European Food Safety Authority

EFSA Journal 2013;11(2):3109

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for pyraclostrobin in cucumbers and Jerusalem artichokes[1]

European Food Safety Authority[2]

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for the active substance pyraclostrobin in cucumbers and Jerusalem artichokes. In order to accommodate for the intended uses of pyraclostrobin, Belgium proposed to raise the existing MRL for cucumbers to 0.5 mg/kg; for Jerusalem artichokes the EMS proposed to raise the existing MRL, which is set at the limit of quantification (0.02 mg/kg), to 0.1 mg/kg. Belgium 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 submitted data fully support the MRL proposals of 0.5 mg/kg on cucumbers. The MRL proposal of 0.09 mg/kg on Jerusalem artichokes is derived by extrapolation from overdosed trials on carrots, given that this crop is classified as very minor. Alternatively, EFSA derived a tentative MRL of 0.06 mg/kg by applying the proportionality approach. Adequate enforcement analytical methods are available to control the residues of pyraclostrobin in the commodities under consideration. Based on the risk assessment results, EFSA concludes that the proposed uses of pyraclostrobin on cucumbers and Jerusalem artichokes in Belgium will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

KEY WORDS

Pyraclostrobin, cucumbers and Jerusalem artichokes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, strobilurin fungicide and plant growth regulator, desmethoxy metabolite 500M07

[1] On request from European Commission, Question No EFSA-Q-2012-00605, approved on 05 February 2013.

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Suggested citation: European Food Safety Authority; Reasoned opinion on the modification of the existing MRLs for pyraclostrobin in cucumbers and Jerusalem artichokes. EFSA Journal 2013;11(2):3109. [27 pp.] doi:10.2903/j.efsa.2013.3109. Available online: www.efsa.europa.eu/efsajournal

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for the active substance pyraclostrobin in cucumbers and Jerusalem artichokes. In order to accommodate for the intended uses of pyraclostrobin, Belgium proposed to raise the existing MRL for cucumbers to 0.5 mg/kg; for Jerusalem artichokes the EMS proposed to raise the existing MRL, which is set at the limit of quantification (0.02 mg/kg), to 0.1 mg/kg. Belgium 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 24 May 2012.

EFSA bases its assessment on the revised evaluation report, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC, the Commission Reports on pyraclostrobin, the JMPR evaluation reports as well as the conclusions from previous EFSA opinions on pyraclostrobin, including the review of all existing MRLs according to Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of pyraclostrobin was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive the value of 0.03 mg/kg bw per day for both the ADI and the ARfD.

The metabolism of pyraclostrobin in primary crops was investigated in three different crop groups. The review of the existing MRLs for pyraclostrobin performed under Article 12 of Regulation (EC) No 396/2005 confirmed the conclusion of the peer review that the relevant residue for enforcement and risk assessment in all plant commodities treated by foliar application is pyraclostrobin. For the uses on the crops under consideration, EFSA concludes that the metabolism of pyraclostrobin is sufficiently addressed and that the derived residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials fully support the MRL proposals of 0.5 mg/kg on cucumbers. The MRL proposal of 0.09 mg/kg on Jerusalem artichokes is derived by extrapolation from overdosed trials on carrots, given that this crop is classified as very minor. Alternatively, EFSA derived a tentative MRL of 0.06 mg/kg by applying the proportionality approach. Adequate enforcement analytical methods are available to control the residues of pyraclostrobin in the commodities under consideration at the validated LOQ of 0.01-0.02 mg/kg.

Under core processing conditions (sterilisation, baking/brewing/boiling and pasteurization) no degradation of pyraclostrobin was observed; therefore for processed commodities the same residue definition as for raw agricultural commodities is applicable. Studies investigating the magnitude of pyraclostrobin residues in cucumbers and Jerusalem artichokes were not submitted and are not required.

The occurrence of pyraclostrobin residues in rotational crops was investigated in radish, lettuce and wheat. These studies showed that the metabolism in rotational crops is similar to the metabolism observed in primary crops and that significant residues in rotational crops are not expected. Based on the available information on the nature and magnitude of residues in succeeding crops, EFSA concludes that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on the crops under consideration according to the proposed GAP (Good Agricultural Practice).

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

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the review of the existing MRLs for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses of pyraclostrobin at the EU level and the acceptable

Codex limits (CXLs) adopted before 2011. EFSA now updates this risk assessment with the median residue values for Jerusalem artichokes and cucumbers derived from the submitted supervised residue trials and other median residue values which have become available since the MRL review. The acute exposure assessment was performed only with regard to the commodities under consideration. The estimated exposure was then compared with the toxicological reference values derived for pyraclostrobin.

Under the assumption that the MRLs will be amended as proposed in the Article 12 review, the total calculated exposure accounted for up to 14.6 % of the ADI (DE child diet). Thus, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The contribution of residues on cucumbers and Jerusalem artichokes to the total consumer exposure accounted for a maximum of 0.82 % and 0.01 % the ADI, respectively.

No acute consumer risk was identified in relation to the MRL proposals for cucumbers and Jerusalem artichokes. The calculated maximum exposure in percentage of the ARfD was 79.9 % for cucumbers and 1.1 % for Jerusalem artichokes.

EFSA concludes that the proposed uses of pyraclostrobin on cucumbers and Jerusalem artichokes in Belgium will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

Thus EFSA proposes to amend the existing MRLs 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: pyraclostrobin (F)				
232010	Cucumbers	0.3 / 0.5[(b)]	0.5	The submitted data confirm the MRL of 0.5 mg/kg voted by the SCFCAH in December 2012 but not yet published in the Official Journal. No consumer health risk was identified for the intended indoor use in Belgium.
213050	Jerusalem artichokes	0.02*	0.09 or 0.06 (tentative)	The MRL proposal of 0.09 mg/kg is derived by extrapolation from overdosed data on carrots; no consumer health risk was identified for the proposed MRL. Alternatively, EFSA derived a tentative MRL proposal from the overdosed trials on carrots by applying the proportionality approach. Risk managers should decide whether this MRL proposal is acceptable since the use of the down-scaling of overdosed trials is not common practice in the EU.

(a): According to Annex I of Regulation (EC) No 396/2005.
(b): The implementation of the MRL of 0.5 mg/kg for cucumbers is in progress (SANCO/12703/2012).
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): Fat-soluble pesticide.

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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.

Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs for the active substance pyraclostrobin in cucumbers and Jerusalem artichokes. 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 24 May 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00605 and the following subject:

Pyraclostrobin - Application to modify the existing MRLs in cucumbers and Jerusalem artichokes.

Belgium proposed to raise the existing MRLs of pyraclostrobin in cucumbers from 0.3 mg/kg to 0.5 mg/kg and in Jerusalem artichokes from the limit of quantification of 0.02 mg/kg to 0.1 mg/kg.

Further clarifications were requested from the EMS regarding the Good Agricultural Practice (GAP) for which authorisation was requested. This information was provided on 8 January 2013 and a revised evaluation report was submitted.

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.

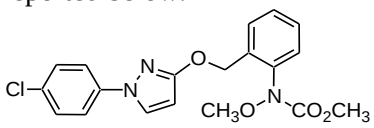
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests 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 24 August 2012

[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

Pyraclostrobin is the ISO common name for methyl *N*-{2-[1-(4-chlorophenyl)pyrazol-3-yloxymethyl]phenyl}(*N*-methoxy)carbamate (IUPAC). The chemical structure of the compound is reported below.



Molecular weight: 387.82 g/mol

Pyraclostrobin is a systemic fungicide belonging to the group of strobilurins. Pyraclostrobin is active against fungi both on the plant surface and within the tissues and acts by inhibition of the mitochondrial respiration. Pyraclostrobin also affects the plant metabolism and physiology exhibiting properties of a plant growth regulator. Pyraclostrobin is used on a wide range of dicotyledonous and monocotyledonous crop species.

Pyraclostrobin was evaluated in the framework of Directive 91/414/EEC with Germany designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Commission Directive 2004/30/EC[6] which entered into force on 1 June 2004 for use as fungicide. The representative use supported for the peer review process was on grapes. Since 2009 pyraclostrobin can be authorised for the used as a plant growth regulator as well (Commission Directive 2009/25/EC[7]). In accordance with Commission Implementing Regulation (EU) No 540/2011[8] pyraclostrobin is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The Draft Assessment Report (DAR) of pyraclostrobin was not peer reviewed by EFSA, therefore no EFSA conclusion is available.

The EU MRLs for pyraclostrobin are established in Annexes II and IIIB of Regulation (EC) No 396/2005 (Appendix C). The existing MRLs for pyraclostrobin were amended four times in the EU legislation[9] taking into account the EFSA recommendations (EFSA, 2009a, 2009b, 2010, 2011a). The MRL proposals for leafy brassica and various cereals were recently assessed by EFSA (EFSA, 2012a) and voted by the Standing Committee on the Food Chain and Animal Health (SCFCAH) on 5 October 2012 (SANCO/12314/2012). On 6 December 2012 Member States voted on a Regulation implementing the acceptable CXLs adopted by Codex Alimentarius Commission in 2012 (SANCO/10703/2012).

In 2011, EFSA issued a reasoned opinion on the review of the existing MRLs for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011b), which reviewed all uses authorised at the EU level and the CXLs adopted by Codex before 2011. Modifications of the existing MRLs were proposed for several crops; these modifications were included in a draft Regulation which is currently under discussion at the SCFCAH (SANCO/10392/2012).

As regards the commodities under consideration in this assessment, the EU MRL on cucumbers is currently set at 0.3 mg/kg. Member States agreed to raise this MRL to 0.5 mg/kg, taking over the CXL value adopted by Codex Alimentarius Commission in July 2012. The vote took place in December 2012 (SANCO/10703/2012) but the new MRL is not yet published in the Official Journal. The existing EU MRL on Jerusalem artichokes is set at the LOQ of 0.02 mg/kg. Codex Alimentarius has not established a CXL on Jerusalem artichokes.

[6] Commission Directive 2004/30/EC of 10 March 2004. OJ L 77, 13.03.2004, p. 50-53.
[7] Commission Directive 2009/25/EC of 2 April 2009. OJ L 91, 03.04.2009, p. 20-22.
[8] Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011. OJ L 153, 11.06.2011, p. 1-186.
[9] Commission Regulation (EU) No 459/2010 of 27 May 2010. OJ L 129 of 28.05.2010, p. 3-49;
Commission Regulation (EU) No750/2010 of 7 July 2010. OJ L 220, 21.08.2010, p. 1-56;
Commission Regulation (EU) No 508/2011 of 24 May 2011. OJ L 137, 25.05.2011, p. 3-52.
Commission Regulation (EU) No 978/2011 of 03 October 2011. OJ L 258, 04.10.2011, p. 12-69.

The details of the intended GAPs for pyraclostrobin in Belgium are given in Appendix A. Since the intended application rate for pyraclostrobin on cucumbers was reported in kg/hectare hedge leaf wall area (LWA)[10], Belgium was asked to recalculate it also in kg/ha (surface area) or kg/hL (Belgium, 2013).

ASSESSMENT

EFSA bases its assessment on the revised evaluation report submitted by the EMS (Belgium, 2013), the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Germany, 2001, 2003), the Commission Report and Review Report on pyraclostrobin (EC, 2002, 2004), the JMPR Evaluation reports (FAO, 2003, 2004, 2006, 2011) as well as the conclusions from previous EFSA opinions on pyraclostrobin (EFSA, 2009a, 2009b, 2010, 2011a, 2011b, 2012a). 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[11] 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

Adequate analytical methods are available to monitor pyraclostrobin residues in high water, high acid and high fat content commodities and in dry commodities with a LOQ of at least 0.02 mg/kg (Germany, 2001; EFSA, 2011b).

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 using high performance liquid chromatography coupled with tandem mass spectrometry detection (HPLC-MS/MS) is also applicable for the determination of residues on high water and acidic content and on dry commodities with a LOQ of 0.01 mg/kg (CEN, 2008).

Since the commodities under consideration belong to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for pyraclostrobin on cucumbers and Jerusalem artichokes are available.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since cucumbers and Jerusalem artichokes are normally not fed to livestock.

[10] Belgium noted that also the application rate of the authorised use on courgettes and gherkins in Belgium assessed in the MRL review under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011b) was expressed in ha/LWA. Therefore, EFSA will amend the PROFile on pyraclostrobin for these two crop uses including the recalculated application rate.

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

2. Mammalian toxicology

The toxicological profile of the active substance pyraclostrobin was assessed in the framework of the peer review under Directive 91/414/EEC (Germany, 2001, 2003; EC, 2004). The data were sufficient to derive toxicological reference values for pyraclostrobin which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Pyraclostrobin					
ADI	EC	2004	0.03 mg/kg bw per day	Rat, chronic study	100
ARfD	EC	2004	0.03 mg/kg bw	Rabbit, developmental toxicity (maternal toxicity)	100

It is noted that JMPR established a higher ARfD (0.05 mg/kg bw) for the compound (FAO, 2003).

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 pyraclostrobin after foliar application was investigated on fruits and fruiting vegetables (grapes), tuber vegetables (potatoes) and cereals (wheat) using the molecule labelled either in the tolyl or the chlorophenyl ring position in the framework of the peer review under Directive 91/414/EEC (Germany, 2001). The metabolic pathway was considered to be similar in all the investigated crops. Pyraclostrobin and its desmethoxy metabolite 500M07[12] constituted the main part of the residues in all tested crops, except in potato tubers (tolyl label study only), where the major part of the residues was identified as the natural amino acid L-tryptophan (29.2 % of the TRR). The supervised residue trials showed that metabolite 500M07 occurred only in small amounts compared to parent pyraclostrobin, therefore the peer review concluded that a general residue definition for risk assessment and enforcement should be set as parent pyraclostrobin only (EC, 2002). The review of the existing MRLs for pyraclostrobin performed under Article 12 of Regulation (EC) No 396/2005 confirmed the conclusion of the peer review (EFSA, 2011b).

For the uses on cucumbers and Jerusalem artichokes, EFSA concludes that the metabolism of pyraclostrobin is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed in the peer review and confirmed during the MRL review under Article 12 of Regulation (EC) No 396/2005 are applicable.

3.1.1.2. Magnitude of residues

a. Cucumbers

In support of the intended use eight residue trials performed on cucumbers over two seasons were submitted. Four of them were already assessed by EFSA (EFSA, 2009a). All the trials were conducted in Belgium according to the intended GAP consisting of maximum two spray applications at 0.1 kg a.s./ha leaf wall area (LWA), equivalent to 0.25 kg a.s./ha surface area (spray concentration of

[12] 500M07: methyl-*N*-(2{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl).

0.013 kg a.s./hL) and a PHI of 1 day. From these studies it is concluded that the MRL of 0.5 mg/kg[13] does not have to be modified.

b. Jerusalem artichokes

The EMS proposed to derive the MRL for Jerusalem artichokes by extrapolation from twelve decline residue trials on carrots already assessed by EFSA (EFSA, 2009a; 2011b). The current EU guidelines allow extrapolation from data on carrots to the whole group of other root and tuber vegetables except sugar beets and EFSA considers the extrapolation to this individual very minor crop feasible even if not explicitly mentioned (EC, 2011). Although the trials on carrots were overdosed (the application rate tested in the trial was 34 % higher, thus exceeding the acceptable variation of ± 25 %), considering that this crop is classified as very minor in NEU (EC, 2011), the residue data on carrots were used to derive the MRL proposal for the intended use on Jerusalem artichokes in Belgium.

Alternatively, EFSA derived a tentative MRL proposal from the overdosed trials on carrots by applying the proportionality approach proposed by JMPR. The results of the overdosed carrot studies were recalculated by applying a correction factor of 0.75 which takes into account that the residues resulting form the lower application rate are expected to be proportionally lower (FAO, 2011). Since the proportionality approach is not common practice in the EU, a further discussion with risk managers is required to decide whether the tentative MRL proposal of 0.06 mg/kg derived with this methodology is acceptable.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-1.

The storage stability of pyraclostrobin was investigated in the DAR under Directive 91/414/EEC (Germany, 2001). Residues of the active substance were found to be stable for up to 18 months in high water, high acid, high oil content and dry commodities when stored deep frozen. As the supervised residue trial samples on cucumbers were stored under conditions for which integrity of the samples was demonstrated (up to 17 months), it is concluded that the residue data are valid with regard to storage stability. Although the period and conditions of storage of the carrot samples are not reported (Belgium, 2013), results are considered valid as these data were used to derive the existing EU MRL for carrots and by extrapolation for beet roots, parsley roots and salsify (EFSA, 2009a, 2011b).

According to the EMS, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (Belgium, 2013).

EFSA considers that the data support the MRL proposals of 0.5 mg/kg on cucumbers. The MRL proposal of 0.09 mg/kg on Jerusalem artichokes is derived by extrapolation from overdosed trials on carrots. Alternatively, EFSA derived a tentative MRL of 0.06 mg/kg by applying the proportionality approach.

[13] MRL voted by the SCFCAH on 6 December 2012 (SANCO/10703/2012).

Table 3-1: 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 (pyraclostrobin)	Risk assessment (pyraclostrobin)					
Enforcement residue definition: pyraclostrobin									
Cucumbers	EU	Indoor	0.07; 2 x 0.1; 0.14; 0.15; 0.20; 0.22; 0.27(f)	0.07; 2 x 0.1; 0.14; 0.15; 0.20; 0.22; 0.27(f)	0.15	0.27	0.5	1	R_{ber}= 0.43 R_{max}= 0.38 MRL_{OECD} = 0.47/0.5
Carrots→ Jerusalem artichokes	NEU	Outdoor	6 x <0.02; 2 x 0.03; 0.03(f); 0.04; 0.05; 0.06	6 x <0.02; 2 x 0.03; 0.03(f); 0.04; 0.05; 0.06	0.03	0.06	0.09	1	MRL proposal derived from overdosed trials on carrots(g). R_{ber}= 0.08 R_{max}= 0.09 MRL_{OECD} =0.08/0.09
			Recalculated results: 6 x <0.02; 2 x 0.02; 0.02(f); 0.03; 0.04; 0.05	6 x <0.02; 2 x 0.02; 0.02(f); 0.03; 0.04; 0.05	0.02	0.05	0.06 (tentative)		MRL proposal derived down-scaling the overdosed trials by a factor of 0.75. R_{ber}= 0.06 R_{max}= 0.05 MRL_{OECD} =0.06/0.06

(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): Highest value measured in the decline studies at a longer PHI (3 days on cucumbers and 21 days on carrots) than the PHI of the intended GAPs.
(g): Trials on carrots performed at an application rate of 0.067 kg a.s./ha compared to the intended rate of 0.05 kg a.s./ha.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of pyraclostrobin was investigated in studies performed at three test conditions (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5, 20 minutes at 120°C, pH 6). The studies were reported in the DAR (Germany, 2001). The results from these studies demonstrate that food processes, such as pasteurisation, baking/brewing/boiling or sterilisation, are not expected to impact on the nature of pyraclostrobin residues. Thus, for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable (Germany, 2001, 2003).

Specific studies to assess the magnitude of pyraclostrobin residues during the processing of cucumbers and Jerusalem artichokes are not necessary as the crops are mostly eaten raw and the residue levels in raw agricultural commodities (RAC) did not exceed the trigger value of 0.1 mg/kg, respectively (EC, 1997d).

3.1.2. Rotational crops

The crops under consideration can be grown in rotation with other plants, therefore the possible occurrence of residues in succeeding crops resulting from the proposed use of pyraclostrobin on cucumbers and Jerusalem artichokes has to be assessed (EC, 1997c).

The nature and magnitude of pyraclostrobin residues in rotational crops was investigated in radish, lettuce and wheat sown into treated soil (0.9 kg a.s./ha) at intervals of 30, 120 and 365 days. These studies showed that the metabolism in rotational crops was comparable to the one in primary crops and that residues in rotational crops were very low (radish root, lettuce ≤0.04 mg/kg and wheat grain ≤0.09 mg/kg) for all plant back intervals (Germany, 2001). For the uses considered under Article 12 MRL review (application rates up to 0.67 kg a.s./ha), EFSA concluded that the residues of pyraclostrobin resulting from the soil uptake are not expected to exceed 0.01 mg/kg (EFSA, 2011b).

Since the intended uses of pyraclostrobin on cucumbers and Jerusalem artichokes are not more critical that the existing uses assessed in the framework of the Article 12 MRL review, EFSA concludes that relevant residue levels are unlikely to occur in rotational crops provided that the compound is applied on the crops under consideration according to the proposed GAPs.

3.2. Nature and magnitude of residues in livestock

Since cucumbers and Jerusalem artichokes are normally not fed to livestock, the nature and magnitude of pyraclostrobin 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 [14] (EFSA, 2007).

In the framework of the review of the existing MRLs for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses of pyraclostrobin at the EU level and the acceptable CXLs adopted before 2011 (EFSA, 2011b; FAO, 2004, 2006). EFSA now updates this risk assessment with the median residue values for Jerusalem artichokes and cucumbers derived from the submitted supervised residue trials. For leafy brassica and millet the input values are also updated considering the median residue concentrations related to the MRL modification proposals (EFSA, 2012a). As regards the CXLs adopted by Codex in 2012, which were recently accepted for implementation in EU legislation (SANCO/12703/2012), the STMRs derived by JMPR were used as input values (FAO, 2011). For courgettes and gherkins the median residue value was also updated, taking into account the four additional residue trials on cucumbers. The remaining commodities of plant and animal origin, were excluded from the exposure calculation, assuming that there is no use on these crops.

The model assumptions for the long-term exposure assessment are considered to be rather conservative. In reality, it is not likely that an individual will consume every food for which a MRL exists and is proposed containing residues at the levels of the median residue values identified in supervised field trials over the lifetime. However, if this 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 commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials on carrots for Jerusalem artichokes (see Table 3-1) and previously reported for cucumbers (FAO, 2011). In addition, a variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation.

The input values used for the dietary exposure calculation are summarized 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: pyraclostrobin (plant origin commodities); sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1*H*-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1*H*-pyrazole moiety, expressed as pyraclostrobin (animal origin commodities)				
Cucumbers	0.15	Median residue (Table 3-1)	0.41	HR (CXL) (JMPR, 2006)
Jerusalem artichokes	0.03	Median residue (carrots, NEU) (Table 3-1)	0.06	Highest residue (carrots, NEU) (Table 3-1)

[14] 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).

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Courgettes, gherkins	0.15[(a)]	Median residue (cucumber, indoor) (Table 3-1)	Acute risk assessment was performed only with regard to the products for which a MRL proposal is requested.	
Oranges	0.07 (0.49*0.14)	Median residue*PeelF (FAO, 2011)		
Cherries	0.51	STMR (FAO, 2011)		
Peaches	0.07	STMR (FAO, 2011)		
Plums	0.09	STMR (FAO, 2011)		
Kale, Chinese cabbage, other leafy brassica	0.19	Median residue (EFSA, 2012a)		
Onions	0.06	STMR (FAO, 2011)		
Barley, oats	0.35	STMR (FAO, 2011)		
Millet	0.01	Median residue (EFSA, 2012a)		
Sorghum	0.03	STMR (FAO, 2011)		
Other commodities of plant and animal origin	See Appendix D (EFSA, 2011b)			

(a): The previous long-term risk assessments were performed using the median residue value of 0.17 for courgette and gherkins derived from four cucumber trials (EFSA, 2011b, 2012a); the value used in this calculation is based on eight cucumber trials (see Table 3-1).

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

Under the assumption that the MRLs will be amended as proposed in the Article 12 review (EFSA, 2011b), the total calculated intake accounted for up to 14.6 % of the ADI (DE child diet). Thus, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The contribution of residues on cucumbers and Jerusalem artichokes to the total consumer exposure accounted for a maximum of 0.82 % (DE child diet) and 0.01 % of the ADI (IE adult diet), respectively.

No acute consumer risk was identified in relation to the MRL proposals for the crops under consideration. The calculated maximum exposure in percentage of the ARfD was 79.9 % for cucumbers (NL child diet) and 1.1 % (UK adult vegetarian diet) for Jerusalem artichokes.

EFSA concludes that the intended uses of pyraclostrobin on cucumbers and Jerusalem artichokes in Belgium will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of pyraclostrobin was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive the value of 0.03 mg/kg bw per day for both the ADI and the ARfD.

The metabolism of pyraclostrobin in primary crops was investigated in three different crop groups. The review of the existing MRLs for pyraclostrobin performed under Article 12 of Regulation (EC) No 396/2005 confirmed the conclusion of the peer review that the relevant residue for enforcement and risk assessment in all plant commodities treated by foliar application is pyraclostrobin. For the uses on the crops under consideration, EFSA concludes that the metabolism of pyraclostrobin is sufficiently addressed and that the derived residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials fully support the MRL proposals of 0.5 mg/kg on cucumbers. The MRL proposal of 0.09 mg/kg on Jerusalem artichokes is derived by extrapolation from overdosed trials on carrots, given that this crop is classified as very minor. Alternatively, EFSA derived a tentative MRL of 0.06 mg/kg by applying the proportionality approach. Adequate enforcement analytical methods are available to control the residues of pyraclostrobin in the commodities under consideration at the validated LOQ of 0.01-0.02 mg/kg.

Under core processing conditions (sterilisation, baking/brewing/boiling and pasteurization) no degradation of pyraclostrobin was observed; therefore for processed commodities the same residue definition as for raw agricultural commodities is applicable. Studies investigating the magnitude of pyraclostrobin residues in cucumbers and Jerusalem artichokes were not submitted and are not required.

The occurrence of pyraclostrobin residues in rotational crops was investigated in radish, lettuce and wheat. These studies showed that the metabolism in rotational crops is similar to the metabolism observed in primary crops and that significant residues in rotational crops are not expected. Based on the available information on the nature and magnitude of residues in succeeding crops, EFSA concludes that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on the crops under consideration according to the proposed GAP (Good Agricultural Practice).

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

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the review of the existing MRLs for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses of pyraclostrobin at the EU level and the acceptable Codex limits (CXLs) adopted before 2011. EFSA now updates this risk assessment with the median residue values for Jerusalem artichokes and cucumbers derived from the submitted supervised residue trials and other median residue values which have become available since the MRL review. The acute exposure assessment was performed only with regard to the commodities under consideration. The estimated exposure was then compared with the toxicological reference values derived for pyraclostrobin.

Under the assumption that the MRLs will be amended as proposed in the Article 12 review, the total calculated exposure accounted for up to 14.6 % of the ADI (DE child diet). Thus, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The contribution of residues on cucumbers and Jerusalem artichokes to the total consumer exposure accounted for a maximum of 0.82 % and 0.01 % the ADI, respectively.

No acute consumer risk was identified in relation to the MRL proposals for cucumbers and Jerusalem artichokes. The calculated maximum exposure in percentage of the ARfD was 79.9 % for cucumbers and 1.1 % for Jerusalem artichokes.

EFSA concludes that the proposed uses of pyraclostrobin on cucumbers and Jerusalem artichokes in Belgium will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

RECOMMENDATIONS

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: pyraclostrobin (F)				
232010	Cucumbers	0.3 / 0.5[(b)]	0.5	The submitted data confirm the MRL of 0.5 mg/kg voted by the SCFCAH in December 2012 but not yet published in the Official Journal. No consumer health risk was identified for the intended indoor use in Belgium.
213050	Jerusalem artichokes	0.02*	0.09 or 0.06 (tentative)	The MRL proposal of 0.09 mg/kg is derived by extrapolation from overdosed data on carrots; no consumer health risk was identified for the proposed MRL. Alternatively, EFSA derived a tentative MRL proposal from the overdosed trials on carrots by applying the proportionality approach. Risk managers should decide whether this MRL proposal is acceptable since the use of the down-scaling of overdosed trials is not common practice in the EU.

(a): According to Annex I of Regulation (EC) No 396/2005.
(b): The implementation of the MRL of 0.5 mg/kg for cucumbers is in progress (SANCO/12703/2012).
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): Fat-soluble pesticide.

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APPENDICES

A. GOOD AGRICULTURAL PRACTICE (GAPS)

Crop and/or situation	Member State or Country	F G or I	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
				type	conc. of a.s.	method kind	growth stage & season	number min max	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
(a)		(b)	(c)	(d - f)	(i)	(f - h)	(j)	(k)					(l)	(m)
Intended GAPs (Belgium, 2013)														
Cucumbers	BE	G	Powdery mildew, leaf mould	WG	67 g/kg	Foliar spray		1-2	14 d			0.25 (n)	1	0.1 kg a.s/ha LWA
Jerusalem artichokes	BE	F	*Erysiphe cichoracearum*	WG	67 g/kg	Foliar spray		1-2	3-4 wks			0.05	14	

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)
(n) Obtained using a conversion factor of 2.5 from ha leaf wall area (LWA) to ha surface area

Pesticide Residues Intake Model (PRIMo)

Pyraclostrobin

Status of the active substance:	**approved**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.03**	ARfD (mg/kg bw):	**0.03**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	2 15
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)
14.6	DE child	5.6	Apples	1.9	Table grapes	0.9	Oranges	
10.8	NL child	3.0	Apples	1.1	Table grapes	1.0	Milk and milk products: Cattle	
8.0	WHO Cluster diet B	1.0	Tomatoes	0.6	Gooseberries	0.6	Wheat	
7.5	IE adult	1.4	Barley	0.4	Apples	0.4	Table grapes	
7.2	UK Toddler	3.0	Sugar beet (root)	0.8	Apples	0.5	Oranges	
6.4	FR toddler	1.2	Apples	1.0	Carrots	0.6	Strawberries	
5.6	FR infant	1.2	Apples	1.1	Carrots	0.9	Milk and milk products: Cattle	
5.2	DK child	1.1	Apples	0.8	Cucumbers	0.5	Carrots	
5.2	UK Infant	1.3	Sugar beet (root)	0.7	Apples	0.5	Carrots	
5.0	WHO cluster diet E	0.9	Barley	0.4	Apples	0.3	Wheat	
4.6	ES child	0.5	Apples	0.5	Oranges	0.4	Milk and milk products: Cattle	
4.6	WHO regional European diet	0.4	Barley	0.4	Tomatoes	0.3	Lettuce	
4.5	WHO cluster diet D	0.4	Wheat	0.3	Tomatoes	0.3	Apples	
4.4	WHO Cluster diet F	0.7	Barley	0.3	Apples	0.3	Lettuce	
4.1	SE general population 90th percentile	0.5	Apples	0.4	Milk and milk products: Cattle	0.3	Carrots	
4.1	NL general	0.6	Apples	0.4	Barley	0.3	Oranges	
3.8	ES adult	0.6	Barley	0.5	Lettuce	0.4	Apples	
3.1	PT General population	0.5	Apples	0.4	Table grapes	0.4	Potatoes	
3.1	IT kids/toddler	0.5	Tomatoes	0.4	Wheat	0.4	Apples	
2.9	PL general population	1.0	Apples	0.5	Table grapes	0.3	Tomatoes	
2.8	LT adult	0.9	Apples	0.2	Potatoes	0.2	Tomatoes	
2.7	IT adult	0.4	Tomatoes	0.4	Apples	0.3	Lettuce	
2.6	UK vegetarian	0.5	Sugar beet (root)	0.3	Apples	0.2	Tomatoes	
2.5	FR all population	0.2	Apples	0.2	Wheat	0.2	Table grapes	
2.1	UK Adult	0.5	Sugar beet (root)	0.2	Apples	0.1	Tomatoes	
1.9	DK adult	0.4	Apples	0.2	Carrots	0.1	Tomatoes	
1.8	FI adult	0.2	Currants (red, black and white)	0.2	Oranges	0.2	Apples	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Pyraclostrobin 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)
	79.9	Cucumbers	0.41 / -	79.9	Cucumbers	0.41 / -	26.9	Cucumbers	0.41 / -	26.9	Cucumbers	0.41 / -
							1.1	Jerusalem artichokes	0.06 / -	0.9	Jerusalem artichokes	0.06 / -
	No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:**		---				**No of commodities for which ARfD/ADI is exceeded:**		---			
			*****)**						*****)**			
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. **) pTMRL: provisional temporary MRL ***) pTMRL: provisional temporary MRL for unprocessed commodity											
	Conclusion:											
	For Pyraclostrobin 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 ARfD/ADI was identified for any unprocessed commodity. For processed commodities, no exceedance of the ARfD/ADI was identified.											

B. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLS)

(Pesticides - Web Version - EU MRLs (File created on 21/12/2012 14:30)

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin (F) [a][b]	Pyraclostrobin (F) [c]
100000	1. FRUIT FRESH OR FROZEN; NUTS		
110000	(i) Citrus fruit		
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	1	1
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	2	2
110030	Lemons (Citron, lemon)	1	1
110040	Limes	1	1
110050	Mandarins (Clementine, tangerine and other hybrids)	1	1
110990	Others	1	1
120000	(ii) Tree nuts (shelled or unshelled)		
120010	Almonds	0.02*	0.02*
120020	Brazil nuts	0.02*	0.02*
120030	Cashew nuts	0.02*	0.02*
120040	Chestnuts	0.02*	0.02*
120050	Coconuts	0.02*	0.02*
120060	Hazelnuts (Filbert)	0.02*	0.02*
120070	Macadamia	0.02*	0.02*
120080	Pecans	0.02*	0.02*
120090	Pine nuts	0.02*	0.02*
120100	Pistachios	1	1
120110	Walnuts	0.02*	0.02*
120990	Others	0.02*	0.02*
130000	(iii) Pome fruit	0.3	0.5
130010	Apples (Crab apple)	0.3	0.5
130020	Pears (Oriental pear)	0.3	0.5
130030	Quinces	0.3	0.5
130040	Medlar	0.3	0.5
130050	Loquat	0.3	0.5
130990	Others	0.3	0.5
140000	(iv) Stone fruit		
140010	Apricots	0.2	1
140020	Cherries (sweet cherries, sour cherries)	3[b]	2
140030	Peaches (Nectarines and similar hybrids)	0.3[b]	0.2
140040	Plums (Damson, greengage, mirabelle)	0.8[b]	1
140990	Others	0.02*	0.02*
150000	(v) Berries & small fruit		
151000	(a) Table and wine grapes		
151010	Table grapes	1	1
151020	Wine grapes	2	2
152000	(b) Strawberries	1.5[b]	1
153000	(c) Cane fruit		
153010	Blackberries	3[b]	2
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	2	2
153030	Raspberries (Wineberries)	3[b]	2
153990	Others	2	2
154000	(d) Other small fruit & berries		
154010	Blueberries (Bilberries cowberries (red bilberries))	4[b]	3
154020	Cranberries	3	3
154030	Currants (red, black and white)	3	3
154040	Gooseberries (Including hybrids with other ribes species)	3	3
154050	Rose hips	3	3
154060	Mulberries (arbutus berry)	3	3
154070	Azarole (mediteranean medlar)	3	3
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	3	3
154990	Others	3	3
160000	(vi) Miscellaneous fruit		
161000	(a) Edible peel	0.02*	0.02*
161010	Dates	0.02*	0.02*
161020	Figs	0.02*	0.02*
161030	Table olives	0.02*	0.02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0.02*	0.02*
161050	Carambola (Bilimbi)	0.02*	0.02*
161060	Persimmon	0.02*	0.02*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0.02*	0.02*
161990	Others	0.02*	0.02*
162000	(b) Inedible peel, small	0.02*	0.02*
162010	Kiwi	0.02*	0.02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0.02*	0.02*
162030	Passion fruit	0.02*	0.02*
162040	Prickly pear (cactus fruit)	0.02*	0.02*
162050	Star apple	0.02*	0.02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0.02*	0.02*
162990	Others	0.02*	0.02*
163000	(c) Inedible peel, large		
163010	Avocados	0.02*	0.02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0.02*	0.02*
163030	Mangoes	0.05	0.05
163040	Papaya	0.07[b]	0.05
163050	Pomegranate	0.02*	0.02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0.02*	0.02*
163070	Guava	0.02*	0.02*
163080	Pineapples	0.02*	0.02*
163090	Bread fruit (Jackfruit)	0.02*	0.02*
163100	Durian	0.02*	0.02*
163110	Soursop (guanabana)	0.02*	0.02*
163990	Others	0.02*	0.02*
200000	2. VEGETABLES FRESH OR FROZEN		
210000	(i) Root and tuber vegetables		
211000	(a) Potatoes	0.02*	0.02*
212000	(b) Tropical root and tuber vegetables	0.02*	0.02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0.02*	0.02*
212020	Sweet potatoes	0.02*	0.02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0.02*	0.02*
212040	Arrowroot	0.02*	0.02*
212990	Others	0.02*	0.02*
213000	(c) Other root and tuber vegetables except sugar beet		
213010	Beetroot	0.1	0.1
213020	Carrots	0.1	0.5

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin (F) [a][b]	Pyraclostrobin (F) [c]
213030	Celeriac	0.3	0.3
213040	Horseradish	0.3	0.3
213050	Jerusalem artichokes	0.02*	0.02*
213060	Parsnips	0.3	0.3
213070	Parsley root	0.1	0.1
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0.2	0.5
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0.1	0.1
213100	Swedes	0.02*	0.02*
213110	Turnips	0.02*	0.02*
213990	Others	0.02*	0.02*
220000	(ii) Bulb vegetables		
220010	Garlic	0.2	0.3
220020	Onions (Silverskin onions)	1.5[b]	0.3
220030	Shallots	0.2	0.3
220040	Spring onions (Welsh onion and similar varieties)	1.5	1
220990	Others	0.02*	0.05*
230000	(iii) Fruiting vegetables		
231000	(a) Solanacea		
231010	Tomatoes (Cherry tomatoes,)	0.3	0.3
231020	Peppers (Chilli peppers)	0.5	0.5
231030	Aubergines (egg plants) (Pepino)	0.3	0.3
231040	Okra, lady's fingers	0.02*	0.02*
231990	Others	0.02*	0.02*
232000	(b) Cucurbits - edible peel	0.5[b]	0.5
232010	Cucumbers	0.5[b]	0.5
232020	Gherkins	0.5	0.5
232030	Courgettes (Summer squash, marrow (patisson))	0.5	0.5
232990	Others	0.5[b]	0.5
233000	(c) Cucurbits-inedible peel	0.5	0.5
233010	Melons (Kiwano)	0.5	0.5
233020	Pumpkins (Winter squash)	0.5	0.5
233030	Watermelons	0.5	0.5
233990	Others	0.5	0.5
234000	(d) Sweet corn	0.02*	0.02*
239000	(e) Other fruiting vegetables	0.02*	0.02*
240000	(iv) Brassica vegetables		
241000	(a) Flowering brassica	0.1	0.1
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0.1	0.1
241020	Cauliflower	0.1	0.1
241990	Others	0.1	0.1
242000	(b) Head brassica		
242010	Brussels sprouts	0.2	0.3
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0.2	0.2
242990	Others	0.02*	0.02*
243000	(c) Leafy brassica	1.5[a]	0.02*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	1.5[a]	0.02*
243020	Kale (Borecole (curly kale), collards)	1.5[a]	0.02*
243990	Others	1.5[a]	0.02*
244000	(d) Kohlrabi	0.02*	0.02*
250000	(v) Leaf vegetables & fresh herbs		
251000	(a) Lettuce and other salad plants including Brassicacea		
251010	Lamb´s lettuce (Italian cornsalad)	10	10
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	2	2
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	2	0.4
251040	Cress	2	10
251050	Land cress	2	10
251060	Rocket, Rucola (Wild rocket)	2	10
251070	Red mustard	2	10
251080	Leaves and sprouts of Brassica spp (Mizuna)	2	10
251990	Others	2	10
252000	(b) Spinach & similar (leaves)		
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0.5	0.5
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	2	0.02*
252030	Beet leaves (chard) (Leaves of beetroot)	0.5	0.5
252990	Others	0.5	0.02*
253000	(c) Vine leaves (grape leaves)	0.02*	0.02*
254000	(d) Water cress	0.02*	0.02*
255000	(e) Witloof	0.02*	0.02*
256000	(f) Herbs	2	2
256010	Chervil	2	2
256020	Chives	2	2
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	2	2
256040	Parsley	2	2
256050	Sage (Winter savory, summer savory,)	2	2
256060	Rosemary	2	2
256070	Thyme (marjoram, oregano)	2	2
256080	Basil (Balm leaves, mint, peppermint)	2	2
256090	Bay leaves (laurel)	2	2
256100	Tarragon (Hyssop)	2	2
256990	Others	2	2
260000	(vi) Legume vegetables (fresh)	0.02*	0.02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0.02*	0.02*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0.02*	0.02*
260030	Peas (with pods) (Mangetout (sugar peas))	0.02*	0.02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.02*	0.02*
260050	Lentils	0.02*	0.02*
260990	Others	0.02*	0.02*
270000	(vii) Stem vegetables (fresh)		
270010	Asparagus	0.02*	0.02*
270020	Cardoons	0.02*	0.02*
270030	Celery	0.02*	0.02*
270040	Fennel	0.02*	0.02*
270050	Globe artichokes	2	2
270060	Leek	0.5	0.7
270070	Rhubarb	0.02*	0.02*
270080	Bamboo shoots	0.02*	0.02*
270090	Palm hearts	0.02*	0.02*
270990	Others	0.02*	0.02*
280000	(viii) Fungi	0.02*	0.02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0.02*	0.02*
280020	Wild (Chanterelle, Truffle, Morel ,)	0.02*	0.02*
280990	Others	0.02*	0.02*
290000	(ix) Sea weeds	0.02*	0.02*
300000	3. PULSES, DRY	0.3	
300010	Beans (Broad beans, navy	0.3	0.3

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin (F) [a][b]	Pyraclostrobin (F) [c]
	beans, flageolets, jack beans, lima beans, field beans, cowpeas)		
300020	Lentils	0.3	0.5
300030	Peas (Chickpeas, field peas, chickling vetch)	0.3	0.3
300040	Lupins	0.3	0.05
300990	Others	0.3	0.3
400000	4. OILSEEDS AND OILFRUITS		
401000	(i) Oilseeds		
401010	Linseed	0.2	0.2
401020	Peanuts	0.04	0.04
401030	Poppy seed	0.2	0.2
401040	Sesame seed	0.2	0.2
401050	Sunflower seed	0.3	0.3
401060	Rape seed (Bird rapeseed, turnip rape)	0.2	0.2
401070	Soya bean	0.02*	0.02*
401080	Mustard seed	0.2	0.2
401090	Cotton seed	0.3	0.3
401100	Pumpkin seeds	0.02*	0.02*
401110	Safflower	0.2	0.2
401120	Borage	0.2	0.2
401130	Gold of pleasure	0.2	0.2
401140	Hempseed	0.02*	0.02*
401150	Castor bean	0.2	0.2
401990	Others	0.02*	0.02*
402000	(ii) Oilfruits	0.02*	0.02*
402010	Olives for oil production	0.02*	0.02*
402020	Palm nuts (palmoil kernels)	0.02*	0.02*
402030	Palmfruit	0.02*	0.02*
402040	Kapok	0.02*	0.02*
402990	Others	0.02*	0.02*
500000	5. CEREALS		
500010	Barley	1[b]	0.5
500020	Buckwheat	0.02*	0.02*
500030	Maize	0.02*[a]	0.02*
500040	Millet (Foxtail millet, teff)	0.02*	0.02*
500050	Oats	1[b]	0.5
500060	Rice	0.02*	0.02*
500070	Rye	0.2[b]	0.1
500080	Sorghum	0.5[b]	0.02*
500090	Wheat (Spelt Triticale)	0.2[b]	0.2
500990	Others	0.02*	0.02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA		
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0.05*	0.1*
620000	(ii) Coffee beans	0.2	0.3
630000	(iii) Herbal infusions (dried)	0.05*	0.1*
631000	(a) Flowers	0.05*	0.1*
631010	Camomille flowers	0.05*	0.1*
631020	Hybiscus flowers	0.05*	0.1*
631030	Rose petals	0.05*	0.1*
631040	Jasmine flowers	0.05*	0.1*
631050	Lime (linden)	0.05*	0.1*
631990	Others	0.05*	0.1*
632000	(b) Leaves	0.05*	0.1*
632010	Strawberry leaves	0.05*	0.1*
632020	Rooibos leaves	0.05*	0.1*
632030	Maté	0.05*	0.1*
632990	Others	0.05*	0.1*
633000	(c) Roots	0.05*	0.1*
633010	Valerian root	0.05*	0.1*
633020	Ginseng root	0.05*	0.1*
633990	Others	0.05*	0.1*
639000	(d) Other herbal infusions	0.05*	0.1*
640000	(iv) Cocoa (fermented beans)	0.05*	0.1*
650000	(v) Carob (st johns bread)	0.05*	0.1*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	10	15
800000	8. SPICES	0.05*	0.1*
810000	(i) Seeds	0.05*	0.1*
810010	Anise	0.05*	0.1*
810020	Black caraway	0.05*	0.1*
810030	Celery seed (Lovage seed)	0.05*	0.1*
810040	Coriander seed	0.05*	0.1*
810050	Cumin seed	0.05*	0.1*
810060	Dill seed	0.05*	0.1*
810070	Fennel seed	0.05*	0.1*
810080	Fenugreek	0.05*	0.1*
810090	Nutmeg	0.05*	0.1*
810990	Others	0.05*	0.1*
820000	(ii) Fruits and berries	0.05*	0.1*
820010	Allspice	0.05*	0.1*
820020	Anise pepper (Japan pepper)	0.05*	0.1*
820030	Caraway	0.05*	0.1*
820040	Cardamom	0.05*	0.1*
820050	Juniper berries	0.05*	0.1*
820060	Pepper, black and white (Long pepper, pink pepper)	0.05*	0.1*
820070	Vanilla pods	0.05*	0.1*
820080	Tamarind	0.05*	0.1*
820990	Others	0.05*	0.1*
830000	(iii) Bark	0.05*	0.1*
830010	Cinnamon (Cassia)	0.05*	0.1*
830990	Others	0.05*	0.1*
840000	(iv) Roots or rhizome	0.05*	0.1*
840010	Liquorice	0.05*	0.1*
840020	Ginger	0.05*	0.1*
840030	Turmeric (Curcuma)	0.05*	0.1*
840040	Horseradish	0.05*	0.1*
840990	Others	0.05*	0.1*
850000	(v) Buds	0.05*	0.1*
850010	Cloves	0.05*	0.1*
850020	Capers	0.05*	0.1*
850990	Others	0.05*	0.1*
860000	(vi) Flower stigma	0.05*	0.1*
860010	Saffron	0.05*	0.1*
860990	Others	0.05*	0.1*
870000	(vii) Aril	0.05*	0.1*
870010	Mace	0.05*	0.1*
870990	Others	0.05*	0.1*
900000	9. SUGAR PLANTS	0.02*	
900010	Sugar beet (root)	0.02*	0.2
900020	Sugar cane	0.02*	0.02*
900030	Chicory roots	0.02*	0.02*
900990	Others	0.02*	0.02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS		
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0.05*	0.05*
1011000	(a) Swine	0.05*	0.05*
1011010	Meat	0.05*	0.05*
1011020	Fat free of lean meat	0.05*	0.05*
1011030	Liver	0.05*	0.05*
1011040	Kidney	0.05*	0.05*
1011050	Edible offal	0.05*	0.05*
1011990	Others	0.05*	0.05*
1012000	(b) Bovine	0.05*	0.05*
1012010	Meat	0.05*	0.05*
1012020	Fat	0.05*	0.05*
1012030	Liver	0.05*	0.05*
1012040	Kidney	0.05*	0.05*
1012050	Edible offal	0.05*	0.05*
1012990	Others	0.05*	0.05*
1013000	(c) Sheep	0.05*	0.05*
1013010	Meat	0.05*	0.05*
1013020	Fat	0.05*	0.05*

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin (F) [a),b)]	Pyraclostrobin (F) [c)]
1013030	Liver	0.05*	0.05*
1013040	Kidney	0.05*	0.05*
1013050	Edible offal	0.05*	0.05*
1013990	Others	0.05*	0.05*
1014000	(d) Goat	0.05*	0.05*
1014010	Meat	0.05*	0.05*
1014020	Fat	0.05*	0.05*
1014030	Liver	0.05*	0.05*
1014040	Kidney	0.05*	0.05*
1014050	Edible offal	0.05*	0.05*
1014990	Others	0.05*	0.05*
1015000	(e) Horses, asses, mules or hinnies	0.05*	0.05*
1015010	Meat	0.05*	0.05*
1015020	Fat	0.05*	0.05*
1015030	Liver	0.05*	0.05*
1015040	Kidney	0.05*	0.05*
1015050	Edible offal	0.05*	0.05*
1015990	Others	0.05*	0.05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0.05*	0.05*
1016010	Meat	0.05*	0.05*
1016020	Fat	0.05*	0.05*
1016030	Liver	0.05*	0.05*
1016040	Kidney	0.05*	0.05*
1016050	Edible offal	0.05*	0.05*
1016990	Others	0.05*	0.05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0.05*	0.05*
1017010	Meat	0.05*	0.05*
1017020	Fat	0.05*	0.05*
1017030	Liver	0.05*	0.05*
1017040	Kidney	0.05*	0.05*
1017050	Edible offal	0.05*	0.05*
1017990	Others	0.05*	0.05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0.01*	0.01*
1020010	Cattle	0.01*	0.01*
1020020	Sheep	0.01*	0.01*
1020030	Goat	0.01*	0.01*
1020040	Horse	0.01*	0.01*
1020990	Others	0.01*	0.01*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0.05*	0.05*
1030010	Chicken	0.05*	0.05*
1030020	Duck	0.05*	0.05*
1030030	Goose	0.05*	0.05*
1030040	Quail	0.05*	0.05*
1030990	Others	0.05*	0.05*
1040000	(iv) Honey (Royal jelly, pollen)	0.05*	**0.02***
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0.05*	0.05*
1060000	(vi) Snails	0.05*	0.05*
1070000	(vii) Other terrestrial animal products	0.05*	0.05*

(*) Indicates lower limit of analytical determination

[a] MRL values as proposed by EFSA in its reasoned opinion (EFSA, 2012a) and voted by the SCFCAH on 5 October 2012. SANCO/12314/2012. Not legally enforced by 9 January 2013.

[b] acceptable CXLs adopted by Codex Alimentarius Commission in 2012 and voted by the SCFCAH on 6 December 2012. SANCO/12703/2012. Not legally enforced by 9 January 2013.

[c] MRL values as proposed by EFSA in its reasoned opinion (EFSA, 2011b) not yet voted in the SCFCAH by 9 January 2013 (working document Doc SANCO/ 10392/2012 rev. 4).

For details on the derived MRLs see the table footnotes of the reasoned opinion on the review of the existing maximum residue levels (MRLs) for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011b).

C. LIST OF AVAIALBLE MEDIAN RESIDUE VALUES FOR CHRONIC RISK ASSESSMENT

Existing uses assessed under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011b)

Commodity	Input value (mg)kg	Comments
Citrus fruit (except orange)	0.03	STMR*PeelF (EFSA, 2011b)
Almonds	0.02	Median residue (EFSA, 2011b)
Brazil nuts	0.02	Median residue (EFSA, 2011b)
Cashew nuts	0.02	Median residue (EFSA, 2011b)
Chestnuts	0.02	Median residue (EFSA, 2011b)
Hazelnuts	0.02	Median residue (EFSA, 2011b)
Macadamia	0.02	Median residue (EFSA, 2011b)
Pecans	0.02	Median residue (EFSA, 2011b)
Pistachios	0.22	Median residue (EFSA, 2011b)
Walnuts	0.02	Median residue (EFSA, 2011b)
Pome fruit	0.14	Median residue (EFSA, 2011b)
Apricots	0.43	STMR (EFSA, 2011b)
Table grapes	0.44	STMR (EFSA, 2011b)
Wine grapes	0.01	Median residue*PF (EFSA, 2011b)
Strawberries	0.31	Median residue (EFSA, 2011b)
Blackberries	0.87	Median residue (EFSA, 2011b)
Dewberries	0.87	Median residue (EFSA, 2011b)
Raspberries	0.87	Median residue (EFSA, 2011b)
Blueberries	0.94	Median residue (EFSA, 2011b)
Cranberries	0.94	Median residue (EFSA, 2011b)
Currants	0.94	Median residue (EFSA, 2011b)
Gooseberries	0.94	Median residue (EFSA, 2011b)
Rose hips	0.94	Median residue (EFSA, 2011b)
Mulberries	0.94	Median residue (EFSA, 2011b)

Commodity	Input value (mg)kg	Comments
Azarole	0.94	Median residue (EFSA, 2011b)
Elderberries	0.94	Median residue (EFSA, 2011b)
Bananas	0.02	Median residue (EFSA, 2011b)
Mangoes	0.05	Median residue (EFSA, 2011b)
Papaya	0.05	STMR (EFSA, 2011b, 2012b)
Potatoes	0.02	Median residue (EFSA, 2011b)
Beetroot	0.03	Median residue (EFSA, 2011b)
Carrots	0.12	STMR (EFSA, 2011b)
Celeriac	0.08	Median residue (EFSA, 2011b)
Horseradish	0.08	Median residue (EFSA, 2011b)
Parsnips	0.08	Median residue (EFSA, 2011b)
Parsley root	0.03	Median residue (EFSA, 2011b)
Radishes	0.08	Median residue (EFSA, 2011b)
Salsify	0.03	Median residue (EFSA, 2011b)
Garlic	0.02	Median residue (EFSA, 2011b)
Shallots	0.02	Median residue (EFSA, 2011b)
Spring onions	0.42	STMR (EFSA, 2011b, 2012b)
Tomatoes	0.1	Median residue (EFSA, 2011b)
Peppers	0.08	STMR (EFSA, 2011b)
Aubergines	0.1	Median residue (EFSA, 2011b)
Melons	0.06	Median residue*PeelF (EFSA, 2011b)
Pumpkins	0.06	Median residue*PeelF (EFSA, 2011b)
Watermelons	0.06	Median residue*PeelF (EFSA, 2011b)
Flow.brassica	0.02	Median residue (EFSA, 2011b)
Brussels sprouts	0.03	Median residue (EFSA, 2011b)

Commodity	Input value (mg)kg	Comments
Head cabbage	0.02	Median residue (EFSA, 2011b)
Kohlrabi	0.02	Median residue (EFSA, 2011b)
Lamb's lettuce	2.5	Median residue (EFSA, 2011b)
Lettuce	0.26	Median residue (EFSA, 2011b)
Scarole	0.04	Median residue (EFSA, 2011b)
Cress	2.5	Median residue (EFSA, 2011b)
Land cress	2.5	Median residue (EFSA, 2011b)
Rocket, Rucola	2.5	Median residue (EFSA, 2011b)
Red mustard	2.5	Median residue (EFSA, 2011b)
Leaves, sprouts Brassica spp	2.5	Median residue (EFSA, 2011b)
Spinach	0.05	Median residue (EFSA, 2011b)
Beet leaves	0.05	Median residue (EFSA, 2011b)
Fresh herbs	0.26	Median residue (EFSA, 2011b)
Peas (w/pods)	0.02	STMR (EFSA, 2011b)
Peas (w/out pod)	0.02	Median residue (EFSA, 2011b)
Asparagus	0.02	Median residue (EFSA, 2011b)
Celery	0.02	EU MRL (EFSA, 2011b)
Glo. artichokes	0.27	Median residue (EFSA, 2011b)
Leek	0.22	STMR (EFSA, 2011b)
Beans (dry)	0.04	Median residue (EFSA, 2011b)
Lentils (dry)	0.13	STMR (EFSA, 2011b)
Peas (dry)	0.04	Median residue (EFSA, 2011b)
Lupins (dry)	0.02	Median residue (EFSA, 2011b)
Peanuts	0.02	Median residue (EFSA, 2011b)

Commodity	Input value (mg)kg	Comments
Sunflower seed	0.04	Median residue (EFSA, 2011b)
Soya bean	0.02	Median residue (EFSA, 2011b)
Cotton seed	0.3	EU MRL (SANCO/10392/2012)
Maize grain	0.02	Median residue (EFSA, 2011b)
Rye grain	0.02	Median residue (EFSA, 2011b)
Wheat grain	0.02	EU MRL (EFSA, 2011b, 2012b
Coffee beans	0.03	STMR (EFSA, 2011b)
Hops (dried)	3.45	Median residue (EFSA, 2011b)
Sugar beet	0.04	Median residue (EFSA, 2011b)
Pig, ruminant meat	0.05(F)	EU MRL*CF(1) (EFSA, 2011b)
Pig, ruminant fat	0.05	EU MRL*CF(1) (EFSA, 2011b)
Pig, ruminant liver	0.2	EU MRL*CF(4) (EFSA, 2011b)
Pig, ruminant kidney	0.05	EU MRL*CF(1) (EFSA, 2011b)
Poultry meat	0.05(F)	EU MRL (EFSA, 2011b)
Poultry fat	0.05	EU MRL (EFSA, 2011b)
Poultry liver	0.05	EU MRL (EFSA, 2011b)
Poultry kidney	0.05	EU MRL (EFSA, 2011b)
Cattle milk	0.01	EU MRL*CF(1) (EFSA, 2011b)
Sheep milk	0.01	EU MRL*CF(1) (EFSA, 2011b)
Goat milk	0.01	EU MRL*CF(1) (EFSA, 2011b)
Birds' eggs	0.05	EU MRL (EFSA, 2011b)

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
BE	Belgium
bw	body weight
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation, *French*)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
DT_{90}	period required for 90 % dissipation (define method of estimation)
EC	European 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
GCPF	Global Crop Protection Federation (former GIFAP)
GLP	Good Laboratory Practice
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
i.e.	that is (id est, Latin)
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
LOQ	limit of quantification
LWA	leaf wall area

MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PeelF	pelling factor
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
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
RMS	rapporteur Member State
SCFCAH	Standing Committee on the Food Chain and Animal Health
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organisation
WG	water dispersible granule
wk	week
yr	year