REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: EF-243

Product name: Lontrel 300

Chemical active substance:

Clopyralid, 300 g a.e./L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Renewal of Authorization under Art.43)

Applicant: Corteva Agriscience

Submission date: 22/12/2021

MS Finalisation date: 05/12/2022

After commenting: 22/02/2023

Version history

When	What
December 2021	Article 43 submission for reregistation of EF-243 following Clopyralid Renewal of approval (Commission Implementing Regulation (EU) 2021/1191)
December 2022	First zRMS evaluation
February 2023	After commenting

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

This core assessment concerns the renewal of authorisation of the field uses of the herbicide EF-243, which is currently authorised under product name Lontrel 300 SL in the Czech Republic, Poland and Slovakia according to Art. 43 of Regulation (EC) No. 1107/2009, following the renewal of active substance clopyralid. EF-243 is formulated as a Soluble Liquid concentrate (SL-formulation) and contains 300 g a.e./L clopyralid. The product is currently authorised for use as a post-emergence herbicide for the control of broadleaf weeds in a range of crops: sugar beet (BEAVA), fodder beet (BEAVC), red beet (BEAVD), mangel (BEAVC) winter oilseed rape (BRSNW), maize (ZEAMX), winter and spring barley (HORVW, HORWS), winter and spring oat (AVESW, AVESP), winter and spring wheat (TRZAW, TRZAS), winter and spring rye (SECCW, SECCS), winter and spring (TTLWI, TTLSO), flax/linseed (LIUUT), grass for seeds (YGRAS), lawn (NNNZW), onion for seeds (ALLCE/ALLXS) and gladiolus (1GLAG).
The renewal is based on an unchanged product, and product formulation remains the same, whereas for grass for seeds, lawn, maize, winter and spring cereals and sugar beet uses, the GAP table has been revised by dose rate reduction and or application timing. The applicant states that these changes were caused by new risk assessment endpoints and were implemented to align with the residue data package.
To support reduced dose rates as a result of new regulatory endpoints, the applicant presented bridging data of other registered clopyralid formulations to demonstrate their equivalence and use them as support of EF-243. Thus, the conclusions drawn from the efficacy evaluation concern uses where the GAP was changed.

For the following intended uses PL as zRMS would accept the efficacy of the applied data:

- cereals, grass for seeds and lawn uses.

For the following application, PL as zRMS would not accept the data provided:

- sugar beet - split dose application use (NE region).

For the following intended uses the concerned Member States are kindly asked to decide themselves whether to accept provided data or not:

- maize, sugar beet - split dose application use (Southeast and Maritime EPPO regions).

In the framework of Article 43 the applicant submitted an updated analysis of the resistance risk (following EPPO guideline PP 1/213 (1) “Resistance risk analysis”) which is required for the renewal of Lontrel 300 SL containing 300 g a.e./L of the active substance clopyralid. Based on the updated resistance risk analysis, zRMS concluded that the resistance risk for the active substance clopyralid within Lontrel 300 SL can be considered acceptable.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

PPP (product name/code):	EF-243	Formulation type:	SL
Active substance 1:	Clopyralid-olamine	Conc. of as 1:	395.26 g/L (a.s.), 300 g/L (a.e.)
Safener:	no	Conc. of safener:	conc. (c)
Synergist:	no	Conc. of synergist:	conc. (c)
Applicant:	Corteva Agriscience	Professional use:	☒
Zone(s):	Central	Non professional use:	☐

Verified by MS:

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: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI (days)**	**Remarks:** **e.g. g safen-er/synergist per ha** (f)	**zRMS Conclusion (efficacy)**
					Method / Kind Equipment Used	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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
TYPE OF APPLICATION - ZONAL														
1	Poland	Sugar beet EPPO Code: BEAVC, BEAVA, BEAVD EU MRL Code: 0213010, 0900010, 0213010 Raw Human consumption Processed goods Cattle consump-tion	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast, Foliar Tractor mounted boom	BBCH 12-39 (until July 1st)	a) 1 b) 1	NA	a) 0,3 to 0,4 b) 03 to 0,4	a) AS1: 118,578 to 158,104 (as/ha), 90 to 120 (ae/ha) b) AS1: 118,578 to 158,104 (as/ha), 90 to 120 (ae/ha)	100-400	42 days	One application every two years. Maximum total dose rate must not exceed 120 g ae clopyralid/ha per crop; maximum individual dose: 120 g ae clopyralid/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	

2	Poland	Sugar beet EPPO Code: BEAVC, BEAVA, BEAVD EU MRL Code: 0213010, 0900010, 0213010 Raw Human consumption Processed goods Cattle consumption	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast, Foliar Tractor mounted boom, split application	BBCH 12-15 First application at BBCH 12-15. Second application at BBCH 12-15.	a) 2 b) 2	7 day interval	a) 0,2 b) 0,4	a) AS1: 79,052 (as/ha), 60 (ae/ha) b) AS1: 158,104 (as/ha), 120 (ae/ha)	100-400	42 days	Only every three years. Split application: First application at 60 gae clopyralid/ha (0,2L of EF-243/ha) at BBCH 12-15 followed 7-days later by a second application at BBCH 12-15 at 60 gae clopyralid/ha (0,2 L EF-243/ha). Maximum total dose rate must not exceed 120 g ae clopyralid/ha per crop; maximum individual dose: 120 g ae clopyralid/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	
3	Czech Republic, Slovakia	Fodder beet, Sugar beet, EPPO Code: BEAVC, BEAVD, BEAVA, BEAVC EU MRL Code: 0213010, 0213010, 0900010, 0213010 Raw Human consumption Processed goods Cattle consumption	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast, Foliar Tractor mounted boom	BBCH 12-39 (until July 1st)	a) 1 b) 1	NA	a) 0,35 b) 0,35	a) AS1: 138,341 (as/ha), 105 (ae/ha) b) AS1: 138,341 (as/ha), 105 (ae/ha)	100-400	42 days	One application every two years. Maximum total dose rate must not exceed 105 g ae clopyralid/ha per crop; maximum individual dose: 105 g ae clopyralid/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	

4	Czech Republic, Slovakia, ~~Poland~~	Fodder beet*, Sugar beet, EPPO Code: BEAVC, BEAVD, BEAVA, BEAVC EU MRL Code: 0213010, 0213010, 0900010, 0213010 Raw Human consumption Processed goods Cattle consumption	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast, Foliar Tractor mounted boom, split application	BBCH 12-15 First application at BBCH 12-15. Second application at BBCH 12-15.	a) 2 b) 2	7 day interval	a) 0,175 b) 0,35	a) AS1: 69,17 (as/ha), 52,5 (ae/ha) b) AS1: 138,341 (as/ha), 105 (ae/ha)	100-400	42 days	*Fodder beet not supported in Poland. Only every three years. Split application: First application at 52,5 gae clopyralid/ha (0,175L of EF-243/ha) at BBCH 12-15 followed 7-days later by a second application at BBCH 12-15 at 52,5 gae clopyralid/ha (0,175 L EF-243/ha). Maximum total dose rate must not exceed 105 g ae clopyralid/ha per crop; maximum individual dose: 105 g ae clopyralid/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	
5	Czech Republic, Slovakia, ~~Poland~~	Fodder beet*, Sugar beet, EPPO Code: BEAVC, BEAVD, BEAVA, BEAVC EU MRL Code: 0213010, 0213010, 0900010, 0213010 Raw Human consumption Processed goods Cattle consumption	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast, Foliar Tractor mounted boom, split application	BBCH 15-31 First application at BBCH 15. Second application at BBCH 31.	a) 2 b) 2	10-day interval	a) 0,175 b) 0,35	a) AS1: 69,17 (as/ha), 52,5 (ae/ha) b) AS1: 138,341 (as/ha), 105 (ae/ha)	100-400	42 days	*Fodder beet not supported in Poland. Every two years. Split application: first application at 52,5 gae clopyralid/ha (0,175L EF243/ha) at BBCH 15 followed 10 days later by a second application (at BBCH 31) at 52,5 gae clopyralid/ha (0,175 L EF-243/ha). Maximum total dose rate must not exceed 105 g ae clopyralid/ha per crop; maximum individual dose: 105 g ae clopyralid/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of	

												clopyralid. For crop rotation management, see label for recommendations.	
6	Poland	Sugar beet, EPPO Code: BEAVC, BEAVA, BEAVD EU MRL Code: 0213010, 0900010, 0213010 Raw Human consumption Processed goods Cattle consump-tion	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast, Foliar Tractor mounted boom, split application	BBCH 15-31 First application at BBCH 15. Second applica-tion at BBCH 31.	a) 2 b) 2	10-day interval	a) 0,2 b) 0,4	a) AS1: 79,05 (as/ha), 60 (ae/ha) b) AS1: 158,1 (as/ha), 120(ae/ha)	100-400	42 days	Every two years. Split application: first application at 60 gae clopyra-lid/ha (0,2 L EF243/ha) at BBCH 15 followed 10 days later by a second application (at BBCH 31) at 60 gae clopyralid/ha (0,2 L EF-243/ha). Maximum total dose rate must not exceed 120 g ae clopyra-lid/ha per crop; maximum individ-ual dose: 120 g ae clopyralid/ha. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	
7	Poland	Winter Oilseed rape EPPO Code: BRSNW EU MRL Code: 0401060 Raw Human consumption Processed goods Cattle consump-tion	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Centaurea cyanus, Matricaria spp)	Broadcast, Foliar Tractor mounted boom	BBCH 30-51	a) 1 b) 1	NA	a) 0,4 b) 0,4	a) AS1: 158,104 (g as/ha), 120 (g ae/ha) b) AS1: 158,104 (g as/ha), 120 (g ae/ha)	100-400	Not applicable*	For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	
8	Slovakia, Czech Rep.	Winter Oilseed rape EPPO Code: BRSNW EU MRL Code: 0401060 Raw Human consumption Processed goods	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Centaurea cyanus, Matricaria spp)	Broadcast, Foliar Tractor mounted boom	BBCH 30-51	a) 1 b) 1	NA	a) 0,35 b) 0,35	a) AS1: 138,341 (g as/ha), 105 (g ae/ha) b) AS1: 138,341 (g as/ha), 105 (g ae/ha)	100-400	Not applicable*	For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of	

		Cattle consump-tion											clopyralid. For crop rotation management, see label for recommendations.	
9	Slovakia	Gladiolus EPPO Code: 1GLAG EU MRL Code: NA	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast foliar Tractor mounted boom	BBCH 12-19 (spring/summer)	a) 1 b) 1	NA	a) 0,4 b) 0,4	a) AS1: 158,104 (as/ha), 120 (ae/ha) b) AS1: 158,104 (as/ha), 120 (ae/ha)	100-400	Not applicable	One application every 2 years. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	
10	Czech Republic, Slovakia	Spring Barley Spring Wheat Spring Oat Spring Rye Spring Triticale EPPO Code: HORVS TRZAS AVESP SECCS TTLSO EU MRL Code: 0500010 0500090 0500050 0500070 0500990 Raw Human consumption Processed goods Cattle consump-tion	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Centaurea cyanus, Matricaria spp)	Broadcast foliar Tractor mounted boom	BBCH 30-39	a) 1 b) 1	NA	a) 0,3 b) 0,3	a) AS1: 118,578 (as/ha), 90 (ae/ha) b) AS1: 118,578 (as/ha), 90 (ae/ha)	100-400	Not applicable*	*BBCH For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	
11	Czech Republic, Slovakia	Winter Barley Winter Wheat Winter Oat Winter Rye Winter Triticale EPPO Code: HORVW TRZAW AVESW SECCW TTL-	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Centaurea cyanus, Matricaria spp)	Foliar broadcast Tractor mounted boom	BBCH 30-39	a) 1 b) 1	NA	a) 0,3 b) 0,3	a) AS1: 118,578 (as/ha), 90 (ae/ha) b) AS1: 118,578 (as/ha), 90 (ae/ha)	100-400	Not applicable*	*BBCH For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of	

		WI EU MRL Code: 0500010 0500090 0500050 0500070 0500990 Raw Human consumption Processed goods Cattle consump-tion											clopyralid. For crop rotation management, see label for recommendations.	
12	Czech Republic, Slovakia	Grass for seeds (more than one-year old) EPPO Code: YGRAS EU MRL Code: NA	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense)	Broadcast foliar Tractor mounted boom	March 01 to July 15, one application every year.	a) 1 b) 1	NA	a) 0,4 b) 0,4	a) AS1: 158,104 (g as/ha), 120 (g ae/ha) b) AS1: 158,104 g (as/ha), 120 (g ae/ha)	100-400	7-days	One application every year. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	
13	Czech Republic, Slovakia	Grass for seeds (less than one-year old) EPPO Code: YGRAS EU MRL Code: NA	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense)	Broadcast foliar Tractor mounted boom	From BBCH 14 Slovakia: 01 March to 01 July Czeck Rep: 01 April to 01 July	a) 1 b) 1	NA	a) 0,4 b) 0,4	a) AS1: 158,104 (g as/ha), 120 (g ae/ha) b) AS1: 158,104 g (as/ha), 120 (g ae/ha)	100-400	7-days	One application every 3 years. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	
14	Czech Republic, Slovakia	Lawn (estab-lished grass, more than one-year old) EPPO Code: NNNZW EU MRL Code: NA	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense)	Broadcast foliar Tractor mounted boom	March 01 to July 01, one application every year.	a) 1 b) 1	NA	a) 0,67 b) 0,67	a) AS1: 264,8 g (as/ha), 200 (g ae/ha) b) AS1: 264,8 (g as/ha), 200 (g	200-400	Not applicable	One application every year. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended	

										ae/ha)			that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	
15	Slovakia	Maize (grain, forage) EPPO Code: ZEAMX EU MRL Code: 0500030 Processed goods Human con-sumption (seeds) Cattle consump-tion	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast foliar Tractor mounted boom	BBCH 10-19	a) 1 b) 1	NA	a) 0,34 b) 0,34	a) AS1: 134,38 (as/ha), 102 (ae/ha) b) AS1: 134,38 (as/ha), 102 (ae/ha)	100-400	60 days for forage, 90 days for grain	One application every year. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	
16	Slovakia	Maize (grain, forage) EPPO Code: ZEAMX EU MRL Code: 0500030 Processed goods Human con-sumption (seeds) Cattle cosump-tion	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast foliar Tractor mounted boom	BBCH 30-32	a) 1 b) 1	NA	a) 0,34 b) 0,34	a) AS1: 134,38 (as/ha), 102 (ae/ha) b) AS1: 134,38 (as/ha), 102 (ae/ha)	100-400	60 days for forage, 90 days for grain	One application every 2 years. For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	
17	Czech Republic, Slovakia, Poland	Onion for Seeds EPPO Code: ALLCE EU MRL Code: 0220020 Raw Human consumption Processed goods	F	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Broadcast Foliar Tractor mounted boom	BBCH 11-16	a) 1 b) 1	NA	a) 0,4 b) 0,4	a) AS1: 158,104 (as/ha), 120 (ae/ha) b) AS1: 158,104 (as/ha), 120 (ae/ha)	100-400	42-days	For residue management in crop rotation: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of clopyralid. For crop rotation management, see label for recommendations.	

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 0columns:

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

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises information relating to the efficacy of the plant protection product EF-243, an SL formulation containing 300 g/L clopyralid intended for use as a systemic, selective herbicide for the post-emergence control of a range of annual and perennial broadleaf weeds in a variety of crops.

Clopyralid was included in Annex I of Directive 91/414/EEC (Directive 2006/64/CE) on 18th July 2006, and approved in accordance with Regulation (EC) No. 540/2011 (25th May 2011) amending Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

An extension of approval until 30th April 2021 was granted by Commission implementing Regulation (EU) 2020/421 (18th March 2020) and a further extension until 30th April 2022 was granted by Commission implementing Regulation (EU) 2021/566 (30 March 2021).

The renewal of clopyralid has been approved in Commission Implementing Regulation (EU) 2021/1191.

The SANCO report for clopyralid renewal (SANTE/10206/2021 Rev 1 – 20 May 2021) and the EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance clopyralid (EFSA Journal 2018;16(8):5389), are considered to provide the relevant review information or a reference to where such information can be found.
The Commission Implementing Regulation (EU) 2021/1191 provides the following specific provisions:

"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."

Information on the detailed composition of EF-243 can be found in the confidential dossier of this submission (Registration report - Part C).

The purpose of this document is to support the renewal of approval of the plant protection product EF-243 (Lontrel 300 SL), in the EU Central Registration Zone where it is currently registered in the Czech Republic, Poland and Slovakia.

There are a number of proposed changes to the currently authorised uses for the re-registration of EF-243 which result in a dose rate reduction and/or application timing amendment. These changes have been driven by new risk assessment endpoints and therefore are being implemented to align to the residue data package. Additionally, some of these GAP changes are intended to harmonise use details within the zone where possible.

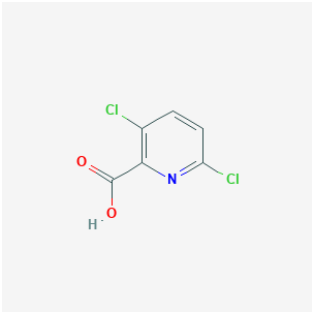
Efficacy data are presented in this document to support the revised use details for the re-registration of EF-243. Data are presented to justify a change in dose rate only; no new efficacy data are presented where there are no proposed changes to the current GAP. An updated resistance section is also provided.

A total of 20 efficacy trials are summarised to demonstrate sufficient effectiveness in product performance that support rate changes for EF-243 at renewal.
A total of 26 efficacy trials are summarised to demonstrate comparability between different clopyralid formulations and thereby justify the use of data from other products to support rate changes for EF-243 at renewal.

Description of active substances

Clopyralid is a systemic, selective, non-residual herbicide for the post-emergence control of broad-leaved weeds in sugar beet, fodder beet, red beet, winter oilseed rape, winter turnip rape, spring oilseed rape, spring turnip rape, cabbage (head, white and savoy), brussels sprouts, flax (fibre), linseed (oil), pasture and established grassland for seed production.

Table 3.2-1: Details of the active substance

Identity	**Clopyralid**
IUPAC	3,6-dichloropyridine-2-carboxylic acid
CA	3,6-dichloro-2-pyridinecarboxylic acid
CAS No.	1702-17-6
Structural formula	
Molecular formula	$C_6H_3Cl_2NO_2$
Molecular weight	192.0

Mode of action

Clopyralid is an “auxin mimic” or synthetic auxin belonging to the chemical family of the Pyridine-carboxylates (HRAC/WSSA group 4 *(O)*). It is a systemic herbicide, absorbed by the leaves and roots, with translocation both acropetally and basipetally, and accumulation in meristematic tissue. This type of herbicide kills the target weed by mimicking the plant growth hormone auxin (indole acetic acid), and when administered at effective doses, cause uncontrolled and disorganized plant growth that leads to plant death in a few days or weeks, depending on the species.

Synthetic auxins bind to receptor sites in plant cells in the place of natural auxins. Due to the higher stability and greater persistence of synthetic auxins compared to the natural counterpart, treatment causes an 'auxin overdose' that leads to uncontrolled and disorganised plant growth and eventually plant death[1].
There are a range of structurally diverse molecules that can act as auxins and evidence exists that clopyralid can act via the same pathways as the plant auxin indole-3-acetic acid (IAA) and 2,4-D, but also through independent pathways explaining how mutations can confer resistance to both pyridine carboxylates and phenoxy-carboxylates, but it is also possible to generate mutations with resistance to pyridine-carboxylates alone. In the field, the general lack of resistance to clopyralid gives weight to the hypothesis that there is a large amount of redundancy among the target auxin receptors.
IAA and 2,4-D act via a ubiquitination mechanism that has been identified and well described[2]. This mechanism involves the stimulation of ubiquitination through a ubiquitin ligase complex and subsequent degradation of a number of specific transcriptional regulators. Their degradation results in derepression of auxin-regulated genes that in turn leads to the physiological and morphological events associated with auxin action. Further targets have been identified in Arabidopsis that confer picolinate-specific resistance that appear to be linked to similar mechanisms within the cell[2].

Table 3.2-2: Details of the active substance

Active substance	**Clopyralid**
Concentration	300 g a.e./L
Chemical group	Pyridine-carboxylates
Mode of action	Auxin mimic
Biological action	Selective, systemic post-emergence herbicide against broadleaf weeds

Description of the plant protection product

Product EF-243 is a Soluble Liquid Concentrate (SL) formulation containing 300 g a.e./L clopyralid.

EF-243 is recommended for use as a post-emergence herbicide for the control of broadleaf weeds, a summary of the currently registered and requested rates for the uses to be defended at renewal is presented in the following table.

Further details are in the table "All intended uses" in Part B - Section 0.

[1] Cox, C (1998) Herbicide Factsheet: Clopyralid, Journal of Pesticide Reform, Winter 1998, Vol.18(4), https://d3n8a8pro7vhmx.cloudfront.net/ncap/pages/26/attachments/original/1428423336/clopyralid.pdf?1428423336
[2] Walsh, T. *et al*. 2006. Mutations in an Auxin Receptor Homolog AFB5 and in SGT1b confer resistance to synthetic picolinate auxins and not to 2,4-dichlorophenoxyacetic acid or indole-3-acetic acid in Arabidopsis[W]. Plant Physiology 142: 542-552

Table 3.2-3: Simplified table of currently registered uses and requested uses for EF-243

Uses		Member State Major / minor status crops	Currently registered rate(s) (no. of applications)	Requested registered rates (no. of applications)	Comments
Crop(s)	**Target(s)**				
Grass for seeds > 1 yr. old (YGRAS)	Broad-leaved weeds inc. CIRAR	Czech Republic Minor	0.4 L/ha (120 g a.e./ha) (1)	0.4 L/ha (120 g a.e./ha) (1)	No rate change Application window adjusted to March 1st to July 15th
		Slovakia Minor	0.5 L/ha (150 g a.e./ha) (1)	0.4 L/ha (120 g a.e./ha) (1)	Rate change Rate reduced from 150 g a.e./ha to 120 g a.e./ha Application window adjusted to March 1st to July 15th
Grass for seeds < 1 yr. old (YGRAS)	Broad-leaved weeds inc. CIRAR	Czech Republic Minor	0.4 L/ha (120 g a.e./ha) (1)	0.4 L/ha (120 g a.e./ha) (1)	No rate change Application window adjusted to April 1st to July 1st, Once every 3 years
		Slovakia Minor	0.5 L/ha (150 g a.e./ha) (1)	0.4 L/ha (120 g a.e./ha) (1)	Rate change Rate reduced from 150 g a.e./ha to 120 g a.e./ha Application window adjusted to March 1st to July 1st, Once every 3 years
Lawn > 1yr old (NNNZW)	Broad-leaved weeds inc. CIRAR	Czech Republic Minor	0.8 L/ha (240 g a.e./ha) (1)	0.67 L/ha (200 g a.e./ha) (1)	Rate Change Dose rate reduced from 240 g a.e./ha to 200 g a.e./ha Application window adjusted to March 1st to July 1st,
		Slovakia Minor	0.4-1.0 L/ha (120-300 g a.e./ha) (1)		Rate Change Maximum dose rate reduced from 300 g a.e./ha to 200 g a.e./ha, within the currently approved rate range. Application window adjusted to March 1st to July 1st,
Maize (ZEAMX)	Broad-leaved weeds inc. CIRAR, MATSS	Slovakia Major	0.4 L/ha (120 g a.e./ha) (1)	0.34 L/ha (102 g a.e./ha) (1)	Rate change Dose rate reduced from 120 g a e./ha to 102 g a.e./ha Application timing harmonised to residue risk envelope. Application each year BBCH 10-19 or every 2 years BBCH 10-32

Uses		Member State Major / minor status crops	Currently registered rate(s) (no. of applications)	Requested registered rates (no. of applications)	Comments
Crop(s)	**Target(s)**				
Winter and spring cereals: Barley (HORVW, HORVS), Wheat (TRZAW, TRZAS), Oats[1] (AVESW, AVESS), Rye (SECCE), Triticale (TTLSS)	Annual broad-leaved weeds	Slovakia Major*	0.3-0.4 L/ha (90-120 g a.e./ha) (1)	0.3 L/ha (90 g a.e./ha) (1)	Rate change Maximum application rate reduced to lower rate in currently approved range (90g ae/ha) Change crop GS at application from BBCH 14-39 to BBCH 30-39
Winter and spring cereals: Barley (HORVW, HORVS), Wheat (TRZAW, TRZAS), Oats (AVESW, AVESS), Rye[2] (SECCE), Triticale[2] (TTLSS)	Broad-leaved weeds	Czech Republic Major*	0.3 L/ha (90 g a.e./ha) (1)	0.3 L/ha (90 g a.e./ha) (1)	No rate change Change crop GS at application from BBCH 14-39 to BBCH 30-39
Winter oilseed rape (BRSNW)	Broad-leaved weeds	Poland Major	0.3-0.4 L/ha (90-120 g a.e./ha) (1)	0.4 L/ha (120 g a.e./ha) (1)	No rate change BBCH aligned to spring window BBCH 30-51
Winter oilseed rape (BRSNW)	Broad-leaved weeds	Slovakia Major	0.35 L/ha (105 g a.e./ha) (1)	0.35 L/ha (105 g a.e./ha) (1)	No rate change BBCH aligned to spring window BBCH 30-51
Sugar beet (BEAVA)	Broad-leaved weeds	Poland Major	0.3-0.4 L/ha (90-120 g a.e./ha) (1)	Every two years 90-120 g a.e./ha BBCH 12-39 (till July 1st). **Split application:** **Option 1:** Every three years 60 g a.e./ha BBCH 12-15 followed 7-days later by a second application at BBCH 12-15 at 60 g a.e./ha. **Option 2:** Every three years 52,5 g a.e./ha BBCH 12-15 followed 7-days later by a second application at BBCH 12-15 at 52,5 g a.e. /ha. **Option 3**: Every two years. 52,5 g a.e./ha at BBCH 15 followed 10 days later by a second application (at BBCH 31) at 52,5 g a.e./ha **Option 4**: Every two years. 60 g a.e./ha at BBCH 15 followed 10 days later by a second application (at BBCH 31) at 60 g a.e./ha.	No rate change BBCH aligned to 12-39 (stop July 1st). Split dose at rate equivalent to single application rate (max 120 g a.e./ha)
Sugar beet (BEAVA) Fodder beet[3] (BEAVC) Red beet[3] (BEAVD)	Broad-leaved weeds	Czech Republic Major*	0.35 L/ha (105 g a.e./ha) (1) **Split application:** 45 g a.e./ha + 45 g a.e./ha + 60 g a.e./ha	Every 2 years 105 g a.e./ha BBCH 12-39 (till July 1st). **Split application:** **Option 1:** Every three years. 52,5 g a.e./ha at BBCH 12-15 followed 7-days later by a second application at BBCH 12-15 at 52,5 g a.e./ha. **Option 2:** Every two years. Split application: first	Rate change For split applications only, change to split dose that totals 105 g a.e./ha equivalent to single application. BBCH aligned to 12-39 (July 1st).

Uses		Member State Major / minor status crops	Currently registered rate(s) (no. of applications)	Requested registered rates (no. of applications)	Comments
Crop(s)	**Target(s)**				
				application at 52,5 g a.e./ha at BBCH 15 followed 10 days later by a second application (at BBCH 31) at 52,5 g a.e./ha (0,175 L EF-243/ha)	
Sugar beet (BEAVA) Fodder beet & mangels[3] (BEAVC) Red beet[3] (BEAVD)	Broad-leaved weeds	Slovakia Major*	0.35 L/ha (105 g a.e./ha) (1) **Split application:** 30 g a.e./ha + 45 g a.e./ha + 60 g a.e./ha 30 g a.e./ha + 45-60 g a.e./ha + 60-90 g a.e./ha	Every 2 years 105 g a.e./ha BBCH 12-39 (till July 1st). **Split application:** **Option 1:** Every three years. 52,5 g a.e./ha at BBCH 12-15 followed 7-days later by a second application at BBCH 12-15 at 52,5 g a.e./ha. **Option 2:** Every two years. Split application: first application at 52,5 g a.e./ha at BBCH 15 followed 10 days later by a second application (at BBCH 31) at 52,5 g a.e./ha (0,175 L EF-243/ha)	Rate change For split applications only, change to split dose that totals 105 g a.e./ha equivalent to single application. BBCH aligned to 12-39 (July 1st).
Onion from seeds, direct-seeded (ALLCE/ALLXS)	Broad-leaved weeds	Poland Minor	0.4 L/ha (120 g a.e./ha) (1)	0.4 L/ha (120 g a.e./ha) (1)	No rate change BBCH aligned to residue package BBCH 11-16
		Czech Republic Minor	0.4 L/ha (120 g a.e./ha) (1)	0.4 L/ha (120 g a.e./ha) (1)	No rate change BBCH aligned to residue package BBCH 11-16
		Slovakia Minor	0.4 L/ha (120 g a.e./ha) (1)	0.4 L/ha (120 g a.e./ha) (1)	No rate change BBCH aligned to residue package BBCH 11-16
Gladiolus (1GLAG)	Broad-leaved weeds	Slovakia Minor	0.4 L/ha (120 g a.e./ha) (1)	0.4 L/ha (120 g a.e./ha) (1)	No rate change BBCH aligned to residue package BBCH 12-19

*No official national resources for crop status are available; major/minor status is based upon crop areas, winter wheat and spring barley considered to be major crops all others ([1,2,3]) considered as minor.

Description of the target pests

Clopyralid products applied post-planting give control of a range of both annual and perennial broadleaf weeds. Broadleaf weed control in beet crops, oilseed rape, brassica vegetable crops, flax/linseed and grassland, is an important measure to safeguard the quantity and quality of yield, particularly during the period of early plant development, when the useful plants are often weak competitors. Due to the characteristics of the active substance, weeds should be emerged at the time of application.

Clopyralid provides control of broad-leaved weeds with good control of CIRAR and MATSS among other species.

CIRAR (*Cirsium arvense*; creeping thistle)
CIRAR is a tall, perennial broad-leaved weed that spreads extensively and rapidly via resilient, horizontal roots that produce aerial shoots. They are a successful invasive species in agricultural crops being considered as a major pest due to characteristic features such as producing over 5,000 seeds per plant, clonal propagation resulting from ploughing and superficial cultivation and allelopathic effects on other plants. CIRAR is present throughout Europe, found in both tilled and no-till fields used for producing annual, winter annual and perennial agronomic and horticultural crops as well as non-cropped areas such as roadsides, riverbanks, forest edges and meadows, and is classified as invasive in the UK, Sweden, Switzerland, Germany, Latvia and Estonia[3].

Studies primarily based in Canada and the USA have investigated the relative extent to which increasing densities of CIRAR reduce yield in tilled cropping systems[3]. The studies show maximum yield losses of 45-55% in winter and spring wheat, 73% in barley, 45% in oats, 60% in oilseed rape, 8-12% in alfalfa and faba bean.

MATSS (Chamomile species)

Mayweed species of the Asteraceae family described either as *Matricaria* and / or *Tripleurospermum* species, are widely distributed, major broad-leaved, annual weed species in agriculture in Europe.

The most problematic species are MATIN (*Tripleurospermum inodorum*), MATMA (*Tripleurospermum maritimum*) and MATCH (*Matricaria chamomilla*). As they develop, the plants become large, fleshy and robust providing substantial competition within a crop and having considerable impact at harvest if left untreated.

Germination of mayweeds can occur all year round, with peaks in the spring and late summer to autumn, flowering in the summer and each plant is capable of producing 5-10,000 seeds which is the main method of reproduction. If germinating later in the autumn, plants can survive through the winter as a rosette[4].

MATIN at 25 plants per m^2 can cause yield losses of 30-80% in spring wheat. It is unpalatable to livestock and can serve as an alternate host to insect species that may damage other crops or be vectors for diseases of other crops[5].

Further weeds that show good susceptibility to clopyralid include AMBEL, ANTAR, CENCY, HELAN, POLPE, PICHI and SONOL among others.

[3] https://www.cabi.org/isc/datasheet/13628 Accessed 29th September 2020
[4] https://www.corteva.co.uk/tools-and-advice/weed-biology/mayweed-species.html Accessed 30th September 2020
[5] http://www.agric.gov.ab.ca/app107/loadPest?action=display&id=83 Accessed 30th September 2020

Table 3.2-4: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name
AETCY	*Aethusa cynapium*
AMARE	*Amaranthus retroflexus*
AMBEL	*Ambrosia artemisiifolia*
ANTAR	*Anthemus arvensis*
CAPBP	*Capsella bursa-pastoris*
CARHI	*Cardamine hirsuta*
CENCY	*Centaurea cyanus*
CHEAL	*Chenopodium album*
CIRAR	*Cirsium arvense*
CNSOR	*Consolida orientalis*
CNSRE	*Consolida regalis*
DATST	*Datura stramonium*
GALAP	*Galium aparine*
HELAN	*Helianthus annuus*
LTHTU	*Lathyrus tuberosus*
MATCH	*Matricaria chamomilla*
MATIN	*Tripleurospermum inodorum*
MATMA	*Tripleurospermum maritimum*
PAPRH	*Papaver rhoeas*
PICHI[a]	*Picris hieracioides*
POLCO	*Fallopia convolvulus*
POLLA	*Persicaria lapathifolia*
SONOL	*Sonchus oleraceus*
VIOAR	*Viola arvensis*

Major / minor status of pest

It is accepted that of all the pests that promote damage or yield losses in worldwide commercial agriculture, weeds pose the biggest problem and cause the highest losses.
It is not only that weeds compete for nutrients and other resources essential for growth and development of the crop, especially in cases where weeds have an extended germination period or the ability to grow above the crop canopy, but also the impact of green material on harvesting equipment, and contamination or other effects on the quality of grain yields, and increased costs (both financial and environmental) due to the need for tillage.
It is therefore considered appropriate that all target weeds for control by the test product EF-243 (Clopyralid 300 g/L) (annual and perennial broad-leaved species) are given ‘major’ pest status for the purposes of this submission.

Major / minor status of crops

The status for each crop, as relevant to the renewal GAP, is considered in

Table 3.2-5. Where available, information from the EUMUDA website has been used.

Table 3.2-5: Major / minor status of uses

Crop and/or situation	Crop status	
	Major	**Minor**
Grassland for Seed > 1yr old (YGRAS)		CZ, SK
Grassland for Seed < 1yr old (YGRAS)		CZ, SK
Lawn (NNNZW)		CZ, SK
Maize (ZEAMX)	SK	
Winter barley (HORVW)		CZ, SK
Winter oat (AVESW)		CZ, SK
Winter wheat (TRZAW)	CZ, SK	
Winter rye (SECCW)		CZ, SK
Winter triticale (TTLWI)		CZ, SK
Spring barley (HORVS)	CZ, SK	
Spring oat (AVESP)		CZ, SK
Spring wheat (TRZAS)		CZ, SK
Spring rye (SECCS)		CZ, SK
Spring triticale (TTLSO)		CZ, SK
Winter oilseed rape (BRSNW)	PL, SK	
Sugar beet (BEAVA)	PL,	CZ, SK
Fodder beet / Mangel (BEAVC)	PL	CZ, SK
Red beet / Beetroot (BEAVD)	PL	CZ, SK
Onion from seeds, direct-seeded (ALLCE/ALLXS)		PL, CZ, SK
Gladiolus (1GLAG)		SK

Compliance with the Uniform Principles

All efficacy and crop safety data summarised in this document have been generated and presented in accordance with the Uniform Principles for evaluation and authorisation of chemical plant protection products, as provided for in Article 29(6) of Regulation (EC) No. 1107/2009 and set out in Commission Regulation (EU) No. 546/2011 (10th June 2011). In compliance with both the general and specific Uniform Principles relating to the evaluation of Efficacy Data and Information for clopyralid formulations, trials were carried out by testing facilities that have been officially authorised and accredited at national level or have been carried out by professional facilities using SOPs and methods based on Good Experimental Practice.

Copies of the GEP certificates for these testing facilities are included in Section 6.7 of the Biological Assessment Dossier.

Several trials have been conducted outside of GEP certification schemes, these trials were conducted in Slovakia by UKSUP, in Hungary at NTSZ Nograd and Dow AgroScience, and by Elanco Hellas, Greece; no GEP status is claimed for these trials. Trials conducted prior to 2014 owned by Corteva do not contain author signatures as they are not available in the trials database.

In addition, trials were conducted according to the most current EPPO standard guidelines, with any deviations from these guidelines being described where they have occurred, and justification given for the inclusion of any resulting data in this BAD. The design, analysis of results and reporting of all trials were carried out in accordance with guidelines set out in EPPO standards PP1/152(3,4) Design and analysis of efficacy evaluation trials and PP1/181(3,4) Conduct and reporting of efficacy evaluation trials. The con-

duct of the field work was commensurate with 'Good Agricultural Practice' and in accordance with general guidelines in EPPO standard PP1/135(2,3,4) Phytotoxicity assessment, and specific guidelines relevant to the crop.

Justification for inclusion of data from other formulations

Data are presented in this document to support dose rate reductions that have been driven by changes in regulatory endpoints.

There are a number of authorised clopyralid formulations that differ in the concentration of active ingredient. The Applicant here provides efficacy data to demonstrate the direct comparability between these formulations where they have been tested in various permutations within individual trials in several different crop types.

According to data summarised in the document, the difference in effectiveness between clopyralid formulations is shown to be statistically comparable in most cases data are discussed in greater detail in Section 3.2.1. It is therefore possible to use efficacy data from comparable formulations to provide sufficient efficacy data to support the dose rate reductions proposed in this renewal submission.

The formulation to be registered is EF-243 (300 g a.e./L clopyralid SL), which is the currently authorised formulation in all concerned Member States of this submission.

Clopyralid formulations have been authorised for use in the EU since 1977, over the intervening years many formulations have been developed and many remain on the market today. This Article 43 submission concerns a reduction in application rate for some uses, resulting from new regulatory endpoints. To demonstrate efficacy at the new lower rates, data generated with EF-243 and other formulations of clopyralid are submitted. The equivalent efficacy of clopyralid formulations when in solution with water for application is demonstrated in Section 3.2.1. A summary of the clopyralid formulations included within the bridging trials is included in Table 3.2-6.

Table 3.2-6: List of clopyralid formulations included in bridging trials to demonstrate equivalence

Formulation code	Active substance	A.S concentration	Formulation type
EF-1136	clopyralid-olamine	100 g/l	SL
EF-243	clopyralid-olamine	300 g/l	SL
GF-2000	clopyralid-olamine	400 g/l	SL
GF-2895	clopyralid-Dimethylammonium	600 g/l	SL
GF-1966	clopyralid-olamine	720 g/kg	SG
EF-797	clopyralid-olamine	750 g/kg	WG
EF-584	clopyralid-olamine	200 g/L	SL
EF-1322	clopyralid-olamine	200.04 g/L	SL
EF-1389	clopyralid-olamine	300 g/L	EW
EF-1412	clopyralid-olamine	50 g/L	SL
EF-333	clopyralid-olamine	425.04 g/L	SL

Highlighted formulations are currently registered for use within Europe and will be supported at Article 43

Justification for the inclusion of data from different nations

Location of trials

The locations and geographical distribution of all individual trials summarised in this dossier are shown in maps presented in Figure 3.2-1 to Figure 3.2-6.

Justification for inclusion of data from different nations

Efficacy and selectivity trials submitted BAD were conducted in Greece in the Mediterranean climatic zone, the Czech Republic, France and Germany within the Maritime EPPO climatic zone, Poland in the North-East climatic zone and Hungary and Slovakia within the South-East EPPO climatic zone, according to guidelines presented in EPPO standard PP 1/241(2); Guidance on comparable climates.

Data generated in trials carried out in countries within the Maritime climatic zone are fully supportive towards demonstrating the proposed label claims for the efficacy and crop safety of EF-243 in the Czech Republic.

Data generated in trials carried out in countries within the South-East climatic zone are fully supportive towards demonstrating proposed label claims for the efficacy and crop safety of EF-243 in Slovakia.

Data generated in trials carried out in countries within the North-East climatic zone are fully supportive towards demonstrating proposed label claims for the efficacy and crop safety of EF-243 in Poland.

Data generated in trials carried out in Greece in the Mediterranean zone are considered as supplementary or partially supportive towards the label claims for efficacy in this document.

A summary of the submitted efficacy trials is provided in Table 3.2-7 below and the geographical location and distribution of all efficacy trials is shown on maps presented in Figure 3.2-1 to Figure 3.2-6.

Table 3.2-7: Presentation of trials (efficacy trials, preliminary trials...)

Crop*	Target*	Country	Year	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime	South-East	North-East	Mediterranean		
Maize (ZEAMX)	Post-emergence Broad-leaved weeds	France	1999	E	1 (1)	-	-	-	GEP	
		Germany	2008	P	8 (8)	-	-	-	GEP	
		Hungary	1999	E	-	2 (2)	-	-	GEP	
			2008	P	-	2 (2)	-	-	GEP	
		Slovakia	2012	E, P	-	2 (2)	-	-	GEP	
				Total	**9 (9)**	**6 (6)**	**0 (0)**	**0 (0)**	-	
Winter oilseed rape (BRSNW)	Post-emergence Broad-leaved weeds	Germany	2012	E	1 (1)	-	-	-	GEP	
		France	2012	E	1 (1)	-	-	-	GEP	
				Total	**2 (2)**	**0 (0)**	**0 (0)**	**0 (0)**	-	
Spring oilseed rape (BRSNS)	Post-emergence Broad-leaved weeds	Poland	2012	E	-	-	1 (1)	-	GEP	
				Total	**0 (0)**	**0 (0)**	**1 (1)**	**0 (0)**	-	
Sugar beet (BEAVA)	Post-emergence Broad-leaved weeds	Czech Republic	2010	P	3 (3)	-	-	-	GEP	
			2011	P	2 (2)	-	-	-	GEP	
		France	2007	E	1 (1)	-	-	-	GEP	
			2008	E, P	2 (2)	-	-	-	GEP	
			2015	E	2 (2)	-	-	-	GEP	
		Slovakia	2011	P	-	2 (2)	-	-	Official	
				Total	**10 (10)**	**2 (2)**	**0 (0)**	**0 (0)**	-	
Winter wheat (TRZAW)	Post-emergence Broad-leaved weeds	Greece	2007	P	-	-	-	1 (1)	GEP	
		Hungary	1998	E,P	-	1 (1)	-	-	non- GEP	
			2002	E	-	2 (2)	-	-	GEP	
			2003	E	-	1 (1)	-	-	non-GEP	
			2008	E, P	-	2 (2)	-	-	GEP	
			2018	E, P	-	1 (2)	-	-	GEP	
				Total	**0 (0)**	**7 (7)**	**0 (0)**	**1 (1)**	-	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).
** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.
*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Figure 3.2-1 Efficacy trials in wheat (TRZAW) – South-East EPPO zone

Figure 3.2-2: Efficacy trials in maize (ZEAMX) –Maritime EPPO zone

Figure 3.2-3: Efficacy trials in maize (ZEAMX) – South-East EPPO zone

Figure 3.2-4: Efficacy trials in Winter(red) & Spring (blue) Oilseed rape (BRSNW, BRSNS) – Maritime and North-East EPPO zone

Figure 3.2-5: Efficacy trials in Sugar beet (BEAVA) – Maritime EPPO zone

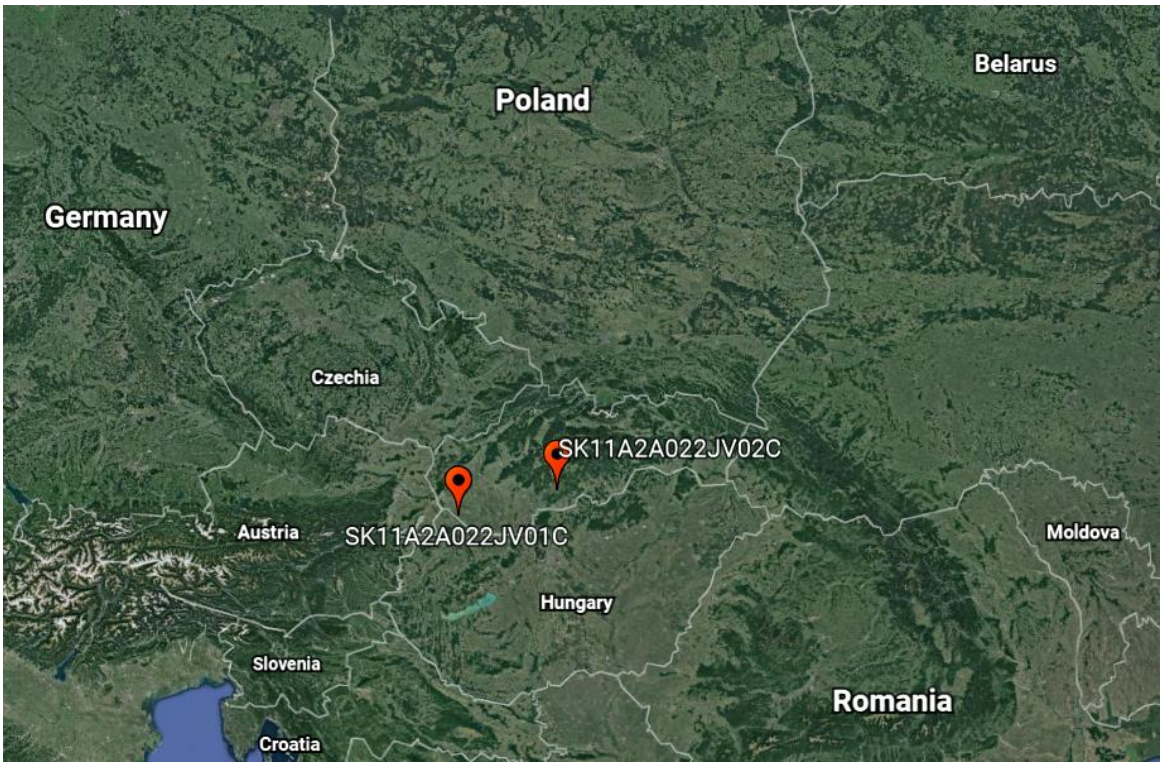


Figure 3.2-6: Efficacy trials in Sugar beet (BEAVA) – South-East EPPO zone

Table 3.2-8: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Crop	Product	Country(ies) where used	Authorization number	Active substance(s)	Formulation		Registered application rate*	Application rate in trials
					Type	Concentration of a.s.		
Test product								
Winter wheat (TRZAW), Maize (ZEAMX), Sugar beet (BEAVA)	EF-243	n.a.	n.a.	clopyralid	SL	300 g/L	n.a.	n.a.
Comparable formulations								
Winter wheat (TRZAW), Maize (ZEAMX) Winter oilseed rape (BRSNW), Spring oilseed rape (BRSNS) Sugar beet (BEAVA)	EF-1136	n.a.	n.a.	clopyralid	SL	100 g/L	n.a.	n.a.
	GF-2895	n.a.	n.a.	clopyralid	SL	600 g/L	n.a.	n.a.
	GF-1996	n.a.	n.a.	clopyralid	SG	720 g/kg	n.a.	n.a.
	EF-797	n.a.	n.a.	clopyralid	WG	750 g/kg	n.a.	n.a.
	GF-2000	n.a.	n.a.	clopyralid	SL	400 g/L	n.a.	n.a.
Standard reference products								
Maize (ZEAMX)	Pyron DE	Hungary France	No longer registered	clopyralid+pyridate	EC	50 g + 450 g/L	-	2 L/ha
	Lontrel 300	Slovakia	3429	clopyralid	SL	300 g/L	0.4 L/ha	0.4 L/ha
Winter wheat (TRZAW)	Starane 250	Hungary	21350/1966 (no longer registered)	Fluroxypyr	EC	250 g/L	0.6-0.8 L/ha	0.6 L/ha
	Galera	Hungary	00951	clopyralid+picloram	SL	267 g + 67 g/L	0.3-0.35 L/ha	0.35 L/ha
Spring oilseed rape (BRSNS)	Lontrel 300 EF-243	Poland	R-88/2010	clopyralid	SL	300 g/L	n.a.	n.a.
Winter oilseed rape (BRSNW)	Lontrel 100 EF-1136	France	7900753	clopyralid	SL	100 g/L	1.25 L/ha	1-1.2 L/ha
	Dow Shield EF-1136	Germany	No longer registered	clopyralid	SL	200 g/L	-	0.35 L/ha
Sugar beet (BEAVA)	Lontrel 100 EF-1136	France	7900753	clopyralid	SL	100 g/L	n.a.	n.a.
	Lontrel SG GF-1996	France	2110063	clopyralid	SG	720 g/kg	n.a.	n.a.

Assessment methods

In all trials, populations of individual weed species present in the untreated controls of the trials were assessed at application either by counts to determine the mean number of plants/m^2 or by visual estimation of the mean percentage ground cover for each species.

Weed control (efficacy) was visually assessed as the percentage weed control relative to the ground cover and vigour of each weed species in the untreated control and/or by estimating the percentage ground cover of individual plots.

Crop phytotoxicity was assessed at regular intervals throughout the duration of the trials by visual assessments for signs of chlorosis, necrosis or other adverse effects on growth and development, using a percentage scale.

In some trials, crop vigour assessed as a scale of 0-100 or 0-10 where 0 = no crop and 100 or 10 = the most vigorous plot within each replicate.

Trials were taken to harvest in four of the efficacy trials (2 maize and 2 Winter oilseed rape). The fresh weight, moisture content and yield (Q/ha) were determined for samples collected at normal commercial harvest.

Numerical and statistical analysis

The results were analysed using a two-way analysis of variance. The probability of no significant differences occurring between treatment means is calculated as the F probability value.

Student-Newman-Keuls test was then applied to separate any treatment differences that may be implied by the ANOVA TEST (Prob (F) <0.05) and these are indicated by the LSD-value and a letter-test. Values followed by the same letter are not significantly different at P=0.05.

Overall summaries of methodology used in different crops

Table 3.2-9 Overall summary of details of methodology used in efficacy trials carried out in maize (ZEAMX)

Guidelines	General guidelines	EPPO PP 1/135, PP 1/152, PP 1/181
	Specific guidelines	CEB 46, EPPO PP 1/50 (Weeds in maize), PP 1/93 (Weeds in cereals)
Experimental design	Plot design	RCBD
	Plot size	20-30 m², except HU08A2A088IMO1C and -O2C = 500 m^2
	Number of replications	3 or 4
Crop	Trials per crop	Maize (ZEAMX); 4 South-East, 1 Maritime climatic zone trials +2 South-East and 8 Maritime zone trials supporting comparability only
	Varieties per crop (number of trials)	Aztec (1), Styra (2), NK Symba (1), P9205 (1), T13 (1), Amadeo (2), Subito (1), Monumental (1), Prinz (1), n.d. (2), LG2372 (1), Alcede (1)
Application	Crop stage (BBCH) at application	BBCH 11-18
	Timing Weed stage at application	Post-emergence BBCH 10-47
	Number of applications	1 (all trials)
	Spray volumes	200 L/ha (8 trials), 250 L/ha (2 trials), 300 L/ha (6 trials)
Assessment	Assessment types	Phytotoxicity (%), weed control (%, visual assessment com-

		pared to the untreated), yield (2 trials)
	Assessment timings	1, 2 and 3-4 weeks after application, at harvest
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Not applicable
	e.g. Natural / artificial inoculation…	Natural (all trials)
	e.g. Field / Greenhouse...	Field (all trials)

Table 3.2-10: Overall summary of details of methodology used in efficacy trials carried out in Winter wheat (TRZAW)

Guidelines	General guidelines	EPPO: PP1/135(2/3/4), PP1/152(2/3/4), PP1/181(2/3/4), PP1/225(2), PP1/214(3)
	Specific guidelines	EPPO PP 1/93(3) Weeds in cereal crops
Experimental design	Plot design	RCBD (6) Split plot (1)
	Plot size	16-1000 m²
	Number of replications	3 or 4
Crop	Trials per crop	TRZAW (7)
	Varieties per crop (number of trials)	Fatima (1), GK Islet (1), Ljuiejnaja (1), Kapo (1), Magdalena (1), Capo (1), ND (1)
Application	Crop stage (BBCH) at application	BBCH 21-31
	Timing Weed stage at application	Post-emergence BBCH 12-63
	Number of applications	1 (all trials)
	Spray volumes	200 L/ha (4 trials), 250 L/ha (2 trials), 300 L/ha (1 trial)
Assessment	Assessment types	Phytotoxicity (%), weed control (%, visual assessment compared to the untreated)
	Assessment timings	1-9 weeks after application, at harvest
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Not applicable
	e.g. Natural / artificial inoculation…	Natural (all trials)
	e.g. Field / Greenhouse...	Field (all trials)

Table 3.2-11: Overall summary of details of methodology used in efficacy trials carried out in Winter and Spring Oilseed rape (BRSNW, BRSNS)

Guidelines	General guidelines	EPPO: PP1/135(3), PP1/152(3), PP1/181(3)
	Specific guidelines	EPPO PP 1/49(3) Weeds in brassica oil crops
Experimental design	Plot design	RCBD (3)
	Plot size	20-31 m²
	Number of replications	4 (3)
Crop	Trials per crop	BRSNW (2) BRSNS (1)
	Varieties per crop (number of trials)	DK Expower (1), Palmedor (1) Larissa (1)
Application	Crop stage (BBCH) at application	BBCH 14-50
	Timing Weed stage at application	Post-emergence BBCH 14-60
	Number of applications	1 (all trials)
	Spray volumes	300 L/ha (3 trials)
Assessment	Assessment types	Phytotoxicity (%), weed control (%, visual assessment compared to the untreated), Harvest
	Assessment timings	1-9 weeks after application, at harvest
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Not applicable
	e.g. Natural / artificial inoculation…	Natural (all trials)
	e.g. Field / Greenhouse...	Field (all trials)

Table 3.2-12: Overall summary of details of methodology used in efficacy trials carried out in sugar beet (BEAVA)

Guidelines	General guidelines	EPPO PP 1/135(2,3,4), PP 1/152(2,3,4), PP 1/181(2,3,4), PP 1/225(2), PP 1/223
	Specific guidelines	CEB 01, CEB 128, EPPO: PP1/52(2) Weeds in sugar and fodder beet and industrial chicory
Experimental design	Plot design	RCBD
	Plot size	12-30 m²
	Number of replications	3 or 4
Crop	Trials per crop	Sugar beet (BEAVA); 10 Maritime, 2 South-East climatic zone trials
	Varieties per crop (number of trials)	Katka (1), Kevin (1), Pohoda (1), Caruso (1), Nordika (1), Galactica (1), Cestus (1), Tisserin (2), Fred (2)
Application	Crop stage (BBCH) at application	BBCH 12-39
	Timing Weed stage at application	Post-emergence BBCH 12-49

	Number of applications	1 (12 trials), split application in 5 trials
	Spray volumes	175 L/ha (1 trial), 200 L/ha (6 trials), 250 L/ha (1 trial), 300 L/ha (4 trial)
Assessment	Assessment types	Phytotoxicity (%), crop vigour (%), weed control (%, visual assessment compared to the untreated)
	Assessment timings	1-8 weeks after application, at harvest
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Not applicable
	e.g. Natural / artificial inoculation…	Natural (all trials)
	e.g. Field / Greenhouse...	Field (all trials)

3.2.1 Preliminary tests (KCP 6.1)

No preliminary data are presented, the activity of clopyralid against broad leaved weeds is well known through decades of research and development and widespread use among growers in the EU. In addition, clopyralid is currently approved for use against broad leaved weeds in a range of crops within the EU Central Regulatory Zone.

3.2.1.1 Comparability between clopyralid formulations

The formulation to be re-registered is EF-243 (300 g a.e./L clopyralid SL), which is the currently authorised formulation in all concerned Member States of this submission. Data are presented in this dossier to support dose rate reductions that have been driven by changes in regulatory endpoints.

Clopyralid formulations have been authorised for use in the EU since 1977, and over the intervening years many formulations have been developed. The Applicant here provides efficacy data to demonstrate the direct comparability between these formulations (as listed in Table 3.2.1-1) where they have been tested in various permutations within individual trials carried out in maize, sugar beet and oilseed rape. Data are presented for all formulations at all rates relevant to the GAP in the Central Regulatory Zone.

Table 3.2.1-1 List of formulations included in bridging trials

Formulation code	Active substance	A.S concentration	Formulation type
EF-1136	clopyralid-olamine	100 g/l	SL
EF-243	clopyralid-olamine	300 g/l	SL
GF-2000	clopyralid-olamine	400 g/l	SL
GF-2895	clopyralid-Dimethylammonium	600 g/l	SL
GF-1966	clopyralid-olamine	720 g/kg	SG
EF-797	clopyralid-olamine	750 g/kg	WG
EF-584	clopyralid-olamine	200 g/L	SL
EF-1322	clopyralid-olamine	200.04 g/L	SL
EF-1389	clopyralid-olamine	300 g/L	EW
EF-1412	clopyralid-olamine	50 g/L	SL
EF-333	clopyralid-olamine	425.04 g/L	SL

Highlighted formulations are currently registered for use within Europe and will be supported at Article 43

Comparability in Wheat (TRZAW)

A total of 5 trials have generated data on the comparability of clopyralid formulations.

Of these trials, 4 were conducted within the South-East climatic zone and 1 was conducted within the Mediterranean climatic zone.

The following formulations were tested in individual trials:

EPPO climatic zone	Formulation	Clopyralid content		Formulation	Clopyralid content	No. of trials
Mediterranean	EF-1136	100 g/L SL	**versus**	GF-2000	400 g/L SL	1
South-East	GF-2895	600 g/L SL		GF-1996	720 g/kg SG	1
	EF-243	300 g/L SL		GF-1996	720 g/kg SG	2
	EF-243	300 g/L SL		EF-797	750 g/kg WG	1

Test site and application details are provided in Appendix 3 and raw data are provided in Appendix 4 of the Biological Assessment Dossier.

Control of individual weed species at the final assessment timings, in trials where two different clopyralid formulations were included in the treatment list at available dose rates most relevant to this submission, is presented in Table 3.2.1-2.

Across 6 data sets from trials conducted in the South-East climatic zone, the efficacy of EF-243 (300 g a.e./L clopyralid SL) is clearly comparable to that of GF-1966 (85.3% versus 86.2% control, respectively).

In addition, the data demonstrate that GF-2895 compares well with GF-1966 (720 g a.e./kg clopyralid) in the South-East zone, 99.8% for both formulations (1 data set), and also that EF-243 compares well with EF-797 in one data set (99% control for both formulations).

In the Mediterranean climatic zone EF-243 and GF-2000 demonstrated equivalent control in one data set (98%).

There was only one significant difference in the comparative performance between formulations, according to the statistical letter test, however numerically the difference was small (2.3%).

Table 3.2.1-2: Comparability of clopyralid formulations in TRZAW – 120 / 122 g a.e. clopyralid/ha, final assessment timings

Efficacy of clopyralid formulations at final assessment: 120-122 g ae/ha												
Trial ID	**Year**	**EPPO zone**	**Crop**	**Weed**	**Assessment timing**	**EF-243 (0.400-120)**	**EF-1136 (1.2-120)**	**GF-2000 (0.300-120)**	**GF-2895 (0.200-120)**	**EF-797 (0.160-120)**	**GF-1966 (0.170-122)**	**Formulations <,=,>**
GR07A2A003CM01C	2007	Mediterranean	TRZDU	ANTAR	55 DAA		98.0	98.0				=
HU08A2A085IMO1C	2008	South-East	TRZAW	CIRAR	61 DAA	89.5					90.3	=
HU08A2A085IMO2C	2008	South-East	TRZAW	CIRAR	63 DAA	88.8					88.8	=
HU18A2A004GK01C	2018	South-East	TRZAW	CIRAR	56 DAA				99.8		99.8	=
HU08A2A085IMO1C	2008	South-East	TRZAW	GALAP	61 DAA	61.3					62.5	=
E81018H1	1998	South-East	TRZAW	MATIN	61 DAA	99.0				99.0		=
HU08A2A085IMO1C	2008	South-East	TRZAW	MATCH	61 DAA	95.5					96.5	=
HU08A2A085IMO1C	2008	South-East	TRZAW	MATIN	61 DAA	91.5					93.8	EF-243<GF-1966
HU08A2A085IMO2C	2008	South-East	TRZAW	MATIN	63 DAA	85.0					85.0	=
Mediterranean												
Mediterranean 1 data set EF-1136 & GF-2000							**98.0**	**98.0**				**1 data set =**
South-East												
South-East 6 data sets EF-243 & GF-1966						**85.3**					**86.2**	**5 data sets =, 1 data set EF-243< GF-1966**
South-East 1 data set GF-2895 & GF-1966									**99.8**		**99.8**	**1 data set =**
South-East 1 data set EF-243 & EF 797						**99.0**				**99.0**		**1 data set =**

Comparability in Maize (ZEAMX)

A total of 12 trials have generated data on the comparability of clopyralid formulations.

Of these trials, 8 were conducted within the Maritime climatic zone and 4 were conducted within the South-East climatic zone.

The following formulations were tested in individual trials:

EPPO climatic zone	Formulation	Clopyralid content		Formulation	Clopyralid content	No. of trials
Maritime	EF-1136	100 g/L SL	**versus**	GF-1996	720 g/kg SG	8
South-East	EF-243	300 g/L SL		GF-2895	600 g/L SL	2
	EF-243	300 g/L SL		GF-1996	720 g/kg SG	2

Test site and application details are provided in Appendix 3 and raw data are provided in Appendix 4 of the Biological Assessment Dossier.

Control of individual weed species at the final assessment timings, in trials where two different clopyralid formulations were included in the treatment list at available dose rates most relevant to this submission, is presented in Table 3.2.1-3 (120 / 122 g a.e. clopyralid/ha).

For this submission, the most important comparisons are between EF-243 and other clopyralid formulations. Comparisons between other formulations are presented as supplementary evidence of comparability.

Across 6 data sets from trials conducted in the South-East climatic zone, the efficacy of EF-243 (300 g/L clopyralid) is clearly comparable to that of GF-2895 (94.6% versus 94.2% control, respectively).

In addition, the data demonstrate that EF-243 compares well with GF-1966 (720 g/kg clopyralid) in the South-East zone (87.5% versus 86.2% control, respectively, 10 data sets), and also that EF-1136 compares well with GF-1966 in the Maritime climatic zone (90.4% versus 94.2% control, respectively, 8 data sets).

There were no significant differences in the comparative performance between formulations, according to the statistical letter test.

Table 3.2.1-3: Comparability of clopyralid formulations in ZEAMX – 120 / 122 g a.e. clopyralid/ha, final assessment timings

Efficacy of clopyralid formulations at final assessment: 120-122 g a.e./ha										
Trial ID	**Year**	**EPPO zone**	**Crop**	**Weed**	**Assessment timing**	**EF-243 120 g a.e./ha**	**EF-1136 120 g a.e./ha**	**GF-1966 120-122 g a.e./ha**	**GF-2895 120 g a.e./ha**	**Statistical comparison between formulations <,=,>**
HU08A2A088IMO1C	2008	South-East	ZEAMX	AMBEL	112 DAA	100	-	100	-	=
HU08A2A088IMO1C	2008	South-East	ZEAMX	CIRAR	112 DAA	95	-	94.3	-	=
HU08A2A088IMO1C	2008	South-East	ZEAMX	LTHTU	112 DAA	97.8	-	98	-	=
HU08A2A088IMO1C	2008	South-East	ZEAMX	POLLA	112 DAA	98.5	-	97.3	-	=
HU08A2A088IMO2C	2008	South-East	ZEAMX	AMARE	34 DAA	98	-	92	-	=
HU08A2A088IMO2C	2008	South-East	ZEAMX	AMBEL	34 DAA	98	-	96	-	=
HU08A2A088IMO2C	2008	South-East	ZEAMX	CIRAR	34 DAA	98	-	94	-	=
HU08A2A088IMO2C	2008	South-East	ZEAMX	CHEAL	34 DAA	50	-	50	-	=
HU08A2A088IMO2C	2008	South-East	ZEAMX	HELAN	34 DAA	100	-	100	-	=
HU08A2A088IMO2C	2008	South-East	ZEAMX	POLLA	34 DAA	40	-	40	-	=
FPT-12-13443-SK04	2012	South-East	ZEAMX	CIRAR	122 DAA	98.8	-	-	98.8	=
FPT-12-13443-SK04	2012	South-East	ZEAMX	GALAP	122 DAA	72.5	-	-	70	=
FPT-12-13443-SK04	2012	South-East	ZEAMX	HELAN	122 DAA	100	-	-	100	=
FPT-12-13443-SK04	2012	South-East	ZEAMX	MATIN	122 DAA	100	-	-	100	=
FPT-12-13443-SK05	2012	South-East	ZEAMX	CIRAR	127 DAA	97.5	-	-	98.8	=
FPT-12-13443-SK05	2012	South-East	ZEAMX	ANTAR	127 DAA	98.8	-	-	97.5	=
DE08A2A001AZ02C	2008	Maritime	ZEAMX	CIRAR	110 DAA	-	85	88.3	-	=
DE08A2A001AZ03C	2008	Maritime	ZEAMX	CIRAR	35 DAA	-	89.3	90.5	-	=
DE08A2A001AZ04C	2008	Maritime	ZEAMX	CIRAR	35 DAA	-	90.5	91	-	=
DE08A2A003UB01C	2008	Maritime	ZEAMX	CIRAR	44 DAA	-	99	99	-	=
DE08A2A003UB02C	2008	Maritime	ZEAMX	CIRAR	78 DAA	-	79.3	98.3	-	=
DE08A2A003UB03C	2008	Maritime	ZEAMX	CIRAR	56 DAA	-	94	97.7	-	=
DE08A2A004TS01	2008	Maritime	ZEAMX	MATIN	40 DAA	-	95	95	-	=
DE08A2A004FS02	2008	Maritime	ZEAMX	MATCH	48 DAA	-	91	94	-	=
South-East										
					South-East EF-243 vs GF-2895, 6 data sets (min-max) SD	**94.6 (72.5-100) 10.9**	**-**	**-**	**94.2 (70-100) 11.9**	**6 data sets =**
					South-East EF-243 vs GF-1966, 10 data sets (min-max) SD	**87.5 (40-100) 22.6**	**-**	**86.2 (40-100) 22**	**-**	**10 data sets =**
Maritime										
					Maritime EF-1136 vs GF-1966, 8 trials (min-max) SD	**-**	**90.4 (79.3-99) 6.1**	**94.2 (88.3-99) 4**	**-**	**8 data sets =**

Comparability in Sugar beet (BEAVA)

A total of 9 trials have generated data on the comparability of clopyralid formulations.

Of these trials, 7 were conducted within the Maritime climatic zone and 2 were conducted within the South-East climatic zone.

The following formulations were tested in individual trials:

EPPO climatic zone	Formulation	Clopyralid content		Formulation	Clopyralid content	No. of trials
Maritime	EF-1136	100 g/L SL	**versus**	GF-1996	720 g/kg SG	2
	EF-243	300 g/L SL		GF-1996	720 g/kg SG	5
South-East	EF-243	300 g/L SL		GF-1996	720 g/kg SG	2

Test site and application details are provided in Appendix 3 and raw data are provided in Appendix 4 of the Biological Assessment Dossier.

Control of individual weed species at the final assessment timings, in trials where two different clopyralid formulations were included in the treatment list at dose rates relevant to this submission, is presented in Table 3.2.1-4 (2x 60 g clopyralid/ha), Table 3.2.1-5 (105 g clopyralid/ha) and Table 3.2.1-6 (119 / 120 g clopyralid/ha).

Across 2 Maritime climatic zone trials where a total of 120 g clopyralid/ha was applied at 2 timings as a split application, there is some variability in performance against CIRAR for EF-1136 (100 g/L clopyralid) and GF-1966 (78.4% versus 89.3% control, respectively, 2 data sets).

At approximately 105 g clopyralid/ha across 10 data sets from trials conducted in the Maritime climatic zone, the efficacy of EF-243 (300 g/L clopyralid) is clearly comparable to that of GF-1966 (79.1% versus 80.1% control, respectively).

At approximately 105 g clopyralid/ha across 4 data sets from trials conducted in the South-East climatic zone, the efficacy of EF-243 is clearly comparable to that of GF-1966 (92.7% versus 91.3% control, respectively).

At 119 / 120 g clopyralid/ha, across 6 data sets from trials conducted in the Maritime climatic zone, the efficacy of EF-243 (300 g/L clopyralid) is clearly comparable to that of GF-1966 (87.5% versus 86.6% control, respectively).

There were no significant differences in the comparative performance between formulations applied at a single timing, according to the statistical letter test. The split applications showed variable statistical differences between EF-1136 and GF-1966.

Table 3.2.1-4: Comparability of clopyralid formulations in BEAVA – 2x 60 g clopyralid/ha, final assessment timings

Trial ID	Year	EPPO zone	Crop	Weed	Assessment timing	EF-1136 2x 60 g a.e./ha	GF-1966 2x 60 g a.e./ha	Statistical comparison between formulations <,=,>
FR08A2A066ML01C	2008	Maritime	BEAVA	CIRAR	111 DAA	56.7	83.3	EF-1136 < GF-1966
FR08A2A066ML02C	2008	Maritime	BEAVA	CIRAR	96 DAA	100.0	95.3	EF-1136 > GF-1966
Maritime								
Maritime EF-1136 vs GF-1966, 2 data sets						**78.4**	**89.3**	**1 data set EF-1136 < GF-1966, 1 data set EF-1136 > GF-1966**

Table 3.2.1-5: Comparability of clopyralid formulations in BEAVA – approx. 105 g clopyralid/ha, final assessment timings

Trial ID	Year	EPPO zone	Crop	Weed	Assessment timing	GF-1966 104-108 g a.e./ha	EF-243 105 g a.e./ha	Statistical comparison between formulations <,=,>
CZ10A2A019KS01C	2010	Maritime	BEAVA	AETCY	90 DAA	75.0	75.0	=
CZ10A2A019KS01C	2010	Maritime	BEAVA	CIRAR	90 DAA	100.0	100.0	=
CZ10A2A019KS02C	2010	Maritime	BEAVX	CIRAR	56 DAA	87.5	86.3	=
CZ10A2A019KS02C	2010	Maritime	BEAVX	MATMA	56 DAA	100.0	100.0	=
CZ10A2A019KS03C	2010	Maritime	BEAVA	CIRAR	73 DAA	55.0	65.0	=
CZ10A2A019KS03C	2010	Maritime	BEAVA	MATIN	73 DAA	62.5	52.5	EF-243 < GF-1966
CZ11A2A022KS01C	2011	Maritime	BEAVA	CIRAR	56 DAA	70.0	62.5	=
CZ11A2A022KS01C	2011	Maritime	BEAVA	MATIN	56 DAA	60.0	60.0	=
CZ11A2A022KS02C	2011	Maritime	BEAVX	CIRAR	56 DAA	91.3	90.0	=
CZ11A2A022KS02C	2011	Maritime	BEAVX	MATMA	56 DAA	100.0	100.0	=
SK11A2A022JV01C	2011	South-East	BEAVA	CIRAR	47 DAA	93.8	93.8	=
SK11A2A022JV01C	2011	South-East	BEAVA	DATST	47 DAA	88.8	90.0	=
SK11A2A022JV02C	2011	South-East	BEAVA	CIRAR	47 DAA	93.8	95.8	=
SK11A2A022JV02C	2011	South-East	BEAVA	DATST	47 DAA	88.8	91.3	=
Maritime								
Maritime GF-1966 vs EF-243, 10 data sets (min-max) SD						**80.1 (55-100) 17.8**	**79.1 (52.5-100) 18.4**	**9 data sets =, 1 data set EF-243 < GF-1966**
South-East								
South-East GF-1966 vs EF-243, 4 data sets (min-max) SD						**91.3 (88.8-93.8) 2.9**	**92.7 (90-95.8) 2.6**	**4 data sets =**

Table 3.2.1-6: Comparability of clopyralid formulations in BEAVA – 119 / 120 g clopyralid/ha, final assessment timings

Trial ID	Year	EPPO zone	Crop	Weed	Assessment timing	GF-1966 119 g a.e./ha	EF-243 120 g a.e./ha	Statistical comparison between formulations <,=,>
CZ10A2A019KS01C	2010	Maritime	BEAVA	AETCY	90 DAA	87.5	87.5	=
CZ10A2A019KS01C	2010	Maritime	BEAVA	CIRAR	90 DAA	100.0	100.0	=
CZ10A2A019KS02C	2010	Maritime	BEAVX	CIRAR	56 DAA	99.5	99.8	=
CZ10A2A019KS02C	2010	Maritime	BEAVX	MATMA	56 DAA	100.0	100.0	=
CZ10A2A019KS03C	2010	Maritime	BEAVA	CIRAR	73 DAA	67.5	65.0	=
CZ10A2A019KS03C	2010	Maritime	BEAVA	MATIN	73 DAA	65.0	72.5	=
Maritime								
Maritime GF-1966 vs EF-243, 6 data sets (min-max) SD						**86.6 (65-100) 16.5**	**87.5 (65-100) 15.5**	**6 data sets =**

Conclusions – Comparability of clopyralid formulations

A total of 26 trials (5 trials in winter wheat, 12 trials in maize and 9 trials in sugar beet) conducted in the Maritime, Mediterranean or South-East climatic zones between 1998 and 2012 have generated data on the direct comparability between clopyralid formulations.

An overall summary of the comparability of clopyralid formulations is presented in Table 3.2.1-7.

Direct comparisons are shown between EF-243 and GF-1996 (Maritime and South-East zone), EF-1136 and GF-1966 (Maritime zone) and EF-243 or GF-1966 and GF-2895 (South-East zone). In addition, comparisons are shown for EF-243 versus EF-797 (South-East zone) and EF-1136 and GF-2000 (Mediterranean zone)

Data on the control of sensitive weed species by clopyralid formulations in the Maritime, Mediterranean and South-East climatic zones has been collated and the results clearly demonstrate that clopyralid formulations perform with good comparability, showing <5% difference between formulations in all cases, with the only exception being that a split application of 2x 60 clopyralid/ha in 2 trials gave an overall 11% difference between EF-1136 and EF-243.

There were no statistically significant differences between directly compared formulations in 50 out of a total 54 data sets.

On the basis of this data, it is possible to conclude that clopyralid formulations applied at equivalent rates will achieve comparable levels of efficacy, by extrapolation therefore, all formulations may be considered to be comparable and data generated with any formulation may be considered equivalent to EF-243.

Table 3.2.1-7: Overall summary – Comparability of clopyralid formulations

EPPO zone	Rate of application (g a.e./ha clopyralid)	Crop	Efficacy of clopyralid formulations at final assessment (no of data sets) (min-max) Standard Deviation[a]						Percentage difference between formulations	Statistical comparison between formulations <,=,>
			EF-1136	EF-243	GF-1966	GF-2895	EF-797	GF-2000		
South-East	120	ZEAMX	-	**94.6** 6 (72.5-100) 10.9	-	**94.2** 6 (70-100) 11.9	-	-	0.4	6 data sets =
Maritime	120-125	ZEAMX	**90.4** 8 (79.3-99) 6.1	-	**94.2** 8 (88.3-99) 4	-	-	-	3.8	8 data sets =
	2x 60	BEAVA	**78.4** 2 (56.7 / 100)	-	**89.3** 2 (83.3-95.3)	-	-	-	10.9	1 data set EF-1136 < GF-1966, 1 data set EF-1136 > GF-1966
Maritime	104-108	BEAVX	-	**79.1** 9 (52.5-100) 18.4	**80.1** 9 (55-100) 17.8	-	-	-	1	8 data sets =, 1 data set EF-243 < GF-1966
	119 / 120	BEAVX	-	**87.5** 6 (65-100) 15.5	**86.6** 6 (65-100) 16.5	-	-	-	0.9	6 data sets =
South-East	104-108	BEAVA	-	**92.7** 4 (90-95.8) 2.6	**91.3** 4 (88.8-93.8) 2.9	-	-	-	1.4	4 data sets =
	120-122	ZEAMX	-	**87.5** 10 (40-100) 22.6	**86.2** 10 (40-100) 22	-	-	-	1.3	10 data sets =
	120-122	TRZAW	-	**85.3** 6 (61.3-95.5) 12.23	**86.15** 6 (62.5-96.5) 12.25	-	-	-	0.85	5 data sets =,1 data set EF-243 < GF-1966

EPPO zone	Rate of application (g a.e./ha clopyralid)	Crop	Efficacy of clopyralid formulations at final assessment (no of data sets) (min-max) Standard Deviation[a]						Percentage difference between formulations	Statistical comparison between formulations <,=,>
			EF-1136	EF-243	GF-1966	GF-2895	EF-797	GF-2000		
South-East	120-122	TRZAW	-	-	99.8 1 (-)	99.8 1 (-)	-	-	0	1 data set =
South-East	120	TRZAW	-	99 1 (-)	-	-	99 1 (-)	-	0	1 data set =
Mediterranean	120	TRZAW	98 1 (-)	-	-	-	-	98 1 (-)	0	1 data set =

3.2.2 Minimum effective dose tests (KCP 6.2)

No data are presented to demonstrate the minimum effective dose of EF-243. The minimum effective dose has been previously demonstrated in earlier dossiers. Data are presented within this dossier to demonstrate that reduced rates of EF-243 provide effective and useful levels of control of the target broad leaved weeds where changing regulatory endpoints require a reduction. The efficacy of these reduced rates is included in Section 3.2.3.

Further to the demonstration of reduced rates following new regulatory endpoints a bridging argument has been presented to demonstrate the equivalence of all formulations of clopyralid once diluted, and to allow the use of data generated with all formulations to be considered as supportive of EF-243 (Section 3.2.1.1).

3.2.3 Efficacy tests (KCP 6.2)

Data are presented within this document demonstrating that changes to the currently authorised dose rates of EF-243 will provide effective levels of control of a range of broad-leaved weeds. Where there are no changes to the currently authorised rate, no new data are presented.

Data presented in Section 3.2.1.1 have demonstrated that efficacy levels are generally comparable between clopyralid solo formulations when in solution with water.

A total of 20 valid efficacy trials have been conducted between 1998 and 2018.

Data have been generated in:

- 7 trials in Winter wheat (TRZAW) carried out in the South-East climatic zone.
- 5 trials in maize (ZEAMX) carried out in the Maritime climatic zone (1 trial) and the South-East climatic zone (4 trials),
- 2 trials in Winter oilseed rape (BRSNW) carried out in the Maritime climatic zone,
- 1 trial in Spring oilseed rape (BRSNS) carried out in the North-Est climatic zone,
- 5 trials in sugar beet (BEAVA) carried out in the Maritime climatic zone.

Summaries of efficacy data are presented by use. Data are shown for final assessment timings, against individual broad leaved weed species present at ≥5 plants per m^2 or 2% ground cover in the untreated controls at the time of application and at the time of assessment.

Summary tables include columns indicating the number of trials where the efficacy of clopyralid formulations are <, > or = compared to the standard reference product, on an individual trial level, which represents differences that are significant (< or >) or non-significant (=), according to the statistical letter test.

The abbreviation DAA refers to days after application. The terms equivalent, superior and inferior, or variable where all three apply, have been adopted to describe the comparative efficacy between test and reference products on the basis of statistical significance between the mean values at the 5% level (Least Significant Difference) regardless of the numerical difference.

The following terminology has been used to describe the levels of control achieved:

- 100% = total control
- 95-99% = excellent control
- 85-95% = very good control
- 75-85% = good control
- 60-75% = moderately good control
- 50-60% = moderately low control
- 0-50% = low control

An overall summary of efficacy according to SANCO/10055/2013 is included in Table 3.2.3-19.

3.2.3.1 Grassland for seed (YGRAS)

Whilst the dose rate remains unchanged at renewal in the Czech Republic, there is a rate reduction required in Slovakia; 150 g a.e./ha reducing to 120 g a.e./ha in line with the currently approved rate in the Czech Republic. No data are available from trials in grass seed crops at this rate however data are available from trials conducted in cereals (TRZAW) from which efficacy data may be extrapolated to grassland (a minor use in CZ and SK), according to EPPO guidance for herbicides (EPPO 11-16629).

A total of 7 trials carried out between 1998 and 2018 have generated data on the efficacy of a single application of clopyralid at 120-122 g a.e./ha to support a rate reduction against broad-leaved weed species in grass seed crops (<1yr old and >1yr old) in Slovakia (please refer to Table 3.2-3 for current and proposed uses for this submission).

All 7 trials were conducted within the South-East climatic zone (Hungary).

A summary of all efficacy trials carried out in cereals (TRZAW) is presented in Table 3.2.3-1.

A list of all trials carried out in cereals is presented in

Table 3.2.**3-2**.

Table 3.2.3-1: A summary of all efficacy trials carried out in winter wheat (TRZAW)

EPPO climatic zone	Country	Crop	No. of trials					Total
			1998	2002	2003	2008	2018	
South-East	Hungary	TRZAW	1	2	1	2	1	7

Table 3.2.3-2: A list of all efficacy trials carried out in winter wheat (TRZAW)

Trial reference no.	Year	Crop	Country	EPPO climatic zone	Testing facility	Official recognition Y/N	Formulation
E81018H1	1998	TRZAW	Hungary	South-East	Dow AgroScience	N	EF-243
H2700201	2002	TRZAW	Hungary	South-East	Dow AgroScience	Y	EF-243
H2700202	2002	TRZAW	Hungary	South-East	Dow AgroScience	Y	EF-243
M3F00101	2003	TRZAW	Hungary	South-East	NTSZ, Dunaszige	N	EF-243
HU08A2A085IMO1C	2008	TRZAW	Hungary	South-East	NTSZ Fejer Megye	Y	EF-243 & GF-1966
HU08A2A085IMO2C	2008	TRZAW	Hungary	South-East	NTSZ Zala Megye	Y	EF-243 & GF-1966
HU18A2A004GK01C	2018	TRZAW	Hungary	South-East	AgroPass Hungaria	Y	GF-1966 & GF-2895

Summary and evaluation of trials results

Label claim:

Countries	Crops	Target	Application timing	No of applications	Application volume (L/ha)	Dose rate L pr/ha
Czech Republic Slovakia	Grass for seeds (more than one-year old) EPPO Code: YGRAS EU MRL Code: NA	Broad-leaved weeds (BBBBB) (including but not only *Cirsium arvense*)	March 01 to July 15, one application every year.	1	100-400	0.4 (120 g a.e./ha)
Czech Republic Slovakia	Grass for seeds (less than one-year old) EPPO Code: YGRAS EU MRL Code: NA	Broad-leaved weeds (BBBBB) (including but not only *Cirsium arvense*)	From BBCH 14 Slovakia: 01 March to 01 July Czech Rep: 01 April to 01 July	1	100-400	0.4 (120 g a.e./ha)

Summaries for efficacy against individual annual and perennial broad-leaved weed species follow below. Detailed individual trials data are given in Appendix 4 of the Biological Assessment Dossier.

Results are shown for clopyralid formulations EF-243 (300 g/L clopyralid) and GF-2895 (600 g/L clopyralid), at the rate of 120-122 g a.e./ha. The comparability between clopyralid formulations has been previously confirmed by the data presented in Section 3.2.1.1
Data are summarised from the final assessment timings, between 56 and 63 days after application.

The efficacy of clopyralid formulations against broad-leaved weeds is summarised and compared to that given by the standard reference products Galera (267 g/L clopyralid + 67 g/L picloram) at 0.35 L product/ha, Starane 250 (250g/L fluroxypyr) at 0.6 L product/ha and GF-1966 (720 g/kg clopyralid) at 120-122 g a.e./ha. The products used as standards may include other clopyralid formulations and are presented with the sole aim of showing that all treatments are performing as expected and therefore that the trial is valid.

Summary tables include columns showing the number of trials where the efficacy of clopyralid is <, > or = to the standard reference product, on an individual trial level, which represents differences that are significant (< or >) or non-significant (=), according to the statistical letter test.

A summary of population density and growth stage of individual weed species present on the trials at the time of application are given in Table 3.2.3-3.

Table 3.2.3-3: List of all broad-leaved weed species assessed across efficacy trials in TRZAW

Crop	Weed EPPO code	Weed scientific name	EPPO climatic zone	No. of trials	Mean population levels at application (range)	Weed growth stage at application (range – BBCH)
TRZAW	ANTAR	*Anthemis arvensis*	South-East	1	-	-
	BRSNW	*Brassica napus*	South-East	1	10 pl/m^2	30
	CNSOR	*Consolida orientalis*	South-East	3	10-20 pl/m^2	30-33
	PAP	*Consolida regalis*	South-East	1	-	32
	GALAP	*Galium aparine*	South-East	5	10-35 pl/m^2	16-26
	HELAN	*Helianthus annuus*	South-East	1	12 pl/m^2	12
	MATCH	*Matricaria chamomilla*	South-East	1	5 pl/m^2	14
	MATIN	*Tripleurospermum inodorum*	South-East	4	10-40 pl/m^2	14-33
	PAPRH	*Papaver rhoeas*	South-East	1	16.7 pl/m^2	51
	POLCO	*Fallopia convolvulus*	South-East	1	-	14
	VIOAR	*Viola arvensis*	South-East	1	-	16-63
	CIRAR	*Cirsium arvense*	South-East	6	8-32 pl/m^2	12-31 (5-50cm)

An overall summary of efficacy at the final assessment timings is presented in

Table 3.2.3-4.

Clopyralid applied at 120-122 g a.e./ha provides no effective control of weed species BRSNW, CNSOR, CNSRE, GALAP, PAPRH and VIOAR; these annual broad-leaved species are not therefore included in the overall average efficacy calculated across weeds.

Excellent control (>85% efficacy) is achieved against annual weed MATCH in 1 trial and against the perennial weed CIRAR in 6 trials. Very good levels of efficacy, 85-95% control, is achieved against annual weeds MATIN (4 trials) and HELAN (1 trial). Against ANTAR and POLCO each present in a single trial, efficacy of 75% and 56.7% was recorded, respectively.

Overall across all annual weed species, 120 g clopyralid/ha achieves 86.7% control, which is similar to that of the standard reference products (82.6% control).

Overall across all trials on perennial weed CIRAR and across both clopyralid formulations, 100 g clopyralid/ha achieves 95.1% control, which is equivalent to that of the standard reference products (95.2% control).

Based on these data, it is can be concluded that very good control of several important weed species is achieved at 120 g clopyralid/ha.

Table 3.2.3-4: Overall summary: Efficacy data generated at 120-122 g a.e./ha in TRZAW – Final assessment timings

Weed EPPO Code	EPPO Climatic zone	Assessment timing	Weed density pl/m²		Clopyralid formulations		Standard ref. products			Statistical comparison between clopyralid formulations and standard ref product
					EF-243 (120 g a.e./ha)	GF-2895 (120 g a.e./ha)	Starane 250 (0.6 L/ha)	Galera (GF-224) (0.35 L/ha)	GF-1966 (120-122 g a.e./ha)	
ANTAR	South-East	56 DAA	n.d.	Mean No. of trials (min-max) SD	75 1 (-) -	-	-	63.3 1 (-) -	-	1 >
BRSNW	South-East	59 DAA	10 pl/m²	Mean No. of trials (min-max) SD	-73 -147 (-) -	-	-	-61.3 -123.6 (-) -	-	2 >
CIRAR	South-East	56-63 DAA	8-32 pl/m²	Mean No. of trials (min-max) SD	94.17 5 (88.75-99.3) 4.8	99.8 1 (-) -	-	-	-	-
Overall summary South-East zone trials, all formulations				**(no. of data sets)** **(min-max)** **SD**	95.1 6 (88.75-99.8) 4.83		-	-	-	-
Overall summary South-East zone trials, EF-243 CIRAR				**(no. of data sets)** **(min-max)** **SD**	97.5 3 (96-99.3) 1.7	-	-	97.5 3 (96-99.3) 1.7	-	3 =
Overall summary South-East zone trials, EF-243 CIRAR				**(no. of data sets)** **(min-max)** **SD**	89.1 2 (88.75-89.5) 0.5	-	-	-	89.5 2 (88.75-90.3) 1.1	2 =
Overall summary South-East zone trials, GF-2895 CIRAR				**(no. of data sets)** **(min-max)** **SD**	-	99.8 1 (-) -	-	-	99.8 1 (-) -	1 =
CNSOR	South-East	56-61 DAA	10-20 pl/m²	Mean No. of trials (min-max) SD	178 3 (0-26.7) 15.41	-	-	-	-	-
Overall summary South-East zone trials, EF-243 CNSOR				**(no. of data sets)** **(min-max)** **SD**	26.7 1 (-) -	-	58.3 1 (-) -	-	-	1 <
Overall summary South-East zone trials, EF-243 CNSOR				**(no. of data sets)** **(min-max)** **SD**	13.35 2 (0-26.7) -	-	-	0 2 (-) -	-	1 =, 1 >
CNSRE	South-East	63 DAA	n.d.	Mean No. of trials (min-max) SD	0 1 (-) -	-	-	-	0 1 (-) -	-
GALAP	South-East	56-61 DAA	10-35 pl/m²	Mean No. of trials (min-max) SD	12.26 5 (0-61.3) 27.41	-	-	-	-	-
Overall summary South-East zone trials, EF-243 GALAP					0	-	98.7	-	-	1 <

Weed EPPO Code	EPPO Climatic zone	Assessment timing	Weed density pl/m²		Clopyralid formulations		Standard ref. products			Statistical comparison between clopyralid formulations and standard ref product
					EF-243 (120 g a.e./ha)	GF-2895 (120 g a.e./ha)	Starane 250 (0.6 L/ha)	Galera (GF-224) (0.35 L/ha)	GF-1966 (120-122 g a.e./ha)	
				(no. of data sets)	1		1			
				(min-max)	(-)		(-)			
				SD	-		-			
				Overall summary South-East zone trials, EF-243 GALAP	13.35			60.76		
				(no. of data sets)	2			3		
				(min-max)	(0-26.7)	-	-	(30-92.3)		3 <
				SD	-			31.15		
				Overall summary South-East zone trials, EF-243 GALAP	61.3				62.5	
				(no. of data sets)	1				1	
				(min-max)	(-)	-	-	-	(-)	1 =
				SD	-				-	
				Mean	93				94	
HELAN	South-East	61 DAA	12 pl/m²	No. of trials	1	-	-	-	1	1 =
				(min-max)	(-)				(-)	
				SD	-				-	
				Mean	95.5				96.5	
MATCH	South-East	61 DAA	5 pl/m²	No. of trials	1	-	-	-	1	1 =
				(min-max)	(-)				(-)	
				SD	-				-	
				Mean	93.3					
MATIN	South-East	56-63 DAA	8-32 pl/m²	No. of trials	4		-	-	-	-
				(min-max)	(85-99)					
				SD	6.4					
				Overall summary South-East zone trials, EF-243 MATIN	99		68.3			
				(no. of data sets)	1	-	1	-	-	1 >
				(min-max)	(-)		(-)			
				SD	-		-			
				Overall summary South-East zone trials, EF-243 MATIN	97.7			88.3		
				(no. of data sets)	1	-	-	1	-	1 >
				(min-max)	(-)			(-)		
				SD	-			-		
				Overall summary South-East zone trials, EF-243 MATIN	88.25				89.4	
				(no. of data sets)	2	-	-	-	6	1 <, 1 =
				(min-max)	(85-91.5)				(85-93.8)	
				SD	4.6				6.2	
				Mean	16.7			0		
PAPRH	South-East	56 DAA	n.d.	No. of trials	1	-	-	1	-	1 >
				(min-max)	(-)			(-)		
				SD	-			-		
				Mean	56.7			71.7		
POLCO	South-East	56 DAA	n.d.	No. of trials	1	-	-	1	-	1 trial <
				(min-max)	(-)			(-)		
				SD	-			-		
				Mean	0				0	
VIOAR	South-East	63 DAA	n.d.	No. of trials	1	-	-		1	-
				(min-max)	(-)				(-)	
				SD	-				-	
				Overall summary claimed weeds EF-243 versus Galera (GF-224) reference	87			85.9		
				(no. of data sets)	6	-	-	6	-	-
				(min-max)	(56.7-99.3)			(66.3-99.3)		
				SD	17.4			15		

Weed EPPO Code	EPPO Climatic zone	Assessment timing	Weed density pl/m^2		Clopyralid formulations		Standard ref. products			Statistical comparison between clopyralid formulations and standard ref product
					EF-243 (120 g a.e./ha)	GF-2895 (120 g a.e./ha)	Starane 250 (0.6 L/ha)	Galera (GF-224) (0.35 L/ha)	GF-1966 (120-122 g a.e./ha)	
Overall summary claimed weeds, EF-243 versus clopyralid (GF-1966) reference					90.54				87.3	
(no. of data sets)					6	-	-		7	-
(min-max)					(85-95.5)				(62.5-96.5)	
SD					3.64				11.6	
Overall summary claimed weeds EF-243 & GF-2895					90.3					
(no. of data sets)					14		-	-	-	-
(min-max)					(56.7-99)					
SD					11.8					

3.2.3.2 Lawn (NNNZW)

As a result of new regulatory endpoints it is necessary to reduce the maximum application rate from 300 g a.e./ha (Slovakia) and 240 g a.e./ha (Czech Republic) to 200 g a.e./ha. In Slovakia the new maximum application rate lies within the current range (120-300 g a.e/ha) whereas in the Czech Republic a reduction is required.

No data are available from trials conducted in grass crops, which is considered to be a minor use in CZ and SK, or cereal crops; however, a total of 3 trials carried in 2012 have generated data on the efficacy of a single application of clopyralid at the relevant rates of 198-200 g a.e./ha. The trials were conducted in crops that are relatively non-competitive with weeds - winter oilseed rape (2), and spring oilseed rape (1) - to support the proposed rate reduction in established lawn in Slovakia and Czech Republic (please refer to Table 3.2-3**Błąd! Nie można odnaleźć źródła odwołania.** for current and proposed uses for this submission).

Lawns may be either competitive or non-competitive with weeds depending upon several factors including the cultivar, aeration of the soil, use of scarification, appropriate mowing height and adequate nutrients which can enable more vigorous growth. The data presented may be considered to provide levels of control indicative of that expected in Lawn at the equivalent rate.

The trials were conducted within the Maritime climatic zone (Germany) and the North-East climatic zone (Poland).

A summary of all efficacy trials carried out in Winter and Spring oilseed rape (BRSNW, BRSNS) is presented in Table 3.2.3-5.

A list of all trials carried out in cereals is presented in Table 3.2.3-6.

Table 3.2.3-5: A summary of all efficacy trials carried out in winter oilseed rape (BRSNW), spring oilseed rape (BRSNS) and sugar beet (BEAVA) in support of uses in lawn (NNNZW)

EPPO climatic zone	Country	Crop	No. of trials 2012	Total
Maritime	France	BRSNW	1	1
	Germany	BRSNW	1	1
North-East	Poland	BRSNS	1	1
Overall total			3	**3**

Table 3.2.3-6: A list of all efficacy trials carried out in winter oilseed rape (BRSNW), spring oilseed rape (BRSNS) and sugar beet (BEAVA) in support of uses in lawn (NNNZW)

Trial reference no.	Year	Crop	Country	EPPO climatic zone	Testing facility	Official recognition Y/N	Formulation
FPT-12-9761-PL05	2012	BRSNS	Poland	North-East	Staphyt	Y	GF-2895
FPT-12-9761-FR03	2012	BRSNW	France	Maritime	Staphyt	Y	GF-2895
FPT-12-9761-DE01	2012	BRSNW	Germany	Maritime	Staphyt	Y	GF-2895

Summary and evaluation of trials results

Label claim:

Countries	Crops	Target	Application timing	No of applications	Application volume (L/ha)	Dose rate L pr/ha
Czech Republic Slovakia	Lawn (established grass, more than one-year old) EPPO Code: NNNZW EU MRL Code: NA	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense)	March 01 to July 1st, one application every year.	1	100-400	0.67 L/ha (200 g a.e./ha)

Summaries for efficacy against individual annual and perennial broad-leaved weed species follow below. Detailed individual trials data are given in Appendix 4 of the Biological assessment Dossier.
Results are shown for clopyralid formulation GF-2895 (600 g/L clopyralid), at the rate of 198-200 g a.e./ha. The comparability between clopyralid formulations has been previously confirmed by the data presented in Section 3.2.1.1.

Data are summarised from the final assessment timings, between 76 and 127 days after application.

In each of the above trials a clopyralid reference (EF-1136, EF-243 or GF-2895) applied at the rate of 120-150g a.e./ha is included. The standards are presented with the sole aim of demonstrating that all treatments are performing as expected and therefore that the trial is valid.

Summary tables include columns showing the number of trials where the efficacy of clopyralid is <, > or = to the standard reference product, on an individual trial level, which represents differences that are significant (< or >) or non-significant (=), according to the statistical letter test.

A summary of population density and growth stage of individual weed species present in the trials at the time of application are given in Table 3.2.3-7.

Table 3.2.3-7: List of all broad-leaved weed species assessed across efficacy trials in BRSNW, BRSNS trials at 200 g a.e./ha

Crop	Weed EPPO code	Weed scientific name	EPPO climatic zone	No. of trials	Mean population levels at application (range)	Weed growth stage at application (range – BBCH)
BRSNW	MATIN	*Tripleurospermum inodorum*	Maritime	1	41 pl/m^2	19
	PICHI	*Picris hieracioides*	Maritime	1	37 pl/m^2	14
	CAPBP	*Capsella bursa-pastoris*	Maritime	1	13 pl/m^2	55
	CARHI	*Cardamine hirsuta*	Maritime	1	26 pl/m^2	60
	CENCY	*Centaurea cyanus*	Maritime	1	42 pl/m^2	19
	MATCH	*Matricaria chamomilla*	Maritime	1	16 pl/m^2	19
BRSNS	CENCY	*Centaurea cyanus*	North-East	1	8 pl/m^2	14
	CHEAL	*Chenopodium album*	North-East	1	32 pl/m^2	14
	GALAP	*Galium aparine*	North-East	1	10 pl/m^2	13
	MATCH	*Matricaria chamomilla*	North-East	1	4 pl/m^2	14
	POLCO	*Fallopia convolvulus*	North-East	1	20 pl/m^2	14
	VIOAR	*Viola arvensis*	North-East	1	8 pl/m^2	14

An overall summary of efficacy at the final assessment timings is presented in Table 3.2.3-8.

Clopyralid applied at 200 g a.e./ha provides no effective control of weed species CAPBP, CARHI, GALAP and VIOAR; these annual broad-leaved species are not therefore included in the overall average efficacy calculated across weeds.

Excellent control (>95% efficacy) is achieved against the annual weeds MATIN and SONOL in one trial and very good control (>90% efficacy) is achieved against annual weeds MATCH and CENCY in 2 trials. Against the biennial/perennial weed PICHI excellent control (99.3%) was achieved in one trial.

Overall across all weed species, 200 g clopyralid/ha achieves 88.3% control. Across all trials control was equivalent or superior to the reference which was included to confirm the validity of the trials (clopyralid formulations applied at 120-150 g a.e./ha).

Based on these data, it is can be concluded that moderately good to excellent control of a number of important weed species is achieved at 200 g a.e.clopyralid/ha.

Table 3.2.3-8: Overall summary: Efficacy data generated at 198/200 g a.e./ha to support use in Lawn NNNZW – Final assessment timings

Weed EPPO Code	Crop Code	EPPO Climatic zone	Assessment timing	Weed density pl/m²		Clopyralid formulation GF-2895 (198-200 g a.e./ha)	Standard ref. products Clopyralid solo (120g a.e./ha)*	Statistical comparison between clopyralid formulations and standard ref product
CAPBP	BRSNW	Maritime	14 DAA	13 pl/m²	Mean No. of trials (min-max) SD	0 1 (-) -	0 1 (-) -	-
CARHI	BRSNW	Maritime	27 DAA	31 pl/m²	Mean No. of trials (min-max) SD	0 1 (-) -	0 1 (-) -	-
CENCY	BRSNS	North-East	106 DAA	8 pl/m²	Mean No. of trials (min-max) SD	81.25 1 (-) -	76.25 1 (-) -	1 >
CENCY	BRSNW	Maritime	127 DAA	42 pl/m²	Mean No. of trials (min-max) SD	100 1 (-) -	100 1 (-) -	1 =
					Overall summary CENCY, GF-2895 versus reference **(no. of data sets)** **(min-max)** **SD**	90.63 2 (81.25-100) 13.26	88.13 2 (76.25-100) 16.79	1 =, 1 >
CHEAL	BRSNS	North-East	106 DAA	8 pl/m²	Mean No. of trials (min-max) SD	63.8 1 (-) -	61.3 1 (-) -	1 =
GALAP	BRSNS	North-East	106 DAA	10 pl/m²	Mean No. of trials (min-max) SD	36.25 1 (-) -	35 1 (-) -	1 =
MATCH	BRSNS	North-East	106 DAA	4 pl/m²	Mean No. of trials (min-max) SD	80 1 (-) -	76.3 1 (-) -	1=
MATCH	BRSNW	Maritime	127 DAA	15 pl/m²	Mean No. of trials (min-max) SD	100 1 (-) -	100 1 (-) -	1 =
					Overall summary MATCH, GF-2895 versus reference **(no. of data sets)** **(min-max)** **SD**	90 2 (80-100) 14.14	88.15 2 (76.3-100) 16.76	2 =

Weed EPPO Code	Crop Code	EPPO Climatic zone	Assessment timing	Weed density pl/m^2		Clopyralid formulation GF-2895 (198-200 g a.e./ha)	Standard ref. products Clopyralid solo (120g a.e./ha)*	Statistical comparison between clopyralid formulations and standard ref product
MATIN	BRSNW	Maritime	87 DAA	29 pl/m^2	Mean No. of trials (min-max) SD	100 1 (-) -	82.5 1 (-) -	1 >
PICHI	BRSNW	Maritime	87 DAA	23 pl/m^2	Mean No. of trials (min-max) SD	99.3 1 (-) -	85 1 (-) -	1 >
POLCO	BRSNS	North-East	106 DAA	20 pl/m^2	Mean No. of trials (min-max) SD	71.25 1 (-) -	67.5 1 (-) -	1 =
SONOL	BRSNW	Maritime	87 DAA	14 pl/m^2	Mean No. of trials (min-max) SD	99.5 1 (-) -	98.3 1 (-) -	1 =
VIOAR	BRSNS	North-East	106 DAA	8 pl/m^2	Mean No. of trials (min-max) SD	33.8 1 (-) -	31.3 1 (-) -	1 =
Overall summary all trials, GF-2895 **(no. of data sets)** **(min-max)** **SD**						88.34 9 (63.8-100) 14.95	-	6 =, 3 >, 1 n.d.
Overall summary Maritime and North-East zone trials, BRSNW & BRSNS, GF-2895 versus reference **(no. of data sets)** **(min-max)** **SD**						88.34 9 (63.8-100) 14.43	83.02 9 (61.3-100) 14.22	6 =, 3 >
Overall summary North-East zone trials, BRSNS, GF-2895 versus reference **(no. of data sets)** **(min-max)** **SD**						74.08 4 (63.8-81.25) 8.17	70.34 4 (61.3-76.3) 7.31	3 =, 1 >
Overall summary Maritime zone trials, BRSNW, GF-2895 versus reference **(no. of data sets)** **(min-max)** **SD**						99.76 5 (99.3-100) 0.34	93.16 5 (82.5-100) 8.66	3 =, 2 >

* Formulations GF-2895, EF-243, EF-1136

3.2.3.3 Maize (ZEAMX)

A total of 5 trials carried out in 1999 and 2012 have generated data on the efficacy of a single application of clopyralid at 100 g a.e./ha to support a rate reduction against broad-leaved weed species in maize in Slovakia (102 g a.e./ha) (please refer to Table 3.2-3 for current and proposed uses for this submission).

Of these trials, 1 was conducted within the Maritime climatic zone (Maritime France) and 4 were conducted within the South-East climatic zone (2 trials in Hungary and 2 trials in Slovakia).

A summary of all efficacy trials carried out in maize is presented in Table 3.2.3-9.

A list of all trials carried out in maize is presented in Table 3.2.3-10.

Table 3.2.3-9: A summary of all efficacy trials carried out in maize (ZEAMX)

EPPO climatic zone	Country	Crop	No. of trials		Total
			1999	2012	
Maritime	France	ZEAMX	1	-	1
South-East	Hungary	ZEAMX	2	-	4
	Slovakia	ZEAMX	-	2	
Overall total			**3**	**2**	**5**

Table 3.2.3-10: A list of all efficacy trials carried out in maize (ZEAMX)

Trial reference no.	Year	Crop	Country	EPPO climatic zone	Testing facility	Official recognition Y/N	Formulation
F9B01301	1999	ZEAMX	France	Maritime	Promo-Vert	Y	EF-1136
EA99A2A013 E9B013H1	1999	ZEAMX	Hungary	South-East	Dow Agroscience	Y	EF-1136
EA99A2A013 E9B013H2	1999	ZEAMX	Hungary	South-East	Dow Agroscience	Y	EF-1136
FPT-12-13443-SK04	2012	ZEAMX	Slovakia	South-East	Gemerprodukt Valice OVD	Y	GF-2895
FPT-12-13443-SK05	2012	ZEAMX	Slovakia	South-East	Gemerprodukt Valice OVD	Y	GF-2895

Summary and evaluation of trials results

Label claim:

Countries	Crops	Target	Application timing	No of applications	Application volume (L/ha)	Dose rate L pr/ha
Slovakia	Maize (grain, forage) EPPO Code: ZEAMX EU MRL Code: 0500030 Human consumption Processed goods Cattle consumption	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Matricaria spp.)	Crop BBCH 10-19 (each year) or BBCH 10-32 (every 2 years)	1	100-400	0.34 L/ha 102 g a.e./ha

Summaries for efficacy against individual annual and perennial broad-leaved weed species follow below. Detailed individual trials data are given in Appendix 4 of the Biological Assessment Dossier.

Results are shown for clopyralid formulations GF-2895 (600 g/L clopyralid) and EF-1136 (100 g/L clopyralid) applied at the rate of 100 g a.e./ha. The comparability between clopyralid formulations has been demonstrated based on the data presented in Section 3.2.1.1, it is considered that data generated with any clopyralid formulation is fully supportive towards demonstrating the efficacy of EF-243.

Data are summarised from the final assessment timings, between 32 and 127 days after application.
The efficacy of clopyralid formulations against broad-leaved weeds is summarised and compared to that given by the standard reference products Pyron at 2 L product/ha (50 g/L clopyralid + 450 g/L pyridate; France and Hungary) and Lontrel 300 (300 g/L clopyralid; Slovakia). The products used as standards may include other clopyralid formulations and are presented with the sole aim of showing that all treatments are performing as expected and therefore that the trial is valid.

Summary tables include columns showing the number of trials where the efficacy of clopyralid is <, > or = to the standard reference product, on an individual trial level, which represents differences that are significant (< or >) or non-significant (=), according to the statistical letter test.

A summary of population density and growth stage of individual weed species present on the trials at the time of application are given in Table 3.2.3-11.

Table 3.2.3-11: List of all broad-leaved weed species assessed across efficacy trials in ZEAMX

Crop	Weed EPPO code	Weed scientific name	EPPO climatic zone	No. of trials	Mean population levels at application (range)	Weed growth stage at application (range – BBCH)
Annual weed species						
ZEAMX	AMARE	*Amaranthus retroflexus*	South-East	2	25 / 30 pl/m^2	12-15
	AMBEL	*Ambrosia artemisiifolia*	South-East	1	5-10 pl/m^2	12-14
	ANTAR	*Anthemis arvensis*	South-East	1	5 pl/m^2	11-12
	CHEAL	*Chenopodium album*	South-East	2	6-10 pl/m^2	14-21
	HELAN	*Helianthus annuus*	South-East	2	6 / 20 pl/m^2	12-16
	MATIN	*Tripleurospermum inodorum*	South-East	1	5.3 pl/m^2	10-11
	POLPE	*Persicaria maculosa*	South-East	1	20-30 pl/m^2	15-16
	SINAR	*Sinapsis arvensis*	South-East	1	50 pl/m^2	15-26
Perennial grass weed species						
ZEAMX	CIRAR	*Cirsium arvense*	South-East	4	4.75-30 pl/m^2	10-26
			Maritime	1	32.3 pl/m^2	47

An overall summary of efficacy at the final assessment timings is presented in Table 3.2.3-12.

Clopyralid applied at 100 g a.e./ha clearly provides no effective control of weed species AMARE, SINAR and CHEAL; these annual broad-leaved species are not therefore included in the overall average efficacy calculated across weeds.

Good control (>85% efficacy) is achieved against annual weed HELAN in 2 trials and against perennial weed CIRAR in 2 trials. Moderately good levels of efficacy, approximately 70-83% control, is achieved against annual weeds AMBEL, ANTAR, MATIN and POLPE, and against perennial CIRAR in 3 trials.

Overall across all annual weed species and across both clopyralid formulations, 100 g clopyralid/ha achieves 78.3% control, which is lower than that of the standard reference products (91.3% control).

Overall across all trials on perennial weed CIRAR and across both clopyralid formulations, 100 g clopyralid/ha achieves 82.1% control, which compares well to that of the standard reference products (85.7% control).

Based on these data, it is can be concluded that moderately good control of a number of important weed species is achieved at 102 g clopyralid/ha.

Table 3.2.3-12: Overall summary: Efficacy data generated at 100 g clopyralid/ha in ZEAMX

Weed EPPO Code	EPPO Climatic zone	Assessment timing	Weed density pl/m²		Clopyralid formulation		Standard ref. products		Statistical comparison between clopyralid formulations and standard ref product
					EF-1136 (100 g a.e./ha)	GF-2895 (100 g a.e./ha)	Pyron DE	Lontrel 300	
AMARE	South-East	81 DAA	5-10 pl/m²	Mean No. of trials (min-max) SD	16.3 2 (11.3-21.3) -	-	94.65 2 (94.3-95) -	-	2 <
AMBEL	South-East	81 DAA	5-10 pl/m²	Mean No. of trials (min-max) SD	81.3 1 (-) -	-	81.3 1 (-) -	-	1 =
ANTAR	South-East	127 DAA	5 pl/m²	Mean No. of trials (min-max) SD	-	70 1 -1 -		98.8 1 (-) -	1 <
CHEAL	South-East	28-81 DAA	6-10 pl/m²	Mean No. of trials (min-max) SD	20.65 2 (20-21.3) -	-	90.8 2 (83.3-98.3) -	-	2 <
CIRAR	Maritime	46 DAA	32.3 pl/m²	Mean No. of trials (min-max) SD	91.3 1 (-) -	-	63.8 1 (-) -	-	1 >
CIRAR	South-East	28-127 DAA	4.75-30 pl/m²	Mean No. of trials (min-max) SD	88.3 2 (82.5-94) -	71.3 2 (67.5-75) -	-	-	-
				Overall average, all CIRAR, SE zone No. of data sets (min-max) SD	79.8 4 (67.5-94) 11.3		-	-	-
				Overall average, all CIRAR, both zones No. of data sets (min-max) SD	89.3 3 (82.5-94) 6.01	71.3 2 (67.5-75) -	-	-	-
				Overall average, all CIRAR, both zones No. of data sets (min-max) SD	82.1 5 (67.5-94) 11.1		-	-	-
				Overall average, EF-1136, SE Zone CIRAR No. of data sets (min-max) SD	88.3 2 (82.5-94) -	-	84.3 2 (74.8-93.8) -	-	1 =, 1>
				Overall average, GF-2895, SE Zone CIRAR No. of data sets (min-max)	-	71.3 2 (67.5-75)	-	98.15 2 (97.5-98.8)	2 <

Weed EPPO Code	EPPO Climatic zone	Assessment timing	Weed density pl/m²		Clopyralid formulation		Standard ref. products		Statistical comparison between clopyralid formulations and standard ref product
					EF-1136 (100 g a.e./ha)	GF-2895 (100 g a.e./ha)	Pyron DE	Lontrel 300	
				SD		-		-	
GALAP	South-East	122 DAA	3.75 pl/m²	Mean No. of trials (min-max) SD	-	52.5 1 (-) -	-	72.5 1 (-) -	1 <
HELAN	South-East	28-122 DAA	6-20 pl/m²	Mean No. of trials (min-max) SD	97 1 (-) -	88.8 1 (-) -	-	-	-
				Overall average, all HELAN, SE zone No. of data sets (min-max) SD	92.9 2 (88.8-97) -		-	-	-
				Overall average, EF-1136, SE Zone HELAN No. of data sets (min-max) SD	97 1 (-) -	-	98 1 (-) -	-	1 =
				Overall average,GF-2895, SE Zone HELAN No. of data sets (min-max) SD	-	88.8 1 (-) -	-	100 1 (-) -	1<
MATIN	South-East	122 DAA	5.3 pl/m²	Mean No. of trials (min-max) SD	-	82.5 1 (-) -	-	100 1 (-) -	1 <
POLPE	South-East	28 DAA	20-30 pl/m²	Mean No. of trials (min-max) SD	76.3 1 (-) -	-	88.8 1 (-) -	-	1 <
SINAR	South-East	81 DAA	50 pl/m²	Mean No. of trials (min-max) SD	21.3 1 (-) -	-	75 1 (-) -	-	1 <

3.2.3.4 Cereals (3CERC; winter and spring)

No new data are presented; the dose in the Czech Republic rate remains unchanged at renewal. In Slovakia the rate at renewal is equivalent to the lower end of the currently authorised range (0.3-0.4 L/ha)

Label claim:

Countries	Crops	Target	Application timing	No of applications	Application volume (L/ha)	Dose rate L pr/ha
Czech Republic	Winter and spring cereals: Barley (HORVW, HORVS), Wheat (TRZAW, TRZAS), Oats (AVESW, AVESS), Rye (SECCE), Triticale (TTLSS)	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Centaurea cyanus, Matricaria spp)	BBCH 30-39	1	100-400	0.3 L/ha (90 g a.e./ha)
Slovakia	Winter and spring cereals: Barley (HORVW, HORVS), Wheat (TRZAW, TRZAS), Rye (SECCE), Triticale (TTLSS)	Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, Centaurea cyanus, Matricaria spp)	BBCH 30-39	1	100-400	0.3 L/ha (90 g a.e./ha)

3.2.3.5 Winter oilseed rape (BRSNW)

No new data are presented; the dose rate remains unchanged at renewal.
Label claim:

Countries	Crops	Target	Application timing	No of applications	Application volume (L/ha)	Dose rate L pr/ha
Slovakia	Winter Oilseed rape EPPO Code: BRSNW EU MRL Code: 0401060 Raw Human consumption Processed goods Cattle consumption	Broad-leaved weeds (BBBBB) (including but not only *Cirsium arvense*, *Centaurea cyanus*, *Matricaria* spp.)	Crop BBCH 30-51	1	100-400	0.35 (105 g a.e./ha)
Poland	Winter Oilseed rape EPPO Code: BRSNW EU MRL Code: 0401060 Raw Human consumption Processed goods Cattle consumption	Broad-leaved weeds (BBBBB) (including but not only *Cirsium arvense*, *Centaurea cyanus*, *Matricaria* spp.)	Crop BBCH 30-51	1	100-400	0.4 (120 g a.e./ha)

3.2.3.6 Beetroot crops (3BERC) – Sugar beet (BEAVA), Fodder beet (BEAVC), Red beet (BEAVD), Mangels (BEAVC)

There is no change to the currently approved dose for single application of EF-243 in Poland, Czech Republic or Slovakia at renewal. Split application dose rates have been altered to reflect the maximum solo application rate in each country (120 g a.e./ha in Poland and 105 g a.e./ha in Czech Republic and Slovakia), this has resulted in a reduced overall dose in some split application uses.

A total of 5 trials carried out between 2007 and 2015 have generated data on the efficacy of clopyralid at as a split application at 60 g a.e./ha, to support rate changes against broad-leaved weed species in sugar beet in the Czech Republic, Slovakia and Poland (please refer to Table 3.2-3 for current and proposed uses for this submission).

All of these trials were conducted within the Maritime climatic zone.

A summary of all efficacy trials carried out in Sugar beet is presented in Table 3.2.3-13.

A list of all trials carried out in Sugar beet is presented in Table 3.2.3-14.

Table 3.2.3-13: A summary of all efficacy trials carried out in Sugar beet (BEAVA)

Crop	EPPO climatic zone	Country	No. of trials			Total
			2007	2008	2015	
Sugar beet BEAVA	Maritime	France	1	2	2	**5**

Table 3.2.3-14: A list of all efficacy trials carried out in Sugar beet (BEAVA)

Trial reference no., Year	Country	EPPO climatic zone	Testing facility	Official recognition Y/N	Formulation
FR07A2A037FT01, 2007	France	Maritime	Dow Agrosciences, France	Y	EF-1136
FR08A2A066ML01C, 2008	France	Maritime	Staphyt, FR	Y	EF-1136
FR08A2A066ML02C, 2008	France	Maritime	Syntech, FR	Y	EF-1136
FR15H2B017FO01, 2015	France	Maritime	Dow Agrosciences, France	Y	GF-1966
FR15H2B017FO02, 2015	France	Maritime			

Summary and evaluation of trials results

Label claim:

Countries	Crops	Target	Application timing	Application volume (L/ha)	No of applications	Dose rate per application L pr/ha	Comments
Poland	Fodder beet, Sugar beet, Red Beet EPPO Code: BEAVC, BEAVA, BEAVD EU MRL Code: 0213010, 0900010, 0213010 Raw Human consumption Processed goods Cattle consumption	Broad-leaved weeds (BBBBB) (including but not only *Cirsium arvense*, *Matricaria* spp.)	BBCH 12-39 (until July 1st)	100-400	1	0.33-0.4 (100-120 g a.e./ha)	One application every two years.
					2	0.2 (60 g a.e./ha)	Only every three years. Split application: First application at 60 g a.e. clopyralid/ha (0,2L of EF-243/ha) at BBCH 12-15 followed 7-days later by a second application at BBCH 12-15 at 60 g a.e. clopyralid/ha (0,2 L EF-243/ha).
							Every two years. Split application: first application at 60 g a.e. clopyralid/ha (0,2 L EF243/ha) at BBCH 15 followed 10 days later by a second application (at BBCH 31) at 60 g a.e. clopyralid/ha (0,2 L EF-243/ha).
Czech Republic, Slovakia	Fodder beet, Red beet, Sugar beet, Mangels EPPO Code: BEAVC, BEAVD, BEAVA, BEAVC EU MRL Code: 0213010, 0213010, 0900010, 0213010 Raw Human consumption Processed goods Cattle consumption	Broad-leaved weeds (BBBBB) (including but not only *Cirsium arvense*, *Matricaria* spp.)	BBCH 12-39 (until July 1st)	100-400	1	0.35 (105 0g a.e./ha)	One application every two years.
					2	0.175 (52.5g a.e./ha)	Only every three years. Split application: First application at 52,5 g a.e. clopyralid/ha (0,175L of EF-243/ha) at BBCH 12-15 followed 7-days later by a second application at BBCH 12-15 at 52,5 g a.e. clopyralid/ha (0,175 L EF-243/ha).
					2	0.175 (52.5g a.e./ha)	Every two years. Split application: first application at 52,5 g a.e. clopyralid/ha (0,175L EF243/ha) at BBCH 15 followed 10 days later by a second application (at BBCH 31) at 52,5 g a.e. clopyralid/ha (0,175 L EF-243/ha).

Summaries for efficacy against individual broad-leaved weed species follow below. Detailed individual trials data are given in Appendix 4 of the Biological Assessment Dossier.

Results are shown for clopyralid formulations EF-1136 (100 g/L clopyralid) and GF-1966 (720 g/kg clopyralid) applied twice at 60 g or 61.5 g a.e./ha which is a proposed application schedule for Poland (60 g a.e./ha x2) though greater than that proposed in Czech Republic and Slovakia (52.5 g a.e./ha x2). All data generated with formulations EF-1136 and GF-1966 are considered to be fully supportive according to the comparability data presented in Section 3.2.1.1.

Data are summarised from approximately 2 weeks after application to the final assessment timings where the density of weed populations are greater than 5 plants per m^2.
The efficacy of split applications of clopyralid formulations against *Cirsium arvense* is summarised and compared to that given by clopyralid formulations applied as a solo application. Where presented, other clopyralid formulations show that all treatments are performing as expected and therefore that the trial is valid.

Summary tables include columns showing the number of trials where the efficacy of clopyralid is <, > or = to the standard reference product, on an individual trial level, which represents differences that are significant (< or >) or non-significant (=), according to the statistical letter test.

A summary of population density and growth stage of individual weed species present on the trials at the time of application are given in Table 3.2.3-15.

Table 3.2.3-15: List of all broad-leaved weed species assessed across efficacy trials in BEAVA

Weed EPPO code	Weed scientific name	EPPO climatic zone	No. of trials	Mean population levels at application (range)	Weed growth stage at application (range – BBCH)	Claims for control Y/N
CIRAR	*Cirsium arvense*	Maritime	5	6-304 pl/m^2 12% GC	12-49	Y

When applied as a split application of 2x 60 g / 61 g a.e./ha, EF-1136 / GF-1966 achieves 90% overall average control of CIRAR at 4-8 weeks after the second application (5 trials). In the following crop, 2x 61 g a.e./ha GF-1966 provides 84% control of newly emerged CIRAR across 2 trials.
While there are no available data supporting a split application at 2x 52.5 g a.e./ha, data summarised across 5 trials in this document demonstrate that 2x 60 g / 61 g a.e./ha provides a comparable level of control of CIRAR compared to a single application of 125 g a.e./ha alone at all assessment timings (Table 3.2.3-16). It is therefore reasonable to conclude that 2x 52.5 g a.e./ha will perform with similar efficacy compared to a single application of approximately 105 g a.e./ha as currently authorised in Czech Republic and Slovakia.

According to the Extrapolation table for Effectiveness of Herbicides – Weeds in beta crops (1/257 HEET 67 (1)), it is possible to extrapolate from any Beta species (BEASS) to any other Beta species (BEASS) due to the close similarities in plant physiology, agronomy and cultivation practices. Efficacy data generated in Sugar beet (BEAVA) is therefore fully supportive towards demonstrating efficacy in Fodder beet (BEAVC) and Red beet (BEAVD) as relevant to the claimed uses for EF-243 at renewal.

Overall, on the basis of the data presented in this document, it is possible to conclude that the requested rate modifications for the split dose applications in Beet crops for the renewal of EF-243 will provide equivalent levels of control to those currently achieved by the authorised solo application rates.

Table 3.2.3-16: Overall summary of efficacy against broad-leaved weeds in BEAVA by weed species - split application (2 applications) of clopyralid at 60 / 61g a.e./ha in BEAVA, Maritime climatic zone

Maritime zone trials CIRAR	Clopyralid formulations Mean percentage efficacy, compared to the untreated			
	EF-1136 2x 60 g a.e./ha	**GF-1966 2x 61 g a.e./ha**	**EF-1136 1x 125 g a.e./ha**	**GF-1966 1x 125 g a.e./ha**
2-3 weeks after second application	72.0 3 (46.7-99.3)	79.2 2 (66.7 / 91.7)	78.1 2 (60-99.3)	84.5 2 (75 / 94)
No. of data sets (min-max)	**74.9 5 (46.7-99.3) SD 21.0**		**80.7 5 (60-99.3) SD 15.9**	
4-8 weeks after second application	95.0 3 (88.3-100)	96.9 2 (95 / 99)	89.4 3 (80-100)	85.4 2 (75 / 95.7)
No. of data sets (min-max)	**90.1 5 (75-100) SD 9.5**		**87.8 5 (80-100) SD 10.4**	
10-14 weeks after second application	98.4 2 (96.7 / 100)	98.7 1 (-)	96.7 2 (93.3 / 100)	96.0 1 (-)
No. of data sets (min-max)	**98.5 3 (96.7-100) SD 1.7**		**96.4 3 (93.3-100) SD 3.4**	
Following crop (spring) No. of data sets (min-max)	- 	84.1 2 (75 / 93.1)	- 	86.1 2 (73.3 / 89.7)

3.2.3.7 Onion (ALLCE/ALLXS)

No new data are presented; the dose rate for onion (from seeds, direct-seeded) remains unchanged at renewal.
Label claim:

Countries	Crops	Target	Application timing	No of applications	Application volume (L/ha)	Dose rate L pr/ha
Czech Republic, Slovakia, Poland	Onion for Seeds EPPO Code: ALL-CE/ALLXS EU MRL Code: 0220020 Raw Human consumption Processed goods	Broad-leaved weeds (BBBBB) (including but not only *Cirsium arvense*, *Matricaria* spp.)	BBCH 11-16	1	100-400	0.4 (120 g a.e./ha)

3.2.3.8 Gladiolus (1GLAG)

No new data are presented; the dose rate for Gladiolus remains unchanged at renewal.
Label claim:

Countries	Crops	Target	Application timing	No of applications	Application volume (L/ha)	Dose rate L pr/ha
Slovakia	Gladiolus EPPO Code: 1GLAG EU MRL Code: NA	Broad-leaved weeds (BBBBB) (including but not only *Cirsium arvense*, *Matricaria* spp.)	BBCH 12-19 (spring/summer)	1	100-400	0.4 (120 g a.e./ha)

3.2.3.9 Efficacy Summary

A summary of efficacy at rates ranging from 100 g a.e./ha to 198/200 g a.e./ha, and also at 120 g a.e./ha applied as a split dose, for claimed weeds in all trials presented in this dossier is included in Table 3.2.3-17. The data are summarised by weed and application rate irrespective of crop. Data are also presented for each climatic zone individually and across all zones. A summary of all currently approved weeds in the concerned member states for this submission is included in Table 3.2.3-18. A summary of control levels achieved across all crops and zone according to SANCO/10055/2013 is presented in **Błąd! Nie można odnaleźć źródła odwołania.**.

Table 3.2.3-17 Summary of efficacy presented by weed and application rate

Weed EPPO code	Climatic Zone		Rate tested (g a.e./ha)			
			100 g a.e./ha	120 g a.e./ha	60 + 60 g a.e./ha)	198-200 g a.e./ha
AMBEL	South-East	Mean Min-Max No. of trials SD	81.3 (-) 1 -	-	-	-
ANTAR	South-East	Mean Min-Max No. of trials SD	70 (-) 1 -	75 (-) 1 -	-	-
CENCY	Maritime	Mean Min-Max No. of trials SD	-	-	-	100 (-) 1 -
	North-East	Mean Min-Max No. of trials SD	-	-	-	81.25 (-) 1 -
	All zones	Mean Min-Max No. of trials SD	-	-	-	90.625 (81.25-100) 2 -
CIRAR	Maritime	Mean Min-Max No. of trials SD	91.3 (-) 1 -	-	95.74 (88.3-100) 5 4.57	68.8 (-) 1 -
	South-East	Mean Min-Max No. of trials SD	79.75 (67.5-94) 4 11.3	95.1 (88.75-99.8) 6 4.83	-	-
	All zones	Mean Min-Max No. of trials SD	82.06 (67.5-94) 5 11.06	95.1 (88.75-99.8) 6 4.83	95.74 (88.3-100) 5 4.57	-
GALAP	South-East	Mean Min-Max No. of trials SD	52.5 (-) 1 -	12.26 (0-61.3) 5 27.41	-	-
	North-East	Mean Min-Max No. of trials SD	-	-	-	36.25 (-) 1 -
	All zones	Mean Min-Max No. of trials SD	52.5 (-) 1 -	93.3 (0-61.3) 5 27.41	-	36.25 (-) 1 -
HELAN	South-East	Mean Min-Max No. of trials SD	92.9 (88.8-97) 2 -	93 (-) 1 -	-	-
MATCH	South-East	Mean Min-Max No. of trials SD	-	95.5 (-) 1 -	-	-
	Maritime	Mean Min-Max No. of trials SD	-	-	-	100 (-) 1 -
	North-East	Mean Min-Max No. of trials SD	-	-	-	80 (-) 1 -
	All zones	Mean Min-Max No. of trials SD	-	95.5 (-) 1 -	-	90 (80-100) 2 -

Weed EPPO code	Climatic Zone		Rate tested (g a.e./ha)			
			100 g a.e./ha	120 g a.e./ha	60 + 60 g a.e./ha)	198-200 g a.e./ha
MATIN	South-East	Mean Min-Max No. of trials SD	82.5 (-) 1 -	93.3 (85-99) 4 6.42	-	-
	Maritime	Mean Min-Max No. of trials SD	-	-	-	100 (-) 1 -
	All zones	Mean Min-Max No. of trials SD	82.5 (-) 1 -	93.3 (85-99) 4 6.42	-	100 (-) 1 -
PICHI	Maritime	Mean Min-Max No. of trials SD	-	-	-	99.3 (-) 1 -
POLCO	South-East	Mean Min-Max No. of trials SD	-	56.7 (-) 1 -	-	-
	North-East	Mean Min-Max No. of trials SD	-	-	-	71.25 (-) 1 -
	All zones	Mean Min-Max No. of trials SD	-	56.7 (-) 1 -	-	71.25 (-) 1 -
POLPE	South-East	Mean Min-Max No. of trials SD	76.3 (-) 1 -	-	-	-
SONOL	Maritime	Mean Min-Max No. of trials SD	-	-	-	99.5 (-) 1 -

Table 3.2.3-18 Summary of currently approved weeds by country

Country	Sensitivity	Weed EPPO code
Poland	Sensitive weeds	CENCY, MATIN, CIRAR, SOLNI, POLPE, ANTAR, MATCH, GASPA, MEDSA
	Moderately Sensitive weeds	CHEAL
	Medium Hardy weeds	AMARE
	Resistant weeds	GERPU, VIOAR, STEME, PAPRH, GALAP, CAPBP, THLAR, TTTMM
Slovakia	Sensitive weeds	CIRAR, ANTAR, MATSS, MATIN, CHYSE, ERICA, TRFLA, TUSFA, CENCY, HELAN, HELSS, POLAV, POLLA, POLCO, MEDSA, SOLNI, SOLTU, AETCY, DAUCA
	Resistant weeds	LAMSS, CAPBP
Czech Re-public	Sensitive weeds	CIRAR, ANTAR, MATSS, CHYSE, ERICA, TRFLA, TUSFA, CENCY, HELAN, POLCO, MEDSA, AETCY, DAUCA, POLCO, POLSS
	Less Sensitive	POLAV

Table 3.2.3-19 Summary of efficacy levels (SANCO/10055/2013*) by application rate across all trials

Weed EPPO code	Rate tested (g a.e./ha)			
	100-105 g a.e./ha	120 g a.e./ha	60 + 60 g a.e./ha	198-200 g a.e./ha
AMBEL	MS	-	-	-
ANTAR	MS	MS	-	-
CENCY	-	-	-	S
CIRAR	MS	HS	HS	-
GALAP	MT	T	-	T
HELAN	S	S	-	-
MATCH	-	HS	-	S
MATIN	MS	S	-	HS
PICHI	-	-	-	HS
POLCO	-	MT	-	MS
POLPE	MS	-	-	-
SONOL	-	-	-	HS

***HS – Highly Susceptible, S – Susceptible, MS – Moderately Susceptible, MT – Moderately Tolerant, T – Tolerant**

Comments of zRMS:	To support reduced dose rates as a result of new regulatory endpoints, the applicant presented 26 bridging data trials of other registered clopyralid formulations to demonstrate their equivalence and use them as support of EF-243. The presented data demonstrate the comparability of clopyralid EF-243 with other currently registered formulations. It is, therefore, acceptable to use these data to support the dose rate reductions proposed in this renewal submission. **Cereals** The applicant, to comply with new risk assessment endpoints for this re-registration the application rate of EF-243 on cereals in South East EPPO zone has been reduced within the currently approved rate range. For evaluation of efficacy at a dose rate of 0.3 l/ha (90 g a.e./ha), reference can be made to evaluation and experience with the product in the past. Therefore efficacy does not need to be evaluated again. If no resistance has developed, it can be expected that the efficacy of the product is unchanged. This approach is acceptable and does not require additional data. Changing crop GS in all concerned cMS at an application from BBCH 14-39 to BBCH 30-39 is an acceptable approach. **Sugar beet** In the GAP on sugar beet, two types of uses are claimed a single application and a split application at 2x60 g a.e./ha. The applicant has explained that the split application is due to the new risk assessment endpoints. Within the five trials, data are presented from a split dose application of clopyralid where the test treatments were applied between BBCH 12 and BBCH 49 at 60 g a.e./ha. The applicant confirmed the effectiveness of the split dose rate only for the control of *Cirsium arvense*. Although *Cirsium arvense* is one of the major weeds in the sugar beet crop, the effectiveness of the new use should be confirmed on a broader spectrum of major weeds adequately to the current national label of the Member States concerned. Furthermore, these trials were conducted in France belonging to the Maritime EPPO zone. In that case, the trials submitted are not considered representative of the requested member states in the South East EPPO zone or the North East EPPO zone.

	Maize Within collected data from five trials, Clopyralid applied once at 100 g a.e./ha provided good (>85%) control of the annual broadleaved weed HELAN. Whereas AMBEL (81,3%), ANTAR (70%), MATIN (82,5), POLPE (76,3%) and CIRAR (82,1%) were only partially controlled. Based on these data, it can be concluded that moderate control of weeds can be achieved at 102 g clopyralid/ha. Therefore, the concerned Member State Slovakia is kindly asked to decide themselves whether to accept provided data or not. **Grass for seeds and lawn uses** Since grass for seeds and lawn uses are classified as minor uses it is not a requirement that specific bridging trials are conducted in these crops. The concerned Czech Republic and Slovakia are kindly asked to decide themselves whether to accept the applicant's proposal or not. **General conclusion** Changing the application window is an acceptable approach for all uses concerned.

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

EF-243 (300 g/L clopyralid) is intended for use as a systemic selective herbicide for the post-emergence control of broad-leaved weed species in a range of broad-leaved crops.

Table 3.1-1 of this document includes the table of intended uses for EF-243.

Mode of action

The active substance clopyralid belongs to the chemical family of pyridine-carboxylates classified as Group 4; auxin mimics/synthetic auxins according to HRAC (Herbicide Resistance Action Committee) and WSSA (Weed Science Society of America). The legacy HRAC classification is Group O, synthetic auxins.

Further Pyridine-carboxylate herbicides and other chemical families belonging to Group 4, but with distinctly different chemical structures are shown below in Table 3.3-1.

Table 3.3-1: Auxin mimic (Group 4 *(O)*) herbicides and chemical families

Chemical Family	Active substance
Arylpicolinate	Florpyrauxifen-benzyl
	Haluxifen
Benzoates	Chloramben
	Dicamba
	TBA
Other	Benazolin-ethyl
Phenoxy-carboxylates	2,4,5-T
	2,4-D
	2,4-DB
	Clomeprop
	Dichlorprop
	Dichlorprop-P
	Fenoprop
	MCPA
	MCPB
	Mecoprop
Phenyl carboxylates	Chlorfenac=fenac
	Chlorfenprop
Pyridine-carboxylate	Aminopyralid
	Clopyralid
	Picloram
Pyridyloxy-carboxylates	Fluroxypyr
	Triclopyr
Pyrimidine-carboxylates	Aminocyclopyrachlor
Quinoline carboxylates	Quinclorac
	Quinmerac

Source: HRAC[8] and Weedscience[9]

Group 4 *(O)* herbicides act by mimicking the plant growth hormone auxin indole-3-acetic acid (IAA) due to structural similarities. Synthetic auxins bind to receptor sites in plant cells in the place of natural auxins. Due to the higher stability and greater persistence of synthetic auxins compared to the natural coun-

terpart, treatment causes an 'auxin overdose' that leads to uncontrolled and disorganized plant growth and eventually plant death[6].

Clopyralid is systemic and enter plants through foliage and roots with translocation through xylem and phloem tissues to all growing parts of the plant. The visible effects of treatment with clopyralid include inhibited root and shoot growth, thickened and curved shoots and leaves, cupping and crinkling of leaves, cracked stems and uncontrolled proliferated growth[7]. Plant death can occur within 1-4 weeks, depending on the plant species[8].

The mode of action of clopyralid is believed to involve cell wall acidification, which results in cell elongation. Low concentrations of clopyralid can stimulate RNA, DNA, and protein synthesis leading to uncontrolled cell division and disorganized growth, and ultimately, vascular tissue destruction. High concentrations of clopyralid can inhibit cell division and growth. (Weed Control Methods Handbook, The Nature Conservancy, Tu & *al*.).

IAA and 2,4-D act via a ubiquitination mechanism that has been identified and well described[9]. This mechanism involves the stimulation of ubiquitination through a ubiquitin ligase complex and subsequent degradation of specific transcriptional regulators that include AXR2 (IAA7), AXR3 (IAA17), and AXR5 (IAA1). Their degradation results in derepression of auxin-regulated genes that in turn leads to the physiological and morphological events associated with auxin action. However, while picolinate auxins (such as clopyralid) appear to act in a similar manner to IAA and 2,4-D, there is also evidence from a study investigating Arabidopsis mutants that there are at least two genetic loci conferring picolinate auxin-specific resistance. Mutations at these loci confer picolinate selectivity via components identified as part of the SCF ubiquitin ligase machinery and F-box protein receptors[10]. This would explain a recorded case of resistance to picloram and clopyralid, but not 2,4-D, in *Centaurea solstitialis*[11]. There is also evidence of a dominant non-selective mutation conferring resistance to both picloram and 2,4-D in *Sinapsis arvensis* illustrating that the similarity of the target sites[12].

The general lack of resistance in the field could be due to the redundancy among auxin receptors and / or fitness penalties resulting from mutations conferring resistance.

Mechanism of resistance

The exact mechanisms of resistance to Group 4 *(O)* herbicides are not fully understood, but it is suggested that both target site and non-target site mechanisms could cause the development of resistance to Group 4 *(O)* herbicides.

Although there have been no recorded cases of field resistance to Group 4 herbicides caused by mutations to the core signalling target sites in plant cells, mutation of other proteins associated with auxin signalling and transport are thought to be the cause of resistance[7]. Auxin receptor proteins TIR1 and AFB1-6 are considered the most common in plant cells[14]; there is very little variation in the sequencing of these pro-

[6] Cox, C (1998) Herbicide Factsheet: Clopyralid, Journal of Pesticide Reform, Winter 1998, Vol.18(4), https://d3n8a8pro7vhmx.cloudfront.net/ncap/pages/26/attachments/original/1428423336/clopyralid.pdf?1428423336
[7] Gilbert, E.J., Barth, J., Favoino, E., Rynk, R. (2009) An investigation of clopyralid and aminopyralid in composting systems, The Waste and Resources Action Programme (WRAP), Project OAV031-002, http://www.wrap.org.uk/sites/files/wrap/Clopyralid%20Report.pdf
[8] Product Safety Assessment: Clopyralid, The Dow Chemical Company (2010) https://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_07e6/0901b803807e65d8.pdf, Accessed 20th August 2020.
[9] Walsh, T. *et al*. 2006. Mutations in an Auxin Receptor Homolog AFB5 and in SGT1b confer resistance to synthetic picolinate auxins and not to 2,4-dichlorophenoxyacetic acid or indole-3-acetic acid in Arabidopsis[W]. Plant Physiology 142: 542-552
[10] Walsh, T. *et al*. 2006. Mutations in an Auxin Receptor Homolog AFB5 and in SGT1b confer resistance to synthetic picolinate auxins and not to 2,4-dichlorophenoxyacetic acid or indole-3-acetic acid in Arabidopsis[W]. Plant Physiology 142: 542-552
[11] Fuerst, E.P. *et al*. 1996. Physiological characterisation of picloram resistance in yellow starthistle. Pestic Biochem Physiol 56: 149–161
[12] Jugulam, M., McLean, M.D., Hall, J.C. 2005. Inheritance of picloram and 2,4-D resistance in wild mustard (Brassica kaber). Weed Sci 53: 417–423

teins and a high level of redundancy, meaning that one target site mutation can be compensated by the activity of another receptor site. There is also a high level of sequence conservancy in these proteins meaning some mutations would compromise plant health and therefore would not be passed on to successive generations and cause further resistance. Some differences in selectivity to Group 4 *(O)* herbicides have been identified between different proteins; AFB5 proteins are the primary site for pyridine-carboxylate picloram, and it is theorised that while a mutation of this protein could cause resistance to picloram, it would not affect phenoxy-carboxylate 2,4-D.

Both target site and non-target site resistance is thought to be associated with transport system proteins. A mutation of the AUX1 protein target site has been associated with resistance to phenoxy-carboxylate 2,4-D[15]. However, it is thought that such a mutation or reduction in AUX1 abundance will not affect all Group 4 *(O)* herbicides, as their structural scaffolds differ. Mutation to efflux proteins such as PIN and ABCB could enhance extrusion of herbicide molecules out of plant cells, but current biochemical knowledge limits further study. Resistance to 2,4-D has been associated with activity of the ABCB protein, but is thought that reduced transport, and not increased efflux was the cause of resistance[16].

Non-target site resistance caused by enhanced metabolism is another possible cause of resistance development to Group 4 *(O)* herbicides. Enzymes such as GH3, glucosyltransferases and GST3 are associated with conjugating with natural auxin IAA to deactivate it. These enzymes have the potential to also deactivate synthetic auxins such as Group 4*(O)* herbicides; however, the different structural scaffolds of each chemical family mean that resistance to all Group 4 *(O)* herbicides is unlikely to occur.

The potential mechanism of resistance to Group 4 *(O)* herbicides have been investigated in studies[7] testing resistance in several common and economically important weed species (weeds which are well established, spreading rapidly and/or require integrated weed control). These are discussed as follows:

Papaver rhoeas (Corn poppy)

Populations resistant to to phenoxy-carboxylates 2,4-D and MCPA have been observed in France, Greece, Italy and Spain between 1993 and 2016. A lack of translocation of the herbicide in resistant plants and presence of 2,4-D metabolites (indicating enhanced metabolism and degradation) is thought to be causes of resistance, but it is not known which is the primary cause.

Kochia scoparia (Kochia)

Populations resistant to benzoate dicamba and pyridyloxy-carboxylate fluroxypyr have been observed between 1995 and 2014 in the United States, and between 2015 and 2017 in Canada. Dicamba resistance is thought to be due selection pressure and a dominant or semi-dominant trait which reduced translocation of dicamba. The mechanism of resistance to fluroxypyr is not known.

Lactuca serriola (Prickly lettuce)

Resistance in this weed is particularly a problem in the Pacific Northwest of the United States were almost 80% of wheat is treated at least once each season with Group 4 *(O)* herbicides. A study found that plants resistant to phenoxy-carboxylate 2,4-D were initially injured after 2-3 weeks, but then began to regrow. The same biotype was also found to be resistant to phenoxy-carboxylate MCPA and benzoate dicamba. Resistance to 2,4-D is thought to be due to an altered auxin signalling response which could have reduced 2,4-D uptake and translocation; no differences were found in metabolism between susceptible and resistant biotypes.

Raphanum raphanistrum (Wild radish/Runch)

There have been many cases of resistance observed in Australia since 1999, partly related to increased use of Group 4 *(O)* herbicides such as benzoate dicamba, and phenoxy-carboxylates 2,4-D and MCPA in response to widespread resistance to ALS-inhibiting herbicides (Group 2 *(B)*). 2,4-D resistance was found to be caused by restricted translocation thought to be caused by loss of function of the target site ATP-

binding cassette type B protein. MCPA resistance is thought to be due to an upregulation of defence genes; this is considered to be a separate mechanism to the 2,4-D resistance, as a study showed 2,4-D was equally translocated out of cells in both resistant and non-resistant populations. Currently there is no indication of enhanced metabolism mechanisms of resistance.

Evidence of resistance

According to The International Herbicide-Resistant Weed Database[13], there are no cases of resistance to pyridine-carboxylate auxins (clopyralid, picloram or aminopyralid) among weed populations in Europe.

Outside of Europe, there have only been 3 cases of resistance to clopyralid.

Globally, there are 79 cases of resistance to Group 4 *(O)* herbicides, predominantly phenoxy-carboxylates 2,4-D, MCPA and benzoate dicamba.

A summary of all cases of resistance in Europe, and those to clopyralid are shown in Table 3.3-2 and Table 3.3-3.

Table 3.3-2: Reported cases of Resistance to Group 4 *(O)* herbicides in Europe

Year	Weed species	Country	Mode of action (HRAC current/legacy code)	Active substance(s)	Situation
1979	*Cirsium arvense*	Sweden	Synthetic Auxins (4 *(O)*)	MCPA	Cropland
1985	*Cirsium arvense*	Hungary	Synthetic Auxins (4 *(O)*)	MCPA, 2,4-D	Pastures
1985	*Stellaria media*	United Kingdom	Synthetic Auxins (4 *(O)*)	mecoprop	Cereals, Wheat
1993	*Papaver rhoeas*	Spain	ALS inhibitors (2 *(B)*), Synthetic Auxins (4 *(O)*)	tribenuron-methyl, 2,4-D	Cereals, Wheat
1998	*Papaver rhoeas*	Italy	ALS inhibitors (2 *(B)*), Synthetic Auxins (4 *(O)*)	tribenuron-methyl, 2,4-D, iodosulfuron-methyl-sodium	Wheat
1998	*Papaver rhoeas*	Italy	Synthetic Auxins (4 *(O)*)	2,4-D	Wheat
2002	*Papaver rhoeas*	Greece	ALS inhibitors (2 *(B)*), Synthetic Auxins (4 *(O)*)	2,4-D, iodosulfuron-methyl-sodium, mesosulfuron-methyl	Wheat
2012	*Centaurea cyanus*	Poland	Synthetic Auxins (4 *(O)*)	dicamba	Winter wheat
2015	*Papaver rhoeas*	France	Synthetic Auxins (4 *(O)*)	2,4-D	Wheat
2016	*Papaver rhoeas*	France	ALS inhibitors (2 *(B)*), Synthetic Auxins (4 *(O)*)	metsulfuron-methyl, MCPA, 2,4-D, iodosulfuron-methyl-sodium, mesosulfuron-methyl	Cereals

Source: Weedscience.org[17]

Table 3.3-3: Reported cases of resistance to Clopyralid (globally)

Year	Weed species	Country	Mode of action (HRAC current/legacy code)	Active substance(s)	Situation
1999	*Soliva sessilis*	New Zealand	Synthetic Auxins (4 *(O)*)	clopyralid, picloram, triclopyr	Golf courses, Turf
2005	*Chenopodium album*	New Zealand	Synthetic Auxins (4 *(O)*)	dicamba, clopyralid, amino-pyralid	Corn (maize)
2013	*Centaurea stoebe ssp. micranthos*	Canada	Synthetic Auxins (4 *(O)*)	clopyralid, picloram	Rangeland

Source: Weedscience.org[17]

The 3 cases of resistance specific to clopyralid all occurred in New Zealand (2) and Canada (1). These occurred in grass (turf and managed rangeland) and maize; and were of biotypes *Soliva sessilis* and

[13] Heap, I. The International Herbicide-Resistant Weed Database, Online, http://www.weedscience.org/Pages/filter.aspx, Accessed 25th August 2020

Centaurea stroebe subsp. micranthos, both belonging to the Asteraceae family and *Chenopodium album*, belonging to the Amaranthaceae family.

Cross-resistance

There is precedent for the appearance of cross-resistance between members of the Synthetic Auxin herbicides; in Spain, resistant populations of *Papaver rhoeas* can contain biotypes cross-resistant to other phenoxy-carboxylates, benzoates or pyridine-carboxylates[14]. It should be assumed that cross-resistance could arise between pyridine carboxylates and between members of the Group 4 *(O) Chenopodium album* herbicide family.

The four recorded cases of *Papaver rhoeas* resistance to both 2,4-D and ALS-inhibitors in Europe (Table 3.3-2) was investigated and found to be the result of multiple resistance, not cross-resistance, in the plant samples from all four countries (Greece, Italy, France and Spain)[15]. Cross-resistance between clopyralid and members of other herbicide mode of action groups (other than Group 4 *(O)*) has not been reported in Europe.

Outside of Europe, cross-resistance between Group 4 *(O)* herbicides and ALS-inhibitors (2 *(B)*), glyphosate, PSII-inhibitors (5 *(C2)*), PDS-inhibitors (12 *(F1)*), PPO-inhibitors (*14 (E)*) and PSI electron diverters (22 *(D)*) has been reported. Among these instances are actives that are no longer approved in the EU (quinclorac, paraquat) or are related to the culture of genetically resistant / tolerant soybean or maize crops (dicamba, 2,4-D and glyphosate) where the herbicide may have been be over-used.

Three cases of resistance specifically to clopyralid show cross-resistance within Group 4 *(O)* (between pyridine-carboxylates clopyralid, aminopyralid and picloram, pyridyloxy-carboxylate triclopyr, and benzoate dicamba), and all are located outside of Europe (New Zealand and Canada, Table 3.3-3).

Globally, there have been no recorded cases of cross-resistance to other modes of action.

Sensitivity data

No sensitivity data have been generated for this BAD. Clopyralid and other pyridine-carboxylates have been approved for use for up~60 years (over 40 years for clopyralid), and therefore it is very difficult to determine baseline sensitivity.

Use pattern

The GAP, shown in Table 3.1-1, gives details of all intended uses for EF-243.

Treatment with EF-243 is limited to one application or split application per season for all crops, and at a timing when the weed targets are actively growing in a vegetative phase for optimal control. In some instances, applications are limited to once every 2 or 3 years.

Resistance risk assessment of unrestricted use pattern

Inherent risk – active substance

While synthetic auxins as a group are classified as medium risk, clopyralid can considered to be at **low** risk of causing resistance among weed populations based on the evidence that there are no confirmed cases of resistance among weed populations in Europe. The majority of cases of Group 4 *(O)* resistance relate to 2,4-D, MCPA and dicamba[21].

[14] Rey-Caballero, J., *et al*. 2016. Unravelling the resistance mechanisms to 2,4-D (2,4-dichlorophenoxyacetic acid) in corn poppy (*Papaver rhoeas*). Pestic Biochem Physiol 133:67–72

[15] Kati, V. *et al*. 2019. Multiple resistance of *Papaver rhoeas* L. to 2,4-D and acetolactate synthase inhibitors in four European countries. Weed Research 59, 367–376

Agronomic risk

Of the many agronomic practices and/or cropping factors with potential to enhance the resistance development, chemical usage is the most important. The regular and repeated use of the same active substance, those with a similar mode of action, and monocultures or rotations that rely on the same herbicide mode of action lead to resistance.

Currently, it is recommended to consider the emergence and composition of the weed population to determine the optimum application timing and rate of an herbicide. The use of herbicides with different modes of action in tank-mixture or in sequence as part of a wider spray programme should also be considered where each herbicide in the mixture targets the same weed or to extend the efficacy on weeds such as *Chenopodium album* or other weed species known to be less susceptible against clopyralid. A regular crop rotation is also necessary to allow the use of different chemicals with various modes of action, applied at different timings. Finally, non-chemical control methods need to be incorporated as part of an overall Integrated Pest Management (IPM) / Integrated Weed Management (IWM) strategy, using cultivation, stubble burning, stale seed beds, cover crops, delayed drilling and increased crop competition alongside chemical control.

Agronomic risk is dependent on growers implementing such practices, and on following all label recommendations. Based on the assumption that Good Agricultural Practice and the guidelines provided by HRAC are followed, it is estimated that there is a **low** risk associated with agronomic factors in this case, according to Moss *et al.*(2019)[16].

Inherent risk – target weeds

The most important factors to consider in terms of the inherent resistance of weed species to herbicides includes the following:

- Propagation method – annual weeds develop resistance more rapidly compared to predominantly vegetatively propagated perennials
- Fecundity - high fecundity results in a greater chance of producing a resistant biotype
- Genetic diversity – a genetically diverse species has a greater chance of containing resistance genes
- Seed persistence - more persistent seeds will inhabit a seedbank that then poses a longer-term resistance problem

Based on these factors, and the number of resistance cases observed, the following broad-leaved weed species have been given a medium or high inherent resistance rating in Moss *et al.*[16] in the EPPO region: Medium – *Conyza* species (ERISS), *Matricaria* species (MATSS), *Senecio vulgaris* and *Stellaria media* (STEME); High - *Amaranthus* species (AMASS), *Chenopodium* species (CHESS) and *Papaver rhoeas* (PAPRH). All other weed species are considered to have an inherent low risk of resistance.

The most common target species for EF-243 are thistles [*Cirsium* and *Sonchus spp.*] (low risk), and *Matricaria* species and *Senecio vulgaris* (medium risk).

Overall risk of resistance

Using the proposed matrix for assessing resistance risk but considering clopyralid to be of **low inherent risk** (Table 3.3-4), it is considered that the overall risk of resistance in an 'unmodified risk' scenario is low (<2) for all low and medium risk weed species, and there is and overall medium risk (3) for high risk weed species.

In a 'partially modified' scenario (use of the herbicide under consideration with other herbicides with different MOA, either in mixture, sequence or alternation), the overall risk of resistance for all weed species is **low (<2)**.

[16] Moss, S., Ulber, L., den Hoed, I. 2019. A herbicide resistance matrix. Crop Protection 115; 13-19.

Table 3.3-4: Resistance risk matrix, according to Moss *et al*. (2019)[16]

			WEED RISK (by species or genera, see Table 2)			
			Low	Medium	High	
			1	2	3	
			All other weed species	(examples) AVESS ECHSS ERISS STEME	(examples) ALOMY AMASS LOLSS PAPRH	
HERBICIDE RISK (by HRAC MoA group, see Table 1)	High (A, B, C1)	3	3	6	9	Unmodified Risk (x1)
			2	4	6	Partially modified (x0.67)
			1	2	3	IWM (x0.33)
	Medium (C2, D, G, O,)	2	2	4	6	Unmodified Risk (x1)
			1.3	2.7	4	Partially modified (x0.67)
			0.7	1.3	2	IWM (x0.33)
	Low (C3, E, F1, F3, H, K1, K3, L, N, Z + very low MOA)	1	1	2	3	Unmodified Risk (x1)
			0.7	1.3	2	Partially modified (x0.67)
			0.3	0.7	1	IWM (x0.33)

Overall score	Herbicide resistance risk
9	Very high risk
6	High risk
3 – 4	Moderate risk
0.3 – 2.7	Low risk

Acceptability of the resistance risk

When used with herbicides of other modes of action as mixtures, in sequences of alternation, the overall risk of resistance to clopyralid is **low** (<2.0), and therefore acceptable for all broad-leaved weed targets.

If there is no modification of the risk and use of only one herbicide mode of action, there is a moderate risk of resistance arising (3) for high risk weed species such as AMASS that may require some resistance management.

Management strategy

The risk of resistance arising through the use of EF-243 is mitigated by label recommendations, including only one application per season, and to be applied at an active stage of weed growth for optimal control.
The current guidelines and recommendations for best practice from HRAC, specifically related to Synthetic Auxin (Group 4 *(O)*) herbicides[13] are as follows:

a) Rotation or mixtures of herbicide mechanisms of action

b) Using at least two herbicides a year from different herbicide mechanisms of action that are still effective on the particular population of the target weed. This may include use of pre-emergence herbicides.

c) Using cultural/mechanical weed control methods including shallow tillage in the spring, crop rotation, and cleaning equipment.

d) Using full herbicide rates applied at the correct weed size and to carefully monitor results.

e) Scouting fields after herbicide application and controlling escapes.

Additionally, HRAC also recommends the following general guidance for use of all herbicides:

f) Consider all chemical control options before planting, in-crop and after harvest.

g) Know the weeds in their fields and nearby non-crop areas and tailor their weed control program to weed densities and economic thresholds.

h) Maintain detailed field records to confirm cropping and herbicide history.

Implementation of the management strategy

Statements relating to resistance risks and best practice management strategies will be included on the proposed label for EF-243.

Following HRAC guidelines and recommendations and prompting the user to follow the specific preventive measures indicated by the label, constitutes an effective implementation of the management strategy.

Monitoring, reporting and reaction to changes in performance

The Applicant is committed to responding to any reports of changes in performance levels following the use of EF-243 in the field. In the event that the Applicant is made aware of a reduction in the performance of EF-243, seed samples will be collected from the treated area and tested for sensitivity using published methodology.

If resistance is confirmed, the Applicant will respond appropriately by informing the relevant authorities and communicating with growers, following the advice of the relevant national authorities and HRAC in cases of confirmed herbicide resistance; and will continue to monitor performance and amend the resistance management strategy if necessary.

Comments of zRMS:	A resistance risk analysis was performed following EPPO guideline PP1/213(2). The applicant provided a comprehensive overview of the current resistance status and the risk of resistance developing with herbicides with a synthetic auxin mode of action. The active substance clopyralid belongs to the chemical family of pyridine-carboxylates classified as Group 4; auxin mimics/synthetic auxins according to HRAC and WSSA. No cases of clopyralid resistance have been reported in Europe. Outside of Europe, there have only been 3 cases (Canada and New Zealand) of resistance to clopyralid. The applicant concluded that the inherent risk of resistance is low but cannot be excluded. The zRMS has concluded that the agronomic risk is also low since there a wide range of control measures for all the major target weeds including various modes of action. Overall, it is expected that cMS will implement latest HRAC recommendations unless their national guidelines indicate more restrictive resistance management measures are required.

3.4 Adverse effects on treated crops (KCP 6.4)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Formulations containing clopyralid have a good safety record having been used successfully by commercial growers for many years.

No specific crop selectivity trials have been conducted; as all rate changes associated with this submission equate to a decrease in the amount of active substance applied, the Applicant considers that no new safety data are required to support this dossier and that previous authorisations are used as a reference source for specific selectivity data.

Assessments for symptoms of phytotoxicity, and other adverse effects on crop growth and development, have been carried out in all 39 efficacy trials presented in this document (comparability and efficacy) which have been conducted between 1998 and 2018 in Winter wheat (8), maize (15 trials), Winter oilseed rape (2 trials), Spring oilseed rape (1 trial) and sugar beet (13 trials) in order to demonstrate the crop safety of EF-243.

Information on efficacy trials submitted are included in the BAD in section **Błąd! Nie można odnaleźć źródła odwołania.**. Trial site and application details of all submitted efficacy trials are given in Appendix 3 of the BAD.

A summary of any symptoms of phytotoxicity observed in the efficacy trials presented in this document is provided in this section.

3.4.1.1 Summary and evaluation of trials results

An overall summary table with details of all submitted trials and any observed phytotoxicity symptoms is provided in Table 3.4-1, detailed tables containing the raw data are provided in Appendix 5 of the Biological Assessment Dossier.

Winter and Durum wheat (TRZAW, TRZDU)

A total of 7 trials carried out in the South-East climatic zone between 1998 and 2018 have generated data on the efficacy of a single application of clopyralid at 120 g a.e./ha to support a rate reduction against broad-leaved weed species in grass seed crops (both < and > one year old).

An additional efficacy trial carried out in Durum wheat in the Mediterranean climatic zone in 2007 is presented to confirm the comparable efficacy of clopyralid fomulations in maize.

There were no symptoms of phytotoxicity, or any other adverse effects on crop growth and development, in any of the 7 efficacy trials conducted in winter wheat or in the single efficacy trial conducted in Durum wheat to demonstrate comparability of clopyralid formulations. According to the extrapolation table for the crop safety of herbicides – grass seed crops (11/16633) it is possible to extrapolate crop safety from wheat to grass seed crops as relevant to the claimed use in grass seed crops.

Maize (ZEAMX)

A total of 5 trials carried out in the Maritime and South-East climatic zones in 1999 or 2012 have generated data on the efficacy of a single application of clopyralid at 100 g a.e./ha to support a rate reduction against broad-leaved weed species in maize.

There were no symptoms of phytotoxicity, or any other adverse effects on crop growth and development, in any of the 5 efficacy trials conducted in maize.

An additional 10 efficacy trials carried out in the Maritime and South-East climatic zones in 2008 and 2009 are presented to confirm the comparable efficacy of clopyralid fomulations in maize. There were no symptoms of phytotoxicity, or any other adverse effects on crop growth and development, in any of the 10 efficacy trials conducted to demonstrate comparability of clopyralid formulations in maize.

Winter oilseed rape (BRSNW)

A total of 2 trials carried out in the Maritime climatic zone in 2012 have generated data on the efficacy of a single application of clopyralid at 200 g a.e./ha to support a rate reduction against broad-leaved weed species in Lawn (NNNWG).

No symptoms of phytotoxicity, or any other adverse effects on crop growth and development, have been observed in either of the trials.

Spring oilseed rape (BRSNS)

One trial carried out in the North-East climatic zone in 2012 has generated data on the efficacy of a single application of clopyralid at 200 g a.e./ha to support a rate reduction against broad-leaved weed species in Lawn (NNNWG).

No symptoms of phytotoxicity, or any other adverse effects on crop growth and development, have been observed in this trial.

Sugar beet (BEAVA)

A total of 6 trials carried out between 2007 and 2015 have generated data on the efficacy of clopyralid at as a split application at 60 g a.e./ha, to support rate changes against broad-leaved weed species in sugar beet in the Czech Republic, Slovakia and Poland.

An additional 7 efficacy trials carried out in the Maritime and South-East climatic zones in 2010 and 2011 are presented to confirm the comparable efficacy of clopyralid fomulations in sugar beet.

There were no symptoms of phytotoxicity, or any other adverse effects on crop growth and development, in any of the 5 efficacy trials conducted in sugar beet or any of the 10 efficacy trials conducted to demonstrate comparability of clopyralid formulations in sugar beet.

Overall conclusions

Data from the 39 trials efficacy trials submitted for this dossier, demonstrate that the tested clopyralid formulations are crop safe in grass seed crops, maize, Winter and Spring oilseed rape and sugar beet.

Table 3.4-1: Phytotoxicity of product

Number of trials with…		Selectivity trials (0 trials)				Efficacy trials (39 trials)	
		Test product		Standard 1		Test product	Standard 1
		N	2N (or other)	N	2N (or other)	N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	-	-	-	-	39	39
	>5% to 10%	-	-	-	-	0	0
	>10% to 15%	-	-	-	-	0	0
	>15 %	-	-	-	-	0	0
Level of symptoms at the last assessments	0% to 5%	-	-	-	-	39	39
	>5% to 10%	-	-	-	-	0	0
	>10% to 15%	-	-	-	-	0	0
	>15 %	-	-	-	-	0	0

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

No new data have been generated. Any rate changes associated with this submission equate to a decrease in the amount of active substance applied and the Applicant considers that there will be no additional increase in risk to crop yield as a result of product renewal.

The Applicant requests that previously evaluated and accepted data and information are considered as fully supportive of the requirements for product renewal.

Comments of zRMS:	The case presented by the applicant is acceptable and no further data are required.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

No new data have been generated. Any rate changes associated with this submission equate to a decrease in the amount of active substance applied and the Applicant considers that there will be no additional increase in risk to yield quality as a result of product renewal.

The Applicant requests that previously evaluated and accepted data and information are considered as fully supportive of the requirements for product renewal.

Comments of zRMS:	The case presented by the applicant is acceptable and no further data are required.

3.4.4 Effects on transformation processes (KCP 6.4.4)

As an herbicide, it is reasonable to anticipate that there will be no adverse effects of the active substance clopyralid on biological agents, such as yeasts, that are used in transformation processes.

No new information is provided; the Applicant refers to previous evaluated submissions that support the current authorisations.

Comments of zRMS:	The case presented by the applicant is acceptable and no further data are required.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

As any rate changes associated with this submission equate to a decrease in the amount of active substance applied, the Applicant considers that there will be no increase in risk to plants or plant products to be used for propagation as a result of product renewal and no new data are required to support this dossier. The Applicant refers to previous evaluated submissions that support the current authorisations.

Comments of zRMS:	The case presented by the applicant is acceptable and no further data are required.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

As any rate changes associated with this submission equate to a decrease in the amount of active substance applied, the Applicant considers that there will be no increase in risk for succeeding or replacement crops as a result of product renewal and no new biology/field data are required to support this dossier.
For the clopyralid residue management in succeeding crops below sentence is valid for EF-243.

For residue management in crop ratation*: no mitigation measures are required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PBI is supported. It is recommended that sugar canes not be planted for 125 days after application of EF-243.*

Thus, to current label recommendations in a normal crop rotation situation and especially in case of crop failure scenario, following clopyralid residue management in succeeding crops following sentence should be added:

Clopyralid products can be applied in the following crops in normal crop rotation situation.
In case of a crop failure situation after spring application of EF-243 an interval of 30 days must be respected before growing spring cereals, beets, maize, spring oilseed rape and Brassica vegetables. Do not growth susceptible crops to clopyralid (e.g. potatoes, legumes, sunflower, etc.).
For residue management*: All crops can be sown or transplanted at least 125 days after an application of EF-243.*
In case a succeeding crop has to be seeded or transplanted less than 125 days after EF-243 application, do not re-apply any clopyralid based products to this succeeding crop.

Thus, to current label recommendations in a normal crop rotation situation and especially in case of crop failure scenario, following clopyralid residue management in succeeding crops following sentence should be added:

Clopyralid products can also be applied in the following crops in normal crop rotation situation.
In case of a crop failure situation after spring application of EF-243:
Any clopyralid containing products should not be applied.

Comments of zRMS:	The case presented by the applicant is acceptable and no further data are required.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

As any rate changes associated with this submission equate to a decrease in the amount of active substance applied, the Applicant considers that there will be no increase in risk for succeeding or replacement crops as a result of product renewal and no new data are required to support this dossier. The Applicant therefore refers to previous evaluated submissions that support the current authorisations.

Comments of zRMS:	The case presented by the applicant is acceptable and no further data are required.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

3.6 Other/special studies

No other/special studies have been carried out.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

All trials presented in this dossier were carried out by testing facilities officially recognised as competent to carry out efficacy testing in accordance with the requirements of Directive 93/71/EEC and according to the principles of GEP, with a few exceptions:

- Two trials conducted by UKSUP, an Official Testing Institute, in 2011
- One trial carried out by NTSZ, Hungary, an Official Testing Institute in 2003.
- One trial conducted by Elanco Hellas, in 2007.
- One trial carried out by Dow AgroScience Hungary in 1998.

For all trials conducted according to GEP, links to the relevant certificates or the certificate are provided below.

Organisation	Town	Country	Valid From	Valid To	Link
AGROPASS Hungaria Kft	Gyor	Hungary	28-Jan-16	28-Jan-18	1d693a0b730
Dow AgroSciences S.A.	Sophia Antipolis CEDEX	France	06-Feb-04	05-Feb-09	1d693a0b673
Staphyt Sp. z o.o.	Poznan	Poland	01-Jan-12	31-Dec-19	1d693a0b620
Agrartest GmbH	Panrod	Germany	16-Dec-05	15-Dec-10	1d693a0b01a
Staphyt (France)	Inchy en Artois	France	14-Jun-16	13-Jun-21	1d693a0b477
Zemedelsky vyzkumny ustav Kromeriz, s.r.o.	Kromeriz	Czech Republic	21-Mar-06	28-Mar-10	1d693a0b40f
Fejer Megyei Mezogaz-dasagi Szakigazgatasi Hivatal Noveny- es Talajvedelmi Igazga-tosag Karosito Diag-nosztikai Laboratoriuma	Velence	Hungary	02-Jul-07	02-Jul-09	1d693a0b395

Organisation	Town	Country	Valid From	Valid To	Link
Zemedelska zkusebni stanice Kujavy, s.r.o.	Kujavy	Czech Republic	14-Apr-09	14-Apr-16	1d693a0ad77
Dow AgroSciences S.A.	Sophia Antipolis	France	25-Oct-15	25-Oct-18	1d693a0b344
Landwirtschaftskammer Niedersachsen - Pflanzenschutzamt	Hannover	Germany	05-Mar-06	31-Dec-00	1d693a0b200
Landesamt fur Landliche Entwicklung, Landwirtschaft und Flurneuordnung	Frankfurt (Oder)	Germany	07-Feb-05	31-Dec-00	1d693a0b2e8
Staphyt (France)	Inchy en Artois	France	31-Jan-06	31-Dec-00	1d693a0b239
STAPHYT GmbH	Blaufelden	Germany	13-Apr-10	12-Apr-15	1d693a0b1be
Agro-Check Dr. Teresiak & Erdmann GbR-Landwirtschaftliche Forschung, Entwicklung undBeratung	Lenzke	Germany	24-Nov-03	24-Mar-09	1d693a0b147
Dow AgroSciences S.A.	Mougins	France	25-Oct-10	25-Oct-15	1d693a0b122
Syntech Research France	La Chapelle de Guinchay	France	11-Oct-02	10-Oct-07	1d693a0afe8
Gemerprodukt Valice ovocinarsko-vinohradnicke druzstvo	Rimavska Sobota	Slovakia	15-Feb-11	15-Feb-16	1d693a0afe3
Zemedelsky vyzkumny ustav Kromeriz, s.r.o.	Kromeriz	Czech Republic	29-Mar-10	29-Mar-15	1d693a0afd5
Syntech Research France	La Chapelle de Guinchay	France	30-Oct-09	30-Oct-14	1d693a0adf1
Staphyt (France)	Inchy-en-Artois	France	15-Jun-11	15-Jun-16	1d693a0ade7
Zala County Agricultural Office, Directorate of Plant Protection and Soil Conservation	Zalaegerszeg	Hungary	30-Mar-04	30-Mar-06	1d693a0ae6e
Dow AgroSciences S.A.	Sophia Antipolis	France	23-Jun-98	23-Jun-03	1d693a0adbc
Dow AgroSciences Hungary Kft.	Szolnok	Hungary	24-Aug-99	24-Aug-01	1d693a0ae61
Zkusebni stanice Nechanice s.r.o.	Nechanice	Czech Republic	07-Sep-09	07-Sep-14	1d693a0ad7d
Dow AgroSciences GmbH	Munchen	Germany	09-Dec-04	09-Dec-04	1d693a0ae1d

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
6.1.1-01 6.4.1-01	Mavrotas, Costas	2007	What ios the efficacy of Lontrel 400 agianst ANTAR in wheat, ELANCO HELLAS SACI. GR, GR07A2A003CM01C, not GEP, Unpublished	N	Dow/Corteva
6.1.1-02 6.2.2-01 6.4.1-02	Mezei, Imre	2008	What is the efficacy of Lontrel 720SG compared to Lontrel 300 in cereals, Dow AgroScience, HU08A2A085IM01C, GEP, Unpublished	N	Dow/Corteva
6.1.1-03 6.2.2-02 6.4.1-03	Mezei, Imre	2008	What is the efficacy of Lontrel 720SG compared tp Lontrel 300 in cereals, Dow AgroScience, HU08A2A085IM02C, GEP, Unpublished	N	Dow/Corteva
6.2.2-03 6.4.1-04	Mezei, Imre	1998	Efficacy of normal stored DAS Herbicides in comparison to samples stored at frozen conditions, Eastern Europe 1998, Dow AgroScience, E81018H1, Not GEP, Unpublished	N	Dow/Corteva
6.2.2-04 6.4.1-05	Mezei, Imre	2002	Efficacy of Mustang on CIRAR in comparison to commercial standards in Cereal, Europe, Dow AgroScience, H2700201, GEP, Unpublished	N	Dow/Corteva
6.2.2-05 6.4.1-06	Mezei, Imre	2002	Efficacy of Mustang on CIRAR in comparison to commercial standards in Cereal, Europe, Dow AgroScience, H2700202, GEP, Unpublished	N	Dow/Corteva

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
6.2.2-06 6.4.1-07	Mezei, Imre	2003	Mustang + (increased 2-4,D) Combination partners against CIRAR, Dow AgroScience, M3F00101, Not GEP, Unpublished	N	Dow/Corteva
6.2.2-07 6.4.1-08	Kerekes, Gabor	2018	Efficacy of clopyralid in winter cereals when applied at B23-30 and B33-39. Hungary, 2018, Agropass Hungaria Kft. HU18A2A004GK01C, GEP, Unpublished	N	Dow/Corteva
6.1.1-04 6.4.1-09	Mezei, Imre	2008	Formulation change of Lontrel in Onion NTSZ Nograd Megye. HU HU08A2A088IMO1C GEP Unpublished	N	Dow/Corteva
6.1.1-05 6.4.1-10	Mezei, Imre	2008	Formulation change of Lontrel in Maize NTSZ Nograd Megye. HU HU08A2A088IMO2C GEP Unpublished	N	Dow/Corteva
6.1.1-06 6.4.1-11	Bernhard, Uli	2008	Efficacy of GF-1633 and GF-1966 against CIRAR in maize, registration trials, Germany 2008 LVLF VS Nuhnen, DE DE08A2A001AZ02C GEP Unpublished	N	Dow/Corteva
6.1.1-07 6.4.1-12	Bernhard, Uli	2009	Efficacy of GF-1633 against CIRAR and other dycot.- weeds in maize, registration trials, Germany 2008 LWK Niedersachse, Hannover, DE DE08A2A001AZ03C GEP Unpublished	N	Dow/Corteva
6.1.1-08 6.4.1-13	Bernhard, Uli	2009	Efficacy of GF-1633 against CIRAR and other dycot.- weeds in maize, registration trials, Germany 2008 LWK Niedersachse, Hannover, DE DE08A2A001AZ04C GEP Unpublished	N	Dow/Corteva

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
6.1.1-09 6.4.1-14	Bernhard, Uli	2009	Efficacy and selectivity of GF-1633 (aminopyralid+clopyralid+picloram) AGRARTEST, DE DE08A2A003UB01C GEP Unpublished	N	Dow/Corteva
6.1.1-10 6.4.1-15	Bernhard, Uli	2009	Efficacy and selectivity of GF-1633 (aminopyralid+clopyralid+picloram) AGRO-CHECK, DE DE08A2A003UB02C GEP Unpublished	N	Dow/Corteva
6.1.1-11 6.4.1-16	Bernhard, Uli	2009	Efficacy and selectivity of GF-1633 (aminopyralid+clopyralid+picloram) AGRARTEST, DE DE08A2A003UB03C GEP Unpublished	N	Dow/Corteva
6.1.1-12 6.4.1-17	Schulz, Thomas	2008	Efficacy and selectivity of GF-1633 (aminopyralid+clopyralid+picloram) applied for BLW control in maize. Germany 2008. Dow AgroScience, DE08A2A004TS01 GEP Unpublished	N	Dow/Corteva
6.1.1-13 6.4.1-18	Schneider, Frank	2008	Efficacy and selectivity of GF-1633 (aminopyralid+clopyralid+picloram) applied for BLW control in maize. Germany 2008. Dow AgroScience, DE08A2A004FS02 GEP Unpublished	N	Dow/Corteva
6.2.2-08 6.4.1-19	Lourdet, Yves	1998	WHAT IS THE BEST RATIO OF CLOPYRALID + CARFENTRAZONE TO ACHIEVE COMMERCIAL CONTROL OF CIRSIUM ARVENSIS IN MAIZE ? Dow Agroscience F9B01301 GEP Unpublished	N	Dow/Corteva
6.2.2-09 6.4.1-20	Kiraly, E	2000	EFFICACY OF CLOPYRALID + CARFENTRAZONE AGAINST CIRSIUM ARVENSE IN MAIZE -EUROPE 1999 Corteva Agroscience, E9B013H1 GEP Unpublished	N	Dow/Corteva

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
6.2.2-10 6.4.1-21	Kiraly, E	2000	EFFICACY OF CLOPYRALID + CARFENTRAZONE AGAINST CIRSIUM ARVENSE IN MAIZE -EUROPE 1999 Corteva Agroscience, E9B013H2 GEP Unpublished	N	Dow/Corteva
6.1.1-14 6.2.2-11 6.4.1-22	Toth, F	2012	EFFICACY EVALUATION OF CLOPYRALID 600 SL APPLIED ON MAIZE CROP 2012 Staphyt, FPT-12-13443-SK04 GEP Unpublished	N	UPL
6.1.1-15 6.2.2-12 6.4.1-23	Toth, F	2012	EFFICACY EVALUATION OF CLOPYRALID 600 SL APPLIED ON MAIZE CROP 2012 Staphyt, FPT-12-13443-SK05 GEP Unpublished	N	UPL
6.1.1-16 6.4.1-25	Karel Sikora	2010	What is the efficacy of GF-1966 in comparison to existing formulations of clopyralid, Zemedelsky Vyzkumny Ustav Kromeriz, S.R.O. CZ, CZ10A2A019KS01C, GEP Unpublished	N	Dow/Corteva
6.1.1-17 6.4.1-26	Karel Sikora	2010	Is GF-1966 bioequivalent to existing and new formulations of clopyralid, ZKUSEBNI STANICE NECHANICE, CZ10A2A019KS02C GEP Unpublished	N	Dow/Corteva
6.1.1-18 06.4.1-27	Karel Sikora	2010	Is GF-1966 bioequivalent to existing and new formulations of clopyralid, ZKUSEBNI STANICE KUJAVY, CZ10A2A019KS03C GEP Unpublished	N	Dow/Corteva
6.1.1-19 6.4.1-28	Karel Sikora	2011	Is GF-1966 bioequivalent to existing and new formulations of clopyralid, ZKUSEBNI STANICE KUJAVY CZ11A2A022KS01C GEP Unpublished	N	Dow/Corteva

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
6.1.1-20 6.4.1-29	Karel Sikora	2011	Is GF-1966 bioequivalent to existing and new formulations of clopyralid, ZKUSEBNI STANICE NECHANICE, CZ11A2A022KS02C GEP Unpublished	N	Dow/Corteva
6.1.1-21 6.2.2-14 6.4.1-30	Michel Luras	2008	Efficacy of two different formulation of clopyralid LONTREL 100 and GF-1966 (sg) against Cirsium arvensis to sugar beet - spring 2008 Staphyt, FR08A2A066ML01C GEP, Unpublished	N	Dow/Corteva
6.1.1-22 6.2.2-15 6.4.1-31	Michel Luras	2008	Efficacy of two different formulation of clopyralid LONTREL 100 and GF-1966 (sg) against Cirsium arvensis to sugar beet - spring 2008 Staphyt, FR08A2A066ML02C, GEP, Unpublished	N	Dow/Corteva
6.1.1-23 6.4.1-32	Vojtko, Jan	2011	Is GF-1966 bioequivalent to existing and new formulations of clopyralid?, UKSUP, SK11A2A022JV01C, Not GEP, Unpublished	N	Dow/Corteva
6.1.1-24 6.4.1-33	Vojtko, Jan	2011	Is GF-1966 bioequivalent to existing and new formulations of clopyralid?, UKSUP, SK11A2A022JV02C, Not GEP, Unpublished	N	Dow/Corteva
6.2.2-16 6.4.1-34	Touzet, Francis	2007	EFFICACY OF LONTREL 100 AGAINST CIRAR IN SUGAR BEETS INCLUDING OIL, Dow Agroscience, FR07A2A037FT01, GEP, Unpublished	N	Dow/Corteva
6.2.2-17 6.4.1-35	Olivier, Francoise	2015	Interest of GF-2607 in mixture with Lontrel SG when applied against CIRAR in BEAVA. FR-2015, Dow AgroScience, FR15H2B017FO01, GEP, Unpublished	N	Dow/Corteva

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
6.2.2-18 6.4.1-36	Olivier, Francoise	2015	Interest of GF-2607 in mixture with Lontrel SG when applied against CIRAR in BEAVA. FR-2015, Dow AgroScience, FR15H2B017FO02, GEP, Unpublished	N	Dow/Corteva
6.2.2-19 6.4.1-37	Schmidt, Ingo	2012	Efficacy evaluation of clopyralid 600 SL applied on Winter oilseed rape crop Germany 2011/2012 Staphyt, FPT-12-9761-DE01 GEP, Unpublished	N	UPL
6.2.2-20 6.4.1-38	Laêtitia VANELLE	2012	Efficacy evaluation of clopyralid 600 SL applied on Winter oilseed rape crop France 2011/2012 Staphyt, FPT-12-9761-FR03 GEP, Unpublished	N	UPL
6.2.2-21 6.4.1-39	Zaremba, Magdelena	2012	Efficacy evaluation of clopyralid 600 SL applied on Spring oilseed rape crop – Poland 2011/12. Staphyt, FPT-12-9761-PL05, GEP Unpublished	N	UPL

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	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

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