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Modification of the existing maximum residue levels for prothioconazole in garlic, onions and shallots

EFSA (European Food Safety Authority),
Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Irene Castellan, Monica Del Aguila, Lucien Ferreira, German Giner Santonja, Luna Greco, Samira Jarrah, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Tobin Robinson, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer SAS – Crop Science Division submitted a request to the competent national authority in the Netherlands to modify the existing maximum residue levels (MRLs) for the active substance prothioconazole in garlic, onions and shallots. The data submitted in support of the request were found to be sufficient to derive MRL proposals for garlic, onion and shallots. Adequate analytical methods for enforcement are available to control the residues of prothioconazole on the commodities under consideration at the validated limit of quantification (LOQ) of 0.02 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 prothioconazole according to the reported agricultural practices is unlikely to present a risk to consumer health. An indicative exposure assessment to triazole derivative metabolites from the intended uses of prothioconazole did not indicate consumer intake concerns.

Keywords: prothioconazole, garlic, onions, shallots, fungicide, MRL, consumer risk assessment

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Correspondence: pesticides.mrl@efsa.europa.eu

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer SAS-Crop Science Division submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance prothioconazole in garlic, onions and shallots. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 1 February 2022. To accommodate for the intended uses of prothioconazole, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 0.02 mg/kg for garlic and to lower the existing tentative MRL from 0.05 mg/kg to 0.02 mg/kg for onions and shallots.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps, which were requested from the EMS. On 8 September 2022, the EMS submitted a revised evaluation report which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of prothioconazole following foliar treatment was investigated in crops belonging to the groups of root crops, cereals and pulses/oilseeds. The metabolic pattern of prothioconazole was shown to be similar in all plant groups with prothioconazole-desthio being the predominant compound of the total residues. Besides prothioconazole-desthio, other metabolites, which are structurally closely related to this compound, and three triazole derivative metabolites (TDMs) were identified in crops treated with prothioconazole. Triazole alanine (TA) represented the main TDM in the crops investigated, followed by triazole acetic acid (TAA) and triazole lactic acid (TLA). The fourth TDM, 1,2,4-triazole (1,2,4-T), was not identified.

Studies investigating the effect of processing on the nature (hydrolysis studies) of prothioconazole-desthio and of the TDMs demonstrated that these compounds are stable.

In the rotational crop metabolism, the major residues identified were prothioconazole-desthio and its hydroxylated derivative metabolites, either free or conjugated. In studies with triazole-labelled prothioconazole, the main residues in rotational crops were TDMs, namely TA, TAA and TLA whereby 1,2,4-T was not reported to have been detected.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and the capabilities of the analytical enforcement methods, the residue definitions for prothioconazole in plant products were derived by the EU pesticide peer review on prothioconazole. Additional risk assessment residue definitions related to the presence of TDMs were derived by the peer review of the risk assessment of the TDMs in the light of confirmatory data. For enforcement, the residue definition is defined as 'prothioconazole-desthio (sum of isomers)' for enforcement and, as follows, for the risk assessment:

1) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2*H*-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).
2) Triazole alanine (TA) and triazole lactic acid (TLA).
3) Triazole acetic acid (TAA).
4) 1,2,4-triazole (1,2,4-T).

These residue definitions are applicable to primary crops, rotational crops and processed products and for both foliar and seed treatments.

EFSA concluded that for the crops assessed in the application, the derived residue definitions are applicable. Sufficiently validated enforcement methods based on chromatography with mass spectrometry (GC-MS) are available to analyse prothioconazole-desthio residues in crops under consideration at the LOQ of 0.02 mg/kg.

The available residue trials are sufficient to derive MRL proposals of 0.02 mg/kg for prothioconazole in garlic, onions and shallots and to derive risk assessment values according to the applicable risk assessment residue definitions, including the available data for the TDMs. In the framework of the evaluation of the Article 12 confirmatory data, it was proposed to lower the existing tentative MRL of 0.05 mg/kg in onions and shallots to the LOQ of 0.02 mg/kg due to data gaps related to residue trials. The applicant has provided new residue trials which justify a lowering of the MRL. The applicant also

provided residue trials investigating the transfer of prothioconazole and TDM residues to honey from the use of prothioconazole on oilseed rape. These data indicate that residues of prothioconazole in honey would not exceed the existing MRL of 0.05 mg/kg (LOQ).

Specific studies investigating the magnitude of prothioconazole residues in processed commodities are not required, as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI and the residues in raw agricultural commodity (RAC) are not exceeding the trigger value of 0.1 mg/kg. From the TDM compounds, only triazole alanine was present in RAC with residues above 0.1 mg/kg. No studies were submitted investigating the magnitude of triazole alanine in processed crops under consideration. However, since the estimated dietary exposure to TA residues is very low (below 0.02% ADI), the lack of processing study in the framework of this assessment is considered a minor deficiency.

The occurrence of prothioconazole residues in rotational crops was investigated in the framework of the EU pesticides peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels of parent prothioconazole are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).

For the triazole derivate metabolites on the other hand, the occurrence of residues in rotational crops cannot be excluded as these metabolites are generated by various pesticides belonging to the group of triazole fungicides. It is noted that rotational crop field trials analysing various TDMs from the uses of prothioconazole were available for the assessment of confirmatory data for TDMs. On the basis of these trials, EFSA concludes that residues of TDMs above 0.01 mg/kg cannot be excluded in rotational crops from the intended use of prothioconazole on primary crops according to the proposed GAP. It is noted that the intended use of prothioconazole is less critical in terms of magnitude of TDM residues in rotational crops than uses of other triazole fungicides assessed in the framework of the pesticide risk assessment of TDMs in light of confirmatory data. Thus, the magnitude of TDMs in rotational crops from the uses of prothioconazole on primary crops is covered by more critical uses of other triazole fungicides. Nevertheless, Member States should consider the need to setting specific risk mitigation measures to avoid additional contribution of TDM residues in rotational crops from the intended use of prothioconazole on garlic, onions and shallots.

Residues of prothioconazole in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.

The toxicological profile of prothioconazole 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 0.01 mg/kg bw. The hydroxy-metabolites included in the residue definition for risk assessment are of similar toxicity as the parent active substance. For residue definitions relating to the TDMs, the following toxicological reference values were considered: for TA and TLA, an ARfD of 0.3 mg/kg bw and an ADI of 0.3 mg/kg bw per day; for TAA, an ARfD of 1 mg/kg bw and an ADI of 1 mg/kg bw per day; for 1,2,4-T, an ARfD of 0.1 mg/kg bw and an ADI of 0.023 mg/kg bw per day.

Under the assumptions that the recommendations derived in the framework of the Article 12 confirmatory data assessment will be implemented in the EU MRL legislation, the previous consumer risk assessment performed in the context of the Article 12 confirmatory data assessment was updated with the new risk assessment values as derived for onions, garlic and shallots from the submitted residue trials. The consumer risk assessment was performed separately for prothioconazole and for TDMs, using the revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo).

For prothioconazole, no long-term consumer intake concerns were identified for any of the diets included in the EFSA PRIMo, as the estimated maximum long-term dietary intake accounted for 9% of the ADI (WHO Cluster diet B). The short-term exposure did not exceed the ARfD for any of the crops under consideration.

Regarding the exposure to TDMs, a comprehensive risk assessment, considering TDMs in all crops from all pesticides belonging to the class of triazole fungicides, could not be performed in the framework of this opinion and a separate risk assessment for TDMs has been performed by EFSA in line with the confirmatory data assessment for triazole compounds in the framework of Regulation (EC) No 1107/2009. The present assessment took into consideration TDMs related to the proposed conditions of use in this application.

For the chronic exposure, EFSA compared the supervised trials median residue (STMR) values derived for garlic, onions and shallots in the current assessment with the highest STMR value derived for onions from the uses of other triazole fungicides in the framework of the pesticide risk assessment

of the TDMs in light of confirmatory data. As the values derived under present assessment were lower, EFSA concludes that the conclusion of the peer review of the assessment of the pesticide risk assessment of the TDMs remains unchanged: 93% of the ADI (NL toddler) for 1,2,4-T, 6% of the ADI (NL toddler) for TA, 1% of the ADI (NL toddler) for TAA and 1% of the ADI (NL toddler) for TLA.

Regarding the acute exposure to TDMS, EFSA assessed potential risks associated with the acute intake of garlic, onions and shallots containing residues of TAA, TLA and TLA and 1,2,4-triazole at the highest levels according to the submitted residue trials. No acute intake concerns were identified.

EFSA concluded that the proposed use of prothioconazole on garlic, onions and shallots will not result in a consumer exposure exceeding the toxicological reference values for prothioconazole and the TDMs and therefore is unlikely to pose a risk to consumers' health.

EFSA notes that the renewal of the approval process of prothioconazole is currently ongoing, and therefore, the conclusions of the present assessment are considered provisional and might need to be reconsidered.

EFSA emphasises that the above assessment took into consideration triazole derivative metabolites (TDMs) related to the proposed conditions of use in this application. As these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA performed a separate risk assessment for TDMs in line with the confirmatory data assessment for triazole compounds in the framework of Regulation (EC) No 1107/2009 and the general methodology on the risk assessment of triazole compounds and their TDMs is available.

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

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Prothioconazole: prothioconazole-desthio (sum of isomers)				
0220010	Garlic	0.01*	0.02	The submitted data are sufficient to derive an MRL proposal for both the intended NEU and SEU use. Risk for consumers unlikely for the residues of prothioconazole including its triazole derivative metabolites (TDMs). Member States should consider the need to setting specific risk mitigation measures to avoid additional contribution of TDM residues in rotational crops from the intended use of prothioconazole on garlic, onions and shallots
0220020	Onions	0.05 (ft)	0.02	
0220030	Shallots	0.05 (ft)	0.02	

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.
(ft): The European Food Safety Authority identified some information on residue trials and storage stability data complying with the proposed residue definition as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it (Regulation (EU) No 2019/552).

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for prothioconazole in garlic, onions and shallots. The detailed description of the intended uses of prothioconazole, which are the basis for the current MRL application, is reported in Appendix A.

Prothioconazole is the ISO common name for (*RS*)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Prothioconazole was evaluated in the framework of Directive 91/414/EEC[1] with United Kingdom designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on cereals and rapeseeds. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2007). Prothioconazole was approved[2] for the use as fungicide on 1 August 2008.

EU MRLs for prothioconazole are established in Annex II of Regulation (EC) No 396/2005.[3] The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for prothioconazole. The proposals from these reasoned opinions have been considered in recent MRL regulations.[4] Certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation. The data submitted to address the Article 12 confirmatory data have been evaluated by EFSA in 2020 (EFSA, 2020), but the proposals so far have not been implemented in the EU MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer SAS-Crop Science Division submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance prothioconazole in garlic, onions and shallots. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 1 February 2022. To accommodate for the intended uses of prothioconazole, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 0.02 mg/kg for garlic and to lower the existing tentative MRL from 0.05 to 0.02 mg/kg for onions and shallots.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps, which were requested from the EMS. On 8 September 2022, the EMS submitted a revised evaluation report (Netherlands, 2021), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Netherlands, 2021), the draft assessment report (DAR) and its addendum (United Kingdom, 2004, 2007) prepared under Council Directive 91/414/EEC, the final Commission review report on prothioconazole (European Commission, 2021), the conclusion on the peer review of the pesticide risk assessment of the active substance prothioconazole (EFSA, 2007), as well as the conclusions from previous EFSA opinions on prothioconazole (EFSA, 2015a,b, 2020), including the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005.

For this application, the data requirements established in Regulation (EU) No 544/2011[5] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000; OECD, 2008, 2010a,b, 2011, 2017a, 2018). The assessment

[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.

[2] Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthiavalicarb, boscalid, carvone, fluoxastrobin, Paecilomyces lilacinus and prothioconazole as active substances. OJ L 94, 5.4.2008, p. 13–20.

[3] 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.

4 For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

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

is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.[6]

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 EMS (Netherlands, 2021) 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.

EFSA notes that the renewal of the approval process of prothioconazole is currently ongoing, and therefore, the conclusions of the present assessment are considered provisional and might need to be reconsidered.

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 prothioconazole has been investigated in root (sugar beet), pulses/oilseeds (peanut) and cereal/grass (wheat) crop groups by foliar treatment and by seed treatment on cereal/grasses crop group (wheat) in the framework of the EU pesticides peer review under Directive 91/414/EEC and the Article 12 MRL review (EFSA, 2007a,b, 2014).

In addition, the metabolism of prothioconazole-desthio labelled in the triazole moiety was investigated after foliar applications on cereals (EFSA, 2007b, 2014). The metabolism of triazole-labelled prothioconazole in root crops (sugar beet) and pulses and oilseeds (peanut) was assessed by the JMPR and reported during the MRL review (FAO, 2008a,b; EFSA, 2014).

In wheat grain following foliar spray application with phenyl- and triazole-labelled prothioconazole, the total radioactive residue (TRR) accounted for 0.08 mg eq./kg and 4.97 mg eq./kg, respectively. In studies with phenyl-label, parent prothioconazole accounted for 1% of the TRR (0.008 mg e.q./kg) and prothioconazole-desthio for 15.9% of the TRR. For the triazole label in grain, triazole alanine (TA) accounted for 71% of the TRR, TAA for 19% of the TRR and TLA for less than 1% of the TRR (FAO, 2008a,b).

In peanut nutmeat following phenyl- and triazole-labelled prothioconazole application, the total residues accounted for 0.3–1.4 mg eq./kg, respectively. Parent prothioconazole was below 10% of the TRR. For the triazole label in nutmeat, TA accounted for 47.8% of the TRR (0.67 mg eq./kg), TLA for 24.5% of the TRR (0.34 mg eq./kg) and TAA for 1.2%TRR (0.02 mg eq./kg), respectively (FAO, 2008a,b).

In sugar beets, for the phenyl and triazole labels, TRR levels were higher in leaves (4.3–5.2 mg eq./kg) than in roots (0.12–0.13 mg eq./kg). Following phenyl-labelled prothioconazole application, prothioconazole–desthio accounted for 58% of the TRR in roots, respectively. Prothioconazole was seen to be extensively degraded in both leaves and roots of sugar beet and accounted for less than 10% of the TRR (FAO, 2008a, 2008b; EFSA, 2014). Regarding the triazole-labelling moiety, besides prothioconazole-desthio that was identified in roots (25% TRR, 0.03 mg eq./kg), triazole alanine (TA) was found to be the predominant compound of the total residues in roots (29% TRR, 0.04 mg eq./kg) (EFSA, 2014).

In plants, prothioconazole is extensively metabolised and the metabolic pathway is similar in all crops investigated. The main metabolic pathway consisted of the formation of prothioconazole-desthio with further hydroxylation (with the formation of several closely related metabolites) and glucosidation steps (EFSA, 2014). The studies with triazole-labelled prothioconazole indicated the cleavage of triazole linkage and formation of three major TDM metabolites: triazole alanine, triazole lactic acid and triazole acetic acid (EFSA, 2014).

For the intended uses on garlic, onion and shallots, the metabolism of prothioconazole is considered sufficiently addressed. The above studies do not investigate the possible impact of plant metabolism on the isomer ratio of prothioconazole. EFSA proposes that this matter is further considered in the framework of the renewal of the approval process of prothioconazole.

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

1.1.2. Nature of residues in rotational crops

Prothioconazole is proposed to be used on garlic, onions and shallots which can be grown in crop rotation with other crops.

According to soil degradation studies, investigated in the framework of the EU pesticides peer review, prothioconazole itself is of a very low persistence in soil ($DT_{90\ field}$ of 5.5 days (median)), whereas prothioconazole-desthio is of low persistence with $DT_{90\ field}$ of 140 days (median) (EFSA, 2007b). Prothioconazole soil metabolite 1,2,4-triazole did not exceed 2% of the AR and was therefore further not assessed by the EU pesticides peer review (EFSA, 2007).

The metabolism of prothioconazole in rotational crops was investigated in the framework of the EU pesticides peer review in Swiss chards, turnips and spring wheat following the treatment of bare soil with prothioconazole at an application rate of 580 g/ha using the compound labelled in the phenyl ring. The main compounds identified were prothioconazole-desthio and its hydroxylated derivative metabolites, either free or conjugated (EFSA, 2014, 2020).

The MRL review concluded that metabolism of prothioconazole in primary and rotational crops was similar (EFSA, 2014).

The metabolism of prothioconazole labelled in the triazole ring was assessed by the JMPR (FAO, 2008a,b) and reported in the MRL review (EFSA, 2014). It was investigated in Swiss chards, turnips and spring wheat following an application of prothioconazole at a rate of 4 × 204 g/ha to bare soil. The studies indicate the cleavage of triazole linkage to form major metabolites triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA), whereas parent prothioconazole and prothioconazole -desthio were identified as minor metabolites (EFSA, 2014). No free 1,2,4-triazole was detected in any matrix (FAO, 2008a,b).

During the peer review of TDMs of the provided confirmatory data, it was also concluded that the metabolic behaviour of TDMs is similar both in primary and rotational crops (EFSA, 2018b, 2020).

For the proposed uses assessed in this application, no further information is required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of prothioconazole was investigated in the framework of the MRL review (EFSA, 2014). The MRL review referred to studies with prothioconazole investigated by the JMPR and studies with prothioconazole-desthio reported by Germany (EFSA, 2014). In the available studies, prothioconazole-desthio was reported to be stable under all standard hydrolysis steps (99.4–99.9% applied radioactivity (AR)), whereas parent prothioconazole slightly degraded to prothioconazole-desthio under sterilisation process (≤ 11% AR) (EFSA, 2014).

The Article 12 MRL review concluded that other compounds, which are included in the risk assessment residue definition and contain the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2*H*-1,2,4-triazole moiety, due to their similar structure to the parent compound and/or prothioconazole-desthio, are expected to remain stable under hydrolysis (EFSA, 2014).

The individual TDMs are stable under hydrolysis studies simulating baking/brewing/boiling, pasteurisation and sterilisation (EFSA, 2018b).

1.1.4. Analytical methods for enforcement in plant commodities

The analytical enforcement method for the determination of prothioconazole-desthio residues in plant commodities was assessed during the EU pesticides peer review and the MRL review (EFSA, 2007b, 2014). The method is not enantioselective, and therefore, the sum of isomers will be analysed. Details are reported in detail in Appendix B.1.1.1.

It is concluded that sufficiently validated enforcement methods are available to analyse prothioconazole-desthio residues in garlic, onions and shallots at the validated LOQ of 0.02 mg/kg. Notably, information on the extraction efficiency of this enforcement methods was not provided. EFSA recommends, therefore, that extraction efficiency is further considered and evaluated in the framework of the ongoing renewal of approval assessment of the active substance.

In the framework of this application, the EMS informed that a lower LOQ of 0.01 mg/kg would be achievable with a new multiresidue Quick, Easy, Cheap, Effective, Rugged and Safe (QUeChERS) method for monitoring of residues in plant matrices which is under evaluation in the ongoing renewal assessment (Netherlands, 2021). For this method, data on extraction efficiency are mentioned as being submitted under the renewal process. Therefore, EFSA recommends evaluating this new

enforcement method and its validation data including the extraction efficiency in the context of the ongoing renewal of approval assessment.

Additionally, in the framework of the present assessment, the applicant submitted a validation data of an HPLC-MS/MS method which was developed to determine prothioconazole and prothioconazole-desthio in honey at an individual LOQ of 0.01 mg/kg according to the applicable guidance (European Commission, 2021). An ILV was submitted. Data on extraction efficiency according to recent guidance (European Commission, 2017b) were not provided which is considered acceptable because the method does have a dilution however no extraction step (Netherlands, 2021). However, the nature of prothioconazole in honey is not addressed to conclude on the relevant residues for enforcement purposes. Therefore, EFSA recommends considering this aspect further under the renewal assessment.

1.1.5. Storage stability of residues in plants

The storage stability of prothioconazole-desthio in plant samples stored under frozen conditions was investigated in the framework of the MRL review and relevant endpoints are summarised in Appendix B.1.1.2. In high water content commodities, relevant for the intended use on garlic, onions and shallots, prothioconazole-desthio is stable for at least 18 months, when stored at −18°C (EFSA, 2014).

A data gap was noted by EFSA during the MRL review for additional storage stability data for at least one hydroxylated metabolite included in the risk assessment residue definition in the relevant commodity groups (i.e. high water, high oil content commodities and dry (high starch/high protein) commodities) (EFSA, 2014). This data gap was addressed in the context of the Article 12 confirmatory data assessment for crops belonging to high water commodities where the hydroxylated metabolites were demonstrated to be stable for 24 months, when stored at −18°C (EFSA, 2020).

The freezer storage stability of various TDMs was investigated in the conclusion of the peer review of the pesticide risk assessment of the TDMs in light of confirmatory data (EFSA, 2018b). In high water content matrices relevant for the present assessment, the storage stability is demonstrated for 6 months for 1,2,4 triazole, 53 months for TA and TAA. For TLA, the storage stability has been demonstrated only in lettuce (48 months) (EFSA, 2018b, 2020).

The overview of available storage stability studies with TDMs and prothioconazole is provided in Appendix B.1.1.2.

1.1.6. Storage stability of residues in honey

The storage stability data for prothioconazole, prothioconazole-desthio, its five hydroxylated metabolites and the four TDMs (TA, TAA, TLA and 1,2,4-T) in honey stored under frozen conditions were provided in the framework of this application (The Netherlands, 2021).

From the provided data, it can be concluded that in honey prothioconazole, prothioconazole-desthio and its hydroxylated metabolites are stable for 6 months and the four TDMs for 5 months at −18°C, respectively. The data are summarised in Appendix B.1.1.2.

1.1.7. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the EU pesticides review of prothioconazole (EFSA, 2014):

- for risk assessment: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2*H*-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).
- for enforcement: prothioconazole-desthio (sum of isomers).

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

In the conclusion on the peer review of the pesticide risk assessment of the TDMs in light of confirmatory data, EFSA proposed the following residue definitions for risk assessment for all active substances belonging to the class of triazole fungicides (EFSA, 2018b):

- Parent compound and any other relevant metabolite exclusively linked to the parent compound.[7]
- Triazole alanine (TA) and triazole lactic acid (TLA) (both metabolites were found to share the same toxicity).
- Triazole acetic acid (TAA).
- 1,2,4-triazole (1,2,4-triazole).

For the uses on the crops under consideration, EFSA concludes that the metabolism of prothioconazole is sufficiently investigated and that the above-mentioned residue definitions are applicable. The same residue definitions are applicable to rotational crops and processed products.

The risk assessment for the crops under consideration is to be performed for parent prothioconazole and for the triazole metabolites (TA and TLA, TAA and 1,2,4-T) (EFSA, 2018b).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials on onions. The applicant proposes to extrapolate residue data from onions to garlic and shallot which is acceptable according to EU guidance document (European Commission, 2017a). The samples were analysed for the parent compound and the metabolites included in the residue definitions for risk assessment, including the TDMs.

In all trials, the samples were analysed using the validated method 01013 with an LOQ of 0.01 mg/kg for prothioconazole-desthio and a method 00979 (including hydrolysis step) for residues of prothioconazole-α-hydroxydesthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio (expressed as prothioconazole-desthio) with an individual LOQ of 0.01 mg/kg. For both methods, extraction efficiency was addressed.

For 1,2,4-triazole, triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA), method 01062 was used with an LOQ of 0.01 mg/kg. The analytical method demonstrated adequate recovery data (Netherlands, 2021).

The applicant in the framework of the present assessment submitted a study where the extraction efficiency of triazole derivative metabolites (triazole alanine, triazole acetic acid and triazole lactic acid) of the method used to analyse onion residue trials was investigated against the method used in the wheat metabolism study with triazole-labelled tebuconazole (seed treatment). Data on extraction efficiency were provided for TA, TAA and TLA in wheat forage (high water content commodity) and grain (dry commodity) and are considered satisfactory (> 74.5%) by the EMS according to the Technical Guideline SANTE/2017/10632 (European Commission, 2022). According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Netherlands, 2021).

The samples of these residue trials were stored for a maximum of 546 days (ca. 18 months) in NEU trials and for 648 days (ca. 21 months) (Netherlands, 2021). The results of the residue trials are considered valid with regard to prothioconazole residues included in the residue definition for risk assessment. The residue data are also considered valid for the storage stability of triazole alanine (TA), TLA, triazole acetic acid (TAA) and 1,2,4-T (EFSA, 2018, 2020).

New intended uses on garlic, onions and shallots (NEU/SEU; foliar application 2 (interval between applications: 7 days) × 100 g a.s./ha; PHI = 7 days) and the newly provided residue data are summarised in Appendix A and Appendix B.1.2.1 accordingly.

NEU use

In support of the intended NEU GAP on garlic, onions and shallots, the applicant submitted eight GAP compliant independent residue trials on onions performed during the growing season of 2017 in Germany (3), northern France (2), Belgium (1) and the Netherlands (1) and one trial performed during the 2020 growing season in Germany. A proposed extrapolation from onions to garlic and shallots is sufficiently supported by residue data. An MRL of 0.02 mg/kg is proposed for prothioconazole-desthio in onions, garlic and shallots. From all TDM compounds only, the triazole

[7] In case of prothioconazole, it refers to sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2*H*-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).

alanine (TA) was detected above the LOQ. The remaining TDM compounds in all trials were below the LOQ of 0.01 mg/kg.

SEU use

The EMS submitted eight GAP compliant independent residue trials on onions performed in southern France (2), Italy (2), Portugal (1), Greece (1) and Spain (2) in the growing season of 2017. A proposed extrapolation from onions to garlic and shallots is sufficiently supported by residue data. An MRL of 0.02 mg/kg is proposed for prothioconazole-desthio in onions, garlic and shallots. From all TDM compounds, only the triazole alanine (TA) was detected above the LOQ. The remaining TDM compounds in all trials were below the LOQ of 0.01 mg/kg.

1.2.2. Magnitude of residues in rotational crops

Since the intended application rate of prothioconazole on garlic, onions and shallots is within the range of application rates assessed on primary crops in the MRL review, the same conclusions are applicable which is that residues of prothioconazole in rotational crops are expected to be covered by the residue levels in primary crops (EFSA, 2014, 2020).

This conclusion is, however, not justified for triazole-derivative metabolites (TDMs) in soil from the uses of prothioconazole and other triazole fungicides. The carry-over of TDMs to plants was considered in the peer review of confirmatory data concerning TDMs (EFSA, 2018b).

In the context of this application, the EMS referred to the rotational crop field trials with prothioconazole which were assessed in the confirmatory data assessment of TDMs (EFSA, 2018b). In these studies, to simulate crop failure, prothioconazole was applied to bare soil at a rate of 630 g a.s./ha (3.1 N the intended use) and the rotational crops (turnips, carrots, lettuce and winter barley) were sown and planted 21–34 days after the soil treatment.

Furthermore, for a normal crop rotation, seeds of winter or spring wheat treated with prothioconazole were sown in field (resulting in a treatment rate equivalent to 30 g a.s./ha) and the wheat subsequently received three spray applications of prothioconazole at a rate of 200 g a.s./ha each (3.1 N of the intended use). Following the harvest of the treated wheat,[8] rotational crops (turnip/carrots, lettuce and spring and/or winter barley) were sown or planted to simulate immediate rotation (plant back intervals of 56–129 days) or an annual rotation (plant back intervals of 277–345 days) (Netherlands, 2021).

In edible commodities, highest residues were observed when bare soil was treated and therefore in the framework of this assessment, EFSA focused on the worst-case scenario of crop failure with reported highest residues in edible commodities (EFSA, 2018b). On the basis of these trials, EFSA concludes that residues of TDMs above 0.01 mg/kg cannot be excluded in rotational crops from the intended use of prothioconazole on primary crops according to the proposed good agricultural practice (GAP).

It is, however, noted that the intended use of prothioconazole assessed in this application is less critical with regard to TDM residues in rotational crops than uses of other triazole fungicides assessed in the framework of the pesticide risk assessment of TDMs in light of confirmatory data (EFSA, 2018b). Thus, the magnitude of TDMs in rotational crops from the uses of prothioconazole on primary crops is covered by more critical uses of other triazole fungicides. Notwithstanding that, EFSA concludes that Member States shall consider the need to set specific risk mitigation measures to avoid additional contribution of TDMs in soil from the intended uses of prothioconazole on garlic, onions and shallots.

1.2.3. Magnitude of residues in honey

It is noted that currently, MRLs set for honey are not applicable to other apicultural products following Commission Regulation (EU) 2018/621.[9] The crops under consideration in the context of the proposed conditions of use are not listed as melliferous crops (European Commission, 2018), and therefore, the magnitude of residues in apicultural products in principle shall not be investigated.

[8] The peer review, however, noted missing storage stability data for TLA in straw and 1,2,4-T in grain in the rotational crop field trials (EFSA, 2018b). Missing storage stability data for TLA in straw were considered meanwhile as a minor deficiency based on available storage stability data in a range of commodities which indicated it stability under frozen conditions of 2 years (EFSA, 2022). 1,2,4-T was not detected in the rotational crop studies following the primary crop treatment with prothioconazole (FAO, 2008a,b).

[9] Commission Regulation (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council. C/2018/0138. OJ L 18, 23.1.2018, p. 1–73.

Nevertheless, the applicant submitted five independent residue trials (tunnel trials) on oilseed rape investigating the residue transfer to honey. Trials were conducted in northern and southern European zones (Germany (2x), southern France, Italy and Spain) to support eventual use of prothioconazole on melliferous crops (Netherlands, 2021). The oilseed rape under semi-field conditions received two applications (interval of 12–14 days) at BBCH 63–65 (flowering) of 200 g prothioconazole/ha during the 2019 growing season (Netherlands, 2021). The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

Trials were provided which indicate that residues of parent are below LOQ; however, TDM residues occur for this specific use pattern. Since in honey, the nature of residues of prothioconazole is not assessed, the residue definition for risk assessment in honey is not confirmed. Therefore, residue values were collated for information purposes only and not considered in the dietary consumer exposure assessment or for deriving MRL proposals. Residues of prothioconazole at the current enforcement residue definition for plants do not occur above the LOQ of 0.01 mg/kg in honey; all analysed hydroxy metabolites of prothioconazole were also below the individual LOQ of 0.01 mg/kg. The summary of residue trial data is provided in Appendix B.1.2.2.

Nevertheless, for the current residue definition for monitoring prothioconazole-desthio (sum of isomers) which is included in EU legislation, it can be concluded that the LOQ of 0.05 mg/kg is conservative enough. The reported data indicate that a lower MRL at the LOQ of 0.01 mg/kg in honey would accommodate the use of prothioconazole on melliferous crops at an proposed application rate of 2 × 200 g/ha. A lowering of the existing EU MRL of 0.05 mg/kg is currently not proposed, pending the conclusion of the renewal of the approval on the availability of sufficiently validated enforcement methods for the determination of prothioconazole and TDM residues in honey. EFSA recommends considering this aspect further under the renewal of approval assessment.

The samples were also analysed according to the residue definitions for risk assessment.

The methods to analyse the hydroxy-metabolites (HPLC-MS/MS) and the TDMs (HPLC-DMS-MS/MS) at the validated LOQ of 0.01 mg/kg for each analyte were provided, and according to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Netherlands, 2021). Data on extraction efficiency of both methods were not provided.

The residue data are summarised for information purposes in Appendix B.1.2.2.

1.2.4. Magnitude of residues in processed commodities

The studies investigating the effect on the magnitude of prothioconazole-desthio, the hydroxy metabolites and the TDMs in processed commodities have not been submitted in the framework of the current assessment.

For prothioconazole and its residues, such studies are currently not required, because the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI and residues in unprocessed onions, garlic and shallots are below 0.1 mg/kg.

Regarding TDMs, only the triazole alanine was present in samples of onions at levels above 0.1 mg/kg (highest residue 0.14 mg/kg), and therefore, the study investigating the effect of processing on the magnitude of TA in processed bulb vegetables in principle is required according to the applicable EU guidance documents. However, since the estimated dietary exposure to TA residues is very low (below 0.02% ADI), the lack of processing study in the framework of this assessment is considered a minor deficiency.

1.2.5. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation (see Appendix B.4).

In Section 3, EFSA assessed whether prothioconazole and TDM residues on these crops resulting from the intended uses on garlic, onions and shallots are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as garlic, onions and shallots are not used for feed purposes. Therefore, the previous livestock dietary burden calculation which was performed in the Article 12 confirmatory data assessment was not updated.

3. Consumer risk assessment

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

3.1. Prothioconazole-desthio

The toxicological reference values for prothioconazole and prothioconazole-desthio used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2007). The metabolites included in the residue definition are covered by the toxicological reference values of prothioconazole-desthio (EFSA, 2007b).

Under the assumptions that the recommendations derived in the framework of the Article 12 confirmatory data assessment will be implemented in the EU MRL legislation, the previous consumer risk assessment performed in the context of the Article 12 confirmatory data assessment was updated (EFSA, 2020) with the new risk assessment values as derived for onions, garlic and shallots from the submitted residue trials. The crops for which no uses were reported in the framework of the MRL review or in subsequent assessments were excluded from the calculation. The summary of the input values is provided in Appendix D.1.

No long-term consumer intake concerns were identified for any of the diets included in the EFSA PRIMo, as the estimated maximum long-term dietary intake accounted for 9% of the ADI (WHO Cluster diet B). The individual contribution of residues in garlic, onions and shallots was below 0.1% of the ADI.

The short-term exposure did not exceed the ARfD for any of the crops under consideration, with maximum individual acute exposure being 0.4% of the ARfD for garlic, 2.7% of the ARfD for onions and 0.04% of the ARfD for shallots.

The results of the calculation are summarised in Appendix B.3.

EFSA concluded that the long-term and short-term intake of residues of prothioconazole-desthio resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

3.2. Triazole-derivate metabolites (TDMs)

A comprehensive risk assessment, including all crops in which TDMs might be present from the uses of all pesticides belonging to the class of triazole fungicides, could not be performed in the framework of this opinion. A separate risk assessment for TDMs has been performed by EFSA in line with the confirmatory data assessment for triazole compounds in the framework of Regulation (EC) No 1107/2009 (EFSA, 2018b). In the framework of the present assessment, an indicative exposure assessment was performed for TDMs related to the proposed use on garlic, onions and shallots.

The toxicological profile for each TDM was assessed in the framework of the pesticide risk assessment of the TDMs in light of confirmatory data (EFSA, 2018c). The acceptable daily intake (ADI) value was derived as 0.3 mg/kg bw day for TA, 0.3 mg/kg bw day for TLA, 1 mg/kg bw day for TAA and 0.023 mg/kg bw day for 1,2,4-T. An acute reference dose (ARfD) was derived as 0.3 mg/kg bw for TA, 0.3 mg/kg bw for TLA, 1 mg/kg bw for TAA and 0.1 mg/kg bw for 1,2,4-T.

The exposure assessment was performed for residues of triazole derivative metabolites in garlic, onions, and shallots, according to residue definitions derived in the framework of the conclusion on TDMs (see also Section 1.1.7; EFSA, 2018b). The input values (HR/STMR values) were as derived from residue trials provided in support of this application (Netherlands, 2021).

Regarding the chronic exposure, EFSA compared the STMR values derived for garlic, onions and shallots in the present assessment (0.05 mg/kg for TA; < 0.01 mg/kg for TLA; < 0.01 mg/kg for TAA and 1,2,4-T) with the highest STMR values for TDMs from the uses of various triazole fungicides on onions as reported in the framework of the pesticide risk assessment of the TDMs in light of confirmatory data (0.06 mg/kg for TA; 0.01 mg/kg for TLA; 0.01 mg/kg for TAA; 0.01 mg/kg for 1,2,4-T).

Since the STMR values derived in the present assessment are lower than the ones previously considered in TDM assessment, it is concluded that the new data assessed in the present evaluation are not expected to trigger a modification of previous consumer dietary exposure calculations.

Therefore, the conclusion of the peer review on the pesticide risk assessment of the TDMs in light of confirmatory data remains unchanged. Using the EFSA PRIMo rev.3.1, the previous assessment concluded that the IEDI accounted for 93% of the ADI (NL toddler) for 1,2,4-T, 6% of the ADI

(NL toddler) for TA, 1% of the ADI (NL toddler) for TAA and 1% of the ADI (NL toddler) for TLA (EFSA, 2018b).

Regarding the acute exposure, EFSA assessed potential risks associated with the acute intake of garlic, onions and shallots containing individual TDMs at the highest levels according to the submitted residue trials (0.14 mg/kg for TA, < 0.01 mg/kg for TLA, < 0.01 mg/kg for TAA and < 0.01 mg/kg for 1,2,4-T).

The estimated acute exposure was the highest for TA in onions (1% of the ARfD) and was individually lower for other TDMs in bulb vegetables under consideration.

The indicative short-term exposure calculated for TDMs was low and did not exceed the corresponding toxicological reference values as derived in the EFSA conclusion on the confirmatory data assessment for TDMs (EFSA, 2018b).

More details can be found in Appendix B.3 and Appendix C.

In the framework of the peer review, it was highlighted that metabolism studies did not investigate the possible impact of plant and animal metabolism on the isomer ratio of the prothioconazole. Further investigation on this matter would in principle be required. It is noted that the EFSA guidance on the risk assessment of compounds that may have stereoisomers has been issued (EFSA, 2019b). EFSA would therefore recommend considering this point in the framework of the peer review for the renewal of approval of the active substance.

For further details on the exposure calculations, screenshots of the Report sheet of the PRIMo are presented in Appendix C.

4. Conclusion and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for prothioconazole in garlic, onions and shallots and to derive risk assessment values for triazole-derivative metabolites in these crops from the intended use of prothioconazole.

EFSA concluded that the proposed use of prothioconazole on garlic, onions and shallots will not result in a consumer exposure exceeding the toxicological reference values for prothioconazole and the TDMs and is therefore unlikely to pose a risk to consumers' health.

Regarding the triazole-derivate metabolites (TDMs), the Member States are recommended to implement the necessary risk mitigation measures to avoid contribution of TDMs in rotational crops from the intended uses of prothioconazole on the primary crops under consideration.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIPAC	Collaborative International Pesticide Analytical Council
CIRCA	(EU) Communication & Information Resource Centre Administrator
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
EC	emulsifiable concentrate
ECD	electron capture detector

EDI	estimated daily intake
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
ESI	electrospray ionisation
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionisation detector
FLD	fluorescence detector
FPD	flame photometric detector
GAP	Good Agricultural Practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
GC-ECD	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-FPD	gas chromatography with flame photometric detector
GC–MS	gas chromatography with mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
GC-NPD	gas chromatography with nitrogen/phosphorous detector
GLP	Good Laboratory Practice
GR	granule
GS	growth stage
HPLC	high performance liquid chromatography
HPLC-DMS/MS/MS	high performance liquid chromatography-differential mobility spectrometry tandem mass spectrometry
HPLC-MS	high performance liquid chromatography with mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UVD	high performance liquid chromatography with ultra-violet detector
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient
LC	liquid chromatography
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
NOAEL	no observed adverse effect level
NPD	nitrogen/phosphorous detector
OECD	Organisation for Economic Co-operation and Development
PAFF	Standing Committee on Plants, Animals, Food and Feed
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File

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

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F, G or I[a]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s, g/l	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Garlic	NEU	F	Various	SE	125	Foliar treatment – broadcast spraying	BBCH 41–47	2	7	–	200–800	0.100	kg a.i./ha	7	see footnote (e)
Garlic	SEU	F	Various	SE	125	Foliar treatment – broadcast spraying	BBCH 41–47	2	7	–	200–800	0.100	kg a.i./ha	7	see footnote (e)
Onions	NEU	F	Various	SE	125	Foliar treatment – broadcast spraying	BBCH 41–47	2	7	–	200–800	0.100	kg a.i./ha	7	see footnote (e)
Onions	SEU	F	Various	SE	125	Foliar treatment – broadcast spraying	BBCH 41–47	2	7	–	200–800	0.100	kg a.i./ha	7	see footnote (e)
Shallots	NEU	F	Various	SE	125	Foliar treatment – broadcast spraying	BBCH 41–47	2	7	–	200–800	0.100	kg a.i./ha	7	see footnote (e)
Shallots	SEU	F	Various	SE	125	Foliar treatment – broadcast spraying	BBCH 41–47	2	7	–	200–800	0.100	kg a.i./ha	7	see footnote (e)

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s: active substance; SE: Suspo-emulsion.
(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 3-8,263-3,152-4), including, where relevant, information on season at time of application.
(d): PHI – minimum preharvest interval.
(e): The GAP refers to the product PROPULSE (SE formulation, 125 g/L fluopyram +125 g/L prothioconazole). Since the MRL application is intended for the a.s. prothioconazole, the concentration (a.s g/l) and the application rate are given for prothioconazole only.

Appendix B – List of end points

Note: in case new tox data are received in the framework of the application, the main findings can be reported at beginning of the LoEPs.

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	Crops	Applications	Sampling (DAT)	Comment/Source
	Root crops	Sugar beet	Foliar: 4 × 0.29 kg/ha; interval 14 days	7 DALA: roots, tops, leaves	[U-^{14}C-phenyl] prothioconazole (EFSA, 2014)
			Foliar: 4 × 0.29 kg/ha; interval 14 days	7 DALA: roots, tops, leaves	[3,5-^{14}C-triazole] prothioconazole (EFSA, 2014)
	Cereals/grass	Wheat	Foliar (spring wheat): 2 × 0.22 kg/ha; BBCH 32–65	6 DALA: forage	[U-14C-phenyl] prothioconazole (EFSA, 2007b)
				26 DALA: hay	
				48 DALA: grain and straw	
			Foliar (summer wheat): 2 × 0.25 kg/ha; interval 27 days (BBCH 31–59)	0, 14 DALA: forage	[3,5-^{14}C-triazole] prothioconazole-desthio (EFSA, 2007b)
				48 DALA: grain and straw	
			Foliar (spring wheat): 2 × 0.18/0.29 kg/ha; BBCH 32–65	Forage, hay, grain, straw	[3,5-^{14}C-triazole] prothioconazole (EFSA, 2014)
			Seed (spring wheat): 1 × 0.02 or 0.10 kg/100 kg seeds (*ca.* 220 kg seeds/ha)	57 DAT: forage	[U-14C-phenyl] prothioconazole (EFSA, 2007b)
				110 DAT: hay	
				153 DAT: grain and straw	
	Pulses/ oilseeds	Peanuts	Foliar: 3 × 0.3 kg/ha; interval 21 days (BBCH 66–75)	14 DALA: hays and nuts without shells	[U-14C-phenyl] prothioconazole (EFSA, 2007b)
			Foliar: 3 × 0.3 kg/ha; interval 21 days (BBCH 66–75)	14 DALA: hays and nuts without shells	[3,5-^{14}C-triazole] prothioconazole (EFSA, 2014)

Rotational crops (available studies)	Crop groups	Crops(s)	Applications	PBI (DAT)	Comment/Source
	Root/tuber crops	Turnips	Soil, 1 × 580 g/ha	28, 146, 269	[U-^{14}C-phenyl] prothioconazole (EFSA, 2007b; FAO, 2008a, 2008b); 2.9 N onion/ shallot/ garlic GAP; Crops of the 1st, 2nd and 3rd rotation were sown at day 28, 149 and 269, respectively. Sampling was done: Turnip roots and tops: 94, 201, 349 DAT; Swiss chard leaves: 80, 188, 348 DAT;
	Leafy crops	Swiss chards			
	Cereal (small grain)	Spring wheat			

					Grain and straw: 145, 269, 412 DAT; Wheat green material: 73, 178, 327 DAT; Wheat hay: 111, 231, 377 DAT.
	Root crops	Turnips	Soil, 4 × 204 g/ha	30, 125, 366	[triazole-3,5-^{14}C] prothioconazole (FAO, 2008a, 2008b; EFSA, 2014; Netherlands, 2021) 4.1 N onion/ shallot/ garlic GAP; Crops of the 1st, 2nd and 3rd rotation were sown at day 30, 125 and 366, respectively. Sampling was done: Turnip roots and tops: 113, 195, 420 DAT; Swiss chard leaves: 77, 169, 406 DAT;Swiss chard leaves: 77, 169, 406 DAT; Grain and straw: 121, 209, 450 DAT; Wheat green material: 62, 154, 388 DAT; Wheat hay: 80, 171, 420 DAT.
	Leafy vegetables	Swiss chards (leaves)			
	Cereal (small grain)	Wheat			

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	yes	Prothioconazole degrades to prothioconazole-desthio under sterilisation process (≤ 11% AR). Prothioconazole-desthio remains stable (99.4–99.9% of AR) (United Kingdom, 2018a)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	yes	
	Sterilisation (20 min, 120°C, pH 6)	yes	
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Triazole-UL-^{14}C labelled triazole alanine, triazole acetic acid, triazole lactic acid and 1,2,4-Triazole; remain stable under sterilisation processes (96.4–100.5% of AR) (United Kingdom, 2018b).
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	
	Sterilisation (20 min, 120°C, pH 6)	Yes	

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2014)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2014)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2014)
Plant residue definition for monitoring (RD-Mo)	Prothioconazole: Prothioconazole-desthio (sum of isomers)	
Plant residue definition for risk assessment (RD-RA)	a) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-*2H*-1,2,4- triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014). b) TDMs (EFSA, 2018), with separate assessment of: – Triazole alanine (TA) and triazole lactic acid (TLA) – Triazole acetic acid (TAA) – 1,2,4-triazole (1,2,4-T)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: GC-MS, LOQ 0.02 mg/kg, straw: 0.05 mg/kg. ILV available (EFSA, 2007b, 2014).	

DALA: days after last application; BBCH: growth stages of mono- and dicotyledonous plants; DAT: days after treatment; PBI: plant-back interval; AR: applied radioactivity; GC–MS: gas chromatography with mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
			Value	Unit		
High water content	Wheat green matter,	−18	18	Months	Prothioconazole-desthio	EFSA, 2014
	Spinaches, sugar beet, tomatoes	−18	24	Months	Prothioconazole-desthio	EFSA, 2014
	Tomatoes, potatoes[(a)]	−18	24	Months	Prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroyxy-desthio, prothioconazole-4-hydroyxy-desthio, prothioconazole-5-hydroyxy-desthio, prothioconazole-6-hydroyxy-desthio	United Kingdom, 2019a
High oil content	Rapeseeds	−18	24	Months	Prothioconazole-desthio	EFSA, 2014
	Soya beans, rapeseeds	−18	24	Months	Prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroyxy-desthio, prothioconazole-4-hydroyxy-desthio, prothioconazole-5-hydroyxy-desthio, prothioconazole-6-hydroyxy-desthio	United Kingdom, 2018a

Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
			Value	Unit		
Dry/High protein content	Dry peas	−18	24	Months	Prothioconazole-desthio	EFSA, 2014
Dry / High starch	Cereals grain	−18	18	Months	Prothioconazole-desthio	EFSA, 2014
High acid content	Oranges	−18	24	Months	Prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio	United Kingdom, 2018a
Others	Cereal straw	−18	18	Months	Prothioconazole-desthio	EFSA, 2014
	Oilseed rape straw	−18	24	Months	Prothioconazole-desthio	EFSA, 2014
High starch content	Barley, wheat	−18	12	Months	1,2,4 - triazole	EFSA, 2018b
			26		Triazole alanine	
			26		Triazole acetic acid	
			48		Triazole lactic acid	
High oil content	Rapeseeds, soya beans	−18	12 (soya beans only)	Months	1,2,4 – triazole. Not stable in rapeseeds	EFSA, 2018b
			26 (soya beans only)		Triazole alanine. Not stable in rapeseeds	
			53		Triazole acetic acid	
			48		Triazole lactic acid	
High protein content	Dry peas, navy beans	−18	No data	Months	1,2,4 – triazole	EFSA, 2018b
			15		Triazole alanine	
			25		Triazole acetic acid	
			48		Triazole lactic acid	
High acid content	Oranges	−18	No data	Months	1,2,4 – triazole	EFSA, 2018b
			No data		Triazole alanine	
			No data		Triazole acetic acid	
			48		Triazole lactic acid	
High water content	Apples, tomatoes, mustard leaves, wheat forage, radishes tops, turnip roots, sugar beet roots, cabbages, lettuces	−18	6	Months	1,2,4 – triazole. Lettuce only.	For TLA storage stability was investigated for high water commodities in lettuce only and not in other high water commodities (EFSA, 2018b)
			53		Triazole alanine	
			53		Triazole acetic acid	
			48		Triazole lactic acid	
Others	Cereal straw	−18	12	Months	1,2,4 – triazole	EFSA, 2018b
			53		Triazole alanine	
			40		Triazole acetic acid	

Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
			Value	Unit		
			–		Triazole lactic acid	No data available (EFSA, 2018b); Considering that in all other matrices, TLA was stable for at least 48 months and samples were stored for a maximum of 15.5 months, only desirable (EFSA, 2022)
	Honey	−18	6	Months	Prothioconazole; Prothioconazole-desthio	Stability was demonstrated for 190 days (Netherlands, 2022)
	Honey	−18	6	Months	Prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroyxy-desthio, prothioconazole-4-hydroyxy-desthio, prothioconazole-5-hydroyxy-desthio, prothioconazole-6-hydroyxy-desthio	Stability was demonstrated for 182 days (Netherlands, 2022)
	Honey	−18	5	Months	1,2,4 – triazole	Stability was demonstrated for 153 days (Netherlands, 2022)
					Triazole alanine	
					Triazole acetic acid	
					Triazole lactic acid	

(a): According to the OECD guideline for the testing of chemicals (OECD, 2007), potatoes are classified as the category of high starch content.

B.1.2. Magnitude of residues in plants and honey

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

Commodity	Region/ NEU/ SEU[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]
Intended GAPs: Garlic, onions, shallots (2 × 0.10 kg a.s./ha, PHI 7 days)	NEU	**Mo**: Prothioconazole-desthio: 6 × < 0.01; 2 × 0.012 Prothioconazole-α-hydroxy-desthio: 8 × < 0.01 Prothioconazole-3-hydroxy-	Residue trials on onions compliant with GAP. Extrapolation to garlic and shallots possible.	**0.02**	**Mo**: 0.012	**Mo**: 0.01	–

Commodity	Region/ NEU/ SEU[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]
		desthio: 8 × < 0.01 Prothioconazole-4-hydroxy-desthio: 8 × < 0.01 Prothioconazole-5-hydroxy-desthio: 8 × < 0.01 Prothioconazole-6-hydroxy-desthio: 8 × < 0.01					
		Residue definition for risk assessment: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-*2H*-1,2,4- triazole moiety, expressed as prothioconazole-desthio (sum of isomers)					
		RA: 6 × < 0.06; 2 × 0.062		–	**RA**: 0.062	**RA**: 0.06	1
		Triazole-derivate metabolites (TDMs)					
		Residue definition for risk assessment: Triazole alanine (TA) and triazole lactic acid (TLA)					
		Triazole alanine (TA): < 0.01; 0.012[e]; 0.018; 0.034[f]; 0.063[f]; 0.074; 0.12[g]; 0.14 Triazole lactic acid (TLA): 8 × < 0.01		– –	RA_{TA}: 0.14 RA_{TLA}: < 0.01	RA_{TA}: 0.05 RA_{TLA}: < 0.01	
		Residue definition for risk assessment: Triazole acetic acid (TAA)					
		Triazole acetic acid (TAA): 8 × < 0.01		–	**RA_{TAA}**: < 0.01	**RA_{TAA}**: < 0.01	
		Residue definition for risk assessment: 1,2,4-triazole (1,2,4-T)					
		1,2,4 – triazole (1,2,4-T): 8 × < 0.01		–	**$RA_{1,2,4\text{-}T}$**: < 0.01	**$RA_{1,2,4\text{-}T}$**: < 0.01	
	SEU	**Mo**: Prothioconazole-desthio: 7 × < 0.01; 1 × 0.01 Prothioconazole-α-hydroxy-desthio: 8 × < 0.01 Prothioconazole-3-hydroxy-	Residue trials on onions compliant with GAP. Extrapolation to garlic and shallots possible.	**0.02**	**Mo**: 0.01	**Mo**: 0.01	

Commodity	Region/ NEU/ SEU[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]
		desthio: 8 × < 0.01 Prothioconazole-4-hydroxy-desthio: 8 × < 0.01 Prothioconazole-5-hydroxy-desthio: 8 × < 0.01 Prothioconazole-6-hydroxy-desthio: 8 × < 0.01					
		Residue definition for risk assessment: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-*2H*-1,2,4- triazole moiety, expressed as prothioconazole-desthio (sum of isomers)					
		RA: 7 × < 0.06; 1 × 0.06		–	**RA**: 0.06	**RA**: 0.06	1
		Triazole-derivate metabolites (TDMs)					
		Residue definition for risk assessment: Triazole alanine (TA) and triazole lactic acid (TLA)					
		Triazole alanine (TA): < 0.01; 0.012[e]; 0.013[e]; 0.029[e]; 0.039[g]; 0.045[g]; 0.048; 0.098[e]; Triazole lactic acid (TLA): 8 × < 0.01		– –	RA_{TA}: 0.098 RA_{TLA}: < 0.01	RA_{TA}: 0.034 RA_{TLA}: < 0.01	
		Residue definition for risk assessment: Triazole acetic acid (TAA)					
		Triazole acetic acid (TAA): 8 × < 0.01		–	RA_{TAA}: < 0.01	RA_{TAA}: < 0.01	
		Residue definition for risk assessment: 1,2,4-triazole (1,2,4-T)					
		1,2,4 – triazole (1,2,4-T): 8 × < 0.01		–	$RA_{1,2,4\text{-}T}$: < 0.01	$RA_{1,2,4\text{-}T}$: < 0.01	

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment. Individual conversion factors (CFs) between residues according to the RD for monitoring and the RD for risk assessment were not derived.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor between monitoring and risk assessment considering the median value of available trials.
(e): Higher residue value at a longer PHI of 14 days.
(f): Higher residue value in control sample.
(g): Higher value in control sample and at a longer PHI of 14 days.

B.1.2.2. Summary of residues data from the semi-field conditions residue trials (tunnel trials) in honey from oilseed rape

Commodity	Region/ NEU/SEU[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)
Honey	NEU (2), SEU (3)	**Enforcement residue definition** (according to Reg/ 2019/552): Prothioconazole-desthio: 5 × < 0.01 [Prothioconazole: 5 × < 0.01] Prothioconazole-α-hydroxy-desthio: 5 × < 0.01 Prothioconazole-3-hydroxy-desthio: 5 × < 0.01 Prothioconazole-4-hydroxy-desthio: 5 × < 0.01 Prothioconazole-5-hydroxy-desthio: 5 × < 0.01 Prothioconazole-6-hydroxy-desthio: 5 × < 0.01	Combined data set of 2 NEU and 3 SEU semi-filed (tunnel) trials on oilseed rape with 2 × 200 g prothioconazole/ha at BBCH 63–65 (flowering). Residue data were provided for fresh and dry honey (> 80% sugar content) separately (Netherlands, 2022).	0.01*	**Mo**: < 0.01	**Mo**: < 0.01
		Residue definition for risk assessment (provisional, pending the investigation of nature of prothioconazole in honey): Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-*2H*-1,2,4- triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
		RA: 5 × < 0.06		–	**RA**: < 0.06	**RA**: < 0.06
		Triazole-derivate metabolites (TDMs)				
		Residue definition for risk assessment: Triazole alanine (TA) and triazole lactic acid (TLA)				
		Triazole alanine (TA): 3 × < 0.01; <u>0.011</u>[d]; 0.043[e,f] Triazole lactic acid (TLA): 4 × < 0.01; 0.13[e]		– –	RA_{TA}: 0.043 RA_{TLA}: 0.13	RA_{TA}: 0.01 RA_{TLA}: 0.01
		Residue definition for risk assessment: Triazole acetic acid (TAA)				
		Triazole acetic acid: 4 × < 0.01; 0.052[e]		–	**RA_{TAA}**: 0.052	**RA_{TAA}**: 0.01
		Residue definition for risk assessment: 1,2,4-triazole (1,2,4-T)				
		1,2,4 – triazole: 5 × < 0.01		–	**$RA_{1,2,4\text{-}T}$**: < 0.01	**$RA_{1,2,4}$-T**: < 0.01

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring RA: risk assessment.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

(d): Higher residues in dry honey than in fresh honey.
(e): Higher residues in fresh than in dry honey.
(f): Residues in control sample (0.014 mg/kg).

B.1.2.3. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	yes	EFSA (2007b)
Residues in rotational and succeeding crops expected based on field rotational crop study?	No: prothioconazole-desthio	EFSA (2007b, 2014)
	Yes: triazole derivate metabolites (TDMs)	EFSA (2007b, 2014, 2018b)

B.1.2.4. Processing factors

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

B.2. Residues in livestock

Not relevant

B.3. Consumer risk assessment

ARfD	Prothioconazole: 0.01 mg/kg bw (European Commission, 2007) Triazole Derivative metabolites (TDMs): Triazole alanine: 0.3 mg/kg bw (EFSA, 2018b) Triazole lactic acid: 0.3 mg/kg bw (EFSA, 2018b) Triazole acetic acid: 1 mg/kg bw (EFSA, 2018b) 1,2,4-triazole: 0.1 mg/kg bw (EFSA, 2018b)
Highest IESTI, according to EFSA PRIMo	Prothioconazole: Garlic: 0.4% of ARfD Onions: 2.7% of ARfD Shallots: 0.04% of ARfD Triazole Derivative metabolites (TDMs): Triazole alanine (TA): Garlic: 0.2% of ARfD (IE child) Onions: 1.1% of ARfD (BE toddlers) Shallots: 0.01% of ARfD (DE child) Triazole lactic acid (TLA): Garlic: < 0.012% of ARfD (IE child) Onions: < 0.08% of ARfD (BE toddlers) Shallots: < 0.001% of ARfD (DE child) Triazole acetic acid (TAA): Garlic: < 0.004% of ARfD (IE child) Onions: < 0.02% of ARfD (BE toddlers) Shallots: < 0.0003% of ARfD (DE child) 1,2,4-triazole (1,2,4-T): Garlic: < 0.04% of ARfD (IE child) Onions: < 0.23% of ARfD (BE toddlers) Shallots: < 0.003% of ARfD (DE child)
Assumptions made for the calculations	Prothioconazole: The calculation is based on the highest residue levels expected in raw agricultural commodities under assessment. TDMs: Indicative exposure assessment for TDMs has been performed only for garlic, onions and shallots by using the highest residue values as derived from the trials on onions which were extrapolated to garlic and shallots. Calculations performed with PRIMo revision 3.1
ADI	Prothioconazole: 0.01 mg/kg bw per day (European Commission, 2007) Triazole Derivative metabolites (TDMs): Triazole alanine: 0.3 mg/kg bw per day (EFSA, 2018b) Triazole lactic acid: 0.3 mg/kg bw per day (EFSA, 2018b) Triazole acetic acid: 1 mg/kg bw per day (EFSA, 2018b) 1,2,4-triazole: 0.023 mg/kg bw per day (EFSA, 2018b)

Highest IEDI, according to EFSA PRIMo	Prothioconazole: 9% of ADI (NL toddler) Highest contribution of: Garlic: 0.01% (RO general) Onions: 0.08% (GEMS/Food G06) Shallots: 0.01% (IE adult) Indicative calculations for TDMs: Triazole alanine (TA): 0.014% of ADI (RO general) Triazole lactic acid (TLA): < 0.003% of ADI (RO general) Triazole acetic acid (TAA): < 0.001% of ADI (RO general) 1,2,4-triazole (1,2,4-T): < 0.036% of ADI (RO general)
Assumptions made for the calculations	Prothioconazole: Under the assumptions that the recommendations derived in the framework of the Article 12 confirmatory data assessment will be implemented in the EU MRL legislation, EFSA updated the exposure assessment performed in the framework of the Article 12 conf data assessment with the new RA values as derived for bulb vegetables under consideration. Conversion factors (CFs) as applied during the confirmatory data assessment were used. The crops on which no uses were reported in the MRL review, were excluded from the calculation (EFSA, 2020). TDMs: A comprehensive risk assessment, considering TDMs in all crops from all pesticides belonging to the class of triazole fungicides, could not be performed in the framework of this opinion and a separate risk assessment for TDMs has been performed by EFSA in line with the confirmatory data assessment for triazole compounds in the framework of Regulation (EC) No 1107/2009. Indicative exposure assessment for TDMs has been performed only for garlic, onions and shallots by using the median residue values as derived from the trials on onions which were extrapolated to garlic and shallots. The derived STMR values in onions, garlic and shallots were compared in Section with the highest STMR values for TDMs from the uses of various triazole fungicides on onions as reported in the framework of the pesticide risk assessment of the TDMs in light of confirmatory data (EFSA, 2018b). Calculations performed with PRIMo revision 3.1

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 (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Prothioconazole: prothioconazole-desthio (sum of isomers)				
0220010	Garlic	0.01*	0.02	The submitted data are sufficient to derive an MRL proposal for both the intended NEU and SEU use. Risk for consumers unlikely for the residues of prothioconazole including its triazole derivative metabolites (TDMs). Member States should consider the need to setting specific risk mitigation measures to avoid additional contribution of TDM residues in rotational crops from the intended use of prothioconazole on garlic, onions and shallots
0220020	Onions	0.05 (ft)	0.02	
0220030	Shallots	0.05 (ft)	0.02	

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.
(ft): The European Food Safety Authority identified some information on residue trials and storage stability data complying with the proposed residue definition as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it (Regulation (EU) No 2019/552).

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Prothioconazole-desthio

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	0.01
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2007	Year of evaluation:	2007

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	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)	9%	NL toddler	0.88	3%	Milk: Cattle	2%	Wheat	0.9%	Carrots	0.0%	9%
	8%	GEMS/Food G11	0.85	4%	Soyabeans	1%	Wheat	0.6%	Barley		8%
	7%	GEMS/Food G10	0.74	3%	Soyabeans	2%	Wheat	0.5%	Barley		7%
	7%	GEMS/Food G15	0.70	2%	Wheat	2%	Soyabeans	0.6%	Barley		7%
	7%	GEMS/Food G08	0.70	2%	Soyabeans	2%	Wheat	0.7%	Barley		7%
	7%	GEMS/Food G07	0.69	2%	Soyabeans	2%	Wheat	0.5%	Barley		7%
	6%	GEMS/Food G06	0.58	3%	Wheat	1%	Soyabeans	0.3%	Cotton seeds		6%
	6%	DK child	0.56	2%	Wheat	1%	Rye	1%	Carrots		6%
	5%	UK infant	0.53	2%	Milk: Cattle	1%	Carrots	1%	Wheat	0.0%	5%
	5%	NL child	0.49	2%	Wheat	1%	Milk: Cattle	0.4%	Rapeseeds/canola seeds	0.0%	5%
	5%	FR child 3 15 yr	0.48	2%	Wheat	1%	Milk: Cattle	0.4%	Carrots	0.0%	5%
	5%	DE child	0.46	2%	Wheat	1.0%	Milk: Cattle	0.8%	Carrots	0.1%	5%
	4%	FR toddler 2 3 yr	0.44	1%	Milk: Cattle	1%	Wheat	0.6%	Carrots	0.0%	4%
	4%	RO general	0.42	2%	Wheat	0.6%	Milk: Cattle	0.4%	Potatoes	0.0%	4%
	4%	SE general	0.42	1%	Wheat	0.7%	Carrots	0.6%	Milk: Cattle	0.0%	4%
	4%	UK toddler	0.41	2%	Wheat	1%	Milk: Cattle	0.4%	Carrots	0.0%	4%
	4%	ES child	0.37	2%	Wheat	0.6%	Milk: Cattle	0.2%	Lentils	0.0%	4%
	4%	IE adult	0.35	0.9%	Wheat	0.3%	Peas	0.3%	Carrots		4%
	3%	PT general	0.32	2%	Wheat	0.5%	Potatoes	0.5%	Potatoes		3%
	3%	IT toddler	0.30	3%	Wheat	0.1%	Carrots	0.1%	Potatoes		3%
	3%	NL general	0.28	0.8%	Wheat	0.4%	Milk: Cattle	0.2%	Potatoes	0.0%	3%
	3%	DE general	0.27	0.8%	Wheat	0.6%	Milk: Cattle	0.4%	Barley	0.0%	3%
	3%	FR infant	0.27	0.9%	Carrots	0.8%	Milk: Cattle	0.3%	Wheat	0.0%	3%
	3%	DE women 14-50 yr	0.25	0.9%	Wheat	0.6%	Milk: Cattle	0.2%	Carrots	0.0%	3%
	2%	ES adult	0.23	0.9%	Wheat	0.4%	Barley	0.2%	Milk: Cattle	0.0%	2%
	2%	FI 3 yr	0.23	0.7%	Carrots	0.5%	Wheat	0.5%	Potatoes	0.0%	2%
	2%	FR adult	0.19	0.9%	Wheat	0.2%	Milk: Cattle	0.2%	Carrots	0.0%	2%
	2%	IT adult	0.19	2%	Wheat	0.1%	Carrots	0.1%	Potatoes		2%
	2%	FI 6 yr	0.18	0.5%	Carrots	0.4%	Wheat	0.4%	Potatoes	0.0%	2%
	2%	LT adult	0.17	0.4%	Wheat	0.3%	Potatoes	0.2%	Rye		2%
	2%	UK vegetarian	0.17	0.8%	Wheat	0.2%	Carrots	0.2%	Milk: Cattle		2%
	2%	DK adult	0.17	0.4%	Wheat	0.4%	Carrots	0.3%	Milk: Cattle		2%
	1%	UK adult	0.14	0.7%	Wheat	0.1%	Milk: Cattle	0.1%	Carrots	0.0%	1%
	1%	PL general	0.10	0.3%	Potatoes	0.2%	Carrots	0.2%	Beetroots		1%
	1.0%	IE child	0.10	0.5%	Wheat	0.2%	Milk: Cattle	0.1%	Carrots	0.0%	1.0%
	0.9%	FI adult	0.09	0.3%	Carrots	0.1%	Rye	0.1%	Wheat		0.9%

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

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
63%	Carrots	0.1/0.1	6.3
57%	Beetroots	0.1/0.1	5.7
55%	Celeriacs/turnip rooted	0.1/0.1	5.5
53%	Head cabbages	0.09/0.12	5.3
52%	Swedes/rutabagas	0.1/0.1	5.2
47%	Leeks	0.06/0.08	4.7
40%	Cranberries	0.15/0.9	4.0
36%	Parsnips	0.1/0.1	3.6
36%	Turnips	0.1/0.1	3.6
31%	Salsifies	0.1/0.1	3.1
23%	Cauliflowers	0.05/0.04	2.3
19%	Bovine: Liver	0.5/0.23	1.9
17%	Broccoli	0.05/0.04	1.7
16%	Sweet corn	0.02/0.04	1.6
15%	Potatoes	0.02/0.01	1.5

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
50%	Head cabbages	0.09/0.12	5.0
34%	Swedes/rutabagas	0.1/0.1	3.4
23%	Beetroots	0.1/0.1	2.3
20%	Carrots	0.1/0.1	2.0
14%	Parsnips	0.1/0.1	1.4
12%	Celeriacs/turnip rooted	0.1/0.1	1.2
11%	Turnips	0.1/0.1	1.1
11%	Salsifies	0.1/0.1	1.1
10%	Leeks	0.06/0.08	1.0
10%	Parsley roots/Hamburg roots	0.1/0.1	1.0
10%	Cranberries	0.15/0.9	1.0
10%	Broccoli	0.05/0.04	0.95
9%	Cauliflowers	0.05/0.04	0.93
9%	Bovine: Liver	0.5/0.23	0.92
8%	Brussels sprouts	0.1/0.14	0.84

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)
51%	Turnips/boiled	0.1/0.1	5.1
51%	Parsnips/boiled	0.1/0.1	5.1
46%	Leeks/boiled	0.06/0.08	4.6
44%	Beetroots/boiled	0.1/0.1	4.4
32%	Broccoli/boiled	0.05/0.04	3.2
29%	Carrots/juice	0.1/0.08	2.9
28%	Cauliflowers/boiled	0.05/0.04	2.8
26%	Salsifies/boiled	0.1/0.1	2.6
14%	Brussels sprouts/boiled	0.1/0.14	1.4
12%	Celeriacs/juice	0.1/0.08	1.2
9%	Potatoes/fried	0.02/0.01	0.93
8%	Lentils/boiled	1/0.1	0.81
7%	Peas/canned	1/0.04	0.71
6%	Potatoes/dried (flakes)	0.02/0.05	0.59
5%	Wheat/milling (flour)	0.1/0.04	0.48

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)
39%	Beetroots/boiled	0.1/0.1	3.9
21%	Parsnips/boiled	0.1/0.1	2.1
19%	Turnips/boiled	0.1/0.1	1.9
18%	Celeriacs/boiled	0.1/0.1	1.8
17%	Cauliflowers/boiled	0.05/0.04	1.7
14%	Leeks/boiled	0.06/0.08	1.4
10%	Broccoli/boiled	0.05/0.04	0.96
8%	Salsifies/boiled	0.1/0.1	0.82
7%	Carrots/canned	0.1/0.08	0.65
6%	Barley/beer	0.2/0.02	0.58
3%	Peas/canned	1/0.04	0.26
2%	Head cabbages/canned	0.09/0.02	0.19
2%	Wheat/bread/pizza	0.1/0.04	0.18
2%	Potatoes/chips	0.02/0.02	0.17
2%	Wheat/pasta	0.1/0.04	0.15

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

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole alanine (TA)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

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)
0.014%	RO general	0.04	0.01%	Onions	0.001%	Garlic				0.0%
0.0%	GEMS/Food G06	0.04	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	GEMS/Food G10	0.03	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	GEMS/Food G15	0.03	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	GEMS/Food G08	0.03	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	SE general	0.03	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
0.0%	FI 3 yr	0.02	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	GEMS/Food G07	0.02	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	PT general	0.02	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	PL general	0.02	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	FI 6 yr	0.01	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	DK child	0.01	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	IE adult	0.01	0.0%	Onions	0.0%	Shallots	0.0%	Garlic		0.0%
0.0%	UK vegetarian	0.01	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	UK toddler	0.01	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
0.0%	FR child 3 15 yr	0.01	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
0.0%	NL general	0.01	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
0.0%	ES adult	0.01	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	GEMS/Food G11	0.01	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	DE child	0.01	0.0%	Onions	0.0%	Garlic	0.0%	Garlic		0.0%
0.0%	ES child	0.01	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	FR toddler 2 3 yr	0.01	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
0.0%	NL toddler	0.01	0.0%	Onions	0.0%	Shallots				0.0%
0.0%	UK infant	0.01	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
0.0%	UK adult	0.01	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	FI adult	0.01	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	DK adult	0.01	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	NL child	0.01	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
0.0%	IT toddler	0.01	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	FR adult	0.01	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
0.0%	FR infant	0.01	0.0%	Onions	0.0%	Garlic				0.0%
0.0%	DE general	0.01	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
0.0%	IT adult	0.01	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
0.0%	DE women 14-50 yr	0.01	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
0.0%	IE child	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

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

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Onions	0/0.14	3.2
0.2%	Garlic	0/0.14	0.49
0.01%	Shallots	0/0.14	0.04

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%	Onions	0/0.14	2.1
0.1%	Shallots	0/0.14	0.37
0.03%	Garlic	0/0.14	0.09

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.8%	Shallots/boiled	0/0.14	2.3
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Onions/boiled	0/0.14	1.3
0.3%	Shallots/boiled	0/0.14	0.87
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole lactic acid (TLA)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.003%	RO general	0.01	0.00%	Onions	0.000%	Garlic				0.0%
	0.0%	GEMS/Food G06	0.01	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G10	0.01	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G15	0.01	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G08	0.01	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	SE general	0.01	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	FI 3 yr	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G07	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	PT general	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	PL general	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	FI 6 yr	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	DK child	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	IE adult	0.00	0.0%	Onions	0.0%	Shallots	0.0%	Garlic		0.0%
	0.0%	UK vegetarian	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	UK toddler	0.00	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
	0.0%	FR child 3 15 yr	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	NL general	0.00	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
	0.0%	ES adult	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G11	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	DE child	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Garlic		0.0%
	0.0%	ES child	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	FR toddler 2 3 yr	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	NL toddler	0.00	0.0%	Onions	0.0%	Shallots				0.0%
	0.0%	UK infant	0.00	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
	0.0%	UK adult	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	FI adult	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	DK adult	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	NL child	0.00	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
	0.0%	IT toddler	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	FR adult	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	FR infant	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	DE general	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	IT adult	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	DE women 14-50 yr	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	IE child	0.00	0.0%	Onions	0.0%	Garlic				0.0%
		Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

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

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.08%	Onions	0/0.01	0.23
0.012%	Garlic	0/0.01	0.04
0.001%	Shallots	0/0.01	0.00

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.05%	Onions	0/0.01	0.15
0.01%	Shallots	0/0.01	0.03
0.00%	Garlic	0/0.01	0.01

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Shallots/boiled	0/0.01	0.16
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.0%	Onions/boiled	0/0.01	0.09
0.02%	Shallots/boiled	0/0.01	0.06
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Triazole acetic acid (TAA)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.001%	RO general	0.01	0.00%	Onions	0.000%	Garlic				0.0%
	0.0%	GEMS/Food G06	0.01	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G10	0.01	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G15	0.01	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G08	0.01	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	SE general	0.01	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	FI 3 yr	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G07	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	PT general	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	PL general	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	FI 6 yr	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	DK child	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	IE adult	0.00	0.0%	Onions	0.0%	Shallots	0.0%	Garlic		0.0%
	0.0%	UK vegetarian	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	UK toddler	0.00	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
	0.0%	FR child 3 15 yr	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	NL general	0.00	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
	0.0%	ES adult	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G11	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	DE child	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Garlic		0.0%
	0.0%	ES child	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	FR toddler 2 3 yr	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	NL toddler	0.00	0.0%	Onions	0.0%	Shallots				0.0%
	0.0%	UK infant	0.00	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
	0.0%	UK adult	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	FI adult	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	DK adult	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	NL child	0.00	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
	0.0%	IT toddler	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	FR adult	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	FR infant	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	DE general	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	IT adult	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	DE women 14-50 yr	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	IE child	0.00	0.0%	Onions	0.0%	Garlic				0.0%
		Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

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

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.02%	Onions	0/0.01	0.23
0.00%	Garlic	0/0.01	0.04
0.00%	Shallots	0/0.01	0.00

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)
0.01%	Onions	0/0.01	0.15
0.00%	Shallots	0/0.01	0.03
0.00%	Garlic	0/0.01	0.01

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.0%	Shallots/boiled	0/0.01	0.16
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.0%	Onions/boiled	0/0.01	0.09
0.01%	Shallots/boiled	0/0.01	0.06
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

1-2-4 triazole

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.0362%	RO general	0.01	0.0326%	Onions	0.0036%	Garlic				0.0%
	0.0%	GEMS/Food G06	0.01	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G10	0.01	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G15	0.01	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G08	0.01	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	SE general	0.01	0.0%	Onions	0.0%	Garlic	0.00072%	Shallots		0.0%
	0.0%	FI 3 yr	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G07	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	PT general	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	PL general	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	FI 6 yr	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	DK child	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	IE adult	0.00	0.0%	Onions	0.0%	Shallots	0.0%	Garlic		0.0%
	0.0%	UK vegetarian	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	UK toddler	0.00	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
	0.0%	FR child 3 15 yr	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	NL general	0.00	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
	0.0%	ES adult	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	GEMS/Food G11	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	DE child	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Garlic		0.0%
	0.0%	ES child	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	FR toddler 2 3 yr	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	NL toddler	0.00	0.0%	Onions	0.0%	Shallots				0.0%
	0.0%	UK infant	0.00	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
	0.0%	UK adult	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	FI adult	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	DK adult	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	NL child	0.00	0.0%	Onions		FRUIT AND TREE NUTS				0.0%
	0.0%	IT toddler	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	FR adult	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	FR infant	0.00	0.0%	Onions	0.0%	Garlic				0.0%
	0.0%	DE general	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	IT adult	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	DE women 14-50 yr	0.00	0.0%	Onions	0.0%	Garlic	0.0%	Shallots		0.0%
	0.0%	IE child	0.00	0.0%	Onions	0.0%	Garlic				0.0%
		Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

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

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Onions	0/0.01	0.23
0.04%	Garlic	0/0.01	0.04
0.003%	Shallots	0/0.01	0.00

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)
0.1%	Onions	0/0.01	0.15
0.03%	Shallots	0/0.01	0.03
0.01%	Garlic	0/0.01	0.01

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Shallots/boiled	0/0.01	0.16
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Onions/boiled	0/0.01	0.09
0.06%	Shallots/boiled	0/0.01	0.06
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

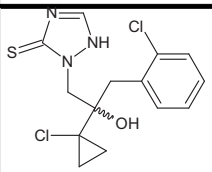
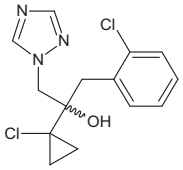
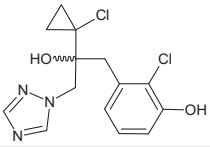
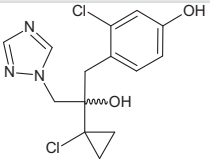
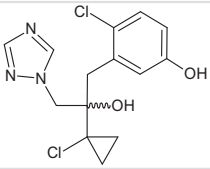
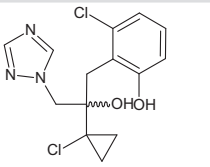
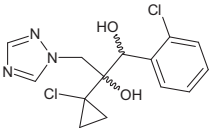
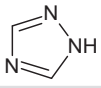
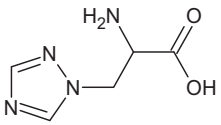
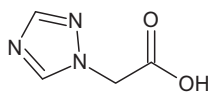
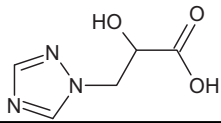
Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment[1]		Acute risk assessment[1]	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-*2H*-1,2,4- triazole moiety, expressed as prothioconazole-desthio (sum of isomers)						
Garlic	**0.02**	**proposed**	0.01	STMR-RAC	0.012	HR-RAC
Onions	**0.02**	**proposed**	0.01	STMR-RAC	0.012	HR-RAC
Shallots	**0.02**	**proposed**	0.01	STMR-RAC	0.012	HR-RAC
Cranberries	0.15	JMPR 2014	0.025	STMR[(a)]-RAC	0.9	HR[(a)]-RAC
Potatoes	0.02*	EU MRL	0.01	STMR-RAC	0.01	HR-RAC
Beetroots	0.1	EFSA, 2014	0.08	STMR-RAC	0.1	HR-RAC
Carrots	0.1	EFSA, 2014	0.08	STMR-RAC	0.1	HR-RAC
Celeriacs/turnip-rooted celeries	0.1	EFSA, 2020 proposed	0.08	STMR-RAC	0.1	HR-RAC
Horseradishes	0.1	EFSA, 2014	0.08	STMR-RAC	0.1	HR-RAC
Parsnips	0.1	EFSA, 2014	0.08	STMR-RAC	0.1	HR-RAC
Parsley roots/Hamburg roots parsley	0.1	EFSA, 2014	0.08	STMR-RAC	0.1	HR-RAC
Salsifies	0.1	EFSA, 2014	0.08	STMR-RAC	0.1	HR-RAC
Swedes/rutabagas	0.1	EFSA, 2014	0.08	STMR-RAC	0.1	HR-RAC
Turnips	0.1	EFSA, 2014	0.08	STMR-RAC	0.1	HR-RAC
Sweet corn	0.02	FAO, 2014	0.018	STMR[(a)]-RAC	0.018	HR[(a)]-RAC
Broccoli	0.05	EFSA, 2014	0.02	STMR-RAC	0.04	HR-RAC
Cauliflowers	0.05	EFSA, 2014	0.02	STMR-RAC	0.04	HR-RAC
Other flowering brassica	0.05	EFSA, 2014	0.02	STMR-RAC		
Brussels sprouts	0.1	EFSA, 2014	0.06	STMR-RAC	0.14	HR-RAC
Head cabbages	0.09	EFSA, 2014	0.02	STMR-RAC	0.12	HR-RAC
Leeks	0.06	EFSA, 2014	0.02	STMR-RAC	0.08	HR-RAC
Beans	0.05	EFSA, 2014	0.02	STMR-RAC*CF(2)	0.02	STMR-RAC*CF(2)
Lentils	1	EFSA, 2014/ FAO, 2009b	0.1	STMR[(a)]-RAC*CF(2)	0.1	STMR[(a)]-RAC*CF(2)
Peas	1	EFSA, 2014/ FAO, 2009b	0.1	STMR[(a)]-RAC*CF(2)	0.1	STMR[(a)]-RAC*CF
Lupins/lupini beans	1	EFSA, 2014/ FAO, 2009b	0.1	STMR[(a)]-RAC*CF(2)	0.1	STMR[(a)]-RAC*CF(2)
Linseeds	0.09	EFSA, 2014	0.06	STMR-RAC*CF(2)	0.06	STMR-RAC*CF(2)
Peanuts/groundnuts	0.02	FAO, 2009a	0.02	STMR-RAC*CF(2)	0.02	STMR-RAC*CF(2)
Poppy seeds	0.09	EFSA, 2014	0.06	STMR-RAC*CF(2)	0.06	STMR-RAC*CF(2)
Sunflower seeds	0.2	EFSA, 2015	0.02	STMR-RAC*CF(2)	0.02	STMR-RAC*CF(2)
Rapeseeds/canola seeds	0.2	EFSA, 2020 proposed	0.08	STMR-RAC	0.08	STMR-RAC

Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment[1]		Acute risk assessment[1]	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Soya beans	0.2	FAO, 2014	0.1	STMR-RAC*CF(2)	0.1	STMR-RAC*CF(2)
Mustard seeds	0.09	EFSA, 2014	0.06	STMR-RAC*CF(2)	0.06	STMR-RAC*CF(2)
Cotton seeds	0.3	FAO, 2018	0.104	STMR-RAC*CF(2)	0.104	STMR-RAC*CF(2)
Gold of pleasure seeds	0.04	EFSA, 2014	0.02	STMR-RAC*CF(2)	0.02	STMR-RAC*CF(2)
Barley	0.2	FAO, 2009b	0.07	STMR[(a)]-RAC*CF(2)	0.07	STMR[(a)]-RAC*CF(2)
Maize/corn	0.1	FAO, 2014	0.02	STMR[(a)]-RAC*CF(2)	0.02	STMR[(a)]-RAC*CF(2)
Wheat	0.1	FAO, 2009b	0.04	STMR[(a)]-RAC*CF(2)	0.04	STMR[(a)]-RAC*CF(2)
Swine: Muscle/meat	0.01	FAO, 2018	0.01	STMR[(b)]-RAC	0.01	HR[(b)]-RAC
Swine: Fat tissue	0.02	FAO, 2018	0.01	STMR[(b)]-RAC	0.018	HR[(b)]-RAC
Swine: Liver	0.5	FAO, 2009b	0.05	STMR[(b)]-RAC	0.23	HR[(b)]-RAC
Swine: Kidney	0.5	FAO, 2009b	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Swine: Edible offals (other than liver and kidney)	0.5	FAO, 2009b	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Bovine: Muscle/meat	0.01	FAO, 2018	0.01	STMR[(b)]-RAC	0.01	HR[(b)]-RAC
Bovine: Fat tissue	0.02	FAO, 2018	0.01	STMR[(b)]-RAC	0.018	HR[(b)]-RAC
Bovine: Liver	0.5	FAO, 2009b	0.05	STMR[(b)]-RAC	0.23	HR[(b)]-RAC
Bovine: Kidney	0.5	FAO, 2009b	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Bovine: Edible offals (other than liver and kidney)	0.5	FAO, 2009b	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Sheep: Muscle/meat	0.01	FAO, 2018	0.01	STMR[(b)]-RAC	0.01	HR[(b)]-RAC
Sheep: Fat tissue	0.02	FAO, 2018	0.01	STMR[(b)]-RAC	0.018	HR[(b)]-RAC
Sheep: Liver	0.5	FAO, 2009b	0.05	STMR[(b)]-RAC	0.23	HR[(b)]-RAC
Sheep: Kidney	0.5	FAO, 2009b	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Sheep: Edible offals (other than liver and kidney)	0.5	FAO, 2009b	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Goat: Muscle/meat	0.01	FAO, 2018	0.01	STMR[(b)]-RAC	0.01	HR[(b)]-RAC
Goat: Fat tissue	0.02	FAO, 2018	0.01	STMR[(b)]-RAC	0.018	HR[(b)]-RAC
Goat: Liver	0.5	FAO, 2009b	0.05	STMR[(b)]-RAC	0.23	HR[(b)]-RAC
Goat: Kidney	0.5	FAO, 2009b	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Goat: Edible offals (other than liver and kidney)	0.5	FAO, 2009b	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Equine: Muscle/meat	0.01	FAO, 2018	0.01	STMR[(b)]-RAC	0.01	HR[(b)]-RAC
Equine: Fat tissue	0.02	FAO, 2018	0.01	STMR[(b)]-RAC	0.018	HR[(b)]-RAC
Equine: Liver	0.5	FAO, 2009b	0.05	STMR[(b)]-RAC	0.23	HR[(b)]-RAC
Equine: Kidney	0.5	FAO, 2009b	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Equine: Edible offals (other than liver and kidney)	0.5	FAO, 2009b	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC

Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment[1]		Acute risk assessment[1]	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Poultry: Muscle/meat	0.01	FAO, 2018	0.0016	STMR[b]-RAC	0.0016	HR[b]-RAC
Poultry: Fat tissue	0.01	FAO, 2018	0.008	STMR[b]-RAC	0.008	HR[b]-RAC
Poultry: Liver	0.1	FAO, 2018	0.071	STMR[b]-RAC	0.071	HR[b]-RAC
Poultry: Kidney	0.1	FAO, 2018	0.071	STMR[b]-RAC	0.071	HR[b]-RAC
Poultry: Edible offals (other than liver and kidney)	0.1	FAO, 2018	0.071	STMR[b]-RAC	0.071	HR[b]-RAC
Other farmed animals: Muscle/meat	0.01	FAO, 2018	0.01	STMR[b]-RAC	0.01	HR[b]-RAC
Other farmed animals: Fat tissue	0.02	FAO, 2018	0.01	STMR[b]-RAC	0.018	HR[b]-RAC
Other farmed animals: Liver	0.5	FAO, 2009b	0.05	STMR[b]-RAC	0.23	HR[b]-RAC
Other farmed animals: Kidney	0.5	FAO, 2009b	0.025	STMR[b]-RAC	0.15	HR[b]-RAC
Other farmed animals: Edible offals (other than liver and kidney)	0.5	FAO, 2009b	0.025	STMR[b]-RAC	0.15	HR[b]-RAC
Milk: Cattle	0.01*	EFSA, 2014	0.005	STMR-RAC	0.005	STMR-RAC
Milk: Sheep	0.01*	EFSA, 2014	0.005	STMR-RAC	0.005	STMR-RAC
Milk: Goat	0.01*	EFSA, 2014	0.005	STMR-RAC	0.005	STMR-RAC
Milk: Horse	0.01*	EFSA, 2014	0.005	STMR-RAC	0.005	STMR-RAC
Milk: Others	0.01*	EFSA, 2014	0.005	STMR-RAC	0.005	STMR-RAC
Eggs: Chicken	0.01*	EFSA, 2014	0.01	STMR-RAC	0.01	LOQ
Eggs: Duck	0.01*	EFSA, 2014	0.01	STMR-RAC	0.01	LOQ
Eggs: Goose	0.01*	EFSA, 2014	0.01	STMR-RAC	0.01	LOQ
Eggs: Quail	0.01*	EFSA, 2014	0.01	STMR-RAC	0.01	LOQ
Eggs: Others	0.01*	EFSA, 2014	0.01	STMR-RAC		
Honey and other apiculture products	0.05*	Current EU MRL	0.05	LOQ	0.05	LOQ
Risk assessment residue definition: Triazole alanine (TA)						
Garlic	–	**proposed**	0.05	STMR-RAC	0.14	HR-RAC
Onions	–	**proposed**	0.05	STMR-RAC	0.14	HR-RAC
Shallots	–	**proposed**	0.05	STMR-RAC	0.14	HR-RAC
Risk assessment residue definition: Triazole lactic acid (TLA)						
Garlic	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Onions	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Shallots	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Risk assessment residue definition: Triazole acetic acid (TAA)						
Garlic	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Onions	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Shallots	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Risk assessment residue definition: 1,2,4-triazole (1,2,4-T)						
Garlic	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Onions	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Shallots	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity.
Consumption figures in the EFSA PRIMo are expressed as meat.
Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.
(1): Refined calculation mode.
*: Indicates a value at the limit of quantification.
(a): Values refer to the residues of prothioconazole-desthio; data according to EU risk assessment residue definition not available (EFSA, 2020).
(b): Values refer to the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates expressed as prothioconazole-desthio (EFSA, 2020).

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Prothioconazole	(*RS*)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione S=C1N=CNN1CC(O)(Cc1ccccc1Cl)C1(Cl)CC1 MNHVNIJQQRJYDH-UHFFFAOYSA-N	
Prothioconazole-**desthio** (M04)	(2*RS*)-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)-2-propanol OC(Cn1cncn1)(Cc1ccccc1Cl)C1(Cl)CC1 HHUQPWODPBDTLI-UHFFFAOYSA-N	
Prothioconazole-3 hydroxy-desthio (M14)	2-chloro-3-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]phenol OC(Cn1cncn1)(Cc1cccc(O)c1Cl)C1(Cl)CC1 OSFCZDFLHQXWKG-UHFFFAOYSA-N	
Prothioconazole-4 hydroxy-desthio (M15)	3-chloro-4-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]phenol OC(Cn1cncn1)(Cc1ccc(O)cc1Cl)C1(Cl)CC1 YZPNFTVYLXGBPC-UHFFFAOYSA-N	
Prothioconazole-5 hydroxy-desthio (M16)	4-chloro-3-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]phenol OC(Cn1cncn1)(Cc1cc(O)ccc1Cl)C1(Cl)CC1 SNUVNTFOEHWABV-UHFFFAOYSA-N	
Prothioconazole-6 hydroxy-desthio (M17)	3-chloro-2-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]phenol OC(Cn1cncn1)(Cc1c(O)cccc1Cl)C1(Cl)CC1 JQRBOBUTGZOYBJ-UHFFFAOYSA-N	
Prothioconazole-α-hydroxy-desthio (M18)	(1*RS*,2*RS*;1*RS*,2*SR*)- 2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)propane-1,2-diol OC(Cn1cncn1)(C(O)c1ccccc1Cl)C1(Cl)CC1 JOFJRMIXOWNPNA-UHFFFAOYSA-N	
Triazole derivative metabolites		
1,2,4-triazole (1,2,4-T)	1*H*-1,2,4-triazole c1ncnn1 NSPMIYGKQJPBQR-UHFFFAOYSA-N	
Triazole alanine (TA)	3-(1*H*-1,2,4-triazol-1-yl)-D,L-alanine NC(Cn1cncn1)C(=O)O XVWFTOJHOHJIMQ-UHFFFAOYSA-N	
Triazole acetic acid (TAA)	1*H*-1,2,4-triazol-1-ylacetic acid O=C(O)Cn1cncn1 RXDBSQXFIWBJSR-UHFFFAOYSA-N	
Triazole lactic acid or triazole hydroxy propionic acid (TLA)	(2*RS*)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propanoic acid OC(Cn1cncn1)C(=O)O KJRGHGWETVMENC-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.