REGISTRATION REPORT
Part A
Risk Management

Product code: 19202

Product name: **KINVARA, Arrva**

Chemical active substances:

MCPA, 233 g/L
Fluroxypyr, 50 g/L
Clopyralid, 28 g/L

Central Zone

Zonal Rapporteur Member State: Poland

cMS: CZ, DE, IE, HU, RO, NI, BE, AT

NATIONAL ASSESSMENT

Poland

(Renewal of Authorization)

Applicant: XXXX

Submission date: 31/01/2024

Evaluation date: October 2024

MS Finalisation date: March 2025

Version history

When	What
January 2024	Article 43 of Regulation (EC) No. 1107/2009
October 2024	Conclusions of zRMS
March 2025	Version modified by zRMS PL to take into account comments of cMSs and the applicant
September 2025	zRMS update in accordance with national requirements
October 2025	zRMS correction

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application is hereby submitted to the Poland for consideration under Article 43 of Regulation (EC) No. 1107/2009 and Regulation (EC) No 396/2005. The application has also been submitted to the following Member States within the Central zone:

Central Zone Submission:

ZRMS	OTHER CENTRAL ZONE MEMBER STATES
Poland	Hungary
	Ireland
	Northern Ireland
	Czech Republic
	Germany
	Romania
	Austria
	Belgium

This application is for the re-authorisation of the product Kinvara, a micro emulsion (ME) formulation containing the active substance MCPA (233g/L), Fluroxypyr (50g/L), Clopyralid (28g/L) for use in cereals and grassland. The following brand names are applied for in each of the individual countries within the Central Zone:

Ireland	Kinvara, Brittas, Pradera
Poland	Kinvara, Arrva
Hungary	Kinvara, Arrva
Northern Ireland	Kinvara
Czech Republic	Kinvara, Arrva
Germany	Kinvara, Arrva
Romania	Kinvara, Arrva
Austria	Kinvara
Belgium	Kinvara

1.2 Letters of Access

XXXX have access to a full Annex II data package from the notifier Nufarm in respect of the active substance MCPA which grants access to all Annex II data including renewal data. Please refer to the enclosed LoA.

XXXX supported the re-inclusion of fluroxypyr on Annex I as part of the fluroxypyr task force (RMS: Ireland). Therefore, no letters of access is required, XXXX have provided sufficient data with this application.

XXXX asks for referral to all relevant data submitted by Corteva (formerly DOW) for Clopyralid during the Community review programme under Council Directive 91/414/EEC. Data submitted under Annex II is no longer considered to be under data protection. XXXX have access to the renewal Annex II data package from the notifier Corteva in respect of the active substance Clopyralid. Please refer to enclosed LoA.

1.3 Justification for submission of tests and studies

Kinvara is being re-authorised as part of this application. New studies have been submitted to address any new data requirements which have arisen since the initial registration of this product. All studies which were previously submitted and evaluated are highlighted in grey. New studies have been left un-highlighted.

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	19202
Product name in MS	Kinvara
Authorization number	R-231/2019
Function	Herbicide
Applicant	XXXX
Active substance(s) (incl. content)	MCPA; 233 g/L Fluroxypyr; 50 g/L Clopyralid; 28 g/L
Formulation type	Micro-emulsion (ME)
Packaging	Currently approved in PL: 1 L, 3 L, 5 L, 10L, 20 L HDPE bottle 5L, 10L FHDE bottle Harmonisation Request for 1-10L, 20L HDPE bottle 1-10L, 20L FHDPE bottle

Coformulants of concern for national authorizations	Not applicable
Restrictions related to identity	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

The evaluation of the application for Kinvara resulted in the decision to grant the authorization. All uses applied for were authorised (see 2.6).

2.3 Substances of concern for national monitoring

No national monitoring information is available.

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:	Acute toxicity (ingestion), hazard category 4 ~~Skin sensitisation, hazard category 1~~ ~~Skin Irritation, hazard category 2~~ Serious eye damage~~/~~eye irritation, hazard category 2 Hazardous to the aquatic environment – Chronic, hazard category ~~1~~ 2 Acute Tox. 4; H302 Eye Irrit. 2; H319 Acute Tox. 4; H302 Aquatic Chronic Category 2; H411

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, GHS09**
Signal word:	**Warning**
Hazard statement(s):	**H302: Harmful if swallowed** **~~H315: Causes skin irritation~~** **~~H317: May cause an allergic skin reaction~~** **H319: Causes serious eye irritation.** **~~H410: Very toxic to aquatic life with long lasting effects.~~** **H411: Toxic to aquatic life with long lasting effects**

Precautionary statement(s):	~~P261: Avoid breathing dust/fume/ gas/mist/vapours/spray.~~ P264: Wash face and hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product ~~P272: Contaminated work clothing should not be allowed out of the workplace~~. P280: Wear protective gloves/eye protection/face protection. P301 + P312, P330: IF SWALLOWED: Rinse mouth. Call a POISON CENTER/doctor, if you feel unwell ~~P302 + P352: IF ON SKIN: Wash with plenty of water/…~~ P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/attention. ~~P362 + P364: Take off contaminated clothing and wash it before reuse.~~ P391: Collect spillage P501: Dispose of contents/container in accordance with local regulation
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:	
Not applicable.	

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/spring cereals: To protect aquatic organisms respect 1 m buffer zone to surface water bodies.
SPe3	To protect arthropods and non-target terrestrial plants a 20m no-spray strip or 10 m with 50% drift reducing nozzle or 5 m with 75% drift reducing nozzle is required.

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:
Results of risk assessment: Gloves during mixing/loading

Worker protection:	
Results of risk assessment: No PPE - Work wear covering arms, body and legs	
Integrated pest management (IPM)/sustainable use:	
Environmental protection	
P391	Collect spillage
P501	Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site
SP1	Do not contaminate water with the product or its container
SPe3	Winter/spring cereals: To protect aquatic organisms respect 1 m buffer zone to surface water bodies.
SPe3	To protect arthropods and non-target terrestrial plants a 20m no-spray strip or 10 m with 50% drift reducing nozzle or 5 m with 75% drift reducing nozzle is required.
Other specific restrictions	

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.
respective code if available	None	N/A
Environmental protection:		Relevant for use no.
EUH401	To avoid risks to man and the environment, comply with the instructions for use.	All

2.6 Intended uses (only accepted NATIONAL GAP)

PPP (product name/code):	Kinvara	Formulation type:	ME
Active substance 1:	MCPA	Conc. of as 1:	233 g/L
Active substance 2:	Fluroxypyr	Conc. of as 2:	50 g/L
Active substance 3:	Clopyralid	Conc. of as ….:	28 g/L)
Safener:	See Document C	Conc. of safener:	See Document C
Synergist:	See Document C	Conc. of synergist:	See Document C
Applicant:	XXXX	Professional use:	☒
Zone(s):	Central(d)	Non professional use:	☐
Verified by MS:	yes		
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	PL	winter wheat, spring wheat, winter triticale, spring barley, rye, winter oats	F	Annual and perennial broadleaf weeds	Foliar spray	BBCH 24-39	a) 1 b) 1	N/A	a) 3 b) 3	a) 0.699 MCPA, 0.150 Flur, 0.084 CLP b) 0.699 MCPA, 0.150 Flur, 0.084 CLP	200-400	N/A	2-3L

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 a uniform reddish-brown liquid with a hydrocarbon odour. It is not explosive and has no oxidising properties. The product is not flammable and has a flash point of >110°C. It has a self ignition temperature of >388°C. In aqueous solution, it has a pH value around 6 at 20°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 stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging. Its technical characteristics are acceptable for a Micro-Emulsion (ME) formulation.

3.2 Efficacy (Part B, Section 3)

No changes in the GAP have been made for this Article 43 re-registration in comparison to the existing approvals. According to SANCO/2010/13170 rev. 14, 7.Oct. 2016, if no changes in the GAP have been made, no new efficacy data have to be submitted and only resistance has to be considered for Article 43 re-registrations.

3.3 Efficacy data

KINVARA is approved to be applied in winter and spring cereals (wheat, barley, rye, triticale and oat) at the rate of 2.0-3.0 L/ha when crops are at the BBCH growth stage BBCH 24-39) and on grassland at the rate of 3.0 L/ha from March to September for the control of broad-leaved weeds.

No changes in the GAP have been made for this Article 43 re-registration in comparison to the existing approvals. According to SANCO/2010/13170 rev. 14, 7.Oct. 2016, if no changes in the GAP have been made, no new efficacy data have to be submitted and only resistance has to be considered for Article 43 re-registrations.

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

The risk for the development of resistance of target species were analysed following EPPO guideline PP1/213(4).

The risk of the development of resistance to KINVARA is real, but low. Resistance to synthetic auxin herbicides is relatively uncommon. Resistance when it occurs may result in a fitness penalty. If the resistance management strategy is followed, this risk would be reduced further to the point where growers could be confident that the use of KINVARA was sustainable for the long term.

The use pattern proposed by the applicant is low risk, and the product itself has a low risk of the development of resistance. The overall risk is therefore considered to be low, and no specific resistance management strategy is required.

No modifiers are required.

3.3.2 Adverse effects on treated crops

No changes in the GAP have been made for this Article 43 re-registration in comparison to the existing approvals. According to SANCO/2010/13170 rev. 14, 7.Oct. 2016, if no changes in the GAP have been made, no new selectivity data have to be submitted for Article 43 re-registrations.

3.3.3 Observations on other undesirable or unintended side-effects

sNo changes in the GAP have been made for this Article 43 re-registration in comparison to the existing approvals. According to SANCO/2010/13170 rev. 14, 7.Oct. 2016, if no changes in the GAP have been made, no new selectivity data have to be submitted for Article 43 re-registrations.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical methods are available for the determination of the active substances MCPA, fluroxypyr and clopyralid, as well as relevant impurities, in the plant protection product KINVARA.

The methods are fully validated in accordance with SANCO/3030/99 rev.5 and are therefore acceptable.

3.4.2 Analytical methods for residues

Validated analytical methods to determine residues of MCPA, fluroxypyr and clopyralid in treated crops are summarised in dRR Part B5 in support of the new residue trials detailed in ~~section 3.6.1 below~~ the RR Part B7.

No new analytical methods for post-authorisation control and monitoring purposes have been submitted in support of the authorisation of KINVARA. The methods considered for the most recent approvals or renewals of the active substances are considered sufficient to fulfil these data requirements.

Full details of the available data are presented in dRR Part B5.

zRMS: acceptable conclusion

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

No studies on Kinvara are available or required for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, skin irritation or skin sensitisation. Classification has been determined using the calculation method described in Globally Harmonised System CLP Regulation 1272/2008. The formulation is not classified for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, skin irritation or skin sensitisation.according to Regulation (EC) No. 1272/2008. Further details are presented in Part C.

Two studies are available for eye irritation. No prediction could be made from the Bovine Corneal Opacity and Permeability (BCOP) Assay (OECD Guideline 437) hence the need for an acute eye irritation study in the rabbit (OECD Guideline 405). The test item is classified as Category 2 (irritating to eyes).

Kinvara requires the following classification:

- H319: Causes serious eye irritation

zRMS:
The product Kinvara require the following classification for health hazards according to regulation 1272/2006 (see part B6 and Part C):
Acute Tox. 4, H302
~~Skin Irrit. 2, H315~~
Eye Irrit. 2; H319

3.5.2 Operator exposure

Exposure estimates have been made using the EFSA exposure model (EFSA Journal 2022;20(1):7032 calculator version: 1.0.1). The operator exposure estimations carried out indicate that the Acceptable Operator Exposure Level (AOEL) and Acute Acceptable Operator Exposure Level (AAOEL) will not be exceeded under conditions of intended uses for operators wearing gloves and standard workwear during mixing and loading. Workwear should be worn during application.

zRMS:
The acute exposure calculated with the EFSA AOEM 2022 to Clopyralid of operator wearing a work clothing (long sleeved shirt, long trousers) during M/L and App. and applying formulation Kinvara on low crops at dose of 3.0L/ha, using tractor-mounted/trailed sprayer (downward spraying), amounted to 82.8 % of respective AAOEL, thus the risk is acceptable. No AAOEL has been set for other actives substances: MCPA and Fluroxypyr.

The short-term exposure calculated with the EFSA AOEM 2022 to MCPA of operator wearing a work clothing (long sleeved shirt, long trousers) during M/L and App. and protective gloves during M/L and applying formulation Kinvara on low crops at dose of 3.0L/ha, using tractor-mounted/trailed sprayer (downward spraying), amounted to 49 % of respective AOEL thus the risk is acceptable.

The short-term exposure calculated with the EFSA AOEM 2022 to Fluroxypyr of operator wearing a work clothing (long sleeved shirt, long trousers) during M/L and App. and applying formulation Kinvara on low crops at dose of 3.0L/ha, using tractor-mounted/trailed sprayer (downward spraying), amounted to 10.6 % of respective AOEL, thus the risk is acceptable.

The short-term exposure calculated with the EFSA AOEM 2022 to Clopyralid of operator wearing a work clothing (long sleeved shirt, long trousers) during M/L and App and applying formulation Kinvara on low crops at dose of 3.0L/ha, using tractor-mounted/trailed sprayer (downward spraying), amounted to 23.8 % of respective AOEL, thus the risk is acceptable.

The hazard index for the combined short-term exposure to all three active substances of operator wearing a work clothing (long sleeved shirt, long trousers) during M/L and App. and protective gloves during M/L calculated with the EFSA AOEM 2022 is 0.5, thus the resulting combined health risk is acceptable.

Given the toxicological properties and classification of the formulation Kinvara according to Regulation 1272/2008/EC) as ~~Skin Irrit. 2, H315 and~~ Eye Irrit. 2; H319 wearing protective gloves and eye protection/face protection is recommended when handling the concentrate.

3.5.3 Worker exposure

Exposure estimates have been made using the EFSA exposure model. The worker exposure estimates indicate that the AOEL will not be exceeded under conditions of intended uses for workers wearing standard workwear re-entering the crop for crop inspection activities.

zRMS:
The exposure calculated with the EFSA AOEM 2022 to MCPA, an active substance of a product Kinvara of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for **2 hours** for inspection a field of cereals treated with this product at maximal dose 3.0 L product/ha as foreseen in GAP, is below AOEL of MCPA, thus it does not pose a systemic health risk.

The potential exposure calculated with the EFSA AOEM 2022 to Fluroxypyr or Clopyralid, two active substances of a product Kinvara, of worker entering for **2 hours** for inspection a field of cereals treated with this product at maximal dose 3.0 L product/ha as foreseen in GAP, is below respective AOELs, thus does not pose a systemic health risk.

The hazard index for the combined exposure to all three active substances of Kinvara of worker wearing a work clothing (long sleeved shirt, long trousers) and entering for **2 hours** for inspection a field of cereals treated with this product at maximal dose 3.0 L product/ha as foreseen in GAP calculated with the EFSA AOEM 2022 is 0.5, thus the resulting combined health risk is acceptable.

Thus, it is concluded that the application of a product Kinavara does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice providing that the worker is wearing a work clothing (long sleeved shirt, long trousers) during 2hrs inspection.

3.5.4 Bystander and resident exposure

Exposure estimates have been made using the EFSA exposure model. The resident and bystander exposure estimates indicate that the AOEL and AAOEL will not be exceeded under conditions of intended uses and without the need for any risk management measures.

zRMS:
The acute exposure of child and adult bystander to Clopyralid, an active substance of a product Kinvara applied on cereals in line with GAP at dose of 3.0 L/ha calculated with the EFSA AOEM 2022 demonstrates that such a exposure is well below AAOEL, therefore the application of product Kinvara does not pose an unacceptable risk to the health of bystanders for its intended use within good agricultural practice. No bystander acute exposure estimation for to MCPA and Fluroxypyr, two other active substances of a product Kinvara is required since no acute acceptable operator exposure values (AAOEL) has be set for any of this active substances

The short-term exposure of child and adult residents to MCPA, Fluroxypyr and Clopyralid, three active substance of a product Kinvara applied on cereals in line with GAP at dose of 3.0 L/ha calculated with the EFSA AOEM 2022 demonstrates that such a exposure to each of these substances is below respective AOELs, therefore the application of product Kinvara does not pose an unacceptable risk to the health of residents for its intended use within good agricultural practice

The hazard index for the combined short-term exposure of residents to all three active substances (MCPA, Fluroxypyr and Clopyralid) of Kinvara applied on cereals in line with GAP at dose of 3.0 L/ha calculated with the EFSA AOEM 2022 is 0.7 for the child residents and 0.3 for adults residents , thus the resulting combined health risk is acceptable.

Summing up an application of a product Kinvara on cereals in line with GAP at dose of 3.0 L/ha using tractor-mounted/trailed boom sprayer does not pose an unacceptable health risk for residents and bystanders.

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

zRMS:
The data available for Kinvara are considered sufficient for risk assessment. An exceedance of the relevant current MRLs for MCPA, fluroxypyr and clopyralid in the intended crops is not expected. The expected clopyralid MRLs are consistent with the intended GAP. The chronic and the short-term intakes of MCPA, fluroxypyr and clopyralid residues are unlikely to present a public health concern. A honey issue is irrelevant since the crops in question are not melliferous ones.
As far as consumer health protection is concerned, PL agrees with the authorization of the intended uses. According to available data, no specific mitigation measures should apply.
For details, please see the RR B7.

3.6.1 Residues

Out-of-protection active substance data evaluated at EU level for MCPA and fluroxypyr are relied upon in support of the authorisation of KINVARA when evaluating against existing EU-agreed endpoints. XXXX have a Letter of Access to the Dow AgroSciences S.A.S. data evaluated for the renewal of clopyralid (EFSA Journal 2018;16(8):5389).

In addition, new crop field trial studies containing data on residues in crops following applications of KINVARA are presented within dRR Part B7 in support of the proposed GAPs.

No exceedances of the current EU MRLs for MCPA, fluroxypyr and clopyralid are expected as a result of the proposed uses of KINVARA. Full details of the available data are presented in dRR Part B7.

3.6.2 Consumer exposure

Chronic and acute exposure calculations were performed using EFSA PRIMo revision 3.1 and calculated exposures were compared with the established toxicological reference values.

MRLs in all commodities were used as inputs for the chronic consumer risk assessments resulting in maximum chronic intakes (TMDI) below the ADI for MCPA, fluroxypyr and clopyralid. Further calculations using the STMR inputs for the commodities under consideration for the chronic consumer risk assessments were performed to determine the International Estimate of Dietary Intakes (IEDI), which are also below the ADI for MCPA, fluroxypyr and clopyralid.

Acute exposure assessments were conducted only for the commodities under consideration, and resulted in a maximum acute intakes (IESTI) below the ARfD for MCPA and clopyralid. As ARfD was not deemed necessary for fluroxypyr, acute risk assessment is not relevant for this active substance.

An acute consumer risk assessment from combined exposure was performed for MCPA and clopyralid using the Hazard Index (HI) concept. The Hazard Index calculated is <1.

A provisional chronic consumer risk assessment from combined exposure was performed for MCPA, fluroxypyr and clopyralid using the similar methodology to that for combined acute exposure. The resultant Hazard Index is <100 % for commodities relevant to the intended uses of KINVARA.

Combined exposure to all active substances in KINVARA is therefore not expected to present unacceptable acute and chronic risks for the consumer.

The proposed uses of MCPA, fluroxypyr and clopyralid in the formulation KINVARA do not represent unacceptable acute and chronic risks for the consumer.

Full details of the consumer exposure assessments are presented in dRR Part B7.

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

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

The predicted environmental concentration in soil (PEC_{soil}) of fluroxypyr MHE, Fluroxypyr, pyridinol, methoxypyridine, MCPA, PCOC and clopyralid were calculated in accordance with standard FOCUS (1997) methodology using the PEC Soil Calculator (version 1.0) (HSE, 2015). The tool assumes SFO degradation and calculations for metabolites were based on total annual applications adjusted for molecular weight differences and occurrence in soil. For methoxypyridine refined PECsoil was calculated using the more realistic parent to two metabolites in parallel functionality in the model ESCAPE v2.0. The results are summarized in dRR Part B 8

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

The groundwater exposure assessment was conducted according to FOCUS guidance using models PEARL v5.5.5 and PELMO v6.6.4. It was not considered necessary to perform additional modelling using the MACRO v5.5.4 model. All endpoints were taken from the peer review conclusions for MCPA, fluroxypyr and clopyralid, with two exceptions. The soil sorption and degradation values for MCPA have been made more conservative than the values reported in the EFSA peer reviews. The derivations of these values are provided in Part B8 (Sections 8.3 and 8.5). They are based on the official EU data but corrected for historic idiosyncrasies. The soil sorption value for clopyralid has been calculated from the agreed EFSA data and applying current EU best practices for selecting modelling endpoints. The approach is described in Part B8 (Section 8.5 and Appendix III).

The maximum 80th percentile PEC_{gw} values for the parent compounds MCPA and fluroxypyr, and their metabolites were <0.1 µg/L for all use and scenario combinations. For clopyralid maximum 80th percentile PEC_{gw} values for all parameterized scenarios for spring and winter cereals were <0.1 µg/L. However, for uses on grassland only summer (June) applications gave rise to PEC_{gw} values <0.1 µg/L. Applications in spring (March) and autumn (September) exceeded the 0.1 µg/L groundwater threshold.

Therefore, the risk to the groundwater environment is concluded to be low.

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

The PECsw assessment was provided for all active substances and their metabolites.
According to proposed intended uses in Poland, the following application pattern was taken into consideration:

- winter and spring cereals.

In accordance with national requirements in Step 3 (PECsw assessment was sufficient) the D3, D4 and R1 scenarios were considered. For spring cereals, the surrogate crop of winter cereals (R1 scenario) was used. The results of PECsw assessment are presented in dRR Part B8 p.8.9.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

Due to its physical-chemical properties, MCPA can be classed with low volatility meaning that no significant loss to the atmosphere is expected and atmospheric accumulation is unlikely.

Due to their physical-chemical properties, fluroxypyr and fluroxypyr-MHE can be classed with low volatility meaning that no significant loss to the atmosphere is expected and atmospheric accumulation is unlikely. In addition, these substances are characterised by rapid photochemical oxidation in the atmosphere.

Due to its physical-chemical properties, clopyralid can be classed with low volatility meaning that no significant loss to the atmosphere is expected and atmospheric accumulation is unlikely.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

A Tier 1 assessment demonstrates acceptable acute and chronic risks to birds and mammals exposed to MCPA, fluroxypyr and clopyralid via contaminated food items. A higher-tier assessment residue decline data for MCPA demonstrates acceptable long-term risk to birds and mammals exposed under the same circumstances. A conservative screening assessment indicates acceptable acute and long-term risk to birds and mammals potentially exposed to MCPA, fluroxypyr or clopyralid residues by drinking water from contaminated puddles. It may therefore be concluded that the proposed use of Kinvara in cereal and grassland crops in accordance with Good Agricultural Practice poses no unacceptable risk to birds.

Winter and spring cereals. The combined and individual risk of the active substances in Kinvara can be resolved at Tier-1 for the proposed applications to cereals.
Grasslands. In accordance with intended uses, the grasslands are not relevant for Poland. Only the mixture toxicity risk to voles in grassland cannot be resolved using the standard EU TER thresholds. This is no different from the previous registration of Kinvara in Central Zone, as neither the endpoints nor the EU guidance has changed meaning the calculations are identical. Previous registrations were granted accepting the full rate and resolving the assessment following German standard guidance. The EU definition of the vole is vastly over-conservative for application in the Central Zone. This has long been recognized in Germany and resolved by reducing the TER criteria for the vole to 5 for the acute assessment and 2 for the chronic assessment. This has long been accepted as a more realistic representation of the risk to small mammals and allows the assessment to be fully resolved.
The German approach is not accepted in Poland. The lower application rate of 2.5 L/ha confirms the safe use for mammals.

3.8.2 Effects on aquatic species

Active substances and formulation risk assessments result in PEC/RAC values above the trigger value of 1 for all scenario using either step 1, Step 2 or Step 3 FOCUS PECsw. MCPA and the metabolite PCOC result in PEC/RAC >1 for D1 and D2 scenarios that are however not relevant for the Central Zone. Therefore it can be concluded that applications of Kinvara to cereals and grassland do not pose a risk to aquatic organisms.

3.8.3 Effects on bees

Neither the Kinvara formulation, nor any of the relevant active substance pose an acute risk to honeybees and bumblebees according to the standard acute risk assessment. A higher-tier field study on Kinvara indicates the formulation also does not pose a risk to honeybee larvae.

3.8.4 Effects on other arthropod species other than bees

Applications of Kinvara to winter and spring cereals and grassland do not pose a risk to non-target arthropods either in-field or off-field.

3.8.5 Effects on soil organisms

The risk MCPA, fluroxypyr-MHE, fluroxypyr (acid), pyridinol, clopyralid and the Kinvara formulation to soil organisms can all be resolved at Tier-1. A previously accepted higher-tier study on methoxypyridine allows the assessment of that substance to be resolved without the need for further testing.

The proposed applications of Kinvara results in an acceptable risk assessment for soil microorganisms.

3.8.6 Effects on non-target terrestrial plants

Spray drift mitigation measures are required to protect non-target plants from the risk of Kinvara. Either a 20 m no spray buffer, 10 m no spray buffer and 50 % spray reducing nozzle or 5 m no spray buffer and 75 % spray reducing nozzle will be required.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Spray drift mitigation measures are required to protect non-target plants from the risk of Kinvara. Either a 20 m no spray buffer, 10 m no spray buffer and 50 % spray reducing nozzle or 5 m no spray buffer and 75 % spray reducing nozzle will be required.

3.9 Relevance of metabolites (Part B, Section 10)

All metabolites covered in Part B10 are considered toxicologically relevant because no regulatory assessments were submitted or accepted as part of active substance approval, and no new data are submitted. All metabolites are predicted to occur in groundwater at concentrations **below 0.1 µg/L** (see sections 8.8.2 and 8.8.3 of the dRR Part B, Section 8). Thus, assessments of relevance of the MCPA metabolite PCOC, and the fluroxypyr metabolites pyridinol and methoxypyridine are not required.

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

This point is not relevant to MCPA, Fluroxypyr or Clopyralid as none of the active substances are candidates 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

None

Appendix 1 Copy of the product authorization

None

Appendix 2 Copy of the product label

Submitted separately.

Appendix 3 Letter of Access

XXXX have access to a full Annex II data package from the notifier Nufarm in respect of the active substance MCPA which grants access to all Annex II data including renewal data. Please refer to the enclosed LoA.

XXXX asks for referral to all relevant data submitted by DOW for Clopyralid during the Community review programme under Council Directive 91/414/EEC. Data submitted under Annex II is no longer considered to be under data protection. XXXX have access to the renewal Annex II data package from the notifier Dow in respect of the active substance Clopyralid. Please refer to enclosed Agreement between Dow and XXXX.

A Letter of Access is provided to XXXX. for fluroxypyr technical source 1 from xxxx
A Letter of Access is provided to XXXX for fluroxypyr technical source 2 from xxx

A Letter of Access is provided to XXXX for clopyralid technical source 1 from xxx

A Letter of Access is provided to XXXX for clopyralid technical source 2 from xxx

A Letter of Access is provided to XXXX for clopyralid technical source 3 from xxx.

Appendix 4 Lists of data considered for national authorization

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
XXXX	XXXX	XXX	XXXX	XX	XX	XXX	XXXX

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
XXXX	XXXX	XXX	XXXX	XX	XX	XXX	XXXX

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	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in **this** MS:	Owner

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
			Published/Unpublished			Data protection started with: <insert authorization number of first authorization>	

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