

REASONED OPINION

Reasoned opinion on the modification of the existing maximum residue level maximum residue level (MRL) for pyridaben in cucurbits – edible peel¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, the Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from Nissan Chemical Europe S.A.R.L. to modify the existing maximum residue level (MRL) for the active substance pyridaben in cucurbits – edible peel. In order to accommodate for the intended uses of pyridaben, the Netherlands proposed to raise the existing MRL from 0.1 mg/kg to a MRL of 0.15 mg/kg. the Netherlands 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 0.15 mg/kg for the proposed use on cucurbits – edible peel. A fully validated analytical enforcement method is available to control the residues of pyridaben in the commodities under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of pyridaben on cucurbits – edible peel will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

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KEY WORDS

pyridaben, cucurbits – edible peel, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, insecticide, acaricide

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, the Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from Nissan Chemical Europe S.A.R.L. to modify the existing maximum residue level (MRL) for the active substance pyridaben in cucurbits – edible peel. In order to accommodate for the intended uses of pyridaben, the Netherlands proposed to raise the existing MRL from 0.1 mg/kg to a MRL of 0.15 mg/kg. The Netherlands 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 1 October 2014.

EFSA bases its assessment on the evaluation report submitted by the EMS (Netherlands, 2014), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Netherlands, 2007), the addendum to the DAR and the revised DAR (Netherlands, 2009), the Commission Review Report on pyridaben (EC, 2010) and the conclusion on the peer review of the pesticide risk assessment of the active substance pyridaben (EFSA, 2010).

The toxicological profile of pyridaben was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg bw per day and an acute reference dose (ARfD) of 0.05 mg/kg bw.

The metabolism of pyridaben in primary crops was investigated in the fruit crop group only (citrus, apple, tomato) following paint and spray applications. From these studies the peer review concluded to establish the residue definition for enforcement and risk assessment as pyridaben only.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.15 mg/kg for the proposed use on cucurbits – edible peel. A fully validated analytical enforcement method is available to control the residues of pyridaben in the commodities under consideration at the validated LOQ of 0.05 mg/kg.

Studies investigating the nature of pyridaben residues in processed commodities were assessed in the framework of the peer review and showed that the compound is hydrolytically stable under standard hydrolysis conditions. Specific studies to assess the magnitude of pyridaben residues during the processing of cucurbits – edible peel are not required since cucumbers and gherkins are mostly eaten raw. For courgettes, since the highest residue levels in the raw agricultural commodity (RAC) do not exceed the trigger value of 0.1 mg/kg and the contribution of this crop to the TMDI/IESTI is less than 10 % of the ADI/ARfD, processing studies on courgettes (cooked) are considered as not triggered.

The occurrence of pyridaben residues in rotational crops was investigated in the framework of the peer review. Based on the available information, it is concluded that significant residue levels are unlikely to occur in rotational crops provided that the active substance is used on cucurbits – edible peel according to the proposed GAP (Good Agricultural Practice).

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

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The total calculated chronic intake accounted for up to 78 % of the ADI (German child). The contribution of residues in the cucurbits – edible peel crop group to the total consumer exposure accounted for less than 1 % of the ADI.

No acute consumer risk was identified in relation to the MRL proposal for cucurbits – edible peel. The calculated maximum exposure in percentage of the ARfD was 11 % for cucumbers (Dutch, child).

EFSA concludes that the intended use of pyridaben on cucurbits – edible peel will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

It is, however, highlighted that the consumer risk assessment has to be considered provisional since the revision of the existing EU MRLs under Article 12 of Regulation (EC) No 396/2005 is not yet finalised and might need to be reconsidered in the light of the outcome of this assessment.

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: Pyridaben				
0232000	Cucurbits – edible peel	0.1	0.15	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the intended use on cucurbits – edible peel (cucumbers, gherkins and courgettes).

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

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BACKGROUND

Regulation (EC) No 396/2005³ establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC⁴, repealed by Regulation (EC) No 1107/2009⁵, shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

The Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from the company Nissan Chemical Europe S.A.R.L.⁶ to modify the existing MRLs for the active substance pyridaben in cucurbits – edible peel. 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 1 October 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00708 and the following subject:

Modification of MRLs for pyridaben in cucurbits – edible peel

The Netherlands proposed to raise the existing MRL of pyridaben in cucurbits – edible peel from the current MRL value of 0.1 mg/kg to the MRL value of 0.15 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 2 January 2015.

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 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

⁶ Nissan Chemical Europe S.A.R.L., Rue Claude Chappe, 2 69370, St-Didier-au Mont-d'Or, France.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Pyridaben is the ISO common name for 2-*tert*-butyl-5-(4-*tert*-butylbenzylthio)-4-chloropyrididin-3(2*H*)-one (IUPAC). The chemical structure of the compound is reported below.

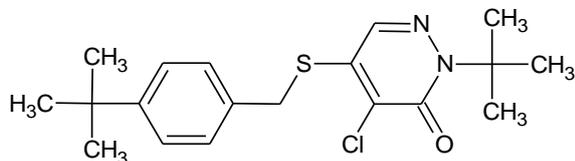


Figure 1: Structure of Pyridaben. Molecular weight: 364.9 g/mol

Pyridaben is a non-systemic unclassified insecticide and acaricide. Pyridaben is orally and/or percutaneously taken by the mobile forms (whiteflies, mites) to stop the embryonic development and to kill embryos when treated on eggs.

Pyridaben was evaluated in the framework of Council Directive 91/414/EEC with the Netherlands designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 90/2010/EC⁷ which entered into force on 1 May 2011 for use as insecticide and acaricide, only. In accordance with Commission Implementing Regulation (EU) No 540/2011⁸ Pyridaben is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The representative uses evaluated in the peer review were indoor foliar applications on tomatoes and outdoor air assisted spraying on citrus against mites and whiteflies. The Draft Assessment Report (DAR) of pyridaben has been peer reviewed by EFSA (EFSA, 2010).

The EU MRLs for pyridaben are established in Annex IIIA of Regulation (EC) No 396/2005. The existing EU MRL for pyridaben on cucurbits – edible peel is set at 0.1 mg/kg. No CXLs are established for pyridaben.

The details of the intended GAPs for pyridaben on cucurbits – edible peel are given in Appendix A.

⁷ Commission Directive 2010/90/EU of 7 December 2010 amending Council Directive 91/414/EEC to include pyridaben as active substance and amending Decision 2008/934/EC. OJ L 322, 08.12.2010, p. 38–41.

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 (Netherlands, 2014), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Netherlands, 2007), the addendum to the DAR and the revised DAR (Netherlands, 2009), the Commission Review Report on pyridaben (EC, 2010) and the conclusion on the peer review of the pesticide risk assessment of the active substance pyridaben (EFSA, 2010). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a,b, 2011; OECD, 2011).

1. Method of analysis

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

During the peer review under Council Directive 91/414/EEC, an analytical method using LC-MS/MS, confirmed by an additional ion transition, and its ILV were evaluated and validated for the determination of pyridaben in high water content matrices (tomato) with an LOQ of 0.05 mg/kg (Netherlands, 2009; EFSA, 2010).

Since the commodities under consideration belong to the group of high water content commodities, EFSA concludes that a sufficiently validated analytical method for enforcing the proposed MRL for pyridaben on cucurbits – edible peel is available.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since the crops under consideration are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance pyridaben was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2010). The data were sufficient to derive toxicological reference values for pyridaben which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Pyridaben					
ADI	EFSA	2010	0.01 mg/kg bw per day	2-year rat, supported by 78-week mouse and 1-year dog	100
ARfD	EFSA	2010	0.05 mg/kg bw	Rabbit and rat, developmental study	100

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.

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 pyridaben in primary crops was evaluated by the Rapporteur Member State in the revised DAR (Netherlands, 2009) and in the framework of the peer review under Directive 91/414/EEC (EFSA, 2010). The overview of the metabolism study designs is presented in table 3-1.

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

Group	Crop	Application details				
		Method	Rate (g/ha)	No/ Interval	Sampling (DALA) ^(a)	Remarks
Fruit crops	Apple	Foliar application	300	3/ 25, 28 days	25 (fruits, leaves)	1 st treatment after the end of blooming.
		Paint application	1 mg/apple	1	40	-
	Citrus	Foliar application	Low dose: 570	2/76 days	0, 7, 14	1 st application at post-blossom 2 nd application on mature fruits.
			High dose: 4760	2/234 days	7, 14	
Tomato	Paint application	1 mg/plant	1	1, 7 (fruits) 14 (fruits, foliage)	Application by brush to leaves and fruits.	

(a): DALA: Days after last application

The metabolism of pyridaben was investigated in the fruit crop group only (apple, citrus and tomato) following foliar applications or leaf and fruit paint applications and using ¹⁴C-benzyl and ¹⁴C-pyridazinone labelled pyridaben. Based on these studies, the residue definition for enforcement and risk assessment was proposed as pyridaben. The proposed residue definition is restricted to foliar application on the fruit crop group only.

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

For the uses on cucurbits – edible peel, EFSA concludes that the metabolism of pyridaben is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed in the peer review are applicable.

3.1.1.2. Magnitude of residues

In support of the MRL application, the EMS provided eight GAP-compliant residue trials conducted on cucumbers grown under indoor conditions. Based on the OECD MRL calculator, EFSA proposed a MRL of 0.15 mg/kg on cucumbers. According to the current guidance documents, an extrapolation to the group of cucurbits – edible peel is possible.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposal are summarised in Table 3-2.

The storage stability of pyridaben in primary crops was investigated in the DAR under Directive 91/414/EEC (Netherlands, 2009). Residues of pyridaben were found to be stable at ≤ -18°C for up to 18 months in high water (apples) and high acid content matrices (grapes). 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 (Netherlands, 2009, 2014).

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.15 mg/kg for the intended use on cucurbits – edible peel under indoor conditions.

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

Commodity	Residue region (a)	Individual trial results (mg/kg)	Comments (b)	EU MRL proposal (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
		Enforcement and risk assessment residue definition (Pyridaben)				
Cucumbers	Indoor EU	4 × <0.05; 0.059; 0.063; 0.081; 0.097	MRL _{OECD} = 0.13/0.15 Extrapolation to the whole group ‘cucurbit – edible peel’	0.15	0.097	0.05

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011).

(b): Statistical estimation of MRLs according to OECD methodology; unrounded/rounded values (OECD, 2011).

(c): HR: Highest value of the individual trial results according to the residue definition for risk assessment.

(d): STMR: Median value of the individual trial results according to the residue definition for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of pyridaben was investigated under standard hydrolytic conditions with the ¹⁴C-pyridazinone labelled pyridaben only. Studies were reported in the DAR and assessed in the framework of the peer review (Netherlands, 2009; EFSA, 2010). Although the nature of the residues under similar hydrolytic conditions was not addressed for the ¹⁴C-benzyl moiety; EFSA is of the opinion that no significant degradation of pyridaben is expected for this part of the molecule and concludes that the compound can be considered as hydrolytically stable under the representative processing conditions. Thus, for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable (EFSA, 2010).

Specific studies to assess the magnitude of pyridaben residues during the processing of cucurbits – edible peel are not required since cucumbers and gherkins are mostly eaten raw. For courgettes, since the residue levels in the raw agricultural commodity (RAC) do not exceed the trigger value of 0.1 mg/kg and the contribution of this crop to the TMDI/IESTI is less than 10 % of the ADI/ARfD, processing studies on courgettes (cooked) are considered as not triggered (EC, 1997d).

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

The cucurbits – edible peel crops 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 a moderate to high persistence of pyridaben. The maximum DT₉₀ calculated from the field dissipation studies was 424 days (EFSA, 2010), which is above the trigger value of 100 days. Thus, further studies investigating the nature and magnitude of the compound uptake in rotational crops are required (EC, 1997c).

The metabolism of pyridaben in rotational crops was assessed in the DAR prepared under Directive 91/414/EEC and in the conclusion on the peer review (Netherlands, 2009; EFSA, 2010). The data demonstrated that the metabolism of pyridaben in rotational crops is similar to the pathway observed in primary crops and the same residue definition therefore applies to rotational crops. Since total radioactive residues (TRR) recovered in all the edible parts of the rotational crops were very low after two applications at 750 g/ha on bare soil, and considering that the annual application rate on cucurbits – edible peel is limited to 200 g/ha, EFSA concludes that significant residues are unlikely to occur in rotational crops provided that the compound is used according to the proposed GAP.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population¹⁰ (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the median residue value (STMR) as derived from the residue trials on cucumbers (see Table 3-2). For further refinement, the median residue values from the residue trials compliant with the authorized European uses and reported in the PROFile prepared under Article 12 of Regulation (EC) No 396/2005 for the assessment of the existing MRLs for pyridaben were also considered in the chronic dietary intake calculation on a tentative basis (see Table 4-1) (Netherlands, 2011). For the remaining commodities of plant and animal origin, the existing MRLs as established in Regulation (EC) No 839/2008, were used as input values.

¹⁰ 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).

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest level (HR) as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

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

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

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Pyridaben				
Cucumbers, gherkins, courgettes	0.05	STMTR	0.097	HR
Citrus fruit	0.09	STMTR (PROFile, 2011)	Acute risk assessment was undertaken only with regard to the crops under consideration.	
Pome fruit	0.3	STMTR (PROFile, 2011)		
Peaches	0.055	STMTR (PROFile, 2011)		
Plums	0.01	STMTR (PROFile, 2011)		
Table grapes	0.05	STMTR (PROFile, 2011)		
Wine grapes ^(a)	0.05	STMTR (PROFile, 2011)		
Strawberries	0.05	STMTR (PROFile, 2011)		
Currants, gooseberries	0.085	STMTR (PROFile, 2011)		
Tomatoes	0.05	STMTR (PROFile, 2011)		
Peppers	0.23	STMTR (PROFile, 2011)		
Aubergines	0.05	STMTR (PROFile, 2011)		
Other commodities of food and animal origin	EU MRLs	See MRLs in Regulation (EC) No 839/2008		

(a): Consumption figures in the EFSA PRIMo are expressed as wine grapes. Since it is assumed that all wine grapes are consumed as wine, the consumption is recalculated to wine using a yield factor (1 kg of wine grapes is needed to produce 0.7 kg of wine) to perform the refined intake calculation for wine grapes.

The total calculated chronic intake accounted for up to 78 % of the ADI (German child). The contribution of residues in the cucurbits – edible peel crop group to the total consumer exposure accounted for less than 1 % of the ADI.

No acute consumer risk was identified in relation to the MRL proposals for cucurbits – edible peel. The calculated maximum exposure in percentage of the ARfD was 11 % for cucumbers (Dutch child).

EFSA concludes that the intended use of pyridaben on cucurbits – edible peel will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

It is, however, highlighted that the consumer risk assessment has to be considered provisional since the revision of the existing EU MRLs under Article 12 of Regulation (EC) No 396/2005 is not yet finalised and might need to be reconsidered in the light of the outcome of this assessment.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of pyridaben was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg bw per day and an acute reference dose (ARfD) of 0.05 mg/kg bw.

The metabolism of pyridaben in primary crops was investigated in the fruit crop group only (citrus, apple, tomato) following paint and spray applications. From these studies the peer review concluded to establish the residue definition for enforcement and risk assessment as pyridaben only.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.15 mg/kg for the proposed use on cucurbits – edible peel. A fully validated analytical enforcement method is available to control the residues of pyridaben in the commodities under consideration at the validated LOQ of 0.05 mg/kg.

Studies investigating the nature of pyridaben residues in processed commodities were assessed in the framework of the peer review and showed that the compound is hydrolytically stable under standard hydrolysis conditions. Specific studies to assess the magnitude of pyridaben residues during the processing of cucurbits – edible peel are not required since cucumbers and gherkins are mostly eaten raw. For courgettes, since the highest residue levels in the raw agricultural commodity (RAC) do not exceed the trigger value of 0.1 mg/kg and the contribution of this crop to the TMDI/IESTI is less than 10 % of the ADI/ARfD, processing studies on courgettes (cooked) are considered as not triggered.

The occurrence of pyridaben residues in rotational crops was investigated in the framework of the peer review. Based on the available information, it is concluded that significant residue levels are unlikely to occur in rotational crops provided that the active substance is used on cucurbits – edible peel according to the proposed GAP (Good Agricultural Practice).

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

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The total calculated chronic intake accounted for up to 78 % of the ADI (German child). The contribution of residues in the cucurbits – edible peel crop group to the total consumer exposure accounted for less than 1 % of the ADI.

No acute consumer risk was identified in relation to the MRL proposal for cucurbits – edible peel. The calculated maximum exposure in percentage of the ARfD was 11 % for cucumbers (Dutch, child).

EFSA concludes that the intended use of pyridaben on cucurbits – edible peel will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

It is, however, highlighted that the consumer risk assessment has to be considered provisional since the revision of the existing EU MRLs under Article 12 of Regulation (EC) No 396/2005 is not yet finalised and might need to be reconsidered in the light of the outcome of this assessment.

RECOMMENDATIONS

Code number^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Pyridaben				
0232000	Cucurbits – edible peel	0.1	0.15	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the intended use on cucurbits – edible peel (cucumbers, gherkins and courgettes).

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

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APPENDICES

Appendix A. GOOD AGRICULTURAL PRACTICE (GAP)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	conc. a.s. (i)	method kind (f - h)	growth stage & season (j)	number min-max (k)	interval min max	g a.s./hL min-max	water L/ha min-max	g a.s./ha min-max		
Cucurbits – edible peel	Belgium, Czech republic, Hungary, The Netherlands, Poland, Romania, Slovak Republic, Bulgaria, France, Greece, Italy, Portugal, Spain	G	Mites, Whitefly	SC	100 g/L	Various hydraulic sprayers	BBCH 51-89	1	-	14-20	1000-1400	200	3	

- 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)

Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations						
The acute risk assessment is based on the ARfD.												
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.												
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.												
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.												
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.												
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
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	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)
	11.3	Cucumbers	0.097 / -	11.3	Cucumbers	0.097 / -	5.2	Courgettes	0.097 / -	3.9	Courgettes	0.097 / -
9.0	Courgettes	0.097 / -	6.4	Courgettes	0.097 / -	3.8	Cucumbers	0.097 / -	3.8	Cucumbers	0.097 / -	
3.2	Gherkins	0.097 / -	2.3	Gherkins	0.097 / -	1.0	Gherkins	0.097 / -	0.7	Gherkins	0.097 / -	

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 to risk assessment residue definition
cGAP	critical GAP
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DAT	days after treatment
DT ₉₀	period required for 90 % dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
GEMS	Global Environment Monitoring System
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
IESTI	International estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry

NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	Pesticide Residues Overview File
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
SC	suspension concentrate
SEU	southern European Union
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization
wk	week
YF	yield factor
yr	year