macrofauna.

The EU agreed endpoints are used for the risk assessment except for formulation, corresponding to data of Pendimethalin 40% SC. Applicant has conducted studies with the formulation Pendimethalin 45.5% CS and the endpoints of these studies were used in the risk assessment.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for Pendimethalin and metabolite M455H001 and does not need to be considered for metabolite M455H033 and Pendimethalin 45.5% CS.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2).

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of Pendimethalin 45.5% CS in bare soil

Intended use	Bare soil		
Chronic effects on earthworms			
Product/active substance	NOEC/EC ₁₀ (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{It} (criterion TER ≥ 5)
Pendimethalin	16.73	2.305*	7.26
M455H001	12	0.183*	65.57
M455H033	7.5	0.491	15.27
Pendimethalin 40% SC	84.1	5.463	15.39
Pendimethalin 45.5% CS	47.50 29.47	5.463	8.69 5.39
Chronic effects on other soil macro- and mesofauna			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{It} (criterion TER ≥ 5)
Pendimethalin (<i>Folsomia candida</i>)	39.1	2.305*	16.96
Pendimethalin 40% SC (<i>Folsomia candida</i>)	48.5	5.463	8.88
Pendimethalin 45.5% CS (<i>Folsomia candida</i>)	85.74	5.463	15.69
Pendimethalin (<i>Hypoaspis aculeifer</i>)	128.5	2.305*	55.75
Pendimethalin 40% SC (<i>Hypoaspis aculeifer</i>)	505	5.463	92.44
Pendimethalin 45.5% CS (<i>Hypoaspis aculeifer</i>)	500	5.463	91.52

TER values shown in bold fall below the relevant trigger.

* PEC_{soil acc}

The TER values are above the trigger showing no chronic risk to after the application of PENSUI according to the GAP.

zRMS comment:

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2.

The TER_{LT} values are above the trigger showing no chronic risk to earthworms and other soil macroorganism after the application of PENSUI according to the GAP.

9.8.2.2 Higher-tier risk assessment

Not relevant

9.8.3 Overall conclusions

The long-term TER values are above the respective trigger indicating no long-term risk to earthworms and soil macrofauna after the application of PENSUI according to the proposed GAP.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with Pendimethalin and its relevant metabolites. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on soil microorganisms of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of Pendimethalin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	BAS 455 48 H	-	Effect on N-transformation rate after 28 days +25% at 6.91 mg formulation/kg soil dw (equivalent to 2.66 mg a.s./kg soil d.w.), and + 27% at 34.55 mg formulation/kg soil d.w. (equivalent to 13.3 mg a.s./kg soil d.w.)	EFSA Journal 2016;14(3):4420
N-mineralisation	AG-P4-400-SC	-	Effect on N-transformation rate +5% at 28.67 mg formulation/kg soil dw, equivalent to 11.00 mg a.s./kg soil d.w. (28 d).	EFSA Journal 2016;14(3):4420
N-mineralisation	M455H001	-	Effect on N-transformation rate +17% at 0.5 mg /kg soil dw, and +11% at 5.0 mg/kg soil dw (28 d).	EFSA Journal 2016;14(3):4420
N-mineralisation	M455H033	-	Effect on N-transformation rate +5% at 0.5 mg /kg soil dw, and +2% at 5.0 mg/kg soil dw (28 d).	EFSA Journal 2016;14(3):4420
N mineralisation	Pendimethalin 40% SC	28 d, aerobic soil type	Nitrate formation rate + 13.75% at 31 L fp/ha, corresponding to 43.46 mg fp/kg soil dw* (16.5 mg a.s./kg soil dw)	KCP 10.5.1-02 XXX, A. 2009 8483
C mineralisation	Pendimethalin 40% SC	28 d, aerobic soil type	CO ₂ formation -22.96 % at 31 L fp/ha, correspondign to 43.46 mg fp/kg soil dw* (16.5 mg a.s./kg soil dw)	KCP 10.5.2-02 XXX, A. 2009 8484

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Pendimethalin 45.5% CS	28 d, aerobic soil type	Nitrate formation rate -21.5% at PEC: 27.53 mg f.p./kg d.w. soil (10.62 mg a.s./kg d.w. soil) -20.5% at upper PEC: 137.67 mg f.p./kg d.w. soil (53.08 mg a.s./kg d.w. soil)	KCP 10.5.1-03 XXX, D., 2021 EMI/4/26/2019

* Considering a product density of 1.0514 mg/L

9.9.1.1 Justification for new endpoints

Sharda has conducted studies on soil microorganisms with the formulation Pendimethalin 40% SC, which is a similar formulation to Pendimethalin 45.5% CS. Similarity of both formulation has been done by comparing the acute oral and contact toxicity endpoints with both formulations to bees.

Pendimethalin 45.5% CS showed that the acute oral and contact toxicity to bees was $LD_{50} > 110.83 \mu\text{g a.s./bee}$ and $LD_{50c} > 100 \mu\text{g a.s./bee}$ respectively and the acute oral and contact toxicity to bees with the formulation Pendimethalin 40% SC was $LD_{50} > 100 \mu\text{g a.s./bee}$ and the $LD_{50c} > 100 \mu\text{g a.s./bee}$ respectively. As it can be observed from the results, the toxicity values observed on bees with both formulations are practically the same. Therefore, it was considered appropriate to refer to studies conducted with the formulation Pendimethalin 40% SC to do the risk assessment for soil microorganisms.

The EU agreed endpoints are used for the risk assessment except for formulation, ~~corresponding to data of Pendimethalin 40% SC.~~ Applicant has conducted study on soil nitrogen transformation with the formulation Pendimethalin 45.5% CS and the endpoint was used in the risk assessment.

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, and were already used in the risk assessment for earthworms (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil (cotton) also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of Pendimethalin 45.5% CS in bare soil

Intended use	Bare soil		
N-mineralisation			
Product/active substance	Max. conc. with effects $\leq 25 \%$ (mg/kg dw)	PEC_{soil} (mg/kg dw)	Risk acceptable?
Pendimethalin	11 (at 28 d)	2.305*	yes

M455H001	5 (at 28 d)	0.183*	yes
M455H033	5 (at 28 d)	0.491	yes
Pendimethalin 40% SC	43.46 (at 28 d)	5.463	yes
Pendimethalin 45.5% CS	137.67 (at 28 d)	5.463	yes
C-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC_{soil} (mg/kg dw)	Risk acceptable?
Pendimethalin 40% SC	43.46 (at 28 d)	5.463	yes

* PEC_{soil} acc

zRMS comment:

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2.

The risk for soil microorganism was considered as acceptable.

9.9.3 Overall conclusions

No risk to soil microorganisms is expected following the application of Pendimethalin 45.5% CS at the proposed rates in the GAP.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with pendimethalin. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on non-target terrestrial plants of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of active substance 1. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
Ryegrass	BAS 455 48 H	Emergence	ER ₅₀ = 543 g a.s./ha	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
Tomato	AG-P4-400-SC	Emergence	ER ₅₀ = 402 g a.s./ha	EFSA Journal 2016;14(3):4420
1)Wheat ^m 2)Ryegrass ^m 3)Lettuce ^d 4)Tomato ^d 5)Oilseed rape ^d 6)Pea ^d	Pendimethalin 40% SC	Seedling emergence	1)ER ₅₀ > 1760 g a.s./ha 2)ER ₅₀ > 1760 g a.s./ha 3)ER ₅₀ = 269.8 g a.s./ha 4)ER ₅₀ = 425.1 g a.s./ha 5)ER ₅₀ = 434.0 g a.s./ha 6)ER ₅₀ > 1760 g a.s./ha	KCP 10.6.2-01 XXX, L. 2013 34SRFR12C6
1)Wheat ^m 2)Ryegrass ^m 3)Lettuce ^d 4)Tomato ^d 5)Oilseed rape ^d 6)Pea ^d	Pendimethalin 40% SC	Vegetative vigour	1)ER ₅₀ > 1760 g a.s./ha 2)ER ₅₀ > 1760 g a.s./ha 3)ER ₅₀ ≥ 196 g a.s./ha 4)ER ₅₀ ≥ 149 g a.s./ha 5)ER ₅₀ > 1760 g a.s./ha 6)ER ₅₀ > 1760 g a.s./ha	KCP 10.6.2-02 XXX, L. 2013 34SRFR12C7
1)Soybean ^d 2)Oilseed rape ^d 3)Onion ^m 4)Oat ^m 5)Lettuce ^d 6)Sugar beet ^d	Pendimethalin 45.5% CS	Seedling emergence	1)ER ₅₀ = 5.639 kg a.s./ha (2.6 kg a.s./ha) 2)ER ₅₀ = 6.726 kg a.s./ha (3.1 kg a.s./ha) 3)ER ₅₀ = 5.112 kg a.s./ha (2.3 kg a.s./ha) 4)ER ₅₀ = 5.342 kg a.s./ha (2.4 kg a.s./ha) 5)ER ₅₀ = 6.896 kg a.s./ha (3.1 kg a.s./ha) 6)ER ₅₀ = 7.260 kg a.s./ha (3.3 kg a.s./ha)	KCP 10.6.2-03 XXX, S. 2021 9419/2021
1)Soybean ^d 2)Oilseed rape ^d 3)Onion ^m 4)Oat ^m 5)Lettuce ^d 6)Sugar beet ^d	Pendimethalin 45.5% CS	Vegetative vigour	1)ER ₅₀ = 6.272 kg a.s./ha (2.9 kg a.s./ha) 2)ER ₅₀ = 6.781 kg a.s./ha (3.1 kg a.s./ha) 3)ER ₅₀ = 5.176 kg a.s./ha (2.4 kg a.s./ha) 4)ER ₅₀ = 5.036 kg a.s./ha (2.3 kg a.s./ha) 5)ER ₅₀ = 7.143 kg a.s./ha (3.3 kg a.s./ha) 6)ER ₅₀ = 7.377 kg a.s./ha (3.4 kg a.s./ha)	KCP 10.6.2-04 XXX, S. 2021 9420/2021

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

Sharda has conducted studies on non-target plants with the formulation Pendimethalin 40% SC, which is a similar formulation to Pendimethalin 45.5% CS. Similarity of both formulation has been done by comparing the acute oral and contact toxicity endpoints with both formulations to bees.

Pendimethalin 45.5% CS showed that the acute oral and contact toxicity to bees was $LD_{50e} > 110.83 \mu\text{g a.s./bee}$ and $LD_{50e} > 100 \mu\text{g a.s./bee}$ respectively and the acute oral and contact toxicity to bees with the formulation Pendimethalin 40% SC was $LD_{50e} > 100 \mu\text{g a.s./bee}$ and the $LD_{50e} > 100 \mu\text{g a.s./bee}$ respectively. As it can be observed from the results, the toxicity values observed on bees with both formulations are practically the same.

Therefore, it was considered appropriate to refer to studies conducted with the formulation Pendimethalin 40% SC to do the risk assessment for non-target plants.

Applicant has conducted studies on seedling emergence and vegetative vigour with the formulation Pendimethalin 45.5% CS and the endpoints were used for the risk assessment.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant for herbicides or plant growth regulators as ER₅₀ tests should be provided.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of Pendimethalin 45.5% CS in winter cereals, maize, pome fruits, stone fruits, bulb vegetables, bean, pe, broad bean, field bean, carrot, parsley, asparagus, brassica vegetables, strawberry, currants, leek, parsnip, lettuce, endive, potato, grapevine, ornamentals, artichoke, fennel and cucurbits

Intended use	Winter cereals, maize, pome fruits, stone fruits, bulb vegetables, bean, pea, broad bean, field bean, carrot, parsley, asparagus, brassica vegetables, strawberry, currants, leek, parsnip, lettuce, endive, potato, grapevine, ornamentals, artichoke, fennel and cucurbits			
Active substance/product	Pendimethalin 45.5% CS			
Application rate (g/ha)	1 × 1590 g a.s./ha			
MAF	1			
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
Tomato	149	2.77	44.04	3.38
Onion	5112 2300	2.77%	44.04	116.07 52.2
Oat	5036 2300		44.04	114.34 52.2

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.10-3: Assessment of the risk for non-target plants due to the use of Pendimethalin 45.5% CS in sunflower, soybean and lupine

Intended use		Sunflower, soybean and lupine		
Active substance/product		Pendimethalin 45.5% CS		
Application rate (g/ha)		1 × 1183 g a.s./ha		
MAF		1		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
Tomato	149	2.77	32.77	4.55
Onion	5112 2300	2.77%	32.77	156.00 70.2
Oat	5036 2300		32.77	153.68 70.2

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.10-4: Assessment of the risk for non-target plants due to the use of Pendimethalin 45.5% CS in winter oilseed rape

Intended use		Winter oilseed rape		
Active substance/product		Pendimethalin 45.5% CS		
Application rate (g/ha)		1 x 910 g a.s./ha		
MAF		1.0		
Test species	ER₅₀ (g a.s./ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
Tomato	149	2.77	25.21	5.94
Onion	5112 2300	2.77%	25.21	202.80 91.24
Oat	5036 2300		25.21	199.79 91.24

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.10-5: Assessment of the risk for non-target plants due to the use of Pendimethalin 45.5% CS in raspberry

Intended use		Raspberry		
Active substance/product		Pendimethalin 45.5% CS		
Application rate (g/ha)		1 x 1365 g a.s./ha		
MAF		1.0		
Test species	ER₅₀ (g a.s./ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
Tomato	149	2.77	37.81	3.94
Onion	5112 2300	2.77%	37.81	135.20 60.8
Oat	5036 2300		37.81	133.191 60.8

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.10-6: Assessment of the risk for non-target plants due to the use of Pendimethalin 45.5% CS in clover, alfalfa

Intended use	Clover, alfalfa			
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Active substance/product		Pendimethalin 45.5% CS		
Application rate (g/ha)		1 x 1000 g a.s./ha		
MAF		1.0		
Test species	ER₅₀ (g a.s./ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
Tomato	149	2.77	27.7	5.38
Onion	5112 2300	2.77%	27.7	184.55 83.03
Oat	5036 2300		27.7	181.81 83.03

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

No risk to non-target plants is observed in winter oilseed rape, clover and alfalfa any of the crops after the application of Pendimethalin 45.5% CS according to the GAP. For the rest of the crops, risk mitigation measures will be needed.

zRMS comments:

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SAN-CO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. The deterministic risk based on the lowest value ER₅₀ of 5036 g a.s./ha value and PER_{off-field} for proposed uses of Penschui. The risk assessment for to non-target plants located outside the treated area is considered as acceptable after the application of PENSHUI.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

In order to reduce the off field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

Table 9.10-7: Risk assessment for non-target terrestrial plants due to the use of Pendimethalin 45.5% CS in winter cereals, maize, pome fruits, stone fruits, bulb vegetables, bean, pe, broad bean, field bean, carrot, parsley, asparagus, brassica vegetables, strawberry, currants, leek, parsnip, lettuce, endive, potato, grapevine, ornamentals, artichoke, fennel and cucurbits considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use	Winter cereals, maize, pome fruits, stone fruits, bulb vegetables, bean, pe, broad bean, field bean, carrot, parsley, asparagus, brassica vegetables, strawberry, currants, leek, parsnip, lettuce, endive, potato, grapevine, ornamentals, artichoke, fennel and cucurbits
Active substance/product	Pendimethalin 45.5% CS
Application rate (g/ha)	1 x 1590 g a.s./ha
MAF	1

Buffer strip (m)	Drift rate (%)	PER _{off-field} (g/ha)	PER _{off-field} 50 % drift red. (g/ha)	PER _{off-field} 75 % drift red. (g/ha)	PER _{off-field} 90 % drift red. (g/ha)
1	2.77	44.08	22.04	-	-
5	0.57	9.06	-	-	-
Toxicity value ER ₅₀ = 149 g/ha		TER criterion: TER ≥ 5			
1		3.38	6.76	-	-
5		16.45	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

Table 9.10-8: Risk assessment for non-target terrestrial plants due to the use of Pendimethalin 45.5% CS in sunflower, soybean and lupine considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Sunflower, soybean and lupine			
Active substance/product		Pendimethalin 45.5% CS			
Application rate (g/ha)		1 × 1183 g a.s./ha			
MAF		1			
Buffer strip (m)	Drift rate (%)	PER _{off-field} (g/ha)	PER _{off-field} 50 % drift red. (g/ha)	PER _{off-field} 75 % drift red. (g/ha)	PER _{off-field} 90 % drift red. (g/ha)
1/3	2.77	32.77	16.39		-
5	0.57	6.74	-	-	-
Toxicity value ER ₅₀ = 149 g/ha		TER criterion: TER ≥ 5			
1/3		4.55	9.09	-	-
5		22.11	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

Table 9.10-9: Risk assessment for non-target terrestrial plants due to the use of Pendimethalin 40% SC in raspberry considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Raspberry			
Active substance/product		Pendimethalin 45.5% CS			
Application rate (g/ha)		1 × 1365 g a.s./ha			
MAF		1			
Buffer strip (m)	Drift rate (%)	PER _{off-field} (g/ha)	PER _{off-field} 50 % drift red. (g/ha)	PER _{off-field} 75 % drift red. (g/ha)	PER _{off-field} 90 % drift red. (g/ha)
1/3	2.77	37.81	18.91	-	-
5	0.57	7.78			
Toxicity value		TER			

ER ₅₀ = 149 g/ha	criterion: TER ≥ 5			
1/3	3.94	7.88	-	-
5	19.15	-	-	-

AF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

According to the risk assessment performed above, no risk to non-target plants is expected after the application of Pendimethalin 45.5% CS when the following risk mitigation measures are considered:

Winter cereals, maize, pome fruits, stone fruits, bulb vegetables, bean, pea, broad bean, field bean, carrot, parsley, asparagus, brassica vegetables, strawberry, currants, leek, parsnip, lettuce, endive, potato, grapevine, ornamentals, artichoke, fennel, cucurbits, sunflower, soybean, lupine and raspberry: 5 m no spray buffer zone or no spray buffer zone with 50% drift reducing nozzles

No risk mitigation measures are needed.

9.10.3 Overall conclusions

No risk to non-target plants located outside the treated area after application of PENSUI is expected in winter oilseed rape, clover and alfalfa. For the other crops, no risk is expected when risk mitigation measures are considered:

~~Winter cereals, maize, pome fruits, stone fruits, bulb vegetables, bean, pea, broad bean, field bean, carrot, parsley, asparagus, brassica vegetables, strawberry, currants, leek, parsnip, lettuce, endive, potato, grapevine, ornamentals, artichoke, fennel, cucurbits, sunflower, soybean, lupine and raspberry~~ **SPe3:** To protect non-target plants respect an unsprayed buffer zone of 5 m or no spray buffer zone with 50% drift reducing nozzles to non-agricultural land

No risk to non-target plants located outside the treated area is expected in any of the crops after the application of PENSUI.

zRMS comment:

The risk assessment for to non-target plants located outside the treated area is considered as acceptable after the application of PENSUI.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

No data on other non-target species is required

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

	PENSHUI
Common Name	PENSHUI
Classification and proposed labelling	
With regard to ecotoxicological endpoints (according to Reg. 1272/2008)	<p>Hazard classes (s), categories: Aquatic acute 1; H400: very toxic to aquatic life Aquatic Chronic 1; H410: very toxic to aquatic life with long lasting effects</p> <p>Code(s) for hazard pictogram(s): GHS 09</p> <p>Signal word: Warning</p> <p>EU specific statements: EUH401</p> <p>Precautionary statement: P391 P501</p>

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.
 MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.1.2-01	XXX, S.	2018	Magnitude of residue of Pendimethain in wheat Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial and 1 refinement decline trial – Poland 2017 Report No.: BPL17-010 BIOTEK Agriculture España GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.1.1.2-02	XXX, T.	2017	Residue study (decline) in wheat following one post emergence application with Pendimethalin 33% EC in Germany 2017. Report no. CT17-1-47 CropTrials GmbH GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.1.1.2-03	XXX, M.	2018	Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-2289-LABCHI-REV.0 Report No 18.618095.0005 CHELAB S.R.L. GLP Unpublished	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.1.2-04	XXX, G.	2020	Determination of the residues of pendimethalin in/on wheat after one application of pendimethalin 33% EC in northern Europe- Hungary in 2019 Report No.: 034SRHU19R35 CPR Europe Kft. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.1.1.2-05	XXX, M	2020	Determination of residual trials Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LABCHI-REV.0 Report No.: 19.528632.0002 Chelab S.R.L. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-01	XXX, E.	2018	Freshwater algae, growth inhibition test with Pendimethalin 40% SC Report No.: 17-99-131-ES Phytosafe s.a.r.l. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-02	XXX, E.	2019	Lemna sp., Growth inhibition test with Pendimethalin 40% SC Report No.: 17-99-134-ES Phytosafe s.a.r.l. GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.2.1-03	XXX, K.	2020	Rainbow trout (<i>Oncorhynchus mykiss</i>), acute toxicity test with Pendimethalin 455 g/l CS Report No.: 7887/2020 Bioscience Research Foundation GLP Unpublished	Y	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1-04	XXX, S.	2021	Study of <i>Daphnia magna</i> acute immobilisation with Pendimethalin 455 g/L CS Report No.: 9010/2021 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.2.1-05	XXX, S.	2021	Study of algal growth inhibition with Pendimethalin 455 g/L CS Report No.: 9008/2021 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.2.1-06	XXX, S.	2021	Study of <i>Lemna gibba</i> growth inhibition with Pendimethalin 455 g/l CS Report No.: 9009/2021 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.1.1.1	XXX, K.	2019	Acute oral toxicity study of Pendimethalin 455 g/L CS in honey bee (<i>Apis mellifera</i>) Report No. 18-212-G Vanta Bioscience Limited GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.1.2	XXX, K.	2019	Acute contact toxicity study of Pendimethalin 455 g/L CS in honeybees (<i>Apis mellifera</i>) Report No. 18-211-G Vanta Bioscience Limited GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.2	XXX, A.	2017	Pendimethalin Technical Honeybees (<i>Apis mellifera</i>), chronic oral toxicity test Report No.: B/107/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.1.3	XXX, K.	2017	Pendimethalin Technical – Repeated exposure of honey bee (<i>Apis mellifera</i> L.) larvae under laboratory conditions (<i>in vitro</i>) Report No.: 17 48 BLC 0083 BioChem agrar GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.1-01	XXX, L.	2009	Toxicity of Pendimetlin 40% SC to the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) under worst case laboratory conditions Report No.: C33732 Harlan Laboratories Ltd. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.1-02	XXX, L.	2009	Toxicity of Pendimethalin 40% SC to adults of the parasitoid wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) under worst case conditions in the laboratory Report No.: C33721 Harlan Laboratories Ltd. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-01	XXX, S.	2018	Pendimethalin 40% SC: toxicity to the aphid parasitoid <i>Aphidius rhopalosiphi</i> De Stefani Perez (Hymenoptera, Braconidae) under extended laboratory conditions Report No.: S18-05327 Trialeamp S.L.U. GLP Unpublished	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.2.2-02	XXX, S.	2018	Pendimethalin 40% SC: Toxicity to the predatory mite, <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) after exposure to freshly applied and aged spray deposits under extended laboratory conditions Report No.: S18-05605 Trialeamp S.L.U. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-03	XXX, K.	2021	An extended laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani - Perez). Report No.: 9006/2021 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-04	XXX, V.	2021	An extended laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on the predatory mite, <i>Typhlodromus pyri</i> (Scheuten). Report No.: 9007/2021 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-05	XXX, V.	2021	A laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on the rove beetle <i>Aleochara bilineata</i> (Gyllenhal). Report No.: 8923/2021 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.2.2-06	XXX, K.	2021	An extended laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on larvae of the green lacewing <i>Chrysoperla carnea</i> L. (Neuroptera: Chrysopidae). Report No.: 8924/2021 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.1.1-01	XXX, E.	2019	Earthworm reproduction test with Pendimethalin 40% SC Report No.: 17-99-135-ES Phytosafe s.a.r.l. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.1.1-02	XXX, T.	2021	Earthworm Reproduction Test (<i>Eisenia andrei</i>) Report No.: EMI/4/40/2019 Ecomelius Institute Sp. z.o. o GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-01	XXX, E.	2019	Collembolan reproduction test in soil with Pendimethalin 40% SC Report No.: 17-99-128-ES Phytosafe s.a.r.l. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-02	XXX, E.	2019	Predatory mite (<i>Hypoaspis aculeifer</i>) reproduction test in soil with Pendimethalin 40% SC Report No.: 17-99-129-ES Phytosafe s.a.r.l. GLP Unpublished	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4.2.1-03	XXX, Dec.	2021	Collembolan (<i>Folsomia candida</i>) Reproduction Test Report No.: EMI/4/17/2020 Ecomelius Institute Sp. z.o. o GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-04	XXX, V.	2021	Effect of Pendimethalin 455 g/L CS on the Reproductive Output of the Predatory Soil Mite <i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari: Laelapidae) in Artificial Soil. Report No.: 8925/2021 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.5.1-02	XXX, A	2009	Effect of Pendimethalin SC on soil microorganisms: Nitrogen transformation test Report No.: 8483 Jai Research Foundation GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.5.1-03	XXX, D.	2021	Soil Microorganisms: Nitrogen Transformation Test Report No.: EMI/4/26/2019 Ecomelius Institute Sp. z o. o GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.5.2-02	XXX, A	2009	Effect of Pendimethalin SC on soil microorganisms: Carbon transformation test Report No.: 8484 Jai Research Foundation GLP Unpublished	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.6.2-01	XXX, L.	2013	A study to determine the effects of Pendimethalin 40% SC (Pendimethalin 400 g/L) on the seedling emergence and growth of terrestrial plants Report No 34SRFR12C6 SynTech Research France S.A.S. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-02	XXX, L.	2013	A study to determine the effects of Pendimethalin 40% SC (Pendimethalin 400 g/L) on the vegetative vigour of higher terrestrial plants Report No 34SRFR12C7 SynTech Research France S.A.S. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-03	XXX, S.	2021	Effect of Pendimethalin 455 g/L CS on seedling emergence and seedling growth of terrestrial plants Report No. 9419/2021 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-04	XXX, S.	2021	Effect of Pendimethalin 455 g/L on vegetative vigour of terrestrial plants Report No. 9420/2021 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Limited

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

Comments of zRMS:	<p>Residue Section. The study was valuated in Residue Section and was considered as an acceptable.</p> <p>In Ecotox perspective the study can not be considered sufficiently acceptable to evaluate the decline of residue. The study was performed at crop growth stage BBCH 25-30 in spring cereals (wheat) in Poland, and do not cover the current GAP (BBCH 10-13) in winter cereals. The application was done on May.</p> <p>It should be noted that if the crop itself is the proven food source treatment should be in line with the GAP (i.e. same crop, BBCH stage, number and spacing of applications, etc.). If the study is not performed according to the GAP, adequate support should be provided that these derivations had no impact on the DT₅₀ estimation.</p> <p>The kinetic evaluation of residue trials from this study provided by the applicant was evaluated by e-fate expert.</p> <p>The derived DT₅₀ - 2.79 d was considered as not reliable by the applicant and zRMS (see Report Izguierro J.J 2021).</p>
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Reference: KCP 10.1.1.2-01

Report Magnitude of residue of Pendimethalin in wheat Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial and 1 refinement decline trial – Poland 2017. S. XXX, 2018, Report No. BPL17-010. (Field phase)

Guideline(s): Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009

Deviations: No

GLP: Yes

Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: wheat

Crop parts(s) or processed commodity: whole plant, grain straw

STUDY DESIGN AND METHODS

Three field trials were conducted in Poland (Northern Europe). The trials were on representative varieties of wheat.

Each trial was comprised of one untreated control plot and one plot treated with Pendimethalin 33% EC (*Pendimethalin* 330 g/l).

One application was performed at crop growth stage BBCH 25-30 and at a dose rate between 4.51 and 4.74 l/ha of test item; corresponding to a total dose of active ingredient between 1497.6 and 1573.9 g/ha.

One trial was performed to gain grain specimens of wheat (raw agricultural commodities) at harvest.

The other two trials were conducted to study the decline curve of the active ingredient in wheat whole plants, grain and straw. In the decline trial specimens were generated at ± 0 DAA, 30-50 DAA and at maturity (harvest at BBCH 89). In the refinement decline trial specimens were generated at ± 0 DAA, 1DAA, 2 DAA, 3 DAA, 4 DAA, 5 DAA; 6 DAA, 7 DAA, 8 DAA, 9 DAA, 10 (+/-) DAA, 12 (+/-) DAA, 14 (+/-) DAA and at maturity (harvest at BBCH 89).

ANALYTICAL PHASE

STUDY DESIGN AND METHODS

The analytical phase was conducted according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 “Analytical Procedure for the Determination of Pendimethalin (CAS: 40487-42-1), in wheat grains by Liquid Chromatography” (applied for specimens of whole plants without roots and grain) and SOPa-289-LABCHI-Rev.0 “Analytical Procedure for the Determination of Pendimethalin (CAS: 40487-42-1), in wheat straw by Liquid Chromatography” applied for specimens of straw).

Residues of pendimethalin were extracted from grinded, homogenized wheat (whole plants and grain) with acetonitrile, acetic acid and water. After vortexing, magnesium sulphate anhydrous and sodium acetate were added and vortexed again. The tube was centrifuged and kept at about -20°C for about 2 hours, following a further centrifugation to purify the supernatant. Then a part was transferred to a mixture of magnesium sulphate anhydrous and PSA resin. It was vortexed and centrifuged again. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

The residues of pendimethalin of grinded, homogenized wheat straw were extracted with acetonitrile, glacial acetic acid and water. After vortexing, magnesium sulphate anhydrous and sodium acetate were added and vortexed again. The tube was centrifuged and the supernatant was purified. Then a part was transferred to a mixture of magnesium sulphate anhydrous and PSA resin. It was vortexed and centrifuged again. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

The quantification as *pendimethalin* was performed by LC-MS (liquid chromatography with mass spectrometry detection).

For *pendimethalin* the limit of quantification (LOQ) was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendi-methalin		
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	
BPL17-010-01/Poland/N-EU/2017	Spring wheat/Arabella	29/03/17 19-28/06/17 3-4/08/18	1574	306	510	18/05/17	BBCH 25-30	Grain	n.d.	78	
BPL17-010-02/Poland/N-EU/2017	Spring wheat/Harenda	14/03/17 12-28/06/17 07/08/17	1510	294	510	08/05/17	BBCH 25-30	Whole plant Whole plant Grain Straw	6.23 0.13 <0.01 0.04	0 30 91 91	
BPL17-010-03/Poland/N-EU/2017	Spring wheat/Rospud	30/03/17 19-26/06/17	1498	291	510	16/05/17	BBCH 25-30	Whole plant Whole plant	6.79 2.80	+0 1	

EU/2017	a	07/08/17						Whole plant	3.19	2	
								Whole plant	2.68	3	
								Whole plant	1.19	4	
								Whole plant	1.16	5	
								Whole plant	1.15	6	
								Whole plant	1.22	7	
								Whole plant	1.34	8	
								Whole plant	1.49	9	
								Whole plant	1.46	10	
								Whole plant	0.68	13	
								Whole plant	0.78	14	
								Grain	n.d.	83	
								Straw	0.04	83	

Comments of zRMS:	<p>Residue Section. The study was valuated in Residue Section and was considered as an acceptable.</p> <p>In Ecotox perspective the study can not be considered sufficiently acceptable to evaluate the decline of residue of a.s.-pendimethalin. The study was performed at crop growth stage BBCH 25-30 in spring cereals (wheat) in Germany and do not cover the current GAP (10-13) in winter cereals. The application was done on May.</p> <p>It should be noted that if the crop itself is the proven food source treatment should be in line with the GAP (i.e. same crop, BBCH stage, number and spacing of applications, etc.). If the study is not performed according to the GAP, adequate support should be provided that these derivations had no impact on the DT₅₀ estimation.</p> <p>From Fate and behaviour perspective the kinetic evaluation of residue trials from this study was considered acceptable (see Report Izguierro J.J 2021).</p> <p>Agreed endpoint: DT₅₀= 1.81 d (at BBCH 25-30, spring cereals, application on May) <u>The value was not considered in the risk assessment.</u></p>
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Reference: KCP 10.1.1.2-02

Report Residue study (Decline) in wheat following one post emergence application with Pendimethalin 33% EC in Germany 2017. T. XXX (Field phase). Report No. CT17-1-47

Guideline(s): OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)

- EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials
- The Principles of Good Laboratory Practice, ChemG 25.07.1994, § 19, Annex 1 (BGBl 21, I, 2001, p. 843-855)
- OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999) 20, Paris 2002
- The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9
- Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992

Deviations: No

GLP: Yes

Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: wheat

Crop parts(s) or processed commodity: whole plant, grain straw

STUDY DESIGN AND METHODS

The trial CT17-1-47DE1 was carried out in open field on the crop spring wheat. The study director assured before start of the trial, that no Pendimethalin containing products would be used on the trial site during the current season (2017). One untreated control plot (U = plot 1) and one treated plot (T = plot 2) were laid out and labelled for each trial. The plot size (8 subplots of 24 m² = 192 m²) was chosen large enough to provide representative specimens for sampling.

Drift of spray solution during the application was avoided by choosing an adequate distance between the untreated and treated plot (10 m).

The application was conducted with a knapsack sprayer with boom. The spraying equipment was cleaned with water before and after use. The output of the nozzles was checked for uniformity before start of application. The speed of walk was adapted to the output of the sprayer and test runs were performed before start of application. The application rate of the test item Pendimethalin 33% EC was 5.0 L/ha. The water volume was 300 L/ha. The application was performed post emergence at crop stage BBCH 30.

The specimens from the untreated plot were always taken prior to the specimens of the treated plot. Ship and retain specimens were taken at each sampling date.

The specimens were taken from all subplots at each sampling date. Specimens of the raw agricultural commodity whole plant without roots were taken from the untreated and treated plot at the day of the application and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 12 and 14 days after the application (DALA). Each of these specimen

consisted of ≥ 1.0 kg plant material. At the time of commercial harvest (crop stage BBCH 89, 73 DALA) specimens of the raw agricultural commodities grain (≥ 1.0 kg) and straw (≥ 0.5 kg) were collected from the untreated and treated plot by using a research size combine harvester.

Comments of zRMS:	Acceptable by residue expert.
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Reference: KCP 10.1.1.2-03

Report Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-2289-LABCHI-REV.0, M. XXX, 2018, Report No 18.618095.0005 (Analytical phase)

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC

Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009
EU Guidance Document SANCO/3029/99 rev. 4
EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No
GLP: Yes
Acceptability: Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Wheat

Crop parts(s) or processed commodity: grain, straw, whole plant

STUDY DESIGN AND METHODS

The analytical phase of the study 18.618095.0005 was conducted to determine the residual level of Pendimethalin in wheat by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 and SOPa-LABCHI-Rev.0 and as described in study No 16.566423.0005 and No 16.566423.0006 validated on the matrix wheat grains and wheat straw.

Storage in laboratory: field samples were stored frozen at about $T < -18^{\circ}\text{C}$ from reception time to extraction date. Before the analysis, the specimens were grinded and stored the extracts in a freezer about -20°C date.

The determination of Pendimethalin in wheat by LC-MS.

SAMPLE EXTRACTION

For whole plants and grain samples

About 5.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture B were added to the sample. After vortexing for about 1 min, about 6 g (± 0.01 g) of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. The tube was centrifuged at 4750 rpm for 5 min and kept at about 20°C for about 2 hours. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

For straw samples

About 3.00 g of sample grinded were introduced into a 50 ml plastic tube. 12.5 ml of milliQ water and 15 ml of extraction mixture A were added to the sample. After vortexing for about 1 min, about 6 g (± 0.01 g) of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1min. The tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample were recovered and transferred into an HPLC vial and injected.

LIMIT OF QUANTIFICATION AND LIMIT OF DETECTION

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in wheat matrices.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for wheat). The chromatographic peaks at the LOD were more than three times the background noise.

ACCURACY

Accuracy evaluation was performed on sample aliquots spiked with Pendimethalin at LOQ (about 0.01 mg/kg) 3 replicate analyses were performed for each spiking level.

Mean recovery was 101.3% with RSD = 9.0% for first mass transition and 90.3% with RSD = 11.0% for the second mass transition in whole plant.

Mean recovery was 103.0% with RSD = 4.0% for first mass transition and 101.4% with RSD = 6.0% for the second mass transition in grain.

Mean recovery was 80.6% with RSD = 13.0% for first mass transition and 92.7% with RSD = 14.0% for the second mass transition in straw.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
(a)	(a)	(b)				(c)			(d)	(e)	
CT17-1-47DE1/Germany/N-EU/2018	Spring wheat/Dino	25/03/2017 - -	1498.6	300	500	26/05/2017	BBCH 30	Whole plant	5.81	0	12 months Analytical report: 18.618095.000 5
								Whole plant	3.69	1	
								Whole plant	3.42	2	
								Whole plant	1.39	3	
								Whole plant	1.19	4	
								Whole plant	1.21	5	
								Whole plant	0.31	6	
								Whole plant	0.34	7	
								Whole plant	0.21	8	
								Whole plant	0.03	9	
								Whole plant	0.19	10	
								Whole plant	0.07	12	
								Whole plant	0.12	14	
								Grain	n.d.	73	
Straw	0.01	73									

Comments of zRMS:	<p>Acceptable for residue expert.</p> <p>In Ecotox perspective the study can not be considered sufficiently acceptable to evaluate the decline of residue of a.s.- pendimethalin. The study was performed at crop growth stage BBCH 30 in winter cereals (wheat) in Hungary and do not cover the current GAP (BBCH 10-13) in winter cereals. The application was done on April or May. It should be noted that if the crop itself is the proven food source treatment should be in line with the GAP (i.e. same crop, BBCH stage, number and spacing of applications, etc.). If the study is not performed according to the GAP, adequate support should be provided that these derivations had no impact on the DT₅₀ estimation.</p> <p>However, the kinetic evaluation of residue trials from this study provided by the applicant was considered acceptable by e- fate expert.</p> <p>Agreed endpoints:</p>
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	DT₅₀= 2.54 d, BBCH 30 (Winter cereals , application on April) <u>The value was not considered in the risk assessment.</u>
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Reference:	KCP 10.1.1.2-04
Report	DETERMINATION OF THE RESIDUES OF PENDIMETHALIN IN/ON WHEAT AFTER ONE APPLICATION OF PENDIMETHALIN 33% EC IN NORTHERN EUROPE - HUNGARY IN 2019. Gábor XXX (Field phase). Report No. 034SRHU19R35
Guideline(s):	Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament. Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997. OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) European Community Guidelines SANCO 7525/VI/95 – Rev 10.3, 13 June 2017: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs.
Deviations:	The temperature of the freezer (SYN-KDL-071) rose above -18.0°C more than 2 hours. The length of the event was 10 hours 20 minutes. In this period the maximum temperature was -17.1°C and the maximum of the average of the 24-hour cycles was -18-13°C. The even happened because of the longer working time in the freezer that is acceptable. This had no impact, because the limit exceeding occurrence did not affect the quality of the samples and the maximum of the average of 24-hours was lower than -18°C.
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-483228)

2. Test Commodity:

Crop: winter wheat

Crop parts(s) or processed commodity: whole plant, seed, straw

STUDY DESIGN AND METHODS

The trial 034SRHU19R35 was carried out in open field on the crop winter wheat. The study director assured before start of the trial, that no Pendimethalin containing products would be used on the trial site during the current season (2019). One untreated control plot (U = plot 1) and one treated plot (T = plot 2) were laid out and labelled for each trial. The plot size (18 m x 10 m = 180 m²) was chosen large enough to provide representative specimens for sampling.

Drift of spray solution during the application was avoided by choosing an adequate distance between the untreated and treated plot (≥10 m).

The application was conducted with an Air compressed backpack boom sprayer. Equipment calibration was performed on treatment dates, before each application. The target application rate of the test item Pendimethalin 33% EC was 5.0 L/ha. The water volume was 300 L/ha. The application was performed post emergence at crop stage BBCH 30.

The specimens from the untreated plot were always taken prior to the specimens of the treated plot. Ship and retain specimens were taken at each sampling date.

The specimens were taken from all subplots at each sampling date. Specimens of the raw agricultural commodity whole plant were taken from the untreated and treated plot at the day of the application and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 12 and 14 days after the application (DALA). Each of these specimen consisted of ≥ 1.0 kg plant material. At the time of commercial harvest (crop stage BBCH 89, 71 DALA) specimens of the raw agricultural commodities grain (≥ 1.0 kg) and straw (≥ 0.5 kg) were collected from the untreated and treated plot by using a research size combine harvester.

Comments of zRMS:	Accepted by residue expert.
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Reference:	KCP 10.1.1.2-05
Report	DETERMINATION OF RESIDUAL TRIALS PENDIMETHALIN (CAS: 40487-42-1) IN WHEAT BY LC-MS ACCORDING TO SOPA-288-LABCHI-REV.0 AND SOPA-2289-LABCHI-REV.0, M. XXX, 2020, Report No 19.528623.0002 (Analytical phase)
Guideline(s):	SOPa-288-LABCHI-Rev.0 "Analytical Procedure for the Determination of Pendimethalin (CAS : 40487-42-1), in wheat grains by Liquid Chromatography". SOPa-289-LABCHI-Rev.0 "Analytical Procedure for the Determination of Pendimethalin (CAS : 40487-42-1), in straw grains by Liquid Chromatography". OECD (1998). The OECD Principles of Good Laboratory Practice (as revised in 1997), ENV/MC/CH EM(98)17. Italian Legislative Decree (D.L. No. 50 dated March 2 nd , 2007) as published in G.U. No. 86 of April 13 th , 2007. Annex II, Regulation EC 1107/2009 concerning the placing of Plant Protection Products on the market. OECD guideline n°509, "Guidance document on crop field trials", (2009). SANCO/825/00 rev. 8.1 guideline, Guidance document on pesticide residue analytical methods. SANCO/3029/99 rev. 4 guideline, Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Study n°16.566423.0005 "Validation of the analytical procedure for Pendimethalin (CAS: 40487-42-1) in what grains by liquid chromatography". Study n°16.566423.0006 "Validation of the analytical procedure for Pendimethalin (CAS: 40487-42-1) in what straw by liquid chromatography".
Deviations:	No
GLP:	Yes
Acceptability:	Yes

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-483228)

2. Test Commodity:

Crop: Winter wheat

Crop part(s) or processed commodity: grain, straw, whole plant

STUDY DESIGN AND METHODS

The analytical phase of the study 19.528623.0002 was conducted to determine the residual level of Pendimethalin in winter wheat by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 and SOPa-LABCHI-Rev.0 and as described in study No 16.566423.0005 and No 16.566423.0006 validated on the matrix wheat grains and wheat straw.

Storage in laboratory: field samples were stored frozen at about $T < -18^{\circ}\text{C}$ from reception time to extraction date. Before the analysis, the specimens were grinded and stored the extracts in a freezer about -20°C date.

The determination of Pendimethalin in wheat by LC-MS.

SAMPLE EXTRACTION

For seed and whole plant samples

5.00 g (± 0.10 g) of ground sample were accurately weighted (weight accuracy ± 0.1 mg) into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction phase A were added to the sample. After vortexing for about 1 min, a QuEChERS Extraction Packet-AOAC was added to the sample. After vortexing again for about 1 min, the tube was centrifuged at 4750 rpm for 5 min and kept at about -20°C for about 2 hours. The tube then was centrifuged at 4750 rpm for 5 min the purification of the supernatant was carried out. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

For straw samples

3.00 g (± 0.10 g) of ground sample were accurately weighted (weight accuracy ± 0.1 mg) into a 50 ml plastic tube; 12.5 ml of milliQ water and 15 ml of extraction phase B were added to the sample. After vortexing for about 1 min, a QuEChERS Extraction Packet-AOAC was added to the sample. After vortexing again for about 1 min, the tube was centrifuged at 4750 rpm for 5 min and the purification of the supernatant was carried out. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample were recovered and transferred into an HPLC vial and injected.

LIMIT OF QUANTIFICATION AND LIMIT OF DETECTION

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in wheat matrices.

The LOD was set at $< 30\%$ of the LOQ (0.003 mg/kg for wheat). The chromatographic peaks at the LOD were more than three times the background noise.

ACCURACY

Accuracy evaluation was performed on sample aliquots spiked with Pendimethalin at LOQ (about 0.01 mg/kg) 3 replicate analyses were performed for each spiking level.

Mean recovery was 107% with RSD = 1% for first mass transition and 101% with RSD = 3% for the second mass transition in whole plant.

Mean recovery was 106% with RSD = 4% for first mass transition and 93% with RSD = 16% for the second mass transition in grain.

Mean recovery was 105% with RSD = 5% for first mass transition and 91% with RSD = 13% for the second mass transition in straw

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./l				Pendimethalin		
(a)	(b)	(b)				(c)			(d)	(e)	
SRHU19-207-034HR/ Hungary/ NEU/ 2019	Winter Wheat/ Pitbull	1) 18/10/2018	1635.39 9	300	5.45 1	24/04/2019	BBCH 30	Whole plant	146.48	0	Analytical report: FR 19.528632.
		2) 20-30/05/2019						Whole plant	102.99	1	
		3) 04/07/2019						Whole plant	90.25	2	
								Whole plant	83.17	3	
								Whole plant	27.51	4	
								Whole plant	17.14	5	
								Whole plant	27.56	6	
								Whole plant	26.83	7	
								Whole plant	16.54	8	
								Whole plant	31.34	9	
								Whole plant	13.47	10	
								Whole plant	11.03	12	
								Whole plant	2.91	14	
								Seed	<LOQ	71	
	Straw	(0.005) 0.052	71								

zRMS comment:

Kinetic analysis of residue decline of a.s. by Juan J. XXX, September 2021 based on the studies provided above was included in separate document and summarised below.

KINETIC REPORT ON RESIDUE DECLINE STUDIES using Cake v3.4.

Author

Juan J. XXX, September 2021

Sharda Cropchem España S.L.

XXX, S (2018) study (KCP 10.1.1.2-01)

Summary

Three field trials were conducted in Poland (Northern Europe). The trials were on representative varieties of wheat.

Each trial was comprised of one untreated control plot and one plot treated with Pendimethalin 33% EC (*Pendimethalin* 330 g/l).

One application was performed at crop growth stage BBCH 25-30 and at a dose rate between 4.51 and 4.74 l/ha of test item; corresponding to a total dose of active ingredient between 1497.6 and 1573.9 g/ha.

One trial was performed to gain grain specimens of wheat (raw agricultural commodities) at harvest.

The other two trials were conducted to study the decline curve of the active ingredient in wheat whole plants, grain and straw. In the decline trial specimens were generated at ±0 DAA, 30-50 DAA and at maturity (harvest at BBCH 89). In the refinement decline trial specimens were generated at ±0 DAA, 1DAA,

Estimated Values:

Parameter	Value	s	Prob. > t	Lower (90%) CI	Upper (90%) CI	Lower (95%) CI	Upper (95%) CI
Parent_0	5.479	0.6715	N/A	4.273	6.685	4	6.957
k_Parent	0.2481	0.05041	2.28E-004	0.1575	0.3386	0.1371	0.359

Sum of Squared Residuals: 7.692

χ^2

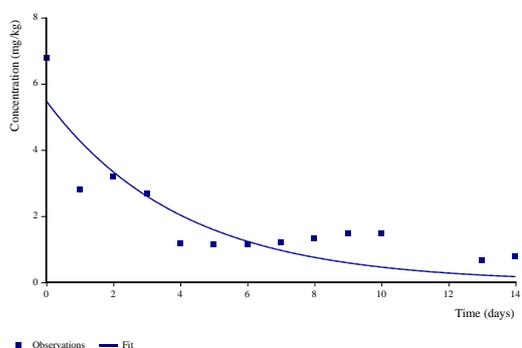
Parameter	Error %	Degrees of Freedom
All data	31.3	11
Parent	31.3	11

Decay Times:

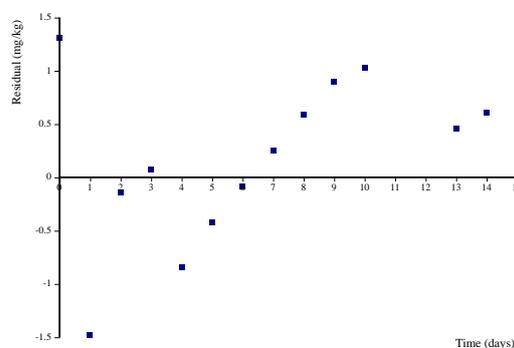
Compartment	DT50 (days)	DT90 (days)
Parent	2.79	9.28

Graphical Summary:

Observations and Fitted Model:



Residuals:



XXX, T. (2017) and XXX, M (2019) studies (KCP 10.1.1.2-02 & 03)

Summary

The trial CT17-1-47DE1 was carried out in open field on the crop spring wheat. The study director assured before start of the trial, that no Pendimethalin containing products would be used on the trial site during the current season (2017). One untreated control plot (U = plot 1) and one treated plot (T = plot 2) were laid out and labelled for each trial. The plot size (8 subplots of 24 m² = 192 m²) was chosen large enough to provide representative specimens for sampling.

Drift of spray solution during the application was avoided by choosing an adequate distance between the untreated and treated plot (10 m).

The application was conducted with a knapsack sprayer with boom. The spraying equipment was cleaned with water before and after use. The output of the nozzles was checked for uniformity before start of application. The speed of walk was adapted to the output of the sprayer and test runs were performed before start of application. The application rate of the test item Pendimethalin 33% EC was 5.0 L/ha. The water volume was 300 L/ha. The application was performed post emergence at crop stage BBCH 30.

The specimens from the untreated plot were always taken prior to the specimens of the treated plot. Ship and retain specimens were taken at each sampling date.

The specimens were taken from all subplots at each sampling date. Specimens of the raw agricultural commodity whole plant without roots were taken from the untreated and treated plot at the day of the application and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 12 and 14 days after the application (DALA). Each of these specimen

consisted of ≥ 1.0 kg plant material. At the time of commercial harvest (crop stage BBCH 89, 73 DALA) specimens of the raw agricultural commodities grain (≥ 1.0 kg) and straw (≥ 0.5 kg) were collected from the untreated and treated plot by using a research size combine harvester.

Residue analysis

The analytical phase of the study 18.618095.0005 was conducted to determine the residual level of Pendimethalin in wheat by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 and SOPa-LABCHI-Rev.0 and as described in study No 16.566423.0005 and No 16.566423.0006 validated on the matrix wheat grains and wheat straw.

Storage in laboratory: field samples were stored frozen at about $T < -18^{\circ}\text{C}$ from reception time to extraction date. Before the analysis, the specimens were grinded and stored the extracts in a freezer about -20°C date.

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in wheat matrices.

The LOD was set at $< 30\%$ of the LOQ (0.003 mg/kg for wheat). The chromatographic peaks at the LOD were more than three times the background noise.

The half life calculations have been done in CT17-1-47DE1 trial using Cake v 3.4, grain and straw data

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pendimethalin		
(a)	(b)	(b)	(c)	(c)	(c)	(c)	(c)	(d)	(d)	(e)	
CT17-1-47DE1/Germany/N-EU/2018	Spring wheat/Dino	25/03/2017	1498.6	300	500	26/05/2017	BBCH 30	Whole plant	5.81	0	12 months Analytical report: 18.618095.0005
		-						Whole plant	3.69	1	
		-						Whole plant	3.42	2	
								Whole plant	1.39	3	
								Whole plant	1.19	4	
								Whole plant	1.21	5	
								Whole plant	0.31	6	
								Whole plant	0.34	7	
								Whole plant	0.21	8	
								Whole plant	0.03	9	
								Whole plant	0.19	10	
								Whole plant	0.07	12	
								Whole plant	0.12	14	
								Grain	n.d.	73	
	Straw	0.01	73								

were not considered for calculations. Below the calculated DT_{50} and DT_{90} for the trials.

Trial	DT_{50} (d)	DT_{90} (d)	χ^2 (%)	MODEL
CT17-1-47DE1	1.81	6.02	16.7	SFO

The derived DT_{50} is considered as reliable although χ^2 value is 17.9, but visual fit is considered as good.

In the next tables and figures are given the data and the summary of the graphics used for half life modelling. The modelling has been done without any improvement, using the data as such (Detailed Cake v3.4 reports will be sent separately).

Estimated Values:

Parameter	Value	s	Prob. > t	Lower (90%) CI	Upper (90%) CI	Lower (95%) CI	Upper (95%) CI
Parent_0	5.81	0.2728	N/A	5.32	6.3	5.209	6.41
k_Parent	0.3822	0.03052	3.74E-008	0.3274	0.4371	0.3151	0.449

Sum of Squared Residuals: 1.168

χ^2

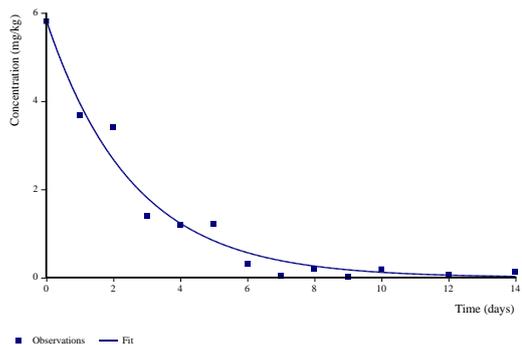
Parameter	Error %	Degrees of Freedom
All data	16.7	11
Parent	16.7	11

Decay Times:

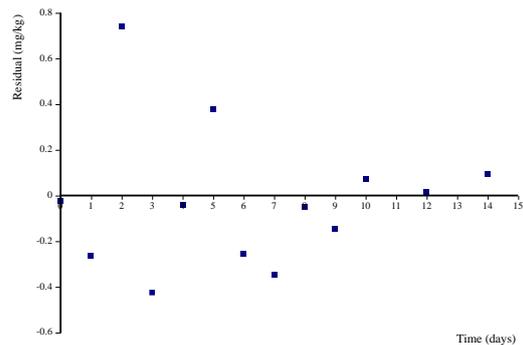
Compartment	DT50 (days)	DT90 (days)
Parent	1.81	6.02

Graphical Summary:

Observations and Fitted Model:



Residuals:



XXX, W. (2019) and XXX, M (2020) (KCP 10.1.1.2-04 & 05)

Summary

The trial 034SRHU19R35 was carried out in open field on the crop winter wheat. The study director assured before start of the trial, that no Pendimethalin containing products would be used on the trial site during the current season (2019). One untreated control plot (U = plot 1) and one treated plot (T = plot 2) were laid out and labelled for each trial. The plot size (18 m x 10 m = 180 m²) was chosen large enough to provide representative specimens for sampling.

Drift of spray solution during the application was avoided by choosing an adequate distance between the untreated and treated plot (≥10 m).

The application was conducted with an Air compressed backpack boom sprayer. Equipment calibration was performed on treatment dates, before each application. The target application rate of the test item Pendimethalin 33% EC was 5.0 L/ha. The water volume was 300 L/ha. The application was performed post emergence at crop stage BBCH 30.

The specimens from the untreated plot were always taken prior to the specimens of the treated plot. Ship and retain specimens were taken at each sampling date.

The specimens were taken from all subplots at each sampling date. Specimens of the raw agricultural commodity whole plant were taken from the untreated and treated plot at the day of the application and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 12 and 14 days after the application (DALA). Each of these specimen

consisted of ≥ 1.0 kg plant material. At the time of commercial harvest (crop stage BBCH 89, 71 DALA) specimens of the raw agricultural commodities grain (≥ 1.0 kg) and straw (≥ 0.5 kg) were collected from the untreated and treated plot by using a research size combine harvester.

The analytical phase of the study 19.528623.0002 was conducted to determine the residual level of Pendimethalin in winter wheat by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 and SOPa-LABCHI-Rev.0 and as described in study No 16.566423.0005 and No 16.566423.0006 validated on the matrix wheat grains and wheat straw.

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in wheat matrices.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for wheat). The chromatographic peaks at the LOD were more than three times the background noise.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./l				Pendimethalin		
(a)	(b)				(c)			(d)	(e)		
SRHU19-207-034HR/ Hungary/ NEU/ 2019	Winter Wheat/ Pitbull	1) 18/10/2018	1635.39 9	300	5.45 1	24/04/2019	BBCH 30	Whole plant	146.48	0	Analytical report: FR 19.528632.
		2) 20-30/05/2019						Whole plant	102.99	1	
		3) 04/07/2019						Whole plant	90.25	2	
		Whole plant						83.17	3		
		Whole plant						27.51	4		
		Whole plant						17.14	5		
		Whole plant						27.56	6		
		Whole plant						26.83	7		
		Whole plant						16.54	8		
		Whole plant						31.34	9		
		Whole plant						13.47	10		
		Whole plant						11.03	12		
		Whole plant						2.91	14		

								Seed Straw	<LOQ (0.005) 0.052	71 71
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The half life calculations have been done in 034SRHU19R35 trial using Cake v 3.4, grain and straw data were not considered for calculations. Below the calculated DT₅₀ and DT₉₀ for the trials.

Trial	DT ₅₀ (d)	DT ₉₀ (d)	χ ² (%)	MODEL
034SRHU19R35	2.54	8.43	20.5	SFO

The derived DT₅₀ is considered as reliable although χ² value is 20.5, but visual fit could be considered as good.

In the next tables and figures are given the data and the summary of the graphics used for half life modelling. The modelling has been done without any improvement, using the data as such (Detailed Cake v3.4 reports will be sent separately).

Estimated Values:

Parameter	Value	s	Prob. > t	Lower (90%) CI	Upper (90%) CI	Lower (95%) CI	Upper (95%) CI
Parent_0	144.4	10.34	N/A	125.9	163	121.7	167.2
k_Parent	0.2731	0.03229	1.92E-006	0.2151	0.3311	0.202	0.344

Sum of Squared Residuals: 1742

χ²

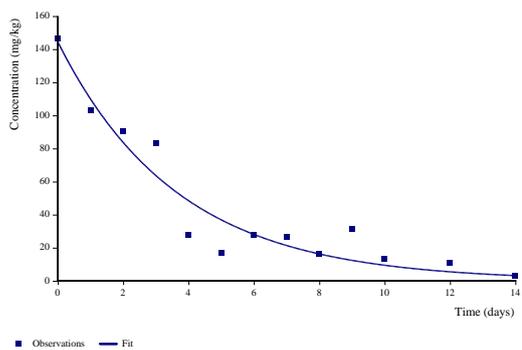
Parameter	Error %	Degrees of Freedom
All data	20.5	11
Parent	20.5	11

Decay Times:

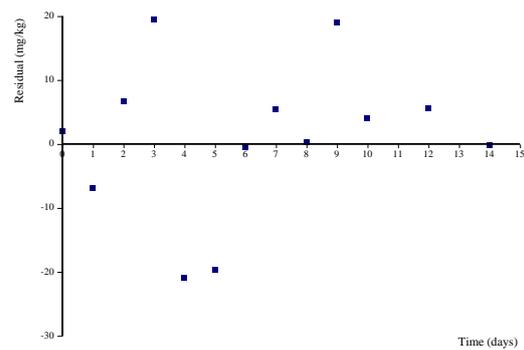
Compartment	DT50 (days)	DT90 (days)
Parent	2.54	8.43

Graphical Summary:

Observations and Fitted Model:



Residuals:



zRMS e-fate expert comment:

The kinetic analysis of residues of pendimethalin in wheat (whole plants) was accepted.

Agreed endpoints:

Trial	DT₅₀ (d)	DT₉₀ (d)	χ^2 (%)	MODEL
BPL17-010-03/Poland/N-EU/2017	2.79*	9.8*	31.3	SFO
CT17-1-47DE1	1.81	6.02	16.7	SFO
034SRHU19R35	2.54	8.43	20.5	SFO

*Considered as not reliable

In conclusion:

The DT50 value were not used for winter cereals/weeds in quantitative risk assessment for bird and mammals for the following reason:

In all of the referenced studies residues of pendimethalin were measured following post - emergence applications on cereals. However, the zRMS identified several shortcomings in the studies that are summarised in the following. For two study sites, applications were carried out in spring for spring cereals on april or May trials from Poland and Germany and BBCH from 25-30 and in spring for winter cereals from Hungary (BBCH 30), which reduces the data set for a refinement of the intended Penschui use in winter cereals/weeds.

In addition during evaluation of the dissipation kinetics of pendimethalin the trials from Poland were excluded from the kinetic analysis. Finally, only one from Germany and one from Hunagary were taken into account to estimate DT₅₀ value in plants for a.s.

The minimum requirement in order to have a reliable refinement of the dissipation as defined by the EF-SA (four sites per regulatory zone) is also not fulfilled.

Summarizing the above, the presented studies are not suitable to derive a DT₅₀ for pendimethalin that is applicable for the intended uses of Penschui in the central zone for winter cereals post- emergence.

For winter cereals new decline studies is recommended with application in autumn to confirm the new DT₅₀ for a.s.-pendimethalin.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

zRMS comment:

The LoA was provided to this study by the applicant. The study was previously assessed by zRMS-PL in Poland. The aim of the study by XXX & XXX (2019) was to determine the proportion of time the brown hares spent potentially foraging in early germinated maize fields (BBCH <20).

The study was well performed and is considered acceptable by the zRMS.

Initial site selection in the study was based on the presence of the European hare, high proportions of maize fields within the landscape and the suitability for performing radio-tracking. To increase representativeness and variability of landscape parameters among Central European maize growing areas, two different study areas in two different countries and five different study sites were chosen in areas of high proportions of maize within Central Europe. The region used for the study represented typical maize growing region in Germany and Hungary and may be thus considered representative for conditions of the Central Zone. However, concerned Member States may wish to re-consider representativeness of the conditions of the study for agronomic conditions in their countries.

At test sites the maize fields represented on average 36% of the landscape surface within the investigated hares home ranges and at some test sites their proportion in the total landscape exceeded 45 or even 50%.

The study was performed at early stages of maize and included BBCH from 00 to 19. However, as the aim of the study was to determine the time that brown hares potentially feed on maize shoots, results for fields with BBCH <09 were excluded from calculation of PT values.

For purposes of the radio-tracking, 23 individual adult brown hares were trapped and equipped with the radio tags. Trapping locations were chosen in areas with high number of maize/future maize fields and hares were captured either in such fields or nearby (e.g. in adjacent off-crop structures or neighbouring fields).

The total weight of the hare collar was about 40 g, representing approximately 1% of the bodyweight of the tagged animals. Due to the low weight of the tags (far below the recommended maximum of 5% of the total bodyweight) it was not expected that they would have influence the animals' behaviour. Visual observations confirmed normal behaviour of the animals. In order to give animal time to acclimatize, the radio-tracking started no earlier than 2 days after tagging with single check telemetry of the individuals.

During the telemetry sessions each individual was tracked continuously for 24 hours, which is in line with recommendations of EFSA (2009). During this time all movements between different habitats and changes of the behaviour (e.g. foraging, resting) were recorded. In addition to that, animals were observed with binoculars, scopes and night observation devices.

During radio-tracking without visual contact, all instances of an active signal were interpreted as potential foraging behaviour and thus included in the calculation of PT values. However, based on the behaviour confirmed by visual contacts during the 24h telemetry, animals foraged for just 32.0% of their visually observed time and showed active behaviour other than foraging in 18.5% of the time. Therefore, the time spent potentially foraging in maize is rather overestimated for this habitat. This confirms that the PT values are conservative and rather overestimate the actual PT values for early maize (BBCH growth stages up to 20) than being a minimum value.

In general, results of the study indicate that brown hares do utilise early maize fields as the feeding habitat. During the 24-hours radio-tracking session most of 23 radio-tagged hares were observed in maize fields with individual PT values ranging from 0.02 to 0.94. One individual (or signal) could not be tracked after tagging and most probably the animal left the study site. One individual was found at the end of May far outside the study site. To increase the number of radio-tracking sessions and to cover wider range of BBCH stages, two individuals were radio-tracked twice, giving 23 radio-tracking sessions in total. One session was excluded from further calculations as being not "consumer session" (animal was never located in a maize field being active during the session, had no maize in the 24h home range and was not caught on a maize field).

Taking into account that 21 individuals (i.e. >20 recommended by EFSA, 2009) were observed potentially foraging during radio-tracking sessions (with one animal observed twice), in opinion of the zRMS the 90th percentile PT value is sufficiently reliable and may be used for purposes of the refinement of the risk for the brown hare.

It should be noted that PT values were derived for maize stages ranging from BBCH 09 to 19, while Peshui is intended to be applied at BBCH 10-18. Nevertheless, obtained results show that different BBCH growth stages up to <20 did not have an impact on the use of maize as foraging habitat by the brown hare. Taking this into account, the overall 90th percentile PT of 0.62 is considered acceptable for purposes of refinement of the risk to the brown hare exposed after application of Peshui according to the intended use pattern. Concerned Member States may wish to re-consider this value.

Agreed endpoint:

PT=0.62

Report	T XXX and I XXX (2019) Generic monitoring of European hares to determine proportion of time spent foraging in early maize in Central Europe Syngenta Limited; unpubl. RIFCON GmbH report No. R1740045, March 2019. Syngenta File No. NA_14950
Guideline(s):	No official test guideline(s) available at present Conducted under consideration of the EFSA Guidance Document on Risk Assessment for Birds & Mammals (EFSA 2009).
Deviations:	Not relevant
GLP:	Yes
Acceptability:	Acceptable
Duplication (if vertebrate study)	No

Executive Summary

The aim of this generic study was to investigate the use of maize fields as foraging habitat by Brown hare (*Lepus europaeus*) in the Central Europe. Focus was the determination of respective PT values (i.e. proportion of diet obtained in treated area, calculated as proportion of potentially foraging time spent in maize fields by hares) during the early growing period of maize via continuous 24-hour radio-tracking sessions of multiple individual hares. In total, radio-tracking sessions of 21 individual hares at five study sites were performed during the early crop development of maize in Central Europe. Radio-tracking sessions were performed from late April until early June 2018. The number of conducted 24h telemetry sessions was 23 (17 in Germany, six in Hungary), since two individuals were radio tracked twice. The calculated single PT values ranged from 0.02 to 0.94 resulting in an average of 0.36 (± 0.26) and 90th percentile of 0.62. Calculated PT values did not differ substantially between different study sites; mean values were slightly higher in Germany (0.38) than in Hungary (0.31).

Materials

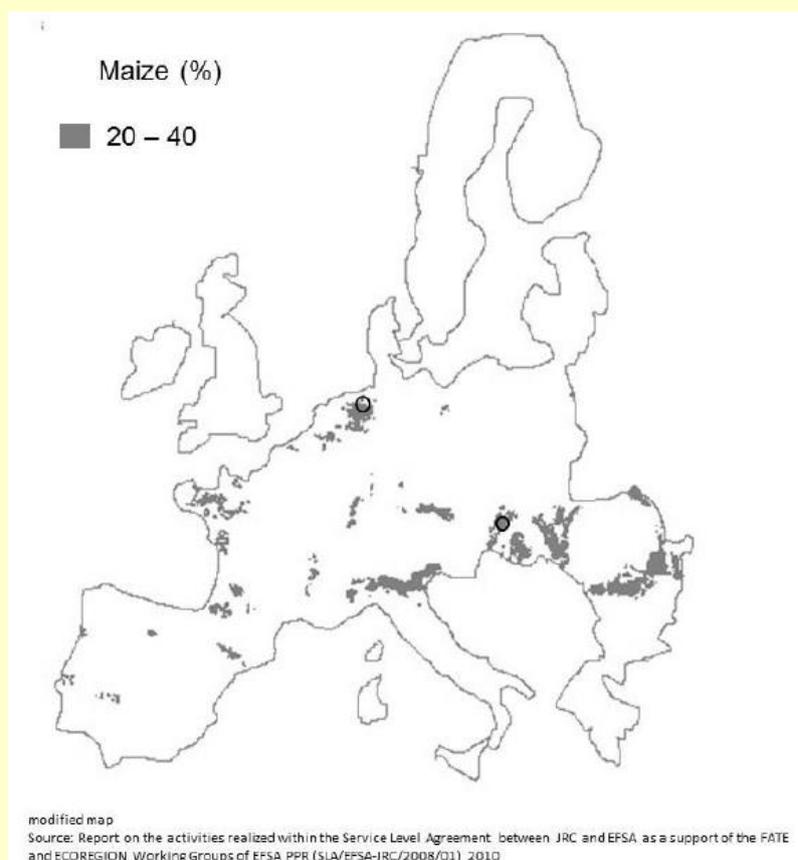
Test Material	No substance was tested.
Test organisms	
Species:	European brown hare (<i>Lepus europaeus</i>)
Crop:	Maize, BBCH 00-19
Test design	
Replication:	5 study sites
Duration of study:	3 months

Study Design and Methods

Experimental dates: April - June 2018

Study sites

The study was conducted in five study sites in Central Europe in two main areas for maize growing (with on average 36 % of the landscape surface within the home ranges of the investigated hares comprising maize). Three study sites were located in Lower Saxony (Germany), near Holtrop, Rastede and Burhufe, and two study sites were located in the administrative county Győr-Moson-Sopron (Hungary), one near Szany and one close to Bösarkany. The proportion of maize of the total landscape surface even exceeded 45% (in the study site Rastede, Germany) and 50 % (in the study site Bösarkany, Hungary) which represents the highest coverage of maize on regional scale known in Central Europe. The crop cover map of maize in Europe (with proportion of maize >20%) together with test sites location (marked with black circles) is presented on figure below.



Crop cover map of maize in Europe and location of the study sites (the map presents all areas in Europe in which the proportion of maize cover of the total land surface is more than 20%)

The vegetation status of maize in the study sites was recorded using BBCH growth stage scale. The study sites, comprising the area around the trapping locations of the tagged animals and the positions in which they were recorded during single checks and 24h telemetry, were mapped. Surveys of drilled maize fields before the emergence of maize plants showed that virtually no weeds occurred on these fields, indicating that pre-emergence maize fields are likely to be unattractive habitats for hares due to their lack of food and cover.

Trapping

The majority of animals were trapped and fitted with radio tags at the beginning of the Field Phase (i.e. before the drilling of maize). All tracked hares were captured either on future maize fields (i.e. fields to become maize fields later once drilled), already drilled maize fields or nearby in off-crop structures around such maize fields.

Hares were trapped using series of nets. The animals were chased into these nets by beaters walking towards the net line.

Each trapped animal was sexed, weighed and equipped with a radio tag (Biotrack Ltd., UK; www.biotrack.co.uk) and released at the trapping site.

Radio-tracking

For radio-tracking, animals were located with Yagi antennas according to two different approaches: single check telemetry and 24h telemetry.

For single check telemetry each animal was located once at the beginning (after all hares were tagged) and the end of the entire Field Phase (when 24h telemetry was finished) in order to survey its presence in the respective study site during the entire Field Phase.

During 24h telemetry sessions the animal was radio-tracked continuously for 24 hours by two observers, locating the animal from two different positions, which allowed triangulating the animal's exact position. Each change of habitat (if possible) and/or each change of behaviour (i.e. active/inactive) was recorded with time and bearing angle to the signal of the animal. The 24h telemetry sessions were conducted when the BBCH growth stages of the maize fields were <20. Main focus was given to the period of emergence until the end of leaf development (i.e. BBCH growth stages 09 to 19).

In order to confirm the animals' behaviour based on the radio signals, animals were observed with binoculars, scopes and night observation devices to get 'visual contact' whenever possible.

Calculation of PT

For each telemetry session, the proportion of diet obtained in maize fields (PT) was calculated as the proportion of the 'potentially foraging' time the individual hare spent in that crop. Thus, the 'time potentially foraging' is the sum of the time periods covered by behavioural categories when foraging could not be excluded. All instances when the animal was definitely known to be performing non-foraging activities (e.g. resting or fighting) were excluded from PT calculations.

A mean PT value (\pm standard deviation) and 90th percentile values were calculated based on all single PT values. In addition, the total visual contact time and the respective behaviour categories during 24h telemetry were calculated in order to compare behaviour categories based on radio-tracking signals with behaviour confirmed via visual contact.

Results and Discussion

In total, radio-tracking sessions of 21 individual hares at five study sites were performed during the early crop development of maize in Central Europe. Radio-tracking sessions were performed from late April until early June 2018. The number of conducted 24h telemetry sessions was 23 (17 in Germany, six in Hungary), since two individuals were radio tracked twice. One session had to be excluded from analysis, as this session was not considered as a 'consumer session' since the animal was never located being 'active' in a maize field during the session, had no maize in the 24h home range, and was not caught on a maize field.

Maize fields covered on average approximately 36% of the total landscape surface and 44% of the arable land surface within the 24h home ranges of hares in all study sites.

The calculated single PT values ranged from 0.02 to 0.94 resulting in an average of 0.36 (\pm 0.26) and 90th percentile of 0.62. Calculated PT values did not differ substantially between different study sites; mean values were slightly higher in Germany (0.38) than in Hungary (0.31).

Drilled maize fields which were not yet emerged were checked in each study site for the occurrence of weeds at the beginning of the Field Phase (except of Szany, where all maize fields, except one, were already emerged). Fields that were still not emerged prior to the start of 24h radio-tracking were checked for weed occurrence again (one field in Holtrop, one field in Szany and two fields in Bösarkany). Each

survey showed that no weeds occurred on not yet emerged maize fields in the five study sites. Therefore since hares on those fields could not be foraging, those results were excluded from the PT analysis. This is clear from the photographs included in the report.

Calculated PT values of hares in maize fields in early BBCH growth stages (BBCH growth stage <20) in Central Europe

Country	Session ID	PT	Date (dd.mm.2018)	BBCH for maize fields inside the 24h home range
Germany	398_GER_01	0.56	18.05.	10-11
	398_GER_02	0.40	19.05.	09-11
	398_GER_03	0.17	20.05.	10-12
	398_GER_04	0.08	23.05.	11-12
	398_GER_05	0.50	22.05.	11-12
	398_GER_06	0.09	23.05.	12
	398_GER_07	0.08	22.05.	11
	398_GER_08	0.02	24.05.	12
	398_GER_09	0.44	25.05.	13
	398_GER_10	0.41	26.05.	13
	398_GER_12	0.18	27.05.	12-14
	398_GER_13	0.89	28.05.	12-14
	398_GER_14	0.37	30.05.	13
	398_GER_15	0.26	01.06.	15-16
	398_GER_16	0.94	04.06.	15-19
	398_GER_17	0.63	05.06.	15-19
	Hungary	398_HU_01	0.42	29.04.
398_HU_02		0.38	30.04.	13
398_HU_03		0.56	02.05.	13-14
398_HU_04		0.28	13.05.	13-15
398_HU_05		0.21	14.05.	14-15
398_HU_06		0.02	15.05.	15
Mean		0.36	-	-
90th percentile		0.62	-	-
SD		0.26	-	-

The total visual contact time during all 24h-telemetry sessions was 68 hours and 39 minutes which reflects 12% of the total radio tracking time of 552 hours. In 49% of the visually observed time, hares were classified as resting. The active behaviour during visual contact was classified as ‘foraging behaviour’ for 32% and as ‘other behaviour’ (such as e.g. fighting, running or grooming) for 19%.

Conclusion

This study demonstrated that maize fields, at pre-emergence growth stage, are in general not relevant foraging habitats for hares.

This report gives most appropriate, reliable and robust PT values for European hares using maize fields during early growth stages (BBCH growth stages < 20) in Central Europe for the use in wildlife risk assessments according to the recommendations of EFSA (2009). Values were calculated under worst-case assumptions (such as highest maize proportions in the study areas, data evaluation of ‘consumers’ only and therefore high exposure risk for each individual) and the PT values are considered to be conservative.

Comments of zRMS:	The study was assessed during evaluation of a.s. mesotrione in the RAR. The LoA was provided by the applicant. Agreed endpoints: PT=0.139
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Reference	KCP 10.1.2.2/01
Report	Generic field study on small mammals focal species and wood mouse (<i>Apodemus sylvaticus</i>) PT in maize field in Germany. XXX T. (2013) Report Number R12225
Guidelines:	None available, the monitoring was especially designed for the objectives of this study.
GLP:	Yes

Summary

The aim of the field study was to gain information on species composition in freshly drilled maize fields (until approximately BBCH growth stage 16) and adjacent habitats, to determine focal species candidates, and to obtain details on home ranges and the proportion of time (PT) wood mice spent (potentially foraging) in maize fields. The study involved five different maize fields in Germany, where live trapping (at times of pre- and post-emergence), scan sampling (at post-emergence), and radio-tracking of woodmouse (at post-emergence), were performed.

The trapping, carried out both in-crop and off-field, showed high presence of mice and voles: woodmouse was by far the most abundant species in both pre- and post-emergence (121 captures), followed by the yellow-necked mouse (25 captures), and the house mouse (1 capture); all the trapped voles (110 captures) were bank voles; no mammals belonging to other species were trapped. Regarding the habitat in which the animals were captured, the off-crop habitats were by far the more attractive habitats in comparison to the maize fields, with only 2 mice (1 woodmouse and 1 house mouse), and no voles at all, captured in-crop.

Trapping success as number of captures separated into in- and off-crop habitats - pre-emergence

Study field	Wood mouse		Yellow-necked mouse		Bank vole	
	in	off	in	off	in	off
1	0	20	0	2	0	34
2	0	20	0	4	0	13
3	0	13	0	3	0	15
4	0	13	0	0	0	0
5	0	4	0	3	0	14
Total	0	70	0	12	0	76

Trapping success as number of captures separated into in- and off-crop habitats - post-emergence

Study field	Wood mouse		Yellow-necked mouse		Bank vole	
	in	off	in	off	in	off
1	0	9	0	1	0	12
2	1	33	0	8	0	8
3	0	2	0	2	0	10
4	0	5	0	1	0	0
5	0	1	0	1	0	4
Total	1	50	0	13	0	34

The scan sampling, performed only in-crop at post-emergence, showed that mice were by far the most abundant species observed in maize fields (15 observations), whereas only 1 vole was observed; in addition, 1 rabbit, 1 marten and 1 fox were observed. This finding for mice is not in contrast with the results of the trapping session in the in-field areas, and can be explained by the behavior of mice, which are very mobile mammals, crossing and fast-exploring open areas (like early-stage maize fields) without necessari-

ly being trapped; on the contrary, voles are rather slow and soil-orientated mover in areas with full ground cover, and tend to avoid open areas such as early-stage maize fields to escape predation.

The tracking, carried out for woodmice at post-emergence, encompassed 17 sessions of 14 individuals. Different approaches were used to derive a PT; the most conservative, based on those individuals having used maize fields as foraging habitat (“consumer-only approach”), resulted in a mean PT of 0.04 (average of all sessions).

PT values for each radio-tracked wood mouse

Session No.*	PT calculation					PT in maize ‘all sessions’ approach	PT in maize ‘home range’ approach	PT in maize ‘consumer only’ approach
	Behaviour in all known habitats [%]			Behaviour in maize fields [%]				
	All behavioural categories	Not foraging	Potentially foraging	Not foraging	Potentially foraging			
1	100	11.68	88.32	0.00	0.00	0.00	0.00	-
2	100	8.43	91.57	0.00	0.00	0.00	0.00	-
3	100	12.67	87.33	3.69	3.00	0.03	0.03	0.03
5	100	0.54	99.46	0.00	0.00	0.00	-	-
6	100	3.90	96.10	0.00	0.00	0.00	-	-
7	100	11.05	88.95	5.90	4.00	0.04	0.04	0.04
8	100	11.96	88.04	0.00	5.98	0.07	0.07	0.07
9	100	6.33	93.67	0.38	13.05	0.14	0.14	0.14
10	100	11.34	88.66	0.00	2.46	0.03	0.03	0.03
11	100	10.60	89.40	0.00	0.00	0.00	0.00	-
12	100	9.56	90.44	0.00	0.76	0.01	0.01	0.01
13	100	15.41	84.59	0.75	1.13	0.01	0.01	0.01
14	100	8.29	91.71	0.36	0.36	<0.01	<0.01	<0.01
15	100	5.80	94.20	0.00	0.00	0.00	-	-
16	100	18.20	81.80	0.00	0.00	0.00	-	-
17	100	4.79	95.21	0.00	0.00	0.00	0.00	-
18	100	9.16	90.84	0.00	2.86	0.03	0.03	0.03
50%tile		9.56	90.44	0.00	0.36	0.00	0.01	0.03
90%tile		13.77	95.57	1.93	4.79	0.05	0.06	0.08
Mean		9.40	90.60	0.65	1.98	0.02	0.03	0.04

* Session No. 4 was incomplete and therefore not used for evaluation

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Comments of zRMS:	
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Reference: KCP 10.2.1-01

Report: Freshwater algae, Growth inhibition test with Pendimethalin 40% SC

XXX, E., 2018. Report No.: 17-99-131-ES. Phytosafe s.a.r.l.

Guideline(s):	OECD Guideline No. 201 (2011)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

~~The purpose of the study was to determine the effects of the test item Pendimethalin 40% SC on the growth of a unicellular green algal species: *Desmodesmus subspicatus*, strain no. 72 of the Museum National d'Historie Naturelle (Paris, France) in an OECD medium.~~

~~Exponentially growing cultures were exposed to the test substance Pendimethalin 40% SC (batch no. SCL-58726) over a period of 72 hours under nutrient sufficient conditions and continuous fluorescent illumination.~~

~~The cell density was counted at test initiation and then after 24 h, 48 h and 72 h of culture.~~

~~A range finding test was performed using one replicate unit for each the controls and the 0.01, 1.0, 10 and 100 mg/L test item treatments (nominal values). The definitive test was performed using three replicate units for each of five test item treatments (0.17, 0.27, 0.55, 1.10 and 2.20 mg/L) and for the controls. The test range was selected in the light of the results of the range finding test.~~

~~In the light of previous analytical validations with Pendimethalin 40% SC, it was anticipated that the test item treatments would not remain within 80 – 120 % of the nominal values during the test period. As a consequence, mean exposure were calculated as the geometric mean of the measured concentrations, at test initiation and test completion.~~

~~The effects were evaluated using the two response variables described below:~~

- ~~— Growth rate: increase in cell density over the exposure period.~~
- ~~— Yield: biomass at the end of the exposure period minus the biomass at the start of the exposure period. Initial biomass did not exceed 0.5 g/L (dry basis).~~

~~The study aimed to determine the treatment concentrations liable to induce x % inhibition for growth rate ($E_r C_x$) and for yield ($E_y C_x$). It should be noted that toxicity values calculated using there two response variables are not comparable and this difference must be recognized when using the results of the test.~~

~~A reference item treatment treated with Potassium dichromate at four distinct concentrations between 0.2 and 1 mg/L (3 replicates for each concentration) was used to confirm the function of the test system: EC_{50} -72 h value for Potassium dichromate should be between 0.60 and 1.00 mg/L for the specific growth rate between 0.20 and 0.75 mg/L for the yield.~~

Results:

Preliminary test

~~The preliminary test was performed using the test item concentrations: 0.01, 1.0, 10 and 100 mg/L.~~

~~At both 10 and 100 mg/L solid particles originated from insolubilized test substance still remained wich interfered with cell counting and the results were obviously biased. The observation showed that algae growth was totally inhibited: no green coloration developed after 3 days of culture.~~

~~No adverse effects were observed in the solvent control and the test item treatments up to and including~~

0.1 mg/L. Both specific growth rate and yield were reduced by more than 50% at 1.0 mg/L.

Preliminary test results

Treatment	Growth rate				% Reduction (total period)	Yield inhibition	
	Measured growth rates					Yield ($\times 10^{-8}$)	% Inhibition
	0–24 h	24–48 h	48–72 h	Total period			
Water control	2.31	1.55	0.68	1.51	-	4.43 $\times 10^{-8}$	-
Solvent control	2.23	1.78	0.35	1.45	4.0	3.69 $\times 10^{-8}$	16.7
Pendimethalin 40% SC							
0.010 mg/L	2.37	2.05	-0.04	1.46	3.4	3.79 $\times 10^{-8}$	14.5
0.10 mg/L	2.04	2.47	-0.18	1.44	4.7	3.56 $\times 10^{-8}$	19.5
1.0 mg/L	1.37	1.24	-0.70	0.64	57.9	2.76 $\times 10^{-7}$	93.8

Definitive test

In the definitive test, the algae, the results are presented on mean measured concentrations over the test period, 0.11, 0.23, 0.39, 0.85 and 1.59 mg/L.

Definitive test results

Treatment	Growth rate				% Reduction (total period)	Yield inhibition	
	Measured growth rates					Yield ($\times 10^{-8}$)	% Inhibition
	0–24 h	24–48 h	48–72 h	Total period			
Water control	2.19	1.75	1.18	1.71	-	1.43 $\times 10^{-9}$	-
Solvent control	2.18	1.76	1.19	1.71	-0.1	1.44 $\times 10^{-9}$	-0.80
Pendimethalin 40% SC							
0.01 mg/L	2.19	1.73	1.18	1.70	0.3	1.41 $\times 10^{-9}$	1.61
0.23 mg/L	2.15	1.76	1.15	1.69	1.4	1.33 $\times 10^{-9}$	6.73
0.39 mg/L	2.07	1.36	0.55	1.33	22.4	4.47 $\times 10^{-8}$	68.78
0.85 mg/L	1.95	0.63	0.34	0.97	43.1	1.49 $\times 10^{-8}$	89.55
1.59 mg/L	1.90	0.36	-0.01	0.75	56.1	7.27 $\times 10^{-7}$	94.92

Validity criteria

The test was considered valid in the light of the following criteria:

- The biomass in the control cultures increased exponentially by a factor of more than 16 over the 72-hour test period (169–170 for the water controls and solvent controls, respectively).
- The mean coefficient of variation for section for section specific growth rates in the control cultures did not exceed 35% (29.6% and 29.1% for the water controls and solvent controls, respectively).
- The coefficient of variation for average specific growth rates over the entire test period in replicate control cultures did not exceed 7% (1.8% and 2.0% for the water controls and solvent controls, respectively).

Additionally, the EC_{50-72h} for Potassium dichromate was between 0.6 and 1.0 mg/L for the specific growth rate and between 0.2 and 0.75 mg/L for the yield. The results fulfilled the validity criteria based on Phytosafe historical data.

Due to adsorption, the test item treatments were not maintained within 80–120 % of the nominal value during the test period. The calculations were based on the geometric mean of the nominal measured concentrations at test initiation and test completion.

Conclusion

The endpoint values based on specific growth rate:

~~NOEC = 0.23 mg/L (0.09 mg a.i./L)
ErC₁₀/72 h = 0.28 mg/L (0.11 mg a.i./L) and 95% confidence limits = 0.14 – 0.56 mg/L
ErC₂₀/72 h = 0.40 mg/L (0.16 mg a.i./L) and 95% confidence limits = 0.21 – 0.77 mg/L
ErC₅₀/72 h = 1.16 mg/L (0.45 mg a.i./L) and 95% confidence limits = 0.59 – 2.29 mg/L~~

The endpoint values based on yield:

~~NOEC = 0.23 mg/L (0.09 mg a.i./L)
EyC₁₀/72 h = 0.17 mg/L (0.06 mg a.i./L) and 95% confidence limits = 0.03 – 0.85 mg/L
EyC₂₀/72 h = 0.21 mg/L (0.08 mg a.i./L) and 95% confidence limits = 0.04 – 1.01 mg/L
EyC₅₀/72 h = 0.40 mg/L (0.15 mg a.i./L) and 95% confidence limits = 0.09 – 1.80 mg/L~~

Reference: KCP 10.2.1 – 02
Report: Lemna sp., Growth inhibition test with Pendimethalin 40% SC
XXX, E., 2019 Report No.: 17-99-134 ES. Phytosafe s.a.r.l.

Guideline(s): OECD Guideline No. 221 (2011)

Deviations: No

GLP: Yes

Acceptability: Yes

**Duplication
(if vertebrate study)** No

Materials and methods

Test item: _____

Description: _____ Pendimethalin 40% SC _____
Batch number: _____ SCL 58726 _____
A.i. content: _____ 407 g/L pendimethalin _____

Test system: _____

Species: _____ Lemna minor _____
Strain: _____ Origin _____
Age: _____
Source: _____ Strain was provided by a commercial breeder and regularly sub-cultured in SIS medium at the Phytosafe site. _____
Medium: _____ Modification of the Swedish standard (SIS) Lemna growth medium was used. _____

Experimental conditions:

Temperature: _____ 24 ± 2°C _____
pH values: _____ 8.0 8.1 (at the beginning of the test), 7.4. 7.7 (at the end of the test) _____
Mean light intensity: _____ artificial light at 90-110 µE/m²/s _____
Test vessels: _____ glass Erlenmeyer flasks filled with 100 mL of culture _____
Initial frond number: 9

Experimental

period: _____ 7 d _____

Test design: _____ Semi-static (7 days); daily renewal, three replicates for control and for each of five test item treatments. _____
_____ Test item concentrations (definitive test): 0.045, 0.101, 0.212, 0.482 and 1.047

mg/L.

In order to quantify the test item related effects on vegetative growth over a period of 7 days, the number of fronds in each replicate was counted. At the same time observations of plant development were performed: frond size, shape and appearance (necrosis, chlorosis, gibbosity or bending of fronds), colony break up or loss of buoyancy, root length and appearance. Growth of plant cultures in the test item concentrations was compared with that of the control. Dry weight was also measured, at the beginning and at the end of the test.

The inhibition of growth was expressed as logarithmic increase in measurement variable (average specific growth rate) during the exposure period. From the average specific growth rates recorded in a series of test solutions, the concentration bringing about a specified x % inhibition of growth rate (e.g. 50 %) was determined and expressed as the ErCx (e.g. ErC₅₀). Yield was defined as measurement variables at the end of the exposure period minus the measurement variables at the start of the exposure period. From the yield recorded in a series of test solutions, the concentration bringing about a specified x % inhibition of yield (e.g. 50 %) was calculated and expressed as the EyCx (e.g. EyC₅₀).

LOEC and NOEC were determined.

It was anticipated that the test item treatments would not remain stable during the test, so the treatments were checked in the old and the new media at each test item adjustment. Mean exposure concentrations were calculated as the geometric mean of the measured concentrations throughout the test period in the old and the new media.

3,5 dichlorophenol was used as reference item to confirm the function of the test system: EC₅₀ value for 3,5 dichlorophenol based on frond numbers should comply with the Phytosafe historical data.

Statistics: SigmaPlot 14.0 was used for statistical analysis and NOEC determination. Normal distribution of data was tested with the Shapiro Wilk test (two-sided, $p \leq 0.05$). Brown Forsythe test for variance homogeneity, Bonferroni t test was used when normality, variance homogeneity were fulfilled. Welch's t test (when normal distribution was observed but variance homogeneity failed). Mann Whitney Rank Sum Test was applied when normal distribution failed.

Results

The endpoint values based on specific growth rate (number of fronds):

NOEC = 0.045 mg/L (0.017 mg a.i./L)

ErC₁₀ = 0.055 mg/L (0.021 mg a.i./L) and 95% confidence limits = 0.044–0.066 mg/L

ErC₂₀ = 0.101 mg/L (0.039 mg a.i./L) and 95% confidence limits = 0.090–0.112 mg/L

ErC₅₀ = 0.318 mg/L (0.123 mg a.i./L) and 95% confidence limits = 0.307–0.329 mg/L

The endpoint values based on specific growth rate (dry weight):

NOEC = 0.101 mg/L (0.039 mg a.i./L)

ErC₁₀ = 0.123 mg/L (0.048 mg a.i./L) and 95% confidence limits = 0.111–0.135 mg/L

ErC₂₀ = 0.285 mg/L (0.110 mg a.i./L) and 95% confidence limits = 0.273–0.297 mg/L

ErC₅₀ = 1.079 mg/L (0.418 mg a.i./L) and 95% confidence limits = 1.067–1.091 mg/L

The endpoint values based on yield (number of fronds):

NOEC = 0.045 mg/L (0.017 mg a.i./L)

EyC₁₀ = 0.040 mg/L (0.015 mg a.i./L) and 95% confidence limits = 0.025–0.055 mg/L

EyC₂₀ = 0.061 mg/L (0.023 mg a.i./L) and 95% confidence limits = 0.046–0.076 mg/L

EyC₅₀ = 0.131 mg/L (0.051 mg a.i./L) and 95% confidence limits = 0.116–0.146 mg/L

The endpoint values based on yield (dry weight):

NOEC = 0.101 mg/L (0.039 mg a.i./L)
 $EyC_{10} = 0.063 \text{ mg/L (0.024 mg a.i./L)}$ and 95% confidence limits = 0.045 – 0.081 mg/L
 $EyC_{20} = 0.114 \text{ mg/L (0.044 mg a.i./L)}$ and 95% confidence limits = 0.096 – 0.132 mg/L
 $EyC_{50} = 0.356 \text{ mg/L (0.138 mg a.i./L)}$ and 95% confidence limits = 0.338 – 0.374 mg/L

The test was considered as valid:

- The doubling time of frond number in the control was 2.1 days, and thus lower than 2.5 days required as a maximum
- The EC50 7 days for 3,5 dichlorophenol was between 1.0 and 3.0 mg/L. The results fulfilled the validity criteria based on Phytosafe historical data

With regard to analytics, the initial values represented 94-96% of the nominal values. On day 3 the nominal values were still recovered by 78-84%, but on day 4 the measured concentrations represented only 68-73% of the nominal values and the test solutions were renewed. Recovery of pendimethalin in the new media was 98-104%, but then decreased down to 73-80% at the end of the test. Based on mean measured concentration on days 0, 4 (old and new media) and 7, the exposure concentrations were calculated as 0.045, 0.101, 0.212, 0.482 and 1.047 mg/L instead of 0.05, 0.12, 0.25, 0.56 and 1.23 mg/L (nominal values).

Conclusions

NOEC was 0.045 mg/L (0.017 mg a.i./L) for the number of fronds, and 0.101 mg/L (0.039 mg a.i./L) for dry weight

The most sensitive parameter was yield in fronds:

$EyC_{10} = 0.040 \text{ mg/L (0.015 mg a.i./L)}$ and 95% confidence limits = 0.025 – 0.055 mg/L
 $EyC_{20} = 0.061 \text{ mg/L (0.023 mg a.i./L)}$ and 95% confidence limits = 0.046 – 0.076 mg/L
 $EyC_{50} = 0.131 \text{ mg/L (0.051 mg a.i./L)}$ and 95% confidence limits = 0.116 – 0.146 mg/L

The least sensitive parameter was specific growth rate for dry weight:

$ErC_{10} = 0.123 \text{ mg/L (0.048 mg a.i./L)}$ and 95% confidence limits = 0.111 – 0.135 mg/L
 $ErC_{20} = 0.285 \text{ mg/L (0.110 mg a.i./L)}$ and 95% confidence limits = 0.273 – 0.297 mg/L
 $ErC_{50} = 1.079 \text{ mg/L (0.418 mg a.i./L)}$ and 95% confidence limits = 1.067 – 1.091 mg/L

Comments of zRMS:	The study is considered valid. All validity criteria were met.		
	- the mortality in the control was 0% after 96 h (criterion: < 10%);		
	- dissolved oxygen concentrations were within the range of 65 – 71 % of air saturation value (criterion: > 60% of air saturation).		
	Agreed endpoint:		
	Endpoint	Test item [mg/L] (nominal concentrations)	Active substance [mg/L] (nominal concentrations*)
LC ₅₀	9.24	3.57	
NOEC	1.56	0.6	
LOEC	3.13	1.2	

Reference:

KCP 10.2.1-03

Report:

“Rainbow trout (*Oncorhynchus mykiss*), acute toxicity test with Pendimethalin

455 g/l CS".
XXX K., 7887/2020, 2020
BIOSCIENCE RESEARCH FOUNDATION

Guideline(s): OECD No. 203 (2019)

Deviations: No

GLP: Yes

Acceptability: Yes

**Duplication
(if vertebrate study):** No

Summary

The aim of the study was to assess the impact of Pendimethalin 455 g/L CS on rainbow trout (*Oncorhynchus mykiss*) to determine the concentration of the test item causing 50% mortality of rainbow trout (LC₅₀ value after 96 h of exposure) as well as the NOEC and LOEC values. The test was conducted in a static design for 96 h with seven concentrations of the test item plus the control. Each concentration was divided into one replicate with ten fish each. The fish were observed for mortality and intoxication symptoms after 2, 5, 24, 30, 48, 54, 72, 78 and 96 h of exposure.

Material and methods

Test item: Name: Pendimethalin 455 g/l CS
Batch number: SCL – 60400
Content: 456 g/L
Production date: 14th December, 2019
Expiry date: 13th December, 2021

Test organism: Rainbow trout (*Oncorhynchus mykiss*)
Supplier: Tharun aqua fish farm, Padappai-601301, Tamil Nadu, India.
Age: approximately 2 months

Test design: Test type: static
Exposure time: 96 hours
Number of replicates: 1 replicates per each concentration and the control
Number of fish: 10 fish in each aquarium

Nominal test item concentration: 1.56, 3.13, 6.25, 12.5, 25, 50, 100 mg/L plus the control

Nominal concentrations of Copper: 0.6, 1.2, 2.4, 4.8, 9.7, 19.3, 38.6 mg/L

Test conditions: Temperature: 12.0 – 12.33°C
pH: 7.1 – 7.4
Oxygen: 65 - 71 %
Lighting: 16 h light : 8 h dark – 659-899 lux

Endpoint values: LC₅₀, LOEC and NOEC.

Statistical analysis: Probit analysis in the NCSS (Number Cruncher Statistical System).

Validity criteria: - the mortality in the control was 0% after 96 h (criterion: < 10%);
- dissolved oxygen concentrations were within the range of 65 – 71 % of air saturation value (criterion: > 60% of air saturation).

Findings

Table 1: Results of the determination of test item

Active substance	Hour	Sample concentration (mg/L)	Nominal concentration* (mg/L)	Mean determined concentration (mg/L)	SD	Recovery (%)	
Pendimethalin	0	Control	0.0	0.0000	ND	0.0000	0.0
		T1	1.56	0.6038	0.6039	0.0354	100.0
		T2	3.13	1.2076	1.2094	0.5982	100.1
		T3	6.25	2.4153	2.4339	0.8613	100.8
		T4	12.5	4.8305	4.8642	0.8062	100.7
		T5	25	9.6610	9.6417	0.2610	99.8
		T6	50	19.3220	19.4950	0.8281	100.9
	T7	100	38.6441	38.9029	1.0772	100.7	
	96	Control	0.0	0.0000	ND	0.0000	0.0
		T1	1.56	0.6038	0.6030	1.1940	99.9
		T2	3.13	1.2076	1.1990	0.6933	99.3
		T3	6.25	2.4153	2.3905	0.0157	99.0
		T4	12.5	4.8305	4.8524	1.0417	100.5
		T5	25	9.6610	9.6669	0.1472	100.1
T6		50	19.3220	19.3075	0.5748	99.9	
T7	100	38.6441	38.5013	0.1539	99.6		

* Based on the content of active substance in the test item determined at BRF at the level of 456 g/L and density of 1.18 g/cm³.
 SD: standard deviation; ND: not detected.

Table 2: Cumulative mortality of fish – definitive test

Treatment / concentration (mg/L)	Number of fish exposed	Hour of exposure / number of dead fish			Dead fish after 96h (%)
		24h	48h	96h	
Control	0	10	0	0	0
T1	1.56	10	0	0	0
T2	3.13	10	0	0	10
T3	6.25	10	0	0	30
T4	12.5	10	1	4	70
T5	25	10	4	5	90
T6	50	10	10		100
T7	100	10			100

Endpoint values for mortality of fish after 96h of exposure

Endpoint	Test item [mg/L] (nominal concentrations)	Active substance [mg/L] (nominal concentrations*)
LC ₅₀	9.24	3.57
NOEC	1.56	0.6
LOEC	3.13	1.2

* Calculated on the basis of the Pendimethalin content in the test item declared by the Sponsor

Comments of zRMS:	The study is considered valid. All validity criteria were met.	
	<ul style="list-style-type: none"> • There was no immobilization of daphnia in the negative control during the test period, which is within the allowed 10 percent immobilization of daphnids. • The dissolved oxygen concentration at the end of the test was more than ≥ 3 mg/L in negative control and other test vessels. 	
	Agreed endpoint:	
	Endpoint	Value [mg test item/L]
	EC₁₀	25.63 (24.23 – 27.03)
	EC₂₀	31.59 (30.22 – 32.97)
	EC₅₀	47.16 (45.58 – 48.74)
	NOEC	29.6
	LOEC	44.4
	Pendimethalin [mg a.s./L]	9.90 (9.36 – 10.44)
		12.21 (11.68 – 12.74)
		18.22 (17.61 – 18.83)
		11.44
		17.16

Reference: KCP 10.2.1-04

Report “Study of *Daphnia magna* acute immobilization with Pendimethalin 455 g/L CS”, Ms. S. XXX (2021), Report No. 9010/2021. Bioscience Research Foundation

Guideline(s): OECD Guideline No. 202 (2004)

Deviations: No

GLP: Yes

Acceptability: Yes

**Duplication
(if vertebrate study)** Not relevant

Materials and methods

The acute immobilization effect of the test item Pendimethalin 455 g/L CS was studied on *Daphnia magna* for 48 hours.

In definitive test, *Daphnia magna* less than 24 hours old were exposed to the nominal concentrations of 19.8, 29.8, 29.6, 44.4, 66.7 and 100 mg/L along with a negative control. Four replicates were maintained for both negative control and test concentrations. The number of daphnia immobilized was recorded at 24 and 48 hours exposure.

All the test concentrations along with the negative control were analysed for the test item concentration at the beginning and end of test. For analysis, single composite sample was drawn from prepared test concentrations. Validation of the analytical methods was done as per SANCO/3029/99. In fresh samples of the test item at exposure initiation, the determined concentrations of Pendimethalin 455 g/L CS were between 99.1 and 101.1 of the nominal concentration and between 102.2 and 100.8 at exposure termination, indicating that the results were within the acceptable limit (80 to 120% of the claimed concentration with an RDS of $\leq 20\%$). Therefore, the concentrations of Pendimethalin 455 g/L CS were stable during 48h under test conditions.

Results

Main test

In the definitive test there was no immobility of daphnia in the negative control at 24 and 48 hour exposure. The daphnids in the control appeared normal throughout the study period. Cumulative immobilization at the end of 48h was 0, 25, 45, 65 and 100% in 19.8, 29.6, 44.4, 66.7 and 100 mg/L test substance, respectively. Lethargy was observed in 29.6, 44.4 and 66.7 mg/L test substance. Surface trapping was observed in 29.6, 44.4 and 66.7 mg/L test substance.

Results of the determination of Pendimethalin 455 g/L CS in the test samples – main test

Test item concentration (mg/L)		Control	T1	T2	T3	T4	T5
		0.0	19.8	29.6	44.4	66.7	100
Nominal concentration * (mg/L)		0.000	7.6515	11.4386	17.158	25.7756	38.6441
0 h (fresh)	Mean determined concentration (mg/L)	ND	7.7345	11.469	17.2689	25.992	38.3002
	SD	0.000	0.0451	0.0799	0.1002	0.0896	0.0616
	Recovery (%)	-	101.1	100.3	100.6	100.9	99.1
Nominal concentration * (mg/L)		0.000	7.6515	11.4386	17.158	25.7756	38.6441
48 h (spent)	Mean determined concentration (mg/L)	ND	7.694	11.5309	17.1934	26.0228	38.7824
	SD	0.000	0.0162	0.0023	0.0924	0.133	0.0803
	Recovery (%)	-	100.6	100.8	100.2	101.0	100.4

* Based on the content of active substance in the test item determined at BRF at the level of 456 g/L and density of 1.18 g/cm³.
 SD: standard deviation; ND: not detected.

Table 1 - Immobilization of *Daphnia magna*, definitive test

Treatment [mg/L]	Number of <i>Daphnia</i> immobilized (5 <i>Daphnia</i> per replicate)								% Immobilization	
	24 h				48 h					
	Replicates								24 h	48 h
	R1	R2	R3	R4	R1	R2	R3	R4		
Negative control	0	0	0	0	0	0	0	0	0	0
19.8	0	0	0	0	0	0	0	0	0	0
29.6	0	0	1	1	0	1	2	2	10	25
44.4	0	1	2	1	1	2	3	3	20	45
66.7	1	2	1	2	2	3	4	4	30	65
100	5	5	5	5	-	-	-	-	100	100

Validity criteria

The results are considered valid because the following criteria were satisfied:

- There was no immobilization of daphnia in the negative control during the test period, which is within the allowed 10 percent immobilization of daphnids.
- The dissolved oxygen concentration at the end of the test was more than ≥ 3 mg/L in negative control and other test vessels.

Conclusion

Table 2 – Immobilization. Endpoint values

Endpoint	Value [mg test item/L]	Pendimethalin [mg a.s./L]
EC ₁₀	25.63 (24.23 – 27.03)	9.90 (9.36 – 10.44)
EC ₂₀	31.59 (30.22 – 32.97)	12.21 (11.68 – 12.74)
EC ₅₀	47.16 (45.58 – 48.74)	18.22 (17.61 – 18.83)
NOEC	29.6	11.44
LOEC	44.4	17.16

Comments of zRMS:	The study is considered valid. All validity criteria were met.		
	<ul style="list-style-type: none"> - The biomass in the control increased by a factor of 71.25 within 72-hour test period (criterion: at least a 16-fold growth) - The coefficient of variation of the mean specific growth rate after 72-hour test period (exposure initiation – exposure termination) in the control culture was 3.10% (criterion: it must not exceed 7%) - The mean coefficient of variation for the section-by-section growth rate in the control culture was 1953 (criterion: it must not exceed 35%). 		
	Agreed endpoint:		
	Observations	EC values (mg test item/L)	EC values

				(mg Pendimethalin/L)
72 hours	E_rC₅₀	1.233 (1.127 – 1.339)	0.476 (0.436 – 0.517)	
	E_rC₂₀	0.447 (0.404 – 0.490)	0.173 (0.156 – 0.189)	
	E_rC₁₀	0.263 (0.229 – 0.297)	0.102 (0.088 – 0.115)	
	LOEC_r	0.313	0.121	
	NOEC_r	0.156	0.060	
	E_yC₅₀	0.386 (0.360 – 0.411)	0.149 (0.139 – 0.159)	
	E_yC₂₀	0.175 (0.157 – 0.193)	0.068 (0.061 – 0.074)	
	E_yC₁₀	0.116 (0.114 – 0.117)	0.045 (0.044 – 0.045)	
	LOEC_y	0.313	0.121	
	NOEC_y	0.156	0.060	
Note: 1) E _r C refers to growth rate, E _y C refers to yield.				

Reference: KCP 10.2.1-05

Report “Study of algal growth inhibition with Pendimethalin 455 g/L CS”, Dr. S. XXX, (2021), Report No. 9008/2021. Bioscience Research Foundation.

Guideline(s): OECD Guideline No. 201 (2006)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Not relevant

Materials and methods

The effect of Pendimethalin 455 g/L CS was tested on the growth of freshwater unicellular green alga *Raphidocelis subcapitata* for 72 hours.

The algae were exposed to the test item at the test concentrations of 0.156, 0.313, 0.625, 1.250 and 2.500 mg/L along with a negative control. Six replicates were maintained for the negative control and three replicates for each of the test concentrations. The initial cell density of algal cells at the start of exposure was 0.9×10^4 cells/mL. The cell growth was measured at 24, 48 and 72 hours after the initiation of the test using a Bürker chamber.

Pendimethalin 455 g/L CS was stable during 72 h under test conditions. In fresh samples of the test item concentrations, the determined concentrations of the active ingredient were between 99.3 and 100.5% of the nominal concentration.

Results

Results of the determination of Pendimethalin 455 g/L CS in the test samples

Test item concentration (mg/L)		Control	T1	T2	T3	T4	T5
		0.0	0.156	0.313	0.625	1.25	2.5
Nominal concentration * (mg/L)		0.000	0.0603	0.121	0.2415	0.4831	0.9661
0 h (fresh)	Mean determined concentration (mg/L)	ND	0.0603	0.1214	0.2417	0.4857	0.9593
	SD	0.000	0.0006	0.0007	0.0014	0.0032	0.0031
	Recovery (%)	-	100	100.3	100.1	100.5	99.3
48 h (spent)	Mean determined concentration (mg/L)	ND	0.0606	0.1212	0.2396	0.4899	0.9801
	SD	0.000	0.000	0.0007	0.0007	0.0009	0.0027
	Recovery (%)	-	100.6	100.2	99.2	101.4	101.4

* Based on the content of active substance in the test item determined at BRF at the level of 456 g/L and density of 1.18 g/cm³.
SD: standard deviation; ND: not detected.

Definitive test

At the end of the test (72 hours), the cell biomass in the test item solutions decreased with the increase in test concentration.

Table 1 Growth rate and yield inhibition, definitive test

Nominal test item concentration [mg/L]	% Inhibition after 72 h of exposure (growth rate)	% inhibition after 72 h of exposure (yield)
Control	-	-
0.156	4.71	18.52
0.313	9.62	33.94
0.625	32.65	76.12
1.250	51.07	89.96
2.50	70.58	96.41

Validity criteria

- The biomass in the control increased by a factor of 71.25 within 72-hour test period (criterion: at least a 16-fold growth)
- The coefficient of variation of the mean specific growth rate after 72-hour test period (exposure initiation – exposure termination) in the control culture was 3.10% (criterion: it must not exceed 7%)
- The mean coefficient of variation for the section-by-section growth rate in the control culture was 1953 (criterion: it must not exceed 35%).

Conclusion

The endpoint values determined for growth rate and yield at 72 hours are presented below based on nominal concentration.

Table 2 - Endpoint values for Growth rate and yield

Observations	EC values (mg test item/L)	EC values (mg Pendimethalin/L)	
72 hours	E _r C ₅₀	1.233 (1.127 – 1.339)	0.476(0.436 – 0.517)
	E _r C ₂₀	0.447 (0.404 – 0.490)	0.173 (0.156 – 0.189)
	E _r C ₁₀	0.263 (0.229 – 0.297)	0.102 (0.088 – 0.115)
	LOEC _r	0.313	0.121
	NOEC _r	0.156	0.060
	E _y C ₅₀	0.386 (0.360 – 0.411)	0.149 (0.139 – 0.159)
	E _y C ₂₀	0.175 (0.157 – 0.193)	0.068 (0.061 – 0.074)
	E _y C ₁₀	0.116 (0.114 – 0.117)	0.045 (0.044 – 0.045)

LOEC_y	0.313	0.121
NOEC_y	0.156	0.060

Note: 1) E_rC refers to growth rate, E_yC refers to yield.
 2) Range mentioned after EC value refers to 95% fiducial limits.

Comments of zRMS:	The study is considered valid. All validity criteria were met.		
	<ul style="list-style-type: none"> - The doubling time of frond number in the control was 2.1 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 10.1). - The average specific growth rate in the control between day 0 and day 7 was 0.321 d⁻¹ (minimum requirement: higher than 0.275 d⁻¹) 		
	Agreed endpoints:		
	-Test item on Lemna gibba growth rate		
	Endpoint	Test item mg/L (based on nominal concentrations)	Active substance mg/L (based on nominal concentrations*)
	Growth rate – based on front number		
	E_rC₁₀	4.310 (3.83 – 4.789)	1.664 (1.478 – 1.849)
	E_rC₂₀	7.207 (6.571 – 7.842)	2.782 (2.536 – 3.027)
	E_rC₅₀	19.271 (17.924 – 20.618)	7.4 (6.919 – 7.959)
	NOEC	3.125	1.21
	LOEC	6.25	2.42
	Growth rate – based on dry weight		
	E_yC₁₀	23.632 (20.581 – 26.68)	9.122 (7.944 – 10.30)
	E_yC₂₀	47.013 (41.46 – 52.57)	18.147 (16.00 – 20.29)
	E_yC₅₀	>100	>38.64
	NOEC	6.25	2.42
	LOEC	12.5	4.83
	*Calculated on the basis of the content in the test item declared by the Sponsor in the Certificate of Analysis		
	Test item on Lemna gibba yield		
	Endpoint	Test item mg/L (based on nominal concentrations)	Active substance mg/L (based on nominal concentrations*)
	Yield based on frond number		
	E_rC₁₀	2.184 (1.928 – 2.440)	0.843 (0.744 – 0.942)
	E_rC₂₀	3.606 (3.268 – 3.943)	1.392 (1.262 – 1.522)
E_rC₅₀	9.407 (8.765 – 10.048)	3.631 (3.383 – 3.878)	
NOEC	1.563	0.60	
LOEC	3.125	1.21	
Yield – based on dry weight			
E_yC₁₀	11.409 (10.048 – 12.769)	4.404 (3.879 – 4.929)	
E_yC₂₀	20.455 (18.581 – 22.329)	7.896 (7.172 – 8.619)	
E_yC₅₀	62.501 (56.014 – 68.988)	24.125 (21.622 – 26.629)	

	NOEC	6.25	2.42
	LOEC	12.5	4.83
*Calculated on the basis of the content in the test item declared by the Sponsor in the Certificate of Analysis			

Reference: KCP 10.2.1-06

Report “Study of *Lemna gibba* growth inhibition with Pendimethalin 455 g/l CS”.
 Dr. S. XXX. 2021. Study code: 9009/2021. Bioscience Research Foundation

Guideline(s): OECD Guideline No. 221 (2006)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication No
 (if vertebrate study)

Materials and methods

Test item: Pendimethalin 455 g/l CS
 Batch no.: SCL-80067
 Active substance content: Pendimethalin 456 (g/L)

Reference item : 3,5-dichlorophenol

Test medium: 20X AAP medium

Biological test system : *Lemna gibba* obtained from a standard laboratory culture at BRF
 Colonies cultured for 8 days before exposure initiation

Test doses: A control, 1.563, 3.125, 6.25, 12.5, 25, 50 and 100 mg test item/L.
 Equivalent to: 0.60, 1.21, 2.42, 4.83, 9.66, 19.32 and 38.64 mg
 Pendimethalin/L. There were 3 replicates of each test concentra-
 tion and 6 replicates for the control. 3 colonies with 3 fronds each
 were introduced into each replicates.

Test conditions: temperature: 22.1 – 24.6°C;
 pH at the beginning of the test: 7.5 – 7.9;
 pH at the end of the test: 7.3 – 7.6;
 lighting: 16 h light and 8h dark;
 light intensity: 7015 - 7553 lux

Endpoints: EC₁₀, EC₂₀, EC₅₀, NOEC, LOEC
 LC₁₀, LC₂₀, LC₅₀, NOEC, LOEC

Results

No distinctive changes from the normal development of plants in the test item concentrations of 1.563, 3.125 and 6.25 mg/L and in the control group, whereas in the test item concentrations of 12.5, 25, 50 and 100 mg/L smaller fronds, spots of chlorosis and/or separated roots were observed during the 7-day experiment.

Values of *Lemna gibba* growth rate and yield inhibition on day 7 – main test

Groups	Concentration of the test item (mg/L)	Based on frond number		Based on dry weight	
		% inhibition (growth rate)	% inhibition (yield)	% inhibition (growth rate)	% inhibition (yield)
Control	0.0				
T1	1.563	1.09	2.66	0.10	0.22
T2	3.125	7.70	18.20	0.43	1.08

T3	6.25	20.00	41.10	1.07	2.81
T4	12.5	35.71	62.37	5.02	12.31
T5	25	50.05	75.87	12.07	27.43
T6	50	75.50	91.18	20.5	42.33
T7	100	98.10	99.31	35.4	62.63

Samples of all the test item concentrations and the control collected at exposure initiation (day 0) and at exposure termination (day 7) were chemically determined. In fresh samples, the determined concentrations were between 99.3 and 101.5% of the nominal concentration. The results confirmed that the test item concentrations were prepared correctly. In spent samples, the determined concentrations were between 99 and 100.6% of the nominal concentrations. Therefore, the concentrations of Pendimethalin 455 g/L CS were stable during 7 days under test conditions.

Results of the determination of Pendimethalin 455 g/L CS in the test samples

Test item conc. (mg/L)		Control	T1	T2	T3	T4	T5	T6	T7
Nominal conc.* (mg/L)		0.000	0.604	1.2076	2.4153	4.8305	9.661	19.322	38.6441
Day 0	Mean determ. conc. (mg/L)	ND	0.5998	1.2221	2.445	4.851	9.7344	19.2849	39.2078
	SD	0.000	0.0019	0.0022	0.0121	0.0086	0.0065	0.1923	0.1166
	Recovery (%)	-	99.3	101.2	101.2	100.4	100.8	99.8	101.5
Day 7	Mean determ. conc. (mg/L)	ND	0.6019	1.1959	2.4306	4.806	9.7067	19.3449	38.6491
	SD	0.000	0.0005	0.0012	0.0143	0.0142	0.0671	0.1823	0.0401
	Recovery (%)	-	99.7	99.0	100.6	99.5	100.5	100.1	100.0

* Based on the content of active substance in the test item determined at BRF at the level of 456 g/L and density of 1.18 g/cm³.
SD: standard deviation; ND: not detected.

Table 10 - Endpoint values – impact of the test item on Lemna gibba growth rate – main test

Endpoint	Test item mg/L	Active substance mg/L
	(based on nominal concentrations)	(based on nominal concentrations*)
Growth rate – based on front number		
E_rC₁₀	4.310 (3.83 – 4.789)	1.664 (1.478 – 1.849)
E_rC₂₀	7.207 (6.571 – 7.842)	2.782 (2.536 – 3.027)
E_rC₅₀	19.271 (17.924 – 20.618)	7.4 (6.919 – 7.959)
NOEC	3.125	1.21
LOEC	6.25	2.42
Growth rate – based on dry weight		
E_yC₁₀	23.632 (20.581 – 26.68)	9.122 (7.944 – 10.30)
E_yC₂₀	47.013 (41.46 – 52.57)	18.147 (16.00 – 20.29)
E_yC₅₀	>100	>38.64
NOEC	6.25	2.42
LOEC	12.5	4.83

*Calculated on the basis of the content in the test item declared by the Sponsor in the Certificate of Analysis

Table 11 - Endpoint values – impact of the test item on Lemna gibba yield – main test

Endpoint	Test item mg/L	Active substance mg/L
	(based on nominal concentrations)	(based on nominal concentrations*)
Yield based on frond number		
E_rC₁₀	2.184 (1.928 – 2.440)	0.843 (0.744 – 0.942)
E_rC₂₀	3.606	1.392

	(3.268 – 3.943)	(1.262 – 1.522)
E_rC₅₀	9.407 (8.765 – 10.048)	3.631 (3.383 – 3.878)
NOEC	1.563	0.60
LOEC	3.125	1.21
Yield – based on dry weight		
E_yC₁₀	11.409 (10.048 – 12.769)	4.404 (3.879 – 4.929)
E_yC₂₀	20.455 (18.581 – 22.329)	7.896 (7.172 – 8.619)
E_yC₅₀	62.501 (56.014 – 68.988)	24.125 (21.622 – 26.629)
NOEC	6.25	2.42
LOEC	12.5	4.83

*Calculated on the basis of the content in the test item declared by the Sponsor in the Certificate of Analysis

Validity Criteria

The results are considered valid because the following criteria were satisfied

- The doubling time of frond number in the control was 2.1 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 10.1).
- The average specific growth rate in the control between day 0 and day 7 was 0.321 d⁻¹ (minimum requirement: higher than 0.275 d⁻¹)

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Comments of zRMS:	<p>The study is considered valid. All validity criteria were met.</p> <ul style="list-style-type: none"> • Mortality in the control should not exceed 10 %. • The 24 hour oral LD50 of the positive control (Dimethoate) should meet the specified range: 0.10 to 0.35 µg a.i. /bee. <p>Agreed endpoint:</p> <p>LD₅₀ of Pendimethalin 455 g/L CS >110.83 µg a.i./bee (based on the actual consumed dose).</p>
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Reference: KCP 10.3.1.1.1

Report “Acute oral toxicity study of Pendimethalin 455 g/L CS in Honey bee (*Apis mellifera*)”. K. XXX, 2019, Study code 18-212-G

Guideline(s):	OECD Guideline for the Testing of Chemicals No. 213 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The acute oral toxicity study of Pendimethalin 455 g/L CS (batch number: SCL-60029) was conducted to determine the LD₅₀ values for honeybees. Five doses of the test item were used. These included: 7.5, 15, 30, 60 and 120 µg/bee (7.40, 14.22, 29.50, 58.27 and 117.08 µg a.i./bee actual consumed dose) and a control (0.0 µg/bee). ~~The range of doses was selected on the basis of the preliminary test results.~~ Each group of 10 bees (3 replicates containing 10 bees each) was fed with 200 µL of a 50% sucrose solution, containing the test item at the doses enumerated above, using a micropipette. During the entire experiment, the insects were caged in groups of 10.

Based on the results of the range finding test, a limit test was conducted with the nominal dose of 120 µg a.i./bee (110.83 µg a.i./bee actual consumed dose). A control group of ten bees were treated with 50% w/v Sucrose solution in RO water.

The general condition of the test honeybees and the reliability of the test conducted on them were controlled using the recommended reference item - dimethoate.

After the administration, the insects were observed for mortality and other signs of toxicity. These observations were made 4 hours after the beginning of the treatment and then every 24 hours after the beginning of the treatment. The acute oral toxicity test ended after the 48-hour exposure.

Dose consumption data – Limit test

Nominal dose (µg a.i./bee)	Weight of the test item in diet (µg a.i./10 bees)	Mean weight of the diet consumed (g)	Mean test item consumed (µg a.i./bee)	Consumption* in %
Pendimethalin 455 g/L CS				
120	1200	0.2107	110.83	94.22

* Diet consumption comparison with treated and control group.

Results

Acute oral toxicity on honeybees (*Apis mellifera L.*) – range finding test

Dose	N° of tested bees	Mortality after 48 h		LD ₅₀
		Total		
[µg a.i./bee] ^b		[no.]	[%]	[µg a.i./bee] ^b
0.0	30	0	0.0	
7.5	30	0	0.0	>110.83
15	30	0	0.0	
30	30	0	0.0	
60	30	0	0.0	
120	30	0	0.0	

Findings

- At the end of 48 hours observation, 13.3%, 60.0% and 96.7% cumulative mortality was observed in the tested doses of 0.06, 0.13 and 0.29 µg a.i./bee respectively (positive control).
- Since there no mortality observed in the limit test dose, the 48 hours acute oral LD₅₀ of Pendimethalin 455 g/L CS is cannot be calculated and could be considered as greater than 110.83 µg a.i./bee (based on the actual consumed dose)
- The range finding test showed no mortality and No bees exhibited abnormal behaviour in the control group and in all the tested nominal doses of 7.5, 15, 30, 60 and 120 µg a.i./bee during 4, 24 and 48 hours test period after dosing.
- Based on the results of the limit test, the 48 hours acute oral LD₅₀ of **Pendimethalin 455 g/L CS** is found to be **greater than 110.83 µg a.i./bee** (based on the actual consumed dose).

Validity criteria

The following validity criteria were met during the test:

- Mortality in the control should not exceed 10 %.
- The 24 hour oral LD₅₀ of the positive control (Dimethoate) should meet the specified range: 0.10 to 0.35 µg a.i./bee.

Conclusion

Based on the results of the limit test, the 48 hours acute oral LD₅₀ of Pendimethalin 455 g/L CS found to be greater than 110.83 µg a.i./bee (based on the actual consumed dose).

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	<p>The study is considered valid. All validity criteria were met.</p> <ul style="list-style-type: none"> • The average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%). • The 24 hour LD₅₀ of the reference item (dimethoate) was 0.12 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee). <p>Agreed endpoints: LD₅₀/48 h contact >100 µg a.i./bee</p>
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Reference:	KCP 10.3.1.1.2
Report	“Acute contact toxicity of Pendimethalin 455 g/L in Honeybees (<i>Apis mellifera</i>)”, K. XXX, 2019, Study code 18-211-G
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method C.17. (2008)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The acute contact toxicity study of Pendimethalin 455 g/L CS (batch No. SCL-60029) was conducted to determine the effects on honeybees. Five doses of the test item were used. These included: 6.25, 12.5, 25, 50 and 100 µg/honeybee. ~~The range of doses was selected on the basis of the preliminary test results.~~

The test item was diluted in distilled water and applied to the dorsal part of thorax using a microapplicator. The volume was 1 µL/bee. During the entire experiment, the insects were caged in groups of 10 under controlled conditions of the temperature and the humidity.

Based on the results of the range finding test, a limit test was conducted with the nominal dose of 100 µg a.i /bee. A control group of ten bees were treated with RO water and a vehicle control group of ten bees were treated with 0.1% w/v Tween 80 in RO water.

The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the honeybees and the precision of the test procedure.

After the application, the insects were observed for mortality and signs of toxicity. These observations were made 4, 24, and 48 hours after the beginning of the treatment. The acute contact toxicity test finished after the 48-hour observation.

Results

Acute contact toxicity on honeybees (*Apis mellifera* L.) – range finding test

Dose	N° of tested bees	Mortality after 48 h		LD ₅₀
		Total		
[µg a.i./bee] ^b		[no.]	[%]	[µg a.i./bee] ^b
0.0	30	0	0.0	>100
6.25	30	0	0.0	
12.5	30	0	0.0	
25	30	0	0.0	
50	30	0	0.0	
100	30	0	0.0	

Findings

- Mortality of the control group after 48 hours of exposure was 0%.
- The range finding test showed no mortality and No bees exhibited abnormal behaviour in the control groups and in all the tested nominal doses of 6.25, 12.5, 25, 50 and 100 µg a.i. /bee during 4,

24 and 48 hours test period after dosing.

- At the end of 24 hours observation, lethargic behaviour was exhibited in the tested dose of 0.06 µg a.i /bee whereas, rest of the bees in the tested dose of 0.13 µg a.i /bee appeared normal. At the end of 48 hours observation, lethargic behaviour was exhibited in the tested doses of 0.06 and 0.13 µg a.i /bee respectively

Validity criteria

The following validity criteria were met during the test:

- The average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%).
- The 24 hour LD₅₀ of the reference item (dimethoate) was 0.12 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee).

Conclusion

The median lethal dose LD₅₀/48 h contact was found to be greater 100 µg a.i./bee

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	The study is considered valid. All validity criteria were met. Agreed endpoints: LDD ₅₀ = 56.58 µg/bee/day LC ₅₀ = 1533.1 mg/kg NOEC = 666.7 mg/kg NOEDD = 25.8 µg/bee/day
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Reference Report	KCP 10.3.1.2 Pendimethalin Technical: Honeybees (<i>Apis mellifera</i> L.), Chronic Oral Toxicity Test". XXX, A. 2017, B/107/17. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	Proposal for a new OECD Guideline for Testing Chemicals (October 2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:

Description:	Pendimethalin Technical
Production batch:	-
A.i. content:	98.09% (w/w)

Test system:

	Species:	<i>Apis mellifera</i>
	Strain:	carnica
	Age:	freshly emerged worker honeybees from the same queen-right colony
	Average weight:	-
	Average length:	-
	Source:	an apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna
	Acclimation period:	3 days
	Diet:	50% solution of sucrose in water (w/v)
Experimental conditions:	Temperature:	31 – 33°C
	Humidity:	60 – 69%
	Hardness:	-
	pH:	-
	Light and photoperiod:	24h darkness (except during observations).
	Loading:	3 replicates per dose, 10 bees per replicate
	Test procedure:	Each group of bees was fed with 2 mL of a 50% sucrose solution containing the reference item or the test item for 10 days.
Experimental period:		10d

Test design and treatment

Cages (8 x 10 x 6 cm) made of stainless steel with the front removable part made of glass and a hole on the upper wall of each cage. The hole was used to introduce the insects into the test cages. Then, it is capped with a feeder (5-mL syringe) containing a sucrose solution treated with the test item or a sucrose solution alone.

In total, 8 treatment groups were set up: 5 doses of the test item (5.00, 10.00, 20.00, 40.00 and 80.00 µg/bee/day), two untreated control groups and 1 dose of the reference item with 3 replicates per dose and 10 insects per replicate.

Food consumption (mg/bee/day) in each study group was determined by weighing the feeders with a sucrose solution and dividing the amount of food by the number of surviving bees in the previous observation time. The doses of the test item (µg/bee/day) consumed by the bees were calculated directly from treated 50% sucrose solution consumption, the concentrations of the test item, and the density of the solutions at each concentration.

Mortality results were analyzed using the log-probit method, in order to determine the LDD₅₀, LC₅₀, NOEDD and NOEC values. The statistical analysis of the data on mortality was conducted using the ToxRat Professional software.

Results

The results are summarized below.

Concentration		Consumed concentration		Number of tested bees [no]	Mortality						LC ₅₀	LDD ₅₀
[mg/kg]	[µg/bee/day] [µg/30 mg/day]	[mg/kg]	[µg/bee/day] [µg/30 mg/day] ^a		Number of dead bees [no.]			Total				
	replicates				No.	[%]	Corr. ^b [%]	[mg/kg]	[µg/bee/day]			
				I			II			III		
Pendimethalin Technical												
0.0 (Control)				30	1	1	0	2	6.7	-		
0.0 (Control with acetone)				30	0	2	1	3	10.0			
166.67	5.00	166.67	6.45	30	1	1	0	2	6.7	(1276.85-1889.89)	56.58 (48.11-66.76)	
333.33	10.00	333.33	11.71	30	1	0	0	1	3.3			(-3.7) *
666.67	20.00	666.67	25.76	30	2	2	1	5	16.7			(-7.4) *
1333.34	40.00	1333.33	58.34	30	7	6	3	16	53.3**			7.4
2666.68	80.00	2666.67	79.99	30	8	9	7	24	80.0**			48.2**
NOEC				666.7 [mg/kg]								
NOEDD				25.8 [µg/bee/day]								
Dimethoate												
Concentration		Consumed concentration										
[mg/kg]	[µg/bee/day] [µg/30 mg/day]	[mg/kg]	[µg/bee/day] [µg/30 mg/day]									
1.67	0.05	1.67	0.08	30	8	8	9	25	83.3	82.1	not determined	

a: ingested doses were calculated on the basis of the concentrations of the test item and average sucrose solution consumption

b: mortality corrected using Abbott's formula [7]

*: mortality in test item was higher from mortality of control

** : statistically significant difference (Step-down Cochran-Armitage Test Procedure, p<0.05)

Conclusion

The validity criterion concerning mortality was met, because mortality in the control and in the control wit acetone was ≤ 15.0% (6.7 and 10.0 %) after 10 days of exposure [1].

The percentages of corrected mortality [7] of the honeybees exposed to the test item, Pendimethalin Technical at the concentrations of 166.67; 333.33; 666.67, 1333.33, 2666.67 mg/kg (6.45, 11.71, 25.76, 58.34 and 79.99 µg/bee/day) were (-3.7), (-7.4), 7.4, 48.2 and 77.8%, respectively. The negative mortality value indicate higher mortality in group treated with the test item than the control with acetone group. Mortality of the group treated with the test item at the doses 79.99 and 58.34 µg/bee/day (2666.67 and 1333.33 mg/kg), was statistically significantly different from the control group (Step-down Cochran-Armitage Test Procedure, p< 0.05).

On the basis of the obtained mortality results the LDD₅₀ value, is 56.58 µg/bee/day. The LC₅₀ is 1533.1 mg/kg, the NOEC is 666.7 mg/kg and NOEDD is 25.8 µg/bee/day were determined.

The validity criterion concerning mortality of the honeybees exposed to the reference item, dimethoate was met, because corrected mortality was 82.1% after 10 days of exposure. The results obtained in the reference item group showed that the insects were sensitive to dimethoate.

Average consumption of a 50% sucrose solution in the control group was 34.37 mg/bee/day and in the control with acetone 34.31 mg/bee/day. Average consumption in the groups treated with the test item at the concentrations of 166.67; 333.33; 666.67, 1333.34, 2666.68 mg/kg (5.00, 10.00, 20.00, 40.00 and 80.00 µg/bee/day) were 38.67, 35.13, 38.65, 43.75, 30.00, respectively.

Average consumption of a 50% sucrose solution containing the reference item at the concentration of 0.05 µg/bee (1.67 mg/kg) was 45.35 mg/bee/day.

In all study groups average consumption of a 50% sucrose solution was 37.53 mg/bee/day. On the basis

of average consumption of a 50% sucrose solution in the study groups, it may be concluded that each bee treated with the test item at the concentration of 5.0, 10.0, 20.0, 40.0 and 80.0 µg/30 mg/day of Pendimethalin Technical ingested 6.45, 11.71, 25.76, 58.34 and 79.99 µg of the test item/day. The ingested concentrations were 166.67; 333.33; 666.67, 1333.33, 2666.67 mg/kg, respectively.

Each insect from the group fed with a 50% sucrose solution containing the reference item at the concentration of 0.05 µg/30 mg of emulsion ingested 0.08 µg of dimethoate/day (1.67 mg/kg).

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Comments of zRMS:	The study is considered valid. All validity criteria were met. Agreed endpoints: ED ₅₀ (successful adult emergence up to D22) =5.8 µg a.i./larva, which is equivalent to an EC ₅₀ of 36.7 mg a.i./kg food. The ED ₁₀ and ED ₂₀ (D22) =0.5 and 1.3 µg product/larva, respectively, which is equivalent to an EC ₁₀ and EC ₂₀ (D22) of 2.9 and 8.0 mg product/kg food, respectively. NOED =0.64 µg a.i./larva and the corresponding NOEC =4.0 mg a.i./kg food.
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Reference Report	KCP 10.3.1.3 Pendimethalin Technical - Repeated exposure of honey bee (<i>Apis mellifera</i> L.) larvae under laboratory conditions (<i>in vitro</i>). XXX, 2017, 17 48 BLC 0083. BioChem agrar
Guideline(s):	OECD (2016), Guidance Document on Honey Bee Larval Toxicity Test following Repeated Exposure, Environment Monograph, Series on Testing and Assessment No. 239, OECD, Paris
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:

Description: Pendimethalin Technical
 Production batch: SCL - 5983
 A.i. content: 98.09% (w/w)

Test system:

Species: *Apis mellifera iberiensis* Engel
 Strain: *Hymenoptera, Apoidea*
 Age: one day old larvae
 Average weight: -
 Average length: -
 Source: from three healthy and queen-right colonies; source: Beekeeper Joaquin Cordero, Paseo de Colón No. 19, 41370 Cazalla (Sevilla), Spain

Experimental conditions:

Acclimation period: 3 days
 Diet: 50% aqueous sugar solution and 50% royal jelly

Temperature: 34.0 – 35.0°C
 Humidity: Day 1 – Day 8: 90 - 100%
 Day 8 – Day 15: 76 – 82%
 Day 15 – Day 22: 52 – 59%

Hardness: -
 pH: -
 Light and photoperiod: 24h darkness (except during observations).
 Loading: 3 replicates per dose, 10 bees per replicate
 Test procedure: On 4 successive days (day 3 to day 6) the larvae were repeatedly exposed to Pendimethalin Technical diluted in the larval food.

Experimental period: 48h

Test design and treatment

Polystyrene grafting cells in 48-well cell culture plates. During 4 successive days the larvae were repeatedly exposed to Pendimethalin Technical diluted in the larval food (aqueous sugar solution mixed with royal jelly). After the applications no additional feedings of the larvae took place.

In total, 8 treatment groups were set up: 5 doses of the test item (63.0, 25.3, 10.1, 4.0 and 1.6 mg a.i./kg food), two untreated control groups and 1 dose of the reference item with 3 replicates per dose and 12 larvae per replicate.

Assessments of cumulated larval mortality were done on days 4, 5, 6, 7 and 8. Additionally, other observations such as small body size or large quantities of remaining food on day 8 were noted. Pupal mortality was assessed at day 15 and emergence of adults was evaluated at day 22.

Descriptive statistics; Step-down Cochran-Armitage Test (one-sided greater, alpha = 0.05) were used for determination of NOED/NOEC. ED/EC_{10/20/50} values were determined using the Weibull analysis using linear max. likelihood regression.

Results

The results are summarised below.

Toxicity of Pendimethalin Technical to larvae of *Apis mellifera* L.

Treatment group	Test solution ID	Dose [µg a.i./larva]	Concentration [mg a.i./kg food]	On day 8			On day 22				
				Larval mortality Day 3 – Day 8		Mean OO	Pupal mortality Day 8 – Day 22		Total mortality Day 3 – Day 22		Adult emergence rate
				abs.	corr.		abs.	corr.	abs.	corr.	
Control	AC	-	-	2.8	0.0	0.0	8.6	0.0	11.1	0.0	88.9
	BC	-	-	0.0	-	0.0	8.3	0.0	8.3	0.0	91.7
Test item	AT	10.0	63.0	2.8	-	0.0	62.9	59.5	63.9*	60.6	36.1
	BT	4.0	25.3	2.8	-	0.0	45.7	40.8	472*	42.4	52.8
	CT	1.6	10.1	2.8	-	0.0	37.1	31.4	38.9*	33.3	61.1
	DT	0.64	4.0	0.0	-	0.0	16.7	9.1	16.7	9.1	83.3
	ET	0.26	1.6	0.0	-	0.0	11.1	3.0	11.1	3.0	88.9
Reference item	AR	7.6	48.0	75.0	74.3	0.0	77.8	75.7	94.4	93.8	5.6
Treatment				Endpoint: Successful adult emergence			Up to day 22				
Test item doses				ED ₅₀ [µg a.i./larva] ² (95% CL)			5.8 (3.9 – 8.7)				
				ED ₂₀ [µg a.i./larva] ² (95% CL)			1.3 (0.8 – 2.2)				
				ED ₁₀ [µg a.i./larva] ² (95% CL)			0.5 (0.2 – 1.1)				
				NOED [µg a.i./larva] ¹			0.64				
Test item concentrations				EC ₅₀ [mg a.i./kg food] ² (95% CL)			36.7 (24.7 – 54.6)				
				EC ₂₀ [mg a.i./kg food] ² (95% CL)			8.0 (4.7 – 13.6)				
				EC ₁₀ [mg a.i./kg food] ² (95% CL)			2.9 (1.3 – 6.6)				
				NOEC [mg a.i./kg food] ¹			4.0				

Results are averages based on 3 replicates, containing 12 larvae each; see Appendix 4 for details
correct.: corrected mortality (according to SCHNEIDER-ORELLI 1947): reference item was corrected by AC and test item was corrected by BC; negative values are set to “0”; calculations are performed with non-rounded values; CL...confidence limit

*Statistically significant difference in pairwise comparison between treatment and untreated control

(Step-down Cochran-Armitage Test; alpha=0.05; one sided greater)

OO: Other observations (e.g. remaining food)

¹ Step-down Cochran-Armitage Test; alpha=0.05; one sided greater

² Weibull analysis using linear max. likelihood regression

On D8, larval mortalities of 2.8 and 0.0% were observed in the both controls AC and BC, respectively. Pupal mortality (between D8 and D22) was 8.6% in the control AC and 8.3% in the solvent control BC. The control groups showed a total mortality of 11.1% (AC), and 8.3% (BC), respectively, at D22. In the test item groups larval mortalities at D8 ranged between 0.0 and 2.8%. Pupal mortalities ranged between 11.1 and 62.9% in the test item treatment groups. Total mortalities at D22 ranged between 11.1 and 63.9%. Mortality in the reference (AR) was above 50% across all replicates on D8, being 75.0%.

On D8, none of all remaining larvae treated with test item showed remaining food or other observations such as a smaller body size.

In the final assessment at D22, adult emergence rates of 88.9% (AC) and 91.7% (BC) were determined for the honey bees in the control groups. In the test item groups the adult honey bees emerged at rates ranging between 36.1% and 88.9% following an application of 10.0, 4.0, 1.6, 0.64 and 0.26 µg a.i./larva, respectively, during the larval stages. On D22, larvae treated with 10.0, 4.0 or 1.6 µg a.i./larva showed a mortality, which was statistically significantly increased if compared to the solvent control.

The concentrations of active substances in the test item stock solutions A and E ranged between 94% and 107% of the respective nominal concentration. No test item was detected in the control specimen.

Because control mortality was ≤ 15% on D8, corrected cumulated mortality in the reference item dose of 7.6 µg a.i./larva was ≥ 50% on D8 and adult emergence in the control was ≥ 70% on D22, the study can be regarded as valid.

Conclusion

In a repeated exposure larval toxicity study with Pendimethalin Technical, the ED₅₀ (successful adult emergence up to D22) was calculated to be 5.8 µg a.i./larva, which is equivalent to an EC₅₀ of 36.7 mg a.i./kg food.

The ED₁₀ and ED₂₀ (D22) was determined to be 0.5 and 1.3 µg product/larva, respectively, which is equivalent to an EC₁₀ and EC₂₀ (D22) of 2.9 and 8.0 mg product/kg food, respectively.

The respective NOED was 0.64 µg a.i./larva and the corresponding NOEC was 4.0 mg a.i./kg food.

A 2.3.1.4	KCP 10.3.1.4	Sub-lethal effects
A 2.3.1.5	KCP 10.3.1.5	Cage and tunnel tests
A 2.3.1.6	KCP 10.3.1.6	Field tests with honeybees
A 2.4	KCP 10.3.2	Effects on non-target arthropods other than bees
A 2.4.1.1	KCP 10.3.2.1	Standard laboratory testing for non-target arthropods

Comments of zRMS:

Reference:	KCP 10.3.2.1-01
Report	Toxicity of Pendimethalin 40% SC to the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) under worst case laboratory conditions. XXX, L., 2009, C33732. Harlan.
Guideline(s):	Blümel, S.F.M., Bakker, B., Baier, K., Brown, M.P., Candolfi, A., Gossmann, C., XXX, B. Jäckel, K., Nienstedt, K.J., Schirra, A., Ufer, A., Walters Dorfer (2000).
Deviations:	None
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

The toxicity of the test item Pendimethalin 40% SC to the predatory mite *Typhlodromus pyri* was determined in a 7-day test under worst case laboratory conditions (i.e. glass plates as substrate) according to the IOBC/WPRS Guidelines.

The test item rates were 0.8, 1.6, 3.2, 6.4 and 12.8 kg a.i./ha corresponding to 2.0, 4.0, 8.0, 16 and 32 L product/ha. A control (i.e. deionized water) and a reference item treatment (i.e. Roxion®, containing 400 g dimethoate/L) was tested in parallel. Four replicates per treatment were set up. The mortality values of the control and reference item were within the study validity criteria. The mortality was observed 7 days after the exposure in the treated and control groups.

Results

The biological study results were as follows:

Treatment (kg ai/ha)	Mortality after 7 days of exposure	
	(% ± SD)	Corr [*]
Control	6.3 ± 6.3	-
0.8	60 ± 12	57
1.6	90 ± 11	89
3.2	81 ± 8.5	80
6.4	100 ± 0.0	100
12.8	99 ± 2.5	99
Reference item	99 ± 2.5	99

* Mortality corrected by means of the formula of Abbott with the improvements by Schenider Orelli.

Conclusion

The endpoints of Pendimethalin 40% SC for this study are the following:

	Endpoint	Endpoint
	kg ai/ha	L product/ha
LR50 (7 days mortality):	0.43	1.07
95% confidence interval:	0.018 – 10	0.045 – 26

Comments of zRMS:

Reference:	KCP 10.3.2.1 02
Report	Toxicity of Pendimethalin 40% SC to Adults of the Parasitoid Wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) Under Worst Case Conditions in the Laboratory. XXX, L. 2009, C33721. Harlan Laboratories Ltd.
Guideline(s):	IOBC (MEAD BRIGGS et al. 2010), Guidelines to evaluate side effects of plant protection products to non target arthropods, IOBC/WPRS, Gent, p. 13-25
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

The purpose of this study was to assess the lethal effects of the test item Pendimethalin 40% SC on survival of the parasitoid wasp *Aphidius rhopalosiphi* De Stephani Perez (Hymenoptera: Braconidae) under worst case laboratory conditions.

The study consisted of seven treatment groups: a control, five test item rates (0.4, 0.8, 1.6, 3.2 and 6.4 kg a.i. Pendimethalin/ha) and a reference item treatment (0.3 mL product/ha). The test was performed with four replicates per control, test item treatment and reference item treatment, respectively. Ten wasps per replicate, including a minimum of 5 females, were used. The previously selected wasps were kept in small tubes with water supply before application.

Two glass plates for each replicate were held apart by a shallow untreated squared frame (internal dimensions: approx. 9.5 × 9.5 cm and approx. 2 cm high), made of stainless steel. Three holes on each of the four sides provided sufficient air ventilation. The holes were covered (except two) by a fine gauge mesh to prevent escaping of the wasps. One hole was left uncovered for the introduction of the parasitoids and was later sealed with a stopper. The solutions were sprayed onto the glass plates of each replicate by means of an adequate spraying apparatus

After approximately 2, 24 and 48 hours of exposure, the condition of the wasps in the treated test units was assessed. Wasp mortality was calculated for each treatment as the number of moribund and dead wasps combined relative to the number of wasps at study initiation.

Results

Treatment group	Rates [kg a.i./ha]	Mortality					
		2 h		24 h		48 h	
		mean [%]	corr. ^a	mean [%]	corr. ^a	mean [%]	corr. ^a
Control	—	0.0	-	3.3	-	3.3	-
Pendimethalin 40% SC	0.4	0.0	0.0	5.0	1.7	40.0	38.0
	0.8	2.5	2.5	10.0	6.9	53.0	51.0
	1.6	0.0	0.0	7.5	4.3	83.0	82.0
	3.2	0.0	0.0	13.0	9.5	90.0	90.0
	6.4	0.0	0.0	20.0	17.2	88.0	87.0
Reference item (0.3 mL/ha)		2.5	2.5	95.0	94.8	100.0	100.0

a: Mortality corrected by means of the formula of Abbott with improvements by Schneider-Orelli.

Conclusion

The endpoints of Pendimethalin 40% SC for this study are the following:

	Endpoint
	kg ai/ha
LR50 (48 hours mortality):	0.58
95% confidence interval:	0.042 – 8.2

A 2.4.1.2 KCP 10.3.2.2 Extended laboratory testing, aged residue with non-target arthropods

Comments of zRMS:	
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Reference:	KCP 10.3.2.2 01
Report	Pendimethalin 40% SC: Toxicity to the Aphid Parasitoid <i>Aphidius rhopalosiphi</i> De Stefani Perez (Hymenoptera, Braconidae) under Extended Laboratory Conditions". XXX, S. 2018, S18-05327. Trialcamp S.L.U.
Guideline(s):	IOBC (MEAD BRIGGS et al. 2010), ESCORT I Guidance Document BARRETT et al., 1994) and ESCORT II Guidance Document (CANDOLFI et al., 2001)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

~~The objectives of the study were to determine the effects of Pendimethalin 40% SC on mortality and reproduction of the parasitoid *Aphidius rhopalosiphi* under extended laboratory conditions (exposure to barley seedlings) and to establish the rate producing 50 % mortality (LR₅₀) and 50 % reduction in reproduction rate (ER₅₀), where possible.~~

The study was conducted as a rate response test with seven treatment groups, including the test item at five application rates (1.2285, 2.4570, 4.9140, 9.8280 and 19.6560 L test item/ha equivalent to 500.00, 1000.00, 2000.00, 4000.00 and 8000.00 g Pendimethalin/ha), the reference item (Dimethoate 40 %, EC) at a single application rate and the control (applied with deionised water). Each treatment group included 6 replicates, containing 5 female adults. For the reproduction test 15 individually confined female survivors (alive or affected) were taken from each treatment group without bias.

Test and reference item were diluted in deionised water and applied with a laboratory track sprayer to barley seedlings. A control group applied with deionised water was included in the study. All applications were performed with a spray volume of 400 L/ha. After assembling of test units five adult female wasps were introduced into each test unit (6 replicates per treatment).

The condition of the test organisms was recorded 2, 24 and 48 hours after introduction. Any change in behaviour with respect to the control was documented if observable (e.g. intense grooming, inactivity). The appearance of any product residue on the leaves (e.g. oily, thick powder, etc.) was checked. The conditions of the wasps were classified as live, affected, moribund or dead.

Reproduction was assessed only for treatment groups with a corrected mortality $\leq 50\%$. After the 48-hour mortality assessment the surviving females were removed from the exposure units and transferred individually to the reproduction units. After an approximately 24 hour parasitisation period females were removed from the reproduction units and their condition (alive, dead or not recovered) were recorded. The number of parasitised aphids was counted in each replicate 11 days after the end of the parasitisation period (14 days after start of exposure).

Results

Treatment group	Rates Test item [g a.i./ha]	Mean mortality [%]	Corrected mortality [%]	Reproduction [mummies/female]	Reduction in reproduction rate [%]
Control	—	0.00	—	25.53	—
Pendimethalin 40% SC	500.00	3.33	3.33	17.73	30.55
	1000.00	16.67	16.67	18.54	27.40
	2000.00	3.33	3.33	14.13**	44.65
	4000.00	23.33*	23.33	20.20	20.89
	8000.00	26.67*	26.67	15.80	38.12

a.i.= active ingredient

*= Significantly different to the control group (Step-down Cochran Armitage Test, exact sig., $\alpha=0.05$)

**= Significantly different to the control group (Dunnett's multiple t test, exact sig., $\alpha=0.05$)

The reference item caused a corrected mortality of 80.00 %.

	Endpoints, [g active ingredient /ha]
LR ₅₀	n.d.; [> 8000.00]
ER ₅₀	n.d.; [> 8000.00]
NOER (mortality)	2000.00
NOER (reproduction)	≥ 8000.00
NOER (repellency)	≥ 8000.00

n.d.: not determined as corrected mortality and reduction on reproduction were below 50% up to 8000.00 g a.i. /ha (relative to the control)

Findings

- Mortality observed was below 50% up to the tested rate of 8000.00 g active ingredient /ha. Pendimethalin 40% SC caused 26.7 % of mortality as maximum at the rate of 8000.00 g active ingredient (a.i.)/ha. As a consequence, statistical analyses regarding mortality data and Standard Probit analysis (Finney, 1971) were not performed in order to obtain the 48 h LR₅₀ value. Therefore, the LR₅₀ was estimated to be equal or higher than 8000.00 g active ingredient /ha.
- The mortality was significantly reduced compared to the control at the rates of 4000.00 and 8000.00 g a.i./ha (Step-down Cochran Armitage Test Procedure, $\alpha = 0.050$; one-sided greater). Therefore, the NOER for lethal effects was determined to be equal to 2000.00 g a.i./ha.
- The mortality in the reference item was 80.00 % (80.00 % corrected to control). Signs of intoxication (uncoordinated movements compared to control) were not observed after 48 h of exposure. The appearance of any product residue (e.g. oily, thick powder, etc.) on the leaves was not observed in the evaluation times, 2, 24 and 48 hours after the exposure.
- Reduction on reproduction values (mummies per female) compared to the control with the test item up to and including the rate of 8000.00 g active ingredient (a.i.)/ha was less than 50 %; actual maximum 44.65 % at the rate of 2000.00 g a.i./ha. Therefore, the ER₅₀ based on the reproductive capacity (estimated application rate at which the fecundity is reduced by 50 % as compared to the control) was estimated to be greater than the tested rate of 8000.00 g a.i./ha.
- Over the 24 h parasitisation period two, four and three female wasps died at the tested rates of 1000.00, 4000.00 and 8000.00 g a.i./ha, respectively. The number of mummies per female was

significantly reduced compared to the control at the tested rate of 2000.00 g a.i./ha (Dunnett's multiple t test, one-sided smaller, $\alpha=0.05$). However, the number of mummies per female was not significantly reduced at the higher tested rates of the test item, 4000.000 and 8000.00 g a.i./ha. Therefore, the NOER for sublethal effects was determined to be equal or higher than the tested rate of 8000.00 g a.i./ha.

Conclusion

Mortality less than 10 % (0.00 %) and acceptable reproductive capacity (25.53 mummies per female) were observed during the 48 hour exposure period and subsequent fecundity assessment in the control group. The toxic reference item caused 80.00 % corrected mortality and confirmed the sensitivity of the test species and the test conditions.

Under these extended laboratory test conditions, LR_{50} was estimated to be greater than the maximum tested rate of 8000.00 g active ingredient/ha.

ER_{50} based on the reproductive capacity (estimated application rate at which the fecundity is reduced by 50 % as compared to the control) was estimated to be greater than the tested rate of 8000.00 g active ingredient/ha.

Therefore, the NOER for lethal effects was estimated to be equal to 2000.00 g active ingredient/ha. The NOER for sublethal effects (fecundity) was determined to be equal or higher than the tested rate of 8000.00 g active ingredient/ha.

Comments of zRMS:	
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Reference KCP 10.3.2.2-02

Report Pendimethalin 40 % SC: Toxicity to the Predatory Mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) after Exposure to Freshly Applied and Aged Spray Deposits under Extended Laboratory Conditions". XXX, 2018, S18-05605. Trialecamp S.L.U.

Guideline (S) IOBC (BLÜMEL et al., 2000) modified, XXX C. et al., 2001 and Pia Ternes et al., 2001

Desviations No

GLP Yes

Acceptability Yes

Duplication (if vertebrate study) No

Material and methods

The objective of the study was to determine the effects of freshly applied and aged spray deposits of Pendimethalin 40 % SC on the mortality and reproduction on the predatory mite *Typhlodromus pyri* under extended laboratory conditions on maize leaves (*Zea mays*).

Protonymphs of *T. pyri* were exposed to dried spray residues of Pendimethalin 40 % SC on maize leaves. The study was conducted as an aged residue test with three exposure periods (0, 7 and 14 DAA1) and four treatment groups, including the test item at two application rates (2000.0 and 2480.0 g a.i./ha), the reference item (Dimethoate 40 % EC) at a single application rate and the control (applied with tap water). Moreover, the reference item was applied at each aging period on the plants. Each treatment group in-

cluded 5 replicates containing 20 impartially selected protonymphs. The mites were exposed on the maize leaves, from the treated plants, for 14 days after each exposure.

The mortality was assessed on days 1 and 7 of each exposure. Dead and surviving mites were counted. The number of escaped mites was determined. Dead mites were removed after counting. Any change in behaviour with respect to the control was recorded if observable. All assessments were conducted using a stereomicroscope. Thus, per each replicate, the combined numbers of escaped and dead individuals were noted as number of responding individuals out of a total of 20 individuals. The glued individuals were assessed to observe the repellence effect. The cumulative number of responding individuals (escaped and dead individuals) within 7 days has been used to determine the overall mortality.

Reproduction was assessed only for treatment groups with a corrected mortality $\leq 50\%$; in this study, with the rates 2000.0 and 2480.0 g active ingredient/ha, and at 0, 7 and 14 days ageing periods. On day seven of exposure the sex of the test organisms was determined by the shape and size of the body (females: big, bulging, pear shaped body; males: small, oval flat body). The sex ratio was always above 5 females to 1 male, therefore, it was not necessary to be adapted for the treatments by transferring males within the treatment group. The number of offspring per female was determined by counting the number of females and eggs/larvae on days 9, 11 and 14. Eggs laid until day seven inclusive were removed from the test arena and were not counted. Males and females were counted and the number of eggs and larvae was determined. Dead animals, eggs and larvae were removed after counting. All assessments were conducted using a stereomicroscope.

Results

The tables below present the cumulative juvenile mortality, the rate of escaping and the rate of immature individuals of *Typhlodromus pyri* (protonymphs) after the 7 day exposure on treated maize leaves in the different bioassays or exposures.

Mortality and reproduction of *T. pyri* in the laboratory test

Exposure 0 DAA1									
Product	Rate	D+E ⁽²⁾	Initial number	Mort. [%]	Corrected Mortality [%]	SD ⁽³⁾	Dead Ind. [%]	Escaped Ind. [%]	Inmature Ind. [%]
Water control	0	10	100	10.00	—	6.12	1.00	9.00	0.00
Pendimethalin 40 % SC	2000	11	100	11.00	1.11	6.52	0.00	11.00	0.00
Pendimethalin 40 % SC	2480	25	100	25.00 [‡]	16.67	10.00	2.00	23.00 [‡]	0.00
Dimethoate 40% w/v EC	0.45	97	100	97.00	96.67	4.47	71.00	26.00	0.00
Exposure 7 DAA1									
Product	Rate	D+E ⁽²⁾	Initial number	Mort. [%]	Corrected Mortality [%]	SD ⁽³⁾	Dead Ind. [%]	Escaped Ind. [%]	Inmature Ind. [%]
Water control	0	16	100	16.00	—	7.42	0.00	16.00	0.00
Pendimethalin 40 % SC	2000	27	100	27.00 [‡]	13.10	7.58	4.00	23.00	0.00
Pendimethalin 40 % SC	2480	14	100	14.00	-2.38	6.52	0.00	14.00	0.00
Dimethoate 40% w/v EC	0.45	100	100	100.00	100.00	0.00	67.00	33.00	0.00
Exposure 14 DAA1									
Product	Rate	D+E ⁽²⁾	Initial number	Mort. [%]	Corrected Mortality [%]	SD ⁽³⁾	Dead Ind. [%]	Escaped Ind. [%]	Inmature Ind. [%]
Water control	0	11	100	11.00	—	4.18	2.00	9.00	0.00
Pendimethalin 40 % SC	2000	19	100	19.00	8.99	2.24	1.00	18.00 [‡]	0.00
Pendimethalin 40 % SC	2480	13	100	13.00	2.25	2.74	0.00	13.00	0.00
Dimethoate 40% w/v EC	0.45	89	100	89.00	87.64	17.46	65.00	24.00	0.00

[‡]Statistically significantly increased compared to control (Chi 2x2 Test, one-sided greater, p<0.05)

(1): Rate of the test item in g of active substance (a.i.) per hectare (ha). Rate of the reference item in L of formulated product per hectare (ha).

(2): "D+E" = Dead + Escaped individuals

(3): SD: Standard deviation

The cumulative reproduction of *Typhlodromus pyri* after 14 days of exposure on maize leaves is shown in the table below.

Bioassay: 0 DAA1⁽¹⁾				
Product	Rate [g a.i./ha]	Fecundity [eggs/female]	Standard Deviation	Progeny reduction [%] ⁽²⁾
Water control	0	7.55	1.14	—
Pendimethalin 40 % SC	2000	10.43	1.69	-38.08
Pendimethalin 40 % SC	2480	8.58	1.91	-13.59
Bioassay: 7 DAA1⁽¹⁾				
Product	Rate [g a.i./ha]	Fecundity [eggs/female]	Standard Deviation	Progeny reduction [%] ⁽²⁾
Water control	0	9.19	0.98	—
Pendimethalin 40 % SC	2000	9.68	2.18	-5.34
Pendimethalin 40 % SC	2480	9.27	2.67	-0.89
Bioassay: 14 DAA1⁽¹⁾				
Product	Rate [g a.i./ha]	Fecundity [eggs/female]	Standard Deviation	Progeny reduction [%] ⁽²⁾
Water control	0	6.98	2.07	—
Pendimethalin 40 % SC	2000	7.99	0.78	-14.51
Pendimethalin 40 % SC	2480	5.89	0.74	15.96

Findings

- The effects on mortality were below the trigger value of 50 % with the tested rates of 2000.0 and 2480.0 g active ingredient (a.i.)/ha from the exposure at 0 DAA1. Maximum corrected mortality to the control was detected with the tested rate of 2480.0 g a.i./ha with 16.67 % at the exposure 0DAA1.

- Pendimethalin 40 % SC did not cause statistically significant increase in the mortality of *T. pyri* at the tested rate of 2000.0 g a.i./ha (Chi² 2 x 2 Test, one sided greater, $p \leq 0.05$) at 0 and 14 days old residue. However, Pendimethalin 40 % SC at the rate of 2000.0 g a.i./ha caused statistically significant increase in the mortality of *T. pyri* at 7 days old residue, being this value below the trigger value of 50 % and an effect probably not related with the tested test item.
- Pendimethalin 40 % SC caused statistically significant increase in the mortality of *T. pyri* at the tested rate of 2480.0 g a.i./ha (Chi² 2 x 2 Test, one sided greater, $p \leq 0.05$) at 0 days old residue. Pendimethalin 40 % SC did not cause statistically significant increase in the mortality of *T. pyri* at the tested rate of 2480.0 g a.i./ha (Chi² 2 x 2 Test, one sided greater, $p \leq 0.05$) from 7 days old residue.
- Pendimethalin 40 % SC did not cause statistically significant increase in the rate of escaped of *T. pyri* at the tested rate of 2000.0 g a.i./ha (Chi² 2 x 2 Test, one sided greater, $p \leq 0.05$) at 0 and 7 days old residue. However, Pendimethalin 40 % SC at the rate of 2000.0 g a.i./ha caused statistically significant increase in the rate of escaped of *T. pyri* at 14 days old residue. Pendimethalin 40 % SC did not cause statistically significant increase in the rate of escaped of *T. pyri* at the tested rate of 2480.0 g a.i./ha (Chi² 2 x 2 Test, one sided greater, $p \leq 0.05$) from 7 days old residue.
- The mites in the test item groups showed no abnormal behaviour compared to the control group.
- The mortality in the reference item was higher than 50 % (corrected to control) in the three performed exposures; 96.67 %, 100.00 % and 87.64 % at 0, 7 and 14 DAA1 respectively.
- The reduction of reproduction in tested rates of 2000.0 and 2480.0 g active ingredient (a.i.)/ha was below the trigger value of 50 % from 0 days old residue; maximum reduction was 15.96 % at 14 DAA1 with the rate of 2480.0 g a.i./ha.
- The Pendimethalin 40 % SC did not cause significantly decreased in the reproduction of *Typhlodromus pyri* at the tested rates of 2000.0 and 2480.0 g a.i./ha (Student t Test, one sided smaller, $p \leq 0.05$) at any of the exposures.

Conclusion

Mortality below 20% (maximum 16%) was achieved 7 days after the exposures of the organisms and an acceptable reproductive capacity (minimum 6.98 eggs /female) was assessed over a further 7 days of each exposure in the control groups, meeting the validity criteria. The toxic reference product caused above 50% mortality (corrected relative to control) and confirmed the sensitivity of the test species and the test conditions.

Based on the results of the present study it can be concluded that, residues of the test item “Pendimethalin 40 % SC” applied up to the rates of 2000.0 and 2480.0 g active ingredient/ha cause mortality less than 50 % compared to the control from 0 day old residue.

Based on the results of the present study it can be concluded that, residues of the test item “Pendimethalin 40 % SC” applied up to the rates of 2000.0 and 2480.0 g active ingredient/ha cause reduction on the reproduction of *Typhlodromus pyri* less than 50 % compared to the control from 0 day old residue.

Comments of zRMS:	<p>The study is considered valid. All validity criteria were met.</p> <ul style="list-style-type: none"> - After 48 hours, mortality in the control group was 0.0% (criterion: a maximum of 10.0%). - After 48 hours, mortality in the group treated with the reference item at a rate of 0.4 mL/ha was 90% (criterion: minimum of 50%). - All wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity). - The mean number of mummies per female in the control was 26.5 (criterion: a minimum of 5.0 mummies/female).
Agreed endpoints:	
Study	Parameter (endpoint)

group (appl. rate L/ha)	Mortality after 48 h of exposure			Fecundity			
	Total (%)	LR ₅₀		Mean no. of mummies/female	Fecundity reduction Pr (%)	ER ₅₀	
		[g/ha]	[g a.i./ha]			[g/ha]	[g a.i./ha]
Control	0.0	-	-	26.3	-	-	-
Pendimethalin 455 g/L CS							
3.5	0	13.32 L/ha (6.07 kg a.i./ha)		25.6	10.63 ⁺	14.31 L/ha (6.53 kg a.i./ha)	
5.6	10			24.7	18.73 ⁺		
9.0	33.33 ⁺			23.9	30.38 ⁺		
14.4	50 ⁺			16.1	-*		
23	80 ⁺			12.5	-*		
NOER_{mortality}		5.6 L/ha (2.6 kg a.i./ha)		NOER_{reproduction}		<3.5 L/ha (<1.6 kg a.i./ha)	
Reference item [L/ha]		TAFGOR					
0.4 mL/ha	90	-	-	-	-	-	-

-*: reproduction phase was not performed due to mortality higher than 50% in comparison with the control group
 +: statistically significant differences at p<0.05
 *: Pendimethalin 455 g/L CS

Reference: KCP 10.3.2.2-03

Report: “An extended laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani - Perez)”. K. XXX, 2021, 9006/2021. Bioscience Research Foundation

Guideline(s): ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication No

(if vertebrate study):

SUMMARY

The laboratory test involved the evaluation of the effects of the test item, Pendimethalin 455 g/L CS on mortality and fecundity of the parasitic wasp, *A. rhopalosiphi*. In the definitive test, five rates of the test item were used. These were 3.5, 5.6, 9.0, 14.4 and 23.0 L/ha (1.6, 2.6, 4.1, 6.6 and 10.5 kg Pendimethalin/ha).

Adult wasps were exposed to the test item applied to bean leaves. The parasitoids were confined for 48 h and their condition was assessed after 2, 24, and 48 hours. Then, females which survived the 48-hour exposure to the test item and the ones from the control group were subjected to fecundity assessments. To allow the oviposition, 15 female wasps from the groups treated with the test item and the ones from the control group were individually introduced into the fecundity units containing the barley plants infested with the aphid, *Rhopalosiphum padi*. After the 24-hour oviposition, the wasps were removed from the test arenas. After 12 days, the number of mummies (parasitized aphids in which the wasp pupae were developing) was recorded.

Mortality of the wasps after 48 hours of the exposure and the percentage of fecundity reduction (Pr) relative to the control group recorded 12 days after the oviposition were the endpoints.

To assess the susceptibility of the test system and the sensitivity of the test method, an insecticide, TAF-GOR (30% dimethoate EC) was used as a reference item. The rate of the reference item was 0.4 mL/ha (0.12 g dimethoate/ha). The control group was comprised of wasps having contact with glass plates sprayed with distilled water.

Materials and methods:

Test item: Name: Pendimethalin 455 g/L CS; content: 456 g/L of Pendimethalin (CAS no.: 40487-42-1) as an active ingredient; batch no.: SCL-80067; manufacturing date: May 18th, 2020; expiry date: May 17th, 2022.

Test system: the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Hymenoptera: *Braconidae*

– **age:** Larvae (24 - 48 hours after emerging from mummies)

– **source:** BRF Insectary

Experimental design: 7 test groups:

- a control group (0.0 L/ha)
- Pendimethalin 455 g/L CS at the rate of 3.5 L/ha (1.6 kg Pendimethalin/ha)
- Pendimethalin 455 g/L CS at the rate of 5.6 L/ha (2.6 kg Pendimethalin/ha)
- Pendimethalin 455 g/L CS at the rate of 9.0 L/ha (4.1 kg Pendimethalin/ha)
- Pendimethalin 455 g/L CS at the rate of 14.4 L/ha (6.6 kg Pendimethalin/ha)
- Pendimethalin 455 g/L CS at the rate of 23.0 L/ha (10.5 kg Pendimethalin/ha)
- ROGOHIT at the rate of 0.4 mL/ha (0.12 g a.i./ha)

6 replicates/group
5 wasps/replicate

Test conditions:

- **temperature:** 18.5-21.4°C
- **relative air humidity:** 66-78%
- **photoperiod:** 16 hours light (5200 - 5780) : 8 hours dark

Statistical analyses: Endpoints values for mortality and reproduction were determined by using Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0. The means and standard deviations were calculated using validated Excel Sheets

Endpoints:

- LR₅₀ and ER₅₀value
- NOER mortality and fecundity

RESULTS AND DISCUSSION:

The mortality assessment of the control group showed that mortality after 48 hours of exposure was 0.0% whereas mortality of wasps after 48 hours of exposure to Pendimethalin 455 g/L CS at rates of 3.5, 5.6, 9.0, 14.4 and 23.0 L/ha was 30, 10, 33.33, 50 and 80%, respectively. There was no statistically significant differences in mortality between group treated with the test item at rates of 3.5 and 5.6 l/ha and the control group.

On the basis of the mortality results, the **LR₅₀** is 13.32 L test item/ha (6.07 kg Pendimethalin/ha). The **NOER_{mortality}** value is 5.6 L Test item/ha (2.6 kg Pendimethalin/ha)

The fecundity assessment showed that the mean number of mummies per female in the control group was 26.5%, whereas in the group treated with Pendimethalin 455 g/L CS at rates of 3.5, 5.6, 9.0, 14.4 and 23.0 L/ha was 26.3, 25.6, 24.7, 23.9, 16.1 and 12.5% respectively. Fecundity reduction (Pr) in the group treated with the test item at rates of 3.5, 5.6, 9.0, 14.4 and 23.0 L/ha was 2.78, 6.08, 9.37, 38.73 and 52.41% respectively.

On the basis of the obtained fecundity results, the **ER₅₀** value is 14.31 L test item/ha (6.53 kg Pendimethalin/ha). The **NOER_{reproduction}** value is <3.5 L test item/ha (<1.6 kg Pendimethalin/ha)

On the basis of the obtained results, it can be concluded that Pendimethalin 455 g/L CS had no adverse effects on mortality of the wasps at rates of 3.5 and 5.6 L/ha.

Study group (appl. rate L/ha)	Parameter (endpoint)						
	Mortality after 48 h of exposure			Fecundity			
	Total (%)	LR ₅₀		Mean no. of mummies/female	Fecundity reduction Pr (%)	ER ₅₀	
	[g/ha]	[g a.i./ha]	[g/ha]			[g a.i./ha]	
Control	0.0	-	-	26.3	-	-	-
Pendimethalin 455 g/L CS							
3.5	0	13.32 L/ha (6.07 kg a.i./ha)	5.6 L/ha (2.6 kg a.i./ha)	25.6	10.63 ⁺	14.31 L/ha (6.53 kg a.i./ha)	<3.5 L/ha (<1.6 kg a.i./ha)
5.6	10			24.7	18.73 ⁺		
9.0	33.33 ⁺			23.9	30.38 ⁺		
14.4	50 ⁺			16.1	-*		
23	80 ⁺			12.5	-*		
NOER_{mortality}				NOER_{reproduction}			
Reference item [L/ha]	TAFGOR						
0.4 mL/ha	90	-	-	-	-	-	-

-*: reproduction phase was not performed due to mortality higher than 50% in comparison with the control group

+ : statistically significant differences at p<0.05

*: Pendimethalin 455 g/L CS

TEST VALIDITY CRITERIA

The following validity criteria were met during the study:

- After 48 hours, mortality in the control group was 0.0% (criterion: a maximum of 10.0%).
- After 48 hours, mortality in the group treated with the reference item at a rate of 0.4 mL/ha was 90% (criterion: minimum of 50%).
- All wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity).
- The mean number of mummies per female in the control was 26.5 (criterion: a minimum of 5.0 mummies/female).

All wasps in control group gave offspring (criterion: a maximum of 2 females giving no offspring).

Comments of zRMS:	The study is considered valid. All validity criteria were met.		
	Agreed endpoints:		
	Parameter (endpoint)		
	LR₅₀		ER₅₀

		9.51 L/ha (4.3 kg a.i./ha)		9.02 L/ha (4.1 kg a.i./ha)
	NOER _{mortality}	5.9 L/ha (2.7 kg a.i./ha)	NOER _{reproduction}	5.9 L/ha (2.7 kg a.i./ha)
	TAFGOR	Mortality after 7 days		
	5.0 mL/ha	96.66%		
+ - statistically significant differences at $p < 0.05$ *: the reproduction was not determined due to the mortality higher than 50% in comparison with the control group				

Reference: KCP 10.3.2.2-04

Report “An extended laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on the predatory mite, *Typhlodromus pyri* (Scheuten)”. Dr. V. XXX 2021, 9007/2021. Bioscience Research Foundation

Guideline(s): ESCORT 1 Guidance Document (Barrett K.L. et al., 1994)
 ESCORT 2 Guidance Document (Candolfi M.P. et al., 2001)
 Guidelines developed by the IOBC, BART and EPPO Joint Initiative (Blumel S. et al., 2000)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Not relevant

Materials and methods

The laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on mortality and reproduction of the predatory mite, *T. pyri* (Sch.) was conducted for Sharda Cropchem Ltd, India at Bioscience Research Foundation.

The study was carried out based on the Sponsor recommended rates for the test item as the definite test. There were 5.9, 7.1, 8.5, 10.2 and 12.2 L/ha. A 24 hours old (protonymphal stage) of predatory mites *T. pyri* were exposed to the test item applied to discs and fed with pine pollen (*Pinus* sp.) during the experimental period.

To verify the sensitivity of the mites and the precision of the test procedure, the insecticide, TAFGOR (30% dimethoate) was used as a reference item. The rate of the reference item was 5.0 mL/ha (1.5 g a.i./ha). The control group was treated with distilled water.

Mortality was observed after 7 days of post treatment of the test item. Observations of reproduction in the control and other groups treated with the test item were made after 8, 11 and 14 days post treatment of the test item.

Endpoints based on mortality of *T. pyri* was 7 days and reproduction reduction (Pr) was 14 days post-test item treatment.

Results

The effects of Pendimethalin 455 g/L CS on mortality and reproduction of *Typhlodromus pyri* in the definitive test are summarized below.

Mortality and reproduction of *T. pyri* in the laboratory test

Study group (application rate) (test item L/ha)	Parameter (endpoint)				
	Mortality after 7 days		Reproduction		
	Total [%]	LR ₅₀	Mean no. of eggs/female (Rr) [No]	Reproduction reduction Pr [%]	ER ₅₀
Control	0	-	4.04	-	-
Pendimethalin 455 g/L CS					
5.9	10.0	9.51 L/ha (4.3 kg a.i./ha)	3.60	10.77	9.02 L/ha (4.1 kg a.i./ha)
7.1	20.0 ⁺		3.10	23.27 ⁺	
8.5	30.0 ⁺		2.28	43.44 ⁺	
10.2	58.33 ⁺		-*	-*	
12.2	80.0 ⁺		-*	-*	
NOER _{mortality}		5.9 L/ha (2.7 kg a.i./ha)	NOER _{reproduction}		5.9 L/ha (2.7 kg a.i./ha)
TAFGOR	Mortality after 7 days				
5.0 mL/ha	96.66%				

+ - statistically significant differences at $p < 0.05$

*: the reproduction was not determined due to the mortality higher than 50% in comparison with the control group

Findings

- There were statistically significant differences in mortality between group treated with the test item at rates of 7.1, 8.5, 10.2 and 12.2 L/ha, and the control group.
- For the reference item TAFGOR (Dimethoate 30% EC, w/w), the mortality of mites after 7 days of exposure at the rate of 5.0 mL/ha, was 96.33%, hence the criterion specified in the method description was met. The results showed that the test organisms were sensitive to dimethoate.
- There were statistically significant differences in reproduction rate (Rr) between group treated with the test item at rates of 7.1 and 8.5 L/ha and the control group.

Conclusion

On the basis of the obtained results it can be concluded that Pendimethalin 455 g/L CS had an adverse effect on mortality and reproduction of the mites at rates of 7.1, 8.5, 10.2 and 12.2 L/ha.

Comments of zRMS:	The study is considered valid. All validity criteria were met. <ul style="list-style-type: none"> - The mean number of beetles emerging from the fly pupae in the control was 834.5 (a criterion: >400). - Reduction in reproduction of beetles in the reference group was 90.92 (a criterion: $\geq 50\%$). Agreed endpoints: LR ₅₀ = 9.14 L test item/ha, i.e. 4.17 kg pendimethalin/ha. NOER _{mortality} = 5.9 L test item/L/ha, i.e. 2.7 kg Pendimethalin/ha. ER ₅₀ = 9.44 L test item/L/ha, i.e. 4.30 kg Pendimethalin/ha. The NOER _{fecundity} = 5.9 L test item, i.e. 2.7 kg Pendimethalin/ha.
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Reference: KCP 10.3.2.2-05

Report "A laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on the rove beetle *Aleochara bilineata* (Gyllenhal)". V. XXX, 2021, 8923/2021. Bioscience Research Foundation

Guideline(s): ESCORT 1 (Barrett K.L. *et al.*, 1994)
 ESCORT 2 (Candolfi M.P. *et al.*, 2000)
 Guidelines developed by the IOBC, BART and EPPO Joint Initiative (XXX C. *et al.*, 2000)

Deviations: No

GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Pendimethalin 455 g/L CS; Batch Number SCL-80067; active substance: Pendimethalin, 456 g/L
Test species:	<i>Aleochara bilineata</i> (Gyll), Coleoptera: Staphylinidae from the BFR insectary. The adult beetles used in the study were 1 – 7 days old.
Diet:	<i>ad libitum</i>
Study design:	Number of replicates: 4 per treatment Number of beetles: 20 (10 female and 10 male) per replicate / 80 (40 female and 40 male) per treatment Test duration: 77 days The test item was sprayed onto the sand surface using a suitable spraying chamber. TAFGOR (Dimethoate 30% EC) was used as reference item whereas deionised water was used as control.
Application rates:	Control, 5.9, 7.1, 8.5, 10.2 and 12.2 L test item/ha
Test conditions:	Temperature: 19.5 – 20.5 °C; humidity: 65 – 75%; lighting: 16 h light : 8 h dark; light intensity: 1500 – 1600 lux
Statistical analysis:	Based upon the results, the LR ₅₀ and NOER for mortality and the ER ₅₀ and NOER for fecundity were determined by using a Probit analysis in NCSS (Number Cruncher Statistical System) and one-way ANOVA using GraphPad Prism 8.0. The means and standard deviations were calculated using validated Excel sheets.
Endpoints:	LR ₅₀ , NOER ER ₅₀ , NOER

Results and Conclusions

The effects of Pendimethalin 455 g/L CS on mortality and fecundity of *Aleochara bilineata* in the extended laboratory test are summarized below:

Study group (application rate) (L/ha)	Mortality		Fecundity	
	Total (%)	Corrected# (%)	Offsprings produced (No)	Fecundity reduction (%)
Control				
0.0	1.25	-	834.5	-
Pendimethalin 455 g/L CS				
5.9	6.25	5.06	787.3	5.66
7.1	17.50	16.46 ⁺	699.3	16.21 ⁺
8.5	42.50	41.77 ⁺	474.0	43.20 ⁺
10.2	66.25	65.82 ⁺	342.3	58.99 ⁺
12.2	85.00	84.81 ⁺	188.0	77.47 ⁺
Reference item – TAFGOR (Dimethoate 30% EC)				
5.0 mL/ha	95.00	94.94 ⁺	71.5	90.92 ⁺
Endpoints	LR ₅₀ mortality	9.14 L/ha (4.17 ^a kg a.i./ha)	ER ₅₀ fecundity	9.44 L/ha (4.30 ^a kg a.i./ha)
	NOERmortality	5.9 L/ha (2.7 ^a kg a.i./ha)	NOERfecundity	5.9 L/ha (2.7 ^a kg a.i./ha)

#: Mortality corrected according to Abbott's formula:

Corrected mortality [%] = ((Mt – Mc) / (100 – Mc)) x 100; Mt = Mortality treated, Mc = Mortality control

+ : statistically significant difference between the control and the treatment group at $p < 0.05$

a: Pendimethalin

There were no statistically significant differences in mortality between groups treated with the test item at 5.9 L and the control group (one-way ANOVA, $p < 0.05$).

On the basis of the obtained mortality results, the **LR₅₀** value is 9.14 L test item/ha, i.e. 4.17 kg pendimethalin/ha. The **NOER_{mortality}** value is 5.9 L test item/L/ha, i.e. 2.7 kg Pendimethalin/ha.

For the reference item TAFGOR (Dimethoate 30% EC, w/w), the mortality % of beetles after 28 days of exposure at the rate of 5.0 mL/ha was 94.94%. The results showed that the test organisms were sensitive to dimethoate.

There were no statistically significant differences in fecundity between group treated with the test item at the rates of 5.9 L/ha and the control group (one-way ANOVA, $p < 0.05$).

On the basis of the obtained fecundity results, the **ER₅₀** value is 9.44 L test item/L/ha, i.e. 4.30 kg Pendimethalin/ha. The **NOER_{fecundity}** value is 5.9 L test item, i.e. 2.7 kg Pendimethalin/ha.

On the basis of the obtained results, it can be concluded that Pendimethalin 455 g/L CS had no adverse effects on mortality and fecundity of the beetles at the rates of 5.9 L/ha.

Test validity criteria

The following validity criteria were met during the study:

- The mean number of beetles emerging from the fly pupae in the control was 834.5 (a criterion: >400).
- Reduction in reproduction of beetles in the reference group was 90.92 (a criterion: ≥50%).

Comments of zRMS:	The study is considered valid. All validity criteria were met.						
	-The mortality of the control group after 10 days of exposure was 6.67% (criterion: ≤20%).						
	-For the reference item TAFGOR (Dimethoate 30% EC, w/w), the corrected mortality of <i>C. carnea</i> after exposure at the rate of 0.65 L/ha was 100%, hence the criterion (>50%)						
	-The validity criterion for fecundity was met, because the mean number of eggs per female per day in the control group was 37.85 (criterion: ≥15)						
	-The validity criterion for fecundity was met, because the mean hatching rate in the control group was 97.55% (criterion: ≥70%).						
	Agreed endpoints:						
			Mortality		Reproduction		
	Endpoints	LR ₅₀ _{mortality}		9.46 L/ha (4.31 kg a.i./ha)	ER ₅₀ _{fecundity}		9.24 L/ha (4.21 kg a.i./ha)
		NOER _{mortality}		5.6 L/ha (2.6 kg a.i./ha)	NOER _{fecundity}		<3.5 L/ha (<1.6 kg a.i./ha)
	Reference item – TAFGOR (DIMETHOATE 30% EC)						
0.65	100	100	-				
#: Mortality corrected according to Abbott's formula: Corrected mortality [%] = ((Mt – Mc) / (100 – Mc)) x 100; Mt = Mortality treated, Mc = Mortality control +: statistically significant difference between the control and the treatment group at $p < 0.05$ *: The reproduction was not determined due to the mortality higher than 50% in comparison with the control group							

Reference:

KCP 10.3.2.2-06

Report

“An extended laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on larvae of the green lacewing *Chrysoperla carnea* L. (Neuroptera:

Chrysopidae).”. Mr. K. XXX, 2021, 8924/2021. Bioscience Research Foundation

Guideline(s):	ESCORT 1 (Barrett K.L. <i>et al.</i> , 1994) ESCORT 2 (Candolfi M.P. <i>et al.</i> , 2001) Guidelines developed by the IOBC/WPRS (Candolfi M. P. <i>et al.</i> , 2001)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Pendimethalin 455 g/L CS; Batch Number SCL-60067; active substance content: Pendimethalin, 456 (g/L)
Test species:	<i>Chrysoperla carnea</i> (L.), Neuroptera, <i>Chrysopidae</i> from the BFR insectary. The larvae used in the study were 2 – 3 days old.
Diet:	Honeybee pollen
Study design:	Number of replicates: 30 replicates for mortality, 10 replicates for reproduction Number of larvae: 1/replicate Test duration: until pupation The test item was applied with a laboratory track sprayer on bean plants at seven application rates. TAFGOR (Dimethoate 30%) was used as reference item whereas deionised water was used as control. After treatment, the treated leaves were transferred to a reproduction unit.
Application rates:	Control, 3.5, 5.6, 9.0, 14.4 and 23.0 L of the test item/ha
Test conditions:	Temperature: 24.3 – 25.9 °C; humidity: 65.9 – 79.4%; lighting: 16 h light : 8 h dark; light intensity: 1352 – 1651 lux
Statistical analysis:	LR ₅₀ and NOER for mortality and ER ₅₀ and NOER for reproduction were determined by using a Probit analysis in NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0. The means and standard deviations were calculated using validated Excel sheets.
Endpoints:	LR ₅₀ , NOER ER ₅₀ , NOER

Results and Conclusions

The effects of Pendimethalin 455 g/L CS on mortality and fecundity of *Chrysoperla carnea* in the extended laboratory test are summarized below:

Study group (application rate) (L/ha)	Mortality		Reproduction			
	Total (%)	Corrected# (%)	Fecundity (No)	Fecundity reduction (%)	Fertility (%)	Fertility reduction (%)
Control						
0.0	6.67	-	38.30	-	97.55	-
Pendimethalin 455 g/L CS						
3.5	13.33	7.14	35.30	7.83*	97.55	0.25

5.6	26.67	21.43	27.60	27.94 ⁺	96.25	1.33
9.0	50.00	46.43 ⁺	20.35	46.87 ⁺	93.44	4.21 ⁺
14.4	73.33	71.43 ⁺	-*	-*	-*	-*
23.0	93.33	92.86 ⁺	-*	-*	-*	-*
Endpoints	LR50 _{mortality}	9.46 L/ha (4.31 kg a.i./ha)	ER50 _{fecundity}	9.24 L/ha (4.21 kg a.i./ha)		
	NOER _{mortality}	5.6 L/ha (2.6 kg a.i./ha)	NOER _{fecundity}	<3.5 L/ha (<1.6 kg a.i./ha)		
Reference item – TAFGOR (DIMETHOATE 30% EC)						
0.65	100	100				

#: Mortality corrected according to Abbott's formula:

Corrected mortality [%] = ((Mt – Mc) / (100 – Mc)) x 100; Mt = Mortality treated, Mc = Mortality control

+: statistically significant difference between the control and the treatment group at $p < 0.05$

*: The reproduction was not determined due to the mortality higher than 50% in comparison with the control group

The validity criterion for mortality was met, because mortality of the control group after 10 days of exposure was 6.67% (criterion: $\leq 20\%$).

There were statistically significant differences in mortality between group treated with the test item at the rate of 9.0, 14.4 and 23.0 L/ha and the control group (one-way ANOVA, $p < 0.05$).

For the reference item Tafgor (Dimethoate 30% EC, w/w), the corrected mortality of *C. carnea* after exposure at the rate of 0.65 L/ha was 100%, hence the criterion ($>50\%$) specified in the method description was met. The results showed that the test organisms were sensitive to dimethoate.

The validity criterion for fecundity was met, because the mean number of eggs per female per day in the control group was 37.85 (criterion: ≥ 15)

There were statistically significant difference in fecundity between group treated with the test item at rates of 3.5, 5.6 and 9.0 L/ha and the control group (one-way ANOVA, $p < 0.05$).

The validity criterion for fecundity was met, because the mean hatching rate in the control group was 97.55% (criterion: $\geq 70\%$).

There was statistically significant difference between group treated with the test item at the rate of 9.0 L/ha and the control group (one-way ANOVA, $p < 0.05$).

On the basis of the obtained results, it can be concluded that Pendimethalin 455 g/L CS had adverse effects on mortality and fecundity of *C. carnea* at rates of 9.0, 14.4 and 23.0 and at rates of 3.5, 5.6 and 9.0 L/ha, respectively.

A 2.5 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.5.1 KCP 10.4.1 Earthworms

A 2.5.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:	
Reference:	KCP 10.4.1.1 01
Report	Earthworm reproduction test with Pendimethalin 40% SC. XXX, E., 2019 Report No.: 17-99-135 ES. Phytosafe s.a.r.l.
Guideline(s):	OECD Guideline No. 222
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Duplication No
(if vertebrate study)

Materials and methods

Test item	Pendimethalin 40% SC, Batch No.SCL-58726
Artificial soil	5 % w/w sphagnum peat (grounded and sieved), 20 % w/w kaolinite clay, 75 % w/w fine sand (50% particles between 50 and 200 µm) —
Test organism	Earthworm, <i>Eisenia fetida</i> . Origin: adult specimens born at the Phytosafe site, of the same generation.
Test design	Test duration: 8 weeks; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicates
Concentration of the test item	Control; 4.8; 9.0; 15.0; 30.0; 51.0; 93.1; 168.2 and 300.4 mg/kg dry soil
Test conditions	Temperature: 18.5—22.3 °C; pH at the beginning of the experiment: 6.2—6.5; pH at the end of the experiment: 6.0—6.6; soil moisture content at the end of the experiment: 40.2—44.8%; light dark cycle: 16h : 8h; light intensity: 400-800 lux
Endpoints	EC ₁₀ , EC ₂₀ , EC ₅₀ , NOEC

Results

Mortality

Percent mortality was 2.5% as maximum at 15.0 mg product/kg dry soil and 1.3% in the control.

Biomass changes

In the control group, mean body weight of the adults was increased by 107.3% as compared to the initial value. In the test item treatments, mean body weight was increased as compared to the initial values. Increase in biomass was similar to that of the control except for treatment 300.4 mg test item/kg soil since gain in biomass was significantly reduced.

For the reference item treatments, the gain of biomass was considered as similar to that of the controls for the 0.5 and 1.0 mg/kg soil, but significantly reduced at 2.5 mg/kg dry soil.

Juveniles number

In the control group, the mean number of juveniles was 163.8 per unit and coefficient of variation amounted to 5.8% of the mean.

The reproductive performance in the test item treatments was similar to the controls up to and including 168.2 mg/kg dry soil, but significantly reduced at 300.4 mg/kg dry soil.

The test was considered valid as the results fulfilled the following conditions:

- Control mortality < 10%
- Production of juveniles in the control \geq 30 per unit (163.8)
- Coefficient of variation of reproduction in the control \leq 30% (5.8%)

Conclusions

NOEC (mortality) \geq 300.4 mg test item/kg dry soil

LC₁₀, LC₂₀ and LC₅₀ (mortality) > 300.4 mg test item/kg dry soil

NOEC (biomass) = 168.2 mg test item/kg dry soil

LOEC (biomass) = 300.4 mg test item/kg dry soil

NOEC (reproduction) = 168.2 mg test item/kg dry soil

LOEC (reproduction) = 300.4 mg test item/kg dry soil

EC₁₀ = 188.9 mg test item/kg dry soil

EC₂₀ and EC₅₀ > 300.4 mg test item/kg dry soil

Comments of zRMS:	The study is considered valid. All validity criteria were met.
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Agreed endpoints:		
Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg active substance/kg dry soil]
EC₁₀	58.94 (26.45 – 93.19)	22.73 (10.20 – 35.93)
EC₂₀	123.02 (73.08 – 169.69)	47.44 (28.18 – 65.43)
EC₅₀	432.81 (338.68 – 579.60)	166.89 (130.59 – 223.49)
NOEC_(offspring number)	95.00	36.63
LOEC_(offspring number)	170.00	65.94
LC₁₀	401.38 (324.04 – 460.10)	154.77 (124.95 – 177.41)
LC₂₀	469.04 (397.25 – 526.82)	180.86 (153.18 – 203.14)
LC₅₀	631.91 (566.47 – 706.75)	243.66 (218.43 – 272.52)
NOEC_(survival)	309.00	119.15
LOEC_(survival)	556.00	214.39

Reference:

KCP 10.4.1.1-02

Report:

“Earthworm Reproduction Test (*Eisenia andrei*)”.
 XXX T., Study Code.: EMI/4/40/2019, 2021
 Ecomelius Institute

Guideline(s):

OECD Guideline No. 222 (2016)

Deviations:

Yes

Study Plan concerning a study completion date occurred. Twelve times during the test temperatures below the range specified in the guideline were recorded. Retention times during analytical verification of pendimethalin content in samples collected on Day 56 of study were changed due to capillary exchange in UHPLC (higher void volume). Retention times were in range 2.2 – 2.4 min. Additional abiotic control was prepared in the same way and incubated under the same conditions as the other abiotic controls made for R1, R4, R8 treatments. This abiotic control was used for sampling for analytical verification of nominal concentration of tested material on Day 0 and on Day 56. According to Study Plan lost soil moisture is replaced by adding deionized water to the soil surface by hand-held sprayer. An automatic pipette was used to make up the water loss. This deviations did not affected the study results.

GLP:

Yes

Acceptability:

Yes

Duplication No
(if vertebrate study):

Summary

The effect on Pendimethalin 455 CS, to the reproduction of the earthworm (*Eisenia andrei*) was studied in the artificial soil substrate for 56 days. The adults earthworms were exposed to the tested item for the first 28 days of the test and were removed from the test vessels on day 28 to be examined for signs of toxicity and mortality. The soil and cocoons were returned to the test vessels for an additional 28 days to determine the numbers of juveniles produced in each replicate by the end of the test on day 56. Each treatment was divided into four replicates and control was divided into eight replicates. Earthworms were exposed to nominal concentrations of 16, 29, 53, 95, 171, 309, 556 and 1000 mg test item/kg soil dry weight. Test item concentrations in soil were not verified. Observations of burrowing behaviour were conducted at the initiation. Mortality, behavioural and morphological changes were assessed after 28 days of exposure. The number of juveniles were determined at test end on day 56.

Material and methods

Test item: Pendimethalin 455 CS
Batch number: SCL- 14177
Content: 455.0 g/L
Production date: 27th October, 2019
Expiry date: 26th October, 2021

Test system: Species: *Eisenia andrei*
Stage: Adult worms
Source: Wurmwelten, Inch. Jasper Rimpau

Test substrate: Artificial soil

Feeding: Alfalfa

Test design: Test duration: 56 days
Number of treatments: 9 (8 treatments, 1 control)
Number of replicates: 4 for treatment, 8 for control
Number of organisms/replicate: 10

Test concentrations: 16, 29, 53, 95, 171, 309, 556 and 1000 mg dry weight of the artificial soil

Test conditions: temperature: 18.0 - 20.2°C;

pH at the beginning of the experiment: 6.05 – 6.17;

pH at the end of the experiment: 6.16 – 6.39;

soil moisture content at the beginning of the experiment: 16.44 – 16.85 %

soil moisture content at the end of the experiment: 16.72 – 17.67 %

photoperiod: 16h light: 8 h dark

light intensity: 487.2 – 573.9 lux

Statistical analysis: EC₅₀, EC₂₀, EC₁₀ and LC₅₀ values were calculated with the probit analysis using linear max. likelihood regressions. NOEC and LOEC values using the Shapiro-Wilk's Test on Normal Distribution, the Levene's Test on Variance Homogeneity (with Residuals), and the Williams Multiple Sequential t-test Procedure.

EC₅₀, EC₂₀, EC₁₀, LC₅₀, NOEC and LOEC values were calculated using Tox-RatPro statistical computer software.

Validity criteria: The following validity criteria were met during the test:

- Mortality of adult worms over initial days of the test was 1.25% (criterion: it have not to exceed 10%).
- The lowest number of offspring produced in replicate was 30 (criterion: a minimum of 30 offspring are produced in each replicate containing 10 adults).
- The highest value of the coefficient of variation (CV) of offspring number was 16.9 (criterion: the CV of offspring number does not exceed 30%)

Findings:

Earthworms mortality, changes in behavior and morphology – 28 days of the test

Concentration (mg/kg dry soil)	Total mortality		Changes in behaviour and morphology
	Number	%	
Control	1	1.25	10 nc x 8
16	0	0	10 nc x 4
29	0	0	10 nc x 4
53	0	0	10 nc x 4
95	0	0	10 nc x 4
171	0	0	10 nc x 4
309	0	0	10 nc x 4
556	17*	42.5	18 nc; 5r; 1 bd
1000	35*	87.5	5 r; 2 bd

nc – no changes in behavior and morphology were observed; r – weak response to stimulation; bd – visible body damage; + - statistically significant

Earthworms reproduction and morphological observations after 8 weeks of the experiment

Concentration (mg/kg dry soil)	Mean ± SD	Coefficient of variation (%)	Morphological observations
Control	46.1 ± 7.77	16.9	nc
16	44.0 ± 7.44	16.9	nc
29	49.8 ± 9.00	18.1	nc
53	40.8 ± 10.01	24.6	nc
95	38.5 ± 5.32	13.8	nc
171	31.5 ± 5.20	16.5	nc
309	29.3 ± 4.27	14.6	nc
556	22.8 ± 6.55	28.8	nc
1000	10.0 ± 4.16	41.6	nc

nc – no changes

Endpoint values determined for earthworm reproduction after 8 weeks and for mortality after 4 weeks – Test item

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg active substance/kg dry soil]
EC ₁₀	58.94 (26.45 – 93.19)	22.73 (10.20 – 35.93)
EC ₂₀	123.02 (73.08 – 169.69)	47.44 (28.18 – 65.43)
EC ₅₀	432.81 (338.68 – 579.60)	166.89 (130.59 – 223.49)

NOEC (offspring number)	95.00	36.63
LOEC (offspring number)	170.00	65.94
LC₁₀	401.38 (324.04 – 460.10)	154.77 (124.95 – 177.41)
LC₂₀	469.04 (397.25 – 526.82)	180.86 (153.18 – 203.14)
LC₅₀	631.91 (566.47 – 706.75)	243.66 (218.43 – 272.52)
NOEC (survival)	309.00	119.15
LOEC (survival)	556.00	214.39

A 2.5.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.5.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.5.2.1 KCP 10.4.2.1 Species level testing

Comments of zRMS:	
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Reference:	KCP 10.4.2.1-01
Report	Collembolan reproduction test in soil with Pendimethalin 40% SC. XXX, E., 2019 Report No.: 17-99-128-ES. Phytosafe s.a.r.l.
Guideline(s):	OECD Guideline No. 232
Deviations:	Yes. The pH of the control soil (6.8) was slightly higher than the recommended threshold value of 6.5. This change did not adversely affect the quality and integrity of the study
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Pendimethalin 40% SC, batch no.SCL 58726
Test species:	Collembolans: Folsomia candida, 9-12 day old juveniles born at the Phytosafe site.
Soil:	Artificial soil: 5% w/w sphagnum peat (grounded and sieved), 20% w/w kaolinite clay, 75% fine sand, 0.3% w/w CaCO ₃
Study design:	Number of replicates: 4 replicates / concentration + 8 replicates / control Number of collembolans: 10 / replicate Test duration: 28 days
Application rates:	Control, 16.7, 30.1, 53.5, 97.0, 167.2, 317.7, 568.5 and 1003.3 mg/kg dry soil
Test conditions:	Temperature: 19.2 – 21.3 °C; pH at the beginning of the experiment: 6.8 – 6.9;

pH at the end of the experiment: 6.9; lighting: 12 h light / 12 h dark; light intensity: 400-800 lux
 Statistical analysis: SigmaStat 4.0 was used for statistical analysis and NOEC determination.
 NOEC determination: the Shapiro-Wilk's Test on Normal Distribution, Brown-Forsythe test on Variance Homogeneity, Student's t-test for parametric pairwise comparison, Welch's t-test (normal distribution observed, variance homogeneity failed), Mann-Whitney Rank Sum Test (when normal distribution failed)
 Endpoints: EC₁₀, EC₂₀, EC₅₀, LC₅₀, NOEC

Results

Test item	Pendimethalin 40% SC		
Test object	<i>Folsomia candida</i>		
Exposure	Artificial soil		
Concentration [mg/kg soil (dw)]	Adult mortality [%]	Number of Juveniles/test vessel [mean ± sd]	Reproduction [% of control]
Control	1.3	149.8 ± 12.9	-
16.7	2.5	150.0 ± 17.3	-0.2
30.1	2.5	145.0 ± 13.3	3.2
53.5	0.0	147.0 ± 25.3	1.8
97.0	0.0	149.0 ± 7.5	0.5
167.2	7.5	85.3 ± 18.5	43.1
317.7	32.5	25.3 ± 14.6	83.1
568.5	72.5	13.0 ± 9.1	91.3
1003.3	92.5	5.5 ± 3.0	96.3
	Mortality	Reproduction	
NOEC (mg a.s./kg soil (dw))	167.2 mg/kg dry soil (64.7 mg a.i./kg soil)	97.0 mg/kg dry soil (37.5 mg a.i./kg dry soil)	
LC/EC ₁₀ (mg a.s./kg soil (dw))	200.6 mg/kg dry soil (77.7 mg a.i./kg soil)	117 mg/kg dry soil (43.2 mg a.i./kg soil)	
LC/EC ₂₀ (mg a.s./kg soil (dw))	261.0 mg/kg dry soil (101.0 mg a.i./kg soil)	133.2 mg/kg dry soil (51.6 mg a.i./kg soil)	
LC/EC ₅₀ (mg a.s./kg soil (dw))	410.8 mg/kg dry soil (159.0 mg a.i./kg soil)	181.6 mg/kg soil (70.3 mg a.i./kg dry soil)	

The test is considered valid since:

- Mean percent mortality in the control group is ≤ 20% at the end of the test (1.3%)
- Reproduction rate in the control group is ≥ 100 juveniles per unit at the end of test (149.8)
- Standard deviation of the reproduction rate within the control group is ≤ 30% of mean value (8.6%)

Conclusions

NOEC (mortality) = 167.2 mg/kg dry soil (64.7 mg a.i./kg dry soil)

LC₅₀ (mortality) = 410.8 mg/kg (159.0 mg a.i./kg dry soil) 95% confidence interval: 393.9-427.8 mg/kg dry soil

NOEC (reproduction) = 97 mg/kg dry soil (37.5 mg a.i./kg dry soil)

EC₁₀ (reproduction) = 111.7 mg/kg (43.2 mg a.i./kg dry soil) 95% confidence interval: 93.0-130.4 mg/kg dry soil

EC₂₀ (reproduction) = 133.2 mg/kg (51.6 mg a.i./kg dry soil) 95% confidence interval: 114.5-151.9 mg/kg dry soil

EC₅₀ (reproduction) = 181.6 mg/kg (70.3 mg a.i./kg dry soil) 95% confidence interval: 162.9-200.2 mg/kg dry soil

Comments of zRMS:

Reference:	KCP 10.4.2.1-02
Report	Predatory mite (<i>Hypoaspis aculeifer</i>) reproduction test in soil with Pendimethalin 40% SC. XXX, E., 2019 Report No.: 17-99-129-ES. Phytosafe s.a.r.l.
Guideline(s):	OECD Guideline No. 226 (July 2016)
Deviations:	Yes. Temporary temperature conditions of 22.5°C were observed which were out the recommended range of 20 ± 2°C. This change did not adversely affect the quality and integrity of the study
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item	Pendimethalin 40% SC, batch no.SCL-58726
Artificial soil	5% w/w sphagnum peat (grounded and sieved), 20% w/w kaolinite clay, 75% fine sand, 0.3% w/w CaCO ₃
Test organism	Laboratory cultured <i>Hypoaspis (Geolaelaps) aculeifer</i> . Adult female mites obtained from a synchronised cohort were used to start the test.
Test design	Test duration: 14 days; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 females/replicate
Concentration of the test item	Control; Range finding test: 0.1,1.0, 10.1,101.3 and 1012.6 mg/kg dry soil; Limit test: 1010.0 mg/kg dry soil
Test conditions	Temperature: 18.5–22.5 °C (range finding test), 19.7–22.3 °C (definitive test); initial pH: 6.2–6.4, final pH: 6.2–6.4; light dark cycle: 12 h : 12 h; light intensity: 400-800 lux
Statistical analysis	SigmaStat 4.0 was used for statistical analysis and NOEC determination. NOEC: the Shapiro-Wilk's Test on Normal Distribution, Brown-Forsythe test on Variance Homogeneity, Student's t-test for parametric pairwise comparison, Welch's t test (normal distribution observed, variance homogeneity failed), Mann-Whitney Rank-Sum Test (when normal distribution failed).
Endpoints	NOEC, LOEC, ECx

Results

Test item	Pendimethalin 40% SC		
Test object	<i>Hypoaspis aculeifer</i>		
Exposure	Artificial soil		
Concentration [mg/kg soil (dw)]	Adult mortality [%]	Number of Juveniles/test vessel [mean ± sd]	Reproduction [% of control]
Control	1.3	212.1 ± 19.0	-
1010.0	1.3	208.0 ± 14.4	1.9
			Reproduction
NOEC (mg a.s./kg soil (dw))	≥ 1010 mg/kg (391.0 mg a.i./kg dry soil)		

The test is considered valid since:

- Mean percent mortality in the control group is ≤ 20% of the initial population at the end of the test (1.3%).
- Reproduction rate in the control group is ≥ 50 juveniles per unit at the end of test (212.1)
- Coefficient of deviation of the reproduction rate within the control group is ≤ 30% of mean value (8.9%).

Conclusions

NOEC (mortality) \geq 1010 mg/kg dry soil (391.0 mg a.i./kg dry soil)
 NOEC (reproduction) \geq 1010 mg/kg dry soil (391.0 mg a.i./kg dry soil)

Comments of zRMS:	The study is considered valid. All validity criteria were met.		
	<ul style="list-style-type: none"> • mean adult mortality: 12.5% (criterion: \leq 20%), • the mean number of juveniles per vessel at the end of the test: 250.1 (criterion: \geq 100 juveniles at the end of the test), • the coefficient of variation calculated for the number of juveniles: 18.0% (criterion: \leq 30%). 		
	Agreed endpoints:		
	Parameter	Test item (mg/kg d.w. soil)	Active substance (mg/kg d.w. soil)
	Mortality		
	LC ₁₀	305.03 (194.80 – 427.62)	117.62 (75.11 – 164.89)
	LC ₂₀	582.62 (415.65 – 919.50)	224.65 (160.27 – 354.55)
	LC ₅₀	> 1000.0	>385.59
	NOEC	308.64	119.01
	LOEC	555.56	214.22
	Reproduction		
	EC ₁₀	225.12 (139.26 – 286.13)	86.80 (53.70 – 110.33)
	EC ₂₀	290.31 (205.65 – 350.10)	111.94 (79.30 – 135.00)
	EC ₅₀	472.24 (401.49 – 556.09)	182.09 (154.81 – 214.42)
	NOEC	171.47	66.12
	LOEC	308.64	119.01

Reference:

KCP 10.4.2.1-03

Report:

“Collembolan (*Folsomia candida*) Reproduction Test”.
 W., Study Code.: EMI/4/17/2020, 2021
 Bioscience Research Foundation

Guideline(s):

OECD Guideline No. 232 (2016)

Deviations:

Yes - An editorial mistake was found in point 5.3.5 (page 12) of the Study Plan. The test item in the form of aqueous suspension was mixed with a suitable amount of the artificial soil, not in the form of aqueous emulsion. Deviation from the Study Plan and SOP/P/62: retention time of pendimethalin at validation was 2.25 ± 0.1 instead of 2.1 ± 0.1 . Deviation from the Study Plan and

SOP/A/4 concerning short term (<1 h) increased air temperature of place where the test item was stored occurred. Deviation from the Study Plan, OECD No. 232, and SOP/B/12 concerning decreased <18°C (17.2 – 17.9°C) air temperature of test room occurred. The increase in temperature in total lasted about 2 days (mainly at night). The validity criteria were met, therefore deviations did not affect the results of the study. Contrary to what had been planned, the study was finalized in March 2021, not in January 2021. An editorial mistake was found in point 11 (page 17) of the Study Plan. Should be: [5] ISO-Guideline No. 10390: 1997. ‘Soil Quality - determination of pH’ [6] ISO-Guideline No. 11465: 1999 ‘Soil Quality - determination of dry matter and water content on a mass basis - gravimetric method’ instead of: [5] ISO-Guideline No. 10390: 1994. “Soil Quality - determination of pH”, Geneve [6] ISO-Guideline No. 11465: 1993 “Soil Quality - determination of dry matter and water content on a mass basis - gravimetric method” Above deviations did not affect the results of the study.

GLP: Yes

Acceptability: Yes

**Duplication
(if vertebrate study):** No

Summary

The aims of the study were to assess the impact of Pendimethalin 455 g/L CS on reproduction of the collembolans, *Folsomia candida* and to determine the EC₁₀, EC₂₀, EC₅₀, and NOEC. Moreover, the LC₁₀, LC₂₀, LC₅₀ were calculated (i.e. the concentration of the test item causing 10 or 20% mortality of adults in comparison to the control). Eight concentrations of the test item were used. These were 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56, and 1000.00 mg of the test item/kg of dry weight of the artificial soil. Each concentration was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in form of aqueous suspension was mixed with the artificial soil. The control artificial soil was mixed with ultrapure water alone. The experiment lasted 28 days. After that, the collembolans were extracted from the artificial soil. The numbers of adults and juveniles were determined separately.

Material and methods

Test item: Pendimethalin 455 g/L CS
Batch number: SCL- 14177
Content: Pendimethalin – 455.0 g/L
Production date: 27th October, 2019
Expiry date: 26th October, 2021

Test system: Species: The collembolan, *Folsomia candida*
Stage: 9-12 days old
Source: laboratory culture from Ecomelius Institute

Artificial soil: Artificial soil: 5% sphagnum peat, 20% kaolin clay, and 75% quartz sand

Test design: Test duration: 28 days
Number of treatments: 10 (8 treatments, 1 control, 1 abiotic control)
Number of replicates: 4 for treatment, 8 for control, 2 for abiotic control
Number of organisms/replicate: 10

Test concentrations: 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56, and 1000.00 mg/kg dry arti-

ificial soil

Test conditions: temperature: 17.2 – 22.0°C;
pH at the beginning of the test: 5.53 – 5.84;
pH at the end of the test: 5.51 – 5.57;
soil moisture content at the beginning of the test: 16.94 – 17.51% (49.53 – 51.20% of the maximum water holding capacity);
soil moisture content at the end of the test: 16.76 – 17.25% (49.02 – 50.44% of the maximum water holding capacity);
lighting: 16 h light and 8h dark;
light intensity at the beginning of the experiment: 492.1 – 541.8 lux
light intensity after two weeks of the experiment: 481.7 – 545.1 lux
light intensity at the end of the experiment: 472.1 – 536.1 lux

Statistical analysis: EC10, EC20, and EC50 – a probit analysis
LC10, LC20, LC50 - a probit analysis
NOEC (number of juveniles):
- Shapiro-Wilk's Test on Normal Distribution,
- Bartlett's Test Procedure on Variance Homogeneity,
- Williams Multiple Sequential t-test Procedure, NOEC (survival):
- Qualitative trend Analysis by Contrast (Monotonicity of Concentration/Response) - Chi2 2x2 Table Test with Bonferroni Correction

Validity criteria: The results are considered valid because the following criteria were satisfied in the controls:
• mean adult mortality: 12.5% (criterion: $\leq 20\%$),
• the mean number of juveniles per vessel at the end of the test: 250.1 (criterion: ≥ 100 juveniles at the end of the test),
• the coefficient of variation calculated for the number of juveniles: 18.0% (criterion: $\leq 30\%$).

Findings:

Mortality of adult collembolans (*Folsomia candida*) – 28 days of the test

Concentration (mg/kg dry soil)	Total mortality	
	Number	%
Control	10	12.5
16.33	5	12.5
29.40	5	12.5
52.92	6	15.0
95.26	6	15.0
171.47	6	15.0
308.64	3	7.5
555.56	15 ⁺	37.5
1000.0	16 ⁺	40.0

+ - statistically significant difference between the control and the treatment group (Chi2 2x2 Table Test with Bonferroni Correction, significance level = 0.05, one-sided greater)

Number of juvenile collembolans (*Folsomia candida*) after 28 days of the experiment

Concentration (mg/kg dry soil)	Mean ± SD	Reduction (%)	CV* (%)
Control	250.125 ± 44.994	-	18.0
16.33	242.750 ± 47.233	2.9	19.5
29.40	242.750 ± 36.719	2.9	15.1
52.92	228.500 ± 54.945	8.6	24.0
95.26	233.750 ± 37.880	6.5	16.2
171.47	232.750 ± 28.076	6.9	12.1
308.64	186.500 ± 34.962	25.4	18.7
555.56	115.750 ± 24.851	53.7	21.5
1000.0	0.000 ± 0.000	100.0	-

*CV – coefficient of variation

+ - statistically significant difference between the control and the treatment group (Williams Multiple Sequential t-test Procedure, significance level = 0.05, one-sided smaller)

- - not determined

The impact of the test item on the survival and reproduction of adult collembolans.

Parameter	Test item (mg/kg d.w. soil)	Active substance (mg/kg d.w. soil)
Mortality		
LC ₁₀	305.03 (194.80 – 427.62)	117.62 (75.11 – 164.89)
LC ₂₀	582.62 (415.65 – 919.50)	224.65 (160.27 – 354.55)
LC ₅₀	> 1000.0	>385.59
NOEC	308.64	119.01
LOEC	555.56	214.22
Reproduction		
EC ₁₀	225.12 (139.26 – 286.13)	86.80 (53.70 – 110.33)

EC₂₀	290.31 (205.65 – 350.10)	111.94 (79.30 – 135.00)
EC₅₀	472.24 (401.49 – 556.09)	182.09 (154.81 – 214.42)
NOEC	171.47	66.12
LOEC	308.64	119.01

Comments of zRMS:

The study is considered valid. All validity criteria were met.

- Mean adult mortality: 0.00% (criterion: ≤20%).
- The mean number of juveniles per replicate at the end of the test: 129.50 (criterion: ≥50 juveniles at the end of the test).
- The coefficient of variation for the number of juveniles: 1.24 (criterion: ≤30%)

Agreed endpoints:

Endpoints	[mg t.i./kg sdw]	[mg Pendimethalin/kg sdw]
NOEC mortality	>1000	>386.44
LOEC mortality	>1000	>386.44
LC ₁₀	>1000 (n.d)	>386.44 (n.d)
LC ₂₀	>1000 (n.d)	>386.44 (n.d)
LC ₅₀	>1000 (n.d)	>386.44 (n.d)
NOEC reproductive output	>1000	>386.44
LOEC reproductive output	>1000	>386.44
EC ₁₀	>1000 (n.d)	>386.44 (n.d)
EC ₂₀	>1000 (n.d)	>386.44 (n.d)
EC ₅₀	>1000 (n.d)	>386.44 (n.d)

n.d. – not determined

Reference:

KCP 10.4.2.1-04

Report

“Effect of Pendimethalin 455 g/L CS on the Reproductive Output of the Predatory Soil Mite *Hypoaspis (Geolaelaps) aculeifer* Canestrini (Acari: Laelapidae) in Artificial Soil”. Dr. V. XXX. 2021. Study code: 8925/2021. Bioscience Research Foundation

Guideline(s):

OECD Guideline No. 226 (2016)

Deviations:

No

GLP:

Yes

Acceptability:

Yes

Duplication

No

(if vertebrate study)

Materials and methods

Test item:	Pendimethalin 455 g/L CS batch no.: SCL-80067 active substance content: Pendimethalin, 456 (g/L)
Artificial soil	5% sphagnum peat (a particle size of 2 ± 1 mm); 20% kaolin clay; 75% air-dried industrial sand (predominantly fine sand with more than 50 % of the particles between 50 and 200 microns)
Biological test system :	<i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari, Laelapidae), from in-house culture, adult mites (33 days after starting of the egg-laying for synchronisation).
Test design:	Adult females were exposed to the test substance in artificial soil. After 14 days, the surviving individuals were extracted from the test units. The number of juveniles per test unit and additionally the number of surviving adult females were determined. The reproductive output and the mortality in each test item group were compared to that of the control group. A Dose-response test with 10 different test substance concentrations and 4 replicates each as well as a water control (without test substance) with eight replicates; 10 adult females were exposed per replicate.
Test doses:	0 (control), 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000.00 mg test substance/kg soil dry weight. Equivalent to 0, 1.95, 3.51, 6.31, 11.36, 20.45, 36.81, 66.26, 119.27, 214.69 and 386.44 mg Pendimethalin/kg soil dry weight.
Test conditions:	Temperature during exposure: 20.5 °C to 21.5 °C pH at the beginning of the test: 5.85 to 6.10 pH at the end of the test: 5.92 to 6.08 Soil moisture content at the beginning of the test: 20.10 % to 21.30 % (corresponding to 51.47 – 52.40 % of the WHCmax) Soil moisture content at the end of the test: 19.32 % to 20.73 % (corresponding to 49.42 – 50.44 % of the WHCmax) Lighting: 16 h light and 8 h dark (long day conditions); light intensity: 595 lux to 650 lux
Endpoints:	LOEC and NOEC for mortality and reproductive output; EC _{10, 20, 50} for reproductive output and LC _{10, 20, 50} for mortality output where possible.

Results and discussions

Mortality after 14 days of experiment at the concentrations of the test item ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil, mortality was between 0.00 and 7.5%. As for the control group, it was 0.00%.

No behavioural abnormalities or any pathological symptoms of the test organisms could be observed in the control group and in any of the test substance groups.

After the application of the test item at the concentration ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 129.25 and 125.25 per replicate. As for the control group, the number of juveniles was equal to 129.50 per replicate.

The toxic reference item (a.i. dimethoate) was conducted between 03.06.2020 and 26.06.2020. The EC₅₀ for reproductive output was determined to be 4.02 mg/kg soil dry weight. This is within the target range of 3.0 to 7.0 mg dimethoate/kg soil dry weight given by the OECD guideline 226 (2016) and hence acceptable sensitivity of the test system was assured.

Mortality and reproductive output of *H. aculeifer* after exposure to artificial soil treated with test item

Treatment group	Test substance concentration [mg t.s./kg sdw]	Mean Mortality [%]	Mean n° of juveniles per replicate	Coefficient of Variation [%]	Reduction in reproductive output compared to control [%]
Control	0	0.0	129.50 ± 1.6	1.24	-
Pendimethalin 455 g/L CS	5.04	0.0	129.25 ± 2.50	1.93	0.19
	9.07	0.0	129.25 ± 2.22	1.72	0.19
	16.33	0.0	129.00 ± 1.63	1.27	0.39
	29.40	0.0	128.75 ± 2.06	1.60	0.58
	52.92	2.5 ± 5	128.50 ± 3.11	2.42	0.77
	95.26	2.5 ± 5	128.25 ± 2.50	1.95	0.97
	171.47	2.5 ± 5	128.00 ± 2.16	1.69	1.16
	308.64	5.0 ± 5.8	126.25 ± 1.71	1.35	2.51
	555.56	5.0 ± 5.8	126.00 ± 1.41	1.12	2.70
	1000	7.5 ± 5.0	125.25 ± 1.26	1.00	3.28

Endpoints	[mg t.i./kg sdw]	[mg Pendimethalin/kg sdw]
NOEC _{mortality}	>1000	>386.44
LOEC _{mortality}	>1000	>386.44
LC ₁₀	>1000 (n.d)	>386.44 (n.d)
LC ₂₀	>1000 (n.d)	>386.44 (n.d)
LC ₅₀	>1000 (n.d)	>386.44 (n.d)
NOEC _{reproductive output}	>1000	>386.44
LOEC _{reproductive output}	>1000	>386.44
EC ₁₀	>1000 (n.d)	>386.44 (n.d)
EC ₂₀	>1000 (n.d)	>386.44 (n.d)
EC ₅₀	>1000 (n.d)	>386.44 (n.d)

n.d. – not determined

Conclusion

All validity criteria were met and the sensitivity of the test organisms was confirmed. Accordingly, the study was deemed valid.

Test validity criteria

The results are considered valid because the following criteria were satisfied in the control:

- Mean adult mortality: 0.00% (criterion: ≤20%).
- The mean number of juveniles per replicate at the end of the test: 129.50 (criterion: ≥50 juveniles at the end of the test).
- The coefficient of variation for the number of juveniles: 1.24 (criterion: ≤30%)

A 2.5.2.2 KCP 10.4.2.2 Higher tier testing

A 2.6 KCP 10.5 Effects on soil nitrogen transformation

A 2.6.1 KCP 10.5.1 Soil Microorganisms: Nitrogen Transformation Test

Comments of zRMS:	
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Reference:	KCP 10.5.1-02
Report	Effect of Pendimethalin SC on soil microorganisms: Nitrogen transformation test XXX, A. 2009. Report No.: 8483. Jai Research Foundation
Guideline(s):	OECD Guideline No. 216 (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material:	Pendimethalin 40% SC (Batch SWEPL 7489)
Soil:	Agricultural soil taken from the surrounding area, free from any chemical and biological contamination
Test design:	3 portions of soil: one control group and two groups containing the test item. Test duration: 28 days
Concentrations:	Control: maximum field application rate 6.2 L test item/ha (0.28 µL/100 g soil) and 5 times maximum field application rate 31.0 L test item/ha (1.40 µL/100 g soil)
Test conditions:	Temperature: 20.0-22.0 °C, soil moisture: 45.7-50.8% of the maximum water holding capacity, incubation in darkness
Endpoints:	The nitrate content in the treated soil samples was compared with that in the control, and the percent deviation of the treated from the control was calculated after 0, 7, 14, and 28 days.
Statistical analysis:	Statistical analysis was performed by using validated software for the data homogeneity (F test for homogeneity of variance).

Study design

~~The study was carried out to evaluate the effect of pendimethalin SC on soil microorganisms (nitrogen transformation test).~~

~~Agricultural soil was used. It was manually cleared of large objects and sieved through 2.0 mm sieve.~~

~~The concentrations of the test item were maximum field application rate 6.2 L test item/ha (0.28 µL/100 g soil) and 5 times maximum field application rate 31.0 L test item/ha (1.40 µL/100 g soil).~~

~~On days 0, 7, 14, and 28 of incubation, soil samples were collected to determine the quantities of nitrate. The nitrate content in each treated and control sample was determined at each sampling interval by dilution and using a precalibrated ISE meter with nitrate electrode.~~

Results

The mean nitrate content in control soil sample on 0, 7, 14 and 28 days were ~~92.27, 121.33, 114.27 and 221.07~~ mg nitrate/kg soil, respectively. The mean nitrate content at dose level 6.2 L/hectare (maximum field application rate) on 0, 7, 14 and 28 days were ~~101.33, 137.07, 140.13 and 224.93~~ mg nitrate/kg soil, respectively. The mean nitrate content at dose level 31.0 L/hectare (5 times maximum field application rate) on 0, 7, 14 and 28 days were ~~101.60, 129.87, 129.87 and 190.67~~ mg nitrate/kg soil, respectively.

The mean nitrate formation rate in control between 0 to 7, 0 to 14 and 0 to 28 days were ~~4.15, 1.57 and 4.60~~ mg nitrate/kg soil/day, respectively. The mean nitrate formation rate at dose level 6.2 L/hectare (maximum field application rate) between 0 to 7, 0 to 14 and 0 to 28 days were ~~5.11, 2.77 and 4.41~~ mg nitrate/kg soil/day, respectively. The mean nitrate formation rate at dose level 31.0 L/hectare (5 times maximum field application rate) between 0 to 7, 0 to 14 and 0 to 28 days were ~~4.04, 2.02 and 3.18~~ mg nitrate/kg soil/day, respectively.

The percent inhibition of microbial activity by pendimethalin SC at 6.2 L/hectare (maximum field application rate) on 0, 7, 14 and 28 days were ~~9.82%, 12.97%, 22.63% and 1.75%~~, respectively. The percent inhibition at 31.0 L/hectare (5 times maximum field application rate) on 0, 7, 14 and 28 days were ~~10.11%, 7.03%, 13.65% and +13.75%~~, respectively. (-) sign shows growth promotion and (+) sign shows growth inhibition.

Conclusions

Pendimethalin SC did not exhibit any toxic effect against the soil microbes at dose level 6.2 L/hectare (maximum field application rate) and 31.0 L/hectare (5 times maximum field application rate) when compared with the control soil sample.

Comments of zRMS:	The study is considered valid. All validity criteria were met. Agreed endpoints: On the basis of the results, it can be concluded that Pendimethalin 455 g/L CS at the concentration corresponding to the PEC and upper PEC, 27.53 and 137.67 mg test item/kg dry weight soil, respectively (10.62 and 53.08 mg Pendimethalin Kg/dry weight soil, respectively) can be perceived as having no long-term influence on nitrogen transformations in soil.
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Reference Report

KCP 10.5.1-03
 “Soil Microorganisms: Nitrogen Transformation Test”. XXX Dec, PhD Eng., 2021. STUDY CODE: EMI/4/26/2019. Ecomelius Institute sp. z.o.o.

Guideline(s)

OECD Guidelines for Testing of Chemicals. Test No. 216 (OECD, 2000)

Deviations

No

GLP

Yes

Acceptability

Yes

Duplication

No

(if vertebrate study)

Material and methods

Test material

Soil

Pendimethalin 455 g/L CS, batch number SCL-14177
 Agricultural soil (Type 5M). The soil was from a place where there was no organic fertilization and pesticides use at the sampling site in neither sampling year.

Test design

Three portions of soil (3 x 1800 g. dry weight), i.e. one control group and two treated groups. Every portion was divided into three

	replicates (3 x 600 g). The soil was amended with a suitable organic substrate, i.e. powdered Lucerne-grass meal (C/N range is 15.85, Nitrogen in dry material % is 2.66) at dose of 5 g/kg dry weight of soil. Test duration: 28 days.
Concentrations of the test material	Control; 27.53 mg of test item/kg dry weight soil (10.62 mg Pendimethalin/kg of dry weight of soil) and 137.67 mg of test item/kg of dry weight soil (53.08 mg Pendimethalin/kg of dry weight of soil)
Test conditions	Temperature: 19.2 – 20.4°C, soil moisture: 49.02 – 54.1% MWHC, pH in Milli-Q water: 6.46
Endpoints	The concentration of nitrate ions [mg/kg dry soil] after 0, 7, 14 and 28 days of incubation and percent deviation from the control in nitrate formation.
Statistical analysis	The statistical tests were performed with the use of ToxRat Professional (version 3.3.0) Shapiro-Wilk's Test on Normal Distribution Levene's Test on Variance Homogeneity STUDENT-t test for Homogeneous Variances

Study design

The aim of the study was to detect long-term adverse effects of Pendimethalin 455 g/L CS on the processes of nitrogen transformation in aerobic surface soils.

Agricultural soil was used. It was manually cleared of large objects and sieved to a particle size of 2 mm. The concentrations of the test item were 27.53 (PEC) and 137.67 (5xPEC) mg of test item/kg of dry weight soil, equivalent to 10.62 and 53.08 mg Pendimethalin/kg of dry weight soil. The treated and the control soils were divided into three replicates. On days 0, 7, 14 and 28 of incubation, soil samples were collected to determine the quantities of nitrates.

The method involves a measurement of the nitrate ion concentration in a soil extract obtained by using 0.1 M KCl. The absorbance of the solution was measured at 500 nm.

The nitrate formation rate in each treated group was compared with that in the control and the percent deviation of the treated from the control was calculated.

Results

Deviations from the control based on nitrogen between the control and the group treated with test item at both concentrations. i.e. PEC: 27.53 mg test Item/kg dry soil and upper PEC: 137.67 mg the test item/kg dry soil in nitrate concentration after 0, 7, 14, and 28 days of incubation.

There were no statistically significant differences between the control and the group with test item at the concentration of 27.53 and 137.67 mg test item/kg dry weight soil in nitrate formation rates at time intervals: 0-7, 0-14, 0-28.

The percent deviation from the control calculated on the basis of the nitrate formation rate at the concentration of 27.53 and 137.67 mg test item/kg dry weight soil did not exceed 25% on 28 day of analysis. Hence it can be evaluated as having no long-term influence on nitrogen formation in soil at the concentrations corresponding to the PEC and upper PEC, 27.53 and 137.67 mg test item/kg dry weight soil, respectively (10.62 and 53.08 mg of pendimethalin/kg dry weight soil, respectively)

Table 1: Nitrate content in soil - deviations from the control [%]:

Day	Sample details	Nitrate ion concentration (mg/kg dws)	Coefficient of variation [%]
0	Control	71.26 ± 3.42	4.8
	PEC	69.19 ± 0.07	4.0
	Upper PEC	58.19 ⁺ ± 8.22	14.1
7	Control	94.78 ± 5.75	6.1
	PEC	115.06 ⁺ ± 11.72	10.2
	Upper PEC	100.63 ± 8.49	8.4

14	Control	166.46 ± 5.30	3.2
	PEC	220.31 ⁺ ± 19.39	8.8
	Upper PEC	125.83 ⁺ ± 3.69	2.9
28	Control	283.54 ± 9.8	3.6
	PEC	313.41 ± 23.06	7.4
	Upper PEC	300.35 ± 43.36	14.4

+: statistically significant differences in nitrate concentrations between the control soil and the soil treated with the test item (STUDENT-t test for homogeneous variances, two-sided)

Control: Milli-Q water

PEC: 27.53 mg of test item/kg of dry weight soil

Upper PEC: 137.67 mg of test item/kg of dry weight soil

Conclusions

On the basis of the results, it can be concluded that Pendimethalin 455 g/L CS at the concentration corresponding to the PEC and upper PEC, 27.53 and 137.67 mg test item/kg dry weight soil, respectively (10.62 and 53.08 mg Pendimethalin Kg/dry weight soil, respectively) can be perceived as having no long-term influence on nitrogen transformations in soil.

A 2.6.2 KCP 10.5.2 Soil Microorganisms: Carbon Transformation Test

Comments of zRMS:	
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Reference:	KCP-10.5.2-02
Report	Effect of Pendimethalin SC on soil microorganisms: Carbon transformation test XXX, A. 2009, 8484. Jai Research Foundation
Guideline(s):	OECD Guideline No. 217 (2000) / EU Method C.22
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material:	Pendimethalin 40% SC (Batch SWEPL 7489)
Soil:	Agricultural soil taken from the surrounding area, free from any chemical and biological contamination
Test design:	3 portions of soil: one control group and two groups containing the test item. Test duration: 28 days
Concentrations:	Control: maximum field application rate 6.2 L test item/ha (0.28 µL/100 g soil)

and 5 times maximum field application rate 31.0 L test item/ha (1.40 µL/100 g soil)

Test conditions: Temperature: 20.0-22.0 °C, soil moisture: 50% of the maximum water holding capacity, incubation in darkness

Statistical analysis: Statistical analysis was performed by using validated software for the data homogeneity (F test for homogeneity of variance).

Study design

The study was carried out to evaluate the effect of pendimethalin SC on the respiration rate (carbon transformation test).

Agricultural soil was used. It was manually cleared of large objects and sieved through 2.0 mm sieve. The concentrations of the test item were maximum field application rate 6.2 L test item/ha (0.28 µL/100 g soil) and 5 times maximum field application rate 31.0 L test item/ha (1.40 µL/100 g soil).

On days 0, 7, 14 and 28 of incubation, soil samples were collected to determine the mean respirates. Glucose induced soil microbial respiration rate was measured at every two hour interval upto 12 hours on each sampling day after treatment.

Results

The optimum glucose concentration was 4000 mg/kg dry soil, and the minimum microbial biomass in selected soil was 1193.56 mg/kg soil.

The mean glucose induced respiration rates in control on 0, 7, 14 and 28 days were 105.84, 105.69, 85.42 and 90.30 mg CO₂/kg soil, respectively. The mean respiration rates at dose level 6.2 L/hectare (maximum field application rate) on 0, 7, 14 and 28 days were 113.77, 123.37, 102.51 and 106.95 mg CO₂/kg soil, respectively. The mean respiration rates at dose level 31.0 L/hectare (5 times maximum field application rate) on 0, 7, 14 and 28 days were 115.99, 128.44, 90.32 and 111.03 mg CO₂/kg soil, respectively.

The percent inhibition of pendimethalin SC at 6.2 L/hectare (maximum field application rate) on 0, 7, 14 and 28 days were 7.49%, 16.73%, 20.01% and 18.44%, respectively. The percent inhibition 31.0 L/hectare (5 times maximum field application rate) on 0, 7, 14 and 28 days were 9.59%, 21.53%, 5.74% and 22.96%, respectively. (-) sign indicates growth promoting nature of the test substance and not the growth inhibitory effect.

Pendimethalin SC did not show any toxic effect against the soil microbes.

Glucose induced soil microbial respiration rate (mg/kg/h)

Day	Control	1T	Percent inhibition (%)	2T	Percent inhibition (%)
0	105.84	113.77	-7.49	115.99	-9.59
7	105.69	123.37	-16.73	128.44	-21.53
14	85.42	102.51	-20.01	90.32	-5.74
28	90.30	106.95	-18.44	111.03	-22.96

Control = 100 g soil (without test substance)

1T = maximum field application rate 6.2 L/hectare (0.28 µL/100 g soil)

2T = 5 times maximum field application rate 31.0 L/hectare (1.40 µL/100 g soil)

Conclusion

The results of the study revealed that pendimethalin SC is non-toxic to [Carbon Transformation Test] at maximum field application rate i.e. 6.2 L/hectare of soil and 5 times of maximum field application rate i.e. 31.0 L/hectare of soil.

A 2.7.1 KCP 10.6.1 Summary of screening data

A 2.7.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	
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Reference: KCP 10.6.2 01

Report A study to determine the effects of Pendimethalin 40% SC (pendimethalin 400 g/L on the seedling emergence and growth of terrestrial plants XXX, L. 2013. Study code: 34SRFR12C6. SynTech Research France S.A.S.

Guideline(s): OECD Guideline No. 208 (2006)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

~~PENDIMETHALIN 40% SC (batch No.0007955648) was diluted in distilled water and applied with a spray application volume of 200 L water/ha onto bare soil. Distilled water was used as a control treatment and KATANA (nominal content of flazasulfuron: 250 g/kg) was applied at 50 g a.s./ha as a reference treatment. Multiple rate testing (5 test item rates per plant species) preceded by a non-GLP range finding test was conducted to establish a rate response relationship and, where possible to determine values for ER50 (effective rate 50%), LOER (lowest observed effect rate) and NOER (no observed effect rate) for each species tested. The plants (wheat, ryegrass, lettuce, tomato, oil seed rape and pea) were evaluated against distilled water control plants for effects on seedling emergence and early growth once a week between 14 and 28 days after 50% emergence of seedlings in the control groups. The main endpoints measured were seedling emergence and biomass (shoot weight). Shoot height and mortality were measured as well and visible detrimental effects (phytotoxicity) were visually assessed. Data were analysed for significant differences compared to the control group using adequate statistical methods and to determine the ER50, LOER and NOER for each species tested.~~

Results

~~Summary of effects of PENDIMETHALIN 40% SC on the seedling emergence and early growth of terrestrial non target plants at 28DAE~~

Test item	PENDIMETHALIN 40% SC (Pendimethalin 400 g/L)					
Test organism /Exposure	Terrestrial non-target plants / Foliar spray application					
Dry weight	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
ER50 [g a.s./ha]	>1760	>1760	269.8	425.1	434.0	>1760
LOER [g a.s./ha]	>1760	>1760	196	587	587	>1760
NOER [g a.s./ha]	1760	1760	66	196	196	1760
Height	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
ER50 [g a.s./ha]	>1760	>1760	>1760	554	>1760	>1760
LOER [g a.s./ha]	>1760	>1760	>587	587	1760	>1760

NOER [g a.s./ha]	1760	1760	587	196	587	1760
Emergence	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
ER50 [g a.s./ha]	>1760	>1760	>1760	>1760	>1760	>1760
LOER [g a.s./ha]	>1760	>1760	>1760	>1760	>1760	>1760
NOER [g a.s./ha]	1760	1760	1760	1760	1760	1760
Mortality	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
LR50 [g a.s./ha]	>1760	>1760	339.2	809.8	1088	>1760
LOER [g a.s./ha]	>1760	1760	587	1760	1760	>1760
NOER [g a.s./ha]	1760	587	196	587	587	1760

Conclusion

The study is valid since the mean seedling emergence was > 70% in the control for each plant species (actual mean values: 100% for tomato, 95% for lettuce, 90 % for wheat, oil seed rape and pea and 80% for ryegrass), mean plant survival in the control was ≥ 90% at the end of the test (actual values: 100% for all species), there was no visible phytotoxic effect in the control and the recovery of the highest test item concentration (1760 g a.s./ha, corresponding to 8.8 g a.s./L) was within the required range of 70-110% of nominal concentration (actual analysed concentration: 7.2 g a.s./L, corresponding to 81.8 % of nominal concentration).

PENDIMETHALIN 40% SC was shown to have rate related effects on the seedling emergence and early growth of terrestrial non target plants.

Lettuce (*Lactuca sativa*) was the most sensitive species in term of effects on biomass (dry weight), with a NOER biomass of 66 g a.s./ha, a LOER biomass of 196 g a.s./ha and an ER50 biomass calculated to be 269.8 g a.s./ha (95% confidence limits not calculable). The least sensitive species were found to be wheat, ryegrass and pea with a NOER biomass of 1760 g a.s./ha and both LOER biomass and ER50 biomass estimated to be > 1760 g a.s./ha.

Tomato (*Solanum lycopersicum*) was the most sensitive species in term of effects on height (shoot length), with a NOER height of 196 g a.s./ha, a LOER height of 587 g a.s./ha and an ER50 height calculated to be 554.0 g a.s./ha (95% confidence limits not calculable). The least sensitive species were wheat, ryegrass and pea with a NOER height of 1760 g a.s./ha and both LOER height and ER50 height estimated to be > 1760 g a.s./ha.

For emergence endpoint, the NOER emergence was 1760 g a.s./ha and both LOER emergence and ER50 emergence were > 1760 g a.s./ha for all species.

Lettuce (*Lactuca sativa*) was the most sensitive species in term of effects on mortality, with a NOER mortality of 196 g a.s./ha, a LOER mortality of 587 g a.s./ha and an LR50 mortality calculated to be 339.2 g a.s./ha (95% confidence limits 307.2 – 374.6 g a.s./ha). The least sensitive species were found to be wheat and pea with a NOER mortality of 1760 g a.s./ha and both LOER mortality and LR50 mortality estimated to be > 1760 g a.s./ha.

The overall lowest ER50 (biomass endpoint; 269.8 g a.s./ha) was observed with the lettuce (*Lactuca sativa*):

Comments of zRMS:

Reference:

KCP-10.6.2-02

Report	A study to determine the effects of Pendimethalin 40% SC (pendimethalin 400 g/L on the vegetative vigour of terrestrial plants XXX, L. 2013. Study code: 34SRFR12C7. SynTech Research France S.A.S.
Guideline(s):	OECD Guideline No. 227 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

PENDIMETHALIN 40% SC (batch No. 0007955648) was diluted in distilled water and applied with a spray application volume of 200 L water/ha to leaves and above ground parts of terrestrial non target plants. Distilled water was used as a control treatment and ROUNDUP FLASH PLUS (nominal content of glyphosate acid: 450 g/L) was applied at 1350 g a.s./ha as a toxic reference treatment.

Multiple rate testing (5 test item rates per plant species) preceded by a non GLP range finding test was conducted to establish a rate response relationship and, where possible to determine values for ER50 (effective rate 50%), LOER (lowest observed effect rate) and NOER (no observed effect rate) for each species tested.

The plants (wheat, ryegrass, lettuce, tomato, oil seed rape and pea) were evaluated against distilled water control plants for effects on vigour and growth once a week between 7 and 28 days after treatment. The main endpoint measured was biomass (shoot weight). Shoot height and mortality were measured as well and visible detrimental effects (phytotoxicity) were visually assessed.

Data were analysed for significant differences compared to the control group using adequate statistical methods and to determine the ER50, LOER and NOER for each species tested.

Results

Summary of effects of PENDIMETHALIN 40% SC on the vegetative vigour of terrestrial non target plants at day 28

Test item	PENDIMETHALIN 40 % EC (Pendimethalin 400 g/L)					
Test organism /Exposure	Terrestrial non target plants / Foliar spray application					
Dry weight	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
ER50 [g a.s./ha]	>1760	>1760	223.8	149.0	>1760	>1760
LOER [g a.s./ha]	>1760	>1760	66	66	66	>1760
NOER [g a.s./ha]	1760	1760	22	22	22	1760
Height	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
ER50 [g a.s./ha]	>1760	>1760	>196	>196	>1760	>1760
LOER [g a.s./ha]	>1760	>1760	>196	196	587	>1760
NOER [g a.s./ha]	1760	1760	196	66	196	1760
Mortality	Wheat	Ryegrass	Lettuce	Tomato	Oil seed rape	Pea
ER50 [g a.s./ha]	>1760	>1760	>196	>196	>1760	>1760
LOER [g a.s./ha]	>176	>1760	>196	>196	>1760	>1760
NOER [g a.s./ha]	1760	1760	196	196	1760	1760

Conclusion

The study is valid since the seedling emergence was > 70% for each plant species (actual values: 100% for wheat, lettuce and pea; 96% for oil seed rape; 95% for ryegrass and 92% for tomato), mean plant survival in the control was > 90% at the end of the test (actual values: 100%) for all species, there was no visible phytotoxic effect in the control and the recovery of the highest test item concentration (1760 g a.s./ha, corresponding to 8.8 g a.s./L) was within the required range of 70-110% of nominal concentration (actual analysed concentration: 6.2 g a.s./L, corresponding to 70.5% of nominal concentration).

PENDIMETHALIN 40% SC was shown to have rate related effects on the vegetative vigour of terrestrial non target plants.

Tomato (*Solanum lycopersicum* L.) was the most sensitive species in term of effects on biomass (dry weight), with a NOER biomass of 22 g a.s./ha, a LOER biomass of 66 g a.s./ha and an ER 50 biomass calculated to be 149.0 g a.s./ha (95% confidence limits not calculable). The least sensitive species were found to be wheat, ryegrass and pea with a NOER biomass of 1760 g a.s./ha and both LOER biomass and ER 50 biomass estimated to be > 1760 g a.s./ha.

Tomato (*Solanum lycopersicum* L.) was the most sensitive species in term of effects on height (shoot height), with a NOER height of 66 g a.s./ha, a LOER height of 196 g a.s./ha and an ER50 height estimated to be > 196 g a.s./ha. The least sensitive species were wheat, ryegrass and pea with a NOER height of 1760 g a.s./ha and both LOER height and ER50 height estimated to be > 1760 g a.s./ha.

For mortality parameter, the NOER mortality was 196 g a.s./ha and both LOER mortality and ER50 mortality were estimated to be > 196 g a.s./ha for lettuce and tomato. For all other species, the NOER mortality was 1760 g a.s./ha and both LOER mortality and ER50 mortality were estimated to be > 1760 g a.s./ha.

The overall lowest ER50 (biomass endpoint; 149.0 g a.s./ha with 95% confidence limits not calculable) was observed with the tomato (*Solanum lycopersicum* L.).

Comments of zRMS:	The study is considered valid. All validity criteria were met.						
	<p>The seedling emergence in the control (validity criterion: at least 70%) was as follows:</p> <ul style="list-style-type: none"> - 100% – Soybean, - 95.2% – Oilseed rape, - 100% – Onion, - 100% – Oats, - 100% – Lettuce, - 100% – Sugar beet, - the mean survival of the emerged control seedlings was 100% in case of all the experimental species (validity criterion: at least 90%) - the control seedlings did not exhibit any visible phytotoxic symptoms - environmental conditions for all plants belonging to the same species were identical <p>Agreed endpoints:</p> <p>Pendimethalin 455 g/L CS: the ER₁₀, ER₂₅, ER₅₀, NOER values.</p>						
	Endpoint value	Soybean (<i>Glycine max</i>)	Oilseed rape (<i>Brassica napus</i>)	Onion (<i>Allium cepa</i>)	Oats (<i>Avena sativa</i>)	Lettuce (<i>Lactuca sativa</i>)	Sugar beet (<i>Beta vulgaris</i>)

Plant number at the end of the experiment							
ER ₁₀	kg/ha ^a	1.307	1.468	1.371	1.371	1.487	1.886
	kg/ha ^b	0.6	0.7	0.6	0.6	0.7	0.9
ER ₂₅	kg/ha ^a	2.813	3.108	2.758	2.758	3.197	3.902
	kg/ha ^b	1.3	1.4	1.3	1.3	1.5	1.8
ER ₅₀	kg/ha ^a	6.589	7.152	5.993	5.993	7.482	8.752
	kg/ha ^b	3.0	3.3	2.7	2.7	3.4	4.0
NOER	kg/ha ^a	2.25	2.25	2.25	2.25	2.25	2.25
	kg/ha ^b	0.5	1.0	1.0	1.0	1.0	1.0
Shoot length (plants without roots)							
ER ₁₀	kg/ha ^a	1.259	1.296	1.165	1.130	1.288	1.551
	kg/ha ^b	0.6	0.6	0.5	0.5	0.6	0.7
ER ₂₅	kg/ha ^a	2.761	2.828	2.542	2.510	3.019	3.380
	kg/ha ^b	1.3	1.3	1.2	1.1	1.4	1.5
ER ₅₀	kg/ha ^a	6.611	6.726	6.052	6.096	7.783	8.031
	kg/ha ^b	3.0	3.1	2.8	2.8	3.5	3.7
NOER	kg/ha ^a	1.125	1.125	1.125	1.125	1.125	1.125
	kg/ha ^b	0.5	0.5	0.5	0.5	0.5	0.5
Plant dry weight (plants without roots)							
ER ₁₀	kg/ha ^a	1.312	1.534	1.081	1.237	1.352	1.747
	kg/ha ^b	0.6	0.7	0.5	0.6	0.6	0.8
ER ₂₅	kg/ha ^a	2.618	3.352	2.256	2.474	2.926	3.430
	kg/ha ^b	1.2	1.5	1.0	1.1	1.3	1.6
ER ₅₀	kg/ha ^a	5.639	7.985	5.112	5.342	6.896	7.260
	kg/ha ^b	2.6	3.6	2.3	2.4	3.1	3.3
NOER	kg/ha ^a	1.125	1.125	1.125	1.125	1.125	1.125
	kg/ha ^b	0.5	0.5	0.5	0.5	0.5	0.5
a: value for the test item, i.e. Pendimethalin 455 g/l CS expressed as Kg/ha b: value for active substance, i.e. Pendimethalin expressed as Kg/ha							

Reference:	KCP 10.6.2-03
Report:	“Effect of Pendimethalin 455 g/L CS on Seedling Emergence and Seedling Growth of Terrestrial Plants”. S. XXX, 9419/2021, 2021. Bioscience Research Foundation
Guideline(s):	OECD No. 208 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The study, aimed at evaluating the effect of Pendimethalin 455 g/L CS on seedling emergence and seedling growth of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species.

The test item was sprayed onto the soil surface. For each species, five application rates were used. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots (3 seeds/pot, i.e. 21 seeds/application rate (7 pots/application rate) for oilseed rape and lettuce, 2 seeds/pot i.e. 20 seeds/application rate (10 pots/application rate) for soybean and sugar beet and 5 seeds/pot i.e. 20 seeds/application rate (4 pots/application rate) for onion and oats). The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for emergence on every day and visual phytotoxicity (after 7 and 14 days). The experiment finished 14 days after the emergence of 50% of the control seedlings. At the end of the experiment, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60°C, and weighed.

The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER10, ER25, ER50, and NOER.

Material and methods

Test item: Name: Pendimethalin 455 g/L CS
Batch number: SCL - 80067
Manufacturing date: 18th May 2020
Expiry date: 17th May 2022

Test species: Soybean (*Glycine max*), Oilseed rape (*Brassica napus*), Onion (*Allium cepa*), Oats (*Avena sativa*), Lettuce (*Lactuca sativa*), Sugar beet (*Beta vulgaris*)

Test design: Number of rates: 5 application rates + control
Number of replicates: 4, 7, 10 per application
Number of seeds: 20, 21 per application
Test termination: 14 days after the emergence of 50% of the control seedlings

Application rates: Control (test soil without test item), 1.125, 2.25, 4.5, 9 and 18 kg/ha Pendimethalin 455 g/L CS

Soil: sandy loam soil containing 1.2% organic carbon, the soil was sieved to 2 mm particle size

Endpoints: ER₁₀, ER₂₅, ER₅₀, NOER

Test conditions: Temperature: 20°C – 23.1°C
Humidity: 58.1 – 64.2
Photoperiod: 16 hours light / 8 hours darkness
Light intensity: 326–400 µE/m²/s
Carbon dioxide concentration: 328 – 341 ppm

Statistical analysis: Probit analysis in the NCSS and one-way ANOVA using GraphPad Prism 8.0

Validity criteria: - the seedling emergence in the control (validity criterion: at least 70%) was as follows:
- 100% – Soybean,
- 95.2% – Oilseed rape,
- 100% – Onion,
- 100% – Oats,
- 100% – Lettuce,
- 100% – Sugar beet,
- the mean survival of the emerged control seedlings was 100% in case of all the experimental species (validity criterion: at least 90%)

- the control seedlings did not exhibit any visible phytotoxic symptoms
- environmental conditions for all plants belonging to the same species were identical

Findings

Compared effect to the control (%)

Appl. Rate (kg/ha)	Soybean			Oilseed rape			Onion		
	Plant n°	Shoot length	Plant weight	Plant n°	Shoot length	Plant weight	Plant n°	Shoot length	Plant weight
Ctrl	-	-	-	-	-	-	-	-	-
1.125	5.0	4.6	3.4	5.0	3.9	2.1	5.0	5.1	6.2
2.25	23.8	24.4	25.3	15.0	21.6	18.6	20.0	27.3	29.2
4.5	38.1	42.4	48.6	45.0	47.5	38.7	45.0	45.0	50.8
9	61.9	57.4	61.4	55.0	54.6	56.1	65.0	58.8	65.7
18	76.2	76.5	83.8	75.0	75.8	68.4	80.0	79.3	83.4
Appl. Rate (kg/ha)	Oats			Lettuce			Sugar beet		
	Plant n°	Shoot length	Plant weight	Plant n°	Shoot length	Plant weight	Plant n°	Shoot length	Plant weight
Ctrl	-	-	-	-	-	-	-	-	-
1.125	5.0	4.1	5.1	4.8	4.7	3.7	5.0	2.8	2.0
2.25	20.0	29.9	25.8	14.3	22.5	23.2	10.0	17.9	14.2
4.5	45.0	43.6	48.5	42.9	39.4	41.4	30.0	39.3	41.9
9	65.0	60.6	65.4	57.1	51.3	55.2	55.0	51.8	56.2
18	80.0	77.1	84.4	71.4	71.3	76.4	70.0	71.0	76.4

Phytotoxicity and plant damage

Appl. Rate (kg/ha)	Soybean		Oilseed rape		Onion	
	Mean effect (%)	Symptoms	Mean effect (%)	Symptoms	Mean effect (%)	Symptoms
Ctrl	0.00	N	0.00	N	0.00	N
1.125	0.00	N	0.00	N	0.00	N
2.25	2.5	N,C	0.00	N	0.71	N,C
4.5	9	N,C,Ld	5.71	N,C	7.5	N,C,Ld
9	14.38	C,Ld,Sd	7.86	N,C,Ld	17.5	C,Ld
18	27.5	C,Ld,Sd,W	18	C,Ld,Sd,Ne	28.33	C,Ld,Sd,W
Appl. Rate (kg/ha)	Oats		Lettuce		Sugar beet	
	Mean effect (%)	Symptoms	Mean effect (%)	Symptoms	Mean effect (%)	Symptoms
Ctrl	0.00	N	0.00	N	0.00	N
1.125	0.00	N	0.00	N	0.00	N
2.25	3.75	N,C	1.43	N,C	1.5	N,C
4.5	10	C,Ld	4.29	N,C,Ld	9.5	N,C
9	20	C,Ld,Sd	11.43	C,Ld	14.38	C,Ld,Sd
18	31.67	C,Ld,Sd,W	26.67	C,Ld,Sd,Ne	19.17	C,Ld,Sd,Ne

N: normal; C: chlorosis; Ld: leaf deformation; Sd: stem deformation; Ne: necrosis; W: wilting

Pendimethalin 455 g/L CS: the ER₁₀, ER₂₅, ER₅₀, NOER values.

Endpoint value	Soybean (<i>Glycine max</i>)	Oilseed rape (<i>Brassica napus</i>)	Onion (<i>Allium cepa</i>)	Oats (<i>Avena sativa</i>)	Lettuce (<i>Lactuca sativa</i>)	Sugar beet (<i>Beta vulgaris</i>)
Plant number at the end of the experiment						
ER ₁₀	kg/ha ^a	1.307	1.468	1.371	1.371	1.487
	kg/ha ^b	0.6	0.7	0.6	0.6	0.7
ER ₂₅	kg/ha ^a	2.813	3.108	2.758	2.758	3.197
	kg/ha ^b	1.3	1.4	1.3	1.3	1.5
ER ₅₀	kg/ha ^a	6.589	7.152	5.993	5.993	7.482
	kg/ha ^b	3.0	3.3	2.7	2.7	3.4
NOER	kg/ha ^a	2.25	2.25	2.25	2.25	2.25
	kg/ha ^b	0.5	1.0	1.0	1.0	1.0
Shoot length (plants without roots)						
ER ₁₀	kg/ha ^a	1.259	1.296	1.165	1.130	1.288

	kg/ha ^b	0.6	0.6	0.5	0.5	0.6	0.7
ER₂₅	kg/ha ^a	2.761	2.828	2.542	2.510	3.019	3.380
	kg/ha ^b	1.3	1.3	1.2	1.1	1.4	1.5
ER₅₀	kg/ha ^a	6.611	6.726	6.052	6.096	7.783	8.031
	kg/ha ^b	3.0	3.1	2.8	2.8	3.5	3.7
NOER	kg/ha ^a	1.125	1.125	1.125	1.125	1.125	1.125
	kg/ha ^b	0.5	0.5	0.5	0.5	0.5	0.5
Plant dry weight (plants without roots)							
ER₁₀	kg/ha ^a	1.312	1.534	1.081	1.237	1.352	1.747
	kg/ha ^b	0.6	0.7	0.5	0.6	0.6	0.8
ER₂₅	kg/ha ^a	2.618	3.352	2.256	2.474	2.926	3.430
	kg/ha ^b	1.2	1.5	1.0	1.1	1.3	1.6
ER₅₀	kg/ha ^a	5.639	7.985	5.112	5.342	6.896	7.260
	kg/ha ^b	2.6	3.6	2.3	2.4	3.1	3.3
NOER	kg/ha ^a	1.125	1.125	1.125	1.125	1.125	1.125
	kg/ha ^b	0.5	0.5	0.5	0.5	0.5	0.5

a: value for the test item, i.e. Pendimethalin 455 g/l CS expressed as Kg/ha

b: value for active substance, i.e. Pendimethalin expressed as Kg/ha

Comments of zRMS:	The study is considered valid. All validity criteria were met.							
	Agreed endpoints: Pendimethalin 455 g/L CS: the ER ₁₀ , ER ₂₅ , ER ₅₀ , NOER values.							
	Endpoint value		Soybean (<i>Glycine max</i>)	Oilseed rape (<i>Brassica napus</i>)	Onion (<i>Allium cepa</i>)	Oats (<i>Avena sativa</i>)	Lettuce (<i>Lactuca sativa</i>)	Sugar beet (<i>Beta vulgaris</i>)
	Plant number							
	ER₁₀	kg/ha ^a	1.733	1.231	1.308	0.989	1.734	1.595
		kg/ha ^b	0.8	0.6	0.6	0.5	0.8	0.7
	ER₂₅	kg/ha ^a	3.576	2.860	2.819	2.203	3.559	3.554
		kg/ha ^b	1.6	1.3	1.3	1.0	1.6	1.6
	ER₅₀	kg/ha ^a	7.996	7.295	6.613	5.362	7.915	8.658
		kg/ha ^b	3.6	3.3	3.0	2.4	3.6	3.9
	NOER	kg/ha ^a	2.25	2.25	2.25	1.125	2.25	2.5
		kg/ha ^b	1.0	1.0	1.0	0.5	1.0	1.1
	Shoot length (plants without roots)							
	ER₁₀	kg/ha ^a	1.315	1.509	1.192	1.197	1.610	1.757
		kg/ha ^b	0.6	0.7	0.5	0.5	0.7	0.8
	ER₂₅	kg/ha ^a	2.757	3.075	2.493	2.402	3.261	3.467
		kg/ha ^b	1.3	1.4	1.1	1.1	1.5	1.6
	ER₅₀	kg/ha ^a	6.272	6.781	5.660	5.208	7.143	7.377
		kg/ha ^b	2.9	3.1	2.6	2.4	3.3	3.4
	NOER	kg/ha ^a	1.125	1.125	1.125	1.125	1.125	1.125
kg/ha ^b		0.5	0.5	0.5	0.5	0.5	0.5	
Plant dry weight (plants without roots)								
ER₁₀	kg/ha ^a	1.357	1.466	1.124	1.161	1.508	1.639	
	kg/ha ^b	0.6	0.7	0.5	0.5	0.7	0.7	

ER ₂₅	kg/ha ^a	2.919	3.202	2.317	2.326	3.202	3.434
	kg/ha ^b	1.3	1.5	1.1	1.1	1.5	1.6
ER ₅₀	kg/ha ^a	6.835	7.631	5.176	5.036	7.394	7.810
	kg/ha ^b	3.1	3.5	2.4	2.3	3.4	3.6
NOER	kg/ha ^a	1.125	1.125	1.125	1.125	1.125	1.125
	kg/ha ^b	0.5	0.5	0.5	0.5	0.5	0.5

^a: value for the test item, i.e. Pendimethalin 455 g/L CS expressed as kg/ha
^b: value for active substance, i.e. Pendimethalin expressed as kg/ha

Reference:	KCP 10.6.2-04
Report:	“Effect of Pendimethalin 455 g/l CS on vegetative vigour of terrestrial plants”. S. XXX, 9420/2021, 2021. Bioscience Research Foundation
Guideline(s):	OECD No. 227 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The study, aimed at evaluating the effect of Pendimethalin 455 g/L CS on vegetative vigour of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. The test item was sprayed onto the plant leaf surface. For each species, five application rates were used. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots (3 seeds/pot, i.e. 21 seeds/application rate (7 pots/application rate) for oilseed rape and lettuce, 2 seeds/pot i.e. 20 seeds/application rate (10 pots/application rate) for soybean and sugar beet and 5 seeds/pot i.e. 20 seeds/application rate (4 pots/application rate) for onion and oats). The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for visual phytotoxicity (7, 14 and 21 days after the test item application) and mortality. The experiment finished 21 days after the spraying. At the end of the experiment, the number of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60°C to a constant weight and weighed.

The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER10, ER25, ER50, and NOER.

Material and methods

Test item: Name: Pendimethalin 455 g/L CS
 Batch number: SCL - 80067
 Manufacturing date: 18th May 2020
 Expiry date: 17th May 2022

Test species: Soybean (*Glycine max*), Oilseed rape (*Brassica napus*), Onion (*Allium cepa*),
 Oats (*Avena sativa*), Lettuce (*Lactuca sativa*), Sugar beet (*Beta vulgaris*)

Test design: Number of rates: 5 application rates + control
 Number of replicates: 4, 7, 10 per application
 Number of seeds: 20, 21 per application

	Test termination: 21 days after the spraying
Application rates:	Control (test soil without test item), 1,125, 2,25, 4,5, 9 and 18 kg/ha Pendimethalin 455 g/L CS
Soil:	sandy loam soil containing 1.2% organic carbon, the soil was sieved to 2 mm particle size
Endpoints:	ER ₁₀ , ER ₂₅ , ER ₅₀ , NOER
Test conditions:	Temperature: 20.5°C – 22.6°C
	Humidity: 54.5 – 65.6
	Photoperiod: 16 hours light / 8 hours darkness
	Light intensity: 328–400 µE/m ² /s
	Carbon dioxide concentration: 332–350 ppm
Statistical analysis:	Probit analysis in the NCSS and one-way ANOVA using GraphPad Prism 8.0
Validity criteria:	- the seedling emergence in the control (validity criterion: at least 70%) was as follows: <ul style="list-style-type: none">- 100% – Soybean,- 100% – Oilseed rape,- 100% – Onion,- 100% – Oats,- 100% – Lettuce,- 100% – Sugar beet,
	- the mean survival of the emerged control seedlings was 100% in case of all the experimental species (validity criterion: at least 90%)
	- the control seedlings did not exhibit any visible phytotoxic symptoms
	- environmental conditions for all plants belonging to the same species were identical

Findings

Compared effect to the control (%)

Appl. Rate (kg/ha)	Soybean			Oilseed rape			Onion		
	Plant n°	Shoot length	Plant weight	Plant n°	Shoot length	Plant weight	Plant n°	Shoot length	Plant weight
Ctrl	-	-	-	-	-	-	-	-	-
1.125	5.0	4.6	3.8	9.5	3.2	1.5	5.0	4.6	4.0
2.25	15.0	22.9	22.1	19.0	19.8	21.5	20.0	25.4	27.9
4.5	30.0	43.2	42.0	38.1	39.9	41.5	45.0	48.5	54.4
9	55.0	61.1	57.5	52.4	60.2	53.0	60.0	65.8	67.3
18	75.0	78.5	75.5	76.2	77.0	71.5	75.0	78.9	80.8
Appl. Rate (kg/ha)	Oats			Lettuce			Sugar beet		
	Plant n°	Shoot length	Plant weight	Plant n°	Shoot length	Plant weight	Plant n°	Shoot length	Plant weight
Ctrl	-	-	-	-	-	-	-	-	-
1.125	10.0	3.9	3.4	4.8	3.0	4.5	5.0	1.6	1.8
2.25	25.0	25.9	28.5	14.3	17.7	19.0	15.0	16.2	19.0
4.5	50.0	53.6	54.6	33.3	38.3	36.0	35.0	37.1	36.4
9	65.0	68.1	68.4	52.4	58.4	56.2	50.0	59.2	54.5
18	80.0	81.8	82.7	76.2	76.1	75.1	70.0	74.8	72.6

Phytotoxicity and plant damage

Appl. Rate (kg/ha)	Soybean		Oilseed rape		Onion	
	Mean effect (%)	Symptoms	Mean effect (%)	Symptoms	Mean effect (%)	Symptoms
Ctrl	0.0	N	0.0	N	0.0	N
1.125	0.0	N	0.0	N	0.0	N
2.25	0.0	N	0.0	N	6.25	N,C
4.5	8.0	N,C	8.57	N,C,Ld	16.25	C,Ld,Sd
9	12.78	N,C,Ld	15.71	C,Ld,Sd	22.5	C,Ld,Sd
18	27.0	C,Ld,Sd,W	26.0	C,Ld,Sd,Ne	28.75	C,Ld,Sd,W
Appl. Rate (kg/ha)	Oats		Lettuce		Sugar beet	
	Mean effect (%)	Symptoms	Mean effect (%)	Symptoms	Mean effect (%)	Symptoms
Ctrl	0.0	N	0.0	N	0.0	N
1.125	0.0	N	0.0	N	0.0	N
2.25	6.25	N,C	2.14	N,C	0.0	N
4.5	17.5	C,Ld	8.57	N,C	8	N,C,Ld
9	23.75	C,Ld	15	C,Ld,Sd	16.88	N,C,Ld
18	30.0	C,Ld,Sd,Ne	27.0	C,Ld,Sd,Ne	23.0	C,Ld,Sd,Ne

N: normal; C: chlorosis; Ld: leaf deformation; Sd: stem deformation; Ne: necrosis; W: wilting

Pendimethalin 455 g/L CS: the ER₁₀, ER₂₅, ER₅₀, NOER values.

Endpoint value		Soybean (<i>Glycine max</i>)	Oilseed rape (<i>Brassica napus</i>)	Onion (<i>Allium cepa</i>)	Oats (<i>Avena sativa</i>)	Lettuce (<i>Lactuca sativa</i>)	Sugar beet (<i>Beta vulgaris</i>)
Plant number							
ER ₁₀	kg/ha ^a	1.733	1.231	1.308	0.989	1.734	1.595
	kg/ha ^b	0.8	0.6	0.6	0.5	0.8	0.7
ER ₂₅	kg/ha ^a	3.576	2.860	2.819	2.203	3.559	3.554
	kg/ha ^b	1.6	1.3	1.3	1.0	1.6	1.6
ER ₅₀	kg/ha ^a	7.996	7.295	6.613	5.362	7.915	8.658
	kg/ha ^b	3.6	3.3	3.0	2.4	3.6	3.9
NOER	kg/ha ^a	2.25	2.25	2.25	1.125	2.25	2.5
	kg/ha ^b	1.0	1.0	1.0	0.5	1.0	1.1
Shoot length (plants without roots)							

ER₁₀	kg/ha ^a	1.315	1.509	1.192	1.197	1.610	1.757
	kg/ha ^b	0.6	0.7	0.5	0.5	0.7	0.8
ER₂₅	kg/ha ^a	2.757	3.075	2.493	2.402	3.261	3.467
	kg/ha ^b	1.3	1.4	1.1	1.1	1.5	1.6
ER₅₀	kg/ha ^a	6.272	6.781	5.660	5.208	7.143	7.377
	kg/ha ^b	2.9	3.1	2.6	2.4	3.3	3.4
NOER	kg/ha ^a	1.125	1.125	1.125	1.125	1.125	1.125
	kg/ha ^b	0.5	0.5	0.5	0.5	0.5	0.5
Plant dry weight (plants without roots)							
ER₁₀	kg/ha ^a	1.357	1.466	1.124	1.161	1.508	1.639
	kg/ha ^b	0.6	0.7	0.5	0.5	0.7	0.7
ER₂₅	kg/ha ^a	2.919	3.202	2.317	2.326	3.202	3.434
	kg/ha ^b	1.3	1.5	1.1	1.1	1.5	1.6
ER₅₀	kg/ha ^a	6.835	7.631	5.176	5.036	7.394	7.810
	kg/ha ^b	3.1	3.5	2.4	2.3	3.4	3.6
NOER	kg/ha ^a	1.125	1.125	1.125	1.125	1.125	1.125
	kg/ha ^b	0.5	0.5	0.5	0.5	0.5	0.5

^a: value for the test item, i.e. Pendimethalin 455 g/L CS expressed as kg/ha

^b: value for active substance, i.e. Pendimethalin expressed as kg/ha

A 2.7.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.8 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.9 KCP 10.8 Monitoring data