FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: PP-113H

Product name(s): BARILOCHE

Chemical active substance:

Clopyralid 100 g/L (10% w/v SL)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: PROPLAN Plant Protection Company, S.L.

Submission date: December 2021

MS Finalisation date: August 2022; April 2023; June 2023

January 2024

Version history

When	What
February 2019	Initial version
December 2021	Version 2, Update for the renewal.
August 2022	ZRMs evaluated submitted by Applicant dRR
April 2023	ZRMs made changes according to commenting period.
June 2023	ZRMs made changes according to second round of commenting period.
January 2024	The final version of RR after 3rd round of commenting period

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The product BARILOCHE (Clopyralid 10% w/v SL), is currently registered in Italy (16096), Spain (ES-00493), UK (Re. No. 17577), Poland (Reg. No. R-26/2018wu), Germany (Reg. No. 008865-00), Czech Republic (Reg. No. 5583-0) and Romania (Reg. No. 466PC) in Sugar beet.
This new dossier has been carried out to support the renewal of the approval of the active substance Clopyralid.
All the changes that have been made in this section, with respect to the original dossier, have been highlighted in yellow. It must be taken into account that the format of the dossier has changed.

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:

Comments of zRMS:	Comments of zRMS are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are marked by grey colour). Changes made during commenting period are marked by green (1st round) and turquoise (2nd round) and red (3rd round).

This New Section B3 corresponds to the former Part B Section 7 of the Final Registration Report issued by zRMS UK. There is not any change in the results of this Section derived from the renewal of Clopyralid.

To address the requirements of Article 4(3) of Regulation (EC) No. 1107/2009 only limited information will be provided. Detailed efficacy information will be provided as needed in the subsequent product authorisation process on zonal / national lever after re-approval of the active ingredient (Article 43 submissions). Therefore, only limited efficacy information is provided in the line with the relevant guidance for renewals- Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No. 844/2012 Appendix II (SANCO/2012/11251).

This document summarises the information related to the efficacy of Clopyralid, it is submitted according to Commission Regulation (EC) No. 844/2012 of 18 September 2012 for the renewal of the regulatory approval of an active substance under Commission Regulation (EC) No. 1107/2009.

Clopyralid was included into Annex I of Directive 91/414 (*Commission Directive 2006/64/EC).*

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Commission Implementing Regulation (EU) 2021/566 of 30 March 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substance Clopyralid and other active substances.

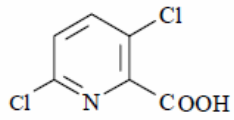
The representative product to support the Clopyralid Annex I renewal is BARILOCHE.
BARILOCHE is an SL formulation containing 100 g/L Clopyralid.

List of authorised uses in the EU for Clopyralid 10% SL

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Central zone	zRMS: Poland Product code: PP-113H Product name: Bariloche **Registration No: R-26/2018wu**	Romania: (Reg No: 466PC) Germany (Reg. No: 008865-00) Czech Republic: (Reg. No: 5583-0) UK (Reg. No. 17577)

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

Description of active substances

End-Point	**Clopyralid***
Common name (ISO)	Clopyralid
Chemical Name (IUPAC)	3,6-dichloropyridine-2-carboxylic acid
Chemical Name (CA)	3,6-dichloro-2-pyridinecarboxylic acid
CIPAC No	455
CAS No	1702-17-6
EEC No	216-935-4
FAO SPECIFICATION	Not available
Minimum purity	950 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Open
Molecular formula	$C_6H_3Cl_2NO_2$
Molecular mass	191.96
Structural formula	

* EFSA Scientific Report (2005) 50, 1-65.
** SANCO/4062/2001-final.

Mode of action

Selective systemic herbicide, absorbed by the leaves and roots, with translocation both acropetally and basipetally, and accumulation in meristematic tissue. Exhibits an auxin-type reaction. Acts on cell elongation and respiration.

Table 3.1-1: Details of the active substances

Active substance	Clopyralid
Concentration (Unit: g/kg or g/L...)	100 g/L
Chemical group	Synthetic auxin
Mode of action	Herbicide

Active substance	Clopyralid
Biological action	Post-emergence herbicide

Description of the plant protection product

PP-113H is a soluble concentrate (SL) containing 100 g/L of Clopyralid.

Description of the target pests

Table 3.1-2: Glossary of pests mentioned in the dossier.

EPPO code	**Scientific name**	**Common name***
CIRAR	*Cirsium arvense*	Canada thistle
MATCH	*Matricaria recutita*	Wild chamomile
CHEAL	*Chenopodium album*	Fat-hen
HELAN	*Helianthus annus*	Common sunflowe
MATIN	*Tripleurospermum mar. inodorum (=Matricaria inodora)*	Scentless mayweed
GASPA	*Galinsoga parviflora*	Gallant soldier
MATSS	*Matricaria sp.*	Chamomile
SONAR	*Sonchus arvensis*	Perennial sowthistle
SENVU	*Senecio vulgaris*	Common groundsel
CENCY	*Centaurea cyanus*	Cornflower
SLYMA	*Silybum marianum*	Blessed milkthistle
AMBEL	*Ambrosia artemisiifolia*	Common ragweed

* optional

Table 3.1-3: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	**Crop status**		**Pests or group of pests controlled**	**Pest status**	
	Major	**minor**		**Major**	**minor**
Sugar beet	PL, CZ, DE, RO	-	MTCH and CIRAR	-	-

Compliance with the Uniform Principles

GEP compliance will be claimed in respect of this study. EUROFINS AGROSCIENCE SERVICES are officially recognised as competent to carry out efficacy testing in accordance with European Commission Directive 93/71/EEC by the relevant authorities in each country. The relevant certificates will be included in the Study Report.
GLP compliance will not be claimed in respect of this study, but certain procedural aspects may be included within the QA programme.
National regulatory guidelines were also followed for the countries involved in the study.

Guidelines	General guidelines	PP 1/152(3) Design and analysis of efficacy evaluation trials.

		PP 1/181(3) PP 1/135(3) PP 1/225(2)	Conduct and reporting of efficacy evaluation trials Phytotoxicity assessment. Minimum effective dose.
	Specific guidelines	PP 1/52(3)	Weeds in sugar and fodder beet.

The relevant certificates are included in point 3.7.

Information on trials submitted (3.1 Efficacy data)

In this dossier there were submitted a total of 21 field trials carried out on sugar beet (17 efficacy-selectivity trials, and 4 crop safety and yield trials) during 2011 and 2012 season in UK (4 trials), Germany (4 trials), France (5 trials), Czech Republic (2 trials), Poland (2 trials), Romania (2 trials) and Hungary (2 trials).

Table 3.1-4: Presentation of trials (efficacy trials, preliminary trials...)

Crop(s)*	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)		GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime zone	Mediterranean zone		
Sugar beet	*Cirsium arvense* (CIRAR) *Sounchus arvensis* (SONAR) *Tripleurospermum mar. inodorum* (MATIN) *Centaurea cyanus* (CENCY) *Silybum marianum* (SLYMA)	PO	2012	E	2(2)	-	GEP	-
	Cirsium arvense (CIRAR) *Chenopodium album* (CHEAL) *Centaurea cyanus* (CENCY) *Matricaria inodora* (MATIN)	DE	2011	E	3(3)	-	GEP	-
	Cirsium arvense (CIRAR) *Somchus arvensis* (SONAR)	UK	2011-2012	E	3(3)	-	GEP	-
	Cirsium arvense (CIRAR) *Matricaria recutita* (MATCH)	FR	2011	E	3(3)	-	GEP	-
	Cirsium arvense (CIRAR) *Matricaria sp.* (MATSS) *Sounchus arvensis* (SONAR)	RO	2012	E	2(2)	-	GEP	-

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)		GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime zone	Mediterranean zone		
	Senecio vulgaris (SENVU)							
	Helianthus annus (HELAN) *Tripleurospermum mar. inodorum* (MATIN) *Galinsoga parviflora* (GASPA) *Cirsium arvense* (CIRAR)	CZ	2012	E	2(2)	-	GEP	-
	Cirsium arvense (CIRAR) *Helianthus annus* (HELAN) *Cirsium arvense* (CIRAR) *Ambrosia artemissifolia* (AMBEL)	HU	2012	E	2(2)	-	GEP	-

* 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.

Comments of zRMS:	This is an Article 43 application (of Reg. (EC) 1107/2009) and as such only specific new data in order to comply with changes in the assessment of the active substance (new endpoints, new guidance applied, conditions or restrictions in the renewal regulation) can be considered (SANCO/2010/13170 rev 13). Plant protection products based on clopyralid are known and used for many years. In Poland many herbicides with clopyralid are registered and used to control weeds in crops. BARILOCHE was submitted and positively evaluated during the authorization process of this product (Reg. No. R-26/2018wu). This report has been discontinued to re-registration of this product. As stated in the draft registration report, the GAP has not been changed compared to current registration. Therefore, in intended uses, there has been no GAP change that impacts the previous efficacy evaluation of BARILOCHE and the effectiveness does not have to be reassessed (according to the regulations). No new efficacy and selectivity data trials of this product have been submitted and no new uses will be considered in this application. Thus, the conclusions of previous assessments are still considered valid and the only aspect that will be considered is the resistance risk assessment, which requires updating at renewal. All necessary information's were provided above by Applicant. This document summarises the information related to the efficacy of the plant protection product – PP-113H (BARILOCHE). The data presented in this dossier fully support the renewal under Article 43 of BARILOCHE for the control of weeds in sugar beet in Poland. In our opinion each cMS should decide if presented documentation is sufficient for re-registered BARILOCHE. The formulation of this product is a

	soluble concentrate (SL) and it is containing one active substance: clopyralid (100 g/l). For now, this active compound is on the list of approved active substances. All needed information's are presented by Applicant in core dossier. **Summary: In Poland (ZRMs) BARILOCHE was registered (Reg. No. R-26/2018wu) in 2018 and now it can be re-registered. In our opinion each cMS should decide if presented documentation is sufficient for re-registered BARILOCHE.** **For Germany** - the present application is a renewal according to the Article 43 of EU Regulation 1107/2009. The GAP has not been changed and the proposed uses are nearly identical to the previous authorised uses in Germany. The assessment is still valid. ~~In this case, it means that the approval from Poland was taken over.~~ The water volume application rate in the GAP table for Germany should be adjusted to the currently applied and previously authorised rate of 200-400 L/ha.

Table 3.1-5: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

GAP rev.1, date: sept, 2021.

PPP (product name/code):	Bariloche (PP-113H)	Formulation type:	SL [a, b]
Active substance 1:	Clopyralid	Conc. of as 1:	100 g/L [c]
Applicant:	PROPLAN Plant Protection Company, S.L.	Professional use:	☒
Zone(s):	Central zone [d]	Non professional use:	☐
Verified by MS:	-		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	C. EU (CZ, DE, PL, RO)	Sugar beet	F	CIRAR and COMPOSITAE	Tractor boom sprayer	BBCH 10-39	1	-	1.2	120	80-400	None	Do not use between the 31st August and 1st March **Eff. section**: For DE recommended water volume is 200-400 L/ha

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3.2 Efficacy data (KCP 6)

There is no change from the original dossier.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.

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

Clopyralid has been in wide scale commercial use in Europe for the control of annual and perennial broad leaved weeds in a wide range of crops since the early 1970's. No reports of resistance in the Europe have been received.
A resistance risk analysis was performed following EPPO guideline PP1/213(2).
All references for the occurrence of resistance are taken from the International Survey ofHerbicide Re istance Weeds supported by HRAC

Evidence of resistance
Herbicides representing this mode of action have been used commercially for more than 35 years. Only two species that are sensitive to clopyralid have been shown to have developed resistance to two herbicides with a synthetic auxin mode of action. In Europe, these were creeping thistle (Cirsium arvensis) and scentless mayweed (Matricaria perforata). Both of these species have shown increased tolerance to MCPA and 2,4-D (International Survey of Herbicide Resistant Weeds). The level of resistance is generally low and restricted to a small area. Furthermore these weeds were detected between 1975 and 1985 and no increase in range has been reported.
No cases of clopyralid resistance have been reported in Europe.
(RAR Clopyralid, May 2017. Annex B1-B5. Point B.3.7).

Comments of zRMS:	Clopyralid belongs to the pyridine carboxylic acids group. Applied post-emergence, clopyralid is effective on a broad spectrum of broad-leaved weeds. Clopyralid belongs to the chemical group of the pyridine carboxylic acid herbicide family, described as a synthetic auxin and classified by HRAC as Group 4 (Legacy HRAC Group O). It acts as 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. The exact mode of action of clopyralid has not been fully described but it is believed to acidify the cell wall, 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. Clopyralid is rapidly degraded in soil (DT_{50} = 34 days) thus a prolonged exposure to weed populations does not occur which is a factor which decreases the re-

sistance risk.

The risk of resistance was analysed following the EPPO-Standard (2003), the classification of the Herbicide Resistance Action Committee (HRAC) and the international Survey of Herbicide Resistant Weeds (Heap, 2016).

The probability of development of resistance or cross-resistance of weeds to BARILOCHE is considered as low to moderate. The evaluation of the agronomic risk concludes that BARILOCHE bears a low to moderate risk of resistance.

Plant protection products containing clopyralid are used from many years and no information's concerning weed resistance for this active substance was noted. However, the information on possible development of resistance or cross-resistance is provided by scientific literature from many different countries and describes different weed species. Product should be used in rates neither lower nor higher than recommended in the label due to prevent resistance development.

According to weedscience.org, up 4 cases of resistance were reported.

#	Year	Species	Country	MOAs	Actives	Situations
1	2013	*Centaurea stoebe ssp. micranthos*	Canada (British Columbia)	Auxin Mimics HRAC Group 4 (Legacy O)	clopyralid, picloram	Rangeland
2	1999	*Soliva sessilis*	New Zealand	Auxin Mimics HRAC Group 4 (Legacy O)	clopyralid, picloram, triclopyr	Golf courses, Turf
3	2005	*Chenopodium album*	New Zealand	Auxin Mimics HRAC Group 4 (Legacy O)	dicamba, clopyralid, aminopyralid	Corn (maize)
4	2022	*Ambrosia artemisiifolia*	United States (Michigan)	Auxin Mimics HRAC Group 4 (Legacy O)	clopyralid	Christmas Trees

Lack of resistance cases for Europe, only one case from Canada (2013), one case from USA (2022) and two cases from New Zealand (1999, 2005) have been already reported.

However, due to ~~September 2022~~ January 2024, ~~41~~ 44 cases of resistance to HRAC group 4 herbicides are reported on weedscience.org. Resistance cases for *Centaurea cyanus* (Dicamba, Poland), *Cirsium arvense* (MCPA, Sweden; 2,4-D and MCPA, Hungary), *Papaver rhoeas* [2,4-D, Spain, Italy (2 cases), Greece; 2,4-D and aminopyralid, France (2 cases)] and *Stellaria media* (mecoprop, UK) are reported from Europe. These cases show that cross-resistances within HRAC group 4 are possible. In addition, HRAC group 4 actives including clopyralid are increasingly applied in cereal crops in Europe. Sugar beet is rotated with cereal crops. Accordingly, consecutive applications of HRAC group 4 herbicides are likely to happen, increasing the selection pressure. In line with this, DE rates the resistance risk for the herbicide Bariloche moderate. ZRMs agree with this opinion. So, in general Bariloche should be characterized as moderate risk of resistance.

Weeds Resistant to Auxin Mimics (O/4) by species and country

#	Species	Country	First Year

	1	***Amaranthus hybridus (syn: quitensis)*** Smooth Pigweed	2016 - Argentina *Multiple - 2 SOA's 2016 - Argentina	**2016**
	2	***Amaranthus palmeri*** Palmer Amaranth	2015 - United States (Kansas) *Multiple - 5 SOA's 2018 - United States (Kansas) 2020 - United States (Tennessee) *Multiple - 2 SOA's	**2015**
	3	***Amaranthus powellii*** Powell Amaranth	2019 - Canada (Ontario) *Multiple - 2 SOA's	**2019**
	4	***Amaranthus tuberculatus (=A. rudis)*** Tall Waterhemp	2009 - United States (Nebraska) *Multiple - 3 SOA's 2016 - United States (Illinois) *Multiple - 5 SOA's 2021 - United States (Iowa)	**2009**
	5	***Ambrosia artemisiifolia*** Common Ragweed	2022 - United States (Michigan)	**2022**
	6	***Arctotheca calendula*** Capeweed	2015 - Australia (South Australia)	**2015**
	7	***Brassica rapa (=B. campestris)*** Birdsrape Mustard	2015 - Argentina	**2015**
	8	***Carduus acanthoides*** Plumeless Thistle	2019 - Argentina *Multiple - 2 SOA's	**2019**
	9	***Carduus nutans*** Musk Thistle	1981 - New Zealand	**1981**
	10	***Carduus pycnocephalus*** Italian Thistle	1997 - New Zealand	**1997**
	11	***Centaurea cyanus*** Cornflower	2012 - Poland	**2012**
	12	***Centaurea solstitialis*** Yellow Starthistle	1988 - United States (Washington)	**1988**
	13	***Centaurea stoebe ssp. micranthos*** Spotted knapweed	2013 - Canada (British Columbia)	**2013**
	14	***Chenopodium album*** Common Lambsquarters	2005 - New Zealand	**2005**
	15	***Cirsium arvense*** Canada thistle	1979 - Sweden 1985 - Hungary	**1979**
	16	***Commelina diffusa*** Spreading Dayflower	1957 - United States (Hawaii)	**1957**
	17	***Conyza sumatrensis*** Sumatran Fleabane	2017 - Brazil *Multiple - 5 SOA's	**2017**
	18	***Daucus carota*** Wild Carrot	1957 - Canada (Ontario) 1993 - United States (Michigan) 1994 - United States (Ohio)	**1957**
	19	***Descurainia sophia*** Flixweed	2011 - China	**2011**
	20	***Digitaria ischaemum*** Smooth Crabgrass	2002 - United States (California)	**2002**
	21	***Echinochloa colona*** Junglerice	2000 - Colombia	**2000**

	22	***Echinochloa crus-galli var. crus-galli*** Barnyardgrass	1998 - United States (Louisiana) 1999 - Brazil 1999 - United States (Arkansas) *Multiple - 2 SOA's 2000 - China 2009 - Brazil *Multiple - 2 SOA's 2013 - Uruguay 2018 - Brazil *Multiple - 3 SOA's	**1998**
	23	***Echinochloa crus-galli var. zelayensis*** Gulf Cockspur Grass	2013 - China	**2013**
	24	***Echinochloa crus-pavonis*** Gulf Cockspur	1999 - Brazil	**1999**
	25	***Fimbristylis miliacea*** Globe Fringerush	1989 - Malaysia	**1989**
	26	***Galeopsis tetrahit*** Common Hempnettle	1998 - Canada (Alberta)	**1998**
	27	***Galium aparine*** Catchweed Bedstraw	2014 - China 2016 - Iran 2017 - Iran *Multiple - 2 SOA's	**2014**
	28	***Galium spurium*** False Cleavers	1996 - Canada (Alberta) *Multiple - 2 SOA's	**1996**
	29	***Hirschfeldia incana*** Shortpod Mustard	2016 - Argentina *Multiple - 2 SOA's	**2016**
	30	***Kochia scoparia*** Kochia	1994 - United States (Montana) 1995 - United States (North Dakota) 1997 - United States (Idaho) 1999 - United States (Colorado) 2009 - United States (Nebraska) 2013 - United States (Kansas) *Multiple - 4 SOA's 2013 - United States (Kansas) *Multiple - 2 SOA's 2015 - Canada (Saskatchewan) *Multiple - 2 SOA's 2017 - Canada (Alberta) *Multiple - 3 SOA's	**1994**
	31	***Lactuca serriola*** Prickly Lettuce	2007 - United States (Washington)	**2007**
	32	***Limnocharis flava*** Sawah Flowering Rush	1995 - Indonesia 1998 - Malaysia *Multiple - 2 SOA's	**1995**
	33	***Limnophila erecta*** Marshweed	2002 - Malaysia *Multiple - 2 SOA's	**2002**
	34	***Papaver rhoeas*** Corn Poppy	1993 - Spain *Multiple - 2 SOA's 1998 - Italy *Multiple - 2 SOA's 1998 - Italy 2002 - Greece *Multiple - 2 SOA's 2015 - France 2016 - France *Multiple - 2 SOA's	**1993**
	35	***Plantago lanceolata*** Buckhorn Plantain	2016 - United States (Indiana)	**2016**
	36	***Ranunculus acris*** Tall Buttercup	1988 - New Zealand 2010 - New Zealand *Multiple - 2 SOA's	**1988**
	37	***Raphanus raphanistrum*** Wild Radish	1999 - Australia (Western Australia) 2006 - Australia (South Austra-	**1999**

		lia) *Multiple - 3 SOA's 2009 - Australia (Victoria) *Multiple - 2 SOA's 2010 - Australia (Western Australia) *Multiple - 4 SOA's 2011 - Australia (Victoria) 2013 - Australia (New South Wales) 2015 - Australia (Western Australia) *Multiple - 5 SOA's 2020 - Australia (Western Australia) *Multiple - 3 SOA's	
38	***Sagittaria montevidensis*** California Arrowhead	2023 - Brazil	**2023**
39	***Sinapis arvensis*** Wild Mustard	1990 - Canada (Manitoba) 2008 - Turkey *Multiple - 2 SOA's	**1990**
40	***Sisymbrium orientale*** Oriental Mustard	2005 - Australia (South Australia) *Multiple - 2 SOA's	**2005**
41	***Soliva sessilis*** Lawn Burweed	1999 - New Zealand	**1999**
42	***Sonchus oleraceus*** Annual Sowthistle	2015 - Australia (South Australia) 2015 - Australia (Victoria)	**2015**
43	***Sphenoclea zeylanica*** Gooseweed	1983 - Philippines 1995 - Malaysia 2000 - Thailand	**1983**
44	***Stellaria media*** Common Chickweed	1985 - United Kingdom 2010 - China	**1985**

Since no resistance to clopyralid has developed in Europe~~, there is no demonstrated cross resistant to other group 4 herbicides~~ and that synthetic auxins have a multi-site mode of action the risk of practical resistance in unrestricted use is very low and the unmodified risk is acceptable. In view of the acceptable risk of unrestricted use no resistance management strategy is deemed necessary. In a crop rotation, herbicides belonging to HRAC group 4 can be applied in various crops and the agronomic practices may differ in the member states. To avoid inherent risk in group 4 herbicides the agronomic risk should be evaluated at member state level.

To avoid resistance, it is important to have a reasonable crop rotation and respect the label recommended application rates and doses. The risk of resistance to clopyralid is believed to be low for the following reasons:

- to minimize the risk of occurrence and development of weed resistance to herbicides, follow Good Agricultural Practice:
- follow strictly the directions on the label of the plant protection product use the product at the recommended dose, at the recommended time to ensure optimal weed control,
- adjust the choice of herbicide and the decision to carry out the treatment to the prevailing (possibly potential) weed infestation, taking into account the dominant species and damage thresholds,
- use a rotation of herbicides (active substances) with different mechanisms of action,
- use a mixture of herbicides (active substances) with different mechanism of action,
- use in rotation and/or mixture herbicides acting on several life processes of weeds (with different mechanism of action),

	- use an herbicide with a given mechanism of action only once during the growing season of the crop, - inform the permit holder of unsatisfactory weed control, - contact your advisor, the permit holder or the permit holder's representative for more information. Taking into consideration inherent factors from weeds and herbicide, the agronomic risks, and the fact that despite many years of intensive use of clopyralid only few cases have been reported, the risk for the development of clopyralid resistant weed biotypes in major crop production and vegetable production areas is considered ~~low~~ as moderate.

3.4 Adverse effects on treated crops (KCP 6.4)

There is no change from the original dossier.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.

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

There is no change from the original dossier.

Comments of zRMS:	Statement accepted. In accordance with the Article 43 of Regulation (EC) No 1107/2009, the already submitted data will not be re-evaluated because the conclusions of previous assessments are still considered valid in the case of no significant change of the GAP table.

3.6 Other/special studies

There is no change from the original dossier.

Comments of zRMS:	Statement accepted.

3.7 List of test facilities including the corresponding certificates

There is no change from the original dossier.

Comments of zRMS:	Statement accepted.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Owner
KCP 6.2 KCP 6.4	Blanco, J.	2011	Determination of efficacy and selectivity of PP-113H (Clopyralid 10% w/v SL) against compositae weeds on sugar beet. 1 trial in Germany and 2 trials in UK. Season 2011 Eurofins Agroscience Services (Spain) Report No: S11-00370 GLP, Unpublished	N	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2011	Determination of efficacy of PP-113H against *Cirsium arvense* on sugar beet. 2 trials in Germany and 1 trial in UK. Season 2011 Eurofins Agroscience Services (Spain) Report No: S11-00371 GLP, Unpublished	N	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2011	Determination of efficacy of PP-113H against compositae weeds and *cirsium arvense* on sugar beet. 3 trials in France. Season 2011 Eurofins Agroscience Services (Spain) Report No: S11-00372 GLP, Unpublished	N	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against *Cirsium arvense*, *Matricaria* sp. and composi-tae weeds on sugar beet. 1 trial in Czech Re-public. Season 2012 Eurofins Agroscience Services (Spain) Report No: S12-00585-01 GLP, Unpublished	N	PROPLAN

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Owner
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against *Cirsium arvense*, *Matricaria* sp. and compositae weeds on sugar beet. 1 trial in Czech Republic. Season 2012 Eurofins Agroscience Services (Spain) Report No: S12-00585-02 GLP, Unpublished	N	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against *Cirsium arvense*, *Matricaria* sp. and compositae weeds on sugar beet. 1 trial in Romania. Season 2012 Eurofins Agroscience Services (Spain) Report No: S12-00585-03 GLP, Unpublished	N	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against *Cirsium arvense*, Matricaria sp. and compositae weeds on sugar beet. 1 trial in Romania. Season 2012 Eurofins Agroscience Services (Spain) Report No: S12-00585-04 GLP, Unpublished	N	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against *Cirsium arvense*, Matricaria sp. and compositae weeds on sugar beet. 1 trial in Poland. Season 2012. Eurofins Agroscience Services (Spain) Report No: S12-00585-05 GLP, Unpublished	N	PROPLAN

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Owner
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against *Cirsium arvense, Matricaria* sp. and compositae weeds on sugar beet. 1 trial in Poland. Season 2012. Eurofins Agroscience Services (Spain) Report No: S12-00585-06 GLP, Unpublished	N	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against *Cirsium arvense, Matricaria* sp. and compositae weeds on sugar beet. 1 trials in Hungary. Season 2012. Eurofins Agroscience Services (Spain) Report No: S12-00585-07 GLP, Unpublished	N	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against *Cirsium arvense, Matricaria* sp. and compositae weeds on sugar beet. 1 trial in Hungary. Season 2012 Eurofins Agroscience Services (Spain) Report No: S12-00585-08 GLP, Unpublished	N	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2012	Determination of efficacy of PP-113H against *Cirsium arvense, Matricaria* sp. and compositae weeds on sugar beet. 1 trial in UK. Season 2012 Eurofins Agroscience Services (Spain) Report No: S12-00585-09 GLP, Unpublished	N	PROPLAN
KCP 6.2 KCP 6.4	Blanco, J.	2011	Determination of selectivity of PP-113H on sugar beet. 1 trial in Germany and 1 trial in UK. Season 2011 Eurofins Agroscience Services (Spain) Report No: S11-00373 GLP, Unpublished	N	PROPLAN

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Owner
KCP 6.2 KCP 6.4	Blanco, J.	2011	Determination of selectivity of PP-113H on sugar beet. 2 trials in France. Season 2011 Eurofins Agroscience Services (Spain) Report No: S11-00374 GLP, Unpublished	N	PROPLAN