

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for picloram in rape seed and mustard seed¹

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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 Dow AgroSciences Ltd. to modify the existing MRLs for the active substance picloram in rape seed and mustard seed. In order to accommodate for the intended use of picloram, the United Kingdom proposed to raise the existing MRL from the limit of quantification to 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 are sufficient to derive a MRL proposal of 0.03 mg/kg for the proposed use on rape seed and mustard seed. Based on the risk assessment results, EFSA concludes that the proposed use of picloram on rape seed and mustard seed will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk. Data gap regarding the lack of rotational crop field study identified by the peer review is confirmed in the current assessment and has to be further considered in the framework of the MRL review according to Article 12 of Regulation (EC) No 396/2005.

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KEY WORDS

picloram, rape seed, mustard seed, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, 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 Dow AgroSciences Ltd. to modify the existing MRLs for the active substance picloram in rape seed and mustard seed. In order to accommodate for the intended use of picloram, the United Kingdom proposed to raise the existing MRL from the limit of quantification to 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 04 December 2012.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/, the Commission Review Report on picloram and the conclusion on the peer review of the pesticide risk assessment of the active substance 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 ADI of 0.3 mg/kg bw per day and an ARfD of 0.3 mg/kg bw.

The metabolism of picloram in primary crops was investigated in rape seed (pulses and oilseeds) and wheat (cereals). The available metabolism studies provide evidence that the enforcement residue definition which currently comprises only the parent compound should be amended as “sum of picloram and its conjugates, expressed as picloram”. However, since such a change might have an impact on the existing MRLs, EFSA recommends to maintain the enforcement residue definition, pending a full revision of the MRLs under Article 12 of Regulation (EC) No 396/2005. For risk assessment, the residue definition is agreed to be the sum of picloram and its conjugates, expressed as picloram. Analytical methods to control residues in rape seed and mustard seed are currently only available for the wider risk assessment residue definition. For the use on rape seed and mustard seed, EFSA concludes that the metabolism of picloram in primary crops is sufficiently addressed.

The rape seed samples were analysed for the extended residue definition (sum of picloram and its conjugates, expressed as picloram). Although no data are available regarding the residue of free picloram, EFSA is of the opinion that the trials can be used to derive a temporary MRL for the existing residue definition anticipating that in the future, the residue definition will be amended. It is noted that this MRL proposal might slightly overestimate the real residue of picloram, but since the total residues were very low, this discrepancy will be of low relevance.

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

The occurrence of picloram residues in rotational crops was investigated in the framework of the peer review and referred to a single application of picloram on rape seed every three years. Based on the available information on the nature and magnitude of residues in succeeding crops, it was not possible to conclude whether significant residues are unlikely to occur in rotational crops according to the proposed Good Agricultural Practice (GAP) that it is supported now (i.e. use of picloram on rape seed every year).

Since rape seed and its by-products are used as feed products, a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg (dry matter) for all relevant species but was mainly driven by the existing MRLs for feed products. The impact of picloram residues in rape seed to the total livestock exposure was insignificant and therefore the modification of the MRLs for commodities of animal origin is not further investigated in the framework of the current application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). No long-term and acute consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated long-term intake values accounted for up to 1% of the ADI (UK Infant). The contribution of residues in oilseed rape to the total consumer exposure was negligible. The calculated maximum exposure in percentage of the ARfD was below 0.1%

EFSA concludes that the proposed use of picloram on rape seed and mustard seed will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk. Data gap regarding the lack of rotational crop field study identified by the peer review is confirmed in the current assessment and has to be further considered in the framework of the MRL review according to Article 12 of Regulation (EC) No 396/2005. .

Thus EFSA proposes to amend the existing MRL as reported in the summary table.

Summary table

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: picloram				
401060	Rape seed	0.01*	0.03	The MRL proposal is based on residue trials which were analysed for the sum of picloram and its conjugates. Although no studies are available for parent picloram only, the MRL is considered acceptable, anticipating a revision of the residue definition under Article 12 of Regulation (EC) No 396/2005. The MRL proposal does not pose a risk to consumers.
401080	Mustard seed	0.01*	0.03	

(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 396/2005³ 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/EEC⁴, repealed by Regulation (EC) No 1107/2009⁵, 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), compiled an application to modify the existing MRLs for picloram in rape seed and mustard seed. This application was notified to the European Commission and EFSA, and was subsequently evaluated 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 04 December 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00982 and the following subject:

Picloram-Application to modify the existing MRL in rape seed (oilseeds).

The United Kingdom proposed to raise the existing MRLs of picloram in oilseed rape and mustard seed from the limit of quantification 0.01 mg/kg to 0.03 mg/kg.

During the assessment of the application, EFSA identified some data gaps which were essential to conclude on the consumer risk assessment. Thus, EFSA asked for further data which were provided by the applicant and evaluated by the EMS. An addendum to the evaluation report was provided on 16 July 2013. Upon reception of this data, EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

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 16 July 2013.

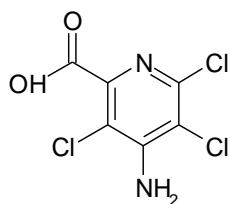
³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

⁴ Council Directive 91/414/EEC of 15 July 1991. 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. OJ L 309, 24.11.2009, p. 1-50.

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.



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/EC⁶ which entered into force on 01 January 2009 for use as herbicide only. In 2010 the Annex I inclusion was amended by Commission Directive 2010/39/EU⁷ taking into account the findings of the EFSA conclusion (EFSA, 2009) and the data gaps identified. Confirmatory information regarding the monitoring analytical method and soil photolysis study were specified; the requested information had to be provided to the European Commission by 30 June 2012. In accordance with Commission Implementing Regulation (EU) No 540/2011⁸ 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 (Appendix C). The existing EU MRLs for picloram on rape seed and mustard seed are 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.

⁶ Commission Directive 2008/69/EC of 1 July 2008. OJ L 172, 2.07.2008, p. 9-14.

⁷ Commission Directive 2010/39/EU of 22 June 2010. OJ L 156, 23.6.2010, p. 7-11

⁸ Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011. OJ L 153, 11.06.2011, p. 1-186.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (United Kingdom, 2012, 2013), the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (United Kingdom, 2007, 2009), the Commission Review Report on picloram (EC, 2010c) and the conclusion on the peer review of the pesticide risk assessment of the active substance picloram (EFSA, 2009). 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 546/2011⁹ 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

Analytical methods for the determination of picloram residues in plant commodities were assessed in the DAR and during the peer review under Directive 91/414/EEC (United Kingdom, 2007, 2009; EFSA, 2010). The available monitoring method for oilseeds is based on GC-MS with a LOQ of 0.01 mg/kg. The peer review experts could not agree on the acceptability of this method as it was unclear if the method covers conjugated picloram. Therefore a data gap concerning analytical methods for enforcement purpose was defined. Confirmatory data have not been peer reviewed yet but were submitted for the current application and were evaluated by the EMS (United Kingdom, 2013). According to the EMS, the results indicate that the method GRM 00.19 is able to quantify picloram, free and conjugated expressed as picloram in high oil content and dry commodities with an LOQ validated at 0.01 mg/kg.

The current enforcement residue definition set in Regulation (EC) No 396/2005 is parent picloram. The applicant did not provide analytical enforcement methods that can be used to monitor parent picloram only. Taking into account that the residue definition should be amended to the sum of picloram and its conjugates, expressed as picloram as proposed in the peer review under Directive 91/414/EEC (see 3.1.1.1) and that the residue trials on which the MRL proposal is based on were also analysed with a method that included the conjugates, the lack of an enforcement method for parent picloram is considered of minor importance.

EFSA concludes that a sufficiently validated analytical method for crops belonging to the group of high oil content is available to control residues of picloram and its conjugates.

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

The analytical methods for the determination of picloram residues in commodities of animal origin were evaluated in the DAR and during the peer review under Directive 91/414/EEC (United Kingdom, 2007, 2009; EFSA, 2010). Residues of parent picloram in foodstuff of animal origin can be determined by GC-MS with a LOQ of 0.01 mg/kg in all relevant animal products.

EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for picloram in food of animal origin are 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.

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

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

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, 2009) 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

Group	Crop	Label position	Application details				
			F or G ^(a)	Rate	No/ Interval	Sampling	Remarks
Pulses and oilseeds	Rape seed	2- and 6- ¹⁴ C pyridine ring	F	0.40 kg a.s./ha	1	0 DAT (whole plant), 30 DAT (leaves, stems and flower buds), 50 DAT (leaves, stems and pods), 84 DAT (stem, chaff and seeds)	Treatment at BBCH 33.
Cereals	Wheat	2- and 6- ¹⁴ C pyridine ring	G ^(b)	0.26 and 0.53 kg a.s./ha	1	0 DAT (immature), 38 DAT (foliage), 104 DAT (grain, chaff and straw)	Treatment at BBCH 13 – 22.

(a): Outdoor/field application (F) or glasshouse/protected crops/indoor application (G)

(b): Semi protected ('screenhouse')

Total residues in oilseed rape plants and seeds at harvest (PHI 84 days) accounted for 0.1 mg/kg and less than 0.01 mg/kg, respectively. Hence, no further attempt was made to characterise or identify residues in the seed. In stem and chaff samples, the main components identified were picloram (28% to 54% TRR), and a conjugated residue which released unchanged picloram (24% to 56%) when subjected to basic or acidic hydrolysis. A metabolite PYR¹⁰ was present in stem and chaff samples at very low levels (<0.005 mg/kg) (EFSA, 2009).

Total residues in wheat grain at harvest (PHI 104 days) were 0.05 mg/kg (lower application rate) and 0.09 mg/kg (higher application rate), and in straw 0.34 mg/kg and 0.52 mg/kg, respectively. The majority of the TRR (75-90%) in straw and grain could be extracted with successive extraction steps.

¹⁰ PYR: 4-amino-2, 3, 5-trichloropyridine

Hydrolysis of extracts using acid, alkali or β -glucosidase released parent picloram. Direct hydrolysis of samples of straw, grain and forage revealed the major component found in all samples to be parent picloram. The 6-OH metabolite and PYR were found at trace levels (≤ 0.002 mg/kg) (EFSA, 2009).

Thus, the main identified components in wheat and rape seed metabolism studies were the parent picloram and its conjugates which released parent picloram upon hydrolytic extraction conditions. At 0 day after application the residue consisted mainly of parent picloram but after longer harvest intervals, picloram is not degraded but quickly forms conjugated picloram in plant material.

The peer review proposed to set the residue definition for risk assessment as picloram, free and conjugated expressed as picloram whereas no final residue definition for enforcement was derived pending confirmatory data on the method of analysis (EFSA 2009).

Considering that the confirmatory data submitted to the EMS confirmed that the method of analysis, which was also used for analysing the residue trials, determines both free and conjugated picloram (see 1.1), EFSA proposes to include picloram conjugates in the residue definition for enforcement. However, as the current residue definition for enforcement set in Regulation (EC) No 396/2005 comprises parent picloram only, a modification of the residue definition requires to assess the impact on the existing MRLs. Currently barley, maize, oats, sorghum, wheat, other cereals and sugar cane are the only crops for which MRLs have been set above the LOQ. If the picloram conjugates are included in the residue definition as proposed by the EFSA, the existing MRLs for these crops might need to be revised. Thus, EFSA proposes to amend the residue definition in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005; only on this occasion a full overview will be available on the authorised GAPs and the relevant residue trials which will allow to take a final decision on the MRLs needed. For the current MRL application the existing enforcement residue definition should be considered.

EFSA concludes that the metabolism of picloram in rape seed is sufficiently addressed. As long as the MRL review under Article 12 of Regulation (EC) No 396/2005 is not yet finalised, the existing enforcement residue definition can be maintained (*i.e.* parent picloram), but in future the picloram conjugates should be included in the enforcement residue definition. For risk assessment, the residue definition is agreed to be the sum of picloram and its conjugates, expressed as picloram.

3.1.1.2. Magnitude of residues

In support of the MRL application, eight GAP compliant residue trials on rape seed in NEU were available. The trials were performed in Germany, Hungary, Poland and France in 2005, 2006 and 2009. Part of the trials was performed as decline studies. The rape seed samples were analysed for the extended residue definition (sum of picloram and its conjugates, expressed as picloram). Although no data are available regarding the residue of free picloram, EFSA is of the opinion that the trials can be used to derive a temporary MRL for the existing residue definition anticipating that in the future the residue definition will be amended. It is noted that this MRL proposal might slightly overestimate the real residue of picloram only, but since the total residues were very low, this discrepancy is of low relevance.

The applicant proposes to extrapolate the results of the rape seed residue trials to mustard seed. According to the EU guidance document (EC, 2011) such an extrapolation is acceptable; the number of trials is sufficient to derive a MRL proposal reflecting the NEU GAP for rape seed and mustard seed.

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 $\leq -20^{\circ}\text{C}$ for up to 36 months in wheat forage, straw and grain samples and up to 24 months for oilseed rape seed and

hay (in matrices with high oil content as well in dry matrices). 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 have been sufficiently validated and was proven to be fit for the purpose (United Kingdom, 2013).

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.03 mg/kg for the intended use on rape seed and mustard seed in NEU.

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

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (picloram ^(f))	Risk assessment (sum of picloram and its conjugates, expressed as picloram)					
Rape seed → mustard seed.	NEU	Outdoor	7x<0.01, 0.02	7x<0.01, 0.02	0.01	0.02	0.03	1	R _{ber} =0.020 R _{max} =0.023 MRL _{OECD} = 0.025/0.03

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011).

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

(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 set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

Specific studies to assess the nature and magnitude of picloram residues during the processing of rape seed and mustard seed are not necessary as the residue levels in raw agricultural commodities (RAC) did not exceed the trigger value of 0.1 mg/kg and as 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

Both crops under consideration 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 DT₉₀ (considered only valid for application rates up 52g/ha) 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, 2009; EFSA, 2009). The overview of the study designs is presented in the table below.

Table 3-3: Overview of the available confined rotational crop studies

Crop group	Crop sown	Label position	Application details				Remarks
			Method	Rate (kg a.s./ha)	Sowing intervals	Harvest time	
Root and tuber vegetables	Turnips	2- and 6- ¹⁴ C pyridine ring	Applied to the bare ground soil.	0.583	30, 120 and 365 DAT	Various growth stages.	Soils analyzed after application, crop planting and each crop harvest.
Cereals	Wheat/ Maize			0.583			
Oilseed and oil fruit	Mustard seed			0.583			

It is noted that the dose rate in the rotational crop metabolism study is ten times higher than that used in the soil degradation study (see 3.1.2.1). At this higher rate microbial activity would be expected to be inhibited causing greater persistence of the active substance than from the patterns of use being assessed.

Characterisation of the nature of the residue in all crops showed the radioactivity to be mainly composed of picloram and its conjugates. Maximum residues were observed in turnip tops (2.18 mg/kg; 120 days aged soil), wheat straw (3.20 mg/kg; 30 days aged soil) and mustard greens (1.17 mg/kg; 365 days aged soil). The highest residues (sum of picloram and its conjugate, expressed as picloram) were found in turnip tops planted 120 days after the soil treatment (2.18 mg/kg), wheat straw planted 30 days after the soil treatment (3.20 mg/kg) and mustard greens planted 365 days after the soil treatment. Metabolite PYR was found in wheat, maize and turnip samples, but in all cases it was present at low levels (< 0.038 mg/kg).

The data on metabolism and distribution of picloram in succeeding crops demonstrate 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

No rotational field crops studies investigating the magnitude of residues are available. The use of picloram assessed in the peer review referred to a single application of picloram on oilseed rape every three years at an application rate of 0.024 kg a.s./ha and the latest growth stage BBCH 31. The applicant now applies for the use of picloram on oilseed rape every year at the same application rate, but with the last application done at the growth stage of BBCH 50.

During the peer review, provisional MRLs were proposed for certain rotational crops, based on the rotational crop metabolism study summarised under 3.1.2.2 and considering the intended GAP defined as a single triennial application (i.e. 0.07 mg/kg for fruiting vegetables, brassica vegetables, leafy vegetables, stem vegetables, herbal infusion and spices; 0.02 mg/kg for legume vegetables, pulses, cereal grains; 0.01*mg/kg for root vegetables and oilseeds) (EFSA, 2009). MRLs on these crops are currently set at the LOQ.

Label restrictions are proposed now by the applicant to ensure that residues in rotational crops do not exceed the current MRLs. The EMS agreed with these restrictions and considered that setting of MRLs in rotational crops should be dealt under the article 12 review (United Kingdom, 2013). EFSA is of the opinion that in order to properly assess the magnitude of picloram residues in rotational crops, the applicant should submit a rotational crop field study according to EU guidelines and reflecting the critical GAP for picloram on a primary annual crop. The EMS has indicated that the applicant is undertaking a further confined rotational study at 1N rate to further address the potential for residues in rotational crops. EFSA notes that the data requirement for rotational crop studies will be reconsidered in the framework of the MRL review of picloram according to Article 12 of Regulation (EC) No 396/2005. As long as these data are not available, Member States when granting authorisations should consider the setting of appropriate restrictions in order to avoid possible contamination of crops grown in rotation on soil that was previously treated with picloram which exceed the current MRLs.

3.2. Nature and magnitude of residues in livestock

The use of picloram resulted in significant residue levels in rape seed and its by-products which might be fed to livestock.

3.2.1. Dietary burden of livestock

The median and maximum dietary burden for livestock was calculated using the agreed European methodology (EC, 1996). The input values for the dietary burden calculation were selected according to the latest FAO recommendations (FAO, 2009) considering the livestock intake from rape seed (meal cake) and from all other feed products on which the existing EU MRL is set above the LOQ (barley, maize, oats, sorghum and wheat) or where residues above the LOQ are expected.

A default processing factor of 2 was used for press-cake of oilseeds containing 50 % of fat (rape seed). The input values for the dietary burden calculation (scenario 1) are summarised in Table 3-4. The default processing factors have been added to the table in brackets.

Table 3-4: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: the sum of picloram and its conjugates, expressed as picloram				
Barley, maize, oats, wheat and sorghum grain	0.2	MRL	0.2	MRL
Rape seed (meal cake)	0.02	Median residue* default PF (2)	0.02	Median residue* default PF (2)

In order to estimate the contribution of picloram residues in rape seed to the total livestock dietary exposure, EFSA calculated a second scenario (scenario 2) without rape seed.

The results of the dietary burden calculations are summarised in the following tables.

Table 3-5: Results of the dietary burden calculation – scenario 1: with rape seed meal.

	Maximum dietary burden (mg/kg bw per day)	Median dietary burden (mg/kg bw per day)	Highest contributing commodity ^(a)	Max dietary burden (mg/kg DM)	Trigger exceeded
Risk assessment residue definition: the sum of picloram and its conjugates, expressed as picloram					
Dairy ruminants	0.004	0.004	Wheat grain	0.100	Yes
Meat ruminants	0.008	0.008	Wheat grain	0.191	Yes
Poultry	0.010	0.010	Wheat grain	0.165	Yes
Pigs	0.008	0.008	Wheat grain	0.191	Yes

(a): Calculated for the maximum dietary burden

Table 3-6: Results of the dietary burden calculation – scenario 2: without rape seed meal.

	Maximum dietary burden (mg/kg bw per day)	Median dietary burden (mg/kg bw per day)	Highest contributing commodity ^(a)	Max dietary burden (mg/kg DM)	Trigger exceeded
Risk assessment residue definition: the sum of picloram and its conjugates, expressed as picloram					
Dairy ruminants	0.003	0.003	Wheat grain	0.093	No
Meat ruminants	0.008	0.008	Wheat grain	0.186	Yes
Poultry	0.010	0.010	Wheat grain	0.163	Yes
Pigs	0.007	0.007	Wheat grain	0.186	Yes

(a): Calculated for the maximum dietary burden

The results indicate that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for all animal commodities in both scenarios. From the comparison of the two scenarios it is evident that the contribution of the rape seed to the total livestock exposure is insignificant. Therefore EFSA did not further investigate the need to modify the existing MRLs for commodities of animal origin in the framework of the current application. A comprehensive assessment, taking into account all authorised uses and the supporting studies will be performed in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005.

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 ¹¹ (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the median residue value as derived from the residue trials on rape seed (see Table 3-2). These values were used as input values both for mustard seed and rape seed. 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. A conversion factor for cereals on the basis of the metabolism study could not be derived given some uncertainties for the risk assessment since the MRL in theory comprises only parent picloram. However, since the total consumer exposure is very low, this discrepancy is of low relevance.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

The acute exposure assessment was performed only with regard to the commodity under consideration assuming the consumption of a large portion of the food item as reported in the national food surveys and that these items contained residues at the highest level as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4-1.

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

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: the sum of picloram and its conjugates, expressed as picloram				
Rape seed	0.01	Median residue (see Table 3-2)	0.02	Highest residue (see Table 3-2)
Mustard seed	0.01	Median residue (see Table 3-2)	0.02	Highest residue (see Table 3-2)
Other commodities of food and animal origin	MRL	See Appendix C	Acute risk assessment was undertaken only with regard to the crop under consideration.	

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.

¹¹ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS 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 MS surveys is used. The complete list of diets incorporated in EFSA PRIMO is given in its reference section (EFSA, 2007).

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 up to 1 % of the ADI (UK Infant). The contribution of residues in rape seed and mustard seed to the total consumer exposure was negligible.

No acute consumer risk was identified in relation to the MRL proposal for rape seed and mustard seed. The calculated maximum exposure in percentage of the ARfD was below 0.1%.

EFSA concludes that the intended use of picloram on rape seed and mustard seed 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 ADI of 0.3 mg/kg bw per day and an ARfD of 0.3 mg/kg bw.

The metabolism of picloram in primary crops was investigated in rape seed (pulses and oilseeds) and wheat (cereals). The available metabolism studies provide evidence that the enforcement residue definition which currently comprises only the parent compound should be amended as “sum of picloram and its conjugates, expressed as picloram”. However, since such a change might have an impact on the existing MRLs, EFSA recommends to maintain the enforcement residue definition, pending a full revision of the MRLs under Article 12 of Regulation (EC) No 396/2005. For risk assessment, the residue definition is agreed to be the sum of picloram and its conjugates, expressed as picloram. Analytical methods to control residues in rape seed and mustard seed are currently only available for the wider risk assessment residue definition. For the use on rape seed and mustard seed, EFSA concludes that the metabolism of picloram in primary crops is sufficiently addressed.

The rape seed samples were analysed for the extended residue definition (sum of picloram and its conjugates, expressed as picloram). Although no data are available regarding the residue of free picloram, EFSA is of the opinion that the trials can be used to derive a temporary MRL for the existing residue definition anticipating that in the future, the residue definition will be amended. It is noted that this MRL proposal might slightly overestimate the real residue of picloram, but since the total residues were very low, this discrepancy will be of low relevance.

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

The occurrence of picloram residues in rotational crops was investigated in the framework of the peer review and referred to a single application of picloram on rape seed every three years. Based on the available information on the nature and magnitude of residues in succeeding crops, it was not possible to conclude whether significant residues are unlikely to occur in rotational crops according to the proposed Good Agricultural Practice (GAP) that it is supported now (i.e. use of picloram on rape seed every year).

Since rape seed and its by-products are used as feed products, a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg (dry matter) for all relevant species but was mainly driven by the existing MRLs for feed products. The impact of picloram residues in rape seed to the total livestock exposure was insignificant and therefore the modification of the MRLs for commodities of animal origin is not further investigated in the framework of the current application.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). No long-term and acute consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMO. The total calculated long-term intake values accounted for up to 1% of the ADI (UK Infant). The contribution of residues in oilseed rape to the total consumer exposure was negligible. The calculated maximum exposure in percentage of the ARfD was below 0.1%

EFSA concludes that the proposed use of picloram on rape seed and mustard seed will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk. Data gap regarding the lack of rotational crop field study identified by the peer review is confirmed in the current assessment and has to be further considered in the framework of the MRL review according to Article 12 of Regulation (EC) No 396/2005. .

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: picloram				
401060	Rape seed	0.01*	0.03	The MRL proposal is based on residue trials which were analysed for the sum of picloram and its conjugates. Although no studies are available for parent picloram only, the MRL is considered acceptable, anticipating a revision of the residue definition under Article 12 of Regulation (EC) No 396/2005. The MRL proposal does not pose a risk to consumers.
401080	Mustard seed	0.01*	0.03	

(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. of a.s. (i)	Method kind (f-h)	Growth stage & season (j)	number min-max (k)	interval min max	kg as/hL min-max	Water L/ha min-max	kg a.s./ha min max		
Rape seed and mustard seed	NEU	F	Broad-leaved weeds	SL	80 g a.s./L	-	BBCH 30-50	1	-	-	-	0.024	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:

- (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				Prepare workbook for refined calculations			
				Status of the active substance: Included		Code no.:					
				LOQ (mg/kg bw): 0.01		proposed LOQ:					
				Toxicological end points				Undo refined calculations			
				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					
Chronic risk assessment - refined calculations											
				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)	
	1.0	UK Infant		0.6	Milk and cream,	0.2	Wheat	0.1	Maize	0.1	
	0.9	NL child		0.5	Milk and cream,	0.3	Wheat	0.0	Apples	0.1	
	0.9	FR toddler		0.7	Milk and cream,	0.2	Wheat	0.0	Potatoes	0.1	
	0.9	WHO Cluster diet B		0.6	Wheat	0.2	Maize	0.1	Milk and cream,	0.1	
	0.7	UK Toddler		0.3	Milk and cream,	0.3	Wheat	0.1	Sugar beet (root)	0.1	
	0.7	DK child		0.4	Wheat	0.2	Milk and cream,	0.0	Oats	0.1	
	0.6	DE child		0.3	Wheat	0.2	Milk and cream,	0.0	Apples	0.1	
	0.6	WHO cluster diet D		0.4	Wheat	0.1	Milk and cream,	0.0	Maize	0.0	
	0.6	IT kids/toddler		0.4	Wheat	0.1	Other cereal	0.0	Tomatoes	0.0	
	0.6	ES child		0.3	Wheat	0.2	Milk and cream,	0.0	Maize	0.0	
	0.5	FR infant		0.4	Milk and cream,	0.1	Wheat	0.0	Potatoes	0.1	
	0.5	IE adult		0.2	Maize	0.2	Maize	0.1	Barley	0.1	
	0.5	SE general population 90th percentile		0.2	Wheat	0.2	Milk and cream,	0.0	Potatoes	0.1	
	0.5	WHO cluster diet E		0.3	Wheat	0.1	Barley	0.0	Milk and cream,	0.1	
	0.4	WHO Cluster diet F		0.2	Wheat	0.1	Milk and cream,	0.0	Barley	0.0	
	0.4	WHO regional European diet		0.2	Wheat	0.1	Milk and cream,	0.0	Barley	0.0	
	0.4	PT General population		0.3	Wheat	0.0	Maize	0.0	Potatoes	0.1	
	0.3	IT adult		0.3	Wheat	0.0	Other cereal	0.0	Tomatoes	0.0	
	0.3	NL general		0.1	Wheat	0.1	Milk and cream,	0.0	Barley	0.0	
	0.3	ES adult		0.2	Wheat	0.1	Milk and cream,	0.0	Barley	0.0	
	0.3	FR all population		0.2	Wheat	0.0	Milk and cream,	0.0	Wine grapes	0.0	
	0.3	DK adult		0.1	Wheat	0.1	Milk and cream,	0.0	Oats	0.0	
	0.2	UK vegetarian		0.1	Wheat	0.1	Milk and cream,	0.0	Sugar beet (root)	0.0	
	0.2	UK Adult		0.1	Wheat	0.0	Milk and cream,	0.0	Sugar beet (root)	0.0	
	0.2	FI adult		0.1	Milk and cream,	0.1	Wheat	0.0	Oats	0.0	
	0.2	LT adult		0.1	Wheat	0.1	Milk and cream,	0.0	Potatoes	0.0	
	0.0	PL general population		0.0	Potatoes	0.0	Apples	0.0	Tomatoes	0.0	
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 ARID.												
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 variability factor of 3.												
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARID.												
Unprocessed commodities	No of commodities for which ARID/ADI is exceeded (IESTI 1):			No of commodities for which ARID/ADI is exceeded (IESTI 2):			No of commodities for which ARID/ADI is exceeded (IESTI 1):			No of commodities for which ARID/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1		*)	**) pTMRL/ threshold MRL (mg/kg)	IESTI 2		*)	**) pTMRL/ threshold MRL (mg/kg)	IESTI 1		*)	**) pTMRL/ threshold MRL (mg/kg)
	Highest % of ARID/ADI	Commodities		Highest % of ARID/ADI	Commodities		Highest % of ARID/ADI	Commodities		Highest % of ARID/ADI	Commodities	
	0.0	Rape seed	0.02 / -	0.0	Rape seed	0.02 / -	0.0	Mustard seed	0.02 / -	0.0	Mustard seed	0.02 / -
	0.0	Mustard seed	0.02 / -	0.0	Mustard seed	0.02 / -						
No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---			
Processed commodities	No of commodities for which ARID/ADI is exceeded:			No of commodities for which ARID/ADI is exceeded:			No of commodities for which ARID/ADI is exceeded:			No of commodities for which ARID/ADI is exceeded:		
	---			---			---			---		
			***) pTMRL/ threshold MRL (mg/kg)			***) pTMRL/ threshold MRL (mg/kg)						
	Highest % of ARID/ADI	Processed commodities		Highest % of ARID/ADI	Processed commodities		Highest % of ARID/ADI	Processed commodities		Highest % of ARID/ADI	Processed commodities	
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARID is exceeded for more than 5 commodities, all IESTI values > 90% of ARID are reported.												
**) pTMRL: provisional temporary MRL												
***) pTMRL: provisional temporary MRL for unprocessed commodity												
Conclusion:												
For Picloram IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.												
No exceedance of the ARID/ADI was identified for any unprocessed commodity.												
For processed commodities, no exceedance of the ARID/ADI was identified.												

Appendix C. Existing EU maximum residue levels (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 06/08/2013 16:45))

Code number	Groups and examples of individual products to which the MRLs apply	Picloram
100000	1. FRUIT FRESH OR FROZEN NUTS	0.01*
110000	(i) Citrus fruit	0.01*
110010	Grapefruit (Shaddocks, pomelos, sweetsies, tangelo (except mineola), ugli and other hybrids)	0.01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.01*
110030	Lemons (Citron, lemon, Buddha's hand (Citrus medica var. sarcodactylis))	0.01*
110040	Limes	0.01*
110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (Citrus reticulata x sinensis))	0.01*
110990	Others	0.01*
120000	(ii) Tree nuts	0.01*
120010	Almonds	0.01*
120020	Brazil nuts	0.01*
120030	Cashew nuts	0.01*
120040	Chestnuts	0.01*
120050	Coconuts	0.01*
120060	Hazelnuts (Filbert)	0.01*
120070	Macadamia	0.01*
120080	Pecans	0.01*
120090	Pine nuts	0.01*
120100	Pistachios	0.01*
120110	Walnuts	0.01*
120990	Others	0.01*
130000	(iii) Pome fruit	0.01*
130010	Apples (Crab apple)	0.01*
130020	Pears (Oriental pear)	0.01*
130030	Quinces	0.01*
130040	Medlar	0.01*
130050	Loquat	0.01*
130990	Others	0.01*
140000	(iv) Stone fruit	0.01*
140010	Apricots	0.01*
140020	Cherries (Sweet cherries, sour cherries)	0.01*
140030	Peaches (Nectarines and similar hybrids)	0.01*
140040	Plums (Damson, greengage,	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Picloram
	mirabelle, sloe, red date/Chinese date/Chinese jujube (Ziziphus zizyphus))	
140990	Others	0.01*
150000	(v) Berries & small fruit	0.01*
151000	(a) Table and wine grapes	0.01*
151010	Table grapes	0.01*
151020	Wine grapes	0.01*
152000	(b) Strawberries	0.01*
153000	(c) Cane fruit	0.01*
153010	Blackberries	0.01*
153020	Dewberries (Loganberries, tayberries, boysenberries, cloudberrries and other Rubus hybrids)	0.01*
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x Rubus idaeus))	0.01*
153990	Others	0.01*
154000	(d) Other small fruit & berries	0.01*
154010	Blueberries (Bilberries)	0.01*
154020	Cranberries (Cowberries/red bilberries (V. vitis-idaea))	0.01*
154030	Currants (red, black and white)	0.01*
154040	Gooseberries (Including hybrids with other Ribes species)	0.01*
154050	Rose hips	0.01*
154060	Mulberries (Arbutus berry)	0.01*
154070	Azarole (mediterranean medlar) (Kiwiberry (Actinidia arguta))	0.01*
154080	Elderberries (Black chokeberry/appleberry, mountain ash, buckthorn/sea sawallowthorn, hawthorn, serviceberries, and other treeberries)	0.01*
154990	Others	0.01*
160000	(vi) Miscellaneous fruit	0.01*
161000	(a) Edible peel	0.01*
161010	Dates	0.01*
161020	Figs	0.01*
161030	Table olives	0.01*
161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (Citrus aurantifolia x Fortunella	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Picloram
	spp.)	
161050	Carambola (Bilimbi)	0.01*
161060	Persimmon	0.01*
161070	Jambolan (java plum) (Java apple/water apple, pomerac, rose apple, Brazilian cherry, Surinam cherry/grumichama (Eugenia uniflora))	0.01*
161990	Others	0.01*
162000	(b) Inedible peel, small	0.01*
162010	Kiwi	0.01*
162020	Lychee (Litchi) (Pulasan, rambutan/hairy litchi, longan, mangosteen, langsat, salak)	0.01*
162030	Passion fruit	0.01*
162040	Prickly pear (cactus fruit)	0.01*
162050	Star apple	0.01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel/yellow sapote, mammy sapote)	0.01*
162990	Others	0.01*
163000	(c) Inedible peel, large	0.01*
163010	Avocados	0.01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0.01*
163030	Mangoes	0.01*
163040	Papaya	0.01*
163050	Pomegranate	0.01*
163060	Cherimoya (Custard apple, sugar apple/sweetsop, ilama (Annona diversifolia) and other medium sized Annonaceae fruits)	0.01*
163070	Guava (Red pitaya/dragon fruit (Hylocereus undatus))	0.01*
163080	Pineapples	0.01*
163090	Bread fruit (Jackfruit)	0.01*
163100	Durian	0.01*
163110	Soursop (guanabana)	0.01*
163990	Others	0.01*
200000	2. VEGETABLES FRESH OR FROZEN	0.01*
210000	(i) Root and tuber vegetables	0.01*
211000	(a) Potatoes	0.01*
212000	(b) Tropical root and tuber	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Picloram
	vegetables	
212010	Cassava (Dasheen, eddoe/Japanese taro, tannia)	0.01*
212020	Sweet potatoes	0.01*
212030	Yams (Potato bean/yam bean, Mexican yam bean)	0.01*
212040	Arrowroot	0.01*
212990	Others	0.01*
213000	(c) Other root and tuber vegetables except sugar beet	0.01*
213010	Beetroot	0.01*
213020	Carrots	0.01*
213030	Celeriac	0.01*
213040	Horseradish (Angelica roots, lovage roots, gentiana roots)	0.01*
213050	Jerusalem artichokes (Crosne)	0.01*
213060	Parsnips	0.01*
213070	Parsley root	0.01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0.01*
213090	Salsify (Scorzonera, Spanish salsify/Spanish oysterplant, edible burdock)	0.01*
213100	Swedes	0.01*
213110	Turnips	0.01*
213990	Others	0.01*
220000	(ii) Bulb vegetables	0.01*
220010	Garlic	0.01*
220020	Onions (Other bulb onions, silverskin onions)	0.01*
220030	Shallots	0.01*
220040	Spring onions and welsh onions (Other green onions and similar varieties)	0.01*
220990	Others	0.01*
230000	(iii) Fruiting vegetables	0.01*
231000	(a) Solanacea	0.01*
231010	Tomatoes (Cherry tomatoes, Physalis spp., goji berry, wolfberry (Lycium barbarum and L. chinense), tree tomato)	0.01*
231020	Peppers (Chilli peppers)	0.01*
231030	Aubergines (egg plants) (Pepino,	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Picloram
	antreowa/white eggplant (S. macrocarpon))	
231040	Okra (lady's fingers)	0.01*
231990	Others	0.01*
232000	(b) Cucurbits — edible peel	0.01*
232010	Cucumbers	0.01*
232020	Gherkins	0.01*
232030	Courgettes (Summer squash, marrow (patisson), lauki (Lagenaria siceraria), chayote, sopropo/bitter melon, snake gourd, angled luffa/teroi)	0.01*
232990	Others	0.01*
233000	(c) Cucurbits-inedible peel	0.01*
233010	Melons (Kiwano)	0.01*
233020	Pumpkins (Winter squash, marrow (late variety))	0.01*
233030	Watermelons	0.01*
233990	Others	0.01*
234000	(d) Sweet corn (Baby corn)	0.01*
239000	(e) Other fruiting vegetables	0.01*
240000	(iv) Brassica vegetables	0.01*
241000	(a) Flowering brassica	0.01*
241010	Broccoli (Calabrese, Broccoli raab, Chinese broccoli)	0.01*
241020	Cauliflower	0.01*
241990	Others	0.01*
242000	(b) Head brassica	0.01*
242010	Brussels sprouts	0.01*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0.01*
242990	Others	0.01*
243000	(c) Leafy brassica	0.01*
243010	Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi, choy sum, Peking cabbage/pe-tsai)	0.01*
243020	Kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0.01*
243990	Others	0.01*
244000	(d) Kohlrabi	0.01*
250000	(v) Leaf vegetables & fresh herbs	0.01*
251000	(a) Lettuce and other salad plants including Brassicaceae	0.01*
251010	Lamb's lettuce (Italian corn salad)	0.01*
251020	Lettuce (Head lettuce, lollo rosso	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Picloram
	(cutting lettuce, iceberg lettuce, romaine (cos) lettuce)	
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curly leaf endive, sugar loaf (C. endivia var. crispum/C. intybus var. foliosum), dandelion greens)	0.01*
251040	Cress (Mung bean sprouts, alfalfa sprouts)	0.01*
251050	Land cress	0.01*
251060	Rocket, Rucola (Wild rocket (Diplotaxis spp.))	0.01*
251070	Red mustard	0.01*
251080	Leaves and sprouts of Brassica spp. including turnip greens (Mizuna, leaves of peas and radish and other babyleaf crops, including brassica crops (crops harvested up to 8 true leaf stage), kohlrabi leaves)	0.01*
251990	Others	0.01*
252000	(b) Spinach & similar (leaves)	0.01*
252010	Spinach (New Zealand spinach, amaranthus spinach (pak-khom, tampara), tajar leaves, bitterblad/bitawiri)	0.01*
252020	Purslane (Winter purslane/miner's lettuce, garden purslane, common purslane, sorrel, glasswort, agretti (Salsola soda))	0.01*
252030	Beet leaves (chard) (Leaves of beetroot)	0.01*
252990	Others	0.01*
253000	(c) Vine leaves (grape leaves) (Malabar nightshade, banana leaves, climbing wattle (Acacia pennata))	0.01*
254000	(d) Water cress (Morning glory/Chinese convolvulus/water convolvulus/water spinach/kangkung (Ipomea aquatica), water clover, water mimosa)	0.01*
255000	(e) Witloof	0.01*
256000	(f) Herbs	0.01*
256010	Chervil	0.01*
256020	Chives	0.01*
256030	Celery leaves (Fennel leaves, coriander leaves, dill leaves,	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Picloram
	caraway leaves, lovage, angelica, sweet cicely and other Apiacea leaves, culantro/stinking/long coriander/stink weed (Eryngium foetidum))	
256040	Parsley (leaves of root parsley)	0.01*
256050	Sage (Winter savory, summer savory, Borago officinalis leaves)	0.01*
256060	Rosemary	0.01*
256070	Thyme (Marjoram, oregano)	0.01*
256080	Basil (Balm leaves, mint, peppermint, holy basil, sweet basil, hairy basil, edible flowers (marigold flower and others), pennywort, wild betel leaf, curry leaves)	0.01*
256090	Bay leaves (laurel) (Lemon grass)	0.01*
256100	Tarragon (Hyssop)	0.01*
256990	Others	0.01*
260000	(vi) Legume vegetables (fresh)	0.01*
260010	Beans (with pods) (Green bean/French beans/snap beans, scarlet runner bean, slicing bean, yard long beans, guar beans, soya beans)	0.01*
260020	Beans (without pods) (Broad beans, flageolet, jack bean, lima bean, cowpea)	0.01*
260030	Peas (with pods) (Mangetout/sugar peas/snow peas)	0.01*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.01*
260050	Lentils	0.01*
260990	Others	0.01*
270000	(vii) Stem vegetables (fresh)	0.01*
270010	Asparagus	0.01*
270020	Cardoons (Borago officinalis stems)	0.01*
270030	Celery	0.01*
270040	Fennel	0.01*
270050	Globe artichokes (Banana flower)	0.01*
270060	Leek	0.01*
270070	Rhubarb	0.01*
270080	Bamboo shoots	0.01*
270090	Palm hearts	0.01*
270990	Others	0.01*
280000	(viii) Fungi	0.01*
280010	Cultivated fungi (Common mushroom, oyster mushroom, shitake, fungus mycelium)	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Picloram
	(vegetative parts))	
280020	Wild fungi (Chanterelle, truffle, morel, cep)	0.01*
280990	Others	0.01*
290000	(ix) Sea weeds	0.01*
300000	3. PULSES, DRY	0.01*
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0.01*
300020	Lentils	0.01*
300030	Peas (Chickpeas, field peas, chickling vetch)	0.01*
300040	Lupins	0.01*
300990	Others	0.01*
400000	4. OILSEEDS AND OILFRUITS	0.01*
401000	(i) Oilseeds	0.01*
401010	Linseed	0.01*
401020	Peanuts	0.01*
401030	Poppy seed	0.01*
401040	Sesame seed	0.01*
401050	Sunflower seed	0.01*
401060	Rape seed (Bird rapeseed, turnip rape)	0.01*
401070	Soya bean	0.01*
401080	Mustard seed	0.01*
401090	Cotton seed	0.01*
401100	Pumpkin seeds (Other seeds of Cucurbitaceae)	0.01*
401110	Safflower	0.01*
401120	Borage (Purple viper's bugloss/Canary flower (Echium plantagineum), Corn Gromwell (Buglossoides arvensis))	0.01*
401130	Gold of pleasure	0.01*
401140	Hempseed	0.01*
401150	Castor bean	0.01*
401990	Others	0.01*
402000	(ii) Oilfruits	0.01*
402010	Olives for oil production	0.01*
402020	Palm nuts (palmoil kernels)	0.01*
402030	Palmfruit	0.01*
402040	Kapok	0.01*
402990	Others	0.01*
500000	5. CEREALS	
500010	Barley	0.2
500020	Buckwheat (Amaranthus, quinoa)	0.01*
500030	Maize	0.2
500040	Millet (Foxtail millet, teff, finger	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Picloram
	millet, pearl millet)	
500050	Oats	0.2
500060	Rice (Indian/wild rice (<i>Zizania aquatica</i>))	0.01*
500070	Rye	0.01*
500080	Sorghum	0.2
500090	Wheat (Spelt, triticale)	0.2
500990	Others (Canary grass seeds (<i>Phalaris canariensis</i>))	0.2
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0.01*
610000	(i) Tea	0.01*
620000	(ii) Coffee beans	0.01*
630000	(iii) Herbal infusions (dried)	0.01*
631000	(a) Flowers	0.01*
631010	Camomille flowers	0.01*
631020	Hybiscus flowers	0.01*
631030	Rose petals	0.01*
631040	Jasmine flowers (Elderflowers (<i>Sambucus nigra</i>))	0.01*
631050	Lime (linden)	0.01*
631990	Others	0.01*
632000	b) Leaves	0.01*
632010	Strawberry leaves	0.01*
632020	Rooibos leaves (<i>Ginkgo</i> leaves)	0.01*
632030	Maté	0.01*
632990	Others	0.01*
633000	(c) Roots	0.01*
633010	Valerian root	0.01*
633020	Ginseng root	0.01*
633990	Others	0.01*
639000	(d) Other herbal infusions	0.01*
640000	(iv) Cacao beans (fermented or dried)	0.01*
650000	(v) Carob (st. johns bread)	0.01*
700000	7. HOPS (dried)	0.01*
800000	8. SPICES	0.01*
810000	(i) Seeds	0.01*
810010	Anise	0.01*
810020	Black caraway	0.01*
810030	Celery seed (Lovage seed)	0.01*
810040	Coriander seed	0.01*
810050	Cumin seed	0.01*

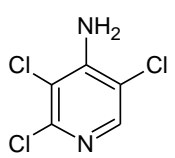
Code number	Groups and examples of individual products to which the MRLs apply	Picloram
810060	Dill seed	0.01*
810070	Fennel seed	0.01*
810080	Fenugreek	0.01*
810090	Nutmeg	0.01*
810990	Others	0.01*
820000	(ii) Fruits and berries	0.01*
820010	Allspice	0.01*
820020	Sichuan pepper (Anise pepper, Japan pepper)	0.01*
820030	Caraway	0.01*
820040	Cardamom	0.01*
820050	Juniper berries	0.01*
820060	Pepper, black, green and white (Long pepper, pink pepper)	0.01*
820070	Vanilla pods	0.01*
820080	Tamarind	0.01*
820990	Others	0.01*
830000	(iii) Bark	0.01*
830010	Cinnamon (Cassia)	0.01*
830990	Others	0.01*
840000	(iv) Roots or rhizome	0.01*
840010	Liquorice	0.01*
840020	Ginger	0.01*
840030	Turmeric (<i>Curcuma</i>)	0.01*
840040	Horseradish	0.01*
840990	Others	0.01*
850000	(v) Buds	0.01*
850010	Cloves	0.01*
850020	Capers	0.01*
850990	Others	0.01*
860000	(vi) Flower stigma	0.01*
860010	Saffron	0.01*
860990	Others	0.01*
870000	(vii) Aril	0.01*
870010	Mace	0.01*
870990	Others	0.01*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0.01*
900020	Sugar cane	0.05
900030	Chicory roots	0.01*
900990	Others	0.01*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL	

Code number	Groups and examples of individual products to which the MRLs apply	Picloram
	ANIMALS	
1010000	(i) Tissue	
1011000	(a) Swine	
1011010	Muscle	0.2
1011020	Fat	0.01*
1011030	Liver	0.01*
1011040	Kidney	5
1011050	Edible offal	0.5
1011990	Others	0.01*
1012000	(b) Bovine	
1012010	Muscle	0.2
1012020	Fat	0.2
1012030	Liver	0.01*
1012040	Kidney	5
1012050	Edible offal	0.5
1012990	Others	0.01*
1013000	(c) Sheep	
1013010	Muscle	0.2
1013020	Fat	0.2
1013030	Liver	0.01*
1013040	Kidney	5
1013050	Edible offal	0.5
1013990	Others	0.01*
1014000	(d) Goat	
1014010	Muscle	0.2
1014020	Fat	0.2
1014030	Liver	0.01*
1014040	Kidney	5
1014050	Edible offal	0.5
1014990	Others	0.01*
1015000	(e) Horses, asses, mules or hinnies	
1015010	Muscle	0.2
1015020	Fat	0.01*
1015030	Liver	0.01*
1015040	Kidney	5
1015050	Edible offal	0.5
1015990	Others	0.01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl, ostrich, pigeon	
1016010	Muscle	0.2
1016020	Fat	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Picloram
1016030	Liver	0.01*
1016040	Kidney	0.01*
1016050	Edible offal	0.01*
1016990	Others	0.01*
1017000	(g) Other farm animals (Rabbit, kangaroo, deer)	
1017010	Muscle	0.2
1017020	Fat	0.01*
1017030	Liver	0.01*
1017040	Kidney	5
1017050	Edible offal	0.5
1017990	Others	0.01*
1020000	(ii) Milk	0.05*
1020010	Cattle	0.05*
1020020	Sheep	0.05*
1020030	Goat	0.05*
1020040	Horse	0.05*
1020990	Others	0.05*
1030000	(iii) Bird eggs	0.01*
1030010	Chicken	0.01*
1030020	Duck	0.01*
1030030	Goose	0.01*
1030040	Quail	0.01*
1030990	Others	0.01*
1040000	(iv) Honey (Royal jelly, pollen, honey comb with honey (comb honey))	0.01*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0.01*
1060000	(vi) Snails	0.01*
1070000	(vii) Other terrestrial animal products (Wild game)	0.01*

(*) Indicates lower limit of analytical determination

Appendix D. List of metabolites and related structural formula

Code/Trivial name	Chemical name ^(a)	Structural formula ^(a)
PYR	2,3,5-trichloropyridin-4-amine (4-amino-3,5,6-trichloropyridine)	

(a): ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

ABBREVIATIONS

ADI	acceptable daily intake
AR	applied radioactivity
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
DM	dry matter
DT ₉₀	period required for 90 % dissipation (define method of estimation)
EC	European Community
EEC	European Economic Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GEMS	Global Environment Monitoring System
GC	gas chromatography
GRM	Global residue method
ha	hectare
hL	hectolitre
HR	highest residue
i.e.	that is (id est, <i>Latin</i>)
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	Member States
MS	mass spectrometry
NEU	northern European Union
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
R _{ber}	statistical calculation of the MRL by using a non-parametric method
R _{max}	statistical calculation of the MRL by using a parametric method
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	Southern European Union
SL	soluble concentrate
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UK	United Kingdom
WHO	World Health Organisation