

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: ADM.01851.H.1.A

Product name(s): see Part A

Chemical active substances:

Ethofumesate, 500 g/L

Clopyralid, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

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

Submission date: July 2024

MS Finalisation date: March 2025 (initial Core Assessment)

June 2025 (final Core Assessment)

Version history

When	What
July 2024	Initial version
March 2025	Initial zRMS assessment 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
June 2025	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application under article 33 of regulation 1107/2009 submitted by the applicant in July 2024 is for first authorisation of the product ADM.01851.H.1.A (containing 500 g/L ethofumesate and 75 g/L clopyralid) follows the data requirements of

- Regulation (EC) No. 283/2013 for the active substances, and
- Regulation (EC) No. 284/2013 for the plant protection product ADM.01851.H.1.A .

Any deviation from this is justified in the relevant parts of the dossier.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	No application	-
Central zone	Poland	-
Southern zone	France	-
Inter-zonal	Not applicable	-
Great Britain	Great Britain	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Ethofumesate

Table 0.1-2: Summary of regulatory history of CAS No: 26225-79-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2002/37/EC of 03 May 2002 amending Council Directive 91/414/EEC Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 Commission Implementing Regulation (EU) 2016/950 of 15 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods Commission Implementing Regulation (EU) 2016/1426 of 25 August 2016 renewing the approval of the active substance in accordance with Regulation (EC) No 1107/2009
RMS	Austria
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.11.2016
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.01.2017 (Art. 43)
Date of final Commission (re-registration) deadline (Step 2)	-

Status	
Current expiration of approval	31.10.2031
Low risk substance or Candidate for Substitution?	-

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States:

- shall pay particular attention to the risk to aquatic organisms.

Conditions of use shall include risk mitigation measures, where appropriate.

Table 0.1-3: Information on minimum purity of ethofumesate

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
970 g/kg	975 g/kg Equivalence report available: Y (Austria) for details refer to Part C

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

For details of the active ingredient source of ethofumesate please refer to Part C.

The Renewal report for ethofumesate (SANTE/10119/2016 Rev. 3) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. However, an EFSA Scientific Report was made available on 19/01/2016 (EFSA Journal 2016;14(1):4374). The list of endpoints from this EFSA Scientific Report is considered in this submission.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints:

No such table is provided here.

Information on deviating endpoints, where relevant, will be specified in the respective Part B documents.

0.1.3.2 Clopyralid

Table 0.1-4: Summary of regulatory history of CAS No: 1702-17-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021 renewing the approval of the active substance in accordance with Regulation (EC) No 1107/2009
RMS	Finland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.10.2021
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.12.2021 (Art. 43)

Status	
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	30.09.2036
Low risk substance or Candidate for Substitution?	-

Issues that need to be considered as part of the EU approval are listed below.

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.

Table 0.1-5: Information on minimum purity of clopyralid

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
950 g/kg	950 g/kg Equivalence report available: this is confidential information, please refer to Part C.

For details of the active ingredient source of clopyralid please refer to Part C.

The Renewal report for clopyralid (SANTE/10206/2021 Rev. 1) is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

However, an EFSA Peer Review was made available in 2018 (EFSA Journal 2018;16(8):5389). The list of endpoints from this EFSA Peer Review is considered in this submission.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints:

No such table is provided here.

0.1.4 Information on deviating endpoints, where relevant, will be specified in the respective Part B documents. Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses to be considered safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses to be considered non-safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

See column 15 of the GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. 1, date: February 2025

PPP (product name/code): ADM.01851.H.1.A
Formulation type: SC
Active substance 1: ethofumesat
Conc. of as 1: 500 g/L
Active substance 2: clopyralid
Conc. of as 2: 75 g/L
Safener/Synergist: not relevant
Conc. of synergist: not relevant
Applicant: ADAMA Agan Ltd.
Professional use: X
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	15							
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)	zRMS comments							
					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			Phys-chem	Analytical methods	Toxicology	Residues	Fate and behavior	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	PL	Sugar beet BEAVA Fodder beet BEAVG	F	annual dicot weeds and annual grass weeds	foliar spraying, overall	BBCH 10-19/ March-June	a) 3 b) 3	a) 5 b) 5	a) 0.66 L/ha b) 1.98 L/ha	a) 330 g ethofumesate/ha 49.5 g clopyralid/ha b) 990 g ethofumesate/ha 148.5 g clopyralid/ha	100-400	n.a.	Total rate per season 2 L/ha Max rate of ethofumesate should not exceed 1.0 kg/ha every 2-3 years Max. rate of clopyralid should not exceed 150 g/ha every 2 years	A	A	A	A	R Biennial application	R ¹ NTTP, Aquatic R3 A Remaining species	A N fodder beet possible authorization based on the art. 51 – minor uses	

2	PL	Sugar beet BEAVA Fodder beet BEAVG	F	annual dicot weeds and an- nual grass weeds	foliar spray- ing, overall	BBCH 10-19/ March- June	a) 3 b) 3	a) 5 b) 5	a) 0.66 L/ha b) 1.98 L/ha	a) 330 g ethofumesate/h a 49.5 g clopyra- lid/ha b) 990 g ethofumesate/h a 148.5 g clopyralid/ha	100- 400	n.a.	Band application applied to 50% of the surface, along the plant rows. Total rate / sea- son = 1 L/ha (500+75 g ai/ha) Max rate of ethofumesate should not ex- ceed 1.0 kg/ha every 2-3 years Max. rate of clopyralid should not ex- ceed 150 g/ha every 2 years	A	A	A	A	R Bien- nial appli- cation	A	A	A	N fodder beet possible authoriza- tion based on the art. 51 – mi- nor uses
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Remarks table heading:

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

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.

(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.

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

¹ Not relevant for Poland