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Evaluation of confirmatory data following the Article 12 MRL review for fenbuconazole

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Abstract

The applicant Corteva Agrosciences submitted a request to the competent national authority in Slovenia to evaluate the confirmatory data that were identified for fenbuconazole in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the Article 12 confirmatory data gaps, new residue trials analysing triazole derivative metabolites (TDMs) were submitted on grapefruits, lemons, apples, pears, peaches, cherries and blueberries. Following the assessment of submitted data, EFSA concluded that Article 12 confirmatory data gaps are considered addressed for grapefruits, oranges, lemons, limes, pome fruits, peaches, cherries and blueberries. The calculated livestock dietary burdens indicated that for the individual TDMs, the trigger value of 0.004 mg/kg bw day is not exceed from the intake of apple pomace and citrus dried pulp. The new information provided required the assessment of consumer exposure to TDMs, which identified no consumer intake concerns for the crops under consideration. No data were submitted to address the Article 12 confirmatory data gaps for tree nuts, apricots, plums, table grapes, wine grapes, cranberries, bananas, sweet peppers/bell peppers, cucurbits with edible/inedible peel, peanuts/groundnuts, sunflower seeds and rapeseeds/canola seeds, barley, rye and wheat. For these commodities, the existing EU MRL could be lowered to the enforcement LOQ.

Keywords: fenbuconazole, confirmatory data, pesticide, MRL review, risk assessment

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Summary

In 2018, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for the active substance fenbuconazole according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

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

The MRL review also highlighted that the consumer risk assessment for triazole derivative metabolites (TDMs) could not be addressed in the absence of supporting residue trials analysing for residues of triazole derivative metabolites: 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid.

Consequently, tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) 2019/1559[1], including a footnote related to data gap number 1, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 17 September 2021. Although not specifically mentioned as a data gap during the MRL review, the risk managers decided to include the lack of information on TDMs as a confirmatory data requirement for all plant and animal commodity MRLs assessed by the MRL review; the confirmatory data should be provided by a party having an interest in maintaining the proposed tentative MRL by 17 September 2021.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, the applicant Corteva Agrosciences submitted an application to the competent national authority in Slovenia (rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review for grapefruits, oranges, limes, lemons, pome fruits, cherries, peaches and blueberries. Considering that fenbuconazole is no longer approved for the uses in plant protection products in Europe, the applicant submitted these data to address the data gap on TDMs in order to, eventually, maintain the existing Codex MRLs in the EU Regulation for grapefruits, oranges, limes, lemons, pome fruits, cherries, peaches and blueberries. It should be clear that the scope of the present application was not to propose new MRLs for fenbuconazole. However, EFSA noted that the provided residue data for parent fenbuconazole gives an indication that fenbuconazole concentrations higher than the existing Codex MRL might occur in grapefruits, oranges, pome fruits, cherries, peaches and blueberries from the authorised good agricultural practice (GAP) in the USA. Nonetheless, EFSA did not propose MRL modifications in these crops as this was out of the scope of the present application.

No data were submitted to address the Article 12 confirmatory data gaps related to the magnitude of TDMs for tree nuts, apricots, plums, table grapes, wine grapes, cranberries, bananas, sweet peppers/bell peppers, cucurbits with edible/inedible peel, peanuts/groundnuts, sunflower seeds and rapeseeds/canola seeds, barley, rye and wheat.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 16 September 2021. The appointed RMS Slovenia assessed the dossier and declared its admissibility on 15 November 2021. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 23 August 2022 to 13 September 2022. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the RMS proceeded to draft the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 30 September 2022. When assessing the evaluation report, EFSA identified data gaps and points which needed further clarification. On 1 March 2023, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the RMS who submitted a revised

[1] Commission Regulation (EU) 2019/1559 of 16 September 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyflufenamid, fenbuconazole, fluquinconazole and tembotrione in or on certain products. OJ L 239, 17.9.2019, p. 1–15.

evaluation report to EFSA on 18 April 2023 (Slovenia, 2022), which replaced the previously submitted evaluation report.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.

Code[a]	Commodity	Existing MRL[b]	Proposed MRL	Existing CXL	Conclusion/recommendation
Enforcement residue definition: fenbuconazole (sum of constituent enantiomers)					
0110010	Grapefruits	0.7 (ft 1)	Risk management consideration required	0.5	Fenbuconazole being no longer approved for the uses in plant protection products in Europe, the applicant tried to address the data gap on TDMs to, eventually, maintain the existing Codex MRLs in the EU Regulation. The data gap identified by EFSA concerning residues of TDMs is considered addressed. Given the wide safety margin of the calculated acute exposure, the lack of decline trials is considered as a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely. However, the submitted 6 residue trials provide an indication that fenbuconazole residues higher than the existing Codex MRL might occur in the crops from the authorised GAP in the USA. A risk management decision is required.
0110020	Oranges	0.9 (ft 1)			
0110030	Lemons	1 (ft 1)	0.9 or 1	1	Fenbuconazole being no longer approved for the uses in plant protection products in Europe, the applicant tried to address the data gap on TDMs to, eventually, maintain the existing Codex MRLs in the EU Regulation. The confirmatory data gap identified by EFSA concerning residues of TDMs is considered addressed. Given the wide safety margin of the calculated acute exposure, the lack of decline trials is considered as a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely. The submitted residue trials indicate that a lower MRL of 0.9 mg/kg for fenbuconazole would be sufficient to support the authorised GAP in the United States.
0110040	Limes	1 (ft 1)			
0120000	Tree nuts	0.01* (ft1)	0.01*	0.01*	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0130000	Pome fruits	0.5 (ft 1)	Risk management consideration required	0.5	Fenbuconazole being no longer approved for the uses in plant protection products in Europe, the

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Existing CXL	Conclusion/recommendation
					applicant tried to address the data gap on TDMs to, eventually, maintain the existing Codex MRLs in the EU Regulation. The data gap identified by EFSA concerning residues of TDMs is considered addressed. Risk to consumers is unlikely from the exposure to TDMs. However, the submitted residue trials provide an indication that fenbuconazole residues higher than the existing Codex MRL might occur in the crops from the authorised GAP in the USA. A risk management decision is required.
0140010	Apricots	0.6 (ft 2)	0.01*	0.5	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0140020	Cherries	1 (ft 1)	Risk management consideration required	1	Fenbuconazole being no longer approved for the uses in plant protection products in Europe, the applicant tried to address the data gap on TDMs to, eventually, maintain the existing Codex MRLs in the EU Regulation. The data gap identified by EFSA concerning residues of TDMs is considered addressed. Given the wide safety margin of the calculated acute exposure, the lack of decline trials is considered as a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely. However, the submitted residue trials provide an indication that fenbuconazole residues higher than the existing Codex MRL might occur in the crops from the authorised GAP in the USA. A risk management decision is required.
0140030	Peaches	0.6 (ft 2)	Risk management consideration required	0.5	Fenbuconazole being no longer approved for the uses in plant protection products in the Europe, the applicant tried to address the data gap on TDMs to, eventually, maintain the existing Codex MRLs in the EU Regulation. The data gap identified by EFSA concerning residues of TDMs is considered addressed. Given the wide safety margin of the calculated acute exposure, the lack of decline trials is considered as a minor

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Existing CXL	Conclusion/recommendation
					deficiency. Risk to consumers from the exposure to TDMs unlikely. However, the submitted residue trials provide an indication that fenbuconazole residues higher than the existing Codex MRL might occur in the crops from the authorised GAP in the USA. A risk management decision is required.
0140040	Plums	0.6 (ft 2)	0.01*	0.3	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0151010 0151020	Table grapes Wine grapes	1.5 (ft1)	0.01*	1	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0154010	Blueberries	0.5 (ft 1)	Risk management consideration required	0.5	Fenbuconazole being no longer approved for the uses in plant protection products in Europe, the applicant tried to address the data gap on TDMs to, eventually, maintain the existing Codex MRLs in the EU Regulation. The confirmatory data gap identified by EFSA concerning residues of TDMs is considered addressed. Risk to consumers is unlikely from the exposure to TDMs. However, the submitted residue trials provide an indication that fenbuconazole residues higher than the existing Codex MRL might occur in the crops from the authorised GAP in the USA. A risk management decision is required.
0154020	Cranberries	1 (ft 1)	0.01*	1	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0163020	Bananas	0.05 (ft 1)	0.01*	0.05	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0231020	Sweet peppers/ bell peppers	0.6 (ft 1)	0.01*	0.6	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0232000	Cucurbits with edible peel	0.3 (ft 2)	0.01*	0.2 (cucumber only)	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0233000	Cucurbits with inedible peel	0.3 (ft 2)	0.01*	0.2 (except watermelon)	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Existing CXL	Conclusion/recommendation
0401020	Peanuts/ groundnuts	0.1 (ft 1)	0.01*	0.1	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0401050	Sunflower seeds	0.05 (ft 1)	0.01*	0.05*	
0401060	Rapeseeds/ canola seeds	0.05 (ft 1)	0.01*	0.05*	
0500010	Barley	0.2 (ft 1)	0.01*	0.2	
0500070	Rye	0.1 (ft 1)	0.01*	0.1	
0500090	Wheat	0.1 (ft 1)	0.01*	0.1	

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
ft 1: The European Food Safety Authority identified some information relating to triazole derivative metabolites (TDMs) as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 September 2021, or, if that information is not submitted by that date, the lack of it.
ft 2: The European Food Safety Authority identified some information on residue trials, including data relating to triazole derivative metabolites (TDMs), as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 September 2021, or, if that information is not submitted by that date, the lack of it.

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Assessment

The review of existing MRLs for the active substance fenbuconazole according to Article 12 of Regulation (EC) No 396/2005[2] (MRL review) has been performed in 2018 (EFSA, 2018c). European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The list of GAPs assessed in the framework of the MRL review that were not fully supported by data and for which confirmatory data were provided under the present assessment are listed in Appendix A.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 2019/1559[3], including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 17 September 2021.

In the meanwhile, the approval period of the active substance expired on 30 April 2021. In order to avoid trade barriers from third countries after the EU active substance approval expiry, the applicant submitted the MRL application to address the Article 12 confirmatory data for several commodities with the intention to maintain EU MRLs at the level of Codex MRLs.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2020) and the 'Transparency Regulation' (EU) 2019/1381[4], the applicant Corteva Agroscience submitted on 16 September 2021 an application to the competent national authority in Slovenia to evaluate the confirmatory data identified during the MRL review, alongside the dossier containing the supporting data using the IUCLID format, for the following commodities with subsequent MRL proposals: grapefruits (0.5 mg/kg), lemons (1 mg/kg), limes (1 mg/kg), oranges (0.5 mg/kg), pome fruit (0.5 mg/kg), cherries (1 mg/kg), peaches (0.5 mg/kg) and blueberries (0.5 mg/kg).

To address the data gaps identified by EFSA in the framework of the MRL review, the applicant provided new residue trials on grapefruits, lemons, apples, pears, peaches, cherries and blueberries in support of the authorised uses in the USA where samples were analysed for residues of triazole derivative metabolites. In addition, a new freezer storage stability, investigating the storage stability of TDMs in high acid content, high protein content and high oil content matrices was submitted.

No information was provided to address the Article 12 confirmatory data gaps referred to in Regulation (EU) No 2019/1559 for tree nuts, apricots, plums, table and wine grapes, cranberries, bananas, sweet peppers/bell peppers, cucurbits with edible peel, cucurbits with inedible peel, peanuts/groundnuts, sunflower seeds, rapeseeds/canola seeds, barley, rye and wheat.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 30 September 2022 (Slovenia, 2022). EFSA assessed the application as requested by the European Commission in accordance with Article 10 of Regulation (EC) No 396/2005. During the detailed assessment, EFSA identified data gaps which needed further clarification. On 1 March 2023, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the evaluating Member State (EMS) who submitted a revised evaluation report to EFSA on 18 April 2023 (Slovenia, 2022), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the RMS (Slovenia, 2022), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2018c).

For this application, the data requirements established in Regulation (EU) No 544/2011[5] and the relevant guidance documents at the date of implementation of the confirmatory data requirements by

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

[3] Commission Regulation (EU) 2019/1559 of 16 September 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyflufenamid, fenbuconazole, fluquinconazole and tembotrione in or on certain products. OJ L 239, 17.9.2019, p. 1–15.

[4] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

[5] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

Regulation (EU) 2019/1559 are applicable (OECD, 2011; European Commission, 2019). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[6].

An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix B.

The evaluation report submitted by the RMS (Slovenia, 2022) is considered a supporting document to this reasoned opinion and, thus, is made publicly available as a background document to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

Not relevant for the current assessment.

1.1.2. Nature of residues in rotational crops

Not relevant for the current assessment.

1.1.3. Nature of residues in processed commodities

Not relevant for the current assessment.

1.1.4. Analytical methods for enforcement purposes in plant commodities

Not relevant for the current assessment.

1.1.5. Stability of residues in plants

The storage stability of TDMs has been investigated in the framework of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data (EFSA, 2018b).

In high water content matrices relevant for the present assessment, the freezer storage stability for 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) is demonstrated for 6 months, 53 months, 53 months and 48 months, respectively (EFSA, 2018b).

In high acid content matrices, the freezer storage stability has been investigated and demonstrated only for TLA for 48 months (EFSA, 2018b).

The applicant in the framework of the present assessment submitted a new freezer storage stability study where the stability of 1,2,4-T was investigated in high oil content matrix (hazelnut), high protein content matrix (bean seed), high acid content matrix (oranges) and the storage stability of TA and TAA was investigated in high acid content matrix (oranges) during a study period of 48 months (Slovenia, 2022). The EMS indicated that this study has been performed for the renewal of the approval process of paclobutrazol and is intended to cover missing storage stability studies on TDMs as identified in the framework of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data.

The storage stability of 1,2,4-T is demonstrated in high oil content matrix for 12 months, in high protein matrix for 48 months and in high acid content matrix for 42 months when samples were stored at −18°C. The storage stability of TA and TAA is demonstrated in high acid content matrix for up to 48 months when samples are stored at −18°C. This study is considered valid to address the storage stability of 1,2,4-triazole, TA and TAA in high acid crops considered in the present assessment. Nevertheless, this study will be subject to the assessment by the EU pesticides peer review for the renewal of the approval of paclobutrazol.

[6] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

1.1.6. Proposed residue definitions

The EU pesticides peer review and the MRL review concluded that in plant commodities, the relevant residue for enforcement and risk assessment is parent fenbuconazole (sum of constituent enantiomers) (EFSA, 2010; EFSA, 2018c).

For the risk assessment, and in line with the conclusions on the peer review of the pesticide risk assessment of the TDMs in light of confirmatory data, for all active substances belonging to the class of triazole fungicides, in addition to the parent compound, the following risk assessment residue definitions are applicable (EFSA, 2018b):

- Triazole alanine (TA) and triazole lactic acid (TLA) (both metabolites were found to share the same toxicity)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-triazole).

The same residue definitions are applicable for rotational crops and processed commodities.

1.2. Magnitude of residues in plants

In order to address the data gap related to the lack of data on TDMs, the applicant submitted new residue trials on grapefruits, lemons, apples, pears, cherries, peaches and blueberries. The trials were provided to support the authorised uses of fenbuconazole in the United States for the GAPs which have been previously assessed by the JMPR (FAO, 1998, 2010, 2014).

Samples were analysed for parent fenbuconazole and metabolites 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA). In cases where untreated control samples contained residue levels of TDMs at higher levels than in treated crops, those were retained for the calculations of risk assessment values for TDMs. When data were reported as below the limit of detection of 0.003 mg/kg, these were considered as below the LOQ of 0.01 mg/kg for the calculation of risk assessment values.

Analytical methods used to analyse residue trial samples were sufficiently validated and were fit for purpose (Slovenia, 2022). The samples of residue trials were stored for a period that ensured the integrity of the samples (Slovenia, 2022).

The overview of residue trial data is presented in Appendix B.1.2.1.

In the absence of decline trials on the fruit crops under consideration, the applicant also provided supplementary residue trials on grapefruits, peaches and bell peppers to investigate the behaviour of TDMs in fruit crops over longer PHI intervals. The overview of the provided data is compiled in Table 1.

Citrus fruits

Grapefruits, oranges

GAP MRL review in the USA (EFSA, 2018c): 3 × 140–280 g/ha, PHI 0 days
GAP JMPR (FAO, 2014; Slovenia, 2022): 3 × 140 g/ha, PHI 0 days

For grapefruits, the existing tentative EU MRL has been set at a level of 0.7 mg/kg for the authorised use in the United States (GAP: 3 × 140–280 g/ha, PHI 0 days) on a basis of 10 GAP compliant residue trials on grapefruits. For oranges, a tentative MRL of 0.9 mg/kg was derived in support of the authorised US GAP on the basis of 15 residue trials on oranges (EFSA, 2018c). The trials have been analysed for parent fenbuconazole alone and no data were provided for the TDMs. Consequently, the MRL review concluded that the consumer risk assessment for TDMs could not be addressed and risk managers set the Article 12 confirmatory data gap for the information on TDMs in oranges and grapefruits.

The authorised GAP in the United States on grapefruits refers to the following use pattern: 3 × 140 g/ha, PHI of 0 days (FAO, 2014; Slovenia, 2022). To derive the Codex MRL of 0.5 mg/kg, residue trials on grapefruits and oranges conducted in the USA were available for the JMPR; the data on both fruits were combined and scaled to match the application rate in the authorised GAP (FAO, 2014).

Now the applicant, in support of this GAP and in order to address the confirmatory data gap related to the lack of TDMs data, submitted eight new GAP compliant residue trials on grapefruits, which have been performed in Australia in 2021. None of the trials was designed as a decline trial. Fruit samples were separated into peel and pulp. No residues of 1,2,4-T, TAA or TLA were found above the LOQ in

any of the treated samples; residues of TA in the whole fruit ranged from < 0.01 to 0.03 mg/kg with the highest residues observed from the control sample.

Residue trials from three sites were not considered independent as these trials were carried out on the same crop variety, had the same treatment days with the same treatment patterns and the distance between trials was not more than 4 km. The applicant claimed that close distances between trial sites were due to limited availability of crops in the region and noted that the soil types and the age of the trees were different among these sites. This is not considered a sufficient justification to consider these trials independent. Thus, finally, six trials on grapefruits were considered valid, but the number of submitted residue trials is not sufficient to support the US GAP on oranges and grapefruits.

Lemons, limes

GAP MRL review (EFSA, 2018a,b,c): no import tolerance GAP
GAP JMPR (FAO, 2014): 3 × 140 g/ha, PHI 0 days
GAP in the USA (Slovenia, 2022) on lemons: 4 × 140 g/ha, PHI 0 days.

The JMPR in 2013 derived a Codex MRL at a level of 1 mg/kg from five overdosed residue trials on lemons performed in the USA. The proportionality principle was applied. Residue data on TDMs were not available to the JMPR.

In the MRL review, no uses of fenbuconazole on lemons and limes were reported. The tentative MRL of 1 mg/kg for lemons and limes was taken over from the Codex MRL.

In order to address the confirmatory data gap related to the lack of TDMs, the applicant submitted nine residue trials on lemons compliant with the US GAP as reported by the JMPR (with 3 applications). Trials were performed in Australia in 2021. None of the trials was designed as a decline trial. Residues of all TDMs in the whole lemon fruit or pulp were within a range of < 0.01 to 0.01 mg/kg. The submitted residue trials indicate that a lower MRL of 0.9 mg/kg for fenbuconazole would be sufficient to support the authorised GAP in the United States.

The applicant proposes to extrapolate residue data from grapefruits to oranges and from lemons to limes. Extrapolation from lemons to limes is sufficiently supported by residue data and is acceptable according to the Technical Guidelines SANTE/2019/12752 (European Commission, 2019). However, the applicant's proposal to extrapolate residue data from grapefruits to oranges is not specifically mentioned in the Technical Guidelines SANTE/2019/12752, where it is said that extrapolation to the whole group of citrus fruits would be acceptable by combining eight residue trials on oranges and/or grapefruits with eight trials on lemons and/or mandarins. EFSA concludes that the data are not sufficient to support the authorised US GAP on oranges and grapefruits as additional two GAP compliant trials on grapefruits or eight trials on oranges would need to be submitted.

Regarding triazole derivative metabolites, the available residue data from six grapefruits and nine lemons trials indicate that residues of all these compounds in all samples are within a range of < 0.01–0.01 mg/kg (except one control sample with residues at 0.03 mg/kg), thus providing sufficient evidence that the presence of TDMs in citrus fruit will be low and therefore the lack of additional two residue trials on grapefruits can be considered a minor deficiency to address the Article 12 confirmatory data gap.

EFSA concludes that the Article 12 confirmatory data gap for citrus fruits under consideration is addressed but is affected by the uncertainty related to the absence of GAP compliant decline trials (see Section 1.2.1).

EFSA noted that the provided residue data for parent fenbuconazole gives an indication that fenbuconazole concentrations higher than the existing Codex MRL might occur in grapefruits, oranges, from the authorised GAP in the USA. Nonetheless, EFSA did not propose MRL modifications in these crops as this was out of the scope of the present application.

Pome fruits

GAP in the USA (FAO, 2010): 4 × 105–130 g/ha, PHI 14 days
GAP in the USA (Slovenia, 2022): 4 × 135 g/ha, PHI 14 days (maximum of three seasonal applications)
Art 12 MRL review: no import tolerance GAP reported

The JMPR in 2009 derived a Codex MRL of 0.5 mg/kg in pome fruits on the basis of authorised US use. In total 16 GAP compliant trials on apples were available.

Article 12 MRL review derived an MRL proposal of 0.5 mg/kg for apples, pears and quinces on the basis of SEU use. For loquats and medlars, a tentative MRL of 0.5 mg/kg was derived for the SEU use.

Now the applicant, in support of the authorised GAP in the United States and in order to address the confirmatory data gap related to the lack of TDMs data, submitted seven independent residue trials on apples which were performed in Australia in 2021. Additionally, two independent residue trials on pears were submitted, being performed in Australia in 1991 and 1996. None of the trials was designed as a decline trial.

In each of the trial, replicate plots were treated and for the residue data set the highest value among these plots was selected. In some cases, the plot with the highest residues for fenbuconazole was not the worst case for the TDM residues; in such situations, the highest residue value of the respective TDM was selected among both trial plots. This is assumed to account for the worst-case situation. The residues of 1,2,4-T and TAA were in all trials below the LOQ of 0.01 mg/kg, except for one trial in pears with residues of TAA at a level of 0.01 mg/kg. Residues of triazole alanine were present at quantifiable levels in all apple samples ranging from 0.02 to 0.15 mg/kg; residues of TLA ranged from < 0.01 to 0.07 mg/kg. The majority of untreated control samples contained residues of TA and TLA.

EFSA concludes that the confirmatory data gap related to the magnitude of TDMs in pome fruits is addressed but is affected by the uncertainty related to the absence of GAP compliant decline trials (see Section 1.2.1).

EFSA noted that the provided residue data for parent fenbuconazole gives an indication that fenbuconazole concentrations higher than the existing Codex MRL might occur in pome fruits from the authorised GAP in the USA. Nonetheless, EFSA did not propose MRL modifications in these crops as this was out of the scope of the present application.

Cherries

GAP in the USA (FAO, *1998): 6 × 105 g/ha, PHI 0 days*
GAP in the USA (Slovenia, 2022): 8 × 105 g/ha, PHI 0 days
Art 12 MRL review: no import tolerance GAP reported

The JMPR in 1997 derived a Codex MRL of 1 mg/kg from the residue trials on cherries which were performed with five to six applications at the authorised application rate (FAO, 1998).

The applicant now, in support of the authorised GAP in the United States and in order to address the confirmatory data gap related to the lack of TDMs data, submitted nine independent GAP compliant residue trials on cherries, which were conducted in the USA and Australia in 2021. In all trials, cherry trees received eight applications of fenbuconazole. None of the trials was designed as a decline trial. Residues of 1,2,4-T were not detected in any of the samples, residues of triazole alanine were within a range of 0.038–0.51 mg/kg, residues of TAA ranged from < 0.01 to 0.018 mg/kg and residues of TLA ranged from < 0.01 to 0.02 mg/kg.

EFSA concludes that the confirmatory data gap related to the magnitude of TDMs in cherries is addressed but is affected by the uncertainty related to the absence of GAP compliant decline trials (see Section 1.2.1).

EFSA noted that the provided residue data for parent fenbuconazole gives an indication that fenbuconazole concentrations higher than the existing Codex MRL might occur in cherries from the authorised GAP in the USA. Nonetheless, EFSA did not propose MRL modifications in cherries as this was out of the scope of the present application.

Peaches

GAP in the USA (FAO, 1998): less/equal to 8 × 105 g/ha, PHI 0 days
GAP in the USA (Slovenia, 2022): 8 × 105 g/ha, interval 7–10 days, PHI 0 days
GAP Art 12 MRL review: no import tolerance GAP reported

The JMPR in 1998 derived a Codex MRL of 0.5 mg/kg on the basis of combined apricots (trials with 6 applications at 140 g/ha) and peaches (7–9 applications at 110 g/ha) residue trials.

The applicant now, in support of the authorised GAP in the United States and in order to address the confirmatory data gap related to the lack of TDMs data, submitted nine GAP compliant residue trials on peaches performed in Australia and the United States in 2021. None of the trials was designed as a decline trial. Residues of 1,2,4-T were not detected, residues of TA ranged from < 0.01 to 0.31 mg/kg, residues of TAA ranged from < 0.01 to 0.02 mg/kg and residues of TLA ranged from < 0.01 to 0.051 mg/kg.

During the MRL review, a confirmatory data gap for two additional trials on peaches and four on apricots compliant with the southern outdoor GAP was identified. However, as fenbuconazole is no more approved for plant protection uses in Europe, this data gap is considered obsolete. The authorised use in the USA is supported by a sufficient number of trials.

EFSA concludes that the confirmatory data gap related to the magnitude of TDMs in peaches is addressed but is affected by the uncertainty related to the absence of GAP compliant decline trials (see Section 1.2.1).

EFSA noted that the provided residue data for parent fenbuconazole give an indication that fenbuconazole concentrations higher than the existing Codex MRL might occur in peaches from the authorised GAP in the USA. Nonetheless, EFSA did not propose MRL modifications in peaches as this was out of the scope of the present application.

Blueberries

GAP in the USA (FAO, 2010; Slovenia, 2022): 4 × 110–140 g/ha, PHI 30 days

GAP MRL review in the USA (EFSA, 2018c): 1–5 × 105 g/ha (not to exceed 426 g/ha per year), 8–14 days interval, PHI 28 days

In 2009 the JMPR derived a Codex MRL of 0.5 mg/kg on the basis of nine residue trials performed on blueberries with five applications at a rate of 105 g/ha, PHIs ranging from 25 to30 days (FAO, 2010).

The applicant now, in support of the authorised GAP in the United States and in order to address the confirmatory data gap related to the lack of TDMs, submitted residue trials where blueberries were treated four times with fenbuconazole at an application rate of 140 g/ha, samples taken at a PHI of 30 days. The trials were performed in the USA in 2021. None of the trials was designed as a decline trial. In one trial, an adjuvant was added and the results were more critical than in other trials. Residues of 1,2,4-T were not present, residues of TA ranged from < 0.01 to 0.022 mg/kg (1 trial), residues of TAA ranged from < 0.01 to 0.014 mg/kg (1 trial) and residues of TLA were present in all but one sample and ranged from < 0.01 to 0.12 mg/kg. Residue data indicate that in blueberries, the pattern of formation of TDMs slightly differs from other fruit crops with TLA being major metabolite.

EFSA concludes that the Article 12 confirmatory data requirement regarding the magnitude of TDMs in blueberries is addressed but is affected by the uncertainty related to the absence of GAP compliant decline trials (see Section 1.2.1).

EFSA noted that the provided residue data for parent fenbuconazole give an indication that fenbuconazole concentrations higher than the existing Codex MRL might occur in blueberries from the authorised GAP in the USA. Nonetheless, EFSA did not propose MRL modifications in this crop as this was out of the scope of the present application.

1.2.1. TDM curves at longer PHI

None of the residue trials provided on grapefruits, lemons, apples, pears, cherries, peaches and blueberries were designed as decline trials. Therefore, as the critical GAPs authorised in the USA are mainly defined with PHI zero days (except for pome fruits 14 days and blueberries 28 days), uncertainty remains regarding potential concentrations of TDMs at longer PHIs. Upon request of EFSA, the applicant submitted additional decline residue trials. These trials were performed on grapefruits (1), bell peppers (2) and peaches (4) and investigated the residue behaviour of TDMs over longer PHIs (up to 42 days). All submitted studies were GLP compliant except the study on grapefruits. None of the trials was fully compliant with the authorised GAPs under consideration; therefore, these additional data are considered as supportive information. The overview of submitted data is provided in Table 1.

Table 1: Overview of residue decline trials submitted in the framework of the present assessment

Crop	GAP	No of decline trials	PHI intervals investigated (days)	Residues of TDMs	Comment
Grapefruit	3 × 140 g/ha, PHI 8 days (non GLP study)	1	1, 8	**1,2,4-T** and **TAA**: not detected **TLA**: not analysed **TA**: PHI 1 day: 0.010 mg/kg PHI 8 days: 0.015 mg/kg	This unique non-GLP decline trial on grapefruits provides very limited information, only for TA. It indicates concentrations of TA remaining within the same order of magnitude from PHI 1 to 8 days.

Crop	GAP	No of decline trials	PHI intervals investigated (days)	Residues of TDMs	Comment
Bell peppers	4 × 210 g/ha, PHI 7 days	2	0, 14, 21	**1,2,4-T** and **TAA**: not detected **TLA**: not analysed **TA**: PHI 0 day: 0.106–0.144 mg/kg PHI 3 day: 0.107–0.158 mg/kg PHI 7 day: 0.084–0.130 mg/kg PHI 10 day: 0.095–0.147 mg/kg PHI 14 day: 0.102–0.128 mg/kg	These 2 trials only provide information only for TA, for which no significant increase is observed from PHI 0 to 21 days.
Peaches	2 × 0.05 kg/ha; PHI 14–42 days	2	3, 14, 21, 28, 35, 42	**1,2,4-T**: not detected **TA**: PHI 3 days: < 0.01–0.26 mg/kg PHI 14 days: 0.05–0.08 mg/kg PHI 21 days: 0.06–0.07 mg/kg PHI 28 days: 0.06–0.11 mg/kg PHI 35 and 42 days: 0.06–0.013 mg/kg **TAA**: PHI 3, 14, 21 days: < 0.01–0.01 mg/kg PHI 28, 35, 42 days: < 0.01–0.02 mg/kg **TLA**: PHI 3 days: < 0.01–0.04 mg/kg PHI 14 days: 0.01–0.03 mg/kg PHI 21 days: 0.01–0.04 mg/kg PHI 28 days: < 0.01–0.06 mg/kg PHI 35 days and 42 days: < 0.01–0.05 mg/kg	These trials provide information for TA, TAA and TLA. TAA and TLA are present at generally low and stable levels. TA is present at higher concentrations (highest observed at PHI 3 days). No significant increases are observed for TAA, TLA and TA from PHI 3 to 42 days.
Peaches	2 × 0.05 kg/ha; PHI 14–42 days	2	14, 21, 28, 35, 42	**1,2,4-T**: not detected **TA**: PHI 14 days: < 0.01–0.18 mg/kg PHI 21 days: < 0.01–0.16 mg/kg PHI 28 days: < 0.01–0.18 mg/kg PHI 35 days: < 0.01–0.16 mg/kg PHI 42 days: < 0.01–0.12 mg/kg **TAA**: PHI 14 days: < 0.01–0.01 mg/kg PHI 21 days: < 0.01–0.01 mg/kg PHI 28, 35, 42 days: < 0.01 mg/kg **TLA**: PHI 14, 21, 28, 35, 42 days: < 0.01–0.02 mg/kg	

Overall, none of the available decline trials indicate a significant increase of TDMs at longer PHIs. There is a body of evidence that TDMs levels overall remain in the same order of magnitude between PHIs of 3 and 42 days. This conclusion is mainly based on data obtained from peaches and bell peppers. It could be extrapolated to other fruit crops.

In addition, information from the available fruit metabolism study (performed with peaches) also indicates that TA is the main component of the total radioactive residue (TRR) and shows that the total radioactivity related to triazole labelling is the highest at the PHI of 0 days with a decline observed at longer PHI intervals of 7, 14 and 22 days (United Kingdom, 2005).

Consequently, EFSA concludes that a significant increase of TDMs at longer PHI intervals is generally not expected in fruit crops and that, overall, the lack of decline trials performed with fenbuconazole in fruit crops is considered a minor deficiency. Therefore, for grapefruits, oranges, lemons, limes, cherries and peaches, where a GAP with PHI zero days has been reported, the lack of

decline trials is deemed as a minor deficiency. Regarding pome fruits and blueberries, for which the reported GAPs are for PHI of 14 and 28 days, the lack of decline trials is considered a very minor deficiency.

2. Residues in livestock

Apple pomace and dried citrus pulp are potential livestock feed items through which livestock can be exposed to triazole derivative metabolites. An estimation of TDM residue levels in animal commodities from the intake of all feed commodities containing TDM residues from the use of various triazole fungicides could not be fully assessed by the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data due to outstanding poultry and ruminant feeding studies with TLA or alternative metabolism studies which could be used as waivers for feeding studies (EFSA, 2018b). Thus, pending these data gaps to be addressed and lacking updated information on TDMs from the uses of all triazole fungicides, the livestock exposure to TDMs from the intake of feed crops treated with triazole fungicides other than fenbuconazole could not be undertaken in the framework of the current assessment.

The peer review, however, calculated the livestock dietary burden, considering the following input values for pome fruit pomaces (data on citrus fruits were not available): 0.05 mg/kg for 1,2,4-triazole, 0.167 mg/kg for triazole alanine, 0.05 mg/kg for TAA and 0.1 mg/kg for TLA (EFSA, 2018b). It is noted that for apple pomace, these input values are the same for TAA (0.05 mg/kg), 1,2,4-triazole (0.05 mg/kg), TLA (0.1 mg/kg) and slightly higher for TA (0.2 mg/kg) than the ones derived for TDMs in the framework of the present assessment (see Appendix D1).

In the framework of the present assessment, the livestock exposure was calculated to individual TDMs originating from the use of fenbuconazole. The input values for apple pomace and dried citrus pulp were as derived from the submitted residue trials (see Table B.1.2.1), considering the default processing factors. The input values are summarised in Appendix D.1. The livestock dietary burden was calculated according to the OECD guidance document (OECD, 2013) using the Animal Model 2017. Fenbuconazole is not approved for the uses in plant protection products (PPP) in Europe and there are no import tolerances on feed items other than considered in this opinion.

The results of the dietary burden are summarised in Appendix B.2 and indicated that for none of the individual TDMs the trigger value of 0.004 mg/kg bw day is exceed for any of livestock species. Apple pomace and citrus dried pulp are not feed items for poultry and fish.

EFSA recommends that the livestock exposure to TDMs from the use of various triazole fungicides on feed crops is reassessed in the framework of the updated confirmatory data assessment of TDMs in the framework of the peer review when more comprehensive TDM residue data are available and all open data gaps have been addressed. EFSA provisionally concludes that significant residues of TDMs are not expected in animal commodities from the reported use of fenbuconazole on pome fruits and citrus fruits.

3. Consumer risk assessment

Although the submitted residue data indicate that potentially higher residues of parent fenbuconazole might occur in the crops under consideration from the reported authorised uses, the modification of existing fenbuconazole MRLs is not in the scope of this application and therefore the consumer exposure for parent **fenbuconazole** as performed in the framework of the MRL review (EFSA, 2018c) remains valid. The highest chronic exposure, considering CXLs, was calculated for DE child, representing 55.7% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for oranges, representing 29.1% of the acute reference dose (ARfD) (EFSA, 2018c).

Considering the new residue data provided on **triazole derivative metabolites**, the consumer exposure to these compounds from the intake of plant commodities under consideration has to be performed. The toxicological profile for each TDM was assessed in the framework of the pesticide risk assessment of the TDMs in light of confirmatory data (EFSA, 2018c). The ADI value was derived as 0.3 mg/kg bw day for TA, 0.3 mg/kg bw day for TLA, 1 mg/kg bw day for TAA and 0.023 mg/kg bw day for 1,2,4-T. An ARfD was derived as 0.3 mg/kg bw for TA, 0.3 mg/kg bw for TLA, 1 mg/kg bw for TAA and 0.1 mg/kg bw for 1,2,4-T.

A comprehensive risk assessment, considering all crops in which TDMs might be present from the uses of all pesticides belonging to the class of triazole fungicides has been performed in the framework of the pesticide risk assessment for the TDMs in light of confirmatory data (EFSA, 2018b). Using the

EFSA PRIMo rev.3.1, the peer review concluded that the chronic exposure accounted for 93% of the ADI (NL toddler) for 1,2,4-T, 6% of the ADI (NL toddler) for TA, 1% of the ADI (NL toddler) for TAA and 1% of the ADI (NL toddler) for TLA (EFSA, 2018b).

An update of the chronic assessment could not be performed in the framework of this opinion, lacking the most recent residue data on the occurrence TDMs from the use of other triazole fungicides in other commodities of plant and animal origin. In order to estimate whether the TDMs in the crops under consideration would have an impact on the estimated chronic exposure, EFSA compared the STMR values used in the peer review[7] with the STMR values derived under the present assessment for the crops under consideration (see Table 2).

Table 2: Comparison of risk assessment values for the chronic exposure

Crop under consideration	STMR value (2018b)/STMR value derived under present assessment			
	1,2,4-triazole	Triazole alanine (TA)	Triazole acetic acid (TAA)	Triazole lactic acid
Oranges, grapefruits	0.05[(a)]/< 0.01	0.32[(a)]/< 0.01	0.05[(a)]/< 0.01	0.04[(a)]/< 0.01
Lemons, limes	0.05[(a)]/< 0.01	0.32[(a)]/< 0.01	0.05[(a)]/< 0.01	0.04[(a)]/< 0.01
Pome fruits	0.01[(b)]/< 0.01	0.039[(b)]/0.04	0.03[(b)]/< 0.01	0.03[(b)]/0.02
Cherries	0.01[(c)]/< 0.01	0.32[(c)]/0.07	0.02[(c)]/0.01	0.038[(c)]/0.01
Peaches	0.01[(c)]/< 0.01	0.32[(c)]/0.04	0.02[(c)]/0.01	0.038[(c)]/0.01
Blueberries	0.01[(d)]/< 0.01	0.06[(d)]/< 0.01	0.05[(d)]/< 0.01	0.04[(d)]/0.02

(a): In the absence of data in citrus fruits, the STMR value was derived as a worst-case value from data on pome fruits, stone fruits, berries and bananas (EFSA, 2018b).
(b): The worst-case STMR value derived from the data on apples and pears (2018b).
(c): The worst-case STMR value derived from the data on apricots, cherries, peaches and plums (EFSA, 2018b).
(d): The worst-case STMR value derived from the data on grapes, strawberries and raspberries (EFSA, 2018b).

Since the STMR values derived in the present assessment are lower or the same (in the case of TA in pome fruits) than the ones previously considered in the TDM assessment, it is concluded that the new data assessed in the present evaluation are not expected to trigger a modification of previous chronic consumer dietary exposure calculations. Therefore, the conclusion of the peer review of the assessment of the pesticide risk assessment of the TDMs in light of confirmatory data remains unchanged.

Regarding the acute exposure, EFSA assessed potential risks associated with the acute intake of crops under consideration containing TDMs from the use of fenbuconazole at the highest estimated levels according to the submitted residue trials (see Table B.1.2.1). The input values used in the acute exposure assessment are compiled in Appendix D.2. The risk assessment was performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

No acute intake concerns were associated with the residues of TDMs in the commodities under consideration. The highest individual acute exposure was calculated for triazole alanine (10% of the ARfD) and was very low for 1,2,4-triazole (1% of the ARfD), triazole acetic acid (< 0.5% ARfD) and triazole lactic acid (3% of the ARfD).

The detailed overview of the results of the acute exposure calculation is presented in Appendix B.3.

4. Conclusion and recommendations

Fenbuconazole is no longer approved for the uses in plant protection products in Europe and the scope of the present application was not to propose new MRLs for fenbuconazole. However, for grapefruits, oranges, limes, lemons, pome fruits, cherries, peaches and blueberries, the applicant tried to address the data gap on TDMs in order to, eventually, maintain the existing Codex MRLs in the EU Regulation for these crops.

[7] In the framework of the pesticide risk assessment of the TDMs in light of confirmatory data, STMRs for TA, TLA, TAA, 1–2-4-T for crops under consideration were derived from different active substances (EFSA, 2018b). For each TDM, the highest STMR value from all substances was used to assess the chronic exposure.

To address data gaps identified in the framework of the MRL review related to the occurrence of triazole derivative metabolites (TDMs), the applicant submitted new residue trials on grapefruits, lemons, apples, pears, cherries, peaches and blueberries supporting the authorised uses of fenbuconazole in the USA as reported by the JMPR, where samples were analysed for residues of triazole derivative metabolites: 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid.

The applicant also provided a new storage stability study investigating the stability of 1,2,4-triazole in high acid, high protein and high oil content matrices and of TAA and TA in high acid content commodities.

The TDMs data submitted for grapefruits, lemons, apples, pears, cherries, peaches and blueberries support the authorised uses. However, due to the limited number of decline studies, some uncertainty remains regarding the concentrations of TDMs over longer PHI. Nevertheless, given the wide margin of safety for the acute exposure and considering the information provided from available supporting decline trials and the metabolism study supporting the uses on fruit commodities, the lack of complete data set on decline trials on the crops under consideration is considered as a minor deficiency. EFSA, therefore, concludes that Article 12 confirmatory data gap related to TDMs data is addressed for grapefruits, oranges, lemons, limes, pome fruits, cherries, peaches and blueberries. The calculated livestock dietary burden indicated that for none of the individual TDMs, the trigger value of 0.004 mg/kg bw day is exceeded for any of the livestock species from the intake of TDM residues via apple pomace and citrus-dried pulp. Consumer exposure concerns were not associated with the residues of TDMs in the commodities under consideration.

The scope of the present application as noted by the applicant was not to propose new MRLs for fenbuconazole but just to address the data gap of the MRL review in order to, eventually, maintain the existing Codex MRLs in the EU Regulation for grapefruits, oranges, lemons, limes, pome fruits, cherries, peaches and blueberries. However, EFSA notes that the provided residue data for parent fenbuconazole give an indication that fenbuconazole concentrations higher than the existing Codex MRL might occur in grapefruits, oranges, pome fruits, cherries, peaches and blueberries from the authorised GAP in the USA. Since the modification of existing fenbuconazole MRLs is not in the scope of this application, the consumer exposure calculated by the MRL review for the parent fenbuconazole was not revised, remains valid and EFSA did not propose MRL modifications in these crops.

No information was provided to address the Article 12 confirmatory data gaps referred to in Regulation (EU) 2019/1559 for tree nuts, apricots, plums, table and wine grapes, cranberries, bananas, sweet peppers/bell peppers, cucurbits with edible peel, cucurbits with inedible peel, peanuts/groundnuts, sunflower seeds, rapeseeds/canola seeds, barley, rye and wheat. EFSA concludes that for these commodities, the Article 12 confirmatory data gaps have not been addressed and the MRL can be lowered to the LOQ for enforcement.

The overview of the assessment of confirmatory data and the recommended MRL modifications are summarised in Appendix B.4.

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Abbreviations

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
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EC	emulsifiable concentrate
EMS	evaluating Member State
Eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organisation of the United Nations
GAP	Good Agricultural Practice
GC	gas chromatography
GC–MS	gas chromatography with mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
GLP	Good Laboratory Practice
GR	granule
GS	growth stage
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation

IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient
LC	liquid chromatography
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	mass spectrometry detector
MS	Member States
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
NOAEL	no observed adverse effect level
NPD	nitrogen/phosphorous detector
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	preharvest interval
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
RA	risk assessment
RAC	raw agricultural commodity
RMS	rapporteur Member State
SC	suspension concentrate
SEU	southern Europe
SG	water-soluble granule
STMR	supervised trials median residue
TRR	total radioactive residue
UV	ultraviolet (detector)
WHO	World Health Organization

Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data

Crop and/or situation	NEU, SEU, MS or country	F, G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
MRL review GAPs referring to import tolerances for the crops under consideration (EFSA, 2018c)															
Grape fruits	USA	F	Greasy spot Scab and sooty mould	SC	240.0 g/L	Foliar spray	15–89	1–3	21			0.14–0.28	kg/ha	0	
Oranges	USA	F	Greasy spot Scab and sooty mould	SC	240.0 g/L	Foliar spray	15–89	1–3	21			0.14–0.28	kg/ha	0	
Blueberries	USA	F	Mummy berry disease, Twig blight, Fruit rot, Powdery mildew	SC	240.0 g/L	Foliar spray	53–87	1–5	8–14			105	kg/ha	28	
GAPs reported under the present assessment (Slovenia, 2022) These GAPs shall be considered the same as the GAPs evaluated by the JMPR for fenbuconazole on pome fruits (FAO, 2010), citrus fruits (FAO, 2014), cherries (FAO, 1998), peaches (FAO, 1998) and blueberries (FAO, 2010)															
Grapefruits	USA	F	Greasy spot (*Mycosphaerella citri*) scab (*Elsinoe fawcettii*) sooty mould (*Capnodium* spp.)	SC	240.0 g/L	Foliar spray		3	21			140	g/ha	0	
Lemons	USA	F	Greasy spot (*Mycosphaerella citri*) scab (*Elsinoe fawcettii*) sooty mould (*Capnodium* spp.)	SC	240.0 g/L	Foliar spray		4	10–14			140	g/ha	0	
Oranges	USA	F	Greasy spot (*Mycosphaerella citri*) scab (*Elsinoe fawcettii*) sooty mould (*Capnodium* spp.)	SC	240.0 g/L	Foliar spray		3	21			140	g/ha	0	

Crop and/or situation	NEU, SEU, MS or country	F, G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Apples	USA	F	Flyspeck (*Zygophiala jamaicensis*) leucotricha) rusts (*Gymnosporangi um* spp.) scab (*Venturia ineaqualis*) sooty blotch (*Gloeodes pomigena*)	SC	240.0 g/L	Foliar spray		4	10–14			135	g/ha	14	
Peaches	USA	F	Blight (*Monilinia* spp.), fruit brown rot (*Monilinia* spp.), scab (*Cladosporium* spp.)	SC	240.0 g/L	Foliar spray		8	7–10			105	g/ha	0	

NEU: northern European Union; SEU: southern European Union; MS: Member State; 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 formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Peaches	Foliar, 5 × 212 g a.s./ha	0, 7, 14, 22	Radiolabelled active substance: phenyl- ^{14}C- or triazole- ^{14}C- label (EFSA, 2018c)
	Root crops	Sugar beet	Foliar, 3 × 1.12 kg a.s./h	7	
	Leafy crops	–	–	–	
	Cereals/grass	Wheat	Foliar, 2 × 403 g a.s./ha	7, 14, 21, 31, 40	
	Pulses/ oilseeds	Peanut	Foliar, 4 × 560 g a.s./ha	28	
	Miscellaneous				
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Turnip (roots and tops)	Bare soil, 8.96 kg a.s./ha	30, 99, 365	EFSA (2018c)
		Radish	Bare soil, 4 × 0.28 kg a.s./ha	210	
		Carrots (roots and leaves)	Bare soil, 3 × 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 × 0.28 kg a.s./ha Bare soil, 3 × 0.07 kg a.s./ha	210 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 × 0.28 kg a.s./ha	210	
		Barley (grain and straw)	Bare soil, 3 × 0.07 kg a.s./ha	35, 260	
	Other				
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		Fenbuconazole (EFSA, 2010); TDMs (EFSA, 2018b)
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes		
	Sterilisation (20 min, 120°C, pH 6)		Yes		
	Other processing conditions				

Can a general residue definition be proposed for primary crops?	yes	EFSA, 2010
Rotational crop and primary crop metabolism similar?	Yes	EFSA, 2010
Residue pattern in processed commodities similar to residue pattern in raw commodities?	yes	EFSA, 2010
Plant residue definition for monitoring (RD-Mo)	RD-monitoring (EFSA, 2010, 2018c): • Fenbuconazole (sum of constituent enantiomers)	
Plant residue definition for risk assessment (RD-RA)	RD-risk assessment (EFSA, 2018b, c): • Fenbuconazole (sum of constituent enantiomers) • 1,2,4- triazole (T) • Triazole alanine (TA) • Triazole acetic acid (TAA) • Triazole lactic acid (TLA)	
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 fororanges, grapes, rape seeds and wheat grain; ILV availablefor 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 withvalidation data on tomatoes, oranges and of an LOQ: 0.01mg/kg on almonds (EFSA, 2018c) Dry commodities: • GC–MS/MS, LOQ: 0.01 mg/kg for fenbuconazole withvalidation data on wheat, rye, barley and rice (EFSA, 2018c)	

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

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/Source**
				Value	**Unit**		
	High water content	Apples	−10	3	Year	Fenbuconazole	Stability equals study duration (EFSA, 2018c)
		Cherries	−15	2.8	Year	Fenbuconazole	
		Peaches	−10 −15	4.5 2.8	Year	Fenbuconazole	
		Plums	−15	2.8	Year	Fenbuconazole	
		Apples, tomatoes, mustard leaves, wheat forage, radishes tops, turnip roots, sugar beet roots, cabbages, lettuces	−18	6	Months	1,2,4-triazole lettuce only	For TLA storage stability was investigated for high water commodities in lettuce only and not in other high-water commodities (EFSA, 2018b)
			−18	53	Months	Triazole alanine	
			−18	53	Months	Triazole acetic acid	
			−18	48	Months	Triazole lactic acid	

	High oil content	Pecan nuts	−10	4.5	Year	Fenbuconazole	Stability equals study duration (EFSA, 2018c)
		Hazelnut	−18	12	Months	1,2,4-triazole	Slovenia, 2022 (study performed for renewal of approval of paclobutrazol; not peer reviewed)
		Rapeseeds, soyabeans	−18	12 (soyabeans only)	Months	1,2,4-triazole. Not stable in rapeseeds.	EFSA (2018b)
			−18	26 (soyabeans only)	Months	Triazole alanine. Not stable in rapeseeds.	
			−18	53	Months	Triazole acetic acid	
			−18	48	Months	Triazole lactic acid	
	High protein content	Dry peas, navy beans	–	–	–	1,2,4 – triazole	EFSA (2018b)
			−18	15	Months	Triazole alanine	
			−18	25	Months	Triazole acetic acid	
			−18	48	Months	Triazole lactic acid	
		Bean seed	−18	48	Months	1,2,4-triazole	Slovenia, 2022 (study performed for renewal of approval of paclobutrazol; not peer reviewed)
	Dry/High starch	Wheat grain	−10	3	Year	Fenbuconazole	Stability equals study duration (EFSA, 2018c)
		Barley, wheat grain	−18	12	Months	1,2,4 – triazole	EFSA (2018b)
			−18	26	Months	Triazole alanine	
			−18	26	Months	Triazole acetic acid	
			−18	48	Months	Triazole lactic acid	
	High acid content	Oranges	−10	1	Year	Fenbuconazole	Stability equals study duration (EFSA, 2018c)
			−18	42	Months	1,2,4 – triazole	Study performed for renewal of approval of paclobutrazol; not peer reviewed (Slovenia, 2022)
			−18	48	Months	Triazole alanine	Slovenia, 2022 (study performed for renewal of approval of paclobutrazol; not peer reviewed)
			−18	48	Months	Triazole acetic acid	
			−18	48	Months	Triazole lactic acid	EFSA (2018b)
	Others	Wheat straw	−10	3	Year	Fenbuconazole	Stability equals study duration (EFSA, 2018c)
		Oranges, dried pulp	−10	1	Year	Fenbuconazole	
		Cereal straw	−18	12	Months	1,2,4 – triazole	EFSA (2018b)
			−18	53	Months	Triazole alanine	
			−18	40	Months	Triazole acetic acid	
			–	–	–	Triazole lactic acid	

B.1.2. Magnitude of residues in plants

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

Commodity	Region/ Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL(mg/kg)	HR[b] (mg/kg)	STM[c] (mg/kg)	CF[d]
Enforcement residue definition (Mo): fenbuconazole (sum of constituent isomers) **Risk assessment residue definition (RA):** (1) fenbuconazole (sum of constituent isomers); (2) 1,2,4-triazole (1,2,4-T); (3) Triazole alanine (TA); (4) Triazole acetic acid (TAA); (5) Triazole lactic acid (TLA)							
Grapefruits, oranges	Import tolerance (USA)	**Mo = RA (1)** Whole fruit: 0.15; 0.22; 0.23; 0.27; 0.32; 0.41 Pulp: 0.022; 0.023; 0.024; 0.032; 0.079; 0.085 **RA (2)**: 1,2,4-T: Whole fruit and pulp: 6 × < 0.01 **RA (3)**: TA: whole fruit: 5 × < 0.01; 0.03[c] Pulp: 2 × < 0.01; 2 × 0.01[c]; 0.02[c]; 0.04[c] **RA (4)**: TAA: Whole fruit and pulp 6 × < 0.01 **RA (5)**: TLA: Whole fruit and pulp 6 × < 0.01	Residue trials on grapefruits compliant with GAP. Insufficient number of residue trials to support the authorised use and extrapolate the residue data to oranges.	0.8	**Mo = RA (1)** (0.41) **RA (2)**: < 0.01 **RA (3)**: 0.03 **RA (4)**: < 0.01 **RA (5)**: < 0.01	**Mo = RA (1)** (0.25) **RA (2)**: < 0.01 **RA (3)**: < 0.01 **RA (4)**: < 0.01 **RA (5)**: < 0.01	
Lemons, limes	Import tolerance (USA)	**Mo = RA (1)** Whole fruit: 0.15; 0.16; 2 × 0.19; 0.21; 0.27; 0.40; 0.44; 0.48 Pulp: 0.02; 2 × 0.026; 3 × 0.027; 0.035; 0.057; 0.069 **RA (2)**: 1,2,4-T: Whole fruit and pulp: 9 × < 0.01 **RA (3)**: TA: Whole fruit 9 × < 0.01 Pulp: 8 × < 0.01; 0.01[c] **RA (4)**: TAA: Whole fruit: 9 × < 0.01 Pulp: 8 × < 0.01; 0.01[c]	Residue trials on lemons compliant with the authorised US GAP. Residue data extrapolation to limes acceptable.	0.9	**Mo = RA (1)** (0.48) **RA (2)**: < 0.01 **RA (3)**: < 0.01 **RA (4)**: < 0.01 **RA (5)**: 0.01	**Mo = RA (1)** (0.21) **RA (2)**: <0.01 **RA (3)**: < 0.01 **RA (4)**: < 0.01 **RA (5)**: < 0.01	

Commodity	Region/ Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL(mg/kg)	HR[b] (mg/kg)	STM[c] (mg/kg)	CF[d]
		RA (5): TLA: Whole fruit 8 × < 0.01; 0.01[c] Pulp: 9 × < 0.01					
Apples, pears	Import tolerance (USA)	**Mo = RA (1)**: 0.12; 0.13; 0.17; 0.18; 0.20; 0.23; 0.29; 0.38; 0.57 **RA (2)**: 1,2,4-T: 9 × < 0.01 **RA (3)**: TA: 3 × 0.02; 0.02[c]; 0.04; 0.07[c]; 0.08; 0.09[c]; 0.12 **RA (4)**: TAA: 7 × < 0.01; < 0.01; 0.01 **RA (5)**: TLA: 4 × < 0.01; 2 × 0.02; 0.02; 0.03; 0.07	Residue trials on apples and pears compliant with the authorised US GAP. Residue trials on pears underlined. Residue trials on apples and pears combined and extrapolated to the whole group of pome fruits.	0.9	**Mo = RA (1)**: 0.57 **RA (2)**: < 0.01 **RA (3)**: 0.12 **RA (4)**: 0.01 **RA (5):** 0.07	**Mo = RA (1)**: 0.20 **RA (2)**: < 0.01 **RA (3)**: 0.04 **RA (4)**: <0.01 **RA (5):** 0.02	
Cherries	Import tolerance (USA)	**Mo = RA (1)**: 0.12; 0.24; 0.27; 0.30; 0.42; 0.47; 0.49; 0.52; 0.60 **RA (2)**: 1,2,4-T: 9 × < 0.01 **RA (3)**: TA: 0.038; 0.04; 0.054; 0.067[c]; 0.074; 0.09[c]; 0.11[c]; 0.11; 0.51 **RA (4)**: TAA: 7 × < 0.01; 0.011; 0.018 **RA (5)**: TLA: 7 × < 0.01; 0.019; 0.02	Residue trials on cherries compliant with the authorised US GAP.	1.5	**Mo = RA (1)**: 0.60 **RA (2)**: <0.01 **RA (3)**: 0.51 **RA (4)**: 0.018 **RA (5):** 0.02	**Mo = RA (1)**: 0.42 **RA (2)**: <0.01 **RA (3)**: 0.07 **RA (4)**: 0.01 **RA (5):** 0.01	
Peaches	Import tolerance (USA)	**Mo = RA (1)**: 0.20; 0.31; 0.33; 0.34; 0.59; 0.62; 0.79; 0.99; 1.3 **RA (2)**: 1,2,4-T: 9 × < 0.01 **RA (3)**: TA: < 0.01; 0.024; 0.032; 0.037; 0.044[c]; 0.051; 0.10; 0.14; 0.31 **RA (4)**: TAA: 6 × < 0.01; 0.01; 0.011; 0.02 **RA (5)**: TLA: 6 × < 0.01; 0.041; 0.048; 0.051	Residue trials on peaches compliant with the authorised US GAP.	2	**Mo = RA (1)**: 1.3 **RA (2)**: < 0.01 **RA (3)**: 0.31 **RA (4)**: 0.02 **RA (5):** 0.051	**Mo = RA (1)**: 0.59 **RA (2)**: <0.01 **RA (3)**: 0.04 **RA (4)**: 0.01 **RA (5):** 0.01	

Commodity	Region/ Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL(mg/kg)	HR[b] (mg/kg)	STM[c] (mg/kg)	CF[d]
Blueberries	Import tolerance (USA)	**Mo = RA (1)**: 0.053; 0.078; 0.085; 0.086; 0.12; 0.21; 0.23; 0.25; 0.43 **RA (2)**: 1,2,4-T: 9 × < 0.01 **RA (3)**: TA: 8 x < 0.01; 0.022 **RA (4)**: TAA: 8 × < 0.01; 0.014 **RA (5)**: TLA: < 0.01; 0.011; 2 × 0.017; 0.019; 0.048; 0.051; 0.089; 0.12	Residue trials on blueberries compliant with the authorised US GAP.	0.7	**Mo = RA (1)**: 0.43 **RA (2)**: < 0.01 **RA (3)**: 0.022 **RA (4)**: 0.014 **RA (5):** 0.12	**Mo = RA (1)**: 0.12 **RA (2)**: < 0.01 **RA (3)**: < 0.01 **RA (4)**: < 0.01 **RA (5):** 0.02	

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
[C]: Residues in control sample.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not relevant for the present assessment
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not relevant for the present assessment

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Dietary burden calculation according to OECD (2013).

1,2,4-triazole

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[(a)]	Most critical commodity[(b)]	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all)	0.001	0.001	0.03	0.03	Dairy cattle	Citrus dried pulp	N
Cattle (dairy only)	0.001	0.001	0.02	0.02	Dairy cattle	Citrus dried pulp	N
Sheep (all)	0.001	0.001	0.01	0.01	Lamb	Apple, wet pomace	N
Sheep (ewe only)	0.0004	0.0004	0.01	0.01	Ram/Ewe	Apple, wet pomace	N
Swine (all)	0.0004	0.0004	0.02	0.02	Swine (breeding)	Citrus dried pulp	N
Poultry (all)	N/A						
Poultry (layer only)	N/A						
Fish	N/A						

Triazole alanine (TA)

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[(a)]	Most critical commodity[(b)]	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all)	0.002	0.002	0.10	0.10	Beef cattle	Apple, wet pomace	N
Cattle (dairy only)	0.002	0.002	0.05	0.05	Dairy cattle	Apple, wet pomace	N
Sheep (all)	0.002	0.002	0.05	0.05	Lamb	Apple, wet pomace	N
Sheep (ewe only)	0.002	0.002	0.05	0.05	Ram/Ewe	Apple, wet pomace	N
Swine (all)	0.0004	0.0004	0.02	0.02	Swine (breeding)	Citrus, dried pulp	N
Poultry (all)	N/A						
Poultry (layer only)	N/A						
Fish	N/A						

Triazole acetic acid (TAA)

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[a]	Most critical commodity[b]	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all)	0.001	0.001	0.03	0.03	Dairy cattle	Citrus dried pulp	N
Cattle (dairy only)	0.001	0.001	0.02	0.02	Dairy cattle	Citrus dried pulp	N
Sheep (all)	0.001	0.001	0.01	0.01	Lamb	Apple, wet pomace	N
Sheep (ewe only)	0.0004	0.0004	0.01	0.01	Ram/Ewe	Apple, wet pomace	N
Swine (all)	0.0004	0.0004	0.02	0.02	Swine (breeding)	Citrus dried pulp	N
Poultry (all)	N/A						
Poultry (layer only)	N/A						
Fish	N/A						

Triazole lactic acid (TLA)

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[a]	Most critical commodity[b]	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all)	0.001	0.001	0.05	0.05	Beef cattle	Apple, wet pomace	N
Cattle (dairy only)	0.001	0.001	0.03	0.03	Dairy cattle	Apple, wet pomace	N
Sheep (all)	0.001	0.001	0.03	0.03	Lamb	Apple, wet pomace	N
Sheep (ewe only)	0.001	0.001	0.03	0.03	Ram/Ewe	Apple, wet pomace	N
Swine (all)	0.0004	0.0004	0.02	0.02	Swine (breeding)	Citrus dried pulp	N
Poultry (all)	N/A						
Poultry (layer only)	N/A						
Fish	N/A						

bw: body weight; DM: dry matter; N/A: not applicable, commodity is not the part of the diet.
(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.3. Consumer risk assessment

ARfD	Triazole Derivative metabolites (TDMs): 1,2,4-triazole: 0.1 mg/kg bw (EFSA, 2018b) Triazole alanine: 0.3 mg/kg bw (EFSA, 2018b) Triazole acetic acid: 1 mg/kg bw (EFSA, 2018b) Triazole lactic acid: 0.3 mg/kg bw (EFSA, 2018b)
Highest IESTI, according to EFSA PRIMo	1,2,4-triazole: Pears, oranges, apples, peaches: 1% of the ARfD Grapefruits: 0.8% of the ARfD Lemons: 0.3% of the ARfD Quinces, limes: 0.2% of the ARfD Medlar, cherries: 1% of the ARfD Blueberries: 0.06% of the ARfD Triazole alanine: Peaches: 10% of the ARfD Pears: 6% of the ARfD Apples: 4% of the ARfD Cherries: 2% of the ARfD Oranges, quinces: 1% of the ARfD Grapefruits, medlar, lemons, limes, blueberries: <1% of the ARfD Triazole acetic acid: Peaches: 0.2% of the ARfD Pears, oranges, apples: 0.1% of the ARfD Grapefruits, lemons, quinces, cherries, limes, medlar, blueberries: <0.1% of the ARfD Triazole lactic acid: Pears, apples: 3% of the ARfD Peaches: 2% of the ARfD Quinces, oranges, medlar, grapefruits, blueberries, lemons, cherries, limes: <1% of the ARfD
Assumptions made for the calculations	The calculation is based on the highest residue levels of individual TDMs as expected according to the submitted residue trials in raw agricultural commodities under consideration. The calculation performed with PRIMo rev.3.1.

Regarding the chronic exposure, the new data assessed in the present evaluation are not expected trigger a modification of previous consumer dietary exposure calculations. Therefore, the conclusion of the peer review of the assessment of the pesticide risk assessment of the TDMs in light of confirmatory data remains unchanged (EFSA, 2018c).

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Existing CXL	Conclusion/recommendation
Enforcement residue definition: fenbuconazole (sum of constituent enantiomers)					
0110010	Grapefruits	0.7 (ft 1)	Risk management consideration required	0.5	Fenbuconazole being no longer approved for the uses in plant protection products in Europe, the applicant tried to address the data gap on TDMs to, eventually, maintain the existing Codex MRLs in the EU Regulation.
0110020	Oranges	0.9 (ft 1)			

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Existing CXL	Conclusion/recommendation
					The data gap identified by EFSA concerning residues of TDMs is considered addressed. Given the wide safety margin of the calculated acute exposure, the lack of decline trials is considered as a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely. However, the submitted 6 residue trials provide an indication that fenbuconazole residues higher than the existing Codex MRL might occur in the crops from the authorised GAP in the USA. A risk management decision is required.
0110030	Lemons	1 (ft 1)	0.9 or 1	1	Fenbuconazole being no longer approved for the uses in plant protection products in Europe, the applicant tried to address the data gap on TDMs to, eventually, maintain the existing Codex MRLs in the EU Regulation. The confirmatory data gap identified by EFSA concerning residues of TDMs is considered addressed. Given the wide safety margin of the calculated acute exposure, the lack of decline trials is considered as a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely. The submitted residue trials indicate that a lower MRL of 0.9 mg/kg for fenbuconazole would be sufficient to support the authorised GAP in the United States.
0110040	Limes	1 (ft 1)			
0120000	Tree nuts	0.01* (ft1)	0.01*	0.01*	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0130000	Pome fruits	0.5 (ft 1)	Risk management consideration required	0.5	Fenbuconazole being no longer approved for the uses in plant protection products in Europe, the applicant tried to address the data gap on TDMs to, eventually, maintain the existing Codex MRLs in the EU Regulation. The data gap identified by EFSA concerning residues of TDMs is considered addressed. Risk to consumers is unlikely from the exposure to TDMs. However, the submitted residue trials provide an indication that fenbuconazole residues higher than the existing Codex MRL might occur in the crops from the authorised GAP in the USA. A risk management decision is required.
0140010	Apricots	0.6 (ft 2)	0.01*	0.5	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.

Code[a]	Commodity	Existing MRL[b]	Proposed MRL	Existing CXL	Conclusion/recommendation
0140020	Cherries	1 (ft 1)	Risk management consideration required	1	Fenbuconazole being no longer approved for the uses in plant protection products in Europe, the applicant tried to address the data gap on TDMs to, eventually, maintain the existing Codex MRLs in the EU Regulation. The data gap identified by EFSA concerning residues of TDMs is considered addressed. Given the wide safety margin of the calculated acute exposure, the lack of decline trials is considered as a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely. However, the submitted residue trials provide an indication that fenbuconazole residues higher than the existing Codex MRL might occur in the crops from the authorised GAP in the USA. A risk management decision is required.
0140030	Peaches	0.6 (ft 2)	Risk management consideration required	0.5	Fenbuconazole being no longer approved for the uses in plant protection products in the Europe, the applicant tried to address the data gap on TDMs to, eventually, maintain the existing Codex MRLs in the EU Regulation. The data gap identified by EFSA concerning residues of TDMs is considered addressed. Given the wide safety margin of the calculated acute exposure, the lack of decline trials is considered as a minor deficiency. Risk to consumers from the exposure to TDMs unlikely. However, the submitted residue trials provide an indication that fenbuconazole residues higher than the existing Codex MRL might occur in the crops from the authorised GAP in the USA. A risk management decision is required.
0140040	Plums	0.6 (ft 2)	0.01*	0.3	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0151010	Table grapes	1.5 (ft1)	0.01*	1	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0151020	Wine grapes				
0154010	Blueberries	0.5 (ft 1)	Risk management consideration required	0.5	Fenbuconazole being no longer approved for the uses in plant protection products in Europe, the applicant tried to address the data gap on TDMs to, eventually, maintain the existing Codex MRLs in the EU Regulation. The confirmatory data gap identified by EFSA concerning residues of TDMs is considered addressed. Risk to consumers is unlikely from the exposure to TDMs.

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Existing CXL	Conclusion/recommendation
					However, the submitted residue trials provide an indication that fenbuconazole residues higher than the existing Codex MRL might occur in the crops from the authorised GAP in the USA. A risk management decision is required.
0154020	Cranberries	1 (ft 1)	0.01*	1	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0163020	Bananas	0.05 (ft 1)	0.01*	0.05	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0231020	Sweet peppers/bell peppers	0.6 (ft 1)	0.01*	0.6	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0232000	Cucurbits with edible peel	0.3 (ft 2)	0.01*	0.2 (cucumber only)	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0233000	Cucurbits with inedible peel	0.3 (ft 2)	0.01*	0.2 (except watermelon)	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the for enforcement.
0401020	Peanuts/ groundnuts	0.1 (ft 1)	0.01*	0.1	The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement.
0401050	Sunflower seeds	0.05 (ft 1)	0.01*	0.05*	
0401060	Rapeseeds/ canola seeds	0.05 (ft 1)	0.01*	0.05*	
0500010	Barley	0.2 (ft 1)	0.01*	0.2	
0500070	Rye	0.1 (ft 1)	0.01*	0.1	
0500090	Wheat	0.1 (ft 1)	0.01*	0.1	

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
ft 1: The European Food Safety Authority identified some information relating to triazole derivative metabolites (TDMs) as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 September 2021, or, if that information is not submitted by that date, the lack of it.
ft 2: The European Food Safety Authority identified some information on residue trials, including data relating to triazole derivative metabolites (TDMs), as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 September 2021, or, if that information is not submitted by that date, the lack of it.

Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo Triazole alanine (TA)

European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

Triazole alanine

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.3	ARfD (mg/kg bw):	0.3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.2%	NL toddler	0.64	0.1%	Apples	0.1%	Pears	0.0%	Oranges		
	0.2%	DE child	0.61	0.2%	Apples	0.0%	Oranges	0.0%	Cherries (sweet)		
	0.1%	NL child	0.31	0.1%	Apples	0.0%	Pears	0.0%	Oranges		
	0.1%	FR toddler 2 3 yr	0.16	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	DE women 14-50 yr	0.15	0.0%	Apples	0.0%	Oranges	0.0%	Cherries (sweet)		
	0.0%	DE general	0.13	0.0%	Apples	0.0%	Oranges	0.0%	Cherries (sweet)		
	0.0%	DK child	0.13	0.0%	Apples	0.0%	Pears	0.0%	Peaches		
	0.0%	FR child 3 15 yr	0.12	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	PL general	0.10	0.0%	Apples	0.0%	Pears	0.0%	Cherries (sweet)		
	0.0%	ES child	0.10	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	UK toddler	0.10	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	UK infant	0.09	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	GEMS/Food G11	0.09	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	LT adult	0.08	0.0%	Apples	0.0%	Pears	0.0%	Cherries (sweet)		
	0.0%	NL general	0.08	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	PT general	0.08	0.0%	Apples	0.0%	Peaches	0.0%	Pears		
	0.0%	RO general	0.08	0.0%	Apples	0.0%	Cherries (sweet)	0.0%	Pears		
	0.0%	IE adult	0.08	0.0%	Apples	0.0%	Pears	0.0%	Peaches		
	0.0%	FR infant	0.08	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	GEMS/Food G08	0.08	0.0%	Apples	0.0%	Peaches	0.0%	Pears		
	0.0%	IT toddler	0.07	0.0%	Apples	0.0%	Peaches	0.0%	Pears		
	0.0%	GEMS/Food G06	0.07	0.0%	Apples	0.0%	Peaches	0.0%	Oranges		
	0.0%	GEMS/Food G15	0.07	0.0%	Apples	0.0%	Cherries (sweet)	0.0%	Oranges		
	0.0%	SE general	0.07	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	GEMS/Food G07	0.07	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	ES adult	0.07	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	IT adult	0.06	0.0%	Apples	0.0%	Peaches	0.0%	Pears		
	0.0%	GEMS/Food G10	0.06	0.0%	Apples	0.0%	Oranges	0.0%	Peaches		
	0.0%	DK adult	0.06	0.0%	Apples	0.0%	Pears	0.0%	Peaches		
	0.0%	FI 3 yr	0.05	0.0%	Apples	0.0%	Pears	0.0%	Peaches		
	0.0%	FR adult	0.05	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	UK vegetarian	0.04	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	FI 6 yr	0.04	0.0%	Apples	0.0%	Pears	0.0%	Peaches		
	0.0%	FI adult	0.03	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	UK adult	0.03	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	IE child	0.02	0.0%	Apples	0.0%	Pears	0.0%	Oranges		

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

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Peaches	0 / 0.31	29
6%	Pears	0 / 0.12	17
4%	Apples	0 / 0.12	13
2%	Cherries (sweet)	0 / 0.51	6.2
1%	Oranges	0 / 0.03	4.0
1.0%	Quinces	0 / 0.12	3.0
0.8%	Grapefruits	0 / 0.03	2.4
0.6%	Medlar	0 / 0.12	1.7
0.1%	Lemons	0 / 0.01	0.34
0.07%	Limes	0 / 0.01	0.20
0.04%	Blueberries	0 / 0.02	0.13

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Peaches	0 / 0.31	5.8
2%	Cherries (sweet)	0 / 0.51	5.1
1%	Pears	0 / 0.12	3.7
1%	Apples	0 / 0.12	3.4
0.6%	Quinces	0 / 0.12	1.8
0.3%	Oranges	0 / 0.03	0.92
0.3%	Medlar	0 / 0.12	0.82
0.2%	Grapefruits	0 / 0.03	0.54
0.07%	Blueberries	0 / 0.02	0.20
0.03%	Lemons	0 / 0.01	0.09
0.02%	Limes	0 / 0.01	0.07

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Peaches / canned	0 / 0.31	8.1
0.7%	Apples / juice	0 / 0.04	2.2
0.4%	Pears / juice	0 / 0.04	1.3
0.2%	Peaches / juice	0 / 0.04	0.66
0.2%	Oranges / juice	0 / 0.01	0.53
0.0%	Quinces / jam	0 / 0.04	0.12
0.0%	Lemons / jam	0 / 0.01	0.03
0.0%	Limes / juice	0 / 0.01	0.00

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.8%	Peaches / canned	0 / 0.31	2.5
0.4%	Apples / juice	0 / 0.04	1.3
0.05%	Oranges / juice	0 / 0.01	0.15
0.04%	Grapefruits / juice	0 / 0.01	0.11
0.02%	Quinces / jam	0 / 0.04	0.05
0.01%	Lemons / juice	0 / 0.01	0.02

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Triazole alanine is unlikely to present a public health risk.

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

- PRIMo Triazole lactic acid (TLA)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole lactic acid

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.3	ARfD (mg/kg bw):	0.3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.1%	DE child	0.18	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.1%	NL toddler	0.18	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	NL child	0.09	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	FR child 3 15 yr	0.06	0.0%	Oranges	0.0%	Apples	0.0%	Pears		
	0.0%	DE women 14-50 yr	0.05	0.0%	Apples	0.0%	Oranges	0.0%	Lemons		
	0.0%	FR toddler 2 3 yr	0.05	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	DE general	0.05	0.0%	Apples	0.0%	Oranges	0.0%	Lemons		
	0.0%	ES child	0.04	0.0%	Oranges	0.0%	Apples	0.0%	Pears		
	0.0%	UK toddler	0.04	0.0%	Oranges	0.0%	Apples	0.0%	Pears		
	0.0%	DK child	0.03	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	IE adult	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Grapefruits		
	0.0%	UK infant	0.03	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	GEMS/Food G11	0.03	0.0%	Apples	0.0%	Oranges	0.0%	Lemons		
	0.0%	GEMS/Food G07	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Lemons		
	0.0%	NL general	0.03	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	GEMS/Food G06	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Lemons		
	0.0%	ES adult	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Pears		
	0.0%	GEMS/Food G10	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Lemons		
	0.0%	PL general	0.03	0.0%	Apples	0.0%	Pears	0.0%	Cherries (sweet)		
	0.0%	SE general	0.03	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	PT general	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Peaches		
	0.0%	GEMS/Food G08	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Lemons		
	0.0%	GEMS/Food G15	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	IT toddler	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Peaches		
	0.0%	RO general	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Cherries (sweet)		
	0.0%	FR infant	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	LT adult	0.02	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	IT adult	0.02	0.0%	Apples	0.0%	Peaches	0.0%	Oranges		
	0.0%	FR adult	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	UK vegetarian	0.02	0.0%	Oranges	0.0%	Apples	0.0%	Grapefruits		
	0.0%	DK adult	0.02	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	FI 3 yr	0.01	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	UK adult	0.01	0.0%	Oranges	0.0%	Apples	0.0%	Grapefruits		
	0.0%	FI adult	0.01	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	FI 6 yr	0.01	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	IE child	0.00	0.0%	Apples	0.0%	Oranges	0.0%	Pears		

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

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Pears	0 / 0.07	9.7
3%	Apples	0 / 0.07	7.5
2%	Peaches	0 / 0.05	4.8
0.6%	Quinces	0 / 0.07	1.7
0.4%	Oranges	0 / 0.01	1.3
0.3%	Medlar	0 / 0.07	0.97
0.3%	Grapefruits	0 / 0.01	0.79
0.2%	Blueberries	0 / 0.12	0.72
0.1%	Lemons	0 / 0.01	0.34
0.08%	Cherries (sweet)	0 / 0.02	0.24
0.07%	Limes	0 / 0.01	0.20

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Pears	0 / 0.07	2.1
0.7%	Apples	0 / 0.07	2.0
0.4%	Blueberries	0 / 0.12	1.1
0.4%	Quinces	0 / 0.07	1.1
0.3%	Peaches	0 / 0.05	0.96
0.2%	Medlar	0 / 0.07	0.48
0.1%	Oranges	0 / 0.01	0.31
0.07%	Cherries (sweet)	0 / 0.02	0.20
0.06%	Grapefruits	0 / 0.01	0.18
0.03%	Lemons	0 / 0.01	0.09
0.02%	Limes	0 / 0.01	0.07

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Peaches / canned	0 / 0.05	1.3
0.2%	Apples / juice	0 / 0.01	0.54
0.2%	Oranges / juice	0 / 0.01	0.53
0.1%	Pears / juice	0 / 0.01	0.33
0.1%	Peaches / juice	0 / 0.01	0.17
0.0%	Lemons / jam	0 / 0.01	0.03
0.0%	Lemons / jam	0 / 0.01	0.03
0.0%	Limes / juice	0 / 0.01	0.00

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Peaches / canned	0 / 0.05	0.42
0.1%	Apples / juice	0 / 0.01	0.33
0.05%	Oranges / juice	0 / 0.01	0.15
0.04%	Grapefruits / juice	0 / 0.01	0.11
0.01%	Lemons / juice	0 / 0.01	0.02
0.00%	Quinces / jam	0 / 0.01	0.01

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Triazole lactic acid is unlikely to present a public health risk.

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

- PRIMo Triazole acetic acid (TAA)

European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

Triazole acetic acid (TAA)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	1	ARfD (mg/kg bw):	1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.0%	DE child	0.18	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	NL toddler	0.18	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	NL child	0.09	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	FR child 3 15 yr	0.06	0.0%	Oranges	0.0%	Apples	0.0%	Pears		
	0.0%	DE women 14-50 yr	0.05	0.0%	Apples	0.0%	Oranges	0.0%	Lemons		
	0.0%	FR toddler 2 3 yr	0.05	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	DE general	0.05	0.0%	Apples	0.0%	Oranges	0.0%	Lemons		
	0.0%	ES child	0.04	0.0%	Oranges	0.0%	Apples	0.0%	Pears		
	0.0%	UK toddler	0.04	0.0%	Oranges	0.0%	Apples	0.0%	Pears		
	0.0%	DK child	0.03	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	IE adult	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Grapefruits		
	0.0%	UK infant	0.03	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	GEMS/Food G11	0.03	0.0%	Apples	0.0%	Oranges	0.0%	Lemons		
	0.0%	GEMS/Food G07	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Lemons		
	0.0%	NL general	0.03	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	GEMS/Food G06	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Lemons		
	0.0%	ES adult	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Pears		
	0.0%	GEMS/Food G10	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Lemons		
	0.0%	PL general	0.03	0.0%	Apples	0.0%	Pears	0.0%	Cherries (sweet)		
	0.0%	SE general	0.03	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	PT general	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Peaches		
	0.0%	GEMS/Food G08	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Lemons		
	0.0%	GEMS/Food G15	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	IT toddler	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Peaches		
	0.0%	RO general	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Cherries (sweet)		
	0.0%	FR infant	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	LT adult	0.02	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	IT adult	0.02	0.0%	Apples	0.0%	Peaches	0.0%	Oranges		
	0.0%	FR adult	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	UK vegetarian	0.02	0.0%	Oranges	0.0%	Apples	0.0%	Grapefruits		
	0.0%	DK adult	0.02	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	FI 3 yr	0.01	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	UK adult	0.01	0.0%	Oranges	0.0%	Apples	0.0%	Grapefruits		
	0.0%	FI adult	0.01	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	FI 6 yr	0.01	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	IE child	0.00	0.0%	Apples	0.0%	Oranges	0.0%	Pears		

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

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Peaches	0 / 0.02	1.9
0.1%	Pears	0 / 0.01	1.4
0.1%	Oranges	0 / 0.01	1.3
0.1%	Apples	0 / 0.01	1.1
0.08%	Grapefruits	0 / 0.01	0.79
0.03%	Lemons	0 / 0.01	0.34
0.02%	Quinces	0 / 0.01	0.25
0.02%	Cherries (sweet)	0 / 0.02	0.22
0.02%	Limes	0 / 0.01	0.20
0.01%	Medlar	0 / 0.01	0.14
0.01%	Blueberries	0 / 0.01	0.08

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.04%	Peaches	0 / 0.02	0.37
0.03%	Oranges	0 / 0.01	0.31
0.03%	Pears	0 / 0.01	0.31
0.03%	Apples	0 / 0.01	0.28
0.02%	Cherries (sweet)	0 / 0.02	0.18
0.02%	Grapefruits	0 / 0.01	0.18
0.02%	Quinces	0 / 0.01	0.15
0.01%	Blueberries	0 / 0.01	0.13
0.01%	Lemons	0 / 0.01	0.09
0.01%	Limes	0 / 0.01	0.07
0.01%	Medlar	0 / 0.01	0.07

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Apples / juice	0 / 0.01	0.54
0.1%	Oranges / juice	0 / 0.01	0.53
0.1%	Peaches / canned	0 / 0.02	0.52
0.0%	Pears / juice	0 / 0.01	0.33
0.0%	Peaches / juice	0 / 0.01	0.17
0.0%	Lemons / jam	0 / 0.01	0.03
0.0%	Lemons / jam	0 / 0.01	0.03
0.0%	Limes / juice	0 / 0.01	0.00

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.0%	Apples / juice	0 / 0.01	0.33
0.02%	Peaches / canned	0 / 0.02	0.16
0.02%	Oranges / juice	0 / 0.01	0.15
0.01%	Grapefruits / juice	0 / 0.01	0.11
0.00%	Lemons / juice	0 / 0.01	0.02
0.00%	Quinces / jam	0 / 0.01	0.01

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Triazole acetic acid (TAA) is unlikely to present a public health risk.

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

- PRIMo 1-2-3 triazole

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

1,2,4-triazole

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.023	ARfD (mg/kg bw):	0.1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.8%	DE child	0.18	0.5%	Apples	0.2%	Oranges	0.0%	Pears		
	0.8%	NL toddler	0.18	0.5%	Apples	0.2%	Pears	0.1%	Oranges		
	0.4%	NL child	0.09	0.3%	Apples	0.1%	Oranges	0.1%	Pears		
	0.2%	FR child 3 15 yr	0.06	0.1%	Oranges	0.1%	Apples	0.0%	Pears		
	0.2%	DE women 14-50 yr	0.05	0.1%	Apples	0.1%	Oranges	0.0%	Lemons		
	0.2%	FR toddler 2 3 yr	0.05	0.1%	Apples	0.1%	Oranges	0.0%	Pears		
	0.2%	DE general	0.05	0.1%	Apples	0.1%	Oranges	0.0%	Lemons		
	0.2%	ES child	0.04	0.1%	Oranges	0.0%	Apples	0.0%	Pears		
	0.2%	UK toddler	0.04	0.1%	Oranges	0.1%	Apples	0.0%	Pears		
	0.1%	DK child	0.03	0.1%	Apples	0.0%	Pears	0.0%	Oranges		
	0.1%	IE adult	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Grapefruits		
	0.1%	UK infant	0.03	0.1%	Apples	0.1%	Oranges	0.0%	Pears		
	0.1%	GEMS/Food G11	0.03	0.1%	Apples	0.0%	Oranges	0.0%	Lemons		
	0.1%	GEMS/Food G07	0.03	0.1%	Oranges	0.0%	Apples	0.0%	Lemons		
	0.1%	NL general	0.03	0.1%	Apples	0.0%	Oranges	0.0%	Pears		
	0.1%	GEMS/Food G06	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Lemons		
	0.1%	ES adult	0.03	0.1%	Oranges	0.0%	Apples	0.0%	Pears		
	0.1%	GEMS/Food G10	0.03	0.0%	Oranges	0.0%	Apples	0.0%	Lemons		
	0.1%	PL general	0.03	0.1%	Apples	0.0%	Pears	0.0%	Cherries (sweet)		
	0.1%	SE general	0.03	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.1%	PT general	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Peaches		
	0.1%	GEMS/Food G08	0.02	0.1%	Apples	0.0%	Oranges	0.0%	Lemons		
	0.1%	GEMS/Food G15	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.1%	IT toddler	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Peaches		
	0.1%	RO general	0.02	0.1%	Apples	0.0%	Oranges	0.0%	Cherries (sweet)		
	0.1%	FR infant	0.02	0.1%	Apples	0.0%	Oranges	0.0%	Pears		
	0.1%	LT adult	0.02	0.1%	Apples	0.0%	Pears	0.0%	Oranges		
	0.1%	IT adult	0.02	0.0%	Apples	0.0%	Peaches	0.0%	Oranges		
	0.1%	FR adult	0.02	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.1%	UK vegetarian	0.02	0.0%	Oranges	0.0%	Apples	0.0%	Grapefruits		
	0.1%	DK adult	0.02	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.1%	FI 3 yr	0.01	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	UK adult	0.01	0.0%	Oranges	0.0%	Apples	0.0%	Grapefruits		
	0.0%	FI adult	0.01	0.0%	Apples	0.0%	Oranges	0.0%	Pears		
	0.0%	FI 6 yr	0.01	0.0%	Apples	0.0%	Pears	0.0%	Oranges		
	0.0%	IE child	0.00	0.0%	Apples	0.0%	Oranges	0.0%	Pears		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of 1,2,4-triazole is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Pears	0 / 0.01	1.4
1%	Oranges	0 / 0.01	1.3
1%	Apples	0 / 0.01	1.1
1.0%	Peaches	0 / 0.01	0.95
0.8%	Grapefruits	0 / 0.01	0.79
0.3%	Lemons	0 / 0.01	0.34
0.2%	Quinces	0 / 0.01	0.25
0.2%	Limes	0 / 0.01	0.20
0.1%	Medlar	0 / 0.01	0.14
0.1%	Cherries (sweet)	0 / 0.01	0.12
0.06%	Blueberries	0 / 0.01	0.06

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Oranges	0 / 0.01	0.31
0.3%	Pears	0 / 0.01	0.31
0.3%	Apples	0 / 0.01	0.28
0.2%	Peaches	0 / 0.01	0.19
0.2%	Grapefruits	0 / 0.01	0.18
0.2%	Quinces	0 / 0.01	0.15
0.1%	Cherries (sweet)	0 / 0.01	0.10
0.09%	Blueberries	0 / 0.01	0.09
0.09%	Lemons	0 / 0.01	0.09
0.07%	Limes	0 / 0.01	0.07
0.07%	Medlar	0 / 0.01	0.07

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.5%	Apples / juice	0 / 0.01	0.54
0.5%	Oranges / juice	0 / 0.01	0.53
0.3%	Pears / juice	0 / 0.01	0.33
0.3%	Peaches / canned	0 / 0.01	0.26
0.2%	Peaches / juice	0 / 0.01	0.17
0.0%	Lemons / jam	0 / 0.01	0.03
0.0%	Lemons / jam	0 / 0.01	0.03
0.0%	Limes / juice	0 / 0.01	0.00

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Apples / juice	0 / 0.01	0.33
0.2%	Oranges / juice	0 / 0.01	0.15
0.1%	Grapefruits / juice	0 / 0.01	0.11
0.08%	Peaches / canned	0 / 0.01	0.08
0.02%	Lemons / juice	0 / 0.01	0.02
0.01%	Quinces / jam	0 / 0.01	0.01

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of 1,2,4-triazole is unlikely to present a public health risk.

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: 1,2,4-triazole				
Apple, pomace, wet	0.05	STMR (< 0.01) × default PF (5)[(a)]	0.05	STMR (< 0.01) × default PF (5)[(a)]
Citrus, dried pulp	0.10	STMR (< 0.01) × default PF (10)[(a)]	0.10	STMR (< 0.01) × default PF (10)[(a)]
Risk assessment residue definition: triazole alanine				
Apple, pomace, wet	0.20	STMR (0.04) × default PF (5)[(a)]	0.20	STMR (0.04) × default PF (5)[(a)]
Citrus, dried pulp	0.10	STMR (< 0.01) × default PF (10)[(a)]	0.10	STMR (< 0.01) × default PF (10)[(a)]
Risk assessment residue definition: triazole acetic acid				
Apple, pomace, wet	0.05	STMR (< 0.01) × default PF (5)[(a)]	0.05	STMR (< 0.01) × default PF (5)[(a)]
Citrus, dried pulp	0.10	STMR (< 0.01) × default PF (10)[(a)]	0.10	STMR (< 0.01) × default PF (10)[(a)]
Risk assessment residue definition: triazole lactic acid				
Apple, pomace, wet	0.10	STMR (0.02) × default PF (5)[(a)]	0.1	STMR (0.02) × default PF (5)[(a)]
Citrus, dried pulp	0.10	STMR (< 0.01) × default PF (10)[(a)]	0.10	STMR (< 0.01) × default PF (10)[(a)]

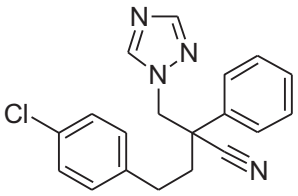
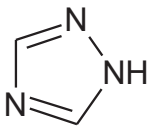
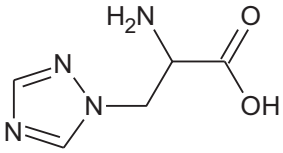
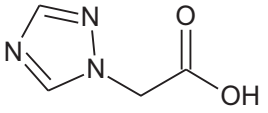
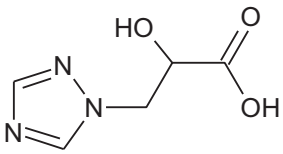
STMR: supervised trials median residue; PF: processing factor.
(a): In the absence of processing factors supported by data, default processing factors (in bracket) were respectively included in the calculation to consider the potential concentration of residues in these commodities.

D.2. Acute consumer risk assessment (triazole derivative metabolites)

Commodity	1,2,4-T (HR-RAC) (mg/kg)	TA (HR-RAC) (mg/kg)	TAA (HR-RAC) (mg/kg)	TLA (HR-RAC) (mg/kg)
Grapefruits, oranges	0.01	0.03	0.01	0.01
Lemons, limes	0.01	0.01	0.01	0.01
Pome fruits	0.01	0.12	0.01	0.07
Cherries	0.01	0.51	0.018	0.02
Peaches	0.01	0.31	0.02	0.051
Blueberries	0.01	0.022	0.014	0.12

HR-RAC: highest residue in raw agricultural commodity.

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Fenbuconazole	(*RS*)-4-(4-chlorophenyl)-2-phenyl-2-(1*H*-1,2,4-triazol-1-ylmethyl)butyronitrile Clc1ccc(CCC(Cn2cncn2)(C#N)c2ccccc2)cc1 RQDJADAKIFFEKQ-UHFFFAOYSA-N	
Triazole derivative metabolites		
1,2,4-triazole 1,2,4-T	1*H*-1,2,4-triazole c1ncnn1 NSPMIYGKQJPBQR-UHFFFAOYSA-N	
Triazole alanine TA	3-(1*H*-1,2,4-triazol-1-yl)-D,L-alanine NC(Cn1cncn1)C(=O)O XVWFTOJHOHJIMQ-UHFFFAOYSA-N	
Triazole acetic acid TAA	1*H*-1,2,4-triazol-1-ylacetic acid O=C(O)Cn1cncn1 RXDBSQXFIWBJSR-UHFFFAOYSA-N	
Triazole lactic acid or Triazole hydroxy propionic acid TLA	(2*RS*)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propanoic acid OC(Cn1cncn1)C(=O)O KJRGHGWETVMENC-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).