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Evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for prothioconazole in celeriacs and rapeseeds

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicants Bayer SAS Crop Science and the Agriculture and Horticulture Development Board submitted two requests to the competent national authority in the United Kingdom to modify the existing maximum residue levels (MRLs) for prothioconazole in rapeseeds and celeriacs, respectively. The data submitted in support of the requests were found to be sufficient to derive MRL proposals for these crops. The applicant Bayer SAS Crop Science additionally submitted a request to the competent national authority in the United Kingdom to evaluate the confirmatory data identified in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gaps, residue trials on carrots, onions, rapeseeds and wheat, and storage stability studies were submitted. The data gaps are considered fully addressed for the root and tuber vegetables, the oilseeds concerned and wheat. The data gaps have been partially addressed for onions, shallots, flowering brassica, Brussels sprouts, head cabbages, leeks, rye, barely and oat. The data gaps were not addressed for pulses and grass. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the existing and intended uses of prothioconazole according to the reported agricultural practices is unlikely to present a risk to consumer health. For the triazole derivative metabolites (TDMs), only an indicative exposure assessment was performed considering celeriacs and rapeseeds; the results showed that the expected exposure to TDMs in these commodities is well below the toxicological reference values derived for the TDMs.

Keywords: Prothioconazole, Celeriacs, Rapeseeds, confirmatory data, pesticide, MRL, consumer risk assessment

Requestor: European Commission

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Summary

In 2014, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for prothioconazole according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) Fully validated analytical methods for the determination of prothioconazole-desthio in eggs
2) at least four residue trials complying with the northern outdoor GAP on grass (in view of deriving robust MRL values in commodities of animal origin)
3) storage stability data for at least one hydroxylated metabolite included in the risk assessment residue definition for plants are required in the relevant crop categories
4) clarification on whether the conjugates of M14, M15, M16, M17 and M18 metabolites were effectively analysed in the residue trials conducted on rape seed
5) sufficient residue trials analysing the residues in compliance with the proposed residue definition for risk assessment in plant commodities (except for the uses on maize and potatoes by seed treatment)
6) a ruminant feeding study to estimate the potential exposure to all the prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 2016/71, including footnotes implementing the data gaps number (2), (3) and (5) as confirmatory data requirements. Data gaps number (1), (4) and (6) were not implemented in the MRL regulation. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 27 January 2018.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, Bayer SAS Crop Science submitted an application to the competent national authority in United Kingdom (rapporteur Member State, RMS) to evaluate the submitted confirmatory data.

Together with the confirmatory data, Bayer SAS Crop Science also submitted in accordance with Article 6 of Regulation (EC) No 396/2005, an application to modify the existing MRLs for prothioconazole in rapeseeds. The EMS produced a single evaluation report, which was submitted to the European Commission and forwarded to EFSA on 24 May 2019.

Subsequently, a third application was submitted to the EMS by the Agriculture & Horticulture Development Board (AHDB) in order to modify the existing MRLs for prothioconazole in celeriacs. A second evaluation report was therefore drafted by the United Kingdom which was submitted to the European Commission and forwarded to EFSA on 20 June 2019.

Based on the intended southern Europe (SEU) use on oilseed rape the EMS, in contrast with the applicant, concluded that no modification of the existing EU MRL of 0.15 mg/kg is necessary. For the intended northern Europe (NEU) use of prothioconazole on celeriacs, the EMS proposed to raise the existing EU MRL from 0.01 mg/kg (limit of quantification (LOQ)) to 0.1 mg/kg.

EFSA assessed the applications and the evaluation reports as required by Articles 9 and 10 of the MRL regulation and in accordance with the procedure set out in the working document SANTE/10235/2016.

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 was investigated by foliar applications on root, pulses/oilseeds and cereal/grass crop groups and by seed treatment on cereals (spring wheat). The metabolic pattern of prothioconazole was shown to be similar 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 the main triazole derivative metabolites (TDMs) were identified.

Studies investigating the effect of processing on the nature of prothioconazole-desthio (hydrolysis studies) and 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, and TDMs.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed as 'prothioconazole-desthio (sum of isomers)' for enforcement and, as follows, for the risk assessment:

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

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

EFSA concluded that for the crops assessed in these applications, the derived residue definitions are applicable. Sufficiently validated enforcement methods 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 0.1 mg/kg for prothioconazole- in celeriacs and of 0.2 mg/kg in rapeseeds.

The storage stability studies submitted are sufficient to address the confirmatory data gap number 3, as identified by the MRL review for all crops, except pulses.

The submitted residue data on carrots, rapeseeds and wheat were sufficient to fully address the data gaps for the root and tuber vegetables (except sugar beet), the oilseeds concerned and wheat. Since the data gaps have been partially addressed for onions, shallots, flowering brassica, Brussels sprouts, head cabbages, leeks, rye, barley and oat and not addressed for pulses, further risk management consideration is required.

Specific studies investigating the magnitude of prothioconazole-desthio, its hydroxy metabolites and TDMs residues in processed commodities have not been submitted and are not necessary, considering that the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI for the individual crops under assessment.

Based on the available information on the nature and magnitude of residues in rotational crops, the peer review concluded that significant residue levels of prothioconazole-desthio and its hydroxy metabolites are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed Good Agricultural Practice (GAP). Since the possible occurrence of TDMs in rotational crops cannot be excluded based on the data available, their occurrence in rotational crops has to be further investigated, taking into account not only the uses of prothioconazole but all triazole fungicides. This information is required to perform a comprehensive risk assessment that covers all sources of triazole related metabolites.

EFSA calculated the livestock dietary burden considering the new residue data submitted on rapeseeds, wheat and carrots (extrapolated to swedes and turnips) as well as taking into account residues in all crops that can be potentially fed to livestock and for which the existing EU MRLs are set above the LOQ.

The calculated livestock dietary burdens exceeded the trigger value 0.1 mg/kg dry matter (DM) for all relevant animal species. The contribution of prothioconazole-desthio residues in rapeseeds to the total livestock exposure was insignificant and therefore a modification of the existing MRLs for commodities of animal origin was considered unnecessary. Since the applicant did not provide residue trials on grass, as requested according to data gap number 2, the calculated livestock dietary burdens do not take into consideration the potential contribution of residue intake from grass. The relevance of this information shall be considered by risk managers, given the fact that the existing EU MRLs for commodities of animal origin are based on Codex maximum residue limits (CXLs), which are derived for significantly higher livestock dietary burdens.

The toxicological profile of prothioconazole and prothioconazole-desthio was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.01 mg/kg bw. The peer review assumed that the metabolites included in the risk assessment residue definition are covered by the toxicological reference values of prothioconazole-desthio. The consumer exposure was calculated considering the existing EU MRLs for prothioconazole-desthio which are set above the LOQ on the basis of EU assessments or taken over as the CXLs from the JMPR assessments. The crops for which no uses were reported in the framework of the MRL review were excluded from the calculation.

No long-term consumer intake concerns were identified for any of the diets included in the EFSA Pesticides Residues Intake Model (PRIMo), as the estimated maximum long-term dietary intake

accounted for 7% of the ADI (WHO Cluster diet B). The individual contribution of residues in celeriacs and rapeseeds were below 1% of the ADI.

The short-term exposure did not exceed the ARfD for any of the crops under consideration, with maximum individual acute exposure being 63% of the ARfD for carrots and head cabbage, 55% of the ARfD for celeriacs, 52% of the ARfD for swedes, 47% of the ARfD for leek, 44% of the ARfD for beetroot and was individually below 40% of the ARfD for other commodities.

EFSA concluded that the proposed use of prothioconazole on celeriac and on oilseed rape and the existing authorised uses of prothioconazole will not result in a consumer exposure exceeding the toxicological reference values for prothioconazole-desthio and therefore is unlikely to pose a risk to consumers' health.

An indicative exposure assessment was performed for the TDMs that showed that the expected exposure resulting from celeriacs and rapeseeds is well below the toxicological reference values derived for the TDMs. A comprehensive risk assessment, including all crops and all pesticides belonging to the class of triazole fungicides has not yet been performed. EFSA recommended elaborating with risk managers a strategy to ensure that the required data are made available to finalise the overall risk assessment for triazole fungicides that are expected to contribute to the dietary exposure.

The peer review for the renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 is ongoing and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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.3–D.1

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)]				
0213010	Beetroots	0.1 (ft 1)	0.1	The data gaps identified in the MRL review concerning residue trials and storage stability have been addressed. The MRL is confirmed. Risk for consumers unlikely
0213020	Carrots			
0213030	Celeriacs/turnip rooted celeries	0.01*	0.1	The submitted data are sufficient to support the intended NEU use. Risk for consumers unlikely
0213040	Horseradishes	0.1 (ft 1)	0.1	The data gaps identified in the MRL review concerning residue trials and storage stability have been addressed. The MRL is confirmed. Risk for consumers unlikely
0213060	Parsnips	0.1 (ft 1)	0.1	
0213070	Parsley roots/ hamburg roots parsley	0.1 (ft 1)	0.1	
0213090	Salsifies	0.1 (ft 1)	0.1	
0213100	Swedes/rutabagas	0.1 (ft 1)	0.1	
0213110	Turnips	0.1 (ft 1)	0.1	
0220020	Onions	0.05 (ft 1)	Further risk management considerations required	The data gap identified in the MRL review concerning residue trials is not addressed, whereas the data gap concerning storage stability has been addressedSince the data gap is not fully addressed, risk managers may consider the lowering of the existing MRL to the LOQ of 0.02 mg/kg
0220030	Shallots	0.05 (ft 2)		
024100	Flowering brassica	0.05 (ft 3)	Further risk management considerations required	The data gap identified in the MRL review concerning residue trials is not addressed, whereas the data gap concerning storage stability has been addressedSince the data gaps are not fully addressed, risk managers may consider the lowering of the existing MRL to the LOQ of 0.02 mg/kg
0242010	Brussels sprouts	0.1 (ft 3)		
0242020	Head cabbages	0.09 (ft 3)		
0270060	Leeks	0.06 (ft 3)		

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0300010	Beans	0.05 (ft 3)	Further risk management considerations required	The data gaps identified by EFSA concerning residue trials and storage stability have not been addressedSince data gaps are not addressed, risk managers may consider lowering of the existing MRL to the LOQ of 0.02 mg/kg
0300020	Lentils	1 (ft 3)		The existing EU MRL reflects CXL MRLThe data gaps identified by EFSA concerning residue trials and storage stability have not been addressedSince data gaps are not addressed, risk managers may consider lowering of the existing MRL to the LOQ of 0.02 mg/kg
0300030	Peas	1 (ft 3)		
0300040	Lupins/lupini beans	1 (ft 3)		
0401010	Linseeds	0.09 (ft 3)	0.09	The data gaps identified in the MRL review concerning residue trials and storage stability have been addressed The MRL is confirmed. Risk for consumers unlikely
0401020	Peanuts/ groundnuts	0.02* (ft 3)	0.02*	The existing EU MRL reflects the CXL MRL. The data gap identified by EFSA concerning storage stability has been addressed. The data gap concerning residue trials is considered addressed since for oilseeds a reliable conversion factor of 2 from enforcement to risk assessment is derived from submitted residue trials on oilseed rape. The MRL is confirmed. Risk for consumers unlikely
0401030	Poppy seeds	0.09 (ft 3)	0.09	The data gaps identified by EFSA concerning residue trials and storage stability have been addressed. The MRL is confirmed. Risk for consumers unlikely
0401060	Rapeseeds/canola seeds	0.15 (ft 3)	0.2	The data gaps identified by EFSA concerning residue trials and storage stability have been addressed. The additional residue trials submitted in support of the intended SEU use indicated that a higher MRL would be required. Risk for consumers unlikely
0401080	Mustard seeds	0.09 (ft 3)	0.09	The data gaps identified by EFSA concerning residue trials and storage stability have been addressed. The MRL is confirmed. Risk for consumers unlikely
0401130	Gold of pleasure seeds	0.04 (ft 3)	0.04	The data gap identified by EFSA concerning storage stability has been addressedThe data gap concerning residue trials is considered addressed since for oilseeds a reliable conversion factor of 2 from enforcement to risk assessment is derived from submitted residue trials on oilseed rapeThe MRL is confirmed. Risk for consumers unlikely
0500010	Barley	0.2 (ft 3)	Further risk management considerations required	The existing EU MRL reflects CXL MRLThe data gap identified by EFSA concerning residue trials is not addressed. The data gap identified by EFSA concerning storage stability has been addressedSince the data gaps are not fully addressed, risk managers may consider lowering of the existing MRL to the LOQ of 0.02 mg/kg
0500050	Oat	0.05 (ft 3)		
0500070	Rye	0.05 (ft 3)	0.05	The existing EU MRL reflects CXL MRLThe data gap identified by EFSA concerning residue trials for NEU use is not addressed. The data gap identified by EFSA concerning storage stability has been addressedSince the data gaps are not fully addressed, risk managers may consider lowering of the existing MRL to the LOQ of 0.02 mg/kg

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0500090	Wheat	0.1 (ft 3)	0.1	The existing EU MRL reflects CXL MRLFor the authorised SEU use the data gaps identified by EFSA concerning residue trials and storage stability has been addressed. The tentative MRL of 0.02* mg/kg as derived by MRL review is confirmed. Risk for consumers unlikely
1011030	Swine liver	0.5 (ft 4)	Further risk management considerations required	The residue trials on grass (major component of livestock dietary burden) have not been submitted and thus the EU livestock dietary burden from existing EU uses including grass cannot be properly calculatedThe relevance of this data gap shall be considered by risk managers, given the fact that the existing EU MRLs for commodities of animal origin are based on CXLs (in 2018 lowered to 0.3 mg/kg), which are derived for significantly higher livestock dietary burdens
1011040	Swine kidney			
1011050	Swine edible offals			
1012030	Bovine liver			
1012040	Bovine kidney			
1012050	Bovine edible offals			
1012030	Sheep liver			
1012040	Sheep kidney			
1012050	Sheep edible offals			
1014030	Goat liver			
1014040	Goat kidney			
1014050	Goat edible offals			
1015030	Equine liver			
1015040	Equine kidney			
1015050	Equine edible offals			
1017030	Other farmed terrestrial animals liver			
1017040	Other farmed terrestrial animals kidney			
1017050	Other farmed terrestrial animals edible offals			
1020000	Milk	0.01* (ft 4)		

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; CXL: codex maximum residue limit.
*: 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.
ft 1: The European Food Safety Authority identified some information on residue trials and storage stability data complying with the proposed residue definition as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gaps No 3 and 5).
ft 2: The European Food Safety Authority identified some information on analytical methods and storage stability data complying with the proposed residue definition as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 3).
ft 3: The European Food Safety Authority identified some information on residue trials and storage stability data complying with the proposed residue definition as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gaps No 3 and 5).
ft 4: The European Food Safety Authority identified some information on residue trials on grass (major component of the livestock dietary burden), as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 2).

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Assessment

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 first 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 outdoor foliar applications on cereals and rape seeds. The draft assessment report (DAR) prepared by the RMS was peer reviewed by EFSA (2007b). Prothioconazole was approved for the use as a fungicide on August 2008.[2] The process of renewal of the first approval is currently on going.

The EU MRLs for prothioconazole are established in Annex II No 396/2005[3]. Following the approval of prothioconazole, the existing MRLs were assessed according to Article 12 of Regulation (EC) No 396/2005 by EFSA (2014) and amended by Commission Regulation (EU) No 2016/71[4]. Footnotes were included for certain tentative MRLs for which some information was identified as missing. Any party having an interest in maintaining these MRLs was requested to submit the respective confirmatory data by 27 January 2018.

After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for prothioconazole (EFSA, 2015a,b). The proposals from these reasoned opinions have been considered in recent regulations for EU MRL legislation.[5] Certain Codex maximum residue limits (CXLs) for prothioconazole were also implemented in EU MRL legislation.

With respect to the requested confirmatory data, the applicant, Bayer SAS Crop Sciences, submitted information on storage stability data and further residue trials to the competent national authority in the United Kingdom (designated rapporteur Member State, RMS) on 18 January 2018. The applicant did not provide further information on the data gap identified for residue trials on grass in view of deriving robust MRL values in commodities of animal origin.

Under the same application and in accordance with Article 6 of Regulation (EC) No 396/2005 Bayer SAS Crop Science also submitted an application to modify the existing MRLs for prothioconazole in rapeseeds. The EMS produced a single evaluation report, which was submitted to the European Commission and forwarded to EFSA on 24 May 2019.

A third application was submitted to the EMS by the Agriculture & Horticulture Development Board (AHDB) in order to modify the existing MRLs for prothioconazole in celeriacs. A second evaluation report was drafted by the United Kingdom which was submitted to the European Commission and forwarded to EFSA on 20 June 2019.

EFSA assessed the applications and the evaluation reports as required by Article 9 and 10 of the MRL regulation and in accordance with the procedure set out in the working document SANTE/10235/2016 (European Commission, 2016).

EFSA based its assessment on the evaluation reports submitted by the EMS (United Kingdom, 2019a, b), the DAR and its addendum prepared under Directive 91/414/EEC (United Kingdom, 2004, 2007), the conclusions from the peer review of the pesticide risk assessment of the active substance prothioconazole (EFSA, 2007b), the European Commission review report on prothioconazole (European Commission, 2007) as well as the conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites (TDMs) in light of confirmatory data submitted (EFSA, 2018b). Furthermore, EFSA considered for its assessment the evaluations of the JMPR on prothioconazole (FAO, 2009a,b, 2014, 2018) as well as conclusions from previous EFSA opinions on prothioconazole (EFSA, 2015a,b, 2018a) including the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014).

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

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

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

[4] Commission Regulation (EU) 2016/71 of 26 January 2016 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1-methylcyclopropene, flonicamid, flutriafol, indolylacetic acid, indolylbutyric acid, pethoxamid, pirimicarb, prothioconazole and teflubenzuron in or on certain product.

[5] For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN

For this application, the data requirements established in Regulation (EU) No 544/2011[6] and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 2016/71 and the guidance documents applicable at the date of submission of the application to the RMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[7].

A detailed description of the good agricultural practices (GAPs) for the uses of prothioconazole based on which tentative MRLs were derived in the framework of the MRL review and the new, intended GAPs, which are relevant for the current MRL applications, are listed in Appendix A.

An updated list of end points of the studies assessed by EFSA in the framework of the MRL review, including the end points of relevant studies assessed previously and under these applications, is presented in Appendix B.

The evaluation reports submitted by the RMS (United Kingdom, 2019a,b) and the exposure calculation using the EFSA Pesticides Residues Intake Model (PRIMo) are considered a supporting document to this reasoned opinion and, thus, are made publicly available as a background document to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

In the framework of the peer review under Directive 91/414/EEC and the Art.12 MRL review (EFSA, 2007b, 2014), the metabolism of prothioconazole was investigated by foliar applications on root (sugar beet), pulses/oilseeds (peanut) and cereal/grass (wheat) crop groups and by seed treatment on cereal (wheat) (EFSA, 2007a,b). In addition, the metabolism of prothioconazole-desthio labelled in the triazole moiety was investigated after foliar applications on cereals (EFSA, 2007b).

Prothioconazole is extensively metabolised and the metabolic pathway was similar in all crops investigated. Prothioconazole-desthio was the predominant compound of the total residues with further hydroxylation (with the formation of several closely related metabolites) and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of TDMs.

As the parent compound was only present in minor amounts and prothioconazole-desthio was shown to more toxic than the parent compound, it was concluded to define prothioconazole-desthio as the relevant residue for enforcement. Based on metabolism study results, the MRL review derived the following tentative conversion factors to account for hydroxy metabolites of prothioconazole-desthio: 2 in cereal grains, pulses and oilseeds, leafy vegetables and tuber vegetables and 3 in cereal straw (EFSA, 2014).

The metabolism studies indicate that in root crops and oilseeds, relevant for the intended uses of prothioconazole on celeriacs and oilseed rape, the main identified TDMs are triazole alanine (TA) (29 total radioactive residue (TRR) in roots; 47.8% TRR in oilseed) and triazole lactic acid (TLA) (24.5% TRR in oilseed).

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

1.1.2. Nature of residues in rotational crops

Oilseed rape and celeriacs can be grown in a crop rotation.

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)),

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

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

whereas prothioconazole-desthio is of low persistence with $DT_{90\ field}$ of 140 days (median) (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.

The MRL review concluded that metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary (EFSA, 2014).

The metabolism of prothioconazole labelled in triazole ring was assessed by the JMPR (FAO, 2009a) as reported in the MRL review. The studies indicate the cleavage of triazole linkage to form major metabolites TA, TLA and TAA (EFSA, 2014). During the peer review of TDMs in light of confirmatory data, the metabolism of various triazole compounds in rotational and primary crops was investigated. It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops (EFSA, 2018b).

1.1.3. Nature of residues in processed commodities

The effect on the nature of prothioconazole and prothioconazole-desthio has not been investigated in the framework of the EU pesticides peer review. The MRL review referred to studies with prothioconazole investigated by the JMPR and studies with prothioconazole-desthio reported by Germany (EFSA, 2014). Prothioconazole-desthio was reported to be stable under all standard hydrolysis steps (99.4–99.9% applied radioactivity (AR)), whereas parent prothioconazole slightly degraded to prothioconazole-desthio under sterilisation process ($\leq$ 11% AR). The same processing study referred to in the MRL review was now submitted for the renewal of the approval (United Kingdom, 2018).

The remaining compounds included in the risk assessment residue definition were concluded to remain stable under standard hydrolysis conditions, considering their structural similarity to parent compound (EFSA, 2014).

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

1.1.4. Methods of analysis in plants

The availability of the analytical enforcement methods for the determination of prothioconazole-desthio residues in plant commodities was assessed during the peer review and the MRL review and are reported in detail in Appendix B.1.1.1. The method is not enantioselective, hence the sum of isomers will be analysed. Sufficiently validated enforcement methods are available to analyse prothioconazole-desthio residues in celeriac and rape seed at the validated limit of quantification (LOQ) of 0.02 mg/kg (EFSA, 2007b, 2014).

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 end points are summarised in Appendix B.1.1.2. In high water and high oil content commodities, relevant for the celeriacs and rapeseeds use, prothioconazole-desthio is stable for a maximum of 24 months, when stored at −18°C (EFSA, 2014).

A data gap was noted by EFSA during the MRL review for the need of further 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).

In order to address this data gap (number 3[8]) the EMS referred to storage stability studies submitted by the applicant in the framework of the renewal of the approval (United Kingdom, 2018). EFSA assessed the submitted studies, noting that the renewal of the approval has not been finalised yet.

[8] Storage stability data for at least one hydroxylated metabolite included in the risk assessment residue definition for plants are required in the relevant crop categories.

Freezer storage stability of prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio was investigated in high water content (tomatoes), high starch content (potatoes), high oil content (soya beans, oilseed rape) and high acid content (oranges) commodities for a period of 24 months. Samples were fortified with a mixture containing all five analytes at a level of 0.1 mg/kg each. Since all these compounds are included in the residue definition for risk assessment, spiking with a mixture was considered acceptable. Results demonstrate stability of all compounds in all matrices for a maximum of 24 months (duration of study) when stored at ≤ 18°C.

It is noted that according to EU guidelines (European Commission, 1997f), applicable for the current assessment, cereals are considered as dry matrix, for which the storage stability of hydroxylated metabolites of prothioconazole-desthio has not been investigated. However, it is noted that the applicant has generated data according to the OECD guidelines (OECD, 2007) in the framework of the renewal of the approval of prothioconazole. According to OECD guideline, cereals are considered as high starch matrix. EFSA accepted the storage stability data on potatoes (high starch matrix) to address the storage stability in cereals.

The data gap identified by the MRL review is considered addressed for all crops, except for dry pulses, which belong to dry (high protein content) commodity group in which the storage stability of any of the hydroxy-metabolites of prothioconazole-desthio has not been investigated.

The freezer storage stability of various TDMs was investigated in the framework of the peer review of TDMs (EFSA, 2018b). In the commodity groups relevant for the current assessment the stability of all TDMs has been investigated, except that of 1,2,4-T in high protein content matrices, and of 1,2,4-T and TA in rapeseeds (see 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, the capabilities of enforcement analytical methods, the following residue definitions were proposed:

- residue 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)
- residue definition for enforcement: prothioconazole-desthio (sum of isomers).

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

In the recently published conclusion on TDMs, EFSA proposed the following residue definitions for risk assessment for active substances belonging to the class of triazole fungicides (EFSA, 2018b) which are considered to replace the previously derived provisional residue definition for TDMs:

- Parent compound and any other relevant metabolite exclusively linked to the parent compound[9]
- Triazole alanine (TA) and triazole lactic acid (TLA) (both metabolites were found to share the same toxicity)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-triazole).

For the uses on the crops under consideration, EFSA concludes that the metabolism of prothioconazole is elucidated and the abovementioned residue definitions are applicable. The same residue definitions are applicable to rotational crops and processed products and for both foliar and seed treatments.

The risk assessment for the crops under consideration has to be performed for parent prothioconazole and should be also performed for the recently derived residue definitions for the metabolites (TA and TLA, TAA and 1,2,4-T) (EFSA, 2018b). Considering that triazole metabolites are common metabolites that are also formed by other triazole fungicides, a comprehensive risk assessment is required which has to take into account all sources of these metabolites. To ensure that all relevant information is made available, a risk management decision is needed to establish the framework to perform the risk assessment for the residue definitions of these metabolites. In the

[9] In case of prothioconazole, it refers to prothioconazole-desthio (sum of isomers).

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.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

New intended uses

In the framework of the current assessment, the applicant did not submit information on the residues of TDMs in primary crops under assessment. For the new intended uses of prothioconazole on celeriacs and oilseed rape, EFSA retrieved the residue data on TDMs in carrots and rapeseed as reported in the framework of the peer review of triazole derivative metabolites (EFSA, 2018b). The residue data submitted are summarised in Appendix B.1.2.1 (prothioconazole-desthio) and Appendix B.1.2.2 (TDMs).

Celeriacs (intended northern Europe (NEU) use)

In support of the intended NEU GAP on celeriacs, the applicant submitted five residue trials on carrots which were already assessed by the MRL review in 2014. The trial samples were analysed according to risk assessment residue definition. The samples prior to analysis were stored frozen for time period not exceeding the demonstrated storage stability of prothioconazole-desthio residues. The applicant proposes to extrapolate residue data on carrots to celeriac. According to EU guidance document (European Commission, 2017) such extrapolation is acceptable and is sufficiently supported by residue data. An MRL of 0.1 mg/kg is proposed for prothioconazole-desthio in celeriac root. A conversion factor of 2.7 from enforcement to risk assessment is derived.

Rapeseeds/canola (intended SEU use)

The EMS submitted 10 residue trials on oilseed rape performed in France, Italy, Spain and Germany in 2011. The available eight southern Europe (SEU) trials are considered as representing four independent trials where two plots per trial were treated. The only difference between trials was the type of formulation (EC or SE). From these trials, the highest residue value was selected, which in all cases was from the trials with the SE formulation. It is also noted that for these trials the analytical method demonstrated adequate recovery data. The trial from Germany was excluded as not compliant with the GAP (seed samples taken at the preharvest interval (PHI) of 50 days instead of 30 days) and not representative for the SEU zone.

In all trials, the rapeseed green plant, pods and seeds were analysed using method 00979/M001 (including hydrolysis step) for residues of prothioconazole-desthio and prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio at various PHI intervals (0, 14, 21, 28).

The samples prior to analysis were stored frozen for time period not exceeding the demonstrated storage stability of prothioconazole-desthio residues. The integrity of samples, however, could not be demonstrated for the storage stability of TA and 1,2,4-T (EFSA, 2018b). The EMS proposes to merge these data with the residue data assessed for the MRL review. Data sets can be merged as the GAPs are similar. A merged data set consisting of 12 residue trials results in a higher MRL proposal of 0.2 mg/kg, confirming the proposal of the applicant but differing from the proposal of 0.15 mg/kg of the EMS. The deviation is due to the fact that EMS selected mean value from the replicate trials, whereas EFSA selected the highest value. A conversion factor of 2 from enforcement to risk assessment is confirmed.

Authorised EU GAPs MRL review

Carrots, beetroots, horseradishes, parsnips, parsley root, salsifies, swedes/rutabaga and turnips (authorised NEU uses)

In order to address the data gap of the MRL review number 5,[10] the applicant re-analysed samples from five residue trials on carrots considered in the MRL review (EFSA, 2014).

Carrot samples of root were re-analysed for prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-

[10] Sufficient residue trials analysing the residues in compliance with the proposed residue definition for risk assessment in plant commodities.

6-hydroxy-desthio. The analytical method includes hydrolysis step (reflux for 2 h in 5N hydrochloric acid) after extraction to cleave the conjugates to aglycones and to convert the metabolites with diene structure back to aromatic compounds. The method was sufficiently validated for the determination of prothioconazole-desthio and its hydroxy metabolites in carrot root samples at the validated LOQ of 0.01 mg/kg. Residue data indicated that all metabolites in root were below individual LOQ of 0.01 mg/kg. The samples prior to analysis were stored frozen for time period not exceeding the demonstrated storage stability of prothioconazole-desthio residues and residues of TDMs.

For the authorised uses on root and tuber vegetables (except sugar beet), the EMS proposes to merge submitted residue data with additional 4 trials on carrots which were assessed by the MRL review, but for which data on hydroxy-metabolites are not available. A merged data set confirm the existing EU MRL of 0.1 mg/kg. The conversion factor of 2.7 from enforcement to risk assessment for root crops is confirmed.

Rapeseeds/canola (authorised NEU/SEU uses); Linseeds, peanuts/groundnuts, poppy seeds, mustard seeds (authorised NEU uses)

For the authorised NEU uses on linseeds, poppy seeds, mustard seeds and the authorised NEU and SEU uses on oilseed rape, the residue trials, analysing residues according to the risk assessment residue definition were available for the MRL review. However, it was not known whether trial samples were analysed with a method capable to release the metabolites included in the risk assessment residue definition. In order to address the data gap number 4[11] and 5[10] the EMS confirmed that residue trials on oilseed rape (NEU residue data set used to extrapolate residues to linseeds, poppy seeds, mustard seeds (EFSA, 2014)), which were assessed in the MRL review, have been analysed with a method (coded as 00979/M001), which included an hydrolysis step (reflux for 2 h in 5N hydrochloric acid) after extraction to cleave the conjugates to aglycones and to convert the metabolites with diene structure back to aromatic compounds (United Kingdom, 2019a). The additional residue trials conducted in SEU oilseed rape and evaluated above (see section new intended uses) sufficiently addressed the data gap number 5.[12]

For peanuts/groundnuts no authorised EU use was reported in the MRL review; the existing EU MRL was proposed at the LOQ of 0.02* mg/kg on the basis of CXL (FAO, 2009b; EFSA, 2014). Residue trials analysing for risk assessment residue definition were not submitted. A conversion factor of 2 from enforcement to risk assessment as derived from rapeseeds is applicable.

EFSA concludes that the data gaps number 4 and 5 are sufficiently addressed.

Gold of pleasure seeds (authorised NEU/SEU uses)

For the gold of pleasure seeds, the data gap number 5 would not be formally addressed. However, in the absence of data on hydroxy metabolites and considering that the MRL is derived by extrapolation from data on rapeseeds (from older trials), EFSA agreed with the RMS that the conversion factor of 2 from enforcement to risk assessment for oilseeds is applicable to derive input values for the consumer risk assessment of prothioconazole-desthio. Therefore, the data gap concerning residue trials is finally considered addressed.

Onions, shallots (authorised NEU use)

Since the re-analysis of samples from trials considered in the MRL review was not possible as samples are no longer available, in order to address the data gap number 5[10] for the authorised NEU use on onions and shallots, the applicant submitted 12 bridging residue trials representing a less critical SEU use (2 applications instead of 4), where onion samples were analysed according to risk assessment residue definition. Six trials were designed as decline trials with samples analysed at the PHI intervals of 0, 3, 7, 12–14 (PHI interval of authorised NEU use), 19–21 days; in remaining six trials, samples were taken only at the PHI of 21 day. It is noted that according to the MRL review, prothioconazole is not authorised on onions in the SEU (EFSA, 2014).

Residues of prothioconazole-desthio in all samples at all PHI intervals (except in one sample at 0 d PHI) and its hydroxy-metabolites were below the LOQ of 0.01 mg/kg, confirming no-residue situation.

[11] Clarification on whether the conjugates of M14, M15, M16, M17 and M18 metabolites were effectively analysed in the residue trials conducted on rape seed.

[12] Data gap number 5 refers to 'Sufficient residue trials analysing the residues in compliance with the proposed residue definition for risk assessment in plant commodities'. It is noted that the GAP assessed as intended use differ from the authorized GAP assessed in the MRL review only for the PHI (30 days, new use; 28 day, authorized use). Residue trials submitted support both uses.

The EMS proposes to use the SEU residue data to address the MRL review confirmatory data gap for onions and, by extrapolation, for shallots in support of the NEU use. Since in the NEU trials, available for the MRL review, residues of prothioconazole-desthio were in two samples above the LOQ (0.01; 0.02 mg/kg) there is an indication that the number of applications affect the final residue levels in a crop and therefore extrapolation from a less critical use is not fully supported.

The EMS alternatively proposed to apply the conversion factors from enforcement to risk assessment as derived from the metabolism studies on root crops as done in the previous EFSA assessments. Since new data were not provided in the current assessment, the proposal of EMS might be considered by the risk managers. EFSA considers this data gap as not addressed.

Broccoli, cauliflower, Brussels sprouts, head cabbages, leeks (authorised NEU use)

In response to the data gap number 5,[10] the applicant informed the EMS that re-analysis of samples from trials considered in the MRL review was not possible as samples are no longer available (United Kingdom, 2019a,b).

In the absence of residue trials analysed according to the risk assessment residue definition, the EMS proposes to apply the conversion factors from enforcement to risk assessment as derived from the metabolism studies on cereals, pulses/oilseeds and root crops. The proposal of EMS might be considered by the risk managers, but it is noted that metabolism studies with leafy crops are not available. EFSA considers this data gap as not addressed.

Beans (dry), peas (dry) (authorised NEU use)

In response to the data gap number 5, the applicant informed the EMS that re-analysis of samples from trials considered in the MRL review was not possible as samples are no longer available (United Kingdom, 2019a).

Instead, the EMS proposes to apply the conversion factors from enforcement to risk assessment as derived from the metabolism studies on cereals, pulses/oilseeds and root crops. However, for pulses the confirmatory data gap related to storage stability of hydroxy-metabolites of prothioconazole-desthio is not addressed; therefore, the tentative MRL cannot be confirmed. EFSA considers this data gap not addressed.

Wheat, barley oats (authorised SEU and NEU uses); Rye (authorised NEU use)

In response to the data gap of the MRL review number 5,[10] the EMS refers to residue trials on cereals that are submitted in the framework of the renewal of the approval of prothioconazole (United Kingdom, 2018).

In the Renewal Assessment Report (United Kingdom, 2018), EFSA identified in total seven new residue trials on wheat supporting the authorised SEU use, two residue trials on barley supporting authorised NEU use and two residue trials on barley supporting SEU authorised use are made available. The samples of grain and straw were analysed for prothioconazole-desthio and prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio. In all grain samples, all hydroxy prothioconazole-desthio metabolites were below the LOQ of 0.01 mg/kg; prothioconazole-desthio was at or below the LOQ of 0.01 mg/kg. The samples prior to analysis were stored frozen for time period not exceeding the demonstrated storage stability of prothioconazole-desthio residues. For wheat straw, the conversion factor of 2.3 from enforcement to risk assessment is confirmed.

The available residue data on barley are insufficient to address the confirmatory data gap for the authorised NEU and SEU uses on barley and oats. The data submitted for the SEU use on wheat are not acceptable to support the authorised NEU use on rye and wheat.

The confirmatory data gap is addressed for the authorised SEU use on wheat only. Since hydroxy metabolites of prothioconazole-desthio were not present in wheat grain and in order to avoid unnecessary overestimation of residue levels for the risk assessment, EFSA proposes to apply the conversion factor of 2 as derived for cereals from the metabolism studies. The tentative MRL of 0.02* mg/kg as derived by MRL review for wheat for SEU use is confirmed.

Grass (authorised EU uses)

The applicant did not provide new residue trials to address the data gap number 2.[13] The applicant provided clarification that prothioconazole is currently authorised as minor use on grass for seed production only in the Netherlands (United Kingdom, 2019a). The applicant is currently generating residue trial data to support a more critical intended GAP for use of prothioconazole on grass for seed production. It is concluded that the authorised GAP of prothioconazole on grass in the NEU is not supported by residue data. EFSA considers this data gap as not addressed.

1.2.2. Magnitude of residues in rotational crops

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

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 of TDMs identified a data gap for prothioconazole related to the submission of rotational crop field residue trials supported by acceptable storage stability data on TDMs (EFSA, 2018b). Without appropriate field data, the magnitude of TDMs in rotational crops currently cannot be estimated.

1.2.3. Magnitude of residues in processed commodities

The studies investigating the effect on the magnitude of prothioconazole-desthio, the hydroxy metabolites and the TDMs in processed commodities have not been submitted in the framework of the current assessment. Such studies are currently not required, as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI for the individual crops under assessment.

1.2.4. Proposed MRLs

The data submitted in support of the intended NEU use of prothioconazole on celeriacs are sufficient to derive an MRL proposal of 0.1 mg/kg. The data submitted in support of the intended SEU use of prothioconazole on rapeseeds are sufficient to derive an MRL of 0.2 mg/kg.

Regarding the MRL review confirmatory data, the data gaps are considered fully addressed for the root and tuber vegetables (except sugar beets), the oilseeds concerned and for wheat. Therefore, the tentative MRLs previously derived were confirmed.

2. Residues in livestock

Celeriacs is not a livestock feed item whereas rapeseeds meal can be fed to livestock and therefore the potential carry-over of residues into commodities of animal origin shall be further assessed. Moreover, new data on carrots, swedes, turnips and wheat were submitted in the framework of the assessment of the Article 12 confirmatory data application (United Kingdom, 2019a). The most recent livestock dietary burden was calculated in the EFSA opinion on the modification of prothioconazole residues in sunflower seeds (EFSA, 2015b), updating the calculation done by the MRL review (EFSA, 2014).

However, due to the fact that existing EU MRLs for livestock and for various feed commodities are set on the basis of CXLs, instead of proposals made by the MRL review, the livestock dietary burden was calculated using Animal Model (OECD methodology), considering the actual existing EU MRLs for feed commodities. The input values for rapeseeds and carrots, swedes, turnips were as derived from the current assessment; for remaining feed commodities the input values were corresponding to the existing EU MRLs and were as reported in the MRL review, or in JMPR reports (in particular for cereals, cotton, maize, peanuts and soya beans, since for these crops the existing EU MRLs are set on the basis of CXLs) (FAO, 2009a,b, 2014, 2018) and in previous EFSA reasoned opinions (for sunflower seeds, EFSA, 2015b). Where residue data according to the risk assessment residue definition were not available, default conversion factors for risk assessment as derived by the MRL review, were applied. The input values for the exposure calculations for livestock are presented in Appendix D.

[13] Submission of at least 4 residue trials complying with the northern outdoor GAP on grass (in view of deriving robust MRL values in commodities of animal origin).

The results of the dietary burden calculation are presented in Section B.2 and demonstrate that the exposure of all livestock species exceeds the trigger value of 0.1 mg/kg DM. The contribution of residues in rapeseeds meal is insignificant. EFSA notes that since the residue trials on grass (major component of livestock dietary burden) have not been submitted, the EU livestock dietary burden from the existing EU uses including grass could not be properly calculated. However, since the existing EU MRLs for livestock commodities reflect CXLs, which are derived on the basis of significantly higher livestock dietary burdens as calculated by the JMPR in 2017 for cattle and poultry (FAO, 2018), the nature and magnitude of prothioconazole residues in livestock was not investigated further.

EFSA notes that the livestock exposure to TDMs from the intake of crops treated with prothioconazole or any other triazole compound was not undertaken in the framework of the current assessment.

2.1. Nature of residues and methods of analysis in livestock

Not relevant for the current assessment.

2.2. Magnitude of residues in livestock

New information was not provided in the current assessment.

3. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2007a). For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

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 were assumed to be covered by the toxicological reference values of prothioconazole-desthio (EFSA, 2007b).

The consumer exposure was calculated considering the existing EU MRLs for prothioconazole-desthio which are set above the LOQ on the basis of EU assessments or taken over as the CXLs from the JMPR assessments. The crops for which no uses were reported in the framework of the MRL review were excluded from the calculation.

The chronic and acute exposure calculation is based on the median and highest residue levels, respectively, estimated in raw agricultural commodities. Conversion factor (CF) of 2 for risk assessment was applied to the input values of those crops where no data according to the risk assessment residue definition are available and for which a risk management decision is pending (pulses, flowering brassica, Brussels sprouts, head cabbages, shallots, onions, leeks, rye, barley, oats). For the remaining commodities the conversion factor as derived from residue trials was applied (oilseeds (CF 2), wheat (CF 2), root and tuber vegetables (except sugar beet) (CF 2.7)). For cranberries and sweetcorn no conversion factor was available as the MRLs for these crops originate from CXLs which are derived according to a different residue definition (i.e., prothioconazole-desthio). For animal commodities the MRLs are based on CXLs and the input values are considered to account for a major part of residues included in the EU risk assessment residue definition (i.e., prothioconazole-desthio and its 3-hydroxy and 4-hydroxy metabolites with its conjugates).

The summary of the input values is provided in Appendix D.1.

No long-term consumer intake concerns were identified for any of the diets included in the EFSA PRIMo, as the estimated maximum long-term dietary intake accounted for 7% of the ADI (WHO Cluster diet B). The individual contribution of residues in celeriacs and rapeseeds were below 1% of the ADI.

The short-term exposure did not exceed the ARfD for any of the crops under consideration, with maximum individual acute exposure being 63% of the ARfD for carrots and head cabbage, 55% of the ARfD for celeriacs, 52% of the ARfD for swedes, 47% of the ARfD for leek, 44% of the ARfD for beetroot and was individually below 40% of the ARfD for other commodities.

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

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

TDMs

An indicative exposure assessment was performed for celeriacs and rapeseeds, considering the additional residue definitions derived in the framework of the conclusion on TDMs (EFSA, 2018b). The input values (HR/STMR values) were as derived from residue trials on oilseed rape and carrots, representative for the intended uses, which were submitted in the addendum to the conclusion on TDMs (EFSA, 2018b). The indicative short- and long-term exposure calculated for the additional residue definitions covering TDMs was low and did not exceed the corresponding toxicological reference values for the relevant TDMs derived in the EFSA conclusion (EFSA, 2018b). More details can be found in Appendix B.3 and Appendix C. EFSA emphasises that a comprehensive risk assessment, including all crops and all pesticides belonging to the class of triazole fungicides, could not be performed in the framework of this opinion.

4. Conclusion and Recommendations

The data submitted in support of the intended uses of prothioconazole on celeriacs and oilseed rape were found to be sufficient to derive MRL proposals for prothioconazole in these crops.

The storage stability study referred to in the renewal assessment report is considered sufficient to address the confirmatory data gap identified in the MRL review for all crops assessed in the MRL review, except for pulses.

The submitted residue data on carrots, oilseed rape and wheat were sufficient to fully address the data gaps for the root and tuber vegetables (except sugar beet), the oilseeds concerned and wheat. Since the data gaps have been partially addressed for onions, shallots, flowering brassica, Brussels sprouts, head cabbages, leeks, rye, barely and oat and not addressed for pulses, further risk management consideration is required.

The applicant addressed the data gaps related to clarification whether prothioconazole-desthio hydroxy metabolites were analysed in oilseed rape residue trials.

Since the applicant did not provide residue trials on grass, as requested according to confirmatory data gap number 2, the calculated livestock dietary burdens do not take into consideration the potential contribution of residue intake from grass. The relevance of the lack of this information shall be considered by risk managers, given the fact that the existing EU MRLs for commodities of animal origin are based on CXLs, which are derived for significantly higher livestock dietary burdens than calculated for EU without consideration of grass.

EFSA concluded that the proposed use of prothioconazole on celeriacs and on oilseed rape and the existing authorised prothioconazole uses will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

1,2,4-T	1,2,4-triazole
a.s.	active substance
ADI	acceptable daily intake
AHDB	Agriculture & Horticulture Development Board
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
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC–MS	gas chromatography with mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
InChiKey	International Chemical Identifier Key
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
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	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SMILES	simplified molecular-input line-entry system
TMR	supervised trials median residue
TA	triazole alanine
TAA	triazole acetic acid
TDM	triazole derivative metabolite
TLA	triazole lactic acid

TMDI	theoretical maximum daily intake
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			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[I]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Intended GAPs															
Cleriacs/turnip rooted celeries	NEU	F	Fungi	SC	480 g/L	Spray	May–October	3	14		200–500	192	g/ha	21	The GAP on root vegetables reported in the MRL review is identical
Oilseed rape	SEU	F	Fungi	EC	150 g/L	Spray		1–2	14		100–300	120	g/ha	30	
MRL review GAPs (authorised uses)															
Carrots, beetroots, horseradishes, parsnips, parsley roots, salsifies, swedes, turnips	NEU	F	Fungi	SC	480 g/L	Spray	19–49	1–3	14			192	g/ha	21	EFSA (2014)
Onions, shallots	NEU	F	Fungi	EC	100 g/L	Spray	47	1–4	5-10			125	g/ha	14	EFSA (2014, 2015a)
Beans, peas	NEU	F	Fungi	EC	125 g/L	Spray	61–69	2				125	g/ha	35	EFSA (2014)
Oilseed rape	NEU	F	Fungi	EC	150 g/L	Spray		2	14			120	g/ha	28	EFSA, 2012 (GAP with PHI of 30 days); 2014
	SEU	F	Fungi	EC	150 g/L	Spray		2	14			120	g/ha	28	EFSA (2014)
Linseeds, poppy seeds, mustard seeds	NEU	F	Fungi	EC	150 g/L	Spray		2	14			120	g/ha	28	EFSA (2014)
Gold of pleasure	NEU	F	Fungi	EC	250 g/L	Spray		2				175	g/ha	56	EFSA (2014)
	SEU	F	Fungi	EC	250 g/L	Spray		2				175	g/ha	56	EFSA (2014)

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			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Wheat, rye	NEU	F	Fungi	EC	250 g/L	Spray	29–69	1–3	14–21			200	g/ha	35	EFSA (2014)
Wheat	SEU	F	Fungi	EC	250 g/L	Spray	32–69	1–2	14–21			200	g/ha	35	EFSA (2014)
Barley, oats	NEU	F	Fungi	EC	250 g/L	Spray	30–69	1–2	14–21			200	g/ha	35	EFSA (2014)
	SEU	F	Fungi	EC	250 g/L	Spray	32–61	1–2	14–21			200	g/ha	35	EFSA (2014)

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

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

(b): Meeting on Pesticide Specifications (JMPS). Manual on development and use of FAO and WHO Specifications for Pesticides, First Edition-Third revision, 2016.

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

(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

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

Primary crops (available studies)	**Crop groups**	**Crops**	**Applications**	**Sampling**	**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**	**Crops**	**Application**	**PBI (DAT)**	**Comment/source**
	Root/tuber crops	Turnips	Soil, 0.58 kg/ha	94, 201, 349 (roots, tops)	[U-^{14}C-phenyl] prothioconazole (EFSA, 2007b)
	Leafy crops	Swiss chards		80, 188, 348	
	Cereals (small grain)	Spring wheat		Green material: 73, 178, 327 Hay: 111, 231, 377 Grain, straw: 1445, 269, 412	

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, 2018)
	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-2*H*-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) and triazole lactic acid (TLA) - Triazole acetic acid (TAA) - 1,2,4-triazole (1,2,4-T)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: GC–MS, LOQ 0.02 mg/kg, straw: 0.05 mg/kg. ILV available (EFSA, 2007b, 2014)	

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

B.1.1.2. Stability of residues in plants

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-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio	United Kingdom, (2019a)
	High oil content	Rapeseeds	−18	24	Months	Prothioconazole-desthio	EFSA (2014)
		Soya beans, rapeseeds	−18	24	Months	Prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio	United Kingdom (2019a)
	Dry/High protein content	Dry peas	−18	24	Months	Prothioconazole-desthio	EFSA (2014)
	Dry/High starch	Cereals grain	−18	18	Months	Prothioconazole-desthio	EFSA (2014)
	High acid content	Oranges	−18	24	Months	Prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio	United Kingdom (2019a)
	Others	Cereal straw	−18	18	Months	Prothioconazole-desthio	EFSA (2014)
		Oilseed rape straw	−18	24	Months	Prothioconazole-desthio	EFSA (2014)
				53		Triazole acetic acid	
				48		Triazole lactic acid (lettuce only)	

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ source
				Value	Unit		
	High starch content	Barley, wheat	−18	12	Months	1,2,4-triazole	EFSA (2018b)
				26		Triazole alanine	
				26		Triazole acetic acid	
				48		Triazole lactic acid	
	High oil content	Rapeseeds, soya beans	−18	12 (soya beans only)	Months	1,2,4-triazole. Not stable in rapeseeds.	EFSA (2018b)
				26 (soyabeans only)		Triazole alanine. Not stable in rapeseeds.	
				53		Triazole acetic acid	
				48		Triazole lactic acid	
	High protein content	Dry peas, navy beans	−18	No data	Months	1,2,4-triazole	EFSA (2018b)
				15		Triazole alanine	
				25		Triazole acetic acid	
				48		Triazole lactic acid	
	High acid content	Oranges	−18	No data	Months	1,2,4-triazole	EFSA (2018b)
				No data		Triazole alanine	
				No data		Triazole acetic acid	
				48		Triazole lactic acid	
	High water content	Apples, tomatoes, mustard leaves, wheat forage, radishes tops, turnip roots, sugar beet roots, cabbages, lettuces	−18	6	Months	1,2,4-triazole. Lettuce only.	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	
				No data		Triazole lactic acid	

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

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials – Prothioconazole-desthio (sum of isomers)

Commodity	Region/ indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Enforcement residue definition: prothioconazole-desthio (sum of isomers) **Risk assessment residue definition:** 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)							
Intended GAPs							
Celeriacs	NEU	**Mo:** 0.02; 0.02; 0.03; 0.04; 0.05 **RA:** 0.07; 0.07; 0.08; 0.09; 0.10	Residue trials on carrots compliant with the intended GAP for celeriacs. Extrapolation to celeriac root acceptable	0.10	**Mo:** 0.05 **RA :** 0.10	**Mo:** 0.03 **RA:** 0.08	2.7
Oilseed rape	SEU	New trials **Mo:** 0.03; 0.04; 0.055; 0.06; 0.13 **RA:** 0.08; 0.093; 0.105; 0.11; 0.18 Trials MRL review (EFSA, 2014) **Mo:** < 0.01; 0.02; 2 × 0.03; 0.04; 0.05; 0.09 **RA:** < 0.01; 0.04; 0.03; 0.04; 2 × 0.07; 0.11	Residue trials on oilseed rape compliant with the GAP	0.20	**Mo:** 0.13 **RA:** 0.18	**Mo:** 0.04 **RA :** 0.08	2.0
MRL review GAPs							
Carrots, beetroots, horseradishes, parsnips, parsley root, salsifies, swedes, turnips	NEU	Trials MRL review (EFSA, 2014): **Mo:** 3 × 0.02; 2 × 0.03; 2 × 0.04; 2 × 0.05 **RA:** 0.07; 0.07; –; 0.08; –; 0.09; –; 0.10; –	Residue trials on carrots compliant with the authorised GAP. Samples from 5 trials re-analysed for residues of the hydroxy metabolitesExtrapolation to beetroot, horseradish, parsnips, parsley root, salsify, swedes and turnips accepted considering a merged residue data set with additional 4 trials on carrots which were assessed by the MRL review (EFSA, 2014)	0.10	**Mo:** 0.05 **RA:** 0.10	**Mo:** 0.03 **RA:** 0.08	2.7

Commodity	Region/ indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Oilseed rape	SEU	New trials **Mo:** 0.03; 0.04; 0.055; 0.06; 0.13 **RA:** 0.08; 0.093; 0.105; 0.11; 0.18 Trials MRL review (EFSA, 2014) **Mo:** < 0.01; 0.02; 2 × 0.03; 0.04; 0.05; 0.09 **RA:** < 0.01; 0.04; 0.03; 0.04; 2 × 0.07; 0.11	Residue trials compliant with the authorised GAP. The applicant confirmed that residue trials were analysed using method that involves hydrolysis step	0.20	**Mo:** 0.13 **RA:** 0.18	**Mo:** 0.04 **RA :** 0.08	2.0
	NEU	Trials MRL review (EFSA, 2014) **Mo:** 2 × 0.01; 0.02; 3 × 0.03; 2 × 0.04; 0.05 **RA:** 0.02; 0.03; 0.02; 3 × 0.03; 2 × 0.04; 0.05	New trials not submittedThe applicant confirmed that residue trials were analysed using method that involves hydrolysis step. Extrapolation to linseeds, poppy seeds, mustard seeds accepted (EFSA, 2014)	0.09	**Mo:** 0.05 **RA:** 0.05	**Mo:** 0.03 **RA:** 0.03	2.0
Wheat grain	SEU	New trials **Mo**: 5 × < 0.01; 2 × 0.01 **RA**: 5 × < 0.06; 2 × 0.06 Trials MRL review (EFSA, 2014) **Mo**: 8 × < 0.01 **RA:** –	Residue trials on wheat, compliant with the authorised GAP	0.02*	**Mo:** 0.01 **RA:** 0.06	**Mo:** 0.01 **RA:** 0.06	2.0[e]
Wheat, rye grain	NEU	Trials MRL review (EFSA, 2014) **Mo**: 12 × < 0.01; 0.02 **RA:** –	Residue trials with samples analysed according to the risk assessment residue definition not available				
Wheat straw	SEU	New trials **Mo**: 0.22; 0.41; 0.85; 1.10; 1.60; 1.80; 2.30 **RA**: 1.03; 1.76; 1.95; 3.00; 2.78; 2.69; 3.35 Trials MRL review (EFSA, 2014) **Mo**: 0.22; 0.41; 0.42; 0.52; 0.53; 0.72; 0.77; 0.85; 0.86; 1.20; 1.90; 2.40 **RA :** –	Residue trials on wheat, compliant with the authorised GAP	5.0	**Mo:** 2.40 **RA:** 3.35	**Mo:** 0.85 **RA:** 2.69	2.3
Wheat, rye straw	NEU	Trials MRL review (EFSA, 2014) **Mo**: 0.08; 0.09; 0.09; 0.11; 0.14; 0.15; 0.19; 0.20; 0.27; 0.31; 0.42; 0.48; 0.66; 0.72; 1.60 **RA :** –	Residue trials with samples analysed according to the risk assessment residue definition not available				

Commodity	Region/ indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Barley, oat grain	NEU	Trials MRL review (EFSA, 2014) **Mo**: 11 × < 0.01;0.01; 0.02 **RA:** – New trials: **Mo**: 2 × < 0.01 **RA:** 2 × < 0.06	Insufficient number of barley trials with samples analysed according to the risk assessment residue definition				
	SEU	Trials MRL review (EFSA, 2014) **Mo:** 3 × < 0.01; 4 × 0.01; 3 × 0.02; 0.03 **RA:** – New trials: **Mo:** < 0.01; 0.01 **RA:** < 0.06; 0.06	Insufficient number of barley trials with samples analysed according to the risk assessment residue definition				
Barley, oat straw	NEU	Trials MRL review (EFSA, 2014) **Mo:** 0.05; 0.08; 2 × 0.1; 0.11; 2 × 0.13; 2 × 0.14; 0.3; 0.36; 0.56 **RA:** – New trials: **Mo:** 0.11; 0.54 **RA:** 0.41; 1.23	Insufficient number of barley trials with samples analysed according to the risk assessment residue definition				
	SEU	Trials MRL review (EFSA, 2014) **Mo:** 0.06; 0.10; 0.16; 0.19; 0.32; 0.41; 0.42; 0.75; 2 × 1.1; 1.1; 2.5 **RA:** – New trials: **Mo:** 0.33; 0.93 **RA:** 0.39; 1.96	Insufficient number of barley trials with samples analysed according to the risk assessment residue definition				

MRL: maximum residue level; GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): Conversion factor derived from metabolism studies.

B.1.2.2. Summary of residues data from the supervised residue trials – TDMs (only for intended uses)

Commodity	Region/ indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Risk assessment residue definition: Triazole alanine (TA) and triazole lactic acid (TLA)							
Celeriacs	NEU	6 × < 0.01; 0.021; 0.023; 0.025; 0.028	Data on TDMs as reported for carrot root in the framework of the peer review of the risk assessment of triazole derivative metabolites (TDMs) (EFSA, 2018b)	N/A	0.028	0.01	N/A
Oilseed rape	SEU	0.185; 1.803; 0.72; 0.03; 0.66; 0.03; 0.27; < 0.01; 2.17; 0.08; 0.11; < 0.01; 0.87; 0.02; 0.17; < 0.01	Data on TDMs as reported for oilseed rape seed in the framework of the peer review of the risk assessment of triazole derivative metabolites (TDMs)Residue data are not supported by acceptable storage stability data for TA (EFSA, 2018b)	N/A	2.17	0.14	N/A
Risk assessment residue definition: Triazole acetic acid (TAA)							
Celeriacs	NEU	5 × < 0.01	Data on TDMs as reported for carrot root in the framework of the peer review of the risk assessment of triazole derivative metabolites (TDMs) (EFSA, 2018b)	N/A	0.01	0.01	n/a
Oilseed rape	SEU	7 × < 0.01; 0.02; 0.062	Data on TDMs as reported for oilseed rape seed in the framework of the peer review of the risk assessment of triazole derivative metabolites (TDMs)	N/A	0.062	0.01	
Risk assessment residue definition 1,2,4-triazole							
Celeriacs	NEU	4 × < 0.01; 0.011	Data on TDMs as reported for carrot root in the framework of the peer review of the risk assessment of triazole derivative metabolites (TDMs) (EFSA, 2018b)	N/A	0.011	0.01	
Oilseed rape	SEU	7 × < 0.01; 0.013; 0.018	Data on TDMs as reported for oilseed rape seed in the framework of the peer review of the risk assessment of triazole derivative metabolites (TDMs). Residue data are not supported by acceptable storage stability data for 1,2,4-T (EFSA, 2018b)	N/A	0.018	0.01	

NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe; N/A not applicable; MRL: maximum residue level; GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor.

B.1.2.2. 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 Yes: triazole derivative metabolites	EFSA (2007b, 2014)

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Relevant groups	Dietary burden expressed in				Most critical diet [a]	Most critical commodity [b]		Trigger exceeded (Yes/No) 0.10 mg/kg DM	JMPR 2017 (FAO, 2018) Max burden
	mg/kg bw per day		mg/kg DM						mg/kg DM
	Median	Maximum	Median	Maximum					
Cattle (all diets)	0.036	0.109	1.15	3.10	Dairy cattle	Barley	Straw	Y	18.42 (AUT dairy cattle)
Cattle (dairy only)	0.036	0.109	0.84	2.85	Dairy cattle	Barley	Straw	Y	21.60 (AUT beef cattle)
Sheep (all diets)	0.075	0.236	1.77	5.55	Lamb	Barley	Straw	Y	Not calculated
Sheep (ewe only)	0.059	0.185	1.77	5.55	Ram/ewe	Barley	Straw	Y	Not calculated
Swine (all diets)	0.015	0.018	0.49	0.64	Swine (finishing)	Swede	Roots	Y	Not calculated
Poultry (all diets)	0.035	0.059	0.52	0.86	Poultry layer	Wheat	Straw	Y	3.05 (EU poultry layer)
Poultry (layer only)	0.035	0.059	0.52	0.86	Poultry layer	Wheat	Straw	Y	Not calculated

bw: body weight; DM: dry matter.
(a): When several diets are relevant (e.g. cattle, sheep and poultry 'all diets'), the most critical diet is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.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: Carrots, head cabbage: 63% of ARfD Celeriacs/turnip rooted: 55.3% of ARfD Swedes: 52% of ARfD Leek: 47% of ARfD Beetroot: 44% of ARfD Other commodities individually below 40% of ARfD Triazole derivative metabolites (TDMs): Triazole alanine and triazole lactic acid Celeriac/turnip rooted celeriacs: 0.5% of ARfD Rapeseeds: 0.8% of ARfD Triazole acetic acid: Celeriac/turnip rooted celeriacs: 0.1% of ARfD Rapeseeds: 0.007% of ARfD 1,2,4-triazole: Celeriac/turnip rooted celeriacs: 0.6% of ARfD Rapeseeds: 0.02% of ARfD
Assumptions made for the calculations	Prothioconazole: The calculation is based on the highest residue levels expected in raw agricultural commodities, for which the existing EU MRLs are set above the LOQ. Default conversion factor (CF) of 2 for risk assessment was applied to the input values of those crops where no data according to the risk assessment residue definition are available (pulses, flowering brassica, Brussels sprouts, head cabbage, shallots, onions, leeks, rye, barley oats). For the remaining commodities, the conversion factor was derived from residue trials (oilseeds concerned (CF 2), wheat (CF 2), root and tuber vegetables (except sugar beet) (CF 2.7)). For cranberries and sweetcorn, no conversion factor was available. The crops on which no uses were reported in the MRL review, were excluded from the calculation For animal commodities, the input values are as derived by the JMPR and are considered to account for a major part of residues included in the EU risk assessment residue definition (i.e., prothioconazole-desthio and its 3-hydroxy and 4-hydroxy metabolites with its conjugates) TDMs: Indicative exposure assessment for TDMs has been performed only for celeriacs and rapeseeds, using the highest residue values as derived from the trials on carrots and oilseed rape submitted in the addendum to the peer review of the pesticide risk assessment of triazole derivative metabolites in light of confirmatory data (EFSA, 2018b). A comprehensive risk assessment, including all crops and all pesticides belonging to the class of triazole fungicides has not yet been performed Calculations performed with PRIMo revision 2

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: 7% of ADI (WHO Cluster diet B) Indicative calculation for TDMs: Triazole alanine and triazole lactic acid: 0.028% of ADI (WHO Cluster diet E) Triazole acetic acid: 0.001% of ADI (WHO Cluster diet E) 1,2,4-triazole: 0.03% of ADI (WHO Cluster diet E)
Assumptions made for the calculations	Prothioconazole: The calculation is based on the median residue levels expected in raw agricultural commodities, for which the existing EU MRLs are set above the LOQ Default conversion factor (CF) of 2 for risk assessment derived from plant metabolism studies was applied to the input values of those crops where no data according to the risk assessment residue definition are available (pulses, flowering brassica, Brussels sprouts, head cabbages, shallots, onions, leeks, rye, barley, oats) For the remaining commodities the conversion factor was derived from residue trials: oilseeds concerned (CF 2), wheat (CF 2), root and tuber vegetables (except sugar beet) (CF 2.7)). For cranberries and sweet corn no conversion factor was available. The crops on which no uses were reported in the MRL review were excluded from the calculation. For animal commodities, the input values are as derived by the JMPR and are considered to account for a major part of residues included in the EU risk assessment residue definition (i.e. prothioconazole-desthio and its 3-hydroxy and 4-hydroxy metabolites with its conjugates) TDMs: Indicative exposure assessment for TDMs has been performed only for celeriacs and rapeseeds, using the median residue values as derived by extrapolation from the trials on carrots and oilseed rape submitted in the addendum to the peer review of the pesticide risk assessment of triazole derivative metabolites in light of confirmatory data (EFSA, 2018b). A comprehensive risk assessment, including all crops and all pesticides belonging to the class of triazole fungicides has not yet been performed. Calculations performed with PRIMo revision 2

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; LOQ: limit of quantification; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level.

B.4. Recommended MRLs

Full details of all end points and the consumer risk assessment can be found in Appendices B.3 to D.1

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)]				
0213010	Beetroots	0.1 (ft 1)	0.1	The data gaps identified in the MRL review concerning residue trials and storage stability
0213020	Carrots			

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
				have been addressed. The MRL is confirmed. Risk for consumers unlikely
0213030	Celeriacs/turnip rooted celeries	0.01*	0.1	The submitted data are sufficient to support the intended NEU use. Risk for consumers unlikely
0213040	Horseradishes	0.1(ft 1)	0.1	The data gaps identified in the MRL review concerning residue trials and storage stability have been addressed. The MRL is confirmed. Risk for consumers unlikely
0213060	Parsnips	0.1(ft 1)	0.1	
0213070	Parsley roots/ hamburg roots parsley	0.1(ft 1)	0.1	
0213090	Salsifies	0.1(ft 1)	0.1	
0213100	Swedes/ rutabagas	0.1(ft 1)	0.1	
0213110	Turnips	0.1(ft 1)	0.1	
0220020	Onions	0.05 (ft 1)	Further risk management considerations required	The data gap identified in the MRL review concerning residue trials is not addressed, whereas the data gap concerning storage stability has been addressedSince the data gap is not fully addressed, risk managers may consider the lowering of the existing MRL to the LOQ of 0.02 mg/kg
0220030	Shallots	0.05 (ft 2)		
024100	Flowering brassica	0.05 (ft 3)	Further risk management considerations required	The data gap identified in the MRL review concerning residue trials is not addressed, whereas the data gap concerning storage stability has been addressedSince the data gaps are not fully addressed, risk managers may consider the lowering of the existing MRL to the LOQ of 0.02 mg/kg
0242010	Brussels sprouts	0.1 (ft 3)		
0242020	Head cabbages	0.09 (ft 3)		
0270060	Leeks	0.06 (ft 3)		
0300010	Beans	0.05 (ft 3)	Further risk management considerations required	The data gaps identified by EFSA concerning residue trials and storage stability have not been addressedSince data gaps are not addressed, risk managers may consider lowering of the existing MRL to the LOQ of 0.02 mg/kg
0300020	Lentils	1 (ft 3)		The existing EU MRL reflects CXL MRLThe data gaps identified by EFSA concerning residue trials and storage stability have not been addressedSince data gaps are not addressed, risk managers may consider lowering of the existing MRL to the LOQ of 0.02 mg/kg
0300030	Peas	1 (ft 3)		
0300040	Lupins/lupini beans	1 (ft 3)		
0401010	Linseeds	0.09 (ft 3)	0.09	The data gaps identified in the MRL review concerning residue trials and storage stability have been addressed. The MRL is confirmed. Risk for consumers unlikely
0401020	Peanuts/ groundnuts	0.02* (ft 3)	0.02*	The existing EU MRL reflects the CXL MRL. The data gap identified by EFSA concerning storage stability has been addressed. The data gap concerning residue trials is considered addressed since for oilseeds a reliable conversion factor of 2 from enforcement to risk assessment is derived from submitted residue trials on oilseed rape. The MRL is confirmed. Risk for consumers unlikely
0401030	Poppy seeds	0.09 (ft 3)	0.09	The data gaps identified by EFSA concerning residue trials and storage stability have been addressed. The MRL is confirmed. Risk for consumers unlikely

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0401060	Rapeseeds/canola seeds	0.15 (ft 3)	0.2	The data gaps identified by EFSA concerning residue trials and storage stability have been addressed. The additional residue trials submitted in support of the intended SEU use indicated that a higher MRL would be required. Risk for consumers unlikely
0401080	Mustard seeds	0.09 (ft 3)	0.09	The data gaps identified by EFSA concerning residue trials and storage stability have been addressed. The MRL is confirmed. Risk for consumers unlikely
0401130	Gold of pleasure seeds	0.04 (ft 3)	0.04	The data gap identified by EFSA concerning storage stability has been addressedThe data gap concerning residue trials is considered addressed since for oilseeds a reliable conversion factor of 2 from enforcement to risk assessment is derived from submitted residue trials on oilseed rapeThe MRL is confirmed. Risk for consumers unlikely
0500010	Barley	0.2 (ft 3)	Further risk management considerations required	The existing EU MRL reflects CXL MRL.The data gap identified by EFSA concerning residue trials is not addressed. The data gap identified by EFSA concerning storage stability has been addressedSince the data gaps are not fully addressed, risk managers may consider lowering of the existing MRL to the LOQ of 0.02 mg/kg
0500050	Oat	0.05 (ft 3)		
0500070	Rye	0.05 (ft 3)	0.05	The existing EU MRL reflects CXL MRLThe data gap identified by EFSA concerning residue trials for NEU use is not addressed. The data gap identified by EFSA concerning storage stability has been addressedSince the data gaps are not fully addressed, risk managers may consider lowering of the existing MRL to the LOQ of 0.02 mg/kg
0500090	Wheat	0.1 (ft 3)	0.1	The existing EU MRL reflects CXL MRLFor the authorised SEU use the data gaps identified by EFSA concerning residue trials and storage stability has been addressed. The tentative MRL of 0.02* mg/kg as derived by MRL review is confirmed. Risk for consumers unlikely
1011030	Swine liver	0.5 (ft 4)	Further risk management considerations required	The residue trials on grass (major component of livestock dietary burden) have not been submitted and thus the EU livestock dietary burden from existing EU uses including grass cannot be properly calculatedThe relevance of this data gap shall be considered by risk managers, given the fact that the existing EU MRLs for commodities of animal origin are based on CXLs (in 2018 lowered to 0.3 mg/kg), which are derived for significantly higher livestock dietary burdens
1011040	Swine kidney			
1011050	Swine edible offals			
1012030	Bovine liver			
1012040	Bovine kidney			
1012050	Bovine edible offals			
1012030	Sheep liver			
1012040	Sheep kidney			
1012050	Sheep edible offals			
1014030	Goat liver			
1014040	Goat kidney			
1014050	Goat edible offals			
1015030	Equine liver			

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
1015040	Equine kidney			
1015050	Equine edible offals			
1017030	Other farmed terrestrial animals liver			
1017040	Other farmed terrestrial animals kidney			
1017050	Other farmed terrestrial animals edible offals			
1020000	Milk	0.01* (ft 4)		

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; CXL: codex maximum residue limit.
*: 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.
ft 1: The European Food Safety Authority identified some information on residue trials and storage stability data complying with the proposed residue definition as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gaps No 3 and 5).
ft 2: The European Food Safety Authority identified some information on analytical methods and storage stability data complying with the proposed residue definition as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 3).
ft 3: The European Food Safety Authority identified some information on residue trials and storage stability data complying with the proposed residue definition as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gaps No 3 and 5).
ft 4: The European Food Safety Authority identified some information on residue trials on grass (major component of the livestock dietary burden), as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 2).

Appendix C – Pesticide Residue Intake Model (PRIMo)

1,2,4-triazole

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
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**

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	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	pTMRLs at LOQ (in % of ADI)
0.026	WHO cluster diet E	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	WHO Cluster diet F	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	IE adult	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	FR toddler	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	WHO regional European diet	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	FR infant	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	DE child	0.0	Celeriac	0.0	Rape seed		FRUIT (FRESH OR FROZEN)	
0.0	DK child	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	PL general population	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	FR all population	0.0	Celeriac	0.0	Rape seed		FRUIT (FRESH OR FROZEN)	
0.0	WHO Cluster diet B	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	DK adult	0.0	Celeriac	0.0	Rape seed		FRUIT (FRESH OR FROZEN)	
0.0	NL child	0.0	Celeriac	0.0	Rape seed		FRUIT (FRESH OR FROZEN)	
0.0	WHO cluster diet D	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	SE general population 90th percentile	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	NL general	0.0	Celeriac	0.0	Rape seed		FRUIT (FRESH OR FROZEN)	
0.0	IT adult	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	UK Adult	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	IT kids/toddler	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of 1,2,4-triazole is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
0.6	Celeriac	0.011/-	0.6	Celeriac	0.011/-	0.2	Celeriac	0.011/-	0.2	Celeriac	0.011/-
0.020	Rape seed	0.018/-	0.0	Rape seed	0.018/-						
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		---			**No of commodities for which ARfD/ADI is exceeded:**		---		
		***)					***)		
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		
0.1	Celeriac juice	0.011/-							

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For 1,2,4-triazole, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

TA and TLA

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
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**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	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	pTMRLs at LOQ (in % of ADI)
0.028	WHO cluster diet E	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	WHO Cluster diet F	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	WHO regional European diet	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	WHO Cluster diet B	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	WHO cluster diet D	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	FR all population	0.0	Rape seed	0.0	Celeriac		FRUIT (FRESH OR FROZEN)	
0.0	DE child	0.0	Rape seed	0.0	Celeriac		FRUIT (FRESH OR FROZEN)	
0.0	IE adult	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	FR toddler	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	FR infant	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	NL child	0.0	Rape seed	0.0	Celeriac		FRUIT (FRESH OR FROZEN)	
0.0	DK child	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	DK adult	0.0	Celeriac	0.0	Rape seed		FRUIT (FRESH OR FROZEN)	
0.0	PL general population	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	NL general	0.0	Rape seed	0.0	Celeriac		FRUIT (FRESH OR FROZEN)	
0.0	SE general population 90th percentile	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	IT adult	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	UK Adult	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	IT kids/toddler	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of TA and TLA is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
0.8 0.5	Rape seed Celeriac	2.17/- 0.028/-	0.8 0.5	Rape seed Celeriac	2.17/- 0.028/-	0.2	Celeriac	0.028/-	0.2	Celeriac	0.028/-
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL.
***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For TA and TLA, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

Triazole acetic acid

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
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**

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	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	pTMRLs at LOQ (in % of ADI)
0.001	WHO cluster diet E	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	WHO Cluster diet F	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	IE adult	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	FR toddler	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	WHO regional European diet	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	FR infant	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	DE child	0.0	Celeriac	0.0	Rape seed		FRUIT (FRESH OR FROZEN)	
0.0	DK child	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	PL general population	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	FR all population	0.0	Celeriac	0.0	Rape seed		FRUIT (FRESH OR FROZEN)	
0.0	WHO Cluster diet B	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	DK adult	0.0	Celeriac	0.0	Rape seed		FRUIT (FRESH OR FROZEN)	
0.0	NL child	0.0	Celeriac	0.0	Rape seed		FRUIT (FRESH OR FROZEN)	
0.0	WHO cluster diet D	0.0	Rape seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	SE general population 90th percentile	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	NL general	0.0	Celeriac	0.0	Rape seed		FRUIT (FRESH OR FROZEN)	
0.0	IT adult	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	UK Adult	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	IT kids/toddler	0.0	Celeriac		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	ES adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Triazole acetic acid is unlikely to present a public health concern.

	Acute risk assessment/children – refined calculations						Acute risk assessment/adults/general population – refined calculations					
	The acute risk assessment is based on the ARfD. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.											
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
	IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	0.1	Celeriac	0.01/-	0.1	Celeriac	0.01/-	0.0	Celeriac	0.01/-	0.0	Celeriac	0.01/-
	0.007	Rape seed	0.062/-	0.0	Rape seed	0.062/-						
	No of critical MRLs (IESTI 1)		---				**No of critical MRLs (IESTI 2)**		---			
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:**		---				**No of commodities for which ARfD/ADI is exceeded:**		---			
			***)						***)			
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. **) pTMRL: provisional temporary MRL. ***) pTMRL: provisional temporary MRL for unprocessed commodity.											
	Conclusion: For triazole acetic acid, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity. For processed commodities, no exceedance of the ARfD/ADI was identified.											

Prothioconazole-desthio			
Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.01**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**CIOM**	Source of ARfD:	**COM**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	1 7
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	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	pTMRLs at LOQ (in % of ADI)
7	WHO Cluster diet B	3.4	Wheat	0.6	Soya bean	0.5	Beetroot	
6	NL child	1.9	Wheat	1.5	Milk and milk products: Cattle	0.6	Potatoes	
5	IE adult	0.9	Wheat	0.9	Barley	0.5	Parsnips	
5	WHO cluster diet E	1.6	Wheat	0.6	Soya bean	0.6	Barley	
5	WHO cluster diet D	2.6	Wheat	0.4	Potatoes	0.4	Soya bean	
5	WHO Cluster diet F	1.4	Wheat	0.7	Soya bean	0.4	Barley	
5	FR infant	2.1	Carrots	1.3	Milk and milk products: Cattle	0.4	Potatoes	
5	DK child	2.2	Wheat	1.1	Carrots	0.9	Rye	
5	FR toddler	2.0	Carrots	1.0	Wheat	0.5	Potatoes	
4	DE child	1.6	Wheat	0.8	Carrots	0.7	Milk and milk products: Cattle	
4	SE general population 90th percentile	1.3	Wheat	0.7	Carrots	0.6	Milk and milk products: Cattle	
4	ES child	1.8	Wheat	0.6	Milk and milk products: Cattle	0.2	Lentils	
4	WHO regional European diet	1.2	Wheat	0.4	Potatoes	0.3	Carrots	
3	PT General population	1.6	Wheat	0.5	Potatoes	0.5	Potatoes	
3	UK Infant	1.1	Carrots	1.0	Wheat	0.3	Potatoes	
3	IT kids/toddler	2.7	Wheat	0.1	Carrots	0.1	Potatoes	
3	UK Toddler	1.6	Wheat	0.4	Carrots	0.3	Potatoes	
3	NL general	0.8	Wheat	0.3	Milk and milk products: Cattle	0.3	Potatoes	
2	ES adult	0.9	Wheat	0.3	Barley	0.2	Milk and milk products: Cattle	
2	FR all population	1.3	Wheat	0.2	Carrots	0.1	Milk and milk products: Cattle	
2	IT adult	1.7	Wheat	0.1	Carrots	0.1	Potatoes	
2	LT adult	0.4	Wheat	0.3	Potatoes	0.2	Rye	
2	DK adult	0.8	Wheat	0.4	Carrots	0.1	Potatoes	
1	UK vegetarian	0.8	Wheat	0.2	Carrots	0.1	Potatoes	
1	UK Adult	0.7	Wheat	0.1	Carrots	0.1	Potatoes	
1	PL general population	0.3	Potatoes	0.2	Carrots	0.2	Beetroot	
1	FI adult	0.4	Wheat	0.2	Carrots	0.1	Rye	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Prothioconazole-desthio is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
63	Carrots	0.1/-	55.3	Celeriac	0.1/-	38.1	Head cabbage	0.12/-	23.9	Swedes	0.1/-
63	Head cabbage	0.12/-	51.7	Swedes	0.1/-	23.9	Swedes	0.1/-	22.9	Head cabbage	0.12/-
55	Celeriac	0.1/-	45.3	Carrots	0.1/-	16.8	Celeriac	0.1/-	16.8	Celeriac	0.1/-
52	Swedes	0.1/-	37.9	Head cabbage	0.12/-	15.3	Leek	0.08/-	12.7	Cauliflower	0.04/-
47	Leek	0.08/-	33.7	Leek	0.08/-	14.1	Parsnips	0.1/-	11.6	Leek	0.08/-
44	Beetroot	0.1/-	32.6	Beetroot	0.1/-	13.8	Beetroot	0.1/-	10.8	Beetroot	0.1/-
39	Salsify	0.1/-	28.1	Salsify	0.1/-	12.7	Cauliflower	0.04/-	10.3	Parsnips	0.1/-
36	Parsnips	0.1/-	26.4	Cauliflower	0.04/-	11.9	Carrots	0.1/-	9.5	Carrots	0.1/-
36	Turnips	0.1/-	25.8	Parsnips	0.1/-	10.7	Salsify	0.1/-	8.5	Broccoli	0.04/-
26	Cauliflower	0.04/-	25.7	Turnips	0.1/-	10.5	Turnips	0.1/-	7.7	Salsify	0.1/-
23	Broccoli	0.04/-	18.6	Bovine: Liver	0.23/-	8.5	Broccoli	0.04/-	7.6	Turnips	0.1/-
19	Bovine: Liver	0.23/-	16.6	Broccoli	0.04/-	7.1	Brussels sprouts	0.14/-	7.1	Brussels sprouts	0.14/-
16	Onions	0.04/-	12.3	Brussels sprouts	0.14/-	6.2	Bovine: Liver	0.23/-	6.2	Bovine: Liver	0.23/-
15	Potatoes	0.01/-	11.4	Onions	0.04/-	5.9	Onions	0.04/-	5.1	Barley	0.07/-
13	Sweet corn	0.018/-	11.1	Cranberries	0.9/-	5.1	Barley	0.07/-	4.4	Bovine: Edible offal	0.15/-
12	Brussels sprouts	0.14/-	11.0	Potatoes	0.01/-	4.4	Bovine: Edible offal	0.15/-	4.2	Onions	0.04/-
No of critical MRLs (IESTI 1)		---				**No of critical MRLs (IESTI 2)**		---			

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		---		**No of commodities for which ARfD/ADI is exceeded:**		---	
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
42.9	Carrot, juice	0.1/-		4.4	Bread/pizza	0.1/-	
13.2	Celeriac juice	0.1/-		1.0	Orange juice	0.01/-	
11.8	Wheat flour	0.1/-		0.7	Apple juice	0.01/-	
5.1	Apple juice	0.01/-		0.4	Wine	0.01/-	
5.0	Orange juice	0.01/-		0.4	Maize flour	0.1/-	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL.
***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Prothioconazole-desthio, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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 in plant commodities: 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)				
Rape seed meal	0.16	STMR × PF (2)[a]	0.16	STMR × PF(2)[a]
Sunflower seed meal	0.04	STMR × CF (2) × PF (2)[a] (EFSA, 2015a,b)	0.04	STMR × CF (2) × PF (2)[a] (EFSA, 2015a,b)[a]
Head cabbage	0.02	STMR × CF (EFSA, 2014)	0.12	HR × CF (EFSA, 2014)
Maize silage	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Maize grain	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Maize, milled by-products[b] Maize, hominy meal[b] Maize gluten feed/ gluten meal[b] Distiller`s grain[b]	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) × CF (2) (EFSA, 2014)
Barley grain	0.07	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)	0.07	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)
Brewer`s grain	0.23	STMR barley grain (FAO, 2009b) × CF (2) (EFSA, 2014) × PF (3.3)[a]	0.23	STMR barley grain (FAO, 2009b) × CF (2) (EFSA, 2014) × PF (3.3)[a]
Oat grain	0.02	STMR (FAO, 2009a) × CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2009a) × CF (2) (EFSA, 2014)
Wheat grain	0.04	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)	0.04	STMR (FAO, 2009b) × CF (2) (EFSA, 2014)
Wheat gluten meal[b]	0.04	STMR wheat grain (FAO, 2009b) × CF (2) × PF (1.8)[a]	0.04	STMR wheat grain (FAO, 2010) × CF (2) × PF (1.8)[a]
Wheat milled by-products[b]	0.28	STMR wheat grain (FAO, 2009b) × CF (2) × PF (7)[a]	0.28	STMR wheat grain (FAO, 2010) × CF (2) × PF (7)[a]
Rye grain	0.02	STMR (FAO, 2009a) × CF (2)	0.02	STMR (FAO, 2009a) × CF (2)
Barley straw	1.96	STMR (FAO, 2009b) × CF (3) (EFSA, 2014)	7.50	HR[d] × CF (3) (EFSA, 2014)
Oats straw	1.26	STMR[d] × CF (3) (EFSA, 2014)	7.50	HR[d] × CF (3) (EFSA, 2014)
Wheat straw	2.69	STMR	5.52	HR[d] (EFSA, 2014) × CF (2.3)
Rye straw	2.25	STMR[d] × CF (3) (EFSA, 2014)	5.52	HR[d] (EFSA, 2014) × CF (2.3)
Cotton seed	0.10	STMR (FAO, 2018) × CF (2)	0.10	STMR (FAO, 2018) × CF (2)
Cotton seed meal	0.14	STMR (FAO, 2018) × CF (2) × PF (1.3)[a]	0.14	STMR (FAO, 2018) × CF (2) × PF (1.3)[a]
Beans (dry)	0.02	STMR × CF (2) (EFSA, 2014)	0.02	STMR × CF (2) (EFSA, 2014)
Peas, lupins (dry)	0.10	STMR (FAO, 2009b) × CF (2)	0.10	STMR (FAO, 2009b) × CF (2)
Lupin seed meal	0.11	STMR (FAO, 2009b) × CF (2) × PF (1.1)[a]	0.11	STMR (FAO, 2009b) × CF (2) × PF (1.1)[a]
Potatoes	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Potato process waste[b] Potato dried pulp[b]	0.01	STMR potato (EFSA, 2014) × PF (1)[c]	0.01	HR potato (EFSA, 2014) × PF (1)[c]
Turnips, swedes, carrot culls	0.08	STMR	0.10	HR
Peanut meal	0.04	STMR (FAO, 2009b) × CF (2) × PF (2)	0.04	STMR (FAO, 2009b) × CF (2) × PF (2)
Linseed meal	0.12	STMR × CF (2) × PF (2)[a] (EFSA, 2015a,b)	0.12	STMR × CF (2) × PF (2)[a] (EFSA, 2015a,b)
Soybean seed	0.10	STMR (FAO, 2014) × CF (2)	0.10	STMR (FAO, 2014) × CF (2)
Soybean seed 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[b]	1.30	STMR soybean (FAO, 2014) × CF (2) × PF (13)[a]	1.30	STMR soybean (FAO, 2014) × CF (2) × PF (13)[a]

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, brewer's grain, wheat gluten meal, wheat milled by-products, cotton seed meal, lupin seed meal, soybean meal, lupin seed meal, and soybean hulls in the absence of processing factors supported by data, default processing factors of 2, 3.3, 1.8, 7, 1.3, 1.1, 1.3 and 13 were, respectively, 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,b) 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	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 1: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2*H*-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
Celeriac	0.08	STMR	0.10	HR
Beetroots, carrots, horseradish, parsnips, parsley roots, salsifies, swedes, turnips	0.08	STMR	0.10	HR
Rape seed	0.08	STMR	0.08	STMR
Cranberries	0.025	STMR[a] (FAO, 2014)	0.90	HR[a] (FAO, 2014)
Potatoes	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Sweet corn	0.018	STMR[a] (FAO, 2014)	0.018	HR[a] (FAO, 2014)
Onions, shallots	0.02	STMR (EFSA, 2014, 2015a) × CF (2)	0.04	HR (EFSA, 2014, 2015a) × CF (2)
Flowering brassica	0.02	STMR × CF (2) (EFSA, 2014)	0.04	HR × CF (2) (EFSA, 2014)
Brussels sprouts	0.06	STMR × CF (2) (EFSA, 2014)	0.14	HR × CF (2) (EFSA, 2014)
Head cabbage	0.02	STMR × CF (2) (EFSA, 2014)	0.12	HR × CF (2) (EFSA, 2014)
Leeks	0.02	STMR × CF (2) (EFSA, 2014)	0.08	HR × CF (2) (EFSA, 2014)
Beans	0.02	STMR × CF (2) (EFSA, 2014)	0.02	STMR × CF (2) (EFSA, 2014)

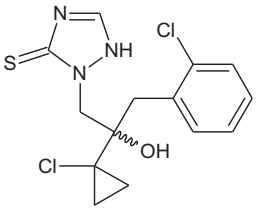
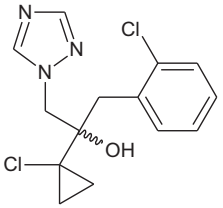
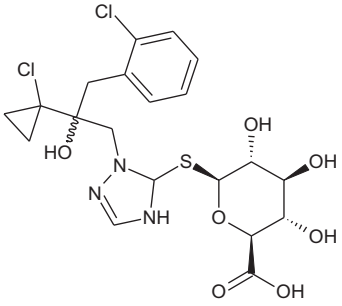
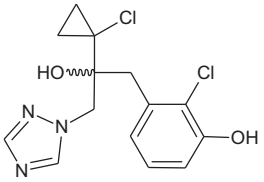
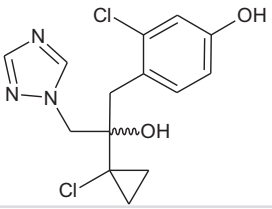
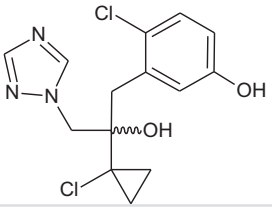
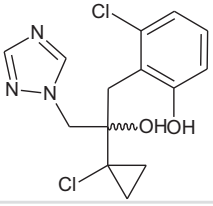
Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Lentils, peas, lupins	0.10	STMR[(a)] (FAO, 2009b) × CF (2)	0.10	STMR[(a)] (FAO, 2009b) × CF (2)
Linseeds, poppy seeds, mustard seeds	0.06	STMR × CF (2) (EFSA, 2014)	0.06	STMR × CF (2) (EFSA, 2014)
Gold of pleasure seeds	0.02	STMR × CF (2) (EFSA, 2014)	0.02	STMR × CF (2) (EFSA, 2014)
Peanuts	0.02	STMR (FAO, 2009b) × CF (2)	0.02	STMR (FAO, 2009b) × CF (2)
Sunflower seeds	0.02	STMR (EFSA, 2015b) × CF (2)	0.02	STMR (EFSA, 2015b) × CF (2)
Cotton seed	0.1	STMR (FAO, 2018) × CF × (2)	0.1	STMR (FAO, 2018) × CF × (2)
Soybean	0.1	STMR (FAO, 2014) × CF (2)	0.1	STMR (FAO, 2014) × CF (2)
Barley grain	0.07	STMR[(a)] (FAO, 2009b) × CF (2)	0.07	STMR[(a)] (FAO, 2009b) × CF (2)
Maize grain	0.02	STMR[(a)] (FAO, 2014) × CF (2)	0.02	STMR[(a)] (FAO, 2014) × CF (2)
Oat, rye grain	0.02	STMR[(a)] (FAO, 2009a) × CF (2)	0.02	STMR[(a)] (FAO, 2009a) × CF (2)
Wheat grain	0.04	STMR[(a)] (FAO, 2009b) × CF (2)	0.04	STMR[(a)] (FAO, 2009b) × CF (2)
Muscle of swine, bovine, sheep, goat, equine, other farmed animals	0.01	STMR[(b)] (FAO, 2018)	0.01	HR[(b)] (FAO, 2018)
Fat of swine, bovine, sheep, goat, equine, other farmed animals	0.01	STMR[(b)] (FAO, 2018)	0.018	HR[(b)] (FAO, 2018)
Liver of swine, bovine, sheep, goat, equine, other farmed animals	0.05	STMR[(b)] (FAO, 2009b)	0.23	HR[(b)] (FAO, 2009b)
Kidney, edible offal of swine, bovine, sheep, goat, equine, other farmed animals	0.025	STMR[(b)] (FAO, 2009b)	0.15	HR[(b)] (FAO, 2009b)
Muscle of poultry	0.0016	STMR[(b)] (FAO, 2018)	0.0016	HR[(b)] (FAO, 2018)
Fat of poultry	0.008	STMR[(b)] (FAO, 2018)	0.008	HR[(b)] (FAO, 2018)
Liver, kidney, edible offal of poultry	0.071	STMR[(b)] (FAO, 2018)	0.071	HR[(b)] (FAO, 2018)
Milks	0.005	STMR (EFSA, 2014)	0.005	HR (EFSA, 2014)
Eggs	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Risk assessment residue definition 2: Triazole alanine (TA) and triazole lactic acid (TLA)				
Celeriacs	0.01	STMR (calculated from trials submitted to addendum of EFSA conclusion 2018)	0.028	HR (calculated from trials submitted to addendum of EFSA conclusion 2018)
Rapeseeds	0.14		2.17	
Risk assessment residue definition 3: Triazole acetic acid (TAA)				
Celeriacs	0.01	STMR (calculated from trials submitted to addendum of EFSA conclusion 2018)	0.01	HR (calculated from trials submitted to addendum of EFSA conclusion 2018)
Rapeseeds	0.01		0.062	
Risk assessment residue definition 4: 1,2,4-triazole				
Celeriacs	0.01	STMR (calculated from trials submitted to addendum of EFSA conclusion 2018)	0.011	HR (calculated from trials submitted to addendum of EFSA conclusion 2018)
Rapeseeds	0.01		0.018	

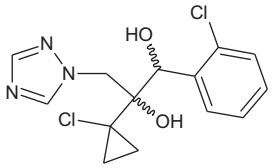
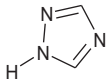
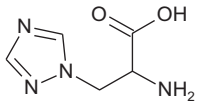
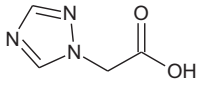
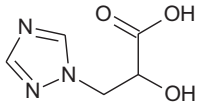
STMR: supervised trials median residue; HR: highest residue; CF: conversion factor for enforcement to risk assessment residue definition.

(a): Values refer to the residues of prothioconazole-desthio; data according to Eu risk assessment residue definition not available.

(b): Values refer to the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates expressed as prothioconazole-desthio.

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-(1H-1,2,4-triazol-1-yl)-2-propanol OC(Cn1cncn1)(Cc1ccccc1Cl)C1(Cl)CC1 HHUQPWODPBDTLI-UHFFFAOYSA-N	
Prothioconazole-S-glucuronide (M06)	1-[(2*RS*)-2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-4,5-dihydro-1*H*-1,2,4-triazol-5-yl 1-thio-β-D-glucopyranosiduronic acid Clc1ccccc1CC(O)(CN1N=CNC1S[C@@H]1O[C@@H]([C@@H](O)[C@H](O)[C@H]1O)C(=O)O)C1(Cl)CC1 WGHNGXVTRJBVMV-NXZBHKIYSA-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	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Prothioconazole-α hydroxy-desthio (M18)	(1*RS*,2*RS;*1*RS*,2*SR)*-2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)propane-1,2-diol OC(Cn1cncn1)(C(O)c1ccccc1Cl)C1(Cl)CC1 JOFJRMIXOWNPNA-UHFFFAOYSA-N	
Triazole derivative metabolites		
1,2,4-triazole	1*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 Triazolehydroxy 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 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).