

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: K-300SL-RR

Product name(s): FAWORYT 300 SL

Chemical active substance:

clopyralid, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT – Art. 43

(Renewal of authorisation)

Applicant: CIECH Sarzyna S.A.

Submission date: 12/2021

MS Finalisation date: 07/2022; 10/2022

Version history

When	What
December 2021	dRR version 1 submitted by applicant
July 2022	zRMs first evaluation
October 2022	ZRMs made changes in dRR during commenting period

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

This documentation is submitted in order to meet legal requirements resulting from renewing the approval of the active substance clopyralid in EU under Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021) and addresses the information related to the efficacy data of the plant protection product FAWORYT 300 SL containing 300 g/l of clopyralid.

The Annex I Renewal process of clopyralid has triggered the application for renewal of authorisation of all clopyralid containing products, including FAWORYT 300 SL. Since the evaluation of clopyralid did not raise a request for new information concerning efficacy and no changes compared to previous authorisations are sought, the application for Product Renewal is done under Article 43 of Regulation (EC) 1107/2009.

According to the SANCO guidance 2010/13170 (rev. 14, 7 Oct 2016)¹, the previous efficacy assessment remains valid and only an updated resistance statement is required if there are no GAP changes: “Where a GAP change is triggered e.g. by new endpoints, new guidance, efficacy data addressing the new GAP should be submitted. Otherwise, for renewal applications, only resistance data are required.”

The only change in GAP is withdrawal of use FAWORYT 300 SL in tank mix with Acord 180 OF in sugar beet. Therefore, in intended uses, there has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL 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.

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:	This is the last version of dRR submitted by the applicant. The grey commenting boxes were used by the zRMS. They were usually placed at the end of each chapter. Changes after commenting period were marked by turquoise.
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

zRMS provided main conclusions on each use. Overall summaries are not necessary here, because they were provided at the end of each chapter of the dRR. It is a renewal of authorization the plant protection product – Faworyt 300 SL. In the opinion of Evaluator, it can be granted.

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat	F	Dicotyledonous weeds (from cotyledon stage to the rosette stage)	Spraying, broadcast- foliar	BBCH 21-29 (Spring)	a) 1* b) 1*	N/A	a) 0.3-0.4 b) 0.3-0.4	a) 90-120 b) 90-120	200/300	N/A	None *Once applica- tion every 2 years	Acceptable
2	PL	Winter rape	F	Dicotyledonous weeds (from cotyledon stage to the rosette stage)	Spraying, broadcast- foliar	BBCH 10-50 (Spring)	a) 1* b) 1*	N/A	a) 0.3-0.4 b) 0.3-0.4	a) 90-120 b) 90-120	200/300	N/A	None *Once applica- tion every 2 years	Acceptable
3	PL	Sugar beet	F	Dicotyledonous weeds (from cotyledon stage to the rosette stage)	Spraying, broadcast- foliar	BBCH 12-14 (Spring)	a) 1 b) 1	N/A	a) 0.3 b) 0.3	a) 90 b) 90	200/300	N/A	none	Acceptable
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
3														
4														
Minor uses according to Article 51 (field uses)														
5														
6														
Minor uses according to Article 51 (interzonal uses)														
7														
8														

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

** 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

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)

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. Information on the efficacy of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013

Comments of zRMS:	<p>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.</p> <p>FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). This report has been discontinued to re-registration of this product.</p> <p>As stated in the draft registration report, the GAP has not been changed compared to current registration. The only change in GAP is withdrawal of use FAWORYT 300 SL in tank mix with Acord 180 OF in sugar beet. Therefore, in intended uses, there has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL 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.</p> <p>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).</p> <p>All necessary information's were provided above by Applicant. This document summarises the information related to the efficacy of the plant protection product – K-300SL-RR (Faworyt 300 SL). The data presented in this dossier fully support the renewal under Article 43 of Faworyt 300 SL for the control of weeds in cereals, sugar beets and winter oilseed rape in Poland. The formulation of this product is a soluble concentrate (SL) and it is containing one active substance: clopyralid (300 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.</p> <p>The change in the label regarding the application of the product once per season every two years in winter rapeseed is due to PECgw calculations – clopyralid was renewed with such endpoints, which do not allow the product to be applied every year. In addition, the calculations made for winter wheat (PECgw conversions) by Applicant show that also in winter wheat the tested plant protection product can be applied only once in two years. For details, please refer to the Environmental Fate section. Considering, the above, an appropriate change has been made in the GAP for winter wheat and winter oilseed rape, as well as in the product label, that the product can be applied once a season every two years. Other provisions remain unchanged.</p>
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3.2.1 Preliminary tests (KCP 6.1)

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. Information on the preliminary tests of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013

Comments of zRMS:	Statement accepted.
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3.2.2 Minimum effective dose tests (KCP 6.2)

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. Information on the minimum effective dose tests of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013

Comments of zRMS:	Statement accepted.
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3.2.3 Efficacy tests (KCP 6.2)

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. Information on the efficacy tests of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013

Comments of zRMS:	Statement accepted.
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3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

The possibility of development of resistance or cross-resistance to the active substance contained in the proposed formulation FAWORYT 300 SL (clopyralid, 300 g/L) is discussed thereafter based on the requirements detailed in EPPO standard PP1/213(3) “*Resistance risk analysis*”. FAWORYT 300 SL is used as post-emergence herbicide to control broadleaved weeds in winter wheat, winter rape and sugar beet.

Resistance is the naturally inherited ability of some weed biotypes in a population to survive an application of herbicides, which would control this weed population on normal application conditions effectively (Heap 1997)¹. Resistance is of great commercial relevance for both, the operator and the manufacturer

¹ Heap, I. (1997): The occurrence of herbicide resistance worldwide. Pesticide Science, v. 51 (3), p. 235 - 243

(Arlt 2002)². For the operator due to the fact that less efficacy represents yield losses of qualitative and quantitative nature and results in higher costs of weed control; for the manufacturer because development of resistance could ruin the return of investment in the development of an active substance. Orson & Harris (1997)³ have pointed out the cost savings by anti-resistance-strategies compared to the potential of the follow-up costs of the development of resistance in blackgrass populations for arable farms in the UK. Therefore, an anti-resistance strategy presumes a long-term view.

The risk and the dynamic of resistance in weed populations are mainly affected by following factors (Arlt 2002)⁴ :

- Number of alleles which are responsible for resistance characteristics
- Frequency of occurrence of resistance-alleles in natural weed populations
- Type of inheritance
- Reproductive characteristics of the weed species (seed production)
- Dormancy and lifetime of seeds in soil
- Fitness of resistant and sensitive biotypes
- Conditions of competition
- Selection pressure of herbicides
- Mode of action of the active substances
- Persistence of the active substances

It is of further importance whether in target organism's resistance mechanisms already exist against the active substance planned for application and whether cross-resistance must be anticipated in relation to other active substances or groups of active substances.

3.3.1 Mode of action

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.

3.3.2 Mechanism of resistance

Herbicides mostly affect a specific target site, which are controlled by one or a few genes, so that one mutation of few genes already can cause a resistance. Use of herbicides with the same mode of action in one population can produce a considerable selection pressure, which may result in fast reproduction of the resistant biotypes. These biotypes can generate increased population sizes and may infest more arable land without limitation, because the sensitive species and varieties are controlled by the herbicide or the same MoA group of herbicides. Although the development of resistance or even reduced susceptibility is a long-term process as weeds usually produce only one generation per year and new, resistant individuals

² Arlt, K. (2002): Herbizidresistenz bei Unkräutern, in "Unkraut – Ökologie und Bekämpfung". Autoren P. Zwerger & H. - U. Ammon. Verlag Eugen Ulmer Stuttgart S. 205

³ Orson, J.H. & Harris, D. (1997): The technical and financial impact of herbicide resistant black grass (*Alopecurus myosuroides*) on individual farm businesses in UK. The 1997 Brighton Crop Protection Conference – Weeds. p.1127 - 1132

⁴ Arlt, K. (2002): Herbizidresistenz bei Unkräutern, in "Unkraut – Ökologie und Bekämpfung". Autoren P. Zwerger & H. - U. Ammon. Verlag Eugen Ulmer Stuttgart S. 205

spread quite slowly within the population, it is evident that a repeated application of herbicides with the same mode of action over 20-30 years results in selection pressure and induces selection of resistant ecotypes.

For herbicides, 4 mechanisms of resistance are known⁵:

1. Altered target site
Herbicides have specific sites (target site of action) where they act to disrupt a particular plant process or function. If this target site is altered, the herbicide can no longer bind to the site of action and is unable to exert its phytotoxic effect. This is the most common mechanism of resistance to herbicides.
2. Enhanced metabolism
Metabolism within the plant is one mechanism a plant uses to detoxify a foreign compound such as an herbicide. A weed with the ability to quickly degrade an herbicide can potentially inactivate it before it can reach its site of action within the plant.
3. Compartmentalization or sequestration
Some plants are capable of restricting the movement of foreign compounds within their cells or tissues to prevent the compounds from causing harmful effects. In this case, an herbicide may be inactivated either through binding (such as to a plant sugar molecule) or removed from metabolically active regions of the cell to inactive regions, the cell wall, for example, where it exerts no effect.
4. Over-expression of the target protein
If the target protein, on which the herbicide acts, can be produced in large quantities by the plant, then the effect of the herbicide becomes insignificant.

3.3.3 Evidence of resistance

As mentioned above, clopyralid belongs to the chemical group of pyridine-carboxylic-acids, with a mode of action like indole acetic acid (synthetic auxins), and is classified with HRAC group 4 (Legacy 0). For group 4, the latest (November 2021) HRAC data base lists 82 cases of 40 resistant species world-wide and only 11 cases of 5 resistant species across Europe. Clopyralid resistance has been described for 3 weed species worldwide since 1999 in altogether 3 confirmed cases. None of these case were reported in Europe and crops, which are target use in this submission. The following table shows the current world-wide resistance weeds specifically to the herbicide clopyralid (according to <http://www.weedscience.org>):

Table 3.3-1 Reported cases of resistance to clopyralid⁶:

#	Year	Species	Country	MOAs	Actives	Situation(s)
1	1999	<i>Soliva sessilis</i>	New Zealand	Auxin Mimics (HRAC Group 4/Legacy O)	clopyralid, picloram, triclopyr	Golf courses, and Turf
2	2005	<i>Chenopodium album</i>	New Zealand	Auxin Mimics (HRAC Group 4/Legacy O)	aminopyralid, clopyralid, dicamba	Corn (maize)
3	2013	<i>Centaurea stoebe ssp. micranthos</i>	Canada (British Columbia)	Auxin Mimics (HRAC Group 4/Legacy O)	clopyralid, picloram	Rangeland

⁵ Available online: <https://pesticidestewardship.org/resistance/herbicide-resistance/mechanisms-of-herbicide-resistance/> (November 2021)

⁶ Available online: <http://www.weedscience.org> (November 2021)

Although clopyralid is used for many years the first evidence of resistance was observed in 1999 and the number of cases has risen only slightly without any obvious core area of distribution.

Up to date (November 2021), there is no report documenting weeds species resistant to clopyralid from the whole of Europe. Cases of resistance occurring in the field worldwide are reported to a specialist herbicide resistance action group and the details are recorded on an internet database.

Based on the fact that 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.

3.3.4 Cross-resistance

Cross resistance is defined as the expression of a genetically-endowed mechanism conferring the ability to withstand herbicides from different chemical classes. According to HRAC there are two broad cross resistance categories: target site cross resistance and non-target site cross resistance.

Target site cross resistance occurs when a change at the biochemical site of action of one herbicide also confers resistance to herbicides from a different chemical class that inhibit the same site of action in the plant. Target site cross resistance does not necessarily result in resistance to all herbicide classes with a similar mode of action or indeed all herbicides within a given herbicide class.

Auxin herbicides belong to different chemical classes, which include phenoxycarboxylic acids, benzoic acids, pyridine- carboxylic acids, aromatic carboxymethyl derivatives and quinolinecarboxylic acids. Their act is similar to that of endogenous auxin (IAA) although the true mechanism is not well understood. The specific cellular or molecular binding site relevant to the action of IAA and the auxin-mimicking herbicides has not been identified. Nevertheless, the primary action of these compounds appears to affect cell wall plasticity and nucleic acid metabolism. These compounds are thought to acidify the cell wall by stimulating the activity of a membrane-bound ATPase proton pump. The reduction in apoplasmic pH induces cell elongation by increasing the activity of enzymes responsible for cell wall loosening. Low concentrations of auxin-mimicking herbicides also stimulate RNA polymerase, resulting in subsequent increases in RNA, DNA and protein biosynthesis. Abnormal increases in these processes presumably lead to uncontrolled cell division and growth, which results in vascular tissue destruction. In contrast, high concentration of these herbicides inhibit cell division and growth, usually in meristematic regions that accumulate photosynthate assimilates and herbicide from the phloem. Auxin-mimicking herbicides stimulate ethylene evolution which may in some cases produce the characteristic epinastic symptoms associated with to these herbicides.

Despite synthetic auxin herbicides being used longer and on a greater area than any other herbicide mechanism of action the area infested with synthetic auxin resistant weeds is low in comparison to many other herbicide mechanism of action.

Target site cross resistances for Auxin Mimics HRAC Group 4 (Legacy O) in Europe have been reported for two dicotyledonous species: *Cirsium arvense* and *Papaver rhoeas*. Research has shown that these particular biotypes are resistant to 2,4-D, and MCPA and 2,4-D, aminopyralid and they may be cross-resistant to other Group 4 (Legacy O) herbicides. However, none of these cases concerned clopyralid.

Table 3.3-2 Reported cases of target site cross-resistance for Auxin Mimics HRAC Group 4 (Legacy O)⁷:

Year	Species	Country	MOAs	Actives	Situations
1985	<i>Cirsium arvense</i>	Hungary	Auxin Mimics HRAC Group 4 (Legacy O)	MCPA, 2,4-D	Pastures

⁷ Available online: <http://www.weedscience.org> (November 2021)

2015	<i>Papaver rhoeas</i>	France	Auxin Mimics HRAC Group 4 (Legacy O)	2,4-D, aminopyralid	Wheat
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Non-target site cross resistance is defined as cross resistance to dissimilar herbicide classes conferred by a mechanism(s) other than resistant enzyme target sites. Non-target site cross resistances for Auxin Mimics HRAC Group 4 (Legacy O) in Europe have been reported for following dicotyledonous species:

- *Papaver rhoeas*: Auxin Mimics HRAC Group 4 (Legacy O) and Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)
- *Sinapis arvensis*: Auxin Mimics HRAC Group 4 (Legacy O) and Synthetic Auxins (O/4) Inhibition of Aceto-lactate Synthase HRAC Group 2 (Legacy B)

Table 3.3-3 Reported cases of non-target site cross-resistance for Auxin Mimics HRAC Group 4 (Legacy O)⁸:

Year	Species	Country	MOAs	Actives	Situations
2016	<i>Papaver rhoeas</i>	France	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	metsulfuron-methyl, MCPA, 2,4-D, iodosulfuron-methyl-Na, mesosulfuron-methyl, amino-pyralid	Cereals
2002	<i>Papaver rhoeas</i>	Greece	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	2,4-D, iodosulfuron-methyl-Na, mesosulfuron-methyl	Wheat
1998	<i>Papaver rhoeas</i>	Italy	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, 2,4-D, iodo-sulfuron-methyl-Na	Wheat
1993	<i>Papaver rhoeas</i>	Spain	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, 2,4-D	Cereals, Wheat
2008	<i>Sinapis arvensis</i>	Turkey	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	thifensulfuron-methyl, tribenuron-methyl, triasulfuron, dicamba, propoxycarbazone-Na	Wheat

None of these cases concerned clopyralid.

Based on the fact that 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.

3.3.5 Risk of resistance development

Acceptability of the resistance risk

Generally, evidences of resistance to HRAC Group 4 and specifically to clopyralid are well documented by Weed Science organization and Herbicide Resistance Action Committee. The risk of resistance development of weeds to substances belongs to Group 4 is defined as low. Three cases of weeds specie resistance for clopyralid are reported worldwide, out of which none were reported in Europe so far. The

⁸ Available online: <http://www.weedscience.org> (November 2021)

resistance risk is really low if FAWORYT 300 SL is used under adherence to the management strategy and label recommendations.

Management strategy for the prevention of herbicide resistance

Diversity in weed control practices is key to delay and manage herbicide resistance in weeds. This involves rotation or mixtures of herbicide mechanisms of action 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 preemergence herbicides. Additionally, cultural/mechanical weed control methods including shallow tillage in the spring, crop rotation, and cleaning equipment can be applied. Generally, the full herbicide rate should be applied at the correct weed size. Fields shall be scouted after herbicide application in order to control any possible escapes.

3.3.6 Implementation of the management strategy

Resistance management guidelines have little or no impact unless they are effectively communicated to the users regarding how this will be achieved. Therefore, a plan will be implemented that will include but will not be limited to label statements, leaflets and training courses. To assist users in the selection of herbicides it is proposed to clearly indicate the HRAC group and description on the product label or promotional materials. Additionally, specific guidelines how to prevent resistance development should be provided in different forms to users.

To prevent further development of resistance or cross-resistance and to maintain effective control of target weeds FAWORYT300 SL shall be applied at the recommended dose rate with a maximum of 1 application per season in the optimum development phase of weeds.

Herbicides shall be used based on actual weed infestation, and use site-specific technology to make applications only where weed numbers exceed economic thresholds, combining herbicides with different modes of action and overlapping weed spectrum. Additionally, weed reproduction by seed or by vegetative proliferation has to be prevented. The farmer should combine, whenever possible, biological, mechanical and cultural weed control practices with herbicides.

Appropriate resistance-management strategies should be followed.

- Where possible, rotate the use of FAWORYT 300 SL with different herbicide groups that control the same weeds in a field.
- Use tank mixtures with herbicides from a different group when such use is permitted.
- Herbicide use should be based on an IPM program that includes scouting, historical information related to herbicide use and crop rotation, and considers tillage (or other mechanical), cultural, biological and other chemical control practices.
- Monitor treated weed populations for resistance development.
- Prevent movement of resistant weed seeds to other fields by cleaning harvesting and tillage equipment and planting clean seed.
- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and/or integrated weed-management recommendations or specific crops and weed biotypes.

Comments of zRMS:	<p>Clopyralid belongs to the pyridine carboxylic acids group. Applied post-emergence, clopyralid is effective on a broad spectrum of broad-leaved weeds.</p> <p>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 resistance risk.</p> <p>The risk of resistance was analysed following the EPPO-Standard (2003), the classification of the Herbicide Resistance Action Committee (HRAC) and the interna-</p>
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tional Survey of Herbicide Resistant Weeds (Heap, 2016).

Applicant submitted detailed information's about possibilities of development the resistance or cross-resistance. Evaluator accepted the strategy management about possible development of resistance or cross-resistance proposed by Applicant.

The probability of development of resistance or cross-resistance of weeds to Faworyt 300 SL is considered as low. The evaluation of the agronomic risk concludes that Clopyralid 30% SL bears a low 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, 3 cases of resistance were reported.

#	Year	Species	Country	MOAs	Actives	Situations
1	2013	<i>Centaurea stoebe ssp. micranthos</i>	Canada (British Columbia)	Auxin Mimics HRAC Group 4 (Legacy O)	clopyralid, picloram	Rangeland
2	1999	<i>Soliva sessilis</i>	New Zealand	Auxin Mimics HRAC Group 4 (Legacy O)	clopyralid, picloram, triclopyr	Golf courses, Turf
3	2005	<i>Chenopodium album</i>	New Zealand	Auxin Mimics HRAC Group 4 (Legacy O)	dicamba, clopyralid, aminopyralid	Corn (maize)

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

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,
- - adapt tillage operations to field conditions, especially to the type and severity of weeds,
- - use various methods of weed control, including crop rotation, etc,
- - use certified seed,
- - clean agricultural machinery to prevent the transfer of weed propagating material to other sites,

	<ul style="list-style-type: none">- - inform the permit holder of unsatisfactory weed control,- - contact your advisor, the permit holder or the permit holder's representative for more information. <p>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 five proven problems with weed resistance have been reported in Europe, the risk for the development of clopyralid resistant weed biotypes in major crop production and vegetable production areas is considered low.</p>
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3.4 Adverse effects on treated crops (KCP 6.4)

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. Information on the adverse effects on treated crops of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013.

Comments of zRMS:	Statement accepted.
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3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. Information on the phytotoxicity to host crop of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013

Comments of zRMS:	Statement accepted.
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3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. Information on the effect on the yield of treated plants or plant product of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013.

Comments of zRMS:	Statement accepted.
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3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. Information on the effect on the quality of plants or plant products of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013.

Comments of zRMS:	Statement accepted.
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3.4.4 Effects on transformation processes (KCP 6.4.4)

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. Information on the effect on transformation processes of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013.

Comments of zRMS:	Statement accepted.
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3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. Information on impact on treated plants or plant products to be used for propagation of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013.

Comments of zRMS:	Statement accepted.
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3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. Information on impact on succeeding crops of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013.

Comments of zRMS:	Statement accepted.
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009. Information on impact on adjacent crops of the product FAWORYT 300 SL was submitted and positively evaluated during the authorization process of this product (Authorization No: R-140/2013 dated of 08.11.2013). Please refer to Registration Report (Part B – Section 3) for the product FAWORYT 300 SL with March 2013.

Comments of zRMS:	Statement accepted.
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3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Please refer to dRR Section 9 Ecotoxicology for detailed assessment.

Comments of zRMS:	Statement accepted.
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3.6 Other/special studies

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009.

Comments of zRMS:	Statement accepted.
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3.7 List of test facilities including the corresponding certificates

There has been no GAP change that impacts the previous efficacy evaluation of FAWORYT 300 SL. Therefore no new data has been provided with this submission that needs listing under this point.

Appendix 1 Lists of data considered in support of the evaluation

Product Renewal under Article 43; no new efficacy data is submitted.