REASONED OPINION

APPROVED: 20 October 2017

doi: 10.2903/j.efsa.2017.5054

Review of the existing maximum residue levels for pyridaben according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance pyridaben. To assess the occurrence of pyridaben residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC and under Commission Regulation (EC) No 33/2008 as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

Keywords: pyridaben, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, insecticide, acaricide

Requestor: European Commission

Question number: EFSA-Q-2009-00071

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Acknowledgement: EFSA wishes to thank the rapporteur Member State Netherlands for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Jose T, Anne T, Vagenende B, Verani A, Villamar-Bouza L and Erdos Z, 2017. Reasoned opinion on the review of the existing maximum residue levels for pyridaben according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017; 15(11):5054, 38 pp. https://doi.org/10.2903/j.efsa.2017.5054

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

Pyridaben was included in Annex I to Directive 91/414/EEC on 1 May 2011 by Commission Directive 2010/90/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As pyridaben was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked the Netherlands, the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 3 October 2016 and finalised on 2 December 2016. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 5 January 2017.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS and Member States, EFSA prepared a draft reasoned opinion in July 2017, which was circulated to Member States for consultation via a written procedure. Comments received by 28 August 2017 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

Based on the available metabolism studies covering apple, citrus and tomato, it can be concluded that pyridaben is the principal residue component in fruit crops. 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. Standard processing studies evidenced that pyridaben was stable under conditions simulating processing by pasteurisation, baking/brewing/boiling and sterilisation.

A residue definition restricted to fruit crops for monitoring and risk assessment was agreed during the peer review as parent compound pyridaben only, which EFSA confirms during the current review. The same definition is applicable to rotational crops and processed commodities. 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 according to the European Union Reference Laboratories for Pesticide Residues (EURLs), a lower LOQ of 0.01 mg/kg is achievable with a liquid chromatography with tandem mass spectrometry (LC–MS/MS) method during routine analysis.

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for citrus fruits, strawberries and cucurbits with edible peel. For plums, table and wine grapes, currants, gooseberries and peppers, the available data were insufficient to derive MRLs and risk assessment values. For all other commodities under evaluation, only tentative MRLs could be derived.

Robust processing factors could be derived for washed oranges, orange juice, orange, dry and wet pomace. For all other orange processed commodities, only indicative processing factors could be derived due to the limited data sets.

Pyridaben is authorised for use on several crops that might be fed to livestock. The dietary burdens calculated for some groups of livestock (cattle, all; cattle, dairy only; sheep all; sheep, ewe only) were found to exceed the trigger value of 0.1 mg/kg dry mater (DM); however, the calculated dietary burden was at the lowest level of dairy cattle feeding study, where residues are expected to be below the LOQ.

Based on the results from the metabolism and livestock feeding studies and considering the calculated dietary burden, a residue definition for both enforcement and risk assessment limited to parent pyridaben only is proposed in this review. Nevertheless, this residue definition may need to be reconsidered in case additional uses on livestock feed items, leading to higher dietary burden will be granted in the future. A GC-ECD and/or LC–MS/MS (liver only) methods with a LOQ of 0.05 mg/kg are available for enforcement of the proposed residue definition in meat, liver, kidney, fat, and with a LOQ of 0.01 mg/kg for milk; however, none of them is fully supported by an independent laboratory validation (ILV) and/or confirmatory method.

MRLs and risk assessment values derived from cattle feeding study data can be extrapolated to all ruminants (e.g. goats and sheep), and other animals such as horses and rabbits. Pending on clarification on the storage temperature of the samples from the livestock feeding studies, also considering that fully validated analytical methods for enforcement are still required for animal commodities; all derived MRLs should be considered tentative only.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). According to the results of this calculation, the highest chronic exposure represented 42.9% of the acceptable daily intake (ADI) (FR, all population) and the highest acute exposure amounted to 94% of the acute reference dose (ARfD) (apples).

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC[2] a reasoned opinion on the review of the existing MRLs for that active substance. As pyridaben was included in Annex I to Council Directive 91/414/EEC on 1 May 2011 by means of Commission Directive 2010/90/EU[3], and has been deemed to be approved under Regulation (EC) No 1107/2009[4], in accordance with Commission Implementing Regulation (EU) No 540/2011[5], as amended by Commission Implementing Regulation (EU) No 541/2011[6], EFSA initiated the review of all existing MRLs for that active substance.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that, in the framework of Directive 91/414/EEC, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the EU, and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

The Netherlands, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for pyridaben and to prepare a supporting evaluation report (Netherlands, 2012). The PROFile and the supporting evaluation report were submitted to EFSA on 16 March 2012 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 3 October 2016 and finalised on 2 December 2016. Additional evaluation reports were submitted by Italy, France and the European Union Reference Laboratories for Pesticide Residues (EURL, 2016; France, 2016; Italy, 2016, 2017) and, after having considered all the information provided by the RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 5 January 2017. Further clarifications were sought from Member States via a written procedure in January 2017.

Based on the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008[7] and the additional information provided by the Member States, EFSA prepared in July

[1] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.

[3] Commission Directive 2010/90/EU of 7 December 2010 amending Council Directive 91/414/EEC to include pyridaben as active substance and amending Decision 2008/934/EC. OJ L 322, 8.12.2010, p. 38–41.

[4] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[5] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

[6] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

[7] Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.

2017 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 28 August 2017 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Netherlands, 2012) and the evaluation reports submitted by the Member States Italy, France (France, 2016; Italy, 2016, 2017) and the EU Reference Laboratories for Pesticide Residues (EURL, 2016) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2017a) and the Member States consultation report (EFSA, 2017b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic and acute exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) (excel file) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

Terms of Reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The active substance and its use pattern

Pyridaben is the ISO common name for 2-*tert*-butyl-5-(4-*tert*-butylbenzylthio)-4-chlorpyrididazin-3(*2H*)-one (IUPAC).

Pyridaben is used as an insecticide or acaricide. Pyridaben is orally and/or percutaneously taken into mobile forms of insects (whiteflies, mites). Pyridaben rapidly paralyses and kills the pests within 24 h after treatment. In addition, pyridaben quickly stops the embryonic development of whiteflies/mites and kills embryos when treated on eggs.

The chemical structure of the active substance and its main metabolite are reported in Appendix F.

Pyridaben was evaluated in the framework of Directive 91/414/EEC with the Netherlands designated as RMS. The representative uses supported for the peer review process comprised indoor foliar spraying against mites and whitefly on tomatoes, and outdoor air-assisted spray to citrus against mites and whitefly. Following the peer review, which was carried out by EFSA following resubmission of the application in accordance with the provisions laid down in Commission Regulation (EC) No 33/2008, a decision on inclusion of pyridaben in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2010/90/EU, which entered into force on 1 May 2011. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, pyridaben is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as insecticide and acaricide only.

The EU MRLs for pyridaben are established in Annex IIIA of Regulation (EC) No 396/2005, as amended by Commission Regulations (EC) No 149/2008[8], No 839/2008[9] and Commission Regulation (EU) No 2016/1[10]. Codex maximum residue limits (CXL(s)) for pyridaben are not available. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

[8] Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto. OJ L 58, 1.3.2008, p. 1–398.

[9] Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products. OJ L 234, 30.8.2008, p. 1–216.

[10] Commission Regulation (EU) No 2016/1 of 3 December 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyriofenone, sulfoxaflor, tebuconazole, tebufenpyrad and thiram in or on certain products. OJ L 2, 5.1.2016, p. 1–62.

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure	Legal implementation	Remarks
MRL application according to Article 10 of the Regulation (EFSA, 2015)	Commission Regulation (EU) No 2016/1	Modification of the MRLs in cucurbits (edible peel)

MRL: maximum residue level.

For the purpose of this MRL review, the critical uses of pyridaben currently authorised within the EU have been collected by the RMS and reported in the PROFile. The additional Good Agricultural Practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAP(s) for pyridaben are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Netherlands, 2012), the draft assessment report (DAR) prepared under Council Directive 91/414/EEC (Netherlands, 2007), the additional report (AR) and its addenda prepared in the framework of Commission Regulation (EC) No 33/2008 (Netherlands, 2009, 2010), the conclusion on the peer review of the pesticide risk assessment of the active substance pyridaben (EFSA, 2010), the confirmatory data addendum (Netherlands, 2014), the previous reasoned opinion on pyridaben (EFSA, 2015) as well as the evaluation reports submitted during the completeness check (EURL, 2016; France, 2016; Italy, 2016, 2017). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011[11] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2016; OECD, 2011, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

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 three representatives of fruit crops: in apple and citrus with benzyl-^{14}C-labelled or pyridazinone-^{14}C-labelled pyridaben with foliar application and in tomatoes with pyridazinone-^{14}C-labelled pyridaben applied by brush to leaves and fruits. In apple and citrus fruits, the main metabolite was pyridaben accounting for 48.8–51.3% of the total radioactive residues (TRR) (2.59–2.78 mg eq/kg) and 11.8–22.1% TRR (0.006–0.02 mg eq/kg), respectively. In apple, five additional metabolites were identified, each accounting for $\leq$ 5.1% TRR. Other unidentified metabolites did not exceed 2.9% TRR. In citrus fruits, six metabolites from 15 metabolite fractions (each $\leq$ 4.78% TRR; $\leq$ 0.006 mg eq/kg) were identified. In tomatoes, the main metabolite was pyridaben ($\geq$ 90% TRR; $\geq$ 0.07 mg eq/kg) and four additional metabolites were identified (each $\leq$ 0.7% TRR) (Netherlands, 2007). From the available studies, it can be concluded that pyridaben is the principal residue component.

1.1.2. Nature of residues in rotational crops

Pyridaben is authorised on strawberries and tomatoes which may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, periods required for 90% dissipation (DT_{90} values) of pyridaben in soil range from 241–4,522 days which is higher than the trigger value of 100 days (EFSA, 2010). Therefore, further investigation of residues in rotational crops was performed.

[11] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11. 6.2011, p. 127–175.

A 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-^{14}C-labelled pyridaben at 2 × 0.75 kg a.s./ha (corresponding to 2.5 N maximum rate).

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. Pyridaben was identified while the residues of metabolites were too low to allow an identification.

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 (Netherlands, 2007). The residue behaviour of pyridazinone-^{14}C-labelled pyridaben was studied under conditions simulating pasteurisation (20 min at 90°C, pH 4), baking/brewing/boiling (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6) in compliance with good laboratory practice (GLP).

From these studies, it can be concluded that pyridaben is stable under conditions simulating processing by pasteurisation, baking/brewing/boiling and sterilisation which are not expected to have a significant impact on the composition of residues in matrices of plant origin.

1.1.4. Methods of analysis in plants

Monitoring methods are available for pyridaben with a limit of quantification (LOQ) of 0.05 mg/kg. Gas chromatography with electron capture detector (GC–ECD) and liquid chromatography with tandem mass spectrometry (LC–MS/MS) methods including independent laboratory validation (ILV) are available for high water content commodities (tomato). For high acid commodities (citrus fruits), a GC-ECD method including ILV is available (Netherlands, 2007). However, during the peer review a data gap was identified for the confirmatory method (EFSA, 2010).

Furthermore, the EURLs provided a Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method using LC–MS/MS supported by validation data in high water, high acid, dry and high oil content plant commodities with a LOQ of 0.01 mg/kg (EURL, 2016). The method can be used for confirmation.

It is concluded that pyridaben can be enforced in high water and high acid content commodities with a LOQ of 0.05 mg/kg by GC-ECD used for analyses of the residue trials. According to the EURLs, a lower LOQ of 0.01 mg/kg is achievable with a LC–MS/MS method during routine analysis.

1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of pyridaben was demonstrated in high acid content commodities at −5°C and −20°C, and in high water content commodities at −20°C for 12 months (EFSA, 2010).

1.1.6. Proposed residue definitions

Pyridaben is a stable and soil persistent compound and it is the significant residue that was observed in the metabolism studies. Therefore, a residue definition restricted to fruit crops for monitoring and risk assessment was agreed during the peer review (EFSA, 2010). Following review of the available metabolism studies, EFSA confirms the residue definition for enforcement and risk assessment in fruit crops as parent compound pyridaben only. The same definition is applicable to rotational crops and processed commodities. A validated GC-ECD method is available for enforcement with a LOQ of 0.05 mg/kg. According to the EURLs, a lower LOQ of 0.01 mg/kg is achievable with a LC–MS/MS method during routine analysis.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of pyridaben residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS during the peer review and in its evaluation report (Netherlands, 2007, 2009, 2012), including residue trials evaluated in the framework of a previous MRL application (EFSA, 2015) and additional data submitted during the completeness check (France, 2016; Italy, 2016,

2017). All residue trial samples considered were stored in compliance with the demonstrated storage conditions. Decline of residues during storage of the trial samples is therefore not expected.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2016).

Sufficient residue trials are not available to support the authorisations on plums, currants, gooseberries, table and wine grapes and peppers. Therefore, MRL or risk assessment values for these crops could not be derived by EFSA and the following data gaps were identified:

- Plums: eight trials on plums compliant with the northern outdoor GAP are required.
- Currants: eight trials on currants compliant with the northern outdoor GAP are required.
- Gooseberries: four trials on gooseberries compliant with the northern outdoor GAP are required.
- Table and wine grapes: only one GAP-compliant trial on grapes is available, and therefore, seven additional trials on table or wine grapes to support the southern outdoor GAP are required.
- Peppers: eight trials on peppers compliant with the EU indoor GAP are required.

For some crops, the number of residue trials reported is not compliant with the data requirements, only tentative MRL and risk assessment values could be derived by EFSA and the following data gaps were identified:

- Pome fruits: only six overdosed trials (five on apples and one on pears) are available to support the northern outdoor GAP, and eight of the 14 available trials supporting the southern outdoor GAP were overdosed (five GAP-compliant trials on apples and one on pears). Although a tentative MRL can be derived from the northern data set, four additional trials on apples and four additional trials on pears compliant with the northern outdoor GAP, and three additional trials on pears compliant with the southern outdoor GAP are still required.
- Peaches and apricots: no residue trials on apricots and only three GAP-compliant trials on peaches are available to support the southern outdoor GAP. Whereby a tentative MRL was derived considering three additional overdosed trials on peaches, five additional trials on peaches and four trials on apricots compliant with the southern outdoor GAP are still required.
- Tomatoes and aubergines: only four trials on tomatoes compliant with the indoor GAPs and one overdosed trial on tomatoes are available and a tentative MRL was derived. Therefore, four additional trials on tomatoes supporting the indoor GAP are still needed.
- Beans with pods: four trials on beans with pods supporting the indoor GAP are available and considering two additional overdosed trials a tentative MRL was derived. Therefore, four additional trials compliant with the indoor GAP are still required.

For all other crops, the available residue trials are sufficient to derive MRL and risk assessment values, taking note of the following considerations:

- Citrus fruits: five of eight available residue trials on oranges and two of eight available trials on mandarins supporting the southern outdoor GAP were overdosed. However, considering that the proportionality approach can be applicable in this case (field trials were conducted within a rate range between 1× and 3× the GAP rate), the residue data were scaled and no additional trials are required.
- Strawberries: only five trials on strawberries to support the indoor GAP are available. Although a MRL was derived from the fully supported northern outdoor GAP, three additional trials to support the indoor GAP are still required.

It is noted that for tomatoes, aubergines and cucurbits with edible peel, more critical indoor GAPs not supported by data are authorised in several Member States (see comment field of the GAP table in Appendix A for details).

1.2.2. Magnitude of residues in rotational crops

In the rotational crop studies evaluated during the peer review (see also Section 1.1.2), TRR recovered in all edible parts of rotational crops were very low after two applications at 750 g/ha onto soil.

The levels of radioactivity in radish (leaves and roots), mustard greens, wheat forage, hay, straw and grain sown 30 days after two applications of labelled pyridaben at a rate of 0.75 kg a.s./ha to bare soil were for individual residues consisting mainly of polar unidentified compounds below 10% TRR, except for one polar peak in 30 DAT (days after treatment) mustard greens (0.003 mg eq/kg; 17% TRR). Pyridaben was determined in radish roots, leaves and mustard greens (< 0.001 mg eq/kg and ≤ 1.5% TRR).

In radish roots and leaves planted 240 DAT, one polar peak of 30% TRR (0.007 mg eq/kg) and a peak of 11% TRR (0.005 mg eq/kg), respectively, above 10% TRR were described. In Swiss chard (planted 240 DAT), the aqueous extraction (53% TRR, 0.023 mg eq/kg) was fractionated into one polar peak (15% TRR, 0.007 mg eq/kg) and others below 10% TRR. In sorghum forage (240 DAT), the residues of the aqueous extraction (36% TRR, 0.009 mg eq/kg) were fractionated into 15 regions all of which were below 10% TRR.

From the available rotational crop studies, it can be concluded that no significant residues are expected in rotational and succeeding crops, provided that pyridaben is used according to the GAPs evaluated in this review.

1.2.3. Magnitude of residues in processed commodities

Studies investigating the magnitude of residues in oranges were provided during the peer review (Netherlands, 2007). An overview of these studies is given in Appendix B.1.2.3.

Robust processing factors could be derived for washed oranges, orange juice, wet and dry pomace based on three studies. For peeled oranges, a processing factor of 0.1 was tentatively derived from two studies only.

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for citrus fruits, strawberries and cucurbits with edible peel. For plums, table and wine grapes, currants, gooseberries and peppers, the available data were insufficient to derive MRLs and risk assessment values. For all other commodities under evaluation only tentative MRLs could be derived.

2. Residues in livestock

Pyridaben is authorised for use on citrus fruits and apples that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for cattle (all), cattle (dairy only), sheep (all) and sheep (ewe only) were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in these groups of livestock.

2.1. Nature of residues and methods of analysis in livestock

During the peer review, metabolism studies performed on domestic animals (goat and hen) indicated that pyridaben should be defined as the residue of concern in food of animal origin (Netherlands, 2009). However, the acceptability of the studies was not agreed upon and the definition of the residue for monitoring in animal commodities could not be finalised (EFSA, 2010).

At that time, EFSA identified a data gap to clarify the identity of residues in ruminant fat. After approval, the RMS submitted confirmatory data showing that a 40-fold increase in dietary intake (5 and 20 mg/day (two goats each)) did not significantly increase the residue in fat (Netherlands, 2014).

While no further information on the identity of residues in ruminant fat was received during the present review, it can be concluded from the study results that no accumulation of fat soluble residues was observed. However, it has to be noted that the study duration was only 5 days. Further information on the nature of the residues are also available in the livestock feeding study, where, after 29 days dosing, pyridaben was detected in fat at the highest dose level only while at this level an additional compound (metabolite PB-7) was measured in liver at higher levels than the parent (see Section 2.2) (Netherlands, 2007).

Nevertheless, considering that according to the results of the available livestock feeding studies, at the calculated livestock dietary burden, no residues above the LOQs of 0.05 mg/kg and 0.01 mg/kg are expected in ruminant tissues and in milk, respectively; it is proposed to define the residue as parent compound only for the time being. This residue definition may need to be reconsidered and additional information on the nature of the residues may be needed, in case additional uses on livestock feed items, leading to higher dietary burden will be granted in the future.

A GC-ECD method for the enforcement of pyridaben with a LOQ of 0.05 mg/kg in meat, fat, liver and kidney and with a LOQ of 0.01 mg/kg in milk is available which is not considered acceptable for post-registration monitoring due to the lack of a confirmatory method. An ILV was provided for liver (Netherlands, 2007). For liver, a LC–MS/MS method with a LOQ of 0.05 mg/kg was considered acceptable for post-registration purposes; however, an ILV was missing (Netherlands, 2009). Additional information on these methods was not received during the current review.

The EURLs provided a liquid chromatography with tandem mass spectrometry quadrupole time of flight (LC–MS-q-ToF) method for food of animal origin (honey, eggs, muscle and milk) supported by screening data indicating that pyridaben could be enforced in commodities of animal origin with an indicative LOQ of 0.01 mg/kg (EURL, 2016).

Storage stability of pyridaben was demonstrated for 27 months in samples stored at −20°C. Additional information on the storage stability were reported in the ruminant feeding study where residues were found to be stable in muscle, liver and milk samples after storage at −5°C for 5 months (Netherlands, 2007).

2.2. Magnitude of residues in livestock

MRLs and risk assessment values for animal products were derived according to the OECD guidance which was agreed upon at the European level (OECD, 2013). The overview of the study results used to derive the risk assessment values and the MRL proposals are summarised in Appendix B.2.2. According to the OECD guidance, MRLs and risk assessment values derived from cattle feeding study data can be extrapolated to all ruminants (e.g. goats and sheep), and other animals such as horses and rabbits.

One feeding study performed on dairy cattle was evaluated by the RMS in the DAR (Netherlands, 2007). Three dose levels were tested (0.08, 0.25 and 0.76 mg pyridaben/kg body weight (bw) per day) for 29 days, whereby the lowest dosing level is closest to the calculated dietary burden for cattle and sheep.

As anticipated in the previous section, according to the results from the livestock feeding studies, at the calculated livestock dietary burden, no residues above the LOQs of 0.05 mg/kg and 0.01 mg/kg are expected in ruminant tissues and in milk, respectively. Notably, at the intermediate and highest dosing level, the metabolite PB-7 was detected with a maximum of 0.05 mg/kg (mean ≤ 0.05 mg/kg) and 0.15 mg/kg (mean 0.11 mg/kg), respectively, in liver, while the parent was below the LOQ. Pyridaben was detected in fat samples of the high dose group at a maximum of 0.08 mg/kg (mean 0.07 mg/kg), which is not considered relevant (Netherlands, 2007).

Samples for the feeding study were stored frozen for ≤ 6.5 months. In case that the samples were stored at −20°C, degradation of the residues is not expected to have occurred. However, it is noted that at higher temperature of −5°C the storage stability has been investigated for a shorter period (5 months) in muscle, liver and milk samples from the livestock feeding study. Therefore, the confirmation that samples from the livestock feeding studies were stored at temperature of −20°C is still required.

Pending a clarification on the storage temperature of the samples from the livestock feeding studies and also considering that fully validated analytical methods for enforcement are still required for animal commodities, all derived MRLs should be considered tentative only.

3. Consumer risk assessment

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009).

For those commodities where data were insufficient to derive a MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix D.

The exposure values calculated were compared with the toxicological reference values for pyridaben, derived by EFSA (2010) under Commission Regulation (EC) No 33/2008. The highest chronic exposure was calculated for FR all population, representing 42.9% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for apples, representing 94% of the acute reference dose (ARfD). Based on these calculations, no apparent unacceptable risk to consumers is identified; however, this can only be considered as an indicative exposure calculation as (major) uncertainties remain due to the data gaps identified in the previous sections.

Conclusions

Based on the available metabolism studies covering apple, citrus and tomato, it can be concluded that pyridaben is the principal residue component in fruit crops. 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. Standard processing studies evidenced that pyridaben was stable under conditions simulating processing by pasteurisation, baking/brewing/boiling and sterilisation.

A residue definition restricted to fruit crops for monitoring and risk assessment was agreed during the peer review as parent compound pyridaben only, which EFSA confirms during the current review. The same definition is applicable to rotational crops and processed commodities. Pyridaben can be enforced in high water and high acid content commodities by using a GC-ECD method with a LOQ of 0.05 mg/kg and according to the EURLs a lower LOQ of 0.01 mg/kg is achievable with a LC–MS/MS method during routine analysis.

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for citrus fruits, strawberries and cucurbits with edible peel. For plums, table and wine grapes, currants, gooseberries and peppers, the available data were insufficient to derive MRLs and risk assessment values. For all other commodities under evaluation, only tentative MRLs could be derived.

Robust processing factors could be derived for washed oranges, orange juice, orange, dry and wet pomace. For all other orange processed commodities, only indicative processing factors could be derived due to the limited data sets.

Pyridaben is authorised for use on several crops that might be fed to livestock. The dietary burdens calculated for some groups of livestock (cattle, all; cattle, dairy only; sheep all; sheep, ewe only) were found to exceed the trigger value of 0.1 mg/kg DM; however, the calculated dietary burden was at the lowest level of dairy cattle feeding study, where residues are expected to be below the LOQ.

Based on the results from the metabolism and livestock feeding studies and considering the calculated dietary burden, a residue definition for both enforcement and risk assessment limited to parent pyridaben only is proposed in this review. Nevertheless, this residue definition may need to be reconsidered in case additional uses on livestock feed items, leading to higher dietary burden will be granted in the future. A GC-ECD and/or LC–MS/MS (liver only) methods with a LOQ of 0.05 mg/kg are available for enforcement of the proposed residue definition in meat, liver, kidney, fat and with a LOQ of 0.01 mg/kg for milk; however, none of them is fully supported by an ILV and/or confirmatory method.

MRLs and risk assessment values derived from cattle feeding study data can be extrapolated to all ruminants (e.g. goats and sheep), and other animals such as horses and rabbits. Pending on clarification on the storage temperature of the samples from the livestock feeding studies, also considering that fully validated analytical methods for enforcement are still required for animal commodities; all derived MRLs should be considered tentative only.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. According to the results of this calculation, the highest chronic exposure represented 42.9% of the ADI (FR, all population) and the highest acute exposure amounted to 94% of the ARfD (apples).

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The

remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details). In particular, some tentative MRLs and existing EU MRLs need to be confirmed by the following data:

- additional residue trials on pome fruits, peaches, apricots, plums, currants, gooseberries, wine and table grapes, tomatoes, peppers, aubergines and beans with pods;
- information on the exact storage temperature of samples from the feeding study or additional studies covering storage stability reflecting storage conditions of samples from the feeding study;
- a validated analytical method with its ILV and a confirmatory method for enforcement of pyridaben in all animal commodities.

It is highlighted, however, that some of the MRLs derived result from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- additional residue trials on strawberries;
- additional residue trials supporting the more critical GAPs authorised in the EU for tomatoes, aubergines and cucurbits with edible peel (indoor).

If the above-reported data, gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Table 2: Summary table

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: pyridaben					
0110010	Grapefruits	0.5	–	0.3	Recommended[d]
0110020	Oranges	0.5	–	0.3	Recommended[d]
0110030	Lemons	0.5	–	0.3	Recommended[d]
0110040	Limes	0.5	–	0.3	Recommended[d]
0110050	Mandarins	0.5	–	0.3	Recommended[d]
0130010	Apples	0.5	–	0.9	Further consideration needed[b]
0130020	Pears	0.5	–	0.9	Further consideration needed[b]
0130030	Quinces	0.5	–	0.9	Further consideration needed[b]
0130040	Medlars	0.5	–	0.9	Further consideration needed[b]
0130050	Loquats	0.5	–	0.9	Further consideration needed[b]
0140010	Apricots	0.5	–	0.3	Further consideration needed[b]
0140030	Peaches	0.5	–	0.3	Further consideration needed[b]
0140040	Plums	0.5	–	0.5	Further consideration needed[c]
0151010	Table grapes	0.5	–	0.5	Further consideration needed[c]
0151020	Wine grapes	1.0	–	1.0	Further consideration needed[c]
0152000	Strawberries	1.0	–	0.9	Recommended[d]
0154030	Currants	0.5	–	0.5	Further consideration needed[c]
0154040	Gooseberries	0.5	–	0.5	Further consideration needed[c]
0231010	Tomatoes	0.3	–	0.05*	Further consideration needed[b]
0231020	Sweet peppers	0.5	–	0.5	Further consideration needed[c]
0231030	Aubergines	0.2	–	0.05*	Further consideration needed[b]
0232010	Cucumbers	0.15	–	0.15	Recommended[d]
0232020	Gherkins	0.15	–	0.15	Recommended[d]
0232030	Courgettes	0.15	–	0.15	Recommended[d]
0260010	Beans with pods	0.5	–	0.2	Further consideration needed[b]
1012010	Bovine muscle	0.02*	–	0.05*	Further consideration needed[b]

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1012020	Bovine fat tissue	0.02*	–	0.05*	Further consideration needed[b]
1012030	Bovine liver	0.02*	–	0.05*	Further consideration needed[b]
1012040	Bovine kidney	0.02*	–	0.05*	Further consideration needed[b]
1013010	Sheep muscle	0.02*	–	0.05*	Further consideration needed[b]
1013020	Sheep fat tissue	0.02*	–	0.05*	Further consideration needed[b]
1013030	Sheep liver	0.02*	–	0.05*	Further consideration needed[b]
1013040	Sheep kidney	0.02*	–	0.05*	Further consideration needed[b]
1014010	Goat muscle	0.02*	–	0.05*	Further consideration needed[b]
1014020	Goat fat tissue	0.02*	–	0.05*	Further consideration needed[b]
1014030	Goat liver	0.02*	–	0.05*	Further consideration needed[b]
1014040	Goat kidney	0.02*	–	0.05*	Further consideration needed[b]
1015010	Equine muscle	0.02*	–	0.05*	Further consideration needed[b]
1015020	Equine fat tissue	0.02*	–	0.05*	Further consideration needed[b]
1015030	Equine liver	0.02*	–	0.05*	Further consideration needed[b]
1015040	Equine kidney	0.02*	–	0.05*	Further consideration needed[b]
1020010	Cattle milk	0.02*	–	0.01*	Further consideration needed[b]
1020020	Sheep milk	0.02*	–	0.01*	Further consideration needed[b]
1020030	Goat milk	0.02*	–	0.01*	Further consideration needed[b]
1020040	Horse milk	0.02*	–	0.01*	Further consideration needed[b]
Other commodities of plant and animal origin	Regulation (EC) No 149/2008	–	–	–	Further consideration needed[e]

MRL: maximum residue level; CXL: Codex maximum residue limit.
*: Indicates that the MRL is set/proposed at the limit of quantification. (F): Residue is fat soluble.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).
(c): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).
(d): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
(e): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

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Abbreviations

a.i.	active ingredient
a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants

bw	body weight
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC-ECD	gas chromatography with electron capture detector
GLP	Good Laboratory Practice
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC	liquid chromatography
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LC–MS-q-ToF	liquid chromatography with tandem mass spectrometry quadrupole time of flight
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry detector
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
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 European Union
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TRR	total radioactive residue
WP	wettable powder

Appendix A – Summary of authorised uses considered for the review of MRLs

Critical outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ indoor[a]	Member state or country	Pest controlled	Formulation			Application										PHI or waiting period (days)[d]	Comments (max. 250 characters)
Common name	Scientific name					Type[b]	Content		Method	Growth stage[c]		Number		Interval (days)		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min	Max	Min	Max	Min	Max	Unit		
Apples	*Malus domestica*	NEU	F	BE, PL, SK	Aphids	WP	200.0	g/kg	Foliar treatment – spraying			1	1			0.14	0.14	kg a.i./ha	7	At infestation
Pears	*Pyrus communis*	NEU	F	BE, PL, SK	Aphids	WP	200.0	g/kg	Foliar treatment – spraying			1	1			0.14	0.14	kg a.i./ha	7	
Quinces	*Cydonia oblonga*	NEU	F	BE, PL, SK	Aphids	WP	200.0	g/kg	Foliar treatment – spraying			1	1			0.14	0.14	kg a.i./ha	7	
Medlars	*Mespilus germanica*	NEU	F	BE, PL, SK	Aphids	WP	200.0	g/kg	Foliar treatment – spraying			1	1			0.14	0.14	kg a.i./ha	7	
Loquats	*Eriobotrya japonica*	NEU	F	BE, PL, SK	Aphids	WP	200.0	g/kg	Foliar treatment – spraying			1	1			0.14	0.14	kg a.i./ha	7	
Plums	*Prunus domestica*	NEU	F	SK, BE	*Tetranychus telarius*	WP	20.0	% (w/w)	Foliar treatment – spraying			1	1			0.10	0.23	kg a.i./ha	14	At infestation
Strawberries	*Fragaria* x *ananassa*	NEU	F	BE, PL	*Tetranychus telarius*	SC	10.0	% (w/w)	Foliar treatment – spraying	67	89	1	1			0.15	0.15	kg a.i./ha	3	
Currants	*Ribes nigrum; Ribes rubrum*	NEU	F	BE	Aphids	WP	20.0	% (w/w)	Foliar treatment – spraying			1	1			0.15	0.15	kg a.i./ha	7	At infestation
Gooseberries	*Ribes uva-crispa*	NEU	F	BE	Aphids	WP	20.0	% (w/w)	Foliar treatment – spraying			1	1			0.15	0.15	kg a.i./ha	7	At infestation

NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: Good Agricultural Practice; WP: wettable powder; a.i.: active ingredient.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(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.

Critical outdoor GAPs for Southern Europe

Crop		Region	Outdoor/ indoor[e]	Member state or country	Pest controlled	Formulation			Application										PHI days[h]	Comments (max. 250 characters)
Common name	Scientific name					Type[f]	Content		Method	Growth stage[g]		Number		Interval days		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min	Max	Min	Max	Min	Max	Unit		
Grapefruits	*Citrus paradisi*	SEU	F	FR	Various mites	EC	200.0	g/L	Foliar treatment – spraying	69	83	1	1				0.30	kg a.i./ha	14	
Oranges	*Citrus sinensis*	SEU	F	FR	Various mites	EC	200.0	g/L	Foliar treatment – spraying	69	83	1	1				0.30	kg a.i./ha	14	
Lemons	*Citrus limon*	SEU	F	FR	Various mites	EC	200.0	g/L	Foliar treatment – spraying	69	83	1	1				0.30	kg a.i./ha	14	
Limes	*Citrus aurantiifolia*	SEU	F	FR	Various mites	EC	200.0	g/L	Foliar treatment – spraying	69	83	1	1				0.30	kg a.i./ha	14	
Mandarins	*Citrus reticulata*, syn: *Citrus deliciosa*	SEU	F	FR	Various mites	EC	200.0	g/L	Foliar treatment – spraying	69	83	1	1				0.30	kg a.i./ha	14	
Apples	*Malus domestica*	SEU	F	IT	Various mites	EC	200.0	g/L	Foliar treatment – spraying			1	1				0.20	kg a.i./ha	14	
Pears	*Pyrus communis*	SEU	F	IT	Various mites	EC	200.0	g/L	Foliar treatment – spraying			1	1				0.20	kg a.i./ha	14	
Quinces	*Cydonia oblonga*	SEU	F	IT	Various mites	EC	200.0	g/L	Foliar treatment – spraying			1	1			0.10	0.23	kg a.i./ha	14	
Medlars	*Mespilus germanica*	SEU	F	IT	Various mites	EC	200.0	g/L	Foliar treatment – spraying			1	1			0.10	0.23	kg a.i./ha	14	
Loquats	*Eriobotrya japonica*	SEU	F	IT	Various mites	EC	200.0	g/L	Foliar treatment – spraying			1	1			0.10	0.23	kg a.i./ha	14	
Apricots	*Armeniaca vulgaris*, syn: *Prunus armeniaca*	SEU	F	IT	Various mites	EC	200.0	g/L	Foliar treatment – spraying			1	1				0.20	kg a.i./ha	14	

Critical outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ indoor[e]	Member state or country	Pest controlled	Formulation			Application										PHI days[h]	Comments (max. 250 characters)
Common name	Scientific name					Type[f]	Content		Method	Growth stage[g]		Number		Interval days		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min	Max	Min	Max	Min	Max	Unit		
Peaches	*Persica vulgaris*, syn: *Prunus persica*	SEU	F	IT	Various mites	EC	200.0	g/L	Foliar treatment – spraying			1	1				0.20	kg a.i./ha	14	
Plums	*Prunus domestica*	SEU	F	IT	Various mites	EC	200.0	g/L	Foliar treatment – spraying			1	1				0.20	kg a.i./ha	14	
Table grapes	*Vitis vinifera*	SEU	F	IT	Various mites	EC	200.0	g/L	Foliar treatment – spraying			1	1				0.20	kg a.i./ha	14	
Wine grapes	*Vitis vinifera*	SEU	F	IT	Various mites	EC	200.0	g/L	Foliar treatment – spraying			1	1				0.20	kg a.i./ha	14	

NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: Good Agricultural Practice; EC: emulsifiable concentrate; a.i.: active ingredient.
(e): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(f): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(g): 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.
(h): PHI: minimum preharvest interval.

Critical outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ indoor[e]	Member state or country	Pest controlled	Formulation			Application										PHI days [h]	Comments (max. 250 characters)
Common name	Scientific name					Type[f]	Content		Method	Growth stage[g]		Number		Interval days		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min	Max	Min	Max	Min	Max	Unit		
Strawberries	*Fragaria* x *ananassa*	NEU/ SEU	Indoor	IT	White flies, red mites	EC	200.0	g/L	Foliar treatment – spraying				1				0.20	kg a.i./ha	7	
Tomatoes	*Lycopersicon esculentum*	NEU/ SEU	Indoor	IT	Mites and white flies	EC	157.0	g/L	Foliar treatment – spraying			1	1				0.20	kg a.i./ha	7	A more critical GAP is authorised in PT and BE (3 × 170 g a.s./ha; PHI = 3 days); however, not supported by data
Sweet peppers	*Capsicum annuum*	NEU/ SEU	Indoor	PT, BE	Mites and white flies	EC	157.0	g/L	Foliar treatment – spraying			1	3	7	10	0.06	0.17	kg a.i./ha	3	
Aubergines	*Solanum melongena*	NEU/ SEU	Indoor	IT	Mites and white flies	EC	157.0	g/L	Foliar treatment – spraying			1	1				0.20	kg a.i./ha	7	A more critical GAP is authorised in PT and BE (3 × 170 g a.s./ha; PHI = 3 days); however, not supported by data
Cucumbers	*Cucumis sativus*	NEU/ SEU	Indoor	BE, CZ, PO, RO, SK, BU, FR, EL, IT, PT	Mites and white flies	WP	200.0	g/kg	Foliar treatment – spraying			1	1				0.20	kg a.i./ha	3	EFSA (2015) A more critical GAP (2 × 200 g a.s./ha; PHI = 3 days) is authorised in SK, PL, BE; however, not supported by data
Gherkins	*Cucumis sativus*	NEU/ SEU	Indoor	BE, CZ, PO, RO, SK, BU, FR, EL, IT, PT	Mites and white flies	WP	200.0	g/kg	Foliar treatment – spraying			1	1			0.10	0.20	kg a.i./ha	3	EFSA (2015) A more critical GAP authorised in BE (2 × 200 g a.s./ha; PHI = 3 days) is not supported by data

Critical outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ indoor[e]	Member state or country	Pest controlled	Formulation			Application										PHI days [h]	Comments (max. 250 characters)
Common name	Scientific name					Type[f]	Content		Method	Growth stage[g]		Number		Interval days		Rate				
							Conc.	Unit		From BBCH	Until BBCH	Min	Max	Min	Max	Min	Max	Unit		
Courgettes	Cucurbita pepo Zucchini Group	NEU/ SEU	Indoor	BE, CZ, PO, RO, SK, BU, FR, EL, IT, PT	Mites and white flies	WP	200.0	g/kg	Foliar treatment – spraying			1	1			0.10	0.20	kg a.i./ha	3	EFSA (2015) A more critical GAP authorised in BE (2 × 200 g a.s./ha; PHI = 3 days) is not supported by data
Beans (with pods)	*Phaseolus vulgaris*	NEU/ SEU	Indoor	IT	White flies, red mites	EC	200.0	g/L	Foliar treatment – spraying				1				0.20	kg a.i./ha	7	

NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: Good Agricultural Practice; EC: emulsifiable concentrate; a.i.: active ingredient; a.s.: active substance.
(i): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(j): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(k): 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.
(l): 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)
	Fruit crops	Apples Citrus fruit Tomato	Foliar, 3 × 300 g a.s./ha Spraying, 2 × 0.57 kg a.s./ha or 2 × 4.76 kg a.s./ha By brush onto leaves, 1 mg a.s./plant	25, 40 0, 1, 3, 7, 1, 7, 14 1, 7, 14
	Source: Netherlands (2007)			

Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)
	Root/tuber crops	Radish	Bare soil, 2 × 0.75 kg a.s./ha	30, 240
	Leafy crops	Swiss chard	Bare soil, 2 × 0.75 kg a.s./ha	30, 240
		Mustard green		30
	Cereal (small grain)	Wheat	Bare soil, 2 × 0.75 kg a.s./ha	30
		Sorghum		30, 240
	Source: Netherlands (2007)			

Processed commodities (hydrolysis study)	Conditions	Investigated?
	Pasteurisation (20 min, 90 °C, pH 4)	Yes
	Baking, brewing and boiling (60 min, 100 °C, pH 5)	Yes
	Sterilisation (20 min, 120 °C, pH 6)	Yes
	Source: Netherlands (2007)	

DAT: days after treatment; PBI: plant back interval; a.s.: active substance.

Can a general residue definition be proposed for primary crops?	No
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 (fruits crops only)
Plant residue definition for risk assessment (RD-RA)	Pyridaben (fruits crops only)
Conversion factor (monitoring to risk assessment)	Not applicable
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) • LC–MS/MS (QuECHERS methods, EN 15662:2008); LOQ = 0.01 mg/kg, sufficient validation data in tomato available (EURL, 2016) 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); confirmatory LC-MS/MS method required (EFSA, 2010) • LC–MS/MS (QuECHERS methods, EN 15662:2008); LOQ = 0.01 mg/kg, sufficient validation data in lemon available (EURL, 2016); 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 (EURL, 2016)

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability (months)**
	High water content	Apples	–20	12
	High acid content	Oranges	–5 –20	12 12
		Orange, dried pulp	–5	12
		Orange molasses	–5	12
		Orange oil	–5	12
		Grapes	–20	12
	Source: Netherlands (2007), EFSA (2010)			

B.1.2. Magnitude of residues in plants

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

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]
Oranges, grapefruits, lemons, limes, mandarins	SEU	GAP-compliant trials on oranges: 0.05; 0.06; 0.10 Overdosed trials on oranges with 1 × 0.5 kg a.i./ha (1.7 N): < 0.05; 0.03; 0.05 Overdosed trials on oranges with 1 × 0.55 kg a.i./ha (1.8N): 0.07 Overdosed trial on oranges with 1 × 0.895 kg a.i./ha (3N): 0.09 GAP compliant trials on mandarins: 0.055; 0.07; 0.08; 0.087; 0.13; 0.22 Overdosed trials on mandarins 1 × 523-529 g a.s./ha (1.8N): 0.17; 0.13	Combined data set, trials on oranges and mandarins (Netherlands 2007, 2012; France, 2016). Overdosed trials were scaled. Extrapolation to all citrus fruits possible	0.3	0.22	0.08
Apples, pears, quinces, medlars, loquats	NEU	Overdosed trials on apples with 2 × 0.1 kg a.i./ha: 0.08; 0.08 Overdosed trials on apples with 2 × 0.2 kg a.i./ha: 0.24; 0.48 Overdosed trial on apples with 1 × 135 g a.i./ha: 0.056 Trial on pears overdosed with 1 × 324 g a.s./ha: 0.171	Combined data set, trials on apples and pears (Netherlands, 2012). Extrapolation to all pome fruits tentatively possible	0.9[d,e] (tentative)	0.48	0.13
	SEU	GAP-compliant trials on apples: < 0.05; < 0.05; < 0.05; < 0.05; < 0.05 GAP-compliant trial on pears: 0.09 Overdosed trial on apples with 1 × 283, 309, 760 g a.s./ha: < 0.05; 0.05; 0.09 Overdosed trial on apples with 2 × 300 – 320 g a.s./ha: < 0.05; < 0.05; 0.07; 0.12 Trial on pears overdosed with 2 × 180 g a.s./ha: < 0.05	Combined data set of trials on apples and on pears (Netherlands, 2012)	0.15[d] (tentative)	0.12	0.05
Peaches, apricots	SEU	GAP-compliant trials: < 0.05; < 0.05; 0.08 Overdosed trials with 1 × 558-560 g a.s./ha: < 0.05; 0.08; 0.15	Trials on peaches (Netherlands, 2012). Extrapolation to apricots tentatively possible	0.3[d,e] (tentative)	0.15	0.07
Plums	NEU	–	No residue trials available	–	–	–

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/ kg)[b]	$STMR_{Mo}$ (mg/kg)[c]
Table and wine grapes	SEU	GAP-compliant trials on grapes: < 0.05	Trial on grapes (Netherlands, 2012)	–	–	–
Strawberries	NEU	< 0.05; < 0.05; < 0.05; < 0.05; < 0.05; 0.0506; 0.072; 0.35; 0.53	GAP-compliant trials on strawberries (Netherlands, 2012)	0.9	0.53	0.05
	EU	GAP-compliant trials on strawberries: 0.10; 0.15; 0.11; 0.11; 0.07 Overdosed trials with 1 × 0.3 kg a.s./ha: 0.25	Trials on strawberries (Italy, 2016, 2017)	0.4[d,e] (tentative)	0.25	0.11
Currants (black, red and white)	NEU	–	No trial summaries available to verify GAP compliance	–	–	–
Gooseberries (green, red and yellow)	NEU	–	No GAP–compliant trials available	–	–	–
Tomatoes, aubergines	EU	GAP-compliant trials on tomatoes: < 0.05; < 0.05; < 0.05; < 0.05 Overdosed trials with 1 × 325 g a.s./ha: < 0.05	Trials on tomatoes (Italy, 2017). An extrapolation to aubergines possible	0.05*[e] (tentative)	0.05	0.05
Sweet peppers/bell peppers	EU	–	No GAP-compliant trials (Netherlands, 2012; Italy, 2016, 2017)	–	–	–
Cucumbers, gherkins, courgettes	EU	< 0.05; < 0.05; < 0.05; < 0.05; 0.059; 0.063; 0.081; 0.097	GAP-compliant trials on cucumber (EFSA, 2015). Extrapolation to gherkins and courgettes possible	0.15	0.10	0.05
Beans (with pods)	EU	GAP-compliant trials: < 0.05; < 0.05; 0.06; 0.09 Overdosed trials with 1 × 0.4; 0.44 kg a.s./ha: 0.06; 0.10	Trials on beans (Netherlands, 2012; Italy, 2016, 2017)	0.2[d,e] tentative	0.10	0.06

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; a.i.: active ingredient; MRL: maximum residue level; a.s.: active substance.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): Tentative MRL derived from trials according to a more critical GAP.
(e): Tentative MRL derived from reduced number of trials.

B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect)	Based on the available information it can be concluded that no significant residues of pyridaben are expected in rotational crops
Field rotational crop study	No studies submitted and not required

B.1.2.3. Processing factors

Processed commodity	Number of studies[a]	Processing factor (PF)	
		Individual values	Median PF
Robust processing factors (sufficiently supported by data)			
Washed oranges	3	0.37, 0.49, 0.66	0.49
Orange juice	3	0.1; 0.12; 0.14	0.1
Orange, wet pomace	3	0.75; 1.05; 1.11	1.05
Orange, dry pomace	3	3.5; 3.6; 5.2	3.6
Indicative processing factors (limited data set)			
Orange peeled	2	0.09; 0.12	0.1
Orange canned fruit	2	0.04; 0.12	0.1
Orange marmalade	2	0.12; 0.21	0.2
Orange molasses	1	0.30	0.3
Orange oil	1	25.3	25

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

B.2. Residues in livestock

Relevant groups	Dietary burden expressed in				Most critical diet[a]	Most critical commodity[a]	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Med.	Max.	Med.	Max.			
Cattle (all diets)	0.0075	0.0075	0.31	0.31	Cattle (beef)	Apple, pomace, wet	Yes
Cattle (dairy only)	0.0060	0.0060	0.16	0.16	Cattle (dairy)	Apple, pomace, wet	Yes
Sheep (all diets)	0.0067	0.0067	0.16	0.16	Sheep (lamb)	Apple, pomace, wet	Yes
Sheep (ewe only)	0.0052	0.0052	0.16	0.16	Sheep (ram/ewe)	Apple, pomace, wet	Yes
Swine (all diets)	0.0010	0.0010	0.04	0.04	Swine (breeding)	Grapefruit, dried pulp	No
Poultry (all diets)	0.0000	0.0000	0.00	0.00	–	–	No
Poultry (layer only)	0.0000	0.0000	0.00	0.00	–	–	No

bw: body weight; DM: dry matter.
(a): Calculated for the maximum dietary burden.

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

Livestock (available studies)	**Animal**	**Dose (mg/kg bw per day)**	**Duration (days)**	**N rate/comment**
	Laying hen	0.006; 0.5	8	The dietary burden for poultry is below the trigger value of 0.1 mg/kg.
	Lactating goat	0.007; 0.29	5	0.93N; 38.67N; compared to cattle all maximum dietary burden
	Source: Netherlands (2007)			

bw: body weight.

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 2–3 days; Eggs: > 8 days
Metabolism in rat and ruminant similar (Yes/No)	Yes
Animal residue definition for monitoring (RD-Mo)	Pyridaben
Animal residue definition for risk assessment (RD-RA)	Pyridaben
Conversion factor (monitoring to risk assessment)	Not applicable
Fat soluble residues (Yes/No)	Yes
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Animal commodities: • GC-ECD (D9405), LOQ: 0.01 mg/kg for milk; LOQ: 0.05 mg/kg (fat, kidney, muscle, liver), ILV for liver only, insufficient information on confirmatory methods available (Netherlands, 2007) • LC–MS/MS (NAS/0865), LOQ: 0.05 mg/kg (liver), ILV not available (Netherlands, 2009) • LC–MS-q-ToF (screening), indicative LOQ: 0.01 mg/kg in honey, eggs, muscle and milk (EURL, 2016)

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	**Animal**	**Commodity**	**T (°C)**	**Stability (months)**
	Lactating goat	Muscle	−20	27
	Dairy cattle		−5	5
	Lactating goat	Fat	−20	27
	Lactating goat	Liver	−20	27
	Dairy cattle		−5	5
	Lactating goat	Kidney	−20	27
	Lactating goat	Milk	−20	27
	Dairy cattle		−5	5
	Lactating goat	Eggs	−20	27
	Source: Netherlands (2007)			

B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		MRL proposal (mg/kg)
	Mean	Highest	STMR[a] (mg/kg)	HR[b] (mg/kg)	
Cattle (all diets) Closest feeding level (0.08 mg/kg bw; 11N rate)[c]					
Muscle	< 0.05	< 0.05	0.05	0.05	0.05*[f] (tentative)
Fat	< 0.05	< 0.05	0.05	0.05	0.05*[f] (tentative)
Liver	< 0.05	< 0.05	0.05	0.05	0.05*[f] (tentative)
Kidney	< 0.05	< 0.05	0.05	0.05	0.05*[f] (tentative)
Cattle (dairy only) Closest feeding level (0.08 × mg/kg bw; 13N rate)[c]					
Milk[d]	< 0.01	< 0.01	0.01	0.01	0.01*[f] (tentative)
Sheep (all diets)[e] Closest feeding level (0.08 mg/kg bw; 12N rate)[c]					
Muscle	< 0.05	< 0.05	0.05	0.05	0.05*[f] (tentative)
Fat	< 0.05	< 0.05	0.05	0.05	0.05*[f] (tentative)
Liver	< 0.05	< 0.05	0.05	0.05	0.05*[f] (tentative)
Kidney	< 0.05	< 0.05	0.05	0.05	0.05*[f] (tentative)
Sheep (dairy only)[e] Closest feeding level (0.08 × mg/kg bw; 15N rate)[c]					
Milk[d]	< 0.01	< 0.01	0.01	0.01	0.01*[f] (tentative)
Swine MRLs are not required since the trigger value for dietary burden is not exceeded					
Poultry (all diets) and Poultry (layer only) MRLs are not required since the trigger value for dietary burden is not exceeded					

STMR: supervised trials median residue; PF: processing factor; bw: body weight; MRL: maximum residue level.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): As the mean residue levels were not reported for tissues and eggs (minor deficiency), the mean residue level for milk and the highest residue levels for eggs and tissues were recalculated at the 1N rate for the median dietary burden.
(b): The mean residue level in milk and the highest residue levels in eggs and tissues were recalculated at the 1N rate for the maximum dietary burden.
(c): Closest feeding level and N dose rate related to the maximum dietary burden.
(d): Highest residue level from day 1 to day 28 (daily mean of 3 cows).
(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep.
(f): MRL proposal is tentative because storage temperature of samples should be clarified and a fully validated analytical method for enforcement in all animal commodities is still required.

B.3. Consumer risk assessment

B.3.1. Consumer risk assessment without consideration of the existing CXLs

ADI	0.01 mg/kg bw per day (EFSA, 2010)
Highest IEDI, according to EFSA PRIMo	42.9% ADI (FR, all population)
Assumptions made for the calculations	The calculation is based on the median residue levels in the raw agricultural commodities, except for citrus fruits, where the tentative peeling factor was applied For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation
ARfD	0.05 mg/kg bw (EFSA, 2010)
Highest IESTI, according to EFSA PRIMo	94% ARfD (apples)
Assumptions made for the calculations	The calculation is based on the highest residue levels in the raw agricultural commodities, except for citrus fruits, where the tentative peeling factor was applied For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation

B.4. Proposed MRLs

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: pyridaben					
0110010	Grapefruits	0.5	–	0.3	Recommended[d]
0110020	Oranges	0.5	–	0.3	Recommended[d]
0110030	Lemons	0.5	–	0.3	Recommended[d]
0110040	Limes	0.5	–	0.3	Recommended[d]
0110050	Mandarins	0.5	–	0.3	Recommended[d]
0130010	Apples	0.5	–	0.9	Further consideration needed[b]
0130020	Pears	0.5	–	0.9	Further consideration needed[b]
0130030	Quinces	0.5	–	0.9	Further consideration needed[b]
0130040	Medlars	0.5	–	0.9	Further consideration needed[b]
0130050	Loquats	0.5	–	0.9	Further consideration needed[b]
0140010	Apricots	0.5	–	0.3	Further consideration needed[b]
0140030	Peaches	0.5	–	0.3	Further consideration needed[b]
0140040	Plums	0.5	–	0.5	Further consideration needed[c]
0151010	Table grapes	0.5	–	0.5	Further consideration needed[c]
0151020	Wine grapes	1.0	–	1.0	Further consideration needed[c]
0152000	Strawberries	1.0	–	0.9	Recommended[d]
0154030	Currants	0.5	–	0.5	Further consideration needed[c]
0154040	Gooseberries	0.5	–	0.5	Further consideration needed[c]
0231010	Tomatoes	0.3	–	0.05*	Further consideration needed[b]
0231020	Sweet peppers	0.5	–	0.5	Further consideration needed[c]
0231030	Aubergines	0.2	–	0.05*	Further consideration needed[b]
0232010	Cucumbers	0.15	–	0.15	Recommended[d]
0232020	Gherkins	0.15	–	0.15	Recommended[d]

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
0232030	Courgettes	0.15	–	0.15	Recommended[d]
0260010	Beans with pods	0.5	–	0.2	Further consideration needed[b]
1012010	Bovine muscle	0.02*	–	0.05*	Further consideration needed[b]
1012020	Bovine fat tissue	0.02*	–	0.05*	Further consideration needed[b]
1012030	Bovine liver	0.02*	–	0.05*	Further consideration needed[b]
1012040	Bovine kidney	0.02*	–	0.05*	Further consideration needed[b]
1013010	Sheep muscle	0.02*	–	0.05*	Further consideration needed[b]
1013020	Sheep fat tissue	0.02*	–	0.05*	Further consideration needed[b]
1013030	Sheep liver	0.02*	–	0.05*	Further consideration needed[b]
1013040	Sheep kidney	0.02*	–	0.05*	Further consideration needed[b]
1014010	Goat muscle	0.02*	–	0.05*	Further consideration needed[b]
1014020	Goat fat tissue	0.02*	–	0.05*	Further consideration needed[b]
1014030	Goat liver	0.02*	–	0.05*	Further consideration needed[b]
1014040	Goat kidney	0.02*	–	0.05*	Further consideration needed[b]
1015010	Equine muscle	0.02*	–	0.05*	Further consideration needed[b]
1015020	Equine fat tissue	0.02*	–	0.05*	Further consideration needed[b]
1015030	Equine liver	0.02*	–	0.05*	Further consideration needed[b]
1015040	Equine kidney	0.02*	–	0.05*	Further consideration needed[b]
1020010	Cattle milk	0.02*	–	0.01*	Further consideration needed[b]
1020020	Sheep milk	0.02*	–	0.01*	Further consideration needed[b]
1020030	Goat milk	0.02*	–	0.01*	Further consideration needed[b]
1020040	Horse milk	0.02*	–	0.01*	Further consideration needed[b]
Other commodities of plant and animal origin	Regulation (EC) No 149/2008	–	–	–	Further consideration needed[e]

MRL: maximum residue level; CXL: Codex maximum residue limit.
*: Indicates that the MRL is set/proposed at the limit of quantification. (F): Residue is fat soluble.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).
(c): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).
(d): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).
(e): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo(EU)

Pyridaben			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):	0.05	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.05
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
4	43
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
42.9	FR all population	40.0	Wine grapes	0.6	Apples	0.5	Table grapes	0.8
29.9	PT General population	24.9	Wine grapes	1.4	Table grapes	1.3	Apples	0.5
29.1	WHO Cluster diet B	17.9	Wine grapes	2.5	Peppers	1.7	Table grapes	2.8
28.4	DE child	15.1	Apples	6.3	Table grapes	1.5	Peppers	2.4
21.1	WHO cluster diet E	16.1	Wine grapes	1.1	Apples	0.8	Table grapes	1.1
20.8	IE adult	12.5	Wine grapes	1.6	Plums	1.3	Table grapes	1.3
19.0	NL child	7.9	Apples	3.8	Table grapes	2.9	Milk and cream	4.2
17.5	DK adult	13.9	Wine grapes	1.0	Apples	0.5	Milk and cream	1.1
12.9	UK Adult	10.8	Wine grapes	0.5	Apples	0.3	Milk and cream	0.6
11.6	NL general	6.3	Wine grapes	1.5	Apples	1.1	Table grapes	1.4
11.5	FR toddler	4.0	Milk and cream	3.3	Apples	1.0	Table grapes	5.2
11.0	UK vegetarian	8.1	Wine grapes	0.7	Apples	0.4	Peppers	0.7
9.8	WHO Cluster diet F	6.0	Wine grapes	0.8	Apples	0.6	Table grapes	1.3
8.8	DK child	2.9	Apples	1.3	Milk and cream	1.1	Peppers	1.6
8.7	WHO cluster diet D	3.6	Wine grapes	0.9	Table grapes	0.8	Apples	1.5
8.6	ES adult	4.2	Wine grapes	1.0	Apples	0.8	Peppers	1.5
8.5	FR infant	3.1	Apples	2.6	Milk and cream	0.5	Strawberries	3.0
7.9	UK Toddler	2.1	Apples	2.1	Milk and cream	1.2	Table grapes	2.6
7.7	WHO regional European diet	2.3	Wine grapes	0.9	Peppers	0.8	Apples	1.7
7.6	UK Infant	3.9	Milk and cream	2.0	Apples	0.3	Currants (red, black and white)	4.2
6.6	PL general population	2.6	Apples	1.6	Table grapes	0.9	Plums	0.5
6.2	ES child	1.4	Apples	1.3	Milk and cream	0.7	Bovine: Meat	2.7
5.5	SE general population 90th percentile	1.3	Apples	1.2	Milk and cream	0.9	Peppers	1.8
5.5	FI adult	3.1	Wine grapes	0.6	Milk and cream	0.5	Apples	0.9
4.1	IT kids/toddler	1.1	Apples	0.7	Tomatoes	0.5	Table grapes	0.8
4.1	LT adult	2.3	Apples	0.4	Milk and cream	0.3	Tomatoes	0.9
4.0	IT adult	1.0	Apples	0.7	Table grapes	0.6	Tomatoes	0.7

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of pyridaben is unlikely to present a public health concern.

Acute risk assessment /children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

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

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

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

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
94.0	Apples	0.48 / -	69.3	Apples	0.48 / -	47.4	Wine grapes	1 / -	47.4	Wine grapes	1 / -
87.4	Pears	0.48 / -	65.5	Table grapes	0.5 / -	31.7	Table grapes	0.5 / -	31.7	Table grapes	0.5 / -
65.5	Table grapes	0.5 / -	62.9	Pears	0.48 / -	21.5	Apples	0.48 / -	17.9	Apples	0.48 / -
63.0	Peppers	0.5 / -	45.0	Peppers	0.5 / -	20.6	Pears	0.48 / -	15.8	Pears	0.48 / -
32.9	Plums	0.5 / -	26.7	Plums	0.5 / -	16.3	Peppers	0.5 / -	11.7	Peppers	0.5 / -
No of critical MRLs (IESTI 1)		---				**No of critical MRLs (IESTI 2)**		---			

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						No of commodities for which ARfD/ADI is exceeded: ---					
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
65.8	Grape juice	1 / -				7.7	Wine	1 / -			
48.9	Apple juice	0.48 / -				6.3	Apple juice	0.48 / -			
16.8	Pear juice	0.48 / -				1.1	Quince jelly	0.48 / -			
13.9	Plums juice	0.5 / -				0.8	Raisins	1 / -			
10.1	Cuurant juice	0.5 / -				0.6	Peach preserved with	0.15 / -			

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

**) pTMRL: provisional temporary MRL.

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

Conclusion:

For pyridaben, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

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

STMR: supervised trials median residue; PF: processing factor.
(a): For apple, pomace, wet, in the absence of a processing factor supported by data, a default processing factor of 5 was included in the calculation to consider the potential concentration of residues in these commodities.

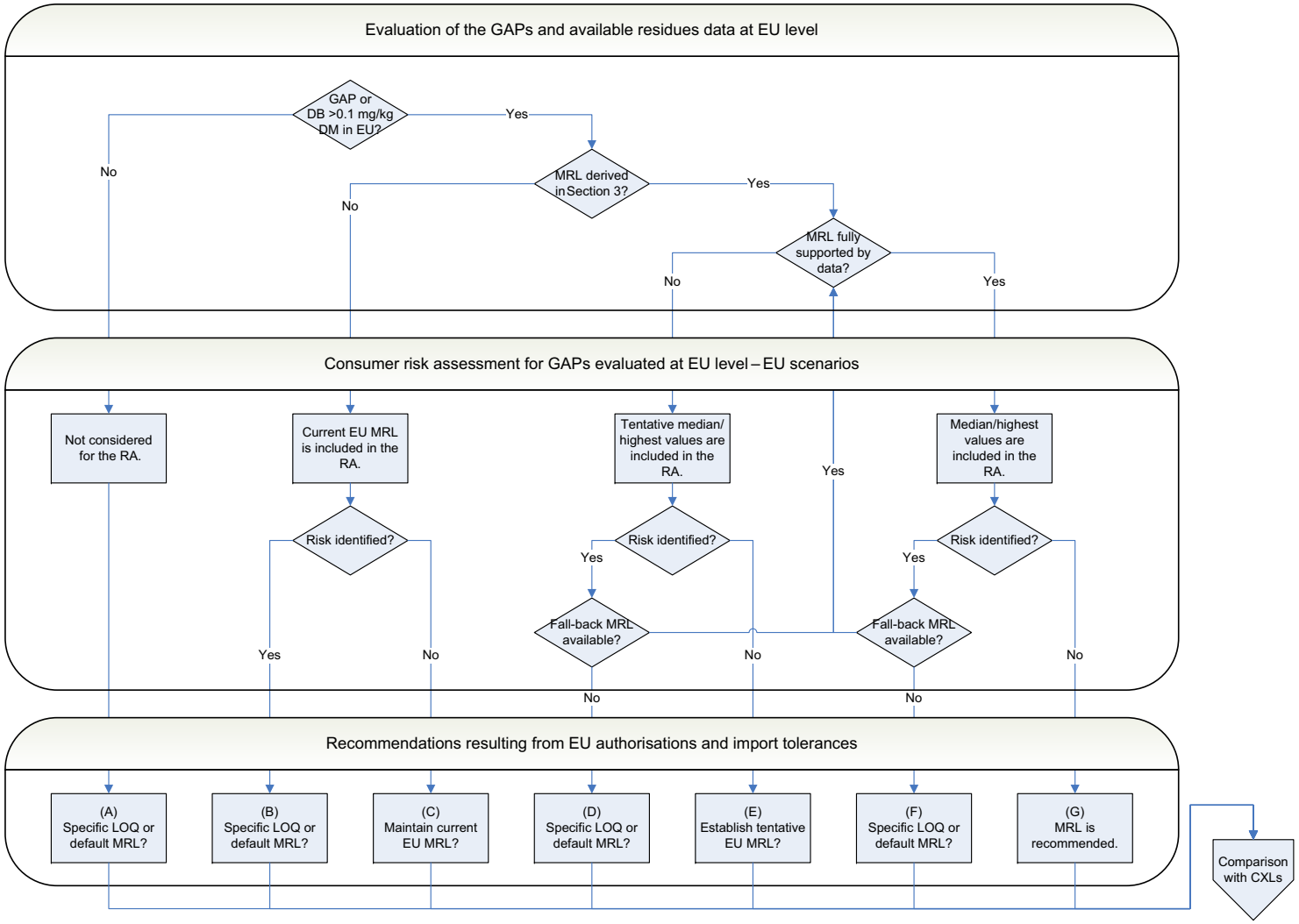
D.2. Consumer risk assessment

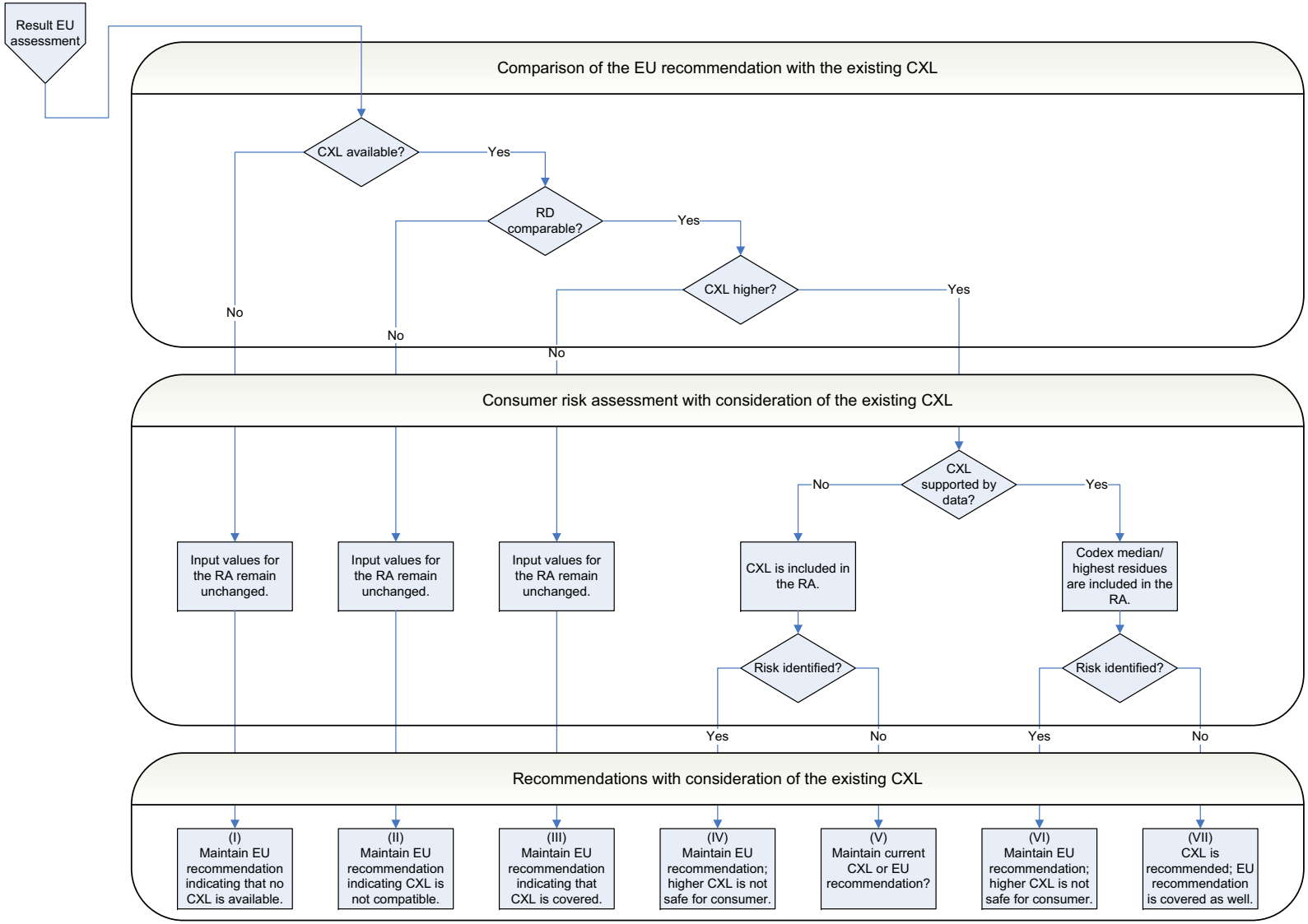
Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk **assessment residue definition: pyridaben**				
Grapefruits	0.01	STMR × PF (tentative)	0.02	HR × PF (tentative)
Oranges	0.01	STMR × PF (tentative)	0.02	HR × PF (tentative)
Lemons	0.01	STMR × PF (tentative)	0.02	HR × PF (tentative)
Limes	0.01	STMR × PF (tentative)	0.02	HR × PF (tentative)
Mandarins	0.01	STMR × PF (tentative)	0.02	HR × PF (tentative)
Apples	0.13	STMR (tentative)	0.48	HR (tentative)
Pears	0.13	STMR (tentative)	0.48	HR (tentative)
Quinces	0.13	STMR (tentative)	0.48	HR (tentative)
Medlar	0.13	STMR (tentative)	0.48	HR (tentative)
Loquats	0.13	STMR (tentative)	0.48	HR (tentative)
Apricots	0.07	STMR (tentative)	0.15	HR (tentative)
Peaches	0.07	STMR (tentative)	0.15	HR (tentative)
Plums	0.50	EU MRL (tentative)	0.50	EU MRL (tentative)
Table grapes	0.50	EU MRL (tentative)	0.50	EU MRL (tentative)
Wine grapes	1.00	EU MRL (tentative)	1.00	EU MRL (tentative)
Strawberries	0.11	STMR	0.53	HR
Currants	0.50	EU MRL (tentative)	0.50	EU MRL (tentative)
Gooseberries	0.50	EU MRL (tentative)	0.50	EU MRL (tentative)
Tomatoes	0.05*	STMR (tentative)	0.05*	HR (tentative)
Sweet peppers/bell peppers	0.50	EU MRL (tentative)	0.50	EU MRL (tentative)
Aubergines/eggplants	0.05*	STMR (tentative)	0.05*	HR (tentative)
Cucumbers	0.06	STMR (tentative)	0.10	HR (tentative)
Gherkins	0.06	STMR (tentative)	0.10	HR (tentative)
Courgettes	0.06	STMR (tentative)	0.10	HR (tentative)
Beans (with pods)	0.06	STMR (tentative)	0.10	HR (tentative)
Bovine meat	0.05*	0.8 × STMR muscle + 0.2 × STMR fat (tentative)	0.05*	0.8 × HR muscle + 0.2 × HR fat (tentative)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Bovine fat tissue	0.05*	STMR (tentative)	0.05*	HR (tentative)
Bovine liver	0.05*	STMR (tentative)	0.05*	HR (tentative)
Bovine kidney	0.05*	STMR (tentative)	0.05*	HR (tentative)
Sheep meat	0.05*	0.8 × STMR muscle + 0.2 × STMR fat (tentative)	0.05*	0.8 × HR muscle + 0.2 × HR fat (tentative)
Sheep fat tissue	0.05*	STMR (tentative)	0.05*	HR (tentative)
Sheep liver	0.05*	STMR (tentative)	0.05*	HR (tentative)
Sheep kidney	0.05*	STMR (tentative)	0.05*	HR (tentative)
Goat meat	0.05*	0.8 × STMR muscle + 0.2 × STMR fat (tentative)	0.05*	0.8 × HR muscle + 0.2 × HR fat (tentative)
Goat fat tissue	0.05*	STMR (tentative)	0.05*	HR (tentative)
Goat liver	0.05*	STMR (tentative)	0.05*	HR (tentative)
Goat kidney	0.05*	STMR (tentative)	0.05*	HR (tentative)
Equine meat	0.05*	0.8 × STMR muscle + 0.2 × STMR fat (tentative)	0.05*	0.8 × HR muscle + 0.2 × HR fat (tentative)
Equine fat tissue	0.05*	STMR (tentative)	0.05*	HR (tentative)
Equine liver	0.05*	STMR (tentative)	0.05*	HR (tentative)
Equine kidney	0.05*	STMR (tentative)	0.05*	HR (tentative)
Cattle milk	0.01*	STMR (tentative)	0.01*	HR (tentative)
Sheep milk	0.01*	STMR (tentative)	0.01*	HR (tentative)
Goat milk	0.01*	STMR (tentative)	0.01*	HR (tentative)
Horse milk	0.01*	STMR (tentative)	0.01*	HR (tentative)

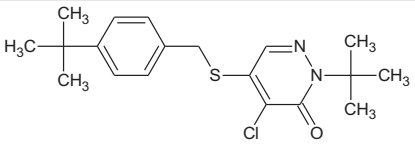
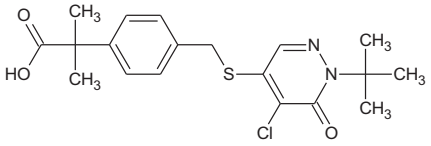
STMR: supervised trials median residue; PF: processing factor; HR: highest residue; MRL: maximum residue level.
*: Indicates that the input value is proposed at the limit of quantification.

Appendix E – Decision tree for deriving MRL recommendations




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

Appendix F – Used compound codes

Code/trivial name	Chemical name/SMILES notation	Structural formula
Pyridaben	2-*tert*-butyl-5-(4-*tert*-butylbenzylthio)-4-chlorpyrididazin-3(2*H*)-one CC(C)(C)N2N=CC(SCc1ccc(cc1)C(C)(C)C)=C(Cl)C2=O	
PB-7	2-(4-{[(1-*tert*-butyl-5-chloro-6-oxo-1,6-dihydropyridazin-4-yl)thio]methyl}phenyl)-2-methylpropanoic acid CC(C)(C)N2N=CC(SCc1ccc(cc1)C(C)(C)C(=O)O)=C(Cl)C2=O	

SMILES: simplified molecular-input line-entry system.