

REGISTRATION REPORT
Part B
Section 3
Efficacy Data and Information
Concise summary

Product code: EF-243 (HCV07)
Product name(s): Vivendi 300 SL, Auksendy 300 SL,
Cliophar Super
Chemical active substance:
Clopyralid – olamine, 395 g/L
(300 g ae/L)

Central Zone
Zonal Rapporteur Member State: Poland

CORE ASSESSMENT
(Article 43 renewal)

Applicant: UPL Holdings Coöperatief U.A.
Submission date: December 2021, updated: February 2022
MS Finalisation date: July 2023 (initial Core Assessment)
April 2024 (final Core Assessment)

Version history

| When | What |
|---------------|--|
| December 2021 | Initial dRR – UPL Holdings Coöperatief U.A. |
| February 2022 | Updated dRR (additional non-target cMS removed) – UPL Holdings Coöperatief U.A. |
| July 2023 | <p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p> |
| April 2024 | <p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the Applicant are highlighted in yellow. Not agreed or not relevant information are struck through and shaded for transparency.</p> |

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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)

Comments of zRMS:

Conclusions from the evaluation were prepared using grey commenting boxes placed at the end of each chapter. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are also ~~visibly marked with the grey font.~~

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

Abstract

Comments of zRMS:

This application has been submitted for the renewal of authorisation of herbicide Vivendi 300 SL/Auksendy 300 SL/Cliophar Super (product codes: EF-243, HCV07), containing 300 g/L clopyralid (chemical group: pyridine carboxylic acid, HRAC group: 4 (legacy O) – synthetic auxins, acting like indole acetic acid), on the grounds of art. 43 of Regulation (EC) No 1107/2009.

Vivendi 300 SL/Auksendy 300 SL/Cliophar Super is post-emergence herbicide intended for the control of broad-leaf weeds, currently authorised in Poland in the following crops: winter oilseed rape (BRSNW), sugar beet (BEAVA), onion from seeds (ALLCE).

The new GAP table contains many amendments compared to the existing product label. These changes are mentioned below:

- additional four new variants of herbicide use in sugar beet involving e.g. dose rate reduction/ split application - proposed due to new risk assessment endpoints, extension of application window,
- the application window in the existing variant of use in sugar beet proposed to be extended from BBCH 12-14 to BBCH 12-39,
- additional minor crops claimed: fodder beet (BEAVC), red beet (BEAVD), turnip (BRSRR), swede (BRSNA), spring oilseed rape (BRSNS), mustard (BRSJU/SINAL), linseed (LIUUT),
- water volume amended: 100-400 L/ha instead of 200-300 L/ha for all claimed uses,
- application window change in the onion from seeds: BBCH 11-16 instead of BBCH 13,
- a little application window change in winter oilseed rape from BBCH 30-50 to BBCH 30-51.

The applicant has submitted new data package presented in the chapter 3.2.1.1 (Comparability between clopyralid formulations, 3.2.3. (Efficacy) and 3.4.1 (Phytotoxicity to host crop).

Comparability between clopyralid formulations

The comparability between various clopyralid formulations (GF-1966, EF-243, EF-1136) applied in a single application timing in the control of various broadleaf weed species (CIRAR, AETCY, MATMA, MATIN, DATST) on sugar beet has been demonstrated in 9 trials carried out in Czech Republic, Slovakia and France.

Efficacy

The submitted 5 French trials do not meet the trial location requirements and are considered not valid for efficacy evaluation of herbicide Vivendi 300 SL/Auksendy 300 SL/Cliophar Super for Polish authorization purpose.

Phytotoxicity

Results from 12 trials carried out in Czech Republic, Slovakia and France (supportive data) indicate that there is no phytotoxic effect of the tested various clopyralid formulations (EF-243, GF-1966, EF-1136) on sugar beet.

The conclusions from the efficacy evaluation are as follows:

1. The general conditions of use of the herbicide Vivendi 300 SL/Auksendy 300 SL/Cliophar Super in sugar beet should remain the same as in the current product labels. An extension of the application timing from BBCH 12-14 to BBCH 12-19, within the same main application window is acceptable.

2. The recommended water volume for ~~at~~ the claimed uses should remain the same as in the current product labels (200-300 L/ha). The slight water volume change from 200-300 L/ha to 150-300 L/ha requested by the applicant for sugar beet during commenting period has been accepted.

3. An extension of the application timing in onion from BBCH 13 to BBCH 11-16, within the same main application window is acceptable,

4. A little application window change in winter oilseed rape from BBCH 30-50 to BBCH 30-51 is acceptable,

5. Additional minor crops, not existing in the current product labels: fodder beet, red beet, turnip, swede, spring oilseed rape, mustard, linseed are proposed to be authorised on the grounds of art. 51 of Regulation (EC) No 1107/2009.

The resistance risk assessment has been updated by the applicant due to requirements of art. 43 of Regulation (EC) No 1107/2009.

Resistance management strategy (accepted by the zRMS with some additional recommendations):

The herbicide EF-243 (HCV07) contains active substance: clopyralid belonging to pyridinecarboxylic acid chemical group, Synthetic auxins (HRAC group: 4). To prevent possible resistance development, the following rules should be applied:

- use the herbicide according to the label recommendations including time and the recommended dose rate,
- use the herbicide alternately or in mixture with other herbicides belonging to different chemical groups with different modes of action,
- Use 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.
- Use cultural/mechanical weed control methods including shallow tillage in the spring, crop rotation, and cleaning equipment.
- use only certified seeds,
- Use full herbicide rates applied at the correct weed size and to carefully monitor results.
- Scout fields after herbicide application and control escapes.
- inform the authorization holder about not satisfying efficacy achieved,
- Consider all chemical control options before planting, in-crop and after harvest,
- Know the weeds in their fields and nearby non-crop areas and tailor their weed control program to weed densities and economic thresholds.
- Maintain detailed field records to confirm cropping and herbicide history

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. (e) | Member state(s) | Crop and/ or situation (crop desti- nation / purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I | Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: e.g. g safener/synergist per ha (f) | zRMS Conclusion (efficacy) |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. inter- val between applications (days) | L product / ha a) max. rate per appl. b) max. total rate per crop/season | 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 | Poland | Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: BEAVC, BEAVA, BEAVD, BRSRR, BRSNA 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 | BBCH 12- 19 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) | 150- 300 400- 400 200- 300 | 42 days | One application every two years. Maximum total dose rate must not exceed 120 g ae/ha per crop; maximum individ- ual dose: 120 g ae/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. | A BEAVA N BEAVC, BEAVD, BRSRR, BRSNA (possible registration on the grounds of article 51) |
| 2 | Poland | Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: | F | Broad-leaved weeds (BBBBB) (including but not only Cirsium | Broadcast, Foliar Tractor mounted boom, | BBCH 12- 15 First 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) | 400- 400 200- 300 | 42 days | Only every three years. Split application: First application at 60 gae/ha (0,2L/ha) at BBCH 12-15 followed 7-days later by a second application at BBCH 12-15 at 60 gae/ha (0,2 L/ha). Maximum total dose rate must not exceed | N (possible registration on the grounds of article 51 for BEAVC, BEAVD, |

| 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 desti- nation / purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I | Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: (i) e.g. g safener/synergist per ha | zRMS Conclusion (efficacy) |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. inter- val between applications (days) | L product / ha a) max. rate per appl. b) max. total rate per crop/season | kg as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min / max | | | |
| | | BEAVC, BEAVA, BEAVD, BRSRR, BRSNA EU MRL Code: 0213010, 0900010, 0213010 Raw Human consumption Processed goods Cattle consumption | | arvense, Matricaria spp.) | split application | Second application at BBCH 12-15. | | | | b) AS1: 158,104 (as/ha), 120 (ae/ha) | | | 120 g ae/ha per crop; maximum individu- al dose: 120 g ae/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.. | BRSRR, BRSNA) |
| 3 | Poland | Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: BEAVC, BEAVD, BEAVA, BRSRR, BRSNA EU MRL Code: 0213010, 0213010, 0900010, | 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) | 400- 400 200- 300 | 42 days | Only every three years. Split application: First application at 52,5 gae/ha (0,175L/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/ha). Maximum total dose rate must not exceed 105 g ae/ha per crop; maximum individu- al dose: 105 g ae/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 | N (possible registration on the grounds of article 51 for BEAVC, BEAVD, BRSRR, BRSNA) |

| 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 desti- nation / purpose of crop) | F, Fn, G, Gn, Gpn or I | Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: e.g. g safener/synergist per ha (i) | zRMS Conclusion (efficacy) |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. inter- val between applications (days) | L product / ha a) max. rate per appl. b) max. total rate per crop/season | kg as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min / max | | | |
| | | Raw Human consumption Processed goods Cattle consumption | | | | | | | | | | | days after application of clopyralid. For crop rotation management, see label for recommendations.. | |
| 4 | Poland | Fodder beet, Sugar beet, Red Beet, Turnip, Swede EPPO Code: BEAVC, BEAVD, BEAVA, BR SRR , BSNA EU MRL Code: 0213010, 0213010, 0900010, 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. Sec- ond appli- cation 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) | 400- 400 200- 300 | 42 days | Every two years. Split application: first application at 52,5 gae/ha (0,175L/ha) at BBCH 15 followed 10 days later by a second application (at BBCH 31) at 52,5 gae /ha (0,175 L/ha). Maximum total dose rate must not exceed 105 g ae/ha per crop; maximum individual dose: 105 g ae/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.. | N (possible registration on the grounds of article 51 for BEAVC, BEAVD, BRSRR, BRSNA) |
| 5 | Poland | Fodder beet, Sugar beet, Red Beet, | F | Broad-leaved weeds (BBBBB) | Broadcast, Foliar | BBCH 15- 31 | a) 2 b) 2 | 10-day interval | a) 0,2 b) 0,4 | a) AS1: 79,05 (as/ha), 60 | 400- 400 200- | 42 days | Every two years. Split application: first application at 60 gae/ha (0,2 L/ha) at BBCH 15 followed 10 days later by a | N (possible registration |

| 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 desti- nation / purpose of crop) | F, Fn, G, Gn, Gpn or I | Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: e.g. g safener/synergist per ha (f) | zRMS Conclusion (efficacy) |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. inter- val between applications (days) | L product / ha a) max. rate per appl. b) max. total rate per crop/season | kg as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min / max | | | |
| | | Turnip, Swede EPPO Code: BEAVC, BEAVA, BEAVD, BRSRR, BRSNA EU MRL Code: 0213010, 0900010, 0213010 Raw Human consumption Processed goods Cattle consumption | | (including but not only Cirsium arvense, Matricaria spp.) | Tractor mounted boom, split application | First application at BBCH 15. Sec- ond appli- cation at BBCH 31. | | | | (ae/ha) b) AS1: 158,1 (as/ha), 120(ae/ha) | 300 | | second application (at BBCH 31) at 60 gae/ha (0,2 L/ha). Maximum total dose rate must not exceed 120 g ae/ha per crop; maximum individual dose: 120 g ae/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.. | on the grounds of article 51 for BEAVC, BEAVD, BRSRR, BRSNA) |
| 6 | Poland | Winter Oilseed rape, Spring Oilseed rape, Mus- tard, Lin- seed | F | Broad-leaved weeds (BBBBB) (including but not only Cirsium arvense, | 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) | 400- 400 200- 300 | Not appli- cable* | 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 | A BRSNW Dose rate range 0,3- 0,4 L/ha recommend- ed according to the current product label. |

| 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 desti- nation / purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I | Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: (i) | zRMS Conclusion (efficacy) |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. inter- val between applications (days) | L product / ha a) max. rate per appl. b) max. total rate per crop/season | kg as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min / max | | | |
| | | EPPO Code: BRSNW, BRSNS, BRSJU, SINAL, LIUUT EU MRL Code: 0401060 Raw Human consumption Processed goods Cattle consumption | | Centaurea cyanus, Matricaria spp) | | | | | | AS1: 158,104 (g as/ha), 120 (g ae/ha) | | | days after application of clopyralid. For crop rotation management, see label for recommendations. | N BRSNS, BRSJU, SINAL, LIUUT (possible registration on the grounds of art. 51) |
| 7 | Poland | Onion from 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) | 400 400 200- 300 | 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.. | A Dose rate range 0,3- 0,4 L/ha recommend- ed according to the current product label. |

* 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

| | |
|---|--|
| A | Acceptable |
| R | Acceptable with further restriction |
| C | To be confirmed by cMS |
| N | Not acceptable / evaluation not possible |

Comment of zRMS – to the GAP table:

Due to the inconsistencies found, after consultation with the applicant, the GAP table was moved from Part A/B0 to part B3, for document consistency.

| 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, Fnp G, Gn, Gnp 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-safener/ synergist-per ha; other-dose-rate expression; dose range (min-max) | zRMS Conclusion (efficacy) |
| | | | | | Method-/ Kind | Timing-/ Growth-stage of-crop-& season | Max.-num- ber a)-per-use b)-per-crop/ season | Min.-interval between applications (days) | kg-or-L-prod- uct-/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 | Poland | Fodder-beet, Sugar-beet, Red 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 <i>Cirsium arvense</i> , <i>Matricaria</i> spp.-) | Broadcast, Foliar Tractor mounted boom | BBCH-12-39 (until-July 1st) | a)-1 b)-1 | NA | a)-0,3-to-0,4 b)-0,3-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/ha-per-crop; maximum-indi- vidual-dose: 120-g ae/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. | |

| 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, Fnp G, Gn, Gnp 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 safener/ synergist per ha; other dose rate expression, dose range (min-max) | zRMS Conclusion (efficacy) |
| | | | | | Method/ Kind | Timing/ Growth stage of crop & season | Max. num- ber a) per use b) per crop/ season | Min. interval between applications (days) | kg or L prod- uct / 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 | | | |
| | | | | | | | | | | | | | It is recommend- ed that sugar canes not be planted for 125 days after appli- cation of clopyra- lid. For crop rotation management, see label for recom- mendations. | |
| 2 | Poland | Fodder beet; Sugar beet, Red 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 <i>Cirsium arvense</i> , <i>Matricaria spp.</i>) | Broadcast, Foliar Tractor mounted boom, split application | BBCH 12-15 First applica- tion at BBCH 12-15. Sec- ond applica- tion at BBCH 12-15. | a) 2 b) 2 | 7-day inter- val | 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/ha (0,2L/ha) at BBCH 12-15 followed 7 days later by a second application at BBCH 12-15 at 60 gae/ha (0,2 L/ha). Maximum total dose rate must not exceed 120 g ae/ha per crop; maximum indi- vidual dose: 120 g ae/ha. For residue management in crop rotation: no mitigation measures are | |

| 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, Fnp G, Gn, Gnp 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 safener/ synergist per ha; other dose rate expression, dose range (min-max) | zRMS Conclusion (efficacy) |
| | | | | | Method/ Kind | Timing/ Growth stage of crop & season | Max. num- ber a) per use b) per crop/ season | Min. interval between applications (days) | kg or L prod- uct / 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 | | | |
| | | | | | | | | | | | | | required for Leafy and Brassica vegetables or for Oilseeds. For all other food and feed commodities except sugar canes, a 30-day PHI is supported. It is recommend- ed that sugar canes not be planted for 125 days after appli- cation of clopyra- lid. For crop rotation management, see label for recom- mendations. | |
| 3 | Poland | Fodder beet, Red beet, Sugar beet, Mangels EPPO-Code: BEAVC, BEAVD, BEAVA, BEAVC EU-MRL-Code: 0213010; 0213010; 0900010; 0213010 Raw Human | F | Broad-leaved weeds (BBBBB) (including but not only <i>Cirsium arvense</i> , <i>Matricaria</i> spp.) | Broadcast, Foliar Tractor mounted boom, split application | BBCH 12-15 First applica- tion at BBCH 12-15. Sec- ond applica- tion at BBCH 12-15. | a) 2 b) 2 | 7 day inter- val | 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 | Only every three years. Split application: First application at 52,5 gae/ha (0,175L/ha) at BBCH 12-15 followed 7 days later by a second application at BBCH 12-15 at 52,5 gae-clopyra- lid/ha (0,175 L/ha). Maximum total | |

| 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, Fnp G, Gn, Gnp 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 safener/ synergist per ha; other dose rate expression, dose range (min-max) | zRMS Conclusion (efficacy) |
| | | | | | Method/ Kind | Timing/ Growth stage of crop & season | Max. num- ber a) per use b) per crop/ season | Min. interval between applications (days) | kg or L prod- uct / 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 | | | |
| | | consumption Processed goods Cattle consump- tion | | | | | | | | | | | dose rate must not exceed 105 g ae/ha per crop; maximum indi- vidual dose: 105 g ae/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 recommend- ed that sugar canes not be planted for 125 days after appli- cation of clopyra- lid. For crop rotation management, see label for recom- mendations. | |
| 4 | Poland | Fodder beet, Red beet, Sugar beet, Mangels EPPO-Code: | F | Broad-leaved weeds (BBBBB) (including but not only <i>Cirsium arvense</i> , <i>Matricaria</i> | Broadcast, Foliar Tractor | BBCH 15-31 First applica- tion at BBCH | a) 2 b) 2 | 10-day interval | a) 0,175 b) 0,35 | a) AS1: 69,17 (as/ha), 52,5 (ae/ha) | 100-400 | 42 days | Every two years. Split application: first application at 52,5 g ae/ha | |

| 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, FnP G, Gn, Gnp 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 safener/ synergist per ha; other dose rate expression, dose range (min-max) | zRMS Conclusion (efficacy) |
| | | | | | Method/ Kind | Timing/ Growth stage of crop & season | Max. num- ber a) per use b) per crop/ season | Min. interval between applications (days) | kg or L prod- uct / 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 | | | |
| | | BEAVC; BEAVD; BEAVA; BEAVC EU-MRL-Code: 0213010; 0213010; 0900010; 0213010 Raw Human consumption Processed goods Cattle consump- tion | | spp.) | mounted boom, split application | 15. Second application at BBCH 31. | | | | b) AS1: 138,341 (as/ha), 105 (ae/ha) | | | (0,175L/ha)-at BBCH 15 fol- lowed 10 days later by a second application (at BBCH 31)-at 52,5 gae/ha (0,175 L/ha). Maximum total dose rate must not exceed 105 g ae/ha per crop; maximum individual dose: 105 g ae/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 recommend- ed that sugar canes not be planted for 125 days after appli- cation of elopyra- lid. For crop rotation | |

| 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, Fnp G, Gn, Gnp 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 safener/ synergist-per-ha; other dose-rate expression, dose range (min-max) | zRMS Conclusion (efficacy) |
| | | | | | Method-/ Kind | Timing-/ Growth-stage of crop-& season | Max.-num- ber a)-per use b)-per crop/ season | Min.-interval between applications (days) | kg or L prod- uct /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 | | | |
| | | | | | | | | | | | | | management, see label for recom- mendations: | |
| 5 | Poland | Fodder beet, Sugar beet, Red 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 <i>Cirsium arvense</i> , <i>Matricaria spp.</i>) | Broadcast, Foliar Tractor mounted boom, split application | BBCH 15-31 First applica- tion at BBCH 15. Second application 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/ha (0,2 L/ha) at BBCH 15 followed 10-days later by a second application (at BBCH 31) at 60 gae/ha (0,2 L/ha). Maximum-total dose-rate must not exceed 120-g ae/ha-per-crop; maximum-indi- vidual-dose: 120-g ae/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-recommend- | |

| 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, Fnp G, Gn, Gnp 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 safener/ synergist per ha; other dose rate expression, dose range (min-max) | zRMS Conclusion (efficacy) |
| | | | | | Method/ Kind | Timing/ Growth stage of crop & season | Max. num- ber a) per use b) per crop/ season | Min. interval between applications (days) | kg or L prod- uct / 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 | | | |
| | | | | | | | | | | | | | ed that sugar canes not be planted for 125 days after appli- cation of elopyra- lid. For crop rotation management, see label for recom- mendations. | |
| 6 | Poland | Winter Oilseed rape EPPQ-Code: BRSNW EU-MRL-Code: 0401060 Raw Human consumption Processed goods Cattle consump- tion | F | Broad-leaved weeds (BBBBB) (including but not only <i>Cirsium arvense</i> , <i>Centaurea cyanus</i> , <i>Matricaria spp</i>) | 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 appli- cable ^z | 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 recommend- ed that sugar canes not be planted for 125 days after appli- cation of elopyra- lid. For crop rotation management, see label for recom- mendations. | |

| 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, FnP G, Gn, GnP 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 safener/ synergist per ha; other dose rate expression, dose range (min-max) | zRMS Conclusion (efficacy) |
| | | | | | Method/ Kind | Timing/ Growth stage of crop & season | Max. num- ber a) per use b) per crop/ season | Min. interval between applications (days) | kg or L prod- uct / 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 | | | |
| 7 | Poland | Onion from Seeds EPPO Code: ALLCE EU MRL Code: 0220020 Raw Human consumption Processed goods | F | Broad-leaved weeds (BBBBB) (including but not only <i>Cirsium arvense</i> , <i>Matricaria spp.</i>) | 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 recommend- ed that sugar canes not be planted for 125 days after appli- cation of clopyra- lid. For crop rotation management, see label for recom- mendations. | |

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 31st April 2021 was granted by Commission implementing Regulation (EU) 2020/421 (18th March 2020). The renewal of clopyralid has been approved in Commission Implementing Regulation (EU) 2021/1191.

The SANCO report for clopyralid (SANCO/10012//2006 rev. 3 – 4th April 2006) and the EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance clopyralid (14th December 2005), are considered to provide the relevant review information or a reference to where such information can be found.

The Annex I of the Inclusion Directive for clopyralid (2006/64/CE) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

In assessing applications to authorise plant protection products containing clopyralid for uses other than spring applications, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009 and shall ensure that any necessary data and information is provided before such an authorisation is granted.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clopyralid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 20 May 2021 shall be taken into account. In this overall assessment Member States must 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.

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 (clopyralid, 300 g/L), in the EU Central Registration Zone where it is currently registered in Poland. EF-243 is also known by the code HCV07, it is referred to throughout this dossier by the code EF-243.

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.

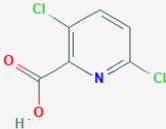
A total of 5 efficacy trials are summarised to demonstrate sufficient effectiveness in product performance that support rate changes for EF-243 at renewal.

A total of 9 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 and onion.

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 ₆ H ₃ Cl ₂ NO 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). 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 death¹.

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

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>

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 described². 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 cell².

Table 3.2-2: Details of the active substance

| Active substance | Clopyralid |
|-------------------|--|
| Concentration | 300 g/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/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.

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) | | | | |
| Winter oilseed rape (BRSNW) | Broad-leaved weeds | Poland Major | 0.3-0.4 L/ha (90-120g a.e./ha) (1) | 0.4 L/ha (120g a.e./ha) (1) | <u>No rate change</u> BBCH aligned to spring window BBCH 30-51 Water volume harmonised to 100-400 L/ha |
| Sugar beet (BEAVA) | Broad-leaved weeds | Poland Major | 0.3-0.4 L/ha (90-120g a.e./ha) (1) | Every two years 90-120 g a.e./ha BBCH 12- 35 39 (till July 1st). <u>Split application:</u> 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. | <u>No rate change</u> BBCH aligned to 12-35 (stop July 1st). Split dose at rate equivalent to single application rate (max 120g ae/ha) |
| Onion for Seeds (ALLCE) | Broad-leaved weeds | Poland Minor | 0.4 L/ha (120g a.e./ha) (1) | 0.4 L/ha (120g a.e./ha) (1) | <u>No rate change</u> BBCH aligned to residue package BBCH 11-16 Water volume harmonised to 100-400 L/ha |
| Gladiolus (GLASS) | Broad-leaved weeds | Slovakia Minor | 0.4 L/ha (120g a.e./ha) (1) | 0.4 L/ha (120g a.e./ha) (1) | <u>No rate change</u> BBCH aligned to residue package BBCH 12-19 Water volume harmonised to 100-400 L/ha |

Description of the target pests

Clopyralid products applied post-planting give control of a range of both annual and perennial broad-leaf 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 Estonia³.

Studies primarily based in Canada and the USA have investigated the relative extent to which increasing densities of CIRAR reduce yield in tilled cropping systems³. 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 recutita*). 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 rosette⁴.

MATIN at 25 plants per m² 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 crops⁵.

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 | <i>Aethusa cynapium</i> |
| CIRAR | <i>Cirsium arvense</i> |
| DATST | <i>Datura stramonium</i> |
| MATIN | <i>Tripleurospermum inodorum</i> |
| MATMA | <i>Tripleurospermum maritimum</i> |

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 |
| Winter oilseed rape (BRSNW) | PL | |
| Sugar beet (BEAVA) | PL | |
| Fodder beet / Mangel (BEAVC) | PL | PL |
| Red beet / Beetroot (BEAVD) | PL | PL |
| Onion for from seed (ALLCE) | | PL |
| Spring oilseed rape (BRSNS) | | PL |
| Turnip (BRSRR) | | PL |
| Swede (BRSNA) | | PL |
| Mustard (BRSJU/SINAL) | | PL |
| Linseed (LIUUT) | | PL |

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.

Two trials have been conducted outside of GEP certification schemes, these trials were conducted in Slovakia by UKSUP, 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 conduct 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 the majority of cases data are discussed in greater detail in Section 3.2.1. It is therefore possible to use efficacy data from comparable formulations in order 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/L clopyralid SC), which is the currently authorised formulation in Poland.

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. In order 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 and Figure 3.2-2

Justification for inclusion of data from different nations

Efficacy and selectivity trials submitted were conducted in the Czech Republic and France within the Maritime EPPO climatic zone 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 and South-East climatic zone are presented to demonstrate the comparability of different clopyralid formulations and also to demonstrate the equivalence of split applications of clopyralid vs a single application at comparable rates. In this regard the trials presented from the Maritime and South-East climatic zones may be considered supportive of the proposed label claims for the efficacy and crop safety of EF-243 in Poland.

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 and Figure 3.2-2.

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

| Crop* | Target* | Country | Year | Type of | Number of trials (number of valid trials) | | | | GEP, non-GEP, | Comments (Any other relevant information) |
|--------------------|-----------------------------------|----------------|------|---------|---|------------|------------|---------------|---------------|--|
| | | | | trial** | Maritime | South-East | North-East | Mediterranean | official*** | |
| 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) | - | |

* 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 Sugar beet (BEAVA) – Maritime EPPO zone

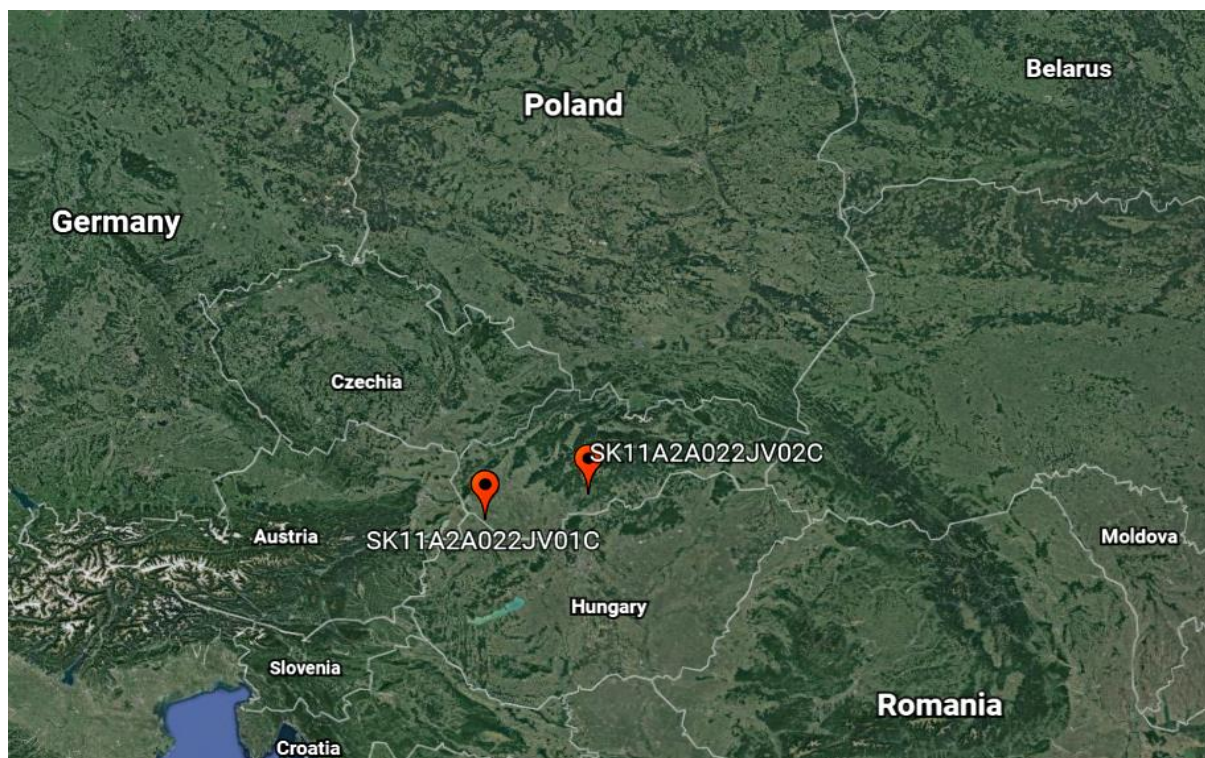


Figure 3.2-2: Efficacy trials in Sugar beet (BEAVA) – South-East EPPO zone

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 | | | | | | | | |
| Sugar beet (BEAVA) | EF-243 | CZ, SK | n.a. | clopyralid | SL | 300 g/L | n.a. | n.a. |
| Comparable formulations | | | | | | | | |
| Sugar beet (BEAVA) | EF-1136 | FR | n.a. | clopyralid | SL | 100 g/L | n.a. | n.a. |
| | GF-1996 | FR, CZ, SK | n.a. | clopyralid | SG | 720 g/kg | n.a. | n.a. |
| Standard reference products | | | | | | | | |
| 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/m² 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.

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 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 | 42-30 18-35 m ² |
| | 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 (± 2), Kevin (1), Pohoda (1), Caruso (1), Nordika (1), Galactica (1), Cestus (1), Tisserin (2), Fred (2) |
| Application | Crop stage (BBCH) at application | BBCH 12 10-39 |
| | Timing | Post-emergence |
| | Weed stage at application | BBCH 12-49 |
| | Number of applications | 1 (12 trials), split application in 5 10 trials |
| Assessment | Spray volumes | 175 L/ha (1 trial), 200 L/ha (6 trials), 250 L/ha (1 trial), 300 L/ha (4 trial) |
| | Assessment types | Phytotoxicity (%), crop vigour (%), weed control (%), visual assessment compared to the untreated) |
| Other relevant information | Assessment timings | 1-8 weeks after application, at harvest |
| | 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/L clopyralid SC), 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 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 | versus | Formulation | Clopyralid content | No. of trials |
|--------------------|-------------|--------------------|--------|-------------|--------------------|---------------|
| Maritime | EF-1136 | 100 g/L SL | | 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 3.2.1-2 (2x 60 g clopyralid/ha), Table 3.2.1-3 (105 g clopyralid/ha) and Table 3.2.1-4 (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 3.2.1-2: 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 3.2.1-3: 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 56 DAA | 75.0 | 75.0 | = |
| CZ10A2A019KS01C | 2010 | Maritime | BEAVA | CIRAR | 90 56 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 57 DAA | 55.0 | 65.0 | = |
| CZ10A2A019KS03C | 2010 | Maritime | BEAVA | MATIN | 73 57 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 3.2.1-4: 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 9 trials in sugar beet conducted in the Maritime and South-East climatic zones between 2008 and 2011 have generated data on the direct comparability between clopyralid formulations.

An overall summary of the comparability of clopyralid formulations is presented in Table 3.2.1-5.

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 and GF-1966 (Maritime zone).

Data on the control of sensitive weed species by clopyralid formulations in the Maritime 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 19 out of a total 21 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 3.2.1-5: 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 | | |
| Maritime | 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 |
| Maritime | 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 = |

Comments of zRMS on:
Comparability between clopyralid formulations (3.2.1).

9 trials presenting data on comparability between clopyralid formulations have been submitted by the applicant. In 7 of 9 trials the formulation GF-1966 (720 g/kg clopyralid) was compared with the target formulation EF-243 (300 g/L clopyralid) applied in a single application timing at equivalent dose rates of clopyralid per hectare (104–108 g. a.s/ha in 7 trials or 119–120 g a.s./ha in 3 trials). In 2 of 9 trials the formulation GF-1966 (720 g/kg clopyralid) was compared with the formulation EF-1136 (100 g/L clopyralid) in a single application timing, at equivalent dose rates of clopyralid per hectare (60 g a.s./ha). Based on the submitted data, it can be concluded the comparability between various clopyralid formulations applied in a single applications timing in the control of various broadleaf weed species (CIRAR, AETCY, MATMA, MATIN, DATST) on sugar beet has been demonstrated.

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).

Comments of zRMS on:
Minimum effective dose tests (3.2.2)

Not applicable.

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 65 valid efficacy trials have been conducted in sugar beet (BEAVA) in the Maritime climatic zone between 2007 and 2015.

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 m² 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

3.2.3.1 Winter oilseed rape (BRSNW) and minor crops: Spring oilseed rape (BRSNS), Mustard (BRSJU, SINAL), Linseed (LIUT)

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 |
|-----------|---|---|--------------------|--------------------|---------------------------|------------------------|
| Poland | Winter Oilseed rape Spring Oilseed rape, Mustard, Linseed EPPO Code: BRSNW, BRSNS, BRSJU, SINAL, LIUT EU MRL Code: 0401060 Raw Human consumption Processed goods Cattle consumption | Broad-leaved weeds (BBBBB) (including but not only <i>Cirsium arvense</i> , <i>Centaurea cyanus</i> , <i>Matricaria</i> spp.) | Crop BBCH 30-51 | 1 | 100-400 | 0.4 (120 g a.e./ha) |

3.2.3.2 Beetroot crops (3BERC) – Sugar beet (BEAVA), Fodder beet (BEAVC), Red beet (BEAVD), Mangels (BEAVC); Turnip (BRSRR), Swede (BRSNA)

There is no change to the currently approved dose for single application of EF-243 in Poland at renewal. Split application dose rates have been altered to reflect the maximum solo application rate (120g a.e./ha in Poland); 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 Poland (please refer to Table 3.2-3 for current and proposed uses for this submission).

All these trials were conducted within the Maritime climatic zone.

A summary of all efficacy trials carried out in Sugar beet is presented in

Table 3.2.3-1.

A list of all trials carried out in Sugar beet is presented in

Table 3.2.3-2.

Table 3.2.3-1: 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 3.2.3-2: 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 Agrosiences, France | Y | EF-1136 |
| FR08A2A066ML01C, 2008 | France | Maritime | Staphyt, FR | Y | EF-1136, GF-1966 |
| FR08A2A066ML02C, 2008 | France | Maritime | Syntech, FR | Y | EF-1136, GF-1966 |
| FR15H2B017FO01, 2015 | France | Maritime | Dow Agrosiences, 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, Turnip, Swede EPPO Code: BEAVC, BEAVA, BEAVD, BRSRR, BRSNA EU MRL Code: 0213010, 0900010, 0213010 Raw Human consumption Processed goods Cattle consumption | Broad-leaved weeds (BBBBB) (including but not only <i>Cirsium arvense</i> , <i>Matricaria</i> spp.) | BBCH 12-35 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 (60g 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). |

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 the proposed application schedule for Poland (60 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 m².

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 3.2.3-3.

Table 3.2.3-3: 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 | <i>Cirsium arvense</i> | 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.

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, based on 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 3.2.3-4: Overall summary of efficacy against broad-leaved weeds in BEAVA by weed species - split application (2 applications) of clopyralid at 60 / 61 g 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 No. of data sets (min-max) | 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) |
| | 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 No. of data sets (min-max) | 95.0 3 (88.3-100) | 96.9 2 (95 / 99) | 89.4 3 (80-100) | 85.4 2 (75 / 95.7) |
| | 90.1 5 (75-100) SD 9.5 | | 87.8 5 (80-100) SD 10.4 | |
| 10-14 weeks after second application No. of data sets (min-max) | 98.4 2 (96.7 / 100) | 98.7 1 (-) | 96.7 2 (93.3 / 100) | 96.0 1 (-) |
| | 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) |

3.2.3.3 Onion (ALLCE)

No new data are presented; the dose rate for onion (for seeds) remains unchanged at renewal.

Label claim:

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

3.2.3.4 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 3.2.3-5. 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 3.2.3-6.

Table 3.2.3-5: Summary of efficacy presented by weed and application rate

| Weed EPPO code | Climatic Zone | | Rate tested (g a.e./ha) | |
|----------------|---------------|---------------|-------------------------|-------------------|
| | | | 120-125 g a.e./ha | 60 + 60 g a.e./ha |
| CIRAR | Maritime | Mean | 93 | 95.74 |
| | | Min-Max | (80-100) | (88.3-100) |
| | | No. of trials | 5 | 5 |
| | | SD | 7.65 | 4.57 |

Table 3.2.3-6: 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 |

Comments of zRMS on: Efficacy tests (3.2.3)

This application has been submitted for the renewal of authorisation of herbicide Vivendi 300 SL/Auksendy 300 SL/Cliophar Super (product codes: EF-243, HCV07), on the grounds of art. 43 of Regulation (EC) No 1107/2009.

Vivendi 300 SL/Auksendy 300 SL/Cliophar Super is post-emergence herbicide intended for the control of broad-leaf weeds, currently authorised in Poland in winter oilseed rape (BRSNW), sugar beet (BEAVA) and onion from seeds (ALLCE).

The new GAP table contains many amendments compared to the existing product label. The changes are mentioned below:

- additional four new variants of herbicide use in sugar beet involving e.g. dose rate reduction/ split application – proposed due to new risk assessment endpoints, extension of application window,
- the application window in the existing variant of use in sugar beet proposed to be extended from BBCH 12-14 to BBCH 12-39,
- additional minor crops claimed: fodder beet (BEAVC), red beet (BEAVD), turnip (BRSRR), swede (BRSNA), spring oilseed rape (BRSNS), mustard (BRSJU/SINAL), linseed (LIUUT),
- water volume amended: 100-400 L/ha instead of 200-300 L/ha for all claimed uses,
- application window change in the onion: BBCH 11-16 instead of BBCH 13,
- a little application window change in winter oilseed rape from BBCH 30-50 to BBCH 30-51.

According to SANCO/2010/13170 rev.14: “Where a GAP change is triggered e.g. by new endpoints, new guidance¹³, efficacy data addressing the new GAP should be submitted. Otherwise, for renewal applications, only resistance data are required”.

Results from 5 efficacy trials have been submitted to support authorisation of Vivendi 300 SL/Auksendy 300 SL/Cliophar Super to be applied at reduced dose rates/ split application: 2 x 0,2 L/ha (2 x 60 g clopyralid/ha), at application timing BBCH 12-39. The trials were carried out in Maritime EPPO zone (France) in the years 2007-2015. Two various clopyralid formulations: GF-1966 and EF-1136 were tested against CIRAR. The French trials do not meet the trial location requirements and cannot be used in the evaluation of herbicide Vivendi 300 SL/Auksendy 300 SL/Cliophar Super in order to be authorised in Poland. Additionally no trials have been submitted to support registration of herbicide Vivendi 300 SL/Auksendy 300 SL/Cliophar Super applied at reduced dose rate/ split application: 2 x 0,175 L/ha (2 x 52,5 g clopyralid/ha).

The conclusion from the evaluation for the individual claimed uses are presented below:

BEAVA

No valid efficacy trials have been submitted to support new variants of use of the herbicide Vivendi 300 SL/Auksendy 300 SL/Cliophar Super in sugar beet in Poland. It is not justifiable to extend the application window from BBCH 12-14 to BBCH 12-39 due to no valid efficacy and selectivity trials (considering trial location requirements) covering entirely BBCH range 12-39. The limited efficacy and phytotoxicity data with EF-243 applied at maximum dose rate of 4 l/ha at BBCH 16-18 or at maximum dose rate of 3,5 L/ha at BBCH 14-16 can be found in the trials: CZ10A2A019KS02C, CZ11A2A022KS01C presented in the chapter 3.2.1.1. (Comparability between clopyralid formulations) but the data package is still not sufficient to accept the whole application window BBCH 12-39. A change in application timing from BBCH 12-14 to BBCH 12-19, within the same main application window is acceptable.

The range of water volume 200-300 L/ha should remain unchanged due to no arguments to consider change to 100-400 L/ha as necessary. Additionally it can be noticed that, the water volume change is not covered by the currently submitted 12 efficacy trials, where the water amount ranged from 175 to 300 L/ha. Moreover, the amount of water recommended in the submitted product labels is unchanged (200-300 L/ha).

The slight water volume change from 200-300 L/ha to 150-300 L/ha requested by the applicant for sugar beet during commenting period has been accepted.

BEAVC, BEAVD, BRSRR, BRSNA

Additional minor crops not existing in the current label of Vivendi 300 SL/Auksendy 300 SL/Cliophar Super are proposed to be authorised on the grounds of art. 51 of Regulation (EC) No 1107/2009.

BRSNW

A little application window change in winter oilseed rape from BBCH 30-50 to BBCH 30-51 is acceptable. The range of water volume 200-300 L/ha should remain unchanged due to no arguments to consider change to 100-400 L/ha as necessary. It should be noted that the amount of water recommended in the submitted product labels is unchanged (200-300 L/ha).

BRSNS, BRSJU/ SINAL, LIUT

Additional minor crops, not existing in the current label of Vivendi 300 SL/Auksendy 300 SL/Cliophar Super are proposed to be authorised on the grounds of art. 51 of Regulation (EC) No 1107/2009.

ALLCE

The range of water volume 200-300 L/ha should remain unchanged due no arguments to consider the proposed amendment as necessary. A change in application timing from BBCH 13 to BBCH 11-16, within the same main application window is acceptable.

Additional remark

The presented data have been submitted to support the proposed new variants of use of Vivendi 300 SL/Auksendy 300 SL/Cliophar Super in sugar beet for the renewal of authorisation purpose in Poland (North-East EPPO zone). The trials presented in the chapter 3.2.1.1 and 3.2.3 were carried out in Maritime (FR, CZ) and South-East EPPO zone (SK) and seems to be not sufficient to cover all the proposed new scenarios of use the product in sugar beet also in Maritime and South-East EPPO zone - in case of possible future authorisation (whereas article 40 of regulation 1107/2009). However the final decision on acceptance the proposed uses/ scenarios of uses in sugar beet is to be made on the national level, according to the national requirements.

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

GF-2895 (600 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) 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-carboxylates | Aminopyralid |
| | Clopyralid |
| | Picloram |
| Pyridyloxy-carboxylates | Fluroxypyr |
| | Triclopyr |
| Pyrimidine-carboxylates | Aminocyclopyrachlor |
| Quinoline carboxylates | Quinclorac |
| | Quinmerac |

Source: HRAC8 and Weedsience9

Group 4 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 counterpart, treatment causes an 'auxin overdose' that leads to uncontrolled and disorganized plant growth and eventually plant death⁶.

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

⁶ Cox, C (1998) Herbicide Factsheet: Clopyralid, Journal of Pesticide Reform, Winter 1998, Vol.18(4).
<https://d3n8a8pro7vbm.cloudfront.net/ncap/pages/26/attachments/original/1428423336/clopyralid.pdf?1428423336>

of leaves, cracked stems and uncontrolled proliferated growth⁷. Plant death can occur within 1-4 weeks, depending on the plant species⁸.

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 described⁹. 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 receptors¹⁰. 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 sites¹².

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 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 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 resistance⁷. Auxin receptor proteins TIR1 and AFB1-6 are considered the most common in plant cells¹⁴; there is very little variation in the sequencing of these proteins 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 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-D¹⁴.

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-

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

carboxylate 2,4-D¹⁵. However, it is thought that such a mutation or reduction in AUX1 abundance will not affect all Group 4 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 it is thought that reduced transport, and not increased efflux was the cause of resistance¹⁶.

Non-target site resistance caused by enhanced metabolism is another possible cause of resistance development to Group 4 herbicides. Enzymes such as GH3, glucosyltransferases and GST3 are associated with conjugating with natural auxin IAA to deactivate it⁷. These enzymes have the potential to also deactivate synthetic auxins such as Group 4 herbicides; however, the different structural scaffolds of each chemical family mean that resistance to all Group 4 herbicides is unlikely to occur.

The potential mechanism of resistance to Group 4 herbicides have been investigated in studies⁷ 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 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 where almost 80% of wheat is treated at least once each season with Group 4 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.

Raphanus raphanistrum (Wild radish/Runch)

There have been many cases of resistance observed in Australia since 1999, partly related to increased use of Group 4 herbicides such as benzoate dicamba, and phenoxy-carboxylates 2,4-D and MCPA in response to widespread resistance to ALS-inhibiting herbicides (Group 2). 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 Database¹³, there are no cases of resistance to pyridine-carboxylate auxins (clopyralid, picloram or aminopyralid) among weed populations in Europe.

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

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

Globally, there are 79 83 cases of resistance to Group 4 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 herbicides in Europe

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

Source: Weedsience.org¹⁷

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 | <i>Soliva sessilis</i> | New Zealand | Synthetic Auxins (4/O) | clopyralid, picloram, triclopyr | Golf courses, Turf |
| 2005 | <i>Chenopodium album</i> | New Zealand | Synthetic Auxins (4/O) | dicamba, clopyralid, aminopyralid | Corn (maize) |
| 2013 | <i>Centaurea stoebe ssp. micranthos</i> | Canada | Synthetic Auxins (4/O) | clopyralid, picloram | Rangeland |

Source: Weedsience.org¹⁷

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 *Centaurea stoebe 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-carboxylates¹⁴. It should be assumed that cross-resistance could arise between pyridine carboxylates and between members of the Group 4 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

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

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) has not been reported in Europe.

Outside of Europe, cross-resistance between Group 4 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 over-used.

Three cases of resistance specifically to clopyralid show cross-resistance within Group 4 (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 be 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 resistance relate to 2,4-D, MCPA and dicamba²¹.

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 a 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)¹⁹.

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

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 an 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).

Table 3.3-4: Resistance risk matrix, according to Moss *et al.* (2019)¹⁹

| 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.

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

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) herbicides¹³ 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 on:

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

The herbicide EF-243 (HCV07) contains active substance: clopyralid (chemical group: pyridine carboxylic acid, HRAC group: 4 (legacy O) – synthetic auxins, acting like indole acetic acid). Clopyralid has been firstly reported by T. Haagsma in 1975 and introduced in France in 1977 by Dow Chemical Co. Clopyralid is systemic herbicide, absorbed by the leaves and roots, with translocation both acropetally and basipetally, and accumulation in meristematic tissue. It exhibits an auxin-type reaction and acts on cell elongation and respiration. Clopyralid is intended for post-emergence control of many annual and perennial broadleaf weeds of the families *Polygonaceae*,

Compositae, *Leguminosae* and *Umbelliferae* in many crops including beets, oilseed rape, maize, cereals, brassicas, onions, leeks, strawberries and flax.

The mechanism of resistance to SAHs is not well known. The candidate mechanisms of resistance can include target site modifications (auxin receptors or auxin-specific transporters) and non-target site mechanisms such as other transporters and enzymes that metabolize SAHs.

According to the International Herbicide-Resistant Weed Database (www.weedscience.org, date of access: July, 2023), cases of 42 weed species (including 4 weed species noted in Europe (CENCY, CIRAR, PAPRH, STEME,) resistant to auxinic herbicides have been reported since 1957 to 2020. The total number of reported cases to the herbicides from HRAC group 4 is 83 (resistance predominantly to phenoxy-carboxylates 2,4-D, MCPA and dicamba herbicides). No cases of resistance to pyridine-carboxylate auxins (clopyralid, picloram or aminopyralid) amongst weed populations in Europe have been reported yet. Outside of Europe, 3 cases of resistance to clopyralid and simultaneously to other synthetic auxins herbicides (picloram and triclopyr or dicamba and aminopyralid or picloram) have been reported in New Zealand and Canada. It has been shown that cross-resistance between members of the Synthetic Auxin herbicides may occur. Cross-resistance between clopyralid and members of other herbicide mode of action groups (other than Group 4) has not been reported yet globally.

The calculated overall risk of resistance for clopyralid, when used with herbicides of other modes of action as mixtures or in sequences of alternation, has been determined as low. If clopyralid is used without modification of the risk and only one herbicide mode of action is used, the risk of resistance may arise to moderate for high risk weed species such as AMASS, ALOMY, PAPRH.

Based on the submitted data and recommendations of Good Experimental Practice, to avoid the possible development of resistance, the resistance management strategy proposed by the applicant to be included in the label of EF-243 (HCV07) is presented below. This strategy has been accepted by the zRMS with some additional recommendations added.

“The herbicide EF-243 (HCV07) contains active substance: clopyralid belonging to pyridinecarboxylic acid chemical group, Synthetic auxins (HRAC group: 4). To prevent possible resistance development, the following rules should be applied:

- *use the herbicide according to the label recommendations including time and the recommended dose rate,*
- *use the herbicide alternately or in mixture with other herbicides belonging to different chemical groups with different modes of action,*
- *Use 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.*
- *Use cultural/mechanical weed control methods including shallow tillage in the spring, crop rotation, and cleaning equipment.*
- *use only certified seeds,*
- *Use full herbicide rates applied at the correct weed size and to carefully monitor results.*
- *Scout fields after herbicide application and control escapes.*
- *inform the authorization holder about not satisfying efficacy achieved,*
- *Consider all chemical control options before planting, in-crop and after harvest,*
- *Know the weeds in their fields and nearby non-crop areas and tailor their weed control program to weed densities and economic thresholds.*
- *Maintain detailed field records to confirm cropping and herbicide history.*

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 12 efficacy trials presented in this document (comparability and

efficacy) which have been conducted between 2007 and 2015 in sugar beet (12 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.

Sugar beet (BEAVA)

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 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 9 efficacy trials conducted to demonstrate comparability of clopyralid formulations in sugar beet.

Overall conclusions

Data from the 12 trials efficacy trials submitted within this dossier, demonstrate that the tested clopyralid formulations are crop safe in sugar beet.

Table 3.4-1: Phytotoxicity of product

| Number of trials with... | | Selectivity trials (0 trials) | | | | Efficacy trials (39 12 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% | - | - | - | - | 12 | 12 |
| | >5% to 10% | - | - | - | - | 0 | 0 |
| | >10% to 15% | - | - | - | - | 0 | 0 |
| | >15 % | - | - | - | - | 0 | 0 |
| Level of symptoms at the last assessments | 0% to 5% | - | - | - | - | 12 | 12 |
| | >5% to 10% | - | - | - | - | 0 | 0 |
| | >10% to 15% | - | - | - | - | 0 | 0 |
| | >15 % | - | - | - | - | 0 | 0 |

Comments of zRMS on: Phytotoxicity to host crop (3.4.1)

Results from 12 efficacy trials indicate, that there is no phytotoxic effect of the tested various clopyralid formulations (EF-243, GF-1966, EF-1136) on sugar beet.

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

3.4.2.1 Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

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

Not applicable.

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 on:
Effect on the quality of plants or plant products (3.4.3)

Not applicable.

3.4.4 Effects on transformation processes (KCP 6.4.4)

As a 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 on:
Effects on transformation processes (3.4.4)

Not applicable.

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 on:

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

Not applicable.

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 data are required to support this dossier. The Applicant therefore refers to previous evaluated submissions that support the current authorisations.

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.

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).

Comments of zRMS on:

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

Not applicable.

3.6 Other/special studies

No other/special studies have been carried out.

3.7 List of test facilities including the corresponding certificates

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 one exception:

- Two trials conducted by UKSUP, an Official Testing Institute, in 2011

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

Table 3.7-1: List of test facilities

| Organisation | Town | Country | Valid From | Valid To | Link |
|--|-------------------------|----------------|------------|-----------|-----------------------------|
| Dow AgroSciences S.A. | Sophia Antipolis CEDEX | France | 06-Feb-04 | 05-Feb-09 | 1d693a0b673 |
| Zemedelsky vyzkumny ustav Kromeriz, s.r.o. | Kromeriz | Czech Republic | 21-Mar-06 | 28-Mar-10 | 1d693a0b40f |
| 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 |
| Staphyt (France) | Inchy en Artois | France | 31-Jan-06 | 31-Dec-00 | 1d693a0b239 |
| Dow AgroSciences S.A. | Mougins | France | 25-Oct-10 | 25-Oct-15 | 1d693a0b122 |
| 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 |
| Zkusebni stanice Nechanice s.r.o. | Nechanice | Czech Republic | 07-Sep-09 | 07-Sep-14 | 1d693a0ad7d |

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 |
|------------------------|--------------|------|---|-------------------------|---------------------|
| KCP 6.0 | UPL/Corteva | 2022 | Biological Assessment Dossier – Article 43 Product Renewal EF-243 – Central Zone (zRMS Poland) UPL/Corteva non GEP Unpublished | N | UPL/Corteva |
| KCP 6.1.1 KCP 6.4.1 | Karel Sikora | 2010 | What is the efficacy of GF-1966 in comparison to existing formulations of clopyralid, ZE-MEDEL SKY VYZKUMNY USTAV KROMERIZ, S.R.O. CZ, EA10A2A019-CZ10A2A019KS01C, GEP Unpublished | N | Corteva Agriscience |
| KCP 6.1.1 KCP 6.4.1 | Karel Sikora | 2010 | Is GF-1966 bioequivalent to existing and new formulations of clopyralid, ZKUSEBNI STANICE NECHANICE, EA10A2A019-CZ10A2A019KS02C GEP Unpublished | N | Corteva Agriscience |
| KCP 6.1.1 KCP 6.4.1 | Karel Sikora | 2010 | Is GF-1966 bioequivalent to existing and new formulations of clopyralid, ZKUSEBNI STANICE KUJAVY, EA10A2A019- EA10A2A019-CZ10A2A019KS03C GEP Unpublished | N | Corteva Agriscience |
| KCP 6.1.1 KCP 6.4.1 | Karel Sikora | 2011 | Is GF-1966 bioequivalent to existing and new formulations of clopyralid, ZKUSEBNI STANICE KUJAVY EA11A2A022-CZ11A2A022KS01C GEP Unpublished | N | Corteva Agriscience |
| KCP 6.1.1 KCP 6.4.1 | Karel Sikora | 2011 | Is GF-1966 bioequivalent to existing and new formulations of clopyralid,ZKUSEBNI STANICE NECHANICE, EA11A2A022-CZ11A2A022KS02C GEP Unpublished | N | Corteva Agriscience |
| KCP | Michel Luras | 2008 | Efficacy of two different formulation of clopyralid LONTREL 100 and GF-1966 (sg) against | N | Corteva Agriscience |

| 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 KCP 6.2.2 KCP 6.4.1 | | | Cirsium arvensis to sugar beet - spring 2008 Staphyt, FR08A2A066ML01C GEP, Unpublished | | |
| KCP 6.1.1 KCP 6.2.2 KCP 6.4.1 | 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 | Corteva Agriscience |
| KCP 6.1.1 KCP 6.4.1 | Vojtko, Jan | 2011 | Is GF-1966 bioequivalent to existing and new formulations of clopyralid?, UKSUP, EA11A2A002-SK11A2A022JV01C, Not GEP, Unpublished | N | Corteva Agriscience |
| KCP 6.1.1 KCP 6.4.1 | Vojtko, Jan | 2011 | Is GF-1966 bioequivalent to existing and new formulations of clopyralid?, UKSUP, EA11A2A002-SK11A2A022JV02C, Not GEP, Unpublished | N | Corteva Agriscience |
| KCP 6.2.2 KCP 6.4.1 | Touzet, Francis | 2007 | EFFICACY OF LONTREL 100 AGAINST CIRAR IN SUGAR BEETS INCLUDING OIL, Dow Agrosience, FR07A2A037FT01, GEP, Unpublished | N | Corteva Agriscience |
| KCP 6.2.2 KCP 6.4.1 | Olivier, Francoise | 2015 | Interest of GF-2607 in mixture with Lontrel SG when applied against CIRAR in BEAVA. FR-2015, FR15H2B017FO01, GEP, Unpublished | N | Corteva Agriscience |
| KCP 6.2.2 KCP 6.4.1 | Olivier, Francoise | 2015 | Interest of GF-2607 in mixture with Lontrel SG when applied against CIRAR in BEAVA. FR-2015, FR15H2B017FO02, GEP, | N | Corteva Agriscience |

| 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 |
|------------|-----------|------|---|-------------------------|-------|
| | | | Unpublished | | |

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

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

List of data submitted by the applicant and not relied on

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

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

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