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Modification of the existing maximum residue level for pyridaben in sweet pepper/bell pepper and setting of an import tolerance in tree nuts

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Nissan Chemical Europe S.A.S. submitted two requests to the competent national authority in the Netherlands, respectively to modify the existing maximum residue level (MRL) in sweet pepper/bell pepper and to set an import tolerance in tree nuts for the active substance pyridaben. The data submitted in support of the requests were found to be sufficient to derive the MRL proposals of 0.3 mg/kg for sweet peppers/bell peppers and of 0.05* mg/kg for tree nuts. Adequate analytical methods for enforcement are available to control the residues of pyridaben in the commodities under consideration, at or above the validated limits of quantification (LOQs) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of pyridaben on imported tree nuts from United States and from the indoor use on sweet peppers/bell peppers according to the reported agricultural practices, is unlikely to present a risk to consumer health. The reliable end points, appropriate for use in regulatory risk assessment are presented.

Keywords: pyridaben, sweet pepper/bell pepper, tree nuts, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Nissan Chemical Europe S.A.S. submitted two applications to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the maximum residue level (MRL) for the active substance pyridaben in sweet pepper/bell pepper and to set an import tolerance in tree nuts. The EMS drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 16 September 2019 and 24 October 2019 respectively. To accommodate for the intended indoor EU use of pyridaben, the EMS proposed to raise the existing EU MRL for sweet pepper/bell pepper from the limit of quantification (LOQ) of 0.01* mg/kg to 0.3 mg/kg. In support of the authorised use of pyridaben in the United States, the EMS proposed to raise existing EU MRL in tree nuts from 0.01* mg/kg (LOQ) to 0.05* mg/kg.

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of the two applications, the following conclusions are derived.

The metabolism of pyridaben following foliar applications was investigated in fruit crops, indicating pyridaben as the relevant residue in fruits at harvest. The metabolism of pyridaben in rotational crops proceeds in a similar pathway to that in primary crops.

Studies investigating the effect of processing on the nature of pyridaben (hydrolysis studies) demonstrated that the active substance is stable upon processing.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites, the residue definitions for plant products were proposed by the peer review as 'pyridaben' for enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products. EFSA concluded that for the fruit crops assessed in this application the metabolism of pyridaben is sufficiently addressed and that the previously derived residue definitions are applicable.

A sufficiently validated analytical method based on liquid chromatography with tandem mass spectrometry (LC–MS/MS) is available to quantify pyridaben residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above the LOQ of 0.01 mg/kg in tree nuts and in sweet peppers/bell peppers.

The available residue trials are sufficient to derive an MRL proposal of 0.05* mg/kg for pyridaben in tree nuts and of 0.3 mg/kg for pyridaben in sweet peppers/bell peppers to support the authorised use in the United States and the intended EU indoor use, respectively.

Specific studies investigating the magnitude of pyridaben residues in processed commodities are not required as residues in the crops under consideration are minor contributors to the overall dietary intake.

From the confined rotational crop study, it can be concluded that significant pyridaben residues are not expected in rotational crops, provided that active substance is applied to sweet peppers/bell peppers according to the intended Good Agricultural Practice (GAP).

Residues of pyridaben in commodities of animal origin were not further assessed, noting insignificant contribution of residues in coconut meal to the livestock exposure.

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

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of chronic and acute consumer exposure, the STMR and HR values, respectively, as derived from the residue trials on tree nuts and sweet peppers/bell peppers were used as input values. For the remaining commodities, the risk assessment values (STMR and HR values) as available from the previous assessments were used as input values. The crops, for which authorised uses were not reported in the MRL review, and crops for which the MRLs were lowered to the LOQ following the MRL review because the assessed uses were not supported by data, were excluded from the exposure calculation.

No long-term consumer intake concerns were identified for any of the European diets incorporated in EFSA PRIMo. The total calculated intake accounted for a maximum of 33% of the ADI (NL toddler

diet). The contribution of residues in tree nuts and sweet peppers/bell peppers to the total exposure was low (0.25% ADI for NL toddler and 0.47% of the ADIGEMS/Food cluster diet G15, respectively).

In the short-term exposure assessment, EFSA focused on the commodities assessed in the present MRL application in accordance with the internationally agreed methodology. The acute exposure calculation did not identify acute consumer intake concerns related to the intended use of pyridaben on sweet peppers/bell peppers (15% of the ARfD) and tree nuts (maximum 1% of the ARfD for coconuts).

EFSA concludes that the proposed use of pyridaben on sweet/bell peppers and the authorised use on tree nuts imported from United States will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Pyridaben[(F)]				
0120000	Tree nuts	0.01*	0.05*	The submitted data are sufficient to derive an import tolerance MRL (USA GAP). Risk for consumers unlikely
0231020	Sweet peppers/bell peppers	0.01*	0.3	The submitted data are sufficient to derive an MRL proposal for the intended EU indoor use. Risk for consumers is unlikely

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

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Assessment

The European Food Safety Authority (EFSA) received two applications from Nissan Chemical Europe S.A.S. to modify the maximum residue level (MRL) for the active substance pyridaben in sweet pepper/bell pepper and to set an import tolerance for the active substance in tree nuts. The detailed description of the intended indoor EU use of pyridaben on sweet peppers/bell peppers and the authorised use of pyridaben on tree nuts in the United States (USA), which is the basis for the current MRL application, is reported in Appendix A.

Pyridaben is the ISO common name for 2-*tert*-butyl-5-(4-*tert*-butylbenzylthio)-4-chlorpyrididazin-3(*2H*)-one (IUPAC). The chemical structure of the active substance is reported in Appendix E.

Pyridaben was evaluated in the framework of Directive 91/414/EEC[1] with the Netherlands designated as rapporteur Member State (RMS) for the representative uses as indoor foliar spray on tomatoes and outdoor air-assisted spray to citrus. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2010). Pyridaben was approved[2] for the use as insecticide and acaricide on 1 May 2011.

The EU MRLs for pyridaben are established in Annex II of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2017) and the proposed modifications have been implemented in the MRL Regulation (EU) 2019/90[4].

After completion of the MRL review, EFSA has issued one reasoned opinion on the modification of MRLs for pyridaben. The proposals from this reasoned opinion have been considered in recent MRL regulation.[5]

In accordance with Article 6 of Regulation (EC) No 396/2005, Nissan Chemical Europe S.A.S. submitted two applications to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the MRL for the active substance pyridaben in sweet pepper/bell pepper and to set an import tolerance in tree nuts. The EMS drafted two evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to EFSA on 16 September 2019 and 24 October 2019 respectively. To accommodate for the intended indoor EU use of pyridaben, the EMS proposed to raise the existing EU MRL for sweet pepper/bell pepper from the limit of quantification (LOQ) of 0.01* mg/kg to 0.3 mg/kg. In support of the authorised use of pyridaben in the USA, the EMS proposed to raise existing EU MRL in tree nuts from 0.01* mg/kg (LOQ) to 0.05* mg/kg.

EFSA based its assessment on the evaluation reports submitted by the EMS (Netherlands, 2019a,b), the DAR (and its addendum) (Netherlands, 2007, 2009) prepared under Council Directive 91/414/EEC, the Commission review report on pyridaben (European Commission, 2010c), the conclusion on the peer review of the pesticide risk assessment of the active substance pyridaben (EFSA, 2010) as well as the conclusions from previous EFSA opinions on pyridaben (EFSA, 2015, 2019).

For this application, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[7].

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

[2] 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, 8.12.2010, p. 38–41.

[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, 16.3.2005, p. 1–16.

[4] Commission Regulation (EU) 2019/90 of 18 January 2019 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bromuconazole, carboxin, fenbutatin oxide, fenpyrazamine and pyridaben in or on certain products C/2019/151 OJ L 22, 24.1.2019, p. 52–73.

[5] For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN

[6] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

[7] 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, 11.6.2011, p. 127–175.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, are presented in Appendix B.

The evaluation reports submitted by the EMS (Netherlands, 2019a,b) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of pyridaben was investigated in the framework of the peer review in three different fruit crops: in apples and citrus with foliar application and in tomatoes with pyridaben applied by brush to tomato leaves and citrus fruits (EFSA, 2010, 2017). In the various crops, a major proportion of the total residue was present as parent pyridaben when the treatment was close to harvest. Levels of individual metabolites or fractions were generally less than 5% of the total radioactive residue (TRR) at harvest of the mature crop. To a small extent pyridaben was cleaved, leading to metabolites containing pyridazinone and benzyl ring moieties. From the available studies, it was concluded that pyridaben is the principal residue component in fruit crops investigated (EFSA, 2010, 2017).

1.1.2. Nature of residues in rotational crops

Peppers can be grown in crop rotation. According to the soil degradation studies evaluated in the framework of the peer review, periods required for 90% dissipation (DT_{90} values) of pyridaben in soil range from 241 to 4522 days which is higher than the trigger value of 100 days (EFSA, 2010). Therefore, further investigation of residues in rotational crops was performed.

A confined rotational crop study was evaluated during the peer review (EFSA, 2010). The rotational crop metabolism was studied in mustard greens, radishes, Swiss chard, wheat and sorghum grown after soil application of pyridazinone-^{14}C-labelled pyridaben at 2 $\times$ 0.75 kg a.s./ha. Pyridaben was identified while the residues of metabolites were too low to allow for identification. The metabolism of pyridaben in the three rotational crop studies covering cereals, root and tuber vegetables and leafy crops was similar to the pathway in primary crops (EFSA, 2017).

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of residues was investigated in the framework of the peer review under conditions simulating pasteurisation, baking/brewing/boiling and sterilisation. From these studies it was concluded that pyridaben is stable upon processing (EFSA, 2010).

1.1.4. Methods of analysis in plants

The availability of analytical methods for the determination of pyridaben residues in plant commodities was investigated in the peer review as well as in the MRL review and the overview of available methods is compiled in Appendix B.1.1.1 (EFSA, 2010, 2017).

It was concluded that a sufficiently validated method using liquid chromatography with tandem mass spectrometry (LC–MS/MS) is available to enforce pyridaben residues at the respective LOQ of 0.01 mg/kg in matrices with high oil and high water content, as relevant for the crops under the current assessment.

1.1.5. Storage stability of residues in plants

The storage stability of pyridaben residues in plant matrices with high water and high acid content was investigated in the framework of the peer review and the MRL review (EFSA, 2010, 2017). Results demonstrate that residues of pyridaben are stable in these matrices for 12 months when samples are stored at −20°C.

A study investigating the stability of pyridaben residues in frozen samples of crops classified as matrices with high oil content (almonds and almond hulls) was submitted with the current application (Netherlands, 2019b). The crop samples were spiked at 1.0 mg/kg and the storage stability was investigated at 1 month and 3, 6, 12, 24 months intervals. Results demonstrated that residues of pyridaben are stable for at least 24 months in plant matrices with high oil content, when stored at −5°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites, the following residue definitions were proposed by the peer review for fruit crops and confirmed by the MRL review:

- residue for risk assessment: pyridaben (fruit crops only)
- residue definition for enforcement: pyridaben (fruit crops only)

The same residue definitions are applicable to rotational crops and processed products.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with this residue definition. For the uses assessed in this application, EFSA concluded that these residue definitions are appropriate and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Tree nuts

Authorised USA Good Agricultural Practice (GAP) on tree nuts: 2 × 0.56 kg/ha, PHI 7 days

In support of the authorised GAP of pyridaben in the USA, the applicant submitted six GAP-compliant residue trials on almonds performed in USA in 1994 and six GAP-compliant residue trials on pecans performed in USA in 1996.

The applicant proposed to extrapolate the merged residue data on almonds and pecans to the whole group of tree nuts which is acceptable according to EU guidance documents (European Commission, 2017). It is concluded that an MRL at the LOQ of 0.05* mg/kg would be sufficient to support the authorised outdoor use of pyridaben on tree nuts.

The samples of these residue trials were stored under conditions for which integrity of the samples is demonstrated. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Netherlands, 2019b).

Sweet peppers/bell peppers

Intended EU GAP: indoor use, 1 × 0.2 kg/ha, PHI 3 days

In support of the intended indoor use of pyridaben, the applicant submitted seven GAP-compliant residue trials on sweet peppers/bell peppers performed in Belgium, Italy, Germany and Spain in 2007 and one GAP-compliant trial on sweet/bell peppers as performed in Spain in 2014. The application rate deviated from the intended application rate, but within the 25% acceptable range.

The samples of these residue trials were stored under conditions for which integrity of the samples is demonstrated. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Netherlands, 2019a).

The residue trial data are summarised in Appendix B.1.2.1.

1.2.2. Magnitude of residues in rotational crops

The studies investigating the magnitude of pyridaben residues in rotational crops are not available and were not considered necessary based on the outcome of metabolism study, i.e. very low residues after two soil applications at 750 g/ha (EFSA, 2017).

It is therefore concluded that, since the intended application rate of pyridaben on sweet/bell peppers is significantly lower than the application rate in the confined study, significant residues are not expected in rotational and succeeding crops, provided that pyridaben is used according to the intended GAP.

1.2.3. Magnitude of residues in processed commodities

New processing studies on the crops under consideration have not been submitted. Since the exposure to residues from the intake of sweet/bell peppers and tree nuts (coconuts) to the overall dietary intake is low (0.47% of the acceptable daily intake (ADI) for GEMS/Food cluster diet G15 and 0.25% ADI for NL toddlers), processing studies are not required as they are not expected to significantly affect the outcome of the exposure assessment.

1.2.4. Proposed MRLs

The submitted data are considered sufficient to derive an MRL proposal of 0.05* mg/kg for tree nuts in support of the authorised use in the USA and of 0.3 mg/kg for sweet/bell peppers in support of the intended indoor use of pyridaben in Europe. In Section 3, the dietary risk assessment for this MRL proposal is presented.

2. Residues in livestock

Pyridaben is authorised for use on coconuts, for which the by-products might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), updating the livestock dietary burden as calculated in the MRL review (EFSA, 2017).

The input values for all relevant commodities are summarised in Appendix D.

The calculated dietary burdens exceed the trigger value of 0.1 mg/kg dry matter (DM) for cattle and sheep diets only. The main contributing commodity is apple pomace. Since residues in coconut meal are not contributing to livestock exposure, the nature and magnitude of pyridaben residues in livestock was not investigated further.

3. Consumer risk assessment

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018, 2019).

For the calculation of chronic and acute consumer exposure, the STMR and HR values as derived from the residue trials on tree nuts and sweet/bell peppers (see Appendix B.1.2.1) were used as input values. For the remaining commodities, the STMR and HR values as derived in the previous EFSA assessments were used as input values (EFSA, 2015, 2017). The crops for which no authorised uses were reported in the MRL review, and crops for which the MRLs were lowered to the LOQ because the assessed uses were not supported by data, were excluded from the exposure calculation.

No long-term consumer intake concerns were identified for any of the European diets incorporated in EFSA PRIMo. The total calculated intake accounted for a maximum of 33% of the ADI (NL toddler). The contribution of residues in tree nuts (coconut) and sweet peppers/bell peppers to the total exposure was low (0.25% ADI for NL toddler and 0.47% of the ADIGEMS/Food cluster diet G15, respectively).

In the short-term exposure assessment, EFSA focused on the commodities assessed in the present MRL application in accordance with the internationally agreed methodology. The acute exposure calculation did not identify acute consumer intake concerns related to pyridaben residues from the intended uses on sweet peppers/bell peppers (15% of the ARfD) and from the authorised uses on tree nuts (highest exposure being from coconuts (1% of the ARfD)).

It is noted that the estimated short-term exposure to pyridaben residues in apples and pears related to the authorised uses of pyridaben slightly exceeded the ARfD for Dutch toddlers while the exposure calculated in the framework of the MRL review, where the MRL recommendations for these two crops were derived, was below the ARfD. The different results are due to the higher large portion consumption data used in PRIMo revision 3.1 compared to the previously used version of the risk assessment model (PRIMo rev. 2). Further refinements of the acute risk assessment for these crops would be possible. EFSA concluded that pyridaben residues from the authorised use on tree nuts and from the intended use on sweet peppers/bell peppers will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a risk to consumers' health.

Further details on the exposure calculations and a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found sufficient to derive MRL proposals for pyridaben in sweet pepper/bell pepper and tree nuts in support of the intended EU indoor use and the authorised USA use, respectively.

EFSA concluded that pyridaben residues from the authorised use on tree nuts in the USA and from the intended indoor use on sweet peppers/bell peppers will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.i.	active ingredient
a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC-ECD	gas chromatography with electron capture detector
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
InChiKey	International Chemical Identifier Key
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization
WP	wettable powder

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Sweet peppers/ bell peppers	Belgium, Netherlands, Poland, Czech Republic, Slovakia, Hungary, Romania. France, Spain, Greece, Bulgaria, Italy	I	Mites and whitefly	SC	100.0 g/L	Foliar treatment – general (see also comment field)	At pest presence, January–December	1			500–1,400	0.20	kg a.i./ha	3	
Almonds, Brazil nuts, cashew nuts, chestnuts, coconuts, hazelnuts/ cobnuts, macadamia, pecans, pine nut kernels, pistachios, walnuts	Non-EU, USA	F	Insects Mites	SC	449.0 g/L	Foliar treatment – broadcast spraying	n.a.	2	30		935–3,742	0.56	kg a.i./ha	7	Max. 17.07 fl.oz. per acre 100–400 gallons per acre

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Almonds, Brazil nuts, cashew nuts, chestnuts, coconuts, hazelnuts/ cobnuts, macadamia, pecans, pine nut kernels, pistachios, walnuts	Non-EU, USA	F	Insects Mites	WP	750.0 g/L	Foliar treatment – broadcast spraying	n.a.	2	30		935–3,742	0.56	kg a.i./ ha	7	10.67 oz. per acre; 100-400 gallons per acre

NEU: northern European Union; SEU: southern European Union; MS; Member State; MRL: maximum residue level; GAP: Good Agricultural Practice; a.s.: active substance; SC: suspension concentrate; WP: wettable powder; a.i.: active ingredient;
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/source**
	Fruit crops	Apples	Foliar, 3 × 300 g a.s./ha	25, 40	Radiolabelled active substance: benzyl-^{14}C- and/or pyridazinone-^{14}-C pyridaben (EFSA, 2010, 2017)
		Citrus fruit	Foliar 2 × 0.57 kg a.s./ha 2 × 4.76 kg a.s./ha	0, 1, 3, 7 1, 7, 14	
		Tomatoes	By brush onto leaves, 1 mg a.s./plant	1, 7, 14	
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/source**
	Root/tuber crops	Radishes	Bare soil, 2 × 0.75 kg a.s./ha	30, 240	Radiolabelled active substance: pyridazinone-^{14}-C pyridaben (EFSA, 2010, 2017)
	Leafy crops	Swiss chards		30, 240	
		Mustard green		30	
	Cereal (small grain)	Wheat		30	
		Sorghum		30, 240	
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		EFSA (2010, 2017)
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes		
	Sterilisation (20 min, 120°C, pH 6)		Yes		
	Other processing conditions		–		–

Can a general residue definition be proposed for primary crops?	No	Fruit crops only (EFSA, 2017)
Rotational crop and primary crop metabolism similar?	Yes	
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	
Plant residue definition for monitoring (RD-Mo)	Pyridaben (fruit crops only) (EFSA, 2017)	
Plant residue definition for risk assessment (RD-RA)	Pyridaben (fruit crops only) (EFSA, 2017)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	High water commodities: • Primary method: GC-ECD (D9312), LOQ = 0.05 mg/kg for apples and apple processed products (for wet pomace LOQ = 0.5 mg/kg); tomato; ILV available (EFSA, 2010); • confirmatory method LC–MS/MS LOQ = 0.05 mg/kg tomato (EFSA, 2010; EFSA, 2017) • LC–MS/MS (QuECHERS methods, EN 15662:2008); LOQ = 0.01 mg/kg, sufficient validation data in tomato available (EFSA, 2017) High acid commodities: • Primary method: GC-ECD (comparable to D9309), LOQ = 0.05 mg/kg; validated for orange peel, dried orange pulp and orange juice; ILV available (EFSA, 2010); • LC–MS/MS (QuECHERS methods, EN 15662:2008); LOQ = 0.01 mg/kg, sufficient validation data in lemon available (EFSA, 2017); may be used as confirmatory method High oil content and dry commodities: LC–MS/MS (QuECHERS methods, EN 15662:2008); LOQ = 0.01 mg/kg, sufficient validation data in wheat, rye, barley, rice and almonds available (EFSA, 2017) High water, high acid, high oil and dry commodities: LC–MS/MS (; LOQ = 0.01 mg/kg; ILV available validation data in barley grain, tomato, oilseed rape and orange (Netherlands, 2019b)	

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; GC-ECD: gas chromatography with electron capture detector; LOQ: limit of quantification; ILV: independent laboratory validation; LC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ source
				Value	Unit		
	High water content	Apples	−20	12	Months	Pyridaben	EFSA (2010, 2017)
	High oil content	Almonds	−5	24	Months	Pyridaben	Netherlands (2019b)
		Almond hulls	−5	24	Months	Pyridaben	Netherlands (2019b)
	High acid content	Oranges	−5/−20	12	Months	Pyridaben	EFSA (2010, 2017)
		Grapes	−20	12	Months	Pyridaben	EFSA (2010, 2017)
	Processed products	Orange, dried pulp	−5	12	Months	Pyridaben	EFSA (2010, 2017)
		Orange molasses	−5	12	Months	Pyridaben	EFSA (2010, 2017)
		Orange oil	−5	12	Months	Pyridaben	EFSA (2010, 2017)

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

Commodity	Region/indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Enforcement residue definition: pyridaben **Risk assessment residue definition: pyridaben**							
Tree nuts (GAP USA: 2 × 560 g/ha, PHI 7 days)	Import tolerance (USA)	12 × < 0.05	GAP-compliant residue trials on almond nut meat and shelled pecan nuts (Netherlands, 2019b). Extrapolation to the crop group or tree nuts possible	**0.05***,[e]	0.05	0.05	1
Peppers (Intended GAP: 1 × 200 g/ha, PHI 3 days)	Indoor	< 0.01; 0.054; 0.073; 0.081; 0.085; 0.104; 0.109; 0.125	GAP-compliant trials on sweet peppers/ bell peppers (Netherlands, 2019a)	**0.3**	0.13	0.08	1

MRL: maximum residue level; GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; PHI: preharvest interval.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): The tolerance established for pyridaben in tree nuts in the USA is 0.05 mg/kg.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No	Based on the available information it can be concluded that no significant residues of pyridaben are expected in rotational crops (EFSA, 2017)
Residues in rotational and succeeding crops expected based on field rotational crop study?	No	No studies submitted and not required

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL applications. Studies are not required.

B.2. Residues in livestock

Dietary burden calculation according to OECD (2013), using Animal Model_2017.

Relevant groups	Dietary burden expressed in				Most critical diet[a]	Most critical commodity[b]	Trigger exceeded (yes/no)	Previous assessment (EFSA, 2017)
	mg/kg bw per day		mg/kg DM				0.10	Max burden
	Median	Maximum	Median	Maximum			mg/kg DM	mg/kg DM
Cattle (all diets)	0.008	0.008	0.33	0.33	Beef cattle	Apple, wet pomace	Yes	0.31
Cattle (dairy only)	0.006	0.006	0.16	0.16	Dairy cattle	Apple, wet pomace	Yes	0.16
Sheep (all diets)	0.007	0.007	0.16	0.16	Lamb	Apple, wet pomace	Yes	0.16
Sheep (ewe only)	0.005	0.005	0.16	0.16	Ram/Ewe	Apple, wet pomace	Yes	0.16
Swine (all diets)	0.001	0.001	0.05	0.05	Swine (breeding)	Citrus, dried pulp	No	0.04
Poultry (all diets)	0.00	0.00	0.00	0.00	–	–	No	0.00
Poultry (layer only)	0.00	0.00	0.00	0.00	–	–	No	0.00

bw: body weight; DM: dry matter.
(a): When several diets are relevant (e.g. cattle, sheep and poultry 'all diets'), the most critical diet is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.3. Consumer risk assessment

ARfD	0.05 mg/kg bw (EFSA, 2010)
Highest IESTI, according to EFSA PRIMo a	Sweet peppers: 15% of ARfD Coconuts: 1% of ARfD Other tree nuts: individually < 1% of the ARfD
Assumptions made for the calculations	Calculation performed with PRIMo rev.3.1. The calculation is based on the highest residue levels expected in tree nuts from the authorised usein the United States and in sweet peppers/bell peppers from the intended indoor use For commodities not included in the present MRL application, the short-term exposure assessment was performed using the risk assessment values derived in previous EFSA reasoned opinions (HR values)

ADI	0.01 mg/kg bw per day (EFSA, 2010)
Highest IEDI, according to EFSA PRIMo	33% of ADI (NL toddler) Contribution of crops assessed: Tree nuts (coconut): 0.25% of ADI (NL toddler) Sweet pepper: 0.47% of ADI (GEMS/Food cluster diet G15)
Assumptions made for the calculations	Calculation performed with PRIMo rev.3.1. The calculation is based on the median residue levels (STMR) derived for tree nuts and sweet/bell peppers from the residue trials submitted in the framework of the current assessment For the remaining commodities, the STMR values derived in previous EFSA assessments were used as input values The contributions of commodities where no GAP was reported in the framework of the MRL review and for commodities where the MRLs lowered to the LOQ because the assessed uses were not supported by data were not included in the calculation

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue; ADI: acceptable daily intake; IEDI: international estimated daily intake; GAP: Good Agricultural Practice; LOQ: limit of quantification.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Pyridaben[(F)]				
120000	Tree nuts	0.01*	0.05*	The submitted data are sufficient to derive an import tolerance MRL (USA GAP). Risk for consumers unlikely
231020	Peppers	0.01*	0.3	The submitted data are sufficient to derive MRL proposals for the intended EU indoor use Risk for consumers is unlikely

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Pyridaben

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.05
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	33%	NL toddler	3.34	14%	Apples	6%	Milk: Cattle	6%	Pears	4%	
	25%	DE child	2.46	16%	Apples	2%	Milk: Cattle	0.8%	Pears	2%	
	17%	NL child	1.74	8%	Apples	2%	Milk: Cattle	2%	Pears	3%	
	12%	FR toddler 2 3 yr	1.19	4%	Apples	3%	Milk: Cattle	0.6%	Bovine: Muscle/meat	2%	
	11%	DK child	1.07	3%	Apples	1%	Milk: Cattle	1%	Swine: Muscle/meat	2%	
	11%	FR child 3 15 yr	1.06	2%	Milk: Cattle	2%	Apples	0.7%	Bovine: Muscle/meat	2%	
	10%	UK infant	0.95	4%	Milk: Cattle	2%	Apples	0.6%	Bovine: Muscle/meat	2%	
	8%	DE women 14-50 yr	0.84	3%	Apples	1%	Milk: Cattle	0.5%	Sugar beet roots	2%	
	8%	ES child	0.83	1%	Apples	1%	Milk: Cattle	0.7%	Bovine: Muscle/meat	2%	
	8%	GEMS/Food G11	0.83	2%	Apples	0.8%	Milk: Cattle	0.6%	Swine: Muscle/meat	3%	
	8%	SE general	0.82	2%	Bovine: Muscle/meat	1%	Apples	1%	Milk: Cattle	2%	
	8%	DE general	0.82	3%	Apples	1%	Milk: Cattle	0.6%	Swine: Muscle/meat	2%	
	8%	GEMS/Food G06	0.81	2%	Tomatoes	1%	Apples	0.7%	Wheat	3%	
	8%	RO general	0.81	2%	Apples	1%	Milk: Cattle	1.0%	Tomatoes	2%	
	8%	UK toddler	0.80	2%	Apples	2%	Milk: Cattle	0.6%	Bovine: Muscle/meat	2%	
	8%	GEMS/Food G08	0.80	2%	Apples	1.0%	Swine: Muscle/meat	0.6%	Tomatoes	2%	
	8%	GEMS/Food G15	0.80	1%	Apples	0.7%	Swine: Muscle/meat	0.7%	Milk: Cattle	2%	
	8%	GEMS/Food G07	0.77	1%	Apples	0.6%	Milk: Cattle	0.6%	Poultry: Muscle/meat	2%	
	7%	GEMS/Food G10	0.74	1.0%	Apples	0.7%	Poultry: Muscle/meat	0.7%	Tomatoes	2%	
	7%	IE adult	0.67	0.9%	Apples	0.6%	Pears	0.4%	Milk: Cattle	2%	
	6%	NL general	0.65	2%	Apples	0.8%	Milk: Cattle	0.5%	Swine: Muscle/meat	2%	
	6%	FR infant	0.62	2%	Apples	2%	Milk: Cattle	0.3%	Beans (with pods)	0.8%	
	5%	LT adult	0.52	2%	Apples	0.5%	Swine: Muscle/meat	0.4%	Milk: Cattle	0.7%	
	5%	ES adult	0.52	1.0%	Apples	0.5%	Milk: Cattle	0.4%	Pears	0.9%	
	5%	FI adult	0.48	3%	Coffee beans	0.8%	Apples	0.3%	Tomatoes	3%	
	5%	FR adult	0.47	1.0%	Apples	0.4%	Milk: Cattle	0.3%	Swine: Muscle/meat	1%	
	5%	PT general	0.45	1%	Apples	0.5%	Potatoes	0.4%	Tomatoes	2%	
	4%	DK adult	0.45	1%	Apples	0.5%	Milk: Cattle	0.4%	Swine: Muscle/meat	0.7%	
	4%	IT toddler	0.43	1%	Apples	0.7%	Tomatoes	0.7%	Wheat	1%	
	4%	FI 3 yr	0.43	1%	Apples	0.5%	Cucumbers	0.5%	Potatoes	1%	
	4%	PL general	0.43	3%	Apples	0.4%	Tomatoes	0.4%	Pears	0.6%	
	4%	IT adult	0.35	1%	Apples	0.6%	Tomatoes	0.4%	Wheat	0.8%	
	3%	FI 6 yr	0.32	0.8%	Apples	0.4%	Potatoes	0.4%	Cucumbers	1%	
	3%	UK vegetarian	0.28	0.8%	Apples	0.3%	Milk: Cattle	0.3%	Tomatoes	0.9%	
	3%	UK adult	0.27	0.5%	Apples	0.3%	Bovine: Muscle/meat	0.3%	Milk: Cattle	0.8%	
	2%	IE child	0.15	0.4%	Apples	0.4%	Milk: Cattle	0.1%	Wheat	0.3%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Pyridaben is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
133%	Pears	0.9/0.48	66
103%	Apples	0.9/0.48	52
29%	Peaches	0.3/0.15	14
24%	Quinces	0.9/0.48	12
17%	Strawberries	0.9/0.53	8.7
15%	Sweet peppers/bell peppers	0.3/0.13	7.4
13%	Medlar	0.9/0.48	6.6
13%	Cucumbers	0.15/0.1	6.6
10%	Apricots	0.3/0.15	5.2
10%	Tomatoes	0.15/0.09	5.2
9%	Courgettes	0.15/0.1	4.6
6%	Oranges	0.3/0.02	2.9
5%	Aubergines/egg plants	0.15/0.09	2.3
3%	Grapefruits	0.3/0.02	1.7
3%	Potatoes	0.01/0.01	1.5

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Pears	0.9/0.48	15
27%	Apples	0.9/0.48	13
15%	Quinces	0.9/0.48	7.3
10%	Strawberries	0.9/0.53	4.9
7%	Medlar	0.9/0.48	3.3
6%	Peaches	0.3/0.15	2.8
6%	Cucumbers	0.15/0.1	2.8
5%	Aubergines/egg plants	0.15/0.09	2.4
5%	Courgettes	0.15/0.1	2.3
4%	Sweet peppers/bell peppers	0.3/0.13	2.0
3%	Apricots	0.3/0.15	1.6
3%	Tomatoes	0.15/0.09	1.4
2%	Beans (with pods)	0.2/0.1	0.77
1%	Oranges	0.3/0.02	0.67
1%	Gherkins	0.15/0.1	0.61

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 2

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
14%	Apples / juice	0.9/0.13	7.0
8%	Pears / juice	0.9/0.13	4.2
8%	Oranges / juice	0.3/0.08	4.2
8%	Peaches / canned	0.3/0.15	3.9
7%	Courgettes / boiled	0.15/0.1	3.5
5%	Gherkins / pickled	0.15/0.1	2.3
3%	Beans (with pods) / boiled	0.2/0.1	1.3
2%	Peaches / juice	0.3/0.07	1.2
2%	Sugar beets (root) / sugar	0.01/0.12	1.1
2%	Tomatoes / juice	0.15/0.05	0.95
2%	Potatoes / fried	0.01/0.01	0.93
2%	Pumpkins / boiled	0.01/0.01	0.89
2%	Witloofs / boiled	0.01/0.01	0.89
2%	Broccoli / boiled	0.01/0.01	0.79
1%	Cauliflowers / boiled	0.01/0.01	0.70

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
9%	Apples / juice	0.9/0.13	4.3
5%	Courgettes / boiled	0.15/0.1	2.3
2%	Peaches / canned	0.3/0.15	1.2
2%	Oranges / juice	0.3/0.08	1.2
2%	Grapefruits / juice	0.3/0.08	0.87
1%	Pumpkins / boiled	0.01/0.01	0.55
0.9%	Sugar beets (root) / sugar	0.01/0.12	0.44
0.8%	Cauliflowers / boiled	0.01/0.01	0.42
0.8%	Tomatoes / sauce/puree	0.15/0.05	0.41
0.8%	Beetroots / boiled	0.01/0.01	0.39
0.7%	Celeries / boiled	0.01/0.01	0.34
0.5%	Broccoli / boiled	0.01/0.01	0.24
0.5%	Coffee beans / extraction	0.05/0.01	0.24
0.4%	Parsnips / boiled	0.01/0.01	0.21
0.4%	Kohlrabies / boiled	0.01/0.01	0.21

Conclusion:
The estimated short term intake (IESTI) exceeded the toxicological reference value for 2 commodities.

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

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: pyridaben				
Coconut, meal	0.05*	STMR[(a)]	0.05*	STMR[(a)]
Grapefruits, dried pulp	0.27	STMR × PF	0.27	STMR × PF
Oranges, dried pulp	0.27	STMR × PF	0.27	STMR × PF
Lemons, dried pulp	0.27	STMR × PF	0.27	STMR × PF
Limes, dried pulp	0.27	STMR × PF	0.27	STMR × PF
Mandarins, dried pulp	0.27	STMR × PF	0.27	STMR × PF
Apple, pomace, wet	0.63	STMR × PF[(b)]	0.63	STMR × PF[(a)]

STMR: supervised trials median residue; PF: processing factor.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): For coconut meal no default processing factor was applied because pyridaben is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.
(b): For apple pomace, wet, in the absence of a processing factor supported by data, a default processing factor of 5 was included in the calculation to consider the potential concentration of residues in these commodities.

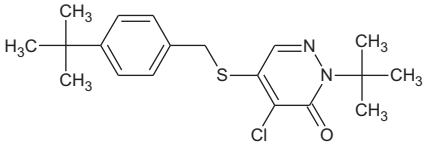
D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Input values derived from the current assessment				
Almonds	0.05	STMR	0.05	HR
Brazil nuts	0.05	STMR	0.05	HR
Cashew nuts	0.05	STMR	0.05	HR
Chestnuts	0.05	STMR	0.05	HR
Coconuts	0.05	STMR	0.05	HR
Hazelnuts/cobnuts	0.05	STMR	0.05	HR
Macadamia	0.05	STMR	0.05	HR
Pecans	0.05	STMR	0.05	HR
Pine nut kernels	0.05	STMR	0.05	HR
Pistachios	0.05	STMR	0.05	HR
Walnuts	0.05	STMR	0.05	HR
Sweet peppers/bell peppers	0.083	STMR	0.125	HR
Input values derived from previous assessments				
Tomatoes	0.05	STMR (EFSA, 2019)	0.09	HR (EFSA, 2019)
Aubergines	0.05	STMR (tomatoes) (EFSA, 2019)	0.09	HR (tomatoes) (EFSA, 2019)
Citrus fruits	0.008	STMR (0.08) × PF (0.1) (EFSA, 2017)	0.022	HR (0.22) × PF (0.1) (EFSA, 2017)
Pome fruits	0.13	STMR (EFSA, 2017)	0.48	HR (EFSA, 2017)
Apricots, peaches	0.07	STMR (EFSA, 2017)	0.15	HR (EFSA, 2017)
Strawberries	0.11	STMR (EFSA, 2017)	0.53	HR (EFSA, 2017)
Cucurbits (edible peel)	0.05	STMR (EFSA, 2015)	0.097	HR (EFSA, 2015)
Beans (with pods)	0.06	STMR (EFSA, 2017)	0.10	HR (EFSA, 2017)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Meat of bovine, sheep, goat equine	0.05	STMR (EFSA, 2017)	0.05	HR (EFSA, 2017)
Fat of bovine, sheep, goat equine	0.05	STMR (EFSA, 2017)	0.05	HR (EFSA, 2017)
Liver of bovine, sheep, goat equine	0.05	STMR (EFSA, 2017)	0.05	HR (EFSA, 2017)
Kidney of bovine, sheep, goat equine	0.05	STMR (EFSA, 2017)	0.05	HR (EFSA, 2017)
Milk of cattle, sheep, goat, horse	0.01	STMR (EFSA, 2017)	0.01	HR (EFSA, 2017)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Pyridaben	2-*tert*-butyl-5-(4-*tert*-butylbenzylthio)-4-chlorpyrididazin-3(2*H*)-one CC(C)(C)N2N=CC(SCc1ccc(cc1)C(C)(C)C)=C(Cl)C2=O DWFZBUWUXWZWKD-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2018.2.2 ACD/Labs 2018 Release (File version N50E41, Build 103230, 21 July 2018).
(c): ACD/ChemSketch 2018.2.2 ACD/Labs 2018 Release (File version C60H41, Build 106041, 7 December 2018).