Modification of the existing maximum residue levels for
clopyralid in various commodities

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Corteva submitted a request to the competent national authority in Finland to modify the existing maximum residue levels (MRLs) for the active substance clopyralid in various commodities. The data submitted in support of the request were found to be sufficient to derive MRL proposals for wheat, oat and for animal commodities. An adequate analytical method for enforcement is available to control the residues of clopyralid in the plant commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. The analytical methods for animal commodities are validated at LOQ of 0.01 mg/kg, but demonstration of extraction efficiency is lacking. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of clopyralid according to the reported agricultural practices is unlikely to present a risk to consumer health provided that risk mitigation measures are in place to avoid clopyralid residues in rotational and/or succeeding crops.

Keywords: clopyralid, wheat, oat, animal commodities, herbicide, MRL, consumer risk assessment

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**Summary**

In accordance with Article 6 of Regulation (EC) No 396/2005, Corteva submitted an application to the competent national authority in Finland (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance clopyralid in oat grain, wheat grain and in fat, liver and kidney of bovine, sheep and goat and in swine kidney on the basis of intended NEU and SEU uses of clopyralid on cereals, pastures and grasslands. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 11 July 2018. To accommodate for the intended NEU/SEU uses of clopyralid, the EMS proposed to raise the existing MRLs from 2 to 3 mg/kg for oats and wheat and to lower the existing MRL from 5 to 3 mg/kg for rye. The EMS noted that the current MRLs for commodities of animal origin are based on old, non-good laboratory practice (GLP) and non-guideline compliant animal feeding studies and proposed revised MRLs for all livestock commodities based on the more recent state-of-the-art livestock feeding studies. Thus, raising of existing MRLs was proposed for a range of animal commodities. The EMS also proposed to lower the MRLs from 0.08 mg/kg to 0.05 mg/kg for bovine, sheep and goat muscle.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification, which were requested from the EMS. On 17 August 2020, the EMS submitted the requested information in a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of the renewal of approval under Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of clopyralid following foliar application was investigated in the EU pesticides peer review in crops belonging to the groups of root crops, leafy crops and pulses/oilseeds. In the framework of the current assessment, a new metabolism study in wheat, representing cereals/grass crop group was submitted. During the peer review, the data gap related to the identification of an unknown compound observed in sugar beet and oilseed rape metabolism studies was identified and, although the applicant and EMS provided further clarifications under the current assessment, EFSA still considers this data gap as not addressed. In addition, the EU pesticides peer review noted that the extraction conditions in metabolism study with leafy crops were not suitable to allow an elucidation of the metabolism of clopyralid. EFSA concludes that for the intended uses in grass and cereals, the metabolic behaviour of clopyralid in these crops is addressed with the new metabolism study in wheat.

Studies investigating the effect of processing on the nature of clopyralid (hydrolysis studies) demonstrated that the active substance is stable.

In rotational crops, the major residue identified was clopyralid and its conjugates in-line with the metabolism in primary crops (wheat).

Based on the metabolic pattern identified in metabolism studies with cereals, rotational crops and the results of hydrolysis studies, the residue definitions were proposed as clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) both, for enforcement and risk assessment. These residue definitions are applicable to cereals/grass crop group, rotational crops and processed products.

EFSA concluded that for the crops assessed in this application, metabolism of clopyralid has been sufficiently addressed to evaluate the proposed uses. The existing enforcement residue definition set in Regulation (EC) No 396/2005 refers to ‘clopyralid’ alone. EFSA proposes that the enforcement residue definition is amended by including salts and the conjugates which are covered by the existing analytical enforcement methods.

Sufficiently validated analytical methods based on LC-MS/MS are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in all crops (limit of quantification (LOQ)).

The available residue trials are sufficient to derive MRL proposals of 3 mg/kg for wheat and oat in support of the intended uses. Processing factors (PF) for the crops under assessment were not derived as new processing studies were not provided and the residue field trials reported in the EU pesticide peer review were not sufficiently reported to conclude on their validity and to derive proper processing factors. It is also noted that according to the EU pesticides peer review, the data need to be provided to exclude that pollen/nectar collection by bees might occur in order to exclude potential residues in pollen and bee products for human consumption. Based on the available information, EFSA could not exclude that the use of clopyralid according to the proposed good agricultural practice (GAP) will result...
in residues in rotational crops. A data gap was identified in the EU pesticide peer review for rotational crop field trials. For the current assessment, no new data were provided. Therefore, risk managers should consider setting specific risk mitigation measures (e.g. not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown) to avoid the presence of clopyralid residues in rotational crops until further data are submitted.

Grass and cereals and their by-products are fed to livestock. Thus, the dietary burden calculated in the previous EFSA assessments were updated with residue data as submitted for the intended uses of clopyralid on grass and cereals. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all animal species, with grass being one of the main contributors. Therefore, the possible occurrence of clopyralid residues in commodities of animal origin was further investigated. The nature of clopyralid residues in livestock has been investigated during the EU pesticides peer review of clopyralid (EFSA, 2018d) and the residue definition for enforcement was proposed as ‘clopyralid and its salts’; and as ‘clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid)’ for risk assessment. It was noted that the enforcement methods for animal commodities employ a hydrolysis step and, although not present or present at low levels (except milk), conjugates will be included in the results. Therefore, a harmonisation of the animal residue definitions as ‘clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid)’ is proposed by EFSA for the consideration by risk managers. EFSA takes also note of the new analytical enforcement method capable of quantifying clopyralid residues in animal commodities at the LOQ of 0.01 mg/kg (below the existing LOQ of 0.05 mg/kg). However, the extraction efficiency of the method remains to be addressed. The new feeding studies, submitted by the applicant, were used to estimate possible carry-over of residues into food of animal origin. Based on the estimated dietary burdens, the results of livestock feeding studies and the new analytical enforcement methods with lower LOQs, modification of existing clopyralid MRLs was proposed for several products of animal origin.

The toxicological profile of clopyralid was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.15 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary. During the process of renewal of the approval under Regulation (EC) No 1107/2009, the same ADI was agreed and an ARfD of 0.17 mg/kg bw has been set. It should be noted that this ARfD has not yet been officially implemented. Nevertheless, EFSA performed an indicative acute exposure calculation, using the new ARfD value.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA used the median residue value derived for the plant commodities assessed in this application; for animal commodities, the median residue value STMR values were used as derived from the feeding studies for the calculated dietary burdens. The other input values selected were the risk assessment values derived by EFSA in previous opinions and corresponding to the MRLs as established in the MRL Regulation. For the calculation of indicative acute exposure, the highest residue derived for the commodities assessed in this MRL application was chosen as input value.

The indicative short-term exposure did not exceed the ARfD for any of the crops assessed in this application. The estimated long-term dietary intake was in the range of 29% of the ADI for NL toddler diet when considering all crops.

EFSA concluded that the proposed use of clopyralid on wheat, oat and grass and the new MRLs in animal commodities will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

EFSA proposes to amend the existing MRLs as reported in the summary table below. Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|------------|------------------------|-------------------------|-----------------------|

Existing enforcement residue definition for commodities of plant origin: Clopyralid

Proposed enforcement residue definition for commodities of plant origin (by the EU pesticides peer review): clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid)
### Modification of the existing MRLs for clopyralid in various commodities

| Code<sup>(a)</sup> | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------------|-----------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0500090           | Wheat           | 2                       | 3                       | The submitted data are sufficient to derive an MRL proposal for the EU uses. Risk for consumers unlikely. Risk managers should consider setting specific risk mitigation measures to avoid the presence of clopyralid residues in rotational crops until further data are submitted |
| 0500050           | Oat             | 2                       | 3                       | The submitted data are sufficient to derive an MRL proposal by extrapolation from wheat. Risk for consumers unlikely. Risk managers should consider setting specific risk mitigation measures to avoid the presence of clopyralid residues in rotational crops until further data are submitted |

**Existing enforcement residue definition for commodities of animal origin:** Chlorpyrifos

**Proposed enforcement residue definition for commodities of animal origin** (by the EU pesticides peer review): chlorpyrifos and its salts OR chlorpyrifos common moiety (sum of chlorpyrifos, its salts and glycine conjugates expressed as chlorpyrifos)

| Code<sup>(a)</sup> | Commodity                          | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------------|------------------------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 1011010           | Swine, muscle/meat                 | 0.05*                   | 0.05<sup>(b)</sup>      | Based on the intended uses, new feeding studies and new enforcement method with lower LOQ of 0.01 mg/kg for all matrices. Risk for consumers unlikely. EFSA notes that on the basis of existing livestock dietary burden and the results of the more recent feeding studies, lower EU MRL of 0.03 mg/kg for bovine muscle/meat and of 0.04 mg/kg for sheep and goat muscle/meat would be sufficient |
| 1011020           | Swine, fat                         | 0.05*                   | 0.05                    |                                                                                       |
| 1011030           | Swine, liver                       | 0.05*                   | 0.05                    |                                                                                       |
| 1011040           | Swine, kidney                      | 0.05*                   | 0.6                     |                                                                                       |
| 1012010           | Bovine, muscle/meat                | 0.08                    | No change               |                                                                                       |
| 1012020           | Bovine, fat                        | 0.05*                   | 0.15                    |                                                                                       |
| 1012030           | Bovine, liver                      | 0.06                    | 0.15                    |                                                                                       |
| 1012040           | Bovine, kidney                     | 0.4                     | 1.5                     |                                                                                       |
| 1013010           | Sheep, muscle/meat                 | 0.08                    | No change               |                                                                                       |
| 1013020           | Sheep, fat                         | 0.05*                   | 0.2                     |                                                                                       |
| 1013030           | Sheep, liver                       | 0.06                    | 0.2                     |                                                                                       |
| 1013040           | Sheep, kidney                      | 0.4                     | 2                       |                                                                                       |
| 1014010           | Goat, muscle/meat                  | 0.08                    | No change               |                                                                                       |
| 1014020           | Goat, fat                          | 0.05*                   | 0.2                     |                                                                                       |
| 1014030           | Goat, liver                        | 0.06                    | 0.2                     |                                                                                       |
| 1014040           | Goat, kidney                       | 0.4                     | 2                       |                                                                                       |
| 1016010           | Poultry, muscle                    | 0.05*                   | 0.05<sup>(b)</sup>      |                                                                                       |
| 1016020           | Poultry, fat                       | 0.05*                   | 0.05<sup>(b)</sup>      |                                                                                       |
| 1016030           | Poultry, liver                     | 0.05*                   | 0.05<sup>(b)</sup>      |                                                                                       |
| 1020000           | Milk                               | 0.05*                   | 0.05<sup>(b)</sup>      |                                                                                       |
| 1030000           | Eggs                               | 0.05*                   | 0.05<sup>(b)</sup>      |                                                                                       |

MRL: maximum residue level.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(b): The MRL of 0.05 mg/kg in these commodities is proposed on basis of the LOQ of 0.05 mg/kg of the former analytical method. It is noted that a new enforcement analytical method is now available with a validated LOQ of 0.01 mg/kg, for which, however, the extraction efficiency has not been addressed.
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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for clopyralid in oat grain, wheat grain and in fat, liver and kidney of bovine, sheep and goat and in swine kidney. The detailed description of the intended uses of clopyralid, which are the basis for the current MRL application, is reported in Appendix A.

Clopyralid is the ISO common name for 3,6-dichloropyridine-2-carboxylic acid or 3,6-dichloropicolinic acid (IUPAC). The chemical structures of the active substance and its main metabolite are reported in Appendix E.

Clopyralid was first evaluated in the framework of Directive 91/414/EEC¹ with Finland designated as rapporteur Member State (RMS) for the representative uses as post-emergence applications on cereals, pasture, oilseed rapes and sugar beets. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2005). Clopyralid was approved for the use as herbicide on 1 May 2007.² In 2018, clopyralid was evaluated for renewal of the approval in the framework of Regulation (EC) No 1107/2009³ with Finland designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on winter cereals and grassland. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2018d). A decision on the renewal of the approval has not yet been taken.

The EU MRLs for clopyralid are established in Annex III of Regulation (EC) No 396/2005⁴. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed. EFSA has issued two reasoned opinions on the modification of MRLs for clopyralid (EFSA, 2011, 2018b). The proposals from these reasoned opinions have been considered in recent MRL regulations.⁵

In accordance with Article 6 of Regulation (EC) No 396/2005, Corteva submitted an application to the competent national authority in Finland (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance clopyralid in oat grain, wheat grain and in fat, liver of bovine, sheep and goat and in swine kidney on the basis of intended NEU and SEU uses of clopyralid on cereals, pastures and grasslands. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the EFSA on 11 July 2018. To accommodate for the intended NEU and SEU uses of clopyralid on cereals, grasslands and pastures, the EMS proposed to raise the existing MRLs as follows: from 2 to 3 mg/kg for oats and wheat; from the limit of quantification (LOQ) of 0.05 to 0.05 mg/kg for milk, poultry liver and swine fat, liver and edible offals; from the LOQ of 0.05 to 0.06 mg/kg for swine kidney; from the LOQ of 0.05 to 0.15 mg/kg for bovine, sheep and goat fat; from 0.06 to 0.15 mg/kg for bovine liver; from 0.4 to 1.5 mg/kg for bovine kidney; from 0.06 to 2 mg/kg for sheep and goat liver; from 0.4 to 2 mg/kg for sheep and goat kidney. The EMS proposed to maintain the existing MRLs as follow: 2 mg/kg for barley; the LOQ of 0.05 mg/kg for swine (muscle), bovine (edible offals), sheep (edible offals), goat (edible offals), equine (muscle, fat, liver, kidney and edible offals), poultry (muscle, fat, kidney and edible offals) and eggs. Finally, the EMS proposed to lower the existing MRL from 5 mg/kg to 3 mg/kg for rye; from 0.08 mg/kg to 0.05 mg/kg for bovine, sheep and goat muscle. The EMS noted that the current MRLs are based on old, non-GLP and non-guideline compliant animal feeding studies and proposed revised MRLs for all commodities of animal origin based on the more recent state-of-the-art livestock feeding studies. EFSA agrees with the argument of the EMS to derive MRLs for all animal commodities. However, EFSA takes note of the new analytical enforcement method capable of quantifying residues below the former LOQ of 0.05 mg/kg. Once the outstanding data gap of extraction efficiency has been addressed the MRL proposals should be based according to the achievable LOQ of 0.01 mg/kg of the new analytical method.

¹ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
² Commission Directive 2006/64/CE of 18 July 2006 amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac as active substances. OJ L 206, 27.7.2006, p. 107–111.
³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
⁴ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
⁵ For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification, which were requested from the EMS. On 17 August 2020, the EMS submitted the requested information in a revised evaluation report, which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Finland, 2018b), the renewal assessment report (RAR) (and its revision) (Finland, 2017, 2018a) prepared under Regulation (EC) 1107/2009, the Commission review report on clopyralid (European Commission, 2006), the conclusions on the peer review of the pesticide risk assessment of the active substance clopyralid (EFSA, 2005, 2018d), as well as the conclusions from previous EFSA opinions on clopyralid (EFSA, 2011, 2018b).

For this application, the data requirements established in Regulation (EU) No 283/2013 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 2000, 2010a,b, 2013, 2017; OECD, 2007, 2011a,b, 2013, 2016). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

As the review of the existing MRLs under Article 12 of Regulation 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the MRL review.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously is presented in Appendix B.

The evaluation report submitted by the EMS (Finland, 2018b) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of clopyralid in primary crops belonging to the group of root crops (sugar beets), leafy crops (head cabbage), pulses/oilseeds (oilseed rape) has been investigated in the framework of the previous MRL application and EU pesticides peer review (EFSA, 2011, 2018d). In the context of the peer review, a data gap was identified for the clarification of the unknown polar compound observed in mature samples of rape seed and sugar beet. Upon request, for this application, the applicant provided explanations and additional analytical work using standards and fortified sample extracts aimed to clarify the nature of this unknown polar compound. EMS is of the opinion that it has been sufficiently demonstrated that the unknown polar compound is an artefact caused by the sample preparation and a polar (protonated) form of clopyralid. EFSA does not find the argumentation and data convincing to finally conclude on the nature of the unknown polar compound. A study with pasture was considered as supportive only as it was not conducted according to GLP and had shortcoming in reporting. Nevertheless, the deficiencies in the studies reported above are not expected to affect the outcome of the current assessment which refers to the intended uses on cereals and grass.

A new metabolism study with wheat covering the group of cereals/grass was submitted in support of the current MRL application (Finland, 2018b). In the wheat plant parts, the parent compound was the only identified residue, representing 20% and 28% of the total radioactive residues (TRR) in straw and grain, respectively. Besides parent, a multitude of partially unresolved and less polar compounds were reported accounting for 30% and 45% TRR in straw and grain, respectively. When the plant extracts were subjected to a base treatment, these compounds disappeared and only clopyralid was observed. It

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6 Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, p. 1-84.

7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
is noted that the unknown less polar fractions of the plant extracts were only characterised as base labile and especially in grain, these residues make up for 48% TRR (0.51 mg eq/kg). In this point, the study does not fulfil the requirements of OECD 501 (OECD, 2007) which stipulates that residues above 10% TRR and above 0.05 mg eq/kg should be identified. The study is reported to be performed according to GLP and further clarification could be provided, e.g. individual MS spectra of the partially separated signals eluting after clopyralid which are no longer present after hydrolysis of the extract. An impact on the magnitude of clopyralid in grass and cereals is not expected given the fact that the not identified but characterised as less polar compounds will be converted to clopyralid by the analytical method used in the residue field trials.

EFSA concludes that for the intended uses in grass and cereals, the metabolic behaviour of clopyralid is addressed.

1.1.2. Nature of residues in rotational crops

Clopyralid is proposed to be used on crops that can be grown in rotation with other crops. It is considered to be low to medium persistent, forming no metabolites at levels triggering identification or further assessment; it does not accumulate in soil (EFSA, 2018d).

From the rotational crop metabolism studies which were assessed in the framework of the EU pesticides peer review, it was concluded that the same metabolic pattern is observed across all rotational crops and that this corresponds with the findings in primary crops with clopyralid and conjugated clopyralid being the major residues (EFSA, 2018d). The studies covered three plant back intervals (PBI), with quantifiable amounts reported at PBI of 30 days (except for radish roots) and identification performed in all plant parts. Low amounts of radioactive residues were still detected at PBI of 125 days in soybeans (0.013 mg eq/kg), soybean plant (0.015 mg eq/kg) and wheat straw (0.015 mg eq/kg).

As residues in rotational crops cannot be excluded based on these findings, the peer review recommended that rotational crop field trials according to current guidelines should be submitted (see 1.2.2) (EFSA, 2018d).

An additional metabolism study was presented in the current MRL application. However, due to several shortcomings (e.g. non-GLP compliance, no information on storage conditions, application to plant and to soil), the study was not considered valid.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of clopyralid was investigated in the framework of the EU pesticides peer review (EFSA, 2018d).

The study showed that clopyralid is hydrolytically stable under standard processing conditions.

1.1.4. Methods of analysis in plants

An analytical method for enforcement analysing for clopyralid, its salts and conjugates was assessed during the EU pesticides peer review (EFSA, 2018d).

The method (based on LC-MS/MS) is sufficiently validated for the determination of residues of clopyralid, its salts and conjugates in the crops under consideration. It allows quantifying residues at or above the LOQ of 0.01 mg/kg for the total residue (sum of clopyralid, its salts and conjugates) in crops with dry/high starch, high water, high acid and high oil content.

1.1.5. Storage stability of residues in plants

The storage stability of clopyralid in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2018d).

It was demonstrated that clopyralid was stable for at least 10 months when stored at –18°C in commodities with high water, high oil, high acid and dry/high starch content (details see Appendix B). In pasture stability was demonstrated up to 17 months, in maize grain and forage/fodder up to 13 months when stored at –20°C.

1.1.6. Proposed residue definitions

The EU pesticides peer review concluded that, based on the metabolic pattern identified in leafy crops, root crops and cereals/oilseeds crop groups, the results of hydrolysis and rotational crop
studies, the data are sufficient to derive the following general residue definitions in primary and rotational crops, pending the outstanding clarification on the nature of ‘polar clopyralid’ in oilseed rape and sugar beet metabolism:

Residue definition for risk assessment: clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid)
Residue definition for enforcement: clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid)

Since the clarification of the unknown polar metabolite (called ‘polar clopyralid’) in mature sugar beet and oilseeds identified by the EU pesticides peer review was not sufficiently addressed under the current assessment, EFSA concludes that the proposed residue definitions are applicable only to cereals/grass crop group for which a new metabolism study was submitted under the current assessment and for which the data gap identified by the peer review is not relevant. For remaining crop groups, the data gap as identified by the EU pesticides peer review remains open.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is currently ‘clopyralid’ alone. EFSA proposes to change the existing enforcement residue definition by including clopyralid salts and conjugates. The proposed change will not have an impact on the existing MRLs, as the analytical methods used to generate data for risk assessment and for enforcement include a hydrolysis step which is capable to cover the common moiety.

The residue definitions are applicable to processed products.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL applications for wheat, oat and animal commodities, residue trials performed on barley, wheat, established grassland and permanent pasture were submitted. The samples were analysed for all compounds included in the residue definitions for enforcement and risk assessment as the analytical methods contained a hydrolysis step. According to the assessment of the EMS, the analytical methods used were sufficiently validated and fit for purpose (Finland, 2018b).

The samples of most residue trials were stored under conditions for which integrity of the samples has been demonstrated; trials which were not covered by storage stability data were excluded (see below).

In support of the intended good agricultural practices (GAPs), the applicant has presented data sets with residue trials which were already evaluated in previous assessments of EFSA (EFSA, 2005, 2018d) and has submitted new residue trials. Only for the newly submitted trials, a detailed description of the residue trial conditions and results was presented in the evaluation report (Finland, 2018b). The residue trials from previous assessment differed only in the application rate but not in the other critical GAP parameters (PHI 7 days for grass and BBCH 39 for cereals). For several trials with grass (NEU and SEU) and wheat (NEU), the application rate was outside the acceptable ±25% range as established in the Guidance Document on Crop Field Trials (OECD, 2016) and the EMS proposed to apply the proportionality principle as described by EFSA (2018e) to scale the results of all valid residue trials to the respective application rate for each zone. EFSA agrees with this approach and used the scaled residue data in the further risk assessment.

Established grassland and permanent pasture

Intended GAP NEU: 1 × 201.6 g a.s./ha, PHI 7 days
Intended GAP SEU: 1 × 120 g a.s./ha, PHI 7 days

All trials were compliant with the critical PHI of 7 days, but the application rate ranged from 104 to 247 g a.s./ha in the NEU and from 121 to 242 g a.s./ha in the SEU.

For the NEU zone in total 16 residue field trials were available:

- eight trials, performed in 2015 in France, United Kingdom and Portugal, were underdosed (123 g a.s./ha).
- two trials, performed in 2007 in United Kingdom and France, were overdosed (234 and 242 g a.s./ha) (Finland, 2018b).
- six previously evaluated trials at the target dose rate were available. Two of them have been evaluated in the context of Annex I inclusion (EFSA, 2005) and disregarded as the storage period of the specimen of 18 months was not covered by storage stability data, and four of
these trials have been assessed in the context of the peer review and were performed in 2014 in Germany, United Kingdom, Portugal and France (Finland, 2018a) and considered GAP compliant and covered by sufficient storage stability data. These latter four trials were considered in the current assessment.

In support of the intended GAPs in the SEU zone in total 10 valid residue field trials were available.

- Two of these trials, performed in 2007 in France and Spain, were overdosed (239 and 247 g a.s./ha) (Finland, 2018b).
- Eight of these trials, performed in 2014 in Spain, Italy and France, have been previously evaluated by EFSA and were slightly underdosed (104–113 g a.s./ha) but within acceptable ±25% deviation (Finland, 2018a).

Overall, in support of the intended NEU and SEU use of clopyralid on grasslands, 14 and 10 GAP compliant residue trials, respectively, are available. The results of these trials have been used for the risk assessment after scaling to the target rate.

**Barley**

Intended GAP NEU: 1 × 122.4 g a.s./ha, up to BBCH 39, PHI not applicable (n.a.)

Intended GAP SEU: 1 × 100.8 g a.s./ha, up to BBCH 39, PHI not applicable (n.a.)

For the NEU zone, 13 GAP compliant residue trials on barley performed with the target application rate were presented; six from previous evaluation (Finland, 2018a) and seven newly submitted (Finland, 2018b). They covered two growth seasons (2014 and 2015) and were conducted in three countries (France, Portugal, United Kingdom). One of the previously evaluated trials was not considered valid due to contamination of the blank sample and was excluded from the residue data set. In one of the new trials, the application was done at BBCH 45. It was considered in the assessment as this is a more critical condition and the only deviation in the application conditions.

For the SEU zone, nine GAP compliant residue trials on barley performed with the target application rate were presented; four from previous evaluation (Finland, 2018a) and five newly submitted (Finland, 2018b). They covered two growth seasons (2014 and 2015) and were performed in three countries (France, Spain, Italy).

Although the intended SEU use has a lower application rate, the residue situation in barley grain was more critical compared to the NEU zone whereas the residues values were slightly lower in straw.

For barley, GAPs in both zones were submitted and supported by a sufficient number of valid residue trials to derive an MRL. The applicant has in the present MRL application not asked for a change of the MRL for barley and EMS has proposed to keep the existing MRL of 2 mg/kg based on the more critical SEU data set (MRL for NEU was calculated as 0.8 mg/kg). EFSA agrees with this proposal.

**Wheat**

Intended GAP NEU: 1 × 122.4 g a.s./ha, up BBCH 39, PHI n.a.

Intended GAP SEU: 1 × 100.8 g a.s./ha, up to BBCH 39, PHI n.a.

For the NEU zone, 12 trials with wheat were presented; 4 trials from previous evaluations (EFSA, 2005) and 8 newly submitted trials (Finland, 2018b).

- From the four previously assessed wheat trials (EFSA, 2005), 2 trials could not be considered valid because the storage period of 595 days is not covered by storage stability data (13 months for grain and straw). The applicant provided explanation to support the validity of the trials. However, the results from the storage stability study with grain showed a trend of decline over time, hence EFSA decided to exclude these trials.
- Eight valid trials (Finland, 2018b) were compliant with the critical growth stage (BBCH 39) at application but were underdosed (79–85 g a.s./ha). EMS proposed to apply the proportionality principle (EFSA, 2018d) and to scale the results for the trials to the target application rate. All trials covered one growth season (2014) and were conducted in four countries (France, Hungary, United Kingdom, Germany).

The results from calculation with the ‘MRL Calculator EU-OECD 2015’ (OECD, 2011a,b) indicated outlier for the NEU data set with wheat. There is no experimental evidence from the description of the residue field trials (Finland, 2018b) to justify removing the outlier. A possible explanation for the higher variability of the results could be the fact that the trials seem to be performed on small-scale size using
boom sprayers to reproduce a normal agricultural application technique. Therefore, it is suggested not to remove the outlier (1.47 mg/kg in grain and 2.17 mg/kg in straw) from the data set.

For the SEU zone, 12 trials were presented; 4 trials from previous evaluations (EFSA, 2005) and 8 newly submitted (Finland, 2018b).

- Four previously assessed wheat trials (EFSA, 2005) could not be considered valid because they were all conducted at a later growth stage (up to BBCH 51), and in addition, they were not covered by storage stability data (6 months longer storage than proven in the storage stability study). Thus, these trials were excluded.
- Eight valid and GAP compliant trials (Finland, 2018b) were presented. They covered one growth season (2018) and were performed in three countries (France, Spain, Portugal).

The resulting MRL for the SEU with lower application rate was 1 mg/kg.

The intended NEU use results in a more critical residue situation in wheat grain, and therefore, these data were used to derive an MRL of 3 mg/kg.

EMS was investigating the possibility to combine residue data for barley and wheat grain from NEU trials as described in the guidance document on extrapolation to obtain a more robust data set for MRL setting and with the intention to propose MRLs also for oat, rye and barley (European Commission, 2017). However, the analysis with the Mann-Whitney test indicated that the populations are not similar. Therefore, EMS proposes to extrapolate the MRL of 3 mg/kg derived for wheat to oat and to rye but not to change the existing MRL of 2 mg/kg for barley. It is noted that the applicant did not apply for the modification (e.g. lowering) of the existing clopyralid MRL in rye. Moreover, the lowering of an MRL is not a normal practice under Article 10 MRL assessments unless consumer intake concerns are identified for certain MRL. Thus, the proposal of the EMS to lower the existing MRL in rye is not supported by EFSA.

EFSA agrees with the proposed extrapolation of the MRL derived for wheat from the more critical use in NEU to oat.

1.2.2. Magnitude of residues in rotational crops

Based on the findings in the rotational crop metabolism studies (see Section 1.1.2), residues of clopyralid cannot be excluded in succeeding crops, and therefore, the magnitude of clopyralid residues in rotational crops should be further investigated.

No studies were provided in the context of previous and the present evaluations. The EU pesticides peer review identified a data gap for the submission of rotational crop field trials according to current guidelines since in the metabolism studies residues of free and conjugated parent were found in all plant parts at PHI 30 days (except in radish roots) and in soybean plant and wheat straw up to 0.015 mg eq/kg at PHI 120 days (EFSA, 2018d).

In the absence of these studies, the applicant and EMS proposed to apply risk mitigation measures and restrict the use for succeeding crops, e.g. with the following label restrictions: ‘If 125 days have elapsed after an application of a clopyralid based product, any crop may be planted, there is no restriction on the use of a clopyralid containing product in that crop. Any crop can be planted after 30 days PBI and less than 125 days PBI with the restriction of not using any clopyralid products on the succeeding crops on the same plot or field during 125 days from the previous use, with the exception of root crops where no restrictions on the use of clopyralid containing products are required’ (Finland, 2018b).

EFSA re-iterates the data gap from the EU pesticides peer review to request rotational crop field studies to address this data requirement. Until these studies become available EFSA suggests to risk managers as risk mitigation measure to label clopyralid containing products with the restriction not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown.

1.2.3. Magnitude of residues in processed commodities

Studies investigating the effect of processing on the magnitude of clopyralid residues in wheat and barley were evaluated in the context of the EU pesticides peer review and used to propose processing factors (EFSA, 2018d). The studies demonstrate that clopyralid residues concentrate in wheat bran and germ whereas a reduction is observed in other processed commodities of wheat and barley. EFSA concluded that the reporting of the respective residue field trials with wheat and barley in the RAR was insufficient to decide on their validity and a data gap was identified to re-evaluate and report the results in a transparent manner. Provided evidence on the validity of the residue field studies is given,
the number and quality of the processing studies would be sufficient to derive robust processing factors. Therefore, the processing factors reported in Appendix B.1.2.3 are tentative, pending the re-evaluation of these residue trials.

1.2.4. Proposed MRLs

A sufficient number of valid residue field trials in wheat and barley are provided to derive MRL proposals as well as risk assessment values for the uses under evaluation (see Appendix B.1.2 and B.2.2).

EFSA proposes to increase the currently in place MRLs for wheat and oat of 2 mg/kg to 3 mg/kg based on residue trials with wheat in the NEU zone. In Section 3 EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Grass and grain, straw and various by-products of wheat and oat are used for feed purposes. Hence, it was necessary to update the previous dietary burden, which was calculated in the framework of the MRL application (EFSA, 2011) and to estimate whether the intake of feed commodities containing clopyralid residues from the new intended uses would have an impact on the residues expected in food of animal origin.

EFSA calculated the animal dietary burdens for different groups of livestock using the animal feedstuff table reported in the OECD guidance No 64 – Series on Pesticides No 32 and Series on Pesticides No 73 (OECD, 2009, 2013) and the animal calculator developed by EFSA.

Input values were derived from residue trials submitted in support of the proposed uses on wheat, oat and grass. For remaining feed commodities, the input values were as derived from previous evaluations (EFSA, 2005, 2011; Finland, 2018a) and for certain commodities MRLs as set in the currently applicable legislation. The EMS proposed to exclude the potatoes from the calculation (MRL 0.5 mg/kg) with the argumentation brought forward by the applicant that clopyralid is very phytotoxic to potatoes and that it is very unlikely that clopyralid is authorised for use on potatoes. EFSA accepted this argumentation as it is supported by scientific articles (Seefeldt et al., 2014). Default processing factors from the OECD guidance as implemented in the animal calculator were applied as the processing factors reported for this assessment were not covering the animal feed brewer’s grain, distiller’s grain, and wheat gluten, except for wheat milled-by products (standard PF 7, proposed PF 5.7).

The overview of input values for the exposure calculations for livestock is presented in Appendix D.1.

The calculated dietary burdens exceeded the trigger values of 0.004 mg/kg body weight (bw) day for ruminants, poultry and swine; the exceedances were confirmed by EMS (Finland, 2018b). The results of the dietary burden calculation are presented in Section B.2.

For ruminants, grass is by far the major contributor followed by swede roots. For poultry, the major contributors are cabbage heads (laying hens) and swede roots (turkey and broiler). However, the second contributor, wheat milled by-products, might have albeit a moderate impact on the dietary burden of poultry.

Considering only the proposed uses in grass, wheat and oat, grass is the major contributor for cattle, sheep and swine (breeding), whereas dietary burden is driven by wheat for swine (finishing) and poultry.

Thus, the potential carry-over of clopyralid residues in the food of animal origin from the intake of treated grass and cereals had to be investigated further.

2.1. Nature of residues and methods of analysis in livestock

Metabolism studies in livestock (laying hens and lactating goats) have been assessed previously in the framework of the EU pesticides peer review (EFSA, 2018d).

Clopyralid was the main residue in all goat and hen tissues with minimum of 74% TRR in goat liver and minimum of 72% TRR in eggs. Only in milk clopyralid glycine conjugate was reported with levels of ca. 20% TRR. Considering the dose rate of the ruminant and poultry studies, a carry-over of clopyralid residues into animal commodities is likely and feeding studies are therefore requested.

The following residue definitions were derived by the EU pesticides peer review: ‘clopyralid and its salts’ for enforcement purposes and ‘clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates)’ for risk assessment.
conjugates expressed as clopyralid) for risk assessment. Conjugated residues were only observed in significant proportions in milk and a conversion factor monitoring/risk assessment is set as 1.3 for milk only (EFSA, 2018d). The EFSA expert consultation meeting (EFSA, 2018c) noted that the proposed enforcement method includes a hydrolysis step which enables the inclusion of conjugates and suggested to including conjugates in the residue definition for enforcement. Currently, the existing enforcement residue definition in Regulation (EC) No 396/2005 is set as ‘clopyralid’ only.

2.2. Magnitude of residues in livestock

The feeding studies with lactating cows and laying hens were assessed in the framework of the EU pesticides peer review (EFSA, 2018d). The analytical method used in the two studies was sufficiently validated. It employs a hydrolysis step with sodium hydroxide converting all eventually present conjugates into clopyralid. Higher values are not expected as conjugates are only found in milk.

Hens were dosed orally with clopyralid at 0, 4.90 (1×), 10.26 (2×) 19.82 (4×) and 50.5 (10×) mg/kg DM feed/day for 28 or 29 consecutive days, corresponding to approximately 0, 0.280, 0.571, 1.086 and 2.779 mg/kg bw per day, respectively. Plateau in eggs was reached after 7 days.

Residues of clopyralid in muscle, liver and eggs increased from the lowest to highest dose groups, with residues in the liver present above LOQ in all treatment groups. No residues of clopyralid above the LOQ were found in the fat in any treatment group. Residues of clopyralid in the tissues and eggs of the depuration animals fell to below the LOQ 3 days after withdrawal of the test item from the hens’ diet.

Lactating cows were dosed orally with clopyralid at 0, 16.70, 56.60, 309.80 and 1,019.5 mg ai/kg DM feed/day for 28 or 29 consecutive days, corresponding to approximately 0, 0.451, 1.670, 8.517 and 30.538 mg/kg bw per day, respectively. Residues above the LOQ were found in liver and kidney at the lowest dose group, in milk, fat and muscle from the second dose group onwards. A plateau was reached in milk within 1 day. Residues of clopyralid declined rapidly following withdrawal of the test item from the cows’ diet.

The dietary burdens calculated in the framework of the current assessment were compared with the feeding levels of available feeding studies in order to estimate whether the existing animal commodity MRLs would need to be modified.

Although the applicant requested only increases of MRLs for fat, liver and kidney of bovine, sheep and goat and swine kidney, EFSA agrees with the proposal of the EMS to recommend new MRLs for all animal commodities based on the latest valid feeding studies.

The data indicate that the proposed use in grass, wheat and oat will lead to higher MRLs in all animal commodities due to a new analytical method (see below) and the more recent guideline compliant feeding studies. EFSA agrees with the proposal of the EMS and applicant to maintain the MRLs at the value of 0.05 mg/kg (LOQ of the previous analytical method) for certain commodities (swine fat, liver, muscle, fat of bovine, sheep, goat and all poultry commodities) because the new analytical method cannot be regarded as fully validated in the absence of data on extraction efficiency. Once this outstanding data gap has been addressed, the MRL proposals should be reconsidered on the basis of the achievable LOQ of 0.01 mg/kg of the new analytical method. A discrepancy is observed in the EMS proposal of 0.15 mg/kg for sheep and goat fat in contrast to the value of 0.2 mg/kg requested by applicant and calculated by EFSA. This might be due to slightly different input values in the dietary burden calculator.

An analytical method for enforcement based on LC-MS/MS for all products of animal origin and a method based on QuEChERs for milk and fat, both with LOQ of 0.01 mg/kg, have been assessed during the EU pesticides peer review and was considered as not fully validated since the extraction efficiency was not demonstrated and a data gap was identified in the peer review (EFSA, 2018d).

The storage stability of clopyralid in commodities of animal origin was investigated in the framework of the EU pesticides peer review. The stability of conjugates has not been tested separately; it is assumed that conjugated clopyralid will be also stable (EFSA, 2018d).

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRiMo (EFSA, 2018a, 2019). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).
The toxicological reference values for clopyralid used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the renewal of the approval of clopyralid (EFSA, 2018d). The ADI value of 0.15 mg/kg bw per day (European Commission, 2006) as derived in the first peer review (EFSA, 2005) remained unchanged after the renewal of the approval of clopyralid and the chronic assessment is based on this value. The ARfD of 0.17 mg/kg bw was newly derived but not yet officially implemented; therefore, the acute exposure assessment is indicative.

**Short-term (acute) dietary risk assessment**

The short-term exposure calculations were based on the HR or STMR derived from supervised field trials for the proposed uses and the complete list of input values can be found in Appendix D.2. The indicative short-term exposure did not exceed the ARfD for any of the crops assessed in this application (see Appendix B.3).

**Long-term (chronic) dietary risk assessment**

The long-term exposure assessment was performed, taking into account the STMR values derived for the commodities assessed in this application; for the remaining commodities covered by the MRL regulation, the existing EU MRLs and STMR values, where available, as derived in previous MRL applications were selected as input values (EFSA, 2011, 2018b). The complete list of input values is presented in Appendix D.2.

The estimated long-term dietary intake was in the range of 29% of the ADI for NL toddler when considering all crops and 3% of the ADI for GEMS population when considering only the uses from the current MRL application. The contribution of residues expected from wheat, barley, oat and animal commodities to the overall long-term exposure is presented in more detail in Appendix B.3. EFSA concluded that the long-term intake of residues of clopyralid resulting from the existing and the intended uses is unlikely to present a risk to consumer health when risk mitigation measures are applied.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

**4. Conclusion and Recommendations**

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals of 3 mg/kg for clopyralid in wheat and oat in support of the intended NEU and SEU uses. In addition, the data provided for barley confirmed the existing MRL. A sufficient number of residue trials with grass were submitted to derive risk assessment values, relevant for the estimation of livestock dietary burden.

The calculated livestock dietary burden exceeds the trigger value and indicates that residues in cereals and grass from the proposed uses are significant contributors to overall livestock exposure. The new proposed uses, the availability of a new more sensitive analytical enforcement method (LOQ of 0.01 mg/kg) and more recent animal feeding studies suggest increasing the MRLs (except for muscle of bovine, sheep and goat) for a range of animal origin commodities. Whenever the previous MRL was set on the basis of the LOQ of 0.05 mg/kg for old analytical method, EFSA suggested keeping the value of 0.05 mg/kg (not marked as LOQ with asterisk).

EFSA concluded that the proposed use of clopyralid on wheat, oat and grass will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers’ health provided that risk mitigation measures are in place.

In the absence of rotational crop field studies, EFSA recommends that Member States, when granting authorisations for the use of clopyralid on primary crops, apply necessary risk mitigation measures (such as restriction on planting intervals for succeeding crops on the label) to avoid clopyralid residues in rotational and/or succeeding crops.

Considering that the new enforcement method for animal commodities includes a hydrolysis step for the analysis of conjugates, EFSA suggests aligning the existing animal residue definition for monitoring with the risk assessment residue definitions as suggested in the EU pesticide peer review.

The MRL recommendations are summarised in Appendix B.4.
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Abbreviations

a.s. active substance
ADi acceptable daily intake
ARFd acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
CAS Chemical Abstract Service
CF conversion factor for enforcement to risk assessment residue definition
CIRCA (EU) Communication & Information Resource Centre Administrator
CS capsule suspension
CV coefficient of variation (relative standard deviation)
DAR draft assessment report
DAT days after treatment
DM dry matter
DP dusty powder
DS powder for dry seed treatment
EC emulsifiable concentrate
EDI estimated daily intake
EMS evaluating Member State
eq residue expressed as a.s. equivalent
FAO Food and Agriculture Organization of the United Nations
FID flame ionisation detector
GAP Good Agricultural Practice
GC gas chromatography
GC-FID gas chromatography with flame ionisation detector
GC-MS gas chromatography with mass spectrometry
GC-MS/MS gas chromatography with tandem mass spectrometry
GLP Good Laboratory Practice
GR granule
GS growth stage
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS mass spectrometry detector
MS/MS tandem mass spectrometry detector
MW molecular weight
Modification of the existing MRLs for clopyralid in various commodities

NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PF processing factor
PHI pre-harvest interval
$P_{ow}$ partition coefficient between n-octanol and water
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SC suspension concentrate
SEU southern Europe
SG water-soluble granule
SL soluble concentrate
SP water-soluble powder
STMR supervised trials median residue
TAR total applied radioactivity
TMDI theoretical maximum daily intake
TRR total radioactive residue
UV ultraviolet (detector)
WG water-dispersible granule
WHO World Health Organization
WP wettable powder
| Crop and/or situation | NEU, SEU, MS or country | F (G or I) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|--------------------------|------------|-------------------------------------|-------------|-------------|---------------------------------|
|                       |                          |            |                                     | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Water L/ha min-max | Rate | Unit | PHI (days)(d) | Remarks |
| Spring Barley, Spring Oat, Spring Wheat, Spring Rye, Spring Triticale | NEU (Hungary) | F | Broadleaved weeds (BBBBB), Cirsium arvense, volunteer sunflower | SG | Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 13-30 Winter-Spring | 1 | n.a. | 31.633-64.532 | 250-300 | 94.9-161.33 | g a.s./ha | n.a. |
| Winter Barley, Winter Oat, Winter Wheat, Winter Rye, Winter Triticale | NEU (Hungary) | F | Broadleaved weeds (BBBBB), Cirsium arvense, volunteer sunflower | SG | Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 13-30 Winter-Spring | 1 | n.a. | 31.633-64.532 | 250-300 | 94.9-161.33 | g a.s./ha | n.a. |
| Spring Barley, Spring Oat, Spring Wheat | NEU (Estonia) | F | Broadleaved weeds (BBBBB) | SG | Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21-37 Spring-Summer | 1 | n.a. | 39.542-156.585 | 100-300 | 118.625-156.585 | g a.s./ha | n.a. |
| Winter barley, Winter wheat, Winter rye, Winter triticale | NEU (Estonia) | F | Broadleaved weeds (BBBBB) | SG | Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21-37 Spring-Summer | 1 | n.a. | 39.542-156.585 | 100-300 | 118.8 | g a.s./ha | n.a. |
| Spring Barley, Spring Oat, Spring Wheat | NEU (Latvia) | F | Broadleaved weeds (BBBBB) | SG | Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21-37 Spring-Summer | 1 | n.a. | 39.542-156.585 | 100-300 | 118.625-156.585 | g a.s./ha | n.a. |
| Winter barley, Winter wheat, Winter rye, Winter triticale | NEU (Latvia) | F | Broadleaved weeds (BBBBB) | SG | Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21-37 Spring-Summer | 1 | n.a. | 39.542-156.585 | 100-300 | 118.625-156.585 | g a.s./ha | n.a. |
| Crop and/or situation | NEU, SEU, MS or country | F G or J (a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|----------------------|-------------------------|-------------|------------------------------------|-------------|-------------|--------------------------------|
|                      |                         |             |                                    | Type(b)     | Conc. a.s.  | Method kind                      | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Water L/ha min-max | Rate | Unit | PHI (days)(d) | Remarks |
| Spring Barley, Spring Oat, Spring Wheat, Spring Rye, Spring Triticale | NEU (Lithuania) | F | Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–37 Spring–Summer | 1 | n.a. | 39.542–156.585 | 100–300 | 118.625–156.585 | g a.s./ha | n.a. |
| Winter Barley, Winter Oat, Winter Wheat, Winter Rye, Winter Triticale | NEU (Lithuania) | F | Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–37 Spring–Summer | 1 | n.a. | 39.542–156.585 | 100–300 | 118.625–156.585 | g a.s./ha | n.a. |
| Spring Barley, Spring Oat, Spring Wheat, Spring Rye, Spring Triticale | NEU (Sweden) | F | Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–37 Spring–Summer | 1 | n.a. | 34.797–156.585 | 100–300 | 104.39–156.585 | g a.s./ha | n.a. |
| Winter Barley, Winter Oat, Winter Wheat, Winter Rye, Winter Triticale | NEU (Sweden) | F | Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–37 Spring–Summer | 1 | n.a. | 34.797–156.585 | 100–300 | 104.39–156.585 | g a.s./ha | n.a. |
| Spring Barley, Spring Oat, Spring Wheat, Spring Rye, Spring Triticale | SEU (Italy) | F | Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–39 Winter–Spring | 1 | n.a. | 26.0975–88.573 | 150–400 | 100.8 | g a.s./ha | n.a. |
## Modification of the existing MRLs for clopyralid in various commodities

| Crop and/or situation | NEU, SEU, MS or country | F | G or J | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|-------------------------|---|--------|-----------------------------------|-------------|-------------|-------------------------------|---------|
|                       |                         |   |        |                                   | Type(b) Conc. a.s. Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Water L/ha min-max | Rate | Unit | PHI (days)(d) |         |
| Winter Barley, Winter Oat, Winter Wheat, Winter Rye, Winter Triticale | SEU (Italy) | F |        | Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L Foliar treatment – broadcast spraying | BBCH 21–39 Winter–Spring | 1 n.a. | 26.0975–88.573 | 150–400 | 100.8 | g a.s./ha | n.a. |
| Spring Barley, Spring Oat, Spring Wheat, Spring Rye, Spring Triticale | SEU (Italy) | F |        | Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L Foliar treatment – broadcast spraying | BBCH 21–39 Winter–Spring | 1 n.a. | 26.0975–88.573 | 150–400 | 104.39–132.86 | g a.s./ha | n.a. |
| Winter Barley, Winter Oat, Winter Wheat, Winter Rye, Winter Triticale | SEU (Italy) | F |        | Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L Foliar treatment – broadcast spraying | BBCH 21–39 Winter–Spring | 1 n.a. | 26.0975–88.573 | 150–400 | 104.39–132.86 | g a.s./ha | n.a. |
| Spring Barley, Spring Oat, Spring Wheat, Spring Rye, Spring Triticale | SEU (Portugal) | F |        | Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L Foliar treatment – broadcast spraying | BBCH 21–39 Winter–Spring | 1 n.a. | 26.0975–88.573 | 150–400 | 104.39–132.86 | g a.s./ha | n.a. |
| Winter Barley, Winter Oat, Winter Wheat, Winter Rye, Winter Triticale | SEU (Portugal) | F |        | Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L Foliar treatment – broadcast spraying | BBCH 21–39 Winter–Spring | 1 n.a. | 26.0975–88.573 | 150–400 | 104.39–132.86 | g a.s./ha | n.a. |
| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-------------------------|------------------------------------|-------------|------------|-------------------------------|
|                       |                         |                                    | Type\(^{(b)}\) | Conc. a.s. | Method kind | Range of growth stages & season\(^{(c)}\) | Number min-max | Interval between application (min) | g a.s./hl min-max | Water L/ha min-max | Rate | Unit | PHI (days)\(^{(d)}\) | Remarks |
| Spring Barley, Spring Oat, Spring Wheat, Spring Rye, Spring Triticale | SEU (Spain) | F Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–39 Autumn–Winter–Spring–Summer | 1 | n.a. | 26.0975–88.573 | 150–400 | 104.39–132.86 | g a.s./ha | n.a. |
| Winter Barley, Winter Oat, Winter Wheat, Winter Rye, Winter Triticale | SEU (Spain) | F Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–39 Autumn–Winter–Spring–Summer | 1 | n.a. | 26.0975–88.573 | 150–400 | 104.39–132.86 | g a.s./ha | n.a. |
| Spring Barley, Spring Wheat | SEU (Bulgaria) | F Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–39 | 1 | n.a. | 26.0975–88.573 | 150–400 | 104.39–132.86 | g a.s./ha | n.a. |
| Winter Barley, Winter Wheat | SEU (Bulgaria) | F Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–39 | 1 | n.a. | 26.0975–88.573 | 150–400 | 104.39–132.86 | g a.s./ha | n.a. |
| Spring Oat, Spring Rye | SEU (Bulgaria) | F Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–39 | 1 | n.a. | 26.0975–88.573 | 150–400 | 104.39–132.86 | g a.s./ha | n.a. |
| Winter Oat, Winter Rye | SEU (Bulgaria) | F Broadleaved weeds (BBBBB) | SG Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–39 | 1 | n.a. | 26.0975–88.573 | 150–400 | 104.39–132.86 | g a.s./ha | n.a. |
| Crop and/or situation | NEU, SEU, MS or country | F G or I(G) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|----------------------|-------------------------|-------------|-----------------------------------|-------------|-------------|--------------------------------|
|                       |                         |             |                                   | Type(b)     | Conc. a.s.   | Water L/ha min-max       |
|                       |                         |             |                                   | Method kind |            | Rate Unit n.a.          |
|                       |                         |             |                                   | Range of growth stages & season(c) | Number min-max | PHI (days)(d) | Remarks |
|                       |                         |             |                                   | Interval between application (min) | g a.s./L/min-max | g a.s./ha n.a. |          |
| Spring Barley, Spring Oat, Spring Wheat, Spring Rye, SEU (Italy) F |                       |             | Spring Barley, Spring Oat, Spring Wheat, Spring Rye, SEU (Italy) F | SL | Clopyralid-olamine 131.75 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21-39 Winter-Spring | 1 | n.a. | 17.567-65.875 | 200-600 | 105.40-131.75 | g a.s./ha n.a. |
| Winter Barley, Winter Oat, Winter Wheat, Winter Rye, SEU (Italy) F |                       |             | Winter Barley, Winter Oat, Winter Wheat, Winter Rye, SEU (Italy) F | SL | Clopyralid-olamine 131.75 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21-39 Winter-Spring | 1 | n.a. | 17.567-65.875 | 200-600 | 105.40-131.75 | g a.s./ha n.a. |
| Crop and/or situation | NEU, SEU, MS or country | F or G | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-------------------------|-------|-----------------------------------|-------------|-------------|---------------------------------|
|                       |                         |       |                                   | Type(b)     | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./L/min-max | Water L/ha min-max | Rate | Unit | PHI (days)(d) | Remarks |
| Spring Barley, Spring Oat, Spring Wheat, Spring Rye, | SEU (Italy) | F | ANTAR MATCH DAUCA BIFSS SONSS TUSFA HELSS XANSI RUMSS CIRAR TRFSS VICSS SOLNI POLSS | SL Clopyralid-olamine 131.75 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–39 Summer–Autumn–Winter | 1 | n.a. | 17.567–65.875 | 200–600 | 105.40–131.75 | g a.s./ha | n.a. |
| Winter Barley, Winter Oat, Winter Wheat, Winter Rye, | SEU (Italy) | F | ANTAR MATCH DAUCA BIFSS SONSS TUSFA HELSS XANSI RUMSS CIRAR TRFSS VICSS SOLNI POLSS | SL Clopyralid-olamine 131.75 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21–39 Summer–Autumn–Winter | 1 | n.a. | 17.567–65.875 | 200–600 | 105.40–131.75 | g a.s./ha | n.a. |
| Winter Barley, Winter Wheat | SEU (Spain) | F | Compositae (FFFCO) Leguminosae (FFFLE) Polygonum spec. (POLSS) | SL Clopyralid-olamine 560 g a.s./L | Foliar treatment – broadcast spraying | BBCH 10–32 Winter–Spring | 1 | n.a. | 28–86.15 | 130–300 | 84–112 | g a.s./ha | n.a. |

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| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-------------------------|------------------------------------|-------------|-------------|--------------------------------|
|                       |                         |                                    | Type(b)     | Method kind  | PHI (days)(d)                  |
|                       |                         |                                    | Conc. a.s.  | Range of growth stages & season(e) | Number min-max | Interval between application (min) | g a.s./hl min-max | Water L/ha min-max | Rate | Unit | Remarks |
| Spring Barley, Spring Wheat | SEU (Spain) | SL Compositae (FFFCO) Leguminoseae (FFFLE) Polygonum spec. (POLSS) | Clopyralid-olamine 560 g a.s./L | Foliar treatment – broadcast spraying | BBCH 10-32 Winter-Spring | 1 | n.a. | 28-86.15 | 130-300 | 84-112 | g a.s./ha | n.a. |
| Spelt | NEU (Belgium) | SL 1COMF Asteraceae (Compositae) 1 CIRG Onurum, 1 CRUG Carduus | Clopyralid-olamine 131.75 g a.s./L | Foliar treatment – broadcast spraying | BBCH 29-31 Winter-Spring | 1 | n.a. | 30.742-79.05 | 150-300 | 92.225-118.575 | g a.s./ha | n.a. |
| Spelt | SEU (Italy) | SG Broadleaved weeds (BBBBB) | Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21-39 Winter-Spring | 1 | n.a. | 26.0975-88.5733 | 150-400 | 104.39-132.86 | g a.s./ha | n.a. |
| Spelt | SEU (Portugal) | SG Broadleaved weeds (BBBBB) | Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21-39 Winter-Spring | 1 | n.a. | 26.0975-88.5733 | 150-400 | 104.39-132.86 | g a.s./ha | n.a. |
| Spelt | SEU (Spain) | SG Broadleaved weeds (BBBBB) | Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | BBCH 21-39 Winter-Spring | 1 | n.a. | 26.0975-88.5733 | 150-400 | 104.39-132.86 | g a.s./ha | n.a. |
| Established grassland > 1 year | NEU (Czech Republic) | SG Broadleaved weeds (BBBBB) | Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | n.a. Winter-Spring | 1 | n.a. | 66.43-88.573 | 300-400 | 265.72-265.72 | g a.s./ha | 7 |
| Established grassland > 1 year | NEU United Kingdom | SG Broadleaved weeds (BBBBB) | Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | n.a. Winter-Spring | 1 | n.a. | 66.43-88.573 | 200-400 | 265.72-265.72 | g a.s./ha | 7 |

Remarks:
- 20–30 cm height, before the formation of the flowering heads
- 7 days before harvest or cutting for hay or silage
| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|------------------------|-----------------------------------|-------------|-------------|------------------------------|
|                       |                        |                                   | Type(b)     | Range of growth stages & season(c) | Method kind                   | Number min-max | Interval between application (min) | Water L/ha min-max | Rate | Unit | PHI (days)(d) | Remarks                          |
| Established grassland > 1 year | NEU (Slovakia) | Broadleaved weeds (BBBBB) | Clopyralid-olamine 949 g a.s./L | Foliar treatment – broadcast spraying | Winter–Spring | 1 | n.a. | 66.43 – 132.86 | 200–400 | 265.72–265.72 | g a.s./ha | 7 | 7 days before harvest or cutting for hay or silage |
| Established Grassland | NEU United Kingdom | Broad-leaved weeds (BBBBB) | Clopyralid-olamine 527 g a.s./L | Foliar treatment – broadcast spraying | NA Winter–Spring | 1 | n.a. | 65.875–131.75 | 200–400 | 263.5–263.5 | g a.s./ha | 7 | 7 days before harvest or cutting for hay or silage |
| Established Grassland | NEU United Kingdom | Broad-leaved weeds (BBBBB) | Clopyralid-olamine 527 g a.s./L | Foliar treatment – broadcast spraying | NA Winter–Spring | 1 | n.a. | 131.75–263.5 | 100–200 | 263.5–263.5 | g a.s./ha | 7 |
| Established Pasture Established Grass | SEU (France) | CIRAR Cirsium arvense SONAR Sonchus arvensis POLCO Polygonum convolvulus SINAR Sinapis arvensis | Clopyralid-olamine 46 g a.s./L + MCPA-olamine 457 g a.s./L | Foliar treatment – broadcast spraying | BBCH 14–39 Winter–Spring | 1 | n.a. | Clopyralid-olamine 34.5 g a.s./L + MCPA-olamine 342.75–685.5 | 200–400 | Clopyralid-olamine 138 g a.s./L + MCPA-olamine 1371–1371 | g a.s./ha | 28 |
| Established permanent pastures and rotational pastures: - Lolium - Festuca - Dactylis - Bromus - Phleum | SEU (France) | Broad-leaved weeds (BBBBB) | Clopyralid 80.0 g a.s./L + Florasulam 2.5 g a.s./L + Fluroxypyr-methylyl 144 g a.s./L | Foliar treatment – broadcast spraying | NA Winter–Spring | 1 (spring) | n.a. | Clopyralid 30 – 120 g a.s./L + Florasulam 0.9375 – 3.75 g a.s./L + Fluroxypyr-methylyl 54 – 216 | 100–400 | Clopyralid 120 – 120 g a.s./L + Florasulam 3.75 – 3.75 g a.s./L + Fluroxypyr-methylyl 216 – 216 | g a.s./ha | 14 |
### Modification of the existing MRLs for clopyralid in various commodities

| Crop and/or situation | NEU, SEU, MS or country | F or G or J(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-------------------------|---------------|-----------------------------------|-------------|-------------|--------------------------------|
|                       |                         |               |                                   | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./L/ha | Water L/ha | Rate | Unit | PHI (days)(d) | Remarks |
| Established permanent pastures and rotational pastures: - Lolium - Festuca - Dactylis - Bromus - Phleum | SEU (France) | F | Broad-leaved weeds (BBBBB) | Clopyralid 80.0 g a.s./L + Florasulam 2.5 g a.s./L + Fluroxypyrmeptyl 144 g a.s./L | Foliar treatment - broadcast spraying | NA Summer - Autumn | 1 in 3 years (Autumn) | n.a. | Clopyralid 15 – 60 + Florasulam 0.46875 – 1.875 + Fluroxypyrmeptyl 27 – 108 | 100–400 | Clopyralid 60 – 60 + Florasulam 1.875 – 1.875 + Fluroxypyrmeptyl 108 – 108 | g a.s./ha | 14 |
| Permanent grassland Rotational Grass | NEU (United Kingdom) | F | CIRAR (Cirsium arvense) | Clopyralid-triethylammonium 305.325 g a.s./L + Triclopyr-triethylammonium 278.99 | Foliar treatment – broadcast spraying | NA Winter - Spring - Summer - Autumn | 1 | n.a. | Clopyralid-triethylammonium 76.3313 – 152.663 + Triclopyr-triethylammonium 50 – 100 | 200–400 | Clopyralid-triethylammonium 305.325 – 305.325 + Triclopyr-triethylammonium 278.99 – 278.99 | g a.s./ha | 7 |
| Permanent grassland Rotational Grass | NEU (Ireland) | F | CIRAR (Cirsium arvense) | Clopyralid-triethylammonium 305.325 g a.s./L + Triclopyr-triethylammonium 278.99 | Foliar treatment – broadcast spraying | NA Winter - Spring - Summer - Autumn | 1 | n.a. | Clopyralid-triethylammonium 76.3313 – 152.663 + Triclopyr-triethylammonium 50 – 100 | 200–400 | Clopyralid-triethylammonium 305.325 – 305.325 + Triclopyr-triethylammonium 278.99 – 278.99 | g a.s./ha | 7 |
| Grassland | NEU (Slovakia) | F | Broad-leaved weeds (BBBBB) | Clopyralid-DMA 740.94 g a.s./L | Foliar treatment – broadcast spraying | NA Winter - Spring - Summer | 1 | n.a. | Clopyralid-DMA 61.128 – 122.255 | 200–400 | Clopyralid-DMA 244.5102–244.5102 | g a.s./ha | 7 |
| Crop and/or situation | NEU, SEU, MS or country | F or G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|----------------|-----------------------------------|-------------|----------------|----------------|----------------|---------|
| Grassland NEU         | United Kingdom          | F              | Broad-leaved weeds (BBBBB)        | SL          | Clopyralid-DMA 740.94 g a.s./L | Foliar treatment – broadcast spraying | NA Winter-Spring-Summer | 1 n.a. | 61.128 - 122.255 | 200 - 400 | 244.5102 - 244.5102 | g a.s./ha | 7 | 7 days before harvest or cutting for hay or silage |
| Pasture NEU (Czech Republic) | F              | Broad-leaved weeds (BBBBB) | SL | Clopyralid-DMA 740.94 g a.s./L | Foliar treatment – broadcast spraying | NA Winter-Spring-Summer | 1 n.a. | 61.128 - 81.503 | 300 - 400 | 244.5102 - 244.5102 | g a.s./ha | 7 |
| Permanent  Pasture NEU (Hungary, Ireland, Luxembourg, Netherlands, UK) | F              | Broad-leaved weeds (BBBBB) | EC | Clopyralid 80.0 g a.s./L + Florasulam 2.5 g a.s./L + Fluroxypyr-meptyl 144 g a.s./L | Foliar treatment – broadcast spraying | BBCH 13-32 Winter-Spring-Summer-Autumn | 1 n.a. | Clopyralid 40 – 160 + Florasulam 1.25 – 5 + Fluroxypyr-meptyl 72 – 288 | 100 - 400 | Clopyralid 160 – 160 + Florasulam 5 – 5 + Fluroxypyr-meptyl 288 – 288 | g a.s./ha | 7 |
| Established pasture SEU (France) | F              | Broad-leaved weeds (BBBBB) | SL | clopyralid-olamine 46.12g a.s./L, MCPA-dimethylammonium 214.46 g a.s./L, 2,4-D-dimethylammonium 180.73 g a.s./L | Foliar treatment – broadcast spraying | NA Spring-Summer | 1 n.a. | Clopyralid 26.3 – 52.5 g a.s./hl + MCPA 131.3 – 262.5 g a.s./hl + 2,4-D 112.5 – 225 g a.s./hl | 200 - 400 | Clopyralid-olamine 46.12 – 46.12 + MCPA-dimethylammonium 214.46 – 214.46 + 2,4-D-dimethylammonium 180.73 – 180.73 | g a.s./ha | 28 |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SG: water-soluble granule; SC: soluble concentrate; EC: emulsifiable concentrate; n.a.: not applicable.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI – minimum preharvest interval.
### Appendix B – List of end points

#### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

#### B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|----------------------------------|-------------|---------|----------------|----------------|----------------|
| Root crops                       | Sugar beet  | Foliar, 1 × 300 g/ha, at BBCH 36 | 0, 28, 105 days (maturity) | Radiolabelled 14C-clopyralid position not reported. No qualitative differences among the tested crops (EFSA, 2005, 2018d). All 3 studies are GLP and guideline compliant and conducted with radiolabelled clopyralid. Characterisation of metabolism is limited in the study with cabbage as the extraction was performed with caustic methanol implying a cleavage of the potentially present conjugates |
| Leafy crops                     | Cabbage     | Foliar, 1 × 420 g/ha, at 8–10 leaf stage BBCH 31 | 0, 5, 38 days | |
| Pulses/Oilseeds                 | Oilseed rape| Foliar, 1 × 300 g/ha, at BBCH 36 | 0, 28, 77 days (maturity) | GLP and guideline compliant study conducted with radiolabelled clopyralid. Clopyralid is the only compound identified in all plant parts. A multitude of less polar compounds in grain and straw was characterised by base hydrolysis as base labile clopyralid (Finland, 2018b) |
| Cereals/grass                   | Wheat       | Foliar, 1 × 125 g a.s./ha, BBCH 39 | 3, 23 and 92 days (maturity) | |
| Other                            | –           | –       | –              | An overdosed (1.121 kg a.s./ha) and non-GLP and non/guideline compliant study on pasture grass provided limited insight in metabolism as extraction was done with caustic methanol and only parent was detected (EFSA, 2005, 2018d) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/ tuber crops                  | Turnip      | 1 × 0.28 kg/ha to bare soil | 125 or 319 days | Radiolabelled 3,6-dichloro-2-6-14C-2-pyridinecarboxylic acid. In rotational crops, clopyralid was metabolised in a similar pathway as in primary crops (EFSA, 2011, 2018d). The 30 DAT mature cabbage was harvested at 128 days (9+ leaves/head; heads failed to fully close due to heat, BBCH 53) |
| Radish                             | 1 × 0.3 kg/ha to bare soil | 30 days | |
| Leafy crops                        | Lettuce     | 1 × 0.28 kg/ha to bare soil | 125 or 319 days | |
| Cabbage                            | 1 × 0.3 kg/ha to bare soil | 30 days | |
| Cereal (small grain)               | Wheat       | 1 × 0.3 kg/ha to bare soil (30 days) | 30, 125, 319 days | |
| Other                              | Soybean     | 1 × 0.28 kg/ha to bare soil | 125 days | |
| Green bean                         | 1 × 0.28 kg/ha to bare soil | 319 days | |

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Processed commodities (hydrolysis study)

| Conditions                              | Stable? | Comment/Source |
|-----------------------------------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)    | Yes     | Radiolabelled 3,6-dichloro-2-6- 14C-2-pyridinecarboxylic acid. Clopyralid was stable (99.3, 96.9, 97.1% TRR, respectively) (EFSA, 2018d) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes     |                |
| Sterilisation (20 min, 120°C, pH 6)    | Yes     |                |
| Other processing conditions             | --      |                |

Can a general residue definition be proposed for primary crops?

- No

Rotational crop and primary crop metabolism similar?

- Yes

Residue pattern in processed commodities similar to residue pattern in raw commodities?

- Yes

Plant residue definition for monitoring (RD-Mo)

- Applicable only for cereals/grass: clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) (EFSA, 2018d)

- Existing residue definition of Regulation (EC) No 396/2005: clopyralid

Plant residue definition for risk assessment (RD-RA)

- Applicable only for cereals/grass: clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) (EFSA, 2018d)

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

- All commodities groups by LC–MS/MS with LOQ 0.01 mg/kg, ILV available (EFSA, 2018d).

Note: This method involves a hydrolysis step that releases free clopyralid from its conjugates.

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**B.1.1.2. Stability of residues in plants**

| Plant products (available studies) | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|-----------|--------|------------------|-------------------|----------------|
| High water content                | Pasture   | -20    | 17 Months        | clopyralid        | EFSA (2018d)   |
|                                   | Maize forage/fodder | -20 | 13 Months | clopyralid | EFSA (2018d) |
| High oil content                  | Rape seed | -20    | 24 Months        | clopyralid        | EFSA (2018d)   |
|                                   | Olive (fruit and oil) | -18 | 10 Months | clopyralid | EFSA (2018d) |
| High protein content              | Maize grain | -20   | 13 Months        | clopyralid        | EFSA (2018d)   |
| Dry/high starch                   | Orange    | -18    | 10 Months        | clopyralid        | EFSA (2018d)   |
| Processed products                | Orange peel | -18   | 10 Months        | clopyralid        | EFSA (2018d)   |

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; LOQ: limit of quantification; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

| Commodity/Region/Indoor | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-------------------------|---------------------------------------------------------------|----------------|------------------------|---------------|-----------------|-------|
| Grassland and established pasture | New data (Finland, 2018b) Trials performed at 1 × 121-125 g a.s./ha, PHI 6-8 days: 2.27(e), 2.45, 4.40(e), 4.77, 7.35, 7.95, 8.65, 9.40 1 × 242 g a.s./ha, PHI 7 days: 8.18, 9.60(e) EU Pesticide Peer Review (Finland, 2018a): Trials performed at 1 × 201-218 g a.s./ha, PHI 7 days: 2.49, 3.48, 3.73, 6.95(e) data scaled to target rate of 201.6 g a.s./ha: 2.30, 3.21, 3.72(e), 3.74, 4.05, 6.81(e), 7.05, 7.10(e), 7.76, 8.0(e), 12.0, 12.9, 14.4, 15.16 | All residue data were scaled to the GAP target rate of 201.6 g a.s./ha | n.a. | 15.16 | 7.08 | n.a. |
| SEU (GAP: 1 × 120 g a.s./ha, PHI 7 days) | New data (Finland, 2018b) Trials performed at 1 × 239-247 g a.s./ha, PHI 6-8 days: 5.64, 11.69 EU Pesticide Peer Review (Finland, 2018a): Trials performed at 1 × 104 - 113 g a.s./ha, PHI 7 days: 1.66(e), 2.49, 2.91, 3.06(e), 3.21, 3.31, 3.93, 4.09 data scaled to target rate of 120 g a.s./ha: 1.79, 2.74, 2.87, 3.09, 3.34, 3.57, 3.71, 4.25, 4.59, 5.87 | All residue data were scaled to the GAP target rate of 120 g a.s./ha but not considered for HR and STMR as the GAP in NEU leads to higher values | n.a. | 5.87 | 3.46 | n.a. |
### Modification of the existing MRLs for clopyralid in various commodities

| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-----------|-----------------------------|----------------------------------------------------------------|-----------------|------------------------|------------------------|------------------------|----------------|
| **Barley** | Grain NEU (GAP: 1 × 122.4 g a.s./ha, BBCH 39) | New data (Finland, 2018b) 
Trials performed at 121–133 g a.s./ha BBCH 39 
Grain: 0.11, 0.19, 0.22, 0.26, 0.26, 0.35<sup>(f)</sup>, 0.39 
EU Pesticide Peer Review (Finland, 2018a): 
Trials performed at 116–133 g a.s./ha BBCH 39 
Grain: 0.17, 0.29, 0.29, 0.33, 0.34 
Barley Grain: 0.11, 0.17, 0.19, 0.22, 0.26, 0.26, 0.29, 0.290, 0.33, 0.34, 0.35<sup>(f)</sup>, 0.39 | Residue trials on barley compliant with GAP | 0.8 | 0.39 | 0.27 | n.a. |
| **Barley** | Straw NEU (GAP: 1 × 122.4 g a.s./ha, BBCH 39) | New data (Finland, 2018b) 
Trials performed at 121–133 g a.s./ha BBCH 39 
Straw: 0.36, 0.44, 0.88, 0.94<sup>(f)</sup>, 1.20, 1.29, 1.70 
EU Pesticide Peer Review (Finland, 2018a): 
Trials performed at 116–133 g a.s./ha BBCH 39 
Straw: 0.24, 0.48, 0.80, 1.71, 1.86 
Barley Straw: 0.24, 0.36, 0.44, 0.48, 0.80, 0.88, 0.94<sup>(f)</sup>, 1.20, 1.29, 1.70, 1.71, 1.86 | Residue trials on barley compliant with GAP | n.a. | 1.86 | 0.91 | n.a. |
| **Barley** | Grain SEU (GAP: 1 × 100.8 g a.s./ha, BBCH 39) | New data (Finland, 2018b) 
Trials performed at 102–108 g a.s./ha BBCH 39 
Grain: 0.10, 0.11, 0.19, 0.37, 0.46 
EU Pesticide Peer Review (Finland, 2018a): 
Trials performed at 101–105 g a.s./ha BBCH 39 
Grain: 0.19, 0.33, 0.84, 0.87 
Barley Grain: 0.10, 0.11, 0.19, 0.19, 0.33, 0.37, 0.46, 0.84, 0.87 | Residue trials on barley compliant with GAP 
Existing MRL is 2 mg/kg. No modification required | 2.0 | 0.87 | 0.33 |
| Commodity | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------|-----------------|---------------------------------------------------------------|-----------------|-----------------------|--------------|----------------|-------|
| Barley    | Straw SEU       | New data (Finland, 2018b) Trials performed at 102–108 g a.s./ha BBCH 39 0.54, 0.68, 0.89, 1.08, 1.83 EU Pesticide Peer Review (Finland, 2018a): Trials performed at 101–105 g a.s./ha BBCH 39 0.45, 0.49, 0.71, 1.57 Barley Straw: 0.45, 0.49, 0.54, 0.68, 0.71, 0.89, 1.08, 1.57, 1.83 | Residue trials on barley compliant with GAP | n.a. | 1.83 | 0.71 | n.a. |
| Wheat     | Grain NEU       | New data (Finland, 2018b) Grain: 1 × 79-85 g a.s./ha, BBCH 37–39: 0.31, 0.36, 0.40, 0.44, 0.45, 0.52, 0.65, 0.96 Annex I inclusion (EFSA, 2005) Grain: 1 × 149-152 g a.s./ha, BBCH 49: 1.06, 1.26 Grain Scaled: 0.46, 0.52, 0.58, 0.66, 0.66, 0.77, 0.87, 1.01, 1.01, 1.47 | Residue trials on wheat compliant with GAP Residue trials on wheat were scaled to the GAP target rate of 0.122 kg a.s./ha | 3 | 1.47 | 0.72 | n.a. |
| Straw     | Straw NEU       | New data (Finland, 2018b) Straw: 1 × 79-85 g a.s./ha, BBCH 37-39: 2 × 0.26, 0.33, 0.37, 0.38, 0.41, 0.43, 1.40 Annex I inclusion (EFSA, 2005) Straw: 1 × 149-152 g a.s./ha, BBCH 49: 0.58, 0.81 Straw Scaled: 0.39, 0.40, 0.49, 0.55, 0.55, 0.61, 0.65, 0.63, 2.17 | Residue trials on wheat compliant with GAP Residue trials on wheat were scaled to the GAP target rate of 0.122 kg a.s./ha | n.a. | 2.17 | 0.55 | n.a. |
### Modification of the existing MRLs for clopyralid in various commodities

| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-----------|-----------------------------|---------------------------------------------------------------|----------------|------------------------|--------------------------|--------------------------|------------|
| Wheat     | Grain                        | New data (Finland, 2018b) Grains: 1 × 96-110 g a.s./ha, BBCH 39: 0.16, 0.3, 0.3, 0.3, 0.34, 0.44, 0.44, 0.46 | Residue trials on wheat compliant with GAP | 1 | 0.46 | 0.32 | n.a. |
|           | SEU (GAP: 1 × 100.8 g a.s./ha, BBCH 39) | | | | | | |
| Straw     | SEU (GAP: 1 × 100.8 g a.s./ha, BBCH 39) | New data (Finland, 2018b) Straw: 1 × 96-110 g a.s./ha, BBCH 39: 0.29, 0.31, 0.37, 0.51, 0.65, 0.66, 0.90, 1.40 | Residue trials on wheat compliant with GAP | n.a. | 1.40 | 0.58 | n.a. |

MRL: maximum residue level; GAP: Good Agricultural Practice; a.s.: active substance; n.a.: not applicable.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

(e): Residue values from PHI 14 because higher residue at later PHI.

(f): Application was at BBCH 45 instead of 39.
B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?

| Processed Commodity | Number of valid studies (a) | Processing Factor (PF) | CF<sub>P</sub> | Comment/Source |
|---------------------|-----------------------------|------------------------|---------------|----------------|
| Wheat/bran          | 4                           | 3.5; 4.3; 6.1; 10.4    | 5.7           | n.a.           |
| Wheat/white flour    | 4                           | 0.1; 0.2; 0.3; 0.6     | 0.25          | n.a.           |
| Wheat/wholemeal flour | 2                          | 0.8; 1.2               | 1             | n.a.           |
| Wheat/germ          | 2                           | 2.3; 4.3               | 3.3           | n.a.           |
| Wheat/white bread   | 2                           | 0.1; 0.1               | 0.1           | n.a.           |
| Wheat/wholemeal bread | 2                      | 0.5; 0.6               | 0.6           | n.a.           |
| Barley/malt sprouts | 2                           | 0.2, 0.2               | 0.2           | n.a.           |
| Barley/brewing malt | 2                           | 0.6; 0.7               | 0.7           | n.a.           |
| Barley/spent grains and flocs | 2 | 0.1; 0.2 | 0.2 | n.a. |
| Barley/brewer's yeast | 2                      | 0.1; 0.1               | 0.1           | n.a.           |
| Barley/beer         | 2                           | 0.1; 0.1               | 0.1           | n.a.           |

*PF: processing factor; n.a.: not applicable.
*(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur)
*(b): The average processing factor is calculated for two values. In case of three or more processing tests, the processing factor is the median of the single factors from each test.*

In rotational crop majority of the residue identified at PBI 30 days was clopyralid conjugates (up to 81% TRR) and unconjugated clopyralid (10–50% TRR) in all crop parts except radish roots. In total, 81–99% of the extractable radioactivity was attributed to clopyralid and its conjugate.

Rotational crop field trials according to current guidelines are requested as residues of free and conjugated parent were found in all plant parts at PHI 30.

Until these studies become available EFSA suggests to risk managers as risk mitigation measure to label clopyralid containing products with the restriction not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown.

PBI: plant-back interval; PHI: preharvest interval; TRR: total radioactive residue.

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies (a) | Processing Factor (PF) | CF<sub>P</sub> | Comment/Source |
|---------------------|-----------------------------|------------------------|---------------|----------------|
| Wheat/bran          | 4                           | 3.5; 4.3; 6.1; 10.4    | 5.7           | n.a.           |
| Wheat/white flour    | 4                           | 0.1; 0.2; 0.3; 0.6     | 0.25          | n.a.           |
| Wheat/wholemeal flour | 2                          | 0.8; 1.2               | 1             | n.a.           |
| Wheat/germ          | 2                           | 2.3; 4.3               | 3.3           | n.a.           |
| Wheat/white bread   | 2                           | 0.1; 0.1               | 0.1           | n.a.           |
| Wheat/wholemeal bread | 2                      | 0.5; 0.6               | 0.6           | n.a.           |
| Barley/malt sprouts | 2                           | 0.2, 0.2               | 0.2           | n.a.           |
| Barley/brewing malt | 2                           | 0.6; 0.7               | 0.7           | n.a.           |
| Barley/spent grains and flocs | 2 | 0.1; 0.2 | 0.2 | n.a. |
| Barley/brewer's yeast | 2                      | 0.1; 0.1               | 0.1           | n.a.           |
| Barley/beer         | 2                           | 0.1; 0.1               | 0.1           | n.a.           |
B.2. Residues in livestock

Dietary burden calculation according to OECD (2013).

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup<sup>(a)</sup> | Most critical commodity<sup>(b)</sup> | Trigger exceeded (Y/N) |
|-----------------------------|-----------------------------|--------------------------------------|-------------------------------------|------------------------|
|                             | mg/kg bw per day            | mg/kg DM                             |                                     |                        |
|                             | Median | Maximum | Median | Maximum |                                    |                        |
| Cattle (all)                | 0.761  | 1.521   | 19.79  | 39.55   | Dairy cattle                        | Grass                  | Yes                    |
| Cattle (dairy only)         | 0.761  | 1.521   | 19.79  | 39.55   | Dairy cattle                        | Grass                  | Yes                    |
| Sheep (all)                 | 0.914  | 1.934   | 27.41  | 58.01   | Ram/Ewe                             | Grass                  | Yes                    |
| Sheep (ewe only)            | 0.914  | 1.934   | 27.41  | 58.01   | Ram/Ewe                             | Grass                  | Yes                    |
| Swine (all)                 | 0.221  | 0.407   | 9.58   | 17.62   | Swine (breeding)                    | Grass                  | Yes                    |
| Poultry (all)               | 0.146  | 0.204   | 2.12   | 2.98    | Poultry layer                       | Cabbage, heads         | Yes                    |
| Poultry (layer only)        | 0.146  | 0.204   | 2.12   | 2.98    | Poultry layer                       | Cabbage, heads         | Yes                    |
| Fish                        | N/A   | –       | –      | –       |                                     |                        |                        |

bw: body weight; DM: dry matter.

<sup>(a)</sup>: When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

<sup>(b)</sup>: The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal | Dose (mg/kg bw per day) | Duration (days) | Comment/Source |
|-------------------------------|--------|-------------------------|-----------------|----------------|
| Laying hen                    | 11.4 mg a.s./kg feed per day, equivalent to 0.56–0.65 mg/kg bw per day | 7 | New GLP and guideline compliant metabolism study with 14C-clopyralid (EFSA, 2018d). 3.3N (Layer)<sup>(a)</sup> |
| Goat                          | 50.9 mg a.s./kg dry feed/day equivalent to 0.484 mg/kg bw per day | 5 | New GLP and guideline compliant metabolism study with 14C-clopyralid (EFSA, 2018d) 1.5N (Beef), 1.3N (Dairy), 0.9N (Ram/ewe)<sup>(a)</sup> In milk over 21% of TRR (corresponding to 0.002 mg eq/kg) was found as clopyralid-glycine conjugate (X36538) |
| Pig                           | –      | –                       | –               | Not considered necessary |
| Fish                          | –      | –                       | –               | No studies submitted and not required |

bw: body weight.

<sup>(a)</sup>: In comparison to the calculated maximum dietary burden (mg a.s./kg DM feed).
### Time needed to reach a plateau concentration in milk and eggs (days)

| Commodity | Time Needed |
|-----------|-------------|
| Milk      | 1 day       |
| Eggs      | 7 days      |

For clopyralid residues in milk, dosing was once a day and the residues had already declined to low levels within one day. Any accumulating potential could not be demonstrated. Plateau was reached at day 1 (EFSA, 2018d).

For eggs residue levels are still slightly increasing at the end of the experiment, i.e. after 7 days of dosing, but a plateau can be assumed at day 7 (EFSA, 2018d).

### Metabolism in rat and ruminant similar

Yes

**EFSA (2018d)**

### Can a general residue definition be proposed for animals?

Yes

A conversion factor of 1.3 is proposed and applicable only for milk (EFSA, 2018d).

### Animal residue definition for monitoring (RD-Mo)

Clopyralid and its salts OR clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid) (EFSA, 2018d)

Existing residue definition of Regulation (EC) No 396/2005: clopyralid

### Animal residue definition for risk assessment (RD-RA)

Clopyralid common moiety (sum of clopyralid, its salts and glycine conjugates expressed as clopyralid) (EFSA, 2018d)

### Fat soluble residues

No

### Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)

- LC–MS/MS, LOQ = 0.01 mg/kg (muscle, fat, kidney, milk, liver, and egg)
- QuEChERS LC–MS/MS, LOQ = 0.01 mg/kg (fat and milk)

ILV available for both methods.

Note: This method involves a hydrolysis step that releases free clopyralid from its conjugates. Proof of extraction efficiency is missing (EFSA, 2018d)

| bw: body weight; LC –MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); ILV: independent laboratory validation. |

#### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/ Source |
|------------------------------------|--------|-----------|--------|-----------------|-------------------|-----------------|
| Bovine                             | Muscle | –20       | 19 Months | Clopyralid      | EFSA (2018d)      |
| Bovine                             | Liver  | –20       | 19 Months | Clopyralid      | EFSA (2018d)      |
| Bovine                             | Kidney | –20       | 19 Months | Clopyralid      | EFSA (2018d)      |
| Bovine                             | Milk   | –20       | 19 Months | Clopyralid      | EFSA (2018d)      |
| Bovine                             | Fat    | –20       | 24 Months | Clopyralid      | EFSA (2018d)      |
| Hen                                | Eggs   | –20       | 19 Months | Clopyralid      | EFSA (2018d)      |

Stability of conjugates has not been tested, though clopyralid conjugates are major metabolites as well. It is assumed that conjugated clopyralid will be also stable.
### B.2.2. Magnitude of residues in livestock

#### B.2.2.1. Summary of the residue data from livestock feeding studies

Calculations performed with Animal model 2017

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N level | MRL proposal (mg/kg) | CF(c) | STMR (mg/kg) | HR (mg/kg) |
|------------------|---------------------------------------------|-----------------------------|----------------------|-------|--------------|------------|
|                  | Mean | Highest | STMR<sub>Mo</sub><sup>(a)</sup> (mg/kg) | HR<sub>Mo</sub><sup>(b)</sup> (mg/kg) |       |              |            |
| **Cattle (all)** |      |         |                                    |                    |       |              |            |
| Closest feeding level (1.67 mg/kg bw; 1.2 N rate)<sup>(c)</sup> |      |         |                                    |                    |       |              |            |
| Muscle | 0.02 | 0.03 | 0.01 | 0.03 | **0.03**<sup>(f)</sup> | n.c. | 0.01 | 0.03 |
| Fat | 0.06 | 0.15 | 0.05 | 0.14 | **0.15** | n.c. | 0.05 | 0.14 |
| Liver | 0.11 | 0.15 | 0.06 | 0.12 | **0.15** | n.c. | 0.06 | 0.13 |
| Kidney | 1.46 | 1.56 | 0.72 | 1.37 | **1.5** | n.c. | 0.72 | 1.44 |
| **Cattle (dairy only)** |      |         |                                    |                    |       |              |            |
| Closest feeding level (1.67 mg/kg bw; 1.2 N rate)<sup>(c)</sup> |      |         |                                    |                    |       |              |            |
| Milk<sup>(d)</sup> | 0.01 | 0.01 | 0.01 | 0.01 | **0.015**<sup>(f)</sup> | 1.2 | 0.01 | 0.01 |
| **Sheep (all)**<sup>(e)</sup> |      |         |                                    |                    |       |              |            |
| Closest feeding level (1.67 mg/kg bw; 0.9 N ram/ewe rate)<sup>(c)</sup> |      |         |                                    |                    |       |              |            |
| Muscle | 0.02 | 0.03 | 0.02 | 0.03 | **0.04**<sup>(f)</sup> | n.c. | 0.02 | 0.03 |
| Fat | 0.06 | 0.15 | 0.06 | 0.17 | **0.2** | n.c. | 0.06 | 0.17 |
| Liver | 0.11 | 0.15 | 0.06 | 0.16 | **0.2** | n.c. | 0.06 | 0.17 |
| Kidney | 1.46 | 1.56 | 0.87 | 1.69 | **2** | n.c. | 0.87 | 1.81 |
| **Sheep (ewe only)**<sup>(e)</sup> |      |         |                                    |                    |       |              |            |
| Closest feeding level (1.67 mg/kg bw; 0.9 N ewe rate)<sup>(c)</sup> |      |         |                                    |                    |       |              |            |
| Milk<sup>(b)</sup> | 0.01 | 0.01 | 0.01 | 0.02 | **0.015** | n.c. | 0.01 | 0.02 |
| **Swine (all)**<sup>(e)</sup> |      |         |                                    |                    |       |              |            |
| Closest feeding level (0.451 mg/kg bw; 1.2 N rate)<sup>(c)</sup> |      |         |                                    |                    |       |              |            |
| Muscle | 0.01 | 0.01 | 0.01 | 0.01 | **0.01**<sup>(f)</sup> | n.c. | 0.01 | 0.01 |
| Fat | 0.02 | 0.02 | 0.01 | 0.05 | **0.05** | n.c. | 0.01 | 0.05 |
| Liver | 0.03 | 0.04 | 0.02 | 0.05 | **0.05** | n.c. | 0.02 | 0.05 |
| Kidney | 0.43 | 0.61 | 0.20 | 0.52 | **0.6** | n.c. | 0.21 | 0.55 |
| **Poultry (all)** |      |         |                                    |                    |       |              |            |
| Closest feeding level (0.28 mg/kg bw; 1.4 N rate)<sup>(c)</sup> |      |         |                                    |                    |       |              |            |
| Muscle | 0.01 | 0.01 | 0.01 | 0.01 | **0.01**<sup>(f)</sup> | n.c. | 0.01 | 0.01 |
| Fat | 0.01 | 0.01 | 0.01 | 0.01 | **0.01**<sup>(f)</sup> | n.c. | 0.01 | 0.01 |
| Liver | 0.02 | 0.03 | 0.01 | 0.02 | **0.03**<sup>(f)</sup> | n.c. | 0.01 | 0.02 |
| **Poultry (layer only)** |      |         |                                    |                    |       |              |            |
| Closest feeding level (0.28 mg/kg bw; 1.4 N rate)<sup>(c)</sup> |      |         |                                    |                    |       |              |            |
| Eggs<sup>(c)</sup> | 0.01 | 0.01 | 0.01 | 0.01 | **0.01**<sup>(f)</sup> | n.c. | 0.01 | 0.01 |

bw: body weight; STMR: supervised trials median residue; HR: highest residue; mo: monitoring; n.c.: not considered.

* Indicates that the result is below the limit of analytical quantification (LOQ).

(a): The mean residue level for milk and the mean residue levels for eggs and tissues were recalculated at the 1N rate for the median dietary burden.

(b): The mean residue level in milk and the highest residue levels in eggs and tissues were recalculated at the 1N rate for the maximum dietary burden.

(c): Closest feeding level and N dose rate related to the maximum dietary burden.

(d): Highest residue level from day 1 to day 28 (daily mean of 3 cows).

(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

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8 https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en
Currently, the MRLs for these commodities of animal origin are proposed at 0.05 mg/kg, i.e. the limit of quantification of the previous analytical method. Once the new analytical method is fully validated (including proof of extraction efficiencies), these MRLs can be reconsidered in the light of the LOQ of 0.01 mg/kg of the new analytical method.

### B.3. Consumer risk assessment

| ARfD | Not necessary (European Commission, 2006) 0.17 mg/kg bw (EFSA, 2018d) |
|------|------------------------------------------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Indicative exposure assessment, using the new ARfD as proposed by the EU pesticides peer review (not yet implemented by Regulation) (EFSA, 2018d) |
| Commodity under assessment: | Wheat: 6% of ARfD  
Bovine, kidney: 3% of ARfD  
Barley: 1% of ARfD |
| Assumptions made for the calculations | The calculation is based on the highest residue levels derived for raw agricultural commodities under consideration (i.e. wheat, oat, barley and animal commodities) as reported in Appendix D.2 for plant commodities and animal commodities. |
| ADI | 0.15 mg/kg bw per day (European Commission, 2006) |
| Highest IEDI, according to EFSA PRIMo | All crops:  
29% ADI (NL toddler)  
Maize: 9%  
Apple: 4%  
Banana: 2%  
Only crops under consideration 3% ADI (GEMS/Food G06)  
Wheat: 3%  
Milk: cattle: 0.0%  
Barley: 0.0% |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities under consideration as derived from submitted residue trials. For animal commodities, the STMR values were as derived from the feeding studies for the calculated dietary burdens (Table B.2.2.1). For milk, the input value was multiplied by the conversion factor of 1.3 for risk assessment. For remaining crops, the input values were the existing EU MRLs and the STMR values as derived in previous MRL applications (EFSA, 2011, 2018b). |
| A chronic risk for consumer is not expected from the intended uses of clopyralid provided that risk mitigation measures to avoid residues in rotational crops are in place. |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue.

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### B.4. Recommended MRLs

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------------|------------|-------------------------|-------------------------|------------------------|
| **Existing enforcement residue definition for commodities of plant origin:** Clopyralid | | | | The submitted data are sufficient to derive an MRL proposal for the EU uses. Risk for consumers unlikely. Risk managers should consider setting specific risk mitigation measures to avoid the presence of clopyralid residues in rotational crops until further data are submitted |
| 0500090 | Wheat | 2 | 3 |  |
| 0500050 | Oat | 2 | 3 |  |

| **Existing enforcement residue definition for commodities of animal origin:** Clopyralid | | | | The submitted data are sufficient to derive an MRL proposal by extrapolation from wheat. Risk for consumers unlikely. Risk managers should consider setting specific risk mitigation measures to avoid the presence of clopyralid residues in rotational crops until further data are submitted |
| 1011010 | Swine, muscle/meat | 0.05* | 0.05\(^{(b)}\) | Based on the intended uses, new feeding studies and new enforcement method with lower LOQ of 0.01 mg/kg for all matrices. Risk for consumers unlikely. EFSA notes that on the basis of existing livestock dietary burden and the results of the more recent feeding studies, lower EU MRL of 0.03 mg/kg for bovine muscle/meat and of 0.04 mg/kg for sheep and goat muscle/meat would be sufficient |
| 1011020 | Swine, fat | 0.05* | 0.05 |  |
| 1011030 | Swine, liver | 0.05* | 0.05 |  |
| 1011040 | Swine, kidney | 0.05* | 0.6 |  |
| 1012010 | Bovine, muscle/meat | 0.08 | No change |  |
| 1012020 | Bovine, fat | 0.05* | 0.15 |  |
| 1012030 | Bovine, liver | 0.06 | 0.15 |  |
| 1012040 | Bovine, kidney | | |  |
| 1013010 | Sheep, muscle/meat | 0.08 | No change |  |
| 1013020 | Sheep, fat | 0.05* | 0.2 |  |
| 1013030 | Sheep, liver | 0.06 | 0.2 |  |
| 1013040 | Sheep, kidney | 0.4 | 2 |  |
| 1014010 | Goat, muscle/meat | 0.08 | No change |  |
| 1014020 | Goat, fat | 0.05* | 0.2 |  |
| 1014030 | Goat, liver | 0.06 | 0.2 |  |
| 1014040 | Goat, kidney | 0.4 | 2 |  |
| 1016010 | Poultry, muscle | 0.05* | 0.05\(^{(b)}\) |  |
| 1016020 | Poultry, fat | 0.05* | 0.05\(^{(b)}\) |  |
| 1016030 | Poultry, liver | 0.05* | 0.05\(^{(b)}\) |  |
| 1020000 | Milk | 0.05* | 0.05\(^{(b)}\) |  |
| 1030000 | Eggs | 0.05* | 0.05\(^{(b)}\) |  |

MRL: maximum residue level.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

\(^{(b)}\): The MRL of 0.05 mg/kg in these commodities is proposed on basis of the LOQ of 0.05 mg/kg of the former analytical method. It is noted that a new enforcement analytical method is now available with a validated LOQ of 0.01 mg/kg, for which, however, the extraction efficiency has not been addressed.
Appendix C – Pesticide Residue Intake Model (PRIMo)

### LOQs (mg/kg)
- Range from: 0.01 to 0.20

### Toxicological reference values
- ADI (mg/kg bw per day): 0.15
- ARfD (mg/kg bw): 0.17
- Source of ADI: EFSA
- Source of ARfD: EFSA

#### EFSA PRIMo revision 3.1; 2019/03/19
- Year of evaluation: 2018

#### No of diets exceeding the ADI:
- ---

### Calculated exposure (% of ADI) MS Diet

| Commodity/group of commodities | Exposure (% of ADI) | Highest contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) | MRLs set at the LOQ (in % of ADI) |
|--------------------------------|---------------------|--------------------------------------------|----------------------------------------|----------------------------------------|----------------------------------|
| Bananas                        | 29% 42.82           | Banana                                     | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Maize/corn                     | 14% 21.54           | Maize                                      | Sugar beet roots                       | Rice                                   | 0.1% 3%                          |
| Oranges                        | 14% 21.31           | Orange                                     | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Wheat                          | 14% 21.31           | Wheat                                      | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Potatoes                       | 11% 16.83           | Potatoes                                   | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Soyabeans                      | 11% 16.64           | Soyabeans                                  | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Soyabeans                      | 10% 14.63           | Soyabeans                                  | Sugar beet roots                       | Rice                                   | 0.1% 2%                          |
| Maize/corn                     | 10% 14.54           | Maize                                      | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Soyabeans                      | 10% 14.45           | Soyabeans                                  | Sugar beet roots                       | Rice                                   | 0.1% 2%                          |
| Soyabeans                      | 10% 14.33           | Soyabeans                                  | Sugar beet roots                       | Rice                                   | 0.1% 2%                          |
| Sugar beet roots               | 9% 13.77            | Sugar beet roots                           | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Potatoes                       | 9% 13.76            | Potatoes                                   | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Rice                           | 9% 13.09            | Rice                                       | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Rice                           | 8% 12.38            | Rice                                       | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Tomatoes                       | 8% 11.95            | Tomatoes                                   | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Rice                           | 8% 11.89            | Rice                                       | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Rice                           | 7% 11.23            | Rice                                       | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Bananas                        | 7% 10.96            | Banana                                     | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Rice                           | 7% 10.96            | Rice                                       | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Apples                         | 6% 9.67             | Apples                                     | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Rye                            | 6% 9.39             | Rye                                        | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Apples                         | 6% 9.00             | Apples                                     | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Sugar beet roots               | 5% 8.20             | Sugar beet roots                           | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Tomatoes                       | 5% 7.57             | Tomatoes                                   | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Apples                         | 5% 7.26             | Apples                                     | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Potatoes                       | 4% 6.70             | Potatoes                                   | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Rye                            | 4% 6.25             | Rye                                        | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Carrots                        | 4% 5.77             | Carrots                                    | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Potatoes                       | 3% 4.80             | Potatoes                                   | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |
| Apples                         | 2% 2.46             | Apples                                     | Sugar beet roots                       | Rice                                   | 0.0% 2%                          |

### Conclusion:
- The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
- The long-term intake of residues of Clopyralid is unlikely to present a public health concern.

### Normal mode

#### Chronic risk assessment: JMPR methodology (IEDI/TMDI)

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Clopyralid is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Acute risk assessment/children

| Highest % of ARfD/ADI Commodities | MRL Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI Commodities | MRL Input for RA (mg/kg) | Exposure (µg/kg bw) |
|----------------------------------|--------------------------|---------------------|----------------------------------|--------------------------|---------------------|
| Cauliflowers                     | 3.142                    | 82                  | Head cabbages                    | 3.152                    | 64                  |
| Potatoes                         | 0.505                    | 77                  | Yams                             | 1/1                      | 28                  |
| Melons                           | 0.565                    | 76                  | Beets                            | 1/1                      | 23                  |
| Pears                            | 0.505                    | 69                  | Watermelons                      | 0.505                    | 20                  |
| Heart cabbages                   | 3.152                    | 67                  | Melons                           | 0.505                    | 20                  |
| Oranges                          | 0.565                    | 66                  | Kales                            | 1/1                      | 19                  |
| Melons                           | 0.565                    | 61                  | Charls/bread leaves              | 1/1                      | 19                  |
| Beets                            | 1/1                      | 57                  | Broccoli                         | 1.507                    | 17                  |
| Pineapples                       | 0.565                    | 51                  | 10% Rice                         | 22                      | 17                  |
| Bananas                          | 0.565                    | 49                  | 10% Table grapes                 | 0.505                    | 17                  |
| Pears                            | 0.565                    | 48                  | 9% Oranges                       | 0.505                    | 15                  |
| Sweet potatoes/boiled            | 1/1                      | 44                  |                                  |                          |                     |
| Sweet potatoes/boiled            | 1/1                      | 44                  |                                  |                          |                     |
| Beets                            | 1/1                      | 44                  |                                  |                          |                     |
| Turnips/boiled                   | 1.508                    | 41                  |                                  |                          |                     |
| Sugar beets (root/sugar)         | 1/1                      | 39                  |                                  |                          |                     |
| Escaroles/broad-leaved endives/boiled | 0.565    | 33                  |                                  |                          |                     |
| Charls/bread leaves/boiled       | 1/1                      | 31                  |                                  |                          |                     |
| Potatoes/boiled                  | 0.523                    | 30                  |                                  |                          |                     |
| Kale/boiled                      | 1/1                      | 28                  |                                  |                          |                     |
| Kale/boiled                      | 1/1                      | 28                  |                                  |                          |                     |
| Apple/jeue                       | 0.565                    | 27                  |                                  |                          |                     |

### Acute risk assessment/adults/general population

The calculation is based on the large portion of the most critical consumer group.

### Results for all crops

#### Unprocessed commodities

| Highest % of ARfD/ADI Commodities | MRL Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI Commodities | MRL Input for RA (mg/kg) | Exposure (µg/kg bw) |
|----------------------------------|--------------------------|---------------------|----------------------------------|--------------------------|---------------------|
| Cauliflowers                     | 3.142                    | 82                  | Head cabbages                    | 3.152                    | 64                  |
| Potatoes                         | 0.505                    | 77                  | Yams                             | 1/1                      | 28                  |
| Melons                           | 0.565                    | 76                  | Beets                            | 1/1                      | 23                  |
| Pears                            | 0.505                    | 69                  | Watermelons                      | 0.505                    | 20                  |
| Heart cabbages                   | 3.152                    | 67                  | Melons                           | 0.505                    | 20                  |
| Oranges                          | 0.565                    | 66                  | Kales                            | 1/1                      | 19                  |
| Melons                           | 0.565                    | 61                  | Charls/bread leaves              | 1/1                      | 19                  |
| Beets                            | 1/1                      | 57                  | Broccoli                         | 1.507                    | 17                  |
| Pineapples                       | 0.565                    | 51                  | 10% Rice                         | 22                      | 17                  |
| Bananas                          | 0.565                    | 49                  | 10% Table grapes                 | 0.505                    | 17                  |
| Pears                            | 0.565                    | 48                  | 9% Oranges                       | 0.505                    | 15                  |
| Sweet potatoes/boiled            | 1/1                      | 44                  |                                  |                          |                     |
| Sweet potatoes/boiled            | 1/1                      | 44                  |                                  |                          |                     |
| Beets                            | 1/1                      | 44                  |                                  |                          |                     |
| Turnips/boiled                   | 1.508                    | 41                  |                                  |                          |                     |
| Sugar beets (root/sugar)         | 1/1                      | 39                  |                                  |                          |                     |
| Escaroles/broad-leaved endives/boiled | 0.565    | 33                  |                                  |                          |                     |
| Charls/bread leaves/boiled       | 1/1                      | 31                  |                                  |                          |                     |
| Potatoes/boiled                  | 0.523                    | 30                  |                                  |                          |                     |
| Kale/boiled                      | 1/1                      | 28                  |                                  |                          |                     |
| Kale/boiled                      | 1/1                      | 28                  |                                  |                          |                     |
| Apple/jeue                       | 0.565                    | 27                  |                                  |                          |                     |

#### Processed commodities

| Highest % of ARfD/ADI Processed commodities | MRL Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI Processed commodities | MRL Input for RA (mg/kg) | Exposure (µg/kg bw) |
|---------------------------------------------|--------------------------|---------------------|---------------------------------------------|--------------------------|---------------------|
| Cauliflowers/boiled                         | 3.142                    | 99                  | Cauliflowers/boiled                         | 3.142                    | 99                  |
| Broccoli/boiled                             | 1.568                    | 58                  | 10% Broccoli/boiled                        | 1.507                    | 18                  |
| Sweet potatoes/boiled                        | 0.505                    | 47                  | 10% Cauliflowers/boiled                    | 0.505                    | 28                  |
| Potatoes/boiled                             | 0.505                    | 47                  | 10% Beets/boiled                           | 0.505                    | 28                  |
| Matzoels                                     | 0.505                    | 47                  | 10% Malatoil                                | 2/50                     | 25                  |
| Pumpkins/boiled                             | 0.505                    | 44                  | 10% Cassava root/boiled                    | 1/1                      | 19                  |
| Potatoes/boiled                             | 0.505                    | 44                  | 10% Kale/boiled                            | 1/1                      | 19                  |
| Beets/boiled                                | 1/1                      | 44                  | 10% Apple/jeue                             | 0.505                    | 17                  |
| Turnips/boiled                              | 1.508                    | 41                  | 9% Sweet potatoes/boiled                   | 0.505                    | 15                  |
| Sugar beets (root/sugar)                    | 1/1                      | 39                  | 9% Sugar beets (root/sugar)                | 1/1                      | 15                  |
| Escaroles/broad-leaved endives/boiled        | 0.565                    | 33                  | 9% Turnips/boiled                          | 1.508                    | 15                  |
| Charls/bread leaves/boiled                  | 1/1                      | 31                  | 7% Charls/bread leaves/boiled              | 1/1                      | 13                  |
| Potatoes/boiled                             | 0.523                    | 30                  | 7% Courgettes/boiled                       | 0.505                    | 11                  |
| Kale/boiled                                 | 1/1                      | 28                  | 6% Parsnips/boiled                         | 0.505                    | 11                  |
| Kale/boiled                                 | 1/1                      | 28                  | 6% Kohlrabins/boiled                       | 0.505                    | 11                  |
| Apple/jeue                                  | 0.565                    | 27                  | 6% Apple/jeue                              | 0.505                    | 11                  |

### Details – acute risk assessment/children

**No exceedance of the toxicological reference value was identified for any unprocessed commodity.**

**For processed commodities, no exceedance of the ARfD/ADI was identified.**

### Details – acute risk assessment/adults

**No exceedance of the toxicological reference value was identified for any unprocessed commodity.**

**For processed commodities, no exceedance of the ARfD/ADI was identified.**

### Conclusion

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

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### Appendix D – Input values for the exposure calculations

#### D.1. Livestock dietary burden calculations

| Feed commodity | Median dietary burden | Maximum dietary burden |
|----------------|-----------------------|------------------------|
|                | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment                |
| Barley, straw  | 0.91                  | STMR (Barley, NEU)     | 1.86                | HR (Barley, NEU)       |
| Grass, forage (fresh) | 7.08                  | STMR (NEU)             | 15.16               | HR (NEU)               |
| Grass, hay     | 24.78                 | STMR (NEU) × PF(a)     | 53.2                | HR (NEU) × PF(a)       |
| Grass, silage  | 11.33                 | STMR (NEU) × PF(a)     | 24.32               | HR (NEU) × PF(a)       |
| Oat, straw(b)  | 0.58                  | STMR (Wheat, SEU)      | 2.17                | HR (Wheat, NEU)        |
| Rye, straw(b)  | 0.58                  | STMR (Wheat, SEU)      | 2.17                | HR (Wheat, NEU)        |
| Triticale, straw(b) | 0.58                  | STMR (Wheat, SEU)      | 2.17                | HR (Wheat, NEU)        |
| Wheat, straw(b) | 0.58                  | STMR (Wheat, SEU)      | 2.17                | HR (Wheat, NEU)        |
| Oat, grain(b)  | 0.72                  | STMR (Wheat, SEU)      |                     |                        |
| Oat, grain(b)  | 0.72                  | STMR (Wheat, NEU)      |                     |                        |
| Rye, grain(b)  | 0.72                  | STMR (Wheat, NEU)      |                     |                        |
| Triticale, grain(b) | 0.72                  | STMR (Wheat, NEU)      |                     |                        |
| Wheat, grain(b) | 0.72                  | STMR (Wheat, NEU)      |                     |                        |
| Brewer’s grain, dried | 1.09              | STMR (Barley, SEU) × PF(a) |                     |                        |
| Distiller grain, dried | 2.38                  | STMR (Wheat, NEU) × PF(a) |                     |                        |
| Wheat gluten, meal | 1.8                    | STMR (Wheat, NEU) × PF(a) |                     |                        |
| Wheat, milled by products | 5.04                | STMR (Wheat, NEU) × PF(a) |                     |                        |

**Feed items related to the previous evaluations (as considered in the evaluation report by the EMS (Finland, 2018b))**

| Feed item | Median dietary burden | Maximum dietary burden |
|-----------|-----------------------|------------------------|
|           | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment                |
| Beet mangel, fodder | 0.47                  | STMR (EFSA, 2005)      | 1.05                | HR (EFSA, 2005)        |
| Beet, sugar (tops)  | 0.47                  | STMR (EFSA, 2005)      | 1.05                | HR (EFSA, 2005)        |
| Cabbage, heads (leaves) | 0.23                  | STMR (EFSA, 2011)      | 1.52                | HR (EFSA, 2011)        |
| Corn, field (stover) | 0.46                  | STMR (Finland, 2018b)  | 0.88                | HR (Finland, 2018b)    |
| Corn, pop (stover)  | 0.46                  | STMR (Finland, 2018b)  | 0.88                | HR (Finland, 2018b)    |
| Kale       | 1                     | MRL                    | 1                   | MRL                    |
| Turnip, tops (leaves) | 0.47                  | STMR (EFSA, 2005)      | 1.05                | HR (EFSA, 2005)        |
| Swede, roots | 0.35                  | STMR (EFSA, 2011)      | 0.80                | HR (EFSA, 2011)        |
| Turnip, roots  | 0.35                  | STMR (EFSA, 2011)      | 0.80                | HR (EFSA, 2011)        |
| Maize, field (grain) | 0.06                  | STMR (Finland, 2018b)  |                     |                        |
| Maize, pop (grain)  | 0.06                  | STMR (Finland, 2018b)  |                     |                        |
| Cotton     | 0.5                   | MRL                    |                     |                        |
| Pea, seed (dry) | 0.5                    | MRL                    |                     |                        |
| Soybean seed | 0.5                    | MRL                    |                     |                        |
| Apple, pomace (wet) | 0.05                  | STMR (EFSA, 2005) × PF(a) |                     |                        |
| Beet, sugar (dried pulp) | 6.30                  | STMR (EFSA, 2005) × PF(a) |                     |                        |
| Beet mangel, fodder | 0.47                  | STMR (EFSA, 2005)      | 1.05                | HR (EFSA, 2005)        |
| Beet, sugar (tops)  | 0.47                  | STMR (EFSA, 2005)      | 1.05                | HR (EFSA, 2005)        |
| Cabbage, heads (leaves) | 0.23                  | STMR (EFSA, 2011)      | 1.52                | HR (EFSA, 2011)        |
### Feed commodity

| Commodity                          | Median dietary burden | Maximum dietary burden |
|-----------------------------------|-----------------------|------------------------|
| **Input value (mg/kg)**           | **Comment**           | **Input value (mg/kg)** | **Comment** |
| Corn, field (stover)              | 0.46 STMR (Finland, 2018b) | 0.88 HR (Finland, 2018b) |
| Beet, sugar (ensiled pulp)        | 1.05 STMR (EFSA, 2005) ⨉ PF<sup>a</sup> | 1.05 |
| Beet, sugar (molasses)            | 9.80 STMR (EFSA, 2005) ⨉ PF<sup>a</sup> | 9.80 |
| Canola (rapeseed), meal           | 0.06 STMR (Finland, 2018b) ⨉ PF<sup>a</sup> | 0.06 |
| Citrus, dried pulp                | 5 MRL ⨉ PF<sup>a</sup>   | 5                     |
| Corn, field (milled by-products)  | 0.06 STMR (Finland, 2018b) ⨉ PF<sup>a</sup> | 0.06 |
| Corn, field (hominy meal)         | 0.36 STMR (Finland, 2018b) ⨉ PF<sup>a</sup> | 0.36 |
| Corn, field (gluten feed)         | 0.15 STMR (Finland, 2018b) ⨉ PF<sup>a</sup> | 0.15 |
| Corn, field (gluten meal)         | 0.06 STMR (Finland, 2018b) ⨉ PF<sup>a</sup> | 0.06 |
| Cotton, meal                      | 0.65 MRL ⨉ PF<sup>a</sup>   | 0.65 |
| Flaxseed/Linseed, meal            | 8.92 STMR (EFSA, 2011) ⨉ PF<sup>a</sup> | 8.92 |
| Peanut, meal                      | 1 MRL ⨉ PF<sup>a</sup>   | 1                     |
| Rape meal                         | 0.06 MRL ⨉ PF<sup>a</sup> | 0.06 |
| Soybean, meal                     | 0.65 MRL ⨉ PF<sup>a</sup> | 0.65 |
| Soybean, hulls                    | 6.50 MRL ⨉ PF<sup>a</sup> | 6.50 |
| Sunflower meal                    | 1 MRL ⨉ PF<sup>a</sup>   | 1                     |

**STMR**: supervised trials median residue; **HR**: highest residue; **PF**: processing factor; **NEU**: northern European Union; **SEU**: southern European Union; **MRL**: maximum residue level.

<sup>a</sup>: Default processing factors as inserted in the Animal model 2017 were used.

<sup>b</sup>: Wheat grain and straw data are extrapolated to oats and rye.

### Consumer risk assessment

| Commodity                  | Chronic risk assessment | Acute risk assessment<sup>b</sup> |
|----------------------------|-------------------------|-----------------------------------|
| **Input value (mg/kg)**    | **Comment<sup>a</sup>** | **Input value (mg/kg)**           | **Comment** |
| Barley                     | 0.330 STMR (SEU trials) | 0.870 HR (SEU trials)             |
| Oat                        | 0.720 STMR (Wheat, NEU trials) | 1.470 HR (Wheat, NEU trials) |
| Wheat                      | 0.720 STMR (NEU trials)  | 1.470 HR (NEU trials)             |
| Swine: Muscle/meat         | 0.010 STMR at 1 N level | 0.010 HR at 1 N level             |
| Swine: Fat tissue          | 0.010 STMR at 1 N level | 0.050 HR at 1 N level             |
| Swine: Liver               | 0.020 STMR at 1 N level | 0.050 HR at 1 N level             |
| Swine: Kidney              | 0.210 STMR at 1 N level | 0.550 HR at 1 N level             |
| Bovine: Muscle/meat        | 0.010 STMR at 1 N level | 0.030 HR at 1 N level             |
| Bovine: Fat tissue         | 0.050 STMR at 1 N level | 0.140 HR at 1 N level             |
| Bovine: Liver              | 0.060 STMR at 1 N level | 0.130 HR at 1 N level             |
| Bovine: Kidney             | 0.720 STMR at 1 N level | 1.440 HR at 1 N level             |
| Sheep: Muscle/meat         | 0.020 STMR at 1 N level | 0.030 HR at 1 N level             |
| Sheep: Fat tissue          | 0.060 STMR at 1 N level | 0.170 HR at 1 N level             |
| Sheep: Liver               | 0.060 STMR at 1 N level | 0.170 HR at 1 N level             |
| Sheep: Kidney              | 0.870 STMR at 1 N level | 1.810 HR at 1 N level             |
| Poultry: Muscle/meat       | 0.010 STMR at 1 N level | 0.010 HR at 1 N level             |
| Commodity                  | Chronic risk assessment | Acute risk assessment<sup>(b)</sup> |
|---------------------------|-------------------------|-------------------------------------|
|                           | Input value (mg/kg)     | Comment<sup>(a)</sup>              | Input value (mg/kg) | Comment |
| Poultry: Fat tissue       | 0.010                   | STMR at 1 N level                  | 0.010              | HR at 1 N level |
| Poultry: Liver            | 0.010                   | STMR at 1 N level                  | 0.020              | HR at 1 N level |
| Milk: Cattle              | 0.013                   | STMR at 1 N level                  | 0.013              | HR at 1 N level |
| Milk: Sheep               | 0.013                   | STMR at 1 N level                  | 0.013              | HR at 1 N level |
| Eggs: Chicken             | 0.010                   | STMR at 1 N level                  | 0.010              | HR at 1 N level |
| Swedes/rutabagas          | 0.350                   | EFSA (2011)                         |                    |          |
| Turnips                   | 0.350                   | EFSA (2018b)                        |                    |          |
| Broccoli                  | 0.300                   | EFSA (2011)                         |                    |          |
| Cauliflowers              | 0.290                   | EFSA (2011)                         |                    |          |
| Head cabbages             | 0.230                   | EFSA (2011)                         |                    |          |
| Leeks                     | 0.180                   | EFSA (2018b)                        |                    |          |
| Sugar beet roots          | 0.350                   | EFSA (2011)                         |                    |          |
| Linseeds                  | 4.460                   | EFSA (2011)                         |                    |          |
| Remaining commodities of plant and animal origin | MRL | Regulation (EU) 2018/1514<sup>(c)</sup> | |

STMR: supervised trials median residue; HR: highest residue; SEU: southern Europe.

(a): STMR and HR values for plants from Table B.1.2.1 and animals from Table B.2.2.1 and MRLs from EFSA (2011, 2018b).
(b): The acute risk assessment is only performed for crops under consideration.
(c): Commission Regulation (EU) 2018/1514 of 10 October 2018 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, acibenzolar-S-methyl, clopyralid, emamectin, fenhexamid, fenpyrazamine, fluazifop-P, isofetamid, Pasteuria nishizawae Pn1, talc E553B and tebuconazole in or on certain products. OJ L 256, 12.10.2018, p. 8–32.
### Appendix E – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|----------------------------------------|-----------------------|
| clopyralid           | 3,6-dichloropyridine-2-carboxylic acid or 3,6-dichloropicolinic acid  
                      | O=C(C1=NC(Cl)=CC=C1Cl)O  
                      | HUBANNPOLNYSAD-UHFFFAOYSA-N |
| clopyralid glycine conjugate | N-(3,6-dichloropyridine-2-carbonyl)glycine  
                               | O=C(O)CNC(C1=NC(Cl)=CC=C1Cl)=O  
                               | QONCEWHCVBAIBS-UHFFFAOYSA-N |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).
(c): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).