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

European Food Safety Authority (EFSA), Alba Brancato, Daniela Brocca, Chloé De Lentdecker, Zoltan Erdos, Lucien Ferreira, Luna Greco, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Christopher Lythgo, Paula Medina, Ileana Miron, Tunde Molnar, Alexandre Nougadere, Ragnor Pedersen, Hermine Reich, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma, José Tarazona, Anne Theobald, Benedicte Vagenende, Alessia Verani and Laura Villamar-Bouza

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 penconazole. To assess the occurrence of penconazole residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission 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 all MRL proposals derived by EFSA still require further consideration by risk managers.

Keywords: penconazole, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, triazole, fungicide, triazole derivative metabolites

Requestor: European Commission

Question number: EFSA-Q-2010-00197

Correspondence: pesticides.mrl@efsa.europa.eu
Acknowledgement: EFSA wishes to thank the rapporteur Member State RMS for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, 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, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017. Reasoned opinion on the review of the existing maximum residue levels for penconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(6):4853, 56 pp. https://doi.org/10.2903/j.efsa.2017.4853

ISSN: 1831-4732

© 2017 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

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

Penconazole was included in Annex I to Directive 91/414/EEC on 31 May 2010 by Commission Directive 2010/34/EC amending Directive 2009/77/EC, 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 the active substance 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 residue data, EFSA asked Germany, 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 19 May 2016 and finalised on 19 July 2016. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 5 September 2016.

Based on the conclusions derived by EFSA (2008) in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS and Member States, EFSA prepared in March 2017 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 6 April 2017 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

Primary crop metabolism of penconazole was investigated in fruit crops (apples and tomatoes) upon foliar treatment. The metabolism in rotational crops was investigated in root and tuber vegetables (radish), leafy vegetables (lettuce) and cereals (wheat). On the basis of the available metabolism studies in primary and rotational crops, the peer review agreed to establish the residue definition for enforcement as parent compound only. For risk assessment, the residue definition was set as the sum of penconazole and free and conjugated CGA 132465, CGA 190503 and CGA 127841, expressed as penconazole. A conversion factor (CF) of 6 from enforcement to risk assessment was set as the sum of penconazole and free and conjugated CGA 132465, CGA 190503 and CGA 127841, expressed as penconazole. A conversion factor (CF) of 6 from enforcement to risk assessment was established on the basis of the metabolism data and available processing studies analysing simultaneously for penconazole and all metabolites containing the dichlorbenzoic acid moiety.

In the present review, EFSA is of the opinion that, according to the results of the metabolism studies, penconazole only cannot be considered a sufficient marker for enforcement. Moreover, available metabolism studies are underdosed compared to the most critical Good Agricultural Practices (cGAPs) authorised in the European Union (EU).

For the time being, in order to perform at least a tentative assessment, EFSA considered the residue definitions and the CF for risk assessment as derived during the peer review. For processed commodities and for rotational crops, the same residue definition as for raw agricultural commodities is tentatively proposed. An analytical method for the enforcement of the proposed residue definition at the limit of quantification (LOQ) of 0.01 mg/kg in all matrices is available.

The proposed tentative residue definitions are only limited to the fruits crops. Therefore, for globe artichokes (leafy vegetables) and fresh peas (pulses), it was not possible to derive even tentative residue definitions and the existing uses on these crops could not be assessed by EFSA.

Regarding the magnitude of residues, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for almonds, hazelnuts, walnuts, peas with pods and peas without pods where the available data were insufficient to derive tentative MRLs. Considering that on the basis of the available metabolism data only tentative residue definitions could be proposed, all the derived MRL and risk assessment values should be considered tentative only.

According to the results from the confined rotational crop studies, it was concluded that, with the possible exception of the triazole metabolites, no significant residues are expected to occur in rotational crops provided that penconazole is applied according to the GAPs considered in this review.

Penconazole is authorised for use on apples and apples pomace might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock and the dietary burdens calculated for cattle (all) were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). However, since metabolism and livestock feeding studies are not available, it was not possible to derive residue definitions and MRL proposals for cattle tissues.
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. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL multiplied by the tentative CF of 6 from enforcement to risk assessment, for an indicative calculation. Since studies addressing the metabolism in leafy vegetables, in pulses and oilseeds and in livestock are not available, it was not possible to include in the calculation the existing MRLs for globe artichokes, fresh peas, bovine and poultry tissues, milk and eggs. For melons, watermelons and pumpkins, EFSA also considered the peeling factor as derived in the framework of this review. The highest chronic exposure was calculated for German children, representing 8.7% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for table grapes, representing 20% of the acute reference dose (ARfD).

Apart from the MRLs evaluated in the framework of this review, internationally recommended codex maximum residue limits (CXLs) have also been established for penconazole. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. A different residue definition for risk assessment including parent compound only has been established by the JMPR. Therefore, to cover the possible contribution of the metabolites included in the residue definition, the tentative CF of 6 has been considered in the risk assessment. Since studies addressing the metabolism in leafy vegetables and in livestock are not available, it was not possible to include in the calculation the existing CXLs for hops, bovine and poultry tissues, milk and eggs. Considering the data gaps identified in the previous sections, all CXLs should be considered as tentative only. The highest chronic exposure was calculated for German child, representing 16% of the ADI, and the highest acute exposure was calculated for table grapes, representing 20% of the ARfD.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism. Considering, however, that toxicological studies have been carried out with the racemic mixture (EFSA, 2008), a change of isomer ratios in the residue might, in the worst case situation, lead to a duplication of the toxicological burden of the residue. Since the exposure calculations represent less than 50% of the ADI or ARfD, EFSA concludes that the potential change of isomer ratios in the final residue will not be of concern for the authorised uses reported in the framework of this review. In case future uses of penconazole would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

EFSA emphasises that the above assessment does not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Directive 91/414/EEC have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available.
Table of contents

Abstract .......................................................................................................................................................... 1
Summary .................................................................................................................................................. 3
Background ........................................................................................................................................... 6
Terms of Reference ............................................................................................................................... 7
The active substance and its use pattern .............................................................................................. 7
Assessment ............................................................................................................................................. 8
1. Residues in plants ............................................................................................................................ 8
   1.1. Nature of residues and methods of analysis in plants .............................................................. 8
      1.1.1. Nature of residues in primary crops ..................................................................................... 8
      1.1.2. Nature of residues in rotational crops .................................................................................... 8
      1.1.3. Nature of residues in processed commodities ........................................................................ 9
      1.1.4. Methods of analysis in plants .................................................................................................. 9
      1.1.5. Stability of residues in plants .................................................................................................. 9
      1.1.6. Proposed residue definitions .................................................................................................. 9
      1.2. Magnitude of residues in plants .............................................................................................. 10
         1.2.1. Magnitude of residues in primary crops ................................................................................. 10
         1.2.2. Magnitude of residues in rotational crops ............................................................................... 12
         1.2.3. Magnitude of residues in processed commodities ............................................................... 12
         1.2.4. Proposed MRLs .................................................................................................................... 12
2. Residues in livestock .......................................................................................................................... 12
3. Consumer risk assessment ................................................................................................................ 12
   3.1. Consumer risk assessment without consideration of the existing CXLs ..................................... 13
   3.2. Consumer risk assessment with consideration of the existing CXLs .......................................... 13
Conclusions ........................................................................................................................................... 14
Recommendations ............................................................................................................................... 15
References ............................................................................................................................................. 17
Abbreviations ........................................................................................................................................ 19
Appendix A – Summary of authorised uses considered for the review of MRLs ................................... 21
Appendix B – List of end points ............................................................................................................ 34
Appendix C – Pesticide Residue Intake Model (PRIMo) .................................................................... 47
Appendix D – Input values for the exposure calculations ................................................................... 51
Appendix E – Decision tree for deriving MRL recommendations ...................................................... 54
Appendix F – Used compound codes ................................................................................................. 56
Review of the existing MRLs for penconazole

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 penconazole was included in Annex I to Council Directive 91/414/EEC on 31 May 2010 by means of Commission Directive 2010/34/EC\(^3\) amending Directive 2009/77/EC\(^4\) and has been deemed to be approved under Regulation (EC) No 1107/2009\(^5\), in accordance with Commission Implementing Regulation (EU) No 540/2011\(^6\), as amended by Commission Implementing Regulation (EU) No 541/2011\(^7\), 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 European Union (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.

Germany, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for penconazole and to prepare a supporting evaluation report (Germany, 2012). The PROFile and the supporting evaluation report were submitted to EFSA on 13 April 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 19 May 2016 and finalised on 19 July 2016. Additional evaluation reports were submitted by Austria, the Czech Republic, France, Germany, Greece, Hungary, Italy, Portugal, Spain, the United Kingdom and the European Union Reference Laboratories for Pesticide Residues (EURLs) (Austria, 2016; Czech Republic, 2016a,b; EURLs, 2016; France, 2016; Germany, 2016; Greece, 2016; Hungary, 2016; Italy, 2016; Portugal, 2016; Spain, 2016; United Kingdom, 2016) and, after having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 6 September 2016. Further clarifications were sought from Member States via a written procedure in September 2016.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission [CAC; codex maximum residue limit (CXLs)] and...
the additional information provided by the Member States, EFSA prepared in March 2017 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 6 April 2017 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation reports submitted by the RMS (Germany, 2012, 2016) and the evaluation reports submitted by Austria, the Czech Republic, France, Germany, Greece, Hungary, Italy, Portugal, Spain, the United Kingdom and the EURLs (Austria, 2016; Czech Republic, 2016a,b; EURLs, 2016; France, 2016; Germany, 2016; Greece, 2016; Hungary, 2016; Italy, 2016; Portugal, 2016; Spain, 2016; United Kingdom, 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, 2016) and the Member States consultation report (EFSA, 2017). 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(EU) 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**

Penconazole is the ISO common name for \((RS)\ 1-[2-(2,4-dichloro-phenyl)-phenyl]-1H-[1,2,4] triazole\ (IUPAC).

Penconazole belongs to the group of triazole compounds which are used as a fungicide. It causes inhibition of C-14-demethylase in sterol biosynthesis. It is a systemic preventative and curative fungicide. Penconazole is used as foliar application for the control of fungal disease in a range of crops.

The chemical structure of the active substance and its main metabolites are reported in Appendix F. Penconazole was evaluated in the framework of Directive 91/414/EEC with Germany designated as RMS. The representative uses supported for the peer review process were as a fungicide on grapes (field) and cucurbits (field and glasshouse). Following the peer review, which was carried out by EFSA (2008), a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2009/77/EC, which entered into force on 1 January 2010. The restriction to greenhouses uses laid down in the approval Directive 2009/77/EC was amended with the extension of the use in the Directive 2010/34/EU. According to Regulation (EU) No 540/2011, penconazole is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as fungicides only.

The EU MRLs for penconazole are established in Annexes II and IIIB of Regulation (EC) No 396/2005 and a CXL for penconazole is also established by the CAC. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided in Table 1.

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

| Procedure | Legal implementation | Remarks |
|-----------|----------------------|---------|
| Modification of the MRLs under Article 10 of Reg. 396/2005 (EFSA, 2014) | (EC) No (EU) 2015/401 | Blackberries and raspberries |

For the purpose of this MRL review, the critical uses of penconazole 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 GAPs for penconazole 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 (Germany, 2012), the draft assessment report (DAR) and its final addendum prepared under Council Directive 91/414/EEC (Germany, 2007, 2008), the conclusion on the peer review of the pesticide risk assessment of the active substance penconazole (EFSA, 2008), the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 1992, 1995), the previous reasoned opinion on penconazole (EFSA, 2014) as well as the evaluation reports submitted during the completeness check (Austria, 2016; Czech Republic, 2016a,b; EURoLs, 2016; France, 2016; Germany, 2016; Greece, 2016; Hungary, 2016; Italy, 2016; Portugal, 2016; Spain, 2016; United Kingdom, 2016). 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 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 penconazole in primary crops was investigated during the peer review on fruits and fruiting vegetables after foliar applications. Studies were conducted on tomatoes (triazole and phenyl labels) and apples (triazole label) (Germany, 2007). In apple and tomato fruits treated at 0.6N and at 0.5N, respectively, compared to most critical GAPs (cGAPs) approved in the EU, the metabolism of penconazole showed to be similar with low residues in absolute amounts. Penconazole represented 12% of the total radioactive residue (TRR) (0.011 mg/kg) in apples and up to 19% of the TRR (0.013 mg/kg) in tomatoes 7 days after last application. A major portion of the total residues, especially in tomato fruits (67% of the TRR corresponding to 0.047 mg/kg), was represented by the hydroxylated metabolites CGA 132465, CGA 190503 and CGA 127841, which were present in the free state or as glucoside conjugates. In the 14C-triazole labelled studies, the triazole derivative metabolites (TDMs) CGA 131013 (triazolyl alanine), CGA 205369 (triazolyl lactic acid) and CGA 142856 (triazolyl acetic acid) represented, respectively, up to 23%, 6.7% and 1% of the TTR. In tomatoes and apples leaves, most of the TRR was represented by metabolites CGA 132465, CGA 190503 and CGA 127841 with conjugated CGA 132465 representing up to 67–73% TTR [tomatoes leaves taken 40 days after treatment (DAT)] while parent compound accounted for a maximum of 9% TTR (EFSA, 2008). A substudy on tomatoes with a higher application rate was performed in parallel to allow metabolites identification but the detailed results from this study were not reported in the DAR.

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

Penconazole is authorised for use on crops that may be grown in rotation. Moreover, according to the field studies evaluated during the peer review, the DT50 values in soil for this active substance ranged from 220 to 380 days exceeding the trigger value of 100 days (EFSA, 2008). Therefore, additional investigation on the metabolism in rotational crops is needed.

Two confined rotational crop studies with radish, lettuce and wheat planted 32, 126 and 358 days after bare soil application of phenyl and triazole labelled penconazole at 0.24 kg/ha were evaluated during the peer review (Germany, 2007).

Total radioactive residues in lettuce and radish roots and tops were below or at 0.08 mg/kg at all the intervals. The radioactive residues in wheat were considerably higher, especially after 14C-triazolyl treatments (up to 3.28 mg/kg, 1.39 mg/kg and 0.23 mg/kg in grain, straw and forage, respectively).

---

8 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.
The metabolites identified in the rotational crop studies were the same as determined in the metabolism studies on primary crops. In all crop parts and at all investigated plant back intervals, penconazole was found only in trace or at very low amounts (up to 3% TRR corresponding to 0.011 mg/kg). The TDMs CGA 131013 (triazolyl alanine), CGA 205369 (triazolyl lactic acid) and CGA 142856 (triazolyl acetic acid) represented the main metabolites in the study performed with the triazole label (up to 95% TRR in wheat grain) while metabolite CGA 132465 was the main compound observed in the phenyl label study (up to 20% TRR in wheat forage).

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of penconazole was investigated in studies performed at three test conditions representing pasteurisation, baking/brewing/boiling and sterilisation (20 min at 90°C, pH 4; 60 min at 100°C pH 5; 20 min at 120°C, pH 6). The peer review concluded that penconazole is hydrolytically stable under the representative processing conditions (EFSA, 2008).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of penconazole residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (Germany, 2007). A gas chromatography-mass spectrometric detection (GC-MSD) method was considered suitable for the enforcement of penconazole at the limit of quantification (LOQ) of 0.01 mg/kg in high water content (lettuce, apple), high oil content (sunflower seeds) and dry commodities (wheat grain). A LC/LC–MS/MS method was also evaluated and considered suitable for confirmation at the LOQ of 0.01 mg/kg in high water content (cucumber, melons, peppers, tomatoes) and acidic commodities (strawberries, grapes) (EFSA, 2008).

According to the RMS, an LOQ of 0.01 mg/kg is achievable in all matrices by using the multiresidue QuEChERS methods coupled with LC–MS/MS or gas chromatography with tandem mass spectrometry (GC–MS/MS) described in the European Standard EN 15662:2008 (Germany, 2012). The same information was also provided by the EURLs during the completeness check (EURLs, 2016).

1.1.5. Stability of residues in plants

The storage stability of penconazole in primary crops was investigated in the DAR under Directive 91/414/EEC (Germany, 2008). Residues of penconazole were found to be stable at ≤ –20°C for up to 16 months in matrices with high water (apples) and high acid (grapes) content (EFSA, 2008). A study investigating the storage stability in high oil content (relevant for the uses on almonds, hazelnuts/cobnuts and walnuts) is not available and is still required.

Studies investigating the storage stability of the relevant metabolites observed in the metabolism studies are not available and are still required.

1.1.6. Proposed residue definitions

On the basis of the available metabolism studies in primary and rotational crops, the peer review agreed to establish the residue definition for enforcement as parent compound only. For risk assessment the residue definition was set as the sum of penconazole and free and conjugated CGA 132465, CGA 190503 and CGA 127841, expressed as penconazole. CGA 127841 was a major rat metabolite (20–40% of the TRR), whereas the other two metabolites (CGA 132465 and CGA 190503) were not found in rat metabolism. Considering their structural similarity to penconazole and to other rat metabolites, the peer review concluded that their toxicity is covered by the toxicity of the parent compound. A conversion factor (CF) of 6 from enforcement to risk assessment was established not only on the basis of the metabolism data but also considering available processing studies analysing simultaneously for penconazole and all metabolites containing the dichlorbenzoic acid (DCBA) moiety. This was considered a worst case CF as other metabolites not included in the residue definition have been measured by this method. The proposed residue definitions and the conversion factor were limited to fruits and fruiting vegetables only (EFSA, 2008).

In the present review, EFSA is of the opinion that, according to the results of the metabolism studies, penconazole only cannot be considered a sufficient marker for enforcement. Moreover, available metabolism studies are underdosed compared to the most cGAPs authorised in the EU. Therefore, a metabolism study reflecting the most cGAPs reported in this review (or detailed results from the substudy on tomatoes performed at higher dose rate) allowing to conclude on the metabolites to be included in the residue definition for enforcement, is still required.
For the time being, in order to perform at least a tentative assessment, EFSA will consider the residue definitions and the CF for risk assessment as derived during the peer review. Considering that the active substance is a racemic mixture of two enantiomers, EFSA also proposes to modify the wording of the residue definition for enforcement as following: penconazole (sum of all constituent isomers). An analytical method for the enforcement of the propose residue definition at the LOQ of 0.01 mg/kg in all matrices is available.

Although some information on the metabolism in leafy vegetables can be derived from the metabolism pattern observed in apples and tomatoes leaves, the proposed tentative residue definitions are only limited to the fruits crops. Studies investigating the metabolism in leafy vegetables and in pulses and oilseeds (relevant for the existing uses on globe artichokes and fresh peas) are missing and are still required. Therefore for globe artichokes and fresh peas it was not possible to derive even tentative residue definitions and the existing uses on these crops could not be assessed by EFSA.

For processed commodities and for rotational crops, the same residue definition as for raw agricultural commodities (RAC) is tentatively proposed.

EFSA emphasises that the above residue definitions do not yet take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Directive 91/414/EEC have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available.

In addition, EFSA underlines that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of penconazole and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

### 1.2. Magnitude of residues in plants
#### 1.2.1. Magnitude of residues in primary crops

To assess the magnitude of penconazole residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Germany, 2012), including residue trials evaluated in the framework of a previous MRL application (EFSA, 2014) and additional data submitted during the completeness check (Czech Republic, 2016a,b; France, 2016; Germany, 2016; Italy, 2016; Portugal, 2016). All residue trial samples considered in this framework were analysed for parent compound only and stored in compliance with the demonstrated storage conditions. Decline of residues during storage of the trial samples is therefore not expected. Metabolites included in the residue definition for risk assessment were not analysed in the residue trials. Therefore, the lack of information on the demonstrated storage stability period for these metabolites (see Section 1.1.5) is not considered relevant for the derived MRL and risk assessment values.

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).

Residue trials are not available to support the authorisations on almonds, hazelnuts, walnuts, peas with pods and peas without pods. Therefore, MRL or risk assessment values for these crops could not be derived by EFSA and the following data gaps were identified:

- **Almonds, hazelnuts and walnuts:** Six residue trials in total on two representatives of the group tree nuts compliant with the northern outdoor GAP are required.
- **Peas with and without pods:** Four residue trials supporting the southern outdoor GAP for peas with pods and eight residue trials supporting the southern outdoor GAP for peas without pods. It is noted that for these crops a study covering the metabolism in pulses and in oilseeds is also still required.

For globe artichoke, residue trials supporting the southern and the northern outdoor GAPs were available. However, this crop was not covered by a proper metabolism study. Therefore, it was not possible to derive MRL and risk assessment values (see also Section 1.1.6).

For some crops, the available residue trials were not fully compliant with the authorised GAP or the number of residue trials was not compliant with the data requirement, only tentative MRL and risk assessment values could be derived by EFSA and the following data gaps were identified:
• Apples, pears, quinces and medlar: Available residue trials supporting the southern outdoor GAP were all performed according to a more cGAP (3 × 60 g/ha instead of 2 × 25 g/ha). Although tentative MRL could be derived from this data set, eight trials compliant with the southern outdoor GAP are still required.

• Apricots: No residue trials on apricots supporting the southern and the northern outdoor GAPs are available. Although not foreseen in the current guidance document on extrapolation, it is tentatively proposed to extrapolate the data set on peaches, which is derived from overdosed trials (3 × 100 g/ha instead of 3 × 50 g/ha), to apricots. Nevertheless, four trials compliant with the northern outdoor GAP and eight residue trials compliant with the southern outdoor GAP are still required.

• Peaches: Available residue trials supporting the southern and the northern outdoor GAPs were all overdosed (3 × 75–100 g/ha or 2 × 75 g/ha instead of 2–3 × 50 g/ha). Although tentative MRL could be derived from the overdosed trials, four trials compliant with the northern outdoor GAP and eight residue trials compliant with the southern outdoor GAP are still required.

• Table and wine grapes: Available residue trials supporting the northern outdoor and the southern outdoor GAPs were all performed according to more cGAPs (performed with 5 or 6 applications instead of 4 and at 3 × 40 g/ha, PHI: 14 days instead of 2 × 24, PHI: 28 days). Although tentative MRL could be derived from the overdosed trials, eight trials compliant with the northern outdoor GAP and eight residue trials compliant with the southern outdoor GAP are still required.

• Gherkins: Although tentative MRL and risk assessment values can be derived from the indoor data set on cucumber and courgettes performed according to a more cGAP (4 × 50 g/ha instead of 3 × 35 g/ha), four residue trials compliant with the northern outdoor GAP and four residue trials compliant with the indoor GAP are still required.

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

• Loquats: Although MRL and risk assessment values can be derived from the northern data, four trials compliant with the southern outdoor GAP are still required.

• Strawberries: Although MRL and risk assessment values can be derived from the northern data, eight trials compliant with the southern outdoor GAP are still required.

• Raspberries: Although MRL and risk assessment values can be derived from the southern data, four trials compliant with the northern outdoor GAP are still required.

• Currants: Although MRL and risk assessment values can be derived from the northern data, two additional trials compliant with the southern outdoor GAP are still required.

• Tomatoes and aubergines: Although MRL and risk assessment values can be derived from the indoor data, available residue trials supporting the southern outdoor GAP were all performed with four applications instead of two and no residue trials supporting the northern outdoor GAP are available. Since the southern GAP is clearly less critical than the indoor GAP, no additional trials supporting this GAP are required. Nevertheless, eight residue trials compliant with the northern outdoor GAP are still required.

• Sweet peppers: Although MRL and risk assessment values can be derived from the indoor data, four out of the eight residue trials supporting the southern outdoor GAP were performed with four applications instead of two and no residue trials supporting the northern outdoor GAP are available. Since the southern GAP is clearly less critical than the indoor GAP, no additional trials supporting this GAP are required. Nevertheless, eight residue trials compliant with the northern outdoor GAP are still required.

• Cucumbers and courgettes: Although MRL and risk assessment values can be derived from the indoor data, available residue trials supporting the southern outdoor GAP were all performed with four applications instead of two and no residue trials supporting the northern outdoor GAP are available. Since the southern GAP is clearly less critical than the indoor GAP, no additional trials supporting this GAP are required. Nevertheless, eight residue trials compliant with the northern outdoor GAP are still required.

• Cucurbits with inedible peel: Although MRL and risk assessment values can be derived from the indoor data, available residue trials supporting the southern outdoor GAP were all performed with four or three applications instead of two and number of residue trials supporting the northern outdoor GAP are not compliant with the data requirement for these crops. Since the southern GAP is clearly less critical than the indoor GAP, no additional trials
supporting this GAP are required. Nevertheless, four additional residue trials compliant with the northern outdoor GAP are still required.

It is noted that for apples, quinces, medlars, peaches, table and wine grapes, gherkins [northern Europe Union (NEU) and southern European Union (SEU)], apricots (NEU), tomatoes, sweet peppers, aubergines, cucumbers, courgettes, cucurbits with inedible peel and globe artichokes (SEU), strawberries, tomatos, sweet peppers, aubergines, cucurbits with edible and inedible peel (indoor), more critical or different 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

According to the results from the confined rotational crop studies, it can be concluded that, with the possible exception of the triazole metabolites, no significant residues are expected to occur in rotational crops provided that penconazole is applied according to the GAPs considered in this review.

1.2.3. Magnitude of residues in processed commodities

Studies investigating the magnitude of residues in processed commodities of apples (Germany, 2012), grapes (Germany, 2008, 2012) and melons (Germany, 2012; Italy, 2016) were reported. In four trials on grapes, residues were analysed for penconazole and for total residues determined as DCBA and it was possible to derive a CF for risk assessment. In all other studies, residues were analysed for parent compound only and the CF as derived for the raw commodities was tentatively considered for risk assessment. Considering the data gaps identified in Section 1.1.6 and that metabolites CGA 132465, CGA 190503 and CGA 127841 were not analysed in the processing studies, no robust processing factors could be derived. The processing factors reported in Appendix B should therefore be considered as indicative only.

1.2.4. Proposed MRLs

Consequently, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for almonds, hazelnuts, walnuts, peas with pods and peas without pods where the available data were insufficient to derive tentative MRLs. For globe artichoke, residue trials supporting the southern and the northern outdoor GAPs were available. However, this crop was not covered by a proper metabolism study. Therefore, it was not possible to derive MRL and risk assessment values. Considering that on the basis of the available metabolism data only tentative residue definitions could be proposed, all the derived MRL and risk assessment values should be considered tentative only.

2. Residues in livestock

Penconazole is authorised for use on apples and apples pomace might be fed to livestock. Livestock dietary burdens were therefore calculated 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) were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Therefore, the behaviour of residues in ruminants needs to be assessed. However, the metabolism in livestock has not been investigated under the framework of the peer review and metabolism and livestock feeding studies are not available. Therefore, it was not possible to derive residue definitions and MRL proposals for cattle tissues.

A study addressing the metabolism in ruminants and, eventually, livestock feeding studies allowing deriving MRLs and risk assessment values for cattle tissues are therefore still required.

3. Consumer risk assessment

In the framework of this review, only the uses of penconazole reported by the RMS in Appendix A were considered; however, the use of penconazole was previously also assessed by the JMPR (FAO, 1992, 1995). The CXLs, resulting from these assessments by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.
3.1. Consumer risk assessment without consideration of the existing CXLs

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 an MRL in Section 3, EFSA considered the existing EU MRL multiplied by the tentative CF from enforcement to risk assessment as derived in Section 1.1.6, for an indicative calculation. Since studies addressing the metabolism in leafy vegetables, in pulses and oilseeds and in livestock are not available, it was not possible to include in the calculation the existing MRLs for globe artichokes, fresh peas, bovine and poultry tissues, milk and eggs. For melons, watermelons and pumpkins, EFSA also considered the peeling factor that was tentatively derived in Section 1.2.3 and reported in Appendix B.1.2.3. All input values included in the exposure calculations are summarised in Appendix D.

The exposures calculated were compared with the toxicological reference values for penconazole, derived by EFSA (2008) under Directive 91/414/EEC. The highest chronic exposure was calculated for German children, representing 8.7% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for table grapes, representing 20% of the acute reference dose (ARfD). Although major uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

3.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. An overview of the input values used for this exposure calculation is also provided in Appendix D. A different residue definition for risk assessment including parent compound only has been established by the JMPR. Therefore, to cover the possible contribution of the metabolites included in the residue definition, the tentative CF of 6 as derived in Section 1.1.6 has been considered in the risk assessment. Since studies addressing the metabolism in leafy vegetables and in livestock are not available, it was not possible to include in the calculation the existing CXLs for hops, bovine and poultry tissues, milk and eggs. Considering the data gaps identified in the previous sections, all CXLs should be considered as tentative only.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and the exposures calculated were compared with the toxicological reference values derived for penconazole. The highest chronic exposure was calculated for German children, representing 16% of the ADI, and the highest acute exposure was calculated for table grapes, representing 20% of the ARfD. Although major uncertainties remain due to the data gaps identified for these CXLs, this indicative exposure calculation did not indicate a risk to consumers.

It is underlined that penconazole was re-evaluated by the JMPR in 2016 and lower CXLs (covered by the MRLs derived from the EU uses) were proposed for pome fruits, tomatoes and cucumbers. Nevertheless, since these CXLs are still undergoing the approval procedure, they could not be considered in the present review. Therefore, the existing CXLs for pome fruits, tomatoes and cucumbers included in this review may need to be reconsidered following the meeting of the CAC that is expected to take place in July 2017.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism. Considering, however, that toxicological studies have been carried out with the racemic mixture (EFSA, 2008), a change of isomer ratios in the residue might, in the worst case situation, lead to a duplication of the toxicological burden of the residue. Since the exposure calculations represent less than 50% of the ADI or ARfD, EFSA concludes that the potential change of isomer ratios in the final residue will not be of concern for the authorised uses reported in the framework of this review. In case future uses of active substance would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

EFSA emphasises that the above assessment does not yet take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA
Conclusions

Primary crop metabolism of penconazole was investigated in fruit crops (apples and tomatoes) upon foliar treatment. The metabolism in rotational crops was investigated in root and tuber vegetables (radish), leafy vegetables (lettuce) and cereals (wheat). On the basis of the available metabolism studies in primary and rotational crops, the peer review agreed to establish the residue definition for enforcement as parent compound only. For risk assessment, the residue definition was set as the sum of penconazole and free and conjugated CGA 132465, CGA 190503 and CGA 127841, expressed as penconazole. A CF of 6 from enforcement to risk assessment was established on the basis of the metabolism data and available processing studies analysing simultaneously for penconazole and all metabolites containing the DCBA molety.

In the present review, EFSA is of the opinion that, according to the results of the metabolism studies, penconazole only cannot be considered a sufficient marker for enforcement. Moreover available metabolism studies are underdosed compared to the most cGAPs authorised in the EU.

For the time being, in order to perform at least a tentative assessment, EFSA considered the residue definitions and the conversion factor for risk assessment as derived during the peer review. For processed commodities and for rotational crops, the same residue definition as for RAC is tentatively proposed. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all matrices is available.

The proposed tentative residue definitions are only limited to the fruits crops. Therefore, for globe artichokes (leafy vegetables) and fresh peas (pulses), it was not possible to derive even tentative residue definitions and the existing uses on these crops could not be assessed by EFSA.

Regarding the magnitude of residues, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for almonds, hazelnuts, walnuts, peas with pods and peas without pods where the available data were insufficient to derive tentative MRLs. Considering that on the basis of the available metabolism data only tentative residue definitions could be proposed, all the derived MRL and risk assessment values should be considered tentative only.

According to the results from the confined rotational crop studies, it was concluded that, with the possible exception of the triazole metabolites, no significant residues are expected to occur in rotational crops provided that penconazole is applied according to the GAPs considered in this review.

Penconazole is authorised for use on apples and apples pomace might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock and the dietary burdens calculated for cattle (all) were found to exceed the trigger value of 0.1 mg/kg DM. However, since metabolism and livestock feeding studies are not available, it was not possible to derive residue definitions and MRL proposals for cattle tissues.

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. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL multiplied by the tentative CF of 6 from enforcement to risk assessment, for an indicative calculation. Since studies addressing the metabolism in leafy vegetables, in pulses and oilseeds and in livestock are not available, it was not possible to include in the calculation the existing MRLs for globe artichokes, fresh peas, bovine and poultry tissues, milk and eggs. For melons, watermelons and pumpkins, EFSA also considered the peeling factor as derived in the framework of this review. The highest chronic exposure was calculated for German children, representing 8.7% of the ADI, and the highest acute exposure was calculated for table grapes, representing 20% of the ARFD.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for penconazole. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. A different residue definition for risk assessment including parent compound only has been established by the JMPR. Therefore, to cover the possible contribution of the metabolites included in the residue definition, the tentative CF of 6 has been considered in the risk assessment. Since studies addressing the metabolism in leafy vegetables and in livestock are not available, it was not possible to include in the calculation the existing CXLs for hops, bovine and poultry tissues, milk and eggs. Considering the data gaps identified in the previous
sections, all CXLs should be considered as tentative only. The highest chronic exposure was calculated for German child, representing 16% of the ADI, and the highest acute exposure was calculated for table grapes, representing 20% of the ARfD.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism. Considering, however, that toxicological studies have been carried out with the racemic mixture (EFSA, 2008), a change of isomer ratios in the residue might, in the worst case situation, lead to a duplication of the toxicological burden of the residue. Since the exposure calculations represent less than 50% of the ADI or ARfD, EFSA concludes that the potential change of isomer ratios in the final residue will not be of concern for the authorised uses reported in the framework of this review. In case future uses of penconazole would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

EFSA emphasises that the above assessment does not yet take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Directive 91/414/EEC have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available.

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). None of the MRL values listed in the table are recommended for inclusion in Annex II to the Regulation as they are not sufficiently supported by data. In particular, all tentative MRLs need to be confirmed by the following data:

- representative studies investigating the metabolism in leafy vegetables, pulses and oilseeds;
- a representative study investigating the metabolism in fruits and fruiting vegetables or detailed results from the sub-study on tomatoes performed at higher dose rate;
- complete sets of residue trials supporting the authorisations for all crops under assessment, analysing simultaneously for monitoring and risk assessment residue definitions as derived from the required new metabolism data;
- a study investigating the storage stability in high oil content (relevant for the uses on almonds, hazelnuts/cobnuts and walnuts);
- studies investigating the storage stability of the relevant metabolites observed in the metabolism studies;
- a metabolism study on ruminants and, eventually, livestock feeding study allowing to derive MRLs for cattle tissues (data gap relevant for commodities of animal origin and for the authorisations on apples which represent the main contributor to the dietary burden);
- a validated analytical method with its independent laboratory validation (ILV) and a confirmatory method) for enforcement in cattle tissues according to the residue definition as derived from the new ruminants metabolism study.

It is highlighted, however, that some of the MRLs derived result from a CXL or from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not 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 supporting the more critical and the different GAPs authorised in EU on apples, quinces, medlars, peaches, table and wine grapes, gherkins (NEU and SEU), apricots (NEU), tomatoes, sweet peppers, aubergines, cucumbers, courgettes, cucurbits with inedible peel and globe artichokes (SEU), strawberries, tomatoes, sweet peppers, aubergines, cucurbits with edible and inedible 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.

It is noted that the proposed MRLs for pome fruits, tomatoes and cucumbers reported in the table are derived from the existing CXLs. Although no risk for consumer was identified for these CXLs, it is underlined that, following re-evaluation of penconazole by the JMPR in 2016, the corresponding existing CXLs were lowered being covered by the MRLs derived from the existing EU GAPs (apples, pears,
tomatoes and cucumbers) or withdrawn (quinces, medlars and loquats). Nevertheless, since these CXLs are still undergoing the approval procedure, they could not be considered in the present review. Therefore, the existing CXLs for pome fruits, tomatoes and cucumbers included in this review may need to be reconsidered following the meeting of the CAC that is expected to take place in July 2017.

Table 2: Summary table

| Code number(a) | Commodity                          | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                                    |
|----------------|-----------------------------------|-------------------------|----------------------|-------------|--------------------------------------------|
|                | Enforcement residue definition (existing): penconazole (F) |                          |                      |             |                                            |
| 120010         | Almonds                           | 0.05*                   | –                    | 0.05        | Further consideration needed(g)            |
| 120060         | Almonds                           | 0.05*                   | –                    | 0.05        | Further consideration needed(g)            |
| 120110         | Walnuts                           | 0.05*                   | –                    | 0.05        | Further consideration needed(g)            |
| 130010         | Apples                            | 0.2                     | 0.2                  | 0.2         | Further consideration needed(g)            |
| 130020         | Pears                             | 0.2                     | 0.2                  | 0.2         | Further consideration needed(g)            |
| 130030         | Quinces                           | 0.2                     | 0.2                  | 0.2         | Further consideration needed(g)            |
| 130040         | Medlars                           | 0.2                     | 0.2                  | 0.2         | Further consideration needed(g)            |
| 130050         | Loquats/Japanese medlars           | 0.2                     | 0.2                  | 0.2         | Further consideration needed(g)            |
|                | Enforcement residue definition (proposed): penconazole (sum of all constituent isomers) (F) |                          |                      |             |                                            |
| 140010         | Apricots                          | 0.1                     | –                    | 0.08        | Further consideration needed(g)            |
| 140020         | Cherries (sweet)                  | 0.05*                   | –                    | 0.15        | Further consideration needed(g)            |
| 140030         | Peaches                           | 0.1                     | 0.1                  | 0.15        | Further consideration needed(g)            |
| 140040         | Plums                             | 0.05*                   | –                    | 0.09        | Further consideration needed(g)            |
| 151010         | Table grapes                      | 0.2                     | 0.2                  | 0.5         | Further consideration needed(g)            |
| 151020         | Wine grapes                       | 0.2                     | 0.2                  | 0.5         | Further consideration needed(g)            |
| 152000         | Strawberries                      | 0.5                     | 0.1                  | 0.3         | Further consideration needed(g)            |
| 153010         | Blackberries                      | 0.1                     | –                    | 0.1         | Further consideration needed(g)            |
| 153030         | Raspberries (red and yellow)      | 0.1                     | –                    | 0.1         | Further consideration needed(g)            |
| 154030         | Currants (black, red and white)   | 0.5                     | –                    | 0.1         | Further consideration needed(g)            |
| 154040         | Gooseberries (green, red and yellow) | 0.05*                   | –                    | 0.1         | Further consideration needed(g)            |
| 231010         | Tomatoes                          | 0.1                     | 0.2                  | 0.2         | Further consideration needed(g)            |
| 231020         | Sweet peppers/bell peppers        | 0.2                     | –                    | 0.2         | Further consideration needed(g)            |
| 231030         | Aubergines/eggplants              | 0.1                     | –                    | 0.1         | Further consideration needed(g)            |
| 232010         | Cucumbers                         | 0.1                     | 0.1                  | 0.1         | Further consideration needed(g)            |
| 232020         | Gherkins                          | 0.1                     | –                    | 0.06        | Further consideration needed(g)            |
| 232030         | Courgettes                        | 0.1                     | –                    | 0.06        | Further consideration needed(g)            |
| 233010         | Melons                            | 0.1                     | 0.1                  | 0.15        | Further consideration needed(g)            |
| 233020         | Pumpkins                          | 0.1                     | –                    | 0.15        | Further consideration needed(g)            |
| 233030         | Watermelons                       | 0.1                     | –                    | 0.15        | Further consideration needed(g)            |
| 260030         | Peas (with pods)                  | 0.05*                   | –                    | –           | Further consideration needed(g)            |
| 260040         | Peas (without pods)               | 0.05*                   | –                    | –           | Further consideration needed(g)            |
| 270050         | Globe artichokes                  | 0.2                     | –                    | –           | Further consideration needed(g)            |
| 700000         | Hops (dried), including hop pellets and unconcentrated powder | 0.5                     | 0.5                  | –           | Further consideration needed(g)            |
| 1012010        | Bovine meat                       | 0.05*                   | 0.05*                | –           | Further consideration needed(g)            |
| 1012020        | Bovine fat                        | 0.05*                   | 0.05*                | –           | Further consideration needed(g)            |

www.efsa.europa.eu/efsajournal 16 EFSA Journal 2017;15(6):4853
## References

Austria, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for penconazole, July 2016. Available online: www.efsa.europa.eu

Czech Republic, 2016a. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for penconazole, June 2016. Available online: www.efsa.europa.eu

Czech Republic, 2016b. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for penconazole, September 2016. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers’ health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. https://doi.org/10.2903/j.efsa.2007.32r

EFSA (European Food Safety Authority), 2008. Conclusion on the peer review of the pesticide risk assessment of the active substance penconazole. EFSA Journal 2008;6(10):RN-175, 104 pp. https://doi.org/10.2903/j.efsa.2008.175r

---

| Code number(a) | Commodity              | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|----------------|------------------------|-------------------------|----------------------|-----------------------|---------|
| 1012030        | Bovine liver           | 0.05*                   | 0.05*                | Further consideration needed(h) |
| 1012040        | Bovine kidney          | 0.05*                   | 0.05*                | Further consideration needed(h) |
| 1015010        | Horse meat             | 0.05*                   | 0.05*                | Further consideration needed(h) |
| 1015020        | Horse fat              | 0.05*                   | –                    | Further consideration needed(d) |
| 1015030        | Horse liver            | 0.05*                   | –                    | Further consideration needed(d) |
| 1015040        | Horse kidney           | 0.05*                   | –                    | Further consideration needed(d) |
| 1016010        | Poultry meat           | 0.05*                   | –                    | Further consideration needed(d) |
| 1016020        | Poultry fat            | 0.05*                   | –                    | Further consideration needed(d) |
| 1016030        | Poultry liver          | 0.05*                   | –                    | Further consideration needed(d) |
| 1016040        | Poultry kidney         | 0.05*                   | –                    | Further consideration needed(d) |
| 1020000        | Milk                   | 0.01*                   | 0.01*                | Further consideration needed(h) |
| 1030000        | Birds’ eggs            | 0.05*                   | 0.05*                | Further consideration needed(h) |
| –              | Other commodities of plant and animal origin | See Reg. No 839/2008 | – | Further consideration needed(d) |

MRL: maximum residue level; CXL: codex maximum residue limit.

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.

(b): 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).

(c): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix E).

(d): 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; no CXL is available (combination E-I in Appendix E).

(e): 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; existing CXL is covered by the tentative MRL (combination E-III in Appendix E).

(f): GAP evaluated at EU level is not supported by data and consumer’s exposure could not be assessed for the existing EU MRL; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (specific case which is not covered by Appendix E).

(g): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix E).

(h): GAP evaluated at EU level is not supported by data and consumer’s exposure could not be assessed for the existing EU MRL; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (specific case which is not covered by Appendix E).

(i): 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).

*: Indicates that the MRL is set at the limit of quantification.
EFSA (European Food Safety Authority), 2014. Reasoned opinion on the modification of the existing MRLs for penconazole in blackberries and raspberries. EFSA Journal 2014;12(3):3618, 24 pp. https://doi.org/10.2903/j.efsajournal.2014.3618

EFSA (European Food Safety Authority), 2016. Completeness check report on the review of the existing MRLs of active substance prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 10 March 2017. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2017. Member States consultation report on the review of the existing MRLs of active substance prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 12 May 2017. Available online: www.efsa.europa.eu

EURL (European Union Reference Laboratories for Pesticide Residues), 2016. Evaluation Report Prepared under Article 12 of Regulation (EC) No 396/2005. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for penconazole. Available online: www.eurl-pesticides-datapool.eu

European Commission, 1997b. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

European Commission, 1997c. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997d. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997e. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.2, September 2016.

European Commission, 1997f. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997h. Appendix G. Calculation of maximum residue level and safety intervals.7039/VI/95-rev. 5, 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2016. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.2, September 2016.

FAO (Food and Agriculture Organization of the United Nations), 1992. Penconazole. In: Pesticide residues in food and environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection. 1992. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection.

FAO (Food and Agriculture Organization of the United Nations), 1995. Penconazole. In: Pesticide residues in food – 1995. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection.

FAO (Food and Agriculture Organization of the United Nations), 1999. Penconazole. In: Pesticide residues in food – 1999. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection.

France, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for penconazole, July 2016. Available online: www.efsa.europa.eu

Germany, 2007. Draft assessment report on the active substance penconazole prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EEC, June, 2007. Available online: www.efsa.europa.eu

Germany, 2008. Final addendum to the draft assessment report on the active substance penconazole prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EEC, July, 2008. Available online: www.efsa.europa.eu

Germany, 2012. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for penconazole, April 2012. Available online: www.efsa.europa.eu

Germany, 2016. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for penconazole, July 2016. Available online: www.efsa.europa.eu

Greece, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for penconazole, July 2016. Available online: www.efsa.europa.eu
Hungary, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for penconazole, June 2016. Available online: www.efsa.europa.eu

Italy, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for penconazole, July 2016. Available online: www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.

Portugal, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for penconazole, September 2016. Available online: www.efsa.europa.eu

Spain, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for penconazole, July 2016. Available online: www.efsa.europa.eu

United Kingdom, 2016. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for penconazole, July 2016. Available online: www.efsa.europa.eu

### Abbreviations

- **a.i.** active ingredient
- **a.s.** active substance
- **ADI** acceptable daily intake
- **ARfD** acute reference dose
- **BBCH** growth stages of mono- and dicotyledonous plants
- **bw** body weight
- **CAC** Codex Alimentarius Commission
- **CEN** European Committee for Standardization (Comité Européen de Normalisation)
- **CF** conversion factor for enforcement residue definition to risk assessment residue definition
- **cGAP** critical GAP
- **CIRCABC** Communication and Information Resource Centre for Administrations, Businesses and Citizens
- **CXL** codex maximum residue limit
- **DALA** days after last application
- **DAR** draft assessment report
- **DAT** days after treatment
- **DB** dietary burden
- **DCBA** dichlorobenzoic acid
- **DM** dry matter
- **DS** powder for dry seed treatment
- **DT₉₀** period required for 90% dissipation (define method of estimation)
- **EC** emulsifiable concentrate
- **ECD** electron capture detector
- **EFSA** European Food Safety Authority
- **EMS** evaluating Member State
- **EURoLs** European Union Reference Laboratories for Pesticide Residues (former CRLs)
- **FAO** Food and Agriculture Organization of the United Nations
- **FID** flame ionisation detector
- **GAP** Good Agricultural Practice
- **GC–MS/MS** gas chromatography with tandem mass spectrometry
- **HR** highest residue
- **IEDI** international estimated daily intake
- **IESTI** international estimated short-term intake
- **ILV** independent laboratory validation
- **ISO** International Organisation for Standardization
- **IUPAC** International Union of Pure and Applied Chemistry
Review of the existing MRLs for penconazole

JMPR Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)

LC-MS/MS liquid chromatography with tandem mass spectrometry

LOQ limit of quantification

Mo monitoring

MRL maximum residue level

MS Member States

MS mass spectrometry detector

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)

Rber statistical calculation of the MRL by using a non-parametric method

Rmax statistical calculation of the MRL by using a parametric method

RA risk assessment

RAC raw agricultural commodity

RD residue definition

RMS rapporteur Member State

RPF relative potency factor

SANCO Directorate-General for Health and Consumers

SEU southern European Union

SMILES simplified molecular-input line-entry system

STMR supervised trials median residue

TDM triazole derivative metabolite

TRR total radioactive residue
## Critical outdoor GAPs for Northern Europe

| Crop          | Scientific name          | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments                                                                 |
|---------------|--------------------------|--------|----------------|-------------------------|-----------------|-------------|-------------|-----------------------------|---------------------------------------------------------------------------|
| Almonds       | Amygdalus communis, syn: Prunus dulcis | NEU    | Outdoor | HU | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. n.a. 3 7 10 – 50.00 g a.i./ha | 14 – More critical GAPs authorised in LV (3 x 100 g/ha; PHI: 14 days) and in HU (4 x 50 g/ha; PHI: 14 days) are not supported by residue trials |
| Hazelnuts     | Corylus avellana         | NEU    | Outdoor | HU | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. n.a. 3 7 10 – 50.00 g a.i./ha | 14 – |
| Walnuts       | Juglans nigra; Juglans regia | NEU    | Outdoor | HU | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. n.a. 3 7 10 – 50.00 g a.i./ha | 14 – |
| Apples        | Malus domestica          | NEU    | Outdoor | CZ | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | 71 89 3 10 – – 50.00 g a.i./ha | 14 |
| Pears         | Pyrus communis           | NEU    | Outdoor | CZ | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | 71 89 3 10 – – 50.00 g a.i./ha | 14 |

**Appendix A – Summary of authorised uses considered for the review of MRLs**
| Crop          | Scientific name          | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Content | Method | Conc. Unit | Formulation | Application | Growth stage | Number | Interval (days) | Rate | PHI or waiting period (days) | Comments (max. 250 characters) |
|--------------|--------------------------|--------|----------------|-------------------------|-----------------|--------------|---------|--------|------------|-------------|-------------|--------------|--------|-----------------|------|----------------|------------------------------------------------|
| Quinces      | Cydonia oblonga          | NEU    | Outdoor        | CZ                      | Fungal disease | EC           | 100.0 g/L | Foliar treatment – spraying | 71 89       | – 3          | 10  –  –  | 50.00 g a.i./ha | 14 | More critical GAP authorised in HU (4 x 50 g/ha; PHI: 14 days) is not supported by residue trials |
| Medlars      | Mespilus germanica       | NEU    | Outdoor        | CZ                      | Fungal disease | EC           | 100.0 g/L | Foliar treatment – spraying | 71 89       | – 3          | 10  –  –  | 50.00 g a.i./ha | 14 | More critical GAP authorised in HU (4 x 50 g/ha; PHI: 14 days) is not supported by residue trials |
| Loquats      | Eriobotrya japonica      | NEU    | Outdoor        | CZ                      | Fungal disease | EC           | 100.0 g/L | Foliar treatment – spraying | 71 89       | – 3          | 10  –  –  | 50.00 g a.i./ha | 14 | – |
| Apricots     | Armeniaca vulgaris, syn: Prunus armeniaca | NEU | Outdoor | DE | Fungal disease | EC           | 100.0 g/L | Foliar treatment – spraying | n.a. n.a. | – 3          | 7 14  –  | 50.00 g a.i./ha | 14 | A different GAP authorised in HU (4 x 50 g/ha; PHI: 7 days) is not supported by residue trials |
| Cherries     | Cerasus avium, syn: Prunus avium | NEU | Outdoor | HU | Fungal disease | EC           | 100.0 g/L | Foliar treatment – spraying | n.a. n.a. | – 4          | 7  –  –  | 50.00 g a.i./ha | 7 | – |
| Peaches      | Persica vulgaris, syn: Prunus persica | NEU | Outdoor | DE | Fungal disease | EC           | 100.0 g/L | Foliar treatment – spraying | n.a. n.a. | – 3          | 7 14  –  | 50.00 g a.i./ha | 14 | A different GAP authorised in HU (4 x 50 g/ha; PHI: 7 days) is not supported by residue trials |
| Common name | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application | Method | Growth stage | Number | Interval (days) | Rate | PHI or waiting period (days) | Comments (max. 250 characters) |
|-------------|-----------------|--------|----------------|-------------------------|----------------|-------------|-------------|--------|--------------|--------|----------------|------|--------------------------|--------------------------------|
| Plums       | Prunus domestica | NEU    | Outdoor        | HU                      | Fungal disease | EC 100.0 g/L | Foliar treatment – spraying | n.a.   | n.a. | 4            | 7     | 50.00 g a.i./ha | 7    | –                       | A different GAP authorised in HU (4 x 30 g/ha; PHI: 14 days) is not fully supported by residue trials |
| Table grapes | Vitis vinifera  | NEU    | Outdoor        | CZ                      | Fungal disease | EC 100.0 g/L | Foliar treatment – spraying | n.a.   | n.a. | 1            | 4     | 18.00 g a.i./ha | 35   | –                       | |
| Wine grapes | Vitis vinifera  | NEU    | Outdoor        | CZ, DE                  | Fungal disease | EC 100.0 g/L | Foliar treatment – spraying | n.a.   | n.a. | 1            | 4     | 18.00 g a.i./ha | 35   | –                       | A different GAP authorised in HU (4 x 30 g/ha; PHI: 14 days) is not fully supported by residue trials |
| Strawberries | Fragaria x ananassa | NEU    | Outdoor        | DE, AT, CZ, HU          | Fungal disease | EC 100.0 g/L | Foliar treatment – spraying | n.a.   | n.a. | 4            | 7     | 50.00 g a.i./ha | 3    | –                       | |
| Raspberries | Rubus idaeus    | NEU    | Outdoor        | EE                      | Fungal disease | EC 100.0 g/L | Foliar treatment – spraying | n.a.   | n.a. | –            | 30.00 | 60.00 g a.i./ha | 20   | –                       | |
| Currants    | Ribes nigrum; Ribes rubrum | NEU    | Outdoor        | CZ                      | Fungal disease | EC 100.0 g/L | Foliar treatment – spraying | 51     | 97   | 2            | 7     | 50.00 g a.i./ha | 20   | –                       | |
| Gooseberries | Ribes uva-crispa | NEU    | Outdoor        | CZ                      | Fungal disease | EC 100.0 g/L | Foliar treatment – spraying | 51     | 97   | 2            | 7     | 50.00 g a.i./ha | 20   | –                       | |
| Tomatoes    | Lycopersicon esculentum | NEU    | Outdoor        | AT                      | Fungal disease | EC 100.0 g/L | Foliar treatment – spraying | n.a.   | n.a. | 4            | 8     | 50.00 g a.i./ha | 3    | –                       | |
| Crop | Common name | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments (max. 250 characters) |
|------|-------------|-----------------|--------|----------------|------------------------|----------------|-------------|-------------|-----------------------------|-------------------------------|
| Sweet peppers | Capsicum annuum | NEU Outdoor AT | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | 4 | 50.00 g a.i./ha | 3 |
| Aubergines | Solanum melongena | NEU Outdoor AT | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | 8 | 50.00 g a.i./ha | 3 |
| Cucumbers | Cucumis sativus | NEU Outdoor AT, DE | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | 8 | 50.00 g a.i./ha | 3 |
| Gherkins | Cucumis sativus | NEU Outdoor CZ, UK | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | 3 | 50.00 g a.i./ha | 3 A different GAP authorised in HU (4 × 35 g/ha; PHI: 7 days) is not supported by residue trials |
| Courgettes | Cucurbita pepo Zucchini Group | NEU Outdoor AT, DE | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | 4 | 50.00 g a.i./ha | 3 |
| Melons | Cucumis melo | NEU Outdoor AT, DE | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | 4 | 50.00 g a.i./ha | 3 |
| Pumpkins | Cucurbita maxima | NEU Outdoor AT, DE | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | 4 | 50.00 g a.i./ha | 3 |
| Watermelons | Citrullus vulgaris, syn: Citrullus lanatus | NEU Outdoor AT | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | 4 | 50.00 g a.i./ha | 3 |
## Critical outdoor GAPs for Southern Europe

| Crop               | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments |
|--------------------|-----------------|--------|----------------|-------------------------|-----------------|-------------|-------------|-----------------------------|----------|
| Globe artichokes   | *Cynara cardunculus* | NEU    | Outdoor        | UK                      | Fungal disease  | EC          | Foliar treatment – spraying | 10–30     | 50.00 g a.i./ha             | 14       |
|                    | Globe artichoke group |        |                |                         |                 |             |                          |            |                          |          |
| Apples             | *Malus domestica*  | SEU    | Outdoor        | FR                      | Fungal disease  | EC          | Foliar treatment – spraying | 71–78     | 25.00 g a.i./ha             | 14       |
|                    | Pears            | SEU    | Outdoor        | FR                      | Fungal disease  | EC          | Foliar treatment – spraying | 71–78     | 25.00 g a.i./ha             | 14       |

Review of the existing MRLs for penconazole

www.efsa.europa.eu/efsajournal 25 EFSA Journal 2017;15(6):4853
| Crop | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application |
|------|----------------|--------|----------------|-------------------------|-----------------|-------------|-------------|
|      |                |        |                |                         |                 | Type        | Content    | Method                  | Growth stage From BBCH | Until BBCH | Number Min. Max. | Interval (days) Min. Max. | Rate Min. Max. | Unit | PHI or waiting period (days) |
| Quinces | *Cydonia oblonga* | SEU     | Outdoor       | FR                      | Fungal disease   | EC          | 100.0 g/L  | Foliar treatment – spraying | 71               | 78          | 1 2           | 10 – – | 25.00 g a.i./ha | 14 | More critical GAPs authorised in IT (5 x 67.5; PHI: 14 days), ES and EL (3 x 150 g/ha; PHI: 14 days) are not supported by residue trials |
| Medlars | *Mespilus germanica* | SEU     | Outdoor       | FR                      | Fungal disease   | EC          | 100.0 g/L  | Foliar treatment – spraying | 71               | 78          | 1 2           | 10 – – | 25.00 g a.i./ha | 14 | A more critical GAP authorised in IT (5 x 67.5; PHI: 14 days) is not supported by residue trials |
| Loquats | *Eriobotrya japonica* | SEU     | Outdoor       | IT                      | Fungal disease   | EC          | 100.0 g/L  | Foliar treatment – spraying | 56               | 89          | 1 5           | 7 – – | 45.00 g a.i./ha | 14 | – |
| Apricots | *Armeniaca vulgaris, syn: Prunus armeniaca* | SEU     | Outdoor       | EL, ES                 | Fungal disease   | EC          | 100.0 g/L  | Foliar treatment – spraying | 71               | 89          | 1 2           | 12 14 | 75.00 g a.i./ha | 14 | – |
| Peaches | *Peaches vulgaris, syn: Prunus persica* | SEU     | Outdoor       | FR                      | Fungal disease   | EC          | 100.0 g/L  | Foliar treatment – spraying | 71               | 89          | 1 2           | 10 – – | 50.00 g a.i./ha | 14 | More critical GAPs authorised in IT (5 x 75; PHI: 14 days), ES and EL (2 x 150 g/ha; PHI: 14 days) are not supported by residue trials |
## Table grapes

**Vitis vinifera**

**SEU** Outdoor FR

**Erysiphe necator**

| Formulation | Growth stage | Method | Content | Application | PHI or waiting period (days) |
|-------------|--------------|--------|---------|-------------|-----------------------------|
| EC 100.0 g/L | Foliar treatment – spraying | EC 100.0 g/L | 53 79 1 2 | 8 – | 25.00 g a.i./ha |

**Comments**

More critical GAPs authorised in IT (5 × 50; PHI: 14 days), ES (3 × 150 g/ha; PHI: 14 days) and EL (2 × 60 g/ha; PHI: 14 days) are not supported by residue trials.

## Wine grapes

**Vitis vinifera**

**SEU** Outdoor FR

**Erysiphe necator**

| Formulation | Growth stage | Method | Content | Application | PHI or waiting period (days) |
|-------------|--------------|--------|---------|-------------|-----------------------------|
| EC 100.0 g/L | Foliar treatment – spraying | EC 100.0 g/L | 53 79 1 2 | 8 – | 25.00 g a.i./ha |

**Comments**

More critical GAPs authorised in IT (5 × 50; PHI: 14 days), ES (3 × 150 g/ha; PHI: 14 days) and EL (2 × 60 g/ha; PHI: 14 days) are not supported by residue trials.

## Strawberries

**Fragaria x ananassa**

**SEU** Outdoor EL, ES

**Podosphaera aphanis**

| Formulation | Growth stage | Method | Content | Application | PHI or waiting period (days) |
|-------------|--------------|--------|---------|-------------|-----------------------------|
| EC 100.0 g/L | Foliar treatment – spraying | EC 100.0 g/L | 41 97 – | 2 10 | 14 | 50.00 100.00 g a.i./ha |

**Comments**

EFSA, 2014

## Blackberries

**Rubus sect. Rubus**

**SEU** Outdoor FR, EL, ES, IT, PT

**Powdery mildew**

| Formulation | Growth stage | Method | Content | Application | PHI or waiting period (days) |
|-------------|--------------|--------|---------|-------------|-----------------------------|
| EC 100.0 g/L | Foliar treatment – spraying | EC 100.0 g/L | n.a. | 89 – | 1 – | 40.00 40.00 g a.i./ha |

**Comments**

EFSA, 2014

## Raspberries

**Rubus idaeus**

**SEU** Outdoor FR, EL, ES, IT, PT

**Powdery mildew**

| Formulation | Growth stage | Method | Content | Application | PHI or waiting period (days) |
|-------------|--------------|--------|---------|-------------|-----------------------------|
| EC 100.0 g/L | Foliar treatment – spraying | EC 100.0 g/L | n.a. | 89 – | 1 – | 40.00 40.00 g a.i./ha |

**Comments**

EFSA, 2014
| Crop               | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation Type | Content | Method                  | Growth stage From BBCH | Growth stage Until BBCH | Application Number | Interval (days) Min. | Interval (days) Max. | Rate | PHI or waiting period (days) | Comments (max. 250 characters) |
|--------------------|-----------------|--------|----------------|-------------------------|-----------------|------------------|---------|-------------------------|------------------------|------------------------|---------------------|-------------------|-------------------|------|-----------------------------|------------------------------------------------|
| Currants           | Ribes nigrum; Ribes rubrum | SEU   | Outdoor IT     | Spherotheca spp.       | EC 100.0 g/L    | Foliar treatment – spraying | 51      | 97                      | –                      | 3                      | Min. 10 Max. 14     | –                | –                | 50.00 g a.i./ha    | 14               | –               | A more critical GAP authorised in EL and ES (2 x 100; PHI: 3 days) is not supported by residue trials |
| Tomatoes           | Lycopersicon esculentum | SEU   | Outdoor FR     | Leveillula spp.        | EC 100.0 g/L    | Foliar treatment – spraying | 21      | 89                      | 1                      | 2                      | Min. 10 Max. –      | –                | –                | 50.00 g a.i./ha    | 3                | A more critical GAP authorised in EL and ES (2 x 100; PHI: 3 days) is not supported by residue trials |
| Sweet peppers     | Capsicum annuum   | SEU   | Outdoor FR     | Leveillula spp.        | EC 100.0 g/L    | Foliar treatment – spraying | 55      | 89                      | 1                      | 2                      | Min. 10 Max. –      | –                | –                | 50.00 g a.i./ha    | 3                | A more critical GAP authorised in EL and ES (2 x 100; PHI: 3 days) is not supported by residue trials |
| Aubergines         | Solanum melongena | SEU   | Outdoor FR     | Leveillula spp.        | EC 100.0 g/L    | Foliar treatment – spraying | 51      | 89                      | 1                      | 2                      | Min. 10 Max. –      | –                | –                | 50.00 g a.i./ha    | 3                | A more critical GAP authorised in EL and ES (2 x 100; PHI: 3 days) is not supported by residue trials |
| Cucumbers          | Cucumis sativus   | SEU   | Outdoor FR     | Erysiphe cichoracearum | EC 100.0 g/L    | Foliar treatment – spraying | 51      | 89                      | 1                      | 2                      | Min. 10 Max. –      | –                | –                | 50.00 g a.i./ha    | 3                | A more critical GAP authorised in EL and ES (2 x 100; PHI: 3 days) is not supported by residue trials |
## Review of the existing MRLs for penconazole

| Common name | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments |
|-------------|-----------------|--------|----------------|-------------------------|-----------------|-------------|-------------|-----------------------------|----------|
| Gherkins    | Cucumis sativus | SEU    | Outdoor        | FR                      | Erysiphe cichoracearum | EC          | 100.0 g/L | Foliar treatment – spraying | 51–89 | 1 2 10 – – 50.00 g a.i./ha | A more critical GAP authorised in ES (2 x 100; PHI: 3 days) is not supported by residue trials |
| Courgettes  | Cucurbita pepo Group | SEU | Outdoor | FR | Erysiphe cichoracearum | EC | 100.0 g/L | Foliar treatment – spraying | 51–89 | 1 2 10 – – 50.00 g a.i./ha | A more critical GAP authorised in EL and ES (2 x 100; PHI: 3 days) is not supported by residue trials |
| Melons      | Cucumis melo | SEU | Outdoor | FR | Oidium | EC | 100.0 g/L | Foliar treatment – spraying | 51–89 | 1 2 10 – – 50.00 g a.i./ha | A more critical GAP authorised in EL and ES (2 x 100; PHI: 3 days) is not supported by residue trials |
| Pumpkins    | Cucurbita maxima | SEU | Outdoor | FR | Oidium | EC | 100.0 g/L | Foliar treatment – spraying | 51–89 | 1 2 10 – – 50.00 g a.i./ha | A more critical GAP authorised in EL and ES (2 x 100; PHI: 3 days) is not supported by residue trials |
### Review of the existing MRLs for penconazole

| Crop | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments |
|---|---|---|---|---|---|---|---|---|---|
| Watermelons | *Citrullus vulgaris*, syn: *Citrullus lanatus* | SEU | Outdoor | FR | Oidium | EC 100.0 g/L | Foliar treatment – spraying | 51 89 1 2 10 – – | 50.00 g a.i./ha | 3 | A more critical GAP authorised in EL and ES (2 x 100; PHI: 3 days) and a different GAP is authorised in IT (4 x 50 g/ha; PHI: 14 days) but not supported by residue trials |
| Peas (with pods) | *Pisum sativum* | SEU | Outdoor | IT | Fungal disease | EC 100.0 g/L | Foliar treatment – spraying | n.a. n.a. 2 4 12 – | 25.00 50.00 g a.i./ha | 14 – |
| Peas (without pods) | *Pisum sativum* | SEU | Outdoor | IT | Fungal disease | EC 100.0 g/L | Foliar treatment – spraying | n.a. n.a. 2 4 12 – | 25.00 50.00 g a.i./ha | 14 – |
| Globe artichokes | *Cynara cardunculus* Globe artichoke group | SEU | Outdoor | IT | Fungal disease | EC 100.0 g/L | Foliar treatment – spraying | n.a. n.a. 2 4 12 – | 25.00 50.00 g a.i./ha | 14 | A different GAP authorised in EL and ES (2 x 100; PHI: 3 days) is not supported by residue trials |
### Critical indoor GAPs for Northern and Southern Europe (including post-harvest treatments)

| Crop | Common name | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Method | Growth stage | Number | Interval (days) | Rate | PHI or waiting period (days) | Comments |
|------|-------------|-----------------|--------|----------------|-------------------------|-----------------|--------------|---------|---------------|--------|----------------|-------|--------------------------|----------|
| Table grapes | Vitis vinifera | NEU/SEU | Indoor | NL | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | n.a. | 1 | 4 | 20.00 g a.i./ha | 28 | A more critical GAP authorised in ES and EL (2 × 100 g/ha) is not supported by residue trials |
| Strawberries | Fragaria x ananassa | NEU/SEU | Indoor | AT | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | n.a. | 4 | 7 | 10 | 50.00 g a.i./ha | 3 | A more critical GAP authorised in ES and EL (2 × 100; PHI: 3 days) is not supported by residue trials |
| Tomatoes | Lycopersicon esculentum | NEU/SEU | Indoor | AT, DE | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | n.a. | 4 | 7 | 10 | 50.00 g a.i./ha | 3 | A more critical GAP authorised in EL and ES (2 × 100; PHI: 3 days) is not supported by residue trials |
| Sweet peppers | Capsicum annuum | NEU/SEU | Indoor | AT, DE | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | n.a. | 4 | 7 | 10 | 50.00 g a.i./ha | 3 | A more critical GAP authorised in EL and ES (2 × 100; PHI: 3 days) is not supported by residue trials |
| Aubergines | Solanum melongena | NEU/SEU | Indoor | AT, DE | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | n.a. | 4 | 7 | 10 | 50.00 g a.i./ha | 3 | A more critical GAP authorised in EL and ES (2 × 100; PHI: 3 days) is not supported by residue trials |
### Cucumbers
**Scientific name:** Cucumis sativus  
**Region:** NEU/SEU  
**Crop:** Indoor  
**PPR state or country:** AT, DE  
**Pest controlled:** Fungal disease  
**Formulation:** EC  
**Conc. Unit:** 100.0 g/L  
**Method:** Foliar treatment – spraying  
**Growth stage:** n.a  
**From BBCH:** n.a  
**Until BBCH:** n.a  
**Number Min:** 4  
**Max:** 7  
**Interval (days):** –  
**Rate Min:** 50.00 g a.i./ha  
**Max:** 3  
**Comments:** A more critical GAP authorised in EL and ES (2 × 100; PHI: 3 days) is not supported by residue trials.

### Gherkins
**Scientific name:** Cucumis sativus  
**Region:** NEU/SEU  
**Crop:** Indoor  
**PPR state or country:** HU  
**Pest controlled:** Fungal disease  
**Formulation:** EC  
**Conc. Unit:** 100.0 g/L  
**Method:** Foliar treatment – spraying  
**Growth stage:** n.a  
**From BBCH:** n.a  
**Until BBCH:** n.a  
**Number Min:** 3  
**Max:** 7  
**Interval (days):** –  
**Rate Min:** 35.00 g a.i./ha  
**Max:** 3  
**Comments:** A more critical GAP authorised in EL and ES (2 × 100; PHI: 3 days) is not supported by residue trials.

### Courgettes
**Scientific name:** Cucurbita pepo  
**Group:** Zucchini  
**Region:** NEU/SEU  
**Crop:** Indoor  
**PPR state or country:** AT, DE  
**Pest controlled:** Fungal disease  
**Formulation:** EC  
**Conc. Unit:** 100.0 g/L  
**Method:** Foliar treatment – spraying  
**Growth stage:** n.a  
**From BBCH:** n.a  
**Until BBCH:** n.a  
**Number Min:** 4  
**Max:** 7  
**Interval (days):** –  
**Rate Min:** 50.00 g a.i./ha  
**Max:** 3  
**Comments:** A more critical GAP authorised in EL and ES (2 × 100; PHI: 3 days) is not supported by residue trials.

### Melons
**Scientific name:** Cucumis melo  
**Region:** NEU/SEU  
**Crop:** Indoor  
**PPR state or country:** AT, DE  
**Pest controlled:** Fungal disease  
**Formulation:** EC  
**Conc. Unit:** 100.0 g/L  
**Method:** Foliar treatment – spraying  
**Growth stage:** n.a  
**From BBCH:** n.a  
**Until BBCH:** n.a  
**Number Min:** 4  
**Max:** 7  
**Interval (days):** –  
**Rate Min:** 50.00 g a.i./ha  
**Max:** 3  
**Comments:** A different GAP authorised in EL and ES (2 × 100; PHI: 3 days) is not supported by residue trials.
| Crop | Scientific name | Region | Outdoor/indoor | Member state or country | Pest controlled | Formulation | Content | Method | Application | PHI or waiting period (days) | Comments |
|------|------------------|--------|----------------|-------------------------|-----------------|--------------|---------|--------|-------------|----------------------------|----------|
| Pumpkins | Cucurbita maxima | NEU/SEU | Indoor | AT, DE | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | n.a. | 4 | 7 | 50.00 g a.i./ha | A different GAP authorised in EL and ES (2 × 100; PHI: 3 days) is not supported by residue trials |
| Watermelons | Citrullus vulgaris, syn: Citrullus lanatus | NEU/SEU | Indoor | DE | Fungal disease | EC | 100.0 g/L | Foliar treatment – spraying | n.a. | n.a. | 4 | 8 | 50.00 g a.i./ha | A different GAP authorised in EL and ES (2 × 100; PHI: 3 days) is not supported by residue trials |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; EC: emulsifiable concentrate; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; a.i.: active ingredient.
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<sup>(a)</sup> | Foliar, 10 × 17 g a.s./ha | 35 |
|                                  | Tomatoes<sup>(b)</sup> | Foliar, 4 × 36 g a.s./ha | 7, 40 |
|                                  | Tomatoes<sup>(c)</sup> | Foliar, 200 g a.s./ha | 40 |
| Leafy crops                       | –             | –       | –              | –              |
| Pulses/oilseeds                   | –             | –       | –              | –              |

Source: Germany, 2007. Metabolism study covering leafy crops and pulses and oilseeds not available and required.

| Rotational crops (available studies) | Crop groups | Crops | Application(s) | PBI (DAT) |
|-------------------------------------|-------------|-------|----------------|-----------|
| Root/tuber crops                    | Radish<sup>(b)</sup> | Bare soil, 240 g a.s./ha | 32, 126, 358 |
| Leafy crops                         | Lettuce<sup>(b)</sup> | Bare soil, 240 g a.s./ha | 32, 126, 358 |
| Cereal (small grain)                | Wheat<sup>(b)</sup> | Bare soil, 240 g a.s./ha | 32, 126, 358 |

Source: Germany, 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 |

Sources: Germany, 2007

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

<sup>(a)</sup>: Study performed with triazole-labelled penconazole.
<br>
<sup>(b)</sup>: Study performed with triazole- and phenyl-labelled penconazole.
<br>
<sup>(c)</sup>: Substudy performed in parallel only to allow metabolites identification. Number of applications not clearly reported.

---

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) Penconazole (sum of all constituent isomers) (tentative, limited to fruit crops only)

Plant residue definition for risk assessment (RD-RA) Sum of penconazole and free and conjugated CGA 132465, CGA 190503 and CGA 127841, expressed as penconazole

Conversion factor (monitoring to risk assessment) 6 (tentative)

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

GC-MSD (EFSA, 2008):
- Validated in high water, high oil and dry matrices
- LOQ: 0.01 mg/kg
- Confirmatory method and ILV available

QuEChERS methods coupled with LC-MS/MS or GC-MS/MS (Germany, 2012; EURL, 2016):
- Validated in high water, high oil, acidic and dry matrices
- LOQ: 0.01 mg/kg
B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category          | Commodity | T (°C) | Stability (months/years) |
|-----------------------------------|-------------------|-----------|--------|--------------------------|
|                                   | High water content| Apples    | –18    | 16 months                |
|                                   | High oil content  | —         | —      | —                        |
|                                   | High acid content | Grapes    | –18    | 16 months                |

Source: Germany, 2007. Storage stability study on high oil content matrices not available and required.
### B.1.2. Magnitude of residues in plants

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

| Crop | Region/indoor | 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) | $STMR_{Mo}$ (mg/kg) | CF<sup>(d)</sup> |
|------|---------------|------------------------------------------------------------------------------------------------|-----------------------------------------------|-----------------------|-----------------|-----------------|----------------|
| Almonds/ Hazelnuts/ cobnuts/ Walnuts | NEU | – | No residue trials compliant with GAP | – | – | – | – |
| Apples/ Pears/ Quinces/ Medlars | NEU | **Apples**<br> Mo: 3 < 0.02; 2 < 0.02; 0.03; 0.038<br> RA: –<br> **Pears**<br> Mo: < 0.01; 0.04 | Combined data set on apples and pears with dose rate within 25% deviation. Extrapolation to pears, quinces and medlars possible (Germany, 2012; Czech Republic, 2016a)<br> MRL<sub>OECD</sub> = 0.06 | **0.07<sup>(e)</sup>** (tentative) | 0.04 | 0.02 | 6 |
| | SEU | **Apples**<br> Mo: 0.02; 0.048; 0.065; 0.079; 0.01; 0.02; RA: –<br> **Pears**<br> Mo: 2 < 0.01; 0.01 | Combined data set on apples and pears performed according to a more critical GAP (3 × 60 g/ha) (Germany, 2012; Portugal, 2016). Extrapolation to pears, quinces and medlars possible<br> MRL<sub>OECD</sub> = 0.14 | **0.15<sup>(e),(f)</sup>** (tentative) | 0.08 | 0.02 | 6 |
| Loquats | NEU | **Apples**<br> Mo: 3 < 0.02; 2 < 0.02; 0.03; 0.038<br> RA: –<br> **Pears**<br> Mo: < 0.01; 0.04 | Combined data set on apples and pears with dose rate within 25% deviation. Extrapolation to loquats possible (Germany, 2012; Czech Republic, 2016a,b)<br> MRL<sub>OECD</sub> = 0.06 | **0.07<sup>(e)</sup>** | 0.04 | 0.02 | 6 |
| | SEU | – | No residue trials compliant with GAP | – | – | – | – |
| Apricots | NEU | **Mo**: 0.02; 0.025; 0.03; 0.03<br> **RA**: – | Trials on peaches overdosed (3 × 100 g/ha) (Germany, 2012, 2016)<br> MRL<sub>OECD</sub> = 0.08 | **0.08<sup>(e),(f)</sup>** (tentative) | 0.03 | 0.03 | 6 |
| | SEU | – | No residue trials compliant with GAP | – | – | – | – |
### Crop

| Crop                  | Region/in 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) | CF(d) |
|-----------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|----------------------|----------------------|------------------------|-------|
| Cherries (sweet)      | NEU                | Mo: 5 $\times$ 0.01; 0.02; 0.05; 0.09  
RA: –  
Trials on cherries compliant with GAP (Germany, 2012)  
$MRL_{OECD}$ = 0.14                                                                 | 0.15$^{(e)}$ (tentative)  
0.09  
0.01  
6                                                                 |                      |                      |                      |       |
| Peaches               | NEU                | Mo: 0.02; 0.025; 2 $\times$ 0.03  
RA: –  
Trials on peaches overdosed (3 $\times$ 100 g/ha) (Germany, 2012, 2016)  
$MRL_{OECD}$ = 0.08                                                                 | 0.08$^{(e),(f)}$ (tentative)  
0.03  
0.03  
6                                                                 |                      |                      |                      |       |
| SEU                   | Trials performed at 2 - 3 $\times$ 75 g/ha  
Mo: 0.03; 2 $\times$ 0.01  
RA: –  
Trials performed at 3 $\times$ 100 g/ha  
Mo: $\leq$0.02; 0.03; 0.04; 0.08; 0.06; 0.033; 0.029  
RA: –  
Trials on peaches overdosed (3 $\times$ 75 - 100 g/ha) (Germany, 2012; France, 2016; Portugal, 2016)  
$MRL_{OECD}$ = 0.12                                                                 | 0.15$^{(e),(f)}$ (tentative)  
0.08  
0.03  
6                                                                 |                      |                      |                      |       |
| Plums                 | NEU                | Mo: 3 $\times$ 0.01; 0.01; 2 $\times$ 0.02; 0.03; 0.06  
RA: –  
Trials on plums compliant with GAP (Germany, 2012)  
$MRL_{OECD}$ = 0.09                                                                 | 0.09$^{(e)}$ (tentative)  
0.06  
0.02  
6                                                                 |                      |                      |                      |       |
| Table grapes          | NEU                | Mo: $\leq$0.02; 0.03; 3 $\times$ 0.04; 0.05; 0.15; 0.23; 0.26  
RA: –  
Trials on grapes performed with 5 or 6 applications instead of 4 (Germany, 2012)  
$MRL_{OECD}$ = 0.47                                                                 | 0.5$^{(e),(f)}$ (tentative)  
0.26  
0.04  
6                                                                 |                      |                      |                      |       |
| Wine grapes           | SEU                | Mo: $\leq$0.01; 3 $\times$ 0.02; 2 $\times$ 0.03; 0.04; 0.18  
RA: –  
Trials on grapes performed according to a more critical GAP (3 $\times$ 40 g/ha; 14 days) (Germany, 2012; Portugal, 2016)  
$MRL_{OECD}$ = 0.27                                                                 | 0.3$^{(e),(f)}$ (tentative)  
0.18  
0.03  
6                                                                 |                      |                      |                      |       |
| Strawberries          | NEU                | Mo: 2 $\times$ 0.03; 0.04; 2 $\times$ 0.1; 0.11; 0.12; 0.14; 0.17  
RA: –  
Trials on strawberries compliant with GAP (Germany, 2012)  
$MRL_{OECD}$ = 0.29                                                                 | 0.3$^{(e)}$ (tentative)  
0.17  
0.10  
6                                                                 |                      |                      |                      |       |
| SEU                   | –                  | No residue trials compliant with GAP                                                                                      | –  
–  
–  
–                                                                 |                      |                      |                      |       |
| EU                    | Mo: 0.03; 0.04; 2 $\times$ 0.07; 0.08; 0.09; 0.15; 0.19  
RA: –  
Trials on strawberries compliant with GAP (Germany, 2012; Portugal, 2016)  
$MRL_{OECD}$ = 0.31                                                                 | 0.3$^{(e)}$ (tentative)  
0.19  
0.08  
6                                                                 |                      |                      |                      |       |
| 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) | HRMo (mg/kg)(b) | STMRMo(c) | CF(d) |
|-----------------------------|-------------------|------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|----------------|----------------|-------|
| Blackberries Raspberries (red and yellow) | NEU | – | No residue trials compliant with GAP. No authorised for use on blackberries in NEU | – | – | – | – |
|                            | SEU | Mo: 0.02; 0.03; 2 × 0.04 RA: – | Trials on raspberries compliant with GAP. Extrapolation to blackberries possible (EFSA, 2014) MRL_{OECD} = 0.1 | 0.1(e) (tentative) | 0.04 | 0.04 | 6 |
| Currants (black, red and white) | NEU | Mo: < 0.01; 0.03; 0.04; 0.05 RA: – | Trials on black currants compliant with GAP (Czech Republic, 2016a) MRL_{OECD} = 0.1 | 0.1(e) (tentative) | 0.05 | 0.04 | 6 |
|                            | SEU | Mo: 0.03; 0.05 RA: – | Trials on currants compliant with GAP (Italy, 2016). Number of trials not sufficient to derive an MRL proposal | – | – | – | – |
| Gooseberries (green, red and yellow) | NEU | Mo: 2 × < 0.01; 0.01; 0.05 RA: – | Trials on gooseberries compliant with GAP (Czech Republic, 2016a) MRL_{OECD} = 0.1 | 0.1(e) (tentative) | 0.05 | 0.01 | 6 |
| Tomatoes Aubergines | NEU | – | No residue trials compliant with GAP. | – | – | – | – |
|                            | SEU | Mo: 3 × < 0.01; 0.01; 0.02; 2 × 0.03; 0.04 RA: – | Trials on tomatoes performed with 4 applications instead of 2 (Germany, 2012; Portugal, 2016) MRL_{OECD} = 0.07 | 0.07(e,f) (tentative) | 0.04 | 0.02 | 6 |
|                            | EU  | Tomatoes Mo: 3 × < 0.01; 3 × < 0.02; 2 × 0.02; 0.03; 0.07 RA: – Cherry tomatoes Mo: 0.03; 0.04 RA: – | Combined data set on tomatoes and cherries tomatoes compliant with GAP (Germany, 2012; Portugal, 2016). Extrapolation to aubergines possible MRL_{OECD} = 0.09 | 0.1(e) (tentative) | 0.07 | 0.02 | 6 |
| 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) | CF(d) |
|-----------------------------|------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|------------------------|-------------------|----------------------|-------|
| Sweet peppers/bell peppers | NEU              | --                                                                                             | No residue trials compliant with GAP.                                                                                                                                   | --                     | --                | --                   | --    |
|                             | SEU              | Trials compliant with GAP                                                                      | Trials on sweet peppers compliant with GAP and performed with 4 applications instead of 2 (Germany, 2012; France, 2016; Portugal, 2016) MRL_{OECD} = 0.09 | 0.09^{(e)}/^{(f)} (tentative) | 0.06              | 0.02                  | 6     |
|                             | EU               | Mo: 2 × < 0.02; 2 × 0.02; 0.036; 0.04; 0.041; 0.12 RA: --                                                                                               | Trials on sweet peppers compliant with GAP (Germany, 2012) MRL_{OECD} = 0.17                                                                                         | 0.2^{(e)} (tentative) | 0.12              | 0.03                  | 6     |
| Cucumbers                   | NEU              | Cucumbers Mo: 2 × < 0.01; 0.02; 0.03 RA: -- Gherkins Mo: 2 × 0.02; 0.03; 0.04 RA: --                                                                         | Combined data set on cucumber and gherkins compliant with GAP for cucumber and courgettes (Germany, 2012; Czech Republic, 2016b) MRL_{OECD} = 0.06 | 0.06^{(e)} (tentative) | 0.04              | 0.02                  | 6     |
|                             | SEU              | Cucumbers Mo: 2 × < 0.01; 2 × 0.01 RA: -- Courgettes Mo: < 0.01; 0.01; 2 × < 0.02 RA: --                                                                     | Combined data set on cucumber and courgettes performed with 4 applications instead of 2 (Germany, 2012; Portugal, 2016) MRL_{OECD} = 0.03 | 0.03^{(e)}/^{(f)} (tentative) | 0.02              | 0.01                  | 6     |
|                             | EU               | Mo: < 0.01; 2 × 0.01; 2 × < 0.02; 0.02; 4 × 0.03 RA: --                                                                                                      | Trials on cucumber compliant with GAP (Germany, 2012; Portugal, 2016) MRL_{OECD} = 0.06                                                                            | 0.06^{(e)} (tentative) | 0.03              | 0.02                  | 6     |
| 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<sub>Mo</sub> (mg/kg)(b) | STMR<sub>Mo</sub> (mg/kg)(c) | CF(d) |
|----------------------|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------|----------------|-----|
| Gherkins NEU         | Cucumbers        | Mo: 2 x 0.01; 0.02; 0.03 RA: – Gherkins Mo: 2 x 0.02; 0.03; 0.04 RA: – Combined data set on cucumber and gherkins (Germany, 2012; Czech Republic, 2016b). Tentative extrapolation to gherkins (less critical GAP) MRL<sub>OECD</sub> = 0.06 | 0.06<sup>(e),(f)</sup> (tentative)                                                                                                                                                                                                                                                                   | 0.04                          | 0.02            | 6              |
|                      | SEU Cucumbers    | Mo: 2 x 0.01; 2 x 0.01 RA: – Courgettes Mo: < 0.01; 0.01; 2 x < 0.02 RA: – Combined data set on cucumber (4) and courgettes (4) performed with 4 applications instead of 2 (Germany, 2012; Portugal, 2016) MRL<sub>OECD</sub> = 0.03 | 0.03<sup>(e),(f)</sup> (tentative)                                                                                                                                                                                                                                                                   | 0.02                          | 0.01            | 6              |
|                      | EU               | Mo: < 0.01; 2 x 0.01; 2 x < 0.02; 0.02; 4 x 0.03 RA: – Trials on cucumber compliant with GAP (Germany, 2012; Portugal, 2016). Tentative extrapolation to gherkins (less critical GAP) MRL<sub>OECD</sub> = 0.06 | 0.06<sup>(e),(f)</sup> (tentative)                                                                                                                                                                                                                                                                   | 0.03                          | 0.02            | 6              |
| Cucurbits with inedible peel NEU | Melons           | Mo: < 0.01; < 0.02 RA: – Pumpkins Mo: 2 x < 0.03 RA: – Combined data set on melons and pumpkins compliant with GAP for cucurbits with inedible peel (Germany, 2012) MRL<sub>OECD</sub> = 0.03 | 0.03<sup>(e),(a)</sup> (tentative)                                                                                                                                                                                                                                                                   | 0.03                          | 0.03            | 6              |
|                      | SEU Trials with 4 applications instead of 2 | Mo: 3 x 0.02; 0.02 RA: – Trials with 3 applications instead of 2 Mo: 2 x 0.01; 2 x 0.02; 3 x 0.03; 0.04 RA: – Trials on melons performed with 4 or 3 applications instead of 2 (Germany, 2012, France, 2016; Italy, 2016; Portugal, 2016) MRL<sub>OECD</sub> = 0.06 | 0.06<sup>(e),(f)</sup> (tentative)                                                                                                                                                                                                                                                                   | 0.04                          | 0.02            | 6              |
|                      | EU               | Mo: 2 x < 0.01; 2 x 0.02; 0.03; 2 x 0.04; 0.05; 0.07 RA: – Trials on melons compliant with GAP for cucurbits with inedible peel (Germany, 2012; Portugal, 2016) MRL<sub>OECD</sub> = 0.11 | 0.15<sup>(e)</sup> (tentative)                                                                                                                                                                                                                                                                       | 0.07                          | 0.03            | 6              |
| 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) | CF(d) |
|-----------------------------|-------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|----------------------|----------------------|------------------------|--------|
| Peas (with pods)            | SEU               |                                                                                               | No residue trials compliant with GAP                                                                                                                                   | –                    | –                    | –                      | –      |
| Peas (without pods)         |                   |                                                                                               |                                                                                                                                                                           |                      |                      |                        |        |
| Globe artichokes            | NEU               | **Trials with dose rate within 25% deviation**  
  Mo: $2 \times 0.01$  
  RA: –  
  **Trials with 4 applications instead of 3**  
  Mo: $2 \times <0.02; 0.02; 0.04$  
  RA: –                                                                                       | Trials on globe artichokes with dose rate within 25% deviation or performed with 4 applications instead of 3 (Germany, 2012; France, 2016)  
  No metabolism study available on leafy vegetables. Not possible to propose residue definitions and CF for risk assessment  
  $MRL_{OECD} = 0.06$                                                                 | –                    | –                    | –                      | –      |
|                             | SEU               | **Mo: $2 \times <0.006; <0.01; 0.02$**  
  RA: –                                                                                       | Trials on globe artichokes compliant with GAP (Germany, 2012; Portugal, 2016). No metabolism study available on leafy vegetables. Not possible to propose residue definitions and CF for risk assessment  
  $MRL_{OECD} = 0.04$                                                                 | –                    | –                    | –                      | –      |

GAP: Good Agricultural Practice; MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development.
(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): In the absence of residue trials analysing simultaneously for enforcement and risk assessment residue definitions, a worst case conversion factor derived from the available metabolism and processing studies has been proposed for risk assessment.
(e): In the absence of a metabolism data allowing concluding on the metabolites to be considered for enforcement, the derived MRLs should be considered tentative only.
(f): Tentative MRL and risk assessment values were derived from trials performed according to a more critical GAP.
(g): Tentative MRL and risk assessment values were derived from a reduced number of trials.
*: Indicates that the MRL is proposed at the limit of quantification.
B.1.2.2. Residues in succeeding crops

According to the results from the confined rotational crop studies, no significant residues (with possible exception of the triazole derivative metabolites) are expected to occur in rotational crops provided that penconazole is applied according to the GAPs considered in this review.

Field rotational crop study
Not available. Required for the assessment of triazole derivative metabolites.

B.1.2.3. Processing factors

| Processed commodity | Number of studies(a) | Processing factor (PF) | Median PF | CF |
|---------------------|----------------------|------------------------|-----------|----|
|                     | Individual values    |                        |           |    |
| Indicative processing factors (limited data set and/or residues analysed for parent only) | | | | |
| Apples, juice       | 4                    | 0.06; 3 × 0.07         | 0.07      | 6.0(b) |
| Apples, dry pomace  | 4                    | 7.3; 8.7; 8.8; 9.3     | 8.7       | 6.0(b) |
| Apples, wet pomace  | 4                    | 2.0; 2.1; 2.1; 3.1     | 2.1       | 6.0(b) |
| Apples, sauce       | 4                    | 2 × 0.13; 2 × 0.20     | 0.17      | 6.0(b) |
| Table grapes, dried (raisins) | 8                   | 0.96; 1.08; 1.28; 1.6; 2.39; 3.6; 2 × 4.0 | 2.0 | 8.6(c) |
| Wine grapes, juice  | 4                    | 0.43; 0.25; 0.4; 1.0   | 0.42      | 5.5(c) |
| Wine grapes, dry pomace | 4                  | 10; 13; 23; 26       | 18        | 4.2(c) |
| Wine grapes, wet pomace | 5                  | 2.5; 3.2; 5.7; 7.5; 11 | 5.65      | 4.0(c) |
| Wine grapes, must   | 2                    | 0.14; 0.37            | 0.26      | 6.0(b) |
| Wine grapes, red wine (unheated) | 5                  | 0.14; 0.25; 0.40; 0.43; 1.0 | 0.4 | 5.5(c) |
| Strawberries, jam   | 4                    | 0.61; 0.65; 0.67; 0.91 | 0.66      | 6.0(b) |
| Strawberries, canned| 4                    | 0.39; 0.44; 0.46; 0.53 | 0.45      | 6.0(b) |
| Melons, peeled      | 13                   | 2 × 0.25; 0.29; 3 × 0.33; 0.40; 5 × 0.50; 0.67 | 0.40 | 6.0(b) |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Since in the processing studies residues were analysed for parent compound only, the CF as derived for the raw commodities has been tentatively considered for risk assessment.
(c): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each residues trial.

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            | Med. | Max. | Med. | Max.          |                         |                         |
| Cattle (all diets) | 0.0030 | 0.0030 | 0.13 | 0.13(b) | Cattle (beef) | Apple, pomace, wet | Yes |
| Cattle (dairy only) | 0.0024 | 0.0024 | 0.06 | 0.06 | Cattle (dairy) | Apple, pomace, wet | No |
| Sheep (all diets) | 0.0027 | 0.0027 | 0.06 | 0.06 | Sheep (lamb) | Apple, pomace, wet | No |
| Sheep (ewe only) | 0.0021 | 0.0021 | 0.06 | 0.06 | Sheep (ram/ewe) | Apple, pomace, wet | No |
| Swine (all diets) | 0.0000 | 0.0000 | 0.00 | 0.00 | Swine (breeding) | – | No |
| Poultry (all diets) | 0.0000 | 0.0000 | 0.00 | 0.00 | Poultry (broiler) | – | No |
### 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 |
|-------------------------------|--------|-------------------------|----------------|---------------|
| Lactating goat/cow            | –      | –                       | –              | –             |
| Not available and required    |        |                         |                |               |

- Time needed to reach a plateau concentration in milk and eggs (days): Inconclusive (livestock metabolism study not available)
- Metabolism in rat and ruminant similar (Yes/No): Inconclusive (livestock metabolism study not available)
- Animal residue definition for monitoring (RD-Mo): Inconclusive (livestock metabolism study not available)
- Animal residue definition for risk assessment (RD-RA): Inconclusive (livestock metabolism study not available)
- Conversion factor (monitoring to risk assessment): Inconclusive (livestock metabolism study not available)
- Fat soluble residues (Yes/No): Inconclusive (livestock metabolism study not available)
- Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs): Not available and required

#### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (months/years) |
|-------------------------------------|--------|-----------|--------|--------------------------|
|                                     | –      | Muscle    | –      | –                        |
|                                     | –      | Fat       | –      | –                        |
|                                     | –      | Liver     | –      | –                        |
|                                     | –      | Kidney    | –      | –                        |
| Not available and required          |        |           |        |                          |
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 (mg/kg) | HR (mg/kg) |                                |
| Cattle (all diets)     | Not available and required                     |                                          |
| Cattle (dairy only)    | MRLs are not required since the trigger value is not exceeded |
| Sheep (all diets)      | MRLs are not required since the trigger value is not exceeded |
| Sheep (dairy only)     | MRLs are not required since the trigger value is not exceeded |
| Swine                  | MRLs are not required since the trigger value is not exceeded |
| Poultry (all diets)    | MRLs are not required since the trigger value is not exceeded |
| Poultry (layer only)   | MRLs are not required since the trigger value is not exceeded |

B.3. Consumer risk assessment

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

ADI
Highest IEDI, according to EFSA PRIMO
Assumptions made for the calculations

ARfD
Highest IESTI, according to EFSA PRIMO
Assumptions made for the calculations

- **ADI**
  0.03 mg/kg bw per day (EFSA, 2008)

  8.7% ADI (DE, child diet)

  The calculation is based on the median residue levels in the raw agricultural commodities multiplied by the conversion factor for risk assessment, except for cucurbits with inedible peel, where the relevant peeling factor was applied.

  For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL multiplied by the conversion factor of 6 for risk assessment, for an indicative calculation.

  Nevertheless, existing MRLs for commodities not covered by a metabolism study (globe artichokes, fresh peas, bovine and poultry tissues, milk and eggs) were not included in the calculation.

  The contributions of commodities where no GAP was reported in the framework of this review, were not included in the calculation.

- **ARfD**
  0.5 mg/kg bw (EFSA, 2008)

  20% ARfD (table grapes)

  The calculation is based on the highest residue levels in the raw agricultural commodities multiplied by the conversion factor for risk assessment, except for cucurbits with inedible peel, where the relevant peeling factor was applied.

  For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL multiplied by the conversion factor of 6 for risk assessment for an indicative calculation. Nevertheless, existing MRLs for commodities not covered by a metabolism study (globe artichokes, fresh peas, bovine and poultry tissues, milk and eggs) were not included in the calculation.
B.3.2. Consumer risk assessment with consideration of the existing CXLs

**ADI**
Highest IEDI, according to EFSA PRIMo
Assumptions made for the calculations

| 0.03 mg/kg bw per day (EFSA, 2008) |
| 16% ADI (DE, child diet) |

For those commodities having a CXL higher than the EU MRL proposal, median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR, multiplied by the tentative conversion factor of 6 for risk assessment. Existing CXLs for commodities not covered by a metabolism study (hops, bovine and poultry tissues, milk and eggs) were not included in the calculation.

**ARfD**
Highest IESTI, according to EFSA PRIMo
Assumptions made for the calculations

| 0.5 mg/kg bw (EFSA, 2008) |
| 20% ARfD (table grapes) |

For those commodities having a CXL higher than the EU MRL proposal, highest residue levels applied in the EU scenario were replaced by the highest residue levels derived by JMPR, multiplied by the tentative conversion factor of 6 for risk assessment. Existing CXLs for commodities not covered by a metabolism study (hops, bovine and poultry tissues, milk and eggs) were not included in the 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 (existing):** penconazole (F) | **Enforcement residue definition (proposed):** penconazole (sum of all constituent isomers) (F) |
| 120010 | Almonds | 0.05* | – | 0.05 | Further consideration needed(b) |
| 120060 | Hazelnuts/cobnuts | 0.05* | – | 0.05 | Further consideration needed(b) |
| 120110 | Walnuts | 0.05* | – | 0.05 | Further consideration needed(b) |
| 130010 | Apples | 0.2 | 0.2 | 0.2 | Further consideration needed(c) |
| 130020 | Pears | 0.2 | 0.2 | 0.2 | Further consideration needed(c) |
| 130030 | Quinces | 0.2 | 0.2 | 0.2 | Further consideration needed(c) |
| 130040 | Medlars | 0.2 | 0.2 | 0.2 | Further consideration needed(c) |
| 130050 | Loquats/Japanese medlars | 0.2 | 0.2 | 0.2 | Further consideration needed(c) |
| 140010 | Apricots | 0.1 | – | 0.08 | Further consideration needed(d) |
| 140020 | Cherries (sweet) | 0.05* | – | 0.15 | Further consideration needed(d) |
| 140030 | Peaches | 0.1 | 0.1 | 0.15 | Further consideration needed(d) |
| 140040 | Plums | 0.05* | – | 0.09 | Further consideration needed(d) |
| 151010 | Table grapes | 0.2 | 0.2 | 0.5 | Further consideration needed(e) |
| 151020 | Wine grapes | 0.2 | 0.2 | 0.5 | Further consideration needed(e) |
| 152000 | Strawberries | 0.5 | 0.1 | 0.3 | Further consideration needed(e) |
| 153010 | Blackberries | 0.1 | – | 0.1 | Further consideration needed(e) |
| 153030 | Raspberries (red and yellow) | 0.1 | – | 0.1 | Further consideration needed(e) |
| 154030 | Currants (black, red and white) | 0.5 | – | 0.1 | Further consideration needed(e) |
| 154040 | Gooseberries (green, red and yellow) | 0.05* | – | 0.1 | Further consideration needed(e) |
| 231010 | Tomatoes | 0.1 | 0.2 | 0.2 | Further consideration needed(f) |
| 231020 | Sweet peppers/bell peppers | 0.2 | – | 0.2 | Further consideration needed(f) |
| Code number(a) | Commodity                                                    | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment                                      |
|---------------|--------------------------------------------------------------|-------------------------|----------------------|-----------------------|----------------------------------------------|
| 231030        | Aubergines/eggplants                                         | 0.1                     | –                    | 0.1                   | Further consideration needed(d)              |
| 232010        | Cucumbers                                                   | 0.1                     | 0.1                  | 0.1                   | Further consideration needed(d)              |
| 232020        | Gherkins                                                    | 0.1                     | –                    | 0.06                  | Further consideration needed(d)              |
| 232030        | Courgettes                                                  | 0.1                     | –                    | 0.06                  | Further consideration needed(d)              |
| 233010        | Melons                                                      | 0.1                     | 0.1                  | 0.15                  | Further consideration needed(d)              |
| 233020        | Pumpkins                                                    | 0.1                     | –                    | 0.15                  | Further consideration needed(d)              |
| 233030        | Watermelons                                                 | 0.1                     | –                    | 0.15                  | Further consideration needed(d)              |
| 260030        | Peas (with pods)                                            | 0.05*                   | –                    | –                     | Further consideration needed(f)              |
| 260040        | Peas (without pods)                                         | 0.05*                   | –                    | –                     | Further consideration needed(f)              |
| 700000        | Hops (dried), including hop pellets and unconcentrated powder | 0.5                     | 0.5                  | –                     | Further consideration needed(g)              |
| 1012010       | Bovine meat                                                 | 0.05*                   | 0.05*                | –                     | Further consideration needed(h)              |
| 1012020       | Bovine fat                                                  | 0.05*                   | 0.05*                | –                     | Further consideration needed(h)              |
| 1012030       | Bovine liver                                                | 0.05*                   | 0.05*                | –                     | Further consideration needed(h)              |
| 1012040       | Bovine kidney                                               | 0.05*                   | 0.05*                | –                     | Further consideration needed(h)              |
| 1015010       | Horse meat                                                  | 0.05*                   | 0.05*                | –                     | Further consideration needed(h)              |
| 1015020       | Horse fat                                                   | 0.05*                   | –                    | –                     | Further consideration needed(h)              |
| 1015030       | Horse liver                                                 | 0.05*                   | –                    | –                     | Further consideration needed(h)              |
| 1015040       | Horse kidney                                                | 0.05*                   | –                    | –                     | Further consideration needed(h)              |
| 1016010       | Poultry meat                                                | 0.05*                   | –                    | –                     | Further consideration needed(h)              |
| 1016020       | Poultry fat                                                 | 0.05*                   | –                    | –                     | Further consideration needed(h)              |
| 1016030       | Poultry liver                                               | 0.05*                   | –                    | –                     | Further consideration needed(h)              |
| 1016040       | Poultry kidney                                              | 0.05*                   | –                    | –                     | Further consideration needed(h)              |
| 1020000       | Milk                                                        | 0.01*                   | 0.01*                | –                     | Further consideration needed(h)              |
| 1030000       | Birds’ eggs                                                 | 0.05*                   | 0.05*                | –                     | Further consideration needed(h)              |
| –             | Other commodities of plant and animal origin                | See Reg. No 839/2008    | –                    | –                     | Further consideration needed(i)              |

MRL: maximum residue level; CXL: codex maximum residue limit.
(F): MRL is expressed as mg/kg of fat contained in the whole product.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): 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).
(c): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix E).
(d): 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; no CXL is available (combination E-I in Appendix E).
(e): 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; existing CXL is covered by the tentative MRL (combination E-III in Appendix E).
(f): GAP evaluated at EU level is not supported by data and consumer’s exposure could not be assessed for the existing EU MRL; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (specific case which is not covered by Appendix E).
(g): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix E).
(h): GAP evaluated at EU level is not supported by data and consumer’s exposure could not be assessed for the existing EU MRL; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (specific case which is not covered by Appendix E).
(i): 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).
*: Indicates that the MRL is set at the limit of quantification.
Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo(EU)

### Penconazole

| Status of the active substance: | Code no. |
|--------------------------------|----------|
| LOQ (mg/kg bw): | 0.01 |
| Proposed LOQ: | 0.01 |

| Toxicological endpoints |
|-------------------------|
| ADI (mg/kg bw per day): | 0.03 |
| ARfD (mg/kg bw): | 0.5 |

| Source of ADI: | EFSA |
|----------------|-------|
| Source of ARfD: | EFSA |

| Year of evaluation: | 2008 |
|---------------------|------|
| Year of evaluation: | 2008 |

| No of diets exceeding ADI: | --- |

| Highest calculated TMDI values in % of ADI | MS Diet | Commodity/group of commodities | 2nd contributor to MS diet | Commodity/group of commodities | 3rd contributor to MS diet | Commodity/group of commodities | pTMRLs at LOQ in % of ADI |
|-------------------------------------------|---------|--------------------------------|---------------------------|--------------------------------|---------------------------|--------------------------------|--------------------------|
| 8.7 DE child | 4.8 | Apples | 10 | Table grapes | 1.0 | Strawberries | |
| 5.2 WHO Cluster diet B | 1.4 | Wine grapes | 12 | Tomatoes | 0.4 | Apples | |
| 4.7 NL child | 2.5 | Apples | 06 | Table grapes | 0.5 | Strawberries | |
| 4.2 FR all population | 3.2 | Wine grapes | 02 | Apples | 0.2 | Strawberries | |
| 4.0 IE adult | 1.0 | Wine grapes | 05 | Strawberries | 0.4 | Tree nuts (shelled or unshelled) | |
| 3.7 PT General population | 2.0 | Wine grapes | 04 | Apples | 0.4 | Tomatoes | |
| 3.2 FR toddler | 1.2 | Strawberries | 10 | Apples | 0.3 | Tomatoes | |
| 2.7 DK child | 0.9 | Apples | 07 | Cucumbers | 0.3 | Peaches | |
| 2.7 WHO cluster diet E | 1.3 | Wine grapes | 03 | Apples | 0.2 | Tomatoes | |
| 2.6 FR infant | 1.0 | Apples | 10 | Strawberries | 0.3 | Courgettes | |
| 2.1 DK adult | 1.1 | Wine grapes | 03 | Apples | 0.2 | Tomatoes | |
| 2.0 UK Toddler | 0.7 | Apples | 04 | Strawberries | 0.2 | Tomatoes | |
| 1.9 IT kids/toddler | 0.6 | Tomatoes | 04 | Apples | 0.2 | Strawberries | |
| 1.9 WHO cluster diet D | 0.4 | Tomatoes | 03 | Wine grapes | 0.3 | Apples | |
| 1.8 WHO regional European diet | 0.4 | Tomatoes | 03 | Apples | 0.2 | Wine grapes | |
| 1.8 SE general population 90th percentile | 0.4 | Apples | 03 | Strawberries | 0.3 | Tomatoes | |
| 1.8 NL general | 0.5 | Wine grapes | 05 | Apples | 0.2 | Table grapes | |
| 1.8 PL general population | 0.8 | Apples | 04 | Tomatoes | 0.3 | Table grapes | |
| 1.7 IT adult | 0.5 | Tomatoes | 03 | Apples | 0.2 | Peaches | |
| 1.7 ES adult | 0.3 | Wine grapes | 03 | Tomatoes | 0.3 | Apples | |
| 1.6 UK vegetarian | 0.7 | Wine grapes | 02 | Tomatoes | 0.2 | Apples | |
| 1.6 WHO Cluster diet F | 0.5 | Wine grapes | 03 | Tomatoes | 0.3 | Apples | |
| 1.6 ES child | 0.5 | Apples | 04 | Tomatoes | 0.2 | Pears | |
| 1.5 UK Infant | 0.6 | Apples | 04 | Strawberries | 0.1 | Tomatoes | |
| 1.5 UK Adult | 0.9 | Wine grapes | 02 | Tomatoes | 0.2 | Apples | |
| 1.4 LT adult | 0.7 | Apples | 02 | Tomatoes | 0.2 | Cucumbers | |
| 1.0 FI adult | 0.2 | Wine grapes | 02 | Tomatoes | 0.2 | Apples | |

### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Penconazole is unlikely to present a public health concern.
### Acute risk assessment /children – refined calculations

The acute risk assessment is based on the ARfD.

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

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

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

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

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

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

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

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

### Table: Processed Commodities

| Commodity       | pTMRL/ threshold MRL (mg/kg) | pTMRL/ threshold MRL (mg/kg) |
|-----------------|------------------------------|------------------------------|
| Grape juice     | 1.56/-                       | 1.56/-                       |
| Apple juice     | 0.474/-                      | 0.474/-                      |
| Peach juice     | 0.48/-                       | 0.48/-                       |
| Pear juice      | 0.474/-                      | 0.474/-                      |
| Tomato juice    | 0.42/-                       | 0.42/-                       |

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

### Conclusion:

For Penconazole, 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.
PRIMo(CXL)

Penconazole

| Toxicological end points |
|--------------------------|
| ADI (mg/kg bw per day): 0.03 |
| ARfD (mg/kg bw): 0.5 |
| Source of ADI: EFSA |
| Source of ARfD: EFSA |
| Year of evaluation: 2008 |
| Year of evaluation: 2008 |

Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI (minimum – maximum) | 1 | 2nd contributor to MS diet (in % of ADI) | Commodity/group of commodities | 3rd contributor to MS diet (in % of ADI) | pTMRLs at LOQ (in % of ADI) |
|-------------------------------|---------------------------------------------|---|-----------------------------------------|-------------------------------|-----------------------------------------|-------------------------------|
| 16.3 DE child                 | 12.1 Apples                                 | 1.0 Table grapes | 1.0 Strawberries                        |
| 8.6 NL child                  | 6.3 Apples                                  | 0.6 Table grapes | 0.5 Strawberries                        |
| 6.1 WHO Cluster diet B        | 1.4 Wine grapes                             | 1.2 Tomatoes     | 1.0 Apples                             |
| 4.9 FR toddler                | 2.6 Apples                                  | 1.2 Strawberries | 0.3 Tomatoes                           |
| 4.9 IE adult                  | 1.0 Wine grapes                             | 0.8 Apples       | 0.7 Pears                             |
| 4.6 FR all population         | 3.2 Wine grapes                             | 0.5 Apples       | 0.2 Strawberries                       |
| 4.6 PT General population     | 2.0 Wine grapes                             | 1.1 Apples       | 0.4 Tomatoes                           |
| 4.5 DK child                  | 2.3 Apples                                  | 0.7 Pears        | 0.7 Cucumbers                         |
| 4.3 FR infant                 | 2.5 Apples                                  | 1.0 Strawberries | 0.3 Pears                             |
| 3.3 WHO cluster diet E        | 1.3 Wine grapes                             | 0.8 Apples       | 0.2 Tomatoes                           |
| 3.2 NL general population     | 2.0 Apples                                  | 0.4 Tomatoes     | 0.3 Pears                             |
| 3.1 UK Toddler                | 1.7 Apples                                  | 0.4 Strawberries | 0.2 Tomatoes                          |
| 2.7 DK adult                  | 1.1 Wine grapes                             | 0.8 Apples       | 0.2 Pears                             |
| 2.7 SE general population 90th percentile | 1.1 Apples | 0.3 Pears | 0.3 Strawberries |
| 2.7 IT kids/toddler           | 0.9 Apples                                  | 0.6 Tomatoes     | 0.3 Pears                             |
| 2.6 NL general                | 1.2 Apples                                  | 0.5 Wine grapes  | 0.2 Table grapes                      |
| 2.6 UK infant                 | 1.6 Apples                                  | 0.4 Strawberries | 0.3 Pears                             |
| 2.6 LT adult                  | 1.9 Apples                                  | 0.2 Tomatoes     | 0.2 Pears                             |
| 2.6 ES child                  | 1.1 Apples                                  | 0.4 Pears        | 0.4 Tomatoes                          |
| 2.4 WHO regional European diet| 0.7 Apples                                  | 0.4 Tomatoes     | 0.3 Wine grapes                       |
| 2.3 WHO cluster diet D        | 0.7 Apples                                  | 0.3 Wine grapes  | 0.2 Pears                             |
| 2.3 ES adult                  | 0.9 Apples                                  | 0.5 Tomatoes     | 0.2 Pears                             |
| 2.3 IT adult                  | 0.8 Apples                                  | 0.5 Wine grapes  | 0.3 Tomatoes                          |
| 2.1 WHO Cluster diet F        | 0.7 Apples                                  | 0.5 Wine grapes  | 0.3 Tomatoes                          |
| 2.0 UK vegetarian             | 0.7 Wine grapes                             | 0.6 Apples       | 0.2 Tomatoes                          |
| 1.8 UK Adult                  | 0.9 Wine grapes                             | 0.4 Apples       | 0.2 Tomatoes                          |
| 1.2 NL adult                  | 0.4 Apples                                  | 0.2 Wine grapes  | 0.2 Tomatoes                          |

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

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

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

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

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

### Table: Acute Risk Assessment

| Commodity          | pTMRL/Threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|--------------------|-----------------------------|-----------------------------------|-------------------------------------------------------------|-------------------------------------------------------------|
| Fruit              |                             |                                   |                                                              |                                                              |
| Table grapes       | 1.56/-                      | 20.4                              |                                                              |                                                              |
| Apples             | 1.02/-                      | 20.0                              |                                                              |                                                              |
| Pears              | 1.02/-                      | 18.6                              |                                                              |                                                              |
| Peppers            | 0.72/-                      | 9.1                               |                                                              |                                                              |
| Tomatoes           | 0.72/-                      | 8.4                               |                                                              |                                                              |
| Wine grapes        | 1.56/-                      | 9.9                               |                                                              |                                                              |
| Pears              | 1.02/-                      | 4.4                               |                                                              |                                                              |
| Peppers            | 0.72/-                      | 2.4                               |                                                              |                                                              |
| Tomato             | 0.72/-                      | 6.1                               |                                                              |                                                              |
| Tomatoes           | 0.72/-                      | 2.1                               |                                                              |                                                              |

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.

For Penconazole 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.

### Table: Processed Commodities

| Commodity          | pTMRL/Threshold MRL (mg/kg) | Highest % of ARfD/ADI Processed commodities | No of commodities for which ARfD/ADI is exceeded: |
|--------------------|-----------------------------|---------------------------------------------|--------------------------------------------------|
| Apple juice        | 1.02/-                      | 1.3                                          |                                                  |
| Grape juice        | 1.56/-                      | 1.3                                          |                                                  |
| Pear juice         | 1.02/-                      | 0.3                                          |                                                  |
| Tomato juice       | 0.72/-                      | 0.2                                          |                                                  |
| Peach juice        | 0.48/-                      | 0.2                                          |                                                  |
| Wine               | 1.56/-                      | 1.2                                          |                                                  |
| Tomato (preserved) | 0.72/-                      | 0.2                                          |                                                  |
| Quince jelly       | 1.02/-                      | 0.2                                          |                                                  |
| Peach preserved    | 0.48/-                      | 0.2                                          |                                                  |

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.

Conclusion:

For Penconazole 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.

**Notes:**
- 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 for unprocessed commodity.
- **pTMRL: provisional temporary MRL for processed commodity.
- ***pTMRL: provisional temporary MRL for unprocessed commodity.
- ***) pTMRL: provisional temporary MRL for unprocessed commodity.
- ****pTMRL: provisional temporary MRL for processed commodity.

www.efsa.europa.eu/efsajournal

50 EFSA Journal 2017;15(6):4853
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: penconazole and free and conjugated CGA 132465, CGA 190503 and CGA 127841, expressed as penconazole |
| Apples pomace, wet   | 0.25                  | STMR × PF × CF (tentative) | 0.25 | STMR × PF × CF (tentative) |

STMR: supervised trials median residue; PF: processing factor; CF: conversion factor for enforcement residue definition to risk assessment residue definition.

D.2. Consumer risk assessment without consideration of the existing CXLs

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Risk assessment residue definition: penconazole and free and conjugated CGA 132465, CGA 190503 and CGA 127841, expressed as penconazole |
| Almonds                          | 0.30                    | EU MRL × CF           | 0.30 | EU MRL × CF           |
| Hazelnuts/cobnuts                | 0.30                    | EU MRL × CF           | 0.30 | EU MRL × CF           |
| Walnuts                          | 0.30                    | EU MRL × CF           | 0.30 | EU MRL × CF           |
| Apples                           | 0.12                    | STMR<sub>95</sub> × CF (tentative) | 0.47 | HR<sub>95</sub> × CF (tentative) |
| Pears                            | 0.12                    | STMR<sub>95</sub> × CF (tentative) | 0.47 | HR<sub>95</sub> × CF (tentative) |
| Quinces                          | 0.12                    | STMR<sub>95</sub> × CF (tentative) | 0.47 | HR<sub>95</sub> × CF (tentative) |
| Medlars                          | 0.12                    | STMR<sub>95</sub> × CF (tentative) | 0.47 | HR<sub>95</sub> × CF (tentative) |
| Loquats/Japanese medlars         | 0.12                    | STMR<sub>95</sub> × CF (tentative) | 0.24 | HR<sub>95</sub> × CF (tentative) |
| Apricots                         | 0.17                    | STMR<sub>95</sub> × CF (tentative) | 0.18 | HR<sub>95</sub> × CF (tentative) |
| Cherries (sweet)                 | 0.06                    | STMR<sub>95</sub> × CF (tentative) | 0.54 | HR<sub>95</sub> × CF (tentative) |
| Peaches                          | 0.18                    | STMR<sub>95</sub> × CF (tentative) | 0.48 | HR<sub>95</sub> × CF (tentative) |
| Plums                            | 0.09                    | STMR<sub>95</sub> × CF (tentative) | 0.36 | HR<sub>95</sub> × CF (tentative) |
| Table grapes                     | 0.24                    | STMR<sub>95</sub> × CF (tentative) | 1.56 | HR<sub>95</sub> × CF (tentative) |
| Wine grapes                      | 0.24                    | STMR<sub>95</sub> × CF (tentative) | 1.56 | HR<sub>95</sub> × CF (tentative) |
| Strawberries                     | 0.60                    | STMR<sub>95</sub> × CF (tentative) | 1.14 | HR<sub>95</sub> × CF (tentative) |
| Blackberries                     | 0.21                    | STMR<sub>95</sub> × CF (tentative) | 0.24 | HR<sub>95</sub> × CF (tentative) |
| Raspberries (red and yellow)     | 0.21                    | STMR<sub>95</sub> × CF (tentative) | 0.24 | HR<sub>95</sub> × CF (tentative) |
| Currants (black, red and white)  | 0.21                    | STMR<sub>95</sub> × CF (tentative) | 0.30 | HR<sub>95</sub> × CF (tentative) |
| Commodity | Chronic risk assessment | Acute risk assessment |
|-----------|-------------------------|-----------------------|
|           | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Gooseberries (green, red and yellow) | 0.06 | $\text{STMR}_{\text{Mo}} \times \text{CF}$ (tentative) | 0.30 | $\text{HR}_{\text{Mo}} \times \text{CF}$ (tentative) |
| Tomatoes  | 0.12 | $\text{STMR}_{\text{Mo}} \times \text{CF}$ (tentative) | 0.42 | $\text{HR}_{\text{Mo}} \times \text{CF}$ (tentative) |
| Sweet peppers/bell peppers | 0.17 | $\text{STMR}_{\text{Mo}} \times \text{CF}$ (tentative) | 0.72 | $\text{HR}_{\text{Mo}} \times \text{CF}$ (tentative) |
| Aubergines/eggplants | 0.12 | $\text{STMR}_{\text{Mo}} \times \text{CF}$ (tentative) | 0.42 | $\text{HR}_{\text{Mo}} \times \text{CF}$ (tentative) |
| Cucumbers | 0.12 | $\text{STMR}_{\text{Mo}} \times \text{CF}$ (tentative) | 0.24 | $\text{HR}_{\text{Mo}} \times \text{CF}$ (tentative) |
| Gherkins | 0.12 | $\text{STMR}_{\text{Mo}} \times \text{CF}$ (tentative) | 0.24 | $\text{HR}_{\text{Mo}} \times \text{CF}$ (tentative) |
| Courgettes | 0.12 | $\text{STMR}_{\text{Mo}} \times \text{CF}$ (tentative) | 0.24 | $\text{HR}_{\text{Mo}} \times \text{CF}$ (tentative) |
| Melons | 0.07 | $\text{STMR}_{\text{Mo}} \times \text{PF} \times \text{CF}$ (tentative) | 0.17 | $\text{HR}_{\text{Mo}} \times \text{PF} \times \text{CF}$ (tentative) |
| Pumpkins | 0.07 | $\text{STMR}_{\text{Mo}} \times \text{PF} \times \text{CF}$ (tentative) | 0.17 | $\text{HR}_{\text{Mo}} \times \text{PF} \times \text{CF}$ (tentative) |
| Watermelons | 0.07 | $\text{STMR}_{\text{Mo}} \times \text{PF} \times \text{CF}$ (tentative) | 0.17 | $\text{HR}_{\text{Mo}} \times \text{PF} \times \text{CF}$ (tentative) |
| Peas (with pods)\(^{(a)}\) | – | – | – | – |
| Peas (without pods)\(^{(a)}\) | – | – | – | – |
| Globe artichokes\(^{(a)}\) | – | – | – | – |

CXL: codex maximum residue limit; MRL: maximum residue level; CF: conversion factor for enforcement residue definition to risk assessment residue definition; STMR: supervised trials median residue; HR: highest residue; PF: processing factor; Mo: monitoring.  
\(^{(a)}\): The existing uses on these crops could not be assessed by EFSA since a metabolism study allowing deriving proper residue definitions for enforcement and risk assessment is not available.

D.3. Consumer risk assessment with consideration of the existing CXLs

| Commodity | Chronic risk assessment | Acute risk assessment |
|-----------|-------------------------|-----------------------|
|           | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition: penconazole and free and conjugated CGA 132465, CGA 190503 and CGA 127841, expressed as penconazole |
| Almonds | 0.30 | EU MRL $\times$ CF | 0.30 | EU MRL $\times$ CF |
| Hazelnuts/cobnuts | 0.30 | EU MRL $\times$ CF | 0.30 | EU MRL $\times$ CF |
| Walnuts | 0.30 | EU MRL $\times$ CF | 0.30 | EU MRL $\times$ CF |
| Apples | 0.30 | $\text{STMR}_{\text{Mo}} \times \text{CF}$ (CXL, tentative) | 1.02 | $\text{HR}_{\text{Mo}} \times \text{CF}$ (CXL, tentative) |
| Pears | 0.30 | $\text{STMR}_{\text{Mo}} \times \text{CF}$ (CXL, tentative) | 1.02 | $\text{HR}_{\text{Mo}} \times \text{CF}$ (CXL, tentative) |
| Quinces | 0.30 | $\text{STMR}_{\text{Mo}} \times \text{CF}$ (CXL, tentative) | 1.02 | $\text{HR}_{\text{Mo}} \times \text{CF}$ (CXL, tentative) |
| Medlars | 0.30 | $\text{STMR}_{\text{Mo}} \times \text{CF}$ (CXL, tentative) | 1.02 | $\text{HR}_{\text{Mo}} \times \text{CF}$ (CXL, tentative) |
| Loquats/Japanese medlars | 0.30 | $\text{STMR}_{\text{Mo}} \times \text{CF}$ (CXL, tentative) | 1.02 | $\text{HR}_{\text{Mo}} \times \text{CF}$ (CXL, tentative) |
| Commodity                          | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|-------------------------|-----------------------|
|                                   | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Apricots                          | 0.17                    | STMR × CF             | 0.18                | HR × CF               |
| Cherries (sweet)                  | 0.06                    | STMR × CF             | 0.54                | HR × CF               |
| Peaches                           | 0.18                    | STMR × CF             | 0.48                | HR × CF               |
| Plums                             | 0.09                    | STMR × CF             | 0.36                | HR × CF               |
| Table grapes                      | 0.24                    | STMR × CF             | 1.56                | HR × CF               |
| Wine grapes                       | 0.24                    | STMR × CF             | 1.56                | HR × CF               |
| Strawberries                      | 0.60                    | STMR × CF             | 1.14                | HR × CF               |
| Blackberries                      | 0.21                    | STMR × CF             | 0.24                | HR × CF               |
| Raspberries (red and yellow)      | 0.21                    | STMR × CF             | 0.24                | HR × CF               |
| Currants (black, red and white)   | 0.21                    | STMR × CF             | 0.30                | HR × CF               |
| Gooseberries (green, red and yellow) | 0.06                | STMR × CF             | 0.30                | HR × CF               |
| Tomatoes                          | 0.12                    | STMR × CF (CXL, tentative) | 0.72                | HR × CF (CXL, tentative) |
| Sweet peppers/bell peppers       | 0.17                    | STMR × CF             | 0.72                | HR × CF               |
| Aubergines/eggplants              | 0.12                    | STMR × CF             | 0.42                | HR × CF               |
| Cucumbers                         | 0.12                    | STMR × CF             | 0.48                | HR × CF               |
| Gherkins                          | 0.12                    | STMR × CF             | 0.24                | HR × CF               |
| Courgettes                        | 0.12                    | STMR × CF             | 0.24                | HR × CF               |
| Melons                            | 0.07                    | STMR × PF × CF        | 0.17                | HR × PF × CF          |
| Pumpkins                          | 0.07                    | STMR × PF × CF        | 0.17                | HR × PF × CF          |
| Watermelons                       | 0.07                    | STMR × PF × CF        | 0.17                | HR × PF × CF          |
| Peas (with pods)\(^{(a)}\)       | –                       | –                     | –                   | –                     |
| Peas (without pods)\(^{(a)}\)    | –                       | –                     | –                   | –                     |
| Globe artichokes \(^{(a)}\)      | –                       | –                     | –                   | –                     |
| Hops (dried)\(^{(a)}\),          | –                       | –                     | –                   | –                     |
| including hop pellets and         | –                       | –                     | –                   | –                     |
| unconcentrated powder             | –                       | –                     | –                   | –                     |

CXL: codex maximum residue limit; MRL: maximum residue level; CF: conversion factor for enforcement residue definition to risk assessment residue definition; STMR: supervised trials median residue; HR: highest residue; PF: processing factor; Mo: monitoring.

\(^{(a)}\): The existing uses on these crops could not be assessed by EFSA since a metabolism study allowing deriving proper residue definitions for enforcement and risk assessment is not available.
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP or DB > 0.1 mg/kg in EU?
  - Yes
    - MRL derived in Section 3?
      - Yes
        - MRL fully supported by data?
          - Yes
          - MRL is recommended.
          - No
          - Fall-back MRL available?
            - Yes
              - Risk identified?
                - Yes
                - Median/highest values are included in the RA.
                - No
                - Not considered for the RA.
            - No
            - Fall-back MRL available?
              - Yes
                - Risk identified?
                  - Yes
                  - Tentative median/highest values are included in the RA.
                  - No
                  - Tentative median/highest values are included in the RA.
              - No
              - Not considered for the RA.

Consumer risk assessment for GAPs evaluated at EU level – EU scenarios

- Risk identified?
  - Yes
    - gap specific LOQ or default MRL?
    - Yes
      - MRL fully supported by data?
        - Yes
        - MRL is recommended.
        - No
        - Fall-back MRL available?
          - Yes
            - Risk identified?
              - Yes
              - Median/highest values are included in the RA.
              - No
              - Not considered for the RA.
          - No
          - Fall-back MRL available?
            - Yes
              - Risk identified?
                - Yes
                - Tentative median/highest values are included in the RA.
                - No
                - Tentative median/highest values are included in the RA.
            - No
            - Not considered for the RA.
    - No
      - Not considered for the RA.

Recommendations resulting from EU authorisations and import tolerances

(A) Specific LOQ or default MRL?
(B) Specific LOQ or default MRL?
(C) Maintain current EU MRL?
(D) Specific LOQ or default MRL?
(E) Establish tentative EU MRL?
(F) Specific LOQ or default MRL?
(G) MRL is recommended.
### Appendix F – Used compound codes

| Code/trivial name | Chemical name/SMILES notation | Structural formula |
|-------------------|--------------------------------|--------------------|
| Penconazole       | (RS)-1-[2-{2-(4-Dichlorophenyl)pentyl]-1H-1,2,4-triazole Clc2ccc(C(CCC)Cn1cn1n1)c(Cl)c2 | ![Penconazole's structural formula](image1) |
| CGA 132465        | 4-(2,4-Dichlorophenyl)-5-(1H-1,2,4-triazol-1-yl)-2-pentanol Clc2ccc(C(CC(C)O)Cn1cn1n1)c(Cl)c2 | ![CGA 132465's structural formula](image2) |
| CGA 190503        | 2-(2,4-Dichlorophenyl)-1-(1H-1,2,4-triazol-1-yl)-3-pentanol OC(CC)C(Cn1cn1n1)c2ccc(Cl)cc2Cl | ![CGA 190503's structural formula](image3) |
| CGA 127841        | 4-(2,4-Dichlorophenyl)-5-(1H-1,2,4-triazol-1-yl)-1-pentanol Clc2ccc(C(CCCO)Cn1cn1n1)c(Cl)c2 | ![CGA 127841's structural formula](image4) |
| CGA 131013 (triazolyl alanine) | 3-(1H-1,2,4-Triazol-1-yl)-α,γ-alanine NC(Cn1cn1n1)C(=O)O | ![CGA 131013 (triazolyl alanine)'s structural formula](image5) |
| CGA 205369 (triazolyl lactic acid) | (2RS)-2-Hydroxy-3-(1H-1,2,4-triazol-1-yl) propanoic acid OC(Cn1cn1n1)C(=O)O | ![CGA 205369 (triazolyl lactic acid)'s structural formula](image6) |
| CGA 142856 (triazolyl acetic acid) | 1H-1,2,4-Triazol-1-ylacetic acid O-C(=O)Cn1cn1n1 | ![CGA 142856 (triazolyl acetic acid)'s structural formula](image7) |

SMILES: simplified molecular-input line-entry system.