

Review of the existing MRLs for propiconazole

Competent Authority Draft Reasoned Opinion

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DRAFT

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Summary

This assessment is a draft only and outlines proposed recommendations for the MRLs for the active substance propiconazole.

According to Article 12 of Regulation (EC) No 396/2005,¹ HSE as a competent authority has reviewed the Maximum Residue Levels (MRLs) currently established in Great Britain (GB) for the pesticide active substance propiconazole. This review of the MRLs has been undertaken by HSE under the GB regulatory regime following the UK leaving the EU. It was required following the earlier non-approval decision for the active substance propiconazole under the EU plant protection product regulatory regime (Regulation (EC) No 1107/2009),² and the subsequent withdrawal of all plant protection authorisations in GB. This EU non-approval decision came into force while the UK was still an EU Member State, and was therefore retained in the national regulatory regime after the UK's departure from the EU.

Based on the review of the MRLs, HSE prepared a Reasoned Opinion (RO). HSE took into account the assessment report and EFSA Conclusion prepared under Regulation (EC) No 1107/2009 for the renewal of the approval of the active substance (the renewal assessment).

Propiconazole does not meet the requirements to be exempt from MRLs and therefore it is not suitable for inclusion in Part 4 (active substances not subject to MRLs) of the GB MRL Statutory Register.

Sufficiently validated analytical methods for the determination of propiconazole (sum of isomers) in plants and in animals are available to enforce MRLs at an LOQ of 0.01 mg/kg.

Toxicological reference values were established in the renewal assessment: an ADI of 0.04 mg/kg bw/day and an ARfD of 0.1 mg/kg bw were established for propiconazole.

¹ Retained [Regulation \(EC\) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin](#) (as it applies in Great Britain, pursuant to the European Union (Withdrawal) Act 2018 and European Union (Withdrawal Agreement Act 2020). Great Britain ("GB") refers to England, Scotland and Wales. All references to this regulation are the retained regulation as it applies in GB.

² EU [Regulation \(EC\) No 1107/2009 concerning the placing of plant protection products on the market](#). All references to this regulation are the EU regulation as it applied to the UK as an EU MS. All references to this regulation are the EU regulation as it applied to the UK as an EU MS.

Residues of the metabolites CGA 118244 , CGA 91305, SYN 547889 and NOA 436613 may occur in products of plant and animal origin. The risk assessment was unable to establish toxicological reference values for these metabolites.

The renewal assessment considered plant and animal metabolism data, processing studies, rotational crop data, residue trials and animal feeding studies: several data gaps within the residues assessment were identified.

In the renewal assessment robust residue definitions for risk assessment for both plants and products of animal origin could not be established and the residue definitions were only provisional.

With regards to the residue definitions for enforcement, HSE recommends retaining the current definitions within the GB MRL Statutory Register:

- Propiconazole (sum of isomers).

The data provided for the renewal assessment are not sufficient to establish robust processing factors for propiconazole. At this time Part 6 of the GB MRL Statutory Register has not been established.

It should be noted that as propiconazole is a triazole pesticide, then in any future submissions to establish MRLs the residue levels of the triazole derivative metabolites (TDMs) in primary crops, rotational crops, processed fractions and products of animal origin will need to be addressed and an appropriate dietary risk assessment presented.

As propiconazole consists of two diastereomeric pairs of enantiomers then the isomeric composition and the possible metabolic conversion of the isomers may also need to be addressed.

A number of the current MRLs in force have footnotes for the submission of supplementary information (MRL confirmatory data). These footnotes are as a result of the review of the MRLs undertaken following the approval decision delivered in 2004. HSE recommends that these footnotes are now deleted as all MRLs are proposed to be lowered to the LOQ.

Proposed Recommendations

Based on the risk assessment conducted in the renewal assessment, HSE concludes that harmful effects on human health cannot be excluded for residues of propiconazole occurring in food. This includes evidence of a potential risk to consumers from exposure to metabolites for which no toxicological reference values could be established. Consequently, the required level of protection has not been met.

The MRLs proposed by HSE are outlined in Table 8.1.

The MRLs should be established on the basis of the following residue definitions:

The residue definition for enforcement (RD-Enf) in plants:

- Propiconazole (sum of isomers)

The residue definition for enforcement (RD-Enf) in animals:

- Propiconazole (sum of isomers)

Notification of the proposed MRLs

To meet the UK's international trade obligations, the measures have been notified to the World Trade Organization (WTO). The WTO/SPS notification can be found at the following link and searching for propiconazole and United Kingdom as the notifying member:

[Home - ePing SPS&TBT platform \(epingalert.org\)](http://epingalert.org)

- **There may be a delay between publication of this draft RO and the notification appearing in the Sanitary and Phytosanitary Information Management System**
- **The notification includes the proposed date of adoption/publication and the proposed date of entry in force of the new MRLs.**

Background

Article 12 of Regulation (EC) No 396/2005 requires the Competent Authority to undertake a review of the GB Maximum Residue Levels (MRLs).

A non-approval decision,³ was delivered for propiconazole on 28 November 2018 and all plant protection product authorisations in GB have been withdrawn. HSE therefore initiated a review of the current MRLs taking into account the assessment report and EFSA Conclusion prepared under Regulation (EC) No 1107/2009 for the renewal of the approval of the active substance (the renewal assessment). As outlined in Article 12 (3) of Regulation (EC) No 396/2005 the following points have been considered within this review:

- The existing MRLs for propiconazole set out in Part 2 or 3 of the GB MRL Statutory Register
- The necessity of setting a new MRL for propiconazole, or its inclusion in Part 4 of the MRLs register
- Specific processing factors as referred to in Article 20(2) that may be needed for propiconazole
- MRLs which the competent authority may consider including in Part 2 or 3 of the MRLs register and those MRLs related to propiconazole which may be deleted

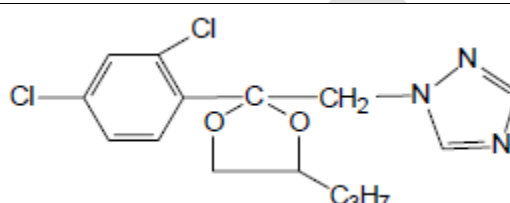
This review is the basis of HSE's draft reasoned opinion: HSE recommends that all the MRLs for propiconazole are lowered to the limit of quantification.

³ [Commission Implementing Regulation \(EU\) 2018/1865 of 28 November 2018](#) concerning the non-renewal of the approval of the active substance propiconazole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. The non-approval decision adopted when the UK was an EU MS.

The active substance and its use pattern

Information on the active substance propiconazole is outlined in Table 0.1.

Table 0.1 Information on the active substance

Common name (ISO)	Propiconazole
Chemical name (IUPAC)	(2 <i>RS</i> ,4 <i>RS</i> ;2 <i>RS</i> ,4 <i>SR</i>)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1 <i>H</i> -1,2,4-triazole
CAS number	60207—90-1
Structural formula	
Molecular formula	C ₁₅ H ₁₇ Cl ₂ N ₃ O ₂
Molecular mass	342.2 g/mol

Propiconazole is not an approved active substance in GB and all plant protection product authorisations have been withdrawn.

A Renewal Assessment Report (RAR) (Finland, 2016, revised 2017) and an EFSA Conclusion on the peer review of the renewal assessment (EFSA, 2017) are available.

MRLs are established for propiconazole in Part 2 of the GB MRL Statutory Register.

Propiconazole is a fungicide. It belongs to the chemical group of the triazoles and has partial systemicity.

The following Codex MRLs (CXLs) are available for propiconazole (Codex Pesticide Residues in food online database).

Table 0.2 CXLs for propiconazole

Commodity	CXL (mg/kg)	Comments	Year of adoption
Banana	0.1	The CXLs are not recommended for adoption as harmful effects on human health cannot be excluded for residues of propiconazole occurring in food	2008
Barley	2		2016
Barley straw and fodder, dry	8		2015

Commodity	CXL (mg/kg)	Comments	Year of adoption
Cherries	3		2019
Coffee beans	0.02		2008
Cranberry	0.3		2008
Edible offal (mammalian)	0.5		2015
Eggs	0.01*		2008
Lemons and limes (including citron) (subgroup)	10		2019
Maize	0.05		2008
Mammalian fats (except milk fats)	0.01* (fat)		2015
Mandarins (including mandarin-like hybrids) (subgroup)	10		2019
Meat (from mammals other than marine mammals)	0.01* (fat)		2015
Milks	0.01*		2015
Oat straw and fodder, dry	8		2015
Oats	0.7		2016
Orange oil, edible	1850		2019
Oranges, sweet, sour (including Orange-like hybrids) (subgroup)	10		2019
Peach	5		2014
Pecan	0.02*		2008
Pineapple	2		2019

Commodity	CXL (mg/kg)	Comments	Year of adoption
Plums (including fresh prunes)	0.4		2019
Popcorn	0.05		2008
Poultry meat	0.01* (fat)		2008
Pummelo and grapefruits (including Shaddock-like hybrids, among others Grapefruit) (subgroup)	4		2019
Rape seed	0.02		2008
Rye	0.09		2016
Rye straw and fodder, dry	15		2015
Soya bean (dry)	0.07		2008
Soya bean fodder	5		2008
Sugar beet	0.02		2008
Sugar cane	0.02*		2008
Sweet corn (corn-on-the- cob)	0.05		2008
Tomato	3		2014
Triticale	0.09		2016
Triticale straw and fodder, dry	15		2015
Wheat	0.09		2016
Wheat straw and fodder, dry	15		2015

* denotes an MRL at the limit of quantification/ limit of determination

(fat): The MRL applies to the fat of meat.

The CXL database is available at the following link:

<http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/en/>

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Assessment

1 Methods of Analysis

1.1 Methods for enforcement and monitoring of residues in food of plant origin

The current residue definition for enforcement is:

- Propiconazole (sum of isomers)

No changes to this residue definition are proposed as a result of this review.

An analytical method for the determination of propiconazole (sum of isomers) in dry, high acid, high oil and high water commodities was considered in the renewal assessment. The LC-MS/MS method was validated with an LOQ of 0.01 mg/kg. The extraction efficiency was not demonstrated. However, as the active substance is no longer approved and all MRLs are recommended to be set at the LOQ further data are not required.

Enforcement of MRLs for products of plant origin at an LOQ of 0.01 mg/kg has been demonstrated.

No specific analytical methods are available for the difficult to analyse matrices. Therefore, the default uncertainty factors outlined as footnotes for Table 8.1 will be applied

1.2 Methods for enforcement and monitoring of residues in food of animal origin

The current residue definition for enforcement is:

- Propiconazole (sum of isomers)

No changes to this residue definition are proposed as a result of this review.

An analytical method for the determination of propiconazole (sum of isomers) was considered in the first MRL review (EFSA, 2015). The LC-MS/MS method was validated with an LOQ of 0.01 mg/kg for meat, fat, liver, kidney, milk and eggs.

Enforcement of MRLs for products of animal origin at an LOQ of 0.01 mg/kg has been demonstrated.

2 Mammalian toxicology

The toxicological end points established in the renewal assessment are summarised in Tables 2.1 and 2.2.

Table 2.1 Overview of the toxicological reference values for propiconazole

TRVs	Source	Year	Value	Study relied upon	Safety factor
ADI	EFSA Conclusion	2017	0.04 mg/kg bw per day	Rat, 2 year	100
ARfD	EFSA Conclusion	2017	0.1 mg/kg bw	Rat, developmental	300

As outlined in the EFSA Conclusion, the genotoxic potential of propiconazole was discussed during the peer review process. No evidence of mutagenicity was observed in available in vitro and in vivo genotoxicity studies. However, there were some uncertainties regarding the clastogenic and aneugenic potential of propiconazole. The design of the in vitro clastogenicity assay showed some limitations and in the in vivo micronucleus test some experts including the RMS considered that there was no clear evidence that the bone marrow was reached in sufficient amount. EFSA considered that overall, available information suggests no evidence of genotoxicity of propiconazole. However, the experts considered that the submission of a new in vitro micronucleus test will decrease the uncertainties regarding the clastogenic and aneugenic endpoint and strengthen the genotoxicity data package on propiconazole. This issue will need to be reconsidered if substantive MRLs for propiconazole are established in the future.

The risk assessment was unable to demonstrate that the necessary requirements were met for the metabolites CGA 91305, CGA 118244, SYN 547889 and NOA 436613 and consequently, toxicological reference values could not be established. It was noted however that the metabolites CGA 91305, SYN 547889 and NOA 436613 are unlikely to be genotoxic.

3 Residues in Plants

The renewal assessment should be consulted for all the available data to support residues in plants.

The consideration of the inclusion in Part 4 of the GB MRL Statutory Register

Propiconazole does not meet the requirements to be exempt from MRLs:

- Active substances approved as a basic substance
- Active substances listed Part 1 of the GB MRL Statutory Register
- Active substances with no identified hazards
- The consumer exposure associated with the use of the active substance as a PPP is negligible compared to other sources/natural background exposure
- The method of application of the PPP will lead to no consumer exposure

Therefore, HSE does not recommend that propiconazole is included in Part 4 (active substances not subject to MRLs) of the GB MRL Statutory Register.

All authorisations in GB have been withdrawn on the basis of the non-approval decision for propiconazole. As outlined in section 7 of this Reasoned Opinion, the renewal assessment establishes that harmful effects for human health cannot be excluded and therefore the required level of protection has not been met.

HSE recommends that all MRLs for products of plant origin are set at the limit of quantification. Therefore, no additional residues data are presented in this Reasoned Opinion. The following is a summary only of the available information from the renewal assessment:

Residues in primary crops

The metabolism of propiconazole in fruit crops (grapes), cereals and grass crops (wheat, rice), pulses and oilseed crops (peanuts), root crops (carrots) and leafy crops (celery) following foliar application was assessed in the renewal assessment. Propiconazole was the predominant residue in fruit crops, root crops and leafy crops. In grain the triazole derivative metabolites were found at significant levels. The metabolite CGA 118244 (free and conjugated) was also a major component of the residue.

Residues in rotational crops and long term accumulation in soil

With respect to residues in rotational crops, all UK authorisations have been withdrawn and therefore no residues in crops grown in rotation in GB are expected.

Residues in rotational crops are usually not relevant for imported crops. It is noted that the metabolites found in rotational crops SYN 547889, NOA 436613, CGA 91305 and the relevant triazole metabolites (CGA 131013 (TA), CGA 142856 (TAA) and CGA 205369 (TLA) are persistent in soil and would be expected to accumulate in the soil from year on year use. Therefore a consideration of residues in rotational crops is relevant to imported crops. As outlined in the OECD guidance document No 97,⁴ in cases of accumulation of the active ingredient or metabolites, concentrations in the soil may also result in residues in permanent crops. The data available from the renewal assessment is not adequate to assess the nature and magnitude of residues in rotational crops. Additional information is required as outlined in the renewal assessment. Furthermore, the application rates must cover the plateau concentration that may arise in soil from year on year use.

Residues in processed commodities

Data evaluated in the renewal assessment demonstrated that propiconazole is stable on processing. However, additional data are required to address the nature of the residue on processing for all the metabolites that are provisionally included in the RD-RA.

The data provided for the renewal assessment are not sufficient to establish processing factors for propiconazole.

Residue definitions for enforcement

Within the renewal assessment the residue definition for enforcement (RD-Enf) was recommended as

- Propiconazole (sum of isomers)

This applies to all crop categories.

The current RD-Enf in the GB MRL Statutory Register is propiconazole (sum of isomers).

Residue definitions for risk assessment

Within the renewal assessment the residue definition for risk assessment (RD-RA) was proposed as:

⁴ [Guidance Document on Residues in Rotational Crops. Series on Pesticide No 97. Series on testing and Assessment No 279. Published May 2018.](#)

1. Propiconazole
2. CGA 118244 free and glucoside conjugate
3. CGA 142856 (TAA) and CGA 131013 (TA)

The RD-RA should be regarded as provisional as the risk assessment was unable to demonstrate that the necessary requirements for the metabolite CGA 118244 were met and toxicological reference values were not established. In addition, for the metabolites SYN 547889 and NOA 436613, found in rotational crops, the risk assessment was also unable to demonstrate the necessary requirements were met and no toxicological reference values were established. However, it is noted these two metabolites found in rotational crops are unlikely to be genotoxic.

Toxicological reference values have been established for the triazole derivative metabolites ie TA, TAA and TLA.

The full details are outlined in the EFSA Conclusion.

As a result of this review no additional conclusions are made on a suitable residue definition for risk assessment. The provisional residue definition outlined in the EFSA Conclusion remains applicable for risk assessment in the absence of additional information.

4 Residues in livestock

The renewal assessment should be consulted for all the available data to support residues in livestock.

As outlined in Section 3, the residue definitions for plants are only provisional. It is therefore not known what specific residues will occur in animal feeds. Hence it is not known what residues livestock will be exposed to and it not possible to undertake an accurate assessment of the livestock dietary burden.

Livestock metabolism data were assessed in the renewal assessment. The metabolism data conducted with propiconazole for ruminants and poultry were acceptable. The predominant compounds of the total residues in poultry and ruminant matrices were CGA 91305 (free and conjugated) and CGA 118244. The triazole derivative metabolite (CGA 71019 (1,2,4-triazole: 1,2,4-T)) also occurred at significant proportions in all matrices. Propiconazole was found at significant levels in some matrices.

The data indicate that the relevant residues in livestock are propiconazole, CGA 91305 (free and conjugated), CGA 118244 and the triazole metabolite 1,2,4-T. The risk assessment was unable to demonstrate that the necessary requirements for the metabolite CGA 118244 and CGA 91305 were met and toxicological reference values were not established. Owing to the lack of toxicological reference values and the uncertainties around the residues that livestock may be exposed to it is not possible to establish a robust residue definition for risk assessment for livestock. HSE recommends that all MRLs for products of plant origin are set at the limit of quantification.

Residue definitions for enforcement

Within the renewal assessment a residue definition for enforcement (RD-Enf) was proposed as:

- CGA 91305 (free and conjugated)

The current RD-Enf in the GB MRL Statutory Register is propiconazole (sum of isomers).

Based on the available metabolism data, CGA 91305 would be a suitable marker compound. However, no suitable methods are available to determine this compound in products of animal origin. In addition, the risk assessment was unable to establish toxicological reference values for this metabolite. HSE recommends that the current RD-Enf is retained i.e. the RD-Enf is proposed as:

- Propiconazole (sum of isomers)

In order to establish substantive MRLs, the RD-Enf will need to be reconsidered.

In liver, kidney and muscle propiconazole was found at levels between 2–14% of the TRR. The level in fat was up to 40 % of the TRR and in eggs it was found at a level of up to 27 % of the TRR. Propiconazole was not found in milk. It is noted that the partition coefficient for propiconazole is 3.72. Based on all this information the active substance should be categorised as fat soluble.

Residue definitions for risk assessment

Within the renewal assessment the residue definition for risk assessment (RD-RA) was proposed as:

1. Propiconazole and CGA 91305 and CGA 118244
2. 1,2,4-Triazole

This residue definition should only be regarded as provisional. As outlined above, toxicological reference values for the metabolites CGA 91305 and CGA 118244 have not been established. However, it was concluded that the metabolite CGA 91305 is unlikely to be genotoxic.

Toxicological reference values have been established for 1,2,4-T.

The full details are outlined in the EFSA Conclusion.

As a result of this review no additional conclusions are made on a suitable residue definition for risk assessment. The provisional residue definition, outlined in the EFSA Conclusion, remains applicable for risk assessment in the absence of additional information.

5 Residues in honey

The potential for residues arising in honey is not relevant as there are no authorisations in GB. The MRL for honey should be set at the default LOQ MRL (for honey) of 0.05* mg/kg. This is based on a RD-Enf of propiconazole (sum of isomers).

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6 MRLs for products not covered in sections 3 and 4

This section is to cover MRLs that can be extrapolated to other products included in Part 1 of the GB MRL Statutory Register but are not covered in sections 3 and 4 of this review. Examples include MRLs for edible offals (other than liver and kidney) or MRLs to cover products derived from other species such as goat or equine.

The MRLs for propiconazole for all products of plant and animal origin are recommended to be set at the limit of quantification and therefore a consideration of the extrapolation of MRLs to additional products of plant or animal origin is not required.

7 Consumer risk assessment

7.1 Dietary Exposure

The following issues were identified in the renewal assessment that are relevant to consumer exposure:

- It is not possible to establish residues definitions for risk assessment for plants and livestock. Consequently, it is not known what residues humans and livestock may be exposed to as a result of crops treated with chlorothalonil. The risk assessment is unable to demonstrate that the necessary requirements are satisfied.
- The risk assessment was unable to demonstrate that the necessary requirements had been met for a range of metabolites that consumers will be exposed to (91305, CGA 118244, SYN 547889 and NOA 436613) and toxicological reference values have not been established.
- The nature and magnitude of the residue on processing should be addressed for all components in the RD-RA.
- The residues in rotational crops should be fully addressed. As the metabolites can accumulate in soil from repeated uses of propiconazole, they may occur in imported crops, including permanent and semi-permanent crops. Therefore, the potential dietary exposure to these metabolites should be fully addressed, which may include the establishment of suitable toxicological reference values.
- It should be noted that as propiconazole is a triazole pesticide, then in any future submissions to establish MRLs the residue levels of the triazole derivative metabolites (TDM) in primary crops, rotational crops, processed fractions and products of animal origin will need to be addressed and an appropriate dietary risk assessment presented.
- As propiconazole consists of two diastereomeric pairs of enantiomers then the isomeric composition and the possible metabolic conversion of the isomers may also need to be addressed.
- The consumer risk assessment from the consumption of water was unable to demonstrate that the necessary requirements are satisfied (See point 7.2, noting this issue would be applicable to authorisations in GB only).

The full list of issues identified in the renewal assessment are available in the EFSA Conclusion. The following additional information is noted:

The outcome of the risk assessment for the renewal of propiconazole is directly relevant to all uses and hence all GB MRLs in the Statutory Register. Therefore, consumer intake calculations have not been performed.

Based on the risk assessment conducted in the renewal assessment, HSE concludes that harmful effects on human health cannot be excluded for residues of propiconazole occurring in food. This includes evidence of a potential risk for consumers from exposure to metabolites for which no toxicological reference values could be established. Consequently, the required level of protection has not been met.

7.2 Other routes of exposure

As there are no authorisations in GB then exposure as a result of metabolites being present in drinking water/ground water is not of concern.

8 The draft conclusion of the competent authority

This assessment is a draft only and outlines proposed recommendations for the MRLs for the active substance propiconazole.

According to Article 12 of Regulation (EC) No 396/2005, HSE as a competent authority has reviewed the Maximum Residue Levels (MRLs) currently established in Great Britain (GB) for the pesticide active substance propiconazole. This review of the MRLs has been undertaken by HSE under the GB regulatory regime following the UK leaving the EU. It was required following the earlier non-approval decision for the active substance propiconazole under the EU plant protection product regulatory regime (Regulation (EC) No 1107/2009), and the subsequent withdrawal of all plant protection authorisations in GB. This EU non-approval decision came into force while the UK was still an EU Member State and was therefore retained in the national regulatory regime after the UK's departure from the EU.

Based on the review of the MRLs, HSE prepared a Reasoned Opinion (RO). HSE took into account the assessment report and EFSA Conclusion prepared under Regulation (EC) No 1107/2009 for the renewal of the approval of the active substance (the renewal assessment).

Propiconazole does not meet the requirements to be exempt from MRLs and therefore it is not suitable for inclusion in Part 4 (active substances not subject to MRLs) of the GB MRL Statutory Register.

Sufficiently validated analytical methods for the determination of propiconazole (sum of isomers) in plants and in animals are available to enforce MRLs at an LOQ of 0.01 mg/kg.

Toxicological reference values were established in the renewal assessment: an ADI of 0.04 mg/kg bw/day and an ARfD of 0.1 mg/kg bw were established for propiconazole.

Residues of the metabolites CGA 118244 , CGA 91305, SYN 547889 and NOA 436613 may occur in products of plant and animal origin. The risk assessment was unable to establish toxicological reference values for these metabolites.

The renewal assessment considered plant and animal metabolism data, processing studies, rotational crop data, residue trials and animal feeding studies: several data gaps within the residues assessment were identified.

In the renewal assessment robust residue definitions for risk assessment for both products of plant and animal origin could not be established and the residue definitions were only provisional. With regards to the residue definitions for enforcement, HSE recommends retaining the current definitions within the GB MRL Statutory Register: Propiconazole (sum of isomers).

The data provided for the renewal assessment are not sufficient to establish robust processing factors for propiconazole. It is noted that at this time Part 6 of the GB MRL Statutory Register has not been established.

It should be noted that as propiconazole is a triazole pesticide, then in any future submissions to establish MRLs the residue levels of the triazole derivative metabolites (TDMs) in primary crops, rotational crops, processed fractions and products of animal origin will need to be addressed and an appropriate dietary risk assessment presented.

As propiconazole consists of two diastereomeric pairs of enantiomers then the isomeric composition and the possible metabolic conversion of the isomers may also need to be addressed.

A number of the current MRLs in force have footnotes for the submission of supplementary information (MRL confirmatory data). These footnotes are as a result of the review of the MRLs undertaken following the approval decision delivered in 2004. HSE recommends that these footnotes are now deleted as all MRLs are proposed to be lowered to the LOQ.

Proposed Recommendations

Based on the risk assessment conducted in the renewal assessment, HSE concludes that harmful effects on human health cannot be excluded for residues of propiconazole occurring in food. This includes evidence of a potential risk to consumers from exposure to metabolites for which no toxicological reference values could be established. Consequently, the required level of protection has not been met.

This conclusion applies to all the current GB MRLs in the Statutory Register. As the required level of protection has not been met, HSE proposes that all MRLs are set at the limit of quantification.

The MRLs proposed by HSE are outlined in Table 8.1.

The MRLs should be established on the basis of the following residue definitions:

The residue definition for enforcement (RD-Enf) in plants:

- Propiconazole (sum of isomers)

The residue definition for enforcement (RD-Enf) in animals:

- Propiconazole (sum of isomers)

Notification of the proposed MRLs

To meet the UK's international trade obligations, the measures have been notified to the World Trade Organization (WTO). The WTO/SPS notification can be found at the following link and searching for propiconazole and United Kingdom as the notifying member:

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- **There may be a delay between publication of this draft RO and the notification appearing in the Sanitary and Phytosanitary Information Management System**
- **The notification includes the proposed date of adoption/publication and the proposed date of entry in force of the new MRLs.**

Table 8.1 MRLs proposed by HSE

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
Enforcement residue definition for products of plant origin: Propiconazole (sum of isomers)			
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	-	-
0110000	Citrus fruits	-	-
0110010	Grapefruits	5	0.01*
0110020	Oranges	9	0.01*
0110030	Lemons	5	0.01*
0110040	Limes	5	0.01*
0110050	Mandarins	5	0.01*
0110990	Others - Citrus Fruit	0.01*	0.01*
0120000	Tree Nuts	-	-
0120010	Almonds	0.01*	0.01*
0120020	Brazil nuts	0.01*	0.01*
0120030	Cashew nuts	0.01*	0.01*
0120040	Chestnuts	0.01*	0.01*
0120050	Coconuts	0.01*	0.01*
0120060	Hazelnuts/cobnuts	0.01*	0.01*
0120070	Macadamias	0.01*	0.01*
0120080	Pecans	0.02*	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0120090	Pine nut kernels	0.01*	0.01*
0120100	Pistachios	0.01*	0.01*
0120110	Walnuts	0.01*	0.01*
0120990	Others - Tree nuts	0.01*	0.01*
0130000	Pome fruits	-	-
0130010	Apples	0.15	0.01*
0130020	Pears	0.01*	0.01*
0130030	Quinces	0.01*	0.01*
0130040	Medlars	0.01*	0.01*
0130050	Loquats/Japanese medlars	0.01*	0.01*
0130990	Others - Pome fruit	0.01*	0.01*
0140000	Stone fruits	-	-
0140010	Apricots	0.15	0.01*
0140020	Cherries (sweet)	0.01*	0.01*
0140030	Peaches	5	0.01*
0140040	Plums	0.01*	0.01*
0140990	Others - Stone fruit	0.01*	0.01*
0150000	Berries and small fruits	-	-
0151000	Grapes	-	-

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0151010	Table grapes	0.3	0.01*
0151020	Wine grapes	0.3	0.01*
0152000	Strawberries	-	-
0152000	Strawberries	0.01*	0.01*
0153000	Cane fruits	-	-
0153010	Blackberries	0.01*	0.01*
0153020	Dewberries	0.01*	0.01*
0153030	Raspberries (red and yellow)	0.01*	0.01*
0153990	Others - Cane fruit	0.01*	0.01*
0154000	Other small fruits and berries	-	-
0154010	Blueberries	0.01*	0.01*
0154020	Cranberries	0.3	0.01*
0154030	Currants (black, red and white)	0.01*	0.01*
0154040	Gooseberries (green, red and yellow)	0.01*	0.01*
0154050	Rose hips	0.01*	0.01*
0154060	Mulberries (black and white)	0.01*	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0154070	Azaroles/Mediterranean medlars	0.01*	0.01*
0154080	Elderberries	0.01*	0.01*
0154990	Others - Other small fruit and berries	0.01*	0.01*
0160000	Miscellaneous fruits with	-	-
0161000	Edible peel	-	-
0161010	Dates	0.01*	0.01*
0161020	Figs	0.01*	0.01*
0161030	Table olives	0.01*	0.01*
0161040	Kumquats	0.01*	0.01*
0161050	Carambolas	0.01*	0.01*
0161060	Kaki/Japanese persimmons	0.01*	0.01*
0161070	Jambuls/jambolans	0.01*	0.01*
0161990	Others - Edible peel	0.01*	0.01*
0162000	Inedible peel, small	-	
0162010	Kiwi fruits (green, red, yellow)	0.01*	0.01*
0162020	Litchis/lychees	0.01*	0.01*
0162030	Passionfruits/maracujas	0.01*	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0162040	Prickly pears/cactus fruits	0.01*	0.01*
0162050	Star apples/cainitos	0.01*	0.01*
0162060	American persimmons/Virginia kaki	0.01*	0.01*
0162990	Others - Inedible peel, small	0.01*	0.01*
0163000	Inedible peel, large	-	-
0163010	Avocados	0.01*	0.01*
0163020	Bananas	0.15	0.01*
0163030	Mangoes	0.01*	0.01*
0163040	Papayas	0.01*	0.01*
0163050	Granate apples/pomegranates	0.01*	0.01*
0163060	Cherimoyas	0.01*	0.01*
0163070	Guavas	0.01*	0.01*
0163080	Pineapples	0.02*	0.01*
0163090	Breadfruits	0.01*	0.01*
0163100	Durians	0.01*	0.01*
0163110	Soursops/guanabanas	0.01*	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0163990	Others - Inedible peel, large	0.01*	0.01*
0200000	VEGETABLES, FRESH or FROZEN	-	-
0210000	Root and tuber vegetables	-	-
0211000	Potatoes	-	-
0211000	Potatoes	0.01*	0.01*
0212000	Tropical root and tuber vegetables	-	-
0212010	Cassava roots/manioc	0.01*	0.01*
0212020	Sweet potatoes	0.01*	0.01*
0212030	Yams	0.01*	0.01*
0212040	Arrowroots	0.01*	0.01*
0212990	Others - Tropical root and tuber vegetables	0.01*	0.01*
0213000	Other root and tuber vegetables except sugar beets	-	-
0213010	Beetroots	0.01*	0.01*
0213020	Carrots	0.01*	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0213030	Celeriacs/turnip rooted celeries	0.01*	0.01*
0213040	Horseradishes	0.01*	0.01*
0213050	Jerusalem artichokes	0.01*	0.01*
0213060	Parsnips	0.01*	0.01*
0213070	Parsley roots/Hamburg roots parsley	0.01*	0.01*
0213080	Radishes	0.01*	0.01*
0213090	Salsifies	0.01*	0.01*
0213100	Swedes/rutabagas	0.01*	0.01*
0213110	Turnips	0.01*	0.01*
0213990	Others - Other root and tuber vegetables except sugar beet	0.01*	0.01*
0220000	Bulb vegetables	-	-
0220010	Garlic	0.01*	0.01*
0220020	Onions	0.01*	0.01*
0220030	Shallots	0.01*	0.01*
0220040	Spring onions/green onions and Welsh onions	0.01*	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0220990	Others - bulb vegetables	0.01*	0.01*
0230000	Fruiting vegetables	-	-
0231000	Solanaceae and Malvaceae	-	-
0231010	Tomatoes	3	0.01*
0231020	Sweet peppers/bell peppers	0.01*	0.01*
0231030	Aubergines/eggplants	0.01*	0.01*
0231040	Okra/lady's fingers	0.01*	0.01*
0231990	Others - Solanacea	0.01*	0.01*
0232000	Cucurbits with edible peel	-	-
0232010	Cucumbers	0.01*	0.01*
0232020	Gherkins	0.01*	0.01*
0232030	Courgettes	0.01*	0.01*
0232990	Others - Cucurbits-edible peel	0.01*	0.01*
0233000	Cucurbits with inedible peel	-	-
0233010	Melons	0.01*	0.01*
0233020	Pumpkins	0.01*	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0233030	Watermelons	0.01*	0.01*
0233990	Others - Cucurbits - inedible peel	0.01*	0.01*
0234000	Sweet corn	-	-
0234000	Sweet corn	0.05	0.01*
0239000	Other fruiting vegetables		
0239000	Other fruiting vegetables	0.01*	0.01*
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	-	-
0241000	Flowering brassica	-	-
0241010	Broccoli	0.01*	0.01*
0241020	Cauliflowers	0.01*	0.01*
0241990	Others - Flowering Brassicas	0.01*	0.01*
0242000	Head brassica	-	-
0242010	Brussels sprouts	0.01*	0.01*
0242020	Head cabbages	0.01*	0.01*
0242990	Others - Head Brassicas	0.01*	0.01*
0243000	Leafy brassica		

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0243010	Chinese cabbages/pe-tsai	0.01*	0.01*
0243020	Kales	0.01*	0.01*
0243990	Others - Leafy Brassicas	0.01*	0.01*
0244000	Kohlrabies	-	-
0244000	Kohlrabies	0.01*	0.01*
0250000	Leaf vegetables, herbs and edible flowers	-	-
0251000	Lettuces and salad plants	-	-
0251010	Lamb's lettuces/corn salads	0.01*	0.01*
0251020	Lettuces	0.01*	0.01*
0251030	Escaroles/broad-leaved endives	0.01*	0.01*
0251040	Cresses and other sprouts and shoots	0.01*	0.01*
0251050	Land cresses	0.01*	0.01*
0251060	Roman rocket/rucola	0.01*	0.01*
0251070	Red mustards	0.01*	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0251080	Baby leaf crops (including brassica species)	0.01*	0.01*
0251990	Others - Lettuce and other salad plants including brassica	0.01*	0.01*
0252000	Spinaches and similar leaves	-	-
0252010	Spinaches	0.01*	0.01*
0252020	Purslanes	0.01*	0.01*
0252030	Chards/beet leaves	0.01*	0.01*
0252990	Others - Spinach and similar (leaves)	0.01*	0.01*
0253000	Grape leaves and similar species	-	-
0253000	Grape leaves and similar species	0.01*	0.01*
0254000	Watercresses	-	-
0254000	Watercresses	0.01*	0.01*
0255000	Witloofs/Belgian endives	-	-
0255000	Witloofs/Belgian endives	0.01*	0.01*
0256000	Herbs and edible flowers	-	-

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0256010	Chervil	0.02*	0.02*
0256020	Chives	0.02*	0.02*
0256030	Celery leaves	0.02*	0.02*
0256040	Parsley	0.02*	0.02*
0256050	Sage	0.02*	0.02*
0256060	Rosemary	0.02*	0.02*
0256070	Thyme	0.02*	0.02*
0256080	Basil and edible flowers	0.02*	0.02*
0256090	Laurel/bay leaves	0.02*	0.02*
0256100	Tarragon	0.02*	0.02*
0256990	Others - Herbs	0.02*	0.02*
0260000	Legume vegetables	-	-
0260010	Beans (with pods)	0.01*	0.01*
0260020	Beans (without pods)	0.01*	0.01*
0260030	Peas (with pods)	0.01*	0.01*
0260040	Peas (without pods)	0.01*	0.01*
0260050	Lentils	0.01*	0.01*
0260990	Others - Legume vegetables (fresh)	0.01*	0.01*
0270000	Stem vegetables	-	-

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0270010	Asparagus	0.01*	0.01*
0270020	Cardoons	0.01*	0.01*
0270030	Celeries	0.01*	0.01*
0270040	Florence fennels	0.01*	0.01*
0270050	Globe artichokes	0.01*	0.01*
0270060	Leeks	0.01*	0.01*
0270070	Rhubarbs	0.01*	0.01*
0270080	Bamboo shoots	0.01*	0.01*
0270090	Palm hearts	0.01*	0.01*
0270990	Others - Stem vegetables (fresh)	0.01*	0.01*
0280000	Fungi, mosses and lichens	-	-
0280010	Cultivated fungi	0.01*	0.01*
0280020	Wild fungi	0.01*	0.01*
0280990	Mosses and lichens	0.01*	0.01*
0290000	Algae and prokaryotes organisms	-	-
0290000	Algae and prokaryotes organisms	0.01*	0.01*
0300000	PULSES, DRY	-	-

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0300010	Beans	0.01*	0.01*
0300020	Lentils	0.01*	0.01*
0300030	Peas	0.01*	0.01*
0300040	Lupins/lupini beans	0.01*	0.01*
0300990	Others - pulses	0.01*	0.01*
0400000	OILSEEDS AND OIL FRUITS	-	-
0401000	Oilseeds	-	-
0401010	Linseeds	0.01*	0.01*
0401020	Peanuts/groundnuts	0.01*	0.01*
0401030	Poppy seeds	0.01*	0.01*
0401040	Sesame seeds	0.01*	0.01*
0401050	Sunflower seeds	0.01*	0.01*
0401060	Rapeseeds/canola seeds	0.05	0.01*
0401070	Soyabeans	0.07	0.01*
0401080	Mustard seeds	0.01*	0.01*
0401090	Cotton seeds	0.01*	0.01*
0401100	Pumpkin seeds	0.01*	0.01*
0401110	Safflower seeds	0.01*	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0401120	Borage seeds	0.01*	0.01*
0401130	Gold of pleasure seeds	0.01*	0.01*
0401140	Hemp seeds	0.01*	0.01*
0401150	Castor beans	0.01*	0.01*
0401990	Others - Oilseeds	0.01*	0.01*
0402000	Oil fruits	-	-
0402010	Olives for oil production	0.01*	0.01*
0402020	Oil palms kernels	0.01*	0.01*
0402030	Oil palms fruits	0.01*	0.01*
0402040	Kapok	0.01*	0.01*
0402990	Others - Oilfruits	0.01*	0.01*
0500000	CEREALS	-	-
0500010	Barley	2	0.01*
0500020	Buckwheat and other pseudocereals	0.01*	0.01*
0500030	Maize/corn	0.05	0.01*
0500040	Common millet/proso millet	0.01*	0.01*
0500050	Oat	0.7	0.01*
0500060	Rice	1.5	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0500070	Rye	0.09	0.01*
0500080	Sorghum	0.01*	0.01*
0500090	Wheat	0.09	0.01*
0500990	Others - cereals	0.01*	0.01*
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	-	-
0610000	Teas	-	-
0610000	Teas	0.05*	0.05*
0620000	Coffee beans	-	-
0620000	Coffee beans	0.02	0.05*
0630000	Herbal infusions from Dried product	-	-
0631000	Flowers	-	-
0631010	Chamomile	0.05*	0.05*
0631020	Hibiscus/roselle	0.05*	0.05*
0631030	Rose	0.05*	0.05*
0631040	Jasmine	0.05*	0.05*
0631050	Lime/linden	0.05*	0.05*
0631990	Others - Flowers	0.05*	0.05*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0632000	Leaves and herbs	-	-
0632010	Strawberry	0.05*	0.05*
0632020	Rooibos	0.05*	0.05*
0632030	Mate	0.05*	0.05*
0632990	Others - Herbal infusions (leaves and herbs)	0.05*	0.05*
0633000	Roots		
0633010	Valerian	0.05*	0.05*
0633020	Ginseng	0.05*	0.05*
0633990	Others - Roots	0.05*	0.05*
0639000	Other herbal Infusions - Parts of the plant other than flowers, leaves and herbs, and roots	-	-
0639000	Any other parts of the plant	0.05*	0.05*
0640000	Cocoa beans	-	-
0640000	Cocoa beans	0.05*	0.05*
0650000	Carobs/Saint John's breads	-	-

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0650000	Carobs/Saint John's breads	0.05*	0.05*
0700000	HOPS	-	-
0700000	Hops	0.05*	0.05*
0800000	SPICES	-	-
0810000	Seed spices	-	-
0810010	Anise/aniseed	0.05*	0.05*
0810020	Black caraway/black cumin	0.05*	0.05*
0810030	Celery seed	0.05*	0.05*
0810040	Coriander seed	0.05*	0.05*
0810050	Cumin seed	0.05*	0.05*
0810060	Dill seed	0.05*	0.05*
0810070	Fennel seed	0.05*	0.05*
0810080	Fenugreek	0.05*	0.05*
0810090	Nutmeg	0.05*	0.05*
0810990	Others - Seeds	0.05*	0.05*
0820000	Fruit spices	-	-
0820010	Allspice/pimento	0.05*	0.05*
0820020	Sichuan pepper	0.05*	0.05*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0820030	Caraway	0.05*	0.05*
0820040	Cardamom	0.05*	0.05*
0820050	Juniper berry	0.05*	0.05*
0820060	Peppercorn (black, green and white)	0.05*	0.05*
0820070	Vanilla	0.05*	0.05*
0820080	Tamarind	0.05*	0.05*
0820990	Others - Fruit spices	0.05*	0.05*
0830000	Bark spices	-	-
0830010	Cinnamon	0.05*	0.05*
0830990	Others - Bark	0.05*	0.05*
0840000	Root and rhizome spices	-	-
0840010	Liquorice	0.05*	0.05*
0840020	Ginger	0.05*	0.05*
0840030	Turmeric/curcuma	0.05*	0.05*
0840040	Horseradish	0.01*	0.01*
0840990	Others - Roots or rhizome	0.05*	0.05*
0850000	Bud spices	-	-
0850010	Cloves	0.05*	0.05*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
0850020	Capers	0.05*	0.05*
0850990	Others - Buds	0.05*	0.05*
0860000	Flower pistil spices	-	-
0860010	Saffron	0.05*	0.05*
0860990	Others - Flower pistil spices	0.05*	0.05*
0870000	Aril spices	-	-
0870010	Mace	0.05*	0.05*
0870990	Others - Aril spices	0.05*	0.05*
0900000	SUGAR PLANTS	-	-
0900010	Sugar beet roots	0.15	0.01*
0900020	Sugar canes	0.02*	0.01*
0900030	Chicory roots	0.01*	0.01*
0900990	Others - Sugar plants	0.01*	0.01*
Enforcement residue definition for products of animal origin: Propiconazole (sum of isomers)			
1000000	PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS	-	-
1010000	Commodities from	-	-

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
1011000	Swine	-	-
1011010	Muscle - swine	0.05	0.01*
1011020	Fat - swine	0.05	0.01*
1011030	Liver - swine	0.5	0.01*
1011040	Kidney - swine	0.5	0.01*
1011050	Edible offals (other than liver and kidney) - swine	0.5	0.01*
1011990	Others - swine	0.01*	0.01*
1012000	Bovine	-	-
1012010	Muscle - bovine	0.05	0.01*
1012020	Fat - bovine	0.07	0.01*
1012030	Liver - bovine	0.5	0.01*
1012040	Kidney - bovine	0.5	0.01*
1012050	Edible offals (other than liver and kidney) - bovine	0.5	0.01*
1012990	Others - bovine	0.01*	0.01*
1013000	Sheep	-	-
1013010	Muscle - sheep	0.05	0.01*
1013020	Fat - sheep	0.07	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
1013030	Liver - sheep	0.5	0.01*
1013040	Kidney - sheep	0.5	0.01*
1013050	Edible offals (other than liver and kidney) - sheep	0.5	0.01*
1013990	Others - sheep	0.01*	0.01*
1014000	Goat	-	-
1014010	Muscle - goat	0.05	0.01*
1014020	Fat - goat	0.07	0.01*
1014030	Liver - goat	0.5	0.01*
1014040	Kidney - goat	0.5	0.01*
1014050	Edible offals (other than liver and kidney) - goat	0.5	0.01*
1014990	Others - goat	0.01*	0.01*
1015000	Equine	-	-
1015010	Muscle - equine	0.05	0.01*
1015020	Fat - equine	0.07	0.01*
1015030	Liver - equine	0.5	0.01*
1015040	Kidney - equine	0.5	0.01*
1015050	Edible offals (other than liver and kidney) - equine	0.5	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
1015990	Others - equine	0.01*	0.01*
1016000	Poultry	-	-
1016010	Muscle - poultry	0.01*	0.01*
1016020	Fat - poultry	0.01*	0.01*
1016030	Liver - poultry	0.01*	0.01*
1016040	Kidney - poultry	0.01*	0.01*
1016050	Edible offals (other than liver and kidney) - poultry	0.01*	0.01*
1016990	Others - poultry	0.01*	0.01*
1017000	Other farmed terrestrial animals	-	-
1017010	Muscle - other farmed terrestrial animals	0.05	0.01*
1017020	Fat - other farmed terrestrial animals	0.07*	0.01*
1017030	Liver - other farmed terrestrial animals	0.5	0.01*
1017040	Kidney - other farmed terrestrial animals	0.5	0.01*
1017050	Edible offals (other than liver and kidney) - other	0.5	0.01*

The review of the existing MRLs for propiconazole – proposed MRLs

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
	farmed terrestrial animals		
1017990	Others - Other farm animals	0.01*	0.01*
1020000	Milk	-	-
1020010	Cattle - milk	0.01*	0.01*
1020020	Sheep - milk	0.01*	0.01*
1020030	Goat - milk	0.01*	0.01*
1020040	Horse - milk	0.01*	0.01*
1020990	Others - Milk and cream	0.01*	0.01*
1030000	Birds eggs	-	-
1030010	Chicken - eggs	0.01*	0.01*
1030020	Duck - eggs	0.01*	0.01*
1030030	Geese - eggs	0.01*	0.01*
1030040	Quail - eggs	0.01*	0.01*
1030990	Others - Birds' eggs	0.01*	0.01*
1040000	Honey and other apiculture products	-	-
1040000	Honey and other apiculture products	0.05*	0.05*
1050000	Amphibians and reptiles	-	-

Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)
1050000	Amphibians and reptiles	0.01*	0.01*
1060000	Terrestrial invertebrate animals	-	-
1060000	Terrestrial invertebrate animals	0.01*	0.01*
1070000	Wild terrestrial vertebrate animals	-	-
1070000	Wild terrestrial vertebrate animals	0.01*	0.01*

* denotes an MRL at the limit of quantification/ limit of determination

MRL changes are highlighted in **bold**

Notes

- Herbs and edible flowers (code 0256000) are regarded as difficult to analyse matrices and therefore the default LOQ MRL for these products should be set at 2 x 0.01* mg/kg
- Teas, coffee, herbal infusions, cocoa and carobs (code 0600000), hops (code 0700000) and spices (code 0800000) are regarded as difficult to analyse matrices and therefore the default LOQ MRL for these products should be set at 5 x 0.01* mg/kg
- The default LOQ MRL for honey is 0.05* mg/kg

References

EFSA (European Food Safety Authority), 2017. Peer review of the pesticide risk assessment of the active substance propiconazole, EFSA Journal 2017;15 (7): 4887

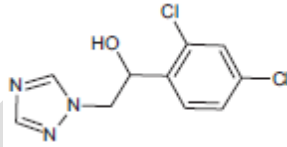
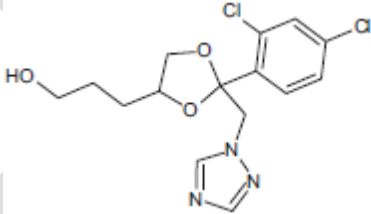
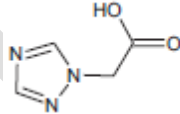
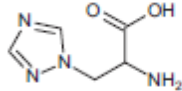

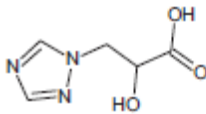
EFSA (European Food Safety Authority), 2015. Reasoned opinion on the review of the existing maximum residue levels for propiconazole according to Article 12 of Regulation (EC) No 396/2005, EFSA Journal 2015;13 (7): 3975

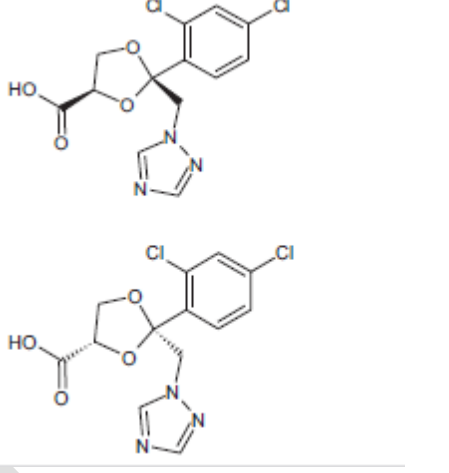
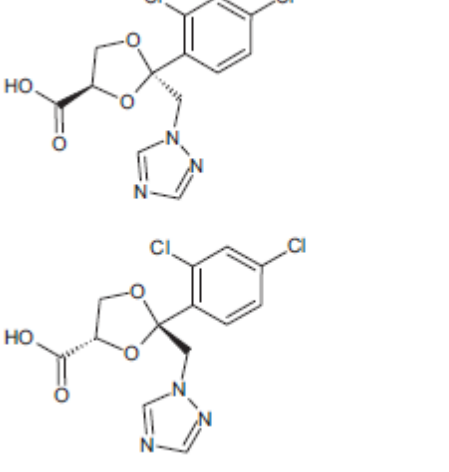
Finland, 2017. Renewal Assessment Report (RAR) on the active substance propiconazole, prepared by the rapporteur Member State Finland in the framework of Regulation (EC) No 1107/2009, April 2017

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Appendix A – Compound codes

Table A.1 List of metabolites identified

Code/Trivial name	Chemical name	Structural formula
CGA 91305	(1 <i>RS</i>)-1-(2,4-dichlorophenyl)-2-(1 <i>H</i> -1,2,4-triazol-1-yl) ethanol	
CGA 118244	3-[(2 <i>RS</i> ,4 <i>RS</i>)-2-(2,4-dichlorophenyl)-2-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]propan-1-ol	
CGA 142856 TAA	1 <i>H</i> -1,2,4-triazol-1-ylacetic acid	
CGA 131013 TA Triazole alanine	3-(1 <i>H</i> -1,2,4-triazol-1-yl)-D,L-alanine	
CGA 71019 1,3,4-T 1,2,4-Triazole	1 <i>H</i> -1,2,4-triazole	
CGA 205369 TLA Triazole lactic acid	(2 <i>RS</i>)-2-hydroxy-3-(1 <i>H</i> -1,2,4-triazol-1-yl)propanoic acid	

<p>SYN 547889</p>	<p>(2R,4R)-2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolane-4-carboxylic acid</p>	
<p>NOA 436613</p>	<p>(2S,4R)-2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolane-4-carboxylic acid</p>	

Appendix B – Abbreviations

Acute_consumer_ver1.2 UK consumer model for acute dietary intake assessments

ADI acceptable daily intake

ADME absorption, distribution, metabolism and excretion

ALARA Principle as low as reasonably achievable

Animal model 2017 EFSA model used to calculate the dietary burden of livestock using the OECD feeding studies

ARfD acute reference dose

a.s. active substance

BBCH growth stages of mono- and dicotyledonous plants

bw body weight

CA Competent authority

Chronic_consumer_ver1.1 UK consumer model for chronic dietary intake assessments

CRD Chemicals Regulation Division of the HSE

CXL Codex maximum residue level

DA Devolved Administrations

DAR draft assessment report

DAT days after treatment

Defra Department of Environment, Food and Rural Affairs

DT90 period required for 90% dissipation (define method of estimation)

DT 50 period required for 50 % dissipation (define method of estimation)

FAO Food and Agriculture Organization of the United Nations

GAP Good Agricultural Practice

HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry

HPLC-UVD high-performance liquid chromatography with ultraviolet detector

HR highest residue

HSE Health and Safety Executive

IEDI international estimated daily intake

IESTI international estimated short-term intake

ISO International Organisation for Standardisation

IUPAC International Union of Pure and Applied Chemistry

JMPR Joint FAO/WHO Meeting on Pesticide Residues

LOD limit of detection or limit of determination (should be defined)

LOQ limit of quantification

NB the limit of quantification and limit of determination are the same.

Regulation (EC) No 396/2005 refers to the limit of determination

Regulation (EC) No 1107/2009 refers to the limit of quantification

MRLs marked with an asterisk (e.g. 0.01* mg/kg) are MRLs set at the limit of quantification/determination

MRL maximum residue level

NEDI national estimated daily intake

NESTI national estimated short-term intake

NRL National reference laboratory

OECD Organisation for Economic Co-operation and Development

PBI plant-back interval

PHI preharvest interval

POAO products of animal origin

PRIMo (EFSA) Pesticide Residues Intake Model

QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)

RA risk assessment

RAR Renewal Assessment Report

RD residue definition

RD-Enf residue definition for enforcement (also referred to as RD-Mo i.e. residue definition for monitoring)

RD-RA residue definition for risk assessment

RTI re-treatment interval

SC suspension concentrate

STMR supervised trials median residue

TRR total radioactive residue

WG water-dispersible granule

WHO World Health Organization

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