REASONED OPINION

Reasoned opinion on the modification of the existing maximum residue level (MRL) for picloram in borage and corn gromwell seeds[1]

European Food Safety Authority[2]

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from Technology Crops Limited to modify the existing maximum residue level (MRL) for the active substance picloram in borage and corn gromwell seeds. In order to accommodate for the intended use of picloram, the United Kingdom proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.01 mg/kg to the proposed MRL of 0.03 mg/kg. The United Kingdom 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 EFSA. According to EFSA the data on rape seed are sufficient to derive a MRL proposal of 0.03 mg/kg extrapolated to borage and corn gromwell seeds. Although the rape seed samples were analysed for picloram and its conjugates, expressed as picloram, EFSA is of the opinion that the trials can be used to derive a MRL according to the current enforcement residue definition limited to picloram. This MRL proposal might slightly overestimate the actual magnitude of picloram residues. However, since the total residues in rape seed are very low, this discrepancy is considered of low relevance. Although the chronic and acute dietary intake for borage and corn gromwell seeds could not be calculated since there is no reported consumption data for these crops, EFSA concludes that the intended use of picloram on borage and corn gromwell seeds will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

KEY WORDS

picloram, borage, corn gromwell seeds, MRL application, Regulation (EC) No 396/2005, picolinic acid, herbicides

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from Technology Crops Limited to modify the existing maximum residue level (MRL) for the active substance picloram in borage and corn gromwell seeds. In order to accommodate for the intended use of picloram, the United Kingdom proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.01 mg/kg to the proposed MRL of 0.03 mg/kg. The United Kingdom 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 EFSA on 31 October 2014.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) (and its addenda) prepared under Council Directive 91/414/EEC, the Commission Review Report on picloram, the conclusion on the peer review of the pesticide risk assessment of the active substance picloram, as well as the conclusions from a previous EFSA opinion on picloram.

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

The metabolism of picloram in primary crops was investigated in the pulses/oilseeds (rape seed) and cereal crop groups (wheat). From these studies the peer review concluded to establish the residue definition for risk assessment as picloram, free and conjugated expressed as picloram. For enforcement purposes, EFSA recommends to maintain the existing residue definition which currently includes the parent compound only. The proposed residue definition for enforcement and risk assessment will be reconsidered in the framework of the MRLs review under Article 12 of Regulation (EC) No 396/2005. Validated analytical methods for the determination of picloram and its conjugates in high oil content commodities are available. For the use on borage and corn gromwell seeds, EFSA concludes that the metabolism of picloram in primary crops is sufficiently addressed.

EFSA concludes that the submitted supervised residue trials on rape seed are sufficient to derive a MRL proposal of 0.03 mg/kg extrapolated to borage and corn gromwell seeds. Although the rape seed samples were analysed for picloram and its conjugates, expressed as picloram, EFSA is of the opinion that the trials can be used to derive a MRL according to the current enforcement residue definition limited to picloram. This MRL proposal might slightly overestimate the actual magnitude of picloram residues. However, since the total residues in rape seed are very low, this discrepancy is considered of low relevance.

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

The metabolism of picloram in rotational crops is similar to the metabolic pathway depicted in primary crops. 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. Nevertheless, EFSA considered that in order to properly assess the magnitude of picloram residues in rotational crops, the applicant should submit rotational crop field studies according to the EU guidelines and reflecting the critical GAP for picloram on a primary annual crop. Meanwhile, Member States when granting authorisations of picloram should take the appropriate risk mitigation measures in order to avoid the presence of picloram residues in rotational crops.

Residues of picloram in commodities of animal origin were not assessed in the framework of this application since borage and corn gromwell seeds are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). Since consumption data were not reported for borage and corn gromwell seeds, the

chronic and acute dietary intake calculations were conducted using the overall consumption data reported for the whole oilseed crop group and using respectively the median (STMR) and highest (HR) residue values derived from the residue trials on oilseed rape. Based on this conservative approach, no long-term and acute consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The highest calculated long-term intake accounted for 1.3 % of the ADI (WHO Cluster B) and the maximum acute exposure was estimated to be 0.04 % of the ARfD.

EFSA concludes that the intended use of picloram on borage and corn gromwell seeds will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. Thus EFSA proposes to amend the existing MRL as reported in the summary table.

SUMMARY TABLE

Code[(a)]	**Commodity**	**Existing EU MRL** (mg/kg)	**Proposed EU MRL** (mg/kg)	**Comment/Justification**
Enforcement residue definition: picloram				
0401120	Borage	0.01*	0.03	Extrapolation from Northern Europe (NEU) trials on rape seed where samples were analysed for the sum of picloram and its conjugates. Although samples were not analysed for picloram only, the MRL is considered acceptable.

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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BACKGROUND

Regulation (EC) No 396/2005[3] establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC,[4] repealed by Regulation (EC) No 1107/2009,[5] shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

The United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from the company Technology Crops Limited[6] to modify the existing MRL for the active substance picloram in borage and corn gromwell seeds. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 31 October 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00787 and the following subject:

Modification of MRLs for picloram in borage and corn gromwell seeds

The United Kingdom proposed to raise the existing MRL of picloram in borage and corn gromwell seeds from the limit of quantification of 0.01* mg/kg to 0.03 mg/kg.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the deadline for providing the reasoned opinion is 31 January 2015.

[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, 16.03.2005, p. 1–16.

[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

[5] 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.

[6] Technology Crops Limited, Gowers Farm, Tumblers Green, Stisted, Nr Braintree, CM77 8AZ, United Kingdom.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Picloram is the ISO common name for 4-amino-3,5,6-trichloropyridine-2-carboxylic acid (IUPAC). The chemical structure of the compound is reported below.

Compound structure

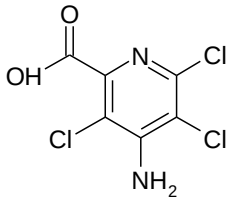

Figure 1: Structure of picloram. Molecular weight: 241.46 g/mol

Picloram is a systemic herbicide belonging to picolinic acid herbicides. It is absorbed by leaves and roots, translocated both acropetally and basipetally and accumulates in meristematic tissues of plants. Picloram has an 'auxinic' mode of action. It is used to control a narrow spectrum of broad-leaved weed species in agricultural crops.

Picloram was evaluated in the framework of Council Directive 91/414/EEC with the United Kingdom designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 69/2008/EC[7] which entered into force on 1 January 2009 for use as herbicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011[8] picloram is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The representative uses evaluated in the peer review were foliar application on winter and spring oilseed rape. The Draft Assessment Report (DAR) of picloram has been peer reviewed by EFSA (EFSA, 2009).

The EU MRLs for picloram are established in Annex IIIA of Regulation (EC) No 396/2005. A MRL proposal for rape seed and mustard seed was evaluated by EFSA (EFSA, 2013). The existing EU MRL for picloram on borage and corn gromwell seeds is set at the LOQ of 0.01* mg/kg. No CXLs are established for picloram.

The details of the intended GAP for picloram are given in Appendix A.

[7] Commission Directive 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances. OJ L 172, 2.7.2008, p. 9–14.

[8] Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.06.2011, p. 1–186.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (United Kingdom, 2014), the Draft Assessment Report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2007, 2009a,b), the Commission Review Report on picloram (EC, 2010c), the conclusion on the peer review of the pesticide risk assessment of the active substance picloram (EFSA, 2009) and the conclusions from a previous EFSA opinion on picloram (EFSA, 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[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

The GC-MS analytical method submitted in the previous EFSA reasoned opinion was demonstrated to be sufficiently validated for the determination of picloram and its conjugates at the limit of quantification (LOQ) of 0.01 mg/kg in high oil content commodities (United Kingdom, 2007, 2013; EFSA, 2013).

Since the commodities under consideration belong to the group of high oil content commodities, EFSA concludes that a sufficiently validated analytical method for borage and corn gromwell seeds is available to enforce residues of picloram and its conjugates.

1.2. Methods for enforcement of residues in food of animal origin

The analytical method for the determination of picloram residues in commodities of animal origin was evaluated in the DAR and during the peer review under Directive 91/414/EEC (United Kingdom, 2007; EFSA, 2009, 2013). Residues of parent picloram in foodstuffs of animal origin can be determined using GC-MS with a LOQ of 0.01 mg/kg in all relevant animal products.

EFSA concludes that a sufficiently validated analytical method for enforcing the proposed MRLs for picloram in food of animal origin is available.

2. Mammalian toxicology

The toxicological profile of the active substance picloram was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2009). The data were sufficient to derive toxicological reference values for picloram which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
picloram					
ADI	EFSA	2009	0.3 mg/kg bw per day	Rabbit developmental supported by 1-year dog	100
ARfD	EFSA	2009	0.3 mg/kg bw	Rabbit developmental supported by 1-year dog	100

[9] 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, 11.06.2011, p. 127–175.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of picloram in primary crops was evaluated by the RMS (United Kingdom, 2007, 2009a) and reviewed by EFSA (EFSA, 2009) in the framework of the peer review under Directive 91/414/EEC. The overview of the metabolism study designs is presented in the table below.

Table 3-1: Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling[(a)] Days after treatment (DAT)	Comments
Pulses/ oilseeds	Rape seed	Foliar, 1x 40 g/ha, BBCH 33	0, 30, 50 and 84 (stem, chaff and seeds)	
Cereals	Wheat	Foliar, 1x 26 & 53 g/ha, BBCH 13–22.	104 DAT (grain, chaff and straw)	

(a): DAT: Days after treatment.

The metabolism of picloram was considered sufficiently investigated in the pulses/oilseeds (rape seed) and cereals groups (wheat). The peer review proposed to set the residue definition for risk assessment as picloram, free and conjugated expressed as picloram. No enforcement residue definition was agreed since there was no data available on whether the analytical method proposed for monitoring fully or partially analysed any conjugated picloram.

The confirmatory data submitted to the EMS submitted in the previous reasoned opinion on the modification of the existing MRLs for picloram in rape seed and mustard seed confirmed that the enforcement method of analysis, which was also used for analysing the residue trials on rape seed, determines both free and conjugated picloram. However, considering that negligible residue levels were observed in the seeds (0.006 mg/kg) from the metabolism data and also the large margin of safety the consumers are exposed to, 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 proposed enforcement and risk assessment residue definitions should be revisited in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005.

3.1.1.2. Magnitude of residues

In support to the intended northern uses on borage and corn gromwell seeds, eight residue trials carried out on rape seed were provided. These trials have already been submitted in the framework of the previous EFSA Reasoned opinion on the modification of the existing MRLs in rape seed and mustard seed (EFSA, 2013). It is noted that the residue samples were analysed for the sum of picloram and its conjugates, expressed as picloram. The MRL proposal is therefore expected to slightly overestimate the actual residues of picloram only but since the total residues are very low, this discrepancy is of minor relevance and will have a negligible impact on the outcome of the consumer exposure assessment. A conversion factor for risk assessment is considered as not necessary.

According to the EU guidance document (EC, 2011) an extrapolation from rape seed to borage and corn gromwell seeds is acceptable and the number of trials is sufficient to derive a MRL proposal reflecting the Northern Europe (NEU) outdoor GAP for these crops.

The results of the residue trials, the related risk assessment input values (highest residue, median residue, conversion factor) and the MRL proposal are summarised in Table 3-2.

The storage stability of picloram in primary crops was investigated in the DAR under Directive 91/414/EEC (United Kingdom, 2007). Residues of picloram were found to be stable at ≤ −20 °C for up to 36 months in high water content (wheat forage), dry (grain) commodities and straw samples and up to 24 months in high oil content (rape seed). As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical method used to analyse the supervised residue trial samples has been sufficiently validated and was proven to be fit for the purpose (EFSA, 2013).

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.03 mg/kg for the intended use on borage and corn gromwell seeds in NEU.

Table 3-2: Overview of the available residues trials data

Crop	**Region/ Indoor (a)**	**Residue levels (mg/kg) observed in the supervised residue trials (b)**	**Recommendations/comments (c)**	**MRL** proposals (mg/kg)	**HR** (mg/kg) (d)	**STMR** (mg/kg) (e)
Rape seed	NEU Outdoor	7x <0.01, 0.02[(f)]	MRL proposal based on the HR value of 0.02 mg/kg; Extrapolation to borage and corn gromwell seeds	0.03	0.02	0.01

(a): NEU (Northern Europe), SEU (Southern Europe), EU (i.e. indoor use) or Import (country code) (EC, 2011).
(b): Individual residue levels considered for MRL calculation are reported in ascending order as following: 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.10, 0.15, 0.17
(c): Any information/comment supporting the decision and OECD MRL calculation (e.g. MRL_{OECD}: 0.82/0.9; unrounded/rounded values)
(d) STMR: Median value of the individual trial results according to residue definition for risk assessment.
(e): HR: Highest value of the individual trial results according to the residue definition for risk assessment.
(f): The trials were analysed for the extended residue definition (i.e. the sum of picloram and its conjugates, expressed as picloram).
*: Indicates that the MRL is proposed at the Limit of Quantification (LOQ).

3.1.1.3. Effect of industrial processing and/or household preparation

Specific studies to assess the magnitude of picloram residues during the processing of borage and corn gromwell seeds are not necessary as the residue levels in raw agricultural commodities (RAC) did not 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 (EC, 1997d).

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Borage can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that the degradation rate of picloram is moderate; the maximum field DT_{90} was 163 days (EFSA, 2009), which is above the trigger value of 100 days. Thus, further studies investigating the nature and magnitude of the compound uptake in rotational crops are required (EC, 1997c).

3.1.2.2. Nature of residues

The metabolism of picloram in rotational crops was assessed in the DAR prepared under Directive 91/414/EEC and in the conclusion on the peer review (United Kingdom, 2007, 2009a,b; EFSA, 2009). It was concluded that the metabolism of the active substance in rotational crops is similar to the pathway observed in primary crops. Thus, the same residue definition applies (EFSA, 2009).

3.1.2.3. Magnitude of residues

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. Nevertheless, EFSA considered that in order to properly assess the magnitude of picloram residues in rotational crops, the applicant should submit rotational crop field studies according to the EU guidelines and reflecting the critical GAP for picloram on a primary annual crop. Meanwhile, EFSA concludes that Member States when granting authorisations of picloram should take the appropriate risk mitigation measures in order to avoid the presence of picloram residues in rotational crops.

3.2. Nature and magnitude of residues in livestock

Since borage and corn gromwell seeds are not normally fed to livestock, the nature and magnitude of picloram residues in livestock is not assessed in the framework of this application (EC, 1996).

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population[10] (EFSA, 2007).

Since consumption data for borage are not reported in the PRIMo model, estimations of the chronic and acute exposures were conducted using the overall consumption data reported for the whole oilseed crop group and using respectively the median (STMR) and highest (HR) residue values derived from the residue trials on oilseed (see Table 3-2). For the remaining commodities of plant and animal origin, the existing MRLs as established in Annex IIIA of Regulation (EC) No 396/2005 were used as input values. Values used for the dietary exposure calculation are summarised in Table 4-1.

[10] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from Member States surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from Member States surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	**Comment**	**Input (mg/kg)**	**Comment**
Risk assessment residue definition: picloram, free and conjugated expressed as picloram				
Oilseeds crops group	0.01	STMR (see Table 3-2)	0.02	HR (see Table 3-2)
Other plant and animal commodities	MRL	MRLs in Regulation (EU) 737/2014		

The estimated exposure was then compared with the toxicological reference values derived for picloram (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 1.3 % of the ADI (WHO Cluster B) when picloram residues are considered for the whole oilseed crop group.

No acute consumer risk was identified with regard to the highest residue (HR) of picloram. The maximum acute exposure was calculated to be 0.04 % of the ARfD for peanuts.

Based on this conservative approach considering the consumption figure for the whole oilseed crop group, EFSA concludes that the intended use of picloram on borage and corn gromwell seeds will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

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

The metabolism of picloram in primary crops was investigated in the pulses/oilseeds (rape seed) and cereal crop groups (wheat). From these studies the peer review concluded to establish the residue definition for risk assessment as picloram, free and conjugated expressed as picloram. For enforcement purposes, EFSA recommends to maintain the existing residue definition which currently includes the parent compound only. The proposed residue definition for enforcement and risk assessment will be reconsidered in the framework of the MRLs review under Article 12 of Regulation (EC) No 396/2005. Validated analytical methods for the determination of picloram and its conjugates in high oil content commodities are available. For the use on borage and corn gromwell seeds, EFSA concludes that the metabolism of picloram in primary crops is sufficiently addressed.

EFSA concludes that the submitted supervised residue trials on rape seed are sufficient to derive a MRL proposal of 0.03 mg/kg extrapolated to borage and corn gromwell seeds. Although the rape seed samples were analysed for picloram and its conjugates, expressed as picloram, EFSA is of the opinion that the trials can be used to derive a MRL according to the current enforcement residue definition limited to picloram. This MRL proposal might slightly overestimate the actual magnitude of picloram residues. However, since the total residues in rape seed are very low, this discrepancy is considered of low relevance.

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

The metabolism of picloram in rotational crops is similar to the metabolic pathway depicted in primary crops. 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. Nevertheless, EFSA considered that in order to properly assess the magnitude of picloram residues in rotational crops, the applicant should submit rotational crop field studies according to the EU guidelines and reflecting the critical GAP for picloram on a primary annual crop. Meanwhile, Member States when granting authorisations of picloram should take the appropriate risk mitigation measures in order to avoid the presence of picloram residues in rotational crops.

Residues of picloram in commodities of animal origin were not assessed in the framework of this application since borage and corn gromwell seeds are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). Since consumption data were not reported for borage and corn gromwell seeds, the chronic and acute dietary intake calculations were conducted using the overall consumption data reported for the whole oilseed crop group and using respectively the median (STMR) and highest (HR) residue values derived from the residue trials on oilseed rape. Based on this conservative approach, no long-term and acute consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The highest calculated long-term intake accounted for 1.3 % of the ADI (WHO Cluster B) and the maximum acute exposure was estimated to be 0.04 % of the ARfD.

EFSA concludes that the intended use of picloram on borage and corn gromwell seeds will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. Thus EFSA proposes to amend the existing MRL as reported in the summary table.

RECOMMENDATIONS

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: picloram				
0401120	Borage	0.01*	0.03	Extrapolation from Northern Europe (NEU) trials on rape seed where samples were analysed for the sum of picloram and its conjugates. Although samples were not analysed for picloram only, the MRL is considered acceptable.

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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APPENDICES

Appendix A. Good Agricultural Practice (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	conc. a.s. (i)	Method kind (f-h)	Growth stage & season (j)	number min-max (k)	interval min-max	g/hL min-max	Water L/ha min-max	g/ha min-max		
Borage and corn gromwell seeds	NEU	F	Broad-leaved weeds	SL	80 g/L	-	BBCH 30-50	1	-	-	200-400	24	NR	Lower water volumes might be used at early application timings, at BBCH 39 a minimum volume would be 220 L/ha as the dense crop would require a higher volume for adequate spray coverage.

Remarks:

NR: Not reported

(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (Growth stages of mono-and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

Appendix B. Pesticide Residue Intake Model (PRIMO)

Picloram				
Status of the active substance:	Included	Code no.		
LOQ (mg/kg bw):		proposed LOQ:		
Toxicological end points				
ADI (mg/kg bw/day):	0.3	ARfD (mg/kg bw):	0.3	
Source of ADI:	EFSA	Source of ARfD:	EFSA	
Year of evaluation:	2009	Year of evaluation:	2009	

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum	
	1
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
1.3	WHO Cluster diet B	0.6	Wheat	0.2	Maize	0.1	Bovine: Kidney	
1.2	NL child	0.5	Milk and cream,	0.3	Wheat	0.1	Swine: Meat	
1.1	FR toddler	0.7	Milk and cream,	0.2	Wheat	0.1	Bovine: Meat	
1.0	UK Infant	0.6	Milk and cream,	0.2	Wheat	0.1	Maize	
0.9	ES child	0.3	Wheat	0.2	Milk and cream,	0.1	Bovine: Meat	
0.8	WHO cluster diet D	0.4	Wheat	0.1	Milk and cream,	0.0	Bovine: Meat	
0.8	UK Toddler	0.3	Milk and cream,	0.3	Wheat	0.1	Sugar beet (root)	
0.7	DE child	0.3	Wheat	0.2	Milk and cream,	0.0	Pome fruit	
0.7	WHO cluster diet E	0.3	Wheat	0.1	Poultry: Meat	0.1	Barley	
0.7	FR infant	0.4	Milk and cream,	0.1	VEGETABLES	0.1	Wheat	
0.7	DK child	0.4	Wheat	0.2	Milk and cream,	0.0	Oats	
0.6	IE adult	0.2	Maize	0.2	Maize	0.1	Barley	
0.6	WHO regional European diet	0.2	Wheat	0.1	Swine: Meat	0.1	Milk and cream,	
0.6	WHO Cluster diet F	0.2	Wheat	0.1	Swine: Meat	0.1	Milk and cream,	
0.6	IT kids/toddler	0.4	Wheat	0.1	Other cereal	0.0	VEGETABLES	
0.5	SE general population 90th percentile	0.2	Wheat	0.2	Milk and cream,	0.0	VEGETABLES	
0.5	ES adult	0.2	Wheat	0.1	Milk and cream,	0.0	Bovine: Meat	
0.4	NL general	0.1	Wheat	0.1	Milk and cream,	0.1	Swine: Meat	
0.4	FR all population	0.2	Wheat	0.0	Milk and cream,	0.0	Poultry: Meat	
0.3	IT adult	0.3	Wheat	0.0	Other cereal	0.0	VEGETABLES	
0.3	PT General population	0.3	Wheat	0.0	Maize	0.0	VEGETABLES	
0.3	DK adult	0.1	Wheat	0.1	Milk and cream,	0.0	Bovine: Meat	
0.3	LT adult	0.1	Wheat	0.1	Milk and cream,	0.1	Swine: Meat	
0.2	UK vegetarian	0.1	Wheat	0.1	Milk and cream,	0.0	Sugar beet (root)	
0.2	UK Adult	0.1	Wheat	0.0	Milk and cream,	0.0	Sugar beet (root)	
0.2	FI adult	0.1	Milk and cream,	0.1	Wheat	0.0	VEGETABLES	
0.0	PL general population	0.0	VEGETABLES	0.0	Pome fruit	0.0	Berries & small fruit	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Picloram is unlikely to present a public health concern.

	Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations					
	The acute risk assessment is based on the ARfD.											
	For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.											
	In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.											
	Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.											
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
	IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	0.04	Peanuts	0.02 / -	0.0	Peanuts	0.02 / -	0.0	Peanuts	0.02 / -	0.0	Peanuts	0.02 / -
	0.02	Safflower	0.02 / -	0.0	Safflower	0.02 / -	0.0	Sunflower seed	0.02 / -	0.0	Sunflower seed	0.02 / -
	0.02	Sunflower seed	0.02 / -	0.0	Sunflower seed	0.02 / -	0.0	Soya bean	0.02 / -	0.0	Soya bean	0.02 / -
	0.02	Soya bean	0.02 / -	0.0	Soya bean	0.02 / -	0.0	Linseed	0.02 / -	0.0	Linseed	0.02 / -
	0.01	Sesame seed	0.02 / -	0.0	Sesame seed	0.02 / -	0.0	Sesame seed	0.02 / -	0.0	Sesame seed	0.02 / -

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
DAR	Draft Assessment Report
DAT	days after treatment
DT_{90}	period required for 90 % dissipation (define method of estimation)
EC	European Community
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GEMS	Global Environment Monitoring System
GC	Gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HR	highest residue
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LOQ	limit of quantification
mg	milligram
MRL	maximum residue level
MS	mass spectrometry detector
NEU	Northern Europe
OECD	Organisation for Economic Co-operation and Development
OJ	Official Journal of the European Union
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model

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
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UK	United Kingdom
WHO	World Health Organization