FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 2619 A

Product name(s): KONARK

Chemical active substances:

Flufenacet, 60 g/L
Pendimethalin, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

Applicant: Sharda Cropchem España S.L.

Submission date: March 2021

MS Finalisation date: January 2023; May 2023; October 2023

Version history

When	What
01.2023	Draft assessment prepared by zRMS
05.2023	zRMS revision after commenting phase – final version of the RR
11.2023	Corrections made in ecotoxicology risk mitigation

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by SHARDA CROPCHEM ESPAÑA S.L.

The application is for approval of KONARK, an emulsifiable concentrate formulation containing 60 g/L flufenacet and 300 g/L pendimethalin, as an herbicide on cereals.

zRMS: Poland

1.2 Letters of Access

Not applicable. Letter of access not needed.

1.3 Justification for submission of tests and studies

This dossier relies on new test and studies providing data and information specific to the formulation Flufenacet 6% + pendimethalin 30% EC as required by the EU regulations.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	SHA 2619 A
Product name in MS	KONARK
Authorization number	First registration
Function	Herbicide
Applicant	Sharda Cropchem España S.L.
Active substance(s) (incl. content)	Flufenacet; 60 g/L Pendimethalin; 300 g/L
Formulation type	Emulsifiable concentrate [Code: EC]
Packaging	250 mL, 500 mL, 1 L, 5 L and 10 L containers of COEX (HDPE/PA) ~~20L containers of HDPE~~ professional user

Coformulants of concern for national authorizations	-
Restrictions related to identiy	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

The evaluation of the application for KONARK resulted in the decision to grant the authorization.

Efficacy section:

Only post-emergence uses on winter wheat, winter triticale and winter barley is accepted. Pre-emergence use and post-emergence use on winter rye should be excluded from GAP table and Polish label project due to not enough trials.

Mammalian Toxicology:

Classification of KONARK Skin Sens.1/H317 ; **Repr.2/H361d** and EUH066- Repeated exposure may cause skin dryness or cracking .According to the AOEM model, calculations, it can be concluded that the risk for the operator using KONARK is acceptable with PPE and no risk for worker wearing adequate work clothing and with work wear.

According to the EFSA calculator, when a 5m buffer zone is employed and drift reduction technology is incorporated, the risk for residents can be considered as acceptable **and when used pre-emergence on exposed soil when sprayed on a tractor mounted boom outside Buffer zone: 2-3 (m).**

Analytical methods for residues

Data gap:

• A method, including confirmation, for the determination of flufenacet + FOE thiadone in tissues is required according to Regulation (EU) 284/2013 (post-registration requirement).

Residues

No data gaps

2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Skin Sens. 1 Repr.2 Aquatic Acute 1

	Aquatic Chronic 1

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	**GHS07, GHS08**
Signal word:	Warning
Hazard statement(s):	**H317**, H361d, H400, **H410**
Precautionary statement(s):	**P261, P272, P273, P280, P333+P313, P308+P313, 3P362, P391, P501**
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	EUH066- Repeated exposure may cause skin dryness or cracking-

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3*	***Winter cereals (pre-emergence):*** *To protect aquatic organisms respect an 20 m no spray vegetated buffer zone together with 75% of nozzles reduction or 15 m no spray vegetated buffer zone together with 90% of nozzles reduction are considered* ***Winter cereals (post-emergence) To protect aquatic organisms respect an winter cereals in post-emergence 20 m no spray vegetated buffer zone together with 90% of nozzles reduction*** ***Spring cereals (pre-emergence) :****To protect aquatic organisms respect an spring cereals pre-emergence 15 m no spray buffer zone together with 15 m vegetated filter strip and 75% of nozzles reduction are considered.* ***Spring cereals (post-emergence):****To protect aquatic organisms respect an spring cereals in post-emergence 15 m no spray buffer zone together with 75% of nozzles reduction* **Zboża ozime** (zastosowanie przedwschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20 m, ~~w tym 10 m zadarnionej~~ strefy od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% lub wyznaczenie zadarnionej strefy ochronnej o szerokości 15 m od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90 %. **Zboża ozime (zastosowanie powschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej szerokości 20 m od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy**

	redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%. **Zboża jare** (zastosowanie przedwschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej szerokości 15 m od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75 % . **Zboża jare** (zastosowanie przedwschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 15 m od zbiorników z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%. –To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 50% drift reducing nozzles. W celu ochrony roślin niebędących celem zwalczania konieczne jest wyznaczenie strefy ochronnej w odległości 5 m od terenów nieużytkowanych rolniczo lub stosowanie rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50 %.

* According conclusion of efficacy section winter cereals post-emergency was accepted only. Due this fact risk mitigation is required for winter cereals post-emergency uses.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

-	-

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
P280	Work wear (arms, body and legs covered) M/L and A + gloves M/L
Worker protection:	
-	Work wear (arms, body and legs covered) - time period of 32 days after application
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SPe3*	***Winter cereals (pre-emergence):*** *To protect aquatic organisms respect an 20 m no spray vegetated buffer zone together with 75% of nozzles reduction or 15 m no spray vegetated buffer zone together with 90% of nozzles reduction are considered* ***Winter cereals (post-emergence)*** *To protect aquatic organisms respect an winter cereals in post-emergence 20 m no spray vegetated buffer zone together with 90% of nozzles reduction*

	Spring cereals (pre-emergence) :*To protect aquatic organisms respect an spring cereals pre-emergence 15 m no spray buffer zone together with 15 m vegetated filter strip and 75% of nozzles reduction are considered.* ***Spring cereals (post-emergence):****To protect aquatic organisms respect an spring cereals in post-emergence 15 m no spray buffer zone together with 75% of nozzles reduction* **Zboża ozime** (zastosowanie przedwschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20 m, ~~w tym 10 m zadarnionej~~ strefy od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% lub wyznaczenie zadarnionej strefy ochronnej o szerokości 15 m od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90 %. **Zboża ozime** (zastosowanie powschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej szerokości 20 m od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%. **Zboża jare** (zastosowanie przedwschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej szerokości 15 m od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75 % . **Zboża jare** (zastosowanie przedwschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 15 m od zbiorników z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%. *To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 50% drift reducing nozzles.* W celu ochrony roślin niebędących celem zwalczania konieczne jest wyznaczenie strefy ochronnej w odległości 5 m od terenów nieużytkowanych rolniczo lub stosowanie rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50 %.
Other specific restrictions	
-	-

* According conclusion of efficacy section winter cereals post-emergency was accepted only. Due this fact risk mitigation is required for winter cereals post-emergency uses.

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.

-	-	-

2.6 Intended uses (only NATIONAL GAP)*

PPP (product name/code):	KONARK / SHA 2619 A	Formulation type:	EC (Emulsifiable Concentrate)
Active substance 1:	Flufenacet	Conc. of as 1:	60 g/L
Active substance 2:	Pendimethalin	Conc. of as 2:	300 g/L
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Sharda Cropchem España S.L.	Professional use:	☒
Zone(s):	Central	Non professional use:	☐
Verified by MS:	yes/no		

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**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 (f)
					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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
~~1~~	~~CEU~~ PL	~~**Winter wheat**~~	~~F~~	~~Broadleaved and grass weeds~~ ~~**Annual** dicotyledonous and **annual** monocotyledonous weeds~~	~~Foliar Spray~~	~~Pre emergence BBCH 00-09~~	~~a) 1~~ ~~b) 1~~	~~NA~~	~~a) 4~~ ~~b) 4~~	~~a) 0.24 flufenacet + 1.2 pendimethanil~~ ~~b) 0.24 flufenacet + 1.2 pendimethanil~~	~~200-400~~	~~-~~	~~Weeds at early stages~~
2	~~CEU~~ PL	**Winter wheat**	F	~~Broadleaved and grass weeds~~ **Annual** dicotyledonous and **annual** monocotyledonous weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages

~~3~~	~~CEU~~ PL	~~**Winter barley**~~	~~F~~	~~Broadleaved and grass weeds~~ **Annual** ~~dicotyledonous and~~ **annual** ~~monocotyledonous weeds~~	~~Foliar Spray~~	~~Pre emergence BBCH 00-09~~	~~a) 1~~ ~~b) 1~~	~~NA~~	~~a) 4~~ ~~b) 4~~	~~a) 0.24 flufenacet + 1.2 pendimethanil~~ ~~b) 0.24 flufenacet + 1.2 pendimethanil~~	~~200-400~~	~~-~~	~~Weeds at early stages~~
4	~~CEU~~ PL	**Winter barley**	F	~~Broadleaved and grass weeds~~ **Annual** dicotyledonous and **annual** monocotyledonous weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages
~~5~~	~~CEU~~ PL	~~**Winter rye**~~	~~F~~	~~Broadleaved and grass weeds~~ **Annual** ~~dicotyledonous and~~ **annual** ~~monocotyledonous weeds~~	~~Foliar Spray~~	~~Pre emergence BBCH 00-09~~	~~a) 1~~ ~~b) 1~~	~~NA~~	~~a) 4~~ ~~b) 4~~	~~a) 0.24 flufenacet + 1.2 pendimethanil~~ ~~b) 0.24 flufenacet + 1.2 pendimethanil~~	~~200-400~~	~~-~~	~~Weeds at early stages~~
~~6~~	~~CEU~~ PL	~~**Winter rye**~~	~~F~~	~~Broadleaved and grass weeds~~ **Annual** ~~dicotyledonous and~~ **annual** ~~monocotyledonous weeds~~	~~Foliar Spray~~	~~Post emergence BBCH 11-25~~	~~a) 1~~ ~~b) 1~~	~~NA~~	~~a) 4~~ ~~b) 4~~	~~a) 0.24 flufenacet + 1.2 pendimethanil~~ ~~b) 0.24 flufenacet + 1.2 pendimethanil~~	~~200-400~~	~~-~~	~~Weeds at early stages~~
~~7~~	~~CEU~~ PL	~~**Winter Triticale**~~	~~F~~	~~Broadleaved and grass weeds~~ **Annual** ~~dicotyledonous and~~ **annual** ~~monocotyledonous weeds~~	~~Foliar Spray~~	~~Pre emergence BBCH 00-09~~	~~a) 1~~ ~~b) 1~~	~~NA~~	~~a) 4~~ ~~b) 4~~	~~a) 0.24 flufenacet + 1.2 pendimethanil~~ ~~b) 0.24 flufenacet + 1.2 pendimethanil~~	~~200-400~~	~~-~~	~~Weeds at early stages~~
8	~~CEU~~ PL	**Winter Triticale**	F	~~Broadleaved and grass weeds~~ **Annual** dicotyledonous and **annual** monocotyledonous weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages
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)													
3													
4													

Minor uses according to Article 51 (zonal uses)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of ambient liquid, with a mild pungent odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point of 109.5°C. It has a self-ignition temperature above 350°C. In aqueous solution, it has a pH value around 4.83 at 25 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The study on the stability for 2-years storage period is on-going and will be provided as soon as possible. Its technical characteristics are acceptable for an *Emulsifiable concentrate* formulation.
The intended concentration of use is 1% to 2%.
The products is not intended to be tank mixed.

3.2 Efficacy (Part B, Section 3)

KONARK (Flufenacet 6% + Pendimethalin 30% EC) is an Emulsifiable Concentrate (EC) containing 60 grams per Litre (g/L) flufenacet and 300 grams per Litre (g/L) pendimethalin for use in winter cereals.

In compliance with the GAP, the following dose rates are applied for registration:

- One application pre-emergence (00-09) in winter cereals to control Broadleaved and Grass weeds, target rate: 4 L/ha
- One application post-emergence (11-25) in winter cereals to control Broadleaved and Grass weeds, target rate: 4 L/ha

This document serves the registration of Flufenacet 6% + Pendimethalin 30% EC in the Central zone of the EU. The objective of this document is to prove and support the label claims of the insecticidal efficacy and crop safety of Flufenacet 6% + Pendimethalin 30% EC in the label claimed crops.

Comprehensive field trials were conducted in Spain, Italy, France, Germany, Czech Republic, UK, Hungary and Poland in 2015/16, 2016/2017 and 2018/19. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

The data demonstrate that the pest control and safety to the crop of Flufenacet 6% + Pendimethalin 30% EC is comparable to that of the flufenacet + pendimethalin co-formulated reference product registered in the EU Central zone, and the applicant therefore wishes to cite the original registrant's data on flufenacet and pendimethalin now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

3.3 Efficacy data

Preliminary tests

The activity of flufenacet and pendimethalin is well known, as both activities have been marketed since the end of the 1990's and the mid-seventies, respectively. Flufenacet is registered as straight product (e.g. Cadou) as well as in mixtures (mainly with diflufenican (e.g. Herold and Fosbury), but also isoxaflutole, pendimethalin, a.o.). Pendimethalin is also registered as straight products (e.g. Stomp) as well as in mix-

tures (mainly with flufenacet (e.g. Frozen, Crystal and Trooper), but also picolinafen, dimethenamid-P, bentazone, imazamox, a.o.).

Both active ingredients are well known. Flufenacet has a broad grass weed spectrum, whereas pendimethalin has effect on some important grass weeds as well as on a wide range of broadleaved weeds and provide also a residual effect. This mixture can be a useful tool in managing or preventing the establishment of resistant weeds.

Based on the knowledge about the active substances and the experiences in the label claimed crops, the necessary application rates to obtain sufficient control of the weeds are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary. However, for PL that justification is is advisable (no plant protection product with flufenacet and pendimenthalin on market). Generally, it can be concluded that combining two actives in flufenacet 60 g/l and pendimethalin 300 g/l has the benefit of reducing the number of products handled by the spray operator as well as an important tool in resistance management.

Minimum effective dose tests

Flufenacet 6% + Pendimethalin 30% EC was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Flufenacet 6% + Pendimethalin 30% EC applied at 1.5 L/ha, 2.0 L/ha, 2.5 L/ha, 3.3 L/ha and 4.0 L/ha was evaluated in 43 cereal trials for the control of the mono- and dicotyledonous weeds present in the trials. The dose rates tested reflects 37.5%, 50%, 62.5%, 82.5% and 100% of the recommended rate of Flufenacet 6% + Pendimethalin 30% EC, in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”. The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy was tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Maritime EPPO zone (i.e. N-France, Germany, Czech Republic and England), the North-east EPPO zone (i.e. Poland), the South-east EPPO zone (i.e. Hungary) and the Mediterranean EPPO zone (i.e. Spain, Italy and S-France).

Efficacy tests and conclusions regarding authorization of intended uses

We are dealing with the active substances used commonly for many years in many countries. According to the EPPO Standard PP1/226: Number of efficacy trials, a major target in a major crop must be supported by 10 trials (range 6-15 trials required depending on factors such as range of environmental and climatic conditions, levels of target pressure and consistency of results) and a minor use/target must be supported by 3 trials (range 2-6 trials).

The field experiments of the herbicide – Konark (product code: SHA 2619 A) were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized. The reports include a detailed data about conditions, agro-technological procedures, fore-crop as well as technical details etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards.

cMS should use scale of efficacy in line with its national guidelines (ex. SANCO). Applicant presented scale of weed sensitivity according to SANCO scale. However, for Poland we should used different scale: S (susceptible) > 85%; MS (moderately susceptible) 70-85%; MT (moderately tolerant) 60-70%; T (tolerant) < 60%.

We are dealing with the active substances used commonly for many years in many countries. However, in PL no product with both substances: pendimenthalin and flufenacet are registered now. So, in the list of weeds controlled should include only those species that occurred (with appropriate intensity) a minimum of three localizations, and in the case of the species with the highest hazard of the plants at least in six locations. The level (>5%) of weed infestation in all studies was sufficient. Only trials with greater than 5 weeds/m^2 or over 2% ground cover have been included.

Also, Concerned Member States will need to consider the relevance of the submitted formulation compa-

rability data in relation to the current authorized uses for the reference product in their own Member State. The evaluation was conducted in accordance with Uniform Principles.

cMS should decide which weed species can be accepted on the basis on presented documentation and their national rules.

Applicant submitted in total 47 efficacy trials: MAR – 15 trials (pre-emergence use – 7 trials: DE-2, CZ-2, UK-2, FR-1 and post-emergence use – 8 trials: DE-2, CZ-2, UK-2, FR-2), MED – 12 trials (pre-emergence use – 7 trials: FR-3, ES-2, IT-2 and post-emergence use – 5 trials: FR-2, ES-1, IT-2), S-E – 4 trials (pre-emergence use – 2 trials: HU and post-emergence use – 2 trials: HU), N-E – 16 trials (pre-emergence use – 2 trials: PL and post-emergence use: 14 trials – PL). In the opinion of Evaluator, Applicant submitted enough number of trials for pre-emeregence use in MAR and MED and for post-emergence use in MAR and N-E. cMS from MED should decide if only 5 valid trials for post-emergence use can be accepted. Also, cMS from S-E should decide if only 2 trials for pre- and post-emergence use can be accepted. cMS from N-E should decide if only 2 trials for pre-emergence use can be accepted.

Following cereals were studied during efficacy trials:

Pre-emergence use:

- HORVW – MAR: 3 trials (DE, CZ, UK), N-E: 1 trial (PL), MED: 2 trials
- TRZAW – MAR: 3 trials (DE, CZ, UK), N-E: 1 trial (PL), MED: 2 trials, S-E: 2 trials
- HORVS – MAR: 1 trial (FR), MED: 1 trial
- HORVX – MED: 1 trial
- TRZDU – MED: 1 trial

Post-emergence use:

- HORVW – MAR: 4 trials (FR, UK, DE, CZ), N-E: 1 trial, MED: 2 trials
- TRZAW – MAR: 4 trials (FR, UK, DE, CZ), N-E: 7 trials, S-E: 2 trials, MED: 2 trials
- TTLWI – N-E: 6 trials
- HORVX – MED: 1 trial

In the opinion of Evaluator, not enough studies have been presented for any of the cereals (in exception of winter triticale in N-E and winter wheat in N-E for post-emergence use). At least 6 valid trials for each EPPO zone should be presented for represenatative crop, to be able to extrapolate the results. However, final decision is left to each cMS. However, based on close comparability in agronomic practices, crop growing areas and conditions, application timing, crop growth habit and weed populations and spectrums between different cereal crops, extrapolation is permitted for efficacy against weeds between different winter cereals and the same can be applicable for spring cereals and between spring and winter cereals. Therefore, the submitted data can also be considered as supportive of demonstrating the efficacy of pre-emergence and post-emergence application of SHA 2619 A at a label rate of 4,0 L product/ha rate against broad-leaved weeds in winter cereals. In the opinion, of Evaluator each cMS should decide if this approach can be acceptable.

Following weed species should be consider by each cMS if they can be acceptable on the basis on submitted documentation:

Pre-emergence use:

- **Maritime EPPO zone:**
  - ✓ 16-48 days after treatment:

AGREE (2 trials), APESV (2 trials), BRSNX (4 trials), MATIN (2 trials), SLYMA (2 trials), STEME (3 trials), THLAR (2 trials), VERHE (3 trials), VIOAR (2 trials).

Following weed species should be excluded due to only 1 valid trial: ALOMY, LOLMU, POAAN, CAPBP, CHEAL, GALAP, MATCH, PAPRH, SINAR, VERPE, VERSS, BRSNN.

  - ✓ 53-204 days after treatment:

ALOMY (2 trials), LOLMU (2 trials), BRSNX (2 trials), FUMOF 92 trials), MATCH (2 trials), VERHE

(2 trials), VIOAR (3 trials), TTTTT (2 trials)

Following weed species should be excluded due to only 1 valid trial: AGREE, APESV, POAAN, CAPBP, GALAP, MATIN, PAPRH, POLAV, SENVU, SLYMA, STEME, THLAR, VERPE.

- **N-E EPPO zone:**
  - ✓ 50 days after treatment:

BRSNW (2 trials), CENCY (2 trials), MATMA (2 trials), VIOAR (2 trials) APESV should be excluded due to only 1 valid trial.

  - ✓ 166-201 days after treatment:

APESV (2 trials), CENCY (2 trials), MATMA (2 trials), VIOAR (2 trials) GALAP should be excluded due to only 1 valid trial.

- **S-E EPPO zone:**
  - ✓ 6-34 days after treatment:

No weed species was represented for at least 2 trials. In the opinion of Evaluator all weed species should be excluded due to only 1 valid trial: ALOMY, APESV, VERHE.

  - ✓ 132-143 days after treatment:

No weed species was represented for at least 2 trials. In the opinion of Evaluator all weed species should be excluded due to only 1 valid trial: ALOMY, APESV, VERHE.

- **MED EPPO zone:**
  - ✓ 12-82 days after treatment:

AMABL (2 trials), ANGAR (2 trials), GALAP (2 trials), SONAS (2 trials), TTTTT (2 trials).

Following weed species should be excluded due to only 1 valid trial: ALOMY, LOLMU, LOLSS, TTTMM, CHYCO, DIPVU, PICHI, POLAV, RANSA, SENVU, VERHE, VERPE, TTTDD.

  - ✓ 98-210 days after treatment:

ALOMY (2 trials), AMABL (2 trials), ANGAR (3 trials), SONAS (2 trials), TTTTT (2 trials).

Following weed species should be excluded due to only 1 valid trial: LOLSS, CHYCO, CIRA, DIPVG, GALAP, MERAN, PICHI, POLAV, POLCO< STEME, VERPE.

Post-emergence use:

- **Maritime EPPO zone:**
  - ✓ 7-78 days after treatment:

ALOMY (4 trials), APESV (2 trials), BRSNW (3 trials), CAPBP (2 trials), GALAP (2 trials), MATIN (2 trials), STEME (3 trials), THLAR (2 trials), VERHE (2 trials), VERPE (2 trials), VIOAR (3 trials), TTTTT (2 trials).

Following weed species should be excluded due to only 1 valid trial: LOLMU, POAAN, FUMOF, MATCH, MEDSA, SINAR.

  - ✓ 75-226 days after treatment:

ALOMY (5 trials), APESV (2 trials), LOLMU (2 trials), BRSNW (2 trials), CAPBP (2 trials), FUMOF (2 trials), GALAP (2 trials), MATCH (2 trials), MATIN (2 trials), STEME (3 trials), THLAR (2 trials), TTTTT (2 trials), VERHE (2 trials), VERPE (3 trials), VIOAR (3 trials).

Following weed species should be excluded due to only 1 valid trial: AVEFA, POAAN, MEDSA, POLCO, SENVU, SINAR, VERSS.

- **N-E EPPO zone:**
  - ✓ 22-31 days after treatment:

APESV (13 trials), ALOMY (3 trials), BRSNW (3 trials), CAPBP (4 trials), CENCY (5 trials), MATMA (8 trials), VERPE (4 trials), VIOAR (12 trials).

- ✓ 154-179 days after treatment:

APESV (14 trials), ALOMY (3 trials), CAPBP (9 trials), CENCY (5 trials), GALAP (4 trials), MATMA (8 trials), VERPE (4 trials), VIOAR (12 trials).

- **S-E EPPO zone:**

- ✓ 14-16 days after treatment:

No weed species was represented for at least 2 trials. In the opinion of Evaluator all weed species should be excluded due to only 1 valid trial: ALOMY, APESV, VERHE.

- ✓ 126-143 days after treatment:

No weed species was represented for at least 2 trials. In the opinion of Evaluator all weed species should be excluded due to only 1 valid trial: ALOMY, APESV, VERHE.

- ✓ 233 days after treatment:

No weed species was represented for at least 2 trials. In the opinion of Evaluator all weed species should be excluded due to only 1 valid trial: APESV.

- **MED EPPO zone:**

- ✓ 14-42 days after treatment:

LOLMU (3 trials), GALAP (2 trials), VERHE (2 trials), TTTTT (2 trials).

Following weed species should be excluded due to only 1 valid trial: LAMAM, PAPRH, RAPRA, SENAG, STEME, URTAN, BBBBB.

- ✓ 28-168 days after treatment:

LOLMU (2 trials), GALAP (2 trials), PAPRH (3 trials), STEME (2 trials).

Following weed species should be excluded due to only 1 valid trial: LAMAM, SENAG, URTAN, VERHE, FUMOF, POLSS, TTTTT, VERPE.

Applicant submitted limited data for most studied weeds. In the opinion of Evaluator weeds studied only in 1 trial should be excluded from GAP table and label project. Applicant correctly presented results. Due to the limited number of results for particular weeds species, it is difficult to make a clear conclusion for the label, especially for weeds which are considered to be major. Therefore, the sufficiency of results should be considered on the national level based on importance of weed in their country.

Extrapolations results from registered products containing flufenacet and pendimethalin should be considered by individual member states on a national level based on current registration, data protection and experience with similar active compounds products. The spectrum of weeds should be checked with label claims on these reference products.

ASSESSMENT FOR POLAND (N-E EPPO ZONE):

Pre-emergence use:

Extrapolation of efficacy data is acceptable from other winter cereals crops based on close comparability in agronomic practices, crop growing areas and conditions, application timing, crop growth habit and weed populations and spectrums. This is endorsed in the EPPO extrapolation table for effectiveness of herbicide in winter cereals, where it is stated that extrapolation of efficacy is acceptable from any winter cereal to all winter cereals. However, for Poland extrapolation is possible only in case when full number of trials is presented for representative cereal (for ex. winter wheat) and at least 3-4 selectivity trials are presented for extrapolated cereal. However, in the opinion of ZRMs winter wheat and winter barley should be registered conditionally in Poland for pre-emergence use. In the pre-emergence applications for winter wheat and winter barley ZRMs and Applicant would like to indicate that the efficacy is independent of the crop present on the field. In these cases, when product is applied crops are not present on the field and have no impact in the efficacy that product can show to control weeds. Additionally, pre-emergence application to all winter cereals is applied on same moment and the target weeds are the same for all winter cereals, thus there is equivalence in terms of application independently of the winter cereal field treated.

Winter wheat is a major crop in PL. Taking into account that the both active substances of KONARK are not currently registered in Poland in other products, the Applicant should submit at least 3 pre-emergence efficacy trials carried out on winter wheat in the N-E EPPO zone within 2 years of obtaining a positive certification. Also, at least 2-3 trials for winter triticale carried out on winter triticale should be submitted (then extrapolation results from winter wheat will be possible).

Classification of weeds (assessed together for winter cereals studied in CZ, DE, and PL).

AGREE – 2 trials (CZ) – due to not enough number of trials, this weed should be excluded from PL label.

APESV – 4 trials (CZ-2, PL-2) – due to not enough number of trials, this weed should be excluded from Polish label.

LOLMU (DE) - 1 trial - due to not enough number of trials, this weed should be excluded from PL label.

BRSNW – 5 trials (DE-1, CZ-2, PL-2) – it is a major weed in cereals. So, at least 6 trials are required. Due to not enough number of trials, this weed should be excluded from Polish label.

CAPBP – 1 trial (DE) - due to not enough number of trials, this weed should be excluded from PL label.

CENCY – 2 trials (PL) - due to not enough number of trials, this weed should be excluded from PL label.

CHEAL – 1 trial (CZ) - due to not enough number of trials, this weed should be excluded from PL label.

GALAP – 1 trial (DE) - due to not enough number of trials, this weed should be excluded from PL label.

MATCH - 1 trial (DE) - due to not enough number of trials, this weed should be excluded from PL label.

MATIN – 2 trials (CZ) - due to not enough number of trials, this weed should be excluded from PL label.

MATMA – 2 trials (PL) - due to not enough number of trials, it should be excluded from PL label.

PAPRH - 1 trial (CZ) - due to not enough number of trials, this weed should be excluded from PL label.

SLYMA – 2 trials (CZ) - due to not enough number of trials, this weed should be excluded from PL label.

STEME – 2 trials (CZ) - due to not enough number of trials, this weed should be excluded from PL label.

THLAR – 2 trials (CZ) - due to not enough number of trials, this weed should be excluded from PL label.

VERHE - 2 trials (CZ) - due to not enough number of trials, this weed should be excluded from PL label.

VIOAR – 4 trials (DE-2, PL-2) - due to not enough number of trials, this weed should be excluded from Polish label. At least 6 trials are required for a major weed.

Since the required number of studies was not submitted for any weed, pre-emergence application will not be included in the Polish label. In the case of a new* active substance, a new active substance, a new mixture of active substances, the number should be increased by a minimum of ½ i.e. 3 and 6). It is also necessary to pay attention to the number of weeds per square meter. For now, no plant protection product with pendimenthalin and flufenacet are registered in PL, so we cannot accepted only 4 trials for major and 2 trials for minor weeds.

Post-emergence use:

Applicant submitted in total 16 valid trials for winter cereals: winter wheat-9 trials (DE-1, CZ-1, PL-7), winter triticale – 6 trials (PL) and winter barley- 3 trials (DE-1, CZ-1, PL-1). Winter barley can be accepted in Polish label on the basis on extrapolation results from winter wheat and winter triticale. Required number of selectivity trials was presented (winter barley – 5 trials, winter wheat-9 trials, winter triticale-4 trials), so that extrapolation of results is possible. Winter rye should be excluded due to lack of selelctivity trials (extrapolation results is not possible).

Classification of weeds (assessed together for winter cereals studied in CZ, DE, and PL).

- APESV – 14 trials (PL) – MS (75,2%) 22-31 days after treatment and S (96,1%) 154-179 days after treatment by recommended dose (4,0 L/ha). It can be concuded that APESV is a susceptibility weed against Konark use at recommended dose. 2 trials from Maritime (CZ) were characterized by very low efficiency after 7-78 days after treatment and excellent efficacy (100%) after treat-

ment (75-226 days).

- ALOMY – 3 trials (PL) – MT (63,3%) 22-31 days after treatment and S (94,3%) 154-179 days after treatment by recommended dose (4,0 L/ha). 2 trials from Maritime (CZ and DE) were characterized by very low efficiency after 7-78 days after treatment and excellent efficacy (96,3%) after treatment (75-226 days). In total 5 trials are not sufficient for including ALOMY in Polish label as susceptible weed. At least 6 trials for major weed is required.
- BRSNW – 3 trials (PL) – T (48,7%) 22-31 days after treatment. 3 trials from CZ and DE – T (41,7%) 7-78 days after treatment and 2 trials from CZ – S (100%) 75-226 days after treatment. In total number of trials is not sufficient. BRSNW is a major weed in PL, so at least 6 trials are required.
- CAPBP – 4 trials (PL) – MS (82,5%) 22-31 days after treatment and 9 trials (PL) – S (92,9%) 154-179 days after treatment. 2 trials from Maritime (DE) were characterized by very low efficiency after 7-78 days after treatment and excellent efficacy (100%) after treatment (75-226 days). CAPBP can be including in Polish label as susceptible weed against Konark use at recommended dose.
- CENCY – 5 trials (PL) – T (47,6%) 22-31 days after treatments and MS (77,2%) 154-179 days after treatment. In total number of trials is not sufficient. CENCY is a major weed in PL, so at least 6 trials are required
- MATMA – 8 trials (PL) – T (48,7%) 22-31 days after treatment and S (91,8%) 154-179 days after treatment. In total number of trials is sufficient. MATMA can be including in Polish label as susceptible weed against Konark use at recommended dose.
- VERPE – 4 trials (PL) – MS (77,3%) 22-31 days after treatment and S (94,3%) 154-179 days after treatment. In total number of trials is sufficient. VERPE can be including in Polish label as susceptible weed against Konark use at recommended dose.
- VIOAR – 12 trials (PL) – T (54,5%) 22-31 days after treatment and S (91,3%) 154-179 days after treatment. 2 trials from Maritime (DE) were characterized by very low efficiency after 7-78 days after treatment and excellent efficacy (97,5%) after treatment (75-226 days). Number of trials is sufficient for including VIOAR in Polish label as susceptible weed.
- GALAP – 4 trials (PL) – MS (72,0%) 154-179 days after treatment and 2 trials from CZ – S (94,4%) 75-226 days after treatment. Number of trials is sufficient for including GALAP in Polish label as moderately susceptible weed.
- MATIN – 2 trials (CZ) – S (100%) 75-226 days after treatment. MATIN is a major weed in winter cereals, so number of trials is not sufficient. In the opinion of Evaluator, MATIN should be excluded from Polish label.
- STEME – 2 trials (CZ) – S (90%) 75-226 days after treatment. STEME is a minor weed in winter cereals, so number of trials is not sufficient for including STEME in Polish label as susceptible weed (at least 3 are required).
- THLAR – 2 trials (CZ) – S (98,8%) 75-226 days after treatment. THLAR is a minor weed in winter cereals, so number of trials is not sufficient for including THLAR in Polish label as susceptible weed (at least 3 are required).

<u>In the Polish label following weeds can be accepted:</u>

- Susceptible weeds: APESV, CAPBP, MATMA, VERPE, VIOAR
- Moderately susceptible weeds: GALAP

Due to not enough trials following weed species should be excluded from polish label: MATIN, STEME, THLAR, ALOMY, BRSNW, CENCY.

Post-emergence use in Poland can be accepted on winter wheat, winter barley and winter triticale. Winter rye should be excluded from label due to lack of trials.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Resistance is a natural phenomenon embodied in the process of the evolution of biological systems and has been experienced over and over again in the past. According to Heap (2018[1]) resistance is the naturally occurring inheritable ability of some weed biotypes within a population to survive an herbicide treatment that would, under normal conditions of use, effectively control that weed population. Selection of resistant biotypes may eventually result in control failures.

The risk of resistance was analysed following the EPPO-Standard (2015[2]), the classification of the Herbicide Resistance Action Committee (HRAC)[3] and the international Survey of Herbicide Resistant Weeds (Heap 2018).

Flufenacet: So far, two cases of resistance with flufenacet in Blackgrass and Italian Ryegrass have been reported worldwide. Of these, one has been reported from Europe. The active substance is therefore classified as having a low inherent risk.

Pendimethalin: So far, ten cases of resistance with pendimethalin in grasses have been reported worldwide. Of these, four has been reported from Europe, i.e. 3 x ALOMY and 1 x ECHCG. The active substance is therefore classified as having a low inherent risk.

~~The evaluation of the agronomic risk concludes, that Flufenacet 6% + Pendimethalin 30% EC bears a low risk of resistance.~~

The Registration of Flufenacet 6% + Pendimethalin 30% EC is endorsed.

Applicant submitted detailed information's about possibilities of development the resistance or cross-resistance. Evaluator accepted the strategy management about possible development of resistance or cross-resistance proposed by Applicant.

Final assessment of the resistance risk has to be carried out on member state level since the agronomic factors influencing the risk of resistance development tend to vary between the Member Without any precautions the resistance risk is unacceptable. The abidance of the requirements within the good agricultural practice is necessary. The resistance management is coordinated by HRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.

The overall resistance risk for KONARK (product code: SHA 2619 A) is moderate.

The herbicide KONARK is intended to control annual mono- and dicotyledonous weed species pre- and early post-emergence in winter cereals and triticale. In Europe, short cereal-based crop rotations are common. Therefore, consecutive uses of KONARK are possible. This enhances the selection pressure. Yet, other herbicide modes of action can be used to control weeds post-emergence. Therefore, the agronomic risk is rated moderate.

The herbicide KONARK is intended to control annual mono- and dicotyledonous weed species such as *Apera spica-venti*, *Digitaria sanguinalis*, *Echinochloa crus-galli*, *Amaranthus retroflexus*, *Capsella bursa-pastoris*, *Chenopodium album*, *Stellaria media* and *Tripleurospermum perforatum*. These weeds have already evolved resistance towards one or more herbicide modes of action. Therefore, the inherent risk of these target species is high.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

[1] Heap, I. M., 2018: The International Survey of Herbicide Resistant Weeds. Web site visited January 2018. http://www.weedscienc.com
[2] EPPO 2015: Standard PP 1/213 (4): Resistance risk analysis.
[3] HRAC: http://www.HRACglobal.com. Web site visited January 2018.

The crop safety of Flufenacet 6% + Pendimethalin 30% EC was assessed in winter cereals in 47 efficacy trials (15 MAR, 16 N-E, 4 S-E and 12 MED) where Flufenacet 6% + Pendimethalin 30% EC was applied at 1.5 L/ha, 2.0 L/ha, 2.5 L/ha and 4.0 L/ha, and in 37 crop safety trials (12 MAR, 12 N-E, 1 S-E and 12 MED) where Flufenacet 6% + Pendimethalin 30% EC was applied at 4.0 L/ha to 8.0 L/ha. In the efficacy- and selectivity trials conducted in winter cereals, Flufenacet 6% + Pendimethalin 30% EC was applied at 2 distinct application timings, i.e. pre-emergence and post-emergence, respectively, and as results from both application timings are included in the summary, a total of 109 applications were assessed in 84 winter cereal trials.

The trials were conducted in the Maritime zone (27; i.e. Germany (8), N-France (7), the Czech Republic (6) and the United Kingdom (6)), the North-east zone (28; i.e. Poland), the South-east zone (5; i.e. Hungary) and the Mediterranean zone (24, i.e. Spain (7), Italy (10) and S-France (7)) in 2015/16 season, 2016/17 season and 2018/19 season, to evaluate the crop safetyness of Flufenacet 6% + Pendimethalin 30% EC in cereals.

Selectivity studies on herbicide were performed by companies authorized to conduct studies on efficacy of plant protection products. The trials were performed with the use of different agricultural practice. The trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. The herbicide has been used in two doses: N and 2N. In all trials studied product was compared to the standard reference products.

Applicant in total submitted 37 selectivity trials: MAR – 12 trials (FR-4, DE-4, CZ-2, UK-2), N-E – 12 trials (PL), S-E – 1 trial (HU) and MED – 12 trials (ES-4, IT-6, FR-2). Trials were performed on winter wheat (17 trials), durum wheat (1 trial), winter barley (15 trials) and winter triticale (4 trials).

- HORVW: MAR-6 trials (DE-2, CZ-1, FR-2, UK-1); MED-7 trials (FR-1, ES-2, IT-4) and N-E-2 trials (PL). Lack of trials from S-E.
- TRZAW: MAR-6 trials (DE-2, CZ-1, FR-2, UK-1); MED-4 trials (ES-2, IT-2); S-E-1 trial (HU) and N-E-6 trials (PL)
- TRZDU: MED-1 trial (FR). Lack of trials from N-E, S-E and MAR.
- TTLWI: N-E-4 trials (PL). Lack of triald from MED, MAR and S-E.

For pre-emergence use Applicant submitted in total 29 selectivity trials carried out on winter barley (MAR: 6 trials, N-E: 2 trials, MED: 7 trials) and winter wheat (MAR: 6 trials, N-E: 2 trials, S-E: 1 trial, MED: 5 trials).

For post-emergence use Applicant submitted in total 37 selelctivity trials carried out on winter barley (MAR: 6 trials, N-E: 2 trials, MED: 7 trials), winter wheat (MAR: 6 trials, N-E: 6 trials, S-E: 1 trial, MED: 5 trials) and winter triticale (N-E: 4 trials).

For Poland (N-E), Applicant submitted enough number of selectivity trials for post-emergence use on winter triticale, winter wheat and winter barley. Lack of trials for winter rye. Extrapolating of phytotoxicity results in Poland between cereals is not allowed.

Pre-emergence - only for winter wheat and winter barley Applicant submitted acceptable number of selectivity trials for Poland. Lack of trials for winter triticale and winter rye (at least 4-5 selectivity trials should be submitted).

The decisions whether each of proposed crop is supported by enough trials considering their importance and possibilities of data extrapolation between EPPO zones is left to each of cMS.

Based on the results, it is reasonable to conclude that a single application of Konark at the proposed label rate of 4,0 L product/ha, and applied according to label recommendations, is crop safe on studied crops. However, in the label should be put an entry about sensitivity of some varieties of cereals (some phytotoxicity effect was observed in few trials. In the opinion of Evaluator, sensitivity varieties can be for example: durum wheat variety Cesare and Babylone, “soft” winter wheat varieties Rebelde, Bologna, Hywin and Matheo winter wheat variety GK Csillag, winter barley variety Beatrix, Etincell and Esterel, Cometa, Volano and Irina.

Effects on yield and quality

35 selectivity trials were conducted between autumn 2015 to summer 2019 to evaluate the effect of Flufenacet 6% + Pendimethalin 30% EC on yield of winter cereals. Two Polish selectivity trials were not harvested due to the poor condition of the crop. In selectivity trials conducted in winter cereals, Flufenacet 6% + Pendimethalin 30% EC was applied at 2 distinct application timings, i.e. pre-emergence and post-emergence, respectively, and as results from both application timings are included in the summary, a total of 62 applications were assessed in 35 selectivity trials.

Flufenacet 6% + Pendimethalin 30% EC was applied on winter cereals in the autumn or early spring (35, i.e. winter wheat (17), winter durum wheat (1), winter barley (13) and triticale (4)) at pre-emergence (i.e. BBCH 00-09) or early post-emergence (i.e. BBCH 10-25). All trials conducted on cereals presented in this Biological Assessment Dossier were located within the Maritime zone (12), the North-east zone (10), the South-East zone (1) and the Mediterranean zone (12), as defined by EPPO Standard PP1/241(1).

Flufenacet 6% + Pendimethalin 30% EC applied at the recommended dose rate (4.0 L/ha) did not affect crop yield significantly in 61 of the 62 application timings evaluated in 35 selectivity trials taken to harvest. In the vast majority of the trials, Flufenacet 6% + Pendimethalin 30% EC applied at dose rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the crop yield.

Pre- and post-emergence application in winter cereals is claimed on the label. For crops and recommendation claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in autumn- and winter-sown cereals where pre- and post-emergence applications were tested. This BAD also clearly demonstrates that the efficacy and crop safety of Flufenacet 6% + Pendimethalin 30% EC is equivalent to the standard flufenacet + pendimethalin co-formulation to which it was compared in 30 of the 35 selectivity trials harvested (52 of 62 applications). The applicant therefore wishes to cite the original registrant's data on flufenacet and pendimethalin now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

Effect on transformation processes

Flufenacet 6% + Pendimethalin 30% SC is composed of flufenacet and pendimethalin which both have widely used for several years on winter wheat and winter barley without identifying any quality problems on the treated crops. According to the Technical circular 471 (December 2015) from the British Beer & Pub association, flufenacet as well as pendimethalin are included in the UK recommended brewing and bread making list.

Flufenacet 6% + Pendimethalin 30% SC is applied early in the season (up to BBCH 25), before inflorescence emergence and heading, and as the active ingredients are not systemic, it is therefore not expected that the active ingredient is transferred to the grains.

According EPPO PP 1/243(1) Effects of plant protection products on transformation processes, " *If the applicant can demonstrate that residues are undetectable, or that any residues will not affect yeasts, a reasoned case may be sufficient to address these requirements*". As can be observed on residues section, Part B, Section 7: Metabolism and residues, residues are below MRL so there is no further testing of transformation processes.

Impact on treated plants or plant products to be used for propagations

Flufenacet 6% + Pendimethalin 30% EC is composed of flufenacet and pendimethalin, which both have been widely used for several years on the GAP claimed crops, without identifying any issues in regard to ability of grains of treated plants to germinate.

Flufenacet 6% + Pendimethalin 30% EC is applied early in the season (pre-emergence to early post-emergence), before inflorescence emergence and heading, and as the active ingredient is not systemic, it is therefore not expected that the active ingredient is transferred to seeds and grains. Thus, no influence on the ability of plant parts from treated crops to germinate is expected.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on succeeding crops.

The applicant conducted a study on seedling emergence to study the impact of the formulation Flufenacet 6% + Pendimethalin 30% EC in succeeding crops.

Conclusions

The test item i.e. **Flufenacet 6% + Pendimethalin 30% EC** had significant impact on the growth and seedling emergence of the perennial ryegrass, oats and cabbage.

Seedling emergence of all tested species was not delayed in comparison to the control group. In case of perennial ryegrass, at the rate equal to 4000.00 mL/ha plants did not emerged.

On the basis of ER10, ER25, ER50 and NOER values determined from final number of plants it was proved that the test item did not inhibit the seedling emergence of sunflower, cabbage, pea, carrot and oats. The test item inhibited the seedling emergence of perennial ryegrass.

On the basis of NOER and ER10, ER25, ER50 values determined from the shoot length and dry shoot weight it was proved that the test item had impact on the process of growth of perennial ryegrass, cabbage and oats.

During the experiment the plant damages as stunted growth and deformations were observed.

The following order of the test plant sensitivity was noticed:

perennial ryegrass > cabbage, oats > sunflower, pea, carrot.

Impact on other plants including adjacent crops

On the basis of the obtained results it was proved that the test item i.e. Flufenacet 6% + Pendimethalin 30% EC had no influence on the plant number.

On the basis of the obtained results it was proved that the test item i.e. Flufenacet 6% + Pendimethalin 30% EC had influence on shoot length and shoot dry weight of cultivation of cabbage, pea, carrot, perennial ryegrass and oats at the end of the experiment. The impact depended on the rate and species.

During the experiment the plant damages were observed: stunted growth, wilting, chlorosis, spots, deformations, necrosis.

The following order of the test plant sensitivity was noticed:

pea > cabbage > perennial ryegrass > oats > carrot > sunflower.

Effects on beneficial and other non-target organisms

From the experimentation carried out with Flufenacet 6% + Pendimethalin 30% EC in 2015/16, 2016/17 and 2018/19, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

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3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

An analytical method for the determination of flufenacet and pendimethalin in KONARK has been developed and sufficiently validated according to SANCO/3030/99 rev. 5.

	Flufenacet	**Pendimethalin**
Author(s), year	B. Rajasekhar, 2020. Report No. 7713/2020	B. Rajasekhar, 2020. Report No. 7713/2020
Principle of method	GC-FID	GC-FID
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	0.1– 0.6 mg/L (*n*=5) y = 6466.3x – 63.2 r = 0.9972 R^2 = 0.9945	1.00 – 3.00 mg/L (*n*=5) y = 7507.8x – 3059.3 r = 0.9936 R^2 = 0.9873
Precision – Repeatability Mean n = 5 (%RSD)	RSD: ~~0.422~~ 0.475 % RSDr (Horwitz): 2.04 % Hr <1 (0.23)	RSD: 1.430 % RSDr (Horwitz): ~~0.89~~ 1.6 % Hr <1 (0.89)
Accuracy (marginal recovery) Blank fortification levels n = 5 (% Recovery)	Low level (2% w/w): 99.03% High level (8% w/w): 98.15%	Low level (20% w/w): 99.70% High level (30% w/w): 100.28%
Interference/ Specificity	- Chromatograms of blank (acetonitrile) was submitted. According to provided chromatograms there were no interferences, method is specific	- Chromatograms of blank (acetonitrile) was submitted. According to provided chromatograms there were no interferences, method is specific
Comment	-	-

Analytical methods for the determination of relevant impurities in KONARK have been developed and sufficiently validated according to SANCO/3030/99 rev. 5.

	N-Nitroso Pendimethalin (Imp 1)	**1,2-Dichloroethane (Imp 9)**	**N-Nitrosodimethylamine (Imp 2)**	**N-Nitrosomethylethylamine (Imp 3)**	**N-Nitrosodiethylamine (Imp 4)**
Author(s), year	S. D. Revankar, 2021				
Principle of method	~~HP~~LC-MS/MS	GC-FID	GC-MS/MS	GC-MS/MS	GC-MS/MS
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	5 points 0.00521 to 0.20832 µg/mL (1.732 – 69.440 µg/g) y=1489096x+6176 R=0.9998	5 points 1.039 to 41.558 µg/mL (10.39 – 415.58 µg/g) y=307.9x-52.5 R=0.9990	5 points 0.0201 to 0.2510 µg/mL (0.9 – 9 µg/g) y=334165x+1505 R=0.9996	5 points 0.0201 to 0.2511 µg/mL (0.9 – 9 µg/g) y=370502x+1328 R=0.9995	5 points 0.0201 to 0.2508 µg/mL (0.9 – 9 µg/g) y=291975x+1067 R=0.9995
Mean Concentration Precision – Repeatability ~~Mean~~ n = 5 (%RSD)	3.955 µg/g RSD = 5.158% RSD_R=13.009% RSDr=8.7158% Hr=0.5918<1	98.688 µg/g RSD = 2.160 % RSD_R=8.016% RSDr=5.371% Hr=0.4022<1	2.406 µg/g RSD = 2.660% RSD_R=14.020% RSDr=9.393% Hr=0.2832<1	2.458 µg/g RSD = 3.580% RSD_R=13.974% RSDr=9.363% Hr=0.~~2~~3824<1	2.476 µg/g RSD = 2.464% RSD_R=13.959% RSDr=9.352% Hr=0.2635<1
Accuracy 3 concentrations n = 3 for each level (% Recovery)	Marginal recovery Low (1.6 µg/g): 96.36% Medium (13 µg/g): 96.74% High (26 µg/g): 107.35%	Marginal recovery Low (20 µg/g): 115.28% Medium (105 µg/g): 100.69% High (202 µg/g): 102.36%	Total recovery Low (0.9 µg/g): 100.11% Medium (2.3 µg/g): 94.91% High (4.5 µg/g): 96.70%	Total recovery Low (0.9 µg/g): 101.91% Medium (2.4 µg/g): 98.79% High (4.8 µg/g): 99.68% Mean recovery = 100.128 ± 2.227%	Total recovery Low (0.9 µg/g): 104.72% Medium (2.4 µg/g): 100.51% High (4.8 µg/g): 100.13%

	N-Nitroso Pendi-methalin (Imp 1)	**1,2-Dichloroethane (Imp 9)**	**N-Nitrosodimethyla-mine (Imp 2)**	**N-Nitrosomethylethylamine (Imp 3)**	**N-Nitrosodiethylamine (Imp 4)**
	Mean recovery = 100.151 ± 6.271%	Mean recovery = 106.110 ± 7.247%	Mean recovery = 97.242 ± 3.169%		Mean recovery = 101.79 ± 3.054%
Interference/ Specificity	According to blank chromatogram (acetonitrile), there were no interference. The method is specific	According to blank chromatogram, there were no interference. The method is specific	According to blank chromatogram, there were no interference. The method is specific	According to blank chromatogram, there were no interference. The method is specific	According to blank chromatogram, there were no interference. The method is specific
LOQ	LOD = 0.225 µg/g LOQ = 1.667 µg/g (the lowest level of fortification)	LOD = 2.943 µg/g LOQ = ~~10.40~~ 20 µg/g (the lowest level of fortification)	LOD = 0.092 µg/g LOQ = 0.971 µg/g (the lowest level of fortification)	LOD = 0.015 µg/g LOQ = 0.972 µg/g (the lowest level of fortification)	LOD = 0.004 µg/g LOQ = 0.970 µg/g (the lowest level of fortification)
Comment	-	-	-	-	-

	N-Nitrosopyrrolidoine (Imp 5)	**N-Nitrosodipropylamine (Imp 6)**	**N-Nitrosopiperidine (Imp 7)**	**N-Nitrosodibutylamine (Imp 8)**
Author(s), year	S. D. Revankar, 2021			
Principle of method	GC-MS/MS	GC-MS/MS	GC-MS/MS	GC-MS/MS
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	5 points 0.0201 to 0.2508 µg/mL (0.9 – 9 µg/g) y=184180x+490 R=0.9995	5 points 0.0201 to 0.2509 µg/mL (0.9 – 9 µg/g) y=283845x+98 R=0.9974	5 points 0.0201 to 0.2508 µg/mL (0.9 – 9 µg/g) y=234217x+835 R=0.9995	5 points 0.0201 to 0.2509 µg/mL (0.9 – 9 µg/g) y=203239x+995 R=0.9996
Mean Concen-tration Precision – Repeatability Mean n = 5 (%RSD)	2.624 µg/g RSD = 3.392% RSD_R=13.8374% RSDr=9.271% Hr=0.3659<1	3.805 µg/g RSD = 2.733% RSD_R=13.086% RSDr=8.768% Hr=0.31<1	3.805 µg/g RSD = 3.222% RSD_R=13.876% RSDr=9.297% Hr=0.3466<1	2.576 µg/g RSD = 4.030% RSD_R=13.699% RSDr=9.178% Hr=0.4391<1
Accuracy 3 concentra-tions n = 3 for each level (% Recovery)	Total recovery Low (0.9 µg/g): 107.03% Medium (2.4 µg/g): 101.04% High (4.8 µg/g): 103.55% Mean recovery = 103.875 ± 3.63%	Total recovery Low (0.9 µg/g): 109.37% Medium (2.4 µg/g): 103.97% High (4.8 µg/g): 116.46% Mean recovery = 109.933 ± 6.390%	Total recovery Low (0.9 µg/g): 109.05% Medium (2.4 µg/g): 101.69% High (4.8 µg/g): 101.19% Mean recovery = 103.978 ± 4.576%	Total recovery Low (0.9 µg/g): 112.17% Medium (2.4 µg/g): 83.18% High (4.8 µg/g): 91.00% Mean recovery = 95.451 ± 13.063%
Interference/ Specificity	According to blank chromatogram, there were no interference. The method is specific	According to blank chromatogram, there were no interference. The method is specific	According to blank chromatogram, there were no interference. The method is specific	According to blank chromatogram, there were no interference. The method is specific
LOQ	LOD = 0.009 µg/g LOQ = 0.970 µg/g (the lowest level of fortification)	LOD = 0.010 µg/g LOQ = 0.971 µg/g (the lowest level of fortification)	LOD = 0.005 µg/g LOQ = 0.970 µg/g (the lowest level of fortification)	LOD = 0.216 µg/g LOQ = 0.971 µg/g (the lowest level of fortification)
Comment	-	-	-	-

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.
Noticed data gaps are:

- ~~None~~

- A method, including confirmation, for the determination of flufenacet + FOE thiadone in tissues is required according to Regulation (EU) 284/2013 (post-registration requirement).

Commodity/crop	**Supported/ Not supported**
Winter wheat	Supported
Winter barley	Supported
Winter rye	Supported
Triticale	Supported

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for Flufenacet 6% + pendimethalin 30% SC were not evaluated as part of the EU review of Flufenacet and Pendimethalin. Therefore, all relevant data were provided and are considered adequate.
Flufenacet 6% + pendimethalin 30% EC has not oral, dermal and inhalation acute toxicity and it is not irritating to the rabbit skin and eye. It has been found to be considered as a skin sensitizer H317) and H361d (pendimethalin- the 18th ATP (Regulation (EU) 2022/692) and Accoeding to the ECHA **Committee for Risk Assessment RAC Opinion** proposing harmonised classification and labelling at EU level of **pendimethalin (ISO); *N*-(1-ethylpropyl)-2,6-dinitro-3,4-xylidene Adopted 8 October 2020** to Regulation (EC) 1272/2008)

Classification: H317 (May cause an allergic skin reaction), H361d (Suspected of damaging the unborn child) and EUH066 - Repeated exposure may cause skin dryness or cracking

3.5.1 Acute toxicity

Type of test, species, model system (Guideline)	**Result**	**Acceptability**	**Classification (acc. to the criteria in Reg. 1272/2008)**	**Reference**
LD_{50} oral (calculation)	> 2000 mg/kg bw	Yes	None	Calculated
LD_{50} dermal (calculation)	> 2000 mg/kg bw	Yes	None	Calculated
LC_{50} inhalation (calculation)	None	Yes	None	Calculated
Skin irritation (calculation)	Non-irritant	Yes	None	Calculated

Eye irritation, rabbit (OECD 405)	Non-irritant	Yes	None	xxx
Skin sensitisation, (calculation)	Sensitising	Yes	H317	Calculated
Supplementary studies for combinations of plant protection products	No data – not required			

3.5.2 Operator exposure

Operator exposure to Flufenacet 6% + pendimethalin 30% EC was not evaluated as part of the EU review of Flufenacet and Pendimethalin. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Estimations of potential operator exposure have been undertaken for both Flufenacet and Pendimethalin using the EFSA AOEM model.

Conclusion
According to the AOEM model, calculations, it can be concluded that the risk for the operator using KONARK is acceptable with the use of gloves and working clothing (long sleeved shirt and trousers) during mixing/loading and application.

Implication for labelling: P280: Wear protective gloves, protective clothing

3.5.3 Worker exposure

Worker exposure to Flufenacet 6% + pendimethalin 30% EC was not evaluated as part of the EU review of Flufenacet and Pendimethalin.
Calculations were made using the standard dermal absorption value and the EFSA model

It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated crop even without suitable protective clothing.

Implication for labelling **Work wear (arms, body and legs covered**

~~It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated crop even without suitable protective clothing. For post-emergence applications, a time period of 32 days for re-entering treated crop is derived from combined exposure.~~Implication for labelling: ~~**Time period for re-entry of 32 days for post-emergence applications**~~**.**

3.5.4 Bystander and resident exposure

Bystander and resident exposures to Flufenacet 6% + pendimethalin 30% EC was not evaluated as part of the EU review of Flufenacet and Pendimethalin. Therefore, all relevant data and risk assessments have been provided and are considered adequate. Calculations were made using the AOEM.
~~According to the EFSA calculator, when a 5m buffer zone is employed and drift reduction technology is incorporated, the risk for residents can be considered as acceptable.~~
According to the EFSA calculator, when a 2-3 m buffer zone is employed and drift reduction technology is incorporated, the risk for residents(child and adult) can be considered as acceptable.

3.6 Residues and consumer exposure (Part B, Section 7)

The preparation Flufenacet 6% + pendimethalin 30% SC is composed of Flufenacet and Pendimethalin.

Toxicological reference values for the dietary risk assessment of Flufenacet and Pendimethalin

Reference value	Source	Year	Value	Study relied upon	Safety factor
Flufenacet - Parent compound					
ADI	SANCO 7469/VI/98-Final	2003	0.005 mg/kg bw/day	2-years rat study (LOEL)	250
ARfD			0.017 mg/kg bw	90d and 1-year dog study	100
Pendimethalin - Parent compound					
ADI	SANTE/11656/2016	2016	0.125 mg/kg bw/day	2-years dog study	100
ARfD			0.3 mg/kg bw	Rabbit developmental toxicity	100

Residue trials were sufficient to support the uses of Flufenacet 6% + pendimethalin 30% SC. An acceptable risk for the consumer is expected after the use of Flufenacet 6% + pendimethalin 30% SC according to the intended GAP.

3.6.1 Residues

Storage stability

Flufenacet

Storage stability is demonstrated for 2 high starch commodities (corn and turnip - root) and there-fore stability can be supported for the entire high starch category in accordance with OECD guideline 506. This covers the stability of the residues in winter cereals.

Pendimethalin

Pendimethalin and metabolite CL 202347 are stable in commodities with high water, high acid, high protein, high starch and in high lipid commodity for at least a period of 12-43 months.

In addition, applicant provided study of residue storage stability of pendimethalin in high water content matrix. Study is accepted. The results of this study showed that pendimethalin is stable in apple when stored at ≤-18ºC for a period at least up to 24 months.

Sufficient stability has been demonstrated to support the residue data presented in this submission.

No further data are required.

Metabolism in plants and animals

Flufenacet

The metabolism in plants and livestock for the active substance was reviewed during the Annex I inclusion process.

Plant residue definition for monitoring and risk assessment Sum of all compounds containing the N fluorophenyl-N-isopropyl moiety expressed as flufenacet (EFSA, 2012, Regulation n°1127/2014)

Pendimethalin

The metabolism in plants and livestock for the active substance was reviewed during the Annex I inclusion and renewal process.

Plant residue definitions for monitoring and risk assessment: Pendimethalin (Reg. (EU) 2019/1791,

EFSA, 2016)

Animal residue definitions for monitoring and risk assessment: Pendimethalin (Reg. (EU) 2019/1791,

EFSA, 2016)

Additionally applicant submitted alternative to the protected high temperature hydrolysis of

14C-Pendimethalin under cooking, baking and pasteurization conditions study. Study is accepted.

The data evaluated are sufficient to support the proposed uses.

Magnitude of residues in plants

Winter cereals (wheat, barley, rye, oats, triticale)

Proposed uses:

1 x 0.24 kg as/ha flufenacet + 1.2 kg as/ha pendimethanil; BBCH 00-09 and 11-25; PHI: not required

Flufenacet

GAP on which N-EU assessment is based: 1 x 240 g as/ha, early post emergence

According to the available unprotected N-EU data, the intended uses on wheat and barley are considered acceptable.

According to SANTE/2019/12752, when the application is before forming of the edible part (in the case of cereals before stage BBCH 51), it is possible to extrapolate from barley and/or wheat to oat, rye.

The data submitted show that no exceedance of the MRL will occur.

Uses are accepted.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies were not included in the evaluation because they were performed in the south of Europe.

Pendimethalin

EU GAP (SANTE/11656/2016, 18 May, 2017, rev.2): 1 x 1.600 kg as/ha, BBCH: 00-29 autumn, PHI: not required

Proposed uses are less critical than uses in the EU GAP.

New acceptable studies on the magnitude of residue have been submitted by the applicant in the framework of this application (harvest and decline in Poland and in Germany).

Trials GAP:

Trials GAP: 1 x 1.5-1.7 kg as/ha, BBCH 25-30, PHI 54-94 days, outdoor

Application rate is more critical compared to the proposed one. However, these trials are acceptable as worst case situation.

Residues: 5x <0.01 mg/kg (wheat), 5x<0.01 mg/kg (barley)

New studies performed in the south of Europe were not included in the evaluation.

The number of trials is sufficient as to support the use of Pendimethalin in winter cereals according to the proposed GAP in Central Zone.

The residues arising from the proposed use will not exceed the MRLs for cereals set at 0.05 mg/kg (Reg. (EU) 2019/1791).

According to SANTE/2019/12752 extrapolation from wheat and barley to rye, oats and triticale is possible.

Uses are accepted.

Note: Some of the studies presented were carried out on spring crops instead of winter. Application tim-

ing in spring is considered more critical due to the shorter interval between application and harvest. Therefore, these trials are accepted.

Magnitude of residues in livestock

There is no risk for animal MRLs to be exceeded.

Magnitude of residues in processed commodities

As quantifiable residues of flufenacet and pendimethalin are not expected in the edible parts of most crops under consideration, and as consumer exposure is far below 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing.

Magnitude of residues in representative succeeding crops

Flufenacet

Residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided Flufenacet is applied in compliance with the GAPs reported."

Pendimethalin

EFSA Journal 2016;14(3):4420:

The radioactive residues were characterised as polar fractions further incorporated into the natural compounds of the plant tissues (16% of TRR in wheat straw, up to 81% of TRR in wheat grain). The parent compound was identified at lower proportions (<1% TRR in wheat grain to 19% TRR in immature lettuce) whilst metabolite M455H030 was identified in radish root only (13% TRR-0.011 mg/kg) at 30 d plant back interval.

Field rotational crop study are not required.

Waiting periods for avoiding residues in succeeding crops are not required.

3.6.2 Consumer exposure

Consumer exposure regarding Flufenacet

TMDI (% ADI) according to EFSA PRIMo 3.1	88% (based on NL Toddler)
IESTI (% ARfD) according to EFSA PRIMo 3.1	Unprocessed commodities Results for children: 136% potato Results for adults: 26% potato Results after refinement: Children: 8% wheat Adults: 5% barley Processed commodities Results for children: 82% potato/fried Results for adults: 16% pumpkins/boiled Results after refinement: Children: 8% wheat/flour Adults: 7% barley/beer

Acute dietary exposure was performed taking into account all the crops with corresponding MRL values. Due to unacceptable results obtained for unprocessed commodities for children, refinement was considered by using MRL for intended uses wheat and barley crops. Final values resulted to be acceptable for acute exposure for processed and unprocessed commodities.

The proposed uses of Flufenacet in the formulation Flufenacet 6% + pendimethalin 30% SC do not represent unacceptable acute and chronic risks for the consumer.

Consumer exposure regarding Pendimethalin

TMDI (% ADI) according to EFSA PRIMo 3.1	4% (based on NL Toddler)
IESTI (% ARfD) according to EFSA PRIMo 3.1	Unprocessed commodities Results for children: 51% lettuce Results for adults: 16% lettuce Processed commodities Results for children: 12% parsnips/boiled Results for adults: 5% parnips/boiled

It can be concluded that the use of Flufenacet 6% + pendimethalin 30% SC do not represents unacceptable acute and chronic risks for the consumer.

3.7 Environmental fate and behaviour (Part B, Section 8)

Concentrations of Flufenacet 6% + pendimethalin 30% SC in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment, ground water and air are provided.

Intended use pattern of Flufenacet 6% + pendimethalin 30% SC

Crop	Application rate (kg ai/ha)	Application method	Max. number of applications	Minimum application interval (days)	Application timing
Winter/spring cereals	Flufenacet: 0.24 Pendimethalin: 1.2	Foliar spray	1	-	BBCH 00-09 BBCH 11-25

The impact of formulants is limited to short-term effects such as formation of stable spray dispersions to facilitate uptake by target organisms, while their influence on long-term processes, such as degradation and distribution is negligible. Therefore, for the purposes of this risk assessment, it is assumed that formulants do not influence the fate and behaviour of the active substance in the environment and are not considered further.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} calculations have been conducted with Flufenacet and its relevant metabolites using the endpoints in the review report of Flufenacet (SANCO 7469/VI/98-Final of 3 July 2003) as well as the endpoints stated in the last Flufenacet BD-C addendum fate of January 2003.

PEC_{soil} calculations have been conducted with Pendimethalin and its relevant metabolites using the end-points of the EFSA conclusion (EFSA Journal 2016;14(3):4420 of 17 March 2016).

The PECsoil ini are listed below:

Flufenacet: 0.320 mg/kg
FOE Sulfonic: 0.064 mg/kg
FOE Oxalate: 0.031 mg/kg
Pendimethalin: 1.600 mg/kg
M455H001: 0.122 mg/kg
M455H033: 0.370 mg/kg

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{gw} have been realised for Flufenacet, Pendimethalin and their relevant metabolites using the FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models according to SANCO 7469/VI/98-Final of 3 July 2003 and EFSA Journal 2016;14(3):4420 of 17 March 2016 endpoints, as well as Flufenacet's addendum fate of January 2003.
The results of both leaching models PELMO 5.5.3 and PEARL 4.4.4 show that when used according to the intended use in winter and spring cereals flufenacet leaches in acceptable amounts to groundwater in every European scenario since all PECgw were found to be under the limit of 0.1 µg/L.
The results of the leaching models PEARL 4.4.4 and PELMO 5.5.3 show that when used according to the intended use of pendimethalin and its metabolites leach in acceptable amounts to groundwater in every European scenario, since all PECgw were found to be under the limit of 0.1 µg/L.
Only the Flufenacet metabolite FOE Sulfonic and Pendimethalin metabolite M455H001 were predicted over 0.1 µg/L and the assessment of their relevance were done accordingly.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The $PEC_{SW/SED}$ of Flufenacet, Pendimethalin and their relevant metabolites has been assessed with the models FOCUS STEP 1/2, FOCUS SWASH, FOCUS PRZM, FOCUS MACRO, FOCUS TOXSWA and FOCUS SWAN, and with the endpoints established in the EU review of each compound, namely SANCO 7469/VI/98-Final of 3 July 2003 and EFSA Journal 2016;14(3):4420 of 17 March 2016. Some metabolites' endpoints were also drawn from addendum to DAR of Flufenacet.
FOCUS Steps 3 and 4 were done for both active substances to determine the mitigation measures necessary to protect aquatic organisms. Dry deposition was considered for both active substances since they are considered as semi-volatile. PECsw/sed calculations was accepted for scenarios important for Poland D3, D4, R1.
Also, for the risk assessment for aquatic organisms have been used the PECsw/sed at STEP 4 calculated according to the Austrian Environmental Agency (AGES) for 5 and 15 meters of vegetative buffer strip and the calculations PECsw/sed at STEP according Step 4 VFSMOD.

3.7.4 Predicted environmental concentrations in air (PECair)

Flufenacet and Pendimethalin are considered as semi-volatile substances. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by these active substances due to volatilization with subsequent deposition was taken into account during surface water assessments.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds

No acute risk was observed for birds after exposure to **Flufenacet and Pendimethalin**. However, long-term risk was observed and further refinement was needed. After the refinement DT50 and ftwa for Flufenacet and after refinement of the endpoint for Pendimethalin, the values were above the trigger showing an acceptable long-term risk for birds.

No risk from drinking water is expected and the risk for earthworm-eating birds was considered acceptable for Flufenacet, however unacceptable risk was detected for Pendimethalin. After refinement, no unacceptable risk was detected. No risk for birds of secondary poisoning via fish is expected.

Mammals

No acute and long-term risk were observed for mammals after exposure to **Flufenace**t.

Regarding **Pendimethalin**, acute risk was not observed, however, long-term risk was observed and further refinement was needed.

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), and France agreed to a NOAEL of 296 mg/kg bw/d (5000 ppm,males).

All these endpoints are derived from the same study. Therefore, to refined **NOAEL of 150 mg/kg bw/d** was used in Poland in the higher tier risk assessment.

Intended use	**Cereals**				
Active substance/product	Pendimethalin				
Application rate (g/ha)	1 x 1440				
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_{lt}**
Cereals Early (shoots)	Large herbivorous mammal "lagomorph" 100% cereal shoots	22.3	1.0 × 0.53	17.02	8.8

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, the value was above the trigger showing an acceptable long-term risk for mammals.

No risk from drinking water is expected and the risk for earthworm-eating mammals was considered acceptable for Flufenacet, however unacceptable risk was detected for **Pendimethalin**. After refinement, no unacceptable risk was detected. No risk for mammals of secondary poisoning via fish is expected.

3.8.2 Effects on aquatic species

The PEC/RAC ratios were calculated based PEC_{SW} on FOCUS Step 3 and 4 considering reduced exposure of surface water bodies.

The PECsw/sed at STEP 4 calculated according to the Austrian Environmental Agency (AGES) for 5 and 15 meters of vegetative buffer strip and the calculations according Step 4 VFSMOD have been used for risk assessment to aquatic.

After Step 4 calculations, PEC/RAC ratios were <1 when the following risk mitigation options are considered:

Regarding ppp **KONARK**, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by an LC_{50} for *Oncorhynchus mykiss* of 483.3 µg/L in connection with an assessment factor of 100) following the next mitigation measures: 10 m no spray buffer zone or 5m no spray buffer zone with the use of 50% NR.
Acceptable risk was obtained due to combined exposure.

CONCLUSION:
Winter cereals (pre-emergence) To protect aquatic organisms respect an 20 m no spray vegetated buffer zone together with 75% of nozzles reduction or 15 m no spray vegetated buffer zone together with 90% of nozzles reduction are considered
According conclusion of efficacy section winter cereals post-emergency was accepted only. Due this fact following risk mitigation is required for:
Winter cereals (post-emergence): To protect aquatic organisms respect an winter cereals in post-emergence 20 m no spray vegetated buffer zone together with 90% of nozzles reduction
Spring cereals (pre-emergence) To protect aquatic organisms respect an spring cereals pre-emergence 15 m no spray buffer zone together with 15 m vegetated filter strip and 75% of nozzles reduction are considered.
Spring cereals (post-emergence) To protect aquatic organisms respect an spring cereals in post-emergence 15 m no spray buffer zone together with 75% of nozzles reduction

3.8.3 Effects on bees

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

3.8.3 Effects on other arthropod species other than bees

The results of the risk assessment show no risk in-field and off-field for *T.Pyri* and *Aphidius rhopalosiphi* when exposed to KONARK according to the proposed GAP.

3.8.4 Effects on soil organisms

Studies on the toxicity to earthworms and other non-target soil organisms show that Flufenacet and Pendimethalin hazard toxicity exposure ratios are clearly over the cut-off value. An application of KONARK in respect of the GAP does not present an unacceptable long-term risk for earthworms and other soil macrofauna.

No risk to soil microorganisms is expected following the application of KONARK at the proposed rates in the GAP.

3.8.5 Effects on non-target terrestrial plants

The calculated TER values are below the Annex VI trigger of 5 for seedling emergence and vegetative vigour when a distance of 1 m is considered. Therefore, no potential risk to non-target plants located outside the treated area after application of KONARK according to the GAP table is expected when risk mitigation measures are considered.

SPe 3: *To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 50% drift reducing nozzles*.

3.8.6 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant

3.9 Relevance of metabolites (Part B, Section 10)

Only the Flufenacet metabolites FOE Sulfonic and Pendimethalin metabolite M455H001 were predicted to occur in groundwater at concentrations above 0.1 µg/L. Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required and presented in section 10.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

KONARK contains flufenacet and pendimethalin which are approved as candidates for substitution.
According to comparative assessment, the plant protection product KONARK is considered as non-suitable for substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Sekcja pozostałości: brak uwag

Los i zachowanie w środowisku: brak uwag
Ekotoksykologia:
wniesiono następujące zapisy dotyczące ograniczenia ryzyka dla organizmów wodnych:
Zboża ozime (zastosowanie przedwschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20 m, ~~w tym 10 m zadarnionej~~ strefy od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%,
lub wyznaczenie zadarnionej strefy ochronnej o szerokości 15 m od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90 %,
According conclusion of efficacy section winter cereals post-emergency was accepted only. Due this fact risk mitigation is required for winter cereals post-emergency uses.
Zboża ozime (zastosowanie powschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej szerokości 20 m od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%,
Zboża jare (zastosowanie przedwschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej szerokości 15 m od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75 %,
Zboża jare (zastosowanie przedwschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 15 m od zbiorników z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%.

W celu ochrony roślin niebędących celem zwalczania konieczne jest wyznaczenie strefy ochronnej w odległości 5 m od terenów nieużytkowanych rolniczo lub stosowanie rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50 %.

Sekcja skuteczności: Nie zaakceptowano zastosowania przedwschodowego. W zastosowaniu powschodowym zaakceptowano: pszenicę ozimą, pszenżyto ozime i jęczmień ozimy. Wprowadzono zmiany do klasyfikacji wrażliwości chwastów. Dodano informacje nt. następstwa roślin i strategii zarządzania odpornością.

Toksykologia:
Dodać H361d, P308+P313 i EUH066

Załącznik do zezwolenia MRiRW nr R - …../…… z dnia ……2021

Posiadacz zezwolenia:
Sharda Cropchem España S.L., Edifico Atalayas Business Center
Carril Condomina n°3, 12th Floor, 30006 Murcia, Hiszpania xxx

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:
Sharda Cropchem Ltd. Prime Business Park, Dashrathlal Joshi Road Vile Parle (West), Mumbai – 400 056, Indie, xxx

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:
(…)

KONARK

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
Pendimetalina (substancja z grupy dinitroanilin) - 300 **g/l** (30,3 %)
Flufenacet (substancja z grupy oksyacetamidów) – 60 **g/l** (6,1 %)

Zezwolenie MRiRW nr R- /2021 z dnia . .2021 r.

UWAGA	
H317	Może powodować reakcję alergiczną skóry.
H361d	Podejrzewa się, że działa szkodliwie na płodność lub na dziecko w łonie matki
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska należy postępować zgodnie z instrukcją użycia.
EUH066	Powtarzające się narażenie może powodować wysuszanie lub pękanie skóry.
P261	Unikać wdychania pyłu/dymu/gazu/mgły/par/rozpylonej cieczy.
P272	Zanieczyszczonej odzieży ochronnej nie wynosić poza miejsce pracy.
P273	~~Nie wypuszczać do środowiska.~~ (Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.)
P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.
P333+P313	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P308+P313	W przypadku narażenia lub styczności: Zasięgnąć porady/ zgłosić się pod opiekę lekarza.
P362	Zdjąć zanieczyszczoną odzież
P391	Zebrać wyciek.
P501	Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi

OPIS DZIAŁANIA

KONARK jest środkiem chwastobójczym w formie emulsji do rozcieńczania w wodzie. KONARK stosuje się doglebowo i nalistnie w celu zwalczania chwastów liściastych i trawiastych w uprawach zbóż. Zgodnie z klasyfikacją według HRAC pendimetalina została zaklasyfikowana do grupy K1, a flufenacet do grupy K3.

Środek do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych wyposażonych w belkę herbicydową oraz opryskiwaczy ręcznych.

DZIAŁANIE NA CHWASTY

KONARK jest pobierany przez korzenie i części nadziemne chwastów. Najskuteczniej zwalcza chwasty w okresie ich kiełkowania i wschodów.

Chwasty wrażliwe: ~~szarłat szorstki, kurzyślad polny,~~ miotła zbożowa, tasznik pospolity, ~~palusznik krwawy, chwastnica jednostronna, przymiotno białe, przytulia czepna, wiechlina roczna, rdest plamisty, jaskier rozłogowy, włośnice, mlecz zwyczajny,~~ przetacznik perski, ~~szarłat szorstki, loboda rozłożysta, burak pospolity, komosa biała, powój polny, popłoch pospolity, marchew zwyczajna, konyza kanadyjska, jasnota purpurowa,~~ maruna nadmorska ~~bezwonna~~, ~~starzec zwyczajny, włośnica sina,~~ gwiazdnica pospolita, ~~psianka czarna,~~ fiołek polny.
Chwasty średnio wrażliwe: ~~ostrożeń polny, dwurząd, bodziszek drobny, mniszek pospolity~~, przytulia czepna.
~~Chwasty odporne~~: ~~owsik wyniosły.~~

STOSOWANIE ŚRODKA

~~**Pszenica ozima** (aplikacja przedwschodowa)~~
~~Chwasty liściaste i trawiaste~~
~~**Maksymalna dawka dla jednorazowego zastosowania:** 4,0 l/ha~~
~~**Zalecana dawka dla jednorazowego zastosowania:** 4 l/ha~~
~~Liczba zabiegów: 1~~
~~Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kiełkowania. (BBCH 00-09)~~
~~Zalecana ilość wody: **200-400 l/ha.**~~
~~Zalecane opryskiwanie: **średniokropliste**~~
~~**Maksymalna liczba zabiegów w sezonie wegetacyjnym**: 1~~

Pszenica ozima (aplikacja powschodowa)
Chwasty liściaste i trawiaste
Maksymalna dawka dla jednorazowego zastosowania: 4,0 l/ha
Zalecana dawka dla jednorazowego zastosowania: 4,0 l/ha
Liczba zabiegów: 1
Termin stosowania środka: stosować od fazy od początku fazy rozwoju liści do fazy gdy widoczne jest piąte rozkrzewienie. (BBCH 11-25)
Zalecana ilość wody: **200-400 l/ha**.
Zalecane opryskiwanie: **średniokropliste**
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

~~**Jęczmień ozimy** (aplikacja przedwschodowa)~~
~~Chwasty liściaste i trawiaste~~
~~**Maksymalna dawka dla jednorazowego zastosowania:** 4,0 l/ha~~
~~**Zalecana dawka dla jednorazowego zastosowania:** 4 l/ha~~
~~Liczba zabiegów: 1~~

~~Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kiełkowania. (BBCH 00-09)~~
~~Zalecana ilość wody: **200-400 l/ha.**~~
~~Zalecane opryskiwanie: **średniokropliste**~~
~~**Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1**~~

Jęczmień ozimy (aplikacja powschodowa)
Chwasty liściaste i trawiaste
Maksymalna dawka dla jednorazowego zastosowania: 4,0 l/ha
Zalecana dawka dla jednorazowego zastosowania: 4,0 l/ha
Liczba zabiegów: 1
Termin stosowania środka: stosować od fazy od początku fazy rozwoju liści do fazy gdy widoczne jest piąte rozkrzewienie. (BBCH 11-25)
Zalecana ilość wody: **200-400 l/ha**.
Zalecane opryskiwanie: **średniokropliste**
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

~~**Żyto ozime** (aplikacja przedwschodowa)~~
~~Chwasty liściaste i trawiaste~~
~~**Maksymalna dawka dla jednorazowego zastosowania:** 4,0 l/ha~~
~~**Zalecana dawka dla jednorazowego zastosowania:** 4 l/ha~~
~~Liczba zabiegów: 1~~
~~Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kiełkowania. (BBCH 00-09)~~
~~Zalecana ilość wody: **200-400 l/ha.**~~
~~Zalecane opryskiwanie: **średniokropliste**~~
~~**Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1**~~

~~**Żyto ozime** (aplikacja powschodowa)~~
~~Chwasty liściaste i trawiaste~~
~~**Maksymalna dawka dla jednorazowego zastosowania:** 4,0 l/ha~~
~~**Zalecana dawka dla jednorazowego zastosowania:** 4,0 l/ha~~
~~Liczba zabiegów: 1~~
~~Termin stosowania środka: stosować od fazy od początku fazy rozwoju liści do fazy gdy widoczne jest piąte rozkrzewienie. (BBCH 11-25)~~
~~Zalecana ilość wody: **200-400 l/ha.**~~
~~Zalecane opryskiwanie: **średniokropliste**~~
~~**Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1**~~

~~**Pszenżyto** (aplikacja przedwschodowa)~~
~~Chwasty liściaste i trawiaste~~
~~**Maksymalna dawka dla jednorazowego zastosowania:** 4,0 l/ha~~

~~**Zalecana dawka dla jednorazowego zastosowania:** 4 l/ha~~
~~Liczba zabiegów: 1~~
~~Termin stosowania środka: stosować zapobiegawczo na glebę wolną od chwastów, od wysiewu do końca fazy kiełkowania. (BBCH 00-09)~~
~~Zalecana ilość wody: **200-400 l/ha.**~~
~~Zalecane opryskiwanie: **średniokropliste**~~
~~**Maksymalna liczba zabiegów w sezonie wegetacyjnym**: 1~~

Pszenżyto (aplikacja powschodowa)
Chwasty liściaste i trawiaste
Maksymalna dawka dla jednorazowego zastosowania: 4,0 l/ha
Zalecana dawka dla jednorazowego zastosowania: 4,0 l/ha
Liczba zabiegów: 1
Termin stosowania środka: stosować od fazy od początku fazy rozwoju liści do fazy gdy widoczne jest piąte rozkrzewienie. (BBCH 11-25)
Zalecana ilość wody: **200-400 l/ha**.
Zalecane opryskiwanie: **średniokropliste**
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zabieg wykonać opryskiwaczem wyposażonym w rozpylacze antyznoszeniowe.

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

Środka nie stosować:
- na rośliny osłabione i uszkodzone przez przymrozki, suszę, szkodniki lub choroby
- na plantacjach nasiennych.

Podczas stosowania środka nie dopuścić do:
- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

Strategia przeciwdziałania rozwojowi odporności: Wielokrotne stosowanie herbicydów o takim samym mechanizmie działania może prowadzić do wzrostu ryzyka pojawienia się w populacjach chwastów biotypów odpornych. Z tego też względu w ramach strategii przeciwdziałania odporności zaleca się m. in. stosowanie środka 1 raz w sezonie i tylko w dawce zalecanej, stosowanie na danym stanowisku w kolejnych zabiegach i sezonach wegetacyjnych herbicydów z innych grup chemicznych, o odmiennym mechanizmie działania, przemiennie (w rotacji) lub łącznie (w mieszaninach). Stosowane w ten sposób zabiegi chemiczne są tylko jednym z elementów metody ograniczania zachwaszczenia oprócz zabiegów uprawowych i właściwego zmianowania.

NASTĘPSTWO ROŚLIN

Nie ma ograniczeń co do następnych upraw, gdy środek jest stosowany samodzielnie. Należy wykonać orkę na co najmniej 15 cm przed sadzeniem wszystkich następujących upraw z wyjątkiem ziemniaków, grochu, pszenicy i jęczmienia.
W przypadku konieczności wcześniejszego zlikwidowania plantacji potraktowanej środkiem w wyniku uszkodzenia roślin przez mrozy, szkodniki lub choroby, po zaoraniu na co najmniej 15 cm można wysiać następujące rośliny: ziemniaki, groch, pszenicę i jęczmień.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.
Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego do połowy wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:
– po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe lub
– unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
– unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.
Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

Środki ostrożności dla osób stosujących środek: (pracowników oraz osób postronnych)

Nie jeść, nie pić ani nie palić podczas używania produktu.
Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.

Środki ostrożności związane z ochroną środowiska naturalnego:

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.
Nie myć aparatury w pobliżu wód powierzchniowych.
Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

~~**Zboża ozime**~~
~~**SPe3**~~
~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej w odległości 5 m od zbiorników lub cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%.~~
~~*LUB*~~
~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej w odległości 10 m od zbiorników lub cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%.~~

~~*LUB*~~
~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej w odległości 20 m od zbiorników lub cieków wodnych.~~

~~**SPe3**~~
~~W celu ochrony roślin niebędących obiektem zwalczania konieczne jest wyznaczenie strefy ochronnej w odległości 5 m od terenów nieużytkowanych rolniczo~~
~~*LUB*~~
~~Zastosowanie rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%.~~

~~**Zboża jare**~~
~~**SPe3**~~
~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej w odległości 10 m od zbiorników lub cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%.~~
~~*LUB*~~
~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej w odległości 15 m od zbiorników lub cieków wodnych.~~

~~**SPe3**~~
~~W celu ochrony roślin niebędących obiektem zwalczania konieczne jest wyznaczenie strefy ochronnej w odległości 5 m od terenów nieużytkowanych rolniczo~~
~~*LUB*~~
~~Zastosowanie rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%.~~

Zboża ozime (zastosowanie przedwschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20 m, ~~w tym 10 m zadarnionej~~ strefy od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%
lub wyznaczenie zadarnionej strefy ochronnej o szerokości 15 m od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90 %.

Zboża ozime (zastosowanie powschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej szerokości 20 m od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.

Zboża jare (zastosowanie przedwschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej szerokości 15 m od zbiorników i cieków wodnych z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75 % .

Zboża jare (zastosowanie przedwschodowe) – W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 15 m od zbiorników z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%.

W celu ochrony roślin niebędących celem zwalczania konieczne jest wyznaczenie strefy ochron-

nej w odległości 5 m od terenów nieużytkowanych rolniczo LUB stosowanie rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50 %.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
Nie dotyczy

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):
Nie dotyczy

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze $0^{o}C$ - $30^{o}C$, z dala od źródeł ciepła.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.
W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - 1 rok
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Appendix 3 Letter of Access

No letters of Access to protected data are required.

Appendix 4 Lists of data considered for national authorization

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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.7.1 KCP 2.7.3 KCP 2.8.6.1 KCP 2.8.6.2 KCP 2.8.6.3	B. Rajasekhar	2020	Accelerated Storage Stability Study of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7713/2020 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 2.2.1	B. Rajasekhar	2020	Determination of Explosive Properties of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7704/2020 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2.2	B. Rajasekhar	2020	Determination of Chemical Oxidizing properties of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7707/2020 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 2.3.1	B. Rajasekhar	2020	Determination of Flash Point of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7703/2020 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 2.3.3	B. Rajasekhar	2020	Determination of Auto-ignition temperature of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7710/2020 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 2.5.1	B. Rajasekhar	2020	Determination of Viscosity of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7708/2020 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 2.5.2	B. Rajasekhar	2020	Determination of Surface Tension of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7706/2020 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.6.1	B. Rajasekhar	2020	Determination of Density of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7705/2020 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 2.7.4	B. Rajasekhar	2020	Low Temperature Stability (0°C) of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7709/2020 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 2.8.2	B. Rajasekhar	2020	Determination of Persistent Foaming of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7711/2020 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 2.11	B. Rajasekhar	2020	Washing efficiency of Flufenacet 6% + Pendimethalin 30% EC after application. Bioscience research foundation Report No. 7712/2020 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 5.1.1	B. Rajasekhar	2020	Accelerated storage stability study of flufenacet 6% + pendimethalin 30% EC. Report No. 7713/2020 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.3.2.2.1	E. Rigamonti	2019	Validation of the Analytical Method for the Determination of Flufenacet and metabolites (Flufenacet Cysteine conjugate (M23), Flufenacet OA, Flufenacet sulfonic acid (M2), Flufenacet thioglycolate sulfoxide (TGS)) Residues in Barley grain Matrix. E. Rigamonti, 2019 Report No. CH - 0753/2019. GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 5.3.3.2.1	M. L. Greco	2017	Validation of the analytical procedure for the determination of pendimethalin (CAS: 40487-42-1), in wheat grains by liquid chromatography. M. L. Greco, 2017 Report No. 16.566423.0005 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 5.3.3.2.2	Paolo Zazzetta	2019	Determination of the residues of pendimethalin applied as “pendimethalin 330 g/l” in barley at one site in Spain, 2016. J. Kicińska, 2017 Report No. ZBBZ-2016/69/DPL/1ES GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 5.3.3.2.3	M. L. Greco	2017	Validation of the analytical procedure for the determination of pendimethalin (CAS: 40487-42-1), in wheat straw by liquid chromatography. M. L. Greco, 2017, Report No. 16.566423.0006 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 5.3.3.7.1	xxx	2017	Validation of the analyticayl procedure for the determination of pendimethalin (CAS: 40487-42-1) in blood by liquid chromatography xxx GLP Unpublished	Y	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.3.3.7.2	xxx	2017	Validation of the analyticayl procedure for the determination of pendimethalin (CAS: 40487-42-1) in liver by liquid chromatography xxx GLP Unpublished	Y	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 6.0-001	Anonymous	2021	Biological Assessment Dossier: Flufenacet 6% + Pendimethalin 30% EC (60 g/L flufenacet + 300 g/L pendimethalin EC) – EU Central zone Sharda Cropchem España -, - Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 7.1.5	xxx	2017	Flufenacet 6% + Pendimethalin 30% EC: Acute eye irritation/corrosion study in rabbit (OECD guideline No. 405) xxx Company Report No. R/16261/AEI/17 GLP, Unpublished	Y	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/01	Casalinuovo, L.	2020	Determination of flufenacet residues in raw agricultural commodities barley and winter wheat following one applica-tion of flufenacet 50%SC. (South Europe-2 harvest trials and 1 multi harvest trial year 2018). Biotecnologie BT report No BIU-004-18. GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/02	Gotsis, G.	2020	Generation of Specimens for the Determination of Magni-tude of Residue of Flufenacet in/on Winter Wheat at Fixed Intervals and at Harvest, following One application of Flufenacet 50% SC herbicide. Greece - 2018. Agriscience, report No S18-0084R. GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1/03	Pardo-Martínez, M.	2020	Determination of Flufenacet and Its metabolites in/on Winter Wheat and Barley at Fixed intervals and at Harvest, following One application of Flufenacet 50% SC herbicide. Greece – 2018. Chemservice, report No CH-0040/2020 (Analytical phase study report). GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/04	Gotsis, G.	2020	Generation of Specimens for the Determination of Magnitude of Residue of Flufenacet in/on Winter Barley at Fixed Intervals and at Harvest, following One application of Flufenacet 50% SC herbicide. Greece - 2018. Agriscience, report No S18-0083R. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/05	Orrico-Marín, A.	2020	Decline residue study with Flufenacet 50% EC (CAS No. 142459-58-3) in barley cultivated in open field after one application. GLP study in Spain. Year 2017. SICOP, report No SI17HR003ES01. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/06	Pardo-Martínez, M.	2020	Determination of flufenacet and its metabolites decline residues in barley cultivated in open field after one application of Flufenacet 50% SC. Chemservice, report No CH-0039/2020 (Analytical phase study report). GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1/07	Peda, T.	2018	Magnitude of the residue of Pendimethalin in wheat (Raw Agricultural Commodity) after one application of Pendimethalin 33% EC – one decline curve trial in Poland - 2017. Report No. 17SGS011 SGS Polska Sp. z o.o. GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/08	Rubino, M.	2018a	Determination of 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. 18.618093.0002 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/09	Romero, S.	2018a	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. Report No. BPL17-010 BIOTEK Agriculture España SL GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/10	Roehl, T.	2018a	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	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1/11	Rubino, M.	2018b	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	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/12	Zazzetta, P.	2019	Determination of pendimethalin residues in Raw Agricultural Commodity wheat (seeds) following one applications of Pendimethalin (F) 33% EC Report No. RA 17 097 BPL SH Research Centre RES AGRARIA GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/13	Orrico-Marin, A.	2019	Decline residue study with Pendimethalin 33% EC 9CAS No. 40487-42-1) in wheat cultivated in open field after one application. GLP study in Spain. Year 2017 Report No SI17HR07ES Sistemas de Control de Producción SL (SICOP) GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/14	M.Rubino	2018d	Determination of 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 18.638294.0002 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1/15	P. Zazzetta	2019b	Determination of pendimethalin residues in raw agricultural commodity barley (seeds) following one application of Pendimethalin (F) 33%, Italy 2018 Report No RA 17 052 BPL SH Research Centre RES AGRARIA S.r.l. GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/16	A. O. Marin	2018a	Harvest residue study with Pendimethalin 33% EC (CAS No. 40487-42-1) in cereal cultivated in open field after one application. GLP study in Spain, 2016. Report No. SI16HR009ES Sistemas de Control de Producción SL (SICOP) GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/17	A. O. Marin	2018b	Decline residue study with Pendimethalin 33% EC (CAS No. 40487-42-1) in cereal cultivated in open field after one application. GLP study in Spain, 2016. Report No. SI16HR010ES Sistemas de Control de Producción SL (SICOP) GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/18	J. Kicińska	2017	Determination of the residues of pendimethalin applied as “Pendimethalin 330 g/L” in barley at one site in Spain, 2016 Report No. ZBBZ-2016/69/DPL/1ES Food Safety Laboratory GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1/19	S. Romero	2018b	Magnitude of residue of Pendimethalin in barley Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial Report No. BPL17-009 BIOTEK Agriculture España SL GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/20	T. Roehl	2018b	Residue study (Harvest and decline) in barley following one post emergence application with Pendimethalin 33% EC in Germany 2017 – field part Report No. CT17-1-45 CropTrials GmbH GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 8.3.1/21	M.Rubino	2018c	Determination of pendimethalin (CAS: 40487-42-1) in barley by LC-MS according to SOPa-288-LABCHI-Rev. 0 and SOPa-289-LABCHI-Rev. 0 Report No. 18.618095.0004 CHELAB S.R.L. GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 10.2.1-01	xxx	2019	Flufenacet 6% + Pendimethaline 30% EC Rainbow trout, xxx GLP Unpublished	Y	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 10.2.1-02	Konfederak, E.	2019	Flufenacet 6% + Pendimethaline 30% EC *Daphnia magna*, Acute immobilisation test Report No: W/194/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.1-03	Konfederak, E.	2019	Flufenacet 6% + Pendimethaline 30% EC *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*) Growth inhibition test Report No: W/193/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 10.2.1-04	Konfederak, E.	2019	Flufenacet 6% + Pendimethaline 30% EC *Lemna gibba* CPCC 310, Growth inhibition test Report No: W/195/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 10.3.1.1.1	Kulec-Płoszczyca, E.	2017	Flufenacet 6% + Pendimethalin 30% SCHoneybees (*Apis mellifera* L.), Acute Oral Toxicity Test Report No: B/160/16 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 10.3.1.1.2	Kulec-Płoszczyca, E.	2017	Flufenacet 6% + Pendimethalin 30% SC Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test Report No: B/161/16 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 10.3.2.2-01	Stalmach, M.	2018	An extended laboratory test for evaluating the effects of Flufenacet 6% + Pendimethalin 30% EC on the predatory mite, *Typhlodromus pyri* (Sch.) Report No: B/163/16 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.2-02	Stalmach, M.	2018	An extended laboratory test for evaluating the effects of Flufenacet 6% + Pendimethalin 30% EC on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani – Perez) Report No: B/162/16 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 10.4.1.1-01	Gierbuszewska A.	2014	Flufenacet 50% SC Earthworm Reproduction Test (*Eisenia fetida*) Institute of industrial organic chemistry Branch Pszczyna, G/22/14 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 10.4.1.1-02	Servajean, E.	2018	Earthworm reproduction test with Pendimethalin 40% SC Report No.: 17-99-135-ES Phytosafe s.a.r.l. GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 10.4.2.1-01	Arendarczyk A.	2015	Flufenacet 50% SC Collembolan (*Folsomia candida*) Reproduction Test Institute of industrial organic chemistry Branch Pszczyna, G/28/15 GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 10.4.2.1-02	Servajean, E.	2018	Collembolan reproduction test in soil with Pendimethalin 40% SC Report No.: 17-99-128-ES Phytosafe s.a.r.l. GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.5.1	Gierbuszewska, A.	2020	Flufenacet 6% + Pendimethaline 30% EC Soil Microorganisms: Nitrogen Transformation Test Report No: G/67/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 10.6.2-01	Gierbuszewska, A.	2020	Flufenacet 6% + Pendimethaline 30% EC Terrestial Plant Test: Seedling Emergence and Seedling Growth Test Report No: G/71/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd
KCP 10.6.2-02	Gierbuszewska, A.	2020	Flufenacet 6% + Pendimethaline 30% EC Terrestial Plant Test: Vegetative Vigour Test Report No: G/72/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submit-ted before to Poland	Sharda Cropchem Ltd

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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in **this** MS: Data protection started with: <insert authorization number of first au-thorization>	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in **this** MS: Data protection started with: <insert authorization number of first authorization>	Owner

List of data relied on and 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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in **this** MS: Data protection started with: <insert authorization number of first authorization>	Owner