

REASONED OPINION

Modification of existing MRLs for pyraclostrobin in various crops¹

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SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, Germany received an application from BASF SE to set import tolerances for pyraclostrobin in various crops. The requested import tolerances require increasing existing EC MRLs for pyraclostrobin in cherries, plums, strawberries, cane fruit, other small fruits and berries, spring onions, cucurbits with edible and inedible peel, sunflower seeds and coffee beans. The RMS Germany drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 30 July 2009.

EFSA derived the following conclusions based on the above mentioned evaluation report and the Draft Assessment Report (DAR) prepared by Germany under Directive 91/414/EEC.

The toxicological profile of the active substance was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.03 mg/kg bw/d and an ARfD value of 0.03 mg/kg bw.

The metabolism of pyraclostrobin in primary crops is elucidated in fruits and fruiting vegetables, root and tuber vegetables and cereals and the risk assessment and enforcement residue definition is established as parent pyraclostrobin for all plant commodities. Consequently, no additional metabolism studies are required for the crops under consideration. The enforcement residue definition for commodities of animal origin is established as parent pyraclostrobin only.

Adequate analytical methods are available for the enforcement of the proposed MRLs for pyraclostrobin in all crops under consideration except for coffee beans for which the applicability of the analytical method should be demonstrated by providing the relevant validation data.

Submitted supervised residue field trials indicate that higher EC MRLs are required to accommodate the authorized GAPs in the USA, Canada and Brazil.

The effects of processing on the nature of pyraclostrobin were studied in a hydrolysis study and no degradation of pyraclostrobin was observed. Data on the indoor residue trials performed in Europe on melons were reported by the EMS and were used to assess the distribution of pyraclostrobin residues in melon pulp and peel. From these data a provisional median peeling factor of 0.5 was derived. Details on the GAP according to which the residue trials have been performed were not reported and a submission of more detailed information would be desirable.

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The occurrence of pyraclostrobin residues in rotational crops was not investigated as it is not of relevance for the import tolerance requests.

The occurrence of pyraclostrobin residues in commodities of animal origin was also investigated since sunflower seeds and/or its by-products can be used as livestock feeding items. The livestock dietary burden calculation was performed considering the livestock exposure to pyraclostrobin residues from sunflower seeds and seed meal and from all other plant commodities which are listed in Annexes II and IIIB of Regulation (EC) No 396/2005 and which are potential feeding items and for which the current MRLs are set above the LOQ. The calculated dietary burden exceeds the trigger value of 0.1 mg/kg DM for all relevant livestock species, but is mainly driven by expected residues in barley. As the proposed import tolerance of pyraclostrobin on sunflower seeds does not affect the dietary burden significantly, the need for the amendment of existing MRLs in food of animal origin was not further investigated in the framework of this application.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 as well as STMR values derived for the requested import tolerances. For certain crops the STMR values were available to refine the consumer intake calculations. For gherkins and courgettes EFSA used STMR values as derived in a previously issued EFSA reasoned opinion since these values were derived for the European GAP and were higher than the values derived from the studies supporting the import tolerance request. The acute intake assessment was performed only with regard to the crops under consideration and the HR values as derived for the requested import tolerances were used as input values in the intake calculation. For cucurbits with inedible peel, the provisional peeling factor of 0.5 was applied to refine the intake calculations.

No long term intake concerns were identified for any of the European diets. The total calculated dietary intake values accounted for a maximum of 33.5 % of the ADI. The individual contribution of crops under consideration was in all cases below 1% of the ADI.

No acute intake concerns were identified for the requested import tolerances. The highest acute consumer exposure to pyraclostrobin residues was identified for melons (73.3% of the ARfD), followed by cherries (65.2% of the ARfD), currants (65.0% of the ARfD), watermelons (59% of the ARfD), blackberries (46.4% of the ARfD), gooseberries (43.3% of the ARfD), cucumbers (42.9% of the ARfD), strawberries (40.5% of the ARfD), plums (36.5% of the ARfD), raspberries (24.3% of the ARfD) and blueberries (21.7% of the ARfD).

Consequently, EFSA concludes that the proposed import tolerance MRLs are acceptable as they will not raise any consumer health concerns. The following recommendations are derived:

Code number	Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: pyraclostrobin				
0140020	Cherries	0.3	2	Proposed import tolerance MRLs are sufficiently supported by data and no risk for consumers was identified.
0140040	Plums	0.2	0.5	
0152000	Strawberries	0.5	1	
0153000	<i>Cane fruit:</i>		2	
0153010	Blackberries	1.0		
0153020	Dewberries	0.02*		
0153030	Raspberries	1.0		

Code number	Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
0154000	<i>Other small fruits and berries:</i>		3	
0154010	Blueberries	0.5		
0154020	Cranberries	0.5		
0154030	Currants (red, black and white)	2.0		
0154040	Gooseberries	0.5		
0154050	Rose hips	0.5		
0154060	Mulberries	0.5		
0154070	Azarole	0.5		
0154080	Elderberries	0.5		
0220040	Spring onions	0.02*	1.5	
0232010	Cucumbers	0.02*	0.3	
0233000	<i>Cucurbits-inedible peel:</i>		0.5	
0233010	Melons	0.02*		
0233020	Pumpkins	0.02*		
0233030	Watermelons	0.02*		
0401050	Sunflower seed	0.02*	0.3	
0620000	Coffee beans	0.05*	0.2	The applicability of the analytical method for coffee beans should be demonstrated by providing the relevant validation data.

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

KEY WORDS

Pyraclostrobin, cherries, plums, strawberries, small fruits and berries, cane fruit, spring onions, cucurbits, sunflower seeds, coffee beans, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, strobilurin fungicide

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that any party having a legitimate commercial interest may submit to the rapporteur Member State designated pursuant to Directive 91/414/EEC an application to set an import tolerance in accordance with the provisions of Article 7 of that regulation.

Germany, hereafter referred to as the evaluating Member State (EMS), received from the company BASF SE³ an application to modify the existing MRLs for the active substance pyraclostrobin in various crops. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 30 July 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00742 and the following subject:

Pyraclostrobin - Application to modify the existing MRLs in various crops.

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE

According to 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.

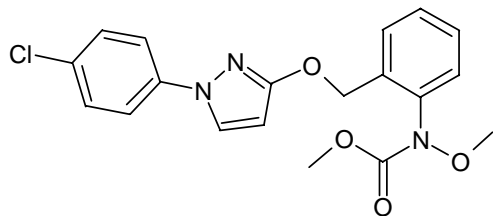
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 30 October 2009.

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THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Pyraclostrobin is the ISO common name for methyl N-(2-{{[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxymethyl}phenyl) N-methoxy carbamate (IUPAC).



Pyraclostrobin is a fungicide belonging to the group of strobilurins. The biochemical mode of action of strobilurins is the inhibition of mitochondrial respiration. Pyraclostrobin is active against fungal development stages both on the plant surface and within the tissues. It has a protective as well as an eradivative/curative action. Pyraclostrobin also affects the plant metabolism and physiology exhibiting properties of a plant growth regulator. It changes the phytohormone relationship in the plant, increases greening effect and improves tolerance against stresses. Pyraclostrobin is used on a wide range of dicotyledonous and monocotyledonous crop species.

Pyraclostrobin was peer reviewed under Directive 91/414/EEC by Germany being the designated Rapporteur Member State. The active substance was included in Annex I to this Directive by the Commission Directive 2004/30/EC for use as a fungicide. Representative uses evaluated under the peer review were foliar application of the active substance on grapes. From 4 August 2009, according to Directive 2009/25/EC which amends Directive 91/414/EEC, pyraclostrobin can also be used as a plant growth regulator. Pyraclostrobin has not been peer reviewed by EFSA.

MRLs for pyraclostrobin were set at EU level for the first time with Directive 2005/70/EC. The MRLs established under Directives 86/362/EEC, 86/363/EEC and 90/642/EEC have been transferred to Annex II of Regulation (EC) No 396/2005. In Annex III temporary MRLs have been established for crops that were not covered by the previous Community legislation. The existing MRLs for pyraclostrobin are established in Annexes II and IIIB of Regulation (EC) No 396/2005 and are summarized in Appendix C to this document. Recently the MRL proposals for courgettes, gherkins and beet root have been assessed by EFSA (EFSA, 2009) and recommendations made by EFSA were considered in the SCoFCAH on 15-16 October 2009.

Codex Alimentarius has established CXLs for a wide range of crops including blueberries 1 mg/kg, coffee beans 0.3 mg/kg, cucumbers 0.5 mg/kg, raspberries 2 mg/kg, stone fruits 1 mg/kg, strawberry 0.5 mg/kg and sunflower seed 0.3 mg/kg.

For the import tolerance requests, the GAPs were reported as authorized in the USA, Canada and Brazil. All authorizations refer to the outdoor applications of pyraclostrobin. The minimum PHI is 0 days for all crops except spring onions (7 days), sunflower seed (21 day) and coffee beans (45 days). The summary of the submitted GAPs is provided in Appendix A.

EFSA bases its assessment on the evaluation report provided by the EMS Germany (2009), the GAP and supervised residue trails data provided by the applicant BASF SE, the Draft Assessment Report prepared under Directive 91/414/EEC and internationally agreed guidance documents available on the following website: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#residues.

ASSESSMENT

1. Methods of analysis

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

The analytical methods for the determination of pyraclostrobin in foodstuffs of plant origin were evaluated in the framework of the peer review of Directive 91/414/EEC (Germany, 2001). Pyraclostrobin residues in commodities of plant origin can be determined by LC-MS-MS or HPLC-UV methods with an LOQ of 0.02 mg/kg. In addition, QuEChERS method (determination using GC-MS and/or LC-MS/MS) is sufficiently validated at the LOQ of 0.01 mg/kg for the determination of pyraclostrobin in plant matrices.

Adequate analytical methods are available for the enforcement of the proposed MRLs for pyraclostrobin in all crops under consideration except for coffee beans for which the applicability of the analytical method should be demonstrated by providing the relevant validation data.

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

The analytical methods for the determination of pyraclostrobin in foodstuffs of animal origin were evaluated in the framework of the peer review of Directive 91/414/EEC (Germany, 2001). Pyraclostrobin residues in commodities of animal origin can be determined by HPLC-UV method with a validated LOQ of 0.01 mg/kg in milk and 0.05 mg/kg in muscle, liver, kidney, fat and eggs.

2. Mammalian toxicology

The toxicological reference values for pyraclostrobin were derived in the peer review under Directive 91/414/EEC and are compiled in Table 2-1 (European Commission, 2004).

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Pyraclostrobin					
ADI	COM	2004	0.03 mg/kg bw/d	Chronic rat	100
ARfD	COM	2004	0.03 mg/kg bw	Rabbit developmental toxicity	100

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Under the peer review of Directive 91/414/EEC, metabolism studies were submitted for the following crop categories (Germany, 2001):

- fruits and fruiting vegetables: grapes (foliar application 1.5 kg a.s./ha)

- root and tuber vegetables: potato (foliar application 6 x 0.3 kg a.s./ha)
- cereals: wheat (foliar application 2 x 0.3 kg a.s./ha)

The metabolism and distribution of pyraclostrobin in plants was investigated using [tolyl-U-¹⁴C]-pyraclostrobin and [chlorophenyl-U-¹⁴C]-pyraclostrobin.

The relevant residue in grapes consisted of parent pyraclostrobin (55.7 - 66% TRR) and its desmethoxy metabolite 500M07⁴ (11.2 - 15.3 % TRR). In potatoes the highest TRR was identified in green matter (41.2 – 57.9 mg/kg) in both studies. Parent pyraclostrobin was the main component of the TRR in green matter and potato tubers in studies with [chlorophenyl-U-¹⁴C]-pyraclostrobin, amounting for 55% and 29.4 % of the TRR, respectively. In the green matter desmethoxy metabolite 500M07 was identified in levels > 20% of the TRR in both studies. In the tolyl study the major component of the TRR in potato tubers was identified as natural amino acid L-tryptophan (29.2% TRR). In cereals, the lowest TRR was found in grains, varying between 0.098 mg/kg in the chlorophenyl labelled and 0.441 mg/kg in the tolyl labelled matrix. The highest TRR was identified in wheat straw, amounting for up to 37.76 mg/kg (chlorophenyl study) and 40.46 mg/kg (tolyl study). The major component of the TRR in straw and grain in the chlorophenyl study was parent pyraclostrobin and its desmethoxy metabolite 500M07. In the tolyl study the major component of the TRR in grain was L-tryptophan (23% TRR), any other components being below 10% of the TRR. L-tryptophan is an essential natural amino acid therefore it is of no toxicological relevance.

Generally it was concluded in the peer review that the metabolic pathway is similar in all crop groups investigated. Results from the supervised residue trials indicated that desmethoxy metabolite 500M07 occurs in crops in small amounts compared to parent pyraclostrobin, therefore in the peer review it was concluded that a general residue definition for risk assessment and monitoring should be set as parent pyraclostrobin only.

Regarding crops under consideration, EFSA concludes that the metabolic pathway is sufficiently addressed and no additional metabolism studies are necessary.

3.1.1.2. Magnitude of residues

In support of the import tolerance requests, a number of GAPs and supervised residue trials were submitted to the EMS Germany. Several residue trials according to the evaluation of the EMS were not performed according to the GAP and therefore no MRL proposals were made.

The residue trials supporting the authorized GAPs in the USA, Canada and Brazil are compiled in the Table 3-1 along with derived MRL proposals and risk assessment values. The MRL proposals for group tolerances (cane fruit, small fruits and berries, cucurbits inedible peel) were derived by extrapolating the residues data.

It should be noted, that the applicant submitted 14 residue trials data on blueberries (high bush) for the extrapolation to the whole group of small fruits and berries. According to EU Guidance document on comparability, extrapolation, group tolerances and data requirements for setting MRLs, at least 8 trials of currants alone or of two representatives (including 4 trials on currants) or trials on any single wild berry crop are required to allow for extrapolation of residue data on the whole group of small fruits and berries (European Commission, 2008). None of these requirements are fulfilled for the requested import tolerance. Since the vegetative structure of high bush blueberries is comparable with that of currants and since crops belonging to the group of small fruits and berries are considered as minor or very minor crops, EFSA is of the opinion that residue data on blueberries can be extrapolated to the whole group of small fruits and berries.

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

In addition, residue trials on cucumbers and courgettes were not used as proposed by the EMS and the applicant for setting the group tolerance MRLs (cucurbits with edible peel) since recently EFSA has assessed and recommended the EC MRL of 0.5 mg/kg for courgettes and gherkins based on the EU GAP (EFSA, 2009). Therefore the submitted residue data for the import tolerance request on cucumbers and courgettes were used to derive the MRL proposal for cucumbers only.

The demonstrated storage stability of pyraclostrobin in treated crops was evaluated under the peer review of Directive 91/414/EEC (Germany, 2001). Studies demonstrated storage stability of pyraclostrobin in commodities with high oil-, water- and acid content as well as in dry commodities for up to 18 months when stored deep frozen.

According to the RMS all residue trial results are considered valid regarding storage stability and the analytical performance of the method applied.

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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement (Pyraclostrobin)	Risk assessment (Pyraclostrobin)					
Cherries	Import tolerance	Outdoor	0.025; 2 x 0.25; 0.27; 0.34;0.38; 0.42; 0.43; 0.47; 0.48; 2 x 0.5; 0.51; 0.56; 0.63; 0.67; 0.82; 2 x 1.1; 1.6	0.025; 2 x 0.25; 0.27; 0.34;0.38; 0.42; 0.43; 0.47; 0.48; 2 x 0.5; 0.51; 0.56; 0.63; 0.67; 0.82; 2 x 1.1; 1.6	0.49	1.6	2.0	1.0	Residue trials were performed on sweet cherries (indicated in italic) and on sour cherries. R _{ber} =1.32 mg/kg R _{max} =1.42 mg/kg
Plums	Import tolerance	Outdoor	0.01; 0.02; 0.023; 0.024; 0.026; 0.035; 0.039; 0.051; 0.059; 0.063; 0.064; 0.065;0.085; 0.12; 0.13; 0.19; 0.22; 0.34; 0.38; 0.4; 0.41	0.01; 0.02; 0.023; 0.024; 0.026; 0.035; 0.039; 0.051; 0.059; 0.063; 0.064; 0.065;0.085; 0.12; 0.13; 0.19; 0.22; 0.34; 0.38; 0.4; 0.41	0.064	0.41	0.5	1.0	R _{ber} = 0.41 mg/kg R _{max} =0.455 mg/kg
Strawberry	Import tolerance	Outdoor	0.059; 0.062; 0.12; 0.14; 0.16; 0.2; 0.24; 0.31; 0.4; 0.43; 0.52; 0.74; 0.78	0.059; 0.062; 0.12; 0.14; 0.16; 0.2; 0.24; 0.31; 0.4; 0.43; 0.52; 0.74; 0.78	0.24	0.78	1.0	1.0	R _{ber} = 0.95 mg/kg R _{max} =0.965 mg/kg
Blackberry, raspberry → Cane fruit	Import tolerance	Outdoor	0.35; 0.4; 0.48; 0.51; 0.63;0.78; 0.86; 0.87; 2 x 0.88; 1.0; 1.1; 1.2; 1.3	0.35; 0.4; 0.48; 0.51; 0.63;0.78; 0.86; 0.87; 2 x 0.88; 1.0; 1.1; 1.2; 1.3	0.865	1.3	2	1.0	Residue trials were performed on blackberries (in italic) and raspberries. Extrapolation to the whole group of cane fruit is acceptable. R _{ber} =2.05 mg/kg R _{max} =1.58 mg/kg

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement (Pyraclostrobin)	Risk assessment (Pyraclostrobin)					
Blueberry (highbush) → Small fruits and berries	Import tolerance	Outdoor	0.19; 0.31; 0.33; 0.35; 0.48; 0.57; 0.78; 1.1; 1.2; 1.4; 1.6; 2.0 2 x 2.1	0.19; 0.31; 0.33; 0.35; 0.48; 0.57; 0.78; 1.1; 1.2; 1.4; 1.6; 2.0 2 x 2.1	0.94	2.10	3	1.0	Residue trials were performed on blueberries but residue data can be extrapolated to the whole group of small fruits and berries R _{ber} =3.4 mg/kg R _{max} =2.88 mg/kg
Spring onions	Import tolerance	Outdoor	0.053; 0.054; 0.34; 0.42; 0.53; 0.58; 0.6	0.053; 0.054; 0.34; 0.42; 0.53; 0.58; 0.6	0.42	0.6	1.5	1.0	R _{ber} =1.16 mg/kg R _{max} =1.16 mg/kg
Cucumbers, courgettes → cucumbers	Import tolerance	Outdoor	0.022; 0.048 ^{PHI1} ; 0.062; 0.09; 0.092; 0.1; 0.12; 0.22	0.022; 0.048 ^{PHI1} ; 0.062; 0.09; 0.092; 0.1; 0.12; 0.22	0.091	0.22	0.3	1.0	Residue trials were performed on cucumbers and courgettes (in italic). Residue data would allow extrapolation to the whole group of cucurbits with edible peel, but since the MRL proposal of 0.5 mg/kg is already assessed and recommended by EFSA for courgettes and gherkins for the EU GAP (EFSA, 2009), the submitted residue data are used to derive MRL proposal for cucumbers only. R _{ber} = 0.23 mg/kg R _{max} = 0.29 mg/kg

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement (Pyraclostrobin)	Risk assessment (Pyraclostrobin)					
Melon → Cucurbits with inedible peel	Import tolerance	Outdoor	0.095; 0.12; 0.053; 0.14; 0.1; 0.29	0.053; 0.095; 0.1; 0.12; 0.14; 0.29	0.11	0.29	0.5	1.0	Residue trials were performed on melons but data can be extrapolated to the whole group of cucurbits with inedible peel. R _{ber} =0.355 mg/kg R _{max} =0.44 mg/kg
Sunflower seeds	Import tolerance	Outdoor	<0.02; 0.033; 0.028; 0.02; 0.099; 0.053; 0.04; 0.17	<0.02;0.02; 0.028; 0.033; 0.04; 0.053; 0.099; 0.17	0.037	0.17	0.3	1.0	R _{ber} =0.175 mg/kg R _{max} =0.22 mg/kg
Coffee	Import tolerance	Outdoor	<0.02; 3 x 0.02; 3 x 0.03; 0.11 ^{PHI60d} , 0.15	<0.02; 3 x 0.02; 3 x 0.03; 0.11 ^{PHI60d} ; 0.15	0.03	0.15	0.2	1.0	R _{ber} =0.14 mg/kg R _{max} =0.19 mg/kg

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(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 residues trial.

3.1.1.3. Effect of industrial processing and/or household preparation

In the peer review the effects of processing on the nature of pyraclostrobin were studied in hydrolysis study by simulating pasteurization, baking, brewing, boiling and sterilization processes (Germany, 2001). Results showed no degradation of pyraclostrobin under these conditions.

The applicant has not submitted specific studies to assess effects of processing on the magnitude of pyraclostrobin residues. Data on the indoor residue trials performed in Europe on melons were reported by the EMS and were used to assess the distribution of pyraclostrobin residues in melon pulp and peel. From these data a provisional median peeling factor of 0.5 was derived. EFSA notes that the details of the GAP according to which the residue trials have been performed were not reported and a submission of a more detailed information would be desirable.

Table 3-2. Overview of the available processing studies

Processed commodity	Number of studies	Median PF ^(a)	Median CF ^(b)	Comments
Pyraclostrobin				
Melons, peeled	7	0.5	1.0	In all studies (except one) the residues in melon pulp were below the LOQ of 0.02 mg/kg. One study was not considered since residues both in pulp and whole fruit were below the LOQ.

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

3.1.2. Rotational crops

The occurrence of pyraclostrobin residues in rotational crops was not investigated and is not of relevance for the import tolerance requested.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

According to the EU Guidance document on livestock feeding studies, sunflower seed and seed meal are potential livestock feeding items for dairy and meat ruminants, poultry and pigs (European Commission, 1996).

EFSA calculated the livestock exposure to pyraclostrobin residues from sunflower seeds and seed meal and from all commodities which are listed in Annexes II and IIIB of Regulation (EC) No 396/2005 and which are potential feeding items and for which the current MRLs are set above the LOQ. For these commodities the STMR and HR values were available as reported by the RMS Germany in the framework of Article 12(2) of Regulation (EC) No 396/2005. For pome fruit and citrus fruit pomace the default processing factor of 2.5 was applied; for wheat and rye bran the default processing factor of 8 was used; for sunflower seed meal the processing factor of 2 was applied.

The overview of input values for dietary burden calculation is provided in the table below:

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: pyraclostrobin				
Sunflower seed	0.037	STMR	0.037	STMR
Sunflower seed meal	0.074	STMR*PF (2.00)	0.074	STMR*PF (2.00)
Citrus pomace	0.6 (0.24*2.5)	STMR*PF (2.5) (Germany, 2008)	0.6 (0.24*2.5)	STMR*PF (2.5) (Germany, 2008)
Apples pomace	0.25 (0.1*2.5)	STMR*PF (Germany, 2008)	0.25 (0.1*2.5)	STMR*PF (Germany, 2008)
Head cabbage	0.02	STMR (Germany, 2008)	0.09	HR (Germany, 2008)
Pulses, dry	0.04	STMR (Germany, 2008)	0.25	HR (Germany, 2008)
Barley, oat grain	0.07	STMR (Germany, 2008)	0.07	STMR (Germany, 2008)
Barley, oat straw	3.38	STMR (Germany, 2008)	6.92	HR (Germany, 2008)
Rye, wheat grain	0.02	STMR (Germany, 2008)	0.02	STMR (Germany, 2008)
Rye, wheat straw	1.85	STMR (Germany, 2008)	5.68	HR (Germany, 2008)
Wheat, rye bran	0.16 (0.02*8)	STMR*PF (Germany, 2008)	0.16 (0.02*8)	STMR*PF (Germany, 2008)

To estimate the contribution of sunflower seed and sunflower seed meal to the overall livestock dietary burden, EFSA performed one dietary burden calculation including sunflower seeds and seed meal and another calculation excluding sunflower seeds and meal. The results of the dietary burden calculation are summarized in Tables 3-4 and 3-5.

Table 3-4. Results of the dietary burden calculation **excluding** sunflower seeds

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded?
Risk assessment residue definition: pyraclostrobin					
Dairy ruminants	0.0697	0.0397	Barley straw	1.92	Yes
Meat ruminants	0.2067	0.1185	Barley straw	4.82	Yes
Poultry	0.0064	0.0048	Barley grain	0.10	Yes
Pigs	0.0066	0.0036	Barley grain	0.16	Yes

Table 3-5. Results of the dietary burden calculation **including** sunflower seeds

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded?
Risk assessment residue definition: pyraclostrobin					
Dairy ruminants	0.0706	0.0407	Barley straw	1.94	Yes
Meat ruminants	0.2067	0.1185	Barley straw	4.82	Yes
Poultry	0.0066	0.0050	Barley grain	0.10	Yes
Pigs	0.0066	0.0036	Barley grain	0.17	Yes

The calculated dietary burdens in both cases exceed the trigger value of 0.1 mg/kg DM for all relevant livestock species, but are mainly driven by expected residues in barley. As the proposed import tolerance of pyraclostrobin on sunflower seeds does not affect the dietary burden significantly, there is no need to amend the MRLs for commodities of animal origin as established in Regulation (EC) No 396/2005.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). For the chronic intake assessment EFSA used existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 as well as STMR values as derived for the requested import tolerances. For certain crops and commodities like oranges, orange juice and grape juice EFSA looked for the available STMR values as reported by the EMS Germany in the framework of Article 12(2) of Regulation (EC) No 396/2005 to refine the consumer intake calculations (Germany, 2008). For gherkins and courgettes EFSA used the STMR values as derived in a previously issued EFSA reasoned opinion (EFSA, 2009) because these risk assessment values are more critical and derived for the EU use of pyraclostrobin on courgettes and gherkins.

The acute intake assessment was performed only with regard to the crops under consideration and the HR values derived for the requested import tolerances were used as input values in the intake calculations.

For cucurbits with inedible peel the provisional peeling factor of 0.5 (see section 3.1.1.3.) was applied to refine the intake calculations. Input values are summarized in Table 4-1.

Table 4-1. Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Pyraclostrobin				
Cherries	0.49	STMR	1.6	HR
Plums	0.064	STMR	0.41	HR
Strawberry	0.24	STMR	0.78	HR
Cane fruit: blackberries, dewberries, raspberries	0.87	STMR	1.3	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Other small fruits and berries: blueberries, cranberries, currants (red, black and white), gooseberries, rose hips, mulberries, azarole, elderberries)	0.94	STMR	2.1	HR
Spring onions	0.42	STMR	0.6	HR
Cucumbers	0.09	STMR	0.22	HR
Melons, pumpkins, watermelons	0.06 (0.11*0.5)	STMR*PF ^a	0.145 (0.29*0.5)	HR*PF ^a
Sunflower seed	0.037	STMR	0.17	HR
Coffee beans	0.03	STMR	0.03	STMR
Beet root	0.024	STMR (EFSA, 2009)	Acute intake assessment was performed only with regard to crops under consideration.	
Gherkins, courgettes	0.147	STMR (EFSA, 2009)		
Citrus fruit	0.24	STMR (Germany, 2008)		
Grape juice	0.01 (0.475*0.03)	STMR*PF (Germany, 2008)		
Orange juice	0.24	STMR (Germany, 2008)		
Currant juice, azarole juice, blueberry juice, elderberry juice	0.94	STMR		
Plum juice	0.064	STMR		
Raspberry juice	0.87	STMR		
Other commodities of plant and animal origin	MRL	Appendix C		

^a – a provisional peeling factor of 0.5 (see section 3.1.1.3.)

Summary of the intake calculation is available in Appendix B.

No long term intake concerns were identified for any of the European diets. The total calculated dietary intake values accounted for a maximum of 33.5 % of the ADI. The individual contribution of crops under consideration was in all cases below 1% of the ADI.

No acute intake concerns were identified for the requested import tolerances. The highest acute consumer exposure to pyraclostrobin residues was identified for melons (73.3% of the ARfD), followed by cherries (65.2% for the ARfD), currants (65.0% of the ARfD), watermelons (59% of the ARfD), blackberries (46.4% of the ARfD) , gooseberries (43.3% of the ARfD), cucumbers (42.9% of the ARfD), strawberries (40.5% of the ARfD), plums (36.5% of the ARfD), raspberries (24.3% of the ARfD) and blueberries (21.7% of the ARfD).

Consequently, EFSA concludes that the proposed import tolerance MRLs are acceptable as they will not raise any consumer health concerns.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of the active substance was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.03 mg/kg bw/d and an ARfD value of 0.03 mg/kg bw.

The metabolism of pyraclostrobin in primary crops is elucidated in fruits and fruiting vegetables, root and tuber vegetables and cereals and the risk assessment and enforcement residue definition is established as parent pyraclostrobin for all plant commodities. Consequently, no additional metabolism studies are required for the crops under consideration. The enforcement residue definition for commodities of animal origin is established as parent pyraclostrobin only.

Adequate analytical methods are available for the enforcement of the proposed MRLs for pyraclostrobin in all crops under consideration except for coffee beans for which the applicability of the analytical method should be demonstrated by providing the relevant validation data.

Submitted supervised residue field trials indicate that higher EC MRLs are required to accommodate the authorized GAPs in the USA, Canada and Brazil.

The effects of processing on the nature of pyraclostrobin were studied in a hydrolysis study and no degradation of pyraclostrobin was observed. Data on the indoor residue trials performed in Europe on melons were reported by the EMS and were used to assess the distribution of pyraclostrobin residues in melon pulp and peel. From these data a provisional median peeling factor of 0.5 was derived. Details on the GAP according to which the residue trials have been performed were not reported and a submission of a more detailed information would be desirable.

The occurrence of pyraclostrobin residues in rotational crops was not investigated as it is not of relevance for the import tolerance requests.

The occurrence of pyraclostrobin residues in commodities of animal origin was also investigated since sunflower seeds and/or its by-products can be used as livestock feeding items. The livestock dietary burden calculation was performed considering the livestock exposure to pyraclostrobin residues from sunflower seeds and seed meal and from all other plant commodities which are listed in Annexes II and IIIB of Regulation (EC) No 396/2005 and which are potential feeding items and for which the current MRLs are set above the LOQ. The calculated dietary burden exceeds the trigger value of 0.1 mg/kg DM for all relevant livestock species, but is mainly driven by existing MRLs for barley. As the proposed import tolerance of pyraclostrobin on sunflower seeds does not affect the dietary burden, the need for amending the existing MRLs in food of animal origin was not further investigated in the framework of this application.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 as well as STMR values derived for requested import tolerances. For certain crops the STMR values were available to refine the consumer intake calculations. For gherkins and courgettes EFSA used the STMR values as derived in a previously issued EFSA reasoned opinion since these values were derived for the European GAP and were higher than the values derived from the studies supporting the import tolerance request. The acute intake assessment was performed only with regard to the crops under consideration and the HR values as derived for the requested import tolerances were used as input values in the intake calculation. For cucurbits with inedible peel, the provisional peeling factor of 0.5 was applied to refine the intake calculations.

No long term intake concerns were identified for any of the European diets. The total calculated dietary intake values accounted for a maximum of 33.5 % of the ADI. The individual contribution of crops under consideration was in all cases below 1% of the ADI.

No acute intake concerns were identified for the requested import tolerances. The highest acute consumer exposure to pyraclostrobin residues was identified for melons (73.3% of the ARfD), followed by cherries (65.2% for the ARfD), currants (65.0% of the ARfD), watermelons (59% of the ARfD), blackberries (46.4% of the ARfD) , gooseberries (43.3% of the ARfD), cucumbers (42.9% of the ARfD), strawberries (40.5% of the ARfD), plums (36.5% of the ARfD), raspberries (24.3% of the ARfD) and blueberries (21.7% of the ARfD).

Consequently, EFSA concludes that the proposed import tolerance MRLs are acceptable as they will not raise any consumer health concerns.

RECOMMENDATIONS

Code number	Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: pyraclostrobin				
0140020	Cherries	0.3	2	Proposed import tolerance MRLs are sufficiently supported by data and no risk for consumers was identified.
0140040	Plums	0.2	0.5	
0152000	Strawberries	0.5	1	
0153000	<i>Cane fruit:</i>		2	
0153010	Blackberries	1.0		
0153020	Dewberries	0.02*		
0153030	Raspberries	1.0		
0154000	<i>Other small fruits and berries:</i>		3	
0154010	Blueberries	0.5		
0154020	Cranberries	0.5		
0154030	Currants (red, black and white)	2.0		
0154040	Gooseberries	0.5		
0154050	Rose hips	0.5		
0154060	Mulberries	0.5		
0154070	Azarole	0.5		
0154080	Elderberries	0.5		
0220040	Spring onions	0.02*	1.5	
0232010	Cucumbers	0.02*	0.3	
0233000	<i>Cucurbits-inedible peel:</i>		0.5	
0233010	Melons	0.02*		
0233020	Pumpkins	0.02*		

Code number	Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
0233030	Watermelons	0.02*		The applicability of the analytical method for coffee beans should be demonstrated by providing the relevant validation data.
0401050	Sunflower seed	0.02*	0.3	
0620000	Coffee beans	0.05*	0.2	

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

DOCUMENTATION PROVIDED TO EFSA

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	No. min max (k)	interval between appl. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Stone fruits	USA	F	<i>Blossom blight, Brown rot, Leaf spot, Powdery mildew, Podospheera spp., Scab, Shot hole</i>	WG	12.8%	Spray	Pink bud or prior to on set of disease	5	7-14	-	Not specified	0.13	0	
Apricot, Cherry (sweet and sour), Nectarine, Peach, Plum, Prune	Canada	F	<i>Blossom blight, Brown rot, Anthracnose, Leaf spot, suppression only: Powdery mildew, Rhizopus rot</i>	WG	12.8%	Spray	Pink bud or prior to on set of disease	5	7-14	-	Not specified	0.128	0	Not more than 2 applications before alternating to fungicide with different mode of action due to resistant management reasons.
Strawberry	USA	F	<i>Anthracnose (Colletotrichum spp.), Botrytis cinerea, Leaf spot (Mycosphaerella fragariae), Powdery mildew (Sphaerotheca macularis)</i>	WG	12.8%	Spray	Not later than 10 % bloom or prior to disease development.	5	7-14	-	Not specified	0.206	0	The restricted entry interval for treated strawberries is 12 hours.

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	No. min max (k)	interval between appl. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Strawberry	Canada	F	<i>Botrytis greymold, Anthracnose, Leaf spot, suppression only; Powdery mildew</i>	WG	12.8%	Spray	Not later than 10 % bloom or prior to disease development.	5	7-14	-	Not specified	0.206	0	Not more than 2 applications before alternating to fungicide with different mode of action due to resistant management reasons.
Berry group	USA	F	<i>Alternaria, Leafspot and fruit rot, Anthracnose, Botrytis greymold, Leafspot and blotch, Monilinia blight and mummy berry, Phomopsis leaf spot, Twig blight and fruit rot, Powdery mildew, Rust, Spur blight</i>	WG	12.8%	Spray	Not later than 10 % bloom or prior to disease development.	4	7-14	-	Not specified	0.206	0	Do not enter treated area within 24 h of the most recent application. Use shorter interval and/or higher rate when disease pressure is high.
Blackberry, Raspberry, Currant, Elderberry, Blueberry, Gooseberry, Huckleberry, Loganberry	Canada	F	<i>Botrytis greymold, Anthracnose, Phomopsis</i>	WG	12.8%	Spray	Not later than 10 % bloom or prior to disease development.	4	7-14	-	Not specified	0.206	0	Not more than 2 applications before alternating to fungicide with different mode of

Crop and/or situation (a)	Member State or Country	F or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	No. min max (k)	interval between appl. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
														action due to resistant management reasons.
Bulb vegetables	USA	F	<i>Botrytis</i> spp./ <i>Alternaria pomii</i> , <i>Stemphylium vesicarium</i> / <i>Downymildew</i> (<i>Percospora destructor</i>)	WG	12.8%	Spray	Prior to onset of disease development	6	14	-	Not specified	0.166	7	Use higher rate when disease pressure is high. Suppression only.
Onions (dry bulb and green)	Canada	F	<i>Alternaria purple blotch</i> , <i>Botrytis leaf spot</i> , suppression only: <i>Downy mildew</i>	WG	12.8%	Spray	Prior to disease development	6	7 – 14	-	Not specified	0.166	7	Not more than 2 applications before alternating to fungicide with different mode of action due to resistant management reasons.
Cucurbit vegetables	USA	F	<i>Downymildew</i> , <i>Alternaria cucumerina</i> , <i>Cercospora cicutaria</i> , <i>Didymella bryoniae</i> , <i>Powderymildew</i> , <i>Colletotrichum orbiculare</i>	WG	12.8%	Spray	Prior to disease development	4	7-14	-	Not specified	0.166	0	

Crop and/or situation (a)	Member State or Country	F or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	No. min max (k)	interval between appl. (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Sunflower seed	USA	F	<i>Alternaria leaf spot, Cercospora leaf spot, Downy mildew, Powdery mildew, Rust, Septoria leaf spot, White rust</i>	EC	250	Spray	Prior to disease development	2	7-14	-	No water volume specified	0.22	21	Formulation: BAS 50000F. Not more than 24 fl oz of product per acre per season due to resistance management reasons. Units according to US label
Coffee beans	Brazil	F	<i>Hemileia vastatrix, Cercospora coffeicola</i>	SE	133	Spray	Foliar infection index of up to 5 %.	2	60	0.04	500	0.2	45	Formulation : BAS 50001F.

(a) In case of group of crops the Codex classification should be used

(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

(d) Suspension concentrate (= flowable concentrate) (SC)

(e) Use CIPAC/FAO Codes where appropriate

(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

(i) g/kg or g/l

(j) Growth stage at last treatment

(k) PHI = Pre-harvest interval

(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Pyraclostrobin			
Status of the active substance:	Included	Code no.:	#N/A
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:	COM	Source of ARfD:	COM
Year of evaluation:	2004	Year of evaluation:	2004

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		5 34							
		No of diets exceeding ADI:		---					
	Highest calculated TMDI values in % of ADI		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)
	MS Diet								
	33.5	FR all population	26.7	Wine grapes	1.3	Other lettuce and other salad plants	1.1	Wheat	
	30.3	WHO Cluster diet B	11.9	Wine grapes	2.8	Wheat	2.4	Lettuce	
	29.6	DE child	12.1	Apples	4.2	Table grapes	3.0	Oranges	
	23.7	NL child	6.3	Apples	2.5	Table grapes	2.5	Oranges	
	23.5	PT General population	16.6	Wine grapes	1.3	Wheat	1.1	Apples	
	23.4	IE adult	8.3	Wine grapes	1.2	Barley	0.9	Table grapes	
	20.6	WHO cluster diet E	10.7	Wine grapes	1.3	Wheat	0.8	Apples	
	14.2	FR toddler	2.6	Apples	1.6	Oranges	1.3	Milk and cream,	
	13.5	NL general	4.2	Wine grapes	1.2	Oranges	1.2	Apples	
	13.5	DK adult	9.3	Wine grapes	0.8	Apples	0.7	Wheat	
	13.3	WHO Cluster diet F	4.0	Wine grapes	2.0	Lettuce	1.2	Wheat	
	12.9	ES adult	3.6	Lettuce	2.8	Wine grapes	1.0	Oranges	
	12.3	DK child	2.3	Apples	1.8	Wheat	1.5	Rye	
	12.1	WHO regional European diet	2.5	Lettuce	1.5	Wine grapes	1.0	Wheat	
	12.0	UK Toddler	1.7	Apples	1.6	Oranges	1.5	Sugar beet (root)	
	12.0	ES child	2.8	Lettuce	1.7	Oranges	1.5	Wheat	
	11.9	UK Adult	7.2	Wine grapes	0.8	Lettuce	0.6	Wheat	
	11.5	UK vegetarian	5.4	Wine grapes	0.9	Lettuce	0.7	Oranges	
	11.3	WHO cluster diet D	2.4	Wine grapes	2.2	Wheat	0.7	Tomatoes	
	10.0	IT kids/toddler	2.2	Wheat	1.9	Lettuce	1.0	Tomatoes	
	9.7	IT adult	2.5	Lettuce	1.4	Wheat	1.1	Other lettuce and other salad	
	9.4	UK Infant	1.6	Apples	1.3	Milk and cream,	1.0	Oranges	
	9.2	FR infant	2.5	Apples	0.9	Carrots	0.9	Milk and cream,	
	8.1	SE general population 90th percentile	1.1	Wheat	1.1	Apples	0.6	Oranges	
	6.5	FI adult	2.0	Wine grapes	0.8	Oranges	0.5	Lettuce	
	5.9	PL general population	2.0	Apples	1.1	Table grapes	0.6	Tomatoes	
	5.3	LT adult	1.9	Apples	0.4	Lettuce	0.4	Tomatoes	

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
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The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead 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)
	73.3	Melons	0.145 / -	73.3	Melons	0.145 / -	25.6	Pumpkins	0.145 / -	25.6	Pumpkins	0.145 / -
	65.2	Cherries	1.6 / -	65.2	Cherries	1.6 / -	22.6	Cherries	1.6 / -	22.6	Cherries	1.6 / -
	65.0	Currants (red, black)	2.1 / -	65.0	Currants (red, black)	2.1 / -	22.2	Blueberries	2.1 / -	22.2	Blueberries	2.1 / -
	59.1	Watermelons	0.145 / -	59.1	Watermelons	0.145 / -	19.6	Watermelons	0.145 / -	19.6	Watermelons	0.145 / -
	46.4	Blackberries	1.3 / -	46.4	Blackberries	1.3 / -	19.1	Melons	0.145 / -	19.1	Melons	0.145 / -
	45.0	Plums	0.41 / -	43.3	Gooseberries	2.1 / -	18.6	Currants (red, black)	2.1 / -	18.6	Currants (red, black and white)	2.1 / -
	43.3	Gooseberries	2.1 / -	42.9	Cucumbers	0.22 / -	17.2	Raspberries	1.3 / -	17.2	Raspberries	1.3 / -
	42.9	Cucumbers	0.22 / -	40.5	Strawberries	0.78 / -	15.4	Gooseberries	2.1 / -	15.4	Gooseberries	2.1 / -
	40.5	Strawberries	0.78 / -	36.5	Plums	0.41 / -	14.4	Cucumbers	0.22 / -	14.4	Cucumbers	0.22 / -
	24.3	Raspberries	1.3 / -	24.3	Raspberries	1.3 / -	13.7	Strawberries	0.78 / -	13.7	Strawberries	0.78 / -
	21.7	Blueberries	2.1 / -	21.7	Blueberries	2.1 / -	12.8	Plums	0.41 / -	10.5	Plums	0.41 / -
	16.5	Pumpkins	0.145 / -	16.5	Pumpkins	0.145 / -	9.3	Blackberries	1.3 / -	9.3	Blackberries	1.3 / -
	9.1	Spring onions	0.6 / -	9.1	Spring onions	0.6 / -	6.3	Dewberries	1.3 / -	6.3	Dewberries	1.3 / -
	8.7	Azarole (mediterranean)	2.1 / -	8.7	Azarole	2.1 / -	1.9	Spring onions	0.6 / -	1.9	Spring onions	0.6 / -
	8.7	Cranberries	2.1 / -	8.7	Cranberries	2.1 / -	0.6	Sunflower seed	0.17 / -	0.6	Sunflower seed	0.17 / -
	7.6	Dewberries	1.3 / -	7.6	Dewberries	1.3 / -	0.1	Coffee beans	0.03 / -	0.1	Coffee beans	0.03 / -
	3.3	Elderberries	2.1 / -	3.3	Elderberries	2.1 / -						
	1.7	Sunflower seed	0.17 / -	1.7	Sunflower seed	0.17 / -						
	0.1	Coffee beans	0.03 / -	0.1	Coffee beans	0.03 / -						
	No of critical MRLs (IESTI 1)			No of critical MRLs (IESTI 1)			No of critical MRLs (IESTI 2)			No of critical MRLs (IESTI 2)		

Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	51.0	Apple juice	0.3 / -	33.5	Orange juice	1 / -
	50.2	Elderberry juice	0.94 / -	25.7	Wine	2 / -
	39.6	Orange juice	0.24 / -	6.6	Apple juice	0.3 / -
	34.8	Raspberries juice	0.87 / -	2.7	Raisins	2 / -
	31.7	Courant juice	0.94 / -	1.5	Bread/pizza	0.1 / -

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL

***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Pyraclostrobin IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

APPENDIX C – EXISTING EC MRLs

Pesticides - Web Version - EU MRLs
(File created on 18/11/2009 11:40)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	1.00
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	1.00
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	1.00
110030	Lemons (Citron, lemon)	1.00
110040	Limes	1.00
110050	Mandarins (Clementine, tangerine and other hybrids)	1.00
110990	Others	1.00
120000	(ii) Tree nuts (shelled or unshelled)	
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	1.00
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	0,3
130010	Apples (Crab apple)	0,3

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
130020	Pears (Oriental pear)	0,3
130030	Quinces	0,3
130040	Medlar	0,3
130050	Loquat	0,3
130990	Others	0,3
140000	(iv) Stone fruit	
140010	Apricots	0,2
140020	Cherries (sweet cherries, sour cherries)	0,3
140030	Peaches (Nectarines and similar hybrids)	0,2
140040	Plums (Damson, greengage, mirabelle)	0,2
140990	Others	0,02*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	
151010	Table grapes	1.00
151020	Wine grapes	2.00
152000	(b) Strawberries	0,5
153000	(c) Cane fruit	
153010	Blackberries	1.00
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,02*
153030	Raspberries (Wineberries)	1.00
153990	Others	0,02*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	0,5

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
154020	Cranberries	0,5
154030	Currants (red, black and white)	2.00
154040	Gooseberries (Including hybrids with other ribes species)	0,5
154050	Rose hips	0,5
154060	Mulberries (arbutus berry)	0,5
154070	Azarole (mediteranean medlar)	0,5
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sawtooth), hawthorn, service berries, and other treeberries)	0,5
154990	Others	0,5
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
161990.00	Others	0,02*
162000.00	(b) Inedible peel, small	0,02*
162010.00	Kiwi	0,02*
162020.00	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030.00	Passion fruit	0,02*
162040.00	Prickly pear (cactus fruit)	0,02*
162050.00	Star apple	0,02*
162060.00	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	0,02*
162990.00	Others	0,02*
163000.00	(c) Inedible peel, large	
163010.00	Avocados	0,02*
163020.00	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030.00	Mangoes	0,05
163040.00	Papaya	0,05
163050.00	Pomegranate	0,02*
163060.00	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,02*
163070.00	Guava	0,02*
163080.00	Pineapples	0,02*
163090.00	Bread fruit (Jackfruit)	0,02*
163100.00	Durian	0,02*
163110.00	Soursop (guanabana)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
163990.00	Others	0,02*
200000.00	2. VEGETABLES FRESH OR FROZEN	
210000.00	(i) Root and tuber vegetables	
211000.00	(a) Potatoes	0,02*
212000.00	(b) Tropical root and tuber vegetables	0,02*
212010.00	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
212020.00	Sweet potatoes	0,02*
212030.00	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040.00	Arrowroot	0,02*
212990.00	Others	0,02*
213000.00	(c) Other root and tuber vegetables except sugar beet	
213010.00	Beetroot	0,02*
213020.00	Carrots	0,1
213030.00	Celeriac	0,02*
213040.00	Horseradish	0,3
213050.00	Jerusalem artichokes	0,02*
213060.00	Parsnips	0,3
213070.00	Parsley root	0,1
213080.00	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,2
213090.00	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,1
213100.00	Swedes	0,02*
213110.00	Turnips	0,02*
213990.00	Others	0,02*
220000.00	(ii) Bulb vegetables	
220010.00	Garlic	0,2

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
220020.00	Onions (Silverskin onions)	0,2
220030.00	Shallots	0,2
220040.00	Spring onions (Welsh onion and similar varieties)	0,02*
220990.00	Others	0,02*
230000.00	(iii) Fruiting vegetables	
231000.00	(a) Solanacea	
231010.00	Tomatoes (Cherry tomatoes,)	0,2
231020.00	Peppers (Chilli peppers)	0,5
231030.00	Aubergines (egg plants) (Pepino)	0,2
231040.00	Okra, lady's fingers	0,02*
231990.00	Others	0,02*
232000.00	(b) Cucurbits - edible peel	0,02*
232010.00	Cucumbers	0,02*
232020.00	Gherkins	0,02*(0,5) ⁵
232030.00	Courgettes (Summer squash, marrow (patisson))	0,02*(0,5) ⁶
232990.00	Others	0,02*
233000.00	c) Cucurbits-inedible peel	0,02*
233010.00	Melons (Kiwano)	0,02*
233020.00	Pumpkins (Winter squash)	0,02*
233030.00	Watermelons	0,02*
233990.00	Others	0,02*
234000.00	(d) Sweet corn	0,02*
239000.00	(e) Other fruiting vegetables	0,02*

⁵ MRL proposal as derived by EFSA (EFSA, 2009) and considered in SCoFAH on 15-16 October, 2009. Not legally enforced by 30 November 2009.

⁶ See footnote for gherkins.

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,1
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,1
241020	Cauliflower	0,1
241990	Others	0,1
242000	(b) Head brassica	
242010	Brussels sprouts	0,2
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,2
242990	Others	0,02*
243000	(c) Leafy brassica	0,02*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,02*
243020	Kale (Borecole (curly kale), collards)	0,02*
243990	Others	0,02*
244000	(d) Kohlrabi	0,02*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb's lettuce (Italian cornsalad)	10
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	2

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	2
251040	Cress	2
251050	Land cress	2
251060	Rocket, Rucola (Wild rocket)	2
251070	Red mustard	2
251080	Leaves and sprouts of Brassica spp (Mizuna)	2
251990	Others	2
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,5
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	2
252030	Beet leaves (chard) (Leaves of beetroot)	0,5
252990	Others	0,5
253000	(c) Vine leaves (grape leaves)	0,02*
254000	(d) Water cress	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	2
256010	Chervil	2
256020	Chives	2
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	2
256040	Parsley	2

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
256050	Sage (Winter savory, summer savory,)	2
256060	Rosemary	2
256070	Thyme (marjoram, oregano)	2
256080	Basil (Balm leaves, mint, peppermint)	2
256090	Bay leaves (laurel)	2
256100	Tarragon (Hyssop)	2
256990	Others	2
260000	(vi) Legume vegetables (fresh)	0,02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,02*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	0,02*
270040	Fennel	0,02*
270050	Globe artichokes	0,02*
270060	Leek	0,5
270070	Rhubarb	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
270080	Bamboo shoots	0,02*
270090	Palm hearts	0,02*
270990	Others	0,02*
280000	(viii) Fungi	0,02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*
280020	Wild (Chanterelle, Truffle, Morel .)	0,02*
280990	Others	0,02*
290000	(ix) Sea weeds	
300000	3. PULSES, DRY	0,3
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,3
300020	Lentils	0,3
300030	Peas (Chickpeas, field peas, chickling vetch)	0,3
300040	Lupins	0,3
300990	Others	0,3
400000	4. OILSEEDS AND OILFRUITS	0,02*
401000	(i) Oilseeds	0,02*
401010	Linseed	0,02*
401020	Peanuts	0,02*
401030	Poppy seed	0,02*
401040	Sesame seed	0,02*
401050	Sunflower seed	0,02*
401060	Rape seed (Bird rapeseed, turnip rape)	0,02*
401070	Soya bean	0,02*
401080	Mustard seed	0,02*
401090	Cotton seed	0,02*
401100	Pumpkin seeds	0,02*
401110	Safflower	0,02*
401120	Borage	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
401130	Gold of pleasure	0,02*
401140	Hempseed	0,02*
401150	Castor bean	0,02*
401990	Others	0,02*
402000	(ii) Oilfruits	0,02*
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,02*
402030	Palmfruit	0,02*
402040	Kapok	0,02*
402990	Others	0,02*
500000	5. CEREALS	
500010	Barley	0,3
500020	Buckwheat	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff)	0,02*
500050	Oats	0,3
500060	Rice	0,02*
500070	Rye	0,1
500080	Sorghum	0,02*
500090	Wheat (Spelt Triticale)	0,1
500990	Others	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	10
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
	and white (Long pepper, pink pepper)	
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	0,02*
900010	Sugar beet (root)	0,02*
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
	TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry - chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pyraclostrobin(F)
	containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	0,01*
1020020	Sheep	0,01*
1020030	Goat	0,01*
1020040	Horse	0,01*
1020990	Others	0,01*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
Bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CS	capsule suspension
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/EEC)
DAT	days after treatment
DM	dry matter
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EC	emulsifiable concentrate
ECD	electron capture detection
EDI	estimated daily intake
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GR	granule
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue

ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K _{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	rapporteur Member State
SC	suspension concentrate
SCoFCAH	Standing Committee on Food Chain and Animal Health
SE	suspoemulsions
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WG	water dispersible granule
WHO	World Health Organisation