Modification of the existing maximum residue level for picloram in flowering brassica

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant, Dienstleistungszentrum Ländlicher Raum Rheinpfalz, submitted a request to the competent national authority in Germany to modify the existing maximum residue level (MRL) for the active substance picloram in flowering brassica. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for broccoli, cauliflowers and other flowering brassica. Adequate analytical methods for enforcement are available to control the residues of picloram and its conjugates in plant matrices under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of picloram according to the reported agricultural practices is unlikely to present a risk to consumer health. The reliable end points, appropriate for use in regulatory risk assessment, are presented.

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Keywords: picloram, flowering brassica, broccoli, cauliflower, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant, Dienstleistungszentrum Ländlicher Raum Rheinpfalz, submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance picloram in flowering brassica. 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 17 July 2019. To accommodate for the intended uses of picloram, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) 0.01 to 0.08 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS. On 3 August 2020, the EMS submitted the requested information.

Based on the conclusions derived by EFSA in the framework of the peer review of the pesticide risk assessment of the active substance picloram under Directive 91/414/EEC, 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 picloram was investigated in crops belonging to the groups of cereals/grass and pulses/oilseeds. A representative metabolism study in primary crops covering the group of leafy crops has not been submitted. Considering that the available metabolism study on rapeseed investigated residues in vegetative parts and that both flowering brassica and oilseed rape belong to the brassica family, EFSA concluded that the metabolic behaviour in primary crops is sufficiently addressed for the intended use in flowering brassica. The metabolism of picloram in rotational crops was assessed in the EFSA conclusion on the peer review. It was concluded that the metabolism of the active substance in rotational crops is similar to the pathway observed in primary crops.

Standard hydrolysis studies on the active substance under conditions representative for pasteurisation, boiling/cooking and sterilisation are not available and not triggered based on the intended uses.

Based on the metabolic pattern identified in metabolism studies, the toxicological significance of metabolites and the available information on the capabilities of enforcement analytical methods, the residue definitions for plant products were proposed as picloram for enforcement and as picloram, free and conjugated, expressed as picloram for risk assessment. These residue definitions are applicable to primary crops and rotational crops. The residue definition for enforcement is open, pending a decision on whether conjugated picloram will be included in the residue definition for monitoring and MRL setting. The residue definition for enforcement set in Regulation (EC) No 396/2005 refers to the active substance picloram only. EFSA has previously derived MRL proposals on the basis of residue trials analysed for the wider residue definition (sum of picloram and its conjugates, expressed as picloram). EFSA concluded that for the crops assessed in this application, metabolism of picloram in primary and rotational crops has been sufficiently addressed.

Analytical methods to control residues are currently only available for the wider residue definition for enforcement which includes the conjugated forms of the active substance. The methods enable quantification of residues at or above 0.01 mg/kg (LOQ) in the crops assessed. EFSA proposes to assess the current MRL application considering the existing enforcement residue definition as picloram only as set in Regulation (EC) No 396/2005. The residue definitions for enforcement and risk assessment will be reconsidered in the framework of the renewal of the approval of the active substance picloram.

In support of the present MRL application, three trials on cauliflower and five trials on broccoli are available whereas extrapolation to the whole subgroup flowering brassica (0241000) is recommended based on four trials on cauliflower and four trials on broccoli. EFSA considered that the proposed extrapolation based on one fewer trial on cauliflower and one further trial on broccoli is likely to be of low significance in the MRL calculation and derivation of risk assessment values, which may be accepted as a minor deviation. Overall, EFSA judged that the available residue trials are sufficient to derive an MRL proposal of 0.08 mg/kg for the whole subgroup flowering brassica, including broccoli, cauliflowers and other flowering brassica.

The occurrence of picloram residues in rotational crops was investigated in the framework of the EU pesticides peer review. The peer review concluded that residues above the LOQ may be expected in rotational crops. Rotational crop field studies reflecting the critical good agricultural practice (GAP) for picloram on primary crops are required. Studies on the magnitude of residues in rotational crop
have not been submitted in the present application. Based on the available information, EFSA could not exclude that the use of picloram according to the proposed GAP will result in significant residues in rotational crops. EFSA recommends that Member States when granting authorisations of picloram should take appropriate risk mitigation measures in order to avoid the presence of picloram residues in rotational crops.

Specific studies investigating the magnitude of picloram residues in processed commodities are not required, as significant residues are not expected in raw agricultural commodities and their contribution to the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI).

Residues of picloram in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.

The toxicological profile of picloram was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.3 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.3 mg/kg bw.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure did not exceed the ARfD for the commodities assessed in this application. The highest estimated long-term dietary intake was 2% of the ADI (NL toddler). The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is less than 0.01% of ADI.

EFSA concluded that the proposed use of picloram on flowering brassica will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

As the renewal of the approval of the active substance picloram and the review of the existing MRLs under Article 12 of Regulation 396/2005 are not yet finalised, the conclusions reported in this reasoned opinion are indicative and may need to be reconsidered in the light of the outcome of these reviews.

EFSA proposes to amend the existing MRL 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 |
|---------|----------------------|-------------------------|-------------------------|-----------------------|
| 0241000 | Flowering brassica   | 0.01*                   | 0.08                    | The submitted data are sufficient to derive an MRL proposal. The MRL proposal is derived from residue trials analysed for the sum of picloram and its conjugates, expressed as picloram, and is expected to overestimate the MRL required for picloram only. According to the guidelines, extrapolation to the whole subgroup flowering brassica (0241000) is recommended based on 4 trials on cauliflower and 4 trials on broccoli. The proposed extrapolation to the whole subgroup flowering brassica from 3 trials on cauliflower and 5 trials on broccoli may be considered a minor deviation. Risk for consumers unlikely |

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.
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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for picloram in flowering brassica. The detailed description of the intended uses of picloram, which is the basis for the current MRL application, is reported in Appendix A.

Picloram is the ISO common name for 4-amino-3,5,6-trichloropyridine-2-carboxylic acid (IUPAC). The chemical structure of the active substance is reported in Appendix E.

Picloram was evaluated in the framework of Directive 91/414/EEC\(^1\) with United Kingdom designated as rapporteur Member State (RMS) for the representative use as a spray treatment on winter or spring oilseed rape. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2009). Picloram was approved\(^2\) for the use as herbicide on 1 January 2009.

The process of renewal of the first approval has not yet been completed. The EU MRLs for picloram are established in Annex III of Regulation (EC) No 396/2005\(^3\). The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been performed. EFSA has issued two reasoned opinions on the modification of MRLs for picloram (EFSA, 2013, 2015). The proposals from these reasoned opinions have been considered in an MRL regulation.\(^4\)

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant, Dienstleistungszentrum Ländlicher Raum Rheinpfalz, submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance picloram in flowering brassica. 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 17 July 2019. To accommodate for the intended use of picloram, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) 0.01 to 0.08 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2019), the DAR and its addendum (United Kingdom, 2007, 2009) prepared under Council Directive 91/414/EEC, the Commission review report on picloram (European Commission, 2018), the conclusion on the peer review of the pesticide risk assessment of the active substance picloram (EFSA, 2009) and the assessment of the requested confirmatory information (EFSA, 2017), as well as the conclusions from previous EFSA opinions on picloram (EFSA, 2013, 2015). EFSA identified points which needed further clarification, which were requested from the EMS. On 3 August 2020, the EMS submitted the requested information.

For this application, the data requirements established in Regulation (EU) No 544/2011\(^5\) and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). 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\(^6\).

As the renewal of the approval of the active substance picloram and the review of the existing MRLs under Article 12 of Regulation 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion are indicative and may need to be reconsidered in the light of the outcome of these reviews.

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 (Germany, 2019) 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.

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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 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC to include clomethiazine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances. OJ L 172, 27.7.2008, p. 9–14.
3. 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.
4. For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/ep-pesticides-database/public/?event=pesticide.residue.selection&language=EN
5. Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
6. 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.
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 picloram in primary crops belonging to the groups of cereals/grass and pulses/oilseeds has been investigated in the framework of the EU pesticides peer review (EFSA, 2009). Both the oilseed rape and wheat studies demonstrate that picloram is not degraded but quickly forms conjugates in plant material. These conjugates released parent picloram upon hydrolytic extraction conditions.

A representative metabolism study in primary crops covering the group of leafy crops has not been submitted. However, the available metabolism study on rapeseed investigated residues in various parts of the plant at 0, 30, 50 and 84 days after treatment. Considering that both flowering brassica and oilseed rape belong to the brassica family, the EMS proposed that, metabolism in vegetative parts can be considered comparable (Germany, 2019). EFSA agreed with the EMS and concluded that the metabolic behaviour in primary crops is sufficiently addressed for the specific use in flowering brassica.

For future applications to set MRLs on leafy crops, the requirement for a representative metabolism study covering a third crop group to support the extension to leafy crops needs to be addressed.

1.1.2. **Nature of residues in rotational crops**

Picloram is proposed to be used on crops that can be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review, the maximum field DT90 value of picloram was 163 days (EFSA, 2009). The trigger value of 100 days was exceeded, and therefore, studies investigating the nature and magnitude of residues in rotational crops are required.

The metabolism of picloram in rotational crops was assessed in the DAR prepared under Directive 91/414/EEC and in the EFSA conclusion on the peer review (EFSA, 2009). It was concluded that the metabolism of the active substance in rotational crops is similar to the pathway observed in primary crops.

1.1.3. **Nature of residues in processed commodities**

Standard hydrolysis studies regarding the effects of processing on the nature of the active substance under conditions representative for pasteurisation, boiling/cooking and sterilisation were not submitted and are not required as the residue levels in raw agricultural commodities (RAC) are not expected to exceed the trigger value of 0.1 mg/kg and the total theoretical maximum daily intake (TMDI) amounts to less than 10% of the ADI (European Commission, 1997d).

1.1.4. **Methods of analysis in plants**

Analytical methods for the determination of picloram residues were assessed during the EU pesticides peer review (EFSA, 2009). Information to confirm that the monitoring analytical method quantifies the residues of picloram and its conjugates was assessed in the consultation on the pesticide risk assessment in light of confirmatory data (EFSA, 2017). The confirmatory data demonstrated that the method of analysis assessed in the framework of the EU pesticides peer review determines both free and conjugated picloram. The residue definition for enforcement and for MRL setting is open, pending on whether conjugated picloram will be included in the residue definition (see Section 1.1.6).

The available methods are validated for residues of picloram and its conjugates, which is not fully in line with the residue definition for enforcement currently set in Regulation (EC) No 396/2005 (picloram only). The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg for the total residue (sum of picloram and its conjugates) in crops belonging to the group of high water content (forage), high oil content (oilseed rape seed) and dry matrices (straw).

1.1.5. **Storage stability of residues in plants**

The storage stability of picloram in plants stored under frozen conditions was investigated in the DAR under Directive 91/414/EEC (EFSA, 2009). Residues of picloram were found to be stable at ≤ −20°C for up to 24 months in high water content (wheat forage), high oil content (rape seed), dry (wheat grain) commodities, and in wheat straw and oilseed rape hay samples.
It was demonstrated that in crops assessed in the framework of this application, residues were stable for at least 24 months when stored at \(-20^\circ C\).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the toxicological significance of metabolites and the available information on the capabilities of enforcement analytical methods, the following residue definitions were proposed in the framework of the EU pesticides peer review (EFSA, 2009):

- residue definition for risk assessment: picloram, free and conjugated, expressed as picloram
- residue definition for enforcement: open, pending a decision on whether conjugated picloram will be included in the residue definition for monitoring and MRL setting.

The same residue definitions are applicable to rotational crops.

The residue definition for enforcement set in Regulation (EC) No 396/2005 refers to the active substance picloram only.

EFSA has previously derived MRL proposals on the basis of residue trials analysed for the wider residue definition (sum of picloram and its conjugates, expressed as picloram) (EFSA, 2013, 2015). These MRL proposals have been implemented in the EU legislation. Considering the large margin of safety in the levels of residues to which consumers are exposed, EFSA proposes to assess the current MRL application and to derive an MRL proposal on the basis of the available residue trials, which were reportedly analysed for sum of picloram and its conjugates, expressed as picloram. The residue definition for enforcement and risk assessment will be reconsidered in the framework of the renewal of the approval of the active substance picloram.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials performed on broccoli (five trials) and cauliflower (three trials) in Germany in 2011 and 2012 (Germany, 2019). Trials were performed with a single foliar spray application (23.5 g a.s./ha) at growth stages BBCH 14–19 (growth stage not reported in two trials) and the intended PHI of 49 day (seven trials) or within 25% variation (56 days PHI, one trial), and are sufficiently compliant with the proposed GAP. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

The samples were subject to acetonitrile extraction after alkaline-hydrolysis step and analysed for the sum of picloram and its conjugates, expressed as picloram. According to the assessment of the EMS, the methods used were sufficiently validated. The MRL calculation is expected to overestimate the MRL required for picloram only. However, since the total residues are low, this discrepancy is considered of low relevance.

According to the guidelines, extrapolation to the whole subgroup flowering brassica (0241000) is recommended based on four trials on cauliflower and four trials on broccoli (European Commission, 2017), whereas only three trials on cauliflower and five trials on broccoli are available in support of the present MRL application. EFSA requested further clarification and the EMS informed EFSA that no further trials have been submitted by the applicant. On 3 August 2020, the EMS provided argumentation that due to its higher surface area, broccoli generally tends to show higher residues than cauliflower following a pesticide spray application, and thus, the realistic worst-case residue to be expected in flowering brassica is covered by the available trials. The EMS considered the deviation from the requirements of the guidance document negligible and the residue database sufficient and appropriate to derive an MRL for the whole group of flowering brassica.

The residue values are low and reasonably homogeneous in the available trials, although the highest residue value in broccoli is identified as an outlier according to Dixon’s Q test. EFSA considered that the proposed extrapolation based on one fewer trial on cauliflower and one further trial on broccoli is likely to be of low significance in the MRL calculation and derivation of risk assessment values (supervised trials median residue (STMR) and highest residue (HR)), which may be accepted as a minor deviation. Overall, EFSA judged that the number and quality of the trials are sufficient to derive an MRL proposal of 0.08 mg/kg for the whole subgroup flowering brassica, including broccoli, cauliflowers and other flowering brassica.
1.2.2. Magnitude of residues in rotational crops

The possible transfer of picloram residues to crops that are grown in crop rotation has been assessed in EU pesticides peer review (EFSA, 2009). The peer review concluded that residues above the LOQ may be expected in rotational crops and proposed MRLs for several rotational crops based on the confined rotational crop metabolism study. EFSA considered that in order to assess the magnitude of picloram residues in rotational crops, rotational crop field studies reflecting the critical GAP for picloram on a primary annual crop are required.

Studies on the magnitude of residues in rotational crop have not been submitted in the present application. In order to properly assess the magnitude of picloram residues in rotational crops, a rotational crop field study according to EU guidelines and reflecting the critical GAP for picloram on primary crops is required. Based on the available information, EFSA could not exclude that the use of picloram according to the proposed GAP will result in significant residues in rotational crops. EFSA recommends that Member States when granting authorisations of picloram should take appropriate risk mitigation measures in order to avoid the presence of picloram residues in rotational crops.

1.2.3. Magnitude of residues in processed commodities

Specific studies to assess the magnitude of picloram residues during the processing are not required as the residue levels in raw agricultural commodities (RAC) are not expected to exceed the trigger value of 0.1 mg/kg and the total theoretical maximum daily intake (TMDI) amounts to less than 10% of the ADI (European Commission, 1997d).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for the commodities under evaluation. The MRL proposal is derived from residue trials analysed for the sum of picloram and its conjugates, expressed as picloram, and is expected to overestimate the MRL required for picloram only. 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

Not relevant as flowering brassica are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 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 picloram used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2018).

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities assessed in this application in accordance with the internationally agreed methodology. The calculations were based on the highest residue (HR) derived from supervised field trials and the complete list of input values can be found in Appendix D.1.

The short-term exposure did not exceed the ARfD for the commodities assessed in this application (see Appendix B.3). The highest estimated short-term intake was 1.0% of ARfD for cauliflowers and 0.7% of ARfD for broccoli.

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 derived in previous MRL applications were selected as input values (EFSA, 2015). The complete list of input values is presented in Appendix D.1.
The highest estimated long-term dietary intake was 2% of the ADI (NL toddler). The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is each less than 0.01% of ADI and is presented in more detail in Appendix B.3.

EFSA concluded that the long-term intake of residues of picloram resulting from the existing and the intended uses is unlikely to present a risk to consumer health. The consumer risk assessment shall be regarded as indicative. A more realistic consumer risk assessment will be performed in the framework of the Article 12 MRL review, when additional information on authorised uses of picloram will be available to EFSA.

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 an MRL proposal for the whole subgroup flowering brassica, including broccoli, cauliflowers and other flowering brassica. The MRL proposal is derived from residue trials analysed for the sum of picloram and its conjugates, expressed as picloram, and is expected to overestimate the MRL required for picloram only.

EFSA concluded that the proposed use of picloram on flowering brassica will not result in consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

EFSA could not exclude that the use of picloram according to the proposed GAP will result in significant residues in rotational crops. EFSA recommends that Member States when granting authorisations of picloram should take appropriate risk mitigation measures in order to avoid the presence of picloram residues in rotational crops.

As the renewal of the approval of the active substance picloram and the review of the existing MRLs under Article 12 of Regulation 396/2005 are not yet finalised, the conclusions reported in this reasoned opinion are indicative and may need to be reconsidered in the light of the outcome of these reviews.

The MRL recommendations are summarised in Appendix B.4.

References

EFSA (European Food Safety Authority), 2009. Conclusion on the peer review of the pesticide risk assessment of the active substance picloram. EFSA Journal 2009;7(12):1390, 78 pp. https://doi.org/10.2903/j.efsajournal.2009.1390

EFSA (European Food Safety Authority), 2013. Reasoned opinion on the modification of the existing MRLs for picloram in rape seed and mustard seed. EFSA Journal 2013;11(10):3439, 27 pp. https://doi.org/10.2903/j.efsa.2013.3439

EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the existing maximum residue level (MRL) for picloram in borage and corn gromwell seeds. EFSA Journal 2015;13(3):4062, 20 pp. https://doi.org/10.2903/j.efsa.2015.4062

EFSA (European Food Safety Authority), 2017. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for picloram in light of confirmatory data. EFSA supporting publication 2017;EN-1258, 12 pp. https://doi.org/10.2903/sp.efsa.2017.en-1258

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1. EFSA supporting publication 2019;16(3):EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.en-1605

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 2, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.
European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.
European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.
European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.
European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.
European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.
European Commission, 2018. Final Review report for the active substance picloram Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 14 March 2008 in view of the inclusion of picloram in Annex I of Directive 91/414/EEC. SANCO/835/08 – final rev. 2, 26 January 2018.
FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper 225, 298 pp.
Germany, 2019. Evaluation report on the modification of MRLs for picloram in flowering brassica June 2019, revised in December 2019, 21 pp.
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org
OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 4 September 2013.
United Kingdom, 2007. Draft Assessment Report by the rapporteur Member State the United Kingdom for the existing active substance Picloram of the third stage Part B of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC, October 2007. Available online: www.efsa.europa.eu
United Kingdom, 2009. Final addendum to the draft assessment report on picloram compiled by EFSA, October 2009. Available online: www.efsa.europa.eu

Abbreviations

- a.s. active substance
- ADI acceptable daily intake
- ARD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- bw body weight
- CAS Chemical Abstract Service
- CF conversion factor for enforcement to risk assessment residue definition
- CS capsule suspension
- CV coefficient of variation (relative standard deviation)
- DAR draft assessment report
- DAT days after treatment
- DM dry matter
- DT$_90$ period required for 90% dissipation (define method of estimation)
- EC emulsiﬁable concentrate
- EMS evaluating Member State
- FAO Food and Agriculture Organization of the United Nations
- GAP Good Agricultural Practice
- GC gas chromatography
- GC-MS gas chromatography with mass spectrometry
- GC-MS/MS gas chromatography with tandem mass spectrometry
- HR highest residue
- IEDI international estimated daily intake
- IESTI international estimated short-term intake
- ISO International Organisation for Standardisation
- IUPAC International Union of Pure and Applied Chemistry
- LC liquid chromatography
Modification of the existing MRL for picloram in flowering brassica

LOQ  limit of quantification
MRL  maximum residue level
MS   Member States
MS/MS tandem mass spectrometry detector
MW   molecular weight
NEU  northern Europe
OECD Organisation for Economic Co-operation and Development
PBI  plant back interval
PHI  preharvest interval
PRIMO (EFSA) Pesticide Residues Intake Model
RA   risk assessment
RAC  raw agricultural commodity
RD   residue definition
RMS  rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC   suspension concentrate
SEU  southern Europe
SL   soluble concentrate
SP   water-soluble powder
STMR supervised trials median residue
TAR  total applied radioactivity
TMDI theoretical maximum daily intake
UV   ultraviolet (detector)
WHO  World Health Organization
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I (a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|----------------------|--------------------------|--------------|-----------------------------------|-------------|-----------------|-------------------------------|----------------|---------|
| Broccoli             | NEU F                     | Annual dicotyl. weeds | CS 67.0 Foliar treatment – broadcast spraying | After planting of crop | 1 n.a. | 5-10 | 200-400 | 23.5 | g a.s./ha | 49 |
| Cauliflower          | NEU F                     | Annual dicotyl. weeds | CS 67.0 Foliar treatment – broadcast spraying | After planting of crop | 1 n.a. | 5-10 | 200-400 | 23.5 | g a.s./ha | 49 |
| Other flowering Brassica | NEU F                  | Annual dicotyl. weeds | CS 67.0 Foliar treatment – broadcast spraying | After planting of crop | 1 n.a. | 5-10 | 200-400 | 23.5 | g a.s./ha | 49 |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SL: capsule suspension; 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 |
|----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                      | –           | –       | –              | –              | –              |
| Root crops                       | –           | –       | –              | –              | –              |
| Leafy crops                      | –           | –       | –              | –              | –              |
| Cereals/grass                    | Wheat       | Foliar, 1 × 26 & 53 g a.s./ha, BBCH 13-22 | 0 (forage), 28 (forage), 104 (grain, chaff and straw) | Label position: 2- and 6-14C pyridine ring (EFSA, 2009) |
| Pulses/oilseeds                  | Rapeseed    | Foliar, 1 × 40 g a.s./ha, BBCH 33 | 0 (whole plant), 30 (leaves, stems, flower buds), 50 (leaves, stems, pods) and 84 (stem, chaff and seeds) | Label position: 2- and 6-14C pyridine ring (EFSA, 2009) |

| Miscellaneous                     | –           | –       | –              | –              | –              |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Turnip      | 583 g a.s./ha to bare soil | 30, 120, 365 | Label position: 2- and 6-14C pyridine ring (EFSA, 2009) |
| Leafy crops                         | Mustard greens | 583 g a.s./ha to bare soil | 30, 120, 365 | Label position: 2- and 6-14C pyridine ring (EFSA, 2009) |
| Cereal (small grain)                | Wheat, maize | 583 g a.s./ha to bare soil | 30, 120, 365 | Label position: 2- and 6-14C pyridine ring (EFSA, 2009) |
| Other                               | –           | –       | –              | –          | –              |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Not triggered |          | EFSA (2009)    |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Not triggered |          | EFSA (2009)    |
| Sterilisation (20 min, 120°C, pH 6)      | Not triggered |          | EFSA (2009)    |
| Other processing conditions              | –          | –       | –              |
Can a general residue definition be proposed for primary crops?

| Inconclusive | Primary crop metabolism studies are available for only two crop groups (cereals/grass and pulses/oilseeds) |
|--------------|--------------------------------------------------------------------------------------------------|

Rotational crop and primary crop metabolism similar?

| Yes | EFSA (2009) |

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

| Not triggered | EFSA (2009) |

Plant residue definition for monitoring (RD-Mo)

Cereals/grass, pulses/oilseeds:
Picloram (Regulation (EU) No 396/2005)
Open (pending whether conjugated picloram will have to be considered in the residue definition for monitoring and MRL setting) (EFSA, 2009)

Plant residue definition for risk assessment (RD-RA)

Cereals/grass, pulses/oilseeds: Picloram, free and conjugated, expressed as picloram (EFSA, 2009)

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

| GC–MS | LOQ 1.0 mg/kg picloram, grass |
|-------|-------------------------------|
| LOQ 0.01 mg/kg picloram, oilseed rape (open) | (EFSA, 2009) |

GC–MS, LC–MS/MS, LOQ 0.01 mg/kg
Analytical method GRM 00.19 is able to quantify picloram residues (free and conjugated) as picloram in matrices with high water content (forage), high oil content (oilseed rape seed) and dry matrices (straw) (EFSA, 2017)

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; LOQ: limit of quantification; GC-MS: gas chromatography with mass spectrometry; LC-MS/MS: liquid chromatography with tandem mass spectrometry.

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

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period (Month) | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|--------------------------|-------------------|---------------|
| High water content                | Wheat forage | ≤ -20     | 24     | Months                  | Picloram          | EFSA (2009)   |
| High oil content                  | Rape seed | ≤ -20     | 24     | Months                  | Picloram          | EFSA (2009)   |
| High protein content              | –        | –         | –      | –                       | –                 | –             |
| Dry/high starch                    | Wheat grain | ≤ -20     | 24     | Months                  | Picloram          | EFSA (2009)   |
| High acid content                 | –        | –         | –      | –                       | –                 | –             |
| Processed products                | –        | –         | –      | –                       | –                 | –             |
| Others                            | Wheat straw | ≤ -20     | 24     | Months                  | Picloram          | EFSA (2009)   |
|                                  | Oilseed rape hay | ≤ -20     | 24     | Months                  | Picloram          | EFSA (2009)   |
### B.1.2. Magnitude of residues in plants

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

| 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) |
|-----------|-----------------|---------------------------------------------------------------|----------------|------------------------|-------------|---------------|-------|
| Broccoli  | NEU             | Mo: –, RA: < 0.010, < 0.010, 0.010, 0.020, 0.050             | Residue trials on broccoli and cauliflower compliant with GAP. Samples were analysed for the sum of picloram and its conjugates, expressed as picloram, and therefore, the calculation is expected to overestimate the MRL proposal required for residues of picloram only. According to the guidelines, extrapolation to the whole subgroup flowering brassica (0241000) is recommended based on 4 trials on cauliflower and 4 trials on broccoli. The proposed extrapolation to the whole subgroup flowering brassica from 3 trials on cauliflower and 5 trials on broccoli may be considered a minor deviation. | 0.08        | 0.05         | 0.01          | –     |
| Cauliflowers | NEU        | Mo: –, RA: 0.010, 0.010, 0.020                                 |                |                        |             |               |       |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.

(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.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Yes |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Inconclusive |

EFSA (2009)
Inconclusive Field trials on rotational crop studies are required (EFSA, 2009)

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application and are not required.

B.2. Residues in livestock

Not relevant as the commodities under consideration are not used for feed purposes.

B.3. Consumer risk assessment

ARfD

| ARfD | 0.3 mg/kg bw (European Commission, 2018) |
| Highest IESTI, according to EFSA PRIMo | Cauliflowers: 1.0% of ARfD  
Broccoli: 0.7% of ARfD |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in raw agricultural commodities.  
Calculations performed with PRIMo revision 3.1 |
| ADI | 0.3 mg/kg bw per day (European Commission, 2018) |
| Highest IEDI, according to EFSA PRIMo | 2% ADI (NL toddler)  
Contribution of crops assessed:  
Broccoli: < 0.01% of ADI  
Cauliflowers: < 0.01% of ADI |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities assessed in this application and in previous MRL applications. The existing EU MRLs were selected as input values for the remaining commodities covered by the MRL regulation  
Calculations performed with PRIMo revision 3.1 |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: pesticide residue intake model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level.
### B.4. Recommended MRLs

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|-----------|------------------------|-------------------------|------------------------|
| 0241000 | Flowering brassica | 0.01* | 0.08 | The submitted data are sufficient to derive an MRL proposal. The MRL proposal is derived from residue trials analysed for the sum of picloram and its conjugates, expressed as picloram and is expected to overestimate the MRL required for picloram only. According to the guidelines, extrapolation to the whole subgroup flowering brassica (0241000) is recommended based on 4 trials on cauliflower and 4 trials on broccoli. The proposed extrapolation to the whole subgroup flowering brassica from 3 trials on cauliflower and 5 trials on broccoli may be considered a minor deviation. Risk for consumers unlikely |

**Enforcement residue definition:** Picloram

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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.
### Appendix C – Pesticide Residue Intake Model (PRiMo)

#### Picloram

| Source of MRL | COM | Source of ADI | COM | Year of evaluation | EFSA PRiMo revision 3.1; 2019/03/19 |
|---------------|-----|---------------|-----|-------------------|-----------------------------------|
| Source: ADI   |     | Source: MRL   |     |                   |                                   |
|               |     |               |     |                   |                                   |

#### Environmental

#### Normal mode

#### Details – chronic risk assessment

#### Input values

#### Supplementary results – chronic risk assessment

#### Details – acute risk assessment

#### Toxicological reference values

| LOQ (mg/kg) range from: | ADI (mg/kg bw per day) | ARfD (mg/kg bw): |
|------------------------|------------------------|-----------------|
| 0.05                   |                        |                 |
| 0.3                    |                        |                 |

#### Toxocological reference values

| Details – acute risk assessment |
|--------------------------------|
| Source of ADI                  |
|                                 |
|                                 |

#### Picloram

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

#### No of diets exceeding the ADI

| Commodity/Group of commodities  | MS Diet NL toddler | MS Diet UK infant | MS Diet FR child 2 3 yr | MS Diet NL child | MS Diet FR toddler 2 3 yr | MS Diet DK child | MS Diet DE child | MS Diet ES child | MS Diet RO general | MS Diet GEMS/Food G15 | MS Diet GEMS/Food G06 | MS Diet GEMS/Food G07 | MS Diet GEMS/Food G08 | MS Diet SE general | MS Diet DE general | MS Diet NL general | MS Diet ES adult | MS Diet IE adult | MS Diet FR infant | MS Diet IT adult | MS Diet IK adult | MS Diet LT adult | MS Diet UK adult | MS Diet UA vegetable | MS Diet PI 3 yr | MS Diet PI 4 yr | MS Diet PI 5 yr | MS Diet PI 6 yr | MS Diet PI 7 yr | MS Diet PI 8 yr | MS Diet PI 9 yr | MS Diet PI adult | MS Diet PL general | MS Diet OAT | MS Diet Oat | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS Diet Potato | MS DI... |
The acute risk assessment is based on the ARfD.

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

### Unprocessed commodities

| Highest % of ARfD/ADI | Commodities          | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|----------------------|--------------------------|---------------------|
| 6%                    | Bovine: Kidney       | 5/5                      | 19                  |
| 2%                    | Swine: Kidney        | 5/5                      | 6.3                 |
| 2%                    | Milk: Cattle         | 0.050.05                 | 6.2                 |
| 1%                    | Bovine: Edible offals (other) | 0.50/0.5 | 3.6                 |
| 1%                    | Poultry: Muscle/meat | 0.20/0.2                 | 3.4                 |
| 1.0%                  | Cauliflowers         | 0.08/0.05                | 2.9                 |
| 1.0%                  | Wheat               | 0.20/0.2                 | 2.9                 |
| 0.8%                  | Swine: Muscle/meat  | 0.20/0.2                 | 2.4                 |
| 0.7%                  | Broccoli            | 0.08/0.05                | 2.1                 |
| 0.5%                  | Potatoes            | 0.01/0.01                | 1.5                 |
| 0.5%                  | Melons              | 0.01/0.01                | 1.5                 |
| 0.5%                  | Swine: Edible offals (other) | 0.50/0.5 | 1.5                 |
| 0.5%                  | Bovine: Muscle/meat | 0.20/0.2                 | 1.4                 |
| 0.5%                  | Pears               | 0.01/0.01                | 1.4                 |
| 0.5%                  | Other farmed animals: | 0.20/0.2                | 1.4                 |

### Processed commodities

| Highest % of ARfD/ADI | Processed commodities | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-----------------------|--------------------------|---------------------|
| 2%                    | Malted               | 0.2/0.5                  | 4.7                 |
| 1%                    | Broccoli/boiled     | 0.08/0.05                | 3.9                 |
| 1%                    | Cauliflowers/boiled | 0.08/0.05                | 3.5                 |
| 0.8%                  | Wheat/milling (floor) | 0.2/0.2                | 2.4                 |
| 0.4%                  | Wheat/milling (wholemeal) | 0.20/0.2 | 1.1                 |
| 0.4%                  | Sugar beets (root)/sugar | 0.01/0.12             | 1.1                 |
| 0.3%                  | Potatoes/fried      | 0.01/0.01                | 0.93                |
| 0.3%                  | Pumpkins/boiled     | 0.01/0.01                | 0.89                |
| 0.3%                  | Willow/boiled       | 0.01/0.01                | 0.89                |
| 0.2%                  | Barley/cocked       | 0.2/0.2                  | 0.73                |
| 0.2%                  | Escaroles/broad-leaved end | 0.01/0.01 | 0.66                |
| 0.2%                  | Oat/milling (flakes) | 0.2/0.2                  | 0.60                |
| 0.2%                  | Potatoes/dried (flakes) | 0.01/0.05             | 0.59                |
| 0.2%                  | Leeks/boiled        | 0.01/0.01                | 0.57                |

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of Picloram is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               |
| Broccoli                         | 0.01 STMR               | 0.05 HR               |
| Cauliflowers                     | 0.01 STMR               | 0.05 HR               |
| Other flowering brassica         | 0.01 STMR (EFSA, 2015)  | Acute risk assessment |
| Oilseeds group                   | MRL See Reg. (EU) No 2016/1 | Undertaken only with regard to the crops under assessment |

Risk assessment residue definition: picloram, free and conjugated, expressed as picloram.

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
### Appendix E – Used compound codes

| Code/trivial name\(^{(a)}\) | IUPAC name/SMILES notation/InChiKey\(^{(b)}\) | Structural formula\(^{(c)}\) |
|-----------------------------|-----------------------------------------------|-----------------------------|
| Picloram                    | 4-amino-3,5,6-trichloropyridine-2-carboxylic acid Nc1c(O)c(nc(Cl)c1Cl)c(=O)O | ![Structural formula](image) NQQVFXUMIDALNH-UHFFFAOYSA-N |

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

\(^{(a)}\): The name in bold is the name used in the reasoned opinion.

\(^{(b)}\): ACD/Name 2018.2.2 ACD/Labs 2018 Release (File version N50E41, Build 103230, 21 July 2018).

\(^{(c)}\): ACD/ChemSketch 2018.2.2 ACD/Labs 2018 Release (File version C60H41, Build 106041, 7 December 2018).