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## Setting of an import tolerance for pyridaben in grapefruits

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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 a request to the competent national authority in the Netherlands to set an import tolerance for the active substance pyridaben in grapefruits imported from the United States of America. The data submitted in support of the requests were found to be sufficient to derive an MRL proposal of 0.5 mg/kg for grapefruits. Adequate analytical methods for enforcement are available to control the residues of pyridaben on the commodity under consideration, at or above the validated LOQ 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 uses of pyridaben on imported grapefruits from United States according to the reported agricultural practices, is unlikely to present a risk to consumer health.

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## Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Nissan Chemical Europe S.A.S. submitted an application to the competent national authority the Netherlands (rapporteur Member State, RMS) to set import tolerance for the active substance pyridaben in grapefruits. The RMS 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 the European Food Safety Authority (EFSA) on 5 May 2022. The RMS proposed to establish maximum residue level (MRL) for grapefruits imported from the United States at the level of 0.5 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the RMS. On 24 May 2022, the RMS submitted the requested information.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional data provided by the RMS in the framework of this application, the following conclusions are derived.

The metabolism of pyridaben following foliar applications was investigated in crops belonging to the group of fruit crops. Studies investigating the effect of processing on the nature of pyridaben (hydrolysis studies) demonstrated that the active substance is stable. As the authorised use of pyridaben is on imported and permanent crop, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies and the hydrolysis studies, the residue definitions for plant products were proposed as 'pyridaben' for enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products and are restricted to fruits. EFSA concluded that for the crop assessed in this application, metabolism of pyridaben in primary crops and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods are available to quantify residues in the crop assessed in this application according to the enforcement residue definition. The methods allow quantification of residues at or above 0.01 mg/kg (limit of quantification (LOQ)).

The uses on grapefruits authorised in the USA and reported in this MRL application are adequately supported by residue data and therefore an MRL of 0.5 mg/kg can be proposed.

Specific studies investigating the magnitude of pyridaben residues in processed commodities are not required, as residues in the crop under consideration are minor contributor to the overall dietary intake. Nevertheless, the applicant assessed the distribution of residues in the peel and the pulp in three grapefruit residue trials and submitted the results of processing studies with oranges processed into juice, marmalade and dry pomace. The number and quality of the processing studies is sufficient to derive a robust processing factor of 0.13 for (pasteurised) orange juice which is recommended to be included in Annex VI of Regulation (EC) No 396/2005.

Although imported grapefruits are not expected to be fed to livestock, a potential carry-over into food of animal origin from residues of pyridaben in the by-feed product dried pulp was assessed, in the unlikely event of these imported fruits may be fed to livestock. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for cattle and sheep only and was driven by the existing use on apples. The contribution of pyridaben residues in the crops under consideration in this MRL application to the livestock exposure of ruminants was insignificant and therefore a modification of the existing MRLs for commodities of animal origin was considered unnecessary. It is noted that the data gaps identified in the MRL review for products of animal origin and implemented in the MRL regulation as a footnote may be considered as addressed by the information and new data submitted in this MRL application.

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 (bw) per day and an acute reference dose (ARfD) of 0.05 mg/kg bw.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo).

The acute exposure calculation did not identify acute consumer intake concerns related to the authorised use of pyridaben on grapefruits (maximum 5.3% of the ARfD). For the calculation of the

chronic exposure, EFSA used the median residue values (STMR) as derived from the residue trials submitted and the STMRs available from previously issued EFSA opinions. No long-term consumer intake concerns were identified for any of the European diets incorporated in EFSA PRIMo. The estimated long-term dietary intake accounted for a maximum of 29% of the ADI (NL toddler diet). The contribution of residues expected in grapefruits to the overall long-term exposure was low and accounted for a maximum of 0.12% of ADI (IE adult diet). The exposure calculations should be regarded as indicative since for certain commodities, only tentative MRLs could be derived during the MRL review.

EFSA concluded that the authorised uses of pyridaben on grapefruits authorised in the USA and assessed in this MRL application 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 MRL as reported in the summary table below.

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

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
<b>Enforcement residue definition:</b> Pyridaben <sup>(F)</sup>				
0110010	Grapefruits	0.3	0.5	The submitted data are sufficient to derive an import tolerance (US GAP). An MRL of 0.9 mg/kg is set in the USA for the whole group of citrus fruits. Risk for consumers unlikely.

MRL: maximum residue level; GAP: Good Agricultural Practice.

(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 an application to set an import tolerance for the active substance pyridaben in grapefruits. The detailed description of the existing use of pyridaben authorised in the USA in grapefruits, which is the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Pyridaben is the ISO common name for 2-*tert*-butyl–5-(4-*tert*-butylbenzylthio)-4-chloropyrididazin-3(2*H*)-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<sup>1</sup> 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 (2010). Pyridaben was approved<sup>2</sup> 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<sup>3</sup>. 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 legislation. After completion of the MRL review, EFSA has issued two reasoned opinions on the modification of MRLs for pyridaben (EFSA, 2019a, 2020). The proposals from these reasoned opinions have been considered in recent MRL regulations.<sup>4</sup>

In accordance with Article 6 of Regulation (EC) No 396/2005, Nissan Chemical Europe S.A.S. submitted an application to the competent national authority in the Netherlands (RMS) to set an import tolerance for the active substance pyridaben in grapefruits. The RMS 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 the European Food Safety Authority EFSA on 5 May 2022. The RMS proposed to establish MRL for grapefruits imported from the USA at the level of 0.5 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the RMS. On 24 May 2022, the RMS submitted the requested information.

EFSA based its assessment on the evaluation report submitted by the RMS (Netherlands, 2022), the DAR and its addendum (Netherlands, 2007, 2009), the Commission review report on pyridaben (European Commission, 2010b), 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, 2015a, 2019a, 2020), including the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005 (EFSA, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011<sup>5</sup> and the guidance documents applicable at the date of submission of the application to the RMS are applicable (European Commission, 1997a–g, 2010a, 2017, 2020, 2021; 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<sup>6</sup>.

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, is presented in Appendix B.

The evaluation report submitted by the RMS (Netherlands, 2022) 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.

<sup>1</sup> 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, pp. 1–32.

<sup>2</sup> 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, pp. 38–41.

<sup>3</sup> 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, pp. 1–16.

<sup>4</sup> For an overview of all MRL Regulations on this active substance, please consult: <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as>

<sup>5</sup> 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, pp. 1–66.

<sup>6</sup> 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, pp. 127–175.

## 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 pesticide EU pesticides peer review and the MRL 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 fruits (EFSA, 2010, 2017). In the various crops, a major proportion of the total radioactive residue (TRR) was present as parent pyridaben. Levels of individual metabolites or fractions were generally less than 5% of the 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).

For the authorised use under assessment, the metabolic behaviour in primary crops is sufficiently addressed.

#### 1.1.2. Nature of residues in rotational crops

As the authorised use of pyridaben is on permanent, imported crops, investigations of residues in rotational crops are not required.

#### 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 EU pesticides peer review (EFSA, 2010) and the MRL review (EFSA, 2017). From these studies, it can be concluded that pyridaben is hydrolytically stable under conditions simulating processing by pasteurisation, baking/brewing/boiling and sterilisation.

#### 1.1.4. Analytical methods for enforcement purposes in plant commodities

Analytical methods for the determination of pyridaben residues in plant commodities were investigated in the EU pesticides peer review as well as in the MRL review (EFSA, 2010, 2017). Pyridaben can be enforced in high water and high acid content commodities by using a gas chromatography with electron capture detector (GC-ECD) method with a limit of quantification (LOQ) of 0.05 mg/kg and a liquid chromatography with tandem mass spectrometry (LC-MS/MS) method with an LOQ of 0.01 mg/kg during routine analysis (EFSA, 2017).

An additional enforcement method of analysis for foodstuffs of plant origin to cover high water, high acid, dry and high oil content matrices and an independent laboratory validation (ILV) study on the same crop categories are available. These studies were previously accepted (EFSA, 2020) and are reconsidered in this MRL application.

According to the RMS, the extraction efficiency of the analytical enforcement method has been sufficiently demonstrated according to the guidance (European Commission, 2017) in high acid content matrices, to which group an analytical method is required in this application. In the metabolism study conducted in oranges using the same extraction solvent of the monitoring method (acetone/water, 8/2 v/v), a large fraction of the TRR (> 70%) was extractable and more than 50% of the TRR was parent compounds (Netherlands, 2022).

EFSA concluded that an LC-MS/MS method with an LOQ of 0.01 mg/kg is sufficiently validated and allows quantifying residues at or above the LOQ of 0.01 mg/kg in crops belonging to the group of high acid content commodities, to which grapefruits belong.

#### 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 EU pesticides peer review and the MRL review (EFSA, 2010, 2017). Results demonstrate that residues of pyridaben are stable in high acid matrices for 12 months when samples are stored at  $-5^{\circ}\text{C}$  and  $-20^{\circ}\text{C}$ , and in high water matrices when samples are stored at  $-20^{\circ}\text{C}$  for 12 months.

A study investigating the stability of pyridaben residues in refrigerated samples of crops classified as matrices with high water-content (plums and apples), high acid content (grapes) and in prunes and



a second study in frozen samples of high acid content (oranges) were submitted with the current application (Netherlands, 2022).

In the first study, the samples were fortified with pyridaben at 1.0 mg/kg, stored at  $-5^{\circ}\text{C}$  and the storage stability was investigated at 1, 3, 6, 12 months intervals. Results demonstrated pyridaben is stable for at least 12 months in plant matrices with high water content and high acid content, when stored at  $-5^{\circ}\text{C}$ .

In the second study, samples of oranges (peel and pulp) were fortified with pyridaben at 0.1 mg/kg, then analysed immediately and after 1, 3, 6, 12 months of frozen storage at  $\leq -18^{\circ}\text{C}$ . Pyridaben was shown to be stable in orange peel and pulp when stored at  $\leq -18^{\circ}\text{C}$  for a period of at least 12 months.

### 1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the following residue definitions were proposed by the MRL review (EFSA, 2017):

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

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 the above-mentioned residue definition. For the use 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

In support of the MRL application for grapefruits imported in the European Union, the applicant submitted eight Good Agricultural Practice (GAP) compliant residue trials on grapefruits performed in the USA in 1993 (5 trials) and 2019 (3 trials) according to the more critical GAP with the higher application rate of 0.56 kg/ha. In three trials, residues of pyridaben were also measured in the pulp. The number of trials is sufficient to support an MRL proposal of 0.5 mg/kg.

The samples of these residue trials were stored under conditions for which integrity of the samples is demonstrated. According to the assessment of the RMS, the methods used were sufficiently validated and fit for purpose (Netherlands, 2022).

### 1.2.2. Magnitude of residues in rotational crops

Rotational field trials are not triggered by the current assessment. Crop rotation is not relevant in imported crops. Furthermore, these commodities are permanent crops and are not grown in rotation.

### 1.2.3. Magnitude of residues in processed commodities

Processing factors and a peeling factor for oranges were derived in the frame of the MRL review (EFSA, 2017). Additional data are available from the residue trials to derive peeling factors for grapefruits and from new processing studies assessing the magnitude of pyridaben residues in the orange pulp and during the processing of oranges with the current application (Netherlands, 2022). In the new processing studies, oranges were collected at a longer preharvest interval (PHI) of 14 days than the PHI of the reported GAP and processed into orange juice and marmalade and into dry pomace.

A median peeling factor for citrus derived combining data on oranges and grapefruits and median processing factors for citrus juice, jam and dry pomace were calculated by taking into account the data generated from the studies mentioned above and the previously assessed studies.

The number and quality of the processing studies are sufficient to derive a robust processing factor of 0.13 for pasteurised orange juice which is recommended to be included in Annex VI of Regulation (EC) No 396/2005.



#### 1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for the commodity under evaluation. The submitted data are considered sufficient to derive an MRL proposal of 0.5 mg/kg for grapefruits in support of the use of pyridaben authorised in the United States. The MRL proposal is lower than the MRL set in the USA for the whole group of citrus fruits (0.09 mg/kg). In Section 3, EFSA assessed whether residues in grapefruits resulting from the use authorised in the USA are likely to pose a consumer health risk.

## 2. Residues in livestock

Imports from the USA will be the raw agricultural commodities intended for human consumption (EFSA, 2015b). However, in the unlikely event of these imported fruits may be fed to livestock, the dietary burden to livestock from intakes of the by-product grapefruit dried pulp was considered by the RMS (Netherlands, 2022). The most recent dietary burden performed according to OECD guidance (OECD, 2013) in the framework of a previous MRL application (EFSA, 2020) was updated with the median residue values (STMR) from US grapefruit trials of 0.13 mg/kg. The dried pulp processing factor of 3.8 for citrus was applied. The estimate of dietary burden is provided in Appendix B.2. The input values for all relevant commodities are summarised in Appendix D.1. 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. Although grapefruits dried pulp was the main contributing product to the dietary burden of pigs and a relevant increase was observed compared to previous calculation (EFSA, 2020), the livestock dietary burden still did not exceed the trigger value of 0.1 mg/kg DM in this animal species. Since residues in dried grapefruits pulp are not contributing significantly to the livestock exposure of ruminants and the exposure is not triggered in pigs and poultry, the nature and magnitude of pyridaben residues in livestock was not investigated further. The results from previous assessments are still valid (EFSA, 2017, 2020).

It is noted that information on the exact storage temperature of samples from the feeding study assessed in the MRL review and tabulated results of the storage stability study performed in 1995 were provided (Netherlands, 2022). Samples of liver, muscle and milk from the feeding study in dairy cattle were stored at  $-5^{\circ}\text{C}$  for a maximum of 5 months (tissues) and 6.5 months (milk). Storage stability investigations were performed in muscle, liver and milk. The selection is in line with the EU guidance (European Commission, 1997f). The stability of pyridaben was demonstrated for up to 5 months, thus covering residue data in tissues but not in milk. Considering that no decline in the level of residues was observed over the period of 5 months in the tested milk samples, EFSA agrees that the active substance shall be sufficiently stable also at 6.5 months in milk.

The results of the validation of a new enforcement analytical method proposed for products of animal origin and its ILV were also provided (Netherlands, 2022). The primary method consisted of a high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) methodology monitoring two ion transitions (quantification and confirmation) and using as extraction solvent methanol/water (80/20, v/v). Untreated samples (five per fortification level) of tissues, milk and eggs were fortified with known amounts of pyridaben at the LOQ and 10× the LOQ. ILV was performed on the same matrices. The validation of the methodology for the determination of pyridaben in foodstuff of animal origin (bovine milk, bovine muscle, bovine fat, bovine liver and poultry eggs) demonstrated that it could be accurately monitored at the LOQ of 0.01 mg/kg by LC–MS/MS analysis. The method was found to be validated according to the guidance document (European Commission, 2021) for the determination of pyridaben in animal matrices with the tested LOQ of 0.01 mg/kg.

Despite that the extraction procedure between the metabolism studies and the proposed analytical method both using methanol is not exactly the same, EFSA agrees with the RMS that the deviation is acceptable for tissue and egg matrices (Netherlands, 2022). For milk, since extraction in the metabolism study was done with ethyl acetate after acidification with a hydrochloric acid solution 6 M, conclusion on extraction efficiency of the proposed method for enforcement cannot be drawn.

Therefore, the data gaps identified in the MRL review for products of animal origin and implemented in the MRL regulation as footnote<sup>7</sup> may be considered as addressed, even though that

<sup>7</sup> Footnote included for products of ruminants and equine: The European Food Safety Authority identified some information on storage stability, feeding studies and analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 24 January 2021, or, if that information is not submitted by that date, the lack of it.

extraction efficiency is not fully addressed in milk matrices (not a requirement at time of the MRL review). Since a change of the existing tentative MRLs in products of animal origin is not required in the context of this application, an overall conclusion on this and the other missing information will be drawn up in the framework of the assessment of the MRL review confirmatory data application.

### 3. Consumer risk assessment

The consumer risk assessment was performed with revision 3.1 of the EFSA PRIMo. This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (EFSA, 2018, 2019b).

The toxicological reference values for pyridaben used in the risk assessment (i.e., acceptable daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU pesticides peer review (European Commission, 2010b).

The input values used in the exposure calculations are summarised in Appendix D.2.

- Short-terms (acute) dietary risk assessment

The short-term risk assessment was performed only with regard to the edible portion of grapefruits using the highest residue (HR) derived from the residue trials submitted and the peeling factor for citrus. For grapefruits, the short-term exposure accounted for a maximum of 5.3% of the ARfD.

EFSA confirms previous finding regarding the exceedance of the estimated short-term exposure to pyridaben residues in apples and pears related to the authorised uses of pyridaben leading to the tentative MRL of 0.9 mg/kg already observed (EFSA, 2019a, 2020). Further refinements of the acute risk assessment for these crops would be possible, also considering that the northern GAP assessed in the MRL review was supported by overdosed trials and that a full set of new northern Europe (NEU) residue trials and three southern Europe (SEU) residue trials were requested to derive a definitive MRL (EFSA, 2017).

- Long-term (chronic) dietary risk assessment

The comprehensive long-term exposure assessment performed in the framework of the MRL review was revised in previous EFSA assessments of MRL applications (EFSA, 2019a, 2020). EFSA is now updating the above-mentioned calculations by including for the STMR value as derived for grapefruits. The peeling factor was applied to the input values for citrus fruits. The contributions of commodities for which no GAP was supported in the framework of the MRL review and in the EFSA opinions issued after the MRL review were not included in the 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 29% of the ADI (NL toddler diet). The contribution of residues in grapefruits to the total exposure was up to 0.12% ADI (IE adult diet).

The consumer risk assessment exposure should be regarded as indicative since for certain commodities only tentative MRLs could be derived during the MRL review (EFSA, 2017). A more reliable consumer risk assessment will be performed in the framework of the assessment of the MRL review confirmatory data for pyridaben when the identified missing information regarding certain authorised uses and additional information will be available to EFSA.

EFSA concluded that pyridaben residues from the uses on grapefruits reported to be authorised in the US 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 to be sufficient to derive an MRL proposal for grapefruits imported from the USA based on the reported authorised uses. EFSA concluded that the authorised use of pyridaben on grapefruits will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health. The exposure calculations should be regarded as indicative since for certain commodities, only tentative MRLs could be derived during the MRL review. A more reliable consumer risk assessment will be performed in the framework of the assessment of the MRL review confirmatory data for pyridaben

when the identified missing information regarding certain authorised uses and additional information will be available to EFSA.

The MRL recommendation is summarised in Appendix B.4.

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## Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
B BCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
DAT	days after treatment
DM	dry matter
GAP	Good Agricultural Practice
GC-ECD	gas chromatography with electron capture detector
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
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
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PeF	peeling factor
PF	processing factor
PHI	preharvest interval
$P_{ow}$	partition coefficient between <i>n</i> -octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
TRR	total radioactive residue
WP	wettable powder

## Appendix A – Summary of uses for import tolerance triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I <sup>(a)</sup>	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days) <sup>(d)</sup>	Remarks
				Type <sup>(b)</sup>	Conc. a.s.	Method kind	Range of growth stages & season <sup>(c)</sup>	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Grapefruits	USA	F	Insects, Mites	SC	424.7 g a.s./L	Foliar treatment – broadcast spraying	NS	2	30 <sup>(e)</sup>	15–60	935–3,742	0.269–0.560	kg a.s./ha	7	Max. 0.560 kg a.s./ha (17.07 fl.oz. per Acre). <sup>(e)</sup> For rates above 0.269 kg a.s./ha (8.32 fl. oz per acre), apply on a 90-day interval.
Grapefruits	USA	F	Insects, Mites	WP	750 g a.s./L	Foliar treatment – broadcast spraying	NS	2	30 <sup>(e)</sup>	15–60	935–3,742	0.269–0.560	kg a.s./ha	7	Max. 0.560 kg a.s./ha (10.67 oz. per Acre). <sup>(e)</sup> For rates above 0.269 kg a.s./ha (5.2 oz. per acre), apply on a 90-day interval.

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; WP: wettable powder, SC: soluble concentrate, NS: Not specified.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. 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 3–8,263–3,152-4), including, where relevant, information on season at time of application.

(d): PHI – minimum pre-harvest interval.

(e): Please refer to Remarks.

## Appendix B – List of end points

### B.1 Residues in plants

#### B.1.1. Nature of residues and analytical methods for enforcement purposes in plant commodities

##### B.1.1.1. Metabolism studies, analytical methods and residue definitions in plants

Primary crops (available studies)	Crop groups	Crops	Applications	Sampling (DAT)	Comment/Source
	Fruit crops	Apples		Foliar, 3 × 0.3 kg a.s./ha	
	Citrus fruits		Foliar, 2 × 0.57 kg a.s./ha	0, 1, 3, 7	
			Foliar, 2 × 4.76 kg a.s./ha	1, 7, 14	
	Tomatoes		Brush onto leaves, fruits, 1 mg a.s./plant	1, 7, 14	
Rotational crops (available studies)	Crop groups	Crops	Applications	PBI (DAT)	Comment/Source
	Root/tuber crops	Radishes	Bare soil, 2 × 0.75 kg a.s./ha	30, 240	
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	
	Baking, brewing, 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)	
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)	<p>High water commodities:</p> <ul style="list-style-type: none"> <li>• 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).</li> <li>• Confirmatory method LC-MS/MS LOQ = 0.05 mg/kg tomato (EFSA, 2010, 2017).</li> <li>• LC-MS/MS (QuEChERS methods, EN 15662:2008); LOQ = 0.01 mg/kg, sufficient validation data in tomato available (EFSA, 2017).</li> </ul> <p>High acid commodities:</p> <ul style="list-style-type: none"> <li>• 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) .</li> <li>• 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.</li> </ul> <p>High oil content and dry commodities:</p> <ul style="list-style-type: none"> <li>• 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).</li> </ul> <p>High water, high acid, high oil and dry commodities:</p> <ul style="list-style-type: none"> <li>• LC-MS/MS; LOQ = 0.01 mg/kg; ILV available validation data in barley grain, tomato, oilseed rape and orange (EFSA, 2020).</li> </ul>	

DAT: days after treatment; PBI: plant-back interval; a.s.: active substance; GC-ECD: gas chromatography with electron capture detector; LOQ: limit of quantification; ILV: independent laboratory validation; LC-MS/MS: 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) OECD Guideline 506	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/Source
				Value	Unit		
High water content		Apples	-5	12	Months	Pyridaben	Netherlands (2022)
		Apples	-20	12	Months	Pyridaben	EFSA (2010, 2017)
		Plums	-5	12	Months	Pyridaben	Netherlands (2022)
High oil content		Almonds	-5	24	Months	Pyridaben	EFSA (2020)
High acid content		Oranges	-18	12	Months	Pyridaben	Netherlands (2022)
		Oranges	-20	12	Months	Pyridaben	EFSA (2010, 2017)
		Grapes	-5	12	Months	Pyridaben	Netherlands (2022)
		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)
		Almond, hulls	-5	24	Months	Pyridaben	EFSA (2020)
		Prunes	-5	12	Months	Pyridaben	Netherlands (2022)

## B.1.2. Magnitude of residues in plants

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

Commodity	Region <sup>(a)</sup>	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR <sup>(b)</sup> (mg/kg)	STMR <sup>(c)</sup> (mg/kg)	CF <sup>(d)</sup>
Grapefruits	USA	<u>0.08</u> ; 0.10; 0.12; 0.124; 0.129; 0.129; 0.17; <u>0.26</u>	Residue trials on grapefruits compliant with US critical GAP. Underlined values correspond to higher residues at a longer PHI of 10 days. Pulp: -; -; -; -; 0.014; 0.018; 0.009; -	<b>0.5</b>	0.26	0.13	N/A

MRL: maximum residue level; GAP: Good Agricultural Practice; PHI: preharvest interval; N/A: not applicable.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: Outdoor EU trials or Country code: if non-EU trials. US, United States.

(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. N/A, not applicable.

### B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	Import tolerance on permanent crops. 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?	Not triggered	Not required (import tolerance on permanent crops).

### B.1.2.3. Processing factors

Processed commodity	Number of valid studies <sup>(a)</sup>	Processing Factor (PF)		CF <sub>P</sub> <sup>(b)</sup>	Comment/Source
		Individual values	Median PF		
Grapefruit, peeled	3	0.07; 0.14; 0.15	0.14	–	Tentative <sup>(c)</sup> (Netherlands, 2022)
Orange, peeled	1	0.13	0.13	–	Tentative <sup>(c)</sup> (Netherlands, 2022)
Orange, peeled	2	0.09; 0.12	0.11	–	Tentative <sup>(c)</sup> (EFSA, 2017)
<b>Citrus, peeled</b>	6	0.07; 0.09; 0.12; 0.13; 0.14; 0.15	0.13	–	Combined, grapefruits and oranges (EFSA, 2017; Netherlands, 2022)
Orange, washed	3	0.37; 0.49; 0.66	0.49	–	(EFSA, 2017)
Orange, washed	2	0.34; 1.08	0.71	–	Netherlands (2022)
Orange, pasteurised juice	3	<0.1; <0.12; 0.14	0.12	–	EFSA (2017)
Orange, pasteurised juice	4	0.08; 0.13; 0.28; 0.32	0.21	–	Netherlands (2022)
Orange, pasteurised juice	7	<0.1; 0.08; <0.12; 0.13; 0.14; 0.28; 0.32	0.13	–	Combined dataset (EFSA, 2017; Netherlands, 2022)
Orange, dried pulp	1	4.0	4.00	–	Tentative <sup>(c)</sup> (Netherlands, 2022)
Orange, dried pomace	3	3.5; 3.6; 5.2	3.60	–	EFSA (2017)
Citrus, dried pulp	4	3.5; 3.6; 4.0; 5.2	3.80	–	Combined dataset (EFSA, 2017; Netherlands, 2022)
Orange, pasteurised marmalade	2	0.12; 0.21	0.17	–	Tentative <sup>(c)</sup> (EFSA, 2017)
Orange, pasteurised marmalade	4	0.15; 0.53; 0.57; 0.64	0.55	–	Netherlands (2022)
Orange, pasteurised marmalade	6	0.12; 0.15; 0.21; 0.53; 0.57; 0.64	0.37	–	Combined dataset (EFSA, 2017; Netherlands, 2022)
Orange, canned fruit	2	0.04; 0.12	0.08	–	Tentative <sup>(c)</sup> (EFSA, 2017)

Processed commodity	Number of valid studies <sup>(a)</sup>	Processing Factor (PF)		CF <sub>p</sub> <sup>(b)</sup>	Comment/Source
		Individual values	Median PF		
Orange, molasses	1	0.30	0.30	–	Tentative <sup>(c)</sup> (EFSA, 2017)
Orange, oil	1	25.3	25.30	–	Tentative <sup>(c)</sup> (EFSA, 2017)

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

(c): A tentative PF is derived based on a limited dataset (EFSA, 2017; Netherlands, 2022).

## 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 <sup>(a)</sup>	Most critical commodity <sup>(b)</sup>		Trigger exceeded (Yes/No)	Previous assessment (EFSA, 2020)
	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 Pomace, wet	Yes	0.31	
Cattle (dairy only)	0.006	0.006	0.16	0.16	Dairy cattle	Apple Pomace, wet	Yes	0.16	
Sheep (all diets)	0.007	0.007	0.16	0.16	Lamb	Apple Pomace, wet	Yes	0.16	
Sheep (ewe only)	0.005	0.005	0.16	0.16	Ram/Ewe	Apple Pomace, wet	Yes	0.16	
Swine (all diets)	0.002	0.002	0.08	0.08	Swine (breeding)	Citrus Dried pulp	No	0.04	
Poultry (all diets)	0.000	0.000	0.00	0.00	–	–	No	–	
Poultry (layer only)	0.000	0.000	0.00	0.00	–	–	No	–	

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 (European Commission, 2010b)
Highest IESTI, according to EFSA PRIMo	Grapefruits: 5.3% of ARfD (DE child)
Assumptions made for the calculations	<p>Calculation performed with PRIMo revision 3.1.</p> <p>The calculation is based on the highest residue level expected in grapefruits from the use authorised in the USA. The peeling factor derived for citrus fruits was applied.</p> <p>For commodities not included in the present MRL application, the short-term exposure assessment was performed using the risk assessment values (HR values) derived in previous EFSA reasoned opinions. EFSA confirms the exceedance of the ARfD in apples and pears previously observed (EFSA, 2019a, 2020).</p>
ADI	0.01 mg/kg bw per day (European Commission, 2010b)
Highest IEDI, according to EFSA PRIMo	<p>29% of ADI (NL toddler)</p> <p>Contribution of crop assessed: Grapefruits: 0.12% of ADI (IE adult diet)</p>
Assumptions made for the calculations	<p>Calculations performed with PRIMo revision 3.1.</p> <p>The calculation is based on the median residue level for raw agricultural commodity (grapefruits) derived from the submitted trials and the median residues derived by EFSA in previous assessments (EFSA 2015a, 2017, 2019a, 2020). The peeling factor of 0.13 derived combining results from oranges and grapefruits was applied to citrus fruits. The contributions of commodities where no GAP was reported in the framework of the MRL review and in the opinions issued after the MRL review were not included in the calculation.</p> <p>The calculation shall be regarded as indicative since for certain commodities only tentative MRLs could be derived during the MRL review.</p>

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

## B.4 Recommended MRLs

Code <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
<b>Enforcement residue definition:</b> Pyridaben <sup>(F)</sup>				
0110010	Grapefruits	0.3	0.5	The submitted data are sufficient to derive an import tolerance (US GAP). An MRL of 0.9 mg/kg is set in the USA for the whole group of citrus fruits. Risk for consumers unlikely.

MRL: maximum residue level; GAP: Good Agricultural Practice.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(F): Fat soluble.

## Appendix C – Pesticide Residue Intake Model (PRIMo)



Pyridaben (F)			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.01	ARID (mg/kg bw):	0.05
Source of ADI:	European	Source of ARID:	European Commission
Year of evaluation:	2016	Year of evaluation:	2016

Input values	
Details – chronic risk assessment	Supplementary results – chronic risk assessment
Details – acute risk assessment/children	Details – acute risk assessment/adults

Refined calculation mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI :										Exposure resulting from	
TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)		Exposure (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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	MS Diet										
	29%	NL toddler	2.87	14%	Apples	6%	Milk: Cattle	6%	Pears		29%
	22%	DE child	2.20	16%	Apples	2%	Milk: Cattle	0.8%	Pears		22%
	14%	NL child	1.39	8%	Apples	2%	Milk: Cattle	2%	Pears		14%
	10%	FR toddler 2-3 yr	0.95	4%	Apples	3%	Milk: Cattle	0.6%	Bovine: Muscle/meat		10%
	8%	UK infant	0.77	4%	Milk: Cattle	2%	Apples	0.6%	Bovine: Muscle/meat		8%
	7%	FR child 3-15 yr	0.74	2%	Milk: Cattle	2%	Apples	0.7%	Bovine: Muscle/meat		7%
	7%	DK child	0.74	3%	Apples	1%	Milk: Cattle	0.9%	Pears		7%
	7%	SE general	0.67	2%	Bovine: Muscle/meat	1%	Apples	1%	Milk: Cattle		7%
	6%	DE women 14-50 yr	0.62	3%	Apples	1%	Milk: Cattle	0.4%	Tomatoes		6%
	6%	UK toddler	0.62	2%	Apples	2%	Milk: Cattle	0.6%	Bovine: Muscle/meat		6%
	6%	DE general	0.59	3%	Apples	1%	Milk: Cattle	0.3%	Tomatoes		6%
	5%	ES child	0.55	1%	Apples	1%	Milk: Cattle	0.7%	Bovine: Muscle/meat		5%
	5%	GEMS/Food G06	0.52	2%	Tomatoes	1%	Apples	0.4%	Sweet peppers/bell peppers		5%
	5%	RO general	0.52	2%	Apples	1%	Milk: Cattle	1.0%	Tomatoes		5%
	5%	FR infant	0.52	2%	Apples	2%	Milk: Cattle	0.3%	Beans (with pods)		5%
	5%	GEMS/Food G11	0.46	2%	Apples	0.8%	Milk: Cattle	0.5%	Tomatoes		5%
	4%	GEMS/Food G15	0.44	1%	Apples	0.7%	Milk: Cattle	0.6%	Tomatoes		4%
	4%	NL general	0.43	2%	Apples	0.8%	Milk: Cattle	0.4%	Bovine: Muscle/meat		4%
	4%	GEMS/Food G07	0.41	1%	Apples	0.6%	Milk: Cattle	0.5%	Tomatoes		4%
	4%	IE adult	0.41	0.9%	Apples	0.6%	Apples	0.4%	Milk: Cattle		4%
	4%	GEMS/Food G08	0.41	2%	Apples	0.6%	Tomatoes	0.6%	Milk: Cattle		4%
	4%	GEMS/Food G10	0.39	1.0%	Apples	0.7%	Tomatoes	0.5%	Milk: Cattle		4%
	4%	LT adult	0.38	2%	Apples	0.4%	Milk: Cattle	0.3%	Tomatoes		4%
	4%	PL general	0.37	3%	Apples	0.4%	Tomatoes	0.4%	Pears		4%
	4%	ES adult	0.35	1.0%	Apples	0.5%	Milk: Cattle	0.4%	Pears		4%
	3%	DK adult	0.32	1%	Apples	0.5%	Milk: Cattle	0.4%	Pears		3%
	3%	IT toddler	0.31	1%	Apples	0.7%	Tomatoes	0.4%	Pears		3%
	3%	FI 3 yr	0.29	1%	Apples	0.5%	Cucumbers	0.4%	Strawberries		3%
	3%	FR adult	0.29	1.0%	Apples	0.4%	Milk: Cattle	0.3%	Bovine: Muscle/meat		3%
	3%	PT general	0.28	1%	Apples	0.6%	Tomatoes	0.4%	Pears		3%
	3%	IT adult	0.27	1%	Apples	0.6%	Tomatoes	0.3%	Pears		3%
	2%	FI 6 yr	0.21	0.8%	Apples	0.4%	Cucumbers	0.3%	Strawberries		2%
	2%	UK vegetarian	0.20	0.8%	Apples	0.3%	Milk: Cattle	0.3%	Tomatoes		2%
	2%	UK adult	0.17	0.5%	Apples	0.3%	Bovine: Muscle/meat	0.3%	Milk: Cattle		2%
	2%	FI adult	0.16	0.8%	Apples	0.3%	Tomatoes	0.2%	Cucumbers		2%
	0.9%	IE child	0.09	0.4%	Apples	0.4%	Milk: Cattle	0.0%	Pears		0.9%

**Conclusion:**  
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.  
The long-term intake of residues of Pyridaben (F) is unlikely to present a public health concern.  
DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.



Acute risk assessment/children				Acute risk assessment/adults/general population				
Details – acute risk assessment/children				Details – acute risk assessment/adults				
<p>The acute risk assessment is based on the ARID. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union. The calculation is based on the large portion of the most critical consumer group.</p>								
<b>Show results for all crops</b>								
Unprocessed commodities	<b>Results for children</b>				<b>Results for adults</b>			
	No. of commodities for which ARID/ADI is exceeded (IESTI):				No. of commodities for which ARID/ADI is exceeded (IESTI):			
	2				---			
	<b>IESTI</b>				<b>IESTI</b>			
	Highest % of ARID/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
	133%	Pears	0.9/0.48	66	29%	Pears	0.9/0.48	15
	103%	Apples	0.9/0.48	52	27%	Apples	0.9/0.48	13
	29%	Peaches	0.3/0.15	14	15%	Quinces	0.9/0.48	7.3
	24%	Quinces	0.9/0.48	12	10%	Strawberries	0.9/0.53	4.9
	17%	Strawberries	0.9/0.53	8.7	7%	Medlar	0.9/0.48	3.3
15%	Sweet peppers/bell peppers	0.3/0.13	7.4	6%	Peaches	0.3/0.15	2.8	
13%	Medlar	0.9/0.48	6.6	5%	Cucumbers	0.15/0.1	2.7	
13%	Cucumbers	0.15/0.1	6.4	5%	Aubergines/egg plants	0.15/0.09	2.4	
10%	Apricots	0.3/0.15	5.2	5%	Courgettes	0.15/0.1	2.3	
10%	Tomatoes	0.15/0.09	5.2	4%	Sweet peppers/bell peppers	0.3/0.13	2.0	
9%	Courgettes	0.15/0.1	4.5	3%	Apricots	0.3/0.15	1.6	
8%	Oranges	0.3/0.03	3.8	3%	Tomatoes	0.15/0.09	1.4	
5%	Grapefruits	0.5/0.03	2.7	2%	Oranges	0.3/0.03	0.88	
5%	Aubergines/egg plants	0.15/0.09	2.3	2%	Beans (with pods)	0.2/0.1	0.77	
3%	Mandarins	0.3/0.03	1.7	1%	Grapefruits	0.5/0.03	0.60	
Expand/collapse list								
<b>Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)</b>								
2								
Processed commodities	<b>Results for children</b>				<b>Results for adults</b>			
	No of processed commodities for which ARID/ADI is exceeded (IESTI):				No of processed commodities for which ARID/ADI is exceeded (IESTI):			
	---				---			
	<b>IESTI</b>				<b>IESTI</b>			
	Highest % of ARID/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
	14%	Apples/juice	0.9/0.13	7.0	9%	Apples/juice	0.9/0.13	4.3
	8%	Pears/juice	0.9/0.13	4.2	4%	Courgettes/boiled	0.15/0.1	2.2
	8%	Oranges/juice	0.3/0.08	4.2	3%	Grapefruits/juice	0.5/0.13	1.4
	8%	Peaches/canned	0.3/0.15	3.9	2%	Peaches/canned	0.3/0.15	1.2
	7%	Courgettes/boiled	0.15/0.1	3.4	2%	Oranges/juice	0.3/0.08	1.2
4%	Gherkins/pickled	0.15/0.1	2.2	0.8%	Tomatoes/sauce/puree	0.15/0.05	0.41	
3%	Beans (with pods)/boiled	0.2/0.1	1.3	0.4%	Coconuts/drink	0.05/0.05	0.18	
2%	Peaches/juice	0.3/0.07	1.2	0.3%	Quinces/jam	0.9/0.13	0.16	
2%	Tomatoes/juice	0.15/0.05	0.95	0.3%	Lemons/juice	0.3/0.08	0.15	
1.0%	Tomatoes/sauce/puree	0.15/0.05	0.48					
0.9%	Coconuts/drink	0.05/0.05	0.43					
0.8%	Quinces/jam	0.9/0.13	0.39					
0.5%	Lemons/jam	0.3/0.08	0.24					
0.0%	Limes/juice	0.3/0.08	0.01					
Expand/collapse list								
<b>Conclusion:</b>								
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 2 commodities.								
For processed commodities, no exceedance of the ARID/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
<b>Risk assessment residue definition:</b> Pyridaben				
Apple pomace, wet	0.65	STMR × PF (5) <sup>(b)</sup> (EFSA, 2017)	0.65	STMR × PF (5) <sup>(b)</sup> (EFSA, 2017)
Citrus (grapefruits), dried pulp	0.50	STMR (0.13) × PF (3.8) (Netherlands, 2022)	0.50	STMR (0.13) × PF (3.8) (Netherlands, 2022)
Coconut, meal	0.05	STMR <sup>(a)</sup> (EFSA, 2020)	0.05	STMR <sup>(a)</sup> (EFSA, 2020)

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

- (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. Also the input value (STMR) was set on a tentative basis from GAPs evaluated in the MRL review, which are not fully supported by data (EFSA, 2017).

### D.2 Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment <sup>(a)</sup>
<b>Risk assessment residue definition</b> Pyridaben (F)						
Grapefruits	0.5	Proposed MRL	0.0169	STMR-RAC × PeF	0.0338	HR-RAC × PeF
Oranges	0.3	EFSA, 2017	0.0104	STMR-RAC × PeF	0.0286	HR-RAC × PeF
Lemons	0.3	EFSA, 2017	0.0104	STMR-RAC × PeF	0.0286	HR-RAC × PeF
Limes	0.3	EFSA, 2017	0.0104	STMR-RAC × PeF	0.0286	HR-RAC × PeF
Mandarins	0.3	EFSA, 2017	0.0104	STMR-RAC × PeF	0.0286	HR-RAC × PeF
Other citrus fruit	0.3	EFSA, 2017	0.0104	STMR-RAC × PeF	0.0286	HR-RAC × PeF
Almonds	0.05	EFSA, 2020	0.05	STMR-RAC	0.05	HR-RAC
Brazil nuts	0.05	EFSA, 2020	0.05	STMR-RAC	0.05	HR-RAC
Cashew nuts	0.05	EFSA, 2020	0.05	STMR-RAC	0.05	HR-RAC
Chestnuts	0.05	EFSA, 2020	0.05	STMR-RAC	0.05	HR-RAC
Coconuts	0.05	EFSA, 2020	0.05	STMR-RAC	0.05	HR-RAC
Hazelnuts/cobnuts	0.05	EFSA, 2020	0.05	STMR-RAC	0.05	HR-RAC
Macadamia	0.05	EFSA, 2020	0.05	STMR-RAC	0.05	HR-RAC
Pecans	0.05	EFSA, 2020	0.05	STMR-RAC	0.05	HR-RAC
Pine nut kernels	0.05	EFSA, 2020	0.05	STMR-RAC	0.05	HR-RAC
Pistachios	0.05	EFSA, 2020	0.05	STMR-RAC	0.05	HR-RAC
Walnuts	0.05	EFSA, 2020	0.05	STMR-RAC	0.05	HR-RAC
Other tree nuts	0.05	EFSA, 2020	0.05	STMR-RAC	0.05	HR-RAC
Apples <sup>(b)</sup>	0.9	EFSA, 2017	0.13	STMR-RAC	0.48	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment <sup>(a)</sup>
Pears <sup>(b)</sup>	0.9	EFSA, 2017	0.13	STMR-RAC	0.48	HR-RAC
Quinces <sup>(b)</sup>	0.9	EFSA, 2017	0.13	STMR-RAC	0.48	HR-RAC
Medlar <sup>(b)</sup>	0.9	EFSA, 2017	0.13	STMR-RAC	0.48	HR-RAC
Loquats/Japanese medlars <sup>(b)</sup>	0.9	EFSA, 2017	0.13	STMR-RAC	0.48	HR-RAC
Other pome fruit	0.9	EFSA, 2017	0.13	STMR-RAC	0.48	HR-RAC
Apricots <sup>(b)</sup>	0.3	EFSA, 2017	0.07	STMR-RAC	0.15	HR-RAC
Peaches <sup>(b)</sup>	0.3	EFSA, 2017	0.07	STMR-RAC	0.15	HR-RAC
Strawberries	0.9	EFSA, 2017	0.11	STMR-RAC	0.53	HR-RAC
Tomatoes	0.15	EFSA, 2019a	0.05	STMR-RAC	0.09	HR-RAC
Sweet peppers/bell peppers	0.3	EFSA, 2020	0.083	STMR-RAC	0.125	HR-RAC
Aubergines/egg plants	0.15	EFSA, 2019a	0.05	STMR-RAC	0.09	HR-RAC
Cucumbers	0.15	EFSA, 2015a	0.05	STMR-RAC	0.097	HR-RAC
Gherkins	0.15	EFSA, 2015a	0.05	STMR-RAC	0.097	HR-RAC
Courgettes	0.15	EFSA, 2015a	0.05	STMR-RAC	0.097	HR-RAC
Other cucurbits - edible peel	0.15	EFSA, 2015a	0.05	STMR-RAC	0.097	HR-RAC
Beans (with pods) <sup>(b)</sup>	0.2	EFSA, 2017	0.06	STMR-RAC	0.1	HR-RAC
Bovine: Muscle/ meat <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Bovine: Fat tissue <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Bovine: Liver <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Bovine: Kidney <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Bovine: Edible offals (other than liver and kidney)	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Bovine: Other products	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Sheep: Muscle/ meat <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Sheep: Fat tissue <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Sheep: Liver <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Sheep: Kidney <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Sheep: Edible offals (other than liver and kidney)	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Sheep: other products	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Goat: Muscle/meat <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Goat: Fat tissue <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Goat: Liver <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Goat: Kidney <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Goat: Edible offals (other than liver and kidney)	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Goat: other products	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC

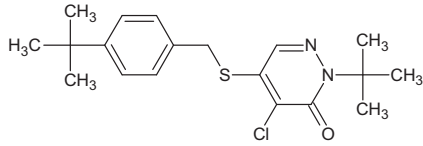
Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment <sup>(a)</sup>
Equine: Muscle/ meat <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Equine: Fat tissue <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Equine: Liver <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Equine: Kidney <sup>(b)</sup>	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Equine: Edible offals (other than liver and kidney)	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Equine: Other products	0.05	EFSA, 2017	0.05	STMR-RAC	0.05	HR-RAC
Milk: Cattle <sup>(b)</sup>	0.01	EFSA, 2017	0.01	STMR-RAC	0.01	STMR-RAC
Milk: Sheep <sup>(b)</sup>	0.01	EFSA, 2017	0.01	STMR-RAC	0.01	STMR-RAC
Milk: Goat <sup>(b)</sup>	0.01	EFSA, 2017	0.01	STMR-RAC	0.01	STMR-RAC
Milk: Horse <sup>(b)</sup>	0.01	EFSA, 2017	0.01	STMR-RAC	0.01	STMR-RAC
Milk: Others	0.01	EFSA, 2017	0.01	STMR-RAC	0.01	STMR-RAC

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: peeling factor.

(a): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

(b): Input values for these commodities were set on a tentative basis from GAPs evaluated in the MRL review, which are not fully supported by data (EFSA, 2017).

## Appendix E – Used compound codes

Code/trivial name <sup>(a)</sup>	IUPAC name/SMILES notation/InChiKey <sup>(b)</sup>	Structural formula <sup>(c)</sup>
Pyridaben	2- <i>tert</i> -butyl-5-(4- <i>tert</i> -butylbenzylthio)-4-chlorpyrididazin-3(2 <i>H</i> )-one <chem>CC(C)(C)N2N=CC(SCc1ccc(cc1)C(C)(C)C)=C(Cl)C2=O</chem> DWFZBUWUXZWKD-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 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116,563, 15 June 2020).

(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121,153, 22 March 2021).