REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for pyraclostrobin in swedes and turnips[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, United Kingdom (UK) hereafter referred to as the evaluating Member State (EMS), received an application from Horticulture Development Company (HDC), to modify the existing maximum residue levels (MRLs) for the active substance pyraclostrobin in swedes and turnip. In order to accommodate for the intended uses of pyraclostrobin in northern Europe (NEU), UK proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.02* mg/kg to 0.09 mg/kg. UK 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 the MRL proposals of 0.09 mg/kg for the proposed uses on swedes and turnips. Based on the risk assessment results, EFSA concludes that the proposed uses of pyraclostrobin on swedes and turnips will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

KEY WORDS

pyraclostrobin, swedes and turnips, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, strobilurin fungicide, plant growth regulator product

[1] On request from the European Commission, Question No EFSA-Q-2014-00398, approved on 14 October 2014.

[2] Correspondence: pesticides.mrl@efsa.europa.eu

Suggested citation: EFSA (European Food Safety Authority), 2014. Reasoned opinion on the modification of the existing MRLs for pyraclostrobin in swedes and turnips. EFSA Journal 2014;12(10):3872, 19 pp. doi:10.2903/j.efsa.2014.3872

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, United Kingdom (UK) hereafter referred to as the evaluating Member State (EMS), received an application from Horticulture Development Company (HDC), to modify the existing maximum residue levels (MRLs) for the active substance pyraclostrobin in swedes and turnip. In order to accommodate for the intended uses of pyraclostrobin in northern Europe (NEU), UK proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.02* mg/kg to 0.09 mg/kg. UK 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 27 May 2014.

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, the JMPR Evaluation report, as well as the conclusions from previous EFSA opinions issued under Article 12 MRL review and under Article 10 applications.

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 acute daily intake (ADI) of 0.03 mg/kg bw per day and an acute reference dose (ARfD) of 0.03 mg/kg bw.

The metabolism of pyraclostrobin in primary crops was investigated in three different crop groups during the peer review and the residue definition for enforcement and risk assessment in all plant commodities was proposed as pyraclostrobin. These residue definitions were confirmed in the framework of the MRLs review under Article 12 of Regulation (EC) 396/2005.

EFSA concludes that the submitted residue trials are sufficient to derive the MRL proposals of 0.09 mg/kg for the proposed uses on swedes and turnips. Adequate analytical enforcement methods are available to control the residues of pyraclostrobin at the validated LOQ of 0.02* mg/kg.

Specific studies investigating the magnitude of residues in processed commodities are not required, as the residue levels in raw agricultural commodities (RAC) did not exceed the trigger value of 0.1 mg/kg.

The occurrence of pyraclostrobin residues in rotational crops was investigated in the DAR. Based on the available information on the nature and magnitude of residues in succeeding crops, it was concluded that significant residue levels are unlikely to occur in rotational crops provided that the active substance is used on swedes and turnips according to the proposed GAP (Good Agricultural Practice).

The contribution of pyraclostrobin residues in swedes and turnips to the overall dietary livestock burden is insignificant. Thus, EFSA concluded that an amendment of the MRLs for the products of animal origin is unnecessary.

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 considering the existing uses of pyraclostrobin at the EU level and all adopted Codex maximum residue levels (CXLs) in European legislation. EFSA updated this consumer risk assessment considering the median residue values derived for swedes and turnips and taking into account the other food commodities assessed under Article 10 of Regulation (EU) 396/2005 after Article 12 MRL review was issued.

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 15 % of the ADI (related DE diet). The contribution of residues in swedes and turnip to the total consumer exposure was lower than 0.1 % of the ADI (IE adult).

No acute consumer risk was identified in relation to the MRL proposals for crops under consideration. The calculated maximum exposure in percentage of the ARfD was 10 % for swedes and 7 % for turnips (UK infant).

EFSA concludes that the proposed uses of pyraclostrobin on swedes and turnips will not result in a consumer exposure exceeding the toxicological reference values and therefore is 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)				
213100	Swedes	0.02*	0.09	The MRL proposals are sufficiently supported by data and no consumer health risk was identified for the intended uses of pyraclostrobin on these crops in NEU.
213110	Turnips	0.02*	0.09	

(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.

TABLE OF CONTENTS

Abstract 1
Summary 2
Background 5
Terms of reference 5
The active substance and its use pattern 5
Assessment 7
1. Method of analysis 7
1.1. Methods for enforcement of residues in food of plant origin 7
1.2. Methods for enforcement of residues in food of animal origin 7
2. Mammalian toxicology 7
3. Residues 8
3.1. Nature and magnitude of residues in plant 8
3.1.1. Primary crops 8
3.1.2. Rotational crops 10
3.2. Nature and magnitude of residues in livestock 10
3.2.1. Dietary burden of livestock 10
4. Consumer risk assessment 11
Conclusions and recommendations 12
References 14
Appendices 16
Appendix A. Good Agricultural Practice (GAPs) 16
Appendix B. Pesticide Residue Intake Model (PRIMo) 17
Abbreviations 18

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 an MRL in accordance with the provisions of Article 7 of that Regulation.

United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from the company HCD[6] to modify the existing MRLs for the active substance pyraclostrobin in swede and turnip. This application was notified to the European Commission and EFSA, and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 27 May 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00398 and the following subject:

Pyraclostrobin - Application to modify the existing MRL in swedes and turnips

United Kingdom proposed to raise the existing MRLs of pyraclostrobin in swedes and turnips 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 27 August 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.

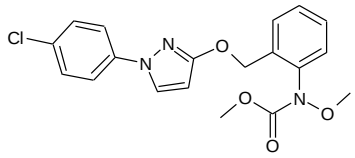
[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

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

[6] HDC (AHDB), c/o STC, Cawood, Selby, North Yorkshire, YO8 3TZ, United Kingdom.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

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



Molecular weight: 387.8 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. In 2009, pyraclostrobin was also authorised for the uses as plant growth regulator (Regulation (EU) No 2009/25[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. 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. An MRL review under article 12 of this Regulation was conducted by EFSA (EFSA, 2011) where existing CXLs were considered also. The EFSA proposals were implemented by Regulation (EU) 668/2010[9]. Additional, CXLs established by Codex Alimentarius Commission in 2012 have been taken over in the EU legislation by Regulation No 293/2013[10]. However, there are not CXLs in place for the crops under consideration. The existing EU MRLs for pyraclostrobin on swedes and turnips are set at the LOQ of 0.02* mg/kg.

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

[7] 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.

[8] 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.

[9] Commission Regulation (EU) No 668/2013 of 12 July 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 2,4-DB, dimethomorph, indoxacarb, and pyraclostrobin in or on certain products OJ L 192, 13.07.2013, p. 39–71.

[10] 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 (United Kingdom, 2014), 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, 2011, 2012, 2013, 2014). 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-g, 2000, 2010a,b, 2011; OECD, 2011).

1. Method of analysis

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

Analytical methods for enforcement were evaluated during the MRL review under Art. 12 and it was concluded that adequate 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 (EFSA, 2011). The LOQ for matrices with high water content like swedes and turnips was reported as 0.02 mg/kg.

The multi-residue QuEChERS method using 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 swedes and turnips are available.

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

Several analytical methods for analysis of pyraclostrobin based on HPLC-MS/MS and GC-MS with validated LOQ of 0.01mg/kg in milk and a LOQ of 0.05 mg/kg in muscle, liver, kidney, fat and eggs were evaluated during the peer review under Directive 91/414/EEC (Germany, 2001).

As parent pyraclostrobin can be enforced in food of animal origin at the above mentioned LOQs, it was concluded that sufficiently validated analytical methods are available (EFSA, 2012).

2. Mammalian toxicology

The toxicological profile of the active substance pyraclostrobin was assessed during the peer review under Directive 91/414/EEC (EC, 2004a). 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	Chronic rat	100
ARfD	EC	2004	0.03 mg/kg bw	Rabbit developmental toxicity	100

[11] 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

During the peer review the metabolism of pyraclostrobin was investigated by foliar application on the fruits (grapes), tubers/roots (potatoes) and cereals (wheat) crop groups. The metabolic pathway was considered to be similar in all investigated crops and the plant residue definitions for monitoring and risk assessment was concluded as pyraclostrobin (EC, 2002). These residue definitions were confirmed during the review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011).

EFSA concludes that for swedes and turnips the metabolism in primary crops is sufficiently addressed and 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 MRL application, the EMS refers to eight residue trials conducted on carrots according to the intended NEU GAP (*2 × 1000 g/ha, PHI 14 days)* to support the extrapolation on the swedes and turnips. These residue trials have already been submitted in the framework of the MRL review under Art. 12 of Regulation (EC) No 396/2005 with a total of 4 additional NEU trials (2 × <0.02 and 2 × 0.05 mg/kg) (EFSA, 2011). Based on these two different datasets, a similar MRL value of 0.09 mg/kg is proposed for carrots (see Table 3-1). According to the guidance document SANCO 7525/VI/95, the residue dataset on carrot is sufficient to extrapolate to swedes and turnips to support an MRL of 0.09 mg/kg.

It is noted that the current EU MRL on carrot is set at 0.5 mg/kg, since the CXL of 0.5 mg/kg based on US GAPs (3 × 225 g/ha, PHI 0 day) (JMPR, 2004), has been transposed in the EU legislation by Regulation (EU) No 668/2013.

The storage stability of pyraclostrobin in primary crops was investigated in the DAR under Directive 91/414/EEC (Germany, 2001). Pyraclostrobin is stable for up to 18 months in high oil content, high water content, acidic and dry commodities when are stored deep frozen. As the supervised residue trial samples were stored for a maximum of 6 months under deep frozen conditions, the residue data are valid with regard to storage stability.

Also, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for the purpose (UK, 2014).

EFSA concludes that the data are sufficient to extrapolate to swedes and turnips the MRL value of 0.09 mg/kg derived from the residue trials conducted on carrots.

Table 3-1: Overview of the available residues trials data

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg) Enforcement & Risk assessment	Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Comments (e)
Enforcement residue definition: pyraclostrobin (F)**							
Carrots → swedes & turnips	NEU	Outdoor	4 × <0.02; 2 × 0.03; 0.04; 0.06	0.02	0.06	0.09	R_{ber}= 0.08 R_{max}= 0.07 MRL_{OECD} = 0.09/0.09
Carrots	NEU	Outdoor	6 × <0.02; 2 × 0.03; 0.04; 2 × 0.05, 0.06 Residue trials submitted under Art. 12 review	0.03	0.06	0.09	R_{ber}= 0.10 R_{max}= 0.07 MRL_{OECD} = 0.09/0.09

(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)** pesticide fat soluble

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 and MRL review (EFSA, 2011).

Under this application specific processing studies of swedes and turnips are not requested as the residue levels in RAC did not exceed the trigger value of 0.1 mg/kg (EC, 1997d).

3.1.2. Rotational crops

Swedes and turnips can be grown in rotation with other plants therefore the possible occurrence of residues in succeeding crops has to be assessed.

The nature and magnitude of pyraclostrobin residues in rotational crops was investigated in the course of the peer review (Germany, 2001). Based on a study conducted following application on bare soil at a dose rate of 900 g/ha, it was concluded that the metabolism in rotational crops is comparable to the one in primary crops and that no significant residues are expected in rotational crops for all plant back intervals (30, 120 and 265 days).

Since the intended uses of pyraclostrobin on swedes and turnips are limited to a maximum application rate of 134 g/ha (2× 67 g/ha), EFSA concludes that significant residues are unlikely to occur in rotational crops provided that the active substance is applied according to the proposed GAPs.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

The median and maximum dietary burden for livestock was calculated using the agreed European methodology (EC, 1996) in the framework of the review of the existing MRLs for pyraclostrobin performed under Article 12 of Regulation (EC) No 396/2005. The input values for all relevant commodities were selected according to the latest recommendations of the JMPR (FAO, 2009) and the results of the calculations indicated a significant intake (exceeding the trigger value of 0.1 mg/kg DM feed) for ruminants, poultry and pigs (EFSA, 2011).

In order to estimate whether the proposed uses of pyraclostrobin on swedes and turnips significantly increases the animal dietary exposure estimated under the previous Art. 10 reasoned opinion (EFSA, 2012) and reported in Table 3.3, EFSA performed a new dietary burden calculation (Table 3-4) including the residue levels observed on swedes and turnips (Table 3-2).

Table 3-2: Input values for the new dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value** (mg/kg)	**Comment**
Pyraclostrobin: residue values from the proposed uses				
Swedes	0.02	Median residue	0.06	Highest residue
Turnips	0.02	Median residue	0.06	Highest residue
Other feed items	See Table 3-2 from the reasoned opinion on the modification of the MRLs for pyraclostrobin in leafy brassica and various cereals (EFSA, 2012)			

The results of the existing and new dietary burden calculation are summarised in the following tables.

Table 3-3: Livestock dietary burden calculation performed with the existing uses (EFSA,2012)

Existing uses (EFSA 2012)[a]	Maximum dietary burden (mg/kg bw per d)	Median dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)[b]	Trigger exceeded (Y/N)
Dairy ruminants	0.129	0.049	Barley straw	3.35	Yes
Muscle ruminants	0.251	0.113	Barley straw	5.85	Yes
Poultry	0.027	0.011	Kale	0.42	Yes
Pigs	0.045	0.015	Kale	1.13	Yes

(a): Retrieved from "Modification of the MRLs for pyraclostrobin in leafy brassica and various cereals according with Art. 10 of Regulation 396/2005" (EFSA, 2012)
(b): Dry matter feed

Table 3-4: Livestock dietary burden calculation including uses on swedes and turnips

Existing uses (EFSA 2012)	Maximum dietary burden (mg/kg bw per d)	Median dietary burden (mg/kg bw per d)	Highest contributing commodity[a]	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Dairy ruminants	0.130	0.049	Kale	3.57	Yes
Muscle ruminants	0.251	0.113	Barley straw	5.86	Yes
Poultry	0.027	0.011	Kale	0.429	Yes
Pigs	0.046	0.014	Kale	1.15	Yes

From the comparison of these two scenarios it is concluded that the contribution of the residues of pyraclostrobin in swedes and turnips to the total livestock exposure is insignificant and therefore, no changes of the MRL values are necessary for the products of animal origin under this application.

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, 2011). 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 Swedes and turnips (see Table 3-1) and the median residue values crops for which the MRLs were recently amended (EFSA, 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 the levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest level as observed in supervised

field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

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

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

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: pyraclostrobin (plant origin commodities)				
Turnips	0.02	Median residue	0.06	Highest residue
Swedes	0.02	Median residue	0.06	Highest residue
Other commodities	See Table 4.1 and Appendix D in EFSA Reasoned Opinion on the modification of the existing MRL for pyraclostrobin in chicory roots (EFSA, 2014)			

(b): Consumption figures in the EFSA PRIMo are expressed as Muscle, therefore the median and highest residue values were calculated considering 80 % of the residue derived for muscle and 20 % of the residue derived for fat (FAO, 2009).

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.

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 15 % of the ADI (related DE diet). The contribution of residues in swedes and turnip to the total consumer exposure was lower than 0.1 % of the ADI (IE adult).

No acute consumer risk was identified in relation to the MRL proposals for crops under consideration. The calculated maximum exposure in percentage of the ARfD was 10 % for swedes and 7 % for turnips (UK infant).

EFSA concludes that the intended use of pyraclostrobin on swedes and turnips will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of 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 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 acute daily intake (ADI) of 0.03 mg/kg bw per day and an acute reference dose (ARfD) of 0.03 mg/kg bw.

The metabolism of pyraclostrobin in primary crops was investigated in three different crop groups during the peer review and the residue definition for enforcement and risk assessment in all plant commodities was proposed as pyraclostrobin. These residue definitions were confirmed in the framework of the MRLs review under Article 12 of Regulation (EC) 396/2005.

EFSA concludes that the submitted residue trials are sufficient to derive the MRL proposals of 0.09 mg/kg for the proposed uses on swedes and turnips. Adequate analytical enforcement methods are available to control the residues of pyraclostrobin at the validated LOQ of 0.02* mg/kg.

Specific studies investigating the magnitude of residues in processed commodities are not required, as the residue levels in raw agricultural commodities (RAC) did not exceed the trigger value of 0.1 mg/kg.

The occurrence of pyraclostrobin residues in rotational crops was investigated in the DAR. Based on the available information on the nature and magnitude of residues in succeeding crops, it was concluded that significant residue levels are unlikely to occur in rotational crops provided that the active substance is used on swedes and turnips according to the proposed GAP (Good Agricultural Practice).

The contribution of pyraclostrobin residues in swedes and turnips to the overall dietary livestock burden is insignificant. Thus, EFSA concluded that an amendment of the MRLs for the products of animal origin is unnecessary.

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 considering the existing uses of pyraclostrobin at the EU level and all adopted Codex maximum residue levels (CXLs) in European legislation. EFSA updated this consumer risk assessment considering the median residue values derived for swedes and turnips and taking into account the other food commodities assessed under Article 10 of Regulation (EU) 396/2005 after Article 12 MRL review was issued.

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 15 % of the ADI (related DE diet). The contribution of residues in swedes and turnip to the total consumer exposure was lower than 0.1 % of the ADI (IE adult).

No acute consumer risk was identified in relation to the MRL proposals for crops under consideration. The calculated maximum exposure in percentage of the ARfD was 10 % for swedes and 7 % for turnips (UK infant).

EFSA concludes that the proposed uses of pyraclostrobin on swedes and turnips will not result in a consumer exposure exceeding the toxicological reference values 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)				
213100	Swedes	0.02*	0.09	The MRL proposals are sufficiently supported by data and no consumer health risk was identified for the intended uses of pyraclostrobin on these crops in NEU.
213110	Turnips	0.02*	0.09	

(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

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. EFSA doi:10.2903/j.efsa.2007.32r. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2011. 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

EFSA (European Food Safety Authority), 2014. Reasoned opinion on the modification of the existing MRL for pyraclostrobin in chicory roots. EFSA Journal 2014;12(5):3685, 23 pp. doi:10.2903/j.efsa.2014.3685

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.

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.

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.

United Kingdom, 2014. Evaluation report on the modification of MRL for pyraclostrobin in Swedes and turnips prepared by the evaluating Member State under Article 8 of Regulation (EC) No 396/2005, 02 April 2014, 26 pp.

APPENDICES

Appendix A. Good Agricultural Practice (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	concentration active substance (i)	method kind (f- h)	growth stage & season (j)	number min-max (k)	interval min-max	g as/hL min max	water L/ha	g a.s./ha min max		
swedes, turnip, celeriac	NEU (UK)	F	Fungus	WG	26.7 % boscalid 6.7 % pyraclostrobin	-	-	2	14 days	-	-	Boscalid: 270 g/ha Pyraclostrobin: 67 g/ha	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)

Appendix B. Pesticide Residue 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

Prepare workbook for refined calculations

Undo refined calculations

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	1st 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)
14.5	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	
4.6	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	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)
10.3	Swedes	0.06 / -	10.3	Swedes	0.06 / -	4.8	Swedes	0.06 / -	4.8	Swedes	0.06 / -
7.2	Turnips	0.06 / -	5.1	Turnips	0.06 / -	2.1	Turnips	0.06 / -	1.5	Turnips	0.06 / -

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)
DAR	Draft Assessment Report
DM	dry matter
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
GC	gas chromatography
GCPF	Global Crop Protection Federation (former GIFAP)
GS	growth stage
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
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry
MSD	mass spectrometry detector
MW	molecular weight

NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
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
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WG	water dispersible granule