

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 5400 A

Product name(s): FASHION

Chemical active substance(s):

Fluroxypyr, 250 g/L

North Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(Authorization)

Applicant: Sharda Cropchem Limited

Submission date: January 2022

MS Finalisation date: September 2023;

January 2025

Version history

When	What
January 2022	Application to Ministry of Agriculture and Rural Development as zRMS, as a "no-data" application based on article 33 and 34 of Regulation (EU) No 1107/2009 using data from the existing reference product Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).
September 2023	ZRMs evaluated dRR submitted by Applicant
January 2025	The final Registration Report

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9 Ecotoxicology (KCP 10)

Introduction

FASHION is a herbicide formulated as a emulsion concentrate [EC] containing 250 g/L of Fluroxypyr for professional use. Sharda Cropchem Limited consider that the proposed formulation is comparable to the Dow AgroSciences Polska Sp. z o.o. product Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99) registered in the Poland under Regulation (EC) 1107/2009. The uses and claims for which approval is being sought are the same as those already approved for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99) in the Poland and for which data are unprotected.

Fluroxypyr was renewed and approved under Commission Implementing Regulation (EU) No 736/2011 of 26 July 2011 and was subsequently listed as an approved active substance under Regulation 1107/2009 on 25th May 2011 (Implementing Regulation 540/2011). Data protection on all active substance data submitted on Fluroxypyr expired on 9th October 2015 – 30 months after renewal on 10.04.2013 reference product Starane 250 EC.

As the data protection period has expired for the active substances Fluroxypyr, Sharda Cropchem Limited are making application for authorisation of FASHION on the basis that FASHION and Starane 250 EC are comparable. Starane 250 EC was registered in the Poland more than 10 years ago – on 19.10.1999. Therefore data supporting the national approval of Starane 250 EC in the Poland should no longer be protected.

Consequently, Sharda Cropchem Limited apply for authorisation in accordance with article 33 of Regulation (EU) No 1107/2009, claiming exemption from provision of any study reports allowed for under article 34 of the same regulation.

The proposed Sharda source of Fluroxypyr was evaluated by UK. The GLP 5-batch data was evaluated as part of this applications. The equivalence report is available on CIRCABC. The applicant considers FASHION to be comparable, to Starane 250 EC: details provided in Table 1.2-1 of Draft Registration Report – Part C.

The risk assessment conclusions are based on the information, data and assessments contained within the EU review of Fluroxypyr and the review carried out for the registration of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99). The data supporting these reviews of Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99) are out of protection and therefore maybe accessed by the evaluating authorities. Therefore, no new data nor risk assessment are required and thus not presented in the current dossier.

Therefore, on the assumption that the products FASHION and Starane 250 EC are sufficiently similar, it is entirely valid scientifically to extrapolate from the Starane 250 EC review to support the authorisation of FASHION in the Poland but also elsewhere in the European Union.

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

PPP (product name/code):	FASHION / SHA 5400 A	Formulation type:	EC (Emulsion Concentrate)
Active substance 1:	Fluroxypyr	Conc. of as 1:	250 g/L
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Sharda Cropchem Limited	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Central	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes/no		

GAP rev. 0, date: January 2022

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use- No. (e)	Member state(s)	Crop and/ or situa- tion (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	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 arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	Winter wheat, winter triticale	F	<i>Dicotyledons weeds</i>	Spraying	BBCH 13- 37	a) 1 b) 1	-	a) 0,6-0,8 b) 0,6-0,8	a) 0.15 – 0.2 b) 0.15 - 0.2	200- 300	-	Tank mixture: 0,3 l/Ha FASH- ION + 15 g/Ha of Tribenuron methyl 750 g/Kg	A	A	A	A	A	A	A
2	PL	Spring wheat, spring barley	F	<i>Dicotyledons weeds</i>	Spraying	BBCH 13- 37	a) 1 b) 1	-	a) 0,6 b) 0,6	a) 0.15 b) 0.15	200- 300	-	Tank mixture: 0,3 l/Ha FASH- ION + 15 g/Ha of Tribenuron methyl 750 g/Kg	A	A	A	A	A	A	A

3.	PL	Grassland	F	<i>Dicotyledons weeds</i>	Spraying	From early spring to middle of September. Weeds in 8-10 cm high or BBCH 13-14.	a) 1 b) 1	-	a) 0,8 b) 0,8	a) 0.2 b) 0.2	200-300	-		A	A	A	A	A	A	A
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Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
 (c) g/kg or g/l

(d) Select relevant
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
 2 Use official codes/nomenclatures of EU Member States
 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
 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
 5 Scientific names and 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.
 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.

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
 8 The maximum number of application possible under practical conditions of use must be provided.
 9 Minimum interval (in days) between applications of the same product
 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.
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
 13 PHI - minimum pre-harvest interval
 14 Remarks may include: Extent of use/economic importance/restrictions

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

9.1.1 Overall conclusions

zRMS comment: No data is provided in support of the application for authorization of FASHION. Reference is made to the unprotected data and dossier in support Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), in accordance with Article 34 of Regulation 1107/2009/EC. All data referred to points 9.1.1 – 9.1.3 are in line EFSA Journal 2011; 9(3): 2091. The evaluation of the application for FASHION resulted in the decision to grant the authorization.

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.1.1.3 Effects on bees (KCP 10.3.1)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

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

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

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

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.1.2 Grouping of intended uses for risk assessment

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.1.3 Consideration of metabolites

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

9.2.1.1 Justification for new endpoints

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.2.2 Risk assessment for spray applications

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

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.2.2.2 Higher-tier risk assessment

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.2.2.3 Drinking water exposure

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.2.2.4 Effects of secondary poisoning

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.2.2.5 Biomagnification in terrestrial food chains

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

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

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.2.4 Overall conclusions

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

zRMS comment: No data is provided in support of the application for authorization of FASHION. Reference is made to the unprotected data and dossier in support Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), in accordance with Article 34 of Regulation 1107/2009/EC. All data referred to points 9.1.1 – 9.13 are in line EFSA Journal 2011; 9(3): 2091. **According to the Registration Report for STARANE 250 EC acute and long-term risk assessment for birds have been accepted.** On the basis of performed calculations in STARANE 250 EC report, acceptable acute and long-term risk to birds may be concluded from proposed uses of FASHION. **No additional risk assessment is required.**

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

9.3.1 Toxicity data

9.3.1.1 Justification for new endpoints

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.3.2 Risk assessment for spray applications

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

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.3.2.2 Higher-tier risk assessment

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.3.2.3 Drinking water exposure

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.3.2.4 Effects of secondary poisoning

It was not considered necessary to produce additional data and the evaluator is referred to the registration

report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.3.2.5 Biomagnification in terrestrial food chains

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

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

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.3.4 Overall conclusions

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

zRMS comment: No data is provided in support of the application for authorization of FASHION. Reference is made to the unprotected data and dossier in support Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), in accordance with Article 34 of Regulation 1107/2009/EC. All data referred to points 9.1.1 – 9.13 are in line EFSA Journal 2011; 9(3): 2091. **According to the Registration Report for STARANE 250 EC acute and long-term risk assessment for mammals have been accepted.** On the basis of performed calculations in STARANE 250 EC report, acceptable acute and long-term risk to mammals may be concluded from proposed uses of FASHION. **No additional risk assessment is required.**

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

9.5.1.1 Justification for new endpoints

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.5.2 Risk assessment

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.5.3 Overall conclusions

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

zRMS comment: No data is provided in support of the application for authorization of FASHION. Reference is made to the unprotected data and dossier in support Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), in accordance with Article 34 of Regulation 1107/2009/EC. All data referred to points 9.1.1 – 9.13 are in line EFSA Journal 2011; 9(3): 2091. **According to the Registration Report for STARANE 250 EC risk assessment for aquatic organisms have been accepted.** On the basis of performed calculations in STARANE 250 EC report, acceptable acute and long-term risk to aquatic organisms may be concluded from proposed uses of FASHION. **No additional risk assessment is required.**

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

9.6.1.1 Justification for new endpoints

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.6.2 Risk assessment

9.6.2.1 Hazard quotients for bees

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.6.3 Effects on bumble bees

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.6.4 Effects on solitary bees

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.6.5 Overall conclusions

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

zRMS comment: No data is provided in support of the application for authorization of FASHION. Reference is made to the unprotected data and dossier in support Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), in accordance with Article 34 of Regulation 1107/2009/EC. All data referred to points 9.1.1 – 9.13 are in line EFSA Journal 2011; 9(3): 2091. **According to the Registration Report for STARANE 250 EC risk assessment for bees have been accepted based on acute and contact toxicity test for bees** (The HQ values are lower than the trigger of 50, indicating low risk to bees from following application of **STARANE 250 EC**). On the basis of performed calculations in STARANE 250 EC report, acceptable acute and contact risk to bees may be concluded from proposed uses of FASHION. **However, according to EU Reg. 284 /2009, the chronic toxicity test for adult bees as well as the chronic test for larvae should be provided for authorisation of plant protection product.** The risk assessment based on this studies should be considered when GD for Bees, 2013 is implemented at EU level.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

9.7.1.1 Justification for new endpoints

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.7.2 Risk assessment

9.7.2.1 Risk assessment for in-field exposure

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.7.2.2 Risk assessment for off-field exposure

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.7.2.3 Additional higher-tier risk assessment

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.7.2.4 Risk mitigation measures

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.7.3 Overall conclusions

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

zRMS comment: No data is provided in support of the application for authorization of FASHION. Reference is made to the unprotected data and dossier in support Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), in accordance with Article 34 of Regulation 1107/2009/EC. All data referred to points 9.1.1 – 9.13 are in line EFSA Journal 2011; 9(3): 2091. **According to the Registration Report for STARANE 250 EC risk assessment for non-target arthropods other than bees have been accepted.** On the basis of performed calculations in STARANE 250 EC report, acceptable in-field and off-field risk to non-target arthropods other than bees may be concluded from proposed uses of FASHION. **No additional risk assessment is required.**

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

9.8.1.1 Justification for new endpoints

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.8.2 Risk assessment

9.8.2.1 First-tier risk assessment

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.8.2.2 Higher-tier risk assessment

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.8.3 Overall conclusions

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

zRMS comment: No data is provided in support of the application for authorization of FASHION. Reference is made to the unprotected data and dossier in support Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), in accordance with Article 34 of Regulation 1107/2009/EC. All data referred to points 9.1.1 – 9.13 are in line EFSA Journal 2011; 9(3): 2091. **According to the Registration Report for STARANE 250 EC risk assessment for earthworms and soil macro-organisms have been accepted.** On the basis of performed calculations in STARANE 250 EC report, acceptable risk to earthworms and soil macro-organisms may be concluded from proposed uses of FASHION. **No additional risk assessment is required.**

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

9.9.1.1 Justification for new endpoints

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.9.2 Risk assessment

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.9.3 Overall conclusions

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

zRMS comment: No data is provided in support of the application for authorization of FASHION. Reference is made to the unprotected data and dossier in support Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), in accordance with Article 34 of Regulation 1107/2009/EC. All data referred to points 9.1.1 – 9.13 are in line EFSA Journal 2011; 9(3): 2091. **According to the Registration Report for STARANE 250 EC risk assessment for micro-organisms have been accepted.** On the basis of performed calculations in STARANE 250 EC report, acceptable risk to micro-organisms may be concluded from proposed uses of FASHION. **No additional risk assessment is required.**

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

9.10.1 Toxicity data

9.10.1.1 Justification for new endpoints

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.10.2.3 Higher-tier risk assessment

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.10.2.4 Risk mitigation measures

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.10.3 Overall conclusions

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

zRMS comment: No data is provided in support of the application for authorization of FASHION. Reference is made to the unprotected data and dossier in support Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99), in accordance with Article 34 of Regulation 1107/2009/EC. All data referred to points 9.1.1 – 9.13 are in line EFSA Journal 2011; 9(3): 2091. **According to the Registration Report for STARANE 250 EC risk assessment for non-target terrestrial plants have been accepted.** On the basis of performed calculations in STARANE 250 EC report, acceptable risk to non-target terrestrial plants may be concluded from proposed uses of FASHION. **No additional risk assessment is required.**

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

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.12 Monitoring data (KCP 10.8)

It was not considered necessary to produce additional data and the evaluator is referred to the registration report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

9.13 Classification and Labelling

It was not considered necessary to produce additional data and the evaluator is referred to the registration

report for Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).

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.

Appendix 2 Detailed evaluation of the new studies

No new additional studies have been submitted.

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
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
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
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
A 2.3.1.1.2	KCP 10.3.1.1.2	Acute contact toxicity to bees
A 2.3.1.2	KCP 10.3.1.2.	Chronic toxicity to bees
A 2.3.1.3	KCP 10.3.1.3	Effects on honey bee development and other honey bee life stages
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 10.4	Effects on non-target soil meso- and macrofauna
A 2.4.1	KCP 10.4.1	Earthworms
A 2.4.1.1	KCP 10.4.1.1	Earthworms - sub-lethal effects
A 2.4.1.2	KCP 10.4.1.2	Earthworms - field studies
A 2.4.2	KCP 10.4.2	Effects on non-target soil meso- and macrofauna (other than earthworms)
A 2.4.2.1	KCP 10.4.2.1	Species level testing
A 2.4.2.2	KCP 10.4.2.2	Higher tier testing
A 2.5	KCP 10.5	Effects on soil nitrogen transformation
A 2.6	KCP 10.6	Effects on terrestrial non-target higher plants
A 2.6.1	KCP 10.6.1	Summary of screening data
A 2.6.2	KCP 10.6.2	Testing on non-target plants

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.8 KCP 10.8 Monitoring data