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REASONED OPINION

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

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Abstract

The applicant Corteva Agriscience submitted a request to the competent national authority in Austria to evaluate the confirmatory data that were identified for myclobutanil in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gap related to the lack of information on the triazole derivative metabolites (TDMs), new residue trials analysing for TDMs were submitted on apples, grapes, strawberries, tomatoes and melons. Following the assessment of the submitted data, EFSA concluded that Article 12 confirmatory data gaps are considered addressed for pome fruits, grapes, cucurbits with inedible peel, strawberries and tomatoes. The new information provided required the assessment of consumer exposure to TDMs, which identified no consumer intake concerns for the crops under consideration. No information was provided to address the Article 12 confirmatory data referred to in Regulation (EU) 2020/770 for blackberries, gooseberries, bananas, aubergines/eggplants, lamb's lettuces/corn salads, beans (with pods), globe artichokes, hops, sugar beet roots and products of animal origin. For these commodities, the existing EU MRL could be lowered to the enforcement limit of quantification (LOQ). For kaki/Japanese persimmon and azararoles/mediterranean medlars, the existing EU MRL is set on the basis of Codex MRL in pome fruits. The applicant did not request maintaining a Codex MRL in these commodities, but should risk managers decide otherwise, the Article 12 data gap is considered addressed for kaki/Japanese persimmon while for azaroles/Mediterranean medlars, a risk management decision might be required. No consumer intake concerns were identified.

KEYWORDS

confirmatory data, MRL review, pesticide, risk assessment, TDMs

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SUMMARY

In 2018, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for myclobutanil 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. A representative rotational crop field study to address the uptake of residues of myclobutanil and metabolites from previous applications (it is noted that a study was reported by JMPR, but a detailed assessment of this study was not available in the MRL review).
2. A representative study investigating the metabolism in leafy vegetables;
3. A representative study investigating the metabolism in pulses and oilseeds;
4. A representative study investigating the metabolism in fruits following post-harvest treatment (to cover the important tolerance for bananas);
5. Hazelnuts/cobnuts; walnuts: Four trials on hazelnuts/cobnuts and walnuts compliant with the southern GAP are required.
6. Raspberries (red and yellow): Four trials on raspberries (red and yellow) compliant with the indoor GAP are required.
7. Blackberries: Four additional trials compliant with the northern GAP, three additional trials compliant with the southern GAP and four additional trials compliant with the indoor GAP are still required.
8. Gooseberries: Four additional trials on currants and gooseberries compliant with the northern GAP and four additional trials compliant with the southern GAP are still required.
9. Tomatoes: Four additional trials compliant with the indoor GAP and four additional trials compliant with the southern GAP are still required.
10. Melons, pumpkins and watermelons: Three additional trials compliant with the southern GAP are still required. For melons, four trials compliant with the indoor GAP are still required, and for pumpkins and watermelons, eight trials compliant with the indoor GAP are still required.
11. Beans (with pods): Five trials on beans (with pods) compliant with the import tolerance GAP are required.
12. Borage seeds: Four trials on borage seeds compliant with the southern GAP are required.
13. Asparagus: Four trials on asparagus compliant with the southern GAP are required.
14. Lamb's lettuce/corn salads: Four additional trials compliant with the northern and indoor GAP analysed with a method that allows the release of RH-9090 conjugates are required.
15. Globe artichokes: Four additional trials compliant with the northern and southern GAP analysed with a method that allows the release of RH-9090 conjugates are required.
16. Hops: Four additional trials compliant with the northern GAP analysed with a method that allows the release of RH-9090 conjugates are required.
17. A fully validated analytical method for the determination of myclobutanil in hops is required.
18. A confirmatory method for the analytical methods for animal matrices is required.
19. A report demonstrating the extraction efficiency of the analytical methods for animal matrices is required.
20. A storage stability study on animal matrices (kidney, fat and milk) is required.

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. Several data gaps which were identified during the peer review were not addressed in the framework of the Article 12 review. In the view of a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides, the following data were considered as still missing:

- Field rotation trials performed with myclobutanil and analysing for TDMs residue levels (data gap relevant for annual crops).
- Residue trials following growing seasons performed with myclobutanil and analysing for TDMs residue levels (data gap relevant for permanent crops).

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) 2020/770, including footnotes related to data gaps number 1–4, and 16–20, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 12 June 2022. The data gaps number 5–15 related to the lack of residue trials were not implemented in the MRL regulation; however, for the crops mentioned in the data gaps No. 7 (blackberries), 8 (gooseberries), 9 (tomatoes), 10 (melons, pumpkins, watermelons), 11 (beans with pods), 14 (lamb's lettuce/corn salad) and 15 (globe artichokes)–general data gaps identified by the MRL review related to primary crop metabolism studies or rotational crop field trials were included in the MRL legislation. Furthermore, the risk managers decided to reiterate the lack of information on TDMs as a confirmatory data requirement for certain plant commodities assessed by the MRL review. The MRLs for hazelnuts (data gap No. 5), raspberries (data gap No. 6) and asparagus (data gap 13) were lowered to the limit of quantification (LOQ). For kaki/Japanese persimmon and azaroles/Mediterranean medlars, data gaps have not been set by the MRL review, but since for these crops, the Codex MRLs are established, the risk

managers decided to apply the same data gap (lack of TDM data) as for pome fruits, since the mentioned commodities are classified under the pome fruit group according to Codex food classification system.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, Corteva Agriscience submitted an application to the competent national authority in Austria (rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review for grapes, apples, pears, quince, medlars, Loquat/Japanese medlars, other pome fruits, melons, pumpkins, watermelons, other cucurbits with inedible peel, strawberries and tomatoes. It is noted that myclobutanil is no longer approved for the uses in plant protection products in Europe, and therefore, the applicant submitted these data mainly to address the data gap on TDMs and in order to eventually maintain the existing Codex MRLs in the EU Regulation for grapes, crops belonging to the group pome fruit and cucurbits with inedible peel, strawberries and tomatoes. It is underlined that the scope of the present application was not to propose new MRLs for myclobutanil.

No information was provided to address the Article 12 confirmatory data gaps referred to in Regulation (EU) 2020/770 for blackberries, gooseberries, bananas, aubergines/eggplants, lamb's lettuces/corn salads, beans (with pods), globe artichokes, hops, sugar beet roots and products of animal origin.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 7 June 2022. The appointed RMS, Austria, assessed the dossier and declared its admissibility on 24 June 2022. 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 was 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 ran from 5 May 2023 to 26 May 2023. No additional data or comments were submitted in the framework of the consultation.

At the end of the commenting period, the RMS proceeded drafting 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 7 July 2023. When assessing the evaluation report, EFSA identified data gaps which needed further clarification. The applicant provided the requested information in an updated IUCLID dossier, which was duly considered by the RMS, who submitted a revised evaluation report to EFSA on 5 January 2024, replacing 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]	Data gap(s) Art. 12 review	Existing CXL	Proposed MRL	Conclusion/Recommendation
	Enforcement residue definition: myclobutanil (sum of constituent isomers)					
0130000 0130010 0130020 0130030 0130040 0130050 0130990	Pome fruits Apples Pears Quinces Medlars Loquats/Japanese medlars Others	0.6 (ft 1)	Footnote related to lack of information on TDMs	0.6	0.6	The existing MRL in pome fruits is set based on Codex MRL Myclobutanil is no longer approved for the use 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 a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely
0151000 0151010 0151020	(a) Grapes Table grapes Wine grapes	1.5 (ft 1)	Footnote related to lack of information on TDMs	0.9	0.9	The existing MRL is based on EU uses which are now revoked The applicant tried to address the data gap on TDMs to, eventually, replace the existing EU MRL with a lower Codex MRL in place for these commodities 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 a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely For strawberries, the data gap related to rotational crop field study is not addressed but is of low relevance in case of import tolerances
0152000	Strawberries	1.5 (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	0.8	0.8	

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Code[a]	Commodity	Existing MRL[b]	Data gap(s) Art. 12 review	Existing CXL	Proposed MRL	Conclusion/Recommendation
0153010	Blackberries	0.8 (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	–	0.01*	The existing MRL is based on EU use which is now revoked. The data gap identified in the MRL review is not addressed. Consequently, the MRL can be lowered to the LOQ for enforcement
0154040	Gooseberries (green, red and yellow)	0.8 (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	–	0.01*	
0154070	Azaroles/ Mediterranean medlars	0.6 (ft 1)	Footnote related to lack of information on TDMs	0.6	0.6 or 0.01* Risk management decision	The existing MRL is set based on Codex MRL for pome fruits The data gap identified by EFSA concerning residues of TDMs is considered addressed by extrapolation of data from pome fruit[c] (see above) The applicant, however, did not request to maintain Codex MRL in this commodity. A risk management decision on the MRL proposal is therefore required Risk to consumers from the exposure to TDMs is unlikely
0161060	Kaki/Japanese persimmons	0.6 (ft 1)	Footnote related to lack of information on TDMs	0.6	0.6 or 0.01* Risk management decision	The existing MRL is set based on Codex MRL for pome fruits. The data gap identified by EFSA concerning residues of TDMs is considered addressed by means of data extrapolation from apples. The applicant, however, did not request to maintain Codex MRL in this commodity. A risk management decision on the MRL proposal is therefore required. Risk to consumers from the exposure to TDMs is unlikely.
0163020	Bananas	3 (ft 3)	Footnote related to data gap No 4 [crop metabolism with post-harvest treatment unavailable]	–	0.01*	The existing MRL is based on the import tolerance from USA and Costa Rica The data gap identified in the MRL review is not addressed. Consequently, the MRL can be lowered to the LOQ for enforcement
0231010	Tomatoes	0.6 (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	0.3	0.3	The existing MRL is based on EU uses which are now revoked. The applicant tried to address the data gap on TDMs to, eventually, replace the existing EU MRL with a lower Codex MRL in place for tomatoes 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 a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely The data gap related to rotational crop field study is not addressed but is of low relevance in case of import tolerances

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Code[a]	Commodity	Existing MRL[b]	Data gap(s) Art. 12 review	Existing CXL	Proposed MRL	Conclusion/Recommendation
0231030	Aubergines/ eggplants	0.2 (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	–	0.01*	The existing MRL is based on EU use which is now revoked. The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement
0233000 0233010 0233020 0233030 0233990	(c) Cucurbits with inedible peel Melons Pumpkins Watermelons Others (2)	0.3 (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	0.2	0.2	The existing MRL is based on EU uses which are now revoked. The applicant tried to address the data gap on TDMs to, eventually, replace the existing EU MRL with a lower Codex MRL in place for cucurbits with inedible peel 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 a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely The data gap related to rotational crop field study is not addressed but is of low relevance in case of import tolerances
0251010	Lamb's lettuces/ corn salads	9 (ft 4)	Footnote related to data gap No 2 [crop metabolism with leafy vegetables unavailable] and lack of information on TDMs	0.5	0.01*	The existing MRL is based on EU use which is now revoked The data gap identified in the MRL review is not addressed. Consequently, the MRL can be lowered to the LOQ for enforcement
0260010	Beans (with pods)	0.8 (ft 5)	Footnote related to data gap No 3 [crop metabolism with pulses and oilseeds unavailable]	0.8	0.01*	The existing MRL is set based on a Codex MRL The data gap identified in the MRL review is not addressed. Consequently, the MRL can be lowered to the LOQ for enforcement
0270050	Globe artichokes	0.8 (ft 6)	Footnote related to data gap No 2 [crop metabolism with leafy vegetables unavailable]	–	0.01*	The existing MRL is based on an EU use which is now revoked. The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement
0700000	Hops	6 (ft 7)	Footnote related to data gap No 2, 16 and 17 [crop metabolism with leafy vegetables, additional residue trials and analytical methods unavailable]	5	0.01*	The existing MRL is based on an EU use which is now revoked. The data gaps identified in the MRL review are not addressed. Consequently, the MRL can be lowered to the LOQ for enforcement.
0900010	Sugar beet roots	0.01* (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	–	0.01*	The existing MRL is based on an EU use which is now revoked. The data gap identified in the MRL review is not addressed. Consequently, MRL can be maintained at the LOQ for enforcement

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Code[a]	Commodity	Existing MRL[b]	Data gap(s) Art. 12 review	Existing CXL	Proposed MRL	Conclusion/Recommendation
1000000	Products of animal origin -terrestrial animals: muscle, liver, edible offal of swine, bovine, sheep, goat, equine, poultry and other farmed animals; Birds eggs **(except kidney, fat and milk)**	0.01* (ft 8)	Footnote related to data gap No. 18 and 19 [confirmatory method and extraction efficiency for the analytical methods unavailable]	0.01*	0.01*	The data gaps identified in the MRL review are not addressed. Consequently, MRL can be maintained at the LOQ for enforcement
1000000	Products of animal origin terrestrial animals: fat and kidney of swine, bovine, sheep, goat, equine, poultry and other farmed animals; Milk **(only kidney, fat and milk)**	0.01* (ft 9)	Footnote related to data gap No. 18, 19 and 20 [confirmatory method and extraction efficiency for the analytical methods and storage stability unavailable]	0.01*	0.01*	

Abbreviations: GAP, Good Agricultural Practice; MRL, maximum residue level; NEU, northern Europe; SEU, southern Europe.

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]Existing EU MRL and corresponding footnote on confirmatory data.

[c]According to the Technical Guidelines SANTE/2019/12752 (European Commission, 2019), extrapolation of residue data from pome fruits to Aazaroles/Mediterranean medlars is not supported.

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 12 June 2022, 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 rotational crop field studies and 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 3: The European Food Safety Authority identified some information on crop metabolism with post-harvest treatment 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 4: The European Food Safety Authority identified some information on crop metabolism with leafy vegetables and 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 5: The European Food Safety Authority identified some information on crop metabolism with pulses and oilseeds 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 6: The European Food Safety Authority identified some information on crop metabolism with leafy vegetables 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 7: The European Food Safety Authority identified some information on residue trials, analytical methods and crop metabolism with leafy vegetables 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 8: The European Food Safety Authority identified some information on analytical methods 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 9: The European Food Safety Authority identified some information on analytical methods and storage stability 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

ASSESSMENT

The review of existing MRLs for the active substance myclobutanil according to Article 12 of Regulation (EC) No 396/2005[1] (MRL review) has been performed in 2018 (EFSA, 2018c). The 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.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) 2020/770,[2] 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 12 June 2022.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2020) and with the 'Transparency Regulation' (EU) 2019/1381,[3] the applicant Corteva Agriscience, on 7 June 2022 submitted an application to the competent national authority in Austria (designated rapporteur Member State, RMS), alongside the dossier containing the supporting data using the IUCLID format, in order to evaluate the confirmatory data identified during the MRL review for the following commodities with subsequent MRL proposals: apples, pears, quinces, medlars, Loquat/Japanese medlar and other pome fruits (0.6 mg/kg), grapes (0.9 mg/kg), melons, pumpkins, watermelons and other cucurbits with inedible peel (0.2 mg/kg), strawberries (0.8 mg/kg), tomatoes (0.3 mg/kg). It is noted that all the proposed MRLs comply with the Codex MRLs established for myclobutanil by the JMPR 2014. In fact, the active substance myclobutanil is no longer approved for the uses in plant protection products in Europe, and therefore, the applicant submitted the confirmatory data mainly to address the data gap on TDMs and in order to eventually maintain the existing Codex MRLs in the EU Regulation.

To address the data gaps identified by EFSA in the framework of the MRL review, the applicant provided new residue trials on apples, grapes, strawberries, tomatoes and melons in line with the uses of myclobutanil reported in the JMPR evaluation (FAO, 2014) 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) 2020/770 for blackberries, gooseberries, bananas, aubergines/eggplants, lamb's lettuces/corn salads, beans (with pods), globe artichokes, hops, sugar beet roots and products of animal origin.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 7 July 2023 (Austria, 2023). 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 clarifications. On 10 November 2023, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the EMS who submitted a revised evaluation report to EFSA on 5 January 2024 (Austria, 2023), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the RMS (Austria, 2023) and 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[4] and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) 2020/770 are applicable. 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.[5]

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 (Austria, 2023) is considered a supporting document to this reasoned opinion and, thus, is made publicly available as a background document to this reasoned opinion.[6]

[1]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.

[2]Commission Regulation EU 2020/770 of 8 June 2020 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 myclobutanil, napropamide and sintofen in or on certain products. OJ L 184, 12.6.2020, p. 1–24.

[3]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.

[4]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.

[5]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.

[6]Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00426

1 | RESIDUES IN PLANTS

1.1 | Nature of residues and methods of analysis in plants

1.1.1 | Nature of residues in primary crops

The metabolism of myclobutanil was investigated after foliar treatment in fruits (apples and grapes), cereals (EFSA, 2010) and root crops (EFSA, 2018c), with myclobutanil radiolabelled in the phenyl or triazole ring of the molecule. The metabolism of myclobutanil was not similar in the crops investigated since in cereals there is a cleavage of myclobutanil at the triazole linkage which leads to the generation of TDMs which did not occur in fruits and roots. Therefore, EFSA review of the existing MRLs for myclobutanil according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2018c) identified data gaps for representative studies investigating primary crop metabolism in other crop groups –leafy crops, pulses and oilseeds – and, considering the import tolerance in banana, also in fruit crops following post-harvest treatment. These data gaps are relevant for bananas, lamb's lettuces/corn salads, beans (with pods), globe artichokes and hops.

New metabolism studies have not been submitted under the present MRL application, and therefore, EFSA concludes that the data gaps number 2,[7] 3,[8] 4[9] have not been addressed. These data gaps, however, are of no relevance to the crops assessed in the present MRL application.

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

During the peer review and the Art. 12 review, several analytical methods were validated for the enforcement of myclobutanil with an LOQ of 0.01 mg/kg in high water content, high acid content, high oil content and dry commodities (EFSA, 2010, 2018c).

No fully validated methods were reported for the determination of myclobutanil in hops, and therefore, a data gap was identified in the MRL review for this commodity. New information on the method validation in hops has not been provided in the framework of the present MRL application, and therefore, EFSA concludes that the data gap number 17[10] has not been addressed.

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 (Austria, 2023). 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.

[7]Data gap Number 2 refers to the submission of a representative study investigating the metabolism in leafy vegetables.

[8]Data gap Number 3 refers to the submission of a representative study investigating the metabolism in pulses and oilseeds.

[9]Data gap Number 4 refers to the submission of a representative study investigating the metabolism in fruits following post-harvest treatment (to cover the important tolerance for bananas).

[10]Data gap Number 17 refers to the submission of a fully validated analytical method for the determination of myclobutanil in hops.

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; therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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 is parent 'myclobutanil (sum of constituent enantiomers)', and for risk assessment, it is 'the sum of myclobutanil and metabolite RH-9090 (free and conjugated), expressed as myclobutanil'. The proposed residue definition was applied on a tentative basis also to leafy vegetables, pulses and oilseeds and post-harvest treatments (EFSA, 2010, 2018c).

The same enforcement residue definition is established in Regulation EC (No) 396/2005.

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 also 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 to rotational crops and processed commodities.

1.2 | Magnitude of residues in plants

1.2.1 | Magnitude of residues in primary crops

In the framework of the MRL review, it was concluded that, due to the lack of residue data on TDMs, the consumer risk assessment for TDMs from the uses of myclobutanil could not be addressed. Risk managers, therefore, set an Article 12 confirmatory data gap for the information on TDMs, which is applicable to all crops included in the present MRL application.

Myclobutanil is no longer approved in plant protection products in Europe and the existing EU uses are now revoked. However, the applicant wishes to support certain EU MRLs at the levels of Codex MRLs for myclobutanil, and therefore, submitted residue trials to address the data gap related to the lack of information on TDMs in pome fruits, grapes, cucurbits with inedible peel, tomatoes and strawberries previously assessed by the JMPR (FAO, 2014). The residue trials were performed according to the GAPs reported on these crops for the JMPR evaluation.

Samples of submitted residue trials were analysed for metabolites 1,2,4- triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA). The applicant did not provide information on the magnitude of parent myclobutanil and its metabolite RH-9090 in the trial samples, however, as the confirmatory data gap on the crops under consideration concerns only TDMs, this lack of information was considered acceptable. In cases where untreated control samples contained residue levels of TDMs at higher levels than in the 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.

Duplicate samples were collected from the treated plots by making separate passes through the treated plots. Furthermore, the original residue samples were reanalysed by a different laboratory. Duplicate and reanalysed samples were not considered independent, and therefore, the mean value was used following the Technical Guidelines SANTE/2019/12752 (European Commission, 2019).

The analytical methods used to analyse residue trial samples were sufficiently validated and fit for purpose (Austria, 2023). The samples of residue trials were stored for a period that ensured the integrity of the samples (Austria, 2023).

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

None of the trials was designed as a decline trial. In the absence of GAP compliant decline trials on the fruit crops under consideration, the applicant also provided supplementary residue trials on apples, grapes, peaches, apricots, cherries and plums to investigate the behaviour of TDMs in fruit crops over longer PHI intervals. The overview of the provided data is compiled in Table 1.

No information was provided to address the data gap related to the lack of information on TDMs for blackberries, gooseberries, aubergines/eggplants, lamb's lettuce/corn salads and sugar beet roots. Furthermore, no additional trials on hops

were provided to address data gap number 16.[11] Thus, for these commodities, the confirmatory data gaps implemented in Regulation EC) No 396/2005 are considered not addressed.

Pome fruits

GAP JMPR (FAO, 2014): 3 × 90 g/ha, interval between applications 7 days, PHI 14 days
GAP Art 12 MRL review (EFSA, 2018c):

NEU: 10 × 90 g/ha, 7 – 10 days interval, PHI 14 days
SEU: 2–4 × 75–85 g/ha, 8–10 days interval, PHI 14 days

The MRL review assessed the reported SEU and NEU uses on pome fruits and derived an MRL proposal of 0.5 mg/kg on the basis of residue trials on apples. However, since a higher Codex MRL of 0.6 mg/kg was in place for myclobutanil in pome fruits which was assessed as safe for EU consumers, the Article 12 MRL review recommended taking over it in the EU MRL legislation. The Codex MRL was derived by the JMPR in 2014 based on the critical GAP in the Czech Republic, which included three applications of 0.09 kg a.s./ha with a retreatment interval of 7 days and a PHI of 14 days. The Codex MRL was based on a combined data set of seven GAP-compliant residue trials on apples and eight GAP-compliant trials on pears performed in Europe. Residue data on TDMs were not available to the JMPR.

To address the confirmatory data gap related to the lack of TDMs, the applicant submitted nine residue trials on apples performed in 2021 in the USA. The trials were compliant with the GAP as reported by the JMPR. Residues were measured in apples collected at maturity (BBCH 81–89) at PHI of 0 and 13–14 days. No residues were measured above the LOQ of 0.01 mg/kg for 1,2,4-T and TAA. TA residues range from < 0.01 to 0.05 mg/kg at PHI of 14 days while TLA residues range from < 0.01 to 0.027 mg/kg.

None of these trials was designed as decline trials, and therefore, the data requirement of having at least half of the supervised residue trials investigating the effect of time on residue levels has not been fulfilled. Upon the request of EFSA to address this uncertainty, the applicant submitted residue trials on apples where samples of residue trials were taken at various intervals after application; however, data on the magnitude of TDMs beyond PHI of 14 days are not available. The results of these trials are further discussed in Section 1.2.2.

The applicant proposes to extrapolate residue data from apples to the whole pome fruit group. This extrapolation is acceptable according to the Technical Guidelines SANTE/2019/12752 (European Commission, 2019). It is noted that according to the Codex classification of food and feed, kaki/Japanese persimmon (classified in the EU as 'miscellaneous fruit with edible peel') and azaroles/Mediterranean medlars (classified in the EU as 'other small fruits and berries of Berries and fruits group') is classified under the pome fruit group and therefore also for these crops the Codex MRL was taken over in the EU legislation, along with the data gap for TDM data. EFSA concludes that the Article 12 data gap is also addressed for kaki/Japanese persimmon by means of data extrapolation from apples. For azaroles/Mediterranean medlars, direct extrapolation from pome fruits is not supported according to the Technical Guidelines SANTE/2019/12752 (European Commission, 2019). However, as the current MRL for this crop in the regulation is based on the Codex MRL in pome fruits, further risk managers considerations are needed. It is noted, that the applicant has not requested to maintain Codex MRL for these commodities.

EFSA concludes that the Article 12 confirmatory data gap for pome fruits under consideration is addressed but is affected by the uncertainty related to the absence of decline trials investigating the magnitude of TDMs at PHI intervals longer than 14 days (see Section 1.2.2).

Grapes

GAP JMPR (FAO, 2014): 5 × 150 g a.s./ha, interval between applications 14 days, PHI 14 days
GAP Art 12 MRL review (EFSA, 2018c):

- NEU: 4–8 × 48 g a.s./ha, interval between applications 10 days, PHI 14 days
- SEU: 2 × 75 g/ha, interval between applications 10 days, PHI 15 days

The Article 12 MRL review proposed an MRL of 1.5 mg/kg for grapes from the NEU GAP evaluated at the EU level. The existing CXL of 0.9 mg/kg was covered by the recommended MRL.

To derive the Codex MRL of 0.9 mg/kg, nine residue trials on grapes conducted in the USA at the critical GAP of five applications of 0.15 kg a.s./ha with a retreatment interval of 14 days and a PHI of 14 days were available to the JMPR (FAO, 2014). Residue data on TDMs were not available.

To address the confirmatory data gap related to the lack of TDMs data to support the existing CXL, the applicant submitted nine residue trials performed in the USA in 2021 on grapes in line with the critical GAP identified by the JMPR. Residues were measured in grapes collected at maturity (BBCH 81–89) at PHI 0 and 14.

[11]Data gap Number 16 refers to the submission of 4 additional trials in hops compliant with the northern GAP analysed with a method that allows the release of RH-9090 conjugates.

No residues were measured above the LOQ of 0.01 mg/kg for 1,2,4-T and TAA. TA residues range from < 0.01 to 0.021 mg/kg at PHI 14, while TLA residues range from < 0.01 to 0.045 mg/kg.

None of these trials were designed as decline trials, and therefore, the data requirement of having at least half of the supervised residue trials investigating the effect of time on residue levels has not been fulfilled. Upon the request of EFSA to address this uncertainty, the applicant submitted residue trials on grapes where samples of residue trials were taken at various intervals after application; however, data on the magnitude of TDMs beyond PHI of 14 days are not available. The results of these trials are further discussed in Section 1.2.2.

EFSA concludes that the Article 12 confirmatory data gap for grapes under consideration is addressed but is affected by the uncertainty related to the absence of GAP-compliant decline trials investigating the magnitude of TDMs at PHI intervals longer than 14 days (see Section 1.2.2).

Strawberries

GAP JMPR (FAO, 2014): 6 × 140 g a.s./ha, interval between applications 14 days, PHI 0 days
GAP Art 12 MRL review (EFSA, 2018c):

- NEU: 6 × 90 g a.s./ha, interval between applications 7 days, PHI 3 days
- SEU: 1 × 4 × 75 g/ha, interval between applications 7 days, PHI 3 days
- Indoor: 3 × 60 g/ha, interval between applications 7 days, PHI 3 days

The Article 12 MRL review proposed a tentative MRL of 1.5 mg/kg for strawberries from the NEU GAP evaluated at the EU level not fully supported by data. The existing CXL of 0.8 mg/kg was covered by the recommended tentative MRL.

The Codex MRL was derived by the JMPR in 2014 based on the critical GAP in the USA of six applications of 0.14 kg a.s./ha with a PHI of 0 days. The MRL of 0.8 mg/kg was derived from a combined data set of seven outdoor residue trials on strawberries performed in the USA based on the cGAP and 19 outdoor and eight indoor trials performed in Europe following a GAP reported in the United Kingdom (6 × 0.09 kg ai/ha with PHI of 3 days). Residue data on TDMs were not available to the JMPR.

To address the confirmatory data gap related to the lack of TDMs data to support the existing CXL in strawberries, the applicant submitted nine residue trials performed in the USA in 2021 on strawberries in line with the US cGAP identified by the JMPR.

Residues were measured in strawberries collected at maturity (BBCH 81–89) at PHI 0 only. No residues were measured above the LOQ of 0.01 mg/kg for 1,2,4-T. TA residues ranged from 0.012 to 0.24 mg/kg, TAA residues were quantified only in one trial at 0.019 and TLA residues ranged from < 0.01 to 0.051 mg/kg.

None of the strawberries residue trials were designed as decline trials, and therefore, the data requirement to have at least half of the supervised residue trials investigating effect of time on residue levels has not been fulfilled. Upon the request of EFSA to address this uncertainty, the applicant submitted residue trials on various fruit crops (apples, grapes, peaches, apricots, cherries and plums) where samples of residue trials were taken at various intervals after application until the PHI of 14 days. The results of these trials are further discussed in Section 1.2.2.

EFSA concludes that the Article 12 confirmatory data gap for strawberries under consideration is addressed but is affected by the uncertainty related to the absence of GAP-compliant decline trials specifically on strawberries (see Section 1.2.2).

Tomatoes

GAP JMPR (FAO, 2014): 4 × 110 g a.s./ha, interval between applications 7 days, PHI 0 days
GAP Art 12 MRL review (EFSA, 2018c):

- SEU: 3 × 75 g/ha, interval between applications 7 days, PHI 3 days
- Indoor: 5 × 100 g a.s./ha, PHI 3 days

The Article 12 MRL review proposed a tentative MRL of 0.6 mg/kg for tomatoes from the indoor GAP evaluated at the EU level not fully supported by data. The existing CXL of 0.3 mg/kg was covered by the recommended tentative MRL.

The Codex MRL was derived by the JMPR in 2014 based on the critical GAP in the USA of 4 × 0.11 kg a.s./ha with a PHI of 0 days. The MRL of 0.3 mg/kg was based on seven outdoor GAP matching residue trials on tomatoes performed in the USA. Residue data on TDMs were not available to the JMPR.

To address the confirmatory data gap related to the lack of TDMs data to support the existing CXL in tomatoes, the applicant submitted nine residue trials performed in the USA in 2021 on tomatoes in line with the US cGAP identified by the JMPR. Residues were measured in tomatoes collected at maturity (BBCH 72–89) at PHI 0 only.

No residues above the LOQ of 0.01 were measured for 1,2,4-T and TAA. TA residues ranged from < 0.01 to 0.065 mg/kg. TLA residues ranged from < 0.01 to 0.032 mg/kg.

None of the tomato residue trials were designed as decline trials, and therefore, the data requirement to have at least half of the supervised residue trials investigating effect of time on residue levels has not been fulfilled. Upon the request of EFSA to address this uncertainty, the applicant submitted residue trials on various fruit crops (apples, grapes, peaches,

apricots, cherries and plums) where samples of residue trials were taken at various intervals after application until the PHI of 14 days. Results of these trials are further discussed in Section 1.2.2.

EFSA concludes that the Article 12 confirmatory data gap for tomatoes under consideration is addressed but is affected by the uncertainty related to the absence of GAP-compliant decline trials specifically on tomatoes (see Section 1.2.2).

Cucurbits with inedible peel

GAP JMPR (FAO, 2014): 5 × 140 g a.s./ha, interval between applications 7, PHI 0 days
GAP Art 12 MRL review (EFSA, 2018c):

- SEU: 2–4 × 70 g/ha, interval between applications 8 days, PHI 3 days
- Indoor: 3 × 75 g/ha (melons) and 4–5 × 60 g/ha (pumpkins, watermelons) interval between applications 8 days (melons) or 10 days (watermelons, pumpkins), PHI 3 days (melons) and 7 days (watermelons, pumpkins)

The Article 12 MRL review proposed a tentative MRL of 0.3 mg/kg for melons, watermelons, pumpkins and other cucurbits with inedible peel from residue trials on melons submitted for the SEU GAP. The existing CXL on cucurbits of 0.2 mg/kg was covered by the recommended tentative MRL.

The Codex MRL was derived by the JMPR in 2014 based on the critical GAP in the USA of five applications at 0.14 kg a.s./ha with a PHI of 0 days. The MRL of 0.2 mg/kg was based on a combined data set of nine outdoor trials on summer squash, seven outdoor trials on cucumbers and two outdoor trials on melons from the USA and two trials on melons from SEU. All trials matched the cGAP. Residue data on TDMs were not available to the JMPR.

To address the confirmatory data gap related to the lack of TDMs data to support the existing CXL for melons, pumpkins, watermelons and other cucurbits with inedible peel, the applicant submitted nine residue trials performed in the USA in 2021 on melons in line with the US cGAP identified by the JMPR. Extrapolations from melons to the rest of the group of cucurbits with inedible peel are possible following the Technical Guidelines SANTE/2019/12752 (European Commission, 2019).

Residues were measured in melons collected at maturity (BBCH 86–89) at PHI 0 only. No residues were measured above the LOQ of 0.01 mg/kg for 1,2,4-T and TAA. TA residues range from 0.016 to 0.054 mg/kg. TLA was quantified in three trials at a range of 0.012–0.019 mg/kg.

None of the melons' residue trials were designed as decline trials, and therefore, the data requirement of having at least half of the supervised residue trials investigating the effect of time on residue levels has not been fulfilled. Upon the request of EFSA to address this uncertainty, the applicant submitted residue trials on various fruit crops (apples, grapes, peaches, apricots, cherries and plums) where samples of residue trials were taken at various intervals after application until the PHI of 14 days. The results of these trials are further discussed in Section 1.2.2.

EFSA concludes that the Article 12 confirmatory data gap for tomatoes under consideration is addressed but is affected by the uncertainty related to the absence of GAP-compliant decline trials specifically on crops belonging to cucurbits with inedible peel group (see Section 1.2.2).

1.2.2 | TDM curves at longer PHI

None of the residue trials provided on the crops under consideration were designed as decline trials, despite the requirement in Regulation (EU) No 544/2011 which states that 'where a significant part of the consumable crop is present at the time of application, half of the supervised residue trials reported shall include data to show the effect of time on the level of residue present'.

The JMPR critical GAPs for strawberries, tomatoes and cucurbits have a PHI of zero days, while the GAPs on pome fruit and grapes have a PHI of 14 days. Longer intervals between the minimum PHI of the JMPR GAP and the harvest of the fruits may occur under practical conditions, thus allowing for a more extensive metabolism of myclobutanil and the formation of higher residues of the TDMs over time. This is especially important in the case of short PHI. Therefore, uncertainty remains regarding potential concentrations of TDMs at longer PHIs.

Upon request of EFSA, the applicant submitted additional decline residue trials performed in 2010 and 2011 in SEU and NEU on apples (8), grapes (8), peaches (4), apricots (4), cherries (5) and plums (8). These trials were also submitted and assessed in the framework of the pesticide risk assessment of TDMs in light of confirmatory data (EFSA, 2018b). All submitted studies were GLP compliant. None of the trials was fully compliant with the critical JMPR GAPs under consideration; therefore, these additional data are considered 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[a]
Apples	3 × 64–89 g/ha, PHI 0–15 days	8	0,3,7,8,13,14	**1,2,4-T:** < 0.01 mg/kg **TA**: PHI 0–3 day: < 0.01–0.02 mg/kg PHI 3 day: < 0.01–0.019 mg/kg PHI 7–8 day: < 0.01–0.018 mg/kg PHI 13–14 day: < 0.01–0.019 mg/kg **TAA**: < 0.01 mg/kg **TLA**: < 0.01 mg/kg
Grapes	3 × 47–75 g/ha, PHI 0–14 days	8	0,3,7,8,14	**1,2,4-T:** PHI 0 days: < 0.01–0.016 mg/kg PHI 3 days: < 0.01–0.022 mg/kg PHI 7–8 days: < 0.01–0.026 mg/kg PHI 14 days: < 0.01–0.015 mg/kg **TA**: PHI 0 days: < 0.01–0.019 mg/kg PHI 3 days: < 0.01–0.016 mg/kg PHI 7–8 days: < 0.01–0.02 mg/kg PHI 14 days: < 0.01–0.019 mg/kg **TAA**: PHI 0–8: < 0.01 mg/kg PHI 14 days: < 0.01–0.013 mg/kg **TLA**: PHI 0 days: < 0.01–0.047 mg/kg PHI 3 days: < 0.01–0.053 mg/kg PHI 7–8 days: < 0.01–0.054 mg/kg PHI 14 days: < 0.01–0.053 mg/kg
Peaches, Apricots	4 trials performed at 3 × 58–61 g/ha; PHI 0–15 days 4 trials performed at 3 × 88–94 g/ha; PHI 0–14 days	8	0,3,6,7,8,13,14	**1,2,4-T**: < 0.01 mg/kg **TA**: PHI 0 days: 0.025–0.432 mg/kg PHI 3 days: 0.031–0.383 mg/kg PHI 6–8 days: 0.028–0.332 mg/kg PHI 13–14 days: 0.025–0.396 mg/kg **TAA**: < 0.01 mg/kg **TLA**: PHI 0 days: < 0.01–0.095 mg/kg PHI 3 days: < 0.01–0.095 mg/kg PHI 6–8 days: < 0.01–0.084 mg/kg PHI 13–14 days: < 0.01–0.087 mg/kg
Cherries	2 × 84–91 g/ha; PHI 0–14 days	5	0,3,7,8,14	**1,2,4-T**: < 0.01 mg/kg **TA**: PHI 0 days: 0.019–0.506 mg/kg PHI 3 days: 0.04–0.59 mg/kg PHI 7–8 days: 0.016–0.442 mg/kg PHI 14 days: 0.049–0.51 mg/kg **TAA**: PHI 0–8: < 0.01–0.023 mg/kg PHI 3 days: < 0.01–0.027 mg/kg PHI 7–8 days: < 0.01–0.02 mg/kg PHI 14 days: < 0.01–0.027 mg/kg **TLA**: PHI 0 days: < 0.01–0.028 mg/kg PHI 3 days: < 0.01–0.031 mg/kg PHI 7–8 days: < 0.01–0.021 mg/kg PHI 14 days: <0.01–0.032 mg/kg
Plums	2 trials performed at 2 × 59–62 g/ha; PHI 0–14 days 6 trials performed at 2 × 87–95 g/ha; PHI 0–14 days	8	0,3,7,14	**1,2,4-T**: < 0.01 mg/kg **TA**: PHI 0 days: 0.019–0.184 mg/kg PHI 3 days: 0.018–0.181 mg/kg PHI 7 days: 0.017–0.190mg/kg PHI 14 days: 0.019–0.183 mg/kg **TAA**: PHI 0: < 0.01–0.013 mg/kg PHI 3 days: < 0.01–0.01 mg/kg PHI 7 days: < 0.01–0.01 mg/kg PHI 14 days: < 0.01–0.011 mg/kg **TLA**: PHI 0: < 0.01–0.035 mg/kg PHI 3 days: < 0.01–0.034 mg/kg PHI 7 days: < 0.01–0.035 mg/kg PHI 14 days: < 0.01–0.031 mg/kg

[a]It should be noted that the residue data reported in the tables provided in Appendix C.3.1.2 of the ER correspond to triazole measurements corrected for residues in the corresponding control specimens (Austria, 2023). However, the results reported in this table correspond to the results in treated crops not corrected for residues in control samples.

Residues of 1,2,4-T were quantified only in grapes. However, samples in all trials submitted to address the decline of TDMs were stored from 269 to 660 days while the storage stability for 1,2,4-T in high water commodities has been demonstrated only for 6 months (ca.180 days). Therefore, there is uncertainty regarding the residues of 1,2,4-T measured in all the decline trials, except for the ones in grapes (high acid commodity).

Residues of TA above the LOQ were measured in all commodities. Triazole alanine is present in fruit crops at quantitively highest concentrations among various TDMs. It reaches its highest levels at the PHI of 0–3 days in apples, cherries, peaches and apricots, while in other crops, higher levels are determined at longer PHI intervals. The concentrations, however, are at a stable level throughout all sampling points and a significant increase or decrease of residues is not observed.

TLA residues were quantified in all commodities except apples. Triazole lactic acid occurs at maximum levels on the day of the treatment (PHI 0 days) peaches and apricots while a slight increase in concentrations at longer PHI intervals (7–14 days) is observed in cherries and grapes. In plums residue levels observed from PHI 0 to 7 were similar with a slight decline at PHI 14.

Finally, TAA residues above the LOQ were measured in grapes (only in one trial at PHI 14), cherries and plums. When detected, the compound is present at low actual levels being at similar stable concentrations throughout all sampling points.

Overall, none of the available decline trials indicates a significant or consistent increase or decrease of TDMs at longer PHIs. There is some evidence, though, that in fruit crops with a PHI of 0 days in the authorised GAP, the worst-case TDM concentrations might not be accounted for when samples are analysed at the authorised PHI. However, the increase of residues between various PHI intervals is not significant. There is a body of evidence that TDM levels overall remain in the same order of magnitude between PHIs of 0 days and 14 days. These data could be extrapolated to other fruit crops. It is also noted that the decline beyond PHI intervals of 14 days is not addressed, and this information is relevant for the authorised uses of myclobutanil on pome fruits and grapes, where the authorised PHI in the GAP refers to 14 days. However, considering that over the period of 14 days, residues remain in the same order of magnitude, the lack of this information is considered as a minor data gap.

1.2.3 | Magnitude of residues in rotational crops

A field rotational crop study was assessed by JMPR (FAO, 2014), but the full report was not provided and could not be fully assessed during the MRL review (EFSA, 2018c). Thus, a general data gap for rotational crop field studies was identified by the MRL review (data gap 1[12]). The data gap was implemented in the EU MRL legislation for all annual crops on which the EU uses have been reported for the MRL review: strawberries, blackberries, gooseberries, tomatoes, aubergines/eggplants, cucurbits with inedible peel and sugar beets.

No information was provided to address this data gap. However, myclobutanil is no longer approved in plant protection products in Europe and the existing EU uses are now revoked; therefore, this data gap is no longer applicable to MRLs supporting EU uses. Some of the crops included in the MRL application for which the applicant wishes to maintain Codex MRL are annual crops with this data gap implemented in the MRL legislation (e.g. strawberries, tomatoes, cucurbits with inedible peel). Investigation of residues in rotational crops is not relevant for the imported crops, and therefore, EFSA concludes that this data gap on rotational crops is not considered relevant for maintaining Codex MRLs.

2 | RESIDUES IN LIVESTOCK

In the framework of the MRL review, two data gaps related to the analytical methods reported for animal matrices (a confirmatory method and the extraction efficiency) and a data gap related to storage stability in kidney, fat and milk were identified (respectively, data gaps 18,[13] 19[14] and 20[15]). New information was not submitted under the present MRL application, and therefore, EFSA concludes that these data gaps have not been addressed.

In addition, apple pomace is a potential livestock feed item 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 assessments of these data gaps 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 myclobutanil could not be undertaken in the framework of the current assessment. Furthermore, the STMR values derived for pome fruits in the peer review (EFSA, 2018b) are higher than the ones derived in the present application (see Table 2) Thus, an update of the calculated dietary burden was not deemed necessary.

[12]Data gap Number 1 refers to the submission of a representative rotational crop field study to address the uptake of residues of myclobutanil and metabolites from previous applications (it is noted that a study was reported by JMPR, but a detailed assessment of this study was not available in the MRL review).

[13]Data gap number 18 refers to the submission of a confirmatory method for the analytical methods for animal matrices.

[14]Data gap Number 19 refers to the submission of a report demonstrating the extraction efficiency of the analytical methods for animal matrices.

[15]Data gap Number 20 refers to the submission of a storage stability study on animal matrices (kidney, fat and milk).

3 | CONSUMER RISK ASSESSMENT

The submitted confirmatory data did not trigger a modification of the previous exposure assessment for parent myclobutanil, which was performed in the framework of the MRL review of myclobutanil (EFSA, 2018c) and the conclusions derived are still valid.

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, 2018b). The acceptable daily intake (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 acute reference dose (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 uses 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[16] 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.

	STMR value (2018b)/STMR value derived under present assessment			
Crop under consideration	**1,2,4-triazole (1,2,4-T)**	**Triazole alanine (TA)**	**Triazole acetic acid (TAA)**	**Triazole lactic acid (TLA)**
Pome fruits	< 0.01[a]/< 0.01	0.039[a]/< 0.01	0.03[a]/< 0.01	0.03[a]/< 0.01
Grapes	< 0.01[b]/< 0.01	0.06[b]/0.011	0.05[b]/< 0.01	0.04[b]/0.013
Strawberries	< 0.01[b]/< 0.01	0.06[b]/0.044	0.05[b]/< 0.01	0.04[b]/< 0.01
Cucurbits with inedible peel	< 0.01[c]/< 0.01	0.2[c]/0.015	< 0.01[c]/< 0.01	0.03[c]/< 0.01
Tomatoes	< 0.01[c]/< 0.01	0.2[c]/0.026	< 0.01[c]/< 0.01	0.03[c]/< 0.01

[a]The worst-case STMR value derived from the data on apples and pears (EFSA, 2018b).

[b]The worst-case STMR value derived from the data on strawberries, raspberries and grapes (EFSA, 2018b).

[c]The worst-case STMR value derived from the data on tomatoes, cucumbers, melons, peppers and sweet corn (EFSA, 2018b).

Since the STMR values derived in the present assessment are lower or the same 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 (EFSA, 2018b).

Regarding the **acute exposure**, EFSA assessed potential risks associated with the acute intake of crops under consideration[17] containing TDMs from the use of myclobutanil 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.1. 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 (3% of the ARfD) and was very low for 1,2,4- triazole (1% of the ARfD), triazole acetic acid (0.1% ARfD) and triazole lactic acid (1% of the ARfD).

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

[16]In the framework of the pesticide risk assessment of the TDMs in light of confirmatory data, STMRs for TA, TLA, TAA and 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.

[17]In the acute exposure calculation EFSA considered also azarole/mediterranean medlar and kaki/Japanese persimmon, should risk managers decide to maintain Codex MRL in these commodities.

4 | CONCLUSION AND RECOMMENDATIONS

Myclobutanil 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 myclobutanil, but to address the Article 12 confirmatory data gap related to the lack of information on TDMs in some crops for which the applicant wishes to support EU MRL at the level of the Codex MRL: pome fruits, grapes, strawberries, cucurbits with inedible peel and tomatoes.

To address the data gap identified in the framework of the MRL review related to the occurrence of triazole derivative metabolites (TDMs), the applicant submitted new residue trials on apples, grapes, strawberries, melons and tomatoes performed in the USA in line with the GAPs reported for the JMPR. Samples were analysed for residues of triazole derivative metabolites: 1,2,4 – triazole, triazole alanine, triazole acetic acid and triazole lactic acid. No information was provided on the residues of myclobutanil and metabolite RH-9090.

The applicant also provided a 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 submitted TDMs data support the authorised uses of myclobutanil on pome fruits, grapes, strawberries, tomatoes and cucurbits with inedible peel in the third countries according to the GAPs reported for the JMPR (FAO, 2014). However, due to the limited number of decline studies on the crops under consideration, some uncertainty remains regarding the concentrations of TDMs over PHIs longer than 14 days. Nevertheless, given the wide margin of safety for the acute exposure and considering the information provided from supporting decline trials, the lack of a complete data set on decline trials on the crops under consideration is considered as a minor deficiency.

No information was provided to address the Article 12 confirmatory data gap for cucurbits with inedible peel, strawberries and tomatoes (crops under consideration) related to the submission of rotational crop field study. Investigation of residues in rotational crops is not relevant for imported crops, and therefore, EFSA concludes that this data gap is not applicable to Codex MRLs in cucurbits with inedible peel, strawberries and tomatoes.

Overall, EFSA concluded that Article 12 confirmatory data gaps are addressed for the crops under consideration: grapes, apples, pears, quince, medlars, Loquat/Japanese medlars, other pome fruits, melons, pumpkins, watermelons, other cucurbits with inedible peel, strawberries and tomatoes. Consumer exposure concerns were not associated with the residues of TDMs in these commodities.

It is noted that, based on pome fruit data, a Codex MRL was set and taken over in EU MRL legislation also for kaki/Japanese persimmon and azaroles/Mediterranean medlars since these crops are classified under the pome fruit group according to the Codex food and feed classification system. The applicant did not request to maintain the Codex MRL for myclobutanil in kaki/Japanese persimmon and azaroles/Mediterranean medlar. However, should risk managers decide to keep the Codex MRL in these crops, EFSA confirms that the Article 12 data gap is addressed for kaki/Japanese persimmon by means of data extrapolation from apples. Regarding azaroles/Mediterranean medlars, such an extrapolation is not acceptable according to EU rules and, therefore, a risk management decision might be required. Nevertheless, consumer exposure assessment was performed for residues in kaki/Japanese persimmon and azaroles/Mediterranean medlars, should risk managers decide to maintain a Codex MRL.

No information was provided to address the Article 12 confirmatory data gaps referred to in Regulation (EU) 2020/770 for blackberries, gooseberries, bananas, aubergines/eggplants, lamb's lettuces/corn salads, beans (with pods), globe artichokes, hops, sugar beet roots and products of animal origin -terrestrial animals. For these commodities, the existing EU MRL could be lowered to or maintained at the LOQ for enforcement.

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

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
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIPAC	Collaborative International Pesticide Analytical Council
CIRCA	(EU) Communication & Information Resource Centre Administrator
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit

DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
Dw	dry weight
EC	emulsifiable concentrate
ECD	electron capture detector
EDI	estimated daily intake
EMS	evaluating Member State
Eq	residue expressed as a.s. equivalent
ESI	electrospray ionisation
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FLD	fluorescence detector
FPD	flame photometric detector
GAP	Good Agricultural Practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
GC-ECD	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-FPD	gas chromatography with flame photometric detector
GC–MS	gas chromatography with mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
GC-NPD	gas chromatography with nitrogen/phosphorous detector
GLP	Good Laboratory Practice
GR	granule
GS	growth stage
HPLC	high performance liquid chromatography
HPLC-MS	high performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UVD	high performance liquid chromatography with ultra-violet detector
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	Member States
MS	mass spectrometry detector
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
PAFF	Standing Committee on Plants, Animals, Food and Feed
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval

P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
Rber	statistical calculation of the MRL by using a non-parametric method
Rmax	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
RPF	relative potency factor
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SCPAFF	Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH)
SEU	southern Europe
SG	water-soluble granule
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TAR	total applied radioactivity
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UV	ultraviolet (detector)
WG	water-dispersible granule
WHO	World Health Organization
WP	wettable powder
YF	yield factor
ZC	mixed CS and SC formulation

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

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APPENDIX A

Summary of GAPs assessed in the evaluation of confirmatory data

Myclobutanil is not approved in EU. All the existing authorised EU uses on myclobutanil are revoked.

The applicant requests to maintain EU MRLs at the level of Codex MRLs which have been set for the authorised uses of myclobutanil reported for the JMPR evaluation (FAO, 2014).

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	Apples	Foliar, 10 × 240 g a.s./ha at 7 days interval between applications	Fruits: 7	Myclobutanil labelled on the phenyl and triazole labels (EFSA, 2010, 2018c)
		Grapes	Foliar, 5 × 50 g a.s./ha at 7 days interval between applications	Fruits: 7, 16	
	Root crops	Sugar beet	Foliar, 1 × 150 g a.s./ha or 1 × 1500 g a.s./ha	Roots: 0, 15, 30 Tops: 0, 15, 30	
	Cereals	Wheat	Foliar, 1 × 240 g a.s./ha	Grain, straw: at maturity after application done at BBCH 30–45	
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	
	Root/tuber crops	Radish; turnip	Bare soil, 3 × 224 g a.s./ha (phenyl label)	30, 120, 210, 365	EFSA (2018)
		Radish	Bare soil, 1 × 360 g a.s./ha (triazole label)	30, 120, 365	
	Leafy crops	Lettuce; mustard	Bare soil, 3 × 224 g a.s./ha (phenyl label)	30, 120, 210, 365	
		Lettuce	Bare soil, 1 × 360 g a.s./ha (triazole label)	30, 120, 365	
	Pulses and oilseeds	Soyabeans	Bare soil, 3 × 224 g a.s./ha (phenyl label)	30, 120, 210, 365	
	Cereal (small grain)	Dwarf sorghum; wheat	Bare soil, 3 × 224 g a.s./ha (phenyl label)	30, 120, 210, 365	
		Wheat	Bare soil, 1 × 360 g a.s./ha (triazole label)	30, 120, 365	
Processed commodities (hydrolysis study)	**Conditions**			**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)			Yes	Studies performed with myclobutanil and metabolite RH-9090 (EFSA, 2010, 2018c)
	Baking, brewing and boiling (60 min, 100 °C, pH 5)			Yes	
	Sterilisation (20 min, 120 °C, pH 6)			Yes	

Can a general residue definition be proposed for primary crops?	No	EFSA, 2018c
Rotational crop and primary crop metabolism similar?	Yes	EFSA, 2018c
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA, 2018c
Plant residue definition for monitoring (RD-Mo)	myclobutanil (sum of constituent isomers) [tentative for leafy vegetables, pulses and oilseeds and post-harvest treatment] (EFSA, 2018c)	
Plant residue definition for risk assessment (RD-RA)	(EFSA, 2018c) sum of myclobutanil and metabolite RH-9090 (free and conjugated), expressed as myclobutanil [tentative for leafy vegetables, pulses and oilseeds and post-harvest treatment] (EFSA, 2018b) • 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)	LC-MS/MS (EFSA, 2018c) : • Method EN 15662:2008 validated in high water and high acid and dry content commodities • Method EN 15662:2008 validated in high oil content commodities • LOQ: 0.01 mg/kg (for high water and high acid content commodities even a LOQ of 0.005 mg/kg would be feasible) LC-MS/MS (EFSA, 2010): • Method EN 15662:2008 • LOQ: 0.025 mg/kg (high water and high acid content commodities) LC-MS/MS (EFSA, 2018c) : • LOQ: 0.01 mg/kg • Validated in high water, high acid and high oil and dry content commodities Extraction efficiency not demonstrated	

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; LOQ: limit of quantification; GC-MS: gas chromatography with mass spectrometry; LC-MS/MS: liquid chromatography with tandem mass spectrometry; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; 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	Tomato, Cucumber	–10	36	Month	Myclobutanil and metabolite RH-9090	EFSA (2010)
		Apples, tomatoes, mustard leaves, wheat forage, radishes tops, turnip roots, sugar beet roots, cabbages, lettuces	–18	6	Month	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	Month	Triazole alanine	
			–18	53	Month	Triazole acetic acid	
			–18	48	Month	Triazole lactic acid	
	High oil content	Almond	–10	18	Month	Myclobutanil and metabolite RH-9090	EFSA (2010)
		Hazelnut	–18	12	Month	1,2,4-triazole	Austria (2023) (study performed for renewal of approval of paclobutrazol; not peer reviewed)
		Rapeseeds, soyabeans	–18	12 (soya beans only)	Month	1,2,4–triazole. Not stable in rapeseeds.	EFSA (2018b)
			–18	26 (soya beans only)	Month	Triazole alanine. Not stable in rapeseeds	
			–18	53	Month	Triazole acetic acid	
			–18	48	Month	Triazole lactic acid	
	High protein content	Dry peas, navy beans	–	–	Month	1,2,4–triazole	EFSA (2018b)
			–18	15	Month	Triazole alanine	
			–18	25	Month	Triazole acetic acid	
			–18	48	month	Triazole lactic acid	
		Bean seed	–18	48	Month	1,2,4-triazole	Austria (2023) (study performed for renewal of approval of paclobutrazol; not peer reviewed)
	Dry/High starch	Barley, wheat grain	–18	12	Month	1,2,4–triazole	EFSA (2018b)
			–18	26	Month	Triazole alanine	
			–18	26	Month	Triazole acetic acid	
			–18	48	Month	Triazole lactic acid	
	High acid content	Grapes	–15	24	Month	Myclobutanil	EFSA (2010)
		Oranges	–18	42	Month	1,2,4–triazole	Austria (2023) (study performed for renewal of approval of paclobutrazol; not peer reviewed)
			–18	48	Month	Triazole alanine	
			–18	48	Month	Triazole acetic acid	
			–18	48	Month	Triazole lactic acid	EFSA (2018b)
	Others	Cereal straw	–18	12	Month	1,2,4–triazole	EFSA (2018b)
			–18	53	Month	Triazole alanine	
			–18	40	Month	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)	STMR[c] (mg/kg)	CF[d]
Risk assessment residue definition (RA): (1) 1,2,4-triazole (1,2,4-T); (2) Triazole alanine (TA); (3) Triazole acetic acid (TAA); (4) Triazole lactic acid (TLA)							
Apples, pears, quince, medlars, Loquat/ Japanese medlars, other pome fruits	USA	**RA (1)**: 1,2,4-T: 9 × < 0.01 **RA (2)**: TA: 6 × < 0.01; 0.014, 0.041, 0.05 **RA (3)**: TAA: 9 × < 0.01 **RA (4)**: TLA: 7 × < 0.01, 0.013, 0.027	Residue trials on apples compliant with cGAP evaluated in the JMPR (FAO, 2014). Extrapolation from apples to the rest of the group of pome fruits possible	NA	**RA (1)**: < 0.01 **RA (2)**: 0.05 **RA (3)**: < 0.01 **RA (4)**: 0.027	**RA (1)**: < 0.01 **RA (2)**: < 0.01 **RA (3)**: < 0.01 **RA (4)**: < 0.01	NA
Grapes	USA	**RA (1)**: 1,2,4-T: 9 × < 0.01 **RA (2)**: TA: 4 × < 0.01; 0.011, 2 × 0.012, 0.018, 0.021 **RA (3)**: TAA: 9 × < 0.01 **RA (4)**: TLA: < 0.01, 0.011, 2 × 0.012, 0.013, 0.014, 0.018, 0.025, 0.045	Residue trials on grapes compliant with cGAP evaluated in the JMPR (FAO, 2014). Underlined values indicate residues in control sample	NA	**RA (1)**: < 0.01 **RA (2)**: 0.021 **RA (3)**: < 0.01 **RA (4)**: 0.045	**RA (1)**: < 0.01 **RA (2)**: 0.011 **RA (3)**: < 0.01 **RA (4)**: 0.013	NA
Melons, pumpkins, watermelons, other cucurbits with inedible peel	USA	**RA (1)**: 1,2,4-T: 9 × < 0.01 **RA (2)**: TA: 0.016; 0.018, 0.023, 0.025, 0.026, 0.028, 2 × 0.05, 0.054 **RA (3)**: TAA: 9 × < 0.01 **RA (4):** TLA: 6 × < 0.01, 2 × 0.012, 0.019	Residue trials on melons compliant with the cGAP evaluated in the JMPR (FAO, 2014). Residue extrapolation from melons to the rest of the group of cucurbits with inedible peel possible. Underlined values indicate residues in control sample	NA	**RA (1)**: < 0.01 **RA (2)**: 0.054 **RA (3)**: < 0.01 **RA (4)**: 0.019	**RA (1)**: < 0.01 **RA (2)**: 0.026 **RA (3)**: < 0.01 **RA (4)**: < 0.01	NA
Strawberries	USA	**RA (1)**: 1,2,4-T: 9 × < 0.01 **RA (2)**: TA: 0.012, 0.014, 0.022, 0.041, 0.044, 0.05, 0.051, 0.13 0.24 **RA (3)**: TAA: 8 × < 0.01, 0.019 **RA (4):** TLA: 6 × < 0.01,0.025, 0.026, 0.051	Residue trials on strawberries compliant with the cGAP evaluated in the JMPR (FAO, 2014). Underlined values indicate residues in control sample	NA	**RA (1)**: < 0.01 **RA (2)**: 0.24 **RA (3)**: 0.019 **RA (4)**: 0.051	**RA (1)**: < 0.01 **RA (2)**: 0.044 **RA (3)**: < 0.01 **RA (4)**: < 0.01	NA
Tomatoes	USA	**RA (1)**: 1,2,4-T: 9 × < 0.01 **RA (2)**: TA: 2 × < 0.01, 0.013, 0.014, 0.015, 0.017, 0.018, 0.03, 0.065 **RA (3)**: TAA: 9 ×< 0.01 **RA (4):** TLA: 6×< 0.01, 0.015, 0.019, 0.032	Residue trials on tomatoes compliant with the cGAP evaluated in the JMPR (FAO, 2014). Underlined values indicate residues in control sample	NA	**RA (1)**: < 0.01 **RA (2)**: 0.065 **RA (3)**: < 0.01 **RA (4)**: 0.032	**RA (1)**: < 0.01 **RA (2)**: 0.015 **RA (3)**: < 0.01 **RA (4)**: < 0.01	NA

Abbreviations: GAP, Good agricultural practice; Mo, monitoring; MRL, maximum residue level; NA, not applicable; RA, risk assessment.

[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

Not relevant

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, apples: 1% of the ARfD Grapes, quinces, medlar, azarole/Mediterranean medlar, kaki/Japanese persimmons, strawberries, tomatoes, melons, watermelons and pumpkins: <1% of the ARfD Triazole alanine: Melons: 3% of the ARfD Pears, watermelons, apples: 2% of the ARfD Tomatoes, strawberries: 1% of the ARfD Grapes, quinces, medlar, azarole/Mediterranean medlar, kaki/Japanese persimmons and pumpkins: <1% of the ARfD Triazole acetic acid: Pears, apples: 0.1% of the ARfD grapes, quinces, medlar, azarole/Mediterranean medlar, kaki/Japanese persimmons, strawberries, tomatoes, melons, watermelons and pumpkins: <0.1% of the ARfD Triazole lactic acid: Pears, apples, table grapes and melons: 1% of the ARfD Quinces, medlar, azarole/Mediterranean medlar, kaki/Japanese persimmons, strawberries, tomatoes, watermelons and pumpkins: <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. Although not requested by the applicant, the exposure for kaki/Japanese persimmon and azaroles/Mediterranean medlars was also considered in the risk assessment should the risk manager decide to maintain the respective CXLs for these crops. 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]	Data gap(s) Art. 12 Review	Existing CXL	Proposed MRL	Conclusion/Recommendation
	Enforcement residue definition: myclobutanil (sum of constituent isomers)					
0130000 0130010 0130020 0130030 0130040 0130050 0130990	Pome fruits Apples Pears Quinces Medlars Loquats/Japanese medlars Others	0.6 (**Error! Reference source not found.**)	Footnote related to lack of information on TDMs	0.6	0.6	The existing MRL in pome fruits is set based on Codex MRL Myclobutanil is no longer approved for the use 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 a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely
0151000 0151010 0151020	(a) Grapes Table grapes Wine grapes	1.5 (ft 1)	Footnote related to lack of information on TDMs	0.9	0.9	The existing MRL is based on EU uses which are now revoked The applicant tried to address the data gap on TDMs to, eventually, replace the existing EU MRL with a lower Codex MRL in place for these commodities 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 a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely
0152000	Strawberries	1.5 (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	0.8	0.8	For strawberries, the data gap related to rotational crop field study is not addressed but is of low relevance in case of import tolerances

(Continues)

(Continued)

Code[a]	Commodity	Existing MRL[b]	Data gap(s) Art. 12 Review	Existing CXL	Proposed MRL	Conclusion/Recommendation
0153010	Blackberries	0.8 (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	–	0.01*	The existing MRL is based on EU use which is now revoked. The data gap identified in the MRL review is not addressed. Consequently, the MRL can be lowered to the LOQ for enforcement
0154040	Gooseberries (green, red and yellow)	0.8 (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	–	0.01*	
0154070	Azaroles/ Mediterranean medlars	0.6 (ft 1)	Footnote related to lack of information on TDMs	0.6	0.6 or 0.01* Risk management decision	The existing MRL is set based on Codex MRL for pome fruits The data gap identified by EFSA concerning residues of TDMs is considered addressed by extrapolation of data from pome fruit[c] (see above) The applicant, however, did not request to maintain Codex MRL in this commodity. A risk management decision on the MRL proposal is therefore required Risk to consumers from the exposure to TDMs is unlikely
0161060	Kaki/Japanese persimmons	0.6 (ft 1)	Footnote related to lack of information on TDMs	0.6	0.6 or 0.01* Risk management decision	The existing MRL is set based on Codex MRL for pome fruits The data gap identified by EFSA concerning residues of TDMs is considered addressed by means of data extrapolation from apples The applicant, however, did not request to maintain Codex MRL in this commodity. A risk management decision on the MRL proposal is therefore required Risk to consumers from the exposure to TDMs is unlikely
0163020	Bananas	3 (ft 3)	Footnote related to data gap No 4 [crop metabolism with post-harvest treatment unavailable]	–	0.01*	The existing MRL is based on the import tolerance from USA and Costa Rica The data gap identified in the MRL review is not addressed. Consequently, the MRL can be lowered to the LOQ for enforcement

(Continued)

Code[a]	Commodity	Existing MRL[b]	Data gap(s) Art. 12 Review	Existing CXL	Proposed MRL	Conclusion/Recommendation
0231010	Tomatoes	0.6 (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	0.3	0.3	The existing MRL is based on EU uses which are now revoked. The applicant tried to address the data gap on TDMs to, eventually, replace the existing EU MRL with a lower Codex MRL in place for tomatoes 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 a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely The data gap related to rotational crop field study is not addressed but is of low relevance in case of import tolerances
0231030	Aubergines/ eggplants	0.2 (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	–	0.01*	The existing MRL is based on EU use which is now revoked. The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement
0233000 0233010 0233020 0233030 0233990	(c) Cucurbits with inedible peel Melons Pumpkins Watermelons Others (2)	0.3 (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	0.2	0.2	The existing MRL is based on EU uses which are now revoked. The applicant tried to address the data gap on TDMs to, eventually, replace the existing EU MRL with a lower Codex MRL in place for cucurbits with inedible peel 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 a minor deficiency. Risk to consumers from the exposure to TDMs is unlikely The data gap related to rotational crop field study is not addressed but is of low relevance in case of import tolerances
0251010	Lamb's lettuces/ corn salads	9 (ft 4)	Footnote related to data gap No 2 [crop metabolism with leafy vegetables unavailable] and lack of information on TDMs	0.5	0.01*	The existing MRL is based on EU use which is now revoked The data gap identified in the MRL review is not addressed. Consequently, the MRL can be lowered to the LOQ for enforcement
0260010	Beans (with pods)	0.8 (ft 5)	Footnote related to data gap No 3 [crop metabolism with pulses and oilseeds unavailable]	0.8	0.01*	The existing MRL is set based on a Codex MRL The data gap identified in the MRL review is not addressed. Consequently, the MRL can be lowered to the LOQ for enforcement

(Continues)

(Continued)

Code[a]	Commodity	Existing MRL[b]	Data gap(s) Art. 12 Review	Existing CXL	Proposed MRL	Conclusion/Recommendation
0270050	Globe artichokes	0.8 (ft 6)	Footnote related to data gap No 2 [crop metabolism with leafy vegetables unavailable]	–	0.01*	The existing MRL is based on an EU use which is now revoked. The data gap identified in the MRL review is not addressed. Consequently, MRL can be lowered to the LOQ for enforcement
0700000	Hops	6 (ft 7)	Footnote related to data gap No. 2, 16 and 17 [crop metabolism with leafy vegetables, additional residue trials and analytical methods unavailable]	5	0.01*	The existing MRL is based on an EU use which is now revoked. The data gaps identified in the MRL review are not addressed. Consequently, the MRL can be lowered to the LOQ for enforcement
0900010	Sugar beet roots	0.01* (ft 2)	Footnote related to data gap No 1 [representative rotational crop field study unavailable] and lack of information on TDMs	–	0.01*	The existing MRL is based on an EU use which is now revoked. The data gap identified in the MRL review is not addressed. Consequently, MRL can be maintained at the LOQ for enforcement
1000000	Products of animal origin terrestrial animals: muscle, liver, edible offal of swine, bovine, sheep, goat, equine, poultry and other farmed animals; Birds eggs **(except kidney, fat and milk)**	0.01* (ft 8)	Footnote related to data gap No 18 and 19 [confirmatory method and extraction efficiency for the analytical methods unavailable]	0.01*	0.01*	The data gaps identified in the MRL review are not addressed. Consequently, MRL can be maintained at the LOQ for enforcement
1000000	Products of animal origin terrestrial animals: fat and kidney of swine, bovine, sheep, goat, equine, poultry and other farmed animals; Milk **(only kidney, fat and milk)**	0.01* (ft 9)	Footnote related to data gap No 18, 19 and 20 [confirmatory method and extraction efficiency for the analytical methods and storage stability unavailable]	0.01*	0.01*	

Abbreviations: GAP, Good Agricultural Practice; MRL, maximum residue level; NEU, northern Europe; SEU, southern Europe.

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]Existing EU MRL and corresponding footnote on confirmatory data.

[c]According to the Technical Guidelines SANTE/2019/12752 (European Commission, 2019), extrapolation of residue data from pome fruits to Aazaroles/Mediterranean medlars is not supported.

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 12 June 2022, 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 rotational crop field studies and 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 3: The European Food Safety Authority identified some information on crop metabolism with post-harvest treatment 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

(Continued)

ft 4: The European Food Safety Authority identified some information on crop metabolism with leafy vegetables and 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 5: The European Food Safety Authority identified some information on crop metabolism with pulses and oilseeds 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 6: The European Food Safety Authority identified some information on crop metabolism with leafy vegetables 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 7: The European Food Safety Authority identified some information on residue trials, analytical methods and crop metabolism with leafy vegetables 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 8: The European Food Safety Authority identified some information on analytical methods 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

ft 9: The European Food Safety Authority identified some information on analytical methods and storage stability 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 12 June 2022, or, if that information is not submitted by that date, the lack of it.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

APPENDIX C

Pesticide Residue Intake Model (PRIMo)

1,2,4-T_Myclobutanil_PRIMo_rev3.1

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

1,2,4-triazole (1,2,4-T)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Refined calculation 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)	0.7%	NL toddler	0.17	0.5%	Apples	0.2%	Pears	0.1%	Table grapes		0.7%
	0.7%	DE child	0.15	0.5%	Apples	0.1%	Table grapes	0.0%	Pears		0.7%
	0.4%	NL child	0.08	0.3%	Apples	0.1%	Pears	0.0%	Table grapes		0.4%
	0.2%	PT general	0.04	0.1%	Wine grapes	0.0%	Apples	0.0%	Pears		0.2%
	0.2%	DE women 14-50 yr	0.04	0.1%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.2%
	0.2%	FR toddler 2 3 yr	0.04	0.1%	Apples	0.0%	Pears	0.0%	Wine grapes		0.2%
	0.2%	DE general	0.04	0.1%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.2%
	0.2%	RO general	0.04	0.1%	Wine grapes	0.1%	Apples	0.0%	Table grapes		0.2%
	0.2%	FR adult	0.03	0.1%	Wine grapes	0.0%	Apples	0.0%	Pears		0.2%
	0.1%	DK child	0.03	0.1%	Apples	0.0%	Pears	0.0%	Table grapes		0.1%
	0.1%	GEMS/Food G11	0.03	0.1%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.1%
	0.1%	GEMS/Food G07	0.03	0.1%	Wine grapes	0.0%	Apples	0.0%	Table grapes		0.1%
	0.1%	FR child 3 15 yr	0.03	0.1%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.1%
	0.1%	IE adult	0.03	0.1%	Wine grapes	0.0%	Apples	0.0%	Pears		0.1%
	0.1%	GEMS/Food G08	0.03	0.1%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.1%
	0.1%	GEMS/Food G15	0.03	0.0%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.1%
	0.1%	PL general	0.03	0.1%	Apples	0.0%	Table grapes	0.0%	Pears		0.1%
	0.1%	NL general	0.03	0.1%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.1%
	0.1%	DK adult	0.02	0.0%	Apples	0.0%	Wine grapes	0.0%	Pears		0.1%
	0.1%	UK toddler	0.02	0.1%	Apples	0.0%	Table grapes	0.0%	Strawberries		0.1%
	0.1%	GEMS/Food G06	0.02	0.0%	Table grapes	0.0%	Apples	0.0%	Pears		0.1%
	0.1%	FR infant	0.02	0.1%	Apples	0.0%	Pears	0.0%	Strawberries		0.1%
	0.1%	LT adult	0.02	0.1%	Apples	0.0%	Pears	0.0%	Strawberries		0.1%
	0.1%	UK infant	0.02	0.1%	Apples	0.0%	Pears	0.0%	Strawberries		0.1%
	0.1%	GEMS/Food G10	0.02	0.0%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.1%
	0.1%	ES child	0.02	0.0%	Apples	0.0%	Pears	0.0%	Strawberries		0.1%
	0.1%	FI 3 yr	0.02	0.0%	Apples	0.0%	Strawberries	0.0%	Table grapes		0.1%
	0.1%	UK adult	0.02	0.0%	Wine grapes	0.0%	Apples	0.0%	Pears		0.1%
	0.1%	ES adult	0.02	0.0%	Apples	0.0%	Wine grapes	0.0%	Pears		0.1%
	0.1%	UK vegetarian	0.02	0.0%	Wine grapes	0.0%	Apples	0.0%	Pears		0.1%
	0.1%	SE general	0.02	0.0%	Apples	0.0%	Pears	0.0%	Strawberries		0.1%
	0.1%	IT toddler	0.01	0.0%	Apples	0.0%	Pears	0.0%	Strawberries		0.1%
	0.1%	FI 6 yr	0.01	0.0%	Apples	0.0%	Strawberries	0.0%	Pears		0.1%
	0.1%	IT adult	0.01	0.0%	Apples	0.0%	Pears	0.0%	Table grapes		0.1%
	0.1%	FI adult	0.01	0.0%	Apples	0.0%	Wine grapes	0.0%	Strawberries		0.1%
	0.0%	IE child	0.00	0.0%	Apples	0.0%	Table grapes	0.0%	Pears		0.0%

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 (1,2,4-T) 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	0.01 / 0.01	1.4
1%	Apples	0.01 / 0.01	1.1
0.7%	Table grapes	0.01 / 0.01	0.73
0.5%	Kaki/Japanese persimmons	0 / 0.01	0.47
0.2%	Quinces	0.01 / 0.01	0.25
0.2%	Strawberries	0.01 / 0.01	0.16
0.1%	Medlar	0.01 / 0.01	0.14
0.09%	Wine grapes	0.01 / 0.01	0.09
0.01%	Azarole/Mediteranean medlar	0 / 0.01	0.01

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%	Table grapes	0.01 / 0.01	0.34
0.3%	Pears	0.01 / 0.01	0.31
0.3%	Apples	0.01 / 0.01	0.28
0.2%	Wine grapes	0.01 / 0.01	0.24
0.2%	Kaki/Japanese persimmons	0 / 0.01	0.22
0.2%	Quinces	0.01 / 0.01	0.15
0.09%	Strawberries	0.01 / 0.01	0.09
0.07%	Medlar	0.01 / 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	0.01 / 0.01	0.54
0.4%	Wine grapes / juice	0.01 / 0.01	0.44
0.3%	Pears / juice	0.01 / 0.01	0.33
0.2%	Tomatoes / juice	0 / 0.01	0.19
0.1%	Tomatoes / sauce/puree	0 / 0.01	0.10
0.1%	Azarole (mediteranean medlar) / juice	0 / 0.01	0.06
0.0%	Quinces / jam	0.01 / 0.01	0.03
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Apples / juice	0.01 / 0.01	0.33
0.2%	Wine grapes / juice	0.01 / 0.01	0.21
0.09%	Wine grapes / wine	0.01 / 0.01	0.09
0.08%	Tomatoes / sauce/puree	0 / 0.01	0.08
0.06%	Table grapes / raisins	0.01 / 0.05	0.06
0.01%	Quinces / jam	0.01 / 0.01	0.01
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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 (1,2,4-T) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

TA_Myclobutanil_PRIMo_rev3.1

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole alanine (TA)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

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)	0.1%	NL toddler	0.20	0.0%	Apples	0.0%	Pears	0.0%	Table grapes		0.1%
	0.1%	DE child	0.19	0.0%	Apples	0.0%	Strawberries	0.0%	Table grapes		0.1%
	0.0%	GEMS/Food G06	0.13	0.0%	Tomatoes	0.0%	Watermelons	0.0%	Melons		0.0%
	0.0%	NL child	0.11	0.0%	Apples	0.0%	Strawberries	0.0%	Pears		0.0%
	0.0%	RO general	0.08	0.0%	Tomatoes	0.0%	Wine grapes	0.0%	Apples		0.0%
	0.0%	GEMS/Food G15	0.07	0.0%	Tomatoes	0.0%	Watermelons	0.0%	Wine grapes		0.0%
	0.0%	IE adult	0.06	0.0%	Melons	0.0%	Wine grapes	0.0%	Strawberries		0.0%
	0.0%	PT general	0.06	0.0%	Wine grapes	0.0%	Tomatoes	0.0%	Apples		0.0%
	0.0%	GEMS/Food G08	0.06	0.0%	Tomatoes	0.0%	Apples	0.0%	Wine grapes		0.0%
	0.0%	GEMS/Food G07	0.06	0.0%	Wine grapes	0.0%	Tomatoes	0.0%	Apples		0.0%
	0.0%	FR child 3 15 yr	0.06	0.0%	Apples	0.0%	Tomatoes	0.0%	Strawberries		0.0%
	0.0%	DE women 14-50 yr	0.06	0.0%	Apples	0.0%	Tomatoes	0.0%	Wine grapes		0.0%
	0.0%	GEMS/Food G10	0.06	0.0%	Tomatoes	0.0%	Apples	0.0%	Watermelons		0.0%
	0.0%	GEMS/Food G11	0.06	0.0%	Apples	0.0%	Tomatoes	0.0%	Wine grapes		0.0%
	0.0%	DK child	0.06	0.0%	Apples	0.0%	Tomatoes	0.0%	Melons		0.0%
	0.0%	DE general	0.05	0.0%	Apples	0.0%	Tomatoes	0.0%	Wine grapes		0.0%
	0.0%	FR adult	0.05	0.0%	Wine grapes	0.0%	Apples	0.0%	Tomatoes		0.0%
	0.0%	FR toddler 2 3 yr	0.05	0.0%	Apples	0.0%	Strawberries	0.0%	Tomatoes		0.0%
	0.0%	FI 3 yr	0.04	0.0%	Strawberries	0.0%	Apples	0.0%	Tomatoes		0.0%
	0.0%	IT toddler	0.04	0.0%	Tomatoes	0.0%	Apples	0.0%	Strawberries		0.0%
	0.0%	ES child	0.04	0.0%	Tomatoes	0.0%	Apples	0.0%	Watermelons		0.0%
	0.0%	PL general	0.04	0.0%	Apples	0.0%	Tomatoes	0.0%	Table grapes		0.0%
	0.0%	UK toddler	0.04	0.0%	Apples	0.0%	Tomatoes	0.0%	Strawberries		0.0%
	0.0%	DK adult	0.04	0.0%	Wine grapes	0.0%	Apples	0.0%	Tomatoes		0.0%
	0.0%	IT adult	0.04	0.0%	Tomatoes	0.0%	Apples	0.0%	Melons		0.0%
	0.0%	ES adult	0.04	0.0%	Tomatoes	0.0%	Apples	0.0%	Melons		0.0%
	0.0%	SE general	0.04	0.0%	Tomatoes	0.0%	Apples	0.0%	Strawberries		0.0%
	0.0%	NL general	0.04	0.0%	Apples	0.0%	Wine grapes	0.0%	Tomatoes		0.0%
	0.0%	FI 6 yr	0.04	0.0%	Strawberries	0.0%	Watermelons	0.0%	Tomatoes		0.0%
	0.0%	UK infant	0.03	0.0%	Apples	0.0%	Strawberries	0.0%	Tomatoes		0.0%
	0.0%	FR infant	0.03	0.0%	Apples	0.0%	Strawberries	0.0%	Pumpkins		0.0%
	0.0%	LT adult	0.03	0.0%	Apples	0.0%	Tomatoes	0.0%	Strawberries		0.0%
	0.0%	UK vegetarian	0.03	0.0%	Tomatoes	0.0%	Wine grapes	0.0%	Apples		0.0%
	0.0%	UK adult	0.03	0.0%	Wine grapes	0.0%	Tomatoes	0.0%	Apples		0.0%
	0.0%	FI adult	0.03	0.0%	Tomatoes	0.0%	Strawberries	0.0%	Apples		0.0%
	0.0%	IE child	0.01	0.0%	Apples	0.0%	Strawberries	0.0%	Tomatoes		0.0%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Triazole alanine (TA) 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%	Melons	0 / 0.05	8.2
2%	Pears	0 / 0.05	6.9
2%	Watermelons	0 / 0.05	6.6
2%	Apples	0 / 0.05	5.4
1%	Strawberries	0 / 0.24	3.9
1%	Tomatoes	0 / 0.07	3.8
0.8%	Kaki/Japanese persimmons	0 / 0.05	2.3
0.5%	Table grapes	0 / 0.02	1.5
0.5%	Pumpkins	0 / 0.05	1.4
0.4%	Quinces	0 / 0.05	1.2
0.2%	Medlar	0 / 0.05	0.69
0.06%	Wine grapes	0 / 0.02	0.19
0.02%	Azarole/Mediteranean medlar	0 / 0.05	0.05

Expand/collapse list

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

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%	Strawberries	0 / 0.24	2.2
0.7%	Watermelons	0 / 0.05	2.2
0.7%	Melons	0 / 0.05	2.1
0.5%	Pears	0 / 0.05	1.5
0.5%	Apples	0 / 0.05	1.4
0.4%	Kaki/Japanese persimmons	0 / 0.05	1.1
0.3%	Tomatoes	0 / 0.07	1.0
0.3%	Pumpkins	0 / 0.05	0.79
0.3%	Quinces	0 / 0.05	0.76
0.2%	Table grapes	0 / 0.02	0.71
0.2%	Wine grapes	0 / 0.02	0.50
0.1%	Medlar	0 / 0.05	0.34

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)
2%	Pumpkins / boiled	0 / 0.05	4.8
0.2%	Apples / juice	0 / 0.01	0.54
0.2%	Wine grapes / juice	0 / 0.01	0.48
0.1%	Pears / juice	0 / 0.01	0.33
0.1%	Tomatoes / juice	0 / 0.02	0.29
0.0%	Tomatoes / sauce/puree	0 / 0.02	0.14
0.0%	Azarole (mediteranean medlar) / juice	0 / 0.01	0.06
0.0%	Quinces / jam	0 / 0.01	0.03
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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)
1.0%	Pumpkins / boiled	0 / 0.05	3.0
0.1%	Apples / juice	0 / 0.01	0.33
0.08%	Wine grapes / juice	0 / 0.01	0.23
0.07%	Wine grapes / wine	0 / 0.02	0.20
0.04%	Tomatoes / sauce/puree	0 / 0.02	0.12
0.04%	Table grapes / raisins	0 / 0.1	0.12
0.00%	Quinces / jam	0 / 0.01	0.01
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Triazole alanine (TA) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

TAA_Myclobutanil_PRIMo_rev3.1

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

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)	0.0%	NL toddler	0.17	0.0%	Apples	0.0%	Pears	0.0%	Table grapes		0.0%
	0.0%	DE child	0.15	0.0%	Apples	0.0%	Table grapes	0.0%	Pears		0.0%
	0.0%	NL child	0.08	0.0%	Apples	0.0%	Pears	0.0%	Table grapes		0.0%
	0.0%	PT general	0.04	0.0%	Wine grapes	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	DE women 14-50 yr	0.04	0.0%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.0%
	0.0%	FR toddler 2 3 yr	0.04	0.0%	Apples	0.0%	Pears	0.0%	Wine grapes		0.0%
	0.0%	DE general	0.04	0.0%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.0%
	0.0%	RO general	0.04	0.0%	Wine grapes	0.0%	Apples	0.0%	Table grapes		0.0%
	0.0%	FR adult	0.03	0.0%	Wine grapes	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	DK child	0.03	0.0%	Apples	0.0%	Pears	0.0%	Table grapes		0.0%
	0.0%	GEMS/Food G11	0.03	0.0%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.0%
	0.0%	GEMS/Food G07	0.03	0.0%	Wine grapes	0.0%	Apples	0.0%	Table grapes		0.0%
	0.0%	FR child 3 15 yr	0.03	0.0%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.0%
	0.0%	IE adult	0.03	0.0%	Wine grapes	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	GEMS/Food G08	0.03	0.0%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.0%
	0.0%	GEMS/Food G15	0.03	0.0%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.0%
	0.0%	PL general	0.03	0.0%	Apples	0.0%	Table grapes	0.0%	Pears		0.0%
	0.0%	NL general	0.03	0.0%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.0%
	0.0%	DK adult	0.02	0.0%	Apples	0.0%	Wine grapes	0.0%	Pears		0.0%
	0.0%	UK toddler	0.02	0.0%	Apples	0.0%	Table grapes	0.0%	Strawberries		0.0%
	0.0%	GEMS/Food G06	0.02	0.0%	Table grapes	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	FR infant	0.02	0.0%	Apples	0.0%	Pears	0.0%	Strawberries		0.0%
	0.0%	LT adult	0.02	0.0%	Apples	0.0%	Pears	0.0%	Strawberries		0.0%
	0.0%	UK infant	0.02	0.0%	Apples	0.0%	Pears	0.0%	Strawberries		0.0%
	0.0%	GEMS/Food G10	0.02	0.0%	Apples	0.0%	Wine grapes	0.0%	Table grapes		0.0%
	0.0%	ES child	0.02	0.0%	Apples	0.0%	Pears	0.0%	Strawberries		0.0%
	0.0%	FI 3 yr	0.02	0.0%	Apples	0.0%	Strawberries	0.0%	Table grapes		0.0%
	0.0%	UK adult	0.02	0.0%	Wine grapes	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	ES adult	0.02	0.0%	Apples	0.0%	Wine grapes	0.0%	Pears		0.0%
	0.0%	UK vegetarian	0.02	0.0%	Wine grapes	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	SE general	0.02	0.0%	Apples	0.0%	Pears	0.0%	Strawberries		0.0%
	0.0%	IT toddler	0.01	0.0%	Apples	0.0%	Pears	0.0%	Strawberries		0.0%
	0.0%	FI 6 yr	0.01	0.0%	Apples	0.0%	Strawberries	0.0%	Pears		0.0%
	0.0%	IT adult	0.01	0.0%	Apples	0.0%	Pears	0.0%	Table grapes		0.0%
	0.0%	FI adult	0.01	0.0%	Apples	0.0%	Wine grapes	0.0%	Strawberries		0.0%
	0.0%	IE child	0.00	0.0%	Apples	0.0%	Table grapes	0.0%	Pears		0.0%

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)
0.1%	Pears	0.01 / 0.01	1.4
0.1%	Apples	0.01 / 0.01	1.1
0.07%	Table grapes	0.01 / 0.01	0.73
0.05%	Kaki/Japanese persimmons	0 / 0.01	0.47
0.03%	Strawberries	0.01 / 0.02	0.31
0.02%	Quinces	0.01 / 0.01	0.25
0.01%	Medlar	0.01 / 0.01	0.14
0.01%	Wine grapes	0.01 / 0.01	0.09
0.00%	Azarole/Mediteranean medlar	0 / 0.01	0.01

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)
0.03%	Table grapes	0.01 / 0.01	0.34
0.03%	Pears	0.01 / 0.01	0.31
0.03%	Apples	0.01 / 0.01	0.28
0.02%	Wine grapes	0.01 / 0.01	0.24
0.02%	Kaki/Japanese persimmons	0 / 0.01	0.22
0.02%	Strawberries	0.01 / 0.02	0.18
0.02%	Quinces	0.01 / 0.01	0.15
0.01%	Medlar	0.01 / 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	0.01 / 0.01	0.54
0.0%	Wine grapes / juice	0.01 / 0.01	0.44
0.0%	Pears / juice	0.01 / 0.01	0.33
0.0%	Tomatoes / juice	0 / 0.01	0.19
0.0%	Tomatoes / sauce/puree	0 / 0.01	0.10
0.0%	Azarole (mediteranean medlar) / juice	0 / 0.01	0.06
0.0%	Quinces / jam	0.01 / 0.01	0.03
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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	0.01 / 0.01	0.33
0.02%	Wine grapes / juice	0.01 / 0.01	0.21
0.01%	Wine grapes / wine	0.01 / 0.01	0.09
0.01%	Tomatoes / sauce/puree	0 / 0.01	0.08
0.01%	Table grapes / raisins	0.01 / 0.05	0.06
0.00%	Quinces / jam	0.01 / 0.01	0.01
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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.

TLA_Myclobutanil_PRIMo_rev3.1

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole lactic acid (TLA)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

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)	0.1%	NL toddler	0.19	0.0%	Apples	0.0%	Pears	0.0%	Table grapes		
	0.1%	DE child	0.17	0.0%	Apples	0.0%	Table grapes	0.0%	Tomatoes		
	0.0%	NL child	0.09	0.0%	Apples	0.0%	Table grapes	0.0%	Pears		
	0.0%	GEMS/Food G06	0.08	0.0%	Tomatoes	0.0%	Table grapes	0.0%	Watermelons		
	0.0%	RO general	0.06	0.0%	Wine grapes	0.0%	Tomatoes	0.0%	Apples		
	0.0%	PT general	0.06	0.0%	Wine grapes	0.0%	Apples	0.0%	Tomatoes		
	0.0%	DE women 14-50 yr	0.05	0.0%	Apples	0.0%	Wine grapes	0.0%	Tomatoes		
	0.0%	GEMS/Food G07	0.05	0.0%	Wine grapes	0.0%	Tomatoes	0.0%	Apples		
	0.0%	GEMS/Food G15	0.05	0.0%	Wine grapes	0.0%	Tomatoes	0.0%	Apples		
	0.0%	FR adult	0.05	0.0%	Wine grapes	0.0%	Apples	0.0%	Tomatoes		
	0.0%	DE general	0.05	0.0%	Apples	0.0%	Wine grapes	0.0%	Tomatoes		
	0.0%	GEMS/Food G11	0.05	0.0%	Apples	0.0%	Wine grapes	0.0%	Tomatoes		
	0.0%	GEMS/Food G08	0.05	0.0%	Wine grapes	0.0%	Apples	0.0%	Tomatoes		
	0.0%	IE adult	0.05	0.0%	Wine grapes	0.0%	Melons	0.0%	Apples		
	0.0%	FR toddler 2 3 yr	0.04	0.0%	Apples	0.0%	Tomatoes	0.0%	Pears		
	0.0%	FR child 3 15 yr	0.04	0.0%	Apples	0.0%	Tomatoes	0.0%	Wine grapes		
	0.0%	DK child	0.04	0.0%	Apples	0.0%	Pears	0.0%	Tomatoes		
	0.0%	GEMS/Food G10	0.04	0.0%	Tomatoes	0.0%	Apples	0.0%	Wine grapes		
	0.0%	PL general	0.04	0.0%	Apples	0.0%	Tomatoes	0.0%	Table grapes		
	0.0%	DK adult	0.04	0.0%	Wine grapes	0.0%	Apples	0.0%	Tomatoes		
	0.0%	NL general	0.03	0.0%	Apples	0.0%	Wine grapes	0.0%	Tomatoes		
	0.0%	IT toddler	0.03	0.0%	Tomatoes	0.0%	Apples	0.0%	Pears		
	0.0%	UK toddler	0.03	0.0%	Apples	0.0%	Tomatoes	0.0%	Table grapes		
	0.0%	ES child	0.03	0.0%	Apples	0.0%	Tomatoes	0.0%	Pears		
	0.0%	ES adult	0.03	0.0%	Tomatoes	0.0%	Apples	0.0%	Wine grapes		
	0.0%	LT adult	0.03	0.0%	Apples	0.0%	Tomatoes	0.0%	Pears		
	0.0%	IT adult	0.03	0.0%	Tomatoes	0.0%	Apples	0.0%	Pears		
	0.0%	FI 3 yr	0.03	0.0%	Apples	0.0%	Tomatoes	0.0%	Strawberries		
	0.0%	UK vegetarian	0.03	0.0%	Wine grapes	0.0%	Tomatoes	0.0%	Apples		
	0.0%	SE general	0.03	0.0%	Apples	0.0%	Tomatoes	0.0%	Pears		
	0.0%	UK infant	0.02	0.0%	Apples	0.0%	Tomatoes	0.0%	Pears		
	0.0%	UK adult	0.02	0.0%	Wine grapes	0.0%	Tomatoes	0.0%	Apples		
	0.0%	FR infant	0.02	0.0%	Apples	0.0%	Pears	0.0%	Strawberries		
	0.0%	FI 6 yr	0.02	0.0%	Apples	0.0%	Tomatoes	0.0%	Strawberries		
	0.0%	FI adult	0.02	0.0%	Apples	0.0%	Tomatoes	0.0%	Wine grapes		
	0.0%	IE child	0.01	0.0%	Apples	0.0%	Table grapes	0.0%	Tomatoes		

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Triazole lactic acid (TLA) 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 / 0.03	3.7
1%	Table grapes	0 / 0.05	3.3
1.0%	Apples	0 / 0.03	2.9
1.0%	Melons	0 / 0.02	2.9
0.8%	Watermelons	0 / 0.02	2.3
0.6%	Tomatoes	0 / 0.03	1.9
0.4%	Kaki/Japanese persimmons	0 / 0.03	1.3
0.3%	Strawberries	0 / 0.05	0.83
0.2%	Quinces	0 / 0.03	0.66
0.2%	Pumpkins	0 / 0.02	0.51
0.1%	Wine grapes	0 / 0.05	0.42
0.1%	Medlar	0 / 0.03	0.37
0.01%	Azarole/Mediteranean medlar	0 / 0.03	0.02

Expand/collapse list

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

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)
0.5%	Table grapes	0 / 0.05	1.5
0.4%	Wine grapes	0 / 0.05	1.1
0.3%	Pears	0 / 0.03	0.82
0.3%	Watermelons	0 / 0.02	0.77
0.3%	Apples	0 / 0.03	0.76
0.2%	Melons	0 / 0.02	0.74
0.2%	Kaki/Japanese persimmons	0 / 0.03	0.59
0.2%	Tomatoes	0 / 0.03	0.51
0.2%	Strawberries	0 / 0.05	0.48
0.1%	Quinces	0 / 0.03	0.41
0.09%	Pumpkins	0 / 0.02	0.28
0.06%	Medlar	0 / 0.03	0.18

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)
0.6%	Pumpkins / boiled	0 / 0.02	1.7
0.2%	Wine grapes / juice	0 / 0.01	0.57
0.2%	Apples / juice	0 / 0.01	0.54
0.1%	Pears / juice	0 / 0.01	0.33
0.1%	Tomatoes / juice	0 / 0.01	0.19
0.0%	Tomatoes / sauce/puree	0 / 0.01	0.10
0.0%	Azarole (mediteranean medlar) / juice	0 / 0.01	0.06
0.0%	Quinces / jam	0 / 0.01	0.03
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Pumpkins / boiled	0 / 0.02	1.0
0.1%	Wine grapes / wine	0 / 0.05	0.43
0.1%	Apples / juice	0 / 0.01	0.33
0.09%	Wine grapes / juice	0 / 0.01	0.27
0.09%	Table grapes / raisins	0 / 0.21	0.26
0.03%	Tomatoes / sauce/puree	0 / 0.01	0.08
0.00%	Quinces / jam	0 / 0.01	0.01
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Triazole lactic acid (TLA) 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 | Consumer risk assessment

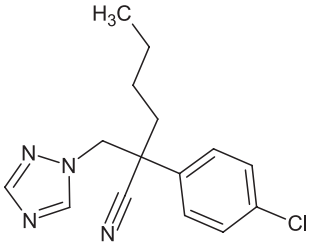
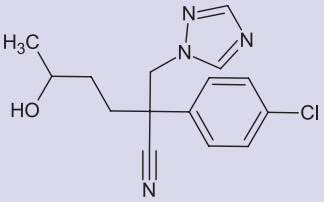
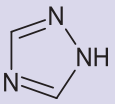
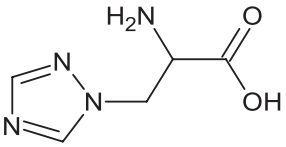
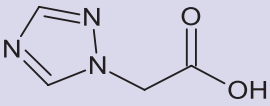
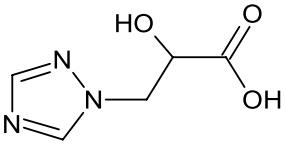
Commodity	1,2,4-T (HR-RAC) (mg/kg)	TA (HR-RAC) (mg/kg)	TAA (HR-RAC) (mg/kg)	TLA (HR-RAC) (mg/kg)
Pome fruits	0.01	0.05	0.01	0.027
Grapes	0.01	0.021	0.01	0.045
Azarole/Mediteranean medlar[a]	0.01	0.05	0.01	0.027
Kaki/Japanese persimmons[a]	0.01	0.05	0.01	0.027
Strawberries	0.01	0.24	0.019	0.051
Cucurbits with inedible peel	0.01	0.054	0.01	0.019
Tomatoes	0.01	0.065	0.01	0.032

Abbreviations: HR-RAC, highest residue in raw agricultural commodity; PeF, Peeling factor.

[a]For azarole/Mediterranean medlar and kaki/Japanese persimmon exposure was also considered should the risk managers decide to maintain the Codex MRL for these commodities. Risk assessment values were as derived for pome fruits.

APPENDIX E

Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
myclobutanil	(*RS*)-2-(4-chlorophenyl)-2-(1*H*-1,2,4-triazol-1-ylmethyl) hexanenitrile Clc1ccc(cc1)C(CCCC)(Cn2cncn2)C#N HZJKXKUJVSEEFU-UHFFFAOYSA-N	
RH-9090	(2*RS*,5*RS*)-2-(4-chlorophenyl)-5-hydroxy-2-(1*H*-1,2,4-triazol-1-ylmethyl)hexanenitrile Clc1ccc(cc1)C(CCC(C)O)(Cn2cncn2)C#N HIUOATAFAFIXAL-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	

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

[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).