Modification of the existing maximum residue levels for pyridaben in tomatoes and aubergines

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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 modify the existing maximum residue levels (MRLs) for the active substance pyridaben in tomatoes and aubergines. An MRL proposal of 0.15 mg/kg was derived for tomatoes and aubergines which reflects the intended use of the plant protection product containing pyridaben. Adequate analytical methods for enforcement are available to control the residues of pyridaben in plant matrices at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concludes that the proposed use of pyridaben on tomatoes and aubergines will not result in a consumer exposure exceeding the toxicological reference values and therefore it is unlikely to pose a risk to consumers’ 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 in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance pyridaben in tomatoes and aubergines. The EMS 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 7 November 2018. To accommodate for the intended indoor use of pyridaben in Italy and Romania, the EMS proposed an MRL of 0.15 mg/kg for pyridaben both in tomatoes and aubergines.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, in the review of the existing pyridaben MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) and the additional data provided by the EMS in the framework of this application, 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.

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

The metabolism of pyridaben in rotational crops proceeds in a similar pathway to that in primary crops.

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 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 crops assessed in this application the metabolism of pyridaben in primary, rotational 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 based on gas chromatography/high-performance liquid chromatography (GC/HPLC) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (limit of quantification (LOQ)).

The available residue trials are sufficient to derive an MRL proposal of 0.15 mg/kg for pyridaben in tomatoes and aubergines in support of the proposed indoor uses.

Specific studies investigating the magnitude of pyridaben residues in processed commodities are not required as residues in tomatoes and aubergines are a minor contributor 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 on tomatoes and aubergines according to the intended Good Agricultural Practice (GAP).

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

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 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of chronic and acute consumer exposure, the supervised trials median residue (STMR) and highest residue (HR) values derived from the residue trials on tomatoes were used as input values for tomatoes and aubergines. For the remaining commodities, the risk assessment values (STMR and HR values) as available from the previous assessments and the MRL review 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 28% of the ADI (NL toddler diet). The contribution of residues in tomatoes and aubergines to the total exposure was low (individually below 2% of the ADI).
The acute exposure calculation did not identify acute consumer intake concerns related to the intended use of pyridaben on tomatoes (10% of the ARfD) and aubergines (5% 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 exceeded the ARfD for Dutch toddlers while the exposure calculated in the framework of the MRL review was below the ARfD. The different results are due to the higher large portion consumption data used in the PRIMo revision 3 compared to the PRIMo revision 2. Further risk management discussions are recommended to follow-up on these observations.

EFSA concludes that the proposed use of pyridaben on tomatoes and aubergines 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 |
|---------|-------------|-------------------------|-------------------------|-----------------------|
| 231010  | Tomatoes    | 0.05* (F) 0: 15         |                         | The submitted data are sufficient to derive MRL proposals for the intended indoor use. Risk for consumers is unlikely. The intended uses are more critical than the uses assessed under the MRL review, for which confirmatory data were requested in Regulation (EU) 2019/90. Since the intended uses assessed in the framework of this application are fully supported by data, the footnote related to the previously assessed uses in tomatoes and aubergines becomes obsolete and can be deleted |
| 231030  | Aubergines  | 0.05* (F) 0: 15         |                         |                       |

MRL: maximum residue level.
*: 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) was requested to assess the application to modify the existing maximum residue levels (MRLs) for pyridaben in tomatoes and aubergines. The detailed description of the intended use of pyridaben, 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-chloropyrididazin-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 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 for the use as acaricide and insecticide on 1 May 2011.

The EU MRLs for pyridaben are established in Annex II of Regulation (EC) No 396/2005. 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 Regulation (EU) 2019/90. In this regulation, the EU MRLs for pyridaben in tomatoes (0.3 mg/kg) and aubergines (0.2 mg/kg) were lowered to the limit of quantification (LOQ) of 0.05 mg/kg.

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 (evaluating Member State, EMS) to modify the MRL proposal derived by the MRL review for the active substance pyridaben in tomatoes and aubergines. The applicant applied for authorisation of a more critical indoor Good Agricultural Practice (GAP) of pyridaben on tomatoes and aubergines compared to the GAP assessed in the framework of the MRL review. According to the EMS, the new use would require to raise the MRL to 0.15 mg/kg.

The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 7 November 2018.

EFSA based its assessment on the evaluation report submitted by the EMS (Netherlands, 2018), the DAR (Netherlands, 2007, 2009) prepared under Council Directive 91/414/EEC, 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, included the MRL review of the MRLs for pyridaben according to Article 12 (EFSA, 2015, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011 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.

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 report submitted by the EMS (Netherlands, 2018) 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 apple and citrus with foliar application and in tomatoes with pyridaben applied by brush to leaves and fruits (EFSA, 2010). 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

Tomatoes and aubergines can be grown in the crop rotation. According to the soil degradation studies evaluated in the framework of the peer review, periods required for 90% dissipation (DT\textsubscript{90} values) of pyridaben in soil range from 241 to 4,522 days which is higher than the trigger value of 100 days (EFSA, 2010). Therefore, further investigation of residues in rotational crops was performed.

A rotational crop study was evaluated during the peer review (Netherlands, 2007). Rotational crop metabolism was studied in mustard greens, radish, Swiss chard, wheat and sorghum grown after soil application of pyridazinone-\textsuperscript{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 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 (Netherlands, 2007). 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 sufficiently validated methods using liquid chromatography with tandem mass spectrometry (LC–MS/MS) and gas chromatography with mass spectrometry (GC–MS) are available to enforce pyridaben residues at the respective LOQs of 0.01 mg/kg and 0.05 mg/kg in matrices with 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 (EFSA, 2010). Results demonstrate that residues of pyridaben are stable in high water content commodities for 12 months when samples are stored at –20°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 and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the peer review and confirmed by the MRL review:

- residue for risk assessment: pyridaben
- residue definition for enforcement: pyridaben
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. Taking into account the proposed 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

Intended GAP: indoor use, 1 \( \times \) 0.2 kg/ha, preharvest interval (PHI) 3 days.

In support of the intended indoor use of pyridaben, the applicant submitted five GAP-compliant residue trials on tomatoes performed in Belgium, the Netherlands, Germany and Spain in 2006. The application rate deviated from the intended application rate, but within the 25% acceptable range. Additionally, the EMS referred to eight indoor trials on tomatoes which were assessed and considered acceptable by the EFSA peer review in 2010. These trials were performed with application rates ranging from 0.25 to 0.28 kg/ha, thus exceeding the acceptable 25% deviation from the intended application rate. The EMS proposed to apply the proportionality principle, which was supported by EFSA (2018b). Residue values from all trials (with results at/above the LOQ) were scaled to the intended application rate. The residue trial data are summarised in Appendix B.1.2.1.

The applicant proposed to extrapolate the residue data from tomatoes to aubergines which is according to EU guidance documents acceptable (European Commission, 2017). It is concluded that an MRL of 0.15 mg/kg would be required to support the indoor use of pyridaben on tomatoes and aubergines.

1.2.2. Magnitude of residues in rotational crops

From the available rotational crop metabolism studies where a single application was more than 3N the intended application rate on tomatoes and aubergines, it can be concluded that 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 residues in tomatoes and aubergines are a minor contributor to the overall dietary intake, processing studies are not required and would not be expected to affect significantly the outcome of the exposure assessment.

1.2.4. Proposed MRLs

The submitted data are considered sufficient to derive an MRL proposal of 0.15 mg/kg for tomatoes and aubergines. In Section 3, the dietary risk assessment for this MRL proposal is presented.

2. Residues in livestock

Not relevant for the current assessment.

3. Consumer risk assessment

The consumer risk assessment was performed with revision 3 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, 2018a).

For the calculation of chronic and acute consumer exposure, the supervised trials median residue (STMR) and highest residue (HR) values derived from the residue trials on tomatoes (see Section B.1.2.1) were used as input values for tomatoes and aubergines. 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 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 28% of the acceptable daily intake (ADI; NL toddler diet). The contribution of residues in tomatoes and aubergines to the total exposure was low (below 2% of the ADI).

The acute exposure calculation did not identify acute consumer intake concerns related to pyridaben residues from the intended use on tomatoes (10% of the acute reference dose (ARfD)) and aubergines (5% 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 exceeded the ARfD for Dutch toddlers while the exposure calculated in the framework of the MRL review was below the ARfD. The different results are due to the higher large portion consumption data used in PRIMo revision 3 compared to PRIMo 2. Further risk management discussions are recommended to follow-up on these observations.

EFSA concluded that the proposed use of pyridaben on tomatoes and aubergines will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

Further details on the exposure calculations, 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 0.15 mg/kg in tomatoes and aubergines in support of the intended indoor use.

EFSA concluded that the proposed uses of pyridaben on tomatoes and aubergines will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a risk to consumers’ health.

Since the intended uses assessed in the framework of this application are fully supported by data, the footnote related to the previously assessed uses in tomatoes and aubergines requesting confirmatory data becomes obsolete and can be deleted.

The MRL recommendations are summarised in Appendix B.4.

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7 The calculated acute exposure accounted for 133% of the ARfD for pears and 103% ARfD for apples, using rev.3 of the PRIMo. In the MRL review, no acute consumer intake concerns were identified for apples (94% ARfD) and pears (87% ARfD), using PRIMo rev.2 (EFSA, 2017).
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**Abbreviations**

| Abbreviation | Description |
|--------------|-------------|
| a.s. | active substance |
| ADI | acceptable daily intake |
| ARfD | acute reference dose |
| BBCH | growth stages of mono- and dicotyledonous plants |
| bw | body weight |
| DAR | draft assessment report |
| DAT | days after treatment |
| DT$_{90}$ | period required for 90% dissipation (define method of estimation) |
| EMS | evaluating Member State |
| GAP | Good Agricultural Practice |
| GC | gas chromatography |
| GC-ECD | gas chromatography with electron capture detector |
| GC-MS | gas chromatography with mass spectrometry |
| GC-MS/MS | gas chromatography with tandem mass spectrometry |
| HPLC | high-performance liquid chromatography |
| 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 |
| Mo | monitoring |
| 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 |
| Acronym  | Description |
|----------|-------------|
| QuEChERS | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA       | risk assessment |
| 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 |
## 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 | PHI (days) (d) | Remarks |
|-----------------------|-------------------------|-------------|-----------------------------------|-------------|-------------|--------------------------------|---------------|---------|
| Tomato, aubergine     | RO IT                   | G           | Mites and whitefly                | SC          | 100 g/L     | Various hydraulic sprayers    | 14–20         | 1,000–1,400 0.2 kg/ha | GAP assessed under the MRL review (1 × 0.2 kg/ha; 7-day PHI) which was insufficiently supported by data (EFSA, 2017) |

**GAP**: Good Agricultural Practice; **MRL**: maximum residue level; **NEU**: northern European Union; **SEU**: southern European Union; **MS**: Member State; **SC**: suspension concentrate; **a.s.**: active substance.

(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-14C- and/or pyridazinone-14-C pyridaben (Netherlands, 2007; EFSA, 2017) |
|                                   | Citrus fruit  |           | Spraying, 2 × 0.57 kg a.s./ha | 0, 1, 3, 7, 14 |                                                                                |
|                                   |               |           | 2 × 4.76 kg a.s./ha | 1, 7, 14       |                                                                                |
|                                   | Tomato        |           | 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 | Radish    | Bare soil, 2 × 0.75 kg a.s./ha | 30, 240 | Radiolabelled active substance: pyridazinone-14-C pyridaben (Netherlands, 2007; EFSA, 2017) |
|                                     | Leafy crops   | Swiss chard, Mustard green |                     | 30, 240 |                                                                                |
|                                     |               |           |                      | 30       |                                                                                |
|                                     | Cereal (small grain) | Wheat, Sorghum |                     | 30       |                                                                                |
|                                     |               |           |                      | 30, 240 |                                                                                |

| Processed commodities (hydrolysis study) | Conditions                      | Stable? | Comment/Source                  |
|------------------------------------------|---------------------------------|---------|---------------------------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | yes     | Netherlands (2007); EFSA (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?

Rotational crop and primary crop metabolism similar?

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Plant residue definition for monitoring (RD-Mo)

Plant residue definition for risk assessment (RD-RA)

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; |
| • Confirmatory method LC–MS/MS LOQ = 0.05 mg/kg tomato (Netherlands, 2007; 2009; 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 (Netherlands, 2007); |
| • 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) |

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 (2017)    |
| High aid content                  | Oranges           | –5/–20              | 12     | Months           | Pyridaben         | EFSA (2017)    |
|                                   | Grapes            | –20                 | 12     | Months           | Pyridaben         | EFSA (2017)    |
| Processed products                | Orange, dried pulp| –5                  | 12     | Months           | Pyridaben         | EFSA (2017)    |
|                                   | Orange molasses   | –5                  | 12     | Months           | Pyridaben         | EFSA (2017)    |
|                                   | Orange oil        | –5                  | 12     | Months           | Pyridaben         | EFSA (2017)    |

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; LOQ: limit of quantification; GC-ECD: gas chromatography with electron capture detector; LOQ: limit of quantification; LC–MS/MS: liquid chromatography with tandem mass spectrometry; QuECHERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); ILV: independent laboratory validation.
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/Indoor | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) |
|-----------|---------------|-----------------------------------------------------------------|-----------------|------------------------|-------------------|-------------------|
| Tomato    | Indoor        | **Unscaled residues:** 0.085; 2 × < 0.05; 0.083; 0.05; 0.07; 3 × < 0.05; 0.05; 0.07; 0.05 | Residue trials on tomatoes. Extrapolation to aubergines acceptable. Residue trials not matching the application rate were scaled. The scaling factors (sf) applied are reported in brackets after the scaled residue value | 0.15 | 0.09 | 0.05 |
|           |               | **Scaled residues:** 0.08 (sf 0.95); 2 × < 0.05\(^{(d)}\); 0.09 (sf 1.08); 0.05\(^{(d)}\); 0.054 (sf 0.77); 3 × < 0.05\(^{(d)}\); 0.052 (sf 0.74); 0.036 (sf 0.72); 0.055 (sf 0.78); 0.038 (sf 0.76) | | | | |

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

(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): Scaling not applied because residues in overdosed trials were < LOQ.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No |
| Residues in rotational and succeeding crops expected based on field 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).

No studies submitted and not required.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant for the current assessment.

B.3. Consumer risk assessment

**ARfD**

0.05 mg/kg bw (EFSA, 2010)

**Highest IESTI, according to EFSA PRIMo**

| Crop | IESTI |
|------|-------|
| Tomatoes | 10% of ARfD |
| Aubergines | 5% of ARfD |

**Assumptions made for the calculations**

The calculation is based on the highest residue levels expected in tomatoes and aubergines from the intended indoor use.

**ADI**

0.01 mg/kg bw per day (EFSA, 2010)

**Highest IEDI, according to EFSA PRIMo**

28% ADI (NL toddler diet)

| Crop | IEDI |
|------|------|
| Tomatoes | 1.79% of ADI (GEMS/Food G06) |
| Aubergines | 0.17% of ADI (GEMS/Food G06) |

**Assumptions made for the calculations**

The calculation is based on the median residue levels (STMR) derived for tomatoes and aubergines from the residue trials submitted in support of the intended use. For the remaining commodities, the STMR values derived in previous EFSA assessments and the MRL review 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; ADI: acceptable daily intake; IEDI: international estimated daily intake; STMR: supervised trials median residue; MRL: maximum residue level; 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 |
|---------------|-----------|------------------------|-------------------------|------------------------|
| 231010        | Tomatoes  | 0.05* \(^{(ft)}\)     | 0.15                    | The submitted data are sufficient to derive MRL proposals for the intended indoor use. Risk for consumers is unlikely. The intended uses are more critical than the uses assessed under the MRL review, for which confirmatory data were requested in Regulation (EU) 2019/90. Since the intended uses assessed in the framework of this application are fully supported by data, the footnote related to the previously assessed uses in tomatoes and aubergines becomes obsolete and can be deleted |
| 231030        | Aubergines| 0.05* \(^{(ft)}\)     | 0.15                    |                        |

**Enforcement residue definition:** Pyridaben\(^{(F)}\)

MRL: maximum residue level.

*: 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.

\(^{(ft)}\): Commission Regulation (EU) 2019/90: In the framework of the MRL review, EFSA identified some information on residue trials as unavailable. When reviewing 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.

\(^{(F)}\): Fat soluble.
Appendix C – Pesticide Residue Intake Model (PRIMo)

### LOQs (mg/kg)

- Ranges from 0.01 to 0.20

### ADI (mg/kg bw per day)
- 0.01

### ARfD (mg/kg bw)
- 0.05

Source of ADI and ARfD: EFSA

Year of evaluation: 2010

No of diets exceeding the ADI:

| Commodity/group of commodities | Exposure resulting from | (µg/kg bw per day) |
|-------------------------------|------------------------|--------------------|
|                               |                         | Highest contributor |
|                               |                         | to ADI (in % of ADI) |
|                               |                         | 2nd contributor     |
|                               |                         | to ADI (in % of ADI) |
|                               |                         | 3rd contributor     |
|                               |                         | to ADI (in % of ADI) |
|                               |                         | Commodity/ group of |
|                               |                         | commodities        |

#### Normal mode

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

| Commodity/group of commodities | Exposure resulting from | (µg/kg bw per day) |
|-------------------------------|------------------------|--------------------|
|                               |                         | Highest contributor |
|                               |                         | to ADI (in % of ADI) |
|                               |                         | 2nd contributor     |
|                               |                         | to ADI (in % of ADI) |
|                               |                         | 3rd contributor     |
|                               |                         | to ADI (in % of ADI) |
|                               |                         | Commodity/ group of |
|                               |                         | commodities        |

**Notes:**
- The estimated long-term dietary intake (TMDI/IEDI/EDTI) was below the ADI.
- The long-term intake of residues of Pyridaben (F) is unlikely to present a public health concern.
- The estimated acute exposure for children from long-term dietary intake is below the ARfD.
- The estimated acute exposure for adults from long-term dietary intake is below the ARfD.

**Details:**
- Chronic risk assessment
- Acute risk assessment
- Supplementary results
- Note: The estimated long-term dietary intake (TMDI/IEDI/EDTI) was below the ADI.

**Conclusion:**
- The long-term intake of residues of Pyridaben (F) is unlikely to present a public health concern.
- The estimated acute exposure for children from long-term dietary intake is below the ARfD.
- The estimated acute exposure for adults from long-term dietary intake is below the ARfD.

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

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- Modificacii of existing MRLs for pyridaben in tomatoes and aubergines
The acute risk assessment is based on the ARfD.

The calculation is based on the large portion of the most critical consumer group.

### Results for children

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

| Highest % of ARfD/ADI | Commodity          | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|--------------------|--------------------------|---------------------|
| 133% Pears            | 0.9/0.48           | 66                       | 29% Pears           | 0.9/0.48  |
| 103% Apples           | 0.9/0.48           | 52                       | 27% Apples          | 0.9/0.48  |
| 25% Peaches           | 0.15/0.1           | 14                       | 15% Quinces         | 0.9/0.48  |
| 24% Quinces           | 0.9/0.48           | 12                       | 10% Strawberries    | 0.9/0.53  |
| 17% Strawberries      | 0.9/0.53           | 7.7                      | 7% Medlar           | 0.9/0.48  |
| 13% Medlar            | 0.9/0.48           | 6.6                      | 6% Peaches          | 0.3/0.15  |
| 13% Cucumbers         | 0.15/0.1           | 6.4                      | 5% Cucumbers        | 0.15/0.1  |
| 10% Apricots          | 0.3/0.15           | 5.2                      | 5% Courgettes       | 0.15/0.1  |
| 10% Tomatoes          | 0.05/0.09          | 5.2                      | 4% Aubergines/egg plants | 0.05/0.09 |
| 9% Courgettes         | 0.15/0.1           | 4.5                      | 3% Apricots         | 0.3/0.15  |
| 6% Oranges            | 0.3/0.02           | 2.9                      | 3% Tomatoes         | 0.05/0.09 |
| 5% Aubergines/egg plants | 0.05/0.09     | 2.3                      | 1% Oranges          | 0.3/0.32  |
| 3% Grapefruits        | 0.3/0.02           | 1.7                      | 1% Gherkins         | 0.15/0.1  |
| 3% Mandarins          | 0.3/0.02           | 1.3                      | 0.8% Mandarins      | 0.3/0.32  |
| 2% Milk: Cattle       | 0.01/0.01          | 1.2                      | 0.8% Grapefruits    | 0.3/0.32  |
| 2% Beans (with pods)  | 0.2/0.1            | 0.88                     | 0.6% Milk: Cattle   | 0.01/0.01 |
| 2% Lemons             | 0.3/0.02           | 0.75                     | 0.6% Bovine: Muscle | 0.05/0.05 |
| 0.9% Limes            | 0.3/0.02           | 0.44                     | 0.5% Equine: Muscle/meat | 0.05/0.05 |
| 0.8% Bovine: Liver    | 0.05/0.05          | 0.40                     | 0.4% Bovine: Liver  | 0.05/0.05 |
| 0.7% Bovine: Muscle/meat | 0.05/0.05    | 0.36                     | 0.4% Sheep: Muscle/meat | 0.05/0.05 |
| 0.6% Equine: Muscle/meat | 0.05/0.05  | 0.30                     | 0.4% Bovine: Liver  | 0.05/0.05 |
| 0.5% Gherkins         | 0.15/0.1           | 0.27                     | 0.4% Lemons         | 0.3/0.32  |
| 0.5% Milk: Goat       | 0.01/0.01          | 0.24                     | 0.4% Milk: Goat     | 0.01/0.01 |
| 0.4% Sheep: Muscle/meat | 0.05/0.05    | 0.21                     | 0.3% Limes          | 0.3/0.32  |
| 0.4% Bovine: Kidney   | 0.05/0.05          | 0.19                     | 0.3% Milk: Sheep    | 0.01/0.01 |
| 0.2% Bovine: Fat tissue | 0.05/0.05    | 0.10                     | 0.3% Sheep: Liver   | 0.05/0.05 |
| 0.07% Milk: Sheep     | 0.01/0.01          | 0.04                     | 0.2% Bovine: Kidney | 0.05/0.05 |
| 0.00% HOPS (dried)    | 0.05/0.05          | 0.00                     | 0.2% Goat: Muscle   | 0.05/0.05 |

**IESTI calculation:** 2

### 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. Consumer risk assessment

| Commodity                      | Chronic risk assessment | Acute risk assessment |
|--------------------------------|-------------------------|-----------------------|
|                                | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Tomatoes                       | 0.05                    | STMR                  | 0.09                | HR                    |
| Aubergines                     | 0.05                    | STMR (tomatoes)       | 0.09                | HR (tomatoes)         |
| 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)       |
| 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 | IUPAC name/SMILES notation/InChiKey | Structural formula |
|-------------------|------------------------------------|--------------------|
| pyridaben         | 2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chlorpyrididazin-3(2H)-one | ![](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.