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REASONED OPINION

Reasoned opinion on the modification of the existing MRL for picoxystrobin in sugar beet[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Sweden hereafter referred to as the evaluating Member State (EMS), received an application from DuPont Sverige AB to modify the MRL at the value of 0.015 mg/kg for the active substance picoxystrobin in sugar beet roots. In order to accommodate for the intended use of picoxystrobin Sweden proposed to raise the MRL from 0.01 mg/kg to the proposed MRL of 0.015 mg/kg. Sweden 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 0.015 mg/kg for the proposed use on sugar beet roots. Adequate analytical enforcement methods are available to control the residues of picoxystrobin in sugar beets . Based on the risk assessment results, EFSA concludes that the intended use of picoxystrobin on sugar beet roots will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health risk.

KEY WORDS

picoxystrobin, sugar beet roots, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, strobilurin group

[1] On request from the European Commission, Question No EFSA-Q-2013- 00985, approved on 23 May 2014.

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[*] An editorial amendment was carried out that does not materially affect the contents or outcome of this reasoned opinion. To avoid confusion, the original version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Sweden hereafter referred to as the evaluating Member State (EMS), received an application from DuPont Sverige AB to modify the MRL at the value of 0.015 mg/kg for the active substance picoxystrobin in sugar beet roots. In order to accommodate for the intended use of picoxystrobin Sweden proposed to raise the MRL from 0.01 mg/kg to the proposed MRL of 0.015 mg/kg. Sweden drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 04 December 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 picoxystrobin, the JMPR Evaluation report as well as the conclusions from a previous EFSA reasoned opinion on picoxystrobin.

The toxicological profile of picoxystrobin was assessed in the DAR by the rapporteur Member State and the data were sufficient to derive an ADI of 0.042 mg/kg bw per day. No ARfD was deemed necessary at the time of evaluation.

The metabolism of picoxystrobin in primary crops was investigated in apples, tomatoes, soybean and wheat. From these studies the residue definition for enforcement and for risk assessment was established as picoxystrobin only.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.015 mg/kg for the proposed use on sugar beet roots. Adequate analytical enforcement methods are available to control the residues of picoxystrobin in sugar beets at the validated LOQ of 0.01 mg/kg.

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

The occurrence of picoxystrobin residues in rotational crops was investigated in the framework of the peer review and the MRL review under Regulation (EC) No 396/2005. 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 compound is used on sugar beet according to the proposed GAP (Good Agricultural Practice).

Since the sugar beet leaves and roots are used as feed products a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg (dry matter) for ruminant and pig species. However, EFSA concluded that the impact of picoxystrobin residue in sugar beet to the total livestock exposure does not require the modification of the existing MRLs.

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 picoxystrobin 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 picoxystrobin at the EU level. EFSA updated this risk assessment with median residue values on sugar beet 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 0.4 % of the ADI (IE adult diet).The contribution of residues in sugar beet to the total consumer exposure accounted for a maximum of 0.2 % of the ADI (UK toddler diet).

EFSA concludes that the intended use of picoxystrobin on sugar beet roots will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public 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: picoxystrobin (F)				
900010	Sugar beet (root)	0.05*/0.01* [(b)]	0.015	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the intended uses on this crop.
1011000	Swine	0.05*/0.01* [(b)]	0.01*	The intended use of picoxystrobin on sugar beet leads to a dietary exposure of pigs and ruminants exceeding the trigger value. However, this does not require the modification of the MRLs for these products.
1012000	Bovine	0.05*/0.01* [(b)]	0.01*	
1013000	Sheep	0.05*/0.01* [(b)]	0.01*	
1014000	Goat	0.05*/0.01* [(b)]	0.01*	
1020000	Milk	0.05*/0.01* [(b)]	0.01*	

(a): According to Annex I of Regulation (EC) No 396/2005.
(b): The MRL voted during the SCoFCAH meeting on 17 September 2013 but not yet implemented in EU legislation
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): Fat-soluble.

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BACKGROUND

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

Sweden hereafter referred to as the evaluating Member State (EMS), received an application from the company DuPont de Nemours[6] to modify the existing MRLs for the active substance picoxystrobin in sugar beet. 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 04 December 2013.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013- 00985 and the following subject:

Picoxystrobin – Application to modify the existing MRL in sugar beet.

Sweden proposed to set the MRL of picoxystrobin in sugar beet at the level of 0.015 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 4 March 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.

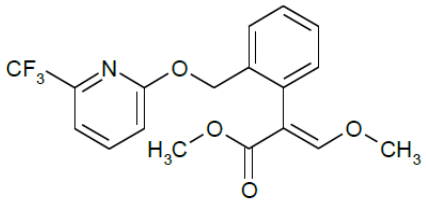
[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

[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] DuPont de Nemours, Via Piero Gobetti, 20063, Cernusco sul Naviglio Milano, Italy

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Picoxystrobin is the ISO common name for methyl (2*E*)-3-methoxy-2-{2-[6-(trifluoromethyl)-2-pyridyloxymethyl]phenyl}acrylate (IUPAC). The chemical structure of the compound is reported below.



Molecular weight: 367.3 g/mol

Picoxystrobin belongs to the group of strobilurin compounds which are used as fungicides against certain fungal diseases. It blocks the electron transport between cytochrom b and cytochrom c1, which causes inhibition of ATP formation. Deprivation of ATP hinders cellular processes requiring energy, such as spore germination and mycelia growth.

Picoxystrobin was evaluated in the framework of Council Directive 91/414/EEC with Ireland designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 84/2003/EC[7] which entered into force on 01 January 2004 for use as fungicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011[8] picoxystrobin is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses evaluated in the peer review was outdoor foliar treatment of cereals at an application rate of 0.25 kg a.s./ha. The Draft Assessment Report (DAR) of picoxystrobin was not peer reviewed by EFSA, therefore no EFSA conclusion is available.

The EU MRLs for picoxystrobin are established in Annexes II of Regulation (EC) No 396/2005. The existing EU MRL for picoxystrobin on sugar beet is set at the LOQ of 0.05* mg/kg. Following the MRL review under Article 12 of Regulation (EC) No 396/2005, the SCoFCAH voted on 17 September 2013 to lower the MRL in sugar beet from the LOQ of 0.05mg/kg to the LOQ of 0.01 mg/kg (SANCO/11037/2012). The existing MRLs along with the MRLs as voted in the SCoFCAH are listed in Appendix C. In 2012 JMPR assessed picoxystrobin, but since the experts were unable to conclude on the toxicological relevance of two metabolites, no CXLs were yet established.

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

[7] Commission Directive 2003/84/EC of 25 September 2003 amending Council Directive 91/414/EEC to include flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate and silthiofam as active substances OJ L 247, 30.9.2003, p.1- 20.

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

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Sweden, 2013), the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Ireland, 2001, 2002), the Commission Review Report on picoxystrobin (EC, 2003), the JMPR Evaluation report (FAO, 2012) as well as the conclusions from a previous EFSA opinion on picoxystrobin (EFSA, 2011.). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a,b, 2011; OECD, 2011).

1. Method of analysis

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

In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 the availability of analytical methods to be used for enforcement of MRLs was assessed. The multi-residue method DFG S19 using GC-ECD was found to be applicable for the determination of picoxystrobin residues in dry crops (cereal grain and straw) with an LOQ of 0.01 mg/kg. However, a confirmatory method was missing (EFSA, 2011).

In support of the current MRL application, the applicant submitted an additional analytical method based on HPLC/MS/MS which can be used to analyse the parent picoxystrobin. The method is also applicable for the quantification of metabolites IN-QDK50[10], IN-QDY62[11] and IN-QDY63[12] in plant matrices (the method was validated for parent picoxystrobin at a LOQ of 0.01 mg/kg in sugar beet leaves, barley straw and sunflower seed). The applicant made available an ILV for this method, demonstrating the LOQ of 0.01 mg/kg being achievable for high water content commodities (corn stover and lettuce leaf) (Sweden 2013).

Since the commodity under consideration belongs to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRL for picoxystrobin on the sugar beet are available.

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

Analytical methods for the determination of picoxystrobin residues in commodities of animal origin, based on GC-MSD and GC-ECD were evaluated in the DAR and during the peer review under Directive 91/414/EEC (Ireland 2001). An additional analytical method for determination of picoxystrobin using LC-MS/MS with an LOQ of 0.01 mg/kg in liver, kidney, muscle, fat, milk and eggs was submitted during the MRL review (EFSA, 2011).

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

2. Mammalian toxicology

The toxicological profile of the active substance picoxystrobin was peer reviewed under Directive 91/414/EEC/ and the data were sufficient to derive toxicological an ADI (see Table 2-1). The setting of an ARfD was considered not necessary (EC, 2003).

[9] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.
[10] IN-QDK50: 6-(trifluoromethyl)-2(1H)-pyridinone
[11] IN-QDY62: (E)-3-methoxy-2-{2-[6-[trifluoromethyl)pyridine-2-yloxymethyl]phenyl}acrylic acid (IUPAC name)
[12] IN-QDY63: 2-[[[6-[trifluoromethyl]-2-pyridinyl]oxy]methyl]benzoic acid

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Picoxystrobin					
ADI	EC	2003	0.042 mg/kg bw per day	1 year dietary, dog	100
ARfD	EC	2003	Not necessary		

The toxicological studies were performed on picoxystrobin. No toxicological data are available for the Z isomer of picoxystrobin.

It is noted that in 2011 JMPR assessed the toxicological properties of picoxystrobin and derived an ADI of 0.09 mg/kg bw per day and an ARfD of 0.09 mg/kg bw (FAO, 2012).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of picoxystrobin in primary crops was investigated in wheat during the peer review (Ireland 2001) and in soya bean. In the framework of this application, additional metabolism studies on apples and tomatoes were submitted. The design of the metabolism studies are outlined in the table below (Table 3-1).

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

Group	Crop	Label position	Application details				
			Method, F or G[(a)]	Rate (kg a.s./ha)	No	Sampling	Remarks
Fruits and fruiting vegetable	apples	[^{14}C-pyridinyl -] and [^{14}C-phenylacrylate]	Foliar, F	0.51 and 0.5	3	14 DALA	1st application at BBCH 69; 2nd and 3rd application 21 and 85 days (Sweden, 2013)
	tomatoes	[pyridine-3 - ^{14}C] and [phenyl(U) - ^{14}C]	Foliar, F	0.11 and 0.10	3	1,7 and 14 DALA for tomato leaf and fruits; 14 DALA for tomato stem	1st application at BBCH 62-64; 2nd and 3rd application: 7 and 14 days later (last application BBCH 71-73) (Sweden, 2013)

Group	Crop	Label position	Application details				
			Method, F or G[(a)]	Rate (kg a.s./ha)	No	Sampling	Remarks
Pulses and oilseeds	soya bean	[pyridinyl-^{14}C] and [phenylacryl-^{14}C]	Foliar, F	0.2	2	14 (forage) 61 (seeds)	(EFSA, 2011)
				1	2	14 (forage) 61 (seeds)	
Cereals	wheat	[pyridinyl-^{14}C] and [phenylacryl-^{14}C]	Foliar, F	0.4	2	14 (forage) and 48 (wheat straw and grain) after 2nd application	Application at BBCH 32 and BBCH 65-69. (EFSA , 2011)

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

The metabolism studies on wheat and soya bean are described in details in the EFSA reasoned opinion on the MRL review under Article 12 of Regulation (EC) No 396/2005. On the basis of these studies, the residue definition for enforcement and risk assessment in cereals, pulses and oilseeds was defined as parent compound. EFSA recommended that since the studies did not investigate the possible impact of plant metabolism on the isomer ratio of picoxystrobin, once guidance is available on this issue, further investigations should be performed (EFSA, 2011).

Apples: In the metabolism study in apples the TRR in treated apples the TRR accounted for 0.2 mg eq./kg (^{14}C-phenylacrylate label) and 0.064 mg eq./kg (^{14}C- phenylacrylate label). Parent picoxystrobin was the main compound present (53 to 54.8 % TRR, 0.035 mg/kg to 0.11 mg/kg for pyridinyl and phenylacrylate label, respectively). Several metabolites were identified, but none of them accounted for more than 10 % TRR; the only metabolite exceeding slightly the trigger of 0.01 mg/kg was IN-QGS44[13] (0.011 mg/kg).

Tomatoes: In tomato fruit collected 1, 7 and 14 DALA the TRR accounted for 1.14 0.8 and 0.68 mg/kg (phenyl-label); in the samples treated with pyridine-labelled active substance the TRR accounted for 0.69, 0.51 and 0.59 mg eq/kg at the corresponding sampling points. In both cases, picoxystrobin was the major metabolite in tomatoes fruits accounting for 30.1 to 63.2 % (0.2 to 0.72 mg/kg) after application of the phenyl-labelled active substance and 62.2 to 80.3 % TRR (0.34 to 0.56 mg/kg) in the samples treated with pyridine-labelled active substance. Additionally, two metabolites were present at significant levels: IN-K2122[14] (7.3 – 29 %) and IN-H8612[15] (7.5 – 27 %) of TRR. A number of additional metabolites were identified, but none of them occurred in concentrations greater than 10 % of TRR.

The EMS described the metabolic reactions as including ester hydrolysis, *O*-demethylation, conjugation, ether cleavage and to a small extent isomerisation to the Z- isomer picoxystrobin (IN-QDC12[16]). The phenyl portion of the molecule underwent extensive side chain metabolism to give benzoic acid metabolites, IN-H8612 and phthalic acid (IN-K2122) (Sweden, 2013).

EFSA concludes that overall metabolism of picoxystrobin in the three crop groups for which metabolism studies are available is comparable. Although no specific metabolism studies are available for crops representative for root and tuber vegetables, it is not expected that metabolism in root crops

[13] IN-QGS44-methyl 2 - hydroxy-{2-[6 trifluoromethyl pyridine-2yloxymethyl]phenyl}acetate
[14] IN-K2122 - o-phthalic acid
[15] IN-H8612 - 1,3-dihydro-isobenzofuran-3-one-1-carboxylic acid
[16] IN-QDC12 – methyl (αZ)- α (methoxymethylene)-2-[[[6-(trifluoromethyl)-2-pyridinyl]oxy]methyl]benzeneacetate

will reveal a different metabolic behaviour. This assumption is also based on the findings of the metabolism studies in rotational crops (see Section 3.1.2). Thus, EFSA concludes that the metabolism of picoxystrobin is addressed and the residue definition for enforcement and risk assessment established during the MRL review is applicable.

The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived during MRL review.

3.1.1.2. Magnitude of residues

In support of the MRL application, 11 residue trials were submitted which were performed in the NEU during 2009 and 2010. The trials did not fully comply with the reported GAP but they were considered acceptable since the applications were within the acceptable deviations (±25 %). All the samples were analysed for picoxystrobin and its metabolites (IN-QDY62, IN-QDY63, IN-QDK50) by LC-MS/MS. The results, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-2.

Data were also provided for sugar beet leaves. Although this part of the crop is not relevant for MRL setting, the results are required for estimating the dietary burden for livestock. Thus, the results are also reported in Table 3-2.

The storage stability was assessed during the peer review and it was demonstrated that picoxystrobin is stable for 22 months at -18°C in barley grain (dry commodities), barley forage (high water content commodity) and barley straw (EFSA, 2011). Additionally information which showed stability of picoxystrobin and its metabolites for 2 years in potato tubers was made available under this application (Sweden, 2013).

As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

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

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.015 mg/kg for the intended use on sugar beet.

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

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (picoxystrobin)	**Risk assessment** (picoxystrobin)					
Enforcement residue definition: picoxystrobin									
Sugar beet (roots)	NEU	Outdoor	10 x <0.003; 0.011	idem	0.003	0.011	0.015	-	R_{ber}= 0.01 R_{max}=0.01 MRL_{OECD} = 0.015 mg/kg
Sugar beet (leaves)	NEU	Outdoor	<0.003, 2 x 0.005, 0.012, 2 x 0.013, 0.025, 0.026, 0.032, 0.037, 0.27,	idem	0.013	0.27	-	-	

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

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of picoxystrobin residues was investigated in the framework of the peer review. A study was conducted only simulating representative hydrolytic conditions for boiling/brewing/baking (60 minutes at 100°C pH 5). This study showed that picoxystrobin is hydrolytically stable under these conditions and that no formation of toxicologically relevant metabolites occurs (EFSA 2011).

Specific studies to assess the magnitude of picoxystrobin residues during the processing of sugar beet are not necessary as the residue levels in raw agricultural commodities (RAC) did not exceed the trigger value of 0.1 mg/kg (EC, 1997d).

3.1.2. Rotational crops

Sugar beet can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that the degradation rate of picoxystrobin is slow in the soil and the DT_{90} value exceeds the trigger value of 100 days.

The metabolism of picoxystrobin in rotational crops was assessed in the DAR (Ireland 2001) and during the MRL review (EFSA, 2011) investigating the nature of residue in carrots, lettuce and spring wheat. The studies were conducted with a higher application rate (0.82-0.83 kg a.s/ha) than the proposed GAP for sugar beet. EFSA concluded that in rotational crops residue concentrations are expected to be below 0.01 mg/kg and no specific residue definition was necessary.

3.2. Nature and magnitude of residues in livestock

Sugar beet roots and sugar beet leaves can be fed to livestock and therefore the nature and magnitude of picoxystrobin residues in livestock had to be assessed in the framework of this application.

3.2.1. Dietary burden of livestock

The median and maximum dietary burden for livestock was calculated using the agreed European methodology (EC, 1996). The input values for the dietary burden calculation were selected according to the latest FAO recommendations (FAO, 2009) considering the livestock intake from sugar beet root, sugar beet leaves and from all other feed products evaluated during the MRL review (reported in Table 3-3).

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

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value** (mg/kg)	**Comment**
Risk assessment residue definition: picoxystrobin				
Wheat and rye grain	0.01	Median residue	0.01	Median residue
Barley and oat grain	0.09	Median residue	0.09	Median residue
Wheat and rye bran	0.03	Median residue x PF	0.03	Median residue x PF
Wheat and rye straw	0.39	Median residue	2.85	Highest residue
Barley and oat straw	0.61	Median residue	2.83	Highest residue
Rape seed	0.003	Median residue	0.003	Median residue
Rape seed meal	0.006	Median residue x 2	0.006	Median residue x 2

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sugar beet root	0.003	Median residue	0.011	Highest residue
Sugar beet leaves	0.013	Median residue	0.27	Highest residue

The results of the dietary burden calculation are summarised in the following table below (Table 3-4).

Table 3-4: Results of the livestock dietary burden calculation.

	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)
Risk assessment residue definition: picoxystrobin					
Dairy ruminants	0.044	0.008	Wheat straw	1.216	Yes
Muscle ruminants	0.094	0.017	Wheat straw	2.181	Yes
Poultry	0.005	0.005	Barley grain	0.084	No
Pigs	0.020	0.004	Sugar beet leaves	0.500	Yes

(a): Calculated for the maximum dietary burden

Comparing the results of the dietary burden calculation with the calculation presented in the previously issued reasoned opinion of EFSA (EFSA, 2011) it becomes evident that sugar beet roots and leaves are significantly contributing to the overall dietary burden of ruminants and pigs. Thus, the occurrence of picoxystrobin residues in food of ruminant and swine commodities has to be reconsidered. For poultry the dietary burden is still below the trigger value of 0.1 mg/kg DM.

3.2.2. Nature and magnitude of residues

The metabolism of picoxystrobin in livestock was assessed in the DAR prepared under Directive 91/414/EEC (Ireland, 2001) and during the MRL review (EFSA, 2011).

The metabolism studies were performed in lactating goats and laying chicken with feeding levels of ca. 10 mg/kg diet, respectively. In all matrices except goat fat the residue levels of picoxystrobin did not exceed the LOQ of 0.01 mg/kg or 0.001 mg/kg for milk. In goat fat the residue concentration of picoxystrobin ranged from 0.012 to 0.024 mg/kg (Ireland, 2001, 2002). The metabolic pattern identified for goats and hens were consistent with the rat metabolism; thus, the findings can be extrapolated to pigs. The residue definition for food of animal origin was proposed as parent picoxystrobin for both enforcement and risk assessment. The residue was classified as fat soluble.

From the metabolism studies, which were performed at a significantly higher dose rate than the expected dietary burden (see Table 3-4), it can be concluded that there is no need to raise the existing MRLs for food of animal origin in case the use in sugar beet (Appendix A) will be approved.

4. Consumer risk assessment

In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 a comprehensive dietary exposure assessment was performed, taking into account the existing uses for picoxystrobin (EFSA, 2011). The long-term consumer exposure assessment was now updated including the median residue concentration for sugar beet.

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[17] (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the median residue value as derived from the residue trials on sugar beet (see Table 3-2), and the median residue values reported in the framework of the review of existing MRLs of picoxystrobin (EFSA, 2011). In addition, EFSA extrapolated the results of ruminant muscle, fat, liver and kidney to pig matrices.

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 acute consumer exposure assessment was performed, due to the low acute toxicity of the active substance.

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	
	Input value (mg/kg)	**Comment**
Risk assessment residue definition: picoxystrobin		
Sugar beet	0.003	STMR
Rape seed	0.003	Median residue (EFSA, 2011)
Barley and oat grain	0.09	Median residue (EFSA, 2011)
Wheat and rye grain	0.01	Median residue (EFSA, 2011)
Milk	0.001	Median residue (EFSA, 2011)
Ruminant muscle, fat, liver and kidney	0.01	Median residue (EFSA, 2011)
Pig muscle, fat. Liver and kidney	0.01	Extrapolation of results from ruminants

The estimated exposure was then compared with the toxicological reference value derived for picoxystrobin (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 0.4 % of the ADI (IE adult diet). The contribution of residues in sugar beet to the total consumer exposure accounted for a maximum of 0.2 % of the ADI (UK toddler diet).

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

EFSA concludes that the intended use of picoxystrobin on sugar beet roots will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of picoxystrobin was assessed in the DAR by the rapporteur Member State and the data were sufficient to derive an ADI of 0.042 mg/kg bw per day. No ARfD was deemed necessary at the time of evaluation.

The metabolism of picoxystrobin in primary crops was investigated in apples, tomatoes, soybean and wheat. From these studies the residue definition for enforcement and for risk assessment was established as picoxystrobin only.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.015 mg/kg for the proposed use on sugar beet roots. Adequate analytical enforcement methods are available to control the residues of picoxystrobin in sugar beets at the validated LOQ of 0.01 mg/kg.

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

The occurrence of picoxystrobin residues in rotational crops was investigated in the framework of the peer review and the MRL review under Regulation (EC) No 396/2005. 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 compound is used on sugar beet according to the proposed GAP (Good Agricultural Practice).

Since the sugar beet leaves and roots are used as feed products a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg (dry matter) for ruminant and pig species. However, EFSA concluded that the impact of picoxystrobin residue in sugar beet to the total livestock exposure does not require the modification of the existing MRLs.

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 picoxystrobin 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 picoxystrobin at the EU level. EFSA updated this risk assessment with median residue values on sugar beet 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 0.4 % of the ADI (IE adult diet).The contribution of residues in sugar beet to the total consumer exposure accounted for a maximum of 0.2 % of the ADI (UK toddler diet).

EFSA concludes that the intended use of picoxystrobin on sugar beet roots will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health risk.

RECOMMENDATIONS

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: picoxystrobin (F)				
900010	Sugar beet (root)	0.05*/0.01* [(b)]	0.015	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the intended uses on this crop.
1011000	Swine	0.05*/0.01* [(b)]	0.01*	The intended use of picoxystrobin on sugar beet leads to a dietary exposure of pigs and ruminants exceeding the trigger value. However, this does not require the modification of the MRLs for these products.
1012000	Bovine	0.05*/0.01* [(b)]	0.01*	
1013000	Sheep	0.05*/0.01* [(b)]	0.01*	
1014000	Goat	0.05*/0.01* [(b)]	0.01*	
1020000	Milk	0.05*/0.01* [(b)]	0.01*	

(a): According to Annex I of Regulation (EC) No 396/2005.
(b): The MRL voted during the SCoFCAH meeting on 17 September 2013 but not yet implemented in EU legislation
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): Fat-soluble.

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APPENDICES

Appendix A. Good Agricultural Practices (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation type (d- f)	Formulation conc. of a.s. (i)	Application method kind (f - h)	Application growth stage & season (j)	Application number min max (k)	Application interval min max	Application rate per treatment kg as/hL min max	Application rate per treatment water L/ha min max	Application rate per treatment kg a.s./ha min max	PHI (days) (l)	Remarks (m)
Sugar beet (9000010)	SE, LT	F	Erysiphebetae, Powdery mildew (ERYSBE), Euromyces betae, Beet rust (UROMBE), Ramularia beticola, leef spot of beet (RAMUBE), Cercospora beticola, Leef spot of beet (CERCBE)	SC	250 g/L	Broadcast, ground directed spraying. Tractor mounted sprayer.	From full crop cover, BBCH 40-49	a) 1 b) 2	10	a) 0.5 L b) 1.0 L	a) 125 g b) 250 g	100-300	42	
Sugar beet (9000010)	SE, LT	F	Erysiphe betae, Powdery mildew (ERYSBE), Euromyces betae, Beet rust (UROMBE), Ramularia beticola, leef spot of beet (RAMUBE), Cercospora beticola, Leef spot of beet (CERCBE)	SC	250 g/L	Broadcast, ground directed spraying. Tractor mounted sprayer.	From full crop cover, BBCH 40-49	a) 1 b) 1	-	a) 1.0 L b) 1.0 L	a) 250 g b) 250 g	100-300	42	

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)

Picoxystrobin

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.042**	ARfD (mg/kg bw):	**n.n**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2003**	Year of evaluation:	**2003**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
0.4	IE adult	0.3	Barley	0.1	Wheat	0.0	Oats	
0.3	DK child	0.1	Wheat	0.1	Rye	0.1	Oats	
0.3	WHO cluster diet E	0.2	Barley	0.1	Wheat	0.0	Oats	
0.3	WHO Cluster diet B	0.2	Wheat	0.1	Barley	0.0	Bovine: Meat	
0.3	WHO Cluster diet F	0.1	Barley	0.1	Wheat	0.0	Oats	
0.3	UK Toddler	0.2	Sugar beet (root)	0.1	Wheat	0.0	Milk and cream,	
0.3	NL child	0.1	Wheat	0.1	Milk and cream,	0.0	Swine: Meat	
0.3	UK Infant	0.1	Milk and cream,	0.1	Sugar beet (root)	0.1	Wheat	
0.3	WHO cluster diet D	0.2	Wheat	0.0	Barley	0.0	Bovine: Meat	
0.2	WHO regional European diet	0.1	Wheat	0.1	Barley	0.0	Swine: Meat	
0.2	DE child	0.1	Wheat	0.0	Oats	0.0	Milk and cream,	
0.2	ES adult	0.1	Barley	0.1	Wheat	0.0	Bovine: Meat	
0.2	ES child	0.1	Wheat	0.0	Bovine: Meat	0.0	Milk and cream,	
0.2	FR toddler	0.1	Milk and cream,	0.1	Wheat	0.0	Bovine: Meat	
0.2	NL general	0.1	Barley	0.0	Wheat	0.0	Swine: Meat	
0.2	IT kids/toddler	0.2	Wheat	0.0	Barley	0.0	Oats	
0.1	LT adult	0.0	Rye	0.0	Wheat	0.0	Swine: Meat	
0.1	DK adult	0.0	Wheat	0.0	Oats	0.0	Rye	
0.1	SE general population 90th percentile	0.1	Wheat	0.0	Milk and cream,	0.0	Rye	
0.1	PT General population	0.1	Wheat	0.0	Barley	0.0	Barley	
0.1	FR all population	0.1	Wheat	0.0	Bovine: Meat	0.0	Swine: Meat	
0.1	IT adult	0.1	Wheat	0.0	Barley	0.0	Oats	
0.1	UK vegetarian	0.0	Wheat	0.0	Sugar beet (root)	0.0	Oats	
0.1	FR infant	0.1	Milk and cream,	0.0	Wheat	0.0	Bovine: Meat	
0.1	UK Adult	0.0	Wheat	0.0	Sugar beet (root)	0.0	Milk and cream,	
0.1	FI adult	0.0	Wheat	0.0	Oats	0.0	Rye	
	PL general population		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:

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

Appendix C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLS)

(Pesticides - Web Version - EU MRLs (File created on 11/04/2014 15:40)

Code number	Groups and examples of individual products to which the MRLs apply	Picoxystrobin	Picoxystrobin [a]
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,05*	0,01*
110000	(i) Citrus fruit	0,05*	0,01*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,05*	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*	0,01*
110030	Lemons (Citron, lemon)	0,05*	0,01*
110040	Limes	0,05*	0,01*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*	0,01*
110990	Others	0,05*	0,01*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*	0,01*
120010	Almonds	0,05*	0,01*
120020	Brazil nuts	0,05*	0,01*
120030	Cashew nuts	0,05*	0,01*
120040	Chestnuts	0,05*	0,01*
120050	Coconuts	0,05*	0,01*
120060	Hazelnuts (Filbert)	0,05*	0,01*
120070	Macadamia	0,05*	0,01*
120080	Pecans	0,05*	0,01*
120090	Pine nuts	0,05*	0,01*
120100	Pistachios	0,05*	0,01*
120110	Walnuts	0,05*	0,01*
120990	Others	0,05*	0,01*
130000	(iii) Pome fruit	0,05*	0,01*
130010	Apples (Crab apple)	0,05*	0,01*
130020	Pears (Oriental pear)	0,05*	0,01*
130030	Quinces	0,05*	0,01*
130040	Medlar	0,05*	0,01*
130050	Loquat	0,05*	0,01*
130990	Others	0,05*	0,01*
140000	(iv) Stone fruit	0,05*	0,01*
140010	Apricots	0,05*	0,01*
140020	Cherries (sweet cherries, sour cherries)	0,05*	0,01*
140030	Peaches (Nectarines and similar hybrids)	0,05*	0,01*
140040	Plums (Damson, greengage, mirabelle)	0,05*	0,01*
140990	Others	0,05*	0,01*
150000	(v) Berries & small fruit	0,05*	0,01*
151000	(a) Table and wine grapes	0,05*	0,01*
151010	Table grapes	0,05*	0,01*
151020	Wine grapes	0,05*	0,01*
152000	(b) Strawberries	0,05*	0,01*
153000	(c) Cane fruit	0,05*	0,01*
153010	Blackberries	0,05*	0,01*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*	0,01*
153030	Raspberries (Wineberries)	0,05*	0,01*
153990	Others	0,05*	0,01*
154000	(d) Other small fruit & berries	0,05*	0,01*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*	0,01*
154020	Cranberries	0,05*	0,01*
154030	Currants (red, black and white)	0,05*	0,01*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*	0,01*
154050	Rose hips	0,05*	0,01*
154060	Mulberries (arbutus berry)	0,05*	0,01*
154070	Azarole (mediteranean medlar)	0,05*	0,01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,05*	0,01*
154990	Others	0,05*	0,01*
160000	(vi) Miscellaneous fruit	0,05*	0,01*
161000	(a) Edible peel	0,05*	0,01*
161010	Dates	0,05*	0,01*
161020	Figs	0,05*	0,01*
161030	Table olives	0,05*	0,01*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*	0,01*
161050	Carambola (Bilimbi)	0,05*	0,01*
161060	Persimmon	0,05*	0,01*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,05*	0,01*
161990	Others	0,05*	0,01*
162000	(b) Inedible peel, small	0,05*	0,01*
162010	Kiwi	0,05*	0,01*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*	0,01*
162030	Passion fruit	0,05*	0,01*
162040	Prickly pear (cactus fruit)	0,05*	0,01*
162050	Star apple	0,05*	0,01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*	0,01*
162990	Others	0,05*	0,01*
163000	(c) Inedible peel, large	0,05*	0,01*
163010	Avocados	0,05*	0,01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*	0,01*
163030	Mangoes	0,05*	0,01*
163040	Papaya	0,05*	0,01*
163050	Pomegranate	0,05*	0,01*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,05*	0,01*
163070	Guava	0,05*	0,01*
163080	Pineapples	0,05*	0,01*
163090	Bread fruit (Jackfruit)	0,05*	0,01*
163100	Durian	0,05*	0,01*
163110	Soursop (guanabana)	0,05*	0,01*
163990	Others	0,05*	0,01*
200000	2. VEGETABLES FRESH OR FROZEN	0,05*	
210000	(i) Root and tuber vegetables	0,05*	0,01*
211000	(a) Potatoes	0,05*	0,01*
212000	(b) Tropical root and tuber vegetables	0,05*	0,01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*	0,01*
212020	Sweet potatoes	0,05*	0,01*
212030	Yams (Potato bean (yam	0,05*	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Picoxystrobin	Picoxystrobin [(a)]
	bean), Mexican yam bean)		
212040	Arrowroot	0,05*	0,01*
212990	Others	0,05*	0,01*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*	0,01*
213010	Beetroot	0,05*	0,01*
213020	Carrots	0,05*	0,01*
213030	Celeriac	0,05*	0,01*
213040	Horseradish	0,05*	0,01*
213050	Jerusalem artichokes	0,05*	0,01*
213060	Parsnips	0,05*	0,01*
213070	Parsley root	0,05*	0,01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*	0,01*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*	0,01*
213100	Swedes	0,05*	0,01*
213110	Turnips	0,05*	0,01*
213990	Others	0,05*	0,01*
220000	(ii) Bulb vegetables	0,05*	0,01*
220010	Garlic	0,05*	0,01*
220020	Onions (Silverskin onions)	0,05*	0,01*
220030	Shallots	0,05*	0,01*
220040	Spring onions (Welsh onion and similar varieties)	0,05*	0,01*
220990	Others	0,05*	0,01*
230000	(iii) Fruiting vegetables	0,05*	0,01*
231000	(a) Solanacea	0,05*	0,01*
231010	Tomatoes (Cherry tomatoes,)	0,05*	0,01*
231020	Peppers (Chilli peppers)	0,05*	0,01*
231030	Aubergines (egg plants) (Pepino)	0,05*	0,01*
231040	Okra, lady's fingers	0,05*	0,01*
231990	Others	0,05*	0,01*
232000	(b) Cucurbits - edible peel	0,05*	0,01*
232010	Cucumbers	0,05*	0,01*
232020	Gherkins	0,05*	0,01*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*	0,01*
232990	Others	0,05*	0,01*
233000	(c) Cucurbits-inedible peel	0,05*	0,01*
233010	Melons (Kiwano)	0,05*	0,01*
233020	Pumpkins (Winter squash)	0,05*	0,01*
233030	Watermelons	0,05*	0,01*
233990	Others	0,05*	0,01*
234000	(d) Sweet corn	0,05*	0,01*
239000	(e) Other fruiting vegetables	0,05*	0,01*
240000	(iv) Brassica vegetables	0,05*	0,01*
241000	(a) Flowering brassica	0,05*	0,01*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*	0,01*
241020	Cauliflower	0,05*	0,01*
241990	Others	0,05*	0,01*
242000	(b) Head brassica	0,05*	0,01*
242010	Brussels sprouts	0,05*	0,01*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*	0,01*
242990	Others	0,05*	0,01*
243000	(c) Leafy brassica	0,05*	0,01*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*	0,01*
243020	Kale (Borecole (curly kale), collards)	0,05*	0,01*
243990	Others	0,05*	0,01*
244000	(d) Kohlrabi	0,05*	0,01*
250000	(v) Leaf vegetables & fresh herbs	0,05*	
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*	0,01*
251010	Lamb´s lettuce (Italian cornsalad)	0,05*	0,01*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*	0,01*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*	0,01*
251040	Cress	0,05*	0,01*
251050	Land cress	0,05*	0,01*
251060	Rocket, Rucola (Wild rocket)	0,05*	0,01*
251070	Red mustard	0,05*	0,01*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*	0,01*
251990	Others	0,05*	0,01*
252000	(b) Spinach & similar (leaves)	0,05*	0,01*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*	0,01*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0,05*	0,01*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*	0,01*
252990	Others	0,05*	0,01*
253000	(c) Vine leaves (grape leaves)	0,05*	0,01*
254000	(d) Water cress	0,05*	0,01*
255000	(e) Witloof	0,05*	0,01*
256000	(f) Herbs	0,05*	0,02*
256010	Chervil	0,05*	0,02*
256020	Chives	0,05*	0,02*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,05*	0,02*
256040	Parsley	0,05*	0,02*
256050	Sage (Winter savory, summer savory,)	0,05*	0,02*
256060	Rosemary	0,05*	0,02*
256070	Thyme (marjoram, oregano)	0,05*	0,02*
256080	Basil (Balm leaves, mint, peppermint)	0,05*	0,02*
256090	Bay leaves (laurel)	0,05*	0,02*
256100	Tarragon (Hyssop)	0,05*	0,02*
256990	Others	0,05*	0,02*
260000	(vi) Legume vegetables (fresh)	0,05*	0,01*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*	0,01*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*	0,01*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*	0,01*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*	0,01*
260050	Lentils	0,05*	0,01*
260990	Others	0,05*	0,01*
270000	(vii) Stem vegetables (fresh)	0,05*	0,01*
270010	Asparagus	0,05*	0,01*
270020	Cardoons	0,05*	0,01*
270030	Celery	0,05*	0,01*
270040	Fennel	0,05*	0,01*
270050	Globe artichokes	0,05*	0,01*
270060	Leek	0,05*	0,01*
270070	Rhubarb	0,05*	0,01*
270080	Bamboo shoots	0,05*	0,01*
270090	Palm hearts	0,05*	0,01*
270990	Others	0,05*	0,01*
280000	(viii) Fungi	0,05*	0,01*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*	0,01*

Code number	Groups and examples of individual products to which the MRLs apply	Picoxystrobin	Picoxystrobin [a]
280020	Wild (Chanterelle, Truffle, Morel ,)	0,05*	0,01*
280990	Others	0,05*	0,01*
290000	(ix) Sea weeds	0,05*	0,01*
300000	3. PULSES, DRY	0,05*	0,01*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*	0,01*
300020	Lentils	0,05*	0,01*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*	0,01*
300040	Lupins	0,05*	0,01*
300990	Others	0,05*	0,01*
400000	4. OILSEEDS AND OILFRUITS	0,05*	
401000	(i) Oilseeds	0,05*	
401010	Linseed	0,05*	0,01*
401020	Peanuts	0,05*	0,01*
401030	Poppy seed	0,05*	0,01*
401040	Sesame seed	0,05*	0,01*
401050	Sunflower seed	0,05*	0,01*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*	0,02 (ft)
401070	Soya bean	0,05*	0,01*
401080	Mustard seed	0,05*	0,01*
401090	Cotton seed	0,05*	0,01*
401100	Pumpkin seeds	0,05*	0,01*
401110	Safflower	0,05*	0,01*
401120	Borage	0,05*	0,01*
401130	Gold of pleasure	0,05*	0,01*
401140	Hempseed	0,05*	0,01*
401150	Castor bean	0,05*	0,01*
401990	Others	0,05*	0,01*
402000	(ii) Oilfruits	0,05*	0,01*
402010	Olives for oil production	0,05*	0,01*
402020	Palm nuts (palmoil kernels)	0,05*	0,01*
402030	Palmfruit	0,05*	0,01*
402040	Kapok	0,05*	0,01*
402990	Others	0,05*	0,01*
500000	5. CEREALS		
500010	Barley	0,2	0,3
500020	Buckwheat	0,05*	0,01*
500030	Maize	0,05*	0,01*
500040	Millet (Foxtail millet, teff)	0,05*	0,01*
500050	Oats	0,2	0,3
500060	Rice	0,05*	0,01*
500070	Rye	0,05*	0,05
500080	Sorghum	0,05*	0,01*
500090	Wheat (Spelt Triticale)	0,05*	0,05
500990	Others	0,05*	0,01*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*	0,05*
620000	(ii) Coffee beans	0,1*	0,05*
630000	(iii) Herbal infusions (dried)	0,1*	0,05*
631000	(a) Flowers	0,1*	0,05*
631010	Camomille flowers	0,1*	0,05*
631020	Hybiscus flowers	0,1*	0,05*
631030	Rose petals	0,1*	0,05*
631040	Jasmine flowers	0,1*	0,05*
631050	Lime (linden)	0,1*	0,05*
631990	Others	0,1*	0,05*
632000	(b) Leaves	0,1*	0,05*
632010	Strawberry leaves	0,1*	0,05*
632020	Rooibos leaves	0,1*	0,05*
632030	Maté	0,1*	0,05*
632990	Others	0,1*	0,05*
633000	(c) Roots	0,1*	0,05*
633010	Valerian root	0,1*	0,05*
633020	Ginseng root	0,1*	0,05*
633990	Others	0,1*	0,05*
639000	(d) Other herbal infusions	0,1*	0,05*
640000	(iv) Cocoa (fermented beans)	0,1*	0,05*
650000	(v) Carob (st johns bread)	0,1*	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*	0,05*
800000	8. SPICES	0,1*	
810000	(i) Seeds	0,1*	0,05*
810010	Anise	0,1*	0,05*
810020	Black caraway	0,1*	0,05*
810030	Celery seed (Lovage seed)	0,1*	0,05*
810040	Coriander seed	0,1*	0,05*
810050	Cumin seed	0,1*	0,05*
810060	Dill seed	0,1*	0,05*
810070	Fennel seed	0,1*	0,05*
810080	Fenugreek	0,1*	0,05*
810090	Nutmeg	0,1*	0,05*
810990	Others	0,1*	0,05*
820000	(ii) Fruits and berries	0,1*	0,05*
820010	Allspice	0,1*	0,05*
820020	Anise pepper (Japan pepper)	0,1*	0,05*
820030	Caraway	0,1*	0,05*
820040	Cardamom	0,1*	0,05*
820050	Juniper berries	0,1*	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*	0,05*
820070	Vanilla pods	0,1*	0,05*
820080	Tamarind	0,1*	0,05*
820990	Others	0,1*	0,05*
830000	(iii) Bark	0,1*	0,05*
830010	Cinnamon (Cassia)	0,1*	0,05*
830990	Others	0,1*	0,05*
840000	(iv) Roots or rhizome	0,1*	
840010	Liquorice	0,1*	0,05*
840020	Ginger	0,1*	0,05*
840030	Turmeric (Curcuma)	0,1*	0,05*
840040	Horseradish	0,1*	(ft)
840990	Others	0,1*	0,05*
850000	(v) Buds	0,1*	0,05*
850010	Cloves	0,1*	0,05*
850020	Capers	0,1*	0,05*
850990	Others	0,1*	0,05*
860000	(vi) Flower stigma	0,1*	0,05*
860010	Saffron	0,1*	0,05*
860990	Others	0,1*	0,05*
870000	(vii) Aril	0,1*	0,05*
870010	Mace	0,1*	0,05*
870990	Others	0,1*	0,05*
900000	9. SUGAR PLANTS	0,05*	0,01*
900010	Sugar beet (root)	0,05*	0,01*
900020	Sugar cane	0,05*	0,01*
900030	Chicory roots	0,05*	0,01*
900990	Others	0,05*	0,01*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS		
1010000	(i) Muscle, preparations of Muscle, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*	0,01*
1011000	(a) Swine	0,05*	0,01*
1011010	Muscle	0,05*	0,01*
1011020	Fat free of lean Muscle	0,05*	0,01*
1011030	Liver	0,05*	0,01*
1011040	Kidney	0,05*	0,01*
1011050	Edible offal	0,05*	0,01*
1011990	Others	0,05*	0,01*
1012000	(b) Bovine	0,05*	0,01*
1012010	Muscle	0,05*	0,01*
1012020	Fat	0,05*	0,01*
1012030	Liver	0,05*	0,01*

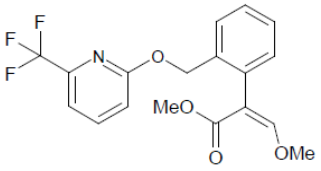
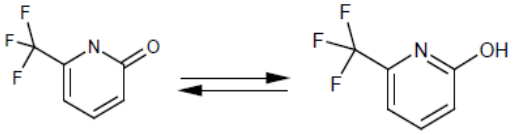
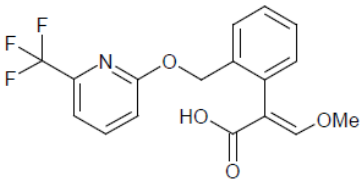
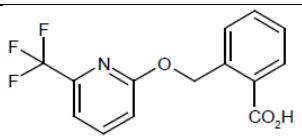
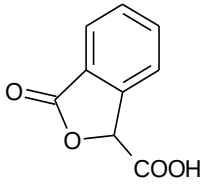
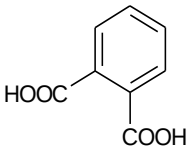
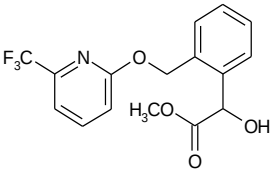
Code number	Groups and examples of individual products to which the MRLs apply	Picoxystrobin	Picoxystrobin [a]
1012040	Kidney	0,05*	0,01*
1012050	Edible offal	0,05*	0,01*
1012990	Others	0,05*	0,01*
1013000	(c) Sheep	0,05*	0,01*
1013010	Muscle	0,05*	0,01*
1013020	Fat	0,05*	0,01*
1013030	Liver	0,05*	0,01*
1013040	Kidney	0,05*	0,01*
1013050	Edible offal	0,05*	0,01*
1013990	Others	0,05*	0,01*
1014000	(d) Goat	0,05*	0,01*
1014010	Muscle	0,05*	0,01*
1014020	Fat	0,05*	0,01*
1014030	Liver	0,05*	0,01*
1014040	Kidney	0,05*	0,01*
1014050	Edible offal	0,05*	0,01*
1014990	Others	0,05*	0,01*
1015000	(e) Horses, asses, mules or hinnies	0,05*	0,01*
1015010	Muscle	0,05*	0,01*
1015020	Fat	0,05*	0,01*
1015030	Liver	0,05*	0,01*
1015040	Kidney	0,05*	0,01*
1015050	Edible offal	0,05*	0,01*
1015990	Others	0,05*	0,01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*	0,01*
1016010	Muscle	0,05*	0,01*
1016020	Fat	0,05*	0,01*
1016030	Liver	0,05*	0,01*
1016040	Kidney	0,05*	0,01*
1016050	Edible offal	0,05*	0,01*
1016990	Others	0,05*	0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*	0,01*
1017010	Muscle	0,05*	0,01*
1017020	Fat	0,05*	0,01*
1017030	Liver	0,05*	0,01*
1017040	Kidney	0,05*	0,01*
1017050	Edible offal	0,05*	0,01*
1017990	Others	0,05*	0,01*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,02*	0,01
1020010	Cattle	0,02*	0,01
1020020	Sheep	0,02*	0,01
1020030	Goat	0,02*	0,01
1020040	Horse	0,02*	0,01
1020990	Others	0,02*	0,01
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*	0,01*
1030010	Chicken	0,05*	0,01*
1030020	Duck	0,05*	0,01*
1030030	Goose	0,05*	0,01*
1030040	Quail	0,05*	0,01*
1030990	Others	0,05*	0,01*
1040000	(iv) Honey (Royal jelly, pollen)		0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)		0,01*
1060000	(vi) Snails		0,01*
1070000	(vii) Other terrestrial animal products	0,05*	0,01*

(*) Indicates lower limit of analytical determination

[a] MRL value as proposed by EFSA in its reasoned opinions (EFSA, 2011) and voted by the SCFCAH on *17 09 2013*. SANCO /11037/2013. Not legally enforced by *22 05 2014*.

[a] The enforcement residue definition and the MRL value by EFSA in its reasoned opinion on the review of the existing maximum residue levels for picoxystrobin (EFSA, 2011)) and voted by the SCoFCAH. For details on the derived MRLs see the table footnotes of the reasoned opinion.

List of metabolites and related structural formula

Code/Trivial name	Chemical name	Structural formula
IN-QCD12	Methyl(αZ)-α-(methoxymethylene)-2-[[[6-(trifluoromethyl)-2-pyridinyl] oxy] methyl] benzeneacetate	
IN-QDK50	6-(trifluoromethyl)-2(1H)-pyridinone	
IN-QDY62	(E)-3-methoxy-2-{2-[6-[trifluoromethyl)pyridine-2-yloxymethyl]phenyl}acrylic acid (IUPAC name)	
IN-QDY63	2-[[[6-[trifluoromethyl]-2-pyridinyl]oxy]methyl]benzoic acid	
IN-H8612	1,3-dihydro-isobenzofuran-3-one-1-carboxylic acid	
IN-K2122	o-phthalic acid	
IN-QGS44 R410101	methyl 2-hydroxy-{2-[6-trifluoromethyl)pyridin-2-yloxymethyl]phenyl} acetate	

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
DAR	Draft Assessment Report
DM	dry matter
DT_{90}	period required for 90 % dissipation (define method of estimation)
EC	European Community
ECD	electron capture detector
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
GCPF	Global Crop Protection Federation (former GIFAP)
GC	gas chromatography
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
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
MSD	mass spectrometry detector

MS/MS	tandem mass spectrometry
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RAC	raw agricultural commodity
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SCoFCAH	Standing Committee on the Food Chain and Animal Health
SC	suspension concentrate
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization