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

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance fenbuconazole. To assess the occurrence of fenbuconazole 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 some MRL proposals derived by EFSA still require further consideration by risk managers.

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Summary

Fenbuconazole was included in Annex I to Directive 91/414/EEC on 1 May 2011 by Commission Directive 2010/87/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 residues data, EFSA asked the United Kingdom, as 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 11 October 2016 and finalised on 9 December 2016. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 8 March 2017.

Based on the conclusions derived by EFSA 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 May 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 12 June 2018 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of fenbuconazole was investigated in fruit and root and tuber crops, in cereals and in pulses and oilseeds. The metabolism was similar in all crop groups with the parent as the major constituent with the exception of peanut meat where the parent was not detected. The triazole derivative metabolites (TDMs) were also present at significant amounts, with triazole alanine (TA) ranging from 47% to 88% total radioactive residue (TRR) in cereal grain, peaches and peanuts.

Fenbuconazole is authorised for use on cucurbits with edible and inedible peel which may be grown in rotation. An investigation of residues in rotational crops was performed covering root, tuber crops, leafy vegetables and cereals indicating that the metabolic pathway of fenbuconazole all crop groups is similar to the pathway observed in primary crops.

It was demonstrated that fenbuconazole remained unchanged after exposure to standard hydrolysis conditions. Storage stability of fenbuconazole was demonstrated at –10°C for a period of up to 4.5 years in high water and high oil content, for up to 3 years in dry and for up to 1 year in high acid content commodities.

In the framework of this MRL review, the parent compound only was considered for both enforcement and risk assessment, noting that parent compound did not represent always the major part of the residues since cleavage of triazole linkage was found to release significant levels of TDMs. In particular in peanut meat, the major residue was triazole alanine (TA). For processed commodities and for rotational crops, the same residue definition as for raw agricultural commodities (RAC) is proposed.

A validated gas chromatography with mass spectrometry (GC–MS) method is available for enforcement of fenbuconazole in high water, high acid, high oil and dry commodities with a limit of quantification (LOQ) of 0.01 mg/kg. According to the EURLs, an LOQ of 0.01 mg/kg is achievable in the four main matrices.

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation except for loquats, medlars, apricots, peaches, cherries, plums, cucurbits with edible and inedible peel where tentative MRLs are derived.

Significant residues of fenbuconazole are not expected in rotational crops, provided that the active substance is used according to the most critical Good Agricultural Practices (GAPs) considered in this review. Possible uptake of triazole metabolites cannot be excluded and should be considered further when a methodology for TDMs assessment is available.

The metabolism in goat and poultry is similar. In hen tissue, the parent compound, RH-9129, RH-9130, RH-0118 (1,2,4-triazole) and RH-3968 were found to be the main components of the residue. In goat, fenbuconazole and its metabolites RH-7968, RH-1311, RH-0118 (1,2,4-triazole) and RH-3968 (TA) are the major constituents in goat tissues. However, considering the new goat metabolism study at the more representative dose rate, these metabolites are not expected to be present in significant levels in ruminant tissues under the considered uses. Therefore, the residue definition for monitoring and risk assessment was limited to parent fenbuconazole only.
A validated GC–MS method for fenbuconazole in milk, meat, kidney, liver, fat and eggs supported by an independent laboratory validation (ILV) for beef fat and milk, with an LOQ of 0.05 mg/kg is available. The EURLs provided a screening LC–MS–Q–TOF method for honey, eggs, muscle (red and white meat and fish) and for milk and milk products with a screening detection limit (SDL) of 0.005 mg/kg.

One feeding study performed on dairy cattle was evaluated in which the dosing level which is equivalent to 14.9N rate covers the calculated maximum dietary burden for cattle. Residues of fenbuconazole were only quantified in liver and considering the N rate corresponding to the calculated dietary burden, residues of the parent above the enforcement LOQ of 0.05 mg/kg are not expected in ruminants’ tissues and in milk.

Storage stability of fenbuconazole was demonstrated in all animal commodities at −10°C for 2 (fat and eggs), 3 (muscle, liver, kidney) to 4 (milk) months. Samples were stored at −10°C for periods between 11 and 109 days prior to analysis and a decline of residues during storage cannot be excluded. Therefore, the MRLs for these commodities should be considered tentative only and a storage stability study covering the storage conditions of the samples analysed in the livestock feeding study is still required.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The highest chronic exposure was calculated for NL child, representing 50.8% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for oranges, representing 29.1% of the acute reference dose (ARfD). Although uncertainties remain due to the data gaps identified, this indicative exposure calculation did not indicate a risk to consumers.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for fenbuconazole. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure was calculated for DE child, representing 55.7% of the ADI, and the highest acute exposure was calculated for oranges, representing 29.1% of the ARfD. Although uncertainties remain due to the data gaps identified, this indicative exposure calculation did not indicate a risk to consumers.

EFSA emphasises that the above assessment does not take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA was asked to perform a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides submitted in the framework of the confirmatory data assessment. However, currently, an overall consumer exposure assessment to relevant TDMs arising from all triazole fungicides could not be concluded on until the outstanding issues and general recommendations highlighted in the assessment are addressed.
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Background

Regulation (EC) No 396/2005 (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 a reasoned opinion on the review of the existing MRLs for that active substance. As fenbuconazole was included in Annex I to Council Directive 91/414/EEC on 1 May 2011 by means of Commission Directive 2010/87/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, EFSA initiated the review of all existing MRLs for that active substance.

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

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

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

The United Kingdom, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for fenbuconazole and to prepare a supporting evaluation report (United Kingdom, 2011). The PROFile and the supporting evaluation report were submitted to EFSA on 21 September 2011 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 which was initiated by EFSA on 11 October 2016 and finalised on 9 December 2016. Additional evaluation reports were submitted by France, Italy, Portugal, Spain, the United Kingdom and the European Union Reference Laboratories for Pesticide Residues (EURL, 2016; France, 2016, 2017; Italy, 2016, 2017; Portugal, 2016; Spain, 2016; United Kingdom, 2016, 2017) 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 8 March 2017. Further clarifications were sought from Member States via a written procedure in March 2017.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission (codex maximum residue limit; CXLs) and the additional information provided by the Member States, EFSA prepared in May 2018 a draft reasoned opinion on the analytical methods for enforcement of the proposed MRLs.
opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 12 June 2018 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (United Kingdom, 2011, 2016, 2017) and the evaluation reports submitted by France, Italy, Portugal, Spain and the European Union Reference Laboratories for Pesticide Residues (EURL, 2016; France, 2016, 2017; Italy, 2016, 2017; Portugal, 2016; Spain, 2016; United Kingdom, 2016, 2017) 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, 2017) and the Member States consultation report (EFSA, 2018a). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic and acute exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) (excel file) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

Terms of reference

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

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

The active substance and its use pattern

Fenbuconazole is the ISO common name for a racemic mixture (RS)-4-(4-chlorophenyl)-2-phenyl-2-(1H-1,2,4-triazol-1-ylmethyl))butyronitrile (IUPAC).

Fenbuconazole belongs to the group of triazole compounds which are used as systemic fungicide; it causes inhibition of demethylation in sterol biosynthesis. It is used as a broad-spectrum fungicide, with preventive and curative action in the control of fungal disease in a range of crops.

The chemical structure of fenbuconazole and its main metabolites are reported in Appendix F.

Fenbuconazole was evaluated in the framework of Directive 91/414/EEC with United Kingdom designated as rapporteur Member State (RMS). Following the Commission Decision 2008/9347 concerning the non-inclusion of fenbuconazole in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, in accordance with Article 11(e) of Commission Regulation (EC) No 1490/20028 the applicant Dow AgroSciences made a resubmission application for the inclusion of fenbuconazole in Annex I in accordance with the provisions laid down in Commission Regulation (EC) No 33/20089.

The applicant resubmission of the additional data via accelerated procedure (Regulation (EC) No 33/2008), was evaluated by the RMS in the format of an Additional Report of fenbuconazole (United Kingdom, 2009a,b). The representative uses supported for the peer review process were as a fungicide foliar spraying against on wheat, apples and grapes. Following the peer review, which was carried out by EFSA (2010), a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2010/87/EU10, which entered into force on

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7 2008/934/EC: Commission Decision of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances. OJ L 333, 11.12.2008, p. 11–14.
8 1490/2002/EC: Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000. OJ L 224, 21.8.2002, p. 23–48.
9 33/2008/EC: Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.
10 2010/87/EU: Commission Directive 2010/87/EU of 3 December 2010 amending Council Directive 91/414/EEC to include fenbuconazole as active substance and amending Decision 2008/934/ECOJ L 318, 4.12.2010, p. 32–35.
1 May 2011. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, fenbuconazole has been approved under Regulation (EC) No 1107/2009. This approval is restricted to fungicide uses only.

According to the Annex of the approval Directive, it was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin by 30 April 2013. An EFSA Conclusion on the confirmatory data assessment is available (EFSA, 2018b).

The EU MRLs for fenbuconazole are established in Annexes II and IIIA of Regulation (EC) No 396/2005 and CXL(s) for this active substance were also established by the Codex Alimentarius Commission (CAC). An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below.

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

| Procedure | Legal implementation | Remarks |
|-----------|----------------------|---------|
| Implementation of CAC, 5 July 2013 | Commission Regulation (EC) No 491/2014 | CXLs adopted by CAC for fenbuconazole on 5 July 2013 following EFSA comments on the proposed Codex MRLs evaluated by JMPR in 2012 |

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

For the purpose of this MRL review, the critical uses of fenbuconazole currently authorised within the EU, as well as uses authorised in third countries that might have a significant impact on international trade, have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAP(s) for fenbuconazole are given in Appendix A.

**Assessment**

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (United Kingdom, 2011), the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2005, 2009a,b), the conclusion on the peer review of the pesticide risk assessment of the active substance fenbuconazole (EFSA, 2010), the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2009, 2013), as well as the evaluation reports submitted during the completeness check (EURL, 2016, France, 2016, 2017; Italy, 2016, 2017; Portugal, 2016; Spain, 2016; United Kingdom, 2016, 2017). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2016b; 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 fenbuconazole was investigated in fruit crops (peaches), cereal (wheat) and root and tuber crops (sugar beet) and in pulses and oilseeds (peanuts). Crops were treated with phenyl- or triazole-labelled fenbuconazole using foliar applications except of sugar beets which was treated with phenyl-labelled fenbuconazole only.

In peach for the phenyl label, parent fenbuconazole was the most abundant component (45% total radioactive residue (TRR); 0.036 mg/kg). The only other metabolite identified was RH-9129 (14.2% TRR, 0.012 mg/kg). For the triazole label, the metabolite triazole alanine (TA) was the most abundant

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11 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127–175.
In peanut meat, the fenbuconazole molecule was cleaved to form mainly triazole-based metabolites as suggested by a significant difference in the TRR values for the phenyl and triazole labels. The majority of radioactivity for the phenyl label was assigned to sugar conjugates (29.7% TRR, 0.019 mg/kg). For the triazole label, the most abundant metabolite identified was TA accounting for 88% TRR (3.504 mg/kg). TAA accounted for 1.9% TRR (0.074 mg/kg) and other identified metabolites were less than 0.002 mg/kg for either label.

In wheat for the phenyl label, no identified compounds were found at levels greater than 0.01 mg/kg (20% TRR). Fenbuconazole was accounting for 12.4% TRR (0.006 mg/kg) for the phenyl label and for the triazole label, TA accounted for 48.3% TRR (0.255 mg/kg) and TAA for 20.1% TRR (0.106 mg/kg), respectively. In straw, for both labels the parent was identified between 60–65% and neither TA nor TAA was detected. Metabolites RH-9129 and RH-6467 were identified for both labels below 8% TRR and triazole-labelled sugar conjugates with 3.2% TRR.

In sugar beet, fenbuconazole was the major component identified in both roots and leaves accounting for 82.5% TRR (0.281 mg/kg) in roots and 91.3% TRR (10.94 mg/kg) in leaves. Other identified metabolites were below 3% TRR.

The metabolism was similar in all crop groups with the parent as major constituent (12–83% TRR) with the exception of peanut meat where the parent was not detected. The TDMs were also present at significant amounts, with TA ranging from 47% to 88% TRR in cereal grain, peaches and peanuts. Additional metabolites were observed in clearly smaller amounts than the parent.

It was further noted during the peer review that fenbuconazole is a racemic mixture of enantiomers, and that the possible preferential metabolism/degradation of each enantiomer in plants and animals was not investigated. Additional information was not received during this MRL review and therefore this data gap remains.

1.1.2. Nature of residues in rotational crops

Fenbuconazole is authorised for use on cucurbits with edible and inedible peel which may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, periods required for 90% dissipation (DT$_{90}$ values) of fenbuconazole in soil were up to 1,219 days for sandy loam, which is above the trigger value of 100 days. As the DT$_{90}$ value is also above 500 days, the impact of year to year use of fenbuconazole in rotational crops should be considered (see Section 1.2.2).

Therefore, further investigation of residues in rotational crops was performed and evaluated in three studies during the peer review covering root and tuber vegetables (carrot, radish and turnip roots and leaves), leafy vegetables (collard and lettuce) and cereals (barley, sorghum grain, forage, stover and wheat grain, straw and chaff) (EFSA, 2010).

Following bare soil application of phenyl- or triazole-labelled fenbuconazole at exaggerated dose rates of 8.96 kg a.s./ha (59.7.1N the maximum rate considered in this review), the metabolic profile in wheat grain, collards and turnip roots and leaves was similar with TA (RH-3968) being the major metabolite identified for all plant-back intervals (PBIs) (55.8–80.9% TRR; 3.9–24 mg/kg for PBI of 365 days). The metabolite TAA (RH-4098) accounted for 7.8–34.2% TRR (0.37–14.71 mg/kg for PBI of 365 days). Parent fenbuconazole was found in all crops only at the PBI of 30 days with the highest TRR of 1.6% (0.240 mg/kg) in turnip leaves. In wheat straw, it was quantified at the PBI of 30 and 365 days with 3.4% (0.476 mg/kg) and 0.2% (0.018 mg/kg).

Two additional studies were conducted following soil application of only phenyl-labelled fenbuconazole 4 × 0.28 kg a.s./ha (total dose of 1.21 kg a.s./ha) (corresponding to 8.1N the maximum rate considered in this review) before planting lettuce, radish and sorghum and at a lower rate of 3 × 0.07 kg a.s./ha (total dose of 0.21 kg a.s./ha) (1.4N rate) before planting lettuce, carrots and barley. The metabolic profile seen in the following crops was consistent with metabolites identified and characterised from the phenyl-labelled primary crop study. Residues of individually identified metabolites were all < 0.02 mg/kg.

During the peer review, it was concluded that the metabolic pathway of fenbuconazole in rotational crops covering all crop groups is similar to the pathway observed in primary crops. This conclusion is supported in this MRL review.
1.1.3. Nature of residues in processed commodities

A hydrolysis study conducted using phenyl-labelled fenbuconazole showed that fenbuconazole remained unchanged after exposure to standard hydrolysis conditions simulating pasteurisation (20 min at 90°C, pH 4), baking, brewing, boiling (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6) conditions of processing in compliance with good laboratory practice (GLP).

However, data were not provided to show the effect of hydrolysis on triazole labelled fenbuconazole. Nevertheless, since phenyl labelled fenbuconazole remained stable it was concluded during the peer review that further studies are not required (EFSA, 2010). This conclusion is supported during this MRL review.

1.1.4. Methods of analysis in plants

In the framework of the peer review (EFSA, 2010), a validated gas chromatography method with mass spectrometry detection (GC-MS) and its independent laboratory validation (ILV) were considered suitable for the monitoring of fenbuconazole in high acid, high oil and dry commodities with a limit of quantification (LOQ) of 0.01 mg/kg. A validated analytical method for enforcement in high water commodities was not available (United Kingdom, 2005; EFSA, 2010) and is in principle still required. Nevertheless, considering that the above reported method was validated in three matrices, including high oil and dry commodities which are more difficult to analyse, it is expected that it would be also suitable for enforcement in high water content commodities. Moreover, as the extraction in the GC-MS method is performed at controlled pH, the method can be considered acceptable for high water content commodities and therefore, additional validation data in high water matrices are not required.

During the completeness check, the EURLs provided a liquid chromatography method coupled with tandem mass spectrometry detection (LC-MS/MS) for fenbuconazole in high water, high acid and high oil commodities with an LOQ of 0.01 mg/kg and a gas chromatography method coupled with tandem mass spectrometry detection (GC-MS/MS) for dry commodities with an LOQ of 0.01 mg/kg (EURLs, 2016).

1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of fenbuconazole was demonstrated at −10°C for a period of up to 4.5 years in high water content, for up to 3 years in dry and for up to 1 year in high acid content commodities. Storage stability of fenbuconazole was also demonstrated at −10°C for a period of 4.5 years in high oil content matrices (pecan nuts) (EFSA, 2010).

1.1.6. Proposed residue definitions

Based on all three available metabolism studies, unchanged fenbuconazole and the TDMs, in particular TA, were the major residues. During the peer review, it was proposed to limit the residue definition for monitoring and risk assessment to fenbuconazole only taking into account the ongoing consideration regarding TDMs (EFSA, 2010).

It is highlighted that residue definitions for monitoring and risk assessment for triazole pesticide active substances in plants have been agreed in the framework of the TDM confirmatory data (EFSA, 2018b). Nevertheless, in the framework of this MRL review, parent compound only was considered for both enforcement and risk assessment, noting that parent compound did not represent always the major part of the residues since cleavage of triazole linkage was found to release significant levels of TDMs. In particular in peanut meat, the major residue was triazole alanine.

A validated GC-MS method is available for enforcement of fenbuconazole in high acid, high oil and dry commodities with a LOQ of 0.01 mg/kg. This method can be used for enforcement in high water content commodities, noting that validation data are still desirable for this matrix.

For processed commodities and for rotational crops, the same residue definition as for raw agricultural commodities (RAC) is 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.
1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of fenbuconazole residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (United Kingdom, 2011), including residue trials evaluated in the framework of the peer review (EFSA, 2010) and additional data submitted during the completeness check (France, 2016, 2017; Italy, 2016, 2017; Portugal, 2016; Spain, 2016; United Kingdom, 2016, 2017). Residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions with the exception of northern European samples for apples, pears, table and wine grapes where storage information was not provided. Considering that storage stability in high water commodities at -10°C was demonstrated for up to 4.5 years, decline of residues during storage of the trials is not expected. As for high acid commodities, storage stability was only demonstrated for one year, storage information to confirm the validity of the residue trials reported for grapes are in principle still required. However considering that in all other matrices the stability has been demonstrated for up to 4.5 years, this additional information is only desirable.

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, 2016b).

The available residue trials and MRL proposals are summarised in Table B.1.2.1.

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

- Medlars and loquats: available residue trials were all performed with four instead of three applications. While a tentative MRL was derived from the available trials, for each crop four residue trials compliant with the northern outdoor GAP and four compliant with the southern outdoor GAP are still required.

- Apricots and peaches: only two GAP-compliant trials on peaches are available and although a tentative MRL was derived from overdosed trials on peaches and apricots, two additional trials on peaches and four on apricots compliant with the southern outdoor GAP are still required.

- Cherries: although a tentative MRL was derived based on two GAP-compliant and a comparable trial with a longer preharvest interval (PHI) from the southern zone, eight trials on cherries compliant with the northern outdoor GAP and one additional trial on cherries compliant with the southern outdoor GAP are still required.

- Plums: all available trials on plums supporting the southern outdoor GAP were overdosed (five instead of three applications). Although a tentative MRL could be derived based on the available trials, eight trials on plums compliant with the southern outdoor GAP are still required.

- Cucurbits with edible peel: three out of the six trials supporting the southern outdoor GAP and all the trials supporting the indoor GAP were overdosed. Although a tentative MRL could be derived, five additional trials on cucumbers compliant with the southern outdoor GAP and eight residue trials on cucumber to support the indoor GAP are still required.

- Cucurbits with inedible peel: eight of nine trials to support the southern outdoor GAP are overdosed and only one overdosed trial is available to support the indoor GAP. Although a tentative MRL was derived, seven GAP compliant trials on melons to support the southern outdoor and eight trials to support the indoor GAPs 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:

- Almonds: the number of trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no residue situation is expected. Further residue trials are therefore not required.

- Quinces: all available trials supporting the northern outdoor GAP were performed with four applications instead of three. Nevertheless, since the southern outdoor GAP is clearly more critical, no additional trials are required to support the northern outdoor GAP.
Table and wine grapes: Out of the fourteen trials available to support the southern outdoor GAP, 10 were overdosed. Nevertheless, since the northern outdoor GAP is clearly more critical, no additional trials are required to support the southern outdoor GAP.

1.2.2. Magnitude of residues in rotational crops

The plateau concentration derived in soil using a DT$_{50}$ in soil of 172 days as agreed by the peer review (EFSA, 2010), taking into account accumulation over the years, is 0.0472 mg/kg considering the critical GAPs (cGAPs) for EU cultivated non-permanent crop reported in this Article 12 review (3 applications per year at BBCH 13 at a rate of 50 g a.s./ha to cucurbits with an 8-day application interval), assuming a soil density of 1.5 kg/L, soil mixing (cultivation) depth of 20 cm and crop interception of 25%.

Based on the results of the confined rotational crop study performed at 8.96 kg a.s./ha (applied to bare soil which was aged for 30, 99 and 365 days prior to planting collards, turnips and wheat outdoors) where mean top soil residues were up to 1 mg/kg and which is covering the most critical GAPs considered in this review (maximal application rates for cucurbits of 3 $\times$ 50 g a.s./ha) and additional studies at lower total application rates, it can be concluded that the plateau concentration is covered and that significant residues of fenbuconazole are not expected in rotational crops, provided that the active substance is used according to the most critical GAPs considered in this review (Section 1.1.2).

Possible uptake of triazole metabolites cannot be excluded and should be considered further when a methodology for TDMs assessment is available.

1.2.3. Magnitude of residues in processed commodities

Studies on apples, grapes, wheat, peaches and plums were conducted with phenyl labelled fenbuconazole and reported (United Kingdom, 2005). An overview of all available processing studies is available in Appendix B.1.2.3.

Robust processing factors could be derived for red wine and for dried plums. For all other processed commodities, only indicative processing factors could be derived due to the limited data sets.

If more robust processing factors were to be required by the risk managers, in particular for enforcement purposes, additional processing studies would be needed.

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 loquats, medlars, apricots, peaches, cherries, plums, cucurbits with edible and inedible peel where tentative MRLs are derived.

2. Residues in livestock

Fenbuconazole is authorised for use on citrus and pome fruits that 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) and cattle (dairy only), and for swine (all) were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in these groups of livestock.

2.1. Nature of residues and methods of analysis in livestock

During the peer review, metabolism studies were performed on goats and hen. Four studies on goats were carried out. In one study, two goats were dosed with triazole-labelled fenbuconazole at a rate of 2.9 mg/kg body weight (bw) per day (180N). In a second study, two goats were dosed either with triazole or phenyl-labelled fenbuconazole at rates of 0.029, 0.29, 2.9 mg/kg bw per day (1.8N, 18N and 180N). In a third study, one goat was dosed with phenyl-labelled fenbuconazole at a rate of 2.3 mg/kg bw per day (146N). In a fourth more recent study, two goats were dosed with 0.29 mg/kg bw per day (180N) triazole or phenyl labelled fenbuconazole.

In the second study performed at the exaggerated rate of up to 2.9 mg/kg bw per day, residues were characterised.
Fenbuconazole represented in liver, kidney and milk 8.2% TRR (0.603 mg/kg), 11% TRR (0.136 mg/kg) and 17.2% TRR (0.013 mg/kg), respectively. Significant metabolites in liver, kidney and milk were RH-3968 (TA) (39.4% TRR (6.427 mg/kg), 22.3% TRR (0.276 mg/kg), 35.5% TRR (0.200 mg/kg)) and RH-0118 (1,2,4-triazole (1,2,4-T)) (13.6% TRR (2.222 mg/kg), 10.4% (0.129 mg/kg), 55% TRR (0.310 mg/kg)). Metabolite RH-7968 was significant in liver and kidney (13.2% TRR (0.970 mg/kg), 13.2% TRR (0.115 mg/kg)). In kidney RH-1311 (25% TRR (0.221 mg/kg) and a benzyl glucuronide conjugate (12.5% TRR, 0.109 mg/kg) and in liver, a gluronide (15.2% TRR (1.122 mg/kg)) were significant.

In muscle, fenbuconazole represented 30.4% TRR (0.018 mg/kg) and significant metabolites were RH-0118 (1,2,4-T) 36.9% TRR (0.115 mg/kg), RH-3968 (TA) for 27.2% TRR (0.085 mg/kg) and RH-7968 21.9% TRR (0.013 mg/kg). In fat, fenbuconazole accounted for 22% TRR (0.024 mg/kg) and a significant metabolite was RH-7968 (39.3% TRR (0.044 mg/kg)).

In the more recent study on goats dosed with 0.29 mg/kg bw per day (18N), fenbuconazole (triazole label) was highest in liver with 3.2% TRR (0.023 mg/kg) and the metabolites RH-9129/RH-9130 and TAA represented 2.6% TRR (0.019 mg/kg) and 0.3% TRR (0.002 mg/kg), respectively. Phenol-labelled fenbuconazole represented 5.8% TRR (0.009 mg/kg) and no further residues were identified for this label.

Two studies are available on poultry both at a rate of 6.31 mg/kg bw per day; one only with triazole-labelled fenbuconazole and a second with either triazole- or phenyl-labelled fenbuconazole at the same rate. Residues were characterised in the second study.

Fenbuconazole accounted in eggs from 32.9% TRR (1.031 mg/kg) to 40.6% TRR (0.887 mg/kg). Significant metabolites were RH-9129 (15.3% TRR (0.33 mg/kg)), RH-0118 (1,2,4-T) (12.7% TRR (0.399 mg/kg)) and RH-9130 (10.4% TRR (0.228 mg/kg)).

In poultry liver, glucuronide conjugate accounted for 28.7% TRR (3.534 mg/kg) to 36.9% TRR (3.842 mg/kg) and significant metabolites were RH-0118 (12.0% TRR (1.246 mg/kg)), RH-1311 (10.8% (1.323 mg/kg)) and RH-6468 (9.9% TRR (1.213 mg/kg)) whereby the parent fenbuconazole accounted only for up to 3.1% TRR (0.383 mg/kg).

For muscle, fenbuconazole was in the same range as in liver and the metabolite RH-0118 (1,2,4-T) accounted for up to 40.1% TRR (0.323 mg/kg). In fat, fenbuconazole accounted for 43% TRR and the metabolite RH 9129 for around 25% TRR for both labels.

The metabolism in goat and poultry is similar. In goat, fenbuconazole and its metabolites RH-7968, RH-1311, RH-0118 (1,2,4-T) and RH-3968 (TA) are the major constituents in goat tissues. However, considering the new goat metabolism study at the more representative dose rate, these metabolites are not expected to be present in significant levels in ruminant tissues at the calculated dietary burden.

In hen tissue, the parent compound, RH-9129, RH-9130, RH-0118 (1,2,4-T) and RH-3968 were found to be the main components of the residue.

The residue definition for monitoring and risk assessment was limited to parent fenbuconazole only during the peer review (EFSA, 2010). This conclusion is supported during this MRL review.

A validated GC–MS method for fenbuconazole in milk, meat, kidney, liver, fat and eggs supported by an ILV for beef fat and milk, with an LOQ of 0.05 mg/kg is available (United Kingdom, 2005). The EURLs provided a screening LC–MS-Q-TOF method for honey, eggs, muscle (red and white meat and fish) and for milk and milk products with a screening detection limit (SDL) of 0.005 mg/kg (EURLs, 2016).

It is highlighted that residue definitions for monitoring and risk assessment for triazole pesticide active substances in animals have been agreed in the framework of the TDM confirmatory data (EFSA, 2018b).

In addition, EFSA emphasises that the above studies do not investigate the possible impact of animal metabolism on the isomer ratio of fenbuconazole 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.

2.2. Magnitude of residues in livestock

MRLs and risk assessment values for animal products were derived according to the OECD guidance which was agreed upon at the European level (OECD, 2013).

One feeding study performed on dairy cattle was evaluated by the RMS in the DAR (United Kingdom, 2005). The overview of the study results used to derive the risk assessment values and the MRL proposals are summarised in Appendix B.2.2. Three dose levels were tested (0.24, 0.71 and 2.36 mg
fenbuconazole (kg bw per day), whereby the first dosing level which is equivalent to 14.9N rate covers the calculated dietary burden for cattle. At this dosing level, residues of fenbuconazole were only quantified in liver with the highest of 0.093 mg/kg. Considering the N rate corresponding to the calculated dietary burden, residues of the parent above the enforcement LOQ of 0.05 mg/kg are not expected in ruminants’ tissues and in milk. It is noted that, if a sufficiently validated analytical method with an LOQ of 0.01 mg/kg would be available for enforcement, in principle MRLs for animal commodities currently proposed at the LOQ of 0.05 mg/kg, could be lowered to an LOQ of 0.01 mg/kg.

Since the metabolism in rat and ruminants is similar, MRLs and risk assessment values derived from cattle feeding study data can be extrapolated to pigs as is relevant since the dietary burden is triggered for this animal species.

MRLs for goats and poultry products are not required because they are not expected to be exposed to significant levels of fenbuconazole residues.

Storage stability of fenbuconazole was demonstrated in all animal commodities at −10°C for 2 (fat and eggs), 3 (muscle, liver, kidney) to 4 (milk) months. Samples were stored at −10°C for periods between 11 and 109 days prior to analysis. Since stability of fenbuconazole in fat, muscle, liver and kidney has been demonstrated under these conditions for up to 90 days only, a decline of residues during storage cannot be excluded. Therefore, the MRLs for these commodities should be considered tentative only and a storage stability study covering the storage conditions of the samples analysed in the livestock feeding study are still required.

3. Consumer risk assessment

In the framework of this review, only the uses of fenbuconazole reported by the RMS in Appendix D were considered; however, the use of fenbuconazole was previously also assessed by the JMPR (FAO, 2009, 2013). The CXLs, resulting from this assessment 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). All input values included in the exposure calculations are summarised in Appendix D.

The exposures calculated were compared with the toxicological reference values for fenbuconazole, derived by EFSA (2010) under Directive 91/414/EEC. The highest chronic exposure was calculated for NL child, representing 50.8% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for oranges, representing 29.1% of the acute reference dose (ARfD). Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of fenbuconazole 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.

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 was asked to perform a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides submitted in the framework of the confirmatory data assessment. However, currently, an overall consumer exposure assessment to relevant TDMs arising from all triazole fungicides could not be concluded on until the outstanding issues and general recommendations highlighted in the assessment are addressed (EFSA, 2018b).
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. Residue definition for risk assessment defined by the JMPR is comparable to the EU, with TDMs equally not considered as outlined in Section 3.1. For animal commodities, CXLs of 0.01* mg/kg was rounded up to the LOQ of 0.05* mg/kg which was derived at EU level for enforcement in these matrices.

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 fenbuconazole. The highest chronic exposure was calculated for DE child, representing 55.7% of the ADI, and the highest acute exposure was calculated for oranges, representing 29.1% of the ARfD. Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

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 was asked to perform a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides submitted in the framework of the confirmatory data assessment. However, currently, an overall consumer exposure assessment to relevant TDMs arising from all triazole fungicides could not be concluded on until the outstanding issues and general recommendations highlighted in the assessment are addressed (EFSA, 2018b).

Conclusions

The metabolism of fenbuconazole was investigated in fruit and root and tuber crops, in cereals and in pulses and oilseeds. The metabolism was similar in all crop groups with the parent as major constituent with the exception of peanut meat where the parent was not detected. The TDMs were also present at significant amounts, with TA ranging from 47% to 88% TRR in cereal grain, peaches and peanuts.

Fenbuconazole is authorised for use on cucurbits with edible and inedible peel which may be grown in rotation. An investigation of residues in rotational crops was performed covering root, tuber crops, leafy vegetables and cereals indicating that the metabolic pathway of fenbuconazole all crop groups is similar to the pathway observed in primary crops.

It was demonstrated that fenbuconazole remained unchanged after exposure to standard hydrolysis conditions. Storage stability of fenbuconazole was demonstrated at -10 °C for a period of up to 4.5 years in high water and high oil content, for up to three years in dry and for up to one year in high acid content commodities.

In the framework of this MRL review, the parent compound only was considered for both enforcement and risk assessment, noting that parent compound did not represent always the major part of the residues since cleavage of triazole linkage was found to release significant levels of TDMs. In particular in peanut meat the major residue was triazole alanine. For processed commodities and for rotational crops, the same residue definition as for RAC is proposed.

A validated GC-MS method is available for enforcement of fenbuconazole in high water, high acid, high oil and dry commodities with a LOQ of 0.01 mg/kg. According to the EURLs, an LOQ of 0.01 mg/kg is achievable in the main four matrices.

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation except for loquats, medlars, apricots, peaches, cherries, plums, cucurbits with edible and inedible peel where tentative MRLs are derived.

Significant residues of fenbuconazole are not expected in rotational crops, provided that the active substance is used according to the most critical GAPs considered in this review. Possible uptake of triazole metabolites cannot be excluded and should be considered further when a methodology for TDMs assessment is available.

The metabolism in goat and poultry is similar. In hen tissue the parent compound, RH-9129, RH-9130, RH-0118 (1,2,4-T) and RH-3968 were found to be the main components of the residue. In goat, fenbuconazole and its metabolites RH-7968, RH-1311, RH-0118 (1,2,4-T) and RH-3968 (TA) are the major constituents in goat tissues. However, considering the new goat metabolism study at the more representative dose rate, these metabolites are not expected to be present in significant levels in
ruminant tissues under the considered uses. Therefore the residue definition for monitoring and risk assessment was limited to parent fenbuconazole only.

A validated GC–MS method for fenbuconazole in milk, meat, kidney, liver, fat and eggs supported by an ILV for beef fat and milk, with an LOQ of 0.05 mg/kg is available. The EURLs provided a screening LC–MS-Q-TOF method for honey, eggs, muscle (red and white meat and fish) and for milk and milk products with an SDL of 0.005 mg/kg.

One feeding study performed on dairy cattle was evaluated in which the dosing level which is equivalent to 14.9N rate covers the calculated maximum dietary burden for cattle. Residues of fenbuconazole were only quantified in liver and considering the N rate corresponding to the calculated dietary burden, residues of the parent above the enforcement LOQ of 0.05 mg/kg are not expected in ruminants’ tissues and in milk.

Storage stability of fenbuconazole was demonstrated in all animal commodities at -10 °C for 2 (fat and eggs), 3 (muscle, liver, kidney) to 4 (milk) months. Samples were stored at -10 °C for periods between 11 and 109 days prior to analysis and a decline of residues during storage cannot be excluded. Therefore, the MRLs for these commodities should be considered tentative only and a storage stability study covering the storage conditions of the samples analysed in the livestock feeding study are still required.

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 for an indicative calculation. The highest chronic exposure was calculated for NL child, representing 50.8% of the ADI, and the highest acute exposure was calculated for oranges, representing 29.1% of the ARfD. Although uncertainties remain due to the data gaps identified, this indicative exposure calculation did not indicate a risk to consumers.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have already been established for fenbuconazole. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure was calculated for DE child, representing 55.7% of the ADI, and the highest acute exposure was calculated for oranges, representing 29.1% of the ARfD. Although uncertainties remain due to the data gaps identified, this indicative exposure calculation did not indicate a risk to consumers.

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 was asked to perform a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides submitted in the framework of the confirmatory data assessment. However, currently, an overall consumer exposure assessment to relevant TDMs arising from all triazole fungicides could not be concluded on until the outstanding issues and general recommendations highlighted in the assessment are addressed (EFSA, 2018b).

In addition, EFSA emphasises that the above studies do not investigate the possible impact of plant and animal metabolism on the isomer ratio of fenbuconazole and further investigation would in principle be required. EFSA recommends that both issues are reconsidered when guidance is available.

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details). In particular, all tentative MRLs and existing EU MRLs need to be confirmed by the following data:

- Additional residue trials on apricots, peaches, plums, cucurbits with edible and non-edible peel.

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

- Additional residue trials on cherries, medlars, loquats;
- Storage stability study covering the storage conditions of the samples of tissue analysed in the livestock feeding study.
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, if a sufficiently validated analytical method with an LOQ of 0.01 mg/kg would be available for enforcement, in principle MRLs for animal commodities currently proposed at the LOQ of 0.05 mg/kg, could be lowered to an LOQ of 0.01 mg/kg.

It is highlighted that the consumer risk assessment for TDMs was not addressed in this review. Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following action and data is therefore considered desirable but not essential:

- Storage condition of the samples from the residue trials on grapes.

Table 2: Summary table

| Code number(a) | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|----------------|-----------|------------------------|---------------------|----------------------|---------|
| Enforced residue definition (existing): fenbuconazole (sum of constituent enantiomers) |
| 110010 | Grapefruit | 1 | 0.5 | 0.7 | Recommended(b) |
| 110020 | Oranges | 1 | 0.5 | 0.9 | Recommended(b) |
| 110030 | Lemons | 0.05* | 1 | 1 | Recommended(c) |
| 110040 | Limes | 0.05* | 1 | 1 | Recommended(c) |
| 110050 | Mandarins | 0.05* | 0.5 | 0.5 | Recommended(c) |
| 120010 | Almonds | 0.05* | 0.01* | 0.01* | Recommended(b) |
| 120020 | Brazil nuts | 0.05* | 0.01* | 0.01* | Recommended(c) |
| 120030 | Cashew nuts | 0.05* | 0.01* | 0.01* | Recommended(c) |
| 120040 | Chestnuts | 0.05* | 0.01* | 0.01* | Recommended(c) |
| 120050 | Coconuts | 0.05* | 0.01* | 0.01* | Recommended(c) |
| 120060 | Hazelnuts | 0.05* | 0.01* | 0.01* | Recommended(c) |
| 120070 | Macadamia | 0.05* | 0.01* | 0.01* | Recommended(c) |
| 120080 | Pecans | 0.05* | 0.01* | 0.01* | Recommended(c) |
| 120090 | Pine nuts | 0.05* | 0.01* | 0.01* | Recommended(c) |
| 120100 | Pistachios | 0.05* | 0.01* | 0.01* | Recommended(c) |
| 120110 | Walnuts | 0.05* | 0.01* | 0.01* | Recommended(c) |
| 130010 | Apples | 0.5 | 0.5 | 0.5 | Recommended(b) |
| 130020 | Pears | 0.5 | 0.5 | 0.5 | Recommended(b) |
| 130030 | Quinces | 0.5 | 0.5 | 0.5 | Recommended(b) |
| 130040 | Medlar | 0.5 | 0.5 | 0.5 | Recommended(d) |
| 130050 | Loquat | 0.5 | 0.5 | 0.5 | Recommended(d) |
| 140010 | Apricots | 1 | 0.5 | 0.6 | Further consideration needed(e) |
| 140020 | Cherries | 1 | 1 | 1 | Recommended(d) |
| 140030 | Peaches | 0.5 | 0.5 | 0.6 | Further consideration needed(e) |
| 140040 | Plums | 0.5 | 0.3 | 0.6 | Further consideration needed(e) |
| 151010 | Table grapes | 1 | 1 | 1.5 | Recommended(b) |
| 151020 | Wine grapes | 1 | 1 | 1.5 | Recommended(b) |
| 154010 | Blueberries | 1 | 0.5 | 0.5 | Recommended(f) |
| 154020 | Cranberries | 1 | 1 | 1 | Recommended(f) |
| 163020 | Bananas | 0.05* | 0.05 | 0.05 | Recommended(c) |
| 231020 | Peppers | 0.6 | 0.6 | 0.6 | Recommended(c) |
| 232010 | Cucumbers | 0.2 | 0.2 | 0.3 | Recommended(c) |
| 232020 | Gherkins | 0.05* | - | 0.3 | Recommended(c) |
| 232030 | Courgettes | 0.2 | 0.05 | 0.3 | Further consideration needed(e) |
| 233010 | Melons | 0.2 | 0.2 | 0.3 | Further consideration needed(e) |
| 233020 | Pumpkins | 0.2 | - | 0.3 | Further consideration needed(e) |

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| Code number(a) | Commodity               | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                        |
|---------------|-------------------------|-------------------------|----------------------|-------------|--------------------------------|
| 233030        | Watermelons             | 0.2                     | -                    | 0.3         | Further consideration needed(i) |
| 401020        | Peanuts                 | 0.1                     | 0.1                  | 0.1         | Recommended (c)                |
| 401050        | Sunflower seed          | 0.05*                   | 0.05*                | 0.05        | Recommended (c)                |
| 401060        | Rape seed               | 0.05*                   | 0.05*                | 0.05        | Recommended (c)                |
| 500010        | Barley grain            | 0.2                     | 0.2                  | 0.2         | Recommended (c)                |
| 500070        | Rye grain               | 0.1                     | 0.1                  | 0.1         | Recommended (c)                |
| 500090        | Wheat grain             | 0.1                     | 0.1                  | 0.1         | Recommended (c)                |
| 1011010       | Swine muscle            | 0.05*                   | 0.05*                | 0.05*       | Recommended (d)                |
| 1011020       | Swine fat tissue        | 0.05*                   | 0.05*                | 0.05*       | Recommended (d)                |
| 1011030       | Swine liver             | 0.1                     | 0.1                  | 0.1         | Recommended (d)                |
| 1011040       | Swine kidney            | 0.1                     | 0.1                  | 0.1         | Recommended (d)                |
| 1012010       | Bovine muscle           | 0.05*                   | 0.05*                | 0.05*       | Recommended (d)                |
| 1012020       | Bovine fat tissue       | 0.05*                   | 0.05*                | 0.05*       | Recommended (d)                |
| 1012030       | Bovine liver            | 0.1                     | 0.1                  | 0.1         | Recommended (d)                |
| 1012040       | Bovine kidney           | 0.1                     | 0.1                  | 0.1         | Recommended (d)                |
| 1013010       | Sheep muscle            | 0.05*                   | 0.05*                | 0.05*       | Recommended (c)                |
| 1013020       | Sheep fat tissue        | 0.05*                   | 0.05*                | 0.05*       | Recommended (c)                |
| 1013030       | Sheep liver             | 0.1                     | 0.1                  | 0.1         | Recommended (c)                |
| 1013040       | Sheep kidney            | 0.1                     | 0.1                  | 0.1         | Recommended (c)                |
| 1014010       | Goat muscle             | 0.05*                   | 0.05*                | 0.05*       | Recommended (c)                |
| 1014020       | Goat fat tissue         | 0.05*                   | 0.05*                | 0.05*       | Recommended (c)                |
| 1014030       | Goat liver              | 0.1                     | 0.1                  | 0.1         | Recommended (c)                |
| 1014040       | Goat kidney             | 0.1                     | 0.1                  | 0.1         | Recommended (c)                |
| 1015010       | Equine muscle           | 0.05*                   | 0.05*                | 0.05*       | Recommended (d)                |
| 1015020       | Equine fat tissue       | 0.05*                   | 0.05*                | 0.05*       | Recommended (d)                |
| 1015030       | Equine liver            | 0.1                     | 0.1                  | 0.1         | Recommended (d)                |
| 1015040       | Equine kidney           | 0.1                     | 0.1                  | 0.1         | Recommended (d)                |
| 1016010       | Poultry muscle          | 0.05*                   | 0.05*                | 0.05*       | Recommended (c)                |
| 1016020       | Poultry fat tissue      | 0.05*                   | 0.05*                | 0.05*       | Recommended (c)                |
| 1016030       | Poultry liver           | 0.05*                   | 0.05*                | 0.05*       | Recommended (c)                |
| 1016040       | Poultry kidney          | 0.05*                   | 0.05*                | 0.05*       | Recommended (c)                |
| 1020101       | Cattle milk             | 0.05*                   | 0.05*                | 0.05*       | Recommended (s)                |
| 1020201       | Sheep milk              | 0.05*                   | 0.05*                | 0.05*       | Recommended (c)                |
| 1020301       | Goat milk               | 0.05*                   | 0.05*                | 0.05*       | Recommended (c)                |
| 1020401       | Horse milk              | 0.05*                   | 0.05*                | 0.05*       | Recommended (f)                |
| 1030000       | Bird eggs               | 0.05*                   | 0.05*                | 0.05*       | Recommended (c)                |

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

*: Indicates that the MRL is set/proposed at the limit of quantification. (F): Residue is fat soluble.

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

(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix E). The possible impact of TDMs on the validity of the MRL proposal was not considered in the assessment.

(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E). The possible impact of TDMs on the validity of the MRL proposal was not considered in the assessment.

(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix E). The possible impact of TDMs on the validity of the MRL proposal was not considered in the assessment.

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(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): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix E).

(g): 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).

(h): CXL of 0.01* mg/kg was rounded up to the LOQ of 0.05* mg/kg which was derived at EU level for enforcement in animal commodities.

(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).

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Abbreviations

a.i. active ingredient
a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
CF conversion factor for enforcement residue definition to risk assessment residue definition
cGAP critical GAP
xx capsule suspension
CV coefficient of variation (relative standard deviation)
CXL codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DB dietary burden
DM dry matter
DT50 period required for 50% dissipation (define method of estimation)
DT90 period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
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## Appendix A – Summary of authorised uses considered for the review of MRLs

### 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 |
|---------------|-----------------|--------|----------------|-------------------------|-----------------------------------------------------|-------------|-------------|-----------------------------|----------|
| Apples        | Malus domestica | NEU    | Outdoor        | UK                      | Apple scab, powdery mildew                          | EW 50.0 g/L | Foliar treatment – spraying | n.a. | 10 | 10 | 0.07 kg a.i./ha | 28 | In the UK, DAR restricted to four applications for resistance reasons |
| Pears         | Pyrus communis  | NEU    | Outdoor        | UK                      | Apple scab, powdery mildew                          | EW 50.0 g/L | Foliar treatment – spraying | n.a. | 10 | 10 | 0.07 kg a.i./ha | 28 | In the UK DAR restricted to four applications for resistance reasons |
| Quinces       | Cydonia oblonga | NEU    | Outdoor        | FR                      | Scab (Venturia)                                     | EW 25.0 g/L | Foliar treatment – spraying | 10 | 80 | 3 | 7 | 0.05 kg a.i./ha | 28 |
| Medlars       | Mespilus germanica | NEU    | Outdoor        | FR                      | Scab (Venturia)                                     | EW 25.0 g/L | Foliar treatment – spraying | 10 | 80 | 3 | 7 | 0.05 kg a.i./ha | 28 |
| Loquats       | Eriobotrya japonica | NEU    | Outdoor        | FR                      | Scab (Venturia)                                     | EW 25.0 g/L | Foliar treatment – spraying | 10 | 80 | 3 | 7 | 0.05 kg a.i./ha | 28 |
| Cherries      | Cerasus avium, syn: Prunus avium | NEU    | Outdoor        | UK                      | Blossom wilt and brown rot                          | EW 50.0 g/L | Foliar treatment – spraying | n.a. | 4 | 10 | 14 | 0.05 kg a.i./ha | 3 |
| Plums         | Prunus domestica | NEU    | Outdoor        | UK                      | Blossom wilt and brown rot                          | EW 50.0 g/L | Foliar treatment – spraying | n.a. | 5 | 10 | 14 | 0.08 kg a.i./ha | 3 |
| Table grapes  | Vitis vinifera  | NEU    | Outdoor        | UK                      | Powdery mildew                                      | EW 50.0 g/L | Foliar treatment – spraying | n.a. | 8 | 10 | 14 | 0.06 kg a.i./ha | 21 |
| Wine grapes   | Vitis vinifera  | NEU    | Outdoor        | UK                      | Powdery mildew                                      | EW 50.0 g/L | Foliar treatment – spraying | n.a. | 8 | 10 | 14 | 0.06 kg a.i./ha | 21 |
## Critical outdoor GAPs for Southern Europe

| Crop | Common name | Scientific name | Region | Outdoor/Indoor | Member state or country | Pest controlled | Formulation | Application | PHI or waiting period (days) | Comments |
|------|-------------|----------------|--------|----------------|------------------------|----------------|-------------|-------------|-----------------------------|----------|
|      |             |                |        |                |                        |                | Type | Content | Method | Growth stage | Number | Interval (days) | Rate | Comment |
|      |             |                |        |                |                        |                |     | Conc. Unit | From BBCH | Until BBCH | Min. Max. | Min. Max. | Min. Max. | Unit |         |
| Almonds | Amygdalus communis, syn: *Prunus dulcis* | SEU Outdoor FR, IT | Monilia (fruit), Oidium | EW | 25.0 g/L | Foliar treatment – spraying | 57 78 | 2 7 | 0.08 kg a.i./ha | 120 |
| Apples | Malus domestica | SEU Outdoor ES, IT | Apple scab (*Venturia inaequalis*) | EW | 50.0 g/L | Foliar treatment – spraying | 13 80 | 4 7 14 | 0.05 kg a.i./ha | 28 |
| Pears | Pyrus communis | SEU Outdoor ES, IT | Pears scab | EW | 50.0 g/L | Foliar treatment – spraying | 10 80 | 4 7 14 | 0.05 kg a.i./ha | 28 |
| Quinces | Cydonia oblonga | SEU Outdoor PT | Scab (*Venturia*) | EW | 25.0 g/L | Foliar treatment – spraying | 10 80 | 4 7 | 0.05 kg a.i./ha | 28 |
| Medlars | Mespilus germanica | SEU Outdoor FR | Scab (*Venturia*) | EW | 25.0 g/L | Foliar treatment – spraying | 10 80 | 3 7 | 0.05 kg a.i./ha | 28 |
| Loquats | Eriobotrya japonica | SEU Outdoor FR | Scab (*Venturia*) | EW | 25.0 g/L | Foliar treatment – spraying | 10 80 | 3 7 | 0.05 kg a.i./ha | 28 |
| Apricots | Armeniaca vulgaris, syn: *Prunus armeniaca* | SEU Outdoor ES, FR, IT | Monilia (fruit), Oidium | EW | 50.0 g/L | Foliar treatment – spraying | 19 87 | 2 3 10 | 75.00 g a.i./ha | 3 |
| Cherries | Cerasus avium, syn: *Prunus avium* | SEU Outdoor ES, FR | Monilia (fruit), Oidium | EW | 50.0 g/L | Foliar treatment – spraying | 11 87 | 3 10 | 75.00 g a.i./ha | 3 |
| Peaches | Persica vulgaris, syn: *Prunus persica* | SEU Outdoor ES, FR, IT | Monilia (fruit), Oidium | EW | 50.0 g/L | Foliar treatment – spraying | 19 87 | 2 3 10 | 75.00 g a.i./ha | 3 |
## Critical outdoor GAPs for Southern Europe

| Crop          | Common name | Scientific name | Region | Outdoor/Indoor | Member state or country | Pest controlled | Formulation | Application | Growth stage | Application | PHI or waiting period (days) | Comments |
|---------------|-------------|-----------------|--------|----------------|-------------------------|-----------------|--------------|-------------|--------------|--------------|-----------------------------|----------|
| Plums         | Prunus domestica | SEU Outdoor ES, FR | Monilia (fruit), Oidium | EW | 50.0 g/L | Foliar treatment – spraying | 11 | 87 | 3 | 10 | 75.00 g a.i./ha | 3 |
| Table grapes  | Vitis vinifera | SEU Outdoor ES, IT | Black rot, powdery mildew | EW | 50.0 g/L | Foliar treatment – spraying | 13 | 80 | 4 | 10 | 14 | 37.50 g a.i./ha | 28 |
| Wine grapes   | Vitis vinifera | SEU Outdoor ES, IT | Black rot, powdery mildew | EW | 50.0 g/L | Foliar treatment – spraying | 13 | 80 | 4 | 10 | 14 | 37.50 g a.i./ha | 28 |
| Cucumbers     | Cucumis sativus | SEU Outdoor ES, FR, IT | Powdery mildew | EW | 25.0 g/L | Foliar treatment – spraying | 13 | 89 | 3 | 8 | 0.05 kg a.i./ha | 3 |
| Gherkins      | Cucumis sativus | SEU Outdoor ES | Oidium | EW | 25.0 g/L | Foliar treatment – spraying | 13 | 89 | 3 | 8 | 0.05 g a.i./ha | 3 |
| Courgettes    | Cucurbita pepo | SEU Outdoor ES, FR, IT | Powdery mildew | EW | 25.0 g/L | Foliar treatment – spraying | 13 | 89 | 3 | 8 | 0.05 kg a.i./ha | 3 |
| Melons        | Cucumis melo | SEU Outdoor ES, FR, IT | Oidium | EW | 25.0 g/L | Foliar treatment – spraying | 13 | 89 | 3 | 8 | 0.05 kg a.i./ha | 3 |
| Pumpkins      | Cucurbita maxima | SEU Outdoor ES, FR, IT | Oidium | EW | 50.0 g/L | Foliar treatment – spraying | 13 | 89 | 3 | 8 | 0.05 kg a.i./ha | 3 |
| Watermelons   | Citrullus vulgaris, syn. Citrullus lanatus | SEU Outdoor ES, FR, IT | Oidium | EW | 50.0 g/L | Foliar treatment – spraying | 13 | 89 | 3 | 8 | 0.05 kg a.i./ha | 3 |
| Crop | Common name | Scientific name      | Region | Outdoor/ Indoor | Member state or country | Pest controlled | Formulation | Content | Method | Growth stage | Number | Interval (days) | Rate | PHI or waiting period (days) | Comments |
|------|-------------|----------------------|--------|----------------|-------------------------|-----------------|--------------|---------|--------|--------------|--------|----------------|------|--------------------------|----------|
|      |             |                      |        |                |                         |                 |              | Conc.   | Unit   | From BBCH | Until BBCH | Min. | Max. | Min. | Max. | Min. | Max. | Unit   |          |
| Cucumbers | Cucumis sativus | NEU/ SEU | Indoor | ES, FR, IT | Powdery mildew | EW | 25.0 | g/l | Foliar treatment – spraying | 13 | 89 | 3 | 8 | 0.05 kg a.i./ha | 3 |
| Gherkins | Cucumis sativus | NEU/ SEU | Indoor | ES | Oidium | EW | 25.0 | g/L | Foliar treatment – spraying | 13 | 89 | 3 | 8 | 0.05 kg a.i./ha | 3 |
| Courgettes | Cucurbita pepo Zucchini Group | NEU/ SEU | Indoor | ES, FR, IT | Powdery mildew | EW | 25.0 | g/L | Foliar treatment – spraying | 13 | 89 | 3 | 8 | 0.05 kg a.i./ha | 3 |
| Melons | Cucumis melo | NEU/ SEU | Indoor | ES | Oidium | EW | 25.0 | g/L | Foliar treatment – spraying | 13 | 89 | 3 | 8 | 0.05 kg a.i./ha | 3 |
| Pumpkins | Cucurbita maxima | NEU/ SEU | Indoor | ES | Oidium | EW | 50.0 | g/L | Foliar treatment – spraying | 13 | 89 | 3 | 8 | 0.05 kg a.i./ha | 3 |
| Watermelons | Citrullus vulgaris, syn: Citrullus lanatus | NEU/ SEU | Indoor | ES | Oidium | EW | 50.0 | g/L | Foliar treatment – spraying | 13 | 89 | 3 | 8 | 0.05 kg a.i./ha | 3 |
| Crop | Common name | Scientific name | Region | Pest controlled | Formulation Type | Content | Method | Growth stage (From BBCH until BBCH) | Number | Interval (days) | Rate | PHI or waiting period (days) | Comments (max 250 characters) |
|------|-------------|-----------------|--------|-----------------|-----------------|---------|-------|------------------------------------|--------|----------------|------|------------------------|-------------------------------|
| Grapefruits | Citrus paradisi | non-EU Outdoor US (UK) | Greasy spot Scab and sooty mould | SC | 240.0 g/L | Foliar treatment – spraying | 15 | 89 | 1 | 3 | 21 | 0.14 | 0.28 kg a.i./ha |
| Oranges | Citrus sinensis | non-EU Outdoor US (UK) | Greasy spot Scab and sooty mould | SC | 240.0 g/L | Foliar treatment – spraying | 15 | 89 | 1 | 3 | 21 | 0.14 | 0.28 kg a.i./ha |
| Almonds | Amygdalus communis, syn: Prunus dulcis | non-EU Outdoor US (UK) | Blossom blight | SC | 240.0 g/L | Foliar treatment – spraying | 57 | 69 | 1 | 3 | 7 | 14 | 0.07 | 0.11 kg a.i./ha |
| Blueberries | Vaccinium angustifolium; Vaccinium corymbosum; Vaccinium formosum; Vaccinium virgatum | Non-EU Outdoor US (UK) | Mummy berry disease, Twig blight, Fruit rot, Powdery mildew | SC | 240.0 g/L | Foliar treatment – spraying | 53 | 87 | 1 | 5 | 8 | 14 | 105.00 G a.i./ha |
| Cranberries | Vaccinium macrocarpon | Non-EU Outdoor US (UK) | Cotton tip blight, cranberry fruit rot complex | SC | 240.0 g/L | Foliar treatment – spraying | 35 | 87 | 1 | 5 | 10 | 14 | 105.00 | 210.00 G a.i./ha |

GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; NEU: northern European Union; SEU: southern European Union; a.i.: active ingredient; MS: Member State; EW: emulsion, oil in water; DAR: draft assessment report; SC: suspension concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, information on season at time of application.
(d): PHI: minimum pre-harvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s)                  | Application(s)                  | Sampling (DAT) |
|----------------------------------|-------------|--------------------------|---------------------------------|----------------|
| Fruit crops                      | Peaches     | Foliar, $5 \times 212$ g a.s./ha | 0, 7, 14, 22                   |
| Root crops                       | Sugar beet  | Foliar, $3 \times 1.12$ kg a.s./ha | 7                              |
| Cereals/grass crops              | Wheat       | Foliar, $2 \times 403$ g a.s./ha | 7, 14, 21, 31, 40               |
| Pulses and oilseeds              | Peanut      | Foliar, $4 \times 560$ g a.s./ha | 28                             |

Source: United Kingdom (2005, 2009a)

| Rotational crops (available studies) | Crop groups | Crop(s)                  | Application(s)                  | PBI (DAT) |
|-------------------------------------|-------------|--------------------------|---------------------------------|-----------|
| Root/tuber crops                    | Turnip (roots and tops) | Bare soil, 8.96 kg a.s./ha | 30, 99, 365                     |
|                                    | Radish      | Bare soil, $4 \times 0.28$ kg a.s./ha | 210                             |
|                                    | Carrots (roots and leaves) | Bare soil, $3 \times 0.07$ kg a.s./ha | 35, 260                         |
| Leafy crops                        | Collards    | Bare soil, 8.96 kg a.s./ha | 30, 99, 365                     |
|                                    | Lettuce     | Bare soil, $4 \times 0.28$ kg a.s./ha | 210                             |
|                                    |             | Bare soil, $3 \times 0.07$ kg a.s./ha | 35, 260                         |
| Cereal (small grain)               | Wheat (grain, straw and chaff) | Bare soil, 8.96 kg a.s./ha | 30, 99, 365                     |
|                                    | Sorghum (grain and stover) | Bare soil, $4 \times 0.28$ kg a.s./ha | 210                             |
|                                    | Barley (grain and straw) | Bare soil, $3 \times 0.07$ kg a.s./ha | 35, 260                         |

Source: United Kingdom (2005)

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

Source: United Kingdom (2005)

Can a general residue definition be proposed for primary crops? Yes
Rotation 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) Fenbuconazole (sum of constituent enantiomers)
Plant residue definition for risk assessment (RD-RA)

| RD-risk assessment 1: | Fenbuconazole (sum of constituent enantiomers) |
|----------------------|--------------------------------------------------|
| RD-risk assessment 2: | A separate risk assessment needs to be carried out for the triazole derivative metabolites (TDMs). This is foreseen in the framework of the ongoing assessment of the confirmatory data for triazole compounds (TDMs) |

Conversion factor (monitoring to risk assessment)
- Not applicable

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
- High acid, high oil and dry commodities:
  - GC–MS, LOQ: 0.01 mg/kg for fenbuconazole, validated for oranges, grapes, rape seeds and wheat grain; ILV available for oranges and rape seeds (United Kingdom, 2005)
- High water, high acid and high oil commodities:
  - LC–MS/MS, LOQ: 0.005 mg/kg for fenbuconazole with validation data on tomatoes, oranges and of an LOQ: 0.01 mg/kg on almonds (EURLs, 2016)
- Dry commodities:
  - GC–MS/MS, LOQ: 0.01 mg/kg for fenbuconazole with validation data on wheat, rye, barley and rice (EURLs, 2016)

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; GC–MS: gas chromatography with mass spectrometry; GC–MS/MS: gas chromatography with tandem mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability (years) |
|-----------------------------------|----------|-----------|--------|------------------|
|                                   | High water content | Apples | –10 | 3 |
|                                   |          | Cherries | –15 | 2.8 |
|                                   |          | Peaches | –10 | 4.5 |
|                                   |          |         | –15 | 2.8 |
|                                   |          | Plum    | –15 | 2.8 |
|                                   | High oil content | Pecan nuts | –10 | 4.5 |
|                                   | Dry/high starch | Wheat grain | –10 | 3 |
|                                   | High acid content | Oranges | –10 | 1 |
|                                   | Others | Wheat straw | –10 | 3 |
|                                   |          | Orange, dried pulp | –10 | 1 |

Stability of fenbuconazole; (a)equals study duration
Source: United Kingdom (2005)
### B.1.2. Magnitude of residues in plants

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

| Crop | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)(b) | STMR (mg/kg)(c) |
|------|------------------|---------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|--------------|---------------|
| Grapefruits | Import (US) | 0.098; 0.123; 0.125; 0.134; 0.155; 0.157; 0.162; 0.190; 0.342; 0.487 | GAP-compliant trials on grapefruits (United Kingdom, 2017) OECD = 0.69 | 0.7 | 0.49 | 0.16 |
| Oranges | Import (US) | 0.12, 0.147, 0.166; 0.170; 0.176; 0.178; 0.187; 0.190; 0.279; 0.3; 0.304; 0.339; 0.442; 0.518; 0.659 | GAP-compliant trials on oranges (United Kingdom, 2017) OECD = 0.9 | 0.9 | 0.66 | 0.19 |
| Almonds | Import (US) | < 0.01; < 0.01; < 0.01; < 0.01; < 0.01 | GAP-compliant trials on almonds (United Kingdom, 2017) OECD = 0.01 | 0.01* | 0.01 | 0.01 |
| SEU | | < 0.01; < 0.01; < 0.01 | GAP-compliant trials on almonds (France, 2017; Italy, 2017) OECD = 0.01 | 0.01* | 0.01 | 0.01 |
| Apples, pears | NEU | GAP-compliant trials: 0.03; 0.03; 0.05; 0.06 Trials with 8 applications: 0.04 Trials with 9 applications: 0.02; 0.03; 0.04 Trials with 11 applications: 0.02; 0.02 | Trials on apples performed with 9–12 applications acceptable since first applications are not expected to have an impact on the final residue level (United Kingdom, 2005). Extrapolation to pears possible OECD = 0.1 | 0.1 | 0.06 | 0.03 |
| SEU | | 0.021; 0.027; 0.027; 0.04; 0.04; 0.06; 0.06; 0.16; 0.17; 0.18; 0.33 | GAP-compliant trials on apples (France, 2017; Italy, 2017). Extrapolated to pears OECD = 0.49 | 0.5 | 0.33 | 0.06 |
| Loquats, medlars | NEU | Trials with 4 × 49–54 g a.s./ha: 0.04; 0.06; 0.06; 0.04 Trials with 4 × 68–75 g a.s./ha: 0.05; 0.05; 0.06; 0.03 | Trials on apples with four instead of three applications (United Kingdom, 2009b). Tentatively extrapolated to loquats and medlars OECD = 0.15 | 0.15 (tentative)(d) | 0.06 | 0.05 |
| SEU | | < 0.01; 0.021; 0.027; 0.027; 0.04; 0.04; 0.06; 0.06; 0.16; 0.17; 0.33 | Trials on apples with four instead of three applications (France, 2017; Italy, 2017). Tentatively extrapolated to quinces, loquats and medlars OECD = 0.49 | 0.5 (tentative)(d) | 0.33 | 0.06 |

(a) Region/indoor: Indoor, outdoor, etc.
(b) HR: Highest residue
(c) STMR: Short-term intake

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| Crop                        | Region/indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)                                                                                                                                                                                                 | Recommendations/comments (OECD calculations)                                                                                                                                                                                                 | MRL proposals (mg/kg) | HR (mg/kg)<sup>(b)</sup> | STMR (mg/kg)<sup>(c)</sup> |
|-----------------------------|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|------------------------|------------------------|
| Quinces                     | NEU                         | Trials with 4 × 49-54 g a.s./ha: 0.04; 0.06; 0.06; 0.04 Trials with 4 × 68-75 g a.s./ha: 0.05; 0.05; 0.06; 0.03                                                                                                                                                           | Trials on apples with four instead of three applications (United Kingdom, 2009b) tentatively extrapolated to quinces. Since the SEU use is clearly more critical, no additional trials are required. OECD = 0.15 | 0.15                   | 0.06                   | 0.05                   |
|                             | SEU                         | < 0.01; 0.021; 0.027; 0.027; 0.04; 0.04; 0.06; 0.06; 0.16; 0.17; 0.33                                                                                                                                                                                              | GAP-compliant trials on apples (France, 2017; Italy, 2017). Extrapolated to quinces. OECD = 0.49 | 0.5                    | 0.33                   | 0.06                   |
| Apricots, peaches           | SEU                         | Trials on apricots: with 5 × 75 g: 0.2; 0.24; 0.33 with 1 × 49 and 4 × 74 g a.s./ha: 0.04 Trials on peaches: GAP compliant: 0.05; 0.07 With 4 × 75 g a.s./ha: 0.15 With 5 × 75 g a.s./ha: 0.067; 0.09 With 5 × 76-116 g a.s./ha: 0.01; 0.13; 0.15; 0.35 | Combined data set of trials on apricots (4) and on peaches (9) (France, 2017; Italy, 2017). OECD = 0.56 | 0.6                    | (tentative)<sup>(d)</sup> | 0.35                   | 0.13                   |
| Cherries (sweet)            | NEU                         | –                                                                                                                                                                                                                                                                  | No GAP-compliant trials available (United Kingdom, 2017) | –                      | –                      | –                      |
|                             | SEU                         | 0.09; 0.16; 0.16<sup>(f)</sup>                                                                                                                                                                                                                                     | GAP-compliant trials on cherries (France, 2017; Italy, 2017) used to derive a tentative MRL. OECD = 0.41 | 0.5                    | 0.16                   | 0.16                   |
| Plums                       | NEU                         | 0.035; 0.04; 0.06; 0.071; 0.08; 0.1; 0.13; 0.17; 0.19; 0.3;                                                                                                                                                                                                       | GAP-compliant trials on plums (United Kingdom, 2017). OECD = 0.45 | 0.5                    | 0.30                   | 0.09                   |
|                             | SEU                         | 0.035; 0.054; 0.071; 0.23; 0.16; 0.19; 0.26; 0.3                                                                                                                                                                                                               | Trials on plums with 5 instead of 3 applications (France, 2017; Italy, 2017). OECD = 0.56 | 0.6                    | 0.30                   | 0.18                   |
| Table and wine grapes       | NEU                         | 0.27; 0.30; 0.36; 0.36; 0.48; 0.54; 0.61; 0.68                                                                                                                                                                                                                 | Trials on grapes performed with 2-3 first applications at lower dose rate; acceptable since first application is not expected to impact on final residue level (United Kingdom, 2005). OECD = 1.27 | 1.5                    | 0.68                   | 0.42                   |
| 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 (mg/kg)(b) | STMR (mg/kg)(c) |
|------|-----------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|---------------|----------------|
| SEU  | GAP-compliant trials: 0.03; 0.12; 0.25; 0.38 Trials with five applications: 0.01; 0.07; 0.11; Trials with six applications: 0.05; 0.08; Trials with seven applications: 0.2; 0.046; Trials with eight applications: 0.3; 0.1; Trials with nine applications: 0.3 | GAP-compliant trials on grapes (4) and ten trials on grapes with higher (5 to 9) applications (Italy, 2017). Since the NEU use is clearly more critical, no additional trials are required. OECD = 0.62 | 0.7 | 0.38 | 0.11 |
| Blueberries | Import (US) | 0.03; 0.06; 0.06; 0.07; 0.07; 0.09; 0.15 | GAP-compliant trials on blueberries (United Kingdom, 2017). OECD = 0.23 | 0.3 | 0.15 | 0.07 |
| Cranberries | Import (US) | 0.08; 0.08; 0.13; 0.14; 0.41 | GAP-compliant trials on cranberries (United Kingdom, 2017). OECD = 0.72 | 0.8 | 0.41 | 0.13 |
| Cucumbers, gherkins, courgettes | SEU | GAP-compliant trials on -cucumber: 0.011 -summer squash: 0.03 -courgette: 0.033 Overdosed (3 × 100-113 g a.s./ha) trials on -cucumber: 0.081 -courgettes: 0.062 -zucchini: 0.044 | Combined data set of trials on cucumber, summer squash, courgettes and zucchini (France, 2017; Italy, 2017). GAP compliant or overdosed used to derive a tentative MRL for cucurbits with edible peel. OECD = 0.14 | 0.15 (tentative)(d),(e) | 0.08 | 0.04 |
| EU | Trials on cucumber (3 × 93-127 g a.s./ha): 0.012; 0.027; 0.089 Trials on squash (3 × 91 g a.s./ha): 0.082 | Combined data set of overdosed trials on cucumber and squash (France, 2017; Italy, 2017) used to derive a tentative MRL for cucurbits with edible peel. OECD = 0.21 | 0.3 (tentative)(d),(e) | 0.09 | 0.06 |
| Melons, pumpkins, watermelons | SEU | GAP-compliant trials: 0.06 Overdosed trials (4 × 100 g a.s./ha): < 0.02; < 0.02; 0.03; 0.068; 0.11; 0.14 Overdosed trials (6 × 100 g a.s./ha): 0.03; 0.06 | Trials on melons (France, 2017; Italy, 2017) used to derive a tentative MRL for all cucurbits with inedible peel. OECD = 0.23 | 0.3 (tentative)(d) | 0.14 | 0.06 |
| EU | 0.04 | Overdosed (4 × 100 g as/ha) trial on melons (Italy, 2017) | – | – | – |
GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.

*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe; SEU: Outdoor trials conducted in southern Europe; Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): Tentative MRL derived from trials according to a more critical GAP.
(e): Tentative MRL derived from a reduced number of trials.
(f): Value taken at longer PHI considered acceptable.
B.1.2.2. Residues in succeeding crops

| Confined rotational crop study (quantitative aspect) | Studies investigating the metabolism of fenbuconazole in leafy, root and cereal following crops indicate that residues of fenbuconazole in following crops are unlikely to be of significance. However, TDMs residues expected to be present in significant levels in rotational/succeeding crops |
|---|---|
| Field rotational crop study | Not available and not required for fenbuconazole |

TDM: triazole derivative metabolite.

B.1.2.3. Processing factors

| Processed commodity | Number of studies\(^{(a)}\) | Processing factor (PF) | Median PF |
|---|---|---|---|
| **Robust processing factors (sufficiently supported by data)** | | Individual values | |
| Grapes, red wine | 4 | 0.02; 0.02; 0.2; 0.2 | 0.11 |
| Plums, sundried | 3 | 2.8; 3.3; 4.2 | 3.3 |
| Plums, dehydrated | 7 | 1.4; 1.9; 2.0; 2.3; 3.1; 3.5 | 2.3 |
| **Indicative processing factors (limited dataset)** | | Individual values | |
| Apple juice (un- and pasteurised) | 2 | 0.16; 0.16 | 0.16 |
| Apple, wet pomace | 1 | 2.5 | 2.5 |
| Grapes, white wine | 2 | 0.02; 0.03 | 0.025 |
| Grapes, red wine pomace (wine dregs) | 2 | 3.4; 3.6 | 3.5 |
| Wheat bran | 2 | 1.32; 1.42 | 1.37 |
| Wheat four | 2 | 0.09; 0.16 | 0.13 |
| Wheat bread | 2 | 0.21; 0.27 | 0.24 |
| Peach puree | 2 | 0.14; 0.23 | 0.19 |

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

B.2. Residues in livestock

| Relevant groups | Dietary burden expressed in mg/kg bw per day | Most critical diet\(^{(a)}\) | Most critical commodity\(^{(a)}\) | Trigger exceeded (Y/N) |
|---|---|---|---|---|
| **Cattle (all diets)** | 0.0161 | Cattle (dairy) | Oranges, dried pulp | Y |
| **Cattle (dairy only)** | 0.0161 | Cattle (dairy) | Oranges, dried pulp | Y |
| **Sheep (all diets)** | 0.0016 | Sheep (lamb) | Apple, pomace, wet | N |
| **Sheep (ewe only)** | 0.0013 | Sheep (ram/ewe) | Apple, pomace, wet | N |
| **Swine (all diets)** | 0.0072 | Swine (breeding) | Oranges, dried pulp | Y |
| **Poultry (all diets)** | 0.0000 | – | – | N |
| **Poultry (layer only)** | 0.0000 | – | – | N |

bw: body weight; DM: dry matter.
\(^{(a)}\): Calculated for the maximum dietary burden.
B.2.1. Nature of residues and methods of analysis in livestock

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

| Livestock (available studies) | Animal      | Dose (mg/kg bw per day) | Duration (days) | N rate/comment                                                                 |
|-------------------------------|-------------|--------------------------|-----------------|--------------------------------------------------------------------------------|
| Laying hen                    |             |                          |                 | None of the crops under review is fed to poultry. Performed with triazole and phenyl labelled fenbuconazole |
|                               |             | 6.32                     | 7               |                                                                                  |
|                               |             | 6.32                     | 7               | None of the crops under review is fed to poultry. Performed with triazole labelled fenbuconazole |
| Lactating goat                |             | 0.029, 0.29, 2.9         | 7               | 1.8N, 18N; 180N; compared to cattle maximum dietary burden. Study with the highest dose performed with triazole and phenyl labelled fenbuconazole. Others with phenyl labelled fenbuconazole only |
|                               |             | 0.29                     | 7               | 18N; compared to cattle maximum dietary burden. Performed with triazole and phenyl labelled fenbuconazole |
|                               |             | 2.9                      | 7               | 180N; compared to cattle maximum dietary burden. Performed with triazole labelled fenbuconazole only |
|                               |             | 2.3                      | 7               | 146N; compared to cattle maximum dietary burden. Study on 1 goat; performed with phenyl labelled fenbuconazole only |

Source: United Kingdom (2005, 2009a)

| Time needed to reach a plateau concentration in milk and eggs (days) | 7 |
|---------------------------------------------------------------------|---|
| Metabolism in rat and ruminant similar (Yes/No)                     | Yes |
| Animal residue definition for monitoring (RD-Mo)                    | Fenbuconazole (sum of constituent enantiomers) |
| Animal residue definition for risk assessment (RD-RA)               | RD-risk assessment 1: |
| | Fenbuconazole (sum of constituent enantiomers)                     |
| RD-risk assessment 2:                                               | |
| | A separate risk assessment needs to be carried out for the triazole derivative metabolites (TDMs). This is foreseen in the framework of the ongoing assessment of the confirmatory data for triazole compounds (TDMs) |
| Conversion factor (monitoring to risk assessment)                   | Not applicable |
| Fat soluble residues (Yes/No)                                       | No |
| Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | GC–MS, LOQ: 0.05 mg/kg for fenbuconazole; validated for milk, meat, kidney, liver, fat, eggs. ILV for beef and milk (United Kingdom, 2005) Screening LC–MS–Q-ToF method, SDL: 0.005 mg/kg for fenbuconazole in honey, eggs, muscle (red and white meat, fish), milk and milk products (EURLs, 2016) |

GC–MS: gas chromatography with tandem mass spectrometry; LC: liquid chromatography; MS: mass spectrometry; Q-ToF: quadrupole time-of-flight.
### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (months) |
|-------------------------------------|--------|-----------|--------|-------------------|
| Cow and hen                         | Muscle | –10       | 3      |
| Cow and hen                         | Fat    | –10       | 2      |
| Cow and hen                         | Liver  | –10       | 3      |
| Cow                                 | Kidney | –10       | 3      |
| Cow                                 | Milk   | –10       | 4      |
| Hen                                 | Egg    | –10       | 2      |

Source: United Kingdom (2005)

### 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) | MRL proposal (mg/kg) |
|------------------|----------------------------------------------|-----------------------------------------|----------------------|
|                  | Mean | Highest | STMR<sup>(a)</sup> | HR<sup>(b)</sup> |                      |
| Cattle (all diets) |     |         |                      |                     |                      |
|                 |      |         |                      |                     |                      |
| Cattle (dairy only) |     |         |                      |                     |                      |
| Sheep (all and ewes) |     |         |                      |                     |                      |
| Swine<sup>(e)</sup> |     |         |                      |                     |                      |
| Poultry (all diets and layer) |     |         |                      |                     |                      |

<sup>(a)</sup> As the mean residue levels were not reported for tissues and eggs (minor deficiency), the mean residue level for milk and the highest residue levels for eggs and tissues were recalculated at the 1N rate for the median dietary burden.

<sup>(b)</sup> The mean residue level in milk and the highest residue levels in eggs and tissues, were recalculated at the 1N rate for the maximum dietary burden.

<sup>(c)</sup> Closest feeding level and N dose rate related to the maximum dietary burden.

<sup>(d)</sup> MRL proposal is tentative because a storage stability study covering the storage conditions of the livestock feeding study samples is still required.

<sup>(e)</sup> Since extrapolation from cattle to swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in swine.

MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue; bw: body weight; n.a: not applicable.

*: Indicates that the MRL is proposed at the limit of quantification.
B.3. Consumer risk assessment

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

| ADI          | 0.006 mg/kg bw per day (EFSA, 2010) |
|--------------|------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 50.8% ADI (NL, child) |
| Assumptions made for the calculations | The calculation is based on the median residue levels in the raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation. |

| ARfD         | 0.3 mg/kg bw (EFSA, 2010) |
|--------------|--------------------------|
| Highest IESTI, according to EFSA PRIMo | 29.1% ARfD (oranges) |
| Assumptions made for the calculations | The calculation is based on the highest residue levels in the raw agricultural commodities |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; ARfD: acute reference dose; IESTI: international estimated short-term intake.

B.3.2. Consumer risk assessment with consideration of the existing CXLs

| ADI          | 0.006 mg/kg bw per day (EFSA, 2010) |
|--------------|------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 55.7% ADI (DE, child) |
| Assumptions made for the calculations | 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. For animal commodities, CXL of 0.01* mg/kg was rounded up to the LOQ of 0.05* mg/kg which was derived at EU level for enforcement in these matrices |

| ARfD         | 0.3 mg/kg bw (EFSA, 2010) |
|--------------|--------------------------|
| Highest IESTI, according to EFSA PRIMo | 29.1% ARfD (oranges) |
| Assumptions made for the calculations | 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. For animal commodities, CXL of 0.01* mg/kg was rounded up to the LOQ of 0.05* mg/kg which was derived at EU level for enforcement in these matrices |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; CXL: codex maximum residue limit; MRL: maximum residue level; LOQ: limit of quantification; ARfD: acute reference dose; IESTI: international estimated short-term intake.

B.4. Proposed MRLs

| Ode number(a) | Commodity          | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|---------------|--------------------|------------------------|----------------------|-----------------------|---------|
| 110010        | Grapefruit         | 1                      | 0.5                  | 0.7                   | Recommended(b) |
| 110020        | Oranges            | 1                      | 0.5                  | 0.9                   | Recommended(b) |
| 110030        | Lemons             | 0.05*                  | 1                    | 1                     | Recommended(c)  |
| 110040        | Limes              | 0.05*                  | 1                    | 1                     | Recommended(c)  |
| 110050        | Mandarins          | 0.05*                  | 0.5                  | 0.5                   | Recommended(c)  |
| 120010        | Almonds            | 0.05*                  | 0.01*                | 0.01*                 | Recommended(b)  |
| 120020        | Brazil nuts        | 0.05*                  | 0.01*                | 0.01*                 | Recommended(c)  |

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| Ode number(a) | Commodity        | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment                |
|--------------|------------------|-------------------------|----------------------|-----------------------------------|------------------------|
| 120030       | Cashew nuts      | 0.05*                   | 0.01*                | 0.01*                             | Recommended(c)         |
| 120040       | Chestnuts        | 0.05*                   | 0.01*                | 0.01*                             | Recommended(c)         |
| 120050       | Coconuts         | 0.05*                   | 0.01*                | 0.01*                             | Recommended(c)         |
| 120060       | Hazelnuts        | 0.05*                   | 0.01*                | 0.01*                             | Recommended(c)         |
| 120070       | Macadamia        | 0.05*                   | 0.01*                | 0.01*                             | Recommended(c)         |
| 120080       | Pecans           | 0.05*                   | 0.01*                | 0.01*                             | Recommended(c)         |
| 120090       | Pine nuts        | 0.05*                   | 0.01*                | 0.01*                             | Recommended(c)         |
| 120100       | Pistachios       | 0.05*                   | 0.01*                | 0.01*                             | Recommended(c)         |
| 120110       | Walnuts          | 0.05*                   | 0.01*                | 0.01*                             | Recommended(c)         |
| 130010       | Apples           | 0.5                     | 0.5                  | 0.5                               | Recommended(b)         |
| 130020       | Pears            | 0.5                     | 0.5                  | 0.5                               | Recommended(b)         |
| 130030       | Quinces          | 0.5                     | 0.5                  | 0.5                               | Recommended(b)         |
| 130040       | Medlar           | 0.5                     | 0.5                  | 0.5                               | Recommended(d)         |
| 130050       | Loquat           | 0.5                     | 0.5                  | 0.5                               | Recommended(d)         |
| 140010       | Apricots         | 1                       | 0.5                  | 0.6                               | Further consideration needed(e) |
| 140020       | Cherries         | 1                       | 1                    | 1                                 | Recommended(d)         |
| 140030       | Peaches          | 0.5                     | 0.5                  | 0.6                               | Further consideration needed(e) |
| 140040       | Plums            | 0.5                     | 0.3                  | 0.6                               | Further consideration needed(e) |
| 151010       | Table grapes     | 1                       | 1                    | 1.5                               | Recommended(b)         |
| 151020       | Wine grapes      | 1                       | 1                    | 1.5                               | Recommended(b)         |
| 154010       | Blueberries      | 1                       | 0.5                  | 0.5                               | Recommended(f)         |
| 154020       | Cranberries      | 1                       | 1                    | 1                                 | Recommended(f)         |
| 163020       | Bananas          | 0.05*                   | 0.05                 | 0.05                              | Recommended(c)         |
| 231020       | Peppers          | 0.6                     | 0.6                  | 0.6                               | Recommended(c)         |
| 232010       | Cucumbers        | 0.2                     | 0.2                  | 0.3                               | Further consideration needed(g) |
| 232020       | Gherkins         | 0.05*                   | –                    | 0.3                               | Further consideration needed(g) |
| 232030       | Courgettes       | 0.2                     | 0.05                 | 0.3                               | Further consideration needed(g) |
| 233010       | Melons           | 0.2                     | 0.2                  | 0.3                               | Further consideration needed(g) |
| 233020       | Pumpkins         | 0.2                     | –                    | 0.3                               | Further consideration needed(g) |
| 233030       | Watermelons      | 0.2                     | –                    | 0.3                               | Further consideration needed(g) |
| 401020       | Peanuts          | 0.1                     | 0.1                  | 0.1                               | Recommended(c)         |
| 401050       | Sunflower seed   | 0.05*                   | 0.05*                | 0.05                              | Recommended(c)         |
| 401060       | Rape seed        | 0.05*                   | 0.05*                | 0.05                              | Recommended(c)         |
| 500010       | Barley grain     | 0.2                     | 0.2                  | 0.2                               | Recommended(c)         |
| 500070       | Rye grain        | 0.1                     | 0.1                  | 0.1                               | Recommended(c)         |
| 500090       | Wheat grain      | 0.1                     | 0.1                  | 0.1                               | Recommended(c)         |
| 1011010      | Swine muscle     | 0.05*                   | 0.05*                | 0.05*                             | Recommended(d)         |
| 1011020      | Swine fat tissue | 0.05*                   | 0.05*                | 0.05*                             | Recommended(d)         |
| 1011030      | Swine liver      | 0.1                     | 0.1                  | 0.1                               | Recommended(d)         |
| 1011040      | Swine kidney     | 0.1                     | 0.1                  | 0.1                               | Recommended(d)         |
| Ode number(a) | Commodity       | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment            |
|-------------|-----------------|------------------------|----------------------|-----------------------|-------------------|
| 1012010     | Bovine muscle   | 0.05*                  | 0.05*                | Recommended          | (d)               |
| 1012020     | Bovine fat tissue | 0.05*               | 0.05*                | Recommended          | (d)               |
| 1012030     | Bovine liver    | 0.1                    | 0.1                  | 0.1                  | Recommended        |
| 1012040     | Bovine kidney   | 0.1                    | 0.1                  | 0.1                  | Recommended        |
| 1013010     | Sheep muscle    | 0.05*                  | 0.05*                | Recommended          | (c)               |
| 1013020     | Sheep fat tissue | 0.05*               | 0.05*                | 0.05*                | Recommended        |
| 1013030     | Sheep liver     | 0.1                    | 0.1                  | 0.1                  | Recommended        |
| 1013040     | Sheep kidney    | 0.1                    | 0.1                  | 0.1                  | Recommended        |
| 1014010     | Goat muscle     | 0.05*                  | 0.05*                | Recommended          | (c)               |
| 1014020     | Goat fat tissue | 0.05*                  | 0.05*                | 0.05*                | Recommended        |
| 1014030     | Goat liver      | 0.1                    | 0.1                  | 0.1                  | Recommended        |
| 1014040     | Goat kidney     | 0.1                    | 0.1                  | Recommended          |
| 1015010     | Equine muscle   | 0.05*                  | 0.05*                | Recommended          | (d)               |
| 1015020     | Equine fat tissue | 0.05*             | 0.05*                | 0.05*                | Recommended        |
| 1015030     | Equine liver    | 0.1                    | 0.1                  | 0.1                  | Recommended        |
| 1015040     | Equine kidney   | 0.1                    | 0.1                  | 0.1                  | Recommended        |
| 1016010     | Poultry muscle  | 0.05*                  | 0.05*                | Recommended          | (c)               |
| 1016020     | Poultry fat tissue | 0.05*         | 0.05*                | 0.05*                | Recommended        |
| 1016030     | Poultry liver   | 0.05*                  | 0.05*                | 0.05*                | Recommended        |
| 1016040     | Poultry kidney  | 0.05*                  | 0.05*                | 0.05*                | Recommended        |
| 1020010     | Cattle milk     | 0.05*                  | 0.05*                | 0.05*                | Recommended        |
| 1020020     | Sheep milk      | 0.05*                  | 0.05*                | 0.05*                | Recommended        |
| 1020030     | Goat milk       | 0.05*                  | 0.05*                | 0.05*                | Recommended        |
| 1020040     | Horse milk      | 0.05*                  | 0.05*                | 0.05*                | Recommended        |
| 1030000     | Bird eggs       | 0.05*                  | 0.05*                | 0.05*                | Recommended        |
| –           | Other commodities of plant and animal origin | Regulation (EC) No 149/2008 | – | – | Further consideration needed(i) |

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

*: Indicates that the MRL is set/proposed at the limit of quantification. (F): Residue is fat soluble.

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

(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix E). The possible impact of TDMs on the validity of the MRL proposal was not considered in the assessment.

(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E). The possible impact of TDMs on the validity of the MRL proposal was not considered in the assessment.

(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix E). The possible impact of TDMs on the validity of the MRL proposal was not considered in the assessment.

(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): Tentative MRL is derived from a GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix E).

(g): 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).

(h): CXL of 0.01* mg/kg was rounded up to the LOQ of 0.05* mg/kg which was derived at EU level for enforcement in animal commodities.

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

#### PRIMo(CXL)

**Fenbuconazole**

| Status of the active substance | LOQ (mg/kg b.w.) | Proposed LOQ |
|--------------------------------|------------------|--------------|
| Code no.                      |                  |              |

**Toxicological end points**

| ADI (mg/kg b.w. per day) | ARfD (mg/kg b.w.) | Source of ADI | Source of ARfD | Year of evaluation |
|----------------------------|-------------------|---------------|----------------|-------------------|
| 0.006                      | 0.3               | EFSA          | EFSA           | 2010              |

| No of diets exceeding ADI | --- |

**Highest calculated TMDI values in % of ADI**

| Commodity/group of commodities | pTMRLs at LOQ (in % of ADI) |
|-------------------------------|-----------------------------|
| 55.7 DE child                  | 0.3                         |
| 54.5 NL child                  | 0.4                         |
| 46.7 FR toddler                | 0.3                         |
| 41.7 UK infant                 | 0.2                         |
| 36.8 FR at population          | 0.1                         |
| 33.6 WHO cluster diet B        | 0.2                         |
| 30.4 FR infant                 | 0.1                         |
| 30.3 UK Toddler                | 0.2                         |
| 27.7 IE adult                  | 0.2                         |
| 26.0 PT General population     | 0.1                         |
| 24.7 WHO cluster diet E        | 0.1                         |
| 22.6 DK child                  | 0.2                         |
| 21.7 NL general                | 0.2                         |
| 18.9 DK adult                  | 0.3                         |
| 18.5 SE general population 90th percentile | 0.3 |
| 17.8 ES adult                  | 0.1                         |
| 17.5 WHO Cluster diet F        | 0.1                         |
| 16.6 WHO cluster diet D        | 0.0                         |
| 16.5 WHO regional European diet | 0.1                        |
| 14.5 UK vegetarian             | 0.1                         |
| 14.2 UK Adult                  | 0.1                         |
| 11.9 FI adult                  | 0.1                         |
| 9.8 LT adult                   | 0.0                         |
| 8.1 IT kids/toddler            | 0.0                         |
| 6.9 FI adult                   | 0.1                         |
| 6.7 FL general population      | 0.0                         |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Fenbuconazole 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.

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

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

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

Conclusion:

For Fenbuconazole, 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.
Review of the existing MRLs for fenbuconazole

• PRIMo(EU)

Fenbuconazole

| Status of the active substance: Code no. | LOQ (mg/kg b.w.) | Toxicological end points |
|----------------------------------------|------------------|--------------------------|
| | 0.01 | ADR (mg/kg b.w.) 0.3 |

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

| Year of evaluation | Year of evaluation |
|--------------------|--------------------|
| 2010               | 2010               |

| No of diets exceeding ADI:  |
|-----------------------------|
| 55                          |

| Commodity/ group of commodities | pTMRLs at LOQ (in % of ADI) |
|---------------------------------|-----------------------------|
| Milk and cream                  | 50.8                        |
| Apples                          | 24.4                        |
| Orange                          | 9.9                         |
| 12.1 Apples Ingested             | 11.9 Milk and cream          |
| 33.0 Milk and cream              | 2.6 Milk and cream           |
| 32.3 Milk and cream              | 1.6 Apples                  |
| 26.0 Wine grapes                 | 0.9 Oranges                 |
| 21.4 Milk and cream              | 2.5 Apples                  |
| 17.2 Milk and cream              | 1.7 Table grapes             |
| 12.5 Wine grapes                 | 2.6 Milk and cream           |
| 17.4 Wine grapes                 | 1.9 Oranges                 |
| 8.8 Wine grapes                  | 1.9 Oranges                 |
| 10.4 Milk and cream              | 1.2 Bovine: Meat             |
| 11.2 Wine grapes                 | 1.4 Oranges                 |
| 5.5 Milk and cream               | 4.4 Wine grapes             |
| 10.5 Milk and cream              | 1.5 Cucumbers               |
| 9.8 Wine grapes                  | 0.8 Apples                  |
| 10.3 Milk and cream              | 2.3 Milk and cream           |
| 4.1 Milk and cream               | 2.1 Wine grapes             |
| 1.9 Milk and cream               | 0.0                        |
| 4.2 Milk and cream               | 1.8 Oranges                 |
| 7.6 Wine grapes                  | 0.0                        |
| 1.1 Milk and cream               | 3.3 Milk and cream           |
| 16.0 Milk and cream              | 2.8 Oranges                 |
| 4.0 Milk and cream               | 1.8 Oranges                 |
| 4.2 Milk and cream               | 2.7 Milk and cream           |
| 4.7 Milk and cream               | 0.0                        |
| 9.8 Milk and cream               | 1.6 Oranges                 |
| 5.7 Milk and cream               | 0.0                        |
| 2.2 Table grapes                 | 3.1 Oranges                 |
| 1.5 Milk and cream               | 2.7 Wine grapes             |
| 0.9 Milk and cream               | 0.0                        |
| 1.2 Oranges                      | 0.0                        |
| 1.2 Table grapes                 | 0.0                        |

**Conclusion:** The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Fenbuconazole 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 leads to an exposure equivalent to 100% of the ARfD.

### Acute risk assessment/children – refined calculations

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | --- | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | --- | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | --- | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | --- |
|-------------------------------------------------------------|------|-------------------------------------------------------------|------|-------------------------------------------------------------|------|-------------------------------------------------------------|------|
| Highest % of ARfD/ADI Commodities | pTMRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL (mg/kg) |
| Orange | 29.1 | 0.659/- | Orange | 21.1 | 0.659/- | Table grapes | 14.8 | 0.659/- |
| Pears | 14.5 | 0.487/- | Pears | 10.0 | 0.33/- | Table grapes | 14.5 | 0.487/- |
| Apple | 10.8 | 0.33/- | Apple | 7.2 | 0.33/- | Orange | 14.5 | 0.487/- |
| | | | | | | | | |

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

| No of critical MRLs (IESTI 1): | --- | No of critical MRLs (IESTI 2): | --- |
|--------------------------------|------|--------------------------------|------|
| Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI Commodities | pTMRL/ threshold MRL (mg/kg) |
| Orange juice | 10.9 | 0.659/- | Orange juice | 2.2 | 0.659/- |
| Apple juice | 5.6 | 0.33/- | Apple juice | 0.7 | 0.33/- |
| Peach juice | 2.1 | 0.35/- | Peach juice | 0.2 | 0.35/- |
| Pear juice | 1.9 | 0.35/- | Pear juice | 0.1 | 0.35/- |

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

### Conclusion:

For Fenbuconazole, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

### D.1. Livestock dietary burden calculations

| Feed commodity                  | Median dietary burden | Maximum dietary burden |
|---------------------------------|-----------------------|------------------------|
|                                 | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment               |
| risk assessment residue definition fenbuconazole (sum of constituent enantiomers) |                       |                        |                       |                      |
| Grapefruits, dried pulp        | 1.56                  | STMR × PF<sup>a</sup>  | 1.56                  | STMR × PF<sup>a</sup> |
| Oranges, dried pulp            | 1.90                  | STMR × PF<sup>a</sup>  | 1.90                  | STMR × PF<sup>a</sup> |
| Apple, pomace, wet             | 0.15                  | STMR × PF<sup>b</sup>  | 0.15                  | STMR × PF<sup>b</sup> |

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

(a): For citrus dried pulp, in the absence of processing factors supported by data, a default processing factor of 10 was included in the calculation to consider the potential concentration of residues in these commodities.

(b): For fruit pomace, the tentative processing factor of 2.5 supported by one processing study was included in the calculation to consider the potential concentration of residues in this commodity.

### 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 fenbuconazole (sum of constituent enantiomers) |                       |                        |                       |                      |
| Grapefruits                    | 0.16                    | STMR                  | 0.49                 | HR                    |
| Oranges                        | 0.19                    | STMR                  | 0.66                 | HR                    |
| Almonds                        | 0.01                    | STMR                  | 0.01                 | HR                    |
| Apples                         | 0.06                    | STMR                  | 0.33                 | HR                    |
| Pears                          | 0.06                    | STMR                  | 0.33                 | HR                    |
| Quinces                        | 0.06                    | STMR (tentative)      | 0.33                 | HR (tentative)        |
| Medlars                        | 0.06                    | STMR (tentative)      | 0.33                 | HR (tentative)        |
| Loquats/Japanese medlars       | 0.06                    | STMR (tentative)      | 0.33                 | HR (tentative)        |
| Apricots                       | 0.13                    | STMR (tentative)      | 0.35                 | HR (tentative)        |
| Cherries (sweet)               | 0.16                    | STMR (tentative)      | 0.16                 | HR (tentative)        |
| Peaches                        | 0.13                    | STMR (tentative)      | 0.35                 | HR (tentative)        |
| Plums                          | 0.18                    | STMR (tentative)      | 0.30                 | HR (tentative)        |
| Table grapes                   | 0.42                    | STMR                  | 0.68                 | HR                    |
| Wine grapes                    | 0.42                    | STMR                  | 0.68                 | HR                    |
| Blueberries                    | 0.07                    | STMR                  | 0.15                 | HR                    |
| Cranberries                    | 0.11                    | STMR                  | 0.41                 | HR                    |
| Cucumbers                      | 0.06                    | STMR (tentative)      | 0.09                 | HR (tentative)        |
| Gherkins                       | 0.06                    | STMR (tentative)      | 0.09                 | HR (tentative)        |
| Courgettes                     | 0.06                    | STMR (tentative)      | 0.09                 | HR (tentative)        |
| Melons                         | 0.06                    | STMR (tentative)      | 0.14                 | HR (tentative)        |
| Pumpkins                       | 0.06                    | STMR (tentative)      | 0.14                 | HR (tentative)        |
| Watermelons                    | 0.06                    | STMR (tentative)      | 0.14                 | HR (tentative)        |
| Bovine muscle                  | 0.05*                   | 0.8 × STMR muscle + 0.2 × STMR fat (tentative) | 0.05* | 0.8 × HR muscle + 0.2 × HR fat (tentative) |
| Bovine fat tissue              | 0.05*                   | STMR (tentative)      | 0.05*                | HR (tentative)        |
| Commodity          | Chronic risk assessment | Acute risk assessment |
|-------------------|-------------------------|-----------------------|
|                   | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Bovine liver      | 0.05* STMR (tentative) | 0.05* HR (tentative)  |
| Bovine kidney     | 0.05* STMR (tentative) | 0.05* HR (tentative)  |
| Swine muscle      | 0.05* 0.8 × STMR muscle + 0.2 × STMR fat (tentative) | 0.05* 0.8 × HR muscle + 0.2 × HR fat (tentative) |
| Swine fat tissue  | 0.05* STMR (tentative) | 0.05* HR (tentative)  |
| Swine liver       | 0.05* STMR (tentative) | 0.05* HR (tentative)  |
| Swine kidney      | 0.05* STMR (tentative) | 0.05* HR (tentative)  |
| Equine muscle     | 0.05* 0.8 × STMR muscle + 0.2 × STMR fat (tentative) | 0.05* 0.8 × HR muscle + 0.2 × HR fat (tentative) |
| Equine fat tissue | 0.05* STMR (tentative) | 0.05* HR (tentative)  |
| Equine liver      | 0.05* STMR (tentative) | 0.05* HR (tentative)  |
| Equine kidney     | 0.05* STMR (tentative) | 0.05* HR (tentative)  |
| Cattle milk       | 0.05* STMR             | 0.05* HR              |
| Horse milk        | 0.05* STMR             | 0.05* HR              |

STMR: supervised trials median residue; HR: highest residue.
*: Indicates that the input value is proposed at the limit of quantification.

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: fenbuconazole (sum of constituent enantiomers) |
| Grapefruits           | 0.16 STMR              | 0.49 HR               |
| Oranges               | 0.19 STMR              | 0.66 HR               |
| Almonds               | 0.01 STMR              | 0.01 HR               |
| Apples                | 0.06 STMR              | 0.33 HR               |
| Pears                 | 0.06 STMR              | 0.33 HR               |
| Quinces               | 0.06 STMR              | 0.33 HR               |
| Medlars               | 0.12 STMR (CXL)        | 0.28 HR (CXL)         |
| Loquats/Japanese medlars | 0.12 STMR (CXL)    | 0.28 HR (CXL)         |
| Apricots              | 0.13 STMR (tentative)  | 0.35 HR (tentative)   |
| Cherries (sweet)      | 0.36 STMR (CXL)        | 0.55 HR (CXL)         |
| Peaches               | 0.13 STMR (tentative)  | 0.35 HR (tentative)   |
| Plums                 | 0.18 STMR (tentative)  | 0.30 HR (tentative)   |
| Table grapes          | 0.42 STMR              | 0.68 HR               |
| Wine grapes           | 0.42 STMR              | 0.68 HR               |
| Blueberries           | 0.06 STMR (CXL)        | 0.20 HR (CXL)         |
| Cranberries           | 0.13 STMR (CXL)        | 0.45 HR (CXL)         |
| Cucumbers             | 0.06 STMR (tentative)  | 0.09 HR (tentative)   |
| Gherkins              | 0.06 STMR (tentative)  | 0.09 HR (tentative)   |
| Courgettes            | 0.06 STMR (tentative)  | 0.09 HR (tentative)   |
| Melons                | 0.06 STMR (tentative)  | 0.14 HR (tentative)   |
| Pumpkins              | 0.06 STMR (tentative)  | 0.14 HR (tentative)   |

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| Commodity       | Chronic risk assessment | Acute risk assessment |
|-----------------|-------------------------|-----------------------|
|                 | Input value (mg/kg)     | Comment               |
|                 |                         |                       |
| Watermelons     | 0.06                    | STMR (tentative)      |
|                 |                         | 0.14                  | HR (tentative) |
| Lemons          | 0.03                    | STMR x PF (CXL)       |
|                 |                         | 0.05                  | HR x PF (CXL) |
| Limes           | 0.03                    | STMR x PF (CXL)       |
|                 |                         | 0.05                  | HR x PF (CXL) |
| Mandarins       | 0.01                    | STMR x PF (CXL)       |
|                 |                         | 0.02                  | HR x PF (CXL) |
| Brazil nuts     | 0.01*                   | STMR (CXL)            |
|                 |                         | 0.01*                 | HR (CXL)      |
| Cashew nuts     | 0.01*                   | STMR (CXL)            |
|                 |                         | 0.01*                 | HR (CXL)      |
| Chestnuts       | 0.01*                   | STMR (CXL)            |
|                 |                         | 0.01*                 | HR (CXL)      |
| Coconuts        | 0.01*                   | STMR (CXL)            |
|                 |                         | 0.01*                 | HR (CXL)      |
| Hazelnuts       | 0.01*                   | STMR (CXL)            |
|                 |                         | 0.01*                 | HR (CXL)      |
| Macadamia       | 0.01*                   | STMR (CXL)            |
|                 |                         | 0.01*                 | HR (CXL)      |
| Pecans          | 0.01*                   | STMR (CXL)            |
|                 |                         | 0.01*                 | HR (CXL)      |
| Pine nuts       | 0.01*                   | STMR (CXL)            |
|                 |                         | 0.01*                 | HR (CXL)      |
| Pistachios      | 0.01*                   | STMR (CXL)            |
|                 |                         | 0.01*                 | HR (CXL)      |
| Walnuts         | 0.01*                   | STMR (CXL)            |
|                 |                         | 0.01*                 | HR (CXL)      |
| Bananas         | 0.01                    | STMR x PF (CXL)       |
|                 |                         | 0.01                  | HR x PF (CXL) |
| Peppers         | 0.15                    | STMR (CXL)            |
|                 |                         | 0.21                  | HR (CXL)      |
| Peanuts         | 0.03                    | STMR (CXL)            |
|                 |                         | 0.05                  | HR (CXL)      |
| Sunflower seed  | 0.02                    | STMR (CXL)            |
|                 |                         | 0.02                  | HR (CXL)      |
| Rape seed       | 0.05                    | STMR (CXL)            |
|                 |                         | 0.05                  | HR (CXL)      |
| Barley grain    | 0.03                    | STMR (CXL)            |
|                 |                         | 0.14                  | HR (CXL)      |
| Rye grain       | 0.02                    | STMR (CXL)            |
|                 |                         | 0.03                  | HR (CXL)      |
| Wheat grain     | 0.02                    | STMR (CXL)            |
|                 |                         | 0.06                  | HR (CXL)      |
| Bovine muscle   | 0.05*(a)                | 0.8 × STMR muscle +  |
|                 |                         | 0.2 × STMR fat (CXL)  |
|                 |                         | 0.05*(a)              | 0.8 × HR muscle + 0.2 × |
|                 |                         |                       | HR fat (CXL)   |
| Bovine fat tissue | 0.05*(a)            | STMR (CXL)            |
|                 |                         | 0.05*(a)              | HR (CXL)      |
| Bovine liver    | 0.02                    | STMR (CXL)            |
|                 |                         | 0.09                  | HR (CXL)      |
| Bovine kidney   | 0.02                    | STMR (CXL)            |
|                 |                         | 0.09                  | HR (CXL)      |
| Swine muscle    | 0.05*(a)                | 0.8 × STMR muscle +  |
|                 |                         | 0.2 × STMR fat (CXL)  |
|                 |                         | 0.05*(a)              | 0.8 × HR muscle + 0.2 × |
|                 |                         |                       | HR fat (CXL)   |
| Swine fat tissue | 0.05*(a)              | STMR (CXL)            |
|                 |                         | 0.05*(a)              | HR (CXL)      |
| Swine liver     | 0.02                    | STMR (CXL)            |
|                 |                         | 0.09                  | HR (CXL)      |
| Swine kidney    | 0.02                    | STMR (CXL)            |
|                 |                         | 0.09                  | HR (CXL)      |
| Sheep muscle    | 0.05*(a)                | 0.8 × STMR muscle +  |
|                 |                         | 0.2 × STMR fat (CXL)  |
|                 |                         | 0.05*(a)              | 0.8 × HR muscle + 0.2 × |
|                 |                         |                       | HR fat (CXL)   |
| Sheep fat tissue | 0.05*(a)              | STMR (CXL)            |
|                 |                         | 0.05*(a)              | HR (CXL)      |
| Sheep liver     | 0.02                    | STMR (CXL)            |
|                 |                         | 0.09                  | HR (CXL)      |
| Sheep kidney    | 0.02                    | STMR (CXL)            |
|                 |                         | 0.09                  | HR (CXL)      |
| Goat muscle     | 0.05*(a)                | 0.8 × STMR muscle +  |
|                 |                         | 0.2 × STMR fat (CXL)  |
|                 |                         | 0.05*(a)              | 0.8 × HR muscle + 0.2 × |
|                 |                         |                       | HR fat (CXL)   |
| Goat fat tissue | 0.05*(a)                | STMR (CXL)            |
|                 |                         | 0.05*(a)              | HR (CXL)      |
| Goat liver      | 0.02                    | STMR (CXL)            |
|                 |                         | 0.09                  | HR (CXL)      |
| Goat kidney     | 0.02                    | STMR (CXL)            |
|                 |                         | 0.09                  | HR (CXL)      |
| Equine muscle   | 0.05*(a)                | 0.8 × STMR muscle +  |
|                 |                         | 0.2 × STMR fat (CXL)  |
|                 |                         | 0.05*(a)              | 0.8 × HR muscle + 0.2 × |
|                 |                         |                       | HR fat (CXL)   |
| Equine fat tissue | 0.05*(a)              | STMR (CXL)            |
|                 |                         | 0.05*(a)              | HR (CXL)      |
| Equine liver    | 0.02                    | STMR (CXL)            |
|                 |                         | 0.09                  | HR (CXL)      |
| Equine kidney   | 0.02                    | STMR (CXL)            |
|                 |                         | 0.09                  | HR (CXL)      |
| Commodity       | Chronic risk assessment | Acute risk assessment |
|-----------------|-------------------------|-----------------------|
|                 | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Poultry muscle  | 0.05* (a)               | 0.9 × STMR muscle + 0.1 × STMR fat (CXL) | 0.05* (a)               | 0.9 × HR muscle + 0.1 × HR fat (CXL) |
| Poultry fat tissue | 0.05* (a)               | STMR (CXL)               | 0.05* (a)               | HR (CXL)               |
| Poultry liver   | 0.05* (a)               | STMR (CXL)               | 0.05* (a)               | HR (CXL)               |
| Poultry kidney  | 0.05* (a)               | STMR (CXL)               | 0.05* (a)               | HR (CXL)               |
| Cattle milk     | 0.05* (a)               | STMR (CXL)               | 0.05* (a)               | HR (CXL)               |
| Sheep milk      | 0.05* (a)               | STMR (CXL)               | 0.05* (a)               | HR (CXL)               |
| Goat milk       | 0.05* (a)               | STMR (CXL)               | 0.05* (a)               | HR (CXL)               |
| Horse milk      | 0.05* (a)               | STMR (CXL)               | 0.05* (a)               | HR (CXL)               |
| Bird eggs       | 0.05* (a)               | STMR (CXL)               | 0.05* (a)               | HR (CXL)               |

STMR: supervised trials median residue; HR: highest residue; CXL: codex maximum residue level.

*: Indicates that the input value is proposed at the limit of quantification.

(a): CXL of 0.01*mg/kg was rounded up to the LOQ of 0.05* mg/kg which was derived at EU level for enforcement in animal commodities.
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP if DB > 0.1 mg/kg QM in EU?
  - Yes
  - No
  - MRL derived in Section 3?
    - Yes
    - No
    - MRL, fully supported by data?
      - Yes
      - No
      - No

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

- Not considered for the RA.
- Current EU MRL is included in the RA.
- Tentative median/highest values are included in the RA.
- Median/highest values are included in the RA.
- Fall-back MRL available?
  - Yes
  - No

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.
- Comparison with CXLs
Comparison of the EU recommendation with the existing CXL

- CXL available? Yes → RD comparable? Yes → CXL higher? Yes
  - No → RD comparable? Yes → CXL higher? Yes
  - No → RD comparable? No → CXL higher? No

Consumer risk assessment with consideration of the existing CXL

- Input values for the RA remain unchanged.
  - No → Input values for the RA remain unchanged.
  - No → Input values for the RA remain unchanged.
  - No → CXL is included in the RA.
    - CXL supported by data? Yes
      - No → CXL supported by data? Yes
        - No → CXL supported by data? Yes
          - No → Risk identified? Yes
          - No → Risk identified? Yes
          - No → Risk identified? Yes

Recommendations with consideration of the existing CXL

- Maintain EU recommendation indicating no CXL is available.
- Maintain EU recommendation indicating CXL is not compatible.
- Maintain EU recommendation indicating CXL is covered.
- Maintain EU recommendation; higher CXL is not safe for consumer.
- Maintain current CXL or EU recommendation?
- Maintain EU recommendation; higher CXL is not safe for consumer.
- CXL is recommended; EU recommendation is covered as well.
### Appendix F – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|---------------------|---------------------------------------|-----------------------|
| Fenbuconazole       | (RS)-4-(4-chlorophenyl)-2-phenyl-2-(1H-1,2,4-triazol-1-ylmethyl)butyronitrile  
Clc1ccc(CCc(Cn2cn1c)cC)cccccc1  
RQDJADAKIFFEKQ-UHFFFAOYSA-N | ![Fenbuconazole structure](#) |
| 1,2,4-triazole      | 1H-1,2,4-triazole  
c1ncn1  
NSPMIYGKQJPBQR-UHFFFAOYSA-N | ![1,2,4-triazole structure](#) |
| Triazole alanine    | 3-(1H-1,2,4-triazol-1-yl)-D,L-alanine  
NC(Cn1cn1c)cC(-O)O  
XVWFTOJHOHJIMQ-UHFFFAOYSA-N | ![Triazole alanine structure](#) |
| Triazole acetic acid| 1H-1,2,4-triazol-1-ylacetic acid  
O=C(Cn1cn1c)cC(-O)O  
RXDBSQXFIWBJSR-UHFFFAOYSA-N | ![Triazole acetic acid structure](#) |
| RH-9129             | (3RS,5SR)-5-(4-chlorophenyl)-3-phenyl-3-(1H-1,2,4-triazol-1-ylmethyl)dihydrofuran-2(3H)-one  
Clc1ccc(cc1)C[C@H]1C[C@H]1Cn2cn1cCccc2ccc1  
C(-O)O1.Clc1ccc(cc1)C[C@H]1C[C@H]1Cn2cn1cCccc2ccc1  
PBYKYQRPVNLIDU-ZCBTZIEGSA-N | ![RH-9129 structure](#) |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---|---|---|
| RH-9130 Lactone Lactone B | (3RS,5RS)-5-(4-chlorophenyl)-3-phenyl-3-(1H-1,2,4-triazol-1-ylmethyl)dihydrofuran-2(3H)-one Clc1ccc(cc1)[C@@H][C@@]
(Cn2cncn2)(c2ccc2)c c(=O)O1.Clc1ccc(cc1)[C@@H][C@@]
(Cn2cncn2)(C(=O)O1)c1ccc1 PBKYQRPVLNIDU-YUEAFXNLSA-N | ![Structural formula](image1) |
| RH-4911 (sugar conjugates) Hydroxy-phenyl | (2RS)-4-(4-chloro-3-hydroxyphenyl)-2-phenyl-2-(1H-1,2,4-triazol-1-ylmethyl)butanenitrile Clc1ccc(CCC(Cn2cncn2)(C#N)c2ccc2)c c1O VUMGNBTRYRONKW-UHFFFAOYSA-N | ![Structural formula](image2) |
| RH-1311 4-phenol | (2RS)-4-(4-chlorophenyl)-2-(4-hydroxyphenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)butanenitrile Oc1ccc(cc1)C(CCc1ccc(Cl)cc1)(Cn1cncn1)C#N IQLGWBRWHSVAGF-UHFFFAOYSA-N | ![Structural formula](image3) |
| RH-7968 | (2RS)-4-(4-chlorophenyl)-2-(hydroxymethyl)-2-phenylbutanenitrile Clc1ccc(CCC(C#N)(CO)c2ccc2)c c1 PSDLEGKEMTXITM-UHFFFAOYSA-N | ![Structural formula](image4) |
| RH-6467 Ketone | (2RS)-4-(4-chlorophenyl)-4-oxo-2-phenyl-2-(1H-1,2,4-triazol-1-ylmethyl)butanenitrile Clc1ccc(cc1)(C(=O)O)CC(Cn1cncn1)C#N)c1ccc c1 AQQYGOKTYQRYOU-UHFFFAOYSA-N | ![Structural formula](image5) |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|------------------------------------------------|---------------------------------|
| RH-6468 inimolactone          | (3RS,5RS; 3RS,5SR)-5-(4-chlorophenyl)-3-phenyl-3-[(1H-1,2,4-triazol-1-yl)methyl]oxolan-2-imine Clc1ccc(cc1)C1CC(Cn2cncn2)(C(=N)O1)c1ccccc1 QYOZGDODKDVGO-UHF0FA0YSA-N | ![Structural formula image] |

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

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup> ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).

<sup>(c)</sup> ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).