ADOPTED: 18 July 2023

doi: 10.2903/j.efsa.2023.8198

Modification of the existing maximum residue levels for prothioconazole in sugar beet and chicory roots

EFSA (European Food Safety Authority),
Giulia Bellisai, Giovanni Bernasconi, Luis Carrasco Cabrera, Irene Castellan, Monica del Aguila, Lucien Ferreira, German Giner Santonja, Luna Greco, Samira Jarrah, Renata Leuschner, Javier Martinez Perez, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Manuela Tiramani and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer CropScience Deutschland GmbH submitted a request to the competent national authority in Germany to modify the existing maximum residue levels (MRLs) for the active substance prothioconazole in sugar beet roots and chicory roots. The data submitted in support of the request were found to be sufficient to derive MRL proposals for sugar beet roots and chicory root. 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, sugar beet roots, chicory roots, pesticide, MRL, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2022-00360

Correspondence: pesticides.mrl@efsa.europa.eu

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

Acknowledgements: EFSA wishes to thank: Stathis Anagnos, Andrea Mioč, Marta Szot, for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Cabrera, L. C., Castellan, I., del Aguila, M., Ferreira, L., Santonja, G. G., Greco, L., Jarrah, S., Leuschner, R., Perez, J. M., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., Scarlato, A. P., ... Verani, A. (2023). Modification of the existing maximum residue levels for prothioconazole in sugar beet and chicory roots. *EFSA Journal*, *21*(8), 1–49. http://doi.org.10.2903/j.efsa.2023.8198

ISSN: 1831-4732

EUROPEAN FOOD SAFETY AUTHORITY

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience Deutschland GmbH submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance prothioconazole in sugar beet roots and chicory roots. 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 2 June 2022. To accommodate for the intended uses of prothioconazole, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) to 0.03 mg/kg.

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 7 March 2023, the EMS submitted a revised evaluation report (Germany, 2022), which replaced the previously submitted evaluation report. EFSA notes that for the present MRL application, since it was submitted before 1 September 2019, the submission of data on triazole derivative metabolites (TDMs) is in principle not required. However, where such information was provided, this was assessed.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments, the JMPR evaluations and the additional data provided by the EMS in the framework of these applications, 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 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 detected.

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 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)' 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-2H-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 this application, the derived residue definitions are applicable. Sufficiently validated enforcement methods based on gas 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 0.03 mg/kg for sugar beet roots and via extrapolation 0.03 mg/kg for chicory roots.

Specific studies investigating the magnitude of prothioconazole residues in processed commodities are not required, as residues above 0.1 mg/kg are not expected in raw agricultural commodities (RAC) and the individual contributions of sugar beet roots (5.1% acceptable daily intake (ADI)) and chicory roots (0.2%) are below the trigger value of 10% of the ADI. One processing study with sugar beet

roots was provided with data for prothioconazole-desthio only and indicated that a reduction of residues is expected in dried sugar beet roots pulp, refined sugar and molasses. The number of available studies is insufficient to derive robust processing factors.

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 prothioconazole-desthio are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed Good Agricultural Practice (GAP). Based on the available information, EFSA could not exclude that the use of prothioconazole according to the proposed GAP will result in significant residues in rotational crops related to the triazole derivate metabolites (TDMs). Therefore, Member States should consider the setting of specific risk mitigation measures to avoid the presence of TDMs in rotational crops.

As sugar beet roots and its by-products are used as feed products, a potential carry-over of prothioconazole residues into the food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species. The contribution of prothioconazole residues in sugar beet tops to the total livestock exposure was significant for cattle and swine. However, the existing EU MRLs for livestock commodities reflect Codex MRLs, which were derived from significantly higher livestock dietary burdens as calculated by the JMPR in 2017. Therefore, EFSA concludes that a change of the existing MRLs for prothioconazole in products of animal origin is not required on the basis of a new use of prothioconazole on sugar beet.

Validated analytical methods for enforcement of the proposed residue definition are available for all animal matrices at the LOQ of 0.01 mg/kg, except for milk where 0.004 mg/kg is achievable. The applicant provided the TDM data both for sugar beet root and tops. The residue levels of TDMs in sugar beet matrices are below the levels assessed by the peer review on the pesticide risk assessment for the TDMs in light of confirmatory data, except for the TAA levels in sugar beet tops. However, since TDM residue data are not available for all feed crops treated with prothioconazole and since the residue data available to the pesticide peer review on the TDM confirmatory data were affected by uncertainties related to storage stability and the number of residue trials, the livestock dietary burden to TDMs cannot be currently estimated. Moreover, the peer review on the TDM confirmatory data identified a data gap related to the lack of poultry and ruminant feeding studies with TLA. EFSA recommends that the livestock exposure to TDMs originating from the use of prothioconazole is further assessed in the framework of the renewal of the approval of active substance.

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 ADI of 0.01 mg/kg body weight (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 and the recent MRL application on bulb vegetables will be implemented in the EU MRL legislation, the previous consumer risk assessment was updated with the new risk assessment values as derived for sugar beet roots and chicory roots from the submitted residue trials. The consumer risk assessment was performed separately for prothioconazole and the four TDMs, using 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 12% of the ADI (NL toddler diet). 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 is considered indicative and took into consideration TDMs related to the proposed conditions of use in this application.

For the chronic exposure, EFSA compared the STMR values derived for sugar beet roots and chicory roots in the current assessment with the highest STMR value derived for sugar beet roots 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 the present assessment were lower, EFSA concludes that the conclusion of the EU pesticide peer review on 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 indicative acute exposure to TDMs, EFSA assessed potential risks associated with the acute intake of sugar beet roots and chicory roots containing residues of TA, TAA, 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 sugar beet roots and chicory roots 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 for prothioconazole is currently ongoing and therefore the conclusions of the present assessment are provisional and might need to be reconsidered.

EFSA emphasises that the above assessment took into consideration 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)[(F)]				
09000010	Sugar beet roots	0.01*	0.03	The submitted data are sufficient to derive an MRL proposal for the NEU use. Risk for consumers is unlikely for the residues from prothioconazole including its triazole derivative metabolites (TDMs). Member States should consider the setting of specific risk mitigation measures to avoid an additional contribution of TDM residues in rotational crops from the intended use of prothioconazole on sugar beets.
09000030	Chicory roots	0.01*	0.03	The MRL proposal for the NEU use is extrapolated from the provided data on sugar beetroot. Risk for consumers is unlikely for the residues from prothioconazole including its triazole derivative metabolites (TDMs). Member States should consider the setting of specific risk mitigation measures to avoid an additional contribution of TDM residues in rotational crops from the intended use of prothioconazole on chicory.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

Table of contents

Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for prothioconazole in sugar beet roots and chicory roots. The detailed description of the intended NEU 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 the 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, 2007b). Prothioconazole was approved[2] for the use as a fungicide on 1 August 2008. The process of renewal of the first approval is currently ongoing.

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). Afterwards, EFSA issued a Reasoned opinion on the modification of MRLs for prothioconazole in garlic, onions and shallots (EFSA, 2023). Although proposals from those opinions have not been implemented so far in the EU MRL legislation these will be taken into consideration for the present assessment.

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience Deutschland GmbH submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing MRLs for the active substance prothioconazole in sugar beet roots and chicory roots. 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 2 June 2022. To accommodate for the intended NEU uses of prothioconazole, the EMS proposed to raise the existing MRLs from the LOQ to 0.03 mg/kg both in sugar beet root and chicory root.

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 7 March 2023, the EMS submitted a revised evaluation report (Germany, 2022), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2022), the 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, 2007b), as well as the conclusions from previous EFSA opinions on prothioconazole (EFSA, 2015a,b, 2020, 2023), including the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005 (EFSA, 2014).

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, 1996, 1997a,b,c,d,e,f,g, 2000, 2010a,b, 2017; OECD, 2008, 2011, 2018). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the

[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, pp. 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, pp. 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, pp. 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, pp. 1–66.

Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.[6]

Furthermore, considering the date for this MRL application (19/07/2016) which is prior to the review of confirmatory data on triazole derivative metabolites (EFSA, 2018b), the submission and assessment of data on TDMs is in principle not required for MRL applications under Art. 6 of Reg. (EC) No 396/2005 submitted before 1 September 2019. However, where such information was provided, this was assessed notwithstanding.

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

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

The evaluation report submitted by the EMS (Germany, 2022) and the exposure calculations using the PRIMo are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.[7]

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 labelled in the phenyl-ring 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, 2009a,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 total radioactive residue (TRR) (0.008 mg e.q./kg) and prothioconazole-desthio for 15.9% of the total radioactive residue (TRR). For the triazole label in grain, Triazole alanine (TA) accounted for 71% of the total radioactive residue (TRR), Triazole acetic acid (TAA) for 19% of the total radioactive residue (TRR) and triazole lactic acid (TLA) for less than 1% of the total radioactive residue (TRR) (FAO, 2009a,b).

In peanut nutmeat following phenyl and triazole labelled prothioconazole application, the total residues accounted for 0.3 to 1.4 mg eq./kg, respectively. Parent prothioconazole was below 10% of the total radioactive residue (TRR). For the triazole label, in nutmeat Triazole alanine (TA) accounted for 47.8% of the total radioactive residue (TRR) (0.67 mg eq./kg), triazole lactic acid (TLA) for 24.5% of the total radioactive residue (TRR) (0.34 mg eq./kg) and Triazole acetic acid (TAA) for 1.2% total radioactive residue (TRR) (0.02 mg eq./kg) (FAO, 2009a,b).

In sugar beets, for the phenyl and triazole labels, total radioactive residue (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 total radioactive residue (TRR) in roots. Prothioconazole was seen to be extensively degraded in both leaves and roots of sugar beet and accounted for less than 10% of the total radioactive residue (TRR) (FAO, 2009a,b; EFSA, 2014). Regarding the triazole labelling moiety, besides prothioconazole-desthio that was identified in roots (25% total radioactive residue (TRR), 0.03 mg eq./kg), Triazole alanine (TA) was found to be the predominant compound of the total residues in roots (29% total radioactive residue (TRR), 0.04 mg eq./kg) (EFSA, 2014). The other TDMs were not reported as quantified in sugar beet roots. In sugar beet tops TA represented 2% of the total radioactive residue (0.084 mg eq/kg) and the only other TDM quantified was triazole lactic acid (TLA) with 4% total radioactive residue (0.207 mg eq/kg) (FAO, 2009a,b).

[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, pp. 127–175.

[7] Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00360

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 (TA), triazole lactic acid (TLA) and Triazole acetic acid (TAA) (EFSA, 2014).

For the intended uses on sugar beets and chicory, 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 (European Commission, 2020). EFSA proposes that this matter is further considered in the framework of the renewal of the approval process of prothioconazole.

1.1.2. Nature of residues in rotational crops

Prothioconazole is proposed to be used on sugar beets and chicory 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 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 applied radioactivity (AR) and was therefore further not assessed by the EU pesticides peer review (EFSA, 2007b).

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 the metabolism of prothioconazole in primary and rotational crops was found to be similar (EFSA, 2014).

The metabolism of prothioconazole labelled in triazole ring was assessed by the JMPR (FAO, 2009a, b) and reported in the MRL review (EFSA, 2014). Swiss chards, turnips and spring wheat were grown in soil treated with prothioconazole at a rate of 4 $\times$ 204 g/ha. The studies indicate the cleavage of triazole linkage to form major metabolites TA, TLA and 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, 2009a,b).

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

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% to 99.9% AR), whereas parent prothioconazole slightly degraded to prothioconazole-desthio under sterilisation process ($\leq$ 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-2H-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, 2015b).

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

1.1.4. Analytical methods for enforcement purposes 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 Appendix B.1.1.1.

It is concluded that sufficiently validated enforcement methods are available to analyse prothioconazole-desthio residues in sugar beet roots and chicory roots at the validated LOQ of 0.02 mg/kg.

In the framework of this application, the EMS informed that a lower LOQ of 0.01 mg/kg would be achievable with a sufficiently validated multi-residue 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 (Germany, 2022). Data on extraction efficiency are also mentioned as being submitted under the renewal process (Germany, 2022). 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.

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 sugar beet and chicory roots, 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 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 to 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).

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

1.1.6. 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 to 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;[8]
- 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).

[8] 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).

For the uses on the crops under consideration, EFSA concludes that the metabolism of prothioconazole is sufficiently investigated and that the abovementioned 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).

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 performed on sugar beet. The applicant proposes to extrapolate residue data from sugar beet roots to chicory roots which is acceptable according to the EU guidance document (European Commission, 2017). The samples were analysed for the parent compound included in the residue definitions for enforcement and the metabolites included in the residue definitions for risk assessment including the TDMs. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Germany, 2022).

The samples of these residue trials were stored under conditions for which the integrity of the samples has been demonstrated for prothioconazole-desthio residues and the metabolites included in the residue definition for risk assessment (Germany, 2022).

Residue trials were analysed using the validated method 01013 with an LOQ of 0.01 mg/kg for prothioconazole-desthio and a modified 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 considered addressed by the previous EFSA assessment where these methods have also been applied (EFSA, 2023).

For 1,2,4-triazole, TA, TAA and TLA, a sufficiently validated liquid chromatography–tandem mass spectrometry detector (LC–MS/MS) method 01062 was used with an LOQ of 0.01 mg/kg for each metabolite. The analytical method demonstrated adequate recovery data (Germany, 2022). Furthermore, extraction efficiency was considered as addressed for this method (EFSA, 2023).

New intended uses on sugar beet and chicory roots refer to the use of prothioconazole in the NEU (foliar application 2 (interval between applications: 21 days) × 150 g a.s./ha; PHI = 7 days). The newly provided residue data are summarised in Appendix B.1.2.1.

NEU use

In support of the intended NEU GAP on sugar beet and chicory, the applicant submitted nine GAP compliant independent residue trials on sugar beets performed during the growing season of 2014, carried out in Belgium (one), Denmark (one), France (one), Germany (two), the Netherlands (two) and the United Kingdom (two). The samples of sugar beet root and tops were analysed separately. The applicant's proposed extrapolation from sugar beet roots to chicory roots is sufficiently supported by residue data.

An MRL of 0.03 mg/kg is proposed for prothioconazole-desthio in sugar beet roots and extrapolated to chicory roots in line with applicable guidance (European Commission, 2017). From all TDM compounds only TA was detected above the LOQ of 0.01 mg/kg with the highest residue of 0.024 mg/kg in the root. 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

Sugar beet and chicory can be grown in rotation. Therefore, residues obtained from crop rotation were considered.

A possible transfer of prothioconazole residues from primary crop uses to crops that are grown in a crop rotation has been assessed in the MRL review (EFSA, 2014). The MRL review concluded that prothioconazole residue levels in food and feed commodities derived from rotational crops are expected to be covered by the residue levels in primary crops (EFSA, 2014).

Since the maximum annual application rate for the crops under consideration (i.e. 2 × 150 g a.s./ha) is lower than the application rate tested in the rotational crop study, it is concluded that the same conclusions are applicable.

This conclusion, nevertheless, is not justified for the occurrence of triazole derivative metabolites in soil from the uses of prothioconazole, other triazole pesticides or fertilisers, and subsequent carry-over to plants. The peer review on the pesticide risk assessment for the TDMs in light of confirmatory data could not conclude on the magnitude of TDMs in rotational crops following the use of triazole fungicides due to data gaps related to storage stability of rotational crop field trial samples (EFSA, 2018b). Thus, without appropriate field data, the magnitude of TDMs in rotational crops currently cannot be estimated. It is nevertheless noted that metabolism studies and residue trials indicate the uptake of TDMs by rotational crops and therefore EFSA recommends that Member States shall consider the need to set specific risk mitigation measures to avoid an additional contribution of TDMs in soil from the intended uses on sugar beets and chicory.

1.2.3. Magnitude of residues in processed commodities

For this application, processing studies would not be required because residues above 0.1 mg/kg prothioconazole-desthio are not expected and the consumer exposure to residues in sugar beet roots and chicory roots is individually less than 10% ADI (European Commission, 1997d).

Nevertheless, one processing study in sugar beets following three treatments with 1000 g a.s./ha (8–10 days interval) and a PHI of 5 days was provided and assessed. Processing of the treated sugar beets to dried pulp, refined sugar and molasses was investigated and indicated that all three processes lead to a reduction of the prothioconazole-desthio residues in the processed product (Germany, 2022). No information was provided on the levels of metabolites that are included in the risk assessment residue definition. One processing study however is not sufficient to derive robust processing factors to be recommended to be included in Annex VI of Regulation (EC) No 396/2005.

Studies investigating the effect on the magnitude of the TDMs in processed commodities have not been submitted in the framework of the current assessment. Such studies are currently not required, because residues above the LOQ of 0.1 mg/kg are not expected in the individual crops under assessment.

1.2.4. 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 residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Sugar beet roots and tops may be used for feed purposes. Hence, it was necessary to perform a dietary burden calculation for livestock to estimate whether the intended use of prothioconazole on sugar beet would have an impact on the residues expected in food of animal origin (European Commission, 1996).

Therefore, the most recent livestock dietary burden which was calculated in the EFSA opinion on the confirmatory data assessment of prothioconazole (EFSA, 2020) was now updated considering the use of prothioconazole on sugar beet.

The results of the dietary burden calculation are presented in Appendix B.2 and demonstrated that the intake of additional prothioconazole residues from treated sugar beet roots and tops increases the dietary burden for beef and dairy ruminants and for pigs. However, the existing EU MRLs for prothioconazole in livestock commodities reflect Codex MRLs, which were derived from a significantly higher livestock dietary burdens as calculated by the JMPR (FAO, 2018). Therefore, EFSA concludes that a change of the existing MRLs for products of animal origin is not required.

The results of the previous calculations are herewith reported for information: Codex Maximum dietary burden 18.42 mg/kg DM, 21.60 mg/kg DM and 3.05 mg/kg DM for beef ruminants, dairy ruminants and poultry, respectively (FAO, 2018).

EU Median dietary burden: 1.15 mg/kg DM, 0.84 mg/kg DM and 0.52 mg/kg DM for beef ruminants, dairy ruminants and poultry, respectively (EFSA, 2020).

The input values for the exposure calculations for livestock are presented in Appendix D.1.

A comprehensive livestock exposure to TDMs from the intake of all feed commodities containing TDM residues from the use of various triazole fungicides could not be fully assessed by the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data due to outstanding poultry and ruminant feeding studies with TLA or alternative metabolism studies which could be used as waivers for feeding studies (EFSA, 2018b). Thus, pending these data gaps to be addressed and lacking updated information on TDMs from the uses of all triazole fungicides, the livestock exposure to TDMs from the intake of feed crops treated with triazole fungicides other than prothioconazole could not be undertaken in the framework of the current assessment.

The applicant provided the TDMs data both for sugar beet root and tops. The residue levels of TDMs in sugar beet tops are below the levels assessed by the peer review on the pesticide risk assessment for the TDMs in light of confirmatory data, except for the TAA levels in sugar beet tops, which were higher (0.076 mg/kg vs. 0.02 mg/kg (from use of various triazole fungicides)) (EFSA, 2018b). Since TDM residue data are not available for all feed crops treated with prothioconazole and since the residue data available to the pesticide peer review on the TDM confirmatory data were affected by uncertainties related to storage stability and the number of residue trials, the livestock dietary burden to TDMs cannot be currently estimated. EFSA recommends that the livestock exposure to TDMs originating from the use of prothioconazole is further assessed in the framework of the renewal of the approval of active substance.

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 sub-groups 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).

In the framework of the current MRL application, the risk assessment was performed for the parent prothioconazole; while for the additional residue definitions related to the TDMs, EFSA performed an indicative exposure assessment, considering only the crops under consideration. The results of the calculation are summarised in Appendix B.3 and a summary of the input values is provided in Appendix D.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 assumption that recommendations derived in the framework of the Article 12 confirmatory data assessment and subsequent reasoned opinion on the modification of MRLs for prothioconazole in garlic, onions and shallots will be implemented in the EU MRL legislation, the previous consumer risk assessment was updated (EFSA, 2023) with the new risk assessment values as derived for sugar beet and chicory roots 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.

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 12% of the ADI (NL toddler diet). The individual contribution of residues in sugar beet and chicory roots was 5.07% of the ADI (NL child) and 0.21% of the ADI (GEMS Food G11), respectively.

The short-term exposure did not exceed the ARfD for any of the crops under consideration, with maximum individual acute exposure for adults being 0.265% of the ARfD for chicory roots (DE general diet). The acute exposure for residues in sugar beet and chicory roots could not be estimated for children and for sugar beet roots also for adults due to missing consumption data.

For processed commodities, sugar from sugar beet roots, the acute exposure was highest for Dutch children with 66.1% ARfD and 26.3% for French adults.

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.

Triazole derivate metabolites (TDMs)

A comprehensive risk assessment, considering all crops in which TDMs might be present from the uses of all pesticides belonging to the class of triazole fungicides has been performed in the framework of the pesticide risk assessment for the TDMs in light of confirmatory data (EFSA, 2018b). An update of this assessment could not be performed in the framework of this opinion, lacking the most recent residue data on the occurrence TDMs from the use of other triazole fungicides. Thus, in the present assessment, an indicative exposure was calculated for TDMs related to the proposed uses on sugar beet roots and chicory roots only. The exposure assessment was performed according to residue definitions derived in the framework of the conclusion on TDMs (see also Section 1.1.6; EFSA, 2018b). The input values (HR/STMR values) were as derived from residue trials provided in support of this application (Germany, 2022).

The toxicological profile for each TDM was assessed in the framework of the pesticide risk assessment of the TDMs in light of confirmatory data (EFSA, 2018b). The 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.

Regarding the chronic exposure, EFSA compared the STMR values derived for sugar beet roots and chicory roots in the present assessment (0.01 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[9] values derived for TDMs from the uses of various triazole fungicides on sugar plants as reported in the framework of the pesticide risk assessment of the TDMs in light of confirmatory data (0.05 mg/kg for TA, 1,2,4-triazole and TAA and 0.01 mg/kg for triazole lactic acid).

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 indicative acute exposure, EFSA assessed potential risks associated with the acute intake of sugar beet roots and chicory roots containing individual TDMs at the highest levels according to the submitted residue trials (0.024 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).

An acute exposure estimate could only be performed for chicory roots for which consumption data for adults were available; consumption data for raw agricultural commodity sugar beet roots are not available. The estimated acute exposure was the highest for 1,2,4-triazole in chicory roots (0.0038% of the ARfD). Notably, for processed commodities (sugar) where consumption data are available for children and adults, the highest acute exposure was estimated for Dutch children for 1,2,4-triazole residues in sugar from sugar beets (1.1% of the ARfD).

The indicative short-term exposure calculated for TDMs was low and did not indicate any consumer intake concern for any individual TDM in sugar beet roots and chicory roots.

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, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for sugar beets and chicory roots.

EFSA concluded that the proposed use of prothioconazole on sugar beet roots and chicory roots will not result in a consumer exposure exceeding the toxicological reference values of parent prothioconazole and TDMs and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

References

EFSA (European Food Safety Authority), 2007a. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. https://doi.org/10.2903/j.efsa.2007.32r

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

EFSA (European Food Safety Authority), 2007b. Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole. EFSA Journal 2007;5(8):RN-106, 98 pp. https://doi.org/10.2903/j.efsa.2007.106r

EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for prothioconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(5):3689, 72 pp. https://doi.org/10.2903/j.efsa.2014.3689

EFSA (European Food Safety Authority), 2015a. Reasoned opinion on the modification of the existing maximum residue level (MRL) for prothioconazole in shallots. EFSA Journal 2015;13(5):4105, 20 pp. https://doi.org/10.2903/j.efsa.2015.4105

EFSA (European Food Safety Authority), 2015b. Reasoned opinion on the modification of the existing maximum residue levels for prothioconazole in sunflower seeds. EFSA Journal 2015;13(12):4371, 24 pp. https://doi.org/10.2903/j.efsa.2015.4371

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018a. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Brancato A, Brocca D, Carrasco Cabrera L, Chiusolo A, Civitella C, Court Marques D, Crivellente F, De Lentdecker C, Erdös Z, Ferreira L, Goumenou M, Greco L, Istace F, Jarrah S, Kardassi D, Leuschner R, Medina P, Mineo, D, Miron I, Molnar T, Nave S, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Terron A, Theobald A, Vagenende B and Villamar-Bouza L, 2018b. Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data. EFSA Journal 2018;16(7):5376, 57 pp. https://doi.org/10.2903/j.efsa.2018.5376

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019a. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). EFSA supporting publication 2019:EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1605

EFSA (European Food Safety Authority), Bura L, Friel A, Magrans JO, Parra-Morte JM and Szentes C, 2019b. Guidance of EFSA on risk assessments for active substances of plant protection products that have stereoisomers as components or impurities and for transformation products of active substances that may have stereoisomers. EFSA Journal 2019;17(8):5804, 33 pp. https://doi.org/10.2903/j.efsa.2019.5804

EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2020. Reasoned Opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for prothioconazole in celeriacs and rapeseeds. EFSA Journal 2020;18(2):5999, 50 pp. https://doi.org/10.2903/j.efsa.2020.5999

EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2022. Reasoned opinion on the review of the existing maximum residue levels for tetraconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2022;20(1):7111, 98 pp. https://doi.org/10.2903/j.efsa.2022.7111

EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Cabrera LC, Castellan I, Del Aguila M, Ferreira L, Santonja GG, Greco L, Jarrah S, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Robinson T, Ruocco S, Santos M, Scarlato AP, Theobald A and Verani A, 2023. Reasoned Opinion on the modification of the existing maximum residue levels for prothioconazole in garlic, onions and shallots. EFSA Journal 2023;21(1):7717, 48 pp. https://doi.org/10.2903/j.efsa.2023.7717

European Commission, 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95-rev.4.

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/VI/95-rev.3, 22 July 1997.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.
European Commission, 2007. Review report for the active substance prothioconazole. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 22 January 2008 in view of the inclusion of prothioconazole in Annex I of Council Directive 91/414/EEC. SANCO/3923/07-Final, 10 December 2007.
European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.
European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.
European Commission, 2020. Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation on residue data on products from plant and animal origin. SANTE/2019/12752, 23 November 2020.
European Commission, 2021. Review report for the active substance prothioconazole. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 22 January 2008 in view of the inclusion of prothioconazole in Annex I of Council Directive 91/414/EEC and updated in the Standing Committee on Plants, Animals, Food and Feed on 26 January 2021. SANCO/3923/07-Final, 26 January 2021.
FAO (Food and Agriculture Organization of the United Nations), 2009a. Prothioconazole. In: Pesticide residues in food–2008. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 193.
FAO (Food and Agriculture Organization of the United Nations), 2009b. Prothioconazole. In: Pesticide residues in food – 2008. Evaluations. Part I. Residues. FAO Plant Production and Protection Paper 194.
FAO (Food and Agriculture Organization of the United Nations), 2009c. Prothioconazole. In: Pesticide residues in food–2009. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 196.
FAO (Food and Agriculture Organization of the United Nations), 2014. Prothioconazole In: Pesticide residues in food – 2014 Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 221.
FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper 225, 298 pp.
FAO (Food and Agriculture Organization of the United Nations), 2018. Prothioconazole In: Pesticide residues in food - 2018. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residuesin Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 234.
Germany, 2022. Evaluation report on the modification of MRLs for prothioconazole in sugar beet and chicory root. May 2022, revised in March 2023, 88 pp. Available online: www.efsa.europa.eu
Netherlands, 2021. Evaluation report on the modification of MRLs for prothioconazole in garlic, onions and shallots. December 2021, revised in March 2022, 128 pp. Available online: www.efsa.europa.eu
OECD (Organisation for Economic Co-operation and Development), 2008. Guidance document on the magnitude of pesticide residues in processed commodities. In: Series of Testing and Assessment No 96. ENV/JM/MONO (2008)23, 29 July 2008.
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org
OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.
OECD (Organisation for Economic Co-operation and Development), 2018. Guidance document on residues in rotational crops. In: Series on Pesticides No. 97, Series on Tesing & Assessment No. 279. ENV/JM/MONO(2018) 9, 22 May 2018.
United Kingdom, 2004. Draft assessment report on the active substance prothioconazole prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, October, 2004.
United Kingdom, 2007. Final addendum to the additional report and the draft assessment report on the active substance prothioconazole prepared by the rapporteur Member State United Kingdom in the framework of Council Regulation (EC) No 33/2008, compiled by EFSA, May 2007.
United Kingdom, 2018a. Draft renewal assessment report on the active substance prothioconazole prepared by the rapporteur Member State the United Kingdom in the framework of Commission Regulation (EU) No 1107/2009, February 2018. Available online: www.efsa.europa.eu

United Kingdom, 2018b. Triazole Derivate Metabolites, addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom in the framework of Regulation (EC) No 1107/2009, revised version of February 2018. Available online: www.efsa.europa.eu

United Kingdom, 2019. Evaluation report on the confirmatory data assessment and setting of prothioconazoleMRLs in oilseed rape. March, 2019, 71 pp.

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
EC	emulsifiable concentrate
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC–MS	gas chromatography with mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
HPLC–MS/MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RMS	rapporteur Member State
SEU	southern Europe
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization

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/kg)	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Sugar beet roots	NEU	F	Cercospora beticola, Erysiphe betae, Ramularia beticola, Uromyces betae, Stemphylium sp.	SE	125 g/l	Foliar treatment - broadcast spraying	BBCH 31–49	2	21		120–400	150	g a.i./ha	7	
Chicory roots	NEU	F	Cercospora beticola, Erysiphe betae, Ramularia beticola, Uromyces betae, Stemphylium sp.	SE	125 g/l	Foliar treatment - broadcast spraying	BBCH 31–49	2	21		120–400	150	g a.i./ha	7	

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. 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.

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

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

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

(d): PHI – minimum pre-harvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	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 26 DALA: hay 48 DALA: grain and straw	[U-^{14}C-phenyl] prothioconazole (EFSA, 2007b)
			Foliar (summer wheat): 2 × 0.25 kg/ha; interval 27 days (BBCH 31–59)	0, 14 DALA: forage 48 DALA: grain and straw	[3,5-^{14}C-triazole] prothioconazole-desthio (EFSA, 2007b)
			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 110 DAT: hay 153 DAT: grain and straw	[U-^{14}C-phenyl] prothioconazole (EFSA, 2007b)
	Pulses/oilseeds	Peanuts	Foliar: 3 × 0.3 kg/ha; interval 21 days (BBCH 66–75)	14 DALA: hays and nuts without shells	[U-^{14}C-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**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Turnips	Soil, 1 × 580 kg/ha	28, 146, 269	[U-^{14}C-phenyl] prothioconazole (EFSA, 2007b; FAO, 2009a); 1.9 N sugar beet and chicory root GAP; Sampling was done: Turnip roots and tops: 94, 201, 349 DAT; Swiss chard leaves: 80, 188, 348 DAT; Grain and straw: 145, 269, 412 DAT; Wheat green material: 73, 178, 327 DAT; Wheat hay: 111, 231, 377 DAT.
	Leafy crops	Swiss chards			
	Cereal (small grain)	Spring wheat			

	Root crops	Turnips	Soil, 4 × 204 g/ha	30, 125, 366	[triazole-3,5-^{14}C] prothioconazole (FAO, 2009a,b; EFSA, 2014, 2023) 2.7 N sugar beet and chicory root 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; Grain and straw: 121, 209, 450 DAT; Wheat green material: 62, 154, 388 DAT; Wheat hay: 80, 171, 420 DAT.
	Leafy vegetables	Swiss chards			
	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, 2018b), with separate assessment of: - Triazole alanine (TA) - 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).	

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; GC-MS: gas chromatography with mass spectrometry; LC-MS/MS: liquid chromatography with tandem mass spectrometry; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/Source**
				Value	**Unit**		
	High-water content	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-hydroy-desthio, prothioconazole-3-hydroyxy-desthio, prothioconazole-4-hydroyxy-desthio, prothioconazole-5-hydroyxy-desthio,prothioconazole-6-hydroyxy-desthio	United Kingdom, 2019
	High-oil content	Rapeseeds	–18	24	months	Prothioconazole-desthio	EFSA, 2014
		Soyabeans, rapeseeds	–18	24	months	Prothioconazole-α-hydroy-desthio, prothioconazole-3-hydroyxy-desthio, prothioconazole-4-hydroyxy-desthio,	United Kingdom, 2019

						prothioconazole-5-hydroyxy-desthio, prothioconazole-6-hydroyxy-desthio	
	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-hydroy-desthio, prothioconazole-3-hydroyxy-desthio, prothioconazole-4-hydroyxy-desthio, prothioconazole-5-hydroyxy-desthio, prothioconazole-6-hydroyxy-desthio	United Kingdom, 2019
	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, soyabeans	−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	–	months	1,2,4 - triazole	EFSA, 2018b
				15		Triazole alanine	
				25		Triazole acetic acid	
				48		Triazole lactic acid	
	High-acid content	Oranges	−18	–	months	1,2,4 - triazole	EFSA, 2018b
				–		Triazole alanine	
				–		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	

				–		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, 2021)
		Honey	–18	6	months	Prothioconazole-α-hydroy-desthio, prothioconazole-3-hydroyxy-desthio, prothioconazole-4-hydroyxy-desthio, prothioconazole-5-hydroyxy-desthio, prothioconazole-6-hydroyxy-desthio	Stability was demonstrated for 182 days (Netherlands, 2021)
		Honey	–18	5	months	1,2,4 - triazoleTriazole alanineTriazole acetic acidTriazole lactic acid	Stability was demonstrated for 153 days (Netherlands, 2021)

B.1.2. Magnitude of residues in plants

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

Commodity	Region [(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
Residue definition for enforcement: prothioconazole-desthio (sum of isomers)							
Sugar beet, Chicory	NEU	**Roots**: **Mo**: 8 × < 0.010; 0.019 Prothioconazole-α-hydroxy-desthio: 8 × < 0.01 Prothioconazole-3-hydroxy-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 trials on sugar beet compliant with GAP (Germany, 2022). Extrapolation to chicory roots possible.	**0.03**	**Mo**: 0.019	**Mo**: 0.010	1
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)							
Sugar beet, Chicory		**Roots**: **RA**: 8 × < 0.060; 0.069 CF for RA: 8 × 1; 3.63	Residue trials on sugar beet compliant with GAP (Germany, 2022). Extrapolation to chicory roots possible.	N/A	**RA**: 0.069	**RA**: 0.060	1
Residue definition for risk assessment: Triazole alanine (TA)							
Sugar beet, Chicory	NEU	**Roots**: 5 × < 0.01; 0.010; 0.013[(e)]; 0.017; 0.024[(e)];	Residue trials on sugar beet compliant with GAP (Germany, 2022). Extrapolation to chicory roots possible.	N/A	$\mathbf{RA_{TA}}$: 0.024	$\mathbf{RA_{TA}}$: 0.010	N/A
Residue definition for risk assessment: Triazole lactic acid (TLA)							
Sugar beet, Chicory	NEU	**Roots**: 9 × < 0.010	Residue trials on sugar beet compliant with GAP (Germany, 2022). Extrapolation to chicory roots possible.	N/A	$\mathbf{RA_{TLA}}$: < 0.010	$\mathbf{RA_{TLA}}$: < 0.010	N/A

Commodity	Region [(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
Residue definition for risk assessment: Triazole acetic acid (TAA)							
Sugar beet, Chicory	NEU	**Roots**: 9 × < 0.010	Residue trials on sugar beet compliant with GAP (Germany, 2022). Extrapolation to chicory roots possible.	N/A	$\mathbf{RA_{TAA}}$: < 0.010	$\mathbf{RA_{TAA}}$: < 0.010	N/A
Residue definition for risk assessment: 1,2,4-triazole (1,2,4-T)							
Sugar beet, Chicory	NEU	**Roots**: 9 × < 0.010	Residue trials on sugar beet compliant with GAP (Germany, 2022). Extrapolation to chicory roots possible.	N/A	$\mathbf{RA_{1,2,4\text{-}T}}$: < 0.010	$\mathbf{RA_{1,2,4\text{-}T}}$: < 0.010	N/A
Residue definition for enforcement: prothioconazole-desthio (sum of isomers)							
Sugar beet	NEU	**Tops**: **Mo**: 0.19[(e)]; 0.86; 0.52; 1.1; 0.63; 1.3; 0.42; 0.61; 0.51 Prothioconazole-α-hydroxy-desthio: < 0.010; 0.025[(e)]; < 0.01; 0.040[(e)]; 0.021; 0.014; 0.011; 0.010; 0.016[(e)] Prothioconazole-3-hydroxy-desthio: 0.058[(e)]; 0.16[(e)]; 0.17; 0.12[(e)]; 0.20[(e)]; 0.10; 0.079[(e)]; 0.12[(e)]; 0.12[(e)] Prothioconazole-4-hydroxy-desthio: 0.039[(e)]; 0.068[(e)]; 0.087; 0.075[(e)]; 0.095[(e)]; 0.051; 0.028[(e)]; 0.064[(e)]; 0.066[(e)]; Prothioconazole-5-hydroxy-desthio: < 0.01; 0.025[(e)]; 0.022; 0.026[(e)]; 0.023; 0.014; < 0.01; 0.012[(e)]; 0.014 Prothioconazole-6-hydroxy-desthio: 9 × < 0.01	Residue data on sugar beet leaves/tops derived from GAP compliant residue trials on sugar beet (Germany, 2022). Extrapolation to chicory leaves possible.	N/A	**Mo**: 1.30	**Mo**: 0.61	1.28
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)							
Sugar beet	NEU	Tops: **RA**: 0.32[(e)]; 1.0; 0.82; 1.3; 0.92; 1.5; 0.53; 0.78; 0.70 CF for RA: 1.68; 1.16; 1.58; 1.46; 1.15; 1.26; 1.28; 1.37	Residue data on sugar beet tops derived from GAP compliant residue trials on sugar beet (Germany, 2022)	N/A	**RA**: 1.50	**RA**: 0.82	1.37

Commodity	Region [(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
Residue definition for risk assessment: Triazole alanine (TA)							
Sugar beet tops	NEU	Tops: 0.036[(e)]; 0.038[(f)]; 0.019; 0.020[(e)]; 0.015; < 0.01; 0.029[(e)]; 0.017[(e)]; < 0.01	Residue data on sugar beet tops derived from GAP compliant residue trials on sugar beet (Germany, 2022)	N/A	$\mathbf{RA}_{TA}$: 0.038	$\mathbf{RA}_{TA}$: 0.019	N/A
Residue definition for risk assessment: Triazole lactic acid (TLA)							
Sugar beet tops	NEU	Tops: 0.093[(e)]; 0.035[(e)]; 0.035; 0.016[(e)]; 0.054; < 0.01; < 0.01; 0.016[(e)]; 0.022	Residue data on sugar beet tops derived from GAP compliant residue trials on sugar beet (Germany, 2022)	N/A	$\mathbf{RA}_{TLA}$: 0.093	$\mathbf{RA}_{TLA}$: 0.022	N/A
Residue definition for risk assessment: Triazole acetic acid (TAA)							
Sugar beet tops	NEU	Tops: 8 × < 0.010; 0.076[(e)]	Residue data on sugar beet tops derived from GAP compliant residue trials on sugar beet (Germany, 2022)	N/A	$\mathbf{RA}_{TAA}$: 0.076	$\mathbf{RA}_{TAA}$: 0.010	N/A
Residue definition for risk assessment: 1,2,4-triazole (1,2,4-T)							
Sugar beet tops	NEU	Tops: 9 × < 0.010	Residue data on sugar beet tops derived from GAP compliant residue trials on sugar beet (Germany, 2022)	N/A	$\mathbf{RA}_{1,2,4\text{-}T}$: < 0.010	$\mathbf{RA}_{1,2,4\text{-}T}$: < 0.010	N/A

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment; N/A: not applicable.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): Higher residue at a PHI of 14 days.
(f): Higher residue at a PHI of 15 days.

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.1.2.2. Processing factors

Processed commodity	Number of valid studies[(a)]	Processing Factor (PF)		CF_P[(b)]	Comment/ Source
		Individual values	Median PF		
Refined sugar	1	0.04	0.04	n.r.	Tentative[(c)] Data only for prothioconazole-desthio (and not for the hydroxy-metabolites included in the residue definition for risk assessment) or the TDMs reported (Germany, 2022)
Dried pulp	1	< 0.01	< 0.01	n.r.	
Molasses	1	0.20	0.20	n.r.	

PF: processing factor. n.r.: data to derive CF not available.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.
(c): A tentative PF is derived based on a limited dataset.

B.2. Residues in livestock

Dietary burden calculation according to OECD, 2013.

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) (EFSA, 2020).

Relevant groups (sub-groups)	Dietary burden expressed in				Most critical sub-group[(a)]	Most critical commodity[(b)]	Trigger exceeded (Y/N)	Previous assessment (EFSA, 2020) Max burden mg/kg	JMPR 2017 (FAO, 2018) Max burden mg/kg
	mg/kg bw per day		mg/kg DM						
	Median	Maximum	Median	Maximum					
Cattle (all)	0.066	0.124	1.72	3.23	Dairy cattle	Barley, straw	Y	3.10	18.42 (AUT dairy cattle)
Cattle (dairy only)	0.066	0.124	1.72	3.22	Dairy cattle	Barley, straw	Y	2.85	21.60 (AUT beef cattle)
Sheep (all)	0.075	0.236	1.77	5.55	Lamb	Barley, straw	Y	5.55	Not calculated
Sheep (ewe only)	0.059	0.185	1.77	5.55	Ram/Ewe	Barley, straw	Y	5.55	Not calculated
Swine (all)	0.022	0.030	0.95	1.32	Swine (breeding)	Sugar beet, tops	Y	0.64	Not calculated
Poultry (all)	0.036	0.059	0.53	0.87	Poultry layer	Wheat, straw	Y	0.87	3.05 (EU poultry layer)

Relevant groups (sub-groups)	Dietary burden expressed in				Most critical sub-group[(a)]	Most critical commodity[(b)]	Trigger exceeded (Y/N)	Previous assessment (EFSA, 2020) Max burden mg/kg	JMPR 2017 (FAO, 2018) Max burden mg/kg
	mg/kg bw per day		mg/kg DM						
	Median	Maximum	Median	Maximum					
Poultry (layer only)	0.036	0.059	0.53	0.87	Poultry layer	Wheat, straw	Y	0.87	Not calculated
Fish	N/A								

bw: body weight; DM: dry matter.
(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.3. Consumer risk assessment

ARfD	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: Sugar beet roots: for children and adults no acute RA possible due to lacking consumption data Processed commodity: Sugar beet sugar: 66.1% (NL child); 26.3% (FR adult) Chicory roots: 0.3% of ARfD (DE adult); for children no acute RA possible due to lacking consumption data Chicory root processed (not specified): 0.4% (NL child); 0.2% (NL general population) Triazole Derivative metabolites (TDMs): Triazole alanine (TA): Sugar beet roots: for children and adults no acute RA possible due to lacking consumption data Processed commodity: Sugar beet sugar 0.367% of ARfD (NL child); 0.1% (FR adults) Chicory roots: for children no acute RA possible due to lacking consumption data; for adults: 0.0031% (DE general diet) Chicory root processed (not specified): 0.0024% (NL child); 0.001% (NL general population) Triazole lactic acid (TLA): Sugar beet roots: for children and adults no acute RA possible due to lacking consumption data Processed commodity: Sugar beet sugar 0.367% of ARfD (NL child); 0.1% (FR adults) Chicory roots: for children no acute RA possible due to lacking consumption data; for adults: 0.0013% (DE general diet) Chicory root processed (not specified): 0.0024% (NL child); 0.001% (NL general population)

	Triazole acetic acid (TAA): Sugar beet roots: for children and adults no acute RA possible due to lacking consumption data Processed commodity: Sugar beet sugar 0.110% of ARfD (NL child); 0.0438% (FR adults) Chicory roots: for children no acute RA possible due to lacking consumption data; for adults: 0.000004% (DE general diet) Chicory root processed (not specified): 0.0007% (NL child); 0.0003% (NL general population) 1,2,4-triazole (1,2,4-T): Sugar beet roots: for children and adults no acute RA is possible due to lacking consumption data Processed commodity: Sugar beet sugar 1.102% of ARfD (NL child); 0.438% (FR adults) Chicory roots: for children no acute RA is possible due to lacking consumption data; for adults: 0.0038% (DE general diet) Chicory root processed (not specified): 0.007% (NL child); 0.003% (NL general population)
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 sugar beet and chicory roots by using the highest residue values as derived from the trials on sugar beets which were extrapolated to chicory roots. 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: 12% of ADI (NL toddler) Highest contribution of crops assessed: Sugar beets: 5.07% (NL child) Chicory roots: 0.21% (GEMS/Food G011) Regarding the chronic exposure, the new TDM data assessed in the present evaluation are not expected to trigger a modification of previous consumer dietary exposure calculations because the input values on sugar beet and chicory roots are lower than the values used in the exposure calculation by the peer review on the pesticide risk assessment for TDM confirmatory data. Therefore, the conclusion of the peer review of the assessment of the pesticide risk assessment of the TDMs in light of confirmatory data remains unchanged (EFSA, 2018b). Triazole derivative metabolites (TDMs) (EFSA, 2018b): 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 1% of the ADI (NL toddler) for TLA. If residues of TDMs from the use of prothioconazole on sugar beet and chicory roots are considered in the chronic exposure, the indicative exposure to residues in these commodities accounts for 0.028% of the ADI for TA and TLA (NL child), 0.008% of the ADI for TAA (NL child) and 0.367% of the ADI for 1,2,4-T (NL child).
Assumptions made for the calculations	Prothioconazole: Under the assumptions that the recommendations derived in the framework of the Article 12 confirmatory data assessment and the subsequent MRL application on garlic, onions and shallots will be implemented in the EU MRL legislation, EFSA updated the exposure assessment performed in the framework of the recent MRL assessment with the new RA values as derived for sugar beet and chicory roots under consideration. Conversion factors (CFs) as applied during the confirmatory data assessment were used (EFSA, 2020). The crops on which no uses were reported, were excluded from the calculation. 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 sugar beet and chicory roots by using the median residue values as derived from the trials on sugar beet roots which were extrapolated to chicory roots. The derived STMR values in sugar beet roots and chicory roots were compared with the highest STMR values for TDMs from the uses of various triazole fungicides on sugar beets 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; CXL: codex maximum residue limit.

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)[(F)]				
09000010	Sugar beet roots	0.01*	0.03	The submitted data are sufficient to derive an MRL proposal for the NEU use. Risk for consumers is unlikely for the residues from prothioconazole including its triazole derivative metabolites (TDMs). Member States should consider the setting of specific risk mitigation measures to avoid an additional contribution of TDM residues in rotational crops from the intended use of prothioconazole on sugar beets.
09000030	Chicory roots	0.01*	0.03	The MRL proposal for the NEU use is extrapolated from the provided data on sugar beet roots. Risk for consumers unlikely for the residues from prothioconazole including its triazole derivative metabolites (TDMs). Member States should consider the setting of specific risk mitigation measures to avoid an additional contribution of TDM residues in rotational crops from the intended use of prothioconazole on chicory.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo Prothioconazole-desthio

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 : ---

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

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)
12%	NL toddler	1.19	3%	Sugar beet roots	3%	Milk: Cattle	2%	Wheat	0.0%	12%
10%	NL child	1.00	5%	Sugar beet roots	2%	Wheat	1%	Milk: Cattle	0.0%	10%
9%	GEMS/Food G11	0.87	4%	Soyabeans	1%	Wheat	0.6%	Barley		9%
7%	GEMS/Food G10	0.74	3%	Soyabeans	2%	Wheat	0.5%	Barley		7%
7%	FR child 3 15 yr	0.70	2%	Sugar beet roots	2%	Wheat	1%	Milk: Cattle	0.0%	7%
7%	GEMS/Food G08	0.70	2%	Soyabeans	2%	Wheat	0.7%	Barley		7%
7%	GEMS/Food G15	0.70	2%	Wheat	2%	Soyabeans	0.6%	Barley		7%
7%	GEMS/Food G07	0.69	2%	Soyabeans	2%	Wheat	0.5%	Barley		7%
7%	GEMS/Food G06	0.67	3%	Wheat	1%	Soyabeans	0.9%	Sugar beet roots		7%
6%	UK infant	0.62	2%	Milk: Cattle	1%	Carrots	1%	Wheat	0.0%	6%
6%	FR toddler 2 3 yr	0.61	2%	Sugar beet roots	1%	Milk: Cattle	1%	Wheat	0.0%	6%
6%	UK toddler	0.60	2%	Sugar beet roots	2%	Wheat	1%	Milk: Cattle	0.0%	6%
6%	DK child	0.56	2%	Wheat	1%	Rye	1%	Carrots		6%
5%	DE women 14-50 yr	0.53	3%	Sugar beet roots	0.9%	Wheat	0.6%	Milk: Cattle	0.0%	5%
5%	DE general	0.53	3%	Sugar beet roots	0.8%	Wheat	0.6%	Milk: Cattle	0.0%	5%
5%	RO general	0.50	2%	Wheat	0.8%	Sugar beet roots	0.6%	Milk: Cattle	0.0%	5%
5%	DE child	0.46	2%	Wheat	1.0%	Milk: Cattle	0.8%	Carrots	0.1%	5%
5%	NL general	0.45	2%	Sugar beet roots	0.8%	Wheat	0.4%	Milk: Cattle	0.0%	5%
4%	SE general	0.42	1%	Wheat	0.7%	Carrots	0.6%	Milk: Cattle	0.0%	4%
4%	ES child	0.38	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%
4%	FR infant	0.35	0.9%	Carrots	0.8%	Milk: Cattle	0.8%	Sugar beet roots	0.0%	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%
2%	FR adult	0.24	0.9%	Wheat	0.5%	Sugar beet roots	0.2%	Milk: Cattle	0.0%	2%
2%	ES adult	0.24	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%	UK vegetarian	0.20	0.8%	Wheat	0.3%	Sugar beet roots	0.2%	Carrots		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%	UK adult	0.18	0.7%	Wheat	0.3%	Sugar beet roots	0.1%	Milk: Cattle	0.0%	2%
2%	LT adult	0.17	0.4%	Wheat	0.3%	Potatoes	0.2%	Rye		2%
2%	DK adult	0.17	0.4%	Wheat	0.4%	Carrots	0.3%	Milk: Cattle		2%
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): ---

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)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
63%	Carrots	0.1/0.1	6.3	50%	Head cabbages	0.09/0.12	5.0
57%	Beetroots	0.1/0.1	5.7	34%	Swedes/rutabagas	0.1/0.1	3.4
55%	Celeriacs/turnip rooted	0.1/0.1	5.5	23%	Beetroots	0.1/0.1	2.3
53%	Head cabbages	0.09/0.12	5.3	20%	Carrots	0.1/0.1	2.0
52%	Swedes/rutabagas	0.1/0.1	5.2	14%	Parsnips	0.1/0.1	1.4
47%	Leeks	0.06/0.08	4.7	12%	Celeriacs/turnip rooted	0.1/0.1	1.2
40%	Cranberries	0.15/0.9	4.0	11%	Turnips	0.1/0.1	1.1
36%	Parsnips	0.1/0.1	3.6	11%	Salsifies	0.1/0.1	1.1
36%	Turnips	0.1/0.1	3.6	10%	Leeks	0.06/0.08	1.0
31%	Salsifies	0.1/0.1	3.1	10%	Parsley roots/Hamburg roots	0.1/0.1	1.0
23%	Cauliflowers	0.05/0.04	2.3	10%	Cranberries	0.15/0.9	1.0
19%	Bovine: Liver	0.5/0.23	1.9	10%	Broccoli	0.05/0.04	0.95
17%	Broccoli	0.05/0.04	1.7	9%	Cauliflowers	0.05/0.04	0.93
16%	Sweet corn	0.02/0.04	1.6	9%	Bovine: Liver	0.5/0.23	0.92
15%	Potatoes	0.02/0.01	1.5	8%	Brussels sprouts	0.1/0.14	0.84

Expand/collapse list

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): ---

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)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
66%	Sugar beets (root)/sugar	0.3/0.72	6.6	39%	Beetroots/boiled	0.1/0.1	3.9
51%	Turnips/boiled	0.1/0.1	5.1	26%	Sugar beets (root)/sugar	0.3/0.72	2.6
51%	Parsnips/boiled	0.1/0.1	5.1	21%	Parsnips/boiled	0.1/0.1	2.1
46%	Leeks/boiled	0.06/0.08	4.6	19%	Turnips/boiled	0.1/0.1	1.9
44%	Beetroots/boiled	0.1/0.1	4.4	18%	Celeriacs/boiled	0.1/0.1	1.8
32%	Broccoli/boiled	0.05/0.04	3.2	17%	Cauliflowers/boiled	0.05/0.04	1.7
29%	Carrots/juice	0.1/0.08	2.9	14%	Leeks/boiled	0.06/0.08	1.4
28%	Cauliflowers/boiled	0.05/0.04	2.8	10%	Broccoli/boiled	0.05/0.04	0.96
26%	Salsifies/boiled	0.1/0.1	2.6	8%	Salsifies/boiled	0.1/0.1	0.82
14%	Brussels sprouts/boiled	0.1/0.14	1.4	7%	Carrots/canned	0.1/0.08	0.65
12%	Celeriacs/juice	0.1/0.08	1.2	6%	Barley/beer	0.2/0.02	0.58
9%	Potatoes/fried	0.02/0.01	0.93	3%	Peas/canned	1/0.04	0.26
8%	Lentils/boiled	1/0.1	0.81	2%	Head cabbages/canned	0.09/0.02	0.19
7%	Peas/canned	1/0.04	0.71	2%	Wheat/bread/pizza	0.1/0.04	0.18
6%	Potatoes/dried (flakes)	0.02/0.05	0.59	2%	Potatoes/chips	0.02/0.02	0.17

Expand/collapse list

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.

- PRIMo Triazole alanine (TA)

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	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)
0.028%	NL child	0.08	0.03%	Sugar beet roots						0.0%
0.0%	NL toddler	0.05	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	DE women 14-50 yr	0.05	0.0%	Sugar beet roots	0.0%	Chicory roots				0.0%
0.0%	DE general	0.04	0.0%	Sugar beet roots	0.0%	Chicory roots				0.0%
0.0%	FR child 3 15 yr	0.04	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	UK toddler	0.03	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	NL general	0.03	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	FR toddler 2 3 yr	0.03	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G06	0.01	0.0%	Sugar beet roots	0.0%	Chicory roots				0.0%
0.0%	UK infant	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	FR infant	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	RO general	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	FR adult	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	UK adult	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	UK vegetarian	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G11	0.00	0.0%	Chicory roots		FRUIT AND TREE NUTS				0.0%
0.0%	ES child	0.00	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	ES adult	0.00	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G08	0.00	0.0%	Chicory roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots	0.0%	Sugar beet roots				0.0%
0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots	0.0%	Sugar beet roots				0.0%
0.0%	GEMS/Food G15	0.00	0.0%	Chicory roots		FRUIT AND TREE NUTS				0.0%
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			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): ---

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)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
				0.00%	Chicory roots	0/0.02	0.01

Expand/collapse list

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): ---

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)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Sugar beets (root)/sugar	0/0.12	1.1	0.1%	Sugar beets (root)/sugar	0/0.12	0.44
0.0%	Chicory roots/processed (no	0/0.01	0.01	0.00%	Chicory roots/processed	0/0.01	0.00

Expand/collapse list

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.

- PRIMo Triazole lactic acid (TLA)

efsa 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 : ---

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)
0.028%	NL child	0.08	0.03%	Sugar beet roots						0.0%
0.0%	NL toddler	0.05	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	DE women 14-50 yr	0.05	0.0%	Sugar beet roots	0.0%	Chicory roots				0.0%
0.0%	DE general	0.04	0.0%	Sugar beet roots	0.0%	Chicory roots				0.0%
0.0%	FR child 3 15 yr	0.04	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	UK toddler	0.03	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	NL general	0.03	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	FR toddler 2 3 yr	0.03	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G06	0.01	0.0%	Sugar beet roots	0.0%	Chicory roots				0.0%
0.0%	UK infant	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	FR infant	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	RO general	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	FR adult	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	UK adult	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	UK vegetarian	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G11	0.00	0.0%	Chicory roots		FRUIT AND TREE NUTS				0.0%
0.0%	ES child	0.00	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	ES adult	0.00	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G08	0.00	0.0%	Chicory roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots	0.0%	Sugar beet roots				0.0%
0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots	0.0%	Sugar beet roots				0.0%
0.0%	GEMS/Food G15	0.00	0.0%	Chicory roots		FRUIT AND TREE NUTS				0.0%
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			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):	---			**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
				0.0013%	Chicory roots	0/0.01	0.00
Expand/collapse list							
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):	---			**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):	---		
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.367%	Sugar beets (root)/sugar	0/0.12	1.1	0.1%	Sugar beets (root)/sugar	0/0.12	0.44
0.002%	Chicory roots/processed (not	0/0.01	0.01	0.00%	Chicory roots/processed	0/0.01	0.00
Expand/collapse list							

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.

- PRIMo Triazole acetic acid (TAA)

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

Triazole acetic acid (TAA)

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

Toxicological reference values

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

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

Comments:

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	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)
0.008%	NL child	0.08	0.01%	Sugar beet roots						0.0%
0.0%	NL toddler	0.05	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	DE women 14-50 yr	0.05	0.0%	Sugar beet roots	0.0%	Chicory roots				0.0%
0.0%	DE general	0.04	0.0%	Sugar beet roots	0.0%	Chicory roots				0.0%
0.0%	FR child 3 15 yr	0.04	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	UK toddler	0.03	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	NL general	0.03	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	FR toddler 2 3 yr	0.03	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G06	0.01	0.0%	Sugar beet roots	0.0%	Chicory roots				0.0%
0.0%	UK infant	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	FR infant	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	RO general	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	FR adult	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	UK adult	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	UK vegetarian	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G11	0.00	0.0%	Chicory roots		FRUIT AND TREE NUTS				0.0%
0.0%	ES child	0.00	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	ES adult	0.00	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G08	0.00	0.0%	Chicory roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots	0.0%	Sugar beet roots				0.0%
0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots	0.0%	Sugar beet roots				0.0%
0.0%	GEMS/Food G15	0.00	0.0%	Chicory roots		FRUIT AND TREE NUTS				0.0%
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			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):			---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (μg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (μg/kg bw)
				0.00038%	Chicory roots	0/0.01	0.00
Expand/collapse list							
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):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (μg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (μg/kg bw)
0.1%	Sugar beets (root)/sugar	0/0.12	1.1	0.0%	Sugar beets (root)/sugar	0/0.12	0.44
0.0%	Chicory roots/processed (no	0/0.01	0.01	0.00%	Chicory roots/processed	0/0.01	0.00
Expand/collapse list							

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

- PRIMo 1-2-3 triazole

efsa 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 : ---

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

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)
0.3671%	NL child	0.08	0.3671%	Sugar beet roots						0.4%
0.2%	NL toddler	0.05	0.2%	Sugar beet roots		FRUIT AND TREE NUTS				0.2%
0.2%	DE women 14-50 yr	0.05	0.2%	Sugar beet roots	0.0%	Chicory roots				0.2%
0.2%	DE general	0.04	0.2%	Sugar beet roots	0.0%	Chicory roots				0.2%
0.2%	FR child 3 15 yr	0.04	0.2%	Sugar beet roots		FRUIT AND TREE NUTS				0.2%
0.1%	UK toddler	0.03	0.1%	Sugar beet roots		FRUIT AND TREE NUTS				0.1%
0.1%	NL general	0.03	0.1%	Sugar beet roots		FRUIT AND TREE NUTS				0.1%
0.1%	FR toddler 2 3 yr	0.03	0.1%	Sugar beet roots		FRUIT AND TREE NUTS				0.1%
0.1%	GEMS/Food G06	0.01	0.1%	Sugar beet roots	0.0%	Chicory roots				0.1%
0.1%	UK infant	0.01	0.1%	Sugar beet roots		FRUIT AND TREE NUTS				0.1%
0.1%	FR infant	0.01	0.1%	Sugar beet roots		FRUIT AND TREE NUTS				0.1%
0.1%	RO general	0.01	0.1%	Sugar beet roots		FRUIT AND TREE NUTS				0.1%
0.0%	FR adult	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	UK adult	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	UK vegetarian	0.01	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G11	0.00	0.0%	Chicory roots		FRUIT AND TREE NUTS				0.0%
0.0%	ES child	0.00	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	ES adult	0.00	0.0%	Sugar beet roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G08	0.00	0.0%	Chicory roots		FRUIT AND TREE NUTS				0.0%
0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots	0.0%	Sugar beet roots				0.0%
0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots	0.0%	Sugar beet roots				0.0%
0.0%	GEMS/Food G15	0.00	0.0%	Chicory roots		FRUIT AND TREE NUTS				0.0%
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DE child			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)

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)
0.00%	Chicory roots	0/0.01	0.00

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)
1%	Sugar beets (root)/sugar	0/0.12	1.1
0.0%	Chicory roots/processed (not	0/0.01	0.01

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%	Sugar beets (root)/sugar	0/0.12	0.44
0.00%	Chicory roots/processed	0/0.01	0.00

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

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

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: 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)				
Barley straw	1.96	STMR (FAO, 2009c) × CF (3) (EFSA, 2014)	7.5	HR[(d)] × CF (3) (EFSA, 2014)
Beet sugar, tops	**0.82**	STMR proposed	**1.5**	HR proposed
Cabbage, heads leaves	0.02	STMR × CF (2) (EFSA, 2014)	0.12	HR × CF(2) (EFSA, 2014)
Corn, field forage/ silage	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Oat straw	1.26	STMR[(d)] × CF (3) (EFSA, 2014)	7.5	HR[(d)] × CF (3) (EFSA, 2014)
Rye straw	2.25	STMR[(d)] × CF (3) (EFSA, 2014)	5.52	HR[(d)] × CF (3) (EFSA, 2014)
Wheat straw	2.69	STMR[(d)] × CF (3) (EFSA, 2014)	5.52	HR[(d)] × CF (3) (EFSA, 2014)
Carrot culls	0.08	STMR (EFSA, 2020)	0.1	HR (EFSA, 2020)
Potato culls	0.01	STMR (EFSA, 2014)	0.01	STMR (EFSA, 2014)
Swede roots	0.08	STMR (EFSA, 2020)	0.1	HR (EFSA, 2020)
Turnip roots	0.08	STMR (EFSA, 2020)	0.1	HR (EFSA, 2020)
Barley grain	0.07	STMR (FAO, 2009c) × CF (2) (EFSA, 2014)	0.07	STMR (FAO, 2009c) × CF (2) (EFSA, 2014)
Bean seed (dry)	0.02	STMR × CF (2) (EFSA, 2014)	0.02	STMR × CF (2) (EFSA, 2014)
Corn, field (Maize) grain	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Corn, pop grain	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Cotton undelinted seed	0.1	STMR (FAO, 2018) × CF (2) (EFSA, 2020)	0.1	STMR (FAO, 2018) × CF (2) (EFSA, 2020)
Lupin seed	0.1	STMR (FAO, 2009c) × CF (2) (EFSA, 2020)	0.1	STMR (FAO, 2009c) × CF (2) (EFSA, 2020)
Oat grain	0.02	STMR (FAO, 2009a) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2009a) × CF (2) (EFSA, 2014)
Pea (Field pea) seed (dry)	0.1	STMR (FAO, 2009c) × CF (2)	0.1	STMR (FAO, 2009c) × CF (2)
Rye grain	0.02	STMR (FAO, 2009a) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2009a) × CF (2) (EFSA, 2014)
Soybean seed	0.10	STMR (FAO, 2014) × CF (2)	0.10	STMR (FAO, 2014) × CF (2)
Wheat grain	0.04	STMR (FAO, 2009c) × CF (2) (EFSA, 2014)	0.04	STMR (FAO, 2009c) × CF (2) (EFSA, 2014)
Beet sugar, ensiled pulp	**1.08**	STMR × PF(18) proposed	**1.08**	STMR × PF(18) proposed
Beet sugar, molasses	**0.18**	STMR × PF(3) proposed	**0.18**	STMR × PF(3) proposed
Brewer's grain dried	0.23	STMR (FAO, 2009c) × CF (2) (EFSA, 2014) × PF (3.3)[(a)] (EFSA, 2020)	0.23	STMR (FAO, 2009c) × CF (2) (EFSA, 2014) × PF (3.3)[(a)] (EFSA, 2020)
Canola (Rape seed) meal	0.16	STMR × PF (2)[(a)] (EFSA, 2020)	0.16	STMR × PF (2)[(a)] (EFSA, 2020)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Corn, field milled by-pdts[(b)]	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Corn, field hominy meal[(b)]	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Corn, field gluten feed[(b)]	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Corn, field gluten, meal[(b)]	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Cotton meal	0.14	STMR (FAO, 2018) × CF (2) × PF (1.3)[(a)] STMR × PF (2)[(a)] (EFSA, 2020)	0.14	STMR (FAO, 2018) × CF (2) × PF (1.3)[(a)] STMR × PF (2)[(a)] (EFSA, 2020)
Distiller's grain dried[(b)]	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Flaxseed/Linseed meal	0.12	STMR × CF (2) × PF (2)[(a)] (EFSA, 2015a, 2015b)	0.12	STMR × CF (2) × PF (2)[(a)] (EFSA, 2015a, 2015b)
Lupin seed meal	0.11	STMR (FAO, 2009c) × CF (2) × PF (1.1)[(a)]	0.11	STMR (FAO, 2009c) × CF (2) × PF (1.1)[(a)]
Peanut meal	0.04	STMR (FAO, 2009c) × CF (2) × PF (2)	0.04	STMR (FAO, 2009c) × CF (2) × PF (2)
Potato process waste	0.01	STMR potato (EFSA, 2014) × PF (1)[(c)]	0.01	HR potato (EFSA, 2014) × PF (1)[(c)]
Potato dried pulp	0.01	STMR potato (EFSA, 2014) × PF (1)[(c)]	0.01	HR potato (EFSA, 2014) × PF (1)[(c)]
Rape meal	0.16	STMR × PF (2)[(a)] (EFSA, 2020)	0.16	STMR × PF (2)[(a)] (EFSA, 2020)
Soybean meal	0.13	STMR (FAO, 2014) × CF (2) × PF (1.3)[(a)]	0.13	STMR (FAO, 2014) × CF (2) × PF (1.3)[(a)]
Soybean hulls	1.3	STMR (FAO, 2014) × CF (2) × PF (13)[(a)]	1.3	STMR (FAO, 2014) × CF (2) × PF (13)[(a)]
Sunflower meal	0.04	STMR × CF (2) × PF (2)[(a)] (EFSA, 2015a,b)	0.04	STMR × CF (2) × PF (2)[(a)] (EFSA, 2015a,b)
Wheat gluten meal	0.07	STMR wheat grain (FAO, 2009c) × CF (2) × PF (1.8)[(a)] (EFSA, 2020)	0.07	STMR wheat grain (FAO, 2009c) × CF (2) × PF (1.8)[(a)] (EFSA, 2020)
Wheat milled by-pdts	0.28	STMR wheat grain (FAO, 2009c) × CF (2) × PF (7)[(a)] (EFSA, 2020)	0.28	STMR wheat grain (FAO, 2009c) × CF (2) × PF (1.8)[(a)] (EFSA, 2020)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor for enforcement to risk assessment residue definition.

(a): For rape seed meal/sunflower seed meal, sugar beet molasses, brewer's grain, wheat gluten meal, wheat milled by-products, cotton seed meal, lupin seed meal, soybean meal, lupin seed meal, soybean hulls and sugar beet ensiled pulp in the absence of processing factors supported by data, default processing factors of 2, 3, 3.3, 1.8, 7, 1.3, 1.1, 1.3, 13 and 18, respectively, were included in the calculation to consider the potential concentration of residues in these commodities.

(b): New commodities (OECD methodology), not considered in MRL review.

(c): Default processing factors were not applied because prothioconazole and its metabolites were below LOQ both in maize and potatoes, indicating no-residue situation. Thus, concentration of residues in these commodities is therefore not expected.

(d): The STMR and HR values derived by the JMPR (FAO, 2009a,c) are lower than the values derived for cereals straws for the authorised EU uses reported in the MRL review.

D.2. Consumer risk assessment

Commodity	Existing/ proposed MRL[(a)]	Source/type of MRL	Chronic risk assessment[(1),(b)] Input value (mg/kg)	Chronic risk assessment[(1),(b)] Comment	Acute risk assessment[(1),(b)] Input value (mg/kg)	Acute risk assessment[(1),(b)] 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)						
Sugar beet roots	**0.03**	**Proposed**	0.06	STMR-RAC	0.069	HR-RAC
Chicory roots	**0.03**	**Proposed**	0.06	STMR-RAC	0.069	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
Garlic	0.02	Proposed (EFSA, 2023)	0.01	STMR-RAC	0.012	HR-RAC
Onions	0.02	Proposed (EFSA, 2023)	0.01	STMR-RAC	0.012	HR-RAC
Shallots	0.02	Proposed (EFSA, 2023)	0.01	STMR-RAC	0.012	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, 2009c	0.1	STMR[(a)]-RAC*CF(2)	0.1	STMR[(a)]-RAC*CF(2)
Peas	1	EFSA, 2014/ FAO, 2009c	0.1	STMR[(a)]-RAC*CF(2)	0.1	STMR[(a)]-RAC*CF
Lupins/lupini beans	1	EFSA, 2014/ FAO, 2009c	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, 2015b	0.02	STMR-RAC*CF(2)	0.02	STMR-RAC*CF(2)

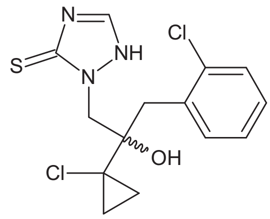
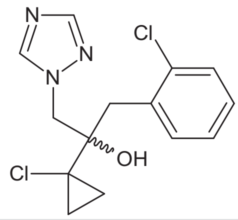
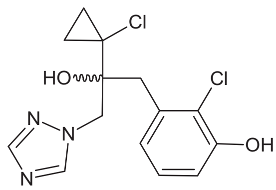
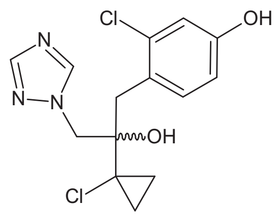
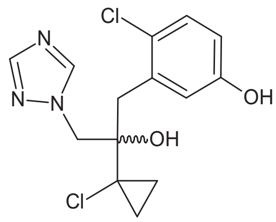
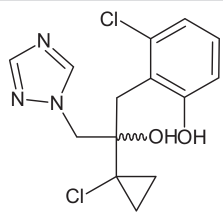
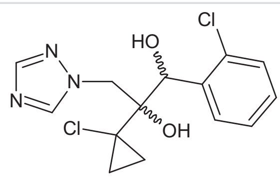
Commodity	Existing/ proposed MRL[(a)]	Source/type of MRL	Chronic risk assessment[(1),(b)]		Acute risk assessment[(1),(b)]	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rapeseeds/ canola seeds	0.2	EFSA, 2020 proposed	0.08	STMR-RAC	0.08	STMR-RAC
Soyabeans	0.2	FAO, 2014	0.1	STMR-RAC*CF(2)	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, 2009c	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, 2009c	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),(c)]-RAC	0.01	HR[(b),(c)]-RAC
Swine: Fat tissue	0.02	FAO, 2018	0.01	STMR[(b)]-RAC	0.018	HR[(b)]-RAC
Swine: Liver	0.5	FAO, 2009c	0.05	STMR[(b)]-RAC	0.23	HR[(b)]-RAC
Swine: Kidney	0.5	FAO, 2009c	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Swine: Edible offals (other than liver and kidney)	0.5	FAO, 2009c	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Bovine: Muscle/ meat	0.01	FAO, 2018	0.01	STMR[(b),(c)]-RAC	0.01	HR[(b),(c)]-RAC
Bovine: Fat tissue	0.02	FAO, 2018	0.01	STMR[(b)]-RAC	0.018	HR[(b)]-RAC
Bovine: Liver	0.5	FAO, 2009c	0.05	STMR[(b)]-RAC	0.23	HR[(b)]-RAC
Bovine: Kidney	0.5	FAO, 2009c	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Bovine: Edible offals (other than liver and kidney)	0.5	FAO, 2009c	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Sheep: Muscle/ meat	0.01	FAO, 2018	0.01	STMR[(b),(c)]-RAC	0.01	HR[(b),(c)]-RAC
Sheep: Fat tissue	0.02	FAO, 2018	0.01	STMR[(b)]-RAC	0.018	HR[(b)]-RAC
Sheep: Liver	0.5	FAO, 2009c	0.05	STMR[(b)]-RAC	0.23	HR[(b)]-RAC
Sheep: Kidney	0.5	FAO, 2009c	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Sheep: Edible offals (other than liver and kidney)	0.5	FAO, 2009c	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Goat: Muscle/ meat	0.01	FAO, 2018	0.01	STMR[(b),(c)]-RAC	0.01	HR[(b),(c)]-RAC
Goat: Fat tissue	0.02	FAO, 2018	0.01	STMR[(b)]-RAC	0.018	HR[(b)]-RAC
Goat: Liver	0.5	FAO, 2009c	0.05	STMR[(b)]-RAC	0.23	HR[(b)]-RAC
Goat: Kidney	0.5	FAO, 2009c	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Goat: Edible offals (other than liver and kidney)	0.5	FAO, 2009c	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC

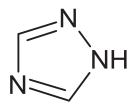
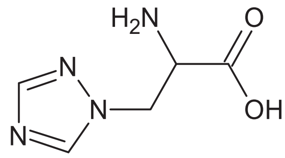
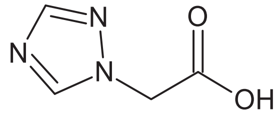
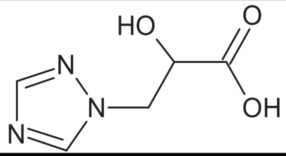
Commodity	Existing/ proposed MRL[(a)]	Source/type of MRL	Chronic risk assessment[(1),(b)]		Acute risk assessment[(1),(b)]	
			Input value (mg/ kg)	Comment	Input value (mg/ kg)	Comment
Equine: Muscle/ meat	0.01	FAO, 2018	0.01	STMR[(b),(c)]-RAC	0.01	HR[(b),(c)]-RAC
Equine: Fat tissue	0.02	FAO, 2018	0.01	STMR[(b)]-RAC	0.018	HR[(b)]-RAC
Equine: Liver	0.5	FAO, 2009c	0.05	STMR[(b)]-RAC	0.23	HR[(b)]-RAC
Equine: Kidney	0.5	FAO, 2009c	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Equine: Edible offals (other than liver and kidney)	0.5	FAO, 2009c	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Poultry: Muscle/ meat	0.01	FAO, 2018	0.0016	STMR[(b),(c)]-RAC	0.0016	HR[(b),(c)]-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),(c)]-RAC	0.01	HR[(b),(c)]-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, 2009c	0.05	STMR[(b)]-RAC	0.23	HR[(b)]-RAC
Other farmed animals: Kidney	0.5	FAO, 2009c	0.025	STMR[(b)]-RAC	0.15	HR[(b)]-RAC
Other farmed animals: Edible offals (other than liver and kidney)	0.5	FAO, 2009c	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

Commodity	Existing/ proposed MRL[(a)]	Source/type of MRL	Chronic risk assessment[(1),(b)]		Acute risk assessment[(1),(b)]	
			Input value (mg/ kg)	Comment	Input value (mg/ kg)	Comment
Risk assessment residue definition: Triazole alanine (TA)						
Sugar beet roots	–	**proposed**	0.01	STMR-RAC	0.024	HR-RAC
Chicory roots	–	**proposed**	0.01	STMR-RAC	0.024	HR-RAC
Risk assessment residue definition: Triazole lactic acid (TLA)						
Sugar beet roots	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Chicory roots	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Risk assessment residue definition: Triazole acetic acid (TAA)						
Sugar beet roots	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Chicory roots	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Risk assessment residue definition: 1,2,4-triazole (1,2,4-T)						
Sugar beet roots	–	**proposed**	0.01*	STMR-RAC	0.01*	HR-RAC
Chicory roots	–	**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.
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).
(c): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticides, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).

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	

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

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 07 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).