

REASONED OPINION

Reasoned opinion on the modification of the existing MRL for pyraclostrobin in chicory roots¹

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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 MRL for the active substance pyraclostrobin in chicory roots. In order to accommodate for the intended use of pyraclostrobin, Belgium proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.02* mg/kg to 0.09 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 data are sufficient to derive a MRL proposal of 0.08 mg/kg for the intended use on chicory roots. Adequate analytical enforcement methods are available to control the residues of pyraclostrobin on the commodity under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of pyraclostrobin on chicory roots will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

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KEY WORDS

pyraclostrobin, chicory roots, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, strobilurin fungicide and plant growth regulator, desmethoxy metabolite 500M07

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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 MRL for the active substance pyraclostrobin in chicory roots. In order to accommodate for the intended use of pyraclostrobin, Belgium proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.02* mg/kg to 0.09 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 10 October 2013.

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/EEC, the Commission Review Report on pyraclostrobin, the JMPR Evaluation report, as well as the conclusions from previous EFSA opinions on pyraclostrobin.

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 an ADI of 0.03 mg/kg bw per day and an ARfD of 0.03 mg/kg bw.

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 definition for enforcement and risk assessment in all plant commodities treated by foliar application is pyraclostrobin. For the uses on the crop under consideration, EFSA concludes that the metabolism of pyraclostrobin is sufficiently addressed, thus the derived residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.08 mg/kg for the intended use on chicory roots. Adequate analytical enforcement methods are available to control the residues of pyraclostrobin on the commodity under consideration at the validated LOQ of 0.02 mg/kg.

Studies investigating the nature of pyraclostrobin residues in processed commodities were assessed in the framework of peer review and showed that the compound is hydrolytically stable under processing conditions representative of pasteurisation, boiling/cooking and sterilisation. Therefore for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable.

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 chicory roots 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. EFSA updates this risk assessment with median residue values on chicory roots derived from the submitted supervised residue trials.

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 14 % of the ADI (DE child). The

contribution of residues in chicory roots to the total consumer exposure is insignificant (lower than 0.1 % of the ADI). The calculated maximum exposure in percentage of ARfD was 0.7 % (Belgian adult).

EFSA concludes that the proposed use of pyraclostrobin on chicory roots will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

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: pyraclostrobin (F)				
900030	Chicory roots	0.02*	0.08	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the intended uses on this crop.

(a): According to Annex I of Regulation (EC) No 396/2005.

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

(F): Fat-soluble.

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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.

Belgium hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRL for the pyraclostrobin in chicory roots. 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 10 October 2013.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013-00820 and the following subject:

Pyraclostrobin - Application to modify the existing MRL in chicory roots

Belgium proposed to raise the existing MRL of pyraclostrobin in chicory roots from the limit of quantification of 0.02* mg/kg to 0.09 mg/kg.

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

TERMS OF REFERENCE

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

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

In this particular case the deadline for providing the reasoned opinion is 10 January 2014.

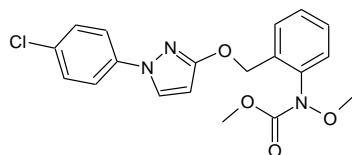
³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.

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

⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

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



Molecular weight: 387.82 g/mol

Pyraclostrobin is a fungicide belonging to the group of strobilurins. Pyraclostrobin is active against fungal diseases both on plant surface and within tissues. It 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 crops.

Pyraclostrobin was evaluated in the framework of Council Directive 91/414/EEC with Germany designated as rapporteur Member State (RMS) and it was included in Annex I for use as fungicide. Since 2009, pyraclostrobin could be also authorised for the uses as plant growth regulator (Regulation (EU) No 2009/25⁶). In accordance with Commission Implementing Regulation (EU) No 540/2011⁷ 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 current EU MRLs for pyraclostrobin are established in Annexes II of Regulation (EC) No 396/2005 (Appendix C). The existing EU MRLs for pyraclostrobin on chicory root is set at the LOQ of 0.02* mg/kg. In 2011, EFSA issued a reasoned opinion on the revision of the existing MRLs for Pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011). Codex Alimentarius has established CXLs for a wide range of commodities, but not for the crop under consideration. The CXLs established by Codex Alimentarius Commission in 2012 have been taken over in the EU legislation by Regulation No 293/2013⁸.

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

⁶ Commission Directive 2009/25/EC of 2 April 2009 amending Council Directive 91/414/EEC as regards an extension of the use of the active substance pyraclostrobin. OJ L 91, 03/04/2009, p. 20–22.

⁷ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances OJ L 153, 11.6.2011, p. 1–186.

⁸ Commission Regulation (EU) No 293/2013 of 20 March 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for emamectin benzoate, etofenprox, etoxazole, flutriafol, glyphosate, phosmet, pyraclostrobin, spinosad and spirotetramat in or on certain products OJ L 96, 05/04/2013, p. 1–30.

ASSESSMENT

EFSA bases its assessment on the 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 Review Report on pyraclostrobin (EC, 2004) the JMPR Evaluation report (FAO, 2011) as well as the conclusions from previous EFSA opinions on pyraclostrobin (EFSA, 2011b, 2012, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a-b, 2011; OECD, 2011).

1. Method of analysis

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

Adequate analytical methods based on HPLC-MS/MS or HPLC-UV are available to monitor pyraclostrobin residues in high water, high acid and high fat content commodities. The LOQ for matrices with high water content like chicory roots was reported as 0.02 mg/kg (Germany, 2001; EFSA, 2011).

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 crop under consideration belongs to high water content group, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRL for pyraclostrobin on chicory roots 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 chicory roots are normally not fed to livestock.

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 (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

⁹ Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

In the framework of the peer review, the metabolism of pyraclostrobin was investigated after foliar application 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. The metabolic pathway was considered to be similar in all investigated crops. For the plant commodities, the peer review concluded the residue definitions for risk assessment and enforcement as parent pyraclostrobin (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, 2011).

EFSA concludes that for chicory roots the metabolism in primary crops is sufficiently elucidated and that the residue definitions derived 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

In support of this application four residue trials were submitted. The trials were performed under field conditions in the Netherlands, France and Italy during 2005-2006 according with the intended GAP (*2 x 0.1 kg a.s/ha with a PHI of 14 days*). As chicory root is a minor crop the number of trials is sufficient to derive a MRL proposal.

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 3-1.

The storage stability of pyraclostrobin in primary crops was investigated in the DAR under Directive 91/414/EEC (Germany, 2001). Residues of pyraclostrobin were found to be stable at ≤ -18 °C for up to 18 months in matrices with high water, high acid, and high oil content as well as in dry matrices. As the crop under consideration belongs to the high water content and the supervised residue trial samples were stored up to 8 months at ≤ -18 °C, it is concluded that the residue data are valid with regard to storage stability.

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

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.08 mg/kg¹⁰ for the intended use on chicory roots.

¹⁰ The difference in the MRL proposed by the EMS is a consequence of the calculation methodology.

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									
Chicory root	NEU	Outdoor	<0.01, 0.03, 0.031, 0.039	<0.01, 0.03, 0.031, 0.039	0.03	0.04	0.08	1	R _{ber} = 0.07 R _{max} = 0.09 MRL _{OECD} = 0.08

(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).

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of pyraclostrobin residues was investigated during the peer review. A study was conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90 °C, pH 4), boiling/brewing/baking (60 minutes at 100 °C pH 5) and sterilisation (20 minutes at 120 °C, pH 6). This study demonstrated that food processes such as brewing, cooking, sterilisation or pasteurisation, will not impact on the nature of pyraclostrobin residues. The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops (EFSA, 2011b).

In general chicory roots are used for different purposes such as production of inulin used as sweeteners for candies, surrogate for coffee, etc. Although, specific processing studies for the chicory roots were not submitted under this application, additional studies are not necessary, since the residue level in the RAC did not exceeded the trigger value of 0.1 mg/kg.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Chicory roots 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. According to the soil degradation studies performed in the framework of the peer review, the highest DT₉₀ value of pyraclostrobin, based on the field and laboratory studies, is 230 and 163 days, respectively. The soil desmethoxy metabolite (500M07)¹¹ shows higher persistency in the soil with a DT₉₀ value amounting to 529 days (Germany, 2001).

3.1.2.2. Nature of residues

The metabolism of pyraclostrobin in rotational crops was assessed during the peer review in lettuce, radish and wheat with [tolyl-U-¹⁴C]-pyraclostrobin and [chlorophenyl-U-¹⁴C]-pyraclostrobin. The radiolabelled active substance was applied on a bare soil once at an application rate of 0.9 kg a.s./ha and respective crops were sown or planted at 30, 120 and 365 DAT. The total radioactive residues in the edible parts of succeeding crops were very low for all plant back intervals: radish roots, lettuce ≤0.04 mg/kg and wheat grain ≤0.089 mg/kg (EFSA 2011b).

The data on metabolism and distribution of pyraclostrobin in succeeding crops demonstrate that the metabolism of the active substance in rotational crops is similar to the pathway observed in primary crops. As the metabolite is of minor relevance, the same residue definition applies. No accumulation of pyraclostrobin or its degradation products (including 500M07) was observed in the parts of plants used for human or animal consumption (EFSA, 2011b).

Based on the available information on the nature and magnitude of the residues, EFSA concludes that relevant residue levels are unlikely to occur in rotational crops provided that the compound is used on chicory roots according to the proposed GAP.

4. Consumer risk assessment

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). 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 (EFSA, 2007). EFSA now updated this risk assessment with the median residue values for chicory roots (see Table 3-1) and the median residue values crops for which the MRLs were recently amended (EFSA,

¹¹ 500M07: Methyl N-(2-[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxymethyl]phenyl) carbamate.

2012, 2013). The updated exposure calculation also took into account the CXLs that were recently taken over in the EU legislation (Regulation No 293/2013).

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.

No consumption data are available in the EFSA PRIMo to estimate the short term dietary exposure resulting from residues in chicory roots. However, based on the data from EFSA comprehensive food consumption database¹² (EFSA, 2011a) and the MRL proposal for chicory roots an acute exposure calculation was performed considering that a Belgian adult consumes a large portion of 189 g of chicory roots per day. The calculated maximum exposure in percentage of ARfD was 0.7 % (Belgian adult diet)

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: Plant commodities: pyraclostrobin Products of animal origin: sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin (EFSA, 2011)				
Chicory roots	0.03	Median residue (Table 3-1)	0.08	MRL proposal
Barley, oats	0.35	STMR (FAO, 2011)	Acute risk assessment was undertaken only with regard to the chicory roots.	
Blackberries	0.87	STMR (FAO, 2011)		
Blueberries	0.78	STMR (FAO, 2011)		
Cherries	0.51	STMR (FAO, 2011)		
Courgettes, gherkins	0.15	Median residue (EFSA 2013)		
Cucumbers	0.15	Median residue (EFSA 2013)		
Jerusalem artichokes	0.03	Median residue (EFSA 2013)		
Kale, Chinese cabbage, other leafy brassica	0.19	Median residue (EFSA, 2012a)		
Millet	0.01	Median residue (EFSA, 2012a)		
Onions	0.06	STMR (FAO, 2011)		
Oranges	0.07 (0.49*0.14)	Median residue* peeling (FAO, 2011)		
Papaya	0.05	STMR (FAO, 2011)		

¹² A Belgian adult weighting 70 kg and consuming 189 g of chicory roots per day, 95 percentile.

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Peaches	0.07	STMR (FAO, 2011)		
Plums	0.09	STMR (FAO, 2011)		
Raspberries	0.87	STMR (FAO, 2011)		
Rye	0.02	STMR (FAO, 2011)		
Sorghum	0.03	STMR (FAO, 2011)		
Strawberries	0.2	STMR (FAO, 2011)		
Wheat	0.02	STMR (FAO, 2011)		
Other commodities of plant and animal origin	See the appendix D (EFSA, 2011b)			

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

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 14 % of the ADI (DE child). The contribution of residues in chicory roots to the total consumer exposure is insignificant (lower than 0.1 % of the ADI).

For the short-term consumer health risk EFSA estimated an exposure of less than 1 %.

EFSA concludes that the intended use of pyraclostrobin on crop under consideration 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

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/EEC, the Commission Review Report on pyraclostrobin, the JMPR Evaluation report, as well as the conclusions from previous EFSA opinions on pyraclostrobin.

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 an ADI of 0.03 mg/kg bw per day and an ARfD of 0.03 mg/kg bw.

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 definition for enforcement and risk assessment in all plant commodities treated by foliar application is pyraclostrobin. For the uses on the crop under consideration, EFSA concludes that the metabolism of pyraclostrobin is sufficiently addressed, thus the derived residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.08 mg/kg for the intended use on chicory roots. Adequate analytical enforcement methods are available to control the residues of pyraclostrobin on the commodity under consideration at the validated LOQ of 0.02 mg/kg.

Studies investigating the nature of pyraclostrobin residues in processed commodities were assessed in the framework of peer review and showed that the compound is hydrolytically stable under processing conditions representative of pasteurisation, boiling/cooking and sterilisation. Therefore for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable.

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 chicory roots 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. EFSA updates this risk assessment with median residue values on chicory roots derived from the submitted supervised residue trials.

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 14 % of the ADI (DE child). The contribution of residues in chicory roots to the total consumer exposure is insignificant (lower than 0.1 % of the ADI). The calculated maximum exposure in percentage of ARfD was 0.7 % (Belgian adult).

EFSA concludes that the proposed use of pyraclostrobin on chicory roots will not result in a consumer exposure exceeding the toxicological reference value and therefore is 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)				
900030	Chicory roots	0.02*	0.08	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the intended uses on this crop.

(a): According to Annex I of Regulation (EC) No 396/2005.

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

(F): Fat-soluble.

REFERENCES

- Belgium, 2013. Evaluation report on the modification of MRL for pyraclostrobin in chicory roots prepared by the evaluating Member State under Article 8 of Regulation (EC) No 396/2005, 04 September 2013, 14 pp.
- CEN (European Committee for Standardisation), 2008. Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE. QuEChERS-method. EN 15662.2008. November 2008.
- EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95-rev.4.
- EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.
- EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realisation of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6.
- EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.
- EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5.
- EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.
- EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.
- EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95.
- EC (European Commission), 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414). SANCO/3029/99-rev.4.
- EC (European Commission), 2004. Review report for the active substance pyraclostrobin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 November 2003 in view of the inclusion of pyraclostrobin in Annex I of Council Directive 91/414/EEC. SANCO/1420/2001-Final, 8 September 2004.
- EC (European Commission), 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.
- EC (European Commission), 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8.1.
- EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9.
- EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs. Available online: www.efsa.europa.eu
- EFSA (European Food Safety Authority), 2011a. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment prepared by EFSA Data Collection and Monitoring (DCM) Unit. EFSA Journal 2011;9(3):2097, 34 pp. doi:10.2903/j.efsa.2011.2097
- EFSA (European Food Safety Authority), 2011b. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005 prepared by EFSA Pesticides (PRAS) Unit. EFSA Journal 2011;9(8):2344, 92 pp. doi:10.2903/j.efsa.2011.2344

- EFSA (European Food Safety Authority), 2012. Reasoned opinion on the modification of the existing MRLs for pyraclostrobin in leafy brassica and various cereals. EFSA Journal 2012;10(3):2606, 36 pp. doi:10.2903/j.efsa.2012.2606
- EFSA (European Food Safety Authority), 2013. 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
- FAO (Food and Agriculture Organization of the United Nations), 2011. Pesticide residues in food – 2011. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 211.
- Germany, 2001. Draft assessment report on the active substance pyraclostrobin prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EEC, August 2001.
- Germany, 2003. Addendum to the draft assessment report on the active substance pyraclostrobin prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EEC, October 2003.
- Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forest. Braunschweig, Germany.
- OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues.

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)
				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	
Chicory root	Belgium (NEU)	F	<i>Sclerotinia</i> , <i>Alternaria</i> , Rust	WG	6.7 % (+26.7 % boscalid)	Spraying		1-2				0.1 (pyraclostrobin) 0.4 (boscalid)	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

Appendix B. PesticideResidue Intake Model

Pyraclostrobin						Prepare workbook for refined calculations	
Status of the active substance:		approved		Code no.			
LOQ (mg/kg bw):				proposed LOQ:			
Toxicological end points						Undo refined calculations	
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 - 14						
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	pTMRs at LOQ (in % of ADI)
	14.5	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	
	7.4	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	
	6.2	FR toddler		1.2	Apples	1.0	Carrots	0.5	Leek	
	5.5	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	
	5.1	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	
	3.0	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	
	2.5	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	
	2.0	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	
	1.7	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 pTMRs 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 variability 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):			---		
	IESTI 1			*)			IESTI 2			*)		
	Highest % of ARfD/ADI			Commodities			Highest % of ARfD/ADI			Commodities		
	0.7			Chicory roots			0.7			Chicory roots		
	pTMR/ threshold MRL (mg/kg)			0.08 / -			pTMR/ threshold MRL (mg/kg)			0.08 / -		

Appendix C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 14/03/2014 10:31))

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	1
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	2
110030	Lemons (Citron, lemon)	1
110040	Limes	1
110050	Mandarins (Clementine, tangerine and other hybrids)	1
110990	Others	1
120000	(ii) Tree nuts (shelled or unshelled)	
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	1
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	0,5
130010	Apples (Crab apple)	0,5
130020	Pears (Oriental pear)	0,5
130030	Quinces	0,5
130040	Medlar	0,5
130050	Loquat	0,5
130990	Others	0,5
140000	(iv) Stone fruit	
140010	Apricots	1
140020	Cherries (sweet cherries, sour cherries)	3
140030	Peaches (Nectarines and similar hybrids)	0,3
140040	Plums (Damson, greengage, mirabelle)	0,8
140990	Others	0,02*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	
151010	Table grapes	1 (ft)

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin
151020	Wine grapes	2
152000	(b) Strawberries	1,5
153000	(c) Cane fruit	
153010	Blackberries	3
153020	Dewberries (Loganberries, Boysenberries, and cloudberrys)	2
153030	Raspberries (Wineberries)	3
153990	Others	2
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	4
154020	Cranberries	3
154030	Curants (red, black and white)	3
154040	Gooseberries (Including hybrids with other ribes species)	3
154050	Rose hips	3
154060	Mulberries (arbutus berry)	3
154070	Azarole (mediterranean medlar)	3
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sawallowthorn), hawthorn, service berries, and other treeberries)	3
154990	Others	3
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomarac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030	Passion fruit	0,02*
162040	Prickly pear (cactus fruit)	0,02*
162050	Star apple	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mamme sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030	Mangoes	0,05
163040	Papaya	0,07
163050	Pomegranate	0,02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,02*
163070	Guava	0,02*
163080	Pineapples	0,02*
163090	Bread fruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
212020	Sweet potatoes	0,02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,1
213020	Carrots	0,5
213030	Celeriac	0,3
213040	Horseradish	0,3
213050	Jerusalem artichokes	0,06
213060	Parsnips	0,3
213070	Parsley root	0,1
213080	Radishes (Black radish, Japanese radish, small radish and similar	0,5

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin
	varieties)	
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,1
213100	Swedes	0,02*
213110	Turnips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	
220010	Garlic	0,3
220020	Onions (Silverskin onions)	1,5
220030	Shallots	0,3
220040	Spring onions (Welsh onion and similar varieties)	1,5
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	0,3
231020	Peppers (Chilli peppers)	0,5
231030	Aubergines (egg plants) (Pepino)	0,3
231040	Okra, lady's fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbits - edible peel	0,5
232010	Cucumbers	0,5
232020	Gherkins	0,5
232030	Courgettes (Summer squash, marrow (patisson))	0,5
232990	Others	0,5
233000	(c) Cucurbits-inedible peel	0,5
233010	Melons (Kiwano)	0,5
233020	Pumpkins (Winter squash)	0,5
233030	Watermelons	0,5
233990	Others	0,5
234000	(d) Sweet corn	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,1
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,1
241020	Cauliflower	0,1
241990	Others	0,1
242000	(b) Head brassica	
242010	Brussels sprouts	0,3
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,2
242990	Others	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin
243000	(c) Leafy brassica	1,5
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	1,5
243020	Kale (Borecole (curly kale), collards)	1,5
243990	Others	1,5
244000	(d) Kohlrabi	0,02*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicaceae	
251010	Lamb's lettuce (Italian cornsalad)	10
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	2
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leave endive, sugar loaf)	0,4
251040	Cress	10
251050	Land cress	10
251060	Rocket, Rucola (Wild rocket)	10
251070	Red mustard	10
251080	Leaves and sprouts of Brassica spp (Mizuna)	10
251990	Others	10
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,5
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,5
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves)	0,02*
254000	(d) Water cress	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	2
256010	Chervil	2
256020	Chives	2
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	2
256040	Parsley	2
256050	Sage (Winter savory, summer savory,)	2
256060	Rosemary	2
256070	Thyme (marjoram, oregano)	2

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin
256080	Basil (Balm leaves, mint, peppermint)	2
256090	Bay leaves (laurel)	2
256100	Tarragon (Hyssop)	2
256990	Others	2
260000	(vi) Legume vegetables (fresh)	0,02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,02*
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	0,02* (ft)
270040	Fennel	0,02*
270050	Globe artichokes	2
270060	Leek	0,7
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*
270090	Palm hearts	0,02*
270990	Others	0,02*
280000	(viii) Fungi	0,02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*
280020	Wild (Chanterelle, Truffle, Morel,)	0,02*
280990	Others	0,02*
290000	(ix) Sea weeds	0,02*
300000	3. PULSES, DRY	
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0,3
300020	Lentils	0,5
300030	Peas (Chickpeas, field peas, chickling vetch)	0,3
300040	Lupins	0,05
300990	Others	0,3
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,2
401020	Peanuts	0,04

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin
401030	Poppy seed	0,2
401040	Sesame seed	0,2
401050	Sunflower seed	0,3
401060	Rape seed (Bird rapeseed, turnip rape)	0,2
401070	Soya bean	0,05
401080	Mustard seed	0,2
401090	Cotton seed	0,3
401100	Pumpkin seeds	0,02*
401110	Safflower	0,2
401120	Borage	0,2
401130	Gold of pleasure	0,2
401140	Hempseed	0,02*
401150	Castor bean	0,2
401990	Others	0,02*
402000	(ii) Oilfruits	0,02*
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,02*
402030	Palmfruit	0,02*
402040	Kapok	0,02*
402990	Others	0,02*
500000	5. CEREALS	
500010	Barley	1
500020	Buckwheat	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff)	0,02*
500050	Oats	1
500060	Rice	0,02*
500070	Rye	0,2
500080	Sorghum	0,5
500090	Wheat (Spelt Triticale)	0,2
500990	Others	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,3 (ft)
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	15
800000	8. SPICES	
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	(ft)
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin
860990	Others	0,1 *
870000	(vii) Aril	0,1 *
870010	Mace	0,1 *
870990	Others	0,1 *
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0,2
900020	Sugar cane	0,02 *
900030	Chicory roots	0,02 *
900990	Others	0,02 *
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Tissue	0,05 *
1011000	(a) Swine	0,05 *
1011010	Muscle	0,05 *
1011020	Fat	0,05 *
1011030	Liver	0,05 *
1011040	Kidney	0,05 *
1011050	Edible offal	0,05 *
1011990	Others	0,05 *
1012000	(b) Bovine	0,05 *
1012010	Muscle	0,05 *
1012020	Fat	0,05 *
1012030	Liver	0,05 *
1012040	Kidney	0,05 *
1012050	Edible offal	0,05 *
1012990	Others	0,05 *
1013000	(c) Sheep	0,05 *
1013010	Muscle	0,05 *
1013020	Fat	0,05 *
1013030	Liver	0,05 *
1013040	Kidney	0,05 *
1013050	Edible offal	0,05 *
1013990	Others	0,05 *
1014000	(d) Goat	0,05 *
1014010	Muscle	0,05 *
1014020	Fat	0,05 *
1014030	Liver	0,05 *
1014040	Kidney	0,05 *
1014050	Edible offal	0,05 *
1014990	Others	0,05 *
1015000	(e) Horses, asses, mules or hinnies	0,05 *
1015010	Muscle	0,05 *
1015020	Fat	0,05 *
1015030	Liver	0,05 *
1015040	Kidney	0,05 *
1015050	Edible offal	0,05 *
1015990	Others	0,05 *
1016000	(f) Poultry -chicken, geese, duck,	0,05 *

Code number	Groups and examples of individual products to which the MRLs apply	Pyraclostrobin
	turkey and Guinea fowl-, ostrich, pigeon	
1016010	Muscle	0,05 *
1016020	Fat	0,05 *
1016030	Liver	0,05 *
1016040	Kidney	0,05 *
1016050	Edible offal	0,05 *
1016990	Others	0,05 *
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05 *
1017010	Muscle	0,05 *
1017020	Fat	0,05 *
1017030	Liver	0,05 *
1017040	Kidney	0,05 *
1017050	Edible offal	0,05 *
1017990	Others	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 *
1020010	Cattle	0,01 *
1020020	Sheep	0,01 *
1020030	Goat	0,01 *
1020040	Horse	0,01 *
1020990	Others	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 *
1030010	Chicken	0,05 *
1030020	Duck	0,05 *
1030030	Goose	0,05 *
1030040	Quail	0,05 *
1030990	Others	0,05 *
1040000	(iv) Honey (Royal jelly, pollen)	0,05 *
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05 *
1060000	(vi) Snails	0,05 *
1070000	(vii) Other terrestrial animal products	0,05 *

(*) Indicates lower limit of analytical determination

Appendix D. LIST OF AVAILABLE MEDIAN RESIDUE VALUES FOR CHRONIC RISK ASSESSMENT

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

Commodity	Input value (mg/kg)	Comments	Commodity	Input value (mg/kg)	Comments	Commodity	Input value (mg/kg)	Comments	Commodity	Input value (mg/kg)	Comments
Citrus fruit	0.03	STMR*PeelF (EFSA, 2011)	Carrots	0.12	STMR (EFSA, 2011)	Land cress	2.5	Median residue (EFSA, 2011)	Pig, ruminant meat	0.05 ^(f)	EU MRL*CF(1) (EFSA, 2011)
Almonds	0.02	Median residue (EFSA, 2011)	Celeriac	0.08	Median residue (EFSA, 2011)	Rocket/Rucola	2.5	Median residue (EFSA, 2011)	Pig, ruminant fat	0.05	EU MRL*CF(1) (EFSA, 2011)
Brazil nuts	0.02	Median residue (EFSA, 2011)	Horseradish	0.08	Median residue (EFSA, 2011)	Red mustard	2.5	Median residue (EFSA, 2011)	Pig, ruminant liver	0.2	EU MRL*CF(4) (EFSA, 2011)
Cashew nuts	0.02	Median residue (EFSA, 2011)	Parasnips	0.08	Median residue (EFSA, 2011)	Leaves, sprouts Brassica spp	2.5	Median residue (EFSA, 2011)	Pig, ruminant kidney	0.05	EU MRL*CF(1) (EFSA, 2011)
Chestnuts	0.02	Median residue (EFSA, 2011)	Parsley root	0.03	Median residue (EFSA, 2011)	Spinach	0.05	Median residue (EFSA, 2011)	Poultry meat	0.05 ^(f)	EU MRL (EFSA, 2011)
Hazelnuts	0.02	Median residue (EFSA, 2011)	Radishes	0.08	Median residue (EFSA, 2011)	Beet leaves	0.05	Median residue (EFSA, 2011)	Poultry fat	0.05	EU MRL (EFSA, 2011)
Macadamia	0.02	Median residue (EFSA, 2011)	Salsify	0.03	Median residue (EFSA, 2011)	Fresh herbs	0.26	Median residue (EFSA, 2011)	Poultry liver	0.05	EU MRL (EFSA, 2011)
Pecans	0.02	Median residue (EFSA, 2011)	Garlic	0.02	Median residue (EFSA, 2011)	Peas (w/pods)	0.02	STMR (EFSA, 2011)	Poultry kidney	0.05	EU MRL (EFSA, 2011b)
Pistachios	0.22	Median residue (EFSA, 2011)	Shallots	0.02	Median residue (EFSA, 2011)	Peas (w/outpod)	0.02	Median residue (EFSA, 2011)	Cattle milk	0.01	EU MRL*CF(1) (EFSA, 2011)
Walnuts	0.02	Median residue (EFSA, 2011)	Spring onions	0.42	STMR (EFSA, 2011b, 2012)	Asparagus	0.02	Median residue (EFSA, 2011)	Sheep milk	0.01	EU MRL*CF(1) (EFSA, 2011)
Pome fruit	0.14	Median residue (EFSA, 2011)	Tomatoes	0.1	Median residue (EFSA, 2011)	Celery	0.02	EU MRL (EFSA, 2011b)	Goat milk	0.01	EU MRL*CF(1) (EFSA, 2011)
Apricots	0.43	STMR (EFSA, 2011)	Peppers	0.08	STMR (EFSA, 2011)	Glo. artichokes	0.27	Median residue (EFSA, 2011b)	Birds' eggs	0.05	EU MRL (EFSA, 2011)
Table grapes	0.44	STMR (EFSA, 2011)	Aubergines	0.1	Median residue (EFSA, 2011)	Leek	0.22	STMR (EFSA, 2011)			
Wine grapes	0.01	Median residue*PF (EFSA, 2011)	Melons	0.06	Median residue*PeelF (EFSA, 2011)	Beans (dry)	0.04	Median residue (EFSA, 2011)			
Dewberries	0.87	Median residue (EFSA, 2011)	Pumpkins	0.06	Median residue*PeelF (EFSA, 2011)	Lentils (dry)	0.13	STMR (EFSA, 2011)			
Cranberries	0.94	Median residue (EFSA, 2011)	Watermelons	0.06	Median residue*PeelF (EFSA, 2011)	Peas (dry)	0.04	Median residue (EFSA, 2011)			
Currants	0.94	Median residue (EFSA, 2011)	Flow brassica	0.02	Median residue (EFSA, 2011)	Lupins (dry)	0.02	Median residue (EFSA, 2011)			
Gooseberries	0.94	Median residue (EFSA, 2011)	Brussels sprouts	0.03	Median residue (EFSA, 2011)	Peanuts	0.02	Median residue (EFSA, 2011)			
Rose hips	0.94	Median residue (EFSA, 2011)	Head cabbage	0.02	Median residue (EFSA, 2011)	Sunflower seed	0.04	Median residue (EFSA, 2011)			
Mulberries	0.94	Median residue (EFSA, 2011)	Kohlrabi	0.02	Median residue (EFSA, 2011)	Soya bean	0.02	Median residue (EFSA, 2011)			
Azarole	0.94	Median residue (EFSA, 2011)	Lamb's lettuce	2.5	Median residue (EFSA, 2011)	Cotton seed	0.3	EU MRL (SANCO/10392/2012)			
Elderberries	0.94	Median residue (EFSA, 2011)	Lettuce	0.26	Median residue (EFSA, 2011)	Maize grain	0.02	Median residue (EFSA, 2011)			
Bananas	0.02	Median residue (EFSA, 2011)	Scarole	0.04	Median residue (EFSA, 2011)	Coffee beans	0.03	STMR (EFSA, 2011)			
Mangoes	0.05	Median residue (EFSA, 2011)	Cress	2.5	Median residue (EFSA, 2011)	Hops (dried)	3.45	Median residue (EFSA, 2011)			
Potatoes	0.02	Median residue (EFSA, 2011)				Sugar beet	0.04	Median residue (EFSA, 2011)			
Beetroot	0.03	Median residue (EFSA, 2011)									

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
DAT	days after treatment
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 Organization of the United Nations
GAP	good agricultural practice
ha	hectare
HPLC	high performance liquid chromatography
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
MRL	maximum residue level
MS/MS	tandem mass spectrometry
OECD	Organisation for Economic Co-operation and Development
Peel _F	peeling factor
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
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
SANCO	Directorate-General for Health and Consumers
STMR	supervised trials median residue
UV	ultra-violet (detector)
WHO	World Health Organization
WG	water dispersible granule