

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: ADM.3304.H.1A

Product name(s): Tricera

Chemical active substance(s):

2,4-D, 375 g/L (562.5 g/L as 2,4-D EHE)

Clopyralid, 30 g/L

Fluroxypyr, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(composition change)

Sponsor: ADAMA Agan Ltd.

Applicant: Country organisation / representative of ADAMA,
as given in Part A

Submission date: February 2021

MS Finalisation date: May 2022 (initial Core Assessment)
November 2022, updated March 2023 (final Core Assessment)

Version history

When	What
January 2021	dRR Part B - Section 7, version 1 submitted by applicant
May 2022	Initial zRMS assessment (with regard to the proposed composition change). The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.
November 2022	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.
March 2023	Final report (Core Assessment updated following the Applicant's comments). Additional information/assessments included by the zRMS in the report in response to comments received from the Applicant are highlighted in green. Information no longer relevant is struck through and shaded.

DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

STATEMENT FOR OWNERSHIP

The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

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- from a second party that has obtained permission from the owner of the data for this purpose or,
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Introduction

General remark:

The product ~~AG-CDF1-480 EC~~ Tricera (ADM.3044.H.1.A) is a herbicide containing the active substance 2,4-D (as the ester variant 2,4-D EHE).

The residue definition for both plant and animal commodities for risk assessment and enforcement purposes for 2,4-D is defined as the sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D (please refer to section 7.4 below).

It is therefore concluded that the data submitted for 2,4-D acid (named as 2,4 D in the dossier below) are applicable for 2,4-D EHE.

This document reviews the information related to the metabolism and residues of the plant protection product ~~AG-CDF1-480 EC~~ ADM.3304.H.1.A containing the active substances 2,4-D, Clopyralid and Fluroxypyr.

2,4-D was reviewed as part of the renewal of approval procedure by the Member States and the Commission and the Commission review report finalised on 13.11.2015 approved 2,4-D in accordance with Regulation (EC) No. 1107/2009 (Regulation 2015/2033).

Clopyralid was included into Annex I of Directive 91/414/EEC according to Commission Regulation (EC) No 451/2000 (renewal of inclusion of the second and third group of active substances in Annex I, see Commission Directive 2006/64/EC of 18 July 2006, Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 that replaced the Directive 2006/64/EC after the application of Regulation 1107/2009, and Commission Implementing Regulation (EU) No 2019/168 of 31 January 2019 that fixes the new expiry date of approval to 30/04/2020.

Commission Implementing Regulation (EU) 2021/566 extended the approval period of clopyralid to 30 April 2022 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance.

Clopyralid was evaluated in accordance with Regulation (EC) No 1107/2009 and Commission Implementing Regulation (EU) No 844/2012 following the submission of an application to renew the approval of this active substance expiring in April 2022. The approval of the active substance clopyralid is renewed as set out in Annex I of Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021.

Date of approval - 1 October 2021

Expiration of approval - 30 September 2036

Applicant provided LoA from Dow AgroSciences for clopyralid: access to Dow AgroSciences data on active substance clopyralid for registration of pesticide AG-CDF1-480 EC and ADM.3304.H.1.A.

Fluroxypyr was included into Annex I of Directive 91/414/EEC according to Commission Regulation (EC) No 736/2011 (renewal of inclusion of the first group of active substances in Annex I).

However, all the relevant information about this last approval are indicated in Review report for active substance Fluroxypyr (SANCO/111019/201, 17 June 2011), as was evaluated within the assessment of active substance Fluroxypyr.

Where appropriate this document refers to the conclusions of the EU review or the Draft Assessment Report (DAR) of the active substances. This will be where:

- the active substance data is relied upon in the risk assessment of the formulation; *or when*
- the EU review or DAR concluded that additional data/information should be considered at national re-registration.

Note: this Part B document only reviews data (Annex II or Annex III) (Chemical Active or Chemical Product) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II (Chemical active) data have only be included if they were considered essential for the evaluation and in this case a full study summary was be

provided. In the case where the formulation has been previously evaluated, at European level, detailed summaries have not been provided.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

The EFSA Report of 2,4-D (EFSA Journal 2014;12(9):3812) that was updated on 21st March 2017, the EFSA report of Clopyralid (EFSA Scientific Report (2005) 50, 1–65,) and the EFSA Report of Fluroxypyr (EFSA Journal 2011;9(3):2091) are considered to provide the relevant review information or a reference to where such information can be found.

For the information on 2,4-D EHE, please refer to the Bridging dossier (2018) prepared by the RMS for the a.i. (Greece).

The Annex I Inclusion Directives for the active substances **2,4-D** (Commission Directive 2001/103/EC) gives specific provisions under Part B which need to be considered by the applicant in the preparation of their submission prior to granting an authorisation.

For the implementation of the uniform principles of Regulation (EC) 546/2011, the conclusions of the review report on **2,4-D**, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28. May 2015 shall be taken into account. In this overall assessment:

Member States must pay particular attention to the:

- *Risk to aquatic organisms, terrestrial organisms and consumers in cases of uses above 750 g/ha.*

The Annex I Inclusion Directives for the active substances **Clopyralid** (Commission Directive 2006/64/CE) gives specific provisions under Part B which need to be considered by the applicant in the preparation of their submission prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the active substance Clopyralid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 04. April 2006 shall be taken into account. In this overall assessment member states should pay particular attention to:

- The protection of non target plants and groundwater under vulnerable conditions. Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate.

The Annex I Inclusion Directives for the active substances **Clopyralid** (COMMISSION IMPLEMENTING REGULATION (EU) 2021/1191 of 19 July 2021) gives specific provisions under Part B which need to be considered by the applicant in the preparation of their submission prior to granting an authorisation.

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on clopyralid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to:

- the specification of the technical material as commercially manufactured;
- the protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment;
- possible presence of clopyralid residues in rotational crops;
- the possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops;
- the protection of groundwater under vulnerable conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water. The applicant shall submit this information within two years after adoption of a guidance document on evaluation of

the effect of water treatment processes on the nature of residues present in surface and groundwater.

Fluroxypyr (Commission Implementing Regulation (EU) No 736/2011) gives specific provisions under Part B which need to be considered by the applicant in the preparation of their submission prior to granting an authorisation.

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on **Fluroxypyr**, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.

- Only uses as herbicides may be authorised.

In this overall assessment Member States shall pay particular attention to:

- The potential contamination of groundwater by metabolite Fluroxypyr Pyridinol, when the active substance is applied in regions with alkaline or vulnerable soil and/or with vulnerable climatic conditions.
- The risk to aquatic organisms.

These concerns have, where relevant, been addressed within the current submission in the respective sections.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Appendix 2 of this document contains the new data of the active substances present in AG-CDF1-480 EC in this section.

Information on the detailed composition of AG-CDF1-480 EC can be found in the confidential dossier of this submission (Registration Report - Part C).

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7 Metabolism and residue data (KCA section 6)

The present dossier is submitted to support a request for composition change.

However, the old and the new compositions are regarded as comparable and no impact on the residue data can be expected from the co-formulant change.

In this way no new information compared to the previously submitted dossier is presented.

7.1 Summary and zRMS Conclusion

zRMS comments:

The reason for the application of this dossier is a composition change of the product. As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented by Applicant. The composition change has no impact on the residue data. No additional data are required.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation AG-CDF1-480 EC are presented in Table 7.1 1. They have been selected from the individual GAPs in the Central zone (N-EU) for cereals and grassland.

Justification for the selection of the critical GAP

The critical GAP uses concern

- the highest single and yearly application rates (highest single application rate of 2 L prod./ha),
- the maximum number of applications, (1) and
- the latest application growth stage in the crop (BBCH 39 in cereals and grassland).

In addition, residue from wheat and barley can be used to support the intended uses on cereals since according to SANCO 7525/VI/95 Rev. 10.3 and 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 to oat, rye and wheat and vice-versa. Therefore, data obtained from barley and wheat can be used together to support the intended uses on cereals (wheat, barley, rye, oat and triticale).

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for 2,4-D, Clopyralid and Fluroxypyr as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of the active substances residues are unlikely to present a public health concern.

According to available data, the following specific mitigation measures are recommended:

- not to use **clopyralid** on the same field for 125 days after the initial application regardless of the crop grown,
- root and tuber crops should not be grown as rotational crops for one year after an application of **fluroxypyr**.

Data gaps (see dRR for AG-CDF1-480 EC (zRMS-PL, May 2022)

The following data gaps were identified by EFSA:

1. For clopyralid – according to the EFSA Journal 2018;16(8):5389 – “Peer review of the pesticide risk assessment of the active substance clopyralid”

- Rotational crop field trials according to current guidelines should be submitted,
 - Data need to be provided to exclude that pollen/nectar collection by bees might occur in order to exclude potential residues in pollen and bee products for human consumption.
2. For fluroxypyr - according to the EFSA Journal 2019;17(9):5816 – “Evaluation of confirmatory data following the Article 12 MRL review for fluroxypyr”
- The assessment of the metabolism study with fluroxypyr-meptyl in lactating goat and toxicological data on fluroxypyr pyridinol and its conjugates should be peer reviewed to revise the residue definition for products of animal origin.

The application of AG-CDF1-480 EC was submitted in October 2019 in Poland. Applicant updated the dRR in May 2022. In our opinion, these data gaps should not affect the registration of AG-CDF1-480 EC and should be filled as part of the product re-authorization procedure.

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
1, 4	Established Grassland	N-EU (UK, PL)	AG- CDF1- 480 EC	F	TTTDD	EC	375 g/L 2,4-D 30 g/L Clopyralid 75 g/L Fluroxypyr	foliar spraying, overall	Mar-Aug/ BBCH 21- 39	1	n.a.	187,5 - 75 2,4-D 15 - 30 Clopyralid 37,5 - 75 Fluroxypyr	200-400	750 2,4-D 60 Clopyralid 150 Fluroxypyr	n.a.	A
2, 5	TRZAS, HORVS, AVESS, TTLSO, SECCS (umbrella GAP)	N-EU (UK, PL)	AG- CDF1- 480 EC	F	TTTDD	EC	375 g/L 2,4-D 30 g/L Clopyralid 75 g/L Fluroxypyr	foliar spraying, overall	Mar-Jun/ BBCH 21- 39	1	n.a.	187,5 - 75 2,4-D 15 - 30 Clopyralid 37,5 - 75 Fluroxypyr	200-400	750 2,4-D 60 Clopyralid 150 Fluroxypyr	n.a.	A
3, 6	TRZAW, HORVW, TTLWI, SECCW, AVESW (umbrella GAP)	N-EU (UK, PL)	AG- CDF1- 480 EC	F	TTTDD	EC	375 g/L 2,4-D 30 g/L Clopyralid 75 g/L Fluroxypyr	foliar spraying, overall	Mar-May/ BBCH 21- 39	1	n.a.	187,5 - 75 2,4-D 15 - 30 Clopyralid 37,5 - 75 Fluroxypyr	200-400	750 2,4-D 60 Clopyralid 150 Fluroxypyr	n.a.	A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

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

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

7.1.2.1 Summary for 2,4-D

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.1.2.2 Summary for Clopyralid

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.1.2.3 Summary for Fluroxypyr

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.1.2.4 Summary for AG-CDF1-480 EC

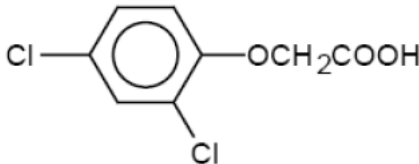
As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

Assessment

7.2 2,4-D

General data on 2,4-D are summarized in the table below (last updated 2019/08/15)

Table 7.2-1: General information on 2,4-D

Active substance (ISO Common Name)	2,4-D
IUPAC	(2,4-dichlorophenoxy)acetic acid
Chemical structure	
Molecular formula	C ₈ H ₆ Cl ₂ O ₃
Molar mass	221 g/mol
Chemical group	Phenoxy acetic compounds
Mode of action (if available)	It induces uncontrolled cell division in the plant tissues which causes such a disproportion between assimilation performed and water balance on the one hand, and the normal vegetative growth process on the other hand, that eventually the plant dies
Systemic	Yes
Company (ies)	Dow, Makhteshim-Agan Agro Poland S.A.*
Rapporteur Member State (RMS)	Greece
Approval status	Approved on 01/01/2016 Commission implementing Regulation (EU) No 540/2011 and Commission implementing Regulation (EU) 2015/2033 http://data.europa.eu/eli/reg_impl/2011/540/oj http://data.europa.eu/eli/reg_impl/2015/2033/oj
Restriction (e.g. is restricted to use as "...")	Only uses as herbicide
Review Report	SANCO/11961/2014 Rev 5 06/10/2017
Current MRL regulation	Commission Regulation (EU) No 1317/2013 2019/1791
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Yes EFSA 2014 (update 2017) **
EFSA Journal: conclusion on article 12	Yes EFSA 2011 **
Current MRL applications on intended uses	None

* Notifier in the EU process to whom the a.s. belong(s)

** see list of references:

- EFSA (European Food Safety Authority), 2011a. Review of the existing maximum residue levels (MRLs) for 2,4-D according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(11):2431. [52 pp.] doi:10.2903/j.efsa.2011.2431.
- EFSA (European Food Safety Authority), 2014. Update from 21st March 2017 Conclusion on the peer review of the pesticide risk assessment of the active substance 2,4-D. EFSA Journal 2014;12(9):3812, 81 pp. doi:10.2903/j.efsa.2014.3812.

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.3.2 Conclusion on the magnitude of residues in plants

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

7.2.6 Magnitude of residues in representative succeeding crops

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.7 Other / special studies (KCA6.10, 6.10.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

7.2.8.1 Input values for the consumer risk assessment

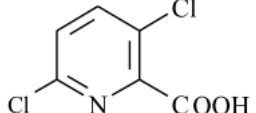
7.2.8.2 Conclusion on consumer risk assessment

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3 Clopyralid

General data on Clopyralid are summarized in the table below (last updated 2019/08/15)

Table 7.3-1: General information on Clopyralid

Active substance (ISO Common Name)	Clopyralid
IUPAC	3,6-dichloropyridine-2-carboxylic acid or 3,6-dichloropicolinic acid
Chemical structure	
Molecular formula	C ₆ H ₃ Cl ₂ NO ₂
Molar mass	191.96 g/mol
Chemical group	Pyridines
Mode of action (if available)	Accumulation in meristematic tissue
Systemic	Yes
Company (ies)	Dow AgroSciences S.A.S. *
Rapporteur Member State (RMS)	Finland
Approval status	Approved on 01/05/2007 Commission implementing Regulation (EU) No 540/2011 and Commission implementing Regulation (EU) 2019/168 http://data.europa.eu/eli/reg_impl/2011/540/oj http://data.europa.eu/eli/reg_impl/2019/168/oj Commission Implementing Regulation (EU) 2021/1191
Restriction (e.g. is restricted to use as "...")	Only uses as herbicide
Review Report	SANCO/10012/2006-rev.3, 04/04/2006 Clopyralid SANTE/10206/2021 Rev 1, 20 May 2021
Current MRL regulation	Commission Regulation (EU) 2018/1514 Commission Regulation (EU) 2021/1807
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	In progress
EFSA Journal: Conclusion on the peer review	Yes EFSA 2005 EFSA Journal 2018;16(8):5389
EFSA Journal: conclusion on article 12	None
Current MRL applications on intended uses	None EFSA Journal 2021;19(1):6389

* Notifier in the EU process to whom the a.s. belong(s)

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

As the two compositions are regarded to be comparable, no new information compared to the previously

submitted dossier is presented

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.3 Magnitude of residues in plants (KCA 6.3)

7.3.3.1 Summary of European data and new data supporting the intended uses

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.3.2 Conclusion on the magnitude of residues in plants

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

7.3.5.1 Available data for all crops under consideration

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.5.2 Conclusion on processing studies

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.6 Magnitude of residues in representative succeeding crops

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.7 Other / special studies (KCA6.10, 6.10.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.3.8 Estimation of exposure through diet and other means (KCA 6.9)

7.3.8.1 Input values for the consumer risk assessment

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

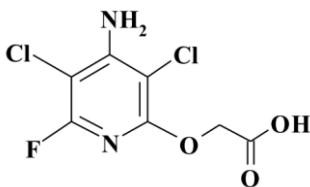
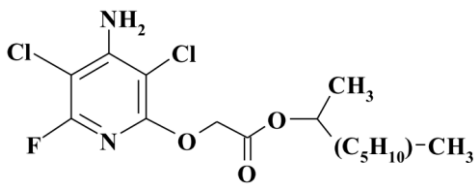
7.3.8.2 Conclusion on consumer risk assessment

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4 Fluroxypyr

General data on fluroxypyr are summarized in the table below (last updated 2019/08/16)

Table 7.4-1: General information on fluroxypyr

Active substance (ISO Common Name)	Fluroxypyr	Fluroxypyr-meptyl
IUPAC	4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid	1-methylheptyl 2-[(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetate
Chemical structure		
Molecular formula	C ₇ H ₅ Cl ₂ FN ₂ O ₃	C ₁₅ H ₂₁ Cl ₂ FN ₂ O ₃
Molar mass	255 g/mol	367.3 g/mol
Chemical group	Herbicide	
Mode of action (if available)	It mimics the action of auxin to induce cell elongation and it also interferes with RNA synthesis.	
Systemic	Yes	
Company (ies)	Dow AgroSciences*	
Rapporteur Member State (RMS)	Ireland	
Approval status	Approved on 01/01/2012 Commission implementing Regulation (EU) 2017/856 of 18 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance fluroxypyr http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0856&from=EN Reg. (EU) 2019/291	
Restriction (e.g. is restricted to use as "...")	Only uses as herbicide	
Review Report	SANCO/11019/2011 – rev. 5 23/03/2017	
Current MRL regulation	Commission Regulation (EU) 2015/1040 of 30 June 2015 Reg. (EU) 2021/1098	
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes	
EFSA Journal : Conclusion on the peer review	Yes EFSA 2011**	
EFSA Journal: conclusion on article 12	Yes EFSA 2013** EFSA Journal 2019;17(9):5816**	
Current MRL applications on intended uses	None	

* Notifier in the EU process to whom the a.s. belong(s)

** see list of references:

- EFSA (European Food Safety Authority), 2011c. Conclusion on the peer review of the pesticide risk assessment of the active substance fluroxypyr. EFSA Journal 2011;9(3):2091. [91 pp.]. doi:10.2903/j.efsa.2011.2091.
- EFSA (European Food Safety Authority), 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for fluroxypyr according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(12):3495,

49 pp. doi:10.2903/j.efsa.2013.3495.

- EFSA (European Food Safety Authority), 2019. Evaluation of confirmatory data following the Article 12 MRL review for fluroxypyr. EFSA Journal 2019;17(9):5816, doi: 10.2903/j.efsa.2019.5816.

7.4.1 Stability of Residues (KCA 6.1)

7.4.1.1 Stability of residues during storage of samples

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.1.2 Stability of residues in sample extracts (KCA 6.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.2 Nature of residues in plants, livestock and processed commodities

7.4.2.1 Nature of residue in primary crops (KCA 6.2.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.2.2 Nature of residue in rotational crops (KCA 6.6.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.2.3 Nature of residues in processed commodities (KCA 6.5.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.3 Magnitude of residues in plants (KCA 6.3)

7.4.3.1 Summary of European data and new data supporting the intended uses

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

submitted dossier is presented

7.4.3.2 Conclusion on the magnitude of residues in plants

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.4 Magnitude of residues in livestock

7.4.4.1 Dietary burden calculation

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.6 Magnitude of residues in representative succeeding crops

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.7 Other / special studies (KCA 6.10, 6.10.1)

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.8 Estimation of exposure through diet and other means (KCA 6.9)

7.4.8.1 Input values for the consumer risk assessment

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.4.8.2 Conclusion on consumer risk assessment

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented

7.5 Combined exposure and risk assessment

7.5.1 Acute consumer risk assessment from combined exposure

Not relevant.

7.5.2 Chronic consumer risk assessment from combined exposure

As the two compositions are regarded to be comparable, no new information compared to the previously submitted dossier is presented.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review for 2,4-D

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data relied on 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	Vertebrate study Y/N	Owner
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the additional studies relied upon

No additional studies are submitted to support this application.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

No additional calculations are submitted to support this application.