REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for prothioconazole according to Article 12 of Regulation (EC) No 396/2005[1]

European Food Safety Authority[2, 3]

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ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance prothioconazole. In order to assess the occurrence of prothioconazole residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission as well as the European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Some information required by the regulatory framework was found to be missing and a possible acute risk to consumers was identified. Hence, the consumer risk assessment is considered indicative only, some MRL proposals derived by EFSA still require further consideration by risk managers and measures for reduction of the consumer exposure should also be considered.

KEY WORDS

prothioconazole, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, triazole, fungicide, prothioconazole-desthio

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SUMMARY

Prothioconazole was included in Annex I to Directive 91/414/EEC on 01 August 2008, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked United Kingdom, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 27 July 2011 and, after having considered several comments made by EFSA, the RMS provided on 31 October 2012 a revised PROFile.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS, EFSA issued on 28 October 2013 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 10 January 2014 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of prothioconazole was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.05 mg/kg bw per d and 0.2 mg/kg bw, respectively. The toxicological profile of prothioconazole-desthio was also evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.01 mg/kg bw per d and 0.01 mg/kg bw, respectively.

Metabolism of prothioconazole in primary crops was investigated for foliar application in root and tuber vegetables, pulses and oilseeds and cereals using phenyl and triazole labellings, and for seed treatment in cereals only. The metabolism of prothioconazole-desthio was also investigated for foliar application on cereals. The metabolic pattern of prothioconazole and prothioconazole-desthio was shown to be similar with prothioconazole-desthio being the predominant compound of the total residues with further hydroxylation and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of triazole derivative metabolites (TDMs). A global residue definition for enforcement was proposed as prothioconazole-desthio (sum of isomers) only whilst for risk assessment, the residue was defined as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). As the residue definitions for enforcement and risk assessment are different, conversion factors for enforcement to risk assessment of 2 for cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables and of 3 for cereal straw were derived on the basis of the available plant metabolism data. For maize and potatoes (seed treatment), no median conversion factors for enforcement to risk assessment were derived since residues in these crops are expected to be below 0.01 mg/kg. Validated analytical methods for enforcement of the proposed residue definition are available.

Sufficient residue trials were available to derive MRL proposals and risk assessment values on potatoes and maize grain. For grass, no residue trial was submitted. For all the other crops, only tentative MRL proposals and risk assessment values could be derived, due to the data gaps identified for additional residue trials analysing the residues in compliance with the proposed residue definition for risk assessment, clarification on the analytical method used in the residue trials on rape seed and further storage stability data. Tentative MRLs were also derived for cereal straw and maize forage in view of the future need to set MRLs in feed items.

Based on the available data for processed commodities, the residue definition for enforcement and risk assessment derived in primary crops can also apply to the processed commodities. No studies investigating the magnitude of residues in processed commodities are available. As such studies are not expected to affect the outcome of the risk assessment, these are not required.

The metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary. Considering the application rates of prothioconazole reported in the authorized European GAPs, it can be concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops and no risk mitigation measures need to be proposed.

The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg DM for ruminants, pigs and poultry. Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products was set as prothioconazole-desthio (sum of isomers) for all the livestock matrices. This compound is fat soluble. It is however noted that in case the livestock dietary burden is further increased in the future due to additional uses on feed items, the residue definition for enforcement might have to be revised by including the glucuronide conjugates of prothioconazole-desthio for all livestock matrices. For risk assessment, the residue was defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). Validated analytical methods for enforcement of the proposed residue definition are available, except for eggs.

Based on the ruminants feeding study tentative MRLs were set at the LOQ for all matrices, except for liver and kidney, where MRLs of respectively 0.05 and 0.02 mg/kg were proposed. Since only the residues of prothioconazole-desthio were determined, conversion factors for enforcement to risk assessment of 2 and 9 were established respectively for liver and kidney based on the goat metabolism study with administration of prothioconazole-desthio. It is noted that no conversion factor was set for milk, muscle and fat as the residue levels in these matrices are expected to be negligible (<0.01 mg/kg) at the calculated dietary burden. Nevertheless, a new feeding study to estimate the potential exposure to all prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment is in principle still required. For poultry, although the maximum dietary burden exceeded the threshold of 0.1 mg/kg DM, no residues above the LOQ were expected in poultry matrices at the calculated dietary burden and no feeding study was triggered. Therefore, MRLs can be established at the LOQ in all poultry commodities and no default conversion factors for risk assessment need to be derived. The MRLs for livestock matrices are all tentative due to the tentative dietary burden calculations, the missing livestock feeding study in ruminants and the required validated analytical method for enforcement in eggs.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 4.3 % of the ADI (Dutch child) and the highest acute exposure amounted to 63.4 % of the ARfD (carrots).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for prothioconazole. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure represented 26.3 % of ADI (UK toddler) whilst exceedances of the ARfD were identified for the existing CXLs in sugar beet root (242.6 %) and dry beans (208.3 %). Excluding these CXLs from the calculation, the highest chronic exposure represented 6.1 % of the ADI (WHO Cluster diet B)) and the highest acute exposure amounted to 70.1 % of the ARfD (lentils).

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk

managers (see summary table footnotes for details). In particular, tentative MRLs need to be confirmed by the following data:

- Fully validated analytical methods for the determination of prothioconazole-desthio in eggs;
- 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);
- 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;
- Clarification on whether the conjugates of M14, M15, M16, M17 and M18 metabolites were effectively analysed in the residue trials conducted on rape seed;
- 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);
- A ruminants 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.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- 1 additional residue trial on rape seed supporting the southern outdoor GAP.
- A study investigating the effects of processing on the nature of all the metabolites included in the residue definition for risk assessment in plant commodities.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA also emphasises that the above assessment does not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition (existing): prothioconazole-desthio **Enforcement residue definition (proposed):** prothioconazole-desthio (sum of isomers)					
211000	Potatoes	0.02*	-	0.05*	Recommended [(a)]
213010	Beetroot	0.1	-	0.1	Further consideration needed [(b)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
213020	Carrots	0.1	-	0.1	Further consideration needed [(b)]
213040	Horseradish	0.1	-	0.1	Further consideration needed [(b)]
213060	Parsnips	0.1	-	0.1	Further consideration needed [(b)]
213070	Parsley root	0.1	-	0.1	Further consideration needed [(b)]
213090	Salsify	0.1	-	0.1	Further consideration needed [(b)]
213100	Swedes	0.1	-	0.1	Further consideration needed [(b)]
213110	Turnips	0.1	-	0.1	Further consideration needed [(b)]
220020	Onions	0.02*	-	0.05*	Further consideration needed [(b)]
241010	Broccoli	0.03	-	0.05*	Further consideration needed [(b)]
241020	Cauliflower	0.03	-	0.05*	Further consideration needed [(b)]
242010	Brussels sprouts	0.1	-	0.1	Further consideration needed [(b)]
242020	Head cabbage	0.1	-	0.09	Further consideration needed [(b)]
270060	Leek	0.05	-	0.06	Further consideration needed [(b)]
300010	Beans (dry)	1	1	0.05	Further consideration needed [(h)]
300020	Lentils (dry)	1	1	1	Further consideration needed [(g)]
300030	Peas (dry)	1	1	1	Further consideration needed [(f)]
300040	Lupins (dry)	1	1	1	Further consideration needed [(g)]
401010	Linseed	0.15	-	0.09	Further consideration needed [(b)]
401020	Peanuts	0.05	0.02*	0.02*	Further consideration needed [(g)]
401030	Poppy seed	0.15	-	0.09	Further consideration needed [(b)]
401060	Rape seed	0.15	0.1	0.15	Further consideration needed [(d)]
401080	Mustard seed	0.15	-	0.09	Further consideration needed [(b)]
401130	Gold of pleasure	0.05	-	0.04	Further consideration needed [(b)]
500010	Barley grain	0.3	0.2	0.2	Further consideration needed [(f)]
500030	Maize grain	0.02*	-	0.02*	Recommended [(a)]
500050	Oats grain	0.05	0.05	0.05	Further consideration needed [(f)]
500070	Rye grain	0.1	0.05	0.05	Further consideration needed [(f)]
500090	Wheat grain	0.1	0.1	0.1	Further consideration needed [(f)]
900010	Sugar beet (root)	0.3	0.3	0.05*	Further consideration needed [(e)]
Enforcement residue definition (existing): Sum of prothioconazole-desthio and its glucuronide conjugate, expressed as prothioconazole-desthio **Enforcement residue definition (proposed):** prothioconazole-desthio (sum of isomers)					
1011010	Swine muscle	0.05	0.01	0.01*	Further consideration needed [(d)]
1011020	Swine fat (free of lean meat)	0.05	0.01	0.01*	Further consideration needed [(d)]
1011030	Swine liver	0.5	0.5	0.5	Further consideration needed [(f)]
1011040	Swine kidney	0.5	0.5	0.5	Further consideration needed [(f)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1012010	Bovine muscle	0.05	0.01	0.01*	Further consideration needed (d)
1012020	Bovine fat	0.05	0.01	0.01*	Further consideration needed (d)
1012030	Bovine liver	0.5	0.5	0.5	Further consideration needed (f)
1012040	Bovine kidney	0.5	0.5	0.5	Further consideration needed (f)
1013010	Sheep muscle	0.05	0.01	0.01*	Further consideration needed (d)
1013020	Sheep fat	0.05	0.01	0.01*	Further consideration needed (d)
1013030	Sheep liver	0.5	0.5	0.5	Further consideration needed (f)
1013040	Sheep kidney	0.5	0.5	0.5	Further consideration needed (f)
1014010	Goat muscle	0.05	0.01	0.01*	Further consideration needed (d)
1014020	Goat fat	0.05	0.01	0.01*	Further consideration needed (d)
1014030	Goat liver	0.5	0.5	0.5	Further consideration needed (f)
1014040	Goat kidney	0.5	0.5	0.5	Further consideration needed (f)
1016010	Poultry muscle	0.05	-	0.01*	Further consideration needed (b)
1016020	Poultry fat	0.05	-	0.01*	Further consideration needed (b)
1016030	Poultry liver	0.05	-	0.01*	Further consideration needed (b)
1020010	Cattle milk	0.01*	0.004*	0.005*	Further consideration needed (d)
1020020	Goat milk	0.01*	0.004*	0.005*	Further consideration needed (d)
1020030	Sheep milk	0.01*	0.004*	0.005*	Further consideration needed (d)
1030000	Birds' eggs	0.05	-	0.01*	Further consideration needed (b)
-	Other products of plant and animal origin	See App C1	-	-	Further consideration needed (c)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk
(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(d): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(e): There are no relevant authorisations or import tolerances reported at EU level; CXL is not sufficiently supported by data and a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-IV in Appendix D).
(f): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix D).
(g): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix D).
(h): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; CXL is higher, but not sufficiently supported by data but a risk to consumers cannot be excluded (combination E-IV in Appendix D).

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BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(2) of that regulation stipulates that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As prothioconazole was included in Annex I to the above mentioned directive on 01 August 2008, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-617 was included in the EFSA Register of Questions.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that in the framework of Directive 91/414/EEC only a few representative uses are evaluated, while MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the EU, and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

In order to gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities and;
- the analytical methods for enforcement of the proposed MRLs.

United Kingdom, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for prothioconazole. The requested information was submitted to EFSA on 27 July 2011 and subsequently checked for completeness. On 31 October 2012, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 28 October 2013 and submitted to Member States (MS) for commenting. All MS comments received by 10 January 2014 were considered by EFSA in the finalisation of the reasoned opinion.

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

[5] 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.

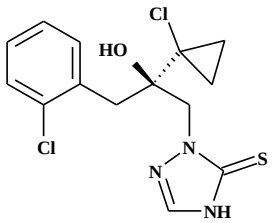
TERMS OF REFERENCE

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

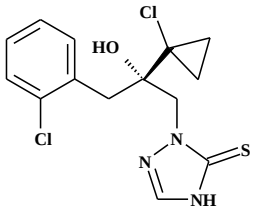
- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

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).



R - enantiomer



S - enantiomer

Prothioconazole belongs to the group of triazole compounds which are used as fungicides. It is a systemic compound which acts against a wide range of fungicidal diseases with protective, curative and eradicative activity. Its mode of action consists of a steroid demethylation in the ergosterol biosynthesis pathway. The technical active substance used in the pesticide formulations is a racemic mixture of the two stereoisomers (R – enantiomer and S – enantiomer).

Prothioconazole was evaluated in the framework of Directive 91/414/EEC with United Kingdom being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were outdoor foliar spray applications on cereals (wheat, rye, triticale, barley, oats) and rape seed, with 2 to 3 applications at rates ranging between 0.175 and 0.2 kg a.s./ha and with a PHI of 35 days (cereals) or 56 days (rape seed) both in Northern and Southern Europe. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2008/44/EC[6], which entered into force on 01 August 2008. According to Regulation (EU) No 540/2011[7], prothioconazole is

[6] 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.

[7] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1-186.

deemed to have been approved under Regulation (EC) No 1107/2009[8]. This approval is restricted to uses as fungicide only.

The EU MRLs for prothioconazole are established in Annex IIIA of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for head cabbage, Brussels sprouts, broccoli, cauliflower, various root vegetables and oilseeds (EFSA, 2009, 2010a, 2010b, 2012) which were legally implemented in Regulations No 1050/2009/EC[9], 893/2010/EU[10], 508/2011/EU[11] and 834/2013/EU[12]. Modifications of the existing MRLs for pulses, rape seed, sugar beet (root), ruminant and swine liver, kidney and honey were also legally implemented in Regulations No 459/2010/EU[13], 520/2011/EU[14] and 834/2013/EU (without involvement of EFSA). All existing EU MRLs are established for prothioconazole-desthio[15] in plant commodities and for the sum of prothioconazole-desthio and its glucuronide conjugates, expressed as prothioconazole-desthio for livestock commodities (except honey). The existing EU MRLs are summarised in Appendix C.1 to this document. CXLs for prothioconazole were also established by the Codex Alimentarius Commission and are reported in Appendix C.2 to this reasoned opinion. These CXLs refer to prothioconazole-desthio only, for both plant and animal commodities.

For the purpose of this MRL review, the critical uses of prothioconazole currently authorised within the EU have been collected by the RMS and reported in the PROFile. The additional GAPs reported during the consultation of Member States were also considered (see Appendix A). These GAPs include post-emergence foliar spray applications on several crops (root and tuber-, bulb-, brassica- and stem vegetables, pulses, oilseeds and cereals), at rates ranging from 120 g a.s./ha to 200 g a.s./ha, 2 to 4 applications at PHIs ranging between 14 and 56 days, both in Northern and Southern Europe. They also include seed treatments on potatoes and maize at rates ranging between 0.64 and 27 g a.s./100 kg seeds respectively, in Northern and Southern Europe. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ 309, 24.11.2009, p. 1-50.

[9] Commission Regulation (EC) No 1050/2009 of 28 October 2009 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, acetamiprid, clomazone, cyflufenamid, emamectin benzoate, famoxadone, fenbutatin oxide, flufenoxuron, fluopicolide, indoxacarb, ioxynil, mepanipyrim, prothioconazole, pyridalyl, thiacloprid and trifloxystrobin in or on certain products. OJ L 290, 6.11.2009, p. 7-55.

[10] Commission Regulation (EU) No 893/2010 of 8 October 2010 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, bentazone, carbendazim, cyfluthrin, fenamidone, fenazaquin, flonicamid, flutriafol, imidacloprid, ioxynil, metconazole, prothioconazole, tebufenozide and thiophanate-methyl in or on certain products. OJ L 266, 9.10.2010, p. 10-38.

[11] Commission Regulation (EU) No 508/2011 of 24 May 2011 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, acetamiprid, cyprodinil, difenoconazole, dimethomorph, fenhexamid, proquinazid, prothioconazole, pyraclostrobin, spirotetramat, thiacloprid, thiamethoxam and trifloxystrobin in or on certain products. OJ L 137, 25.5.2011, p. 3-52.

[12] Commission Regulation (EU) No 834/2013 of 30 August 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, bixafen, diazinon, difenoconazole, etoxazole, fenhexamid, fludioxonil, isopyrazam, lambda-cyhalothrin, profenofos and prothioconazole in or on certain products. OJ L 233, 31.8.2013, p. 11-42.

[13] Commission Regulation (EU) No 459/2010 of 27 May 2010 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products. OJ L 129, 28.5.2010, p. 3-49.

[14] Commission Regulation (EU) No 520/2011 of 25 May 2011 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benalaxyl, boscalid, buprofezin, carbofuran, carbosulfan, cypermethrin, fluopicolide, hexythiazox, indoxacarb, metaflumizone, methoxyfenozide, paraquat, prochloraz, spirodiclofen, prothioconazole and zoxamide in or on certain products. OJ L 140, 27.5.2011, p. 2-47.

[15] M04 or prothioconazole-desthio : (2RS)-2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)propan-2-ol. See Appendix E.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS (United Kingdom, 2012), the Draft Assessment Report (DAR), its revised version and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2004, 2007, 2012), the conclusion on the peer review of the pesticide risk assessment of the active substance prothioconazole (EFSA, 2007b), the JMPR Evaluation reports (FAO, 2008a, 2008b, 2009a, 2009b), the previous reasoned opinions on prothioconazole (EFSA, 2009, 2010a, 2010b, 2012), the evaluation report for the modifications of the MRLs for prothioconazole in head cabbage and Brussel sprouts (Netherlands, 2007) as well as the evaluation reports submitted during the consultation of Member States (France, 2014; Germany, 2014a, 2014b; Netherlands, 2014). The assessment is performed in accordance with the legal provisions of the Uniform Principles for Evaluation and Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[16] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a-b, 2011 and OECD, 2011).

1. Methods of analysis

1.1. Methods for enforcement of residues in food of plant origin

During the peer review under Directive 91/414/EEC, an analytical method using GC-MS and its ILV were evaluated and validated for the determination of prothioconazole-desthio in plant matrices with an LOQ of 0.02 mg/kg in high water content (tomato), high oil content (rape seed), acidic (orange), dry (wheat grain) commodities and an LOQ of 0.05 mg/kg in straw. This method can be confirmed by an independent analytical method using HPLC-MS/MS fully validated for the determination of prothioconazole-desthio in high water content commodities and in straw with an LOQ of 0.05 mg/kg and in high oil content and in dry commodities with an LOQ of 0.01 mg/kg (United Kingdom, 2004). The analytical methods are not enantioselective, hence the sum of isomers will be analyzed.

The multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008), is also available to analyse the prothioconazole-desthio in plant commodities. Nevertheless, the validation data reported are too limited to conclude on the validity of this analytical method (EURL, 2013).

Hence it is concluded that prothioconazole-desthio can be enforced in food of plant origin with an LOQ of 0.02 mg/kg in high oil content and dry commodities and an LOQ of 0.05 mg/kg in high water content commodities and in straw taking into account the highest LOQ of both methods.

1.2. Methods for enforcement of residues in food of animal origin

During the peer review under Directive 91/414/EEC, an analytical method using HPLC-MS/MS and its ILV were evaluated and validated for the determination of prothioconazole-desthio only in food of animal origin with an LOQ of 0.004 mg/kg in milk and an LOQ of 0.01 mg/kg in muscle, fat, liver and kidney (United Kingdom, 2004; EFSA, 2007b). Hence it is concluded that prothioconazole-desthio can be enforced in food of animal origin with an LOQ of 0.004 mg/kg in milk and an LOQ of 0.01 mg/kg in muscle, fat, liver and kidney. Nevertheless, prothioconazole-desthio cannot be enforced in eggs. Therefore, a fully validated analytical method for the determination of prothioconazole-desthio in eggs is required.

The available analytical method is not enantioselective, hence the sum of isomers will be analyzed.

2. Mammalian toxicology

The toxicological assessment of prothioconazole and its metabolite prothioconazole-desthio were peer reviewed under Directive 91/414/EEC and toxicological reference values were established by EFSA

[16] 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, 11.06.2011, p. 127-175.

(2007b). These toxicological reference values are summarised in Table 2-1. They apply to the racemic mixture (50:50) of the constituent isomers of prothioconazole and prothioconazole-desthio respectively.

Metabolism studies in both mammalians and plants have shown that active substances belonging to the chemical class of triazoles are metabolized to common metabolites known as triazole derivative metabolites (TDMs), the major ones being the metabolites 1,2,4-triazole[17], triazole alanine[18], triazole lactic acid[19] and triazole acetic acid[20]. The toxicological properties of TDMs were discussed by the EFSA Pesticide Risk Assessment Peer Review Expert Meeting on mammalian toxicology of January 2007 (PRAPeR 14); the agreed toxicological reference values are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Prothioconazole					
ADI	EFSA	2007	0.05 mg/kg bw per d	Rat, 2 year study ; dog, 1 year study	100
ARfD	EFSA	2007	0.2 mg/kg bw	Rat, developmental study	100
Prothioconazole-desthio					
ADI	EFSA	2007	0.01 mg/kg bw per d	Rat, carcinogenicity study	100
ARfD	EFSA	2007	0.01 mg/kg bw	Rat, developmental study	100
1,2,4-triazole, triazole acetic acid [(a)] and triazole lactic acid [(a)]					
ADI	PRAPeR 14	2007	0.02 mg/kg bw per d	Rat, multigeneration study	1000
ARfD	PRAPeR 14	2007	0.06 mg/kg bw	Rat, developmental study	500
Triazole alanine					
ADI	PRAPeR 14	2007	0.1 mg/kg bw per d	Rat, developmental study	1000
ARfD	PRAPeR 14	2007	0.1 mg/kg bw	Rat, developmental study	1000

(a): EFSA PRAPeR Expert Meeting 14 concluded to apply the same toxicological reference values as for 1,2,4 triazole in absence of reproductive toxicity data.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of prothioconazole was investigated for foliar application on root and tuber vegetables (sugar beet), pulses and oilseeds (peanut) and cereals (wheat) as well as for seed treatment on cereals (wheat) using [U-^{14}C-phenyl]-labelled prothioconazole. In addition, the metabolism of prothioconazole-desthio was investigated for foliar application on cereals (wheat) using [3,5-^{14}C-triazole]-labelled prothioconazole-desthio (EFSA, 2007b, 2009, 2010a, 2010b, 2012; FAO, 2008a, 2008b; Netherlands, 2007; United Kingdom, 2004, 2007). Furthermore, three additional metabolism studies were conducted on root and tuber vegetables (sugar beet), pulses and oilseeds (peanut) and

[17] 1,2,4-triazole: 1*H*-[1,2,4]triazole. See Appendix E.
[18] triazole alanine: 3-(1*H*-1,2,4-triazol-1-yl)-DL-alanine. See Appendix E.
[19] triazole lactic acid: (2*RS*)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propanoic acid. See Appendix E.
[20] triazole acetic acid: 1*H*-1,2,4-triazol-1-ylacetic acid. See Appendix E.

cereals (wheat) by foliar application using [3,5-^{14}C-triazole]-labelled prothioconazole (FAO, 2008a, 2008b). The characteristics of all these studies are summarised in Table 3-1.

In the foliar treated wheat samples, the TRR levels accounted for 0.08 and 5 mg eq/kg in grain, 10 and 8 mg eq/kg in forage, 8.9 and 11.2 mg eq/kg in hay and 27 and 7.9 mg eq/kg in straw, respectively for the phenyl and the triazole labelling forms of prothioconazole. The level of metabolites identification accounted for 73 % and 66 % of the TRR in forage, 65 % and 75 % of the TRR in hay, 66 % and 61 % of the TRR in straw and 34 % and 94 % TRR in grain, respectively for the phenyl and triazole labellings. In all the wheat matrices, prothioconazole was extensively metabolized.

Prothioconazole-desthio was the major compound of the total residues in all wheat plant parts for the phenyl labelling form: 35.4 % of the TRR (3.70 mg eq/kg) in forage, 18.5 % of the TRR (1.64 mg eq/kg) in hay, 22.3 % of the TRR (5.95 mg eq/kg) in straw and 16 % of the TRR (0.014 mg eq/kg) in grain. The hydroxylated derivative metabolites of prothioconazole-desthio (M14[21], M15[22], M17[23]) and their glucoside conjugates were also identified in forage (13.4 % of the TRR, 1.42 mg eq/kg), hay (19.5 % of the TRR, 1.74 mg eq/kg), grain (9.5 % of the TRR, 0.007 mg eq/kg) and straw (14.8 % of the TRR, 3.93 mg eq/kg). The parent compound and other minor metabolites were identified in all matrices and accounted each for less than 10 % TRR.

For the triazole labelling form, a similar metabolic pattern as for the phenyl labelling was observed in all wheat plant parts with the parent prothioconazole being also extensively metabolised (< 10 % TRR). Besides, cleavage of the triazole moiety of the prothioconazole-desthio occurred in all wheat matrices resulting in the formation of the following 'triazole derivative metabolites' (TDMs): triazole alanine and triazole acetic acid mainly recovered in grain at proportions of 71 % and 19 % of the TRR, respectively. It is noted that these compounds are common, unspecific metabolites of triazole fungicides.

In wheat after foliar application using [3,5-^{14}C-triazole]-prothioconazole-desthio, the highest total residues levels were identified in straw (28.67 mg eq/kg), in forage (10.87 mg eq/kg) and to a minor extent in grain (2.85 mg eq/kg). Prothioconazole-desthio constituted the major compound of the total radioactive residues in forage (up to 86.8 % TRR, 8.94 mg eq/kg in green material) and in straw (71.9 % TRR, 20.61 mg eq/kg) whilst the triazole alanine and triazole acetic acid metabolites were significantly translocated to wheat grains, where they both represented 92.1 % of the TRR (2.63 mg eq/kg).

[21] M14 or prothioconazole-3-hydroxy-desthio: 2-chloro-3-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]phenol. See Appendix E.
[22] M15 or prothioconazole-4-hydroxy-desthio: 3-chloro-4-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]phenol. See Appendix E.
[23] M17 or prothioconazole-6-hydroxy-desthio: 3-chloro-2-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]phenol. See Appendix E.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Application and sampling details				
			Method, F or G [a]	**Rate (kg a.s./ha)**	**No (Interval in days)**	**Sampling (DAT)**	**Remarks**
Root and tuber vegetables	Sugar beet	[U-^{14}C-phenyl] prothioconazole	Foliar, F [b]	0.29	4 (14 days)	Roots & Tops/leaves: 7	Sources: EFSA, 2009; FAO, 2008a, 2008b; Netherlands, 2007
		[3,5-^{14}C-triazole] prothioconazole	Foliar, F [c]	0.29	4 (14 days)	Roots & Tops/leaves: 7	Source: FAO, 2008a, 2008b
Pulses and oilseeds	Peanut	[U-^{14}C-phenyl] prothioconazole	Foliar, G	0.30 [d]	3 (21 days) (BBCH 66 -75)	Hay & nuts without shells: 14	Sources: EFSA, 2007b; FAO, 2008a, 2008b; United Kingdom, 2004, 2007
		[3,5-^{14}C-triazole] prothioconazole	Foliar, G	0.30	3 (21 days) (BBCH 66-75)	Hay & nuts without shells: 14	Source: FAO, 2008a, 2008b
Cereals	Wheat	[U-^{14}C-phenyl] prothioconazole	Foliar, G (spring wheat) [e]	0.22	2 (BBCH 32-65)	Forage: 6 Hay: 26 Grain & straw: 48	Sources: EFSA, 2007b; FAO, 2008a, 2008b; United Kingdom, 2004, 2007
		[3,5-^{14}C-triazole] prothioconazole-desthio	Foliar, G (summer wheat) [e]	0.25	2 (27 days) (BBCH 31-59)	Forage: 0, 14 Grain & straw: 48	Sources: EFSA, 2007b; FAO, 2008a, 2008b; United Kingdom, 2004, 2007
		[3,5-^{14}C-triazole] prothioconazole	Foliar, F (spring wheat) [f]	0.18 and 0.29	2 (BBCH 32-65)	Forage, hay, grain, straw	Source: FAO, 2008a, 2008b
		[U-^{14}C-phenyl] prothioconazole	Seed, G (spring wheat)	0.02 or 0.10 kg/100 kg seeds (*ca*. 220 kg seeds/ha)	1	Forage: 57 Hay: 110 Grain & straw : 153	Sources: EFSA, 2007b; FAO, 2008a, 2008b; United Kingdom, 2004, 2007

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): Sugar beets were grown in boxes in a greenhouse until seedlings were approximately 2 inches tall. The sugar plants were then planted outdoor and treated (Netherlands, 2007).
(c): The sugar beet plants were moved to a fenced area outside of the greenhouse and remained there until harvest.
(d): In the JMPR report, it is stated, that a 5x application was also tested in order to collect sufficient amounts of radioactivity to identify metabolites.
(e): The plants were grown under environmental conditions (sunlight and temperatures). A glass roof protected the plants from rainfall. The soil was surface irrigated.
(f): 1 day after application, the soil tub was moved to the outside of the greenhouse.

Following seed treatment on wheat with the phenyl labelled prothioconazole, very low levels of radioactive residues were recovered in wheat grain (TRR <0.01 mg/kg) and no metabolites' identification could be attempted. In straw, forage and hay, TRR accounted for 0.03 - 0.28, 0.02 - 0.07 and 0.02 - 0.09 mg eq/kg, after the 1X and 5X experiments, respectively. Identification procedures in these matrices were performed in the 5X experiment and showed that the metabolic pattern of prothioconazole in the wheat plant parts after seed treatment was similar to the one depicted following foliar applications. Indeed, parent compound was extensively metabolised: prothioconazole-desthio and its hydroxylated forms (including their glucosides) (M14, M15, M17) constituted the major compounds in all crop parts. Prothioconazole-desthio represented 10.9 % of the TRR (0.008 mg eq/kg) in forage, 6.6 % of the TRR (0.019 mg eq/kg) in straw and 6.4 % of the TRR (0.005 mg eq/kg) in hay. Its hydroxylated metabolites and their corresponding glucosides amounted together to 19.7 % of the TRR (0.055 mg eq/kg) in straw, 13.5 % of the TRR (0.011 mg eq/kg) in fodder and 5.6 % of the TRR (0.005 mg eq/kg) in hay. Parent and all other metabolites were below 10 % of the TRR.

In peanuts, following both labelling applications, the highest total radioactive residues were identified in peanut hay (47.4 - 107.5 mg eq/kg). In nutmeat, the total residues accounted for only 0.29 to 1.40 mg eq/kg. The level of identification of the total residues in hay and nutmeat for both labels ranged from 65.1 % to 82.7 % of the TRR. In peanut hay, following both labels, prothioconazole-desthio constituted the major component of the total radioactive residues (up to 28.2 % TRR, 30.4 mg eq/kg), whilst metabolite M27[24] was also recovered as a significant metabolite in hay after phenyl label application only (14.1 % TRR, 15.09 mg eq/kg). The hydroxylated derivative metabolites of prothioconazole-desthio (M14, M15) accounted together for 9.6 % of the TRR (up to 10.31 mg eq/kg). Parent compound and all other identified metabolites were recovered at levels below 10 % of the TRR. In nutmeat, after phenyl label application, M27 was the predominant compound of the total residues, accounting for up to 12.2 % of the TRR (0.04 mg/eq/kg). M24[25] was also identified and accounted for up to 9 % of the TRR (0.03 mg eq/kg). Neither parent compound nor prothioconazole-desthio were detected and the major part of the radioactivity was incorporated into the fatty acids matrix (up to 47.8 % TRR, 0.14 mg eq/kg). For the triazole labelling form, the major compounds identified in nutmeat were triazole lactic acid and triazole alanine (24.5 % and 47.8 % TRR, respectively) whilst other compounds amongst which the parent compound and prothioconazole-desthio were identified at a level below 10 % of the TRR.

In sugar beets, for the phenyl and triazole labellings, TRR levels were higher in leaves (4.3 - 5.2 mg eq/kg) than in roots (0.12 - 0.13 mg eq/kg). Following phenyl labelled prothioconazole application, prothioconazole–desthio accounted for 28 % and 58 % of the TRR in leaves and roots, respectively. Metabolite M24 was also recovered in leaves at 10 % TRR (0.45 mg eq/kg). Regarding the triazole labelling moiety, besides prothioconazole-desthio that was identified in leaves (19 % TRR, 0.99 mg eq/kg) and in roots (25 % TRR, 0.03 mg eq/kg) and the metabolite M24 detected in leaves (10 % TRR, 0.51 mg eq/kg), triazole alanine was found to be the predominant compound of the total residues in roots (29 % TRR, 0.04 mg eq/kg). Prothioconazole was seen to be extensively degraded in both leaves and roots and accounted for less than 10 % of the TRR.

Based on the available metabolism studies, prothioconazole is extensively metabolised and the metabolic pathway is similar in all crops investigated. The main metabolic pathway consisted in the formation of prothioconazole-desthio: the sulphur group of the triazolinethione ring of parent prothioconazole is firstly oxidized to the corresponding sulfonic acid with subsequent elimination of the sulfonic acid moiety. This metabolite subsequently undergoes different pathways either by hydroxylation on the chlorophenyl ring, forming various hydroxyl-desthio isomers (M14, M15, M17), dihydroxy-olefins (M27) and hydroxy-dienyl-cysteine (M24) isomers followed by a glucosidation step or by cleavage of the triazole moiety of prothioconazole-desthio resulting in the formation of 'triazole derivative metabolites' (TDMs), mainly triazole alanine, triazole lactic acid and triazole acetic acid.

[24] M27: 4-chloro-5-[2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]cyclohex-4-ene-1,2-diol. See Appendix E.

[25] M24: *S*-{3-chloro-2-[2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]-6-hydroxycyclohexa-2,4-dien-1-yl}cysteine. See Appendix E.

These compounds are common metabolites to all triazole fungicides. Finally, a dimerisation of the parent molecule was observed resulting from the combined oxidation of the sulphur atom followed by hydroxylation of the chlorophenyl ring.

Apart from the triazole derivative metabolites (TDMs), all the identified metabolites are structurally closely related to prothioconazole-desthio, being formed by hydroxylation on the phenyl ring. During the peer review, it was assumed as a worst case that the toxicological end points allocated to prothioconazole-desthio should also be applied to these metabolites.

EFSA concludes that a general residue definition which includes prothioconazole-desthio (sum of isomers) only can be proposed for enforcement purposes. For risk assessment, EFSA proposes to take into account the numerous metabolites which are structurally related to prothioconazole-desthio. As they occur together at a significant proportion, they may have a significant contribution to the toxicological burden the consumer is exposed to. Assuming that all these metabolites have a toxicological profile similar to prothioconazole-desthio, the residue for risk assessment is defined as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). The proposed residue definitions apply for all plant commodities, for both foliar and seed treatments. Since all compounds included in the residue definitions are a mixture of enantiomers and since there are no enantiospecific analytical methods, the residue definitions are expressed as "sum of isomers". Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.1).

It is noted that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of prothioconazole and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA also emphasises that the above residue definitions do not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

3.1.1.2. Magnitude of residues

According to the RMS, the active substance prothioconazole is authorised in northern and southern Europe for foliar treatment on root and tuber vegetables, bulb vegetables, brassica vegetables, stem vegetables, pulses and oilseeds, cereals and grass as well as for seed treatment in cereals and potatoes, only under outdoor conditions (see Appendix A). To assess the magnitude of prothioconazole residues resulting from these GAPs, EFSA considered all residue trials reported in the PROFile, including residue trials evaluated in the framework of the peer review (EFSA, 2007b; United Kingdom, 2004, 2007) or in the framework of a previous MRL application (EFSA, 2009, 2010a, 2010b, 2012), and additional data submitted during the consultation of Member States (France, 2014; Germany, 2014a; Netherlands, 2014). All available residue trials that, according to the RMS, comply with the authorised GAPs, are summarised in Table 3-2.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). A sufficient number of trials complying with the reported GAPs was reported by the RMS for all crops under assessment, except in the following cases:

- Potatoes: the southern data are not compliant with the southern outdoor GAP on potatoes because the application rate in the trials amounted to 0.6 g a.s./100 kg seeds instead of 0.48 g

a.s./100 kg seeds (France, 2014). However, as the residue values were all below the LOQ, confirming the no residue situation expected according to the metabolism study on sugar beet (see also section 3.1.1.1), the data are considered acceptable and further residue trials are not required.

- Rape seed: the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this major crop (7 trials instead of 8) (EFSA, 2012). Although MRL and risk assessment values can be derived from the southern data, 1 additional trial on rape seed complying with the southern outdoor GAP is still desirable.

- Maize grain: the number of residue trials supporting respectively the northern and southern GAPs is not compliant with the data requirements for this major crop (6 trials instead of 8 in each zone). Besides, the application rate in the northern and southern trials ranged respectively from 8.1 to 24.8 g a.s./ha and from 6.9 to 26.6 g a.s./ha, instead of 9 g a.s./ha (France, 2014). However, the northern and southern available data packages are considered acceptable in view of the no residue situation expected in cereal grain after seed treatment (see also section 3.1.1.1). Further residue trials are therefore not required.

- Maize forage: the northern and southern data packages are not compliant with the northern and southern GAPs on maize forage because the application rate in the northern and southern trials ranged respectively from 8.1 to 24.8 g a.s./ha and from 6.9 to 26.6 g a.s./ha, instead of 9 g a.s./ha (France, 2014). However, as results were all below the LOQ, the data package is considered acceptable and further residue trials are not required.

- Grass: no trials are available to support the use on grass in northern Europe and no MRL or risk assessment values can be derived. At least 4 residue trials compliant with the northern outdoor GAP are required. EFSA highlights that an extrapolation from cereal straw to straw from grass for seed production was requested (Netherlands, 2014). This extrapolation was not accepted since grass for seed production cannot be considered biologically identical to cereals. Moreover, this commodity is not accurately defined in legislation and there is also no guidance available at EU level on extrapolation or consumption of this commodity.

The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of prothioconazole-desthio residues was demonstrated at -18 °C for 18 months in high water content matrices (wheat green matter), dry commodities (cereal grain) and straw (EFSA, 2007b; United Kingdom, 2004, 2007). Furthermore, storage stability of prothioconazole-desthio residues was subsequently demonstrated for a period of 24 months at – 18 °C in commodities with high water content (spinach, sugar beet, tomatoes), high oil content (canola seeds), dry commodities (dried peas) and canola straw (EFSA, 2009, 2010a, 2010b, 2012; Netherlands, 2007). According to the RMS and the Member States which submitted additional data during the MS consultation, all residue trial samples reported in the PROFile were stored in compliance with the storage conditions reported above. Degradation of prothioconazole-desthio residues during storage of the trial samples is therefore not expected. However, storage stability was demonstrated for prothioconazole and prothioconazole-desthio only, while further metabolites are included in the residue definition for risk assessment. Therefore, further storage stability data for at least one hydroxylated metabolite included in the risk assessment residue definition are still required in the relevant commodity groups.

As the proposed residue definitions for enforcement and risk assessment are different (see also Section 3.1.1.1), conversion factors (CF) for enforcement to risk assessment of 2 in cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables and of 3 in cereal straw were derived on the basis of the available metabolism data on wheat, peanut and sugar beet (roots, tops) (EFSA, 2007b, 2009, 2010a, 2010b, 2012; United Kingdom, 2007). It is noted that for pulses and oilseeds crops (dry beans, dry peas, linseed, rapeseed, poppy seed, mustard seed and gold of pleasure), conversion factors of 1 or 1.3, depending on the region, were derived based on the residue trials conducted on rape seed

(EFSA, 2012). Although these trials analysed the residues of M14, M15, M16[26], M17 and M18[27] metabolites, it is not clear to EFSA whether the conjugates of these hydroxylated compounds were also analysed. This information should be provided. If it turns out that the conjugates were not determined, additional residue trials on rape seed analysing the residues in compliance with the proposed residue definition for risk assessment will have to be submitted in order to derive a reliable conversion factor for enforcement to risk assessment. Meanwhile, EFSA proposes to use on a tentative basis the conversion factor of 2 derived from the metabolism studies also for pulses and oilseeds. Furthermore, for all the other reported uses on cereal grains, vegetables (root and tuber-, bulb-, brassica-, leafy- and stem-) and straw, sufficient residue trials analysing the residues in compliance with the proposed residue definition for risk assessment are required to derive reliable conversion factors for enforcement to risk assessment.

For the seed treatments on maize (grain, forage) and potatoes, no median conversion factors for enforcement to risk assessment were derived and no additional trials analysing the residues in compliance with the proposed residue definition for risk assessment are required. Indeed, according to the available metabolism studies on cereals after seed treatment and on sugar beet after foliar treatment, total residues in maize (grain, forage) and in potatoes are expected to be below 0.01 mg/kg (see also section 3.1.1.1).

Consequently, the available residues data are considered sufficient to derive reliable MRL proposals and risk assessment values on potatoes and maize grain. For all the other crops, only tentative MRL proposals and risk assessment values can be derived (see also Table 3-2), due to the data gaps identified for further clarification on whether the method used in the residue trials on rape seed also analysed the conjugates of the hydroxylated compounds, residue trials analysing the residues in compliance with the proposed residue definition for risk assessment for all the other reported uses on cereal grains, vegetables (root and tuber-, bulb-, brassica-, leafy- and stem-) and straw and the corresponding storage stability data. Where several uses are authorised for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in Table 3-2. Tentative MRLs were also derived for cereal straw and maize forage in view of the future need to set MRLs in feed items. For grass, no residue trial was submitted to derive any MRL and risk assessment values.

[26] M16 or prothioconazole-5-hydroxy-desthio: 4-chloro-3-[(2RS)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]phenol. See Appendix E.

[27] M18 or prothioconazole-α-hydroxy-desthio: (1RS,2RS)-2-(1- chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)propane-1,2-diol. See Appendix E.

Table 3-2: Overview of the available residue trials data

Commodity	Residue region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF	Comments
			Enforcement	Risk assessment					
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-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)									
Potatoes	NEU	Outdoor	8x <0.01	-	0.01	0.01	0.05*	1.0 (d)	Trials on potatoes compliant with GAP (Germany, 2014a).
	SEU	Outdoor	8x <0.01	-	0.01	0.01	0.05*	1.0 (d)	Overdosed trials on potatoes (France, 2014); see also body text.
Beetroot, Carrots, Horseradish, Parsnips, Parsley root, Salsify, Swedes, Turnips	NEU	Outdoor	3x 0.02; 2x 0.03; 2x 0.04; 2x 0.05	-	0.03	0.05	0.1 (tentative)	2.0 (e)	Trials on carrots compliant with GAP. Extrapolation to the other root and tuber vegetables possible. (EFSA, 2010b) MRL_{OECD} = 0.1 R_{ber} = 0.09 R_{max} = 0.07
Onions	NEU	Outdoor	7x <0.01; 0.01; 0.02	-	0.01	0.02	0.05* (tentative)	2.0 (e)	Trials on onions compliant with GAP (Netherlands, 2014). MRL_{OECD} = 0.02 R_{ber} = 0.02 R_{max} = 0.02
Broccoli, Cauliflower	NEU	Outdoor	6x <0.01; 0.01; 0.02	-	0.01	0.02	0.05* (tentative)	2.0 (e)	Combined dataset of trials on cauliflower (4) and broccoli (4) compliant with GAPs (EFSA, 2010a). MRL_{OECD} = 0.03 R_{ber} = 0.02 R_{max} = 0.02

Commodity	Residue region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF	Comments
			Enforcement	Risk assessment					
Brussels sprouts	NEU	Outdoor	3x 0.02; 2x 0.03; 2x 0.04; 0.07	-	0.03	0.07	0.1 (tentative)	2.0 [e]	Trials on Brussels sprouts compliant with GAP (EFSA, 2009). MRL_{OECD} = 0.10 R_{ber} = 0.08 R_{max} = 0.09
Head cabbage	NEU	Outdoor	4x <0.01; 2x 0.01; 0.02; 0.06	-	0.01	0.06	0.09 (tentative)	2.0 [e]	Trials on head cabbage compliant with GAP (EFSA, 2009). MRL_{OECD}= 0.09 R_{ber}= 0.04 R_{max}= 0.07
Leek	NEU	Outdoor	5x <0.01; 0.01; 0.03; 0.04	-	0.01	0.04	0.06 (tentative)	2.0 [e]	Trials on leek compliant with GAP. MRL_{OECD} = 0.06 R_{ber} = 0.05 R_{max} = 0.05
Beans (dry), Peas (dry)	NEU	Outdoor	4x <0.01; 2x 0.01; 0.02; 0.03	-	0.01	0.03	0.05 (tentative)	2.0 [f]	Combined data set of trials on dry beans (4) and dry peas (4) compliant with GAPs (France, 2014). MRL_{OECD} = 0.04 R_{ber} = 0.04 R_{max} = 0.04

Commodity	Residue region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF	Comments
			Enforcement	Risk assessment					
Rape seed	NEU	Outdoor	2x 0.01; 0.02; 3x 0.03; 2x 0.04; 0.05	0.02; 0.03; 0.02; 3x 0.03; 2x 0.04; 0.05	0.03	0.05	0.09 (tentative)	2.0 [f]	Trials on rape seed compliant with GAP (EFSA, 2012). MRL_{OECD} = 0.09 R_{ber} = 0.08 R_{max} = 0.07
	SEU	Outdoor	<0.01; 0.02; 2x 0.03; 0.04; 0.05; 0.09	<0.01; 0.04; 0.03; 0.04; 2x 0.07; 0.11	**0.03**	**0.09**	**0.15 (tentative)**	**2.0** [f]	Trials on rape seed compliant with GAP (EFSA, 2012). MRL_{OECD} = 0.14 R_{ber} = 0.10 R_{max} = 0.13
Linseed, Poppy seed, Mustard seed	NEU	Outdoor	2x 0.01; 0.02; 3x 0.03; 2x 0.04; 0.05	0.02; 0.03; 0.02; 3x 0.03; 2x 0.04; 0.05	0.03	0.05	0.09 (tentative)	2.0 [f]	Direct extrapolation from the northern outdoor dataset on rape seed is possible.
Gold of pleasure	NEU	Outdoor	5x <0.01; 0.01; 2x 0.02	-	**0.01**	**0.02**	**0.04 (tentative)**	**2.0** [f]	Trials performed on rape seed (EFSA, 2007b) compliant with GAP on gold of pleasure. MRL_{OECD} = 0.03 R_{ber} = 0.04 R_{max} = 0.03
	SEU	Outdoor	2x <0.01; 2x 0.01	-	0.01	0.01	0.02* (tentative)	2.0 [f]	Trials performed on rape seed (EFSA, 2007b) compliant with GAP on gold of pleasure. MRL_{OECD} = 0.02 R_{ber} = 0.02 R_{max} = 0.01

Commodity	Residue region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF	Comments
			Enforcement	Risk assessment					
Barley grain, Oats grain	NEU	Outdoor	9x <0.01; 2x <0.01[h]; 0.01[h]; 0.02[h]	-	0.01	0.02	0.02 (tentative)	2.0 [g]	Trials on barley compliant with GAP or performed with a less critical GAP (see footnotes). Extrapolation to oats grain possible (EFSA, 2007b; France, 2014). MRL_{OECD} = 0.02 R_{ber} = 0.02 R_{max} = 0.02
	SEU	Outdoor	2x <0.01; <0.01[h]; 3x 0.01; 0.01[h]; 3x 0.02; 0.03[h]	-	**0.01**	**0.03**	**0.04** (tentative)	**2.0** [g]	Trials on barley compliant with GAP or performed with a less critical GAP (see footnotes). Extrapolation to oats grain possible (EFSA, 2007b; France, 2014). MRL_{OECD}= 0.04 R_{ber}= 0.04 R_{max}= 0.03
Barley straw, Oats straw	NEU	Outdoor	0.05; 0.08; 2x 0.1; 0.11[h]; 2x 0.13; 2x 0.14; 0.30; 0.36[h]; 0.56[h]	-	0.13	0.56	0.8 (tentative)	3.0 [g]	Trials on barley compliant with GAP or performed with a less critical GAP (see footnotes). Extrapolation to oats straw possible (EFSA, 2007b; France, 2014). MRL_{OECD}= 0.78 R_{ber}= 0.52 R_{max}= 0.59
	SEU	Outdoor	0.06[h] ; 0.10[h]; 0.16; 0.19; 0.32; 0.41; 0.42; 0.75; 2x 1.1; 1.1[h]; 2.5[h]	-	**0.42**	**2.50**	**4 (tentative)**	**3.0** [g]	Trials on barley compliant with GAP or performed with a less critical GAP (see footnotes). Extrapolation to oat straw possible (EFSA, 2007b; France, 2014). MRL_{OECD}= 3.47 R_{ber}= 2.20 R_{max}= 2.59

Commodity	Residue region [a]	Outdoor/ Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF	Comments
			Enforcement	Risk assessment					
Maize grain	NEU	Outdoor	6x <0.01	-	0.01	0.01	0.02*	1.0 [d]	Overdosed trials on maize (France, 2014); see body text.
	SEU	Outdoor	6x <0.01	-	0.01	0.01	0.02*	1.0 [d]	Overdosed trials on maize (France, 2014); see body text.
Wheat grain, Rye grain	NEU	Outdoor	11 <0.01; <0.01[h]; 0.02[h]	-	**0.01**	**0.02**	**0.02 (tentative)**	**2.0 [g]**	Trials on wheat compliant with GAP or performed with a less critical GAP (see footnotes). Extrapolation to rye grain possible (EFSA, 2007b; France, 2014). MRL_{OECD}= 0.02 R_{ber}= 0.02 R_{max}= 0.02
	SEU	Outdoor	8x <0.01	-	0.01	0.01	0.02* (tentative)	2.0 [g]	Trials on wheat compliant with GAP (EFSA, 2007b). No authorised use on rye grain in SEU.
Wheat straw, Rye straw	NEU	Outdoor	0.08; 0.09; 0.09[h]; 0.11; 0.14; 0.15; 0.19; 0.20; 0.27; 0.31; 0.42[h]; 0.48[h]; 0.66; 0.72; 1.60[h]	-	0.20	1.60	2 (tentative)	3.0 [g]	Trials on wheat compliant with GAP or performed with a less critical GAP (see footnotes). Extrapolation to rye straw possible (EFSA, 2007b; France, 2014). MRL_{OECD}= 1.96 R_{ber}= 0.96 R_{max}= 1.39
	SEU	Outdoor	0.22; 0.41; 0.42; 0.52; 0.53; 0.72; 0.77; 0.85; 0.86[h]; 1.20[h]; 1.90[h]; 2.40[h]	-	**0.75**	**2.40**	**4 (tentative)**	**3.0 [g]**	Trials on wheat compliant with GAP or performed with a less critical GAP (see footnotes) (EFSA, 2007b; France, 2014). No authorised use on rye straw in SEU. MRL_{OECD}= 3.49 R_{ber}= 2.23 R_{max}= 2.67

Commodity	Residue region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF	Comments
			Enforcement	Risk assessment					
Grass	NEU	Outdoor	-	-	-	-	-	-	No residue trials available.
Maize forage	NEU	Outdoor	6x <0.01	-	0.01	0.01	0.05* (tentative)	1.0 (d)	Overdosed trials on maize (France, 2014); see body text.
	SEU	Outdoor	6x <0.01	-	0.01	0.01	0.05* (tentative)	1.0 (d)	Overdosed trials on maize (France, 2014); see body text.

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e outdoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): No median conversion factor for enforcement to risk assessment has been derived as, according to the available metabolism studies on sugar beet (foliar treatment) and cereals (seed treatment), residues in potatoes, maize grain and maize forage after seed treatment are expected to be well below 0.01 mg/kg (see also section 3.1.1.1).
(e): The median conversion factor for enforcement to risk assessment has been tentatively obtained on the basis of the available metabolism study on sugar beet root and tops (see also section 3.1.1.1).
(f): The median conversion factor for enforcement to risk assessment has been tentatively obtained on the basis of the available metabolism study on peanuts (see also section 3.1.1.1).
(g): The median conversion factor for enforcement to risk assessment has been tentatively obtained on the basis of the available metabolism studies on cereals after foliar treatment (grain, straw) (see also section 3.1.1.1).
(h): Trials assessed by FR performed at a similar or less critical GAP than the authorised European cGAP and leading to similar or higher residue levels than the ones assessed in the peer-review (EFSA, 2007b; France, 2014).
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of prothioconazole residues was not investigated in the framework of the peer review. Nevertheless, studies were assessed by the JMPR (FAO, 2008a, 2008b), simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90 °C, pH 4), boiling/brewing/baking (60 minutes at 100 °C, pH 5) and sterilisation (20 minutes at 120 °C, pH 6). From these studies, it was concluded that parent compound prothioconazole is stable under processing by pasteurisation and baking/brewing/boiling. However, under sterilisation, prothioconazole slightly degrades (≤ 11 %) to prothioconazole-desthio.

Furthermore, Germany also assessed studies investigating the fate of processing on the nature of prothioconazole-desthio residues under representative hydrolytic conditions for pasteurisation (20 minutes at 90 °C, pH 4), boiling/brewing/baking (60 minutes at 100 °C, pH 5) and sterilisation (20 minutes at 120 °C, pH 6). It was concluded that prothioconazole-desthio remains stable under these hydrolytic conditions; the levels of prothioconazole-desthio in the samples after hydrolysis ranged from 99.4 to 99.9 % of the AR (Germany, 2014b).

Considering that all the metabolites included in the residue definition for risk assessment in primary crops, i.e. compounds containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-*2H*-1,2,4-triazole moiety, have a similar structure to parent compound and/or prothioconazole-desthio, it can be assumed that they are also expected to remain stable under hydrolysis. Studies investigating the fate of these metabolites under the representative hydrolytic conditions are therefore desirable only, and it can be concluded that the relevant residue for enforcement and risk assessment in processed commodities is expected to be the same as for primary crops.

Moreover, no studies investigating the magnitude of residues in processed commodities are available. As such studies are not expected to affect the outcome of the risk assessment, they are not required. However, if robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, $DT_{90field}$ values of prothioconazole and prothioconazole-desthio range between 4.4 – 9.3 days (median: 5.5 days) and 54 – 240 days (median: 140 days), respectively. The $DT_{90field}$ value of prothioconazole-desthio is therefore higher than the trigger value of 100 days (EFSA, 2007b). According to the European guidelines on rotational crops (EC, 1997b), further investigation of the nature of the residues in rotational crops is relevant.

3.1.2.2. Nature of residues

The metabolism of prothioconazole in rotational crops – Swiss chard, turnips, spring wheat - has been evaluated (EFSA, 2007b, 2009, 2010a, 2010b, 2012; FAO, 2008a, 2008b; United Kingdom, 2004, 2007). A confined rotational crop study investigating the nature of residues following different plant-back intervals is available. The characteristics of this study are summarised in Table 3-3.

Table 3-3: Summary of available metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks
Leafy vegetables	Swiss chard	[U-^{14}C-phenyl] prothioconazole	Bare soil application	0.58	28, 146, 269	80, 188, 348	-
Root and tuber vegetables	Turnip	[U-^{14}C-phenyl] prothioconazole	Bare soil application	0.58	28, 146, 269	Roots, tops: 94, 201, 349	-
Cereals	Spring wheat	[U-^{14}C-phenyl] prothioconazole	Bare soil application	0.58	28, 146, 269	Green material: 73, 178, 327 Hay: 111, 231, 377 Grain, straw: 145, 269, 412	-

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

In wheat grain, the total radioactive residues were recovered at a trace level at all DATs (≤ 0.007 mg eq/kg) and no further metabolites' identification was attempted. In wheat green material, hay and straw, TRR ranged from 0.021 mg eq/kg (green material, DAT 28) to 0.450 mg eq/kg (straw, DAT 28). In turnip roots, tops and Swiss chard, the highest residue levels ranged from 0.043 mg eq/kg (turnip root, DAT 28) to 0.053 mg eq/kg (Swiss chard, DAT 146). No significant decline of the residue levels was observed for any crop part throughout the first, second and third rotation.

In the edible parts of the crops at harvest 61 to 87 % of the total residues were extracted and the level of identification ranged between 34.4 % TRR (Swiss chard, DAT 269) to 77.2 % TRR (turnip leaves, DAT 28). The major compounds of the total residues were identified as prothioconazole-desthio, its hydroxylated derivative metabolites, either free or conjugated (M14, M15, M16, M17), M27, free and conjugated and M02[30]. Residue levels of the main metabolites recovered in wheat were in general higher in straw than in hay. In straw, they reached the following levels: prothioconazole-desthio (0.066 mg eq/kg) (DAT 28), M02 (0.063 mg eq/kg) (DAT 269), glucoside of M27 (0.056 mg eq/kg) (DAT 269) and glucosides of the hydroxylated metabolites of prothioconazole-desthio (0.097 mg eq/kg) (DAT 28). In Swiss chard, levels of prothioconazole-desthio reached 0.014 mg eq/kg at 28 DAT, while levels of M27 glucosides were below 0.01 mg eq/kg at all sowing intervals. In turnip roots and leaves, the residue levels of the identified major metabolites were always below 0.01 mg eq/kg.

Consequently, the metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

No rotational crop studies with prothioconazole radiolabelled on the triazole ring were assessed in the framework of the peer review but such studies were reported and assessed by the JMPR (FAO, 2008a, 2008b). These indicated a cleavage of the triazole linkage with the formation of the major metabolites found in all rotational crop matrices as triazole alanine, triazole lactic acid and triazole acetic acid. Both the parent prothioconazole and prothioconazole-desthio were identified as minor metabolites.

[30] M02 or prothioconazole-sulfonic acid: 1-[(2RS)-2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1H-pyrazole-5-sulfonic acid. See Appendix E.

3.1.2.3. Magnitude of residues

Based on the confined rotational crop study, considering that the application rate of prothioconazole within the EU ranges between 0.009 – 0.600 kg a.s./ha and due to the fact that prothioconazole was applied to a bare soil in the metabolism study (interception of prothioconazole by the plants is expected in practice), it can be concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops (see also section 3.1.2.2). Therefore, no risk mitigation measures (plant back restrictions) need to be proposed.

The studies on the nature of prothioconazole residues in rotational crops assessed by the JMPR indicate a potential uptake of the triazole derivative metabolites (TDMs) by the rotational crops. Noting that these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs in rotational crops as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Prothioconazole is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009b) and are summarised in Table 3-4. The tentative conversion factors derived in section 3.1.1.2 were used for the relevant commodities. Furthermore, for cereals bran and oilseeds meal, the respective default processing factors of 8 and 2 , have been included in the calculation in order to consider the potential concentration of residues in these commodities. It is also highlighted that for grass, no residue data were available: the animal intake of prothioconazole residues via this commodity has therefore not been assessed and may have been underestimated. Considering that grass is a major feed item and that this commodity is expected to have a major impact on the outcome of the livestock dietary burden, the present calculation should be considered on a tentative basis only.

Table 3-4: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
Head cabbage	0.02	Median residue x CF	0.12	Highest residue x CF
Maize silage	0.01	Median residue	0.01	Highest residue
Maize grain	0.01	Median residue	0.01	Median residue
Barley, oats, rye and wheat grain	0.02	Median residue x CF	0.02	Median residue x CF
Wheat and rye bran	0.16	Median residue x CF x 8	0.16	Median residue x CF x 8
Barley and oats straw	1.25	Median residue x CF	7.50	Highest residue x CF
Wheat straw	2.24	Median residue x CF	7.20	Highest residue x CF
Rye straw	0.60	Median residue x CF	4.80	Highest residue x CF

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Peas and beans (dry)	0.02	Median residue x CF	0.02	Median residue x CF
Potatoes	0.01	Median residue	0.01	Highest residue
Turnips and swedes	0.06	Median residue x CF	0.10	Highest residue x CF
Rape seed meal	0.12	Median residue x CF x 2	0.12	Median residue x CF x 2
Linseed meal	0.12	Median residue x CF x 2	0.12	Median residue x CF x 2

The results of the calculations are reported in Table 3-5. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

Table 3-5: Results of the dietary burden calculation

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition : sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (tentative)					
Dairy ruminants	0.028	0.086	Barley straw	2.40	Y
Meat ruminants	0.069	0.208	Barley straw	4.84	Y
Poultry	0.011	0.018	Turnips	0.29	Y
Pigs	0.017	0.031	Turnips	0.77	Y

3.2.2. Nature of residues

The nature of prothioconazole residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (United Kingdom, 2004, 2007). Reported metabolism studies include two studies in lactating goats using respectively [U-^{14}C-phenyl]-labelled prothioconazole and prothioconazole-desthio and one study in laying hens using [U-^{14}C-phenyl]-labelled prothioconazole. Besides, two additional studies were assessed by the JMPR (FAO, 2008a, 2008b) on lactating goats and laying hens, using both [3,5-^{14}C-triazole]-labelled prothioconazole. The characteristics of these studies are summarised in Table 3-6.

Table 3-6: Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg bw per d)	Duration (days)	Commodity	Time
Lactating ruminants	Goat	[U-^{14}C-phenyl] prothioconazole (a)	1	10 (250 mg a.s./kg feed)	3	Milk	Twice daily
						Urine and faeces	Daily And at sacrifice
						Tissues	At sacrifice
		[U-^{14}C-phenyl] prothioconazole-desthio (a)	1	10 (195 mg a.s./kg feed)	3	Milk	Twice daily
						Urine and faeces	Daily And at sacrifice
						Tissues	At sacrifice
		[3,5-^{14}C-triazole] prothioconazole (b)	1	10	3	Milk	Twice daily
						Urine and faeces	Daily And at sacrifice
						Tissues	At sacrifice
Laying poultry	Hens	[U-^{14}C-phenyl] prothioconazole (a)	6	10	3	Eggs	Once daily
						Excreta	At regular intervals
						Tissues	At sacrifice (5 h after last administration)
		[3,5-^{14}C-triazole] prothioconazole (b)	6	10	3	Eggs	Once daily
						Excreta	At regular intervals
						Tissues	At sacrifice (5 h after last administration)

(a): Sources: United Kingdom, 2004, 2007; JMPR, 2008a, 2008b
(b): Source: JMPR, 2008a, 2008b

Lactating goats

In each study, lactating goats were dosed with 10 mg/kg bw per d of prothioconazole or prothioconazole-desthio. The metabolism study conducted with prothioconazole was reported for information purposes only since the animals are mainly exposed to the prothioconazole-desthio residues. For prothioconazole-desthio, the application rate was overdosed, corresponding to approximately 48 times the exposure of meat ruminants.

In the studies performed with both phenyl and triazole labellings of prothioconazole, the highest residue levels were found in kidney (6.8 - 4.5 mg eq/kg) and liver (6.1 - 6.2 mg eq/kg), respectively.

The total radioactive residues accounted respectively for 0.037 - 0.15 mg eq/kg in milk, 0.088 - 0.117 mg eq/kg in muscle and 0.169 - 0.174 mg eq/kg in fat. The extractabilities of the radioactive residues in all matrices ranged from 77 % (fat) to 98 % of the TRR (kidney). Identified radioactivity accounted for 57 % to 78 % of the TRR. Prothioconazole was rapidly adsorbed and extensively metabolised in all matrices but remained a significant compound of the residues in liver (13 – 17 % TRR), muscle, kidney and fat (7 - 20 % TRR) and to a minor extent in milk (0.9 % - 3 % TRR). Prothioconazole-desthio was detected at low levels in all matrices (< 5 % TRR), except in fat (19 % TRR, 0.032 mg eq/kg). The only identified triazole related metabolite was the thiocyanate metabolite: 41 % TRR (0.061 mg eq/kg) in milk, 30 % TRR (0.035 mg eq/kg) in muscle, 12 % TRR (0.022 mg eq/kg) in fat, 9 % TRR (0.41 mg eq/kg) in kidney and 2 % TRR (0.13 mg eq/kg) in liver. At the maximum dietary burden of meat ruminants, this metabolite is expected to occur at a trace level in all matrices (up to 0.004 mg eq/kg in kidney). There is therefore no need to further address its toxicological properties.

In the study performed with [U-^{14}C-phenyl]-labelled prothioconazole-desthio, the highest residue levels were found in kidney and liver (up to 19 mg eq/kg). Total radioactive residues in milk, muscle and fat accounted for 0.286 mg eq/kg, 0.266 mg eq/kg and 0.231 mg eq/kg, respectively. The extractabilities of the residues in all matrices ranged from 82 % (liver) to 97 % of TRR (kidney). The rate of identification amounted to 70 % to 89 % of the TRR. Prothioconazole-desthio was the predominant compound of the total residues in liver (31.2 % TRR - 5.7 mg eq/kg) and in kidney both under its free and glucuronide conjugated forms (32 % TRR – 6 mg eq/kg) whilst it was extensively metabolised as glucuronide conjugates of the hydroxylated related metabolites in milk, muscle and fat. Metabolite M32[31] both under its free and glucuronide conjugated form was the predominant compound of the total residues in muscle (32 % TRR – 0.085 mg eq/kg), fat (27 % TRR – 0.063 mg eq/kg) and kidney (23 % TRR - 4.299 mg eq/kg). In milk, only prothioconazole-desthio under its glucuronide conjugated form was detected at a rather low level (6 % TRR – 0.017 mg eq/kg) whilst the sulphate conjugates of hydroxylated derivative prothioconazole-desthio metabolites (M14/M15/M16/M17/M28[32]/M34[33]/M35[34]) constituted the major part of the total residue in milk (44 % TRR, 0.126 mg eq/kg). All other compounds accounted for less than 10 % TRR.

Following prothioconazole administration to rats, metabolite 1,2,4-triazole was recovered in urine at minor amounts (2.3 % AR), whilst it was not recovered in goats. Therefore, meanwhile a harmonized approach on how to consider TDMs in the risk assessment, the general metabolic pathways in rodents and ruminants can be considered as comparable, mainly involving various types of hydroxylation affecting the chlorophenyl ring and leading to the formation of metabolites both under their free and glucuronide or sulphate conjugated forms. The metabolic pathway of prothioconazole-desthio depicted in ruminants can therefore be extrapolated to pigs.

Laying hens

Laying hens were dosed with 10 mg/kg bw per d of phenyl and triazole labelled prothioconazole, respectively. The major part of the total administered dose (AR) was recovered in excreta (66 % and 78 % AR for the triazole and phenyl labellings, respectively) and only trace amounts of radioactivity were detected both in eggs (0.01 % AR) and tissues (about 0.9 % AR).

The total radioactive residues accounted for 4.0 – 3.5 mg eq/kg in liver, 0.036 – 0.05 mg eq/kg in eggs, 0.45 – 0.29 mg eq/kg in subcutaneous fat and 0.089 – 0.12 mg eq/kg in muscle, respectively for the phenyl and triazole labellings. The extractability of the total radioactive residues ranged from 77 % TRR in eggs to 98 % TRR in fat.

[31] M32: 3-chloro-4-[(2RS)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]cyclohexa-3,5-diene-1,2-diol. See Appendix E.
[32] M28: 3-chloro-2-[2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]-6-methoxyphenol. See Appendix E.
[33] M34: 3-chloro-4-[2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]benzene-1,2-diol. See Appendix E.
[34] M35: 4-chloro-5-[(2RS)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]benzene-1,2-diol. See Appendix E.

Prothioconazole was the major compound of the total residues in liver (25 % - 31 % TRR, 1.0 - 1.1 mg/kg) and in fat (30 % - 16 % TRR, 0.14 - 0.046 mg/kg) for the phenyl and triazole labels, respectively. Prothioconazole-desthio (29 % - 27 % TRR, 0.13 - 0.08 mg eq/kg) and M01[35] (20 % - 29 % TRR, 0.083 - 0.088 mg eq/kg) in fat as well as M06[36] in liver (12 % - 15 % TRR, 0.48 - 0.53 mg eq/kg) were the only metabolites exceeding 10 % of the TRR in these commodities. In muscle, the major compounds were M45[37] (28 % TRR, 0.035 mg eq/kg) and 1,2,4-triazole (19 % TRR, 0.023 mg eq/kg) specific to the triazole labelling, and M06 (16 % - 10 % TRR, 0.014 - 0.012 mg eq/kg) and parent prothioconazole (11 % - 2.5 % TRR, 0.01 - 0.003 mg eq/kg) for phenyl and triazole labelling, respectively. Prothioconazole-desthio accounted for only 7 % - 2.1 % TRR (0.006 - 0.003 mg eq/kg). In eggs, the major compounds of the total residues were M06 (24 % - 16 % TRR, 0.012 - 0.014 mg eq/kg) and prothioconazole-desthio (20 % - 6.2 % TRR, 0.007 - 0.003 mg eq/kg) for phenyl and triazole label, respectively. For the triazole labelling moiety, the metabolites M45 (15.6 % TRR, 0.008 mg eq/kg) and 1,2,4-triazole (11 % TRR, 0.006 mg eq/kg) were also identified. Prothioconazole accounted for only 3.6 % - 3.4 % TRR (0.001 - 0.002 mg eq/kg), for phenyl and triazole label, respectively. All other metabolites identified were either glucuronic acid or sulphate conjugates of the hydroxylated prothioconazole and accounted for less than 10 % TRR.

Overall assessment

It is noted that in poultry no study was performed with prothioconazole-desthio and that the fate of the triazole moiety in livestock was only investigated for prothioconazole. However, the available studies indicate similar metabolic patterns for the different compounds and moieties investigated. Additional studies addressing these requirements are therefore not expected to provide different results. It is also noted that no livestock metabolism study was performed with administration of all the metabolites included in the residue definition set for risk assessment in plants. Nevertheless, EFSA assumes that the administration of prothioconazole-desthio only in the livestock metabolism studies is acceptable since no different metabolic route of degradation would be expected if all the metabolites containing the moiety of the residue definition for risk assessment in plants were considered. Therefore, no additional metabolism data are deemed necessary.

Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products is proposed as prothioconazole-desthio (sum of isomers) for all livestock matrices. It is noted that although only the glucuronide conjugates of prothioconazole-desthio were detected in milk, the actual residue levels are expected at a trace level at the calculated dietary burden (< 0.01 mg/kg) and EFSA considers that analysing the conjugates of prothioconazole-desthio would have a negligible impact on the residue levels enforced in milk. In case the livestock dietary burden is further increased in the future due to additional uses on feed items, the residue definition for enforcement might have to be revised by including the glucuronide conjugates of prothioconazole-desthio for all livestock matrices.

For risk assessment, since all the metabolites are structurally related to prothioconazole-desthio and consist mainly in hydroxylated derivatives, EFSA assumes as a worst case that the toxicological end points allocated to prothioconazole-desthio should also be applied to these metabolites. The residue is therefore defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2- chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).

Validated analytical methods for enforcement of the proposed residue definition are available except for eggs (see also section 1.2). The log $P_{o/w}$ of prothioconazole-desthio equals 3.04 (EFSA, 2007b). Since higher prothioconazole-desthio residue levels were found in fat compared to fat free muscle,

[35] M01 or prothioconazole-S-methyl: (2RS)-2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-[5-(methylsulfanyl)-2,5-dihydro-1H-1,2,4-triazol-1-yl]propan-2-ol. See Appendix E.
[36] M06 or prothioconazole-S-glucuronide: 1-[(2RS)-2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-4,5-dihydro-1H-1,2,4-triazol-5-yl 1-thio-β-D-glucopyranosiduronic acid. See Appendix E.
[37] M45: (1RS)-1-(1-chlorocyclopropyl)-2-(1H-1,2,4-triazol-1-yl)ethanol. See Appendix E.

EFSA concludes that the residue definition for enforcement in commodities of animal origin is fat soluble.

It is noted that the above studies do not investigate the possible impact of livestock metabolism on the isomer ratio of prothioconazole and the same considerations as for plant commodities apply.

EFSA emphasises that the above residue definitions do not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

3.2.3. Magnitude of residues

During the peer review under Directive 91/414/EEC, the magnitude of prothioconazole residues in ruminants was investigated in a feeding study with lactating cows (EFSA, 2007b; FAO, 2008a, 2008b; United Kingdom, 2004, 2007). Three groups of lactating cows, each consisting of three animals, were dosed for 28 consecutive days with prothioconazole-desthio at levels of 4, 25, and 100 mg/kg in the diet (equivalent to 0.145, 0.909 and 3.636 mg/kg bw per d, respectively). The samples were analysed for prothioconazole-desthio, M14 and M15. Results of the ruminant livestock feeding study are summarised in Table 3-7. In milk, a plateau level was reached after 1 or 2 days of exposure, according to the dose level group. Since neither the metabolites (free and conjugated) containing the common moiety and included in the residue definition for risk assessment nor the glucuronide conjugates of prothioconazole-desthio were analysed, EFSA reported the residue levels for enforcement only (prothioconazole-desthio) and considered the conversion factors for enforcement to risk assessment of 2 and 9 respectively for liver and kidney based on the goat metabolism study with administration of prothioconazole-desthio. No tentative CF was derived for milk, muscle and fat since the residue levels in these matrices are expected to be negligible (<0.01 mg/kg) at the calculated dietary burden. However, conversion factors reported above should in principle be covered by a new feeding study to estimate prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.

Furthermore, in the framework of the reported feeding study, the storage stability of prothioconazole-desthio, M14 and M15 was demonstrated in all matrices for up to 1 month when stored deep frozen and was shown to cover the storage time interval of the residue samples of the feeding study. Degradation of prothioconazole-desthio residues during storage of the feeding study residue samples is therefore not expected.

Consequently, the available data allow deriving tentative MRLs in ruminants and pigs. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009b) and are summarised in Table 3-7. Tentative MRLs in all commodities are established at the LOQ, except in liver and kidney of ruminants, where MRLs of 0.05 and 0.02 mg/kg respectively are proposed. EFSA notes that all the MRLs in ruminant and pig matrices can only be derived on a tentative basis, due to the data gaps identified in section 3.1.1.2, leading to a provisional dietary burden calculation (see also section 3.2.1) and the missing livestock feedin study.

Finally, although the maximum dietary burden for poultry exceeds the threshold of 0.1 mg/kg DM, no appropriate feeding study is available and is required, since based on the metabolism study, no residues above the LOQ are expected in poultry matrices at the calculated dietary burden. Therefore, tentative MRLs can be established at the LOQ in all poultry commodities and no default conversion factors for risk assessment need to be derived. These MRLs can only be tentatively derived due to the tentative dietary burden calculations (see also sections 3.1.1.2 and 3.2.1) and the required validated analytical method for enforcement in eggs (see also section 1.2).

Table 3-7: Overview of the values derived from the livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[c]	Highest residue (mg/kg)[d]	MRL proposal (mg/kg)	CF for RA[e]
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)[a]	Dose Level (mg/kg bw per d)	No	Result for enf.		Result for RA[b]					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
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-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).												
Pig muscle	0.017	0.031	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	1.0
			0.91	3	<0.01	<0.01	n.a.	n.a.				
			3.64	3	<0.01	<0.01	n.a.	n.a.				
Pig fat			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	1.0
			0.91	3	<0.01	0.01	n.a.	n.a.				
			3.64	3	0.02	0.04	n.a.	n.a.				
Pig liver			0.15	3	0.02	0.03	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	2.0
			0.91	3	0.14	0.18	n.a.	n.a.				
			3.64	3	0.68	1.20	n.a.	n.a.				
Pig kidney			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	9.0
			0.91	3	0.03	0.03	n.a.	n.a.				
			3.64	3	0.13	0.24	n.a.	n.a.				
Milk	0.028	0.086	0.15	42	<0.005[f]	N/A	n.a.	n.a.	<0.005	<0.005	0.005* (tentative)	1.0
			0.91	42	<0.005[f]	N/A	n.a.	n.a.				
			3.64	39	0.005[f]	N/A	n.a.	n.a.				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[c]	Highest residue (mg/kg)[d]	MRL proposal (mg/kg)	CF for RA[e]
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)[a]	Dose Level (mg/kg bw per d)	No	Result for enf.		Result for RA[b]					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Ruminant muscle	0.069	0.208	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	1.0
			0.91	3	<0.01	<0.01	n.a.	n.a.				
			3.64	3	<0.01	<0.01	n.a.	n.a.				
Ruminant fat			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	1.0
			0.91	3	<0.01	0.01	n.a.	n.a.				
			3.64	3	0.02	0.04	n.a.	n.a.				
Ruminant liver			0.15	3	0.02	0.03	n.a.	n.a.	0.01	0.042	0.05 (tentative)	2.0
			0.91	3	0.14	0.18	n.a.	n.a.				
			3.64	3	0.68	1.20	n.a.	n.a.				
Ruminant kidney			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	0.012	0.02 (tentative)	9.0
			0.91	3	0.03	0.03	n.a.	n.a.				
			3.64	3	0.13	0.24	n.a.	n.a.				

N/A: Not applicable.
n.a.: Not analysed.
(a): Based on a 560 kg animal consuming approximately 20 kg feed DM/day.
(b): In the feeding study, residues were not determined according to the residue definition for risk assessment. Indeed, only prothioconazole-desthio, M14 and M15 were analysed.
(c): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009b).
(d): Highest residue value (tissues) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009b).
(e): The tentative conversion factors for enforcement to risk assessment in liver and kidney were derived on the basis of the available metabolism study on ruminants. For muscle, fat and milk, no CF was derived as residue levels are expected at the maximum meat ruminant dietary burden in these matrices are negligible (<0.01 mg/kg).
(f): Mean residue level from day 1 or 4 until day 29 (3 cows, 13 or 14 sampling days).
(*): Indicates that the MRL is set at the limit of analytical quantification.

4. Consumer risk assessment

In the framework of this review, only the uses of prothioconazole reported by the RMS in Appendix A were considered, however the use of prothioconazole was previously also assessed by the JMPR (FAO, 2008a, 2008b, 2009a). The CXLs, resulting from these assessments by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs (see Appendix C.2).

4.1. Consumer risk assessment without consideration of the existing CXLs

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007a). Input values for the exposure calculations were derived in compliance with Appendix D and are summarised in Table 4-1. The tentative median and highest residue values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities reported in section 3, multiplied by the tentative conversion factors derived in sections 3.1.1. and 3.2. The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation.

Table 4-1: Input values for the consumer risk assessment (without consideration of CXLs)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).				
Potatoes	0.01*	Median residue [a]	0.01*	Highest residue [a]
Beetroot	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Carrots	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Horseradish	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Parsnips	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Parsley root	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Salsify	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Swedes	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Turnips	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Onions	0.02	Median residue x CF (tentative) [b]	0.04	Highest residue x CF (tentative) [b]
Broccoli	0.02	Median residue x CF (tentative) [b]	0.04	Highest residue x CF (tentative) [b]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cauliflower	0.02	Median residue x CF (tentative) [b]	0.04	Highest residue x CF (tentative) [b]
Brussels sprouts	0.06	Median residue x CF (tentative) [b]	0.14	Highest residue x CF (tentative) [b]
Head cabbage	0.02	Median residue x CF (tentative) [b]	0.12	Highest residue x CF (tentative) [b]
Leek	0.02	Median residue x CF (tentative) [b]	0.08	Highest residue x CF (tentative) [b]
Beans (dry)	0.02	Median residue x CF (tentative) [b]	0.06	Highest residue x CF (tentative) [b]
Peas (dry)	0.02	Median residue x CF (tentative) [b]	0.06	Highest residue x CF (tentative) [b]
Linseed	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Poppy seed	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Rape seed	0.06	Median residue x CF (tentative) [b]	0.18	Highest residue x CF (tentative) [b]
Mustard seed	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Gold of pleasure	0.02	Median residue x CF (tentative) [b]	0.04	Highest residue x CF (tentative) [b]
Barley grain	0.02	Median residue x CF (tentative) [b]	0.06	Highest residue x CF (tentative) [b]
Maize grain	0.01*	Median residue [a]	0.01*	Highest residue [a]
Oats grain	0.02	Median residue x CF (tentative) [b]	0.06	Highest residue x CF (tentative) [b]
Rye grain	0.02	Median residue x CF (tentative) [b]	0.04	Highest residue x CF (tentative) [b]
Wheat grain	0.02	Median residue x CF (tentative) [b]	0.04	Highest residue x CF (tentative) [b]
Swine meat	0.01*	0.8 x Median muscle + 0.2 x Median fat (tentative) [c]	0.01*	0.8 x Highest muscle + 0.2 x Highest fat (tentative) [c]
Swine fat (free of lean meat)	0.01*	Median residue (tentative) [c]	0.01*	Highest residue (tentative) [c]
Swine liver	0.02	Median residue x CF (tentative) [c]	0.02	Highest residue x CF (tentative) [c]
Swine kidney	0.09	Median residue x CF (tentative) [c]	0.09	Highest residue x CF (tentative) [c]
Ruminant meat	0.01*	0.8 x Median muscle + 0.2 x Median fat (tentative) [c]	0.01*	0.8 x Highest muscle + 0.2 x Highest fat (tentative) [c]
Ruminant fat	0.01*	Median residue (tentative) [c]	0.01*	Highest residue (tentative) [c]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Ruminant liver	0.02	Median residue x CF (tentative) (c)	0.09	Highest residue x CF (tentative) (c)
Ruminant kidney	0.09	Median residue x CF (tentative) (c)	0.11	Highest residue x CF (tentative) (c)
Poultry meat	0.01*	0.8 x Median muscle + 0.2 x Median fat (tentative) (c)	0.01*	0.8 x Highest muscle + 0.2 x Highest fat (tentative) (c)
Poultry fat	0.01*	Median residue (tentative) (c)	0.01*	Highest residue (tentative) (c)
Poultry liver	0.01*	Median residue (tentative) (c)	0.01*	Highest residue (tentative) (c)
Ruminant milk	0.005*	Median residue (tentative) (c)	0.005*	Highest residue (tentative) (c)
Birds' eggs	0.01*	Median residue (tentative) (c)	0.01*	Highest residue (tentative) (c)

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(b): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(c): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference values derived for prothioconazole-desthio (see Table 2-1); detailed results of the calculations are presented as the EU scenario in Appendix B.1. The highest chronic exposure was calculated for Dutch children, representing 4.3 % of the ADI, and the highest acute exposure was calculated for carrots, representing 63.4 % of the ARfD.

Based on the above calculations, EFSA concludes that the use of prothioconazole on crops fully supported by data (footnote (a) in Table 4-1), is acceptable with regard to consumer exposure. For the other commodities, major uncertainties remain due to the data gaps identified in section 3, but considering tentative MRLs in the exposure calculation did not indicate a risk to consumers.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA also emphasises that the above assessment does not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Directive 91/414/EEC have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

4.2. Consumer risk assessment with consideration of the existing CXLs

In order to include the CXLs in the calculations of the consumer exposure, all data relevant to the consumer exposure assessment have been collected from JMPR evaluations and reported in Appendix

C.2 to this document. These CXLs were compared with the EU MRL proposals in compliance with Appendix D and input values resulting from this comparison are summarised in Table 4-2.

It is noted that the same residue definitions for enforcement were derived for plant and animal commodities by EFSA and the JMPR (FAO, 2008a, 2008b) whilst the proposed residue definitions for risk assessment are different. Therefore, the CXLs are not considered to be fully supported by data, but in order to conduct the consumers exposure assessment considering the CXLs for plants and animals, the JMPR STMR and HR values for enforcement were multiplied by the tentative conversion factor for enforcement to risk assessment of 2 derived for all plant commodities (except for potatoes and maize grain) and by a conversion factors of 2 and 9 for ruminant liver and kidney, respectively (see section 3). It is also noted that when including the CXLs in the EU risk assessment, there is no need to consider the CXLs that have been established for edible offal, horses and other farm animals because there are no agreed extrapolations for these commodities of animal origin at EU level.

Table 4-2: Input values for the consumer risk assessment (with consideration of CXLs)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).				
Potatoes	0.01*	Median residue [a]	0.01*	Highest residue [a]
Beetroot	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Carrots	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Horseradish	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Parsnips	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Parsley root	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Salsify	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Swedes	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Turnips	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Onions	0.02	Median residue x CF (tentative) [b]	0.04	Highest residue x CF (tentative) [b]
Broccoli	0.02	Median residue x CF (tentative) [b]	0.04	Highest residue x CF (tentative) [b]
Cauliflower	0.02	Median residue x CF (tentative) [b]	0.04	Highest residue x CF (tentative) [b]
Brussels sprouts	0.06	Median residue x CF (tentative) [b]	0.14	Highest residue x CF (tentative) [b]
Head cabbage	0.02	Median residue x CF (tentative) [b]	0.12	Highest residue x CF (tentative) [b]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Leek	0.02	Median residue x CF (tentative) [b]	0.08	Highest residue x CF (tentative) [b]
Beans (dry)	0.10	Median residue (CXL) x CF (tentative) [d]	1.14	Highest residue (CXL) x CF (tentative) [d]
Lentils (dry)	0.10	Median residue (CXL) x CF (tentative) [d]	1.14	Highest residue (CXL) x CF (tentative) [d]
Peas (dry)	0.10	Median residue (CXL) x CF (tentative) [d]	1.14	Highest residue (CXL) x CF (tentative) [d]
Lupins (dry)	0.10	Median residue (CXL) x CF (tentative) [d]	1.14	Highest residue (CXL) x CF (tentative) [d]
Linseed	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Peanuts	0.04	Median residue (CXL) x CF (tentative) [d]	0.04	Highest residue (CXL) x CF (tentative) [d]
Poppy seed	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Rape seed	0.06	Median residue x CF (tentative) [b]	0.18	Highest residue x CF (tentative) [b]
Mustard seed	0.06	Median residue x CF (tentative) [b]	0.10	Highest residue x CF (tentative) [b]
Gold of pleasure	0.02	Median residue x CF (tentative) [b]	0.04	Highest residue x CF (tentative) [b]
Barley grain	0.08	Median residue (CXL) x CF (tentative) [d]	0.18	Highest residue (CXL) x CF (tentative) [d]
Maize grain	0.01*	Median residue [a]	0.01*	Highest residue [a]
Oats grain	0.02	Median residue (CXL) x CF (tentative) [d]	0.04	Highest residue (CXL) x CF (tentative) [d]
Rye grain	0.02	Median residue (CXL) x CF (tentative) [d]	0.04	Highest residue (CXL) x CF (tentative) [d]
Wheat grain	0.04	Median residue (CXL) x CF (tentative) [d]	0.10	Highest residue (CXL) x CF (tentative) [d]
Sugar beet (root)	0.10	Median residue (CXL) x CF (tentative) [d]	0.38	Highest residue (CXL) x CF (tentative) [d]
Swine meat	0.01*	0.8 x Median muscle + 0.2 x Median fat (tentative) [c]	0.01*	0.8 x Highest muscle + 0.2 x Highest fat (tentative) [c]
Swine fat (free of lean meat)	0.01*	Median residue (tentative) [c]	0.01*	Highest residue (tentative) [c]
Swine liver	0.10	Median residue (CXL) x CF (tentative) [d]	0.46	Highest residue (CXL) x CF (tentative) [d]
Swine kidney	0.23	Median residue (CXL) x CF (tentative) [d]	1.35	Highest residue (CXL) x CF (tentative) [d]
Ruminant meat	0.01*	0.8 x Median muscle + 0.2 x Median fat (tentative) [c]	0.01*	0.8 x Highest muscle + 0.2 x Highest fat (tentative) [c]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Ruminant fat	0.01*	Median residue (tentative) (c)	0.01*	Highest residue (tentative) (c)
Ruminant liver	0.10	Median residue (CXL) x CF (tentative) (d)	0.46	Highest residue (CXL) x CF (tentative) (d)
Ruminant kidney	0.23	Median residue (CXL) x CF (tentative) (d)	1.35	Highest residue (CXL) x CF (tentative) (d)
Poultry meat	0.01*	0.8 x Median muscle + 0.2 x Median fat (tentative) (c)	0.01*	0.8 x Highest muscle + 0.2 x Highest fat (tentative) (c)
Poultry fat	0.01*	Median residue (tentative) (c)	0.01*	Highest residue (tentative) (c)
Poultry liver	0.01*	Median residue (tentative) (c)	0.01*	Highest residue (tentative) (c)
Ruminant milk	0.005*	Median residue (tentative) (c)	0.005*	Highest residue (tentative) (c)
Birds' eggs	0.01*	Median residue (tentative) (c)	0.01*	Highest residue (tentative) (c)

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(b): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(c): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.
(d): CXL is not sufficiently supported by data; the corresponding risk assessment values are used for indicative exposure calculations.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and calculated exposures were compared with the toxicological reference values derived for prothioconazole-desthio (see Table 2-1); detailed results of the calculations are presented as EU/Codex scenario 1, in Appendix B.2. The highest chronic exposure was calculated for British toddlers, representing 26.3 % of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for sugar beet root and beans (dry), representing 242.6 % and 208.3 % of the ARfD, respectively. A second exposure calculation was therefore performed, excluding these CXLs. According to the results of this second calculation (see Appendix B.3 – EU/Codex scenario 2), the highest chronic exposure declined to 6.1 % of the ADI (WHO Cluster diet B); the highest acute exposure was then calculated for lentils, representing 70.1 % of the ARfD.

For all CXLs, uncertainties remain as these are not well supported by data for risk assessment. Nevertheless, inclusion of these CXLs in the exposure calculation did not indicate any risk to European consumers, except for sugar beet (root) and beans (dry).

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of prothioconazole was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.05 mg/kg bw per d and 0.2 mg/kg bw, respectively. The toxicological profile of prothioconazole-desthio was also evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.01 mg/kg bw per d and 0.01 mg/kg bw, respectively.

Metabolism of prothioconazole in primary crops was investigated for foliar application in root and tuber vegetables, pulses and oilseeds and cereals using phenyl and triazole labellings, and for seed treatment in cereals only. The metabolism of prothioconazole-desthio was also investigated for foliar application on cereals. The metabolic pattern of prothioconazole and prothioconazole-desthio was shown to be similar with prothioconazole-desthio being the predominant compound of the total residues with further hydroxylation and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of triazole derivative metabolites (TDMs). A global residue definition for enforcement was proposed as prothioconazole-desthio (sum of isomers) only whilst for risk assessment, the residue was defined as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). As the residue definitions for enforcement and risk assessment are different, conversion factors for enforcement to risk assessment of 2 for cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables and of 3 for cereal straw were derived on the basis of the available plant metabolism data. For maize and potatoes (seed treatment), no median conversion factors for enforcement to risk assessment were derived since residues in these crops are expected to be below 0.01 mg/kg. Validated analytical methods for enforcement of the proposed residue definition are available.

Sufficient residue trials were available to derive MRL proposals and risk assessment values on potatoes and maize grain. For grass, no residue trial was submitted. For all the other crops, only tentative MRL proposals and risk assessment values could be derived, due to the data gaps identified for additional residue trials analysing the residues in compliance with the proposed residue definition for risk assessment, clarification on the analytical method used in the residue trials on rape seed and further storage stability data. Tentative MRLs were also derived for cereal straw and maize forage in view of the future need to set MRLs in feed items.

Based on the available data for processed commodities, the residue definition for enforcement and risk assessment derived in primary crops can also apply to the processed commodities. No studies investigating the magnitude of residues in processed commodities are available. As such studies are not expected to affect the outcome of the risk assessment, these are not required.

The metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary. Considering the application rates of prothioconazole reported in the authorized European GAPs, it can be concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops and no risk mitigation measures need to be proposed.

The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg DM for ruminants, pigs and poultry. Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products was set as prothioconazole-desthio (sum of isomers) for all the livestock matrices. This compound is fat soluble. It is however noted that in case the livestock dietary burden is further increased in the future due to additional uses on feed items, the residue definition for enforcement might have to be revised by including the glucuronide conjugates of prothioconazole-desthio for all livestock matrices. For risk assessment, the residue was defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). Validated analytical methods for enforcement of the proposed residue definition are available, except for eggs.

Based on the ruminants feeding study tentative MRLs were set at the LOQ for all matrices, except for liver and kidney, where MRLs of respectively 0.05 and 0.02 mg/kg were proposed. Since only the residues of prothioconazole-desthio were determined, conversion factors for enforcement to risk assessment of 2 and 9 were established respectively for liver and kidney based on the goat metabolism study with administration of prothioconazole-desthio. It is noted that no conversion factor was set for

milk, muscle and fat as the residue levels in these matrices are expected to be negligible (<0.01 mg/kg) at the calculated dietary burden. Nevertheless, a new feeding study to estimate the potential exposure to all prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment is in principle still required. For poultry, although the maximum dietary burden exceeded the threshold of 0.1 mg/kg DM, no residues above the LOQ were expected in poultry matrices at the calculated dietary burden and no feeding study was triggered. Therefore, MRLs can be established at the LOQ in all poultry commodities and no default conversion factors for risk assessment need to be derived. The MRLs for livestock matrices are all tentative due to the tentative dietary burden calculations, the missing livestock feeding study in ruminants and the required validated analytical method for enforcement in eggs.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 4.3 % of the ADI (Dutch child) and the highest acute exposure amounted to 63.4 % of the ARfD (carrots).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for prothioconazole. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure represented 26.3 % of ADI (UK toddler) whilst exceedances of the ARfD were identified for the existing CXLs in sugar beet root (242.6 %) and dry beans (208.3 %). Excluding these CXLs from the calculation, the highest chronic exposure represented 6.1 % of the ADI (WHO Cluster diet B)) and the highest acute exposure amounted to 70.1 % of the ARfD (lentils).

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, tentative MRLs need to be confirmed by the following data:

- Fully validated analytical methods for the determination of prothioconazole-desthio in eggs;
- 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);
- 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;
- Clarification on whether the conjugates of M14, M15, M16, M17 and M18 metabolites were effectively analysed in the residue trials conducted on rape seed;
- 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);
- A ruminants 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.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- 1 additional residue trial on rape seed supporting the southern outdoor GAP.
- A study investigating the effects of processing on the nature of all the metabolites included in the residue definition for risk assessment in plant commodities.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA also emphasises that the above assessment does not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition (existing): prothioconazole-desthio **Enforcement residue definition (proposed):** prothioconazole-desthio (sum of isomers)					
211000	Potatoes	0.02*	-	0.05*	Recommended [(a)]
213010	Beetroot	0.1	-	0.1	Further consideration needed [(b)]
213020	Carrots	0.1	-	0.1	Further consideration needed [(b)]
213040	Horseradish	0.1	-	0.1	Further consideration needed [(b)]
213060	Parsnips	0.1	-	0.1	Further consideration needed [(b)]
213070	Parsley root	0.1	-	0.1	Further consideration needed [(b)]
213090	Salsify	0.1	-	0.1	Further consideration needed [(b)]
213100	Swedes	0.1	-	0.1	Further consideration needed [(b)]
213110	Turnips	0.1	-	0.1	Further consideration needed [(b)]
220020	Onions	0.02*	-	0.05*	Further consideration needed [(b)]
241010	Broccoli	0.03	-	0.05*	Further consideration needed [(b)]
241020	Cauliflower	0.03	-	0.05*	Further consideration needed [(b)]
242010	Brussels sprouts	0.1	-	0.1	Further consideration needed [(b)]
242020	Head cabbage	0.1	-	0.09	Further consideration needed [(b)]
270060	Leek	0.05	-	0.06	Further consideration needed [(b)]
300010	Beans (dry)	1	1	0.05	Further consideration needed [(h)]
300020	Lentils (dry)	1	1	1	Further consideration needed [(g)]
300030	Peas (dry)	1	1	1	Further consideration needed [(f)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
300040	Lupins (dry)	1	1	1	Further consideration needed [g]
401010	Linseed	0.15	-	0.09	Further consideration needed [b]
401020	Peanuts	0.05	0.02*	0.02*	Further consideration needed [g]
401030	Poppy seed	0.15	-	0.09	Further consideration needed [b]
401060	Rape seed	0.15	0.1	0.15	Further consideration needed [d]
401080	Mustard seed	0.15	-	0.09	Further consideration needed [b]
401130	Gold of pleasure	0.05	-	0.04	Further consideration needed [b]
500010	Barley grain	0.3	0.2	0.2	Further consideration needed [f]
500030	Maize grain	0.02*	-	0.02*	Recommended [a]
500050	Oats grain	0.05	0.05	0.05	Further consideration needed [f]
500070	Rye grain	0.1	0.05	0.05	Further consideration needed [f]
500090	Wheat grain	0.1	0.1	0.1	Further consideration needed [f]
900010	Sugar beet (root)	0.3	0.3	0.05*	Further consideration needed [e]
Enforcement residue definition (existing): Sum of prothioconazole-desthio and its glucuronide conjugate, expressed as prothioconazole-desthio **Enforcement residue definition (proposed):** prothioconazole-desthio (sum of isomers)					
1011010	Swine muscle	0.05	0.01	0.01*	Further consideration needed [d]
1011020	Swine fat (free of lean meat)	0.05	0.01	0.01*	Further consideration needed [d]
1011030	Swine liver	0.5	0.5	0.5	Further consideration needed [f]
1011040	Swine kidney	0.5	0.5	0.5	Further consideration needed [f]
1012010	Bovine muscle	0.05	0.01	0.01*	Further consideration needed [d]
1012020	Bovine fat	0.05	0.01	0.01*	Further consideration needed [d]
1012030	Bovine liver	0.5	0.5	0.5	Further consideration needed [f]
1012040	Bovine kidney	0.5	0.5	0.5	Further consideration needed [f]
1013010	Sheep muscle	0.05	0.01	0.01*	Further consideration needed [d]
1013020	Sheep fat	0.05	0.01	0.01*	Further consideration needed [d]
1013030	Sheep liver	0.5	0.5	0.5	Further consideration needed [f]
1013040	Sheep kidney	0.5	0.5	0.5	Further consideration needed [f]
1014010	Goat muscle	0.05	0.01	0.01*	Further consideration needed [d]
1014020	Goat fat	0.05	0.01	0.01*	Further consideration needed [d]
1014030	Goat liver	0.5	0.5	0.5	Further consideration needed [f]
1014040	Goat kidney	0.5	0.5	0.5	Further consideration needed [f]
1016010	Poultry muscle	0.05	-	0.01*	Further consideration needed [b]
1016020	Poultry fat	0.05	-	0.01*	Further consideration needed [b]
1016030	Poultry liver	0.05	-	0.01*	Further consideration needed [b]
1020010	Cattle milk	0.01*	0.004*	0.005*	Further consideration needed [d]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1020020	Goat milk	0.01*	0.004*	0.005*	Further consideration needed (d)
1020030	Sheep milk	0.01*	0.004*	0.005*	Further consideration needed (d)
1030000	Birds' eggs	0.05	-	0.01*	Further consideration needed (b)
-	Other products of plant and animal origin	See App C1	-	-	Further consideration needed (c)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk
(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(d): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(e): There are no relevant authorisations or import tolerances reported at EU level; CXL is not sufficiently supported by data and a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-IV in Appendix D).
(f): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix D).
(g): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix D).
(h): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; CXL is higher, but not sufficiently supported by data but a risk to consumers cannot be excluded (combination E-IV in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on prothioconazole prepared by the rapporteur Member State United Kingdom in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 27 July 2011. Last updated on 31 October 2012.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Potatoes	*Tuber form Solanum Spp*	NEU	Outdoor	DE	Helminthosporium solani	FS	8.0	g/L	Seed treatment - dipping	0	0	1	1				0.64	g a.i./100 kg	n.a.	For a seed rate of 50 dt/ha, the application rate corresponds to 32 g a.s./ha (DE, 2014).
Beetroot	*Beta vulgaris subsp. Vulgaris*	NEU	Outdoor	UK	Sclerotinia sclerotiorum, Erysiphe heraclei	SC	480.0	g/L	Foliar treatment - spraying	19	49	1	3		14		192.00	g a.i./ha	21	EFSA Journal 2010; 8(7):1675
Carrots	*Daucus carota*	NEU	Outdoor	UK	Alternaria dauci, Sclerotinia sclerotiorum, Erysiphe heraclei	SC	480.0	g/L	Foliar treatment - spraying	19	49	1	3		14		192.00	g a.i./ha	21	EFSA Journal 2010; 8(7):1675
Horseradish	*Armoracia rusticana*	NEU	Outdoor	UK	Sclerotinia sclerotiorum, Erysiphe heraclei	SC	480.0	g/L	Foliar treatment - spraying	19	49	1	3		14		192.00	g a.i./ha	21	EFSA Journal 2010; 8(7):1675
Parsnips	*Pastinaca sativa*	NEU	Outdoor	UK	Sclerotinia sclerotiorum, Erysiphe heraclei	SC	480.0	g/L	Foliar treatment - spraying	19	49	1	3		14		192.00	g a.i./ha	21	EFSA Journal 2010; 8(7):1675
Parsley root	*Petroselinum crispum*	NEU	Outdoor	UK	Sclerotinia sclerotiorum, Erysiphe heraclei	SC	480.0	g/L	Foliar treatment - spraying	19	49	1	3		14		192.00	g a.i./ha	21	EFSA Journal 2010; 8(7):1675
Salsify	*Tragopogon porrifolius*	NEU	Outdoor	UK	Sclerotinia sclerotiorum, Erysiphe heraclei	SC	480.0	g/L	Foliar treatment - spraying	19	49	1	3		14		192.00	g a.i./ha	21	EFSA Journal 2010; 8(7):1675
Swedes	*Brassica napus var. napobrassica*	NEU	Outdoor	UK	Sclerotinia sclerotiorum, Erysiphe heraclei	SC	480.0	g/L	Foliar treatment - spraying	19	49	1	3		14		192.00	g a.i./ha	21	EFSA Journal 2010; 8(7):1675
Turnips	*Brassica rapa*	NEU	Outdoor	UK	Sclerotinia sclerotiorum, Erysiphe heraclei	SC	480.0	g/L	Foliar treatment - spraying	19	49	1	3		14		192.00	g a.i./ha	21	EFSA Journal 2010; 8(7):1675
Onions	*Allium cepa*	NEU	Outdoor	NL, UK	Peronospora destructor, Botryotinia squamosa	EC	100.0	g/L	Foliar treatment - spraying		47	1	4	5	10		125.00	g a.i./ha	14	NL, 2014
Broccoli	*Brassica oleracea var. italica*	NEU	Outdoor	UK	Fungi	SC	480.0	g/L	Foliar treatment - spraying	15	49		3	14	21		192.00	g a.i./ha	21	EFSA Journal 2010; 8(4):1577
Cauliflower	*Brassica oleracea var. botrytis*	NEU	Outdoor	UK	Fungi	SC	480.0	g/L	Foliar treatment - spraying	15	49		3	14	21		192.00	g a.i./ha	21	EFSA Journal 2010; 8(4):1577
Brussels sprouts	*Brassica oleracea var. gemmifera*	NEU	Outdoor	NL	Mycosphaerella brassicicola	SC	480.0	g/L	Foliar treatment - spraying	15	49		3		14		192.00	g a.i./ha	21	EFSA Scientific Report (2009)261; 15-24
Head cabbage	*Brassica oleracea convar capitata*	NEU	Outdoor	NL	Mycosphaerella brassicicola	SC	480.0	g/L	Foliar treatment - spraying	15	49		3		14		192.00	g a.i./ha	21	EFSA Scientific Report (2009)261; 15-24
Leek	*Allium porrum*	NEU	Outdoor	UK	Fungi	SC	480.0	g/L	Foliar treatment - spraying	15	49	1	3	21			192.00	g a.i./ha	21	
Beans (dry)	*Phaseolus vulgaris*	NEU	Outdoor	FR	Mycosphaerella pinodes, Ascochyta pisi, Phoma medicaginis, Erysiphe pisi, Uromyces posi	EC	125.0	g/L	Foliar treatment - spraying	61	69		2				125.00	g a.i./ha	35	FR, 2014
Peas (dry)	*Pisum sativum*	NEU	Outdoor	FR	Mycosphaerella pinodes, Ascochyta pisi, Phoma medicaginis, Erysiphe pisi, Uromyces posi	EC	125.0	g/L	Foliar treatment - spraying	61	69		2				125.00	g a.i./ha	35	FR, 2014
Linseed	*Linum usitatissimum*	NEU	Outdoor	FR	Stem and leaf diseases	EC	150.0	g/L	Foliar treatment - spraying				2	14			120.00	g a.i./ha	28	PHI: 30 days is notified - EFSA Journal 2012;10(11):2952
Poppy seed	*Papaver somniferum*	NEU	Outdoor	FR	Stem and leaf diseases	EC	150.0	g/L	Foliar treatment - spraying				2	14			120.00	g a.i./ha	28	PHI: 30 days is notified - EFSA Journal 2012;10(11):2952
Rape seed	*Brassica napus*	NEU	Outdoor	FR	Stem and leaf diseases	EC	150.0	g/L	Foliar treatment - spraying				2	14			120.00	g a.i./ha	28	PHI: 30 days is notified - EFSA Journal 2012;10(11):2952
Mustard seed	*Brassica nigra*	NEU	Outdoor	FR	Stem and leaf diseases	EC	150.0	g/L	Foliar treatment - spraying				2	14			120.00	g a.i./ha	28	PHI: 30 days is notified - EFSA Journal 2012;10(11):2952
Gold of pleasure	*Camelina sativa*	NEU	Outdoor	FR	Fungi	EC	250.0	g/L	Foliar treatment - spraying				2				175.00	g a.i./ha	56	FR, 2014
Barley	*Hordeum spp.*	NEU	Outdoor	SE	Eyespot, barley leaf rust, mildew, Rhyncosporium, Ramularia, net blotch, Fusarium	EC	250.0	g/L	Foliar treatment - spraying	30	69	1	2	14	21		200.00	g a.i./ha	35	The use on barley by seed treatment is also authorised in FR but leads to lower (or similar) residue levels in grain and straw: all below the LOQ (FR, 2014).
Maize	*Zea mays*	NEU	Outdoor	FR	Fungi	FS	300.0	g/L	Seed treatment - general (see also comment field)	0	0	1	1				27.00	g a.i./100 kg	n.a.	The application rate corresponds to 9 g a.s./ha (FR, 2014).

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or waiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Oats	*Avena fatua*	NEU	Outdoor	SE	Mildew, oat leaf spot, crown rust, Fusarium	EC	250.0	g/L	Foliar treatment - spraying	30	69	1	2	14	21		200.00	g a.i./ha	35	The use on oats by seed treatment is also authorised in FR but leads to lower (or similar) residue levels in grain and straw: all below the LOQ (FR, 2014).
Rye	*Secale cereale*	NEU	Outdoor	UK	Eyespot, Rusts, Powd. Mildew, Rhyncosporium, Fusarium spp., Pyren.teres	EC	250.0	g/L	Foliar treatment - spraying	29	69	1	3	14	21		200.00	g a.i./ha	35	The use on rye by seed treatment is also authorised in FR but leads to lower (or similar) residue levels in grain and straw: all below the LOQ (FR, 2014).
Wheat	*Triticum aestivum*	NEU	Outdoor	UK	Eyespot, Rusts, Powd. Mildew, Rhyncosporium, Fusarium spp., Pyren.teres	EC	250.0	g/L	Foliar treatment - spraying	29	69	1	3	14	21		200.00	g a.i./ha	35	The use on wheat by seed treatment is also authorised in FR but leads to lower (or similar) residue levels in grain and straw: all below the LOQ (FR, 2014).
Grass	*not specified*	NEU	Outdoor	NL	Leaf- and ear diseases	EC	125.0	g/L	Foliar treatment - spraying		59	1	2				125.00	g a.i./ha	35	The use on grass seed is authorised in NL. Growth stage at application: "shortly before flowering". After harvest of grains, remaining parts of the plants are left in the field for subsequent cattle grazing (35 days after treatment) (NL, 2014).
Maize (for forage)	*Zea mays*	NEU	Outdoor	FR	Fungi	FS	300.0	g/L	Seed treatment - general (see also comment field)	0	0	1	1				27.00	g a.i./100 kg	n.a.	The application rate corresponds to 9 g a.s./ha (FR, 2014).

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or waiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Potatoes	*Tuber form Solanum Spp*	SEU	Outdoor	FR	Rhizoctonia solani, Helminthosporium solani	FS	8.0	g/L	Seed treatment - spraying	0	3	1	1				0.48	g a.i./100 kg	n.a.	The seed treatment can also be done by furrow application. The application rate varies from 12 g a.s./ha (i.e. 2,5 t seeds/ha: for food potatoes) to 24 g a.s./ha (or 5 t seeds/ha: for seed production) (FR, 2014).
Rape seed	*Brassica napus*	SEU	Outdoor	FR	Stem and leaf diseases	EC	150.0	g/L	Foliar treatment - spraying				2	14			120.00	g a.i./ha	28	PHI: 30 days is notified - EFSA Journal 2012;10(11):2952
Gold of pleasure	*Camelina sativa*	SEU	Outdoor	FR	Fungi	EC	250.0	g/L	Foliar treatment - spraying				2				175.00	g a.i./ha	56	FR, 2014
Barley	*Hordeum spp.*	SEU	Outdoor	IT	Fusarium spp., Puccinia spp., Septoria spp., Erysiphe graminis, Pyrenophora spp.	EC	250.0	g/L	Foliar treatment - spraying	32	61	1	2				200.00	g a.i./ha	35	The use on barley by seed treatment is also authorised in FR but leads to lower (or similar) residue levels in grain and straw: all below the LOQ (FR, 2014).
Maize	*Zea mays*	SEU	Outdoor	FR	Fungi	FS	300.0	g/L	Seed treatment - general (see also comment field)	0	0	1	1				27.00	g a.i./100 kg	n.a.	The application rate corresponds to 9 g a.s./ha (FR, 2014).
Oats	*Avena fatua*	SEU	Outdoor	FR	Fusarium spp., Puccinia spp., Septoria spp., Erysiphe graminis, Pyrenophora spp.	EC	250.0	g/L	Foliar treatment - spraying	32	61	1	2				200.00	g a.i./ha	35	The use on oats by seed treatment is also authorised in FR but leads to lower (or similar) residue levels in grain and straw: all below the LOQ (FR, 2014).
Wheat	*Triticum aestivum*	SEU	Outdoor	IT	Fusarium spp., Puccinia spp., Septoria spp., Erysiphe graminis, Pyrenophora spp.	EC	250.0	g/L	Foliar treatment - spraying	32	69	1	2	14	21		200.00	g a.i./ha	35	The use on wheat by seed treatment is also authorised in FR but leads to lower (or similar) residue levels in grain and straw: all below the LOQ (FR, 2014).
Maize (for forage)	*Zea mays*	SEU	Outdoor	FR	Fungi	FS	300.0	g/L	Seed treatment - general (see also comment field)	0	0	1	1				27.00	g a.i./100 kg	n.a.	The application rate corresponds to 9 g a.s./ha (FR, 2014).

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – EU scenario including all EU MRL proposals resulting from the GAPs reported by the RMS

Appendix B.2 – EU/Codex scenario 1 including EU MRL proposals and all CXLs

Appendix B.3 – EU/Codex scenario 2 including EU MRL proposals and demonstrated safe CXLs

APPENDIX B.1 – EU SCENARIO INCLUDING ALL EU MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

Prothioconazole-desthio (M04)

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
1	4

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)
4.3	NL child	1.5	Milk and milk products: Cattle	0.9	Wheat	0.6	Potatoes	
4.0	FR infant	1.6	Carrots	1.3	Milk and milk products: Cattle	0.4	Potatoes	
3.8	WHO Cluster diet B	1.7	Wheat	0.4	Beetroot	0.3	Potatoes	
3.4	FR toddler	1.5	Carrots	0.5	Wheat	0.5	Potatoes	
3.3	DK child	1.1	Wheat	0.9	Rye	0.8	Carrots	
3.1	DE child	0.8	Wheat	0.7	Milk and milk products: Cattle	0.6	Carrots	
2.9	IE adult	0.5	Wheat	0.4	Parsnips	0.2	Barley	
2.9	WHO cluster diet E	0.8	Wheat	0.4	Potatoes	0.4	Rape seed	
2.8	SE general population 90th percentile	0.6	Wheat	0.6	Milk and milk products: Cattle	0.5	Carrots	
2.8	WHO Cluster diet F	0.7	Wheat	0.3	Potatoes	0.3	Carrots	
2.8	WHO cluster diet D	1.3	Wheat	0.4	Potatoes	0.2	Milk and milk products: Cattle	
2.5	ES child	0.9	Wheat	0.6	Milk and milk products: Cattle	0.2	Potatoes	
2.4	WHO regional European diet	0.6	Wheat	0.4	Potatoes	0.2	Milk and milk products: Cattle	
2.4	UK Infant	0.8	Carrots	0.5	Wheat	0.3	Potatoes	
1.9	PT General population	0.8	Wheat	0.5	Potatoes	0.4	Carrots	
1.9	UK Toddler	0.8	Wheat	0.3	Potatoes	0.3	Carrots	
1.8	NL general	0.4	Wheat	0.3	Milk and milk products: Cattle	0.3	Potatoes	
1.6	IT kids/toddler	1.3	Wheat	0.1	Carrots	0.1	Potatoes	
1.4	LT adult	0.3	Potatoes	0.2	Rye	0.2	Wheat	
1.4	ES adult	0.5	Wheat	0.2	Milk and milk products: Cattle	0.1	Barley	
1.4	FR all population	0.7	Wheat	0.2	Carrots	0.1	Milk and milk products: Cattle	
1.2	DK adult	0.4	Wheat	0.3	Carrots	0.1	Potatoes	
1.0	IT adult	0.8	Wheat	0.1	Carrots	0.1	Potatoes	
1.0	UK vegetarian	0.4	Wheat	0.1	Potatoes	0.1	Carrots	
0.9	PL general population	0.3	Potatoes	0.2	Carrots	0.1	Beetroot	
0.8	UK Adult	0.3	Wheat	0.1	Potatoes	0.1	Carrots	
0.7	FI adult	0.2	Wheat	0.1	Rye	0.1	Potatoes	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Prothioconazole-desthio (M04) 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)
	63.4	Carrots	0.1 / -	51.7	Swedes	0.1 / -	38.1	Head cabbage	0.12 / -	23.9	Swedes	0.1 / -
	63.2	Head cabbage	0.12 / -	45.3	Carrots	0.1 / -	23.9	Swedes	0.1 / -	22.9	Head cabbage	0.12 / -
	51.7	Swedes	0.1 / -	37.9	Head cabbage	0.12 / -	15.3	Leek	0.08 / -	12.7	Cauliflower	0.04 / -
	47.2	Leek	0.08 / -	33.7	Leek	0.08 / -	14.1	Parsnips	0.1 / -	11.6	Leek	0.08 / -
	43.8	Beetroot	0.1 / -	32.6	Beetroot	0.1 / -	13.8	Beetroot	0.1 / -	10.8	Beetroot	0.1 / -
	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 / -				1.8	Bread/pizza	0.04 / -			
	4.7	Wheat flour	0.04 / -				0.1	Potato uree (flakes)	0.01 / -			
	1.4	Potato puree (flakes)	0.01 / -				0.1	Fried potatoes	0.01 / -			
	0.4	Maize flour	0.01 / -				0.0	Maize flour	0.01 / -			
	0.1	Fried potatoes	0.01 / -									
	*) 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											

APPENDIX B.2 – EU/CODEX SCENARIO 1 INCLUDING EU MRL PROPOSALS AND ALL CXLS

Prothioconazole-desthio (M04)			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	1 - 26
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)
26.3	UK Toddler	22.9	Sugar beet (root)	1.6	Wheat	0.8	Beans	
13.5	UK Infant	10.1	Sugar beet (root)	1.0	Wheat	0.8	Carrots	
6.8	WHO Cluster diet B	3.4	Wheat	0.7	Sugar beet (root)	0.4	Beetroot	
5.6	NL child	1.9	Wheat	1.5	Milk and milk products: Cattle	0.6	Potatoes	
5.5	UK vegetarian	3.8	Sugar beet (root)	0.8	Wheat	0.4	Beans	
5.4	UK Adult	4.0	Sugar beet (root)	0.7	Wheat	0.2	Beans	
4.8	IE adult	1.0	Barley	0.9	Wheat	0.4	Parsnips	
4.5	DK child	2.2	Wheat	0.9	Rye	0.8	Carrots	
4.5	WHO cluster diet D	2.6	Wheat	0.4	Potatoes	0.2	Milk and milk products: Cattle	
4.4	WHO cluster diet E	1.6	Wheat	0.6	Barley	0.4	Potatoes	
4.1	FR infant	1.6	Carrots	1.3	Milk and milk products: Cattle	0.4	Potatoes	
4.0	WHO Cluster diet F	1.4	Wheat	0.5	Barley	0.3	Potatoes	
3.9	FR toddler	1.5	Carrots	1.0	Wheat	0.5	Potatoes	
3.9	DE child	1.6	Wheat	0.7	Milk and milk products: Cattle	0.6	Carrots	
3.8	ES child	1.8	Wheat	0.6	Milk and milk products: Cattle	0.2	Lentils	
3.5	SE general population 90th percentile	1.3	Wheat	0.6	Milk and milk products: Cattle	0.5	Carrots	
3.4	WHO regional European diet	1.2	Wheat	0.4	Potatoes	0.3	Barley	
3.0	IT kids/toddler	2.7	Wheat	0.1	Carrots	0.1	Potatoes	
2.9	PT General population	1.6	Wheat	0.5	Potatoes	0.4	Carrots	
2.6	NL general	0.8	Wheat	0.3	Milk and milk products: Cattle	0.3	Barley	
2.4	ES adult	0.9	Wheat	0.4	Barley	0.2	Milk and milk products: Cattle	
2.1	FR all population	1.3	Wheat	0.2	Carrots	0.1	Milk and milk products: Cattle	
2.0	IT adult	1.7	Wheat	0.1	Carrots	0.1	Potatoes	
1.7	LT adult	0.4	Wheat	0.3	Potatoes	0.2	Rye	
1.6	DK adult	0.8	Wheat	0.3	Carrots	0.1	Potatoes	
1.0	FI adult	0.4	Wheat	0.1	Rye	0.1	Potatoes	
0.9	PL general population	0.3	Potatoes	0.2	Carrots	0.1	Beetroot	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Prothioconazole-desthio (M04) 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):**		**2**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**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)
	242.6	Sugar beet (root)	0.38 / 0.15	242.6	Sugar beet (root)	0.38 / 0.15	98.6	Sugar beet (root)	0.38 / -	98.6	Sugar beet (root)	0.38 / -
	208.3	Beans	1.14 / 0.54	208.3	Beans	1.14 / 0.54	71.8	Beans	1.14 / -	71.8	Beans	1.14 / -
	70.1	Lentils	1.14 / -	70.1	Lentils	1.14 / -	38.1	Head cabbage	0.12 / -	37.9	Peas	1.14 / -
	63.4	Carrots	0.1 / -	51.7	Swedes	0.1 / -	37.9	Peas	1.14 / -	35.1	Lentils	1.14 / -
	63.2	Head cabbage	0.12 / -	50.8	Bovine: Kidney	1.35 / -	35.1	Lentils	1.14 / -	23.9	Swedes	0.1 / -
	No of critical MRLs (IESTI 1)		2				**No of critical MRLs (IESTI 2)**		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 / -			
	11.8	Wheat flour	0.1 / -				0.1	Potato uree (flakes)	0.01 / -			
	1.4	Potato puree (flakes)	0.01 / -				0.1	Fried potatoes	0.01 / -			
	0.4	Maize flour	0.01 / -				0.0	Maize flour	0.01 / -			
	0.1	Fried potatoes	0.01 / -									

APPENDIX B.3 – EU/CODEX SCENARIO 2 INCLUDING EU MRL PROPOSALS AND DEMONSTRATED SAFE CXLS

Prothioconazole-desthio (M04)			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	1 – 6
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)
6.1	WHO Cluster diet B	3.4	Wheat	0.4	Beetroot	0.3	Potatoes	
5.9	FR toddler	2.0	Milk and cream,	1.5	Carrots	1.0	Wheat	
5.5	NL child	1.9	Wheat	1.5	Milk and cream,	0.6	Potatoes	
5.2	DK child	2.2	Wheat	0.9	Rye	0.8	Carrots	
5.0	UK Infant	1.9	Milk and cream,	1.0	Wheat	0.8	Carrots	
4.7	IE adult	1.0	Barley	0.9	Wheat	0.4	Parsnips	
4.4	WHO cluster diet D	2.6	Wheat	0.4	Potatoes	0.3	Milk and cream,	
4.3	WHO cluster diet E	1.6	Wheat	0.6	Barley	0.4	Potatoes	
4.1	FR infant	1.6	Carrots	1.3	Milk and cream,	0.4	Potatoes	
4.0	WHO Cluster diet F	1.4	Wheat	0.5	Barley	0.3	Potatoes	
3.9	DE child	1.6	Wheat	0.7	Milk and cream,	0.6	Carrots	
3.8	UK Toddler	1.6	Wheat	1.0	Milk and cream,	0.3	Potatoes	
3.7	ES child	1.8	Wheat	0.6	Milk and cream,	0.2	Lentils	
3.5	SE general population 90th percentile	1.3	Wheat	0.6	Milk and cream,	0.5	Carrots	
3.3	WHO regional European diet	1.2	Wheat	0.4	Potatoes	0.3	Barley	
3.0	IT kids/toddler	2.7	Wheat	0.1	Carrots	0.1	Potatoes	
2.7	PT General population	1.6	Wheat	0.5	Potatoes	0.4	Carrots	
2.5	NL general	0.8	Wheat	0.3	Milk and cream,	0.3	Barley	
2.3	ES adult	0.9	Wheat	0.4	Barley	0.2	Milk and cream,	
2.1	FR all population	1.3	Wheat	0.2	Carrots	0.1	Milk and cream,	
1.9	IT adult	1.7	Wheat	0.1	Carrots	0.1	Potatoes	
1.9	DK adult	0.8	Wheat	0.3	Milk and cream,	0.3	Carrots	
1.7	LT adult	0.4	Wheat	0.3	Potatoes	0.2	Rye	
1.6	UK vegetarian	0.8	Wheat	0.2	Milk and cream,	0.1	Potatoes	
1.3	UK Adult	0.7	Wheat	0.1	Milk and cream,	0.1	Potatoes	
1.2	FI adult	0.4	Wheat	0.3	Milk and cream,	0.1	Rye	
0.9	PL general population	0.3	Potatoes	0.2	Carrots	0.1	Beetroot	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Prothioconazole-desthio (M04) 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)
	70.1	Lentils	1.14 / -	70.1	Lentils	1.14 / -	38.1	Head cabbage	0.12 / -	37.9	Peas	1.14 / -
	63.4	Carrots	0.1 / -	51.7	Swedes	0.1 / -	37.9	Peas	1.14 / -	35.1	Lentils	1.14 / -
	63.2	Head cabbage	0.12 / -	50.8	Bovine: Kidney	1.35 / -	35.1	Lentils	1.14 / -	23.9	Swedes	0.1 / -
	51.7	Swedes	0.1 / -	48.0	Peas	1.14 / -	23.9	Swedes	0.1 / -	23.0	Bovine: Kidney	1.35 / -
	50.8	Bovine: Kidney	1.35 / -	45.3	Carrots	0.1 / -	23.0	Bovine: Kidney	1.35 / -	22.9	Head cabbage	0.12 / -
	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 / -			
	11.8	Wheat flour	0.1 / -				0.1	Potato uree (flakes)	0.01 / -			
	1.4	Potato puree (flakes)	0.01 / -				0.1	Fried potatoes	0.01 / -			
	0.4	Maize flour	0.01 / -				0.0	Maize flour	0.01 / -			
	0.1	Fried potatoes	0.01 / -									
	*) 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											

APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLS) AND CODEX LIMITS (CXLS)

Appendix C.1 – Existing EU MRLs

Appendix C.2 – Existing CXLs

APPENDIX C.1 – EXISTING EU MRLS

(Pesticides - Web Version - EU MRLs - File created on 04/10/2013 18:38)

Code number	Groups and examples of individual products to which the MRLs apply [a]	Prothioconazole (Prothioconazole-desthio) (R)
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,02*
110000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
110030	Lemons (Citron, lemon)	0,02*
110040	Limes	0,02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,02*
110990	Others	0,02*
120000	(ii) Tree nuts (shelled or unshelled)	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	0,02*
130010	Apples (Crab apple)	0,02*
130020	Pears (Oriental pear)	0,02*
130030	Quinces	0,02*
130040	Medlar	0,02*
130050	Loquat	0,02*
130990	Others	0,02*
140000	(iv) Stone fruit	0,02*
140010	Apricots	0,02*
140020	Cherries (sweet cherries, sour	0,02*
	cherries)	
140030	Peaches (Nectarines and similar hybrids)	0,02*
140040	Plums (Damson, greengage, mirabelle)	0,02*
140990	Others	0,02*
150000	(v) Berries & small fruit	0,02*
151000	(a) Table and wine grapes	0,02*
151010	Table grapes	0,02*
151020	Wine grapes	0,02*
152000	(b) Strawberries	0,02*
153000	(c) Cane fruit	0,02*
153010	Blackberries	0,02*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,02*
153030	Raspberries (Wineberries)	0,02*
153990	Others	0,02*
154000	(d) Other small fruit & berries	0,02*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,02*
154020	Cranberries	0,02*
154030	Currants (red, black and white)	0,02*
154040	Gooseberries (Including hybrids with other ribes species)	0,02*
154050	Rose hips	0,02*
154060	Mulberries (arbutus berry)	0,02*
154070	Azarole (mediteranean medlar)	0,02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash,	0,02*
	azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	
154990	Others	0,02*
160000	(vi) Miscellaneous fruit	0,02*
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030	Passion fruit	0,02*
162040	Prickly pear (cactus fruit)	0,02*
162050	Star apple	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	0,02*
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030	Mangoes	0,02*
163040	Papaya	0,02*
163050	Pomegranate	0,02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,02*
163070	Guava	0,02*
163080	Pineapples	0,02*
163090	Bread fruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
212020	Sweet potatoes	0,02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0.1
213020	Carrots	0.1
213030	Celeriac	0,02*
213040	Horseradish	0.1
213050	Jerusalem artichokes	0,02*
213060	Parsnips	0.1
213070	Parsley root	0.1

Code number	Groups and examples of individual products to which the MRLs apply [a]	Prothioconazole (Prothioconazole-desthio) (R)
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0.1
213100	Swedes	0.1
213110	Turnips	0.1
213990	Others	0,02*
220000	(ii) Bulb vegetables	0,02*
220010	Garlic	0,02*
220020	Onions (Silverskin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	0,02*
231000	(a) Solanacea	0,02*
231010	Tomatoes (Cherry tomatoes,)	0,02*
231020	Peppers (Chilli peppers)	0,02*
231030	Aubergines (egg plants) (Pepino)	0,02*
231040	Okra, lady's fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbits - edible peel	0,02*
232010	Cucumbers	0,02*
232020	Gherkins	0,02*
232030	Courgettes (Summer squash, marrow (patisson))	0,02*
232990	Others	0,02*
233000	(c) Cucurbits-inedible peel	0,02*
233010	Melons (Kiwano)	0,02*
233020	Pumpkins (Winter squash)	0,02*
233030	Watermelons	0,02*
233990	Others	0,02*
234000	(d) Sweet corn	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0.03
241020	Cauliflower	0.03
241990	Others	0,02*
242000	(b) Head brassica	
242010	Brussels sprouts	0.1
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0.1
242990	Others	0,02*
243000	(c) Leafy brassica	0,02*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,02*
243020	Kale (Borecole (curly kale), collards)	0,02*
243990	Others	0,02*
244000	(d) Kohlrabi	0,02*
250000	(v) Leaf vegetables & fresh herbs	0,02*
251000	(a) Lettuce and other salad plants including Brassicacea	0,02*
251010	Lamb´s lettuce (Italian cornsalad)	0,02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,02*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,02*
251040	Cress	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket)	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,02*
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	0,02*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,02*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves)	0,02*
254000	(d) Water cress	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	0,02*
256010	Chervil	0,02*
256020	Chives	0,02*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,02*
256040	Parsley	0,02*
256050	Sage (Winter savory, summer savory,)	0,02*
256060	Rosemary	0,02*
256070	Thyme (marjoram, oregano)	0,02*
256080	Basil (Balm leaves, mint, peppermint)	0,02*
256090	Bay leaves (laurel)	0,02*
256100	Tarragon (Hyssop)	0,02*
256990	Others	0,02*
260000	(vi) Legume vegetables (fresh)	0,02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,02*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	0,02*
270040	Fennel	0,02*
270050	Globe artichokes	0,02*
270060	Leek	0.05
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*
270090	Palm hearts	0,02*
270990	Others	0,02*
280000	(viii) Fungi	0,02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,02*
280990	Others	0,02*
290000	(ix) Sea weeds	0,02*
300000	3. PULSES, DRY	1
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	1
300020	Lentils	1
300030	Peas (Chickpeas, field peas, chickling vetch)	1
300040	Lupins	1
300990	Others	1

Code number	Groups and examples of individual products to which the MRLs apply [a]	Prothioconazole (Prothioconazole-desthio) (R)
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0.15
401020	Peanuts	0.05
401030	Poppy seed	0.15
401040	Sesame seed	0.05
401050	Sunflower seed	0.05
401060	Rape seed (Bird rapeseed, turnip rape)	0.15
401070	Soya bean	0.05
401080	Mustard seed	0.15
401090	Cotton seed	0.05
401100	Pumpkin seeds	0.05
401110	Safflower	0.05
401120	Borage	0.05
401130	Gold of pleasure	0.05
401140	Hempseed	0.05
401150	Castor bean	0.05
401990	Others	0.05
402000	(ii) Oilfruits	0,02*
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,02*
402030	Palmfruit	0,02*
402040	Kapok	0,02*
402990	Others	0,02*
500000	5. CEREALS	
500010	Barley	0.3
500020	Buckwheat	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff)	0,02*
500050	Oats	0.05
500060	Rice	0,02*
500070	Rye	0.1
500080	Sorghum	0,02*
500090	Wheat (Spelt Triticale)	0.1
500990	Others	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,02*
620000	(ii) Coffee beans	0,02*
630000	(iii) Herbal infusions (dried)	0,02*
631000	(a) Flowers	0,02*
631010	Camomille flowers	0,02*
631020	Hybiscus flowers	0,02*
631030	Rose petals	0,02*
631040	Jasmine flowers	0,02*
631050	Lime (linden)	0,02*
631990	Others	0,02*
632000	(b) Leaves	0,02*
632010	Strawberry leaves	0,02*
632020	Rooibos leaves	0,02*
632030	Maté	0,02*
632990	Others	0,02*
633000	(c) Roots	0,02*
633010	Valerian root	0,02*
633020	Ginseng root	0,02*
633990	Others	0,02*
639000	(d) Other herbal infusions	0,02*
640000	(iv) Cocoa (fermented beans)	0,02*
650000	(v) Carob (st johns bread)	0,02*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,02*
800000	8. SPICES	0,02*
810000	(i) Seeds	0,02*
810010	Anise	0,02*
810020	Black caraway	0,02*
810030	Celery seed (Lovage seed)	0,02*
810040	Coriander seed	0,02*
810050	Cumin seed	0,02*
810060	Dill seed	0,02*
810070	Fennel seed	0,02*
810080	Fenugreek	0,02*
810090	Nutmeg	0,02*
810990	Others	0,02*
820000	(ii) Fruits and berries	0,02*
820010	Allspice	0,02*
820020	Anise pepper (Japan pepper)	0,02*
820030	Caraway	0,02*
820040	Cardamom	0,02*
820050	Juniper berries	0,02*
820060	Pepper, black and white (Long pepper, pink pepper)	0,02*
820070	Vanilla pods	0,02*
820080	Tamarind	0,02*
820990	Others	0,02*
830000	(iii) Bark	0,02*
830010	Cinnamon (Cassia)	0,02*
830990	Others	0,02*
840000	(iv) Roots or rhizome	0,02*
840010	Liquorice	0,02*
840020	Ginger	0,02*
840030	Turmeric (Curcuma)	0,02*
840040	Horseradish	0,02*
840990	Others	0,02*
850000	(v) Buds	0,02*
850010	Cloves	0,02*
850020	Capers	0,02*
850990	Others	0,02*
860000	(vi) Flower stigma	0,02*
860010	Saffron	0,02*
860990	Others	0,02*
870000	(vii) Aril	0,02*
870010	Mace	0,02*
870990	Others	0,02*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0.3
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these [a]	
1011000	(a) Swine	
1011010	Meat	0.05
1011020	Fat free of lean meat	0.05
1011030	Liver	0.5
1011040	Kidney	0.5
1011050	Edible offal	0.5
1011990	Others	0,01*
1012000	(b) Bovine	
1012010	Meat	0.05
1012020	Fat	0.05
1012030	Liver	0.5
1012040	Kidney	0.5
1012050	Edible offal	0.5
1012990	Others	0.05
1013000	(c) Sheep	
1013010	Meat	0.05
1013020	Fat	0.05
1013030	Liver	0.5
1013040	Kidney	0.5
1013050	Edible offal	0.5
1013990	Others	0,01*
1014000	(d) Goat	
1014010	Meat	0.05
1014020	Fat	0.05
1014030	Liver	0.5
1014040	Kidney	0.5
1014050	Edible offal	0.5
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	0.05
1015020	Fat	0.05
1015030	Liver	0.5
1015040	Kidney	0.5
1015050	Edible offal	0.5
1015990	Others	0,01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	0.05
1016020	Fat	0.05
1016030	Liver	0.05
1016040	Kidney	0.05
1016050	Edible offal	0,01*
1016990	Others	0,01*
1017000	(g) Other farm animals (Rabbit,	

Code number	Groups and examples of individual products to which the MRLs apply [a]	Prothioconazole (Prothioconazole-desthio) (R)
	Kangaroo)	
1017010	Meat	0.05
1017020	Fat	0.05
1017030	Liver	0.5
1017040	Kidney	0.5
1017050	Edible offal	0.5
1017990	Others	0,01*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and	0,01*
	curd [a]	
1020010	Cattle	0,01*
1020020	Sheep	0,01*
1020030	Goat	0,01*
1020040	Horse	0,01*
1020990	Others	0,01*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved	0.05
	whether or not containing added sugar or sweetening matter [a]	
1030010	Chicken	0.05
1030020	Duck	0.05
1030030	Goose	0.05
1030040	Quail	0.05
1030990	Others	0.05
1040000	(iv) Honey (Royal jelly, pollen)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles) [a]	0,01*
1060000	(vi) Snails [a]	0,01*
1070000	(vii) Other terrestrial animal products [a]	0,01*

(*) Indicates lower limit of analytical determination
(a) For these commodities, the residue definition is: "sum of prothioconazole-desthio and its glucuronide conjugates, expressed as prothioconazole-desthio"

APPENDIX C.2 – EXISTING CXLS

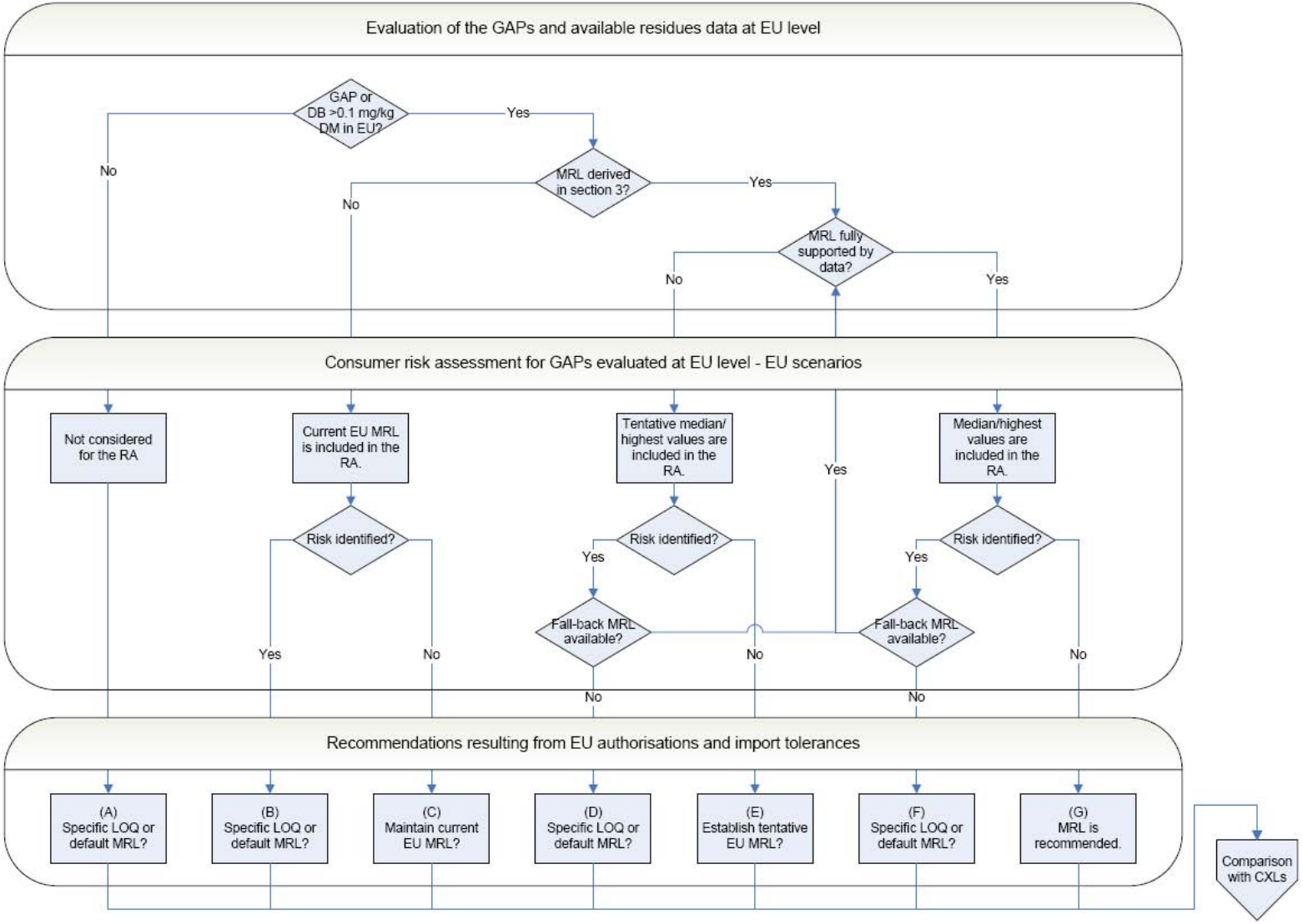
Summary of CXLs for prothioconazole in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
300010	Beans (dry)	Prothioconazole-desthio	1	Prothioconazole-desthio	0.05	n.c.	1	n.c.	0.05	0.57	n.a.	1	2009	No	All trials were conducted in the US and Canada according to GAP. Data on beans (dry) and peas (dry) were combined.
300020	Lentils (dry)	Prothioconazole-desthio	1	Prothioconazole-desthio	0.05	n.c.	1	n.c.	0.05	0.57	n.a.	1	2009	No	
300030	Peas (dry)	Prothioconazole-desthio	1	Prothioconazole-desthio	0.05	n.c.	1	n.c.	0.05	0.57	n.a.	1	2009	No	
300040	Lupins (dry)	Prothioconazole-desthio	1	Prothioconazole-desthio	0.05	n.c.	1	n.c.	0.05	0.57	n.a.	1	2009	No	
401020	Peanuts	Prothioconazole-desthio	0.02 *	Prothioconazole-desthio	0.01	n.c.	1	n.c.	0.02	0.02	n.a.	1	2008	No	All trials were conducted in the USA according to GAP.
401060	Rape seed	Prothioconazole-desthio	0.1	Prothioconazole-desthio	0.02	n.c.	1	n.c.	0.02	0.08	n.a.	1	2009	No	Trials were conducted in the US and Canada according to US GAP.
500010	Barley grain	Prothioconazole-desthio	0.2	Prothioconazole-desthio	0.035	n.c.	1	n.c.	0.04	0.09	n.a.	1	2009	No	Trials were conducted in the US and Canada according to US GAP.
500050	Oats grain	Prothioconazole-desthio	0.05	Prothioconazole-desthio	0.01	n.c.	1	n.c.	0.01	0.02	n.a.	1	2008	yes	All GAP-compliant trials were conducted in the EU. Data on barley and wheat were combined.
500070	Rye grain	Prothioconazole-desthio	0.05	Prothioconazole-desthio	0.01	n.c.	1	n.c.	0.01	0.02	n.a.	1	2008	yes	All GAP-compliant trials were conducted in the EU. Data on barley and wheat were combined.
500090	Wheat grain	Prothioconazole-desthio	0.1	Prothioconazole-desthio	0.02	n.c.	1	n.c.	0.02	0.05	n.a.	1	2009	No	Trials were conducted in the US and Canada according to US GAP.
900010	Sugar beet (root)	Prothioconazole-desthio	0.3	Prothioconazole-desthio	0.050	n.c.	1	n.c.	0.05	0.19	n.a.	1.00	2009	No	Trials were conducted in the US and Canada according to US GAP.

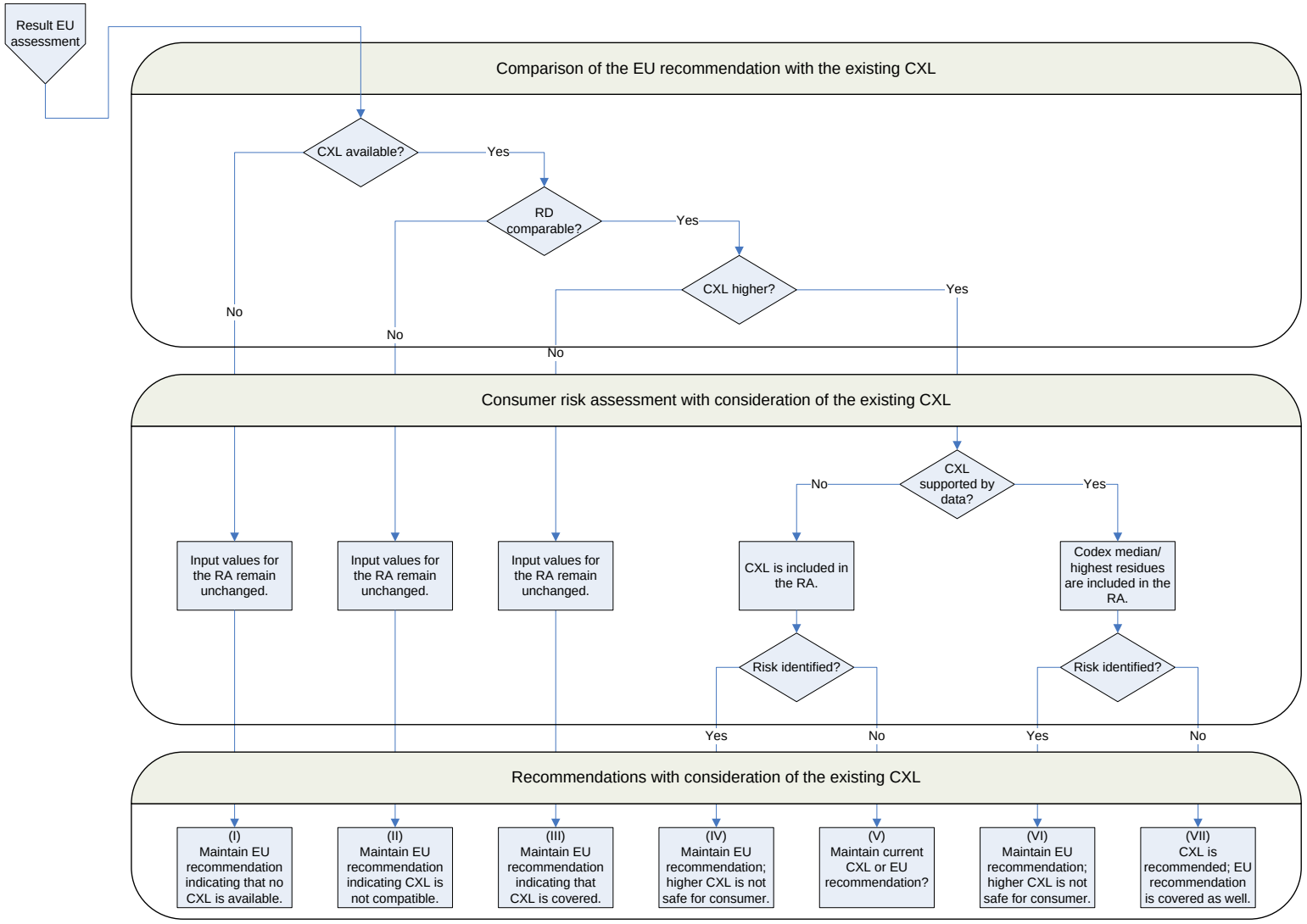
(*) Indicates the lower limit of analytical quantification.
n.a.: not applicable
n.c.: not considered
n.k.: not known

Summary of CXLs for prothioconazole in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1011010	Swine meat	Prothioconazole-desthio	no	0.01	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.01	0.01	2008-2009	no	Intakes based on Australian dietary burden for beef cattle of 4.8 and 21.6 ppm for STMR and MRL purposes respectively.
1011030	Swine liver	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.05	0.23	2008-2009	no	
1011040	Swine kidney	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.025	0.15	2008-2009	no	
1011050	Swine edible offal	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.05	0.23	2008-2009	no	
1012010	Bovine meat	Prothioconazole-desthio	no	0.01	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.01	0.01	2008-2009	no	Intakes based on Australian dietary burden for beef cattle of 4.8 and 21.6 ppm for STMR and MRL purposes respectively.
1012030	Bovine liver	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.05	0.23	2008-2009	no	
1012040	Bovine kidney	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.025	0.15	2008-2009	no	
1012050	Bovine edible offal	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.05	0.23	2008-2009	no	
1013010	Sheep meat	Prothioconazole-desthio	no	0.01	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.01	0.01	2008-2009	no	Intakes based on Australian dietary burden for beef cattle of 3.84 and 10.4 ppm for STMR and MRL purposes respectively, and 7.8 ppm for dairy cattle.
1013030	Sheep liver	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.05	0.23	2008-2009	no	
1013040	Sheep kidney	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.025	0.15	2008-2009	no	
1013050	Sheep edible offal	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.05	0.23	2008-2009	no	
1014010	Goat meat	Prothioconazole-desthio	no	0.01	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.01	0.01	2008-2009	no	Intakes based on Australian dietary burden for beef cattle of 4.8 and 21.6 ppm for STMR and MRL purposes respectively.
1014030	Goat liver	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.05	0.23	2008-2009	no	
1014040	Goat kidney	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.025	0.15	2008-2009	no	
1014050	Goat edible offal	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.05	0.23	2008-2009	no	

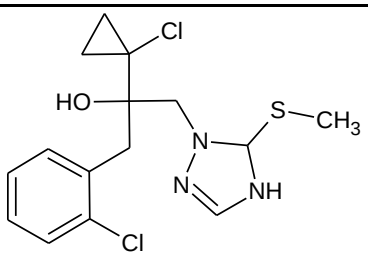
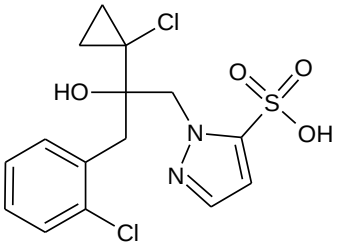
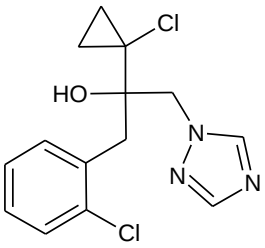
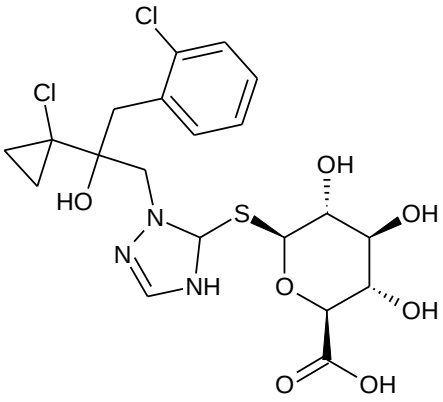
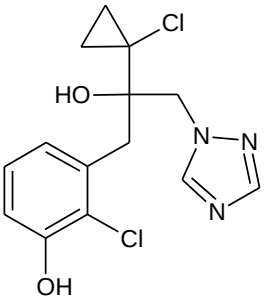
Summary of CXLs for prothioconazole in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1015010	Horses, asses, mules or hinnies meat	Prothioconazole-desthio	no	0.01	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.01	0.01	2008-2009	no	Intakes based on Australian dietary burden for beef cattle of 4.8 and 21.6 ppm for STMR and MRL purposes respectively.
1015030	Horses, asses, mules or hinnies liver	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.05	0.23	2008-2009	no	
1015040	Horses, asses, mules or hinnies kidney	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.025	0.15	2008-2009	no	
1015050	Horses, asses, mules or hinnies edible offal	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.05	0.23	2008-2009	no	
1017010	Other farm animals meat	Prothioconazole-desthio	no	0.01	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.01	0.01	2008-2009	no	Intakes based on Australian dietary burden for beef cattle of 4.8 and 21.6 ppm for STMR and MRL purposes respectively.
1017030	Other farm animals liver	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.05	0.23	2008-2009	no	
1017040	Other farm animals kidney	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.025	0.15	2008-2009	no	
1017050	Other farm animals edible offal	Prothioconazole-desthio	n.a.	0.5	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.05	0.23	2008-2009	no	
1020010	Cattle milk	Prothioconazole-desthio	no	0.004 *	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.004	n.c.	2008-2009	no	Intakes based on Australian dietary burden for beef cattle of 4.8 and 21.6 ppm for STMR and MRL purposes respectively.
1020020	Sheep milk	Prothioconazole-desthio	no	0.004 *	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.004	n.c.	2008-2009	no	
1020030	Goat milk	Prothioconazole-desthio	no	0.004 *	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.004	n.c.	2008-2009	no	
1020040	Horse milk	Prothioconazole-desthio	no	0.004 *	Sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-4-hydroxy and their conjugates expressed as prothioconazole-desthio	0.004	n.c.	2008-2009	no	

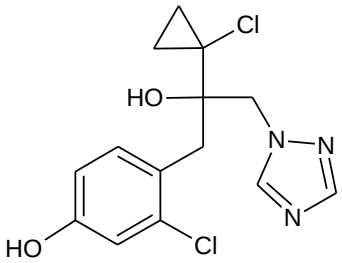
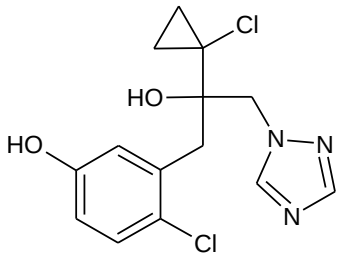
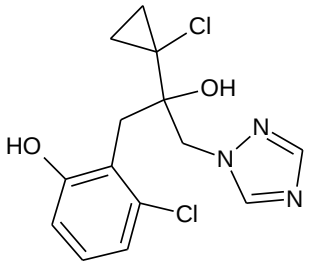
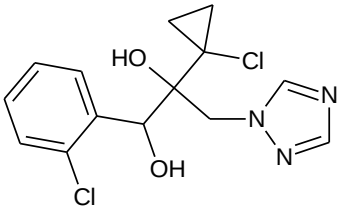
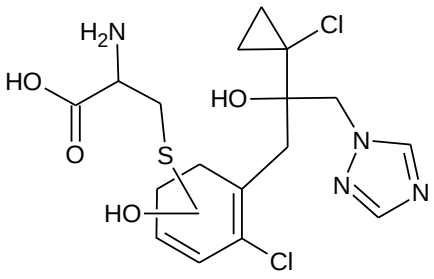
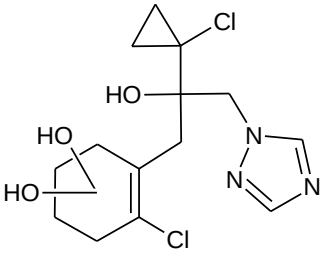
APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS

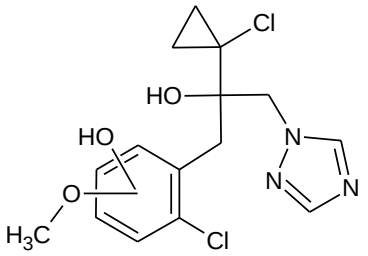
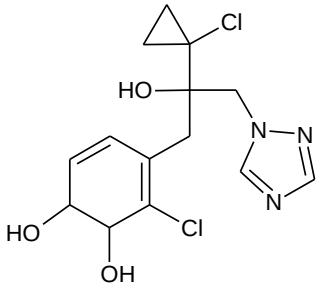
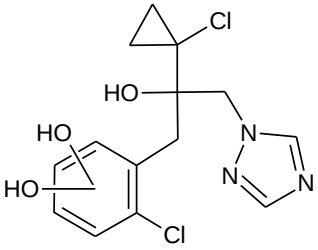
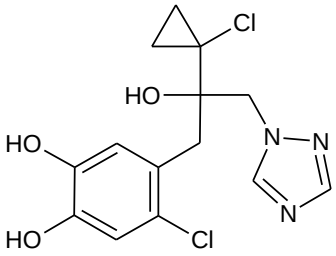
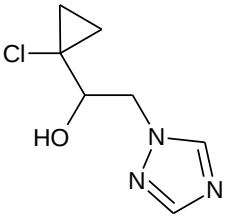
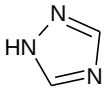
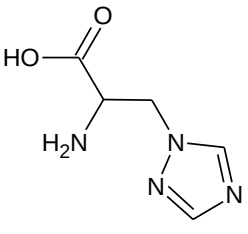


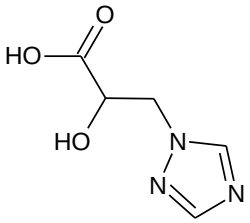
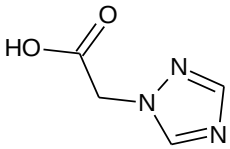

Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name*	Structural formula
M01 (prothioconazole-S-methyl)	(2*RS*)-2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-[5-(methylsulfanyl)-2,5-dihydro-1*H*-1,2,4-triazol-1-yl]propan-2-ol	
M02 (prothioconazole-sulfonic acid)	1-[(2*RS*)-2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1*H*-pyrazole-5-sulfonic acid	
M04 (prothioconazole-desthio)	(2*RS*)-2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)propan-2-ol	
M06 (prothioconazole-S-glucuronide)	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	
M14 (prothioconazole-3 hydroxy-desthio)	2-chloro-3-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]phenol	

Common name	IUPAC name*	Structural formula
M15 (prothioconazole-4 hydroxy-desthio)	3-chloro-4-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]phenol	
M16 (prothioconazole-5 hydroxy-desthio)	4-chloro-3-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]phenol	
M17 (prothioconazole-6 hydroxy-desthio)	3-chloro-2-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]phenol	
M18 (prothioconazole-α hydroxy-desthio)	(1*RS*,2*RS*)-2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)propane-1,2-diol	
M24	*S*-{3-chloro-2-[2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]-6-hydroxycyclohexa-2,4-dien-1-yl}cysteine Unstated stereochemistry	
M27	4-chloro-5-[2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]cyclohex-4-ene-1,2-diol Unstated stereochemistry	

Common name	IUPAC name*	Structural formula
M28	3-chloro-2-[2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]-6-methoxyphenol Unstated stereochemistry	
M32	3-chloro-4-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]cyclohexa-3,5-diene-1,2-diol	
M34	3-chloro-4-[2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]benzene-1,2-diol Unstated stereochemistry	
M35	4-chloro-5-[(2*RS*)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propyl]benzene-1,2-diol	
M45	(1*RS*)-1-(1-chlorocyclopropyl)-2-(1*H*-1,2,4-triazol-1-yl)ethanol	
Triazole derivative metabolites (TDMs)		
1,2,4-triazole (free triazole)	1*H*-1,2,4-triazole	
triazole alanine	3-(1*H*-1,2,4-triazol-1-yl)-DL-alanine	

Common name	IUPAC name*	Structural formula
triazole lactic acid	(2*RS*)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propanoic acid	
triazole acetic acid	1*H*-1,2,4-triazol-1-ylacetic acid	

* ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC-MS	gas chromatography with mass spectrometry
ha	hectare

HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
P_{ow}	partition coefficient n-octanol/water
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SEU	Southern European Union
TRR	total radioactive residue
WHO	World Health Organization