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REASONED OPINION

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Setting of import tolerances for difenoconazole in various crops

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta Crop Protection AG submitted an application to the competent national authority in Spain (rapporteur Member State, RMS) to set import tolerances for the active substance difenoconazole in various crops imported from the United States and Brazil. The data submitted in support of the request were found to be sufficient to derive maximum residue level (MRL) proposals for citrus fruits, tree nuts, mangoes, papayas, dry peas and soya beans. Adequate analytical methods for enforcement are available to control the residues of difenoconazole in the commodities under consideration, animal tissues and eggs at the validated limit of quantification (LOQ) of 0.01 mg/kg and in milk at the validated LOQ of 0.005 mg/kg. Quick, Easy, Cheap, Effective, Rugged, and Safe (QuECHERs) methods are also available for the determination of difenoconazole alcohol (CGA205375) in animal matrices at the validated LOQ of 0.012 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of difenoconazole according to the reported agricultural practices is unlikely to present a risk to consumer health.

KEYWORDS

consumer risk assessment, difenoconazole, import tolerance, MRL, pesticide, TDMs, various crops

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Spain (Rapporteur Member State, RMS) to set import tolerances for the active substance difenoconazole in various crops imported from the United States and Brazil.

The application alongside the dossier containing the supporting data in IUCLID format was submitted through the European Food Safety Authority (EFSA) Central Submission System on 9 December 2022. The appointed RMS, Spain, assessed the dossier and declared its admissibility on 19 June 2023. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 28 July 2023 to 18 August 2023. No additional data nor 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 EFSA on 21 September 2023. The RMS proposed to set import tolerances for soya beans, and tree nuts imported from the United Sates at the level of 0.15 and 0.02 mg/kg, respectively, and for mangoes and papayas imported from Brazil at the level of 0.02 and 0.03 mg/kg, respectively. For citrus fruits and dry peas, no maximum residue level (MRL) modifications were considered needed based on the submitted trials.

The European Commission sent a mandate to EFSA on 15 November 2023 to assess the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and requested the RMS to address them. The applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the RMS who submitted a revised evaluation report to EFSA on 24 January 2025, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC for the EU pesticides peer review of the approval of the active substance, the updated conclusions derived in the framework of the assessment of difenoconazole in light of confirmatory data according to the conditions for approval set by Regulation (EU) No 1100/2011, the data evaluated under previous MRL assessments, including the MRL review, and the additional data provided by the RMS in the framework of this application, the following conclusions are derived.

The metabolism of difenoconazole following foliar applications was investigated in crops belonging to the groups of fruit crops, cereals/grass, root crops and pulses/oilseeds. Difenoconazole and triazole derivative metabolites (TDMs) were main metabolites in all plants. In rotational crops, the major residues identified in cereals/grasses, leafy and root crops were the parent compound, difenoconazole alcohol (CGA205375) and triazole metabolites. Studies investigating the effect of processing on the nature of difenoconazole (hydrolysis studies) demonstrated that difenoconazole is hydrolytically stable.

Based on the metabolic pattern identified in metabolism studies and considering the results of hydrolysis studies, the residue definitions for plant products were proposed as difenoconazole (sum of isomers) for enforcement. As regards risk assessment, also considering the agreement on the residue definitions in the framework of the triazole derivative metabolites (TDMs) confirmatory data, four residue definitions were set separately, namely, RD-RA1: difenoconazole (sum of isomers); RD-RA2: triazole alanine (TA) and triazole lactic acid (TLA); RD-RA3: triazole acetic acid (TAA); RD-RA4: 1,2,4-triazole (1,2,4-T). These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that, for the crops assessed in this application, the metabolism of difenoconazole in primary crops and the possible degradation in processed products have been sufficiently addressed, and the previously derived residue definitions are applicable. Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) are available to quantify residues at the limit of quantification (LOQ) of 0.01 mg/kg in the crops assessed in this application according to the residue definition for enforcement. The extraction efficiency of the analytical method for enforcement of difenoconazole was sufficiently demonstrated in all plant commodity groups. These methods are not stereoselective. The analytical standard for difenoconazole is commercially available.

The submitted residue trials are sufficient to support authorised uses in the USA and Brazil and to derive import tolerances for difenoconazole in citrus fruits (0.6 mg/kg), tree nuts (0.03 mg/kg), mangoes (0.2 mg/kg), papayas (0.3 mg/kg), dry peas (0.15 mg/kg) and soya beans (0.15 mg/kg), as well as risk assessment values for difenoconazole and TDMs. Additional residue data on TDMs were provided on blueberries to supplement the TDM database. The present assessment takes into consideration triazole derivative metabolites (TDMs), which are generated by difenoconazole and by several other pesticides belonging to the group of triazole fungicides.

Processing studies investigating the effect of processing on the magnitude of difenoconazole and TDM residues in processed commodities of citrus fruits (oranges, mandarins and lemons), almonds and soya beans were submitted for the present assessment, and robust processing factors were derived and proposed for the inclusion in Annex VI of Regulation (EC) 396/2005.

The occurrence of difenoconazole residues in rotational crops is not relevant for imported crops.

Citrus (dried pulp) and soya beans (seed, meal, hulls) might be used as feed products, and therefore, a potential carry-over of difenoconazole and TDM residues into the food of animal origin was assessed. The calculated livestock dietary burden for difenoconazole exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all livestock groups. However, as there is no difference between the results of the updated calculations and the dietary burdens calculated in the MRL review,

no further assessment of difenoconazole residues in commodities of animal origin was needed, as this is covered by the outcome of the MRL review. Regarding TDMs, as the STMR values for TA, TLA, TAA and 1,2,4-triazole derived for citrus fruits and soya beans in the present assessment are lower than those used in the peer review of the pesticide risk assessment for the triazole derivative metabolites, an update of the livestock dietary burden for TDMs was not considered necessary.

The toxicological profile of difenoconazole was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg bw per day and an acute reference dose (ARfD) of 0.16 mg/kg bw. For the metabolite CGA205375, which is included in the risk assessment residue definition for commodities of animal origin, no conclusions on its toxicity were derived and no toxicological reference values were derived in the EU pesticides peer review. The toxicological profile of this metabolite is being assessed in the framework of the renewal of the approval process of difenoconazole which is currently ongoing. Depending on the outcome of this assessment, the conclusions derived in the previous and present opinions on the consumer risk assessment might need to be revised. The toxicological reference values for each triazole derivative metabolite were derived in the framework of the pesticide risk assessment of the TDMs in light of confirmatory data and formally taken note by the European Commission.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). Separate calculations were performed for difenoconazole and the TDMs. The current assessment for difenoconazole considers the possible impact of plant and livestock metabolism on the isomer ratio of difenoconazole and difenoconazole-alcohol. Therefore, uncertainty factors of 1.3 for plant commodities and 2 for animal commodities were applied in the consumer exposure assessment to account for potential shifts in the isomer ratio.

The short-term exposure to difenoconazole residues did not exceed the ARfD for any of the commodities under consideration, with the highest acute exposures being 3.8% of the ARfD for oranges and 6.9% of the ARfD for orange juice.

The long-term consumer exposure calculation performed in the MRL review was now updated with the residue data on the crops under consideration. Provided that the conclusions of the MRL review are endorsed, no long-term consumer intake concerns were identified for the existing uses of difenoconazole and the import tolerances under assessment. The estimated long-term dietary exposure accounted for a maximum of 85% of the ADI (NL toddler diet), with the highest contribution of 0.63% of the ADI for soya beans considering the commodities under assessment. However, the long-term assessment for difenoconazole is affected by uncertainties related to the toxicological profile of animal metabolite CGA205375 and remains indicative.

Regarding TDMs, no long-term or short-term consumer intake concerns were identified. However, the risk assessment for the sum of TA and TLA is affected by uncertainties related to the lack of information on the storage stability of TA in tree nuts.

EFSA concluded that the dietary exposure to difenoconazole and TDM residues from the intake of the commodities under assessment will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health. EFSA highlights that some of the conclusions reached in the present assessment might be reconsidered in the framework of the ongoing peer review for renewal of the approval of active substance.

EFSA proposes to amend the existing MRL as reported in the summary table below.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

Code[a]	Commodity	Existing EU MRL/MRL (EFSA, 2024c)[b] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Difenoconazole (sum of isomers)				
0110000	Citrus fruits	0.6/0.6 tentative[c] Data gap #8	0.6	The submitted data are sufficient to derive an MRL of 1 mg/kg for the authorised US use. To align with the US tolerance, an MRL of 0.6 mg/kg is proposed. Since the existing EU MRL is in line with the US tolerance, no modification of the current MRL is necessary. This dossier provides peel and pulp data as well as residue data on TDMs. The data gap identified in the MRL review is therefore addressed. The tentative MRL derived in the MRL review is confirmed. Risk for consumers is unlikely.
0120010	Almonds	0.05*/0.05 tentative[c] Data gap #1 and #8	0.03	Lower LOQ of 0.01 mg/kg is available according to data from latest assessments. The submitted data are sufficient to derive an MRL proposal for the authorised US use. The tolerance in US is 0.03 mg/kg. The data gaps identified in the MRL review are addressed. A new lower MRL, fully supported by data, is proposed. Risk for consumers is unlikely.

(Continued)

Code[a]	Commodity	Existing EU MRL/MRL (EFSA, 2024c)[b] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0120020 0120030 0120040 0120050 0120060 0120070 0120080 0120090 0120100 0120110	Brazil nuts Cashew nuts Chestnuts Coconuts Hazelnuts/ cobnuts Macadamias Pecans Pine nut kernels Pistachios Walnuts	0.05*/0.03 tentative[c] data gap #8	0.03	Lower LOQ of 0.01 mg/kg is available according to data from latest assessments. The submitted data are sufficient to derive an MRL proposal for the authorised US use. The tolerance in US is 0.03 mg/kg. The data gap identified in the MRL review is addressed. The tentative MRL derived in the MRL review is confirmed. Risk for consumers is unlikely.
0154010	Blueberries	4/4 tentative[c] data gap #1	No MRL modification	The existing EU MRL is based on the Codex MRL. No MRL modification was requested under the present assessment. In the present dossier, the applicant provided data on TDMs to supplement the TDM database. The data gap identified in the MRL review is not addressed.
0163030	Mangoes	0.1/0.1 tentative[c] data gap #2	0.2	The submitted data are sufficient to derive an MRL proposal for the authorised Brazilian use. The tolerance in Brazil is 0.2 mg/kg. The data gap identified in the MRL review is addressed. A new higher MRL, fully supported by data, is proposed. Risk for consumers is unlikely.
0163040	Papayas	0.2/0.2 Tentative[c] data gap #1	0.3	The submitted data are sufficient to derive an MRL proposal for the authorised Brazilian use. The tolerance in Brazil is 0.3 mg/kg. The data gap identified in the MRL review is addressed. A new higher MRL, fully supported by data, is proposed. Risk for consumers is unlikely.
0300030	Peas (dry)	0.15/0.15 tentative[c] data gap #2 and 8	0.15	The submitted data are sufficient to derive an MRL proposal for the authorised US use. The tolerance in US is 0.2 mg/kg. The data gaps identified in the MRL review are addressed. The tentative MRL derived in the MRL review is confirmed. Risk for consumers is unlikely.
0401070	Soya beans	0.1/0.1 tentative[c] data gap #2 and 8	0.15	The submitted data are sufficient to derive an MRL of 0.3 mg/kg for the authorised US use. To align with the US tolerance, an MRL of 0.15 mg/kg is proposed. The data gaps identified in the MRL review are addressed. Risk for consumers is unlikely.

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

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

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

[b] MRLs proposed in EFSA (2024c), not yet implemented in the regulation.

[c] A tentative MRL was derived in the MRL review with the data gaps identified (see below).

Data gap #1: A full data set of GAP compliant residue trials analysing for difenoconazole, 1,2,4-T, TAA and the sum of TA and TLA, supporting the authorised uses.

Data gap #2: A full data set of GAP compliant residue trials analysing for 1,2,4-T, TAA and the sum of TA and TLA, supporting the authorised uses.

Data gap #8: CXLs set for animal and plant commodities are not fully supported by data, as trials analysing for all TDMs are not available.

ASSESSMENT

The European Food Safety Authority (EFSA) received an application to set import tolerances for difenoconazole in various crops. The detailed description of the existing uses of difenoconazole authorised in the United States and Brazil, which are the basis for the current maximum residue level (MRL) application, are reported in Appendix A.

Difenoconazole is the ISO common name for 3-chloro-4-[(2*RS*,4*RS*;2*RS*,4*SR*)-4-methyl-2-(1*H*-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Difenoconazole was evaluated in the framework of Directive 91/414/EEC[1] with Sweden designated as rapporteur Member State (RMS) for the representative uses as foliar applications on pome fruits and carrots and as seed treatment

[1]Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

on cereals. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2011a). Difenoconazole was approved[2] for the use as a fungicide on 1 January 2009. Furthermore, according to the provisions of the approval directive as amended by Commission Implementing Regulation (EU) No 1100/2011,[3] confirmatory information was requested, among others as regards: (a) residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops, processed commodities and products of animal origin to be submitted by 30 November 2013; (b) the possible impact of the variable isomer ratio in the technical material and of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and on the environment, to be submitted within 2 years from the adoption of specific guidance. The required confirmatory data related to residues for the TDMs were submitted by the applicant in November 2013. These data were evaluated by the United Kingdom and a peer review in light of confirmatory data was subsequently conducted by EFSA (EFSA, 2018; European Commission, 2020a). The confirmatory data related to the preferential degradation/conversion of the mixture of isomers in plants were submitted by the applicant in an updated dossier in December 2022 and were assessed by the RMS Spain in the form of an addendum to the draft assessment report (Spain, 2023a). EFSA assessed these confirmatory data and first issued a technical report (EFSA, 2023d), where the need for further discussion in a peer review expert meeting was raised. The meeting took place in March 2024 (EFSA, 2024a), followed by the publication of an EFSA conclusion in light of confirmatory data (EFSA, 2024).

The process of renewal of the first approval of difenoconazole is currently ongoing. The EU MRLs for difenoconazole are established in Annex IIIA of Regulation (EC) No 396/2005.[4] The review of the existing EU MRLs of difenoconazole according to Article 12 of Regulation (EC) No 396/2005 was finalised in September 2024 (EFSA, 2024c). The conclusions of the MRL review have not been implemented yet in the MRL regulation, but are considered for the present assessment. To date, EFSA has issued several reasoned opinions on the modification of MRLs for difenoconazole. The proposals from these reasoned opinions have been considered in recent MRL regulations,[5] except the EFSA reasoned opinion on the modification of existing EU MRLs for difenoconazole in leafy brassica (EFSA, 2021). The conclusions of this reasoned opinion will not be taken into consideration for the present assessment. Certain Codex maximum residue limits (CXLs) have also been taken over in the EU MRL legislation.[6,7,8,9]

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Spain (Rapporteur Member State, RMS) to set import tolerances for the active substance difenoconazole in various crops imported from the United States and Brazil.

The application alongside the dossier containing the supporting data in IUCLID format was submitted through the EFSA Central Submission System on 9 December 2022. The appointed RMS Spain assessed the dossier and declared its admissibility on 19 June 2023. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 28 July 2023 to 18 August 2023. No additional data nor 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 EFSA on 21 September 2023. The RMS proposed to set import tolerances for soya beans, and tree nuts imported from the United Sates at the level of 0.15 and 0.02 mg/kg, respectively, and for mangoes and papayas imported from Brazil at the level of 0.02 and 0.03 mg/kg respectively. For citrus fruits and dry peas, no MRL modifications were considered needed based on the submitted trials. For blueberries, no residue data on difenoconazole were provided and no MRL modification was requested.

[2]Commission Directive 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances OJ L 172, 2.7.2008, p. 9–14.

[3]Commission Implementing Regulation (EU) No 1100/2011 of 31 October 2011 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances dicamba, difenoconazole, and imazaquin. OJ L 285, 1.11.2011, p. 10–14.

[4]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.

[5]For an overview of all MRL Regulations on this active substance, please consult: https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en.

[6]Commission Regulation (EU) No 441/2012 of 24 May 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, bifenthrin, boscalid, cadusafos, chlorantraniliprole, chlorothalonil, clothianidin, cyproconazole, deltamethrin, dicamba, difenoconazole, dinocap, etoxazole, fenpyroximate, flubendiamide, fludioxonil, glyphosate, metalaxyl-M, meptyldinocap, novaluron, thiamethoxam, and triazophos in or on certain products OJ L 135, 25.5.2012, p. 4–56.

[7]Commission Regulation (EU) 2015/845 of 27 May 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, chlorantraniliprole, cyantraniliprole, dicamba, difenoconazole, fenpyroximate, fludioxonil, glufosinate-ammonium, imazapic, imazapyr, indoxacarb, isoxaflutole, mandipropamid, penthiopyrad, propiconazole, pyrimethanil, spirotetramat and trinexapac in or on certain products OJ L 138, 4.6.2015, p. 1–69.

[8]Commission Regulation (EU) 2017/626 of 31 March 2017 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 acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products C/2017/2035 OJ L 96, 7.4.2017, p. 1–43.

[9]Commission Regulation (EU) 2019/552 of 4 April 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim in or on certain products C/2019/2496 OJ L 96, 5.4.2019, p. 6–49.

The European Commission sent a mandate to EFSA on 15 November 2023 to assess the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and requested the RMS to address them. The applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the RMS who submitted a revised evaluation report to EFSA on 24 January 2025, which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the RMS (Spain, 2022), the draft assessment report (DAR) (Sweden, 2006, 2010) prepared under Council Directive 91/414/EEC, the Commission review report on difenoconazole (European Commission, 2013; as revised in 2020a) and the conclusions on the peer review of the pesticide risk assessment of the active substance difenoconazole (EFSA, 2011a). EFSA also duly considered the conclusions from the updated assessment of difenoconazole in light of confirmatory data (EFSA, 2023d, 2024), as well as the conclusions from previous EFSA opinions on difenoconazole (EFSA, 2009, 2010a, 2010b, 2011b, 2012, 2013, 2014a, 2014b, 2017, 2018a, 2021, 2023b), including MRL review of difenoconazole according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2024c) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) evaluations (FAO and WHO, 2011, 2013, 2015, 2021).

For this application, the data requirements established in Regulation (EU) No 544/2011[10] and the guidance documents applicable at the date of submission of the application to the RMS are applicable (European Commission, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b; OECD, 2011, 2013). 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.[11]

As the EU pesticides peer review on the renewal of the approval of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the EU pesticides peer review.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application, including the end points of relevant studies assessed previously, is presented in Appendix B.

The evaluation report submitted by the RMS (Spain, 2023b; as revised in 2025) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.[12]

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 difenoconazole in primary crops was investigated in the framework of the EU pesticides peer review of the approval of the active substance difenoconazole following foliar applications in fruit crops (tomatoes and grapes), cereals/grass crops (wheat), root crops (potatoes) and pulses/oilseed crops (rapeseeds). Studies in cereals following seed application were also considered (EFSA, 2011a; Sweden, 2006). The metabolism was found comparable in the four crop groups. Difenoconazole was the major component of the residues in the major plant parts (mostly > 40% total radioactive residue (TRR)), except for cereal grains, potato tubers and rape seeds, where the major components of the residues were the triazole derivative metabolites (TDMs): triazole alanine (TA), triazole acetic acid (TAA) and 1,2,4-triazole (1,2,4-T). In addition, triazole alanine was detected up to 42% TRR in tomato fruits and 1,2,4-triazole up to 12% in grapes. Metabolites CGA205374 (ketone), CGA205375 (alcohol) and CGA189138 (benzoic acid) were also identified in low proportions (below 5% TRR).

A data gap on the investigation of the preferential metabolism/degradation of the four stereoisomers of difenoconazole in plants was identified in the framework of the peer review (EFSA, 2011a). Additional data were provided and assessed as confirmatory data (EFSA, 2023d, 2024a, 2024b; Spain, 2023a). It was concluded that there is no shift observed in the ratio of enantiomers within the pairs of stereoisomers but a tendency of a preferential degradation of *trans* isomers and a shift to the *cis* isomers of difenoconazole.

1.1.2 | Nature of residues in rotational crops

Investigations of residues in rotational crops are not required for imported crops. Therefore, for the uses assessed in this application, no further information is required.

[10]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.

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

[12]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-2023-00421.

1.1.3 | Nature of residues in processed commodities

The effect of processing on the nature of difenoconazole and TDMs (hydrolysis study) was investigated in the frameworks of the EU pesticides peer review under Directive 91/414/EEC and the EU pesticide peer review of confirmatory data for triazole metabolites (EFSA, 2011a, Sweden, 2006; United Kingdom, 2018). These studies showed that difenoconazole and TDMs are hydrolytically stable under the standard hydrolysis conditions simulating processing of pasteurisation, baking, brewing and boiling and sterilisation.

1.1.4 | Analytical methods for enforcement purposes in plant commodities

Analytical methods for the determination of difenoconazole residues were assessed in the framework of the EU pesticides peer review (EFSA, 2011a). These are based on liquid chromatography with tandem mass spectrometry (LC–MS/MS) and were validated in high water content commodities (apples, lettuces) at the LOQ of 0.02 mg/kg, in dry commodities (wheat grain) at the LOQ of 0.05 mg/kg and in high oil content commodities (rapeseeds) at the LOQ of 0.05 mg/kg, including independent laboratory validation (ILV).

A multiresidue Quick, Easy, Cheap, Effective, Rugged, and Safe method (QuEChERS) as reported in the European Standard EN 15662:2008 (CEN, 2008) is also available for the analysis of difenoconazole residues in high water content, high acid content and dry commodities with an LOQ of 0.01 mg/kg (EFSA, 2017).

Additional validation data for a multiresidue method QuEChERS based on EN15662:2009-02 (CEN, 2008) was submitted in the framework of a recent MRL application (EFSA, 2021). This method based on HPLC-MS/MS was sufficiently validated for enforcement purposes for the determination of difenoconazole residues in matrices with high water content (tomatoes), high oil content (oilseed rape), high acid content (grapes), high protein content/dry (dried broad bean), high starch content/dry (wheat grain) commodities and herbal infusion (a matrix difficult to analyse) at an LOQ of 0.01 mg/kg. An ILV was provided (EFSA, 2021). In that framework, extraction efficiency of the analytical method for enforcement of difenoconazole in high water commodities was demonstrated.

In the framework of the MRL review, the European Union Reference Laboratories (EURLs) provided a QuEChERS multiresidue analytical method using HPLC-MS/MS technique with an LOQ of 0.01 mg/kg for the routine analysis of difenoconazole in high water content, high acid content, high oil content, dry commodities and matrices which are difficult to analyse (tea). Even lower levels were successfully validated down to 0.005 mg/kg for high oil content commodities and in black tea, and down to 0.002 mg/kg for the other three main commodity groups. The analytical standard for difenoconazole is commercially available (EFSA, 2024c; EURLs, 2022).

It should be noted that the above-mentioned methods are not stereoselective and are analysing for difenoconazole (sum of isomers).

An extraction efficiency study was submitted in the context of the MRL application and has been resubmitted in the current one (EFSA, 2021; Spain, 2023b). The efficiency of the extraction procedure used in the analytical method for enforcement of difenoconazole in plant matrices (QuEChERS) was investigated via cross validation against the solvent systems used in the metabolism studies in high water, high acid, high oil content and dry commodities, i.e. methanol/water (80/20 v/v) (used in the metabolism studies on potatoes, grapes, oilseed rape, wheat grain) and acetonitrile (used in the metabolism studies on tomatoes and potatoes), according to SANTE/2017/10632 rev.5 (European Commission, 2023). Comparable levels of incurred residues were extracted from lettuces, olives, strawberries, dry beans (i.e. absolute amounts of extracted residues differed by no more than 30% among the extraction procedures tested) and wheat grains (i.e. absolute amounts of extracted residues differed by no more than 30% between the extraction procedure of the QuEChERS method and the one using methanol/water 80/20 v/v). Therefore, extraction efficiency of the analytical method for enforcement of difenoconazole is sufficiently demonstrated in all plant commodity groups.

The commodities under assessment belong to the high-water content (mangoes, papayas), high acid content (blueberries, citrus fruits), high oil content (soya beans, tree nuts) and dry (chickpeas) commodity groups. EFSA concludes that the methods available are sufficiently validated for the determination of residues of difenoconazole at or above the LOQ of 0.01 mg/kg in the crops under consideration.

1.1.5 | Storage stability of residues in plants

The storage stability of **difenoconazole** in high water content, high oil content, high acid content and dry matrices (covering high starch and high protein matrices[13]) under frozen conditions was assessed in the framework of the MRL review (EFSA, 2024c). The available studies demonstrated storage stability for difenoconazole for at least 24 months when stored under frozen conditions in high water content, high acid content and dry commodities and up to 16 months in high oil content commodities (Appendix B.1.1.2).

[13]According to OECD Guideline 506, not applicable for the present assessment.

The storage stability of the TDMs 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in high water content, high oil content and dry commodities and of triazole lactic acid in high acid content commodities under frozen conditions was investigated in the framework of the EU pesticide peer review of TDMs in light of confirmatory data (EFSA, 2018) and confirmed in the context of the MRL review (EFSA, 2024c).

Additional data on the storage stability of 1,2,4-triazole in hazelnut (high oil content commodity), orange (high acid content commodity) and dried bean (dry commodity) and of TA and TAA in orange (high acid content commodity) were submitted and assessed in the framework of the MRL applications (on fenbuconazole and mefentrifluconazole (EFSA, 2023a, 2023c)). Since the peer review for the renewal of the approval of paclobutrazol is not yet completed, conclusions which are based on these data should be taken as provisional and might need to be reconsidered in the light of the outcome of the peer review.

Overall, for triazole derivative metabolites, it was demonstrated that:

- **1,2,4-T** is stable for up to 6 months in high-water content commodities, up to 12 months in cereals (dry commodities), soya beans and hazelnuts, but not stable in rapeseeds (high-oil content commodities), up to 42 months in high acid content commodities (oranges) and at least 48 months in dried beans (dry commodities);
- **TA** is stable for 15 months in pulses (dry/high protein content commodities), 26 months in cereals (dry/high starch content commodities) and soya beans (high oil content commodity), while the storage stability in rapeseeds (high oil content commodity) remains inconclusive, at least 48 months in high acid content commodities (oranges) and at least 53 months in high water content commodities;
- **TAA**, for at least 25 months in pulses (dry/high protein content commodities), 26 months in cereals (dry/high starch content commodities), 48 months in high acid content commodities (oranges), 53 months in soya beans and rapeseeds (high oil content commodities) and at least 53 months in high water content commodities;
- **TLA**, for at least 48 months in high water content (lettuce) and high acid content commodities (oranges), for 48 months in high oil content (rapeseeds and soya beans), dry/high protein content (dry peas and navy beans) and dry/high starch content commodities (wheat and barley grain).

Considering the lack of stability of 1,2,4-T in rapeseeds and the inconclusive storage stability evidence for TA in rapeseeds, a general conclusion for all high-oil content commodities or across the five different commodity categories cannot be made but individual categories or commodities need to be considered.

Overall, for the commodities under assessment, storage stability is demonstrated for all TDMs, except for TA in tree nuts due to unavailability of specific storage stability data.

The additional studies on storage stability of TDMs provided by Slovenia (2022) and Austria (2022) and assessed in EFSA (2023a, 2023c) 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 should be taken as provisional and might need to be reconsidered in the light of the outcome of the peer review.

1.1.6 | Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological relevance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed for primary crops, rotational crops and processed commodities (EFSA, 2011a, 2018):

- Residue definition for risk assessment:
  - RD-RA1: difenoconazole (sum of isomers);
  - RD-RA2: triazole alanine (TA) and triazole lactic acid (TLA), since these compounds share the same toxicity;
  - RD-RA3: triazole acetic acid (TAA);
  - RD-RA4: 1,2,4- triazole (1,2,4-T).

  Risk assessment residue definitions n. 2, 3 and 4 have been established for triazole active substances by the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted (EFSA, 2018)

- Residue definition for enforcement: difenoconazole (sum of isomers)

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical to the above-mentioned residue definition. The residue definitions for enforcement and risk assessment previously agreed are still applicable to the commodities under the present assessment. However, these residue definitions might be reconsidered in the framework of the ongoing peer review for the renewal of the approval of difenoconazole.

Since difenoconazole consists of four stereo isomers and since the available analytical methods are not stereo selective, the proposed residue definitions for enforcement and risk assessment are derived for the sum of the *R*- and *S*-isomers.

A data gap on the possible preferential metabolism/degradation of the four stereo isomers of difenoconazole in plants was identified during the peer review (EFSA, 2011a). Nonetheless, further data were submitted as confirmatory data and assessed by EFSA (EFSA, 2024). In the absence of toxicological data on the individual isomers of difenoconazole, it was concluded to apply an uncertainty factor (UF) to all plant commodities to accommodate the preferential degradation of diastereomers observed. In order to derive an UF, field trials were submitted for the assessment of the confirmatory data and, in accordance with the EFSA guidance document on stereoisomers (EFSA, 2019b), a UF of 1.3 was derived and is applicable to all plant commodities (EFSA, 2024b, 2024c). This UF was considered in the consumer risk assessment calculations performed under the present assessment for the RD-RA1 (see Section 3).

1.2 | Magnitude of residues in plants

1.2.1 | Magnitude of residues in primary crops

In support of the authorised US uses of difenoconazole on citrus fruits, tree nuts, blueberries, dry peas and soya beans, and the authorised Brazilian uses of difenoconazole on mangoes and papayas, the applicant submitted supervised residue trials on the relevant commodities as described further in detail below.

The samples of the residue trials on citrus fruits, blueberries, mangoes, papayas, chickpeas (dry peas) and soya beans were stored under conditions for which storage stability has been demonstrated for difenoconazole and for the TDMs, with acceptable deviations for difenoconazole in soya bean samples and 1,2,4-T in mango samples. Soya bean samples for difenoconazole quantification were stored for up to 415 days, exceeding the demonstrated storage stability period of 365 days (12 months) in this commodity. However, as no residue decline was observed in the 12-month storage stability study on soya bean and considering that difenoconazole was shown to be stable for up to 16 months in another high oil content commodity (i.e. cotton seed), this deviation is considered minor and is not expected to impact the reliability of the measured residue levels. The same applies to 1,2,4-T in mango samples, which were stored for up to 187 days, slightly exceeding the demonstrated storage stability period of up to 6 months in high water content commodities.

Regarding tree nuts, all samples were stored for up to 25 months, under conditions for which storage stability has been demonstrated for TAA and TLA. For difenoconazole and 1,2,4-T, only samples from 15 of 19 trials were stored within the demonstrated storage stability period (i.e. ≤ 16 months for difenoconazole in high-oil content commodities and ≤ 12 months for 1,2,4-T in hazelnuts). In particular, samples from five trials were stored for up to 15 months, which is beyond the reported storage stability period for 1,2,4-T in hazelnuts. However, this extended storage duration is acceptable based on extrapolated stability data, which supports stability beyond 12 months and up to 15 months. Since a sufficient number of trials is available in support of the authorised US good agricultural practice (GAP) on tree nuts, EFSA disregarded the trials with samples stored beyond the demonstrated storage stability period to exclude uncertainties in the assessment. For TA, there is an indication that the storage period may be covered by the storage stability period in soya beans; however, given the lack of stability of TA in rapeseeds and the unavailability of specific storage stability data on tree nuts, some uncertainties remain.

The methods used in the residue trials for the analysis of difenoconazole (REM 147.08, GRM 066.003A, QuEChERS) and TDM (01062/M004, 160 rev.2) residues are based on HPLC–MS/MS and enable the quantification of residues at or above the following limits of quantification (LOQs):

- **Difenoconazole:** 0.01 mg/kg in citrus fruits, tree nuts, mangoes, papayas, chickpeas and soya beans;
- **1,2,4-T:** 0.01 mg/kg in citrus fruits, tree nuts, blueberries, chickpeas and soya beans, and 0.05 mg/kg in mangoes and papayas;
- **TA:** 0.01 mg/kg in citrus fruits, tree nuts, blueberries, papayas, chickpeas and soya beans, and 0.05 mg/kg in mangoes;
- **TAA:** 0.01 mg/kg in citrus fruits, tree nuts, blueberries, mangoes, papayas, chickpeas and soya beans;
- **TLA:** 0.01 mg/kg in citrus fruits, tree nuts, blueberries, papayas (pulp), chickpeas and soya beans and 0.05 mg/kg in papayas (whole fruit and peel) and mangoes.

According to the assessment of the RMS, the analytical methods were sufficiently validated and fit for purpose (Spain, 2023b). The efficiency of the extraction procedure used in the analytical methods for the quantification of difenoconazole from the residue trials (REM 147.08, GRM 066.003A, QuEChERS) was sufficiently demonstrated via cross validation against the solvent systems used in the metabolism studies in high water, high acid, high oil content and dry commodities, as described for the analytical method for enforcement (Section 1.1.4). The extraction efficiency of the analytical methods for the quantification of TDMs from the residue trials (01062/M004, 160 rev.2) was not assessed in the context of the present application.

In response to EFSA's request for data on the extraction efficiency of analytical methods for TDMs, a study summary from the triazole-derived metabolite group (TDMG) was provided by the applicant for transparency purposes and included in the evaluation report. However, in accordance with the agreement between the TDMG and the European Commission, any new TDMG data will be assessed by the Austrian authority AGES in parallel with the AIR evaluation of paclobutrazol. Therefore, the submitted information were not further assessed by the RMS and EFSA in the current output.

The commodities under assessment belong to the high water content (mangoes, papayas), high acid content (blueberries, citrus fruits), high oil content (soya beans, tree nuts) and dry (chickpeas) commodity groups. EFSA concludes that the methods used to analyse residue trial samples are sufficiently validated and fit for purpose.

Citrus fruits

In support of the authorised US uses of difenoconazole on citrus fruits, the applicant submitted a total of 19 independent supervised residue trials on oranges (10), mandarins (4) and lemons (5).

Trials were conducted in the United States in the 2020 and 2021 growing seasons and consisted of four foliar treatments at a nominal application rate of 140 g a.s./ha performed at BBCH stages between 79 and 89 with an interval between applications of 6–7 days. The trials are compliant with the authorised GAP.

More than half of the trials (11) were designed as decline trials (samples were taken at 0 (corresponding to the intended preharvest interval, PHI), 1, 3, 7 (10 trials) and 10 (10 trials) days after the last application). Samples were analysed for residues of difenoconazole, 1,2,4-triazole, triazole acetic acid, triazole lactic acid and triazole alanine.

Residues were measured in the peel, pulp and whole fruit. Additionally, residues in the whole fruit were recalculated from residues in peel and pulp. The RMS calculated the average residue levels for the whole fruit based on both whole and reconstituted samples, treating them as duplicates. However, EFSA only considered residue levels measured directly from the whole fruit. Residues in the treated samples were in the range of 0.168–0.568 mg/kg in the whole fruit and < 0.01–0.070 mg/kg in the pulp for difenoconazole.

Regarding TDMs, residues were below the LOQ of 0.01 mg/kg for 1,2,4-triazole, triazole acetic acid and triazole lactic acid in pulp and in the range of < 0.01–0.021 mg/kg for triazole alanine in pulp. In the untreated samples, residues above the LOQ of 0.01 mg/kg were measured in the whole fruit for TA (range of < 0.01–0.016 mg/kg) and TLA (range of < 0.01–0.012 mg/kg) and in pulp for TA (range of < 0.01–0.020 mg/kg). If TDM residues were higher in untreated samples than in the treated ones, the higher values were considered for the risk assessment to represent the worst-case scenario. For the purpose of this assessment, only residue levels measured in the whole fruit (for difenoconazole) and in pulp (for difenoconazole and TDMs) are reported in the overview of residue data (Appendix B.1.2.1).

The submitted data are sufficient to derive an MRL of 1 mg/kg for difenoconazole in the whole group of citrus fruits. However, the derived MRL is higher than the MRL in place in the exporting country (0.6 mg/kg)[14]; therefore, to align with the US tolerance, an MRL of 0.6 mg/kg is proposed. Given that the proposed MRL is identical to the existing MRL (Reg. 2024/2612) and the tentative MRL proposed by the MRL review (not implemented yet), no MRL modification was requested by the RMS and the applicant. It has to be noted that, following the MRL review, two options were proposed for the MRL in citrus fruits: maintaining the MRL at 0.6 mg/kg or lowering it to the LOQ. Based on the data assessed in the present application, an MRL of 0.6 mg/kg is supported.

Tree nuts

In support of the authorised US GAP of difenoconazole on tree nuts, the applicant submitted 20 GAP-compliant supervised residue trials on almond (10) and pecan (10). This data set includes 10 trials (5 on almonds and 5 on pecans) which were used for MRL setting in USA. Two of the submitted residue trials on almonds were considered not independent by EFSA and were therefore treated as replicates, in accordance with SANTE/2019/12752. As a consequence, the final data set included 19 independent and GAP-compliant residue trials. As reported above, due to sample storage exceeding the demonstrated storage stability period in five trials (three independent and two non-independent trials), only data from 15 trials were used to calculate MRL for difenoconazole and risk assessment values for difenoconazole and TDMs.

Trials were conducted in the United States in the 2006 (4), 2007 (5) and 2020 (10) growing season and consisted of four foliar treatments at a nominal application rate of 128 g a.s./ha performed at BBCH stages between 68 and 89 with an interval between application of 11–16 days (max 19 days between the second and the third applications in one trial on almonds).

Seven residue trials (more than half of the minimum number of required trials) were designed as decline trials (samples were taken at 7, 9–10 (in 6 trials), 13–14 (corresponding to the intended preharvest interval, PHI), 17–18 (in 6 trials) and 21 days after the last application). A decline in residue levels was not evident, as higher residues were frequently recorded at the latest sampling points. In these cases, the highest residue value was selected for MRL and risk assessment value calculations. Samples were analysed for residues of difenoconazole, 1,2,4-triazole, triazole acetic acid and triazole alanine in all trials and for residues of triazole lactic acid in the 10 trials conducted in 2020. Duplicate samples were collected and analysed separately; residue results are reported as the mean of the two residue values measured in each duplicate.

Residues in the treated samples were in the range of < 0.01–0.02 mg/kg for difenoconazole, in the range of < 0.01–0.187 mg/kg for 1,2,4-triazole, in the range of < 0.01–0.045 mg/kg for triazole acetic acid, in the range of 0.018–4.234 mg/kg for triazole alanine and in the range of < 0.01–0.082 mg/kg for triazole lactic acid.

In the untreated samples, residues above the LOQ of 0.01 mg/kg were measured for 1,2,4-T (range < 0.01–0.128 mg/kg), TAA (range of < 0.01–0.134 mg/kg), TA (range of < 0.01–3.505 mg/kg) and TLA (range of < 0.01–0.399 mg/kg). If residues were higher in untreated samples than in treated ones, the higher values were considered for the risk assessment to represent a worst-case scenario.

The applicant and the RMS proposed to extrapolate the residue data on almonds and pecans to the whole group of tree nuts. Such an extrapolation is acceptable according to EU Technical Guidelines SANTE/2019/12752 (European Commission, 2020b) and is sufficiently supported by data. Based on the submitted data from 15 trials, an MRL proposal of

[14] https://www.govinfo.gov/content/pkg/CFR-2021-title40-vol26/pdf/CFR-2021-title40-vol26-sec180-475.pdf.

0.03 mg/kg is derived for difenoconazole in the whole group of tree nuts. It is noted that this differs from the RMS proposal of 0.02 mg/kg, calculated based on 19 trials, including those with longer storage intervals. The US tolerance is set at 0.03 mg/kg.[14]

The existing EU MRL is set at the LOQ of 0.05 mg/kg. It has to be noted that, following the MRL review, different MRL options were proposed for almonds and all other tree nuts (not implemented yet): maintaining the MRL at 0.05 mg/kg or lowering it to the LOQ for almonds; lowering the MRL to 0.03 mg/kg or to the LOQ for all other tree nut commodities. However, the data assessed in the present application support an MRL of 0.03 mg/kg for the whole group of tree nuts. The overview of residue data is provided in Appendix B.1.2.1.

Blueberries

To provide new residue data on TDMs, the applicant submitted five independent supervised residue trials on blueberries, compliant with the critical authorised US GAP of difenoconazole on blueberries (4 × 128 g a.s./ha, interval: 7 days, PHI: 7 days). No MRL modification was requested.

Trials were conducted in the United States in the 2020 growing season and consisted of four foliar treatments at a nominal application rate of 128 g a.s./ha performed at BBCH stages between 76 and 89 with an interval between application of 6–8 days.

All trials were designed as decline trials (samples were taken at 0, 3, 7 (corresponding to the intended preharvest interval, PHI), 10 and 14 days after the last application). Samples were analysed for residues of 1,2,4-triazole, triazole acetic acid, triazole lactic acid and triazole alanine. Duplicate samples were collected and analysed separately; residue results are reported as the mean of the two residues values measured in each duplicate.

Residues in the treated samples were all below the LOQ of 0.01 mg/kg for 1,2,4-triazole, in the range of < 0.01–0.01 mg/kg for triazole acetic acid, in the range of < 0.01–0.033 mg/kg for triazole alanine and in the range of < 0.01–0.121 for triazole lactic acid. In the untreated samples, residues above the LOQ of 0.01 mg/kg were measured for TAA (range of < 0.01–0.01 mg/kg), TA (range of < 0.01–0.01 mg/kg) and TLA (range of < 0.01–0.10 mg/kg). If residues were higher in untreated samples than in treated ones, the higher values were considered for the risk assessment to represent a worst-case scenario.

Mangoes

In support of the authorised Brazilian use of difenoconazole on mangoes, the applicant submitted four independent and GAP-compliant supervised residue trials on mangoes.

The trials were conducted in Brazil in the 2020 and 2021 growing seasons and consisted of three foliar treatments at a nominal application rate of 125 g a.s./ha performed at BBCH stages between 73 and 85 with an interval between application of 14 days.

Half of the trials were designed as decline trials (samples were taken at 0, 3, 7 (corresponding to the intended preharvest interval, PHI), 10 and 14 days after the last application). Residues were measured in peel and pulp; residues in the whole fruit were recalculated from residues in peel and pulp. Samples were analysed for residues of difenoconazole, 1,2,4-triazole, triazole acetic acid, triazole lactic acid and triazole alanine.

Residues in the treated samples (whole fruit) were in the range of 0.03–0.11 mg/kg for difenoconazole and were below the LOQ of 0.05 mg/kg for 1,2,4-triazole, in the range of < 0.01–0.11 mg/kg for triazole acetic acid, in the range of < 0.05–0.68 mg/kg for triazole alanine and in the range of < 0.05–0.67 for triazole lactic acid.

No residues of difenoconazole and 1,2,4-triazole were measured in any of the untreated plot samples at or above the LOQs of 0.01 mg/kg for difenoconazole and 0.05 mg/kg for 1,2,4-triazole whereas residues above the LOQs of 0.01 and 0.05 mg/kg were measured in untreated mango fruit samples for TAA (range of < 0.01–0.1 mg/kg), TA (range of < 0.05–0.42 mg/kg) and TLA (range of < 0.05–0.42 mg/kg). If residues were higher in untreated samples than in treated ones, the higher values were considered for the risk assessment to represent a worst-case scenario.

The submitted data are sufficient to derive an MRL proposal of 0.2 mg/kg for difenoconazole in mangoes. The tolerance in Brazil is 0.2 mg/kg (Spain, 2023b). The overview of residue data is provided in Appendix B.1.2.1.

Papayas

In support of the authorised Brazilian use of difenoconazole on papayas, the applicant submitted four independent and GAP-compliant supervised residue trials on papayas.

The trials were conducted in Brazil in the 2021 growing season and consisted of four foliar treatments at a nominal application rate of 62.5 g a.s./ha performed at BBCH stages between 71 and 89 with an interval between application of 14 days.

Half of the trials were designed as decline trials (samples were taken at 0, 1, 3 (corresponding to the intended preharvest interval, PHI), 7 and 10 days after the last application). Residues were measured in peel and pulp; residues in the whole fruit were recalculated from residues in peel and pulp. Samples were analysed for residues of difenoconazole, 1,2,4-triazole, triazole acetic acid, triazole lactic acid and triazole alanine.

Residues in the treated samples (whole fruit) were in the range of 0.03–0.13 mg/kg for difenoconazole, all below the LOQ of 0.05 mg/kg for 1,2,4-triazole, in the range of < 0.01–0.04 mg/kg for triazole acetic acid, in the range of < 0.01–1.98 mg/kg for triazole alanine and in the range of < 0.05–0.22 for triazole lactic acid.

No residues of difenoconazole, 1,2,4-triazole, triazole acetic acid and triazole lactic acid were measured in whole fruit from any of the untreated plots at or above the LOQs of 0.01 mg/kg (for difenoconazole and triazole acetic acid) and 0.05 mg/kg (for 1,2,4-triazole and triazole lactic acid); whereas residues above the LOQs of 0.01 mg/kg were measured in untreated papaya fruit samples for triazole alanine (range of < 0.01–0.03 mg/kg in whole fruit; highest residue in peel of 0.08 mg/kg). If residues were higher in untreated samples than in treated ones, the higher values were considered for the risk assessment to represent a worst-case scenario.

The submitted data are sufficient to derive an MRL proposal of 0.3 mg/kg for difenoconazole in papayas. The tolerance in Brazil is 0.3 mg/kg (Spain, 2023b). The overview of residue data is provided in Appendix B.1.2.1.

Chickpeas (dry peas)

In support of the authorised US GAP of difenoconazole on chickpeas (classified under code 0300030 Peas), the applicant submitted eight independent and GAP-compliant supervised residue trials on chickpeas. An additional GAP-compliant trial was initially included in the dossier and an MRL modification for difenoconazole was originally proposed. However, this trial was later excluded from the data set by the RMS after being identified as an outlier, and, as a result, no modification of the existing MRL was necessary nor requested by the RMS and the applicant. Nevertheless, the remaining trials were assessed by EFSA since these provide new residue data on TDMs. Furthermore, considering the options proposed in the MRL review to either maintain the existing MRL of 0.15 mg/kg or lower it to the LOQ (EFSA, 2024c), the data assessed in the present application are relevant to support maintaining the existing MRL in chickpeas.

Trials were conducted in the United States in the 2020 growing season and consisted of four foliar treatments at a nominal application rate of 128 g a.s./ha performed at BBCH stages between 50 and 88 with an interval between application of 12–16 days.

More than half of the trials (5) were designed as decline trials (samples were taken at 7–8, 10, 14–17 (corresponding to the intended preharvest interval, PHI of 14 days) and 21–22 days after the last application). Samples were analysed for residues of difenoconazole, 1,2,4-triazole, triazole acetic acid, triazole lactic acid and triazole alanine. Duplicate samples were collected and analysed separately; residue results are reported as the mean of the two residue values measured in each duplicate.

Residues in the treated samples were in the range of < 0.01–0.068 mg/kg for difenoconazole, all below the LOQ of 0.01 mg/kg for 1,2,4-triazole, in the range of 0.02–0.338 mg/kg for triazole alanine, in the range of < 0.005–0.023 mg/kg for triazole acetic acid and in the range of < 0.01–0.053 mg/kg for triazole lactic acid. In the untreated samples, residues above the LOQ of 0.01 mg/kg were measured for TAA (range of < 0.01–0.015 mg/kg), TA (range of < 0.01–0.464 mg/kg) and TLA (range of < 0.01–0.039 mg/kg). If residues were higher in untreated samples than in treated ones, the higher values were considered for the risk assessment to represent a worst-case scenario.

The submitted data were sufficient to derive an MRL of 0.15 mg/kg for difenoconazole in chickpeas (0300030). The tolerance in the USA is 0.2 mg/kg. As the MRL derived is equal to the existing one, no MRL modification is needed or was requested. The trials assessed provide indication that the current MRL should be maintained. The risk assessment values derived from the submitted data set are lower than those from a previous assessment. The overview of residue data is provided in Appendix B.1.2.1.

Soya beans

In support of the authorised US GAP of difenoconazole on soya bean, the applicant submitted nine independent and GAP-compliant supervised residue trials on soya beans.

The trials were conducted in USA in the 2020 growing season and consisted of two foliar treatments at a nominal application rate of 128 g a.s./ha performed at BBCH stages between 79 and 89 with an interval between applications of 6–8 days.

Half of the trials (5) were designed as decline trials (samples were taken at 6–8, 9–11, 13–15 (corresponding to the intended preharvest interval, PHI of 14 days), 16–18 and 20–22 days after the last application). Samples were analysed for residues of difenoconazole, 1,2,4-triazole, triazole acetic acid, triazole lactic acid and triazole alanine. Duplicate samples were collected and analysed separately; residue results are reported as the mean of the two residues values measured in each duplicate. Residues in the treated samples were in the range of < 0.01–0.169 mg/kg for difenoconazole, all below the LOQ of 0.01 mg/kg for 1,2,4-triazole, in the range of < 0.01–0.056 mg/kg for triazole acetic acid, in the range of < 0.01–0.537 mg/kg for triazole alanine and in the range of < 0.01–0.127 for triazole lactic acid.

No residues of difenoconazole and 1,2,4-triazole were measured from any of the untreated plots at or above the LOQ of 0.01 mg/kg; whereas residues above the LOQs of 0.01 mg/kg were measured in untreated soya bean samples for triazole alanine (range of < 0.01–0.407 mg/kg), triazole acetic acid (range of < 0.01–0.039 mg/kg) and triazole lactic acid (range of < 0.01–0.097 mg/kg). If residues were higher in untreated samples than in treated ones, the higher values were considered for the risk assessment to represent a worst-case scenario.

The submitted data are sufficient to derive an MRL of 0.3 mg/kg for difenoconazole in soya beans. The tolerance in the USA is 0.15 mg/kg.[14] It is noted that the MRL derived is driven by the HR of 0.169 mg/kg and that both the MRL and HR exceed the current MRL of 0.15 mg/kg in the exporting country. In EU, the current MRL for difenoconazole in soya beans is 0.1 mg/kg (Reg. (EU) No 2024/2612). Based on the available residue data, an increase of the EU MRL would be necessary, but should be limited to 0.15 mg/kg, corresponding to the MRL in place in the exporting country. The overview of residue data is provided in Appendix B.1.2.1.

1.2.2 | Magnitude of residues in rotational crops

Investigations of residues in rotational crops are not required for imported crops.

1.2.3 | Magnitude of residues in processed commodities

Three new processing studies on oranges, almonds and soya beans were submitted in the context of the present assessment (Spain, 2023b). The studies investigate the effect of industrial processing of the above-mentioned raw agricultural commodities (RACs) on the magnitude of difenoconazole and TDM residues in processed commodities of soya beans, oranges and almonds.

The number and quality of the processing studies on oranges, almonds and soya beans is sufficient to derive robust processing factors for **difenoconazole**, which are recommended to be included in Annex VI of Regulation (EC) No 396/2005. The submitted trials indicate that industrial processing leads to a reduction of residues of difenoconazole in orange juice, marmalade and molasses, and soya bean seed pollards, toasted meal, defatted flour, soy milk, miso, soy sauce, refined oil, crude oil and tofu and in almonds 'milk' (median PFs ranging between 0.03 and 0.45). When concentrations of difenoconazole were below the LOQ in processed commodities while quantified in RAC, a PF could be calculated based on the LOQ value in processed commodities. In these cases, the PF was reported with the qualifier '<'. In orange wet pomace, dry pomace, oil and meal, soya bean seed hulls and roasted almonds, a concentration of residues of difenoconazole was observed.

Regarding the TDMs, PF values could also be calculated for each metabolite separately. PFs were calculated and reported with the qualifier '<' when concentrations of the metabolite were below the LOQ in processed commodities while quantified in RAC. For certain combination TDM/processed commodities, the formation of TDM during the process was observed, which is indicated by metabolite concentrations below the LOQ in RAC but quantified above LOQ in processed commodity (PC). In those cases, PFs were calculated and reported with the qualifier '>'. These PFs are not considered precise enough for the derivation of median PF but still provide relevant information on the TDM formation during processing. In those cases, the individual PFs were therefore considered as qualitative information only. Finally, when TDM concentrations were below LOQ in RAC and in PC, no PFs were calculated. The following considerations could be made for each TDM:

- For **1,2,4-triazole**, PFs could only be calculated for orange oil, orange meal, orange molasses, almond oil, almond 'milk' and roasted almonds due to the levels below LOQ in RAC and PC for these commodities. It can be noted that, in orange oil, orange meal and orange molasses, the formation of 1,2,4-triazole was observed in the processed commodities as residue concentration in the RAC were below the LOQ but were quantified in PC. In almond oil and 'milk', a reduction of residues was observed (PF < 0.08), with no quantified 1,2,4-triazole in these processed commodities. In roasted almonds, a concentration of residues was observed (PF = 2). However, no median PFs could be derived due to the lack of robust data.
- Regarding **triazole alanine**, a reduction of residues was observed in soya bean seed hulls, pollards, soy milk, miso, soy sauce, refined oil, crude oil and tofu, almond oil, almond 'milk' and roasted almonds (median PFs ranging between < 0.01 and 0.93) and a concentration of residues was observed in soya bean seed toasted meal and defatted flour (median PFs of 1.57 and 1.20, respectively). It is noted that, for orange wet pomace and molasses, no precise PFs could be derived as residue concentrations were below LOQ in RAC, but the formation of triazole alanine was observed with quantified concentration these processed commodities. Robust median PFs could be derived for all listed commodities, except orange wet pomace and molasses.
- Regarding **triazole acetic acid**, a reduction of residues was observed in soya bean seed hulls, soy 'milk', refined oil, crude oil and tofu, almond oil, almond 'milk' and roasted almonds (median PFs ranging between < 0.38 and 0.73) and a concentration of residues was found in soya bean seed pollards, toasted meal, defatted flour, miso, soy sauce and roasted almonds (median PFs ranging between 1.11 and 2.76). For orange molasses, no precise PFs could be derived as residue concentrations were below LOQ in RAC but the formation of triazole acetic acid was observed with quantified concentration in this processed commodity. Robust median PFs could be derived for all listed commodities, except orange molasses.
- Regarding **triazole lactic acid**, a reduction of residues was observed in soya bean seed soy 'milk', miso, soy sauce, refined oil, crude oil and tofu, almond oil and almond 'milk' (median PFs ranging between < 0.16 and 0.63). A concentration of residues was found in soya bean seed hulls, pollards, toasted meal, defatted flour and in roasted almonds (median PFs ranging between 1.02 and 1.70). For orange dry pomace, orange meal and orange molasses, no precise PFs could be derived as residue concentrations were below the LOQ in RAC but the formation of triazole lactic acid was observed with quantified concentration these processed commodities. Robust median PFs could be derived for all listed commodities, except lemon peeled, orange dry pomace, orange meal and orange molasses.

In addition, the primary crop residue trials performed on orange, mandarin and lemons allowed calculations of peeling factors for citrus fruits. For difenoconazole, an important decrease of concentration is observed in citrus pulp with an overall median PF of 0.072 (considering all data on citrus). For triazole alanine, a median PF of 1.15 was derived based on orange and mandarin data, suggesting that this metabolite is more present in the pulp than in the peel. For 1,2,4-triazole and

triazole acetic acid, no peeling factor could be derived because this metabolite remained below LOQ in whole fruits and in pulp. For triazole lactic acid, only one lemon trial with residue above LOQ in RAC and below LOQ in pulp was available (< 0.935), which did not allow to derive a median PF.

For the other commodities under assessment in the present opinion (blueberries, chickpeas, mangoes and papayas), no studies on the effects of processing on the magnitude of difenoconazole and TDM residues have been submitted. However, such studies are not required considering the low individual contribution of these crops to the total consumer exposure.

1.2.4 | Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for citrus fruits, tree nuts, peas (dry) and soya beans in support of the authorised US GAPs and for mangoes and papayas in support of the authorised Brazilian GAPs (Section B.4). In Section 3, EFSA assessed whether residues in these crops resulting from the authorised uses are likely to pose a consumer health risk.

2 | RESIDUES IN LIVESTOCK

Citrus (dried pulp) and soya beans (seed, meal, hulls) can be used for feed purposes. Considering that the MRL request for dry peas is triggered by the US authorised use in chickpeas only, the input of dry pea seeds in the livestock dietary burden was not considered relevant. Hence, the previous dietary burden calculation for livestock was updated to estimate whether the authorised uses of difenoconazole in the USA on citrus fruits and soya beans would have an impact on residues expected in food of animal origin.

For difenoconazole (RD-RA1), the latest livestock dietary burden has been calculated in the previous EFSA reasoned opinion on the review of the existing MRLs for difenoconazole (EFSA, 2024c). This dietary burden calculation was now updated with the new risk assessment values for difenoconazole derived for citrus fruits (dried pulp) and soya beans (seed, meal, hulls) under the present MRL application. For both commodities, the STMR values derived in the present opinion were added in the dietary burden calculation. The PF derived in the present opinion for citrus-dried pulp was also considered.

The input values for the exposure calculations for livestock are presented in Appendix D.1. The results of the dietary burden calculation are presented in Section B.2. The trigger value of 0.1 mg/kg DM is exceeded for all livestock groups, but there is no difference between the results of updated calculations and the dietary burdens calculated in the MRL review (EFSA, 2024c). The main feed contributors are still mangel beet fodder and sugar beet tops. Consequently, it is not needed to further assess the residues of difenoconazole in commodities of animal origin as this assessment is covered by the outcome of the MRL review. The uses under assessment do not trigger any modifications of the existing MRLs. The MRL proposals calculated in the MRL review were lower than the existing Codex MRLs for commodities from swine, bovine, sheep and goat, which are still implemented in the MRL Regulation. For poultry products, the MRLs were set at the enforcement LOQ of 0.01 mg/kg (EFSA, 2024c).

In addition, livestock are exposed to triazole derivative metabolites (TDMs)**: TA and TLA (RD-RA2), TAA (RD-RA3) and 1,2,4-triazole (RD-RA4)**. The livestock dietary burden for the TDM residues arising from the use of various triazole fungicides has been calculated in the framework of the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data (EFSA, 2018). An update of these dietary burden calculations with the new risk assessment values for TA, TLA, TAA and 1,2,4-triazole derived for citrus fruits (dried pulp) and soya beans (seed, meal, hulls) under the present MRL application would in theory be needed. However, a comparison of the risk assessment values for citrus and soya beans derived in the present opinion with those derived in the peer review (EFSA, 2018) indicated that such an update was not necessary since the worst-case STMR values considered in the peer review were higher than those derived in the present opinion (see **Table 1**). It is therefore concluded that the new data on TDMs assessed in the present dossier do not affect the current residue levels in commodities of animal origin.

TABLE 1 Comparison of risk assessment values for animal dietary burden.

	STMR value (EFSA, 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)**
Citrus (whole fruits)	0.05[a]/0.01	0.32[b]/0.019	0.05[a]/< 0.01	0.04[c]/0.012
Soya beans (seeds)	0.05[d]/0.01	1.04[e]/0.038	0.12[f]/0.015	0.065[g]/0.047

[a]The worst-case STMR value derived from the data on bananas (2018b).
[b]The worst-case STMR value derived from the data on stone fruits (EFSA, 2018).
[c]The worst-case STMR value derived from the data on berries (EFSA, 2018).
[d]The worst-case STMR value derived from the data on soya beans (EFSA, 2018).
[e]The worst-case STMR value derived from the data on rapeseeds (EFSA, 2018).
[f]The worst-case STMR value derived from the data on sunflower seeds (EFSA, 2018).
[g]The worst-case STMR value derived from the data on linseeds (EFSA, 2018).

Although further assessment of the residues in commodities of animal origin is not needed, EFSA reported below a summary of the residue definitions derived for commodities of animal origin and an update on the assessment of the analytical methods and extraction efficiency.

The residue definition for enforcement proposed in the peer review was limited to the metabolite difenoconazole-alcohol (CGA205375) only. It is noted that although metabolite CGA205375 was found to be the main residue in products of animal origin, the existing residue definition for enforcement as set in Regulation (EC) No 396/2005 is difenoconazole alone. A revision of the residue definition for enforcement might be considered by the risk managers to reflect the proposal of the EU pesticides peer review and MRL review: difenoconazole-alcohol (CGA205375), free and conjugated, expressed as difenoconazole.

For risk assessment, the following residue definitions were proposed in the peer review of difenoconazole (EFSA, 2011a) and confirmatory data of TDMs (EFSA, 2018):

1. Difenoconazole alcohol (CGA205375), expressed as difenoconazole.
2. Triazole alanine (TA) and triazole lactic acid (TLA), since these compounds share the same toxicity.
3. Triazole acetic acid (TAA).
4. 1,2,4- triazole (1,2,4-T).

It is noted that the risk assessment residue definition derived by the JMPR is the sum of difenoconazole and difenoconazole alcohol (CGA205375) expressed as difenoconazole (FAO and WHO, 2013).

An analytical method for enforcement using HPLC-MS/MS was assessed in the framework of the peer review and was fully validated for the determination of difenoconazole and of CGA205375, with an LOQ of 0.01 mg/kg for each compound, in all animal tissues, fat and eggs, and of 0.005 mg/kg in milk (EFSA, 2011a; Sweden, 2006). An additional method was provided and assessed in a previous MRL application (EFSA, 2021), based on HPLC-MS/MS with the same LOQs.

According to the EURLs, metabolite CGA205375 can be monitored in liver and milk by using the QuEChERS method in routine analyses, with an LOQ of 0.01 mg/kg (even lower levels down to 0.005 mg/kg were successfully validated). Based on the experience gained in these matrices, it is concluded that the LOQ of 0.01 mg/kg is also achievable for muscle, fat, kidney and eggs. The LOQ of 0.01 mg/kg is also achievable for the enforcement of parent difenoconazole in muscle, fat, liver, kidney and milk. Considering the molecular weights of these two compounds, an LOQ of 0.012 mg/kg was calculated for the enforcement of the proposed residue definition, namely difenoconazole-alcohol (CGA205375), expressed as difenoconazole (EURLs, 2022). According to the EURLs, the analytical standard for difenoconazole and CGA205375 is commercially available.

A study to demonstrate **the extraction efficiency** of analytical method for enforcement in muscle, fat, liver and egg yolk was submitted in the context of the previous MRL application (EFSA, 2021). The extraction efficiency of acetonitrile/water (80/20 v/v), which is the extraction media used to extract difenoconazole and CGA205375 from animal products, was investigated in muscle, fat, liver and egg yolk using incurred radiolabelled sample material from poultry metabolism study (radio-cross-validation) according to the requirements of SANTE/2017/10632 rev. 5 (European Commission, 2023). Difenoconazole and CGA205375 residue amounts extracted by the extraction procedures of the analytical method for enforcement were compared to the residue amounts extracted by the extraction procedures of the analytical method used in the metabolism studies. Comparable levels of incurred residues were extracted from meat, fat, liver and egg yolk (i.e. absolute amounts of extracted residues and %TRR differ by no more than 30% with the extraction procedures tested); therefore, extraction efficiency is sufficiently demonstrated in these commodities (European Commission, 2023). Additional information on the extraction efficiency of the analytical method for enforcement in milk were requested to the applicant and were provided for the current assessment. Considering that the extraction procedures used in the analytical method for enforcement in milk (acetonitrile/water 80/20 v/v) are comparable to those used in the lactating goat metabolism studies (acetonitrile), with an acceptable difference of no more than 20%, the extraction efficiency in milk is also considered sufficiently demonstrated (Spain, 2023b).

3 | CONSUMER RISK ASSESSMENT

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018c, 2019a). 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).

Separate consumer risk assessments were conducted for the parent difenoconazole and the TDMs.

Difenoconazole

The toxicological reference values for difenoconazole used in the risk assessment (i.e. ADI of 0.01 mg/kg body weight (bw) and acute reference dose (ARfD) value of 0.16 mg/kg bw) were derived in the framework of the EU pesticides peer review (EFSA, 2011a; European Commission, 2013). For the metabolite difenoconazole alcohol (CGA205375), no toxicological reference values were derived in the EU pesticides peer review and no conclusion on its toxicity was derived (EFSA, 2011a).

The toxicological profile of this metabolite is being assessed in the framework of the renewal of the approval process of difenoconazole which is currently ongoing. Depending on the outcome of this assessment, the conclusions derived in the previous and present opinions on the consumer risk assessment resulting from the intake of animal commodities might need to be revised.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities under assessment (except for blueberries for which data on difenoconazole were not submitted), in accordance with the internationally agreed methodology. The calculations were based on the highest residue (HR) levels expected in tree nuts, mangoes and papayas according to the submitted residue trials, and in citrus fruits according to the FAO and the WHO (2013). The median residue (STMR) levels were considered for soya beans (according to the submitted residue trials) and for dry peas (according to FAO and WHO, 2017). The risk assessment values were multiplied by the uncertainty factor (UF) of 1.3 to accommodate the preferential degradation of difenoconazole diastereomers as proposed in the MRL review (EFSA, 2024c). For mangoes and papayas, the HR levels measured in the pulp were used. For citrus fruits, the peeling factor (PeF) derived in the present assessment was also applied. The complete list of input values can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for any of the crops assessed in this application. The highest estimated exposure for raw agricultural commodities accounted to 3.8% of the ARfD for oranges. The highest estimated exposure for processed commodities accounted to 6.9% of the ARfD for orange juice (see Appendix B3).

Long-term (chronic) dietary risk assessment

A comprehensive long-term exposure assessment was performed in the framework of the MRL review, considering the existing uses at EU and non-EU level (EFSA, 2024c). EFSA updated the calculation with the median residue (STMR) values expected in tree nuts, mangoes, papayas and soya beans according to the residue trials submitted in support of this MRL application. For citrus fruits and dry peas, the higher STMR values derived in the FAO and the WHO (2013, 2017), which are associated with the current MRLs in place, were used. For blueberries, the tentative MRL option of 4 mg/kg derived by EFSA (2024c) was considered in the chronic exposure, although not supported by data. Uncertainty factors (UFs) of 1.3 and 2 were also applied, to accommodate the preferential degradation of difenoconazole diastereomers in plant and animal commodities, respectively.

For several commodities (e.g. blueberries, passion fruits, spices (buds, flower stigma, aril)), the MRL review concluded that the existing MRLs were not supported by data and a risk management decision was required on whether to maintain these MRLs or to lower their value to the enforcement LOQ. The conclusions of the MRL review have not been endorsed yet, however, to refine the chronic exposure, which showed a narrow margin of safety in the previous Art. 10 MRL application on wheat and rye (EFSA, 2023b) reaching 98% of the ADI for NL toddler diet, the highest between the MRL options proposed in the MRL review for these commodities were tentatively considered in the present chronic exposure estimates.

For animal commodities, the STMR values supporting the existing EU MRLs and derived by the JMPR (FAO and WHO, 2013) were used as input values. It is noted that the risk assessment values correspond to the sum of difenoconazole and difenoconazole alcohol (CGA205375) expressed as difenoconazole, assuming that parent and metabolite have a similar toxicological profile. Noting that the toxicological profile of metabolite CGA205375 has not been addressed, the consumer risk assessment resulting from the intake of animal commodities remains indicative and might be subject to revision once the renewal of the approval process for difenoconazole is finalised. The risk assessment values associated with the Codex MRLs have been assessed in the MRL review (EFSA, 2024c) and are still considered in the present chronic estimates on a tentative basis.

Provided that conclusions of the MRL review are endorsed, no long-term consumer intake concerns were identified for the existing uses of difenoconazole and for the import tolerances under assessment. The estimated indicative long-term dietary exposure accounted for a maximum of 85% of the ADI (NL toddler diet). The highest estimated exposure from the commodities under assessment accounted to 0.63% of the ADI for soya beans (see Appendix B3).

TDMs

The toxicological reference values for each triazole derivative metabolite (i.e. ADI of 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; ARfD of 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) were derived in the framework of the pesticide risk assessment of the TDMs in light of confirmatory data (EFSA, 2018b) and formally taken note by the European Commission (European Commission, 2020a).

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities under assessment, in accordance with the internationally agreed methodology. The calculations were based on the highest residue (HR) levels expected in citrus fruits, tree nuts, blueberries, mangoes and papayas, and the median residue (STMR) levels expected in dry peas and soya

beans, according to the submitted residue trials. For citrus fruits, mangoes and papayas, the HR levels measured in the pulp were used. The complete list of input values can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for any of the crops assessed in this application. The highest estimated exposures (% of the ARfD) accounted to 3.9% in mangoes for 1,2,4-T, 0.9% in mangoes for TAA and to 22.3% in coconuts for the sum of TA and TLA (see Appendix B3). However, the short-term risk assessment for the sum of TA and TLA is affected by uncertainties due to the lack of information on storage stability of TA in tree nuts.

Long-term (chronic) dietary risk assessment

A comprehensive long-term exposure assessment, considering all crops in which TDMs might be present from the uses of all pesticides belonging to the class of triazole fungicides, was performed in the framework of the pesticide risk assessment for the TDMs in light of confirmatory data (EFSA, 2018b).[15] An update of this calculation was performed under the previous assessment on mefentrifluconazole in various commodities (EFSA, 2023c).[16]

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 derived in previous assessments triggering update of the consumer exposure to TDMs (EFSA, 2018b, 2023c) 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 (EFSA, 2018b, 2023c)/STMR value derived under present assessment[a]			
Crop under consideration	**1,2,4-triazole (1,2,4-T)**	**Triazole alanine (TA)**	**Triazole acetic acid (TAA)**	**Triazole lactic acid (TLA)**
Citrus fruits	0.05[b]/0.01[c]	0.32[d]/0.01[c]	0.05[e]/0.01[c]	0.04[f]/0.01[c]
Tree nuts, except hazelnuts/cobnuts and pistachios	–/**0.01**	–/**0.26**	–/**0.01**	–/**0.02**
Hazelnuts/cobnuts	–/**0.01**	0.15[g]/**0.26**	0.01[g]/0.01	0.08[g]/0.02
Pistachios	–/**0.01**	1.15[h]/0.26	0.01[h]/0.01	0.12[h]/0.02
Blueberries	0.01[i]/0.01	0.06[j]/0.01	0.05[e]/0.01	0.04[f]/0.04
Mangoes	–/**< 0.05**[c]	–/**0.42**[c]	–/**0.07**[c]	–/**0.26**[c]
Papayas	–/**< 0.05**[c]	–/**0.10**[c]	–/**< 0.01**[c]	–/**0.03**[c]
Dry peas	0.05[k]/0.01	0.20[l]/0.12	0.05[m]/0.01	0.01[m]/**0.02**
Soya beans	0.05[n]/< 0.01	1.04[o]/0.04	0.12[p]/0.02	0.07[q]/0.05

[a]STMR values in bold indicate those newly derived (previously not available) or higher than the ones considered in the previous TDM assessments (EFSA, 2018, 2023c).
[b]Worst-case STMR value derived from residue data on epoxiconazole in bananas (EFSA, 2018).
[c]STMR derived from residue data on fruit pulp.
[d]Worst-case STMR value derived from residue data on fenbuconazole in cherries (EFSA, 2018).
[e]Worst-case STMR value derived from residue data on penconazole in raspberries (EFSA, 2018).
[f]Worst-case STMR value derived from residue data on difenoconazole in grapes (EFSA, 2018).
[g]Worst-case STMR value derived from residue data on mefentrifluconazole in hazelnuts (EFSA, 2023c).
[h]Worst-case STMR value derived from residue data on mefentrifluconazole in pistachios (EFSA, 2023c).
[i]Worst-case STMR value derived from residue data on myclobutanil in grapes (EFSA, 2018).
[j]Worst-case STMR value derived from residue data on difenoconazole in raspberries (EFSA, 2018).
[k]Worst-case STMR value derived from residue data on epoxiconazole in dry beans (EFSA, 2018).
[l]Worst-case STMR value derived from residue data on mefentrifluconazole in dry peas (EFSA, 2023c).
[m]Worst-case STMR value derived from residue data on epoxiconazole in dry peas (EFSA, 2018).
[n]Worst-case STMR value derived from residue data on metconazole in soya beans (EFSA, 2018).
[o]Worst-case STMR value derived from residue data on tetraconazole in rapeseeds (EFSA, 2018).
[p]Worst-case STMR value derived from residue data on prothioconazole in sunflower seeds (EFSA, 2018).
[q]Worst-case STMR value derived from residue data on prothioconazole in linseed (EFSA, 2018).

Since new STMR values (previously not available), as well as higher STMR values than those considered in the previous TDM assessments (EFSA, 2018, 2023c), were derived in the present assessment, an update of the previous chronic consumer dietary exposure calculations was performed.

[15]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.
[16]In the framework of the MRL application on mefentrifluconazole in various commodities (EFSA, 2023c), new STMR values were derived, as well as higher STMR values than the ones previously derived in the pesticide risk assessment for TDMs in light of confirmatory data (EFSA, 2018b), for the commodities under consideration.

Based on the updated consumer risk assessment, the estimated long-term dietary exposure accounted for a maximum of 93% of the ADI (NL toddler diet) for 1,2,4-T, 1% of the ADI (NL toddler diet) for TAA and 7% of the ADI (NL toddler diet) for the sum of TA and TLA.

The individual contributions of the commodities under assessment in the present opinion were very minor, with the highest estimated long-term dietary exposure accounting to 1.36% of the ADI (GEMS/Food G11 diet) for the sum of TA and TLA in soya beans (see Appendix B3). However, the long-term risk assessment for the sum of TA and TLA is affected by uncertainties due to the lack of information on storage stability of TA in tree nuts.

Overall, EFSA concluded that the short-term and the long-term dietary exposure to difenoconazole and TDM residues resulting from the authorised uses of difenoconazole and on the crops under consideration is unlikely to present a risk to consumer health. The assessment is affected by uncertainties related to the toxicological profile of animal metabolite difenoconazole alcohol (CGA205375).

The complete list of input values is presented in Appendix D.2. The results of the calculations are summarised in Appendix B.2. For further details on the exposure calculations, screenshots of the Report sheet of the PRIMo is presented in Appendix C.

4 | CONCLUSION AND RECOMMENDATIONS

The data submitted in support of this MRL application were found sufficient to derive MRL proposals for the commodities under assessment, except blueberries, for which no modification of the MRL was requested by the applicant and the residue data on TDMs were submitted only to supplement the TDM database.

Higher MRL proposals than the existing EU MRLs or the MRLs proposed by the MRL review were derived for difenoconazole in mangoes, papayas and soya beans. For these crops, the data gaps identified during the MRL review related to the lack of residue trials analysing for TDMs are deemed addressed and new higher MRLs can be implemented without Article 12 confirmatory data gap.

For citrus fruits, tree nuts and dry peas, the data gaps identified during the MRL review related to the lack of residue trials analysing for TDMs are also addressed. For almonds, a new MRL is proposed, which is fully supported by data and is lower than the existing EU MRL and the value tentatively derived in the MRL review. For citrus fruits, tree nuts (other than almonds) and dry peas, the MRL proposal confirms the existing EU MRL and the MRL proposal derived by the MRL review and can be implemented without Article 12 confirmatory data gap.

The results of the updated livestock exposure indicate no need to modify the existing EU MRLs for difenoconazole in animal matrices. Also, new data provided on TDMs in potential feed items confirm no need to update the existing livestock exposure to TDMs.

The consumer exposure assessment takes into consideration triazole derivative metabolites (TDMs) which may be generated by several pesticides belonging to the group of triazole fungicides.

EFSA concluded that the dietary exposure to difenoconazole residues from the intake of the commodities under assessment is unlikely to present a risk for consumers, noting that the consumer exposure to residues from the intake of animal commodities is affected by uncertainties related to the toxicological profile of animal metabolite CGA CGA205375.

The MRL recommendations are summarised in Appendix B.4.

ABBREVIATIONS

ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
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
CIRCA	(EU) Communication & Information Resource Centre Administrator
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
EC	emulsifiable concentrate

EDI	estimated daily intake
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionisation detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation 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
GR	granule
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
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
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
NPD	nitrogen/phosphorous detector
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PC	Processed commodity
PF	processing factor
PHI	pre-harvest interval
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SC	suspension concentrate
SEU	southern Europe
SG	water-soluble granule
SL	soluble concentrate
STMR	supervised trials median residue
TAR	total applied radioactivity
TRR	total radioactive residue
UF	uncertainty factor
UV	ultraviolet (detector)
WHO	World Health Organization
WP	wettable powder
YF	yield factor
ZC	mixed CS and SC formulation

REQUESTOR

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APPENDIX A

Summary of intended GAP triggering the amendment of existing EU MRLs

				Formulation		Application				Application rate per treatment					
Crop and/or situation[e]	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Type[b]	Conc. a.s. (g/L)	Method kind	Range of growth stages & season[c]	Number min-max	Interval between application (days) min-max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit	PHI (days)[d]	Remarks
Grapefruits (0110010), Oranges (0110020), Lemons (0110030), Limes (0110040), Mandarins (0110050), Other citrus fruits (0110990)	USA	F	Foliar fungi	EC	250	Foliar spray	Prior to disease onset	1–4	7	96–149 87–135 (ground)	Min. 94 Min. 104 (ground)	90–140	g a.s./ha	0	The product can be applied by either ground or aerial application. The different water dilutions reported result in the same application rate expressed as g a.s./ha.
Almonds (0120010), Brazil nuts (0120020), Cashew nuts (0120030), Chestnuts (0120040), Coconuts (0120050), Hazelnuts/cobnuts (0120060), Macadamias (0120070), Pecans (0120080), Pine nut kernels (0120090), Pistachios (0120100), Walnuts (0120110), Other tree nuts (0120990)	USA	F	Foliar fungi	EC	250	Foliar spray	Prior to disease onset	1–4	14	96–136 (aerial) 87–123 (ground)	Min. 94 (aerial) Min. 104 (ground)	90–128	g a.s./ha	14	The product can be applied by either ground or aerial application. The different water dilutions reported result in the same application rate expressed as g a.s./ha.

(Continued)

Crop and/or situation[e]	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s. (g/L)	Method kind	Range of growth stages & season[c]	Number min-max	Interval between application (days) min-max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Blueberry (0154010)	USA	F	Foliar fungi	EC	250	Foliar spray	Prior to disease onset	1–4	7	Min. 136 Min. 123 (ground)	Min. 94 Min. 104 (ground)	128	g a.s./ha	7	The product can be applied by either ground or aerial application. The different water dilutions reported result in the same application rate expressed as g a.s./ha.
Mangoes (0163030)	Brazil	F	Foliar fungi	EC	250	Foliar spray	Prior to disease onset	1–3	14	12.5–25	500–1000	125	g a.s./ha	7	
Papayas (0163040)	Brazil	F	Foliar fungi	SC	100	Foliar spray	Prior to disease onset	1–4	14	6.25–10.4	600–1000	62.5	g a.s./ha	3	
Peas (dry) (0300030)[e]	USA	F	Foliar fungi	EC	250	Foliar spray	Prior to disease onset	1–4	14	97–123 (aerial) 1×10^{6}–3.2×10^{6} (chemigation)	Min. 104 (ground) 0.004–0.010 (chemigation)	101–128	g a.s./ha	14	The product can be applied by either ground, chemigation or aerial application. The different water dilutions reported result in the same application rate expressed as g a.s./ha.

(Continues)

(Continued)

Crop and/or situation[e]	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s. (g/L)	Method kind	Range of growth stages & season[c]	Number min-max	Interval between application (days) min-max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Soya beans (0401070)	USA	F	Foliar fungi	EC	250	Foliar spray	Prior to disease onset	1–2	7	532–674 1×10^6–3.2×10^6 (chemigation)	Min. 19 0.004–0.010 (chemigation)	101–128	g a.s./ha	14	The product can be applied by either ground, chemigation or aerial application. The different water dilutions reported result in the same application rate expressed as g a.s./ha.

Abbreviations: a.s., active substance; EC, Emulsifiable concentrate; GAP, Good Agricultural Practice; MS, Member State; MRL, maximum residue level; NEU, northern European Union; SC, Suspension concentrate; SEU, southern European Union.

[a] Outdoor or field use (F), greenhouse application (G) or indoor application (I).

[b] CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

[c] Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

[d] PHI – minimum pre-harvest interval.

[e] Original submission for chickpeas (0300030-003).

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	Tomato	Foliar (indoor), 6 × 123 g a.s./ha (7-day interval)	Foliage (mature) and fruits (green and ripe): 34	Radiolabelled active substance: [phenyl-^{14}C]-difenoconazole, [triazole-^{14}C]-difenoconazole (EFSA, 2011a; Sweden, 2006)
			Foliar (indoor), 6 × 123.5 g a.s./ha (7-day interval)	Foliage (mature) and fruits (green and ripe): 16	
			Foliar (field), 3 × 247 g a.s./ha (14-day interval)	Foliage (mature) and fruits (green and ripe): 40	
		Grapes	Foliar (field), 5 × 247 g a.s./ha (14-, 28-, 14-, 15-day interval)	Fruits and leaves (mature): 20	
	Root crops	Potato	Foliar (indoor), 6 × 123.5 g a.s./ha (7-day interval)	Foliage and tubers (mature): 11	
	Cereals/grass	Spring wheat	Foliar (indoor), 4 × 247 g a.s./ha (7-, 8-day interval)	Foliage (half mature): 58 Straw, hulls and grains (mature): 29	
			Seed (outdoor grown): 1 × 23–32 g a.s./100 kg seed	Foliage (half mature): 48 Straw, hulls and grains (mature): 59–83	
			Seed (indoor): 1 × 25–30 g a.s./100 kg seed	Foliage (half mature): 72 Straw, hulls and grains (mature): 236	
	Pulses/oilseeds	Rapeseeds	Foliar (field), 2 × 125 g a.s./ha (14-day interval)	Straw, pods and seeds (mature): 39	
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Turnip*	Soil, 1 × 32.4 g a.s./ha	30–33	Radiolabelled active substance: [phenyl-^{14}C]- and [triazole-^{14}C]-labelled difenoconazole (Sweden, 2006; EFSA, 2021) *Study performed with [phenyl-^{14}C] difenoconazole only (EFSA, 2021)
		Sugar beet	Soil, 1 × 125 g a.s./ha	98, 126, 342, 369	
		Radishes*	Soil, 1 × 516 g a.s./ha	30, 60, 120, 270	
	Leafy crops	Mustard*	Soil, 1 × 32.4 g a.s./ha	30–33	
		Lettuces	Soil, 1 × 125 g a.s./ha	98, 126, 342, 369	
		Lettuces*	Soil, 1 × 516 g a.s./ha	30, 60, 120, 270	
	Cereal (small grain)	Maize	Soil, 1 × 125 g a.s./ha	98, 126, 342, 369	
		Wheat	Soil, 1 × 125 g a.s./ha		
		Wheat*	Soil, 1 × 32.4 g a.s./ha	30–33	
			Soil, 1 × 516 g a.s./ha	30, 60, 120, 270	
		Sorghum*	Soil, 1 × 516 g a.s./ha	30, 60, 120, 270	
	Other	–	–	–	–

(Continued)

Processed commodities (hydrolysis study)	Conditions	Stable?	Comment/Source
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Parent difenoconazole: hydrolysis studies performed with [triazole-^{14}C]-labelled difenoconazole (EFSA, 2011a; Sweden, 2006). Studies also assessed for TDMs: TA, TAA, TLA and 1,2,4-T were found to be stable (United Kingdom, 2018; EFSA, 2018b).
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	
	Sterilisation (20 min, 120°C, pH 6)	Yes	
	Other processing conditions	–	–

Abbreviations: 1,2,4-T, 1,2,4-triazole; a.s., active substance; DAT, days after treatment; DALT, days after last treatment; DAP, days after planting; PBI, plant-back interval; TA, triazole alanine; TAA, triazole acetic acid; TDM, triazole derivative metabolite; TLA, triazole lactic acid.

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2024c)
Rotational crop and primary crop metabolism similar?	Yes	Parent difenoconazole was not found and residues are mainly composed of TDMs (TA, TAA and TLA) (EFSA, 2024c)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2024c)
Plant residue definition for monitoring (RD-Mo)	Difenoconazole (sum of isomers)	
Plant residue definition for risk assessment (RD-RA)	RD-RA1: Difenoconazole (sum of isomers) RD-RA2: TA and TLA; RD-RA3: TAA; RD-RA4: 1,2,4-triazole. The previously derived provisional residue definitions (1. difenoconazole, 2. TDMs; EFSA, 2011a) have been replaced by the abovementioned residue definitions derived during the peer review of the confirmatory data assessment of the TDMs (EFSA, 2018b). EFSA highlights that the residue definitions might still be reconsidered in the framework of the on-going peer review for renewal. In the framework of the assessment of confirmatory data for difenoconazole (Spain, 2023a; EFSA, 2024b), an uncertainty factor (UF) of 1.3 was derived from field residue trials submitted for this purpose, to reflect the tendency of a preferential degradation of *trans* isomers and a shift to the *cis* isomers of difenoconazole. This UF is applicable to all plant commodities and is considered for the risk assessment calculations according to RD-RA1.	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	<u>Matrices with high water content, high acid content, high oil content, dry/high starch matrices and difficult matrices (herbal infusion):</u> Multiresidue method QuEChERS (HPLC–MS/MS), LOQ 0.01 mg/kg. Confirmation by monitoring 1 additional MRM transition. ILV available in high water content, high oil content, dry/high starch content commodities and herbal infusion (EFSA, 2021, 2024c). <u>Matrices with high water content, high acid content, high oil content, dry and difficult matrices in routine analysis:</u> Multiresidue method QuEChERS (HPLC–MS/MS), LOQ 0.01 mg/kg (EURLs, 2022, EFSA 2024c). Extraction efficiency of the analytical method for enforcement of difenoconazole is sufficiently demonstrated in all plant commodity groups (Spain, 2023b).	

HPLC-MS/MS, high-performance liquid chromatography with tandem mass spectrometry; ILV, independent laboratory validation; LOQ, limit of quantification; MRM, multiple reaction monitoring; QuEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); TA, triazole alanine; TAA, triazole acetic acid; TDM, triazole derivative metabolite; TLA, triazole lactic acid; 1,2,4-T, 1,2,4-triazole; UF, uncertainty factor.

B.1.1.2 | Storage stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/Source
				Value	Unit		
	High water content	Lettuce, banana	–20	12	Months	Difenoconazole	EFSA (2024c). Longer storage period was not investigated.
		Tomato, wheat forage, potato	–20	24	Months	Difenoconazole	EFSA (2024c). Longer storage period was not investigated.
		Apple, tomato, mustard leave, radish tops/ roots, turnip roots, sugar beet roots, cabbage, lettuce, wheat forage	–20	≤ 6	Months	1,2,4-T	EFSA (2018b, 2024c)
			–20	53	Months	TA, TAA	EFSA (2018b, 2024c)
		Lettuce	–20	48	Months	TLA	EFSA (2018b, 2024c)
		Sugar beet	–18	12	Months	*cis*-difenoconazole, *trans*-difenoconazole, difenoconazole-alcohol (CGA295375)	EFSA (2024c). Longer storage period was not investigated.
	High oil content	Cotton seed	–20	≤ 16	Months	Difenoconazole	EFSA (2024c). Longer period was investigated but the analysis at 24 months was not reliable.
		Soya beans	–20	12	Months	Difenoconazole	EFSA (2024c). Longer storage period was not investigated.
			–20	26	Months	TA	EFSA (2018b, 2024c)
			–20	12	Months	1,2,4-T	EFSA (2018b, 2024c)
		Rapeseeds	–18	12	Months	*cis*-difenoconazole, *trans*-difenoconazole, difenoconazole-alcohol (CGA295375)	EFSA (2024c). Longer storage period was not investigated.
			–20	–	–	TA	EFSA (2018b, 2024c). Inconclusive study (data gap).
			–20	≤ 3	Months	1,2,4-T	EFSA (2018b, 2024c). Not stable in rapeseeds (data gap)
		Rapeseeds, soya beans	–20	53	Months	TAA	EFSA (2018b, 2024c)
			–20	48	Months	TLA	EFSA (2018b, 2024c)
		Hazelnuts	–18	≤ 12	Months	1,2,4-T	EFSA (2023a, 2023c)

(Continued)

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/Source
				Value	Unit		
	Dry/High protein content	Dried broad bean	–18	24	Months	Difenoconazole	EFSA (2024c). Longer storage period was not investigated.
		Dry peas, navy beans	–20	48	Months	TLA	EFSA (2018b, 2024c)
			–20	25	Months	TAA	EFSA (2018b, 2024c). Longer storage period was not investigated.
			–20	15	Months	TA	EFSA (2018b, 2024c)
		Dried beans	–18	48	Months	1,2,4-T	EFSA (2023a, 2023c)
	Dry/high starch content	Wheat grain	–20	24	Months	Difenoconazole	EFSA (2024c). Longer storage period was not investigated.
			–18	12	Months	*cis*-difenoconazole, *trans*-difenoconazole, difenoconazole-alcohol (CGA295375)	EFSA (2024c). Longer storage period was not investigated.
		Wheat and barley grain	–20	48	Months	TLA	EFSA (2018b, 2024c)
			–20	26	Months	TA, TAA	EFSA (2018b, 2024c)
			–20	≤ 12	Months	1,2,4-T	EFSA (2018b, 2024c)
	High acid content	Grapes	–18	12	Months	*cis*-difenoconazole, *trans*-difenoconazole, difenoconazole-alcohol (CGA295375)	EFSA (2024c). Longer storage period was not investigated.
		Oranges	–18	24	Months	Difenoconazole	EFSA (2024c). Longer storage period was not investigated.
			–20	48	Months	TLA	EFSA (2018b, 2024c). Longer storage period was not investigated.
			–18	≤ 42	Months	1,2,4-T	EFSA (2023a, 2023c)
			–18	48	Months	TA	EFSA (2023a, 2023c)
			–18	48	Months	TAA	EFSA (2023a, 2023c)
	Others	Wheat straw	–20	24	Months	Difenoconazole	EFSA (2024c). Longer storage period was not investigated.
		Barley and wheat straw	–20	53	Months	TA	EFSA (2018b, 2024c). No data available for TLA. No data gap identified considering that in all other matrices TLA was stable for at least 48 months.
			–20	40	Months	TAA	
			–20	12	Months	1,2,4-T	
	Processed products	–	–	–	–	–	–

Abbreviations: 1,2,4-T: 1,2,4-triazole; TA, triazole alanine; TAA, triazole acetic acid; TDM, triazole derivative metabolite; TLA, 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[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]
Citrus fruits	USA	**Difenoconazole:** Whole fruit: Orange: 0.168$^{(1d\ PHI)}$; 0.181; 0.295; 0.297$^{(1d\ PHI)}$; 0.302; 0.326; 0.332$^{(10d\ PHI)}$; 0.339; 0.356$^{(7d\ PHI)}$; 0.400 Mandarin: 0.217; 0.273; 0.380$^{(3d\ PHI)}$; 0.424$^{(1d\ PHI)}$ Lemon: 0.131; 0.243; 0.280; 0.299$^{(1d\ PHI)}$; 0.568 Pulp: Orange: 5 × < 0.01; 0.011; 0.012; 0.044$^{(1d\ PHI)}$; 0.054; 0.070$^{(10d\ PHI)}$ Mandarin: < 0.01; 0.011; 0.019; 0.038$^{(3d\ PHI)}$ Lemon: 2 × < 0.01; 0.016; 0.023$^{(1d\ PHI)}$; 0.039 **1,2,4-triazole:** Pulp: Orange: 10 × < 0.01 Mandarin: 4 × < 0.01 Lemon: 5 × < 0.01 **Triazole alanine:** Pulp: Orange: 6 × < 0.01; 0.010; 0.016; 0.019$^{(10d\ PHI)}$; 0.021 Mandarin: 3 × < 0.01; 0.012$^{(control)}$ Lemon: 5 × < 0.01 **Triazole acetic acid:** Pulp: Orange: 10 × < 0.01 Mandarin: 4 × < 0.01 Lemon: 5 × < 0.01 **Triazole lactic acid:** Pulp: Orange: 10 × < 0.01 Mandarin: 4 × < 0.01 Lemon: 5 × < 0.01	Residue trials on oranges, mandarins and lemons compliant with US GAP. Extrapolation to the whole group of citrus fruits acceptable from the combined residue data set on oranges, mandarins and lemons.	1 (higher than the MRL in place in the exporting country, i.e. 0.6 mg/kg)	**Difenoconazole:** 0.070 (pulp) **1,2,4-T:** 0.010 (pulp) **TA:** 0.021 (pulp) **TAA:** 0.010 (pulp) **TLA:** 0.010 (pulp) **TLA + TA:** 0.031 (pulp)	**Difenoconazole:** 0.011 (pulp) **1,2,4-T:** 0.010 (pulp) **TA:** 0.010 (pulp) **TAA:** 0.010 (pulp) **TLA:** 0.010 (pulp) **TLA + TA:** 0.02 (pulp)	

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Commodity	Region[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]
Tree nuts	USA	**Difenoconazole[e]:** New trials (2020): Almond: 3 × < 0.01; 2 × 0.012 Pecan: 5 × < 0.01 Trials used to set the USA MRL (2006–2007): Almond: trials disregarded (see Section 1.2.1) Pecans: 4 × < 0.01; 0.02 **1,2,4-triazole[e]:** New trials (2020): Almond: < 0.01; 0.016$^{(21d\ PHI)}$; 0.031$^{(21d\ PHI)}$; 0.037$^{(21d\ PHI)}$; 0.187 Pecan: 4 × < 0.01; 0.034$^{(control)}$ Trials used to set the USA MRL (2006–2007): Almond: trials disregarded (see Section 1.2.1) Pecans: 5 × < 0.01 **Triazole alanine[e]:** New trials (2020): Almond: 0.351; 1.091$^{(21d\ PHI)}$; 1.379$^{(control)}$; 1.887$^{(18d\ PHI)}$; 4.234 Pecan: 0.026; 0.034$^{(control)}$; 0.077$^{(control)}$; 0.123$^{(21d\ PHI)}$; 3.285$^{(control)}$ Trials used to set the USA MRL (2006–2007): Almond: 0.140$^{(control)}$; 0.258; 0.417[f]; 0.442 Pecans: 0.018; 0.095; 0.220; 0.230; 0.410 **Triazole acetic acid[e]:** New trials (2020): Almond: < 0.01; 0.011; 0.012; 0.016$^{(18d\ PHI)}$; 0.043 Pecan: 3 × < 0.01; 0.022$^{(control)}$; 0.134$^{(control)}$ Trials used to set the USA MRL (2006–2007): Almond: 3 × < 0.01; < 0.01[f] Pecans: 3 × < 0.01; 0.020; 0.045 **Triazole lactic acid[e]:** New trials (2020): Almond: < 0.01; 0.014$^{(control)}$; 0.015$^{(control)}$; 0.032$^{(18d\ PHI)}$; 0.082 Pecan: 0.011$^{(control)}$; 0.015; 0.017$^{(21d\ PHI)}$; 0.053; 0.399 Trials used to set the USA MRL (2006–2007): Almond: not analysed Pecan: not analysed	Residue trials on almonds and pecans (nutmeat) compliant with US GAP. Extrapolation to the whole group of tree nuts acceptable.	0.03	**Difenoconazole:** 0.02 **1,2,4-T:** 0.187 **TA:** 4.234 **TAA:** 0.134 **TLA:** 0.399[g] **TA + TLA:** 4.633[g]	**Difenoconazole:** 0.01 **1,2,4-T:** 0.01 **TA:** 0.258 **TAA:** 0.01 **TLA:** 0.016[g] **TA + TLA:** 0.274[g]	

(Continues)

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Commodity	Region[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]
Blueberry	USA	**Difenoconazole: -** **1,2,4-triazole[e]:** 5 × < 0.01 **Triazole alanine[e]:** < 0.01; 0.012; 0.012$^{(10d)}$, 0.015$^{(10d)}$; 0.033$^{(14d)}$ **Triazole acetic acid[e]:** 4 × < 0.01; 0.01$^{(14d)}$ **Triazole lactic acid[e]:** < 0.01; 0.022$^{(10d)}$; 0.036$^{(14d)}$; 0.104; 0.121$^{(10d)}$	Residue trials on blueberries compliant with US GAP.	No MRL modification requested	**Difenoconazole: -** **1,2,4-T:** 0.01 **TA:** 0.033 **TAA:** 0.01 **TLA:** 0.121 **TA + TLA:** 0.135	**Difenoconazole: -** **1,2,4-T:** 0.01 **TA:** 0.012 **TAA:** 0.01 **TLA:** 0.036 **TA + TLA:** 0.041	N/A
Mangoes	Brazil	**Difenoconazole:** Whole fruit: 0.03; 0.05; 0.08; 0.11 Pulp: 4 × < 0.01 **1,2,4-triazole:** Whole fruit: 4 × < 0.05 Pulp: 4 × < 0.05 **Triazole alanine:** Whole fruit: < 0.05; 0.07; 0.59; 0.68 Pulp: 0.05; 0.09; 0.75; 0.76 **Triazole acetic acid:** Whole fruit: < 0.01; 0.05; 0.1$^{(10d\ PHI)}$; 0.11 Pulp: < 0.01; 0.05; 0.09; 0.11 **Triazole lactic acid:** Whole fruit: < 0.05; 0.13; 0.58; 0.67 Pulp: < 0.05; 0.1; 0.42; 0.52	Residue trials on mangoes compliant with Brazilian GAP.	0.2	**Difenoconazole:** < 0.01 (pulp) **1,2,4-T:** < 0.05 (pulp) **TA:** 0.76 (pulp) **TAA:** 0.11 (pulp) **TLA:** 0.52 (pulp) **TA + TLA:** 1.28 (pulp)	**Difenoconazole:** < 0.01 (pulp) **1,2,4-T:** < 0.05 (pulp) **TA:** 0.42 (pulp) **TAA**: 0.07 (pulp) **TLA:** 0.26 (pulp) **TA + TLA:** 0.88 (pulp)	
Papayas	Brazil	**Difenoconazole:** Whole fruit: 0.03; 0.08; 0.12; 0.13 Pulp: 4 × < 0.01 **1,2,4-triazole:** Whole fruit: 4 × < 0.05 Pulp: 4 × < 0.05 **Triazole alanine:** Whole fruit: < 0.01; 0.12; 0.26$^{(7d\ PHI)}$; 1.98$^{(10d\ PHI)}$ Pulp: < 0.01; 0.08; 0.11$^{(7d\ PHI)}$; 0.95 **Triazole acetic acid:** Whole fruit: 3 × < 0.01; 0.04$^{(10d\ PHI)}$ Pulp: 3 × < 0.01; 0.04$^{(10d\ PHI)}$ **Triazole lactic acid:** Whole fruit: 3 × < 0.05; 0.22$^{(10d\ PHI)}$ Pulp: < 0.01; 0.02; 0.04; 0.22	Residue trials on papayas compliant with Brazilian GAP.	0.3	**Difenoconazole:** < 0.01 (pulp) **1,2,4-T:** < 0.05 (pulp) **TA:** 0.95 (pulp) **TAA:** 0.04 (pulp) **TLA:** 0.22 (pulp) **TA + TLA:** 1.17 (pulp)	**Difenoconazole:** < 0.01 (pulp) **1,2,4-T:** < 0.05 (pulp) **TA:** 0.10 (pulp) **TAA:** < 0.01 (pulp) **TLA:** 0.03 (pulp) **TA + TLA:** 0.13 (pulp)	

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Commodity	Region[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]
Dry peas (chickpeas)	USA	**Difenoconazole**[e]: < 0.01; 2 × 0.011; 0.014; 0.018; 0.033; 0.047; 0.068 **1,2,4-triazole**[e]: 4 × < 0.005; 0.008; 3 × < 0.01 **Triazole alanine**[e]: 0.020$^{(21d\ PHI)}$; 0.037$^{(control)}$; 0.041; 2 × 0.115; 0.158; 0.338$^{(21\ d\ PHI)}$; 0.464$^{(control)}$ **Triazole acetic acid**[e]: < 0.005; 3 × < 0.01; 0.010; 0.012; 0.013; 0.023 **Triazole lactic acid**[e]: 2 × < 0.01; 0.010; 0.012; 0.019; 0.028; 0.030$^{(control)}$; 0.053	Residue trials on chickpeas compliant with US GAP.	0.15 (corresponding to the current MRL in place)	**Difenoconazole:** 0.068 **1,2,4-T:** 0.01 **TA:** 0.464 **TAA:** 0.023 **TLA:** 0.053 **TA + TLA:** 0.517	**Difenoconazole:** 0.016 **1,2,4-T:** 0.01 **TA:** 0.115 **TAA:** 0.010 **TLA:** 0.016 **TA + TLA:** 0.131	
Soya beans	USA	**Difenoconazole**[e]: 3 × < 0.01; 0.013$^{(20d\ PHI)}$; 0.013$^{(21d\ PHI)}$; 0.016; 0.029; 0.037; 0.169$^{(20d\ PHI)}$ **1,2,4-triazole**[e]: 9 × < 0.01 **Triazole alanine**[e]: < 0.01; 0.019; 0.023$^{(21d\ PHI)}$; 0.024$^{(22d\ PHI)}$; 0.038$^{(20d\ PHI)}$; 0.070; 0.138; 0.166$^{(control)}$; 0.537$^{(20d\ PHI)}$ **Triazole acetic acid**[e]: 3 × < 0.01; 0.011$^{(21d\ PHI)}$; 0.015$^{(control)}$; 0.024$^{(control)}$; 0.035$^{(control)}$; 0.044; 0.056$^{(20d\ PHI)}$ **Triazole lactic acid**[e]: 2 × < 0.01; 0.012; 0.021$^{(21d\ PHI)}$; 0.047$^{(control)}$; 0.052$^{(control)}$; 0.082; 0.121$^{(20d\ PHI)}$; 0.127	Residue trials on soya beans compliant with GAP.	0.3 (higher than the MRL in place in the exporting country, i.e. 0.15 mg/kg)	**Difenoconazole:** 0.169 **1,2,4-T:** < 0.01 **TA:** 0.537 **TAA:** 0.056 **TLA:** 0.127 **TA + TLA:** 0.664	**Difenoconazole:** 0.013 **1,2,4-T:** < 0.01 **TA:** 0.038 **TAA:** 0.015 **TLA:** 0.047 **TA + TLA:** 0.085	

Abbreviations: c, control sample; GAP, Good Agricultural Practice; N/A, not applicable; Mo, monitoring; MRL, maximum residue level; RA, risk assessment.

[a]NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: 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, unless this is explicitly mentioned. The highest residue level of the sum of TA and TLA is calculated as the sum of the individual highest residue levels of TA and TLA.

[c]Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion, unless this is explicitly mentioned. The median residue level of the sum of TA and TLA is calculated as the sum of the individual median residue levels of TA and TLA.

[d]Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

[e]Residue levels calculated as average of two (or more, in some cases) replicate samples.

[f]Residue level calculated as the average of measurements from pair of non-independent trials.

[g]TLA residue levels were measured in the 'new' data set, including 10 trials (2020). TLA was not analysed in the 'old' dataset (2006–2007).

B.1.2.2 | Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	Investigations of residues in rotational crops are not required for imported crops.
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	Investigations of residues in rotational crops are not required for imported crops.

B.1.2.3 | Processing factors

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/Source
		Individual values	Median PF		
Difenoconazole					
Orange, peeled	10	< 0.025; 0.037; 2 × < 0.043; < 0.055; 0.060; < 0.071; 0.160; 0.182; 0.813	0.072[c]	–	Spain (2023b)
Mandarin, peeled	4	< 0.037; < 0.052; 0.087; 0.104			
Lemon, peeled	5	0.072; 0.075; < 0.076; 0.114; 0.160			
Orange, juice	3	0.02; 0.03; 0.05	0.03	–	Spain (2023b)
Orange, wet pomace	3	1.40; 1.43; 1.74	1.43	–	Spain (2023b)
Orange, dry pomace	3	3.96; 5.13; 6.44	5.13	–	Spain (2023b)
Orange, marmalade	3	0.15; 0.18; 0.42	0.18	–	Spain (2023b)
Orange, oil	3	39; 59; 61	59	–	Spain (2023b)
Orange, meal	3	6.03; 7.07; 8.28	7.07	–	Spain (2023b)
Orange, molasses	3	0.16; 0.26; 1.21	0.26	–	Spain (2023b)
Almond (nutmeat), oil	3	0.68; 1.0; 1.11	1.0	–	Spain (2023b)
Almond (nutmeat), 'milk'	3	0.13; 0.45; 1.0	0.45	–	Spain (2023b)
Almond (nutmeat), roasted almonds	3	0.68; 1.25; 1.30	1.25	–	Spain (2023b)
Soya bean (seed), hulls	3	1.19; 1.85; 5.73	1.85	–	Spain (2023b)
Soya bean (seed), pollards	3	0.18; 0.27; 0.58	0.27	–	Spain (2023b)
Soya bean (seed), toasted meal	3	< 0.07; < 0.11; < 0.17	< 0.11	–	Spain (2023b)
Soya bean (seed), defatted flour	3	< 0.07; < 0.11; < 0.17	< 0.11	–	Spain (2023b)
Soya bean (seed), soy milk	3	< 0.07; < 0.11; < 0.17	< 0.11	–	Spain (2023b)
Soya bean (seed), miso	3	< 0.11; 0.17; 0.36	0.17	–	Spain (2023b)
Soya bean (seed), soy sauce	3	< 0.07; < 0.11; < 0.17	< 0.11	–	Spain (2023b)
Soya bean (seed), refined oil	3	< 0.07; < 0.11; < 0.17	< 0.11	–	Spain (2023b)
Soya bean (seed), crude oil	3	0.09; 0.40; 1.19	0.40	–	Spain (2023b)
Soya bean (seed), tofu	3	< 0.07; < 0.11; 0.22	< 0.11	–	Spain (2023b)
1,2,4-triazole					
Orange, oil	1	> 1.81[d]	–	–	Spain (2023b)
Orange, meal	3	> 1.28[d]; > 1.64[d]; > 1.69[d]	–	–	Spain (2023b)
Orange, molasses	1	> 2.09[d]	–	–	Spain (2023b)
Almond (nutmeat), oil	1	< 0.08[e]	–	–	Spain (2023b)
Almond (nutmeat), milk	1	< 0.08[e]	–	–	Spain (2023b)
Almond (nutmeat), roasted almonds	3	2; > 2.5[d]; > 7;5[d]	–	–	Spain (2023b)
Triazole alanine					
Orange, peeled	5	< 0.935; > 1.03[d]; 1.116; 1.181; 1.827	1.15	–	Spain (2023b)
Mandarin, peeled	2	< 0.641; < 0.962			

(Continued)

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/Source
		Individual values	Median PF		
Orange, wet pomace	2	> 1.08[d]; > 1.15[d]	-	–	Spain (2023b)
Orange, molasses	3	> 1.98[d]; > 2.25[d]; > 2.58[d]	-	–	Spain (2023b)
Almond (nutmeat), oil	3	< 0.01; < 0.01; < 0.02	< 0.01	–	Spain (2023b)
Almond (nutmeat), milk	3	0.10; 0.11; 0.11	0.11	–	Spain (2023b)
Almond (nutmeat), roasted almonds	3	0.26; 0.56; 0.58	0.56	–	Spain (2023b)
Soya bean (seed), hulls	3	< 0.06; 0.26; 0.29	0.26	–	Spain (2023b)
Soya bean (seed), pollards	3	0.92; 0.93; 1.03	0.93	–	Spain (2023b)
Soya bean (seed), toasted meal	3	1.54; 1.57; 1.82	1.57	–	Spain (2023b)
Soya bean (seed), defatted flour	3	1.05; 1.20; 1.26	1.20	–	Spain (2023b)
Soya bean (seed), soy milk	3	0.16; 0.17; 0.21	0.17	–	Spain (2023b)
Soya bean (seed), miso	3	0.18; 0.28; 0.44	0.28	–	Spain (2023b)
Soya bean (seed), soy sauce	3	0.35; 0.43; 0.66	0.43	–	Spain (2023b)
Soya bean (seed), refined oil	3	< 0.05; < 0.06; < 0.12	< 0.06	–	Spain (2023b)
Soya bean (seed), crude oil	3	< 0.05; < 0.06; < 0.12	< 0.06	–	Spain (2023b)
Soya bean (seed), tofu	3	0.11; < 0.12; 0.12	0.12	–	Spain (2023b)
Triazole acetic acid					
Orange, molasses	2	> 1.04[d]; > 1.31[d]	–	–	Spain (2023b)
Almond (nutmeat), oil	2	< 0.34[e]; < 0.77[e]	< 0.56	–	Spain (2023b)
Almond (nutmeat), milk	2	< 0.34; < 0.77	< 0.56	–	Spain (2023b)
Almond (nutmeat), roasted almonds	3	> 1.2[d]; 1.46; 2.55	2.01	–	Spain (2023b)
Soya bean (seed), hulls	3	< 0.25; 0.73; 0.92	0.73	–	Spain (2023b)
Soya bean (seed), pollards	3	0.89; 1.11; 1.15	1.11	–	Spain (2023b)
Soya bean (seed), toasted meal	3	1.38; 1.54; 1.69	1.54	–	Spain (2023b)
Soya bean (seed), defatted flour	3	1.10; 1.24; 1.47	1.24	–	Spain (2023b)
Soya bean (seed), soy milk	3	< 0.25; < 0.38; < 0.90	< 0.38	–	Spain (2023b)
Soya bean (seed), miso	3	0.97; 1.57; 2.30	1.57	–	Spain (2023b)
Soya bean (seed), soy sauce	3	1.70; 2.76; 5.37	2.76	–	Spain (2023b)
Soya bean (seed), refined oil	3	< 0.25; < 0.38; < 0.90	< 0.38	–	Spain (2023b)
Soya bean (seed), crude oil	3	< 0.25; < 0.38; < 0.91	< 0.38	–	Spain (2023b)
Soya bean (seed), tofu	3	< 0.25; < 0.38; < 0.92	< 0.38	–	Spain (2023b)
Triazole lactic acid					
Lemon, peeled	1	< 0.935	–	–	Spain (2023b)
Orange, dry pomace	3	> 1.47[d]; > 2.53[d]; > 2.60[d]	–	–	Spain (2023b)
Orange, meal	3	> 1.14[d]; > 1.81[d]; > 2.13[d]	–	–	Spain (2023b)
Orange, molasses	3	> 1.65[d]; > 2.09[d]; > 2.91[d]	–	–	Spain (2023b)
Almond (nutmeat), oil	3	< 0.20; < 0.48[e]; < 0.91[e]	< 0.48	–	Spain (2023b)
Almond (nutmeat), milk	3	< 0.20; < 0.48; < 0.91	< 0.48	–	Spain (2023b)
Almond (nutmeat), roasted almonds	3	1.22; 1.36; 1.38	1.36	–	Spain (2023b)
Soya bean (seed), hulls	3	0.10; 1.70; 1.80	1.70	–	Spain (2023b)
Soya bean (seed), pollards	3	0.99; 1.02; 1.02	1.02	–	Spain (2023b)
Soya bean (seed), toasted meal	3	0.99; 1.30; 1.32	1.30	–	Spain (2023b)
Soya bean (seed), defatted flour	3	1.00; 1.19; 1.24	1.19	–	Spain (2023b)
Soya bean (seed), soy milk	3	0.09; < 0.16; < 0.40	< 0.16	–	Spain (2023b)

(Continues)

(Continued)

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/Source
		Individual values	Median PF		
Soya bean (seed), miso	3	0.28; 0.63; 0.74	0.63	–	Spain (2023b)
Soya bean (seed), soy sauce	3	0.31; 0.43; 0.56	0.43	–	Spain (2023b)
Soya bean (seed), refined oil	3	< 0.08; < 0.16; < 0.40	< 0.16	–	Spain (2023b)
Soya bean (seed), crude oil	3	< 0.08; < 0.16; < 0.40	< 0.16	–	Spain (2023b)
Soya bean (seed), tofu	3	< 0.08; < 0.16; < 0.40	< 0.17	–	Spain (2023b)

Abbreviation: PF, processing factor.

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

[b]Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

[c]The calculated PeF is derived from a residue data measured at the PHI of 0 days.

[d]The calculated PF is considered as qualitative information only and cannot be used for the calculation of the median PF, since residues in the RAC were below the LOQ of 0.01 mg/kg and no precise PF can be estimated (in line with Scholz, 2018).

[e]When no residues were detected in processed fractions, but residues were quantified above LOQ in RAC, the PF was derived on the basis of LOQ in PC divided by residue concentration in RAC.

B.2 | RESIDUES IN LIVESTOCK

Dietary burden calculation according to OECD (2013).

	Dietary burden expressed in							
	mg/kg bw per day		mg/kg DM					
Relevant groups	Median	Maximum	Median	Maximum	Most critical diet[a]	Most critical commodity[b]	Trigger exceeded (Yes/No) 0.10 mg/kg DM	Previous assessment (EFSA, 2024c) Max burden mg/kg DM
Cattle (all diets)	0.135	0.311	3.51	8.34	Dairy cattle	Beet, mangel (fodder)	Yes	8.34
Cattle (dairy only)	0.135	0.311	3.51	8.09	Dairy cattle	Beet, mangel (fodder)	Yes	8.09
Sheep (all diets)	0.159	0.285	3.73	6.71	Lamb	Beet, sugar (tops)	Yes	6.71
Sheep (ewe only)	0.124	0.224	3.73	6.71	Ram/Ewe	Beet, sugar (tops)	Yes	6.71
Swine (all diets)	0.049	0.127	2.14	5.51	Swine (breeding)	Beet, mangel (fodder)	Yes	5.51
Poultry (all diets)	0.077	0.105	1.08	1.54	Poultry layer	Beet, sugar (tops)	Yes	1.54
Poultry (layer only)	0.051	0.105	0.74	1.54	Poultry layer	Beet, sugar (tops)	Yes	1.54

[a]When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day".

[b]The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

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

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

Livestock (available studies)	Animal	Dose (mg/kg bw/day)	Duration (days)	Comment/Source
	Laying hen	0.36–0.38	14	3.5N rate compared to the maximum DB calculated for poultry layer. [phenyl-^{14}C] and [triazole-^{14}C]-difenoconazole (Sweden, 2006, 2010).
		5	3	48N rate compared to the maximum DB calculated for poultry layer. [phenyl-^{14}C] and [triazole-^{14}C]-difenoconazole (Sweden, 2006, 2010).
		7.7	4	73N rate compared to the maximum DB calculated for poultry layer. [triazole-^{14}C]-difenoconazole (Sweden, 2006, 2010).
		0.81	14	23N rate compared to the maximum DB calculated for poultry broiler. Study performed with TA, available from the assessment of TDMs (UK, 2018; EFSA, 2018b) Compiled metabolism data from six studies, conducted with approved triazole active substances, were also used to derive the residue definitions for risk assessment (UK, 2018; EFSA, 2018b)

(Continues)

(Continued)

Livestock (available studies)	Animal	Dose (mg/kg bw/day)	Duration (days)	Comment/Source
	Lactating ruminants	0.23	10	0.7N rate compared to the maximum DB calculated for dairy cattle. Goat, [phenyl-^{14}C] and [triazole-^{14}C]-difenoconazole (Sweden, 2006, 2010).
		3.75	3	12N rate compared to the maximum DB calculated for dairy cattle. Goat, [phenyl-^{14}C] and [triazole-^{14}C]-difenoconazole (Sweden, 2006, 2010).
		3.10	4	10N rate compared to the maximum DB calculated for dairy cattle. Goat, [phenyl-^{14}C]-difenoconazole (Sweden, 2006, 2010).
		0.7	7	17.5N rate compared to the maximum DB calculated for lamb. Study performed with TA, available from the assessment of TDMs (UK, 2018; EFSA, 2018b) Compiled metabolism data from six studies, conducted with approved triazole active substances, were also used to derive the residue definitions for risk assessment (UK, 2018; EFSA, 2018b)
	Pig	–	–	Not required, as metabolism in rat and in ruminants is similar.
	Fish	–	–	–

Abbreviations: bw, body weight; DB, dietary burden; TA, triazole alanine; TDMs, triazole derivative metabolites.

Time needed to reach a plateau concentration in milk and eggs (days)

Milk:	Difenoconazole: 2 days (phenyl label) 6 days (triazole label) Triazole alanine (TA): 2.5 days
Eggs:	Difenoconazole: Egg yolk: 7 days (triazole and phenyl label) Egg white: 5 days (triazole label) Triazole alanine (TA): 8 days

Metabolism in rat and ruminant similar	yes	-
Can a general residue definition be proposed for animals?	Yes	-
Animal residue definition for monitoring (RD-Mo)	Difenoconazole-alcohol (CGA205375), free and conjugated, expressed as difenoconazole (EFSA, 2024c) [the existing residue definition for enforcement as set in Regulation (EC) No 396/2005 is still difenoconazole alone. A revision of the residue definition for enforcement might be considered by the risk managers to reflect the EFSA proposal (EFSA, 2024c)]	
Animal residue definition for risk assessment (RD-RA)	<u>For all animal commodities</u>: RD-RA1: Difenoconazole-alcohol (CGA205375), expressed as difenoconazole; RD-RA2: TA and TLA; RD-RA3: TAA; RD-RA4: 1,2,4-T. (EFSA, 2011a, 2018b) The previously derived provisional residue definitions (1. Difenoconazole, 2. TDMs; EFSA, 2011a) have been replaced by the abovementioned residue definitions derived during the peer review of the pesticide risk assessment of the TDMs (EFSA, 2018b) EFSA highlights that the residue definitions might still be reconsidered in the framework of the on-going peer review for renewal of the approval. In the framework of the assessment of confirmatory data (EFSA, 2024a,c), an indicative uncertainty factor (UF) of 2 was derived following the EFSA guidance document on stereoisomers, to reflect the possible shift in the isomers ratio of difenoconazole-alcohol (CGA205375). This worst-case UF is applicable to all livestock commodities and is considered under this review for the risk assessment calculations according to RD-RA1.	
Fat soluble residues	Yes	Log P_{OW} difenoconazole = 4.36 (>3) Log P_{OW} CGA205375 = 3.81 (>3)
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	<u>Muscle, liver, kidney, fat, eggs, milk</u>: • HPLC-MS/MS for the determination of CGA205375. LOQ 0.01 mg/kg (tissues, fat, eggs), LOQ 0.005 mg/kg (milk). Calculated LOQ for the above-proposed enforcement residue definition (considering the molecular weights of each compound): 0.012 mg/kg (rounded to 0.01 mg/kg in the MRL review). ILV available (fat, liver, eggs, milk). (EFSA, 2021) • QuECHERs method in routine analysis, for the determination of CGA205375. LOQ 0.01 mg/kg (muscle, fat, liver, kidney, milk and eggs). Calculated LOQ for the above-proposed enforcement residue definition (considering the molecular weights of each compound): 0.012 mg/kg. (EURLs, 2022) Extraction efficiency has been sufficiently demonstrated (Spain, 2023b).	

Abbreviations: TDMs, triazole derivative metabolites; P_{OW}, partition coefficient between *n*-octanol and water; HPLC-MS/MS, high performance liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation; LOQ, limit of quantification; QuECHERs, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

B.3 | CONSUMER RISK ASSESSMENT

ARfD	**Difenoconazole** 0.16 mg/kg bw (European Commission, 2013) **1,2,4-triazole** 0.1 mg/kg bw (European Commission, 2020a) **Triazole alanine** 0.3 mg/kg bw (European Commission, 2020a) **Triazole acetic acid** 1 mg/kg bw (European Commission, 2020a) **Triazole lactic acid** 0.3 mg/kg bw (European Commission, 2020a)
Highest IESTI, according to EFSA PRIMo	**Difenoconazole** Grapefruits: 2.3% of ARfD Oranges: 3.8% of ARfD Lemons: 1.0% of ARfD Limes: 0.6% of ARfD Mandarins: 1.7% of ARfD Other citrus fruit: no acute RA performed Orange juice: 6.9% of ARfD Lemon jam: 0.4% of ARfD Lime juice: <0.01% of ARfD Almonds: <0.01% of ARfD Brazil nuts: <0.01% of ARfD Cashew nuts: <0.01% of ARfD Chestnuts: 0.1% of ARfD Coconuts: 0.2% of ARfD Hazelnuts/cobnuts: 0.1% of ARfD Macadamia: 0.03% of ARfD (adults) Pecans: 0.04% of ARfD Pine nut kernels: 0.02% of ARfD (adults) Pistachios: 0.1% of ARfD Walnuts: 0.1% of ARfD Other tree nuts: no acute RA performed Coconut drink: 0.1% of ARfD Mangoes: 0.6% of ARfD Papayas: 0.3% of ARfD Peas (dry): 0.1% of ARfD Peas, canned: 0.2% of ARfD Soyabeans: 0.1% of ARfD Soya drink: 0.04% of ARfD Soyabeans, boiled: 0.02% of ARfD **1,2,4-T** Grapefruits: 0.8% of ARfD Oranges: 1.3% of ARfD Lemons: 0.3% of ARfD Limes: 0.2% of ARfD Mandarins: 0.6% of ARfD Other citrus fruit: no acute RA performed Almonds: 0.5% of ARfD Brazil nuts: 0.2% of ARfD Cashew nuts: 0.5% of ARfD

Chestnuts: 0.8% of ARfD
Coconuts: 2.7% of ARfD
Hazelnuts/cobnuts: 0.6% of ARfD
Macadamia: 0.4% of ARfD
Pecans: 0.5% of ARfD
Pine nut kernels: 0.2% of ARfD
Pistachios: 1.1% of ARfD
Walnuts: 0.6% of ARfD
Other tree nuts: no acute RA performed

Blueberries: 0.1% of ARfD

Mangoes: 3.9% of ARfD
Papayas: 2.1% of ARfD

Peas (dry): 0.1% of ARfD

Soyabeans: 0.1% of ARfD

TAA
Grapefruits: 0.1% of ARfD
Oranges: 0.1% of ARfD
Lemons: <0.01% of ARfD
Limes: <0.01% of ARfD
Mandarins: 0.1% of ARfD
Other citrus fruit: no acute RA performed

Almonds: <0.01% of ARfD
Brazil nuts: <0.01% of ARfD
Cashew nuts: <0.01% of ARfD
Chestnuts: 0.1% of ARfD
Coconuts: 0.2% of ARfD
Hazelnuts/cobnuts: <0.01% of ARfD
Macadamia: <0.01% of ARfD
Pecans: <0.01% of ARfD
Pine nut kernels: <0.01% of ARfD
Pistachios: 0.1% of ARfD
Walnuts: <0.01% of ARfD
Other tree nuts: no acute RA performed

Blueberries: <0.01% of ARfD

Mangoes: 0.9% of ARfD
Papayas: 0.2% of ARfD

Peas (dry): <0.01% of ARfD

Soyabeans: <0.01% of ARfD

TA + TLA
Grapefruits: 0.8% of ARfD [0.5% of ARfD (TA) + 0.3% of ARfD (TLA)]
Oranges: 1.3% of ARfD [0.9% of ARfD (TA) + 0.4% of ARfD (TLA)]
Lemons: 0.3% of ARfD [0.2% of ARfD (TA) +0.1% of ARfD (TLA)]
Limes: 0.2% of ARfD [0.1% of ARfD (TA) +0.1% of ARfD (TLA)]
Mandarins: 0.6% of ARfD [0.4% of ARfD (TA) + 0.2% of ARfD (TLA)]
Other citrus fruit: no acute RA performed

	Almonds: 4.5% of ARfD [4.1% of ARfD (TA) + 0.4% of ARfD (TLA)] Brazil nuts: 1.3% of ARfD [1.2% of ARfD (TA) + 0.1% of ARfD (TLA)] Cashew nuts: 3.9% of ARfD [3.6% of ARfD (TA) + 0.3% of ARfD (TLA)] Chestnuts: 6.5% of ARfD [5.9% of ARfD (TA) + 0.6% of ARfD (TLA)] Coconuts: 22.3% of ARfD [20.4% of ARfD (TA) +1.9% of ARfD (TLA)] Hazelnuts/cobnuts: 5% of ARfD [4.6% of ARfD (TA) + 0.4% of ARfD (TLA)] Macadamia: 3.3% of ARfD [3% of ARfD (TA) + 0.3% of ARfD (TLA)] Pecans: 4.3% of ARfD [3.9% of ARfD (TA) + 0.4% of ARfD (TLA)] Pine nut kernels: 1.5% of ARfD [1.4% of ARfD (TA) + 0.1% of ARfD (TLA)] Pistachios: 9% of ARfD [8.2% of ARfD (TA) + 0.8% of ARfD (TLA)] Walnuts: 5.2% of ARfD [4.8% of ARfD (TA) +0.4% of ARfD (TLA)] Other tree nuts: no acute RA performed Blueberries: 0.5% of ARfD [0.1% of ARfD (TA) + 0.4% of ARfD (TLA)] Mangoes: 33.5% of ARfD [19.9% of ARfD (TA) + 13.6% of ARfD (TLA)] Papayas: 16.5% of ARfD [13.4% of ARfD (TA) +3.1% of ARfD (TLA)] Peas (dry): 0.3% of ARfD [0.3% of ARfD (TA) + <0.01% of ARfD (TLA)] Soyabeans: 0.2% of ARfD [0.1% of ARfD (TA) + 0.1% of ARfD (TLA)]
Assumptions made for the calculations	Calculations were performed with PRIMo revision 3.1. **Difenoconazole** The calculation is based on the highest residue (HR) levels expected in citrus fruits, tree nuts, mangoes and papayas, and the median residue (STMR) levels expected in dry peas and soyabeans, multiplied by the Uncertainty Factor (UF) of 1.3 to accommodate the preferential degradation of difenoconazole diastereomers. For mangoes and papayas, the HR levels measured in the pulp were used. For citrus fruits, the PeF derived in the present assessment was also applied. **TDMs:** The calculations are based on the highest residue (HR) levels expected in citrus fruits, tree nuts, blueberries, mangoes and papayas and the median residue (STMR) levels in dry peas and soyabeans, according to the submitted residue trials. For citrus fruits, mangoes and papayas, the HR levels measured in the pulp were used. The short-term risk assessment for the sum of TA and TLA is affected by uncertainties due to the lack of information on storage stability of TA in tree nuts.

ADI	**Difenoconazole:** 0.01 mg/kg bw per day (European Commission, 2013) **1,2,4-triazole:** 0.023 mg/kg bw (European Commission, 2020a) **Triazole alanine:** 0.3 mg/kg bw (European Commission, 2020a) **Triazole acetic acid:** 1 mg/kg bw (European Commission, 2020a) **Triazole lactic acid:** 0.3 mg/kg bw (European Commission, 2020a)
Highest IEDI, according to EFSA PRIMo	**Difenoconazole** 85% of ADI (NL toddlers diet) <u>Contribution of crops assessed:</u> Grapefruits: 0.1% of ADI (IE adult diet) Oranges: 0.6% of ADI (DE child diet) Lemons: 0.06% of ADI (GEMS/Food G11 diet) Limes: 0.01% of ADI (IE adult diet) Mandarins: 0.12% of ADI (FR toddler 2 3 yr diet) Other citrus fruit: <0.01% of ADI (PL general diet) Almonds: <0.01% of ADI (GEMS/Food G08 diet) Brazil nuts: 0.01% of ADI (IE adult diet) Cashew nuts: <0.01% of ADI (IE adult diet) Chestnuts: 0.01% of ADI (FR child 3-15 yr diet) Coconuts: 0.06% of ADI (NL toddler diet) Hazelnuts/cobnuts: 0.01% of ADI (DE child diet) Macadamia: <0.01% of ADI (GEMS/Food G08 diet) Pecans: 0.01% of ADI (IE adult diet) Pine nut kernels: <0.01% of ADI (GEMS/Food G11) Pistachios: 0.01% of ADI (IE adult diet) Walnuts: 0.01% of ADI (IE adult diet) Other tree nuts: <0.01% of ADI (IT toddler diet) Mangoes: 0.03% of ADI (IE adult diet) Papayas: <0.01% of ADI (SE general diet) Peas (dry): 0.10% of ADI (IE adult diet) Soyabeans: 0.63% of ADI (GEMS/Food G11) **1,2,4-T** 93% of ADI (NL Toddler diet) <u>Contribution of crops assessed:</u> Grapefruits: 0.15% of ADI (IE adult diet) Oranges: 0.87% of ADI (DE child diet) Lemons: 0.08% of ADI (GEMS/Food G11 diet) Limes: 0.01% of ADI (IE adult diet) Mandarins: 0.17% of ADI (FR toddler diet) Other citrus fruit: <0.01% of ADI (PL general diet) Almonds: <0.01% of ADI (GEMS/Food G08 diet) Brazil nuts: <0.01% of ADI (IE adult diet) Cashew nuts: <0.01% of ADI (IE adult diet) Chestnuts: <0.01% of ADI (FR child 3 15 yr diet) Coconuts: 0.02% of ADI (NL toddler diet) Hazelnuts/cobnuts: <0.01% of ADI (DE child diet)

Macadamia: <0.01% of ADI (GEMS/Food G08 diet)
Pecans: <0.01% of ADI (IE adult diet)
Pine nut kernels: <0.01% of ADI (GEMS/Food G11 diet)
Pistachios: <0.01% of ADI (IE adult diet)
Walnuts: <0.01% of ADI (IE adult diet)
Other tree nuts: <0.01% of ADI (IT toddler diet)

Blueberries: <0.01% of ADI (NL toddler diet)

Mangoes: 0.06% of ADI (IE adult diet)
Papayas: <0.01% of ADI (SE general diet)

Peas (dry): 0.06% of ADI (IE adult diet)

Soyabeans: 0.81% of ADI (GEMS/Food G11 diet)

TAA
1% of ADI (NL toddler diet)

Contribution of crops assessed:
Grapefruits: <0.01% of ADI (IE adult diet)
Oranges: 0.02% of ADI (DE child diet)
Lemons: <0.01% of ADI (GEMS/Food G11 diet)
Limes: <0.01% of ADI (IE adult diet)
Mandarins: <0.01% of ADI (FR toddler diet)
Other citrus fruit: <0.01% of ADI (PL general diet)

Almonds: <0.01% of ADI (GEMS/Food G08 diet)
Brazil nuts: <0.01% of ADI (IE adult diet)
Cashew nuts: <0.01% of ADI (IE adult diet)
Chestnuts: <0.01% of ADI (FR child 3 15 yr diet)
Coconuts: <0.01% of ADI (NL toddler diet)
Hazelnuts/cobnuts: <0.01% of ADI (DE child diet)
Macadamia: <0.01% of ADI (GEMS/Food G08 diet)
Pecans: <0.01% of ADI (IE adult diet)
Pine nut kernels: <0.01% of ADI (GEMS/Food G11 diet)
Pistachios: <0.01% of ADI (IE adult diet)
Walnuts: <0.01% of ADI (IE adult diet)
Other tree nuts: <0.01% of ADI (IT toddler diet)

Blueberries: <0.01% of ADI (NL toddler diet)

Mangoes: <0.01% of ADI (IE adult diet)
Papayas: <0.01% of ADI (SE general diet)

Peas (dry): <0.01% of ADI (IE adult diet)

Soyabeans: 0.04% of ADI (GEMS/Food G11 diet)

TA + TLA
7% of ADI (NL toddler diet)

Contribution of crops assessed:
Grapefruits: 0.08% of ADI (IE adult)
Oranges: 0.48% of ADI (DE child diet)
Lemons: 0.04% of ADI (GEMS/Food G11 diet)
Limes: <0.01% of ADI (IE adult diet)
Mandarins: 0.09% of ADI (FR toddler diet)
Other citrus fruit: <0.01% of ADI (PL general diet)

Almonds: <0.01% of ADI (GEMS/Food G08 diet)

	Brazil nuts: <0.01% of ADI (IE adult diet) Cashew nuts: <0.01% of ADI (IE adult diet) Chestnuts: <0.01% of ADI (FR child 3 15 yr diet) Coconuts: 0.04% of ADI (NL toddler diet) Hazelnuts/cobnuts: 0.01% of ADI (DE child diet) Macadamia: <0.01% of ADI (GEMS/Food G08 diet) Pecans: 0.01% of ADI (IE adult diet) Pine nut kernels: <0.01% of ADI (GEMS/Food G11 diet) Pistachios: 0.02% of ADI (IE adult diet) Walnuts: <0.01% of ADI (IE adult diet) Other tree nuts: <0.01% of ADI (IT toddler diet) Blueberries: <0.01% of ADI (NL toddler diet) Mangoes: 0.06% of ADI (IE adult diet) Papayas: <0.01% of ADI (SE general diet) Peas (dry): 0.02% of ADI (IE adult diet) Soyabeans: 1.36% of ADI (GEMS/Food G11 diet)
Assumptions made for the calculations	Calculations were performed with PRIMo revision 3.1. The calculation updates the comprehensive long-term consumer exposure calculation performed by the MRL review (EFSA, 2024c), noting that the conclusions of the MRL have not been endorsed yet. **Difenoconazole** The calculation is based on the median residue (STMR) levels derived for plant and animal commodities, multiplied by the uncertainty factors (UFs) of 1.3 and 2, respectively, to accommodate the preferential degradation of difenoconazole diastereomers. For citrus fruits and cucurbits with inedible peel, peeling factors were also applied. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation. For animal commodities the STMR values supporting the existing EU MRLs as derived by the JMPR assessments were used as input values, highlighting that these values correspond to the sum of difenoconazole and difenoconazole alcohol (CGA205375) expressed as difenoconazole, assuming that parent and metabolite have a similar toxicological profile. Noting that the toxicological profile of metabolite CGA205375 has not been addressed, the consumer risk assessment resulting from the intake of animal commodities remains indicative and might be subject to revision once the renewal of the approval process for difenoconazole is finalised. **TDMs:** The calculations are based on the median residue (STMR) levels derived for plant and animal commodities. For mangoes and papayas, the STMR levels measured in the pulp were used. The contributions of commodities where no GAP was reported in the framework of the assessment of TDMs in light of confirmatory data and the following assessments (EFSA, 2018b, 2023; Spain, 2023b) were not included in the calculation. The long-term risk assessment for the sum of TA and TLA is affected by uncertainties due to the lack of information on storage stability of TA in tree nuts.

ArfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue

B.4 | RECOMMENDED MRLS

Code[a]	Commodity	Existing EU MRL/ MRL (EFSA, 2024c)[b] (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Difenoconazole (sum of isomers)				
0110000	Citrus fruits	0.6/0.6 tentative[c] Data gap #8	0.6	The submitted data are sufficient to derive an MRL of 1 mg/kg for the authorised US use. To align with the US tolerance, an MRL of 0.6 mg/kg is proposed. Since the existing EU MRL is in line with the US tolerance, no modification of the current MRL is necessary. This dossier provides peel and pulp data as well as residue data on TDMs. The data gap identified in the MRL review is therefore addressed. The tentative MRL derived in the MRL review is confirmed. Risk for consumers is unlikely.
0120010	Almonds	0.05*/0.05 tentative[c] Data gap #1 and #8	0.03	Lower LOQ of 0.01 mg/kg is available according to data from latest assessments. The submitted data are sufficient to derive an MRL proposal for the authorised US use. The tolerance in US is 0.03 mg/kg. The data gaps identified in the MRL review are addressed. A new lower MRL, fully supported by data, is proposed. Risk for consumers is unlikely.
0120020 0120030 0120040 0120050 0120060 0120070 0120080 0120090 0120100 0120110	Brazil nuts Cashew nuts Chestnuts Coconuts Hazelnuts/cobnuts Macadamias Pecans Pine nut kernels Pistachios Walnuts	0.05*/0.03 tentative[c] data gap #8	0.03	Lower LOQ of 0.01 mg/kg is available according to data from latest assessments. The submitted data are sufficient to derive an MRL proposal for the authorised US use. The tolerance in US is 0.03 mg/kg. The data gap identified in the MRL review is addressed. The tentative MRL derived in the MRL review is confirmed. Risk for consumers is unlikely.
0154010	Blueberries	4/4 tentative[c] data gap #1	No MRL modification	The existing EU MRL is based on the Codex MRL. No MRL modification was requested under the present assessment. In the present dossier, the applicant provided data on TDMs to supplement the TDM database. The data gap identified in the MRL review is not addressed.
0163030	Mangoes	0.1/0.1 tentative[c] data gap #2	0.2	The submitted data are sufficient to derive an MRL proposal for the authorised Brazilian use. The tolerance in Brazil is 0.2 mg/kg. The data gap identified in the MRL review is addressed. A new higher MRL, fully supported by data, is proposed. Risk for consumers is unlikely.
0163040	Papayas	0.2/0.2 tentative[c] data gap #1	0.3	The submitted data are sufficient to derive an MRL proposal for the authorised Brazilian use. The tolerance in Brazil is 0.3 mg/kg. The data gap identified in the MRL review is addressed. A new higher MRL, fully supported by data, is proposed. Risk for consumers is unlikely.
0300030	Peas (dry)	0.15/0.15 tentative[c] data gap #2 and 8	0.15	The submitted data are sufficient to derive an MRL proposal for the authorised US use. The tolerance in US is 0.2 mg/kg. The data gaps identified in the MRL review are addressed. The tentative MRL derived in the MRL review is confirmed. Risk for consumers is unlikely.
0401070	Soya beans	0.1/0.1 tentative[c] data gap #2 and 8	0.15	The submitted data are sufficient to derive an MRL of 0.3 mg/kg for the authorised US use. To align with the US tolerance, an MRL of 0.15 mg/kg is proposed. The data gaps identified in the MRL review are addressed. Risk for consumers is unlikely.

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

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

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

[b]MRLs proposed in EFSA (2024c), not yet implemented in the regulation.

[c]A tentative MRL was derived in the MRL review with the data gaps identified (see below).

Data gap #1: A full data set of GAP compliant residue trials analysing for difenoconazole, 1,2,4-T, TAA and the sum of TA and TLA, supporting the authorised uses.

Data gap #2: A full data set of GAP compliant residue trials analysing for 1,2,4-T, TAA and the sum of TA and TLA, supporting the authorised uses.

Data gap #8: CXLs set for animal and plant commodities are not fully supported by data, as trials analysing for all TDMs are not available.

APPENDIX C

Pesticide Residue Intake Model (PRIMo)

1. PRIMo file DIFENOCONAZOLE – acute and chronic exposure

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Difenoconazole (F)

LOQs (mg/kg) range from: 0.01 to: 0.01

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.16
Source of ADI:	EC, 2013	Source of ARfD:	EC, 2013
Year of evaluation:		Year of evaluation:	

Input values

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

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

Comments: **Scenario CX considering existing CXLs**
UF 1.3 applied to accommodate the potential shift in the isomers ratio of parent difenoconazole in plants.
Indicative UF 2 applied to accommodate the potential shift in the isomers ratio of metabolite CGA205375 in livestock.

Refined calculation 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)	85%	NL toddler	8.53	15%	Apples	13%	Milk: Cattle	10%	Table grapes		85%
	61%	DE child	6.12	18%	Apples	9%	Table grapes	4%	Milk: Cattle		61%
	61%	GEMS/Food G06	6.10	18%	Rice	12%	Tomatoes	7%	Table grapes		61%
	52%	GEMS/Food G10	5.17	14%	Rice	4%	Tomatoes	3%	Wine grapes		52%
	48%	IE adult	4.85	8%	Wine grapes	8%	Tea (dried leaves of Camellia sinensis)	3%	Sheep: Liver		48%
	48%	GEMS/Food G07	4.84	10%	Wine grapes	4%	Rice	4%	Tomatoes		48%
	48%	NL child	4.75	8%	Apples	7%	Table grapes	5%	Milk: Cattle		48%
	47%	GEMS/Food G08	4.70	7%	Wine grapes	5%	Olives for oil production	4%	Tomatoes		47%
	45%	GEMS/Food G11	4.53	7%	Wine grapes	3%	Rice	3%	Tomatoes		45%
	42%	PT general	4.20	17%	Wine grapes	9%	Rice	3%	Tomatoes		42%
	41%	GEMS/Food G15	4.13	7%	Wine grapes	4%	Tomatoes	4%	Rice		41%
	40%	FR adult	3.95	16%	Wine grapes	9%	Tea (dried leaves of Camellia sinensis)	2%	Rice		40%
	39%	FR child 3 15 yr	3.88	5%	Rice	5%	Milk: Cattle	3%	Tomatoes		39%
	37%	RO general	3.68	11%	Wine grapes	6%	Tomatoes	3%	Rice		37%
	35%	FR toddler 2 3 yr	3.53	7%	Rice	6%	Milk: Cattle	5%	Apples		35%
	34%	ES child	3.40	5%	Rice	4%	Olives for oil production	3%	Tomatoes		34%
	34%	UK infant	3.40	9%	Milk: Cattle	7%	Rice	4%	Tea (dried leaves of Camellia sinens		34%
	33%	SE general	3.31	6%	Bovine: Muscle/meat	5%	Rice	3%	Lettuces		33%
	32%	DK child	3.17	3%	Rice	3%	Apples	3%	Swine: Muscle/meat		32%
	32%	DE women 14-50 yr	3.16	6%	Wine grapes	4%	Apples	3%	Milk: Cattle		32%
	30%	DE general	3.03	6%	Wine grapes	3%	Apples	3%	Milk: Cattle		30%
	30%	UK toddler	2.96	7%	Rice	5%	Milk: Cattle	2%	Apples		30%
	26%	NL general	2.63	4%	Wine grapes	2%	Tea (dried leaves of Camellia sinensis)	2%	Apples		26%
	26%	ES adult	2.60	4%	Lettuces	3%	Wine grapes	3%	Rice		26%
	23%	UK adult	2.33	7%	Wine grapes	4%	Rice	3%	Tea (dried leaves of Camellia sinens		23%
	23%	UK vegetarian	2.30	6%	Wine grapes	4%	Rice	3%	Tea (dried leaves of Camellia sinens		23%
	21%	DK adult	2.13	6%	Wine grapes	2%	Tomatoes	1%	Apples		21%
	20%	IT toddler	2.04	5%	Tomatoes	3%	Wheat	2%	Rice		20%
	20%	FI 3 yr	1.95	6%	Rice	2%	Strawberries	2%	Tomatoes		20%
	19%	IT adult	1.87	4%	Tomatoes	3%	Lettuces	2%	Wheat		19%
	17%	FR infant	1.68	4%	Milk: Cattle	2%	Apples	1%	Carrots		17%
	15%	FI 6 yr	1.54	5%	Rice	2%	Strawberries	1%	Tomatoes		15%
	14%	LT adult	1.40	3%	Apples	2%	Rice	2%	Tomatoes		14%
	12%	PL general	1.16	3%	Apples	3%	Tomatoes	2%	Table grapes		12%
	12%	FI adult	1.16	2%	Wine grapes	2%	Tomatoes	1%	Rice		12%
	8%	IE child	0.78	3%	Rice	0.8%	Milk: Cattle	0.6%	Wheat		8%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Difenoconazole (F) is unlikely to present a public health concern.

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.
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)
89%	Table grapes	3 / 1.95	142
79%	Celeries	5 / 3.37	126
78%	Rhubarbs	5 / 3.37	125
78%	Lettuces	4 / 3.26	124
61%	Tomatoes	2 / 1.69	98
49%	Escaroles/broad-leaved	3 / 1.95	78
48%	Spring onions/green onions	9 / 4.94	77
37%	Spinaches	4 / 2.6	59
34%	Florence fennels	5 / 3.37	55
32%	Pears	0.4 / 0.36	50
31%	Chinese cabbages/pe-tsai	3 / 1.52	49
25%	Apples	0.4 / 0.36	39
20%	Kales	1.5 / 0.74	33
20%	Peaches	0.5 / 0.34	32
20%	Sweet peppers/bell peppers	0.9 / 0.53	32

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)
41%	Table grapes	3 / 1.95	66
39%	Florence fennels	5 / 3.37	63
34%	Celeries	5 / 3.37	54
30%	Blueberries	4 / 5.2	47
29%	Wine grapes	3 / 1.95	46
25%	Lettuces	4 / 3.26	40
25%	Escaroles/broad-leaved	3 / 1.95	39
24%	Chinese cabbages/pe-tsai	3 / 1.52	39
22%	Cardoons	5 / 3.37	35
20%	Chards/beet leaves	3 / 1.69	32
20%	Rhubarbs	5 / 3.37	31
17%	Tomatoes	2 / 1.69	27
15%	Red mustards	4 / 4.42	23
14%	Spring onions/green onions	9 / 4.94	22
9%	Strawberries	2 / 1.56	15

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)
95%	Florence fennels / boiled	5 / 3.37	153
81%	Escaroles/broad-leaved end	3 / 1.95	129
78%	Rhubarbs / sauce/puree	5 / 3.37	126
33%	Chards/beet leaves / boiled	3 / 1.69	53
26%	Broccoli / boiled	0.7 / 0.53	42
23%	Spinaches / frozen; boiled	4 / 2.6	36
19%	Leeks / boiled	0.6 / 0.52	30
18%	Wine grapes / juice	3 / 0.68	30
13%	Kales / boiled	1.5 / 0.74	20
12%	Turnips / boiled	0.5 / 0.39	20
12%	Parsnips / boiled	0.5 / 0.39	20
11%	Beetroots / boiled	0.5 / 0.39	17
9%	Pumpkins / boiled	0.2 / 0.16	14
7%	Oranges / juice	0.6 / 0.21	11
6%	Salsifies / boiled	0.5 / 0.39	10

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)
71%	Celeries / boiled	5 / 3.37	114
41%	Florence fennels / boiled	5 / 3.37	65
31%	Rhubarbs / sauce/puree	5 / 3.37	49
26%	Cardoons / boiled	5 / 3.37	41
25%	Escaroles/broad-leaved	3 / 1.95	40
13%	Spinaches / frozen; boiled	4 / 2.6	22
13%	Chards/beet leaves / boiled	3 / 1.69	21
9%	Beetroots / boiled	0.5 / 0.39	15
9%	Wine grapes / juice	3 / 0.68	14
8%	Broccoli / boiled	0.7 / 0.53	13
7%	Table grapes / raisins	3 / 9.17	11
6%	Leeks / boiled	0.6 / 0.52	9.1
5%	Pumpkins / boiled	0.2 / 0.16	8.6
5%	Parsnips / boiled	0.5 / 0.39	8.3
5%	Turnips / boiled	0.5 / 0.39	7.4

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

2. PRIMo file 1,2,4-Triazole (1,2,4-T) – acute exposure

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:	COM	Source of ARfD:	COM
Year of evaluation:	2021	Year of evaluation:	2021

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)	93%	NL toddler	21.37	83%	Milk: Cattle	2%	Maize/corn	1%	Bovine: Muscle/meat		93%
	58%	UK infant	13.45	54%	Milk: Cattle	1%	Bovine: Muscle/meat	0.6%	Wheat		58%
	46%	FR toddler 2 3 yr	10.68	41%	Milk: Cattle	1%	Bovine: Muscle/meat	0.7%	Wheat		46%
	41%	NL child	9.47	34%	Milk: Cattle	2%	Sugar beet roots	1%	Bovine: Muscle/meat		41%
	39%	FR child 3 15 yr	8.95	32%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		39%
	34%	UK toddler	7.75	29%	Milk: Cattle	2%	Bovine: Muscle/meat	0.9%	Wheat		34%
	32%	DE child	7.45	27%	Milk: Cattle	0.9%	Wheat	0.9%	Oranges		32%
	25%	FR infant	5.80	23%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.3%	Sugar beet roots		25%
	25%	SE general	5.69	17%	Milk: Cattle	5%	Bovine: Muscle/meat	0.7%	Wheat		25%
	24%	DK child	5.51	18%	Milk: Cattle	2%	Bovine: Muscle/meat	1%	Swine: Muscle/meat		24%
	23%	ES child	5.30	17%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		23%
	21%	DE women 14-50 yr	4.90	17%	Milk: Cattle	1.0%	Sugar beet roots	0.5%	Swine: Muscle/meat		21%
	21%	DE general	4.88	17%	Milk: Cattle	0.9%	Sugar beet roots	0.6%	Swine: Muscle/meat		21%
	20%	RO general	4.66	16%	Milk: Cattle	1%	Wheat	0.7%	Swine: Muscle/meat		20%
	16%	GEMS/Food G11	3.62	11%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.8%	Wheat		16%
	16%	NL general	3.58	12%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.6%	Sugar beet roots		16%
	15%	GEMS/Food G15	3.47	10%	Milk: Cattle	1.0%	Wheat	0.8%	Swine: Muscle/meat		15%
	15%	GEMS/Food G07	3.38	9%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		15%
	13%	GEMS/Food G08	3.00	8%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Wheat		13%
	13%	GEMS/Food G10	2.97	8%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		13%
	11%	IE adult	2.42	6%	Milk: Cattle	0.5%	Wheat	0.5%	Bovine: Muscle/meat		11%
	10%	ES adult	2.36	7%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.5%	Wheat		10%
	10%	DK adult	2.22	7%	Milk: Cattle	0.6%	Bovine: Muscle/meat	0.5%	Swine: Muscle/meat		10%
	9%	FR adult	2.12	6%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.5%	Wheat		9%
	9%	GEMS/Food G06	2.09	3%	Milk: Cattle	2%	Wheat	0.4%	Sugar canes		9%
	8%	LT adult	1.74	6%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.3%	Bovine: Muscle/meat		8%
	6%	UK adult	1.43	4%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.4%	Wheat		6%
	6%	UK vegetarian	1.38	5%	Milk: Cattle	0.4%	Wheat	0.2%	Oranges		6%
	6%	IE child	1.33	5%	Milk: Cattle	0.3%	Wheat	0.1%	Swine: Muscle/meat		6%
	2%	IT toddler	0.56	1%	Wheat	0.3%	Other cereals	0.1%	Bananas		2%
	2%	PT general	0.50	0.9%	Wheat	0.2%	Potatoes	0.2%	Rice		2%
	2%	FI 3 yr	0.38	0.3%	Bananas	0.3%	Wheat	0.2%	Potatoes		2%
	2%	IT adult	0.37	0.9%	Wheat	0.2%	Other cereals	0.1%	Oranges		2%
	1%	FI 6 yr	0.29	0.2%	Wheat	0.2%	Potatoes	0.2%	Bananas		1%
	0.7%	FI adult	0.17	0.2%	Rye	0.1%	Oranges	0.1%	Wheat		0.7%
	0.5%	PL general	0.12	0.1%	Potatoes	0.1%	Apples	0.1%	Head cabbages		0.5%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of 1,2,4-T is unlikely to present a public health concern.

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.
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)
40%	Milk: Cattle	0 / 0.32	40
8%	Milk: Goat	0 / 0.32	7.7
7%	Cauliflowers	0 / 0.11	6.5
6%	Kohlrabies	0 / 0.11	5.9
5%	Head cabbages	0 / 0.11	5.0
5%	Kales	0 / 0.11	5.0
5%	Bananas	0 / 0.05	4.9
5%	Broccoli	0 / 0.11	4.7
5%	Melons	0 / 0.03	4.6
4%	Mangoes	0 / 0.05	3.9
4%	Watermelons	0 / 0.03	3.7
4%	Chinese cabbages/pe-tsai	0 / 0.11	3.6
3%	Pears	0 / 0.02	2.9
3%	Bovine: Liver	0 / 0.36	2.9
3%	Coconuts	0 / 0.19	2.7

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)
12%	Milk: Cattle	0 / 0.32	12
6%	Milk: Goat	0 / 0.32	5.9
5%	Milk: Sheep	0 / 0.32	4.8
5%	Head cabbages	0 / 0.11	4.8
3%	Chinese cabbages/pe-tsai	0 / 0.11	2.9
3%	Broccoli	0 / 0.11	2.7
3%	Cauliflowers	0 / 0.11	2.6
2%	Kales	0 / 0.11	2.2
2%	Other farmed animals:	0 / 0.33	1.8
2%	Bovine: Muscle	0 / 0.31	1.8
2%	Coconuts	0 / 0.19	1.6
2%	Kohlrabies	0 / 0.11	1.6
2%	Sheep: Muscle/meat	0 / 0.33	1.6
1%	Equine: Muscle/meat	0 / 0.31	1.5
1%	Bovine: Liver	0 / 0.36	1.4

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)
9%	Broccoli / boiled	0 / 0.11	8.9
8%	Cauliflowers / boiled	0 / 0.11	7.9
6%	Sugar beets (root) / sugar	0 / 0.6	5.5
3%	Kales / boiled	0 / 0.11	3.1
3%	Pumpkins / boiled	0 / 0.03	2.7
3%	Oranges / juice	0 / 0.05	2.6
2%	Witloofs / boiled	0 / 0.02	1.8
1%	Potatoes / fried	0 / 0.02	1.5
1%	Escaroles/broad-leaved endi	0 / 0.02	1.3
1%	Maize / oil	0 / 1.25	1.2
1%	Brussels sprouts / boiled	0 / 0.11	1.1
1%	Courgettes / boiled	0 / 0.03	1.1
0.8%	Turnips / boiled	0 / 0.02	0.81
0.8%	Parsnips / boiled	0 / 0.02	0.81
0.8%	Sweet potatoes / boiled	0 / 0.02	0.81

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)
5%	Cauliflowers / boiled	0 / 0.11	4.7
3%	Broccoli / boiled	0 / 0.11	2.7
2%	Kohlrabies / boiled	0 / 0.11	2.4
2%	Sugar beets (root) / sugar	0 / 0.6	2.2
2%	Pumpkins / boiled	0 / 0.03	1.7
0.8%	Oranges / juice	0 / 0.05	0.76
0.7%	Courgettes / boiled	0 / 0.03	0.69
0.6%	Maize / oil	0 / 1.25	0.63
0.6%	Beetroots / boiled	0 / 0.02	0.62
0.5%	Grapefruits / juice	0 / 0.05	0.54
0.4%	Escaroles/broad-leaved	0 / 0.02	0.41
0.4%	Witloofs / boiled	0 / 0.02	0.37
0.4%	Head cabbages / canned	0 / 0.04	0.37
0.4%	Barley / beer	0 / 0.01	0.36
0.4%	Beans / canned	0 / 0.05	0.36

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of 1,2,4-T is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

3. PRIMo file 1,2,4-Triazole (1,2,4-T) – chronic exposure

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

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:	COM	Source of ARfD:	COM
Year of evaluation:	2021	Year of evaluation:	2021

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)	93%	NL toddler	21.38	83%	Milk: Cattle	2%	Maize/corn	1%	Bovine: Muscle/meat		93%
	58%	UK infant	13.45	54%	Milk: Cattle	1%	Bovine: Muscle/meat	0.6%	Wheat		58%
	46%	FR toddler 2 3 yr	10.68	41%	Milk: Cattle	1%	Bovine: Muscle/meat	0.7%	Wheat		46%
	41%	NL child	9.47	34%	Milk: Cattle	2%	Sugar beet roots	1%	Bovine: Muscle/meat		41%
	39%	FR child 3 15 yr	8.95	32%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		39%
	34%	UK toddler	7.75	29%	Milk: Cattle	2%	Bovine: Muscle/meat	0.9%	Wheat		34%
	32%	DE child	7.45	27%	Milk: Cattle	0.9%	Wheat	0.9%	Oranges		32%
	25%	FR infant	5.80	23%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.3%	Sugar beet roots		25%
	25%	SE general	5.69	17%	Milk: Cattle	5%	Bovine: Muscle/meat	0.7%	Wheat		25%
	24%	DK child	5.51	18%	Milk: Cattle	2%	Bovine: Muscle/meat	1%	Swine: Muscle/meat		24%
	23%	ES child	5.30	17%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		23%
	21%	DE women 14-50 yr	4.90	17%	Milk: Cattle	1.0%	Sugar beet roots	0.5%	Swine: Muscle/meat		21%
	21%	DE general	4.88	17%	Milk: Cattle	0.9%	Sugar beet roots	0.6%	Swine: Muscle/meat		21%
	20%	RO general	4.66	16%	Milk: Cattle	1%	Wheat	0.7%	Swine: Muscle/meat		20%
	16%	GEMS/Food G11	3.78	11%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.8%	Soyabeans		16%
	16%	NL general	3.58	12%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.6%	Sugar beet roots		16%
	15%	GEMS/Food G15	3.54	10%	Milk: Cattle	1.0%	Wheat	0.8%	Swine: Muscle/meat		15%
	15%	GEMS/Food G07	3.45	9%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		15%
	13%	GEMS/Food G10	3.10	8%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		13%
	13%	GEMS/Food G08	3.08	8%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Wheat		13%
	11%	IE adult	2.43	6%	Milk: Cattle	0.5%	Wheat	0.5%	Bovine: Muscle/meat		11%
	10%	ES adult	2.36	7%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.5%	Wheat		10%
	10%	DK adult	2.22	7%	Milk: Cattle	0.6%	Bovine: Muscle/meat	0.5%	Swine: Muscle/meat		10%
	9%	GEMS/Food G06	2.15	3%	Milk: Cattle	2%	Wheat	0.4%	Sugar canes		9%
	9%	FR adult	2.12	6%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.5%	Wheat		9%
	8%	LT adult	1.74	6%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.3%	Bovine: Muscle/meat		8%
	6%	UK adult	1.43	4%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.4%	Wheat		6%
	6%	UK vegetarian	1.38	5%	Milk: Cattle	0.4%	Wheat	0.2%	Oranges		6%
	6%	IE child	1.33	5%	Milk: Cattle	0.3%	Wheat	0.1%	Swine: Muscle/meat		6%
	2%	IT toddler	0.56	1%	Wheat	0.3%	Other cereals	0.1%	Bananas		2%
	2%	PT general	0.52	0.9%	Wheat	0.2%	Potatoes	0.2%	Rice		2%
	2%	FI 3 yr	0.38	0.3%	Bananas	0.3%	Wheat	0.2%	Potatoes		2%
	2%	IT adult	0.37	0.9%	Wheat	0.2%	Other cereals	0.1%	Oranges		2%
	1%	FI 6 yr	0.29	0.2%	Wheat	0.2%	Potatoes	0.2%	Bananas		1%
	0.7%	FI adult	0.17	0.2%	Rye	0.1%	Oranges	0.1%	Wheat		0.7%
	0.5%	PL general	0.13	0.1%	Potatoes	0.1%	Apples	0.1%	Head cabbages		0.5%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of 1,2,4-T is unlikely to present a public health concern.

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.
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)
40%	Milk: Cattle	0 / 0.32	40
8%	Milk: Goat	0 / 0.32	7.7
7%	Oranges	0 / 0.05	6.6
7%	Cauliflowers	0 / 0.11	6.5
6%	Kohlrabies	0 / 0.11	5.9
5%	Head cabbages	0 / 0.11	5.0
5%	Kales	0 / 0.11	5.0
5%	Bananas	0 / 0.05	4.9
5%	Broccoli	0 / 0.11	4.7
5%	Melons	0 / 0.03	4.6
4%	Mangoes	0 / 0.05	3.9
4%	Grapefruits	0 / 0.05	3.9
4%	Watermelons	0 / 0.03	3.7
4%	Chinese cabbages/pe-tsai	0 / 0.11	3.6
3%	Mandarins	0 / 0.05	3.0

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)
12%	Milk: Cattle	0 / 0.32	12
6%	Milk: Goat	0 / 0.32	5.9
5%	Milk: Sheep	0 / 0.32	4.8
5%	Head cabbages	0 / 0.11	4.8
3%	Chinese cabbages/pe-tsai	0 / 0.11	2.9
3%	Broccoli	0 / 0.11	2.7
3%	Cauliflowers	0 / 0.11	2.6
2%	Kales	0 / 0.11	2.2
2%	Other farmed animals:	0 / 0.33	1.8
2%	Bovine: Muscle	0 / 0.31	1.8
2%	Coconuts	0 / 0.19	1.6
2%	Kohlrabies	0 / 0.11	1.6
2%	Sheep: Muscle/meat	0 / 0.33	1.6
2%	Oranges	0 / 0.05	1.5
1%	Equine: Muscle/meat	0 / 0.31	1.5

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)
9%	Broccoli / boiled	0 / 0.11	8.9
8%	Cauliflowers / boiled	0 / 0.11	7.9
6%	Sugar beets (root) / sugar	0 / 0.6	5.5
3%	Kales / boiled	0 / 0.11	3.1
3%	Pumpkins / boiled	0 / 0.03	2.7
3%	Oranges / juice	0 / 0.05	2.6
2%	Witloofs / boiled	0 / 0.02	1.8
1%	Potatoes / fried	0 / 0.02	1.5
1%	Escaroles/broad-leaved endi	0 / 0.02	1.3
1%	Maize / oil	0 / 1.25	1.2
1%	Brussels sprouts / boiled	0 / 0.11	1.1
1%	Courgettes / boiled	0 / 0.03	1.1
0.8%	Turnips / boiled	0 / 0.02	0.81
0.8%	Parsnips / boiled	0 / 0.02	0.81
0.8%	Sweet potatoes / boiled	0 / 0.02	0.81

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)
5%	Cauliflowers / boiled	0 / 0.11	4.7
3%	Broccoli / boiled	0 / 0.11	2.7
2%	Kohlrabies / boiled	0 / 0.11	2.4
2%	Sugar beets (root) / sugar	0 / 0.6	2.2
2%	Pumpkins / boiled	0 / 0.03	1.7
0.8%	Oranges / juice	0 / 0.05	0.76
0.7%	Courgettes / boiled	0 / 0.03	0.69
0.6%	Maize / oil	0 / 1.25	0.63
0.6%	Beetroots / boiled	0 / 0.02	0.62
0.5%	Grapefruits / juice	0 / 0.05	0.54
0.4%	Escaroles/broad-leaved	0 / 0.02	0.41
0.4%	Witloofs / boiled	0 / 0.02	0.37
0.4%	Head cabbages / canned	0 / 0.04	0.37
0.4%	Barley / beer	0 / 0.01	0.36
0.4%	Beans / canned	0 / 0.05	0.36

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of 1,2,4-T is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

4. PRIMo file Triazole Acetic Acid (TAA) – acute exposure

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

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:	2018	Year of evaluation:	2018

Input values

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

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

Comments: EFSA-Q-2019-00082. The risk assessment for TA conducted in the framework of the EU peeer review of the confirmatory data for TDMs (EFSA, 2018) was update only if the residue level of TA on the specific crop generated from the intended and authrorised uses of mefentrifluconazole was higher than the "v

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)	1%	NL toddler	14.07	0.6%	Maize/corn	0.3%	Wheat	0.2%	Milk: Cattle		1%
	0.9%	DK child	9.35	0.4%	Rye	0.3%	Wheat	0.1%	Milk: Cattle		0.9%
	0.9%	GEMS/Food G06	8.87	0.6%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.9%
	0.7%	IT toddler	6.81	0.5%	Wheat	0.1%	Other cereals	0.0%	Rice		0.7%
	0.6%	DE child	6.35	0.3%	Wheat	0.1%	Milk: Cattle	0.1%	Rye		0.6%
	0.6%	FR child 3 15 yr	6.21	0.4%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.6%
	0.6%	GEMS/Food G10	6.16	0.3%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.6%
	0.6%	GEMS/Food G15	6.12	0.4%	Wheat	0.1%	Barley	0.1%	Maize/corn		0.6%
	0.6%	NL child	6.10	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.6%
	0.6%	GEMS/Food G08	6.05	0.3%	Wheat	0.1%	Barley	0.0%	Rye		0.6%
	0.6%	RO general	5.99	0.4%	Wheat	0.1%	Maize/corn	0.0%	Milk: Cattle		0.6%
	0.6%	UK infant	5.66	0.2%	Wheat	0.2%	Milk: Cattle	0.1%	Maize/corn		0.6%
	0.6%	GEMS/Food G07	5.54	0.3%	Wheat	0.0%	Barley	0.0%	Rice		0.6%
	0.5%	ES child	5.24	0.4%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.5%
	0.5%	UK toddler	5.09	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.5%
	0.5%	FR toddler 2 3 yr	4.91	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.5%
	0.5%	GEMS/Food G11	4.88	0.3%	Wheat	0.1%	Barley	0.0%	Milk: Cattle		0.5%
	0.5%	PT general	4.66	0.3%	Wheat	0.1%	Rice	0.0%	Maize/corn		0.5%
	0.4%	IT adult	4.15	0.3%	Wheat	0.1%	Other cereals	0.0%	Rice		0.4%
	0.4%	SE general	4.12	0.3%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.4%
	0.4%	DE general	3.61	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.4%
	0.4%	DE women 14-50 yr	3.53	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.4%
	0.3%	IE adult	3.47	0.2%	Wheat	0.0%	Buckwheat and other pseudo-cereals	0.0%	Rice		0.3%
	0.3%	ES adult	3.10	0.2%	Wheat	0.0%	Barley	0.0%	Milk: Cattle		0.3%
	0.3%	NL general	2.95	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Barley		0.3%
	0.3%	FI 3 yr	2.73	0.1%	Wheat	0.1%	Rye	0.0%	Oat		0.3%
	0.3%	FR adult	2.56	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.3%
	0.3%	LT adult	2.51	0.1%	Rye	0.1%	Wheat	0.0%	Rice		0.3%
	0.2%	UK vegetarian	2.38	0.2%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.2%
	0.2%	FI 6 yr	2.12	0.1%	Wheat	0.0%	Rye	0.0%	Rice		0.2%
	0.2%	UK adult	2.04	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.2%
	0.2%	DK adult	1.85	0.1%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.2%
	0.2%	FR infant	1.67	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Sugar beet roots		0.2%
	0.1%	IE child	1.38	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.1%
	0.1%	FI adult	1.18	0.1%	Rye	0.0%	Wheat	0.0%	Oat		0.1%
	0.0%	PL general	0.18	0.0%	Apples	0.0%	Potatoes	0.0%	Table grapes		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.

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.
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%	Wheat	0 / 0.79	11
1.0%	Rice	0 / 0.79	10.0
0.9%	Mangoes	0 / 0.11	8.6
0.8%	Pears	0 / 0.06	8.3
0.7%	Table grapes	0 / 0.1	7.3
0.6%	Apples	0 / 0.06	6.5
0.5%	Maize/corn	0 / 0.79	5.3
0.5%	Rye	0 / 0.79	5.0
0.5%	Milk: Cattle	0 / 0.04	5.0
0.5%	Bananas	0 / 0.05	4.9
0.4%	Barley	0 / 0.79	4.4
0.4%	Buckwheat and other	0 / 0.79	3.9
0.3%	Peaches	0 / 0.03	3.2
0.3%	Melons	0 / 0.02	3.0
0.3%	Sorghum	0 / 0.79	2.5
0.2%	Watermelons	0 / 0.02	2.4
0.2%	Coconuts	0 / 0.13	1.9
0.2%	Leeks	0 / 0.03	1.8
0.2%	Papayas	0 / 0.04	1.7
0.2%	Strawberries	0 / 0.1	1.6
0.2%	Bovine: Edible offals (other	0 / 0.22	1.6
0.2%	Potatoes	0 / 0.01	1.5
0.1%	Quinces	0 / 0.06	1.5
0.1%	Escaroles/broad-leaved	0 / 0.04	1.4
0.1%	Plums	0 / 0.03	1.4
0.1%	Witloofs/Belgian endives	0 / 0.04	1.4
0.1%	Lettuces	0 / 0.04	1.4
0.1%	Oranges	0 / 0.01	1.3
0.1%	Cucumbers	0 / 0.02	1.3
0.1%	Sweet peppers/bell peppers	0 / 0.02	1.2
0.1%	Apricots	0 / 0.03	1.2
0.1%	Tomatoes	0 / 0.02	1.2
0.1%	Celeries	0 / 0.03	1.1
0.1%	Rhubarbs	0 / 0.03	1.1
0.1%	Common millet/proso millet	0 / 0.79	1.1
0.1%	Blackberries	0 / 0.1	1.1
0.10%	Milk: Goat	0 / 0.04	0.97
0.09%	Courgettes	0 / 0.02	0.93
0.09%	Wine grapes	0 / 0.1	0.93
0.09%	Raspberries (red and	0 / 0.1	0.92
0.09%	Beans	0 / 0.05	0.91
0.09%	Oat	0 / 0.79	0.88
0.09%	Sweet corn	0 / 0.02	0.87
0.08%	Medlar	0 / 0.06	0.83
0.08%	Bovine: Kidney	0 / 0.22	0.83
0.08%	Spinaches	0 / 0.04	0.81
0.08%	Currants (red, black and	0 / 0.1	0.79
0.08%	Grapefruits	0 / 0.01	0.79
0.08%	Pistachios	0 / 0.13	0.78
0.07%	Poultry: Muscle/meat	0 / 0.04	0.68

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Rice	0 / 0.79	6.7
0.7%	Wheat	0 / 0.79	6.6
0.4%	Rye	0 / 0.79	3.8
0.4%	Barley	0 / 0.79	3.8
0.3%	Table grapes	0 / 0.1	3.4
0.3%	Mangoes	0 / 0.11	2.8
0.3%	Buckwheat and other	0 / 0.79	2.7
0.2%	Wine grapes	0 / 0.1	2.4
0.2%	Pears	0 / 0.06	1.8
0.2%	Maize/corn	0 / 0.79	1.7
0.2%	Apples	0 / 0.06	1.7
0.2%	Milk: Cattle	0 / 0.04	1.5
0.1%	Coconuts	0 / 0.13	1.2
0.1%	Bananas	0 / 0.05	1.1
0.09%	Strawberries	0 / 0.1	0.93
0.09%	Quinces	0 / 0.06	0.91
0.08%	Blackberries	0 / 0.1	0.82
0.08%	Watermelons	0 / 0.02	0.81
0.08%	Melons	0 / 0.02	0.78
0.07%	Milk: Goat	0 / 0.04	0.74
0.07%	Bovine: Edible offals (other	0 / 0.22	0.73
0.07%	Escaroles/broad-leaved	0 / 0.04	0.73
0.07%	Common millet/proso millet	0 / 0.79	0.71
0.07%	Chards/beet leaves	0 / 0.04	0.68
0.07%	Witloofs/Belgian endives	0 / 0.04	0.66
0.07%	Currants (red, black and	0 / 0.1	0.66
0.06%	Peaches	0 / 0.03	0.64
0.06%	Plums	0 / 0.03	0.61
0.06%	Milk: Sheep	0 / 0.04	0.60
0.06%	Chestnuts	0 / 0.13	0.60
0.06%	Florence fennels	0 / 0.03	0.56
0.06%	Papayas	0 / 0.04	0.56
0.06%	Cucumbers	0 / 0.02	0.56
0.05%	Aubergines/egg plants	0 / 0.02	0.54
0.05%	Raspberries (red and	0 / 0.1	0.54
0.05%	Oat	0 / 0.79	0.51
0.05%	Celeries	0 / 0.03	0.48
0.05%	Poultry: Muscle	0 / 0.04	0.47
0.05%	Courgettes	0 / 0.02	0.47
0.05%	Bovine: Kidney	0 / 0.22	0.46
0.05%	Gooseberries (green, red	0 / 0.1	0.45
0.04%	Lettuces	0 / 0.04	0.44
0.04%	Head cabbages	0 / 0.01	0.42
0.04%	Medlar	0 / 0.06	0.41
0.04%	Leeks	0 / 0.03	0.39
0.04%	Globe artichokes	0 / 0.03	0.39
0.04%	Apricots	0 / 0.03	0.37
0.04%	Swine: Edible offals (other	0 / 0.14	0.37
0.04%	Pistachios	0 / 0.13	0.36
0.03%	Swedes/rutabagas	0 / 0.01	0.34

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)
2%	Maize / oil	0 / 19.75	18
1.0%	Wheat / milling (flour)	0 / 0.79	9.6
0.6%	Sugar beets (root) / sugar	0 / 0.6	5.5
0.5%	Rice / milling (polishing)	0 / 0.32	4.8
0.4%	Wheat / milling (wholemeal)	0 / 0.79	4.4
0.4%	Millet / boiled	0 / 0.32	4.3
0.4%	Buckwheat / bulgur and grits	0 / 0.79	4.2
0.3%	Witloofs / boiled	0 / 0.04	3.2
0.3%	Rye / boiled	0 / 0.79	2.9
0.3%	Oat / boiled	0 / 0.79	2.9
0.3%	Buckwheat / boiled	0 / 0.79	2.9
0.3%	Barley / cooked	0 / 0.79	2.9
0.3%	Rye / milling (wholemeal)-ba	0 / 0.79	2.8
0.3%	Oranges / juice	0 / 0.05	2.6
0.2%	Escaroles/broad-leaved end	0 / 0.04	2.4

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%	Maize / oil	0 / 19.75	10
0.6%	Barley / beer	0 / 0.16	5.7
0.3%	Wheat / bread/pizza	0 / 0.79	3.5
0.3%	Rice / milling (polishing)	0 / 0.32	3.1
0.3%	Wheat / pasta	0 / 0.79	3.0
0.3%	Wheat / bread (wholemeal)	0 / 0.79	2.8
0.2%	Sugar beets (root) / sugar	0 / 0.6	2.2
0.2%	Millet / boiled	0 / 0.32	1.8
0.1%	Oat / boiled	0 / 0.79	1.2
0.1%	Pumpkins / boiled	0 / 0.02	1.1
0.1%	Wine grapes / juice	0 / 0.05	1.0
0.1%	Celeries / boiled	0 / 0.03	1.0
0.10%	Apples / juice	0 / 0.03	1.00
0.09%	Wine grapes / wine	0 / 0.1	0.95
0.08%	Oranges / juice	0 / 0.05	0.76

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.

5. PRIMo file Triazole Acetic Acid (TAA) – chronic exposure

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

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:	2018	Year of evaluation:	2018

Input values

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

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

Comments: EFSA-Q-2019-00082. The risk assessment for TA conducted in the framework of the EU peeer review of the confirmatory data for TDMs (EFSA, 2018) was update only if the residue level of TA on the specific crop generated from the intended and authorised uses of mefentrifluconazole was higher than the "v

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)	1%	NL toddler	14.09	0.6%	Maize/corn	0.3%	Wheat	0.2%	Milk: Cattle		1%
	0.9%	DK child	9.35	0.4%	Rye	0.3%	Wheat	0.1%	Milk: Cattle		0.9%
	0.9%	GEMS/Food G06	9.00	0.6%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.9%
	0.7%	IT toddler	6.81	0.5%	Wheat	0.1%	Other cereals	0.0%	Rice		0.7%
	0.7%	GEMS/Food G10	6.50	0.3%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.7%
	0.6%	DE child	6.36	0.3%	Wheat	0.1%	Milk: Cattle	0.1%	Rye		0.6%
	0.6%	GEMS/Food G15	6.31	0.4%	Wheat	0.1%	Barley	0.1%	Maize/corn		0.6%
	0.6%	GEMS/Food G08	6.26	0.3%	Wheat	0.1%	Barley	0.0%	Rye		0.6%
	0.6%	FR child 3 15 yr	6.22	0.4%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.6%
	0.6%	NL child	6.12	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.6%
	0.6%	RO general	5.99	0.4%	Wheat	0.1%	Maize/corn	0.0%	Milk: Cattle		0.6%
	0.6%	GEMS/Food G07	5.73	0.3%	Wheat	0.0%	Barley	0.0%	Rice		0.6%
	0.6%	UK infant	5.66	0.2%	Wheat	0.2%	Milk: Cattle	0.1%	Maize/corn		0.6%
	0.5%	GEMS/Food G11	5.27	0.3%	Wheat	0.1%	Barley	0.0%	Soyabeans		0.5%
	0.5%	ES child	5.25	0.4%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.5%
	0.5%	UK toddler	5.09	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.5%
	0.5%	FR toddler 2 3 yr	4.92	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.5%
	0.5%	PT general	4.69	0.3%	Wheat	0.1%	Rice	0.0%	Maize/corn		0.5%
	0.4%	IT adult	4.15	0.3%	Wheat	0.1%	Other cereals	0.0%	Rice		0.4%
	0.4%	SE general	4.12	0.3%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.4%
	0.4%	DE general	3.61	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.4%
	0.4%	DE women 14-50 yr	3.54	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.4%
	0.3%	IE adult	3.48	0.2%	Wheat	0.0%	Buckwheat and other pseudo-cereals	0.0%	Rice		0.3%
	0.3%	ES adult	3.11	0.2%	Wheat	0.0%	Barley	0.0%	Milk: Cattle		0.3%
	0.3%	NL general	2.96	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Barley		0.3%
	0.3%	FI 3 yr	2.73	0.1%	Wheat	0.1%	Rye	0.0%	Oat		0.3%
	0.3%	FR adult	2.56	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.3%
	0.3%	LT adult	2.51	0.1%	Rye	0.1%	Wheat	0.0%	Rice		0.3%
	0.2%	UK vegetarian	2.38	0.2%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.2%
	0.2%	FI 6 yr	2.13	0.1%	Wheat	0.0%	Rye	0.0%	Rice		0.2%
	0.2%	UK adult	2.04	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.2%
	0.2%	DK adult	1.85	0.1%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.2%
	0.2%	FR infant	1.67	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Sugar beet roots		0.2%
	0.1%	IE child	1.38	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.1%
	0.1%	FI adult	1.19	0.1%	Rye	0.0%	Wheat	0.0%	Oat		0.1%
	0.0%	PL general	0.18	0.0%	Apples	0.0%	Potatoes	0.0%	Table grapes		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.

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.
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%	Oranges	0 / 0.1	13
1%	Wheat	0 / 0.79	11
1.0%	Rice	0 / 0.79	10.0
0.9%	Mangoes	0 / 0.11	8.6
0.8%	Pears	0 / 0.06	8.3
0.8%	Grapefruits	0 / 0.1	7.9
0.7%	Table grapes	0 / 0.1	7.3
0.6%	Apples	0 / 0.06	6.5
0.6%	Mandarins	0 / 0.1	5.9
0.5%	Maize/corn	0 / 0.79	5.3
0.5%	Rye	0 / 0.79	5.0
0.5%	Milk: Cattle	0 / 0.04	5.0
0.5%	Bananas	0 / 0.05	4.9
0.4%	Barley	0 / 0.79	4.4
0.4%	Buckwheat and other	0 / 0.79	3.9
0.3%	Lemons	0 / 0.1	3.4
0.3%	Peaches	0 / 0.03	3.2
0.3%	Melons	0 / 0.02	3.0
0.3%	Sorghum	0 / 0.79	2.5
0.2%	Watermelons	0 / 0.02	2.4
0.2%	Limes	0 / 0.1	2.0
0.2%	Coconuts	0 / 0.13	1.9
0.2%	Leeks	0 / 0.03	1.8
0.2%	Papayas	0 / 0.04	1.7
0.2%	Strawberries	0 / 0.1	1.6
0.2%	Bovine: Edible offals (other	0 / 0.22	1.6
0.2%	Potatoes	0 / 0.01	1.5
0.1%	Quinces	0 / 0.06	1.5
0.1%	Escaroles/broad-leaved	0 / 0.04	1.4
0.1%	Plums	0 / 0.03	1.4
0.1%	Witloofs/Belgian endives	0 / 0.04	1.4
0.1%	Lettuces	0 / 0.04	1.4
0.1%	Cucumbers	0 / 0.02	1.3
0.1%	Sweet peppers/bell peppers	0 / 0.02	1.2
0.1%	Apricots	0 / 0.03	1.2
0.1%	Tomatoes	0 / 0.02	1.2
0.1%	Celeries	0 / 0.03	1.1
0.1%	Rhubarbs	0 / 0.03	1.1
0.1%	Common millet/proso millet	0 / 0.79	1.1
0.1%	Blackberries	0 / 0.1	1.1
0.10%	Milk: Goat	0 / 0.04	0.97
0.09%	Courgettes	0 / 0.02	0.93
0.09%	Wine grapes	0 / 0.1	0.93
0.09%	Raspberries (red and	0 / 0.1	0.92
0.09%	Beans	0 / 0.05	0.91
0.09%	Oat	0 / 0.79	0.88
0.09%	Sweet corn	0 / 0.02	0.87
0.09%	Pistachios	0 / 0.15	0.87
0.08%	Medlar	0 / 0.06	0.83
0.08%	Bovine: Kidney	0 / 0.22	0.83

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Rice	0 / 0.79	6.7
0.7%	Wheat	0 / 0.79	6.6
0.4%	Rye	0 / 0.79	3.8
0.4%	Barley	0 / 0.79	3.8
0.3%	Table grapes	0 / 0.1	3.4
0.3%	Oranges	0 / 0.1	3.1
0.3%	Mangoes	0 / 0.11	2.8
0.3%	Buckwheat and other	0 / 0.79	2.7
0.2%	Wine grapes	0 / 0.1	2.4
0.2%	Pears	0 / 0.06	1.8
0.2%	Mandarins	0 / 0.1	1.8
0.2%	Grapefruits	0 / 0.1	1.8
0.2%	Maize/corn	0 / 0.79	1.7
0.2%	Apples	0 / 0.06	1.7
0.2%	Milk: Cattle	0 / 0.04	1.5
0.1%	Coconuts	0 / 0.13	1.2
0.1%	Bananas	0 / 0.05	1.1
0.09%	Strawberries	0 / 0.1	0.93
0.09%	Quinces	0 / 0.06	0.91
0.09%	Blueberries	0 / 0.1	0.91
0.09%	Lemons	0 / 0.1	0.90
0.08%	Blackberries	0 / 0.1	0.82
0.08%	Watermelons	0 / 0.02	0.81
0.08%	Melons	0 / 0.02	0.78
0.07%	Milk: Goat	0 / 0.04	0.74
0.07%	Bovine: Edible offals (other	0 / 0.22	0.73
0.07%	Escaroles/broad-leaved	0 / 0.04	0.73
0.07%	Common millet/proso millet	0 / 0.79	0.71
0.07%	Limes	0 / 0.1	0.70
0.07%	Chards/beet leaves	0 / 0.04	0.68
0.07%	Witloofs/Belgian endives	0 / 0.04	0.66
0.07%	Soyabeans	0 / 0.12	0.66
0.07%	Currants (red, black and	0 / 0.1	0.66
0.06%	Peaches	0 / 0.03	0.64
0.06%	Plums	0 / 0.03	0.61
0.06%	Milk: Sheep	0 / 0.04	0.60
0.06%	Chestnuts	0 / 0.13	0.60
0.06%	Florence fennels	0 / 0.03	0.56
0.06%	Papayas	0 / 0.04	0.56
0.06%	Cucumbers	0 / 0.02	0.56
0.05%	Aubergines/egg plants	0 / 0.02	0.54
0.05%	Raspberries (red and	0 / 0.1	0.54
0.05%	Oat	0 / 0.79	0.51
0.05%	Celeries	0 / 0.03	0.48
0.05%	Poultry: Muscle	0 / 0.04	0.47
0.05%	Courgettes	0 / 0.02	0.47
0.05%	Bovine: Kidney	0 / 0.22	0.46
0.05%	Gooseberries (green, red	0 / 0.1	0.45
0.04%	Lettuces	0 / 0.04	0.44
0.04%	Head cabbages	0 / 0.01	0.42

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)
2%	Maize / oil	0 / 19.75	18
1.0%	Wheat / milling (flour)	0 / 0.79	9.6
0.6%	Sugar beets (root) / sugar	0 / 0.6	5.5
0.5%	Rice / milling (polishing)	0 / 0.32	4.8
0.4%	Wheat / milling (wholemeal)	0 / 0.79	4.4
0.4%	Millet / boiled	0 / 0.32	4.3
0.4%	Buckwheat / bulgur and gris	0 / 0.79	4.2
0.3%	Witloofs / boiled	0 / 0.04	3.2
0.3%	Rye / boiled	0 / 0.79	2.9
0.3%	Oat / boiled	0 / 0.79	2.9
0.3%	Buckwheat / boiled	0 / 0.79	2.9
0.3%	Barley / cooked	0 / 0.79	2.9
0.3%	Rye / milling (wholemeal)-ba	0 / 0.79	2.8
0.3%	Oranges / juice	0 / 0.05	2.6
0.2%	Escaroles/broad-leaved end	0 / 0.04	2.4

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%	Maize / oil	0 / 19.75	10
0.6%	Barley / beer	0 / 0.16	5.7
0.3%	Wheat / bread/pizza	0 / 0.79	3.5
0.3%	Rice / milling (polishing)	0 / 0.32	3.1
0.3%	Wheat / pasta	0 / 0.79	3.0
0.3%	Wheat / bread (wholemeal)	0 / 0.79	2.8
0.2%	Sugar beets (root) / sugar	0 / 0.6	2.2
0.2%	Millet / boiled	0 / 0.32	1.8
0.1%	Oat / boiled	0 / 0.79	1.2
0.1%	Pumpkins / boiled	0 / 0.02	1.1
0.1%	Wine grapes / juice	0 / 0.05	1.0
0.1%	Celeries / boiled	0 / 0.03	1.0
0.10%	Apples / juice	0 / 0.03	1.00
0.09%	Wine grapes / wine	0 / 0.1	0.95
0.08%	Oranges / juice	0 / 0.05	0.76

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.

6. PRIMo file Triazole Alanine (TA) – acute exposure

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

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:	2018	Year of evaluation:	2018

Input values

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

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

Comments: EFSa-Q-2019-00082

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)	6%	NL toddler	17.09	1%	Maize/corn	0.8%	Wheat	0.8%	Milk: Cattle		6%
	4%	GEMS/Food G06	11.24	1%	Wheat	0.3%	Rice	0.3%	Maize/corn		4%
	3%	DK child	10.11	1%	Rye	0.9%	Wheat	0.2%	Bovine: Muscle/meat		3%
	3%	GEMS/Food G08	9.34	0.8%	Wheat	0.3%	Olives for oil production	0.2%	Potatoes		3%
	3%	NL child	9.19	0.9%	Wheat	0.3%	Milk: Cattle	0.2%	Potatoes		3%
	3%	FR child 3 15 yr	9.13	1.0%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		3%
	3%	GEMS/Food G07	9.09	0.9%	Wheat	0.2%	Potatoes	0.2%	Rapeseeds/canola seeds		3%
	3%	DE child	9.02	0.9%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		3%
	3%	GEMS/Food G10	8.93	0.8%	Wheat	0.3%	Rice	0.2%	Potatoes		3%
	3%	GEMS/Food G15	8.81	0.9%	Wheat	0.2%	Potatoes	0.2%	Sunflower seeds		3%
	3%	RO general	8.05	1%	Wheat	0.2%	Sunflower seeds	0.2%	Potatoes		3%
	3%	ES child	7.82	0.9%	Wheat	0.3%	Olives for oil production	0.2%	Oranges		3%
	2%	GEMS/Food G11	7.47	0.7%	Wheat	0.2%	Potatoes	0.2%	Barley		2%
	2%	SE general	7.43	0.7%	Bovine: Muscle/meat	0.7%	Wheat	0.3%	Potatoes		2%
	2%	UK infant	7.40	0.5%	Wheat	0.5%	Milk: Cattle	0.2%	Maize/corn		2%
	2%	IE adult	7.30	0.5%	Wheat	0.2%	Sweet potatoes	0.1%	Potatoes		2%
	2%	FR toddler 2 3 yr	7.11	0.6%	Wheat	0.4%	Milk: Cattle	0.2%	Bovine: Muscle/meat		2%
	2%	UK toddler	6.85	0.8%	Wheat	0.3%	Milk: Cattle	0.2%	Potatoes		2%
	2%	IT toddler	6.56	1%	Wheat	0.3%	Other cereals	0.1%	Tomatoes		2%
	2%	PT general	6.14	0.8%	Wheat	0.3%	Potatoes	0.2%	Rice		2%
	2%	DE women 14-50 yr	5.02	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		2%
	2%	DE general	5.00	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		2%
	2%	NL general	4.93	0.4%	Wheat	0.1%	Potatoes	0.1%	Milk: Cattle		2%
	2%	ES adult	4.79	0.5%	Wheat	0.1%	Olives for oil production	0.1%	Oranges		2%
	1%	IT adult	4.33	0.9%	Wheat	0.1%	Other cereals	0.1%	Tomatoes		1%
	1%	FI 3 yr	4.14	0.3%	Potatoes	0.2%	Wheat	0.1%	Rye		1%
	1%	FR adult	3.74	0.5%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Oranges		1%
	1%	LT adult	3.39	0.2%	Rye	0.2%	Wheat	0.2%	Potatoes		1%
	1%	FI 6 yr	3.27	0.2%	Potatoes	0.2%	Wheat	0.1%	Rye		1%
	1%	UK vegetarian	3.02	0.4%	Wheat	0.1%	Oranges	0.1%	Potatoes		1%
	1.0%	FR infant	2.89	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes		1.0%
	0.9%	UK adult	2.81	0.3%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Potatoes		0.9%
	0.9%	DK adult	2.77	0.2%	Wheat	0.1%	Rye	0.1%	Bovine: Muscle/meat		0.9%
	0.6%	FI adult	1.79	0.1%	Rye	0.1%	Potatoes	0.1%	Wheat		0.6%
	0.5%	IE child	1.46	0.2%	Wheat	0.1%	Rice	0.0%	Milk: Cattle		0.5%
	0.5%	PL general	1.40	0.2%	Potatoes	0.1%	Tomatoes	0.0%	Apples		0.5%

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.

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.
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)
24%	Pears	0 / 0.53	73
23%	Melons	0 / 0.46	70
20%	Coconuts	0 / 4.23	61
20%	Mangoes	0 / 0.76	60
20%	Peaches	0 / 0.63	60
19%	Apples	0 / 0.53	57
19%	Watermelons	0 / 0.46	56
13%	Papayas	0 / 0.95	40
12%	Potatoes	0 / 0.24	37
10%	Cucumbers	0 / 0.46	30
10%	Cauliflowers	0 / 0.5	29
9%	Sweet peppers/bell peppers	0 / 0.46	27
9%	Tomatoes	0 / 0.46	27
9%	Plums	0 / 0.63	26
9%	Kohlrabies	0 / 0.5	26

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)
12%	Coconuts	0 / 4.23	36
7%	Head cabbages	0 / 0.5	21
7%	Mangoes	0 / 0.76	20
6%	Chestnuts	0 / 4.23	19
6%	Watermelons	0 / 0.46	19
6%	Melons	0 / 0.46	18
5%	Pears	0 / 0.53	16
5%	Apples	0 / 0.53	15
4%	Papayas	0 / 0.95	13
4%	Cucumbers	0 / 0.46	13
4%	Chinese cabbages/pe-tsai	0 / 0.5	13
4%	Aubergines/egg plants	0 / 0.46	12
4%	Broccoli	0 / 0.5	12
4%	Peaches	0 / 0.63	12
4%	Cauliflowers	0 / 0.5	12

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)
14%	Pumpkins / boiled	0 / 0.46	41
13%	Broccoli / boiled	0 / 0.5	39
12%	Cauliflowers / boiled	0 / 0.5	35
7%	Potatoes / fried	0 / 0.24	22
6%	Oranges / juice	0 / 0.32	17
5%	Peaches / canned	0 / 0.63	16
5%	Courgettes / boiled	0 / 0.46	16
5%	Maize / oil	0 / 15.53	14
5%	Kales / boiled	0 / 0.5	14
4%	Turnips / boiled	0 / 0.24	12
4%	Parsnips / boiled	0 / 0.24	12
4%	Sweet potatoes / boiled	0 / 0.24	12
4%	Potatoes / dried (flakes)	0 / 0.85	11
4%	Beetroots / boiled	0 / 0.24	11
4%	Gherkins / pickled	0 / 0.46	11

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)
8%	Pumpkins / boiled	0 / 0.46	25
7%	Cauliflowers / boiled	0 / 0.5	21
4%	Broccoli / boiled	0 / 0.5	12
4%	Kohlrabies / boiled	0 / 0.5	11
4%	Courgettes / boiled	0 / 0.46	11
3%	Beetroots / boiled	0 / 0.24	9.3
3%	Maize / oil	0 / 15.53	7.9
2%	Peaches / canned	0 / 0.63	5.1
2%	Parsnips / boiled	0 / 0.24	5.1
2%	Peas (without pods) / boiled	0 / 1.6	5.0
2%	Oranges / juice	0 / 0.32	4.8
2%	Turnips / boiled	0 / 0.24	4.6
2%	Cassava roots / boiled	0 / 0.24	4.5
1%	Barley / beer	0 / 0.12	4.5
1%	Celeriacs / boiled	0 / 0.24	4.3

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.

7. PRIMo file Triazole Alanine (TA) – chronic exposure

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

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:	2018	Year of evaluation:	2018

Input values

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

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

Comments: EFSa-Q-2019-00082

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)	6%	NL toddler	17.26	1%	Maize/corn	0.8%	Wheat	0.8%	Milk: Cattle		6%
	4%	GEMS/Food G06	12.47	1%	Wheat	0.4%	Soyabeans	0.3%	Rice		4%
	4%	GEMS/Food G10	12.20	1%	Soyabeans	0.8%	Wheat	0.3%	Rice		4%
	4%	GEMS/Food G08	11.31	0.8%	Wheat	0.7%	Soyabeans	0.3%	Olives for oil production		4%
	4%	GEMS/Food G11	11.18	1%	Soyabeans	0.7%	Wheat	0.2%	Potatoes		4%
	4%	GEMS/Food G07	10.87	0.9%	Wheat	0.6%	Soyabeans	0.2%	Potatoes		4%
	4%	GEMS/Food G15	10.55	0.9%	Wheat	0.6%	Soyabeans	0.2%	Potatoes		4%
	3%	DK child	10.11	1%	Rye	0.9%	Wheat	0.2%	Bovine: Muscle/meat		3%
	3%	NL child	9.40	0.9%	Wheat	0.3%	Milk: Cattle	0.2%	Potatoes		3%
	3%	FR child 3 15 yr	9.16	1.0%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		3%
	3%	DE child	9.06	0.9%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		3%
	3%	RO general	8.05	1%	Wheat	0.2%	Sunflower seeds	0.2%	Potatoes		3%
	3%	ES child	7.84	0.9%	Wheat	0.3%	Olives for oil production	0.2%	Oranges		3%
	2%	SE general	7.43	0.7%	Bovine: Muscle/meat	0.7%	Wheat	0.3%	Potatoes		2%
	2%	UK infant	7.40	0.5%	Wheat	0.5%	Milk: Cattle	0.2%	Maize/corn		2%
	2%	IE adult	7.32	0.5%	Wheat	0.2%	Sweet potatoes	0.1%	Potatoes		2%
	2%	FR toddler 2 3 yr	7.15	0.6%	Wheat	0.4%	Milk: Cattle	0.2%	Bovine: Muscle/meat		2%
	2%	UK toddler	6.85	0.8%	Wheat	0.3%	Milk: Cattle	0.2%	Potatoes		2%
	2%	IT toddler	6.56	1%	Wheat	0.3%	Other cereals	0.1%	Tomatoes		2%
	2%	PT general	6.45	0.8%	Wheat	0.3%	Potatoes	0.2%	Rice		2%
	2%	DE women 14-50 yr	5.06	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		2%
	2%	NL general	5.05	0.4%	Wheat	0.1%	Potatoes	0.1%	Milk: Cattle		2%
	2%	DE general	5.03	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		2%
	2%	ES adult	4.80	0.5%	Wheat	0.1%	Olives for oil production	0.1%	Oranges		2%
	1%	IT adult	4.33	0.9%	Wheat	0.1%	Other cereals	0.1%	Tomatoes		1%
	1%	FI 3 yr	4.14	0.3%	Potatoes	0.2%	Wheat	0.1%	Rye		1%
	1%	FR adult	3.75	0.5%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Oranges		1%
	1%	LT adult	3.39	0.2%	Rye	0.2%	Wheat	0.2%	Potatoes		1%
	1%	FI 6 yr	3.28	0.2%	Potatoes	0.2%	Wheat	0.1%	Rye		1%
	1%	UK vegetarian	3.02	0.4%	Wheat	0.1%	Oranges	0.1%	Potatoes		1%
	1.0%	FR infant	2.90	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes		1.0%
	0.9%	UK adult	2.81	0.3%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Potatoes		0.9%
	0.9%	DK adult	2.77	0.2%	Wheat	0.1%	Rye	0.1%	Bovine: Muscle/meat		0.9%
	0.6%	FI adult	1.82	0.1%	Rye	0.1%	Potatoes	0.1%	Wheat		0.6%
	0.5%	IE child	1.46	0.2%	Wheat	0.1%	Rice	0.0%	Milk: Cattle		0.5%
	0.5%	PL general	1.40	0.2%	Potatoes	0.1%	Tomatoes	0.0%	Apples		0.5%

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.

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.
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)
75%	Pistachios	0 / 39	226
28%	Oranges	0 / 0.63	83
24%	Pears	0 / 0.53	73
23%	Melons	0 / 0.46	70
20%	Coconuts	0 / 4.23	61
20%	Mangoes	0 / 0.76	60
20%	Peaches	0 / 0.63	60
19%	Apples	0 / 0.53	57
19%	Watermelons	0 / 0.46	56
16%	Grapefruits	0 / 0.63	49
13%	Papayas	0 / 0.95	40
12%	Mandarins	0 / 0.63	37
12%	Potatoes	0 / 0.24	37
10%	Cucumbers	0 / 0.46	30
10%	Cauliflowers	0 / 0.5	29

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)
35%	Pistachios	0 / 39	104
12%	Coconuts	0 / 4.23	36
7%	Head cabbages	0 / 0.5	21
7%	Mangoes	0 / 0.76	20
6%	Oranges	0 / 0.63	19
6%	Chestnuts	0 / 4.23	19
6%	Watermelons	0 / 0.46	19
6%	Melons	0 / 0.46	18
5%	Pears	0 / 0.53	16
5%	Apples	0 / 0.53	15
4%	Papayas	0 / 0.95	13
4%	Cucumbers	0 / 0.46	13
4%	Chinese cabbages/pe-tsai	0 / 0.5	13
4%	Aubergines/egg plants	0 / 0.46	12
4%	Broccoli	0 / 0.5	12

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)
14%	Pumpkins / boiled	0 / 0.46	41
13%	Broccoli / boiled	0 / 0.5	39
12%	Cauliflowers / boiled	0 / 0.5	35
7%	Potatoes / fried	0 / 0.24	22
6%	Oranges / juice	0 / 0.32	17
5%	Peaches / canned	0 / 0.63	16
5%	Courgettes / boiled	0 / 0.46	16
5%	Maize / oil	0 / 15.53	14
5%	Kales / boiled	0 / 0.5	14
4%	Turnips / boiled	0 / 0.24	12
4%	Parsnips / boiled	0 / 0.24	12
4%	Sweet potatoes / boiled	0 / 0.24	12
4%	Potatoes / dried (flakes)	0 / 0.85	11
4%	Beetroots / boiled	0 / 0.24	11
4%	Gherkins / pickled	0 / 0.46	11

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)
8%	Pumpkins / boiled	0 / 0.46	25
7%	Cauliflowers / boiled	0 / 0.5	21
4%	Broccoli / boiled	0 / 0.5	12
4%	Kohlrabies / boiled	0 / 0.5	11
4%	Courgettes / boiled	0 / 0.46	11
3%	Beetroots / boiled	0 / 0.24	9.3
3%	Maize / oil	0 / 15.53	7.9
2%	Peaches / canned	0 / 0.63	5.1
2%	Parsnips / boiled	0 / 0.24	5.1
2%	Peas (without pods) / boiled	0 / 1.6	5.0
2%	Oranges / juice	0 / 0.32	4.8
2%	Turnips / boiled	0 / 0.24	4.6
2%	Cassava roots / boiled	0 / 0.24	4.5
1%	Barley / beer	0 / 0.12	4.5
1%	Celeriacs / boiled	0 / 0.24	4.3

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.

8. PRIMo file Triazole Lactic Acid (TLA) – acute exposure

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

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:	2018	Year of evaluation:	2018

Input values

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

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

Comments: EFSA-Q-2019-00082. The risk assessment for TA conducted in the framework of the EU peeer review of the confirmatory data for TDMs (EFSA, 2018) was update only if the residue level of TA on the specific crop generated from the intended and authrorised uses of mefentrifluconazole was higher than the "v

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)	1%	NL toddler	3.98	0.8%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn		1%
	0.7%	UK infant	2.07	0.5%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat		0.7%
	0.7%	NL child	1.99	0.3%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.7%
	0.7%	DE child	1.97	0.3%	Milk: Cattle	0.1%	Apples	0.1%	Oranges		0.7%
	0.6%	FR toddler 2 3 yr	1.84	0.4%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.6%
	0.6%	FR child 3 15 yr	1.74	0.3%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.6%
	0.5%	UK toddler	1.40	0.3%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.5%
	0.4%	DK child	1.25	0.2%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.4%
	0.4%	GEMS/Food G11	1.21	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Potatoes		0.4%
	0.4%	ES child	1.19	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.4%
	0.4%	GEMS/Food G07	1.16	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Soyabeans		0.4%
	0.4%	RO general	1.16	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.4%
	0.4%	SE general	1.15	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Potatoes		0.4%
	0.4%	GEMS/Food G08	1.14	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.4%
	0.4%	GEMS/Food G10	1.13	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Wheat		0.4%
	0.4%	GEMS/Food G15	1.13	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Soyabeans		0.4%
	0.4%	DE women 14-50 yr	1.07	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.4%
	0.4%	GEMS/Food G06	1.05	0.1%	Wheat	0.0%	Tomatoes	0.0%	Milk: Cattle		0.4%
	0.3%	DE general	1.04	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.3%
	0.3%	FR infant	0.97	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Potatoes		0.3%
	0.3%	IE adult	0.95	0.1%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Mangoes		0.3%
	0.3%	NL general	0.86	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.3%
	0.2%	ES adult	0.68	0.1%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.2%
	0.2%	FR adult	0.62	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.2%
	0.2%	PT general	0.56	0.0%	Potatoes	0.0%	Wine grapes	0.0%	Wheat		0.2%
	0.2%	DK adult	0.54	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Swine: Muscle/meat		0.2%
	0.2%	LT adult	0.49	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.2%
	0.1%	IT toddler	0.43	0.0%	Wheat	0.0%	Tomatoes	0.0%	Other cereals		0.1%
	0.1%	UK vegetarian	0.41	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.1%
	0.1%	UK adult	0.40	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.1%
	0.1%	FI 3 yr	0.38	0.0%	Potatoes	0.0%	Cucumbers	0.0%	Apples		0.1%
	0.1%	IT adult	0.35	0.0%	Wheat	0.0%	Tomatoes	0.0%	Lettuces		0.1%
	0.1%	FI 6 yr	0.30	0.0%	Potatoes	0.0%	Wheat	0.0%	Cucumbers		0.1%
	0.1%	IE child	0.25	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.1%
	0.1%	PL general	0.24	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.1%
	0.1%	FI adult	0.19	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.1%

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.

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.
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)
14%	Mangoes	0 / 0.52	41
7%	Potatoes	0 / 0.13	20
6%	Melons	0 / 0.11	17
5%	Pears	0 / 0.11	15
4%	Watermelons	0 / 0.11	13
4%	Peaches	0 / 0.14	13
4%	Apples	0 / 0.11	12
3%	Table grapes	0 / 0.14	10
3%	Papayas	0 / 0.22	9.3
3%	Carrots	0 / 0.13	8.3
2%	Beetroots	0 / 0.13	7.5
2%	Celeriacs/turnip rooted	0 / 0.13	7.2
2%	Cucumbers	0 / 0.11	7.2
2%	Swedes/rutabagas	0 / 0.13	6.8
2%	Sweet peppers/bell peppers	0 / 0.11	6.5
2%	Tomatoes	0 / 0.11	6.4
2%	Onions	0 / 0.27	6.1
2%	Plums	0 / 0.14	5.8
2%	Coconuts	0 / 0.4	5.8
2%	Escaroles/broad-leaved	0 / 0.14	5.6
2%	Witloofs/Belgian endives	0 / 0.14	5.6
2%	Lettuces	0 / 0.14	5.3
2%	Courgettes	0 / 0.11	5.1
2%	Milk: Cattle	0 / 0.04	5.0
2%	Apricots	0 / 0.14	4.8

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)
4%	Mangoes	0 / 0.52	13
2%	Table grapes	0 / 0.14	4.7
1%	Swedes/rutabagas	0 / 0.13	4.5
1%	Watermelons	0 / 0.11	4.5
1%	Melons	0 / 0.11	4.3
1%	Onions	0 / 0.27	4.0
1%	Potatoes	0 / 0.13	3.9
1%	Yams	0 / 0.13	3.7
1%	Coconuts	0 / 0.4	3.4
1%	Pears	0 / 0.11	3.4
1%	Wine grapes	0 / 0.14	3.3
1%	Apples	0 / 0.11	3.1
1%	Papayas	0 / 0.22	3.1
1%	Cucumbers	0 / 0.11	3.1
1%	Beetroots	0 / 0.13	3.0
1.0%	Aubergines/egg plants	0 / 0.11	3.0
0.9%	Escaroles/broad-leaved	0 / 0.14	2.8
0.9%	Sweet potatoes	0 / 0.13	2.7
0.9%	Chards/beet leaves	0 / 0.14	2.6
0.9%	Peaches	0 / 0.14	2.6
0.9%	Carrots	0 / 0.13	2.6
0.9%	Witloofs/Belgian endives	0 / 0.14	2.6
0.9%	Courgettes	0 / 0.11	2.6
0.8%	Plums	0 / 0.14	2.5
0.6%	Parsnips	0 / 0.13	1.8

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)
4%	Witloofs / boiled	0 / 0.14	12
4%	Potatoes / fried	0 / 0.13	12
3%	Pumpkins / boiled	0 / 0.11	9.8
3%	Escaroles/broad-leaved end	0 / 0.14	9.3
2%	Turnips / boiled	0 / 0.13	6.6
2%	Parsnips / boiled	0 / 0.13	6.6
2%	Sweet potatoes / boiled	0 / 0.13	6.6
2%	Beetroots / boiled	0 / 0.13	5.8
1%	Shallots / boiled	0 / 0.27	4.4
1%	Chards/beet leaves / boiled	0 / 0.14	4.4
1%	Courgettes / boiled	0 / 0.11	3.9
1%	Peaches / canned	0 / 0.14	3.6
1%	Salsifies / boiled	0 / 0.13	3.4
1%	Jerusalem artichokes / boile	0 / 0.13	3.3
0.8%	Gherkins / pickled	0 / 0.11	2.5

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)
2%	Pumpkins / boiled	0 / 0.11	6.1
2%	Beetroots / boiled	0 / 0.13	5.1
1.0%	Escaroles/broad-leaved	0 / 0.14	2.9
0.9%	Parsnips / boiled	0 / 0.13	2.8
0.9%	Witloofs / boiled	0 / 0.14	2.6
0.8%	Onions / boiled	0 / 0.27	2.5
0.8%	Courgettes / boiled	0 / 0.11	2.5
0.8%	Turnips / boiled	0 / 0.13	2.5
0.8%	Cassava roots / boiled	0 / 0.13	2.5
0.8%	Celeriacs / boiled	0 / 0.13	2.4
0.7%	Sweet potatoes / boiled	0 / 0.13	2.0
0.6%	Chards/beet leaves / boiled	0 / 0.14	1.8
0.6%	Shallots / boiled	0 / 0.27	1.7
0.4%	Wine grapes / wine	0 / 0.14	1.3
0.4%	Spinaches / frozen; boiled	0 / 0.14	1.2

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.

9. PRIMo file Triazole Lactic Acid (TLA) – chronic exposure

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

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:	2018	Year of evaluation:	2018

Input values

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

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

Comments: EFSA-Q-2019-00082. The risk assessment for TA conducted in the framework of the EU peeer review of the confirmatory data for TDMs (EFSA, 2018) was update only if the residue level of TA on the specific crop generated from the intended and authrorised uses of mefentrifluconazole was higher than the "v

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)	1%	NL toddler	3.99	0.8%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn		1%
	0.7%	UK infant	2.07	0.5%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat		0.7%
	0.7%	NL child	1.99	0.3%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.7%
	0.7%	DE child	1.97	0.3%	Milk: Cattle	0.1%	Apples	0.1%	Oranges		0.7%
	0.6%	FR toddler 2 3 yr	1.84	0.4%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.6%
	0.6%	FR child 3 15 yr	1.75	0.3%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.6%
	0.5%	UK toddler	1.40	0.3%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.5%
	0.4%	GEMS/Food G11	1.28	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Potatoes		0.4%
	0.4%	DK child	1.25	0.2%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.4%
	0.4%	GEMS/Food G07	1.19	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.4%
	0.4%	ES child	1.19	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.4%
	0.4%	GEMS/Food G10	1.19	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Wheat		0.4%
	0.4%	GEMS/Food G08	1.17	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.4%
	0.4%	GEMS/Food G15	1.16	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.4%
	0.4%	RO general	1.16	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.4%
	0.4%	SE general	1.15	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Potatoes		0.4%
	0.4%	GEMS/Food G06	1.07	0.1%	Wheat	0.0%	Tomatoes	0.0%	Milk: Cattle		0.4%
	0.4%	DE women 14-50 yr	1.07	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.4%
	0.3%	DE general	1.04	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.3%
	0.3%	FR infant	0.98	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Potatoes		0.3%
	0.3%	IE adult	0.96	0.1%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Mangoes		0.3%
	0.3%	NL general	0.86	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.3%
	0.2%	ES adult	0.68	0.1%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.2%
	0.2%	FR adult	0.62	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.2%
	0.2%	PT general	0.56	0.0%	Potatoes	0.0%	Wine grapes	0.0%	Wheat		0.2%
	0.2%	DK adult	0.54	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Swine: Muscle/meat		0.2%
	0.2%	LT adult	0.49	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.2%
	0.1%	IT toddler	0.43	0.0%	Wheat	0.0%	Tomatoes	0.0%	Other cereals		0.1%
	0.1%	UK vegetarian	0.41	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.1%
	0.1%	UK adult	0.40	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.1%
	0.1%	FI 3 yr	0.38	0.0%	Potatoes	0.0%	Cucumbers	0.0%	Apples		0.1%
	0.1%	IT adult	0.35	0.0%	Wheat	0.0%	Tomatoes	0.0%	Lettuces		0.1%
	0.1%	FI 6 yr	0.30	0.0%	Potatoes	0.0%	Wheat	0.0%	Cucumbers		0.1%
	0.1%	IE child	0.25	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.1%
	0.1%	PL general	0.24	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.1%
	0.1%	FI adult	0.19	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.1%

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.

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.
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)
14%	Mangoes	0 / 0.52	41
7%	Potatoes	0 / 0.13	20
6%	Oranges	0 / 0.14	19
6%	Melons	0 / 0.11	17
5%	Pears	0 / 0.11	15
5%	Pistachios	0 / 2.4	14
4%	Watermelons	0 / 0.11	13
4%	Peaches	0 / 0.14	13
4%	Apples	0 / 0.11	12
4%	Grapefruits	0 / 0.14	11
3%	Table grapes	0 / 0.14	10
3%	Papayas	0 / 0.22	9.3
3%	Carrots	0 / 0.13	8.3
3%	Mandarins	0 / 0.14	8.3
2%	Beetroots	0 / 0.13	7.5
2%	Celeriacs/turnip rooted	0 / 0.13	7.2
2%	Cucumbers	0 / 0.11	7.2
2%	Swedes/rutabagas	0 / 0.13	6.8
2%	Sweet peppers/bell peppers	0 / 0.11	6.5
2%	Tomatoes	0 / 0.11	6.4
2%	Onions	0 / 0.27	6.1
2%	Plums	0 / 0.14	5.8
2%	Coconuts	0 / 0.4	5.8
2%	Escaroles/broad-leaved	0 / 0.14	5.6
2%	Witloofs/Belgian endives	0 / 0.14	5.6

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)
4%	Mangoes	0 / 0.52	13
2%	Pistachios	0 / 2.4	6.4
2%	Table grapes	0 / 0.14	4.7
1%	Swedes/rutabagas	0 / 0.13	4.5
1%	Watermelons	0 / 0.11	4.5
1%	Melons	0 / 0.11	4.3
1%	Oranges	0 / 0.14	4.3
1%	Onions	0 / 0.27	4.0
1%	Potatoes	0 / 0.13	3.9
1%	Yams	0 / 0.13	3.7
1%	Coconuts	0 / 0.4	3.4
1%	Pears	0 / 0.11	3.4
1%	Wine grapes	0 / 0.14	3.3
1%	Apples	0 / 0.11	3.1
1%	Papayas	0 / 0.22	3.1
1%	Cucumbers	0 / 0.11	3.1
1%	Beetroots	0 / 0.13	3.0
1.0%	Aubergines/egg plants	0 / 0.11	3.0
0.9%	Escaroles/broad-leaved	0 / 0.14	2.8
0.9%	Sweet potatoes	0 / 0.13	2.7
0.9%	Chards/beet leaves	0 / 0.14	2.6
0.9%	Peaches	0 / 0.14	2.6
0.9%	Carrots	0 / 0.13	2.6
0.9%	Witloofs/Belgian endives	0 / 0.14	2.6
0.9%	Courgettes	0 / 0.11	2.6

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)
4%	Witloofs / boiled	0 / 0.14	12
4%	Potatoes / fried	0 / 0.13	12
3%	Pumpkins / boiled	0 / 0.11	9.8
3%	Escaroles/broad-leaved end	0 / 0.14	9.3
2%	Turnips / boiled	0 / 0.13	6.6
2%	Parsnips / boiled	0 / 0.13	6.6
2%	Sweet potatoes / boiled	0 / 0.13	6.6
2%	Beetroots / boiled	0 / 0.13	5.8
1%	Shallots / boiled	0 / 0.27	4.4
1%	Chards/beet leaves / boiled	0 / 0.14	4.4
1%	Courgettes / boiled	0 / 0.11	3.9
1%	Peaches / canned	0 / 0.14	3.6
1%	Salsifies / boiled	0 / 0.13	3.4
1%	Jerusalem artichokes / boile	0 / 0.13	3.3
0.8%	Gherkins / pickled	0 / 0.11	2.5

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)
2%	Pumpkins / boiled	0 / 0.11	6.1
2%	Beetroots / boiled	0 / 0.13	5.1
1.0%	Escaroles/broad-leaved	0 / 0.14	2.9
0.9%	Parsnips / boiled	0 / 0.13	2.8
0.9%	Witloofs / boiled	0 / 0.14	2.6
0.8%	Onions / boiled	0 / 0.27	2.5
0.8%	Courgettes / boiled	0 / 0.11	2.5
0.8%	Turnips / boiled	0 / 0.13	2.5
0.8%	Cassava roots / boiled	0 / 0.13	2.5
0.8%	Celeriacs / boiled	0 / 0.13	2.4
0.7%	Sweet potatoes / boiled	0 / 0.13	2.0
0.6%	Chards/beet leaves / boiled	0 / 0.14	1.8
0.6%	Shallots / boiled	0 / 0.27	1.7
0.4%	Wine grapes / wine	0 / 0.14	1.3
0.4%	Spinaches / frozen; boiled	0 / 0.14	1.2

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 | LIVESTOCK DIETARY BURDEN CALCULATIONS

	Median dietary burden		Maximum dietary burden	
Feed commodity	**Input value (mg/kg)**	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition 1: difenoconazole (sum of isomers)				
Alfalfa forage (green)	0.01*	STMR (EFSA, 2024c)	0.01*	HR (EFSA, 2024c)
Alfalfa hay (fodder)	0.01*	STMR[a] (EFSA, 2024c)	0.01*	HR[a] (EFSA, 2024c)
Alfalfa meal	0.01*	STMR[a] (EFSA, 2024c)	0.01*	HR[a] (EFSA, 2024c)
Alfalfa silage	0.01*	STMR[a] (EFSA, 2024c)	0.01*	HR[a] (EFSA, 2024c)
Barley straw	0.31	STMR (EFSA, 2024c)	0.71	HR (EFSA, 2024c)
Bean vines (fodder green)	0.01*	STMR (EFSA, 2024c)	0.01*	HR (EFSA, 2024c)
Beet, mangel fodder	0.84	STMR (EFSA, 2024c)	3.32	HR (EFSA, 2024c)
Beet, sugar tops	0.65	STMR (EFSA, 2024c)	3.32	HR (EFSA, 2024c)
Cabbage, heads leaves	0.02	STMR (EFSA, 2024c)	0.19	HR (EFSA, 2024c)
Clover forage	0.01*	STMR (EFSA, 2024c)	0.01*	HR (EFSA, 2024c)
Clover hay	0.01*	STMR[a] (EFSA, 2024c)	0.01*	HR[a] (EFSA, 2024c)
Clover silage	0.01*	STMR[a] (EFSA, 2024c)	0.01*	HR[a] (EFSA, 2024c)
Kale leaves (forage)	0.38	STMR (EFSA, 2024c)	0.57	HR (EFSA, 2024c)
Oat straw	0.02	STMR (EFSA, 2024c)	0.05	HR (EFSA, 2024c)
Pea vines (green)	0.01*	STMR (EFSA, 2024c)	0.01*	HR (EFSA, 2024c)
Pea hay (hay or fodder)	0.01*	STMR[a] (EFSA, 2024c)	0.01*	HR[a] (EFSA, 2024c)
Pea silage	0.01*	STMR[a] (EFSA, 2024c)	0.01*	HR[a] (EFSA, 2024c)
Rice straw	1.9	STMR (EFSA, 2024c)	2.6	HR (EFSA, 2024c)
Rye straw	0.67	STMR (EFSA, 2024c)	4.56	HR (EFSA, 2024c)
Triticale straw	0.67	STMR (EFSA, 2024c)	4.56	HR (EFSA, 2024c)
Vetch forage	0.01*	STMR (EFSA, 2024c)	0.01*	HR (v)
Vetch hay	0.01*	STMR[a] (EFSA, 2024c)	0.01*	HR[a] (EFSA, 2024c)
Wheat straw	0.67	STMR (EFSA, 2024c)	4.56	HR (EFSA, 2024c)
Carrot culls	0.08	STMR (EFSA, 2024c)	0.30	HR (EFSA, 2024c)
Cassava/tapioca roots	0.01*	STMR (EFSA, 2024c)	0.01*	HR (EFSA, 2024c)
Potato culls	0.01	STMR (EFSA, 2024c)	0.07	HR (EFSA, 2024c)
Swede roots	0.08	STMR (EFSA, 2024c)	0.30	HR (EFSA, 2024c)
Turnip roots	0.08	STMR (EFSA, 2024c)	0.30	HR (EFSA, 2024c)
Barley grain	0.03	STMR (EFSA, 2024c)	0.03	STMR (EFSA, 2024c)
Bean seed (dry)	0.02	STMR (EFSA, 2024c)	0.02	STMR (EFSA, 2024c)
Corn, field (Maize) grain	0.01*	STMR (EFSA, 2024c)	0.01*	STMR (EFSA, 2024c)
Corn, pop grain	0.01*	STMR (EFSA, 2024c)	0.01*	STMR (EFSA, 2024c)
Cotton undelinted seed	0.01*	STMR (EFSA, 2024c)	0.01*	STMR (EFSA, 2024c)
Cowpea seed	0.02	STMR (EFSA, 2024c)	0.02	STMR (EFSA, 2024c)
Lupin seed	0.02	STMR (EFSA, 2024c)	0.02	STMR (EFSA, 2024c)
Millet grain	0.01*	STMR (EFSA, 2024c)	0.01*	STMR (EFSA, 2024c)
Oat grain	0.02	STMR (EFSA, 2024c)	0.02	STMR (EFSA, 2024c)
Pea (Field pea) seed (dry)	0.02	STMR (EFSA, 2024c)	0.02	STMR (EFSA, 2024c)
Rye grain	0.04	STMR (EFSA, 2024c)	0.04	STMR (EFSA, 2024c)

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Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sorghum grain	0.01*	STMR (EFSA, 2024c)	0.01*	STMR (EFSA, 2024c)
Soya bean seed	**0.013**	**STMR**	**0.013**	**STMR**
Triticale grain	0.04	STMR (EFSA, 2024c)	0.04	STMR (EFSA, 2024c)
Wheat grain	0.04	STMR (EFSA, 2024c)	0.04	STMR (EFSA, 2024c)
Apple pomace, wet	0.37	STMR × PF (3.4) (EFSA, 2024c)	0.37	STMR × PF (3.4) (EFSA, 2024c)
Beet, sugar-dried pulp	0.81	STMR × default PF (18)[b] (EFSA, 2024c)	0.81	STMR × default PF (18)[b] (EFSA, 2024c)
Beet, sugar ensiled pulp	0.14	STMR × default PF (3)[b] (EFSA, 2024c)	0.14	STMR × default PF (3)[b] (EFSA, 2024c)
Beet, sugar molasses	1.26	STMR × default PF (28)[b] (EFSA, 2024c)	1.26	STMR × default PF (28)[b] (EFSA, 2024c)
Brewer's grain dried	0.08	STMR × default PF (3.3)[b] (EFSA, 2024c)	0.08	STMR × default PF (3.3)[b] (EFSA, 2024c)
Canola (Rape seed) meal	0.04	STMR × default PF (2)[b] (EFSA, 2024c)	0.04	STMR × default PF (2)[b] (EFSA, 2024c)
Citrus, dried pulp	**1.53**	**STMR × PF (5.1)**	**1.53**	**STMR × PF (5.1)**
Corn, field milled by-products	0.01*	STMR[a] (EFSA, 2024c)	0.01*	STMR[a] (EFSA, 2024c)
Corn, field hominy meal	0.01*	STMR[a] (EFSA, 2024c)	0.01*	STMR[a] (EFSA, 2024c)
Corn, field gluten feed	0.01*	STMR[a] (EFSA, 2024c)	0.01*	STMR[a] (EFSA, 2024c)
Corn, field gluten, meal	0.01*	STMR[a] (EFSA, 2024c)	0.01*	STMR[a] (EFSA, 2024c)
Cotton meal	0.01*	STMR[a] (EFSA, 2024c)	0.01*	STMR[a] (EFSA, 2024c)
Distiller's grain dried	0.13	STMR × default PF (3.3)[b] (EFSA, 2024c)	0.13	STMR × default PF (3.3)[b] (EFSA, 2024c)
Flaxseed/Linseed meal	0.04	STMR × default PF (2)[b] (EFSA, 2024c)	0.04	STMR × default PF (2)[b] (EFSA, 2024c)
Lupin seed meal	0.02	STMR × default PF (1.1)[b] (EFSA, 2024c)	0.02	STMR × default PF (1.1)[b] (EFSA, 2024c)
Potato process waste	0.20	STMR × default PF (20)[b] (EFSA, 2024c)	0.20	STMR × default PF (20)[b] (EFSA, 2024c)
Potato-dried pulp	0.38	STMR × default PF (38)[b] (EFSA, 2024c)	0.38	STMR × default PF (38)[b] (EFSA, 2024c)
Rape meal	0.04	STMR × default PF (2)[b] (EFSA, 2024c)	0.04	STMR × default PF (2)[b] (EFSA, 2024c)
Rice bran/pollard	8.75	STMR × default PF (10)[b] (EFSA, 2024c)	8.75	STMR × default PF (10)[b] (EFSA, 2024c)
Safflower meal	0.02	STMR × default PF (2)[b] (EFSA, 2024c)	0.02	STMR × default PF (2)[b] (EFSA, 2024c)
Soya bean meal	**0.02**	**STMR × default PF (1.3)[b]**	**0.02**	**STMR × default PF (1.3)[b]**
Soya bean hulls	**0.17**	**STMR × default PF (13)[b]**	**0.17**	**STMR × default PF (13)[b]**
Sunflower meal	0.02	STMR × default PF (2)[b] (EFSA, 2024c)	0.02	STMR × default PF (2)[b] (EFSA, 2024c)
Wheat gluten meal	0.07	STMR × default PF (1.8)[b] (EFSA, 2024c)	0.07	STMR × default PF (1.8)[b] (EFSA, 2024c)
Wheat milled by-products	0.28	STMR × default PF (7)[b] (EFSA, 2024c)	0.28	STMR × default PF (7)[b] (EFSA, 2024c)

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

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

[a]No default processing factor was applied to the risk assessment values for these commodities because residues of difenoconazole are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

[b]In the absence of processing factors supported by data, a default processing factor was included in the calculation to consider the potential concentration of residues in these commodities.

D.2 | CONSUMER RISK ASSESSMENT

Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Risk assessment residue definition: Difenoconazole						
Citrus fruits	**0.6**	FAO and WHO (2013) **= MRL proposal**	0.015	STMR-RAC (0.16) × UF (1.3) × PeF[b] (0.07)	0.046	HR-RAC (0.49) × UF (1.3) × PeF(b) (0.07)
Tree nuts	**0.03**	**MRL proposal**	0.013	STMR-RAC (0.01) × UF (1.3)	0.026	HR-RAC (0.02) × UF (1.3)
Blueberries	4	EFSA (2024c)[c]	5.2	MRL × UF (1.3)	5.2	MRL × UF (1.3)
Mangoes	**0.2**	**MRL proposal**	0.013	STMR-RAC$_{pulp}$ (0.01) × UF (1.3)	0.013	HR-RAC$_{pulp}$ (0.01) × UF (1.3)
Papayas	**0.3**	**MRL proposal**	0.013	STMR-RAC$_{pulp}$ (0.01) × UF (1.3)	0.013	HR-RAC$_{pulp}$ (0.01) × UF (1.3)
Peas (dry)	**0.15**	FAO and WHO (2017) **= MRL proposal**	0.036	STMR-RAC (0.03) × UF (1.3)	0.036	STMR-RAC (0.03) × UF (1.3)
Soya beans	**0.15**	**MRL proposal**	0.017	STMR-RAC (0.013) × UF (1.3)	0.017	STMR-RAC (0.013) × UF (1.3)
Apples, Pears, Quinces, Medlars	0.4	EFSA (2024c)[c]	0.14	STMR-RAC (0.11) × UF (1.3)	0.36	HR-RAC (0.28) × UF (1.3)
Loquats/Japanese medlars	0.6	EFSA (2024c)[c]	0.16	STMR-RAC (0.12) × UF (1.3)	0.46	HR-RAC (0.35) × UF (1.3)
Apricots	0.7	EFSA (2024c)[c]	0.22	STMR-RAC (0.17) × UF (1.3)	0.48	HR-RAC (0.37) × UF (1.3)
Cherries (sweet)	0.4	EFSA (2024c)[c]	0.16	STMR-RAC (0.13) × UF (1.3)	0.20	HR-RAC (0.15) × UF (1.3)
Peaches	0.5	EFSA (2024c)[c]	0.18	STMR-RAC (0.14) × UF (1.3)	0.34	HR-RAC (0.26) × UF (1.3)
Plums	0.4	EFSA (2024c)[c]	0.06	STMR-RAC (0.05) × UF (1.3)	0.27	HR-RAC (0.21) × UF (1.3)
Table grapes, wine grapes	3	FAO and WHO (2013)	0.68	STMR-RAC (0.52) × UF (1.3)	1.95	HR-RAC (1.5) × UF (1.3)
Strawberries	2	FAO and WHO (2017)	0.55	STMR-RAC (0.42) × UF (1.3)	1.56	HR-RAC (1.2) × UF (1.3)
Blackberries	1.5	EFSA (2024c)[c]	0.38	STMR-RAC (0.29) × UF (1.3)	1.00	HR-RAC (0.77) × UF (1.3)
Raspberries (red and yellow)	1.5	EFSA (2024c)[c]	0.38	STMR-RAC (0.29) × UF (1.3)	1.00	HR-RAC (0.77) × UF (1.3)
Cranberries	0.6	FAO and WHO (2021)/ EFSA (2024c)[c]	0.26	STMR-RAC (0.20) × UF (1.3)	0.34	HR-RAC (0.26) × UF (1.3)
Table olives	2	EFSA (2024c)[c]	0.60	STMR-RAC (0.47) × UF (1.3)	1.50	HR-RAC (1.15) × UF (1.3)
Kaki/Japanese persimmons	0.01*	EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.013	HR-RAC (0.01) × UF (1.3)
Passion fruits	0.1	EFSA (2024c)[c]	0.13	MRL × UF (1.3)	0.13	MRL × UF (1.3)
Prickly pears/cactus fruits	0.15	FAO and WHO (2017)	0.044	STMR-RAC (0.03) × UF (1.3)	0.11	HR-RAC (0.08) × UF (1.3)
Avocados	0.6	FAO and WHO (2015)	0.065	STMR-RAC (0.05) × UF (1.3)	0.34	HR-RAC (0.26) × UF (1.3)
Bananas	0.1	EFSA (2024c)[c]	0.026	STMR-RAC (0.02) × UF (1.3)	0.091	HR-RAC (0.07) × UF (1.3)
Guavas	0.15	FAO and WHO (2021)/ EFSA (2024c)[c]	0.044	STMR-RAC (0.03) × UF (1.3)	0.12	HR-RAC (0.10) × UF (1.3)
Potatoes, sweet potatoes	0.07	EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.091	HR-RAC (0.07) × UF (1.3)

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Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Cassava roots/ manioc, Yams, Arrowroots	0.01*	EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.013	HR-RAC (0.01) × UF (1.3)
Beetroots, Carrots, Celeriacs/turnip-rooted celeries, Horse radishes, Jerusalem artichokes, Parsnips, Parsley roots/ Hamburg roots parsley, Salsifies, Swedes/rutabagas, Turnips, Other root and tuber vegetables	0.5	EFSA (2024c)[c]	0.10	STMR-RAC (0.08) × UF (1.3)	0.39	HR-RAC (0.30) × UF (1.3)
Radishes	0.5	EFSA (2024c)[c]	0.10	STMR-RAC (0.08) × UF (1.3)	0.36	HR-RAC (0.28) × UF (1.3)
Garlic, Onions	0.2	EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.22	HR-RAC (0.17) × UF (1.3)
Shallots	0.2	EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.14	HR-RAC (0.11) × UF (1.3)
Spring onions/green onions and Welsh onions	9	FAO and WHO (2013)	3.64	STMR-RAC (2.8) × UF (1.3)	4.94	HR-RAC (3.8) × UF (1.3)
Tomatoes	2	EFSA (2024c)[c]	0.33	STMR-RAC (0.25) × UF (1.3)	1.69	HR-RAC (1.3) × UF (1.3)
Sweet peppers/bell peppers	0.9	FAO and WHO (2017)	0.31	STMR-RAC (0.24) × UF (1.3)	0.53	HR-RAC (0.41) × UF (1.3)
Aubergines/egg plants	0.5	EFSA (2024c)[c]	0.17	STMR-RAC (0.13) × UF (1.3)	0.47	HR-RAC (0.36) × UF (1.3)
Okra/lady's finger	0.6	EFSA (2024c)[c]	0.78	MRL × UF (1.3)	0.78	MRL × UF (1.3)
Cucumbers	0.3	EFSA (2024c)[c]	0.026	STMR-RAC (0.02) × UF (1.3)	0.23	HR-RAC (0.18) × UF (1.3)
Gherkins, Courgettes	0.3	EFSA (2024c)[c]	0.039	STMR-RAC (0.03) × UF (1.3)	0.23	HR-RAC (0.18) × UF (1.3)
Cucurbits with inedible peel	0.2	EFSA (2024c)[c]	0.014	STMR-RAC (0.06) × UF (1.3) × PeF (0.20)	0.031	HR-RAC (0.12) × UF (1.3) × PeF (0.20)
Sweet corn	0.01*	FAO and WHO (2017)/EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.013	HR-RAC (0.01) × UF (1.3)
Broccoli	0.7	EFSA (2024c)[c]	0.13	STMR-RAC (0.10) × UF (1.3)	0.53	HR-RAC (0.41) × UF (1.3)
Cauliflowers	0.15	EFSA (2024c)[c]	0.026	STMR-RAC (0.02) × UF (1.3)	0.13	HR-RAC (0.10) × UF (1.3)
Brussels sprouts	0.4	EFSA (2024c)[c]	0.11	STMR-RAC (0.09) × UF (1.3)	0.23	HR-RAC (0.18) × UF (1.3)
Head cabbages	0.3	EFSA (2024c)[c]	0.020	STMR-RAC (0.02) × UF (1.3)	0.25	HR-RAC (0.19) × UF (1.3)
Chinese cabbages/ pe-tsai	3	EFSA (2024c)[c]	0.95	STMR-RAC (0.73) × UF (1.3)	1.52	HR-RAC (1.17) × UF (1.3)
Kales	1.5	EFSA (2024c)[c]	0.49	STMR-RAC (0.38) × UF (1.3)	0.74	HR-RAC (0.57) × UF (1.3)

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Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Kohlrabies	0.02	EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.013	HR-RAC (0.01) × UF (1.3)
Lamb's lettuce/corn salads	7	EFSA (2024c)[c]	1.89	STMR-RAC (1.45) × UF (1.3)	4.42	HR-RAC (3.4) × UF (1.3)
Lettuces, Cress and other sprouts and shoots, Land cress	4	EFSA (2024c)[c]	0.68	STMR-RAC (0.52) × UF (1.3)	3.26	HR-RAC (2.51) × UF (1.3)
Escaroles/broad-leaved endives	3	EFSA (2024c)[c]	0.42	STMR-RAC (0.33) × UF (1.3)	1.95	HR-RAC (1.5) × UF (1.3)
Roman rocket/rucola	4	EFSA (2024c)[d]	0.68	STMR-RAC (0.52) × UF (1.3)	3.26	HR-RAC (2.51) × UF (1.3)
Red mustards, Baby leaf crops (including brassica species)	4	EFSA (2024c)[c]	0.68	STMR-RAC (0.52) × UF (1.3)	4.42	HR-RAC (3.4) × UF (1.3)
Spinaches	4	EFSA (2024c)[c]	0.36	STMR-RAC (0.28) × UF (1.3)	2.6	HR-RAC (2) × UF (1.3)
Purslanes	2	EFSA (2024c)[c]	0.12	STMR-RAC (0.09) × UF (1.3)	1.3	HR-RAC (1) × UF (1.3)
Chards/beet leaves	3	EFSA (2024c)[c]	0.72	STMR-RAC (0.55) × UF (1.3)	1.69	HR-RAC (1.3) × UF (1.3)
Witloofs/Belgian endives	0.8	EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.052	HR-RAC (0.04) × UF (1.3)
Chervil, Celery leaves, Parsley	15	EFSA (2024c)[c]	6.05	STMR-RAC (4.65) × UF (1.3)	7.38	HR-RAC (5.68) × UF (1.3)
Chives, Sage, Rosemary, Thyme, Laurel/ bay leaves, Tarragon	4	EFSA (2024c)[c]	0.36	STMR-RAC (0.28) × UF (1.3)	2.6	HR-RAC (2) × UF (1.3)
Basil and edible flowers	4	EFSA (2024c)[c]	0.36	STMR-RAC (0.28) × UF (1.3)	2.6	HR-RAC (2) × UF (1.3)
Beans (with pods), Peas (with pods)	0.7	FAO and WHO (2011)/EFSA (2024c)[c]	0.09	STMR-RAC (0.07) × UF (1.3)	0.65	HR-RAC (0.50) × UF (1.3)
Beans (without pods), Peas (without pods)	0.6	EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.53	HR-RAC (0.41) × UF (1.3)
Lentils (fresh)	0.01*	EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.013	HR-RAC (0.01) × UF (1.3)
Asparagus	0.03	FAO and WHO (2007)/EFSA (2024c)[c]	0.026	STMR-RAC (0.02) × UF (1.3)	0.026	HR-RAC (0.02) × UF (1.3)
Cardoons, Celeries	5	EFSA (2024c)[c]	0.91	STMR-RAC (0.70) × UF (1.3)	3.37	HR-RAC (2.59) × UF (1.3)
Florence fennels, Rhubarbs	5	EFSA (2024c)[c]	0.91	STMR-RAC (0.70) × UF (1.3)	3.37	HR-RAC (2.59) × UF (1.3)
Globe artichokes	1.5	FAO and WHO (2017)	0.66	STMR-RAC (0.51) × UF (1.3)	0.83	HR-RAC (0.64) × UF (1.3)
Leeks	0.6	EFSA (2024c)	0.16	STMR-RAC (0.12) × UF (1.3)	0.52	HR-RAC (0.40) × UF (1.3)
Beans (dry)	0.05	FAO and WHO (2017)/EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.013	STMR-RAC (0.01) × UF (1.3)

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Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Lentils, Lupins/lupini beans (dry)	0.04	EFSA (2024c)[c]	0.026	STMR-RAC (0.02) × UF (1.3)	0.026	STMR-RAC (0.02) × UF (1.3)
Linseeds, Mustard seeds, Borage seeds	0.5	EFSA (2024c)[c]	0.026	STMR-RAC (0.02) × UF (1.3)	0.026	STMR-RAC (0.02) × UF (1.3)
Rapeseeds/canola seeds	0.5	EFSA (2024c)[c]	0.026	STMR-RAC (0.02) × UF (1.3)	0.026	STMR-RAC (0.02) × UF (1.3)
Peanuts/groundnuts	0.01*	FAO and WHO (2015)/ EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.013	STMR-RAC (0.01) × UF (1.3)
Poppy seeds, Gold of pleasure seeds	0.05	EFSA (2024c)[c]	0.026	STMR-RAC (0.02) × UF (1.3)	0.026	STMR-RAC (0.02) × UF (1.3)
Sunflower seeds, Safflower seeds	0.05	EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.013	STMR-RAC (0.01) × UF (1.3)
Cotton seeds	0.4	FAO and WHO (2021)/ EFSA (2024c)[c]	0.027	STMR-RAC (0.02) × UF (1.3)	0.027	STMR-RAC (0.02) × UF (1.3)
Olives for oil production	2	EFSA (2024c)[c]	0.60	STMR-RAC (0.47) × UF (1.3)	0.60	STMR-RAC (1.15) × UF (1.3)
Barley	0.3	EFSA (2024c)[c]	0.032	STMR-RAC (0.03) × UF (1.3)	0.032	STMR-RAC (0.03) × UF (1.3)
Buckwheat and other pseudo-cereals, Maize/ corn, Common millet/proso millet, Sorghum	0.01*	EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.013	STMR-RAC (0.01) × UF (1.3)
Oat	0.02	EFSA (2024c)[c]	0.026	STMR-RAC (0.02) × UF (1.3)	0.026	STMR-RAC (0.02) × UF (1.3)
Rice	3	EFSA (2024c)[c]	1.14	STMR-RAC (0.88) × UF (1.3)	1.14	STMR-RAC (1.4) × UF (1.3)
Rye, Wheat	0.3	EFSA (2024c)[c]	0.052	STMR-RAC (0.04) × UF (1.3)	0.052	STMR-RAC (0.04) × UF (1.3)
Tea (dried leaves of Camellia sinensis)	20	FAO and WHO (2021)/ EFSA (2024c)[c]	6.31	STMR-RAC (4.85) × UF (1.3)	6.31	STMR-RAC (4.85) × UF (1.3)
Coffee beans	0.01*	FAO and WHO (2017) / EFSA (2024c)[c]	0.013	STMR-RAC (0.01) × UF (1.3)	0.013	STMR-RAC (0.01) × UF (1.3)
Herbal infusions (dried flowers, dried leaves)	20	EFSA (2024c)[c]	5.92	STMR-RAC (4.55) × UF (1.3)	15.6	HR-RAC (12) × UF (1.3)
Herbal infusions (dried roots)	4	EFSA (2024c)[c]	0.83	STMR-RAC (0.64) × UF (1.3)	2.91	HR-RAC (2.24) × UF (1.3)
Spices (seeds, fruits)	0.15	EFSA (2024c)[c]	0.052	STMR-RAC (0.04) × UF (1.3)	0.13	HR-RAC (0.10) × UF (1.3)
Spices (bark)	0.3	EFSA (2024c)[c]	0.39	MRL × UF (1.3)	0.39	MRL × UF (1.3)
Spices (roots or rhizome)	1.5	EFSA (2024c)[c]	0.73	STMR-RAC (0.56) × UF (1.3)	0.94	HR-RAC (0.72) × UF (1.3)
Spices (buds)	0.3	EFSA (2024c)[c]	0.39	MRL × UF (1.3)	0.39	MRL × UF (1.3)
Spices (flower stigma)	0.3	EFSA (2024c)[c]	0.39	MRL × UF (1.3)	0.39	MRL × UF (1.3)
Spices aril	0.3	EFSA (2024c)[c]	0.39	MRL × UF (1.3)	0.39	MRL × UF (1.3)
Sugar beet roots	0.2	FAO and WHO (2007)	0.026	STMR-RAC (0.020) × UF (1.3)	0.13	HR-RAC (0.10) × UF (1.3)
Chicory roots	0.6	EFSA (2024c)[c]	0.26	STMR-RAC (0.20) × UF (1.3)	0.42	HR-RAC (0.32) × UF (1.3)

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Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Risk assessment residue definition: Difenoconazole alcohol (CGA-205375), expressed as difenoconazole						
Muscle/meat (mammals)	0.08	EFSA (2024c)[c]	0.14	STMR-RAC (0.07) × UF (2)	0.19	HR-RAC (0.10) × UF (2)
Fat tissue (mammals)	0.2	EFSA (2024c)[c]	0.28	STMR-RAC (0.14) × UF (2)	0.38	HR-RAC (0.19) × UF (2)
Liver (mammals)	1.5	EFSA (2024c)[c]	1.42	STMR-RAC (0.71) × UF (2)	1.9	HR-RAC (0.95) × UF (2)
Kidney (mammals)	1.5	EFSA (2024c)[c]	0.26	STMR-RAC (0.13) × UF (2)	0.34	HR-RAC (0.17) × UF (2)
Poultry: Muscle/ meat	0.01*	EFSA (2024c)[c]	0.020	STMR-RAC (0.01) × UF (2)	0.020	HR-RAC (0.01) × UF (2)
Poultry: Fat tissue	0.01*	EFSA (2024c)[c]	0.020	STMR-RAC (0.01) × UF (2)	0.020	HR-RAC (0.01) × UF (2)
Poultry: Liver	0.01*	EFSA (2024c)[c]	0.020	STMR-RAC (0.01) × UF (2)	0.020	HR-RAC (0.01) × UF (2)
Milk	0.02	EFSA (2024c)[c]	0.020	STMR-RAC (0.01) × UF (2)	0.020	STMR-RAC (0.01) × UF (2)
Eggs	0.03	EFSA (2024c)[c]	0.020	STMR-RAC (0.01) × UF (2)	0.046	HR-RAC (0.023) × UF (2)
Risk assessment residue definition: 1,2,4-triazole						
Citrus fruits	-	EFSA (2018b)	0.05	STMR-RAC (EFSA, 2018b)	0.01	$HR\text{-}RAC_{(pulp)}$ (Spain, 2023b)
Tree nuts	-	Spain (2023b)	0.01	STMR-RAC	0.187	HR-RAC
Blueberries	-	EFSA (2018b)	0.01	STMR-RAC (EFSA, 2018b)	0.01	HR-RAC (Spain, 2023b)
Mangoes		Spain (2023b)	0.05	STMR-RAC	0.05	$HR\text{-}RAC_{(pulp)}$
Papayas		Spain (2023b)	0.05	STMR-RAC	0.05	$HR\text{-}RAC_{(pulp)}$
Peas (dry)		EFSA (2018b)	0.05	STMR-RAC (EFSA, 2018b)	0.01	STMR-RAC (Spain, 2023b)
Soya beans		EFSA (2018b)	0.05	STMR-RAC (EFSA, 2018b)	0.01	STMR-RAC (Spain, 2023b)
Pome fruits		EFSA (2018b)	0.01	STMR-RAC	Acute risk assessment not performed	
Stone fruits		EFSA (2018b)	0.01	STMR-RAC		
Table and wine grapes		EFSA (2018b)	0.01	STMR-RAC		
Strawberries		EFSA (2018b)	0.01	STMR-RAC		
Cane fruits		EFSA (2018b)	0.01	STMR-RAC		
Other small fruits and berries, except blueberries		EFSA (2018b)	0.01	STMR-RAC		
Table olives		EFSA (2023c)	0.01	STMR-RAC		
Kaki/Japanese persimmons		EFSA (2023c)	0.01	STMR-RAC		
Bananas		EFSA (2018b)	0.05	STMR-RAC		
Root and tuber vegetables		EFSA (2018b)	0.01	STMR-RAC		
Bulb vegetables		EFSA (2018b)	0.01	STMR-RAC		
Fruiting vegetables		EFSA (2018b)	0.01	STMR-RAC		

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Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Brassica vegetables		EFSA (2018b)	0.039	STMR-RAC		
Leaf vegetables, herbs and edible flowers		EFSA (2018b)	0.015	STMR-RAC		
Legume vegetables		EFSA (2018b)	0.01	STMR-RAC		
Stem vegetables		EFSA (2018b)	0.01	STMR-RAC		
Pulses, except peas		EFSA (2018b)	0.05	STMR-RAC		
Oilseeds, except soya beans		EFSA (2018b)	0.05	STMR-RAC		
Olives for oil production		EFSA (2018b)	0.05	STMR-RAC		
Cereals		EFSA (2018b)	0.05	STMR-RAC		
HOPS (dried)		EFSA (2023c)	0.013	STMR-RAC		
Sugar plants		EFSA (2018b)	0.05	STMR-RAC		
Swine: Muscle/meat		EFSA (2018b)	0.13	STMR-RAC		
Swine: Fat tissue		EFSA (2018b)	0.1	STMR-RAC		
Swine: Liver		EFSA (2018b)	0.13	STMR-RAC		
Swine: Kidney		EFSA (2018b)	0.14	STMR-RAC		
Swine: Edible offals (other than liver and kidney)		EFSA (2018b)	0.14	STMR-RAC		
Bovine and equine: Muscle/meat		EFSA (2018b)	0.27	STMR-RAC		
Bovine and equine: Fat tissue		EFSA (2018b)	0.18	STMR-RAC		
Bovine and equine: Liver		EFSA (2018b)	0.31	STMR-RAC		
Bovine and equine: Kidney		EFSA (2018b)	0.32	STMR-RAC		
Bovine and equine: Edible offals (other than liver and kidney)		EFSA (2018b)	0.32	STMR-RAC		
Sheep and goat: Muscle/meat		EFSA (2018b)	0.29	STMR-RAC		
Sheep and goat: Fat tissue		EFSA (2018b)	0.19	STMR-RAC		
Sheep and goat: Liver		EFSA (2018b)	0.34	STMR-RAC		
Sheep and goat: Kidney		EFSA (2018b)	0.34	STMR-RAC		
Sheep and goat: Edible offals (other than liver and kidney)		EFSA (2018b)	0.34	STMR-RAC		
Poultry: Muscle/ meat		EFSA (2023c)	0.041	STMR-RAC		
Poultry: Fat tissue		EFSA (2023c)	0.04	STMR-RAC		
Poultry: Liver		EFSA (2023c)	0.041	STMR-RAC		
Poultry: Kidney		EFSA (2023c)	0.041	STMR-RAC		
Poultry: Edible offals (other than liver and kidney)		EFSA (2023c)	0.041	STMR-RAC		

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Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Other farmed animals: Muscle/ meat		EFSA (2018b)	0.19	STMR-RAC		
Other farmed animals: Fat tissue		EFSA (2018b)	0.19	STMR-RAC		
Other farmed animals: Liver		EFSA (2018b)	0.34	STMR-RAC		
Other farmed animals: Kidney		EFSA (2018b)	0.34	STMR-RAC		
Other farmed animals: Edible offals (other than liver and kidney)		EFSA (2018b)	0.34	STMR-RAC		
Milk		EFSA (2018b)	0.32	STMR-RAC		
Eggs		EFSA (2023c)	0.04	STMR-RAC		
Other crops/ commodities		–				
Risk assessment residue definition: Triazole acetic acid						
Citrus fruits		EFSA (2018b)	0.05	STMR-RAC (EFSA, 2018b)	0.01	$HR\text{-}RAC_{(pulp)}$ (Spain, 2023b)
Almonds, **Brazil nuts**, **Cashew nuts**, **Chestnuts**, **Coconuts**, **Macadamia**, **Pecans**, **Pine nut kernels**, **Walnuts**		Spain (2023b)	0.01	STMR-RAC	0.134	HR-RAC
Hazelnuts/cobnuts		EFSA (2023c)	0.011	STMR-RAC (EFSA, 2023c)	0.134	HR-RAC (Spain, 2023b)
Pistachios		EFSA (2023c)	0.01	STMR-RAC (EFSA, 2023c)	0.15	HR-RAC (Spain, 2023b)
Other tree nuts		Spain (2023b)	0.01	STMR-RAC	–	–
Blueberries		EFSA (2018b)	0.05	STMR-RAC (EFSA, 2018b)	0.01	HR-RAC (Spain, 2023b)
Mangoes		Spain (2023b)	0.07	STMR-RAC	0.11	$HR\text{-}RAC_{(pulp)}$
Papayas		Spain (2023b)	0.01	STMR-RAC	0.04	$HR\text{-}RAC_{(pulp)}$
Peas (dry)		EFSA (2018b)	0.05	STMR-RAC (EFSA, 2018b)	0.01	STMR-RAC (Spain, 2023b)
Soya beans		EFSA (2018b)	0.12	STMR-RAC (EFSA, 2018b)	0.015	STMR-RAC (Spain, 2023b)
Pome fruits		EFSA (2018b)	0.03	STMR-RAC	Acute risk assessment not performed	
Stone fruits		EFSA (2018b)	0.02	STMR-RAC		
Table and wine grapes		EFSA (2018b)	0.05	STMR-RAC		
Strawberries		EFSA (2018b)	0.05	STMR-RAC		
Cane fruits		EFSA (2018b)	0.05	STMR-RAC		
Other small fruits and berries, except blueberries		EFSA (2018b)	0.05	STMR-RAC		
Table olives		EFSA (2023c)	0.01	STMR-RAC		
Kaki/Japanese persimmons		EFSA (2023c)	0.01	STMR-RAC		

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Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Bananas		EFSA (2018b)	0.05	STMR-RAC		
Root and tuber vegetables		EFSA (2018b)	0.01	STMR-RAC		
Bulb vegetables		EFSA (2018b)	0.01	STMR-RAC		
Fruiting vegetables		EFSA (2018b)	0.01	STMR-RAC		
Brassica vegetables		EFSA (2018b)	0.01	STMR-RAC		
Leaf vegetables, herbs and edible flowers		EFSA (2018b)	0.023	STMR-RAC		
Legume vegetables		EFSA (2018b)	0.01	STMR-RAC		
Stem vegetables		EFSA (2018b)	0.02	STMR-RAC		
Pulses, except peas		EFSA (2018b)	0.05	STMR-RAC		
Oilseeds, except soya beans		EFSA (2018b)	0.12	STMR-RAC		
Olives for oil production		EFSA (2018b)	0.12	STMR-RAC		
Cereals		EFSA (2018b)	0.79	STMR-RAC		
HOPS (dried)		EFSA (2023c)	0.012	STMR-RAC		
Sugar plants		EFSA (2018b)	0.05	STMR-RAC		
Swine: Muscle/meat		EFSA (2018b)	0.04	STMR-RAC		
Swine: Fat tissue		EFSA (2018b)	0.04	STMR-RAC		
Swine: Liver		EFSA (2018b)	0.04	STMR-RAC		
Swine: Kidney		EFSA (2018b)	0.11	STMR-RAC		
Swine: Edible offals (other than liver and kidney)		EFSA (2018b)	0.11	STMR-RAC		
Bovine and equine: Muscle/meat		EFSA (2018b)	0.04	STMR-RAC		
Bovine and equine: Fat tissue		EFSA (2018b)	0.05	STMR-RAC		
Bovine and equine: Liver		EFSA (2018b)	0.05	STMR-RAC		
Bovine and equine: Kidney		EFSA (2018b)	0.15	STMR-RAC		
Bovine and equine: Edible offals (other than liver and kidney)		EFSA (2018b)	0.15	STMR-RAC		
Sheep and goat: Muscle/meat		EFSA (2018b)	0.04	STMR-RAC		
Sheep and goat: Fat tissue		EFSA (2018b)	0.06	STMR-RAC		
Sheep and goat: Liver		EFSA (2018b)	0.05	STMR-RAC		
Sheep and goat: Kidney		EFSA (2018b)	0.18	STMR-RAC		
Sheep and goat: Edible offals (other than liver and kidney)		EFSA (2018b)	0.18	STMR-RAC		
Poultry: Muscle/meat		EFSA (2018b) EFSA (2018b)	0.04	STMR-RAC		
Poultry: Fat tissue		EFSA (2018b)	0.04	STMR-RAC		

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Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Poultry: Liver		EFSA (2018b)	0.05	STMR-RAC		
Poultry: Kidney		EFSA (2018b)	0.05	STMR-RAC		
Poultry: Edible offals (other than liver and kidney)		EFSA (2018b)	0.05	STMR-RAC		
Other farmed animals: Muscle/ meat		EFSA (2018b)	0.06	STMR-RAC		
Other farmed animals: Fat tissue		EFSA (2018b)	0.06	STMR-RAC		
Other farmed animals: Liver		EFSA (2018b)	0.05	STMR-RAC		
Other farmed animals: Kidney		EFSA (2018b)	0.18	STMR-RAC		
Other farmed animals: Edible offals (other than liver and kidney)		EFSA (2018b)	0.18	STMR-RAC		
Milk		EFSA (2018b)	0.04	STMR-RAC		
Eggs		EFSA (2018b)	0.04	STMR-RAC		
Other crops/ commodities		–				
Risk assessment residue definition: Triazole Alanine						
Citrus fruits		EFSA (2018b)	0.32	STMR-RAC	0.021	$HR\text{-}RAC_{(pulp)}$ (Spain, 2023b)
Tree nuts, except pistachios and other tree nuts		Spain (2023b)	0.258	STMR-RAC	4.234	HR-RAC
Pistachios		EFSA (2023c)	1.15	STMR-RAC (EFSA, 2023c)	4.234	HR-RAC (Spain, 2023b)
Other tree nuts		Spain (2023b)	0.258	STMR-RAC	–	–
Blueberries		EFSA (2018)	0.06	STMR-RAC (EFSA, 2018b)	0.033	HR-RAC (Spain, 2023b)
Mangoes		Spain (2023b)	0.42	STMR-RAC	0.76	$HR\text{-}RAC_{(pulp)}$
Papayas		Spain (2023b)	0.1	STMR-RAC	0.95	$HR\text{-}RAC_{(pulp)}$
Peas (dry)		EFSA (2023c)	0.2	STMR-RAC (EFSA, 2023c)	0.115	STMR-RAC (Spain, 2023b)
Soya beans		EFSA (2018)	1.039	STMR-RAC (EFSA, 2018b)	0.038	STMR-RAC (Spain, 2023b)
Pome fruits		EFSA (2018b)	0.039	STMR-RAC	Acute risk assessment not performed	
Stone fruits		EFSA (2018b)	0.32	STMR-RAC		
Table and wine grapes		EFSA (2018b)	0.06	STMR-RAC		
Strawberries		EFSA (2018b)	0.06	STMR-RAC		
Cane fruits		EFSA (2018b)	0.06	STMR-RAC		
Other small fruits and berries, except blueberries		EFSA (2018b)	0.06	STMR-RAC		
Table olives		EFSA (2023c)	0.6	STMR-RAC		
Kaki/Japanese persimmons		EFSA (2023c)	0.069	STMR-RAC		

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Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Bananas		EFSA (2018b)	0.05	STMR-RAC		
Root and tuber vegetables		EFSA (2018b)	0.184	STMR-RAC		
Bulb vegetables		EFSA (2018b)	0.06	STMR-RAC		
Fruiting vegetables		EFSA (2018b)	0.21	STMR-RAC		
Brassica vegetables		EFSA (2018b)	0.17	STMR-RAC		
Leaf vegetables, herbs and edible flowers		EFSA (2018b)	0.047	STMR-RAC		
Beans (with pods), Peas (with pods), Lentils (fresh)		EFSA (2018b)	0.09	STMR-RAC		
Beans (without pods)		EFSA (2023c)	0.135	STMR-RAC		
Peas (without pods)		EFSA (2023c)	0.27	STMR-RAC		
Other legume vegetables (fresh)		EFSA (2018b)	0.09	STMR-RAC		
Stem vegetables		EFSA (2018b)	0.09	STMR-RAC		
Beans (dry)		EFSA (2018b)	0.17	STMR-RAC		
Lentils (dry), Lupins/lupini beans (dry)		EFSA (2023c)	0.2	STMR-RAC		
Other pulses		EFSA (2023c)	0.2	STMR-RAC		
Oilseeds, except soya beans		EFSA (2018b)	1.039	STMR-RAC		
Olives for oil production		EFSA (2018b)	1.039	STMR-RAC		
Cereals		EFSA (2018b)	0.621	STMR-RAC		
HOPS (dried)		EFSA (2023c)	0.455	STMR-RAC		
Sugar plants		EFSA (2018b)	0.05	STMR-RAC		
Swine: Muscle/meat		EFSA (2018b)	0.21	STMR-RAC		
Swine: Fat tissue		EFSA (2018b)	0.09	STMR-RAC		
Swine: Liver		EFSA (2018b)	0.5	STMR-RAC		
Swine: Kidney		EFSA (2018b)	0.22	STMR-RAC		
Swine: Edible offals (other than liver and kidney)		EFSA (2018b)	0.5	STMR-RAC		
Bovine and equine: Muscle/meat		EFSA (2018b)	0.46	STMR-RAC		
Bovine and equine: Fat tissue		EFSA (2018b)	0.22	STMR-RAC		
Bovine and equine: Liver		EFSA (2018b)	1.01	STMR-RAC		
Bovine and equine: Kidney		EFSA (2018b)	0.49	STMR-RAC		
Bovine and equine: Edible offals (other than liver and kidney)		EFSA (2018b)	1.01	STMR-RAC		
Sheep and goat: Muscle/meat		EFSA (2018b)	0.51	STMR-RAC		
Sheep and goat: Fat tissue		EFSA (2018b)	0.23	STMR-RAC		

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Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Sheep and goat: Liver		EFSA (2018b)	1.13	STMR-RAC		
Sheep and goat: Kidney		EFSA (2018b)	0.55	STMR-RAC		
Sheep and goat: Edible offals (other than liver and kidney)		EFSA (2018b)	1.13	STMR-RAC		
Poultry: Muscle/ meat		EFSA (2018b)	0.11	STMR-RAC		
Poultry: Fat tissue		EFSA (2018b)	0.1	STMR-RAC		
Poultry: Liver		EFSA (2018b)	0.27	STMR-RAC		
Poultry: Kidney		EFSA (2018b)	0.27	STMR-RAC		
Poultry: Edible offals (other than liver and kidney)		EFSA (2018b)	0.27	STMR-RAC		
Other farmed animals: Muscle/ meat		EFSA (2018b)	0.23	STMR-RAC		
Other farmed animals: Fat tissue		EFSA (2018b)	0.23	STMR-RAC		
Other farmed animals: Liver		EFSA (2018b)	1.13	STMR-RAC		
Other farmed animals: Kidney		EFSA (2018b)	0.55	STMR-RAC		
Other farmed animals: Edible offals (other than liver and kidney)		EFSA (2018b)	1.13	STMR-RAC		
Milk		EFSA (2018b)	0.04	STMR-RAC		
Eggs		EFSA (2018b)	0.06	STMR-RAC		
Other crops/ commodities		–				
Risk assessment residue definition: Triazole lactic acid						
Citrus fruits		EFSA (2018b)	0.04	STMR-RAC	0.01	HR-RAC$_{(pulp)}$ (Spain, 2023b)
Tree nuts, except hazelnuts/ cobnuts, pistachios and other tree nuts		Spain (2023b)	0.016	STMR-RAC	0.399	HR-RAC
Hazelnuts/cobnuts		EFSA (2023c)	0.077	STMR-RAC	0.399	HR-RAC(Spain, 2023b)
Pistachios		EFSA (2023c)	0.116	STMR-RAC	0.399	HR-RAC (Spain, 2023b)
Other tree nuts		Spain (2023b)	0.016	STMR-RAC	–	–
Blueberries		EFSA (2018b)	0.04	STMR-RAC	0.121	HR-RAC (Spain, 2023b)
Mangoes		Spain (2023b)	0.26	STMR-RAC	0.52	HR-RAC$_{(pulp)}$
Papayas		Spain (2023b)	0.03	STMR-RAC	0.22	HR-RAC$_{(pulp)}$
Peas		Spain (2023b)	0.016	STMR-RAC	0.016	STMR-RAC
Soya beans		EFSA (2018b)	0.065	STMR-RAC	0.047	STMR-RAC (Spain, 2023b)

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Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Pome fruits		EFSA (2018b)	0.03	STMR-RAC		
Stone fruits		EFSA (2018b)	0.038	STMR-RAC		
Table and wine grapes		EFSA (2018b)	0.04	STMR-RAC		
Strawberries		EFSA (2018b)	0.04	STMR-RAC		
Cane fruits		EFSA (2018b)	0.04	STMR-RAC		
Other small fruits and berries, except blueberries		EFSA (2018b)	0.04	STMR-RAC		
Table olives		EFSA (2023c)	0.01	STMR-RAC		
Kaki/Japanese persimmons		EFSA (2023c)	0.01	STMR-RAC		
Bananas		EFSA (2018b)				
Root and tuber vegetables		EFSA (2018b)	0.021	STMR-RAC		
Bulb vegetables		EFSA (2018b)	0.01	STMR-RAC		
Fruiting vegetables		EFSA (2018b)	0.03	STMR-RAC		
Brassica vegetables		EFSA (2018b)	0.01	STMR-RAC		
Leaf vegetables, herbs and edible flowers		EFSA (2018b)	0.08	STMR-RAC		
Legume vegetables		EFSA (2018b)	0.01	STMR-RAC		
Stem vegetables		EFSA (2018b)	0.01	STMR-RAC		
Pulses, except peas		EFSA (2018b)	0.01	STMR-RAC		
Oilseeds, except soya beans		EFSA (2018b)	0.065	STMR-RAC		
Olives for oil production		EFSA (2018b)	0.065	STMR-RAC		
Cereals		EFSA (2018b)	0.022	STMR-RAC		
HOPS (dried)		EFSA (2023c)	0.2	STMR-RAC		
Sugar plants		EFSA (2018b)	0.01	STMR-RAC		
Muscle/meat (swine, bovine, sheep, goat, equine, poultry and other farmed animals)		EFSA (2018b)	0.04	STMR-RAC		
Fat tissue (swine, bovine, sheep, goat, equine, other farmed animals)		EFSA (2018b)	0.07	STMR-RAC		
Fat tissue (poultry)		EFSA (2018b)	0.04	STMR-RAC		
Liver (swine, bovine, sheep, goat, equine, poultry and other farmed animals)		EFSA (2018b)	0.04	STMR-RAC		
Kidney (swine)		EFSA (2018b)	0.05	STMR-RAC		
Kidney (bovine, sheep, goat, equine and other farmed animals)		EFSA (2018b)	0.09	STMR-RAC		
Kidney (poultry)		EFSA (2018b)	0.04	STMR-RAC		

(Continued)

Commodity	Existing/ Proposed MRL (mg/kg)	Source of existing/ proposed MRL	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Edible offals other than liver and kidney (swine)		EFSA (2018b)	0.05	STMR-RAC		
Edible offals other than liver and kidney (bovine, sheep, goat, equine and other farmed animals)		EFSA (2018b)	0.09	STMR-RAC		
Edible offals other than liver and kidney (poultry)		EFSA (2018b)	0.04	STMR-RAC		
Milk		EFSA (2018b)	0.04	STMR-RAC		
Eggs		EFSA (2018b)	0.04	STMR-RAC		
Other crops/ commodities		–				

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

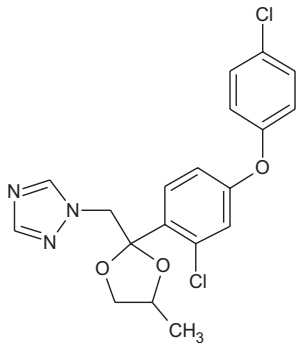
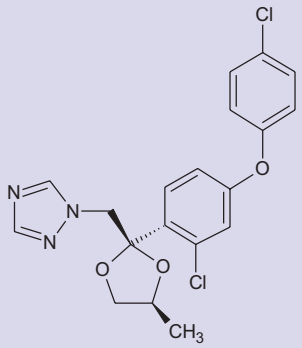
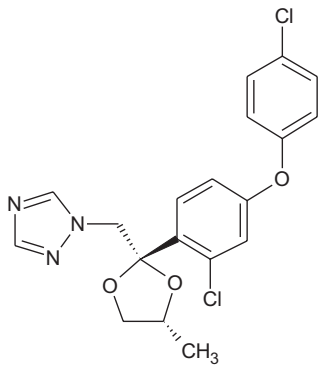
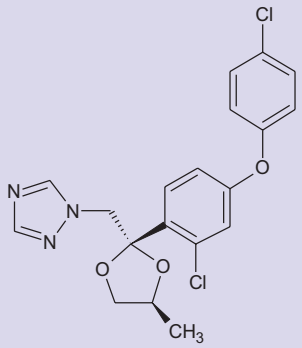
[a]Figures in the table are rounded to 2 digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

[b]PeF derived in the context of the current application based on residues measured at PHI of 0 days, applicable to CXL values, which were measured at the same PHI.

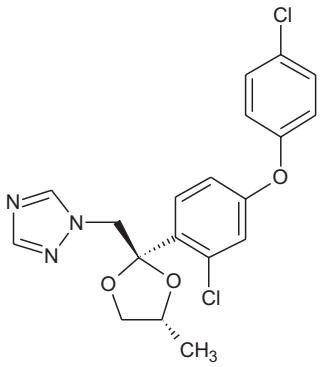
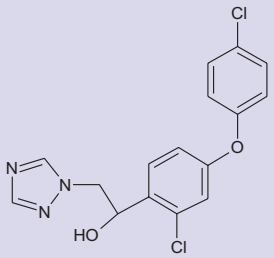
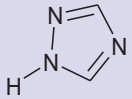
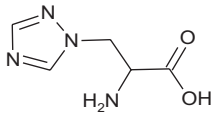
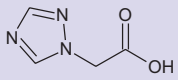
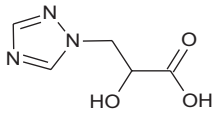
[c]MRL (and risk assessment values) tentatively derived in the MRL review but not yet implemented in Regulation; when 2 MRL options were reported in the MRL review, the highest of the 2 options is retained for the present risk assessment, even if tentative. For blueberries, passion fruits, okra, spices (bark, buds, flower, aril), the existing MRL was directly used for the risk assessment because no risk assessment values were derived during the MRL review.

APPENDIX E

Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Difenoconazole	3-chloro-4-[(2*RS*,4*RS*;2*RS*,4*SR*)-4-methyl-2-(1*H*-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether BQYJATMQXGBDHF-UHFFFAOYSA-N Clc1ccc(cc1)Oc1ccc(c(Cl)c1)C1(Cn2ncnc2)OCC(C)O1	
2*R*,4*S*-Difenoconazole (*cis*-diastereomer)	1-{{(2*R*,4*S*)-2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1*H*-1,2,4-triazole BQYJATMQXGBDHF-DJJJIMSYSA-N Clc1cc(ccc1[C@@]1(O[C@@H](C)CO1)Cn1ncnc1)Oc1ccc(Cl)cc1	
2*S*,4*R*-Difenoconazole (*cis*-diastereomer)	1-{{(2*S*,4*R*)-2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1*H*-1,2,4-triazole BQYJATMQXGBDHF-BFUOFWGJSA-N Clc1cc(ccc1[C@]1(O[C@H](C)CO1)Cn1ncnc1)Oc1ccc(Cl)cc1	
2*S*,4*S*-Difenoconazole (*trans*-diastereomer)	1-{{(2*S*,4*S*)-2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1*H*-1,2,4-triazole BQYJATMQXGBDHF-ORAYPTAESA-N Clc1cc(ccc1[C@]1(O[C@@H](C)CO1)Cn1ncnc1)Oc1ccc(Cl)cc1	

(Continued)

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
2*R*,4*R*-Difenoconazole (*trans*-diastereomer)	1-{[(2*R*,4*R*)-2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl} methyl)-1*H*-1,2,4-triazole BQYJATMQXGBDHF-YJYMSZOUSA-N Clc1cc(ccc1[C@@]1(O[C@H](C)CO1)Cn1ncnc1)Oc1ccc(Cl)cc1	
Difenoconazole-alcohol CGA205375	1-[2-chloro-4-(4-chlorophenoxy)phenyl]-2-(1*H*-1,2,4-triazol-1-yl)ethanol OC(Cn1ncnc1)c1ccc(cc1Cl)Oc1ccc(Cl)cc1 NBYSKMWDHCZSIP-UHFFFAOYSA-N	
Triazole derivative metabolites (TDMs)		
1,2,4-triazole (1,2,4-T) CGA71019	1*H*-1,2,4-triazole c1ncnn1 NSPMIYGKQJPBQR-UHFFFAOYSA-N	
Triazole alanine (TA) CGA131013	3-(1*H*-1,2,4-triazol-1-yl)-D,L-alanine NC(Cn1cncn1)C(=O)O XVWFTOJHOHJIMQ-UHFFFAOYSA-N	
Triazole acetic acid (TAA) CGA142856	1*H*-1,2,4-triazol-1-ylacetic acid O=C(O)Cn1cncn1 RXDBSQXFIWBJSR-UHFFFAOYSA-N	
Triazole lactic acid (TLA) or Triazole hydroxy propionic acid	(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 2023.2.4 ACD/Labs 2023.2.4 (File Version N25E41, Build 137185, 31 January 2024).

[c]ACD/ChemSketch 2023.2.4 ACD/Labs 2024.2.4 (File Version C45H41, Build 137017, 18 January 2024).