REASONED OPINION

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Modification of the existing maximum residue level for penconazole in grapes

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State, Italy, received an application from Syngenta to modify the existing maximum residue level (MRL) for the active substance penconazole in grapes. The data submitted in support of the request are sufficient to derive a MRL proposal of 0.4 mg/kg for the intended use on grapes. Adequate analytical enforcement methods are available to control the residues of penconazole in grapes. Based on the risk assessment results, EFSA concludes that the intended use of penconazole on grapes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk. However, these results should be considered provisional due to the fact that the risk assessment for triazole derivate metabolites is still pending.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), Italy, received an application from Syngenta to modify the existing maximum residue levels (MRLs) for the active substance penconazole in grapes. To accommodate for the intended use of penconazole, Italy proposed to raise the existing MRL from the value of 0.2 mg/kg to the proposed MRL of 0.4 mg/kg. Italy drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 3 October 2016.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) (and its addendum) prepared under Council Directive 91/414/EEC, the Commission review report on penconazole, the conclusion on the peer review of the pesticide risk assessment of the active substance penconazole as well as the previous EFSA reasoned opinion on penconazole in raspberries and blackberries.

The toxicological profile of penconazole was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.03 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.5 mg/kg bw.

The metabolism of penconazole in primary crops was investigated in the fruit crop group (apples and tomatoes) following foliar applications. From these studies, the peer review established the residue definition for enforcement as penconazole and as sum of penconazole and its metabolites (CGA 132465, CGA 190503, CGA 127841) and the conjugates of the metabolites, expressed as penconazole for risk assessment purposes. For the uses on grapes, EFSA concludes that the metabolism of penconazole in primary crops has been addressed for the uses on grapes and the residue definitions derived are applicable. From the metabolism studies, a risk assessment conversion factor (CF) of 6 has been derived to consider the metabolites of penconazole relevant according to the reside definition for risk assessment.

Adequate analytical enforcement methods are available to monitor the residues of penconazole in grapes at the validated limit of quantification (LOQ) of 0.01 mg/kg. EFSA concludes that the submitted residue trials are sufficient to derive a MRL proposal of 0.4 mg/kg on wine grapes, which can be extrapolated to table grapes.

Studies investigating the nature of penconazole residues under standard hydrolysis conditions were assessed during peer review and showed the active substance to be hydrolytically stable under standard processing conditions. Therefore, for processed commodities, the same residue definitions as for raw agricultural commodities (RAC) are applicable. Several processing studies were evaluated previously and the various processing factors (PFs) were recommended to be included in Annex VI of Regulation (EC) No 396/2005 for grape-related processed commodities.

Specific studies investigating the magnitude of penconazole residues in processed commodities are not required since significant residues are not expected to occur in processed commodities since the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI.

Moreover, the investigations of residues of penconazole in rotational crops and the potential carry-over of possible residues into food of animal origin are not required since the proposed uses in grapes are on permanent crops and grapes and their by-products are not used as feed items.

A long-term consumer intake concern was not identified for any of the European diets incorporated in the revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The highest chronic intake was calculated to be 67% of the ADI (German, children). An acute consumer risk was not identified in relation to the MRL proposal for table and wine grapes. The highest acute consumer exposure was calculated to be around 20% of the ARfD in table grapes and around 7% of the ARfD in wine grapes.

EFSA concludes that the proposed use of penconazole on grapes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a health risk to consumers.

EFSA emphasises that the above assessment does not yet take into consideration triazole derivative metabolites (TDMs). As these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, as penconazole, 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 TDMs is available.

The current consumer risk assessment should be considered in tentative basis.

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Penconazole[(F)]				
0151000	Table and wine grapes	0.2	0.4	NEU residue trials are sufficient to support the intended use in wine grapes. The extrapolation from wine grapes to table grapes is acceptable. No risk for consumers has been identified. However, EFSA suggests considering the risk assessment in tentative basis in view of the possible occurrence of triazole derivate metabolites (TDMs) as result of the use of penconazole

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

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the MRL regulation') establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC[2], repealed by Regulation (EC) No 1107/2009[3], shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of the MRL regulation.

Italy, hereafter referred to as the evaluating Member State (EMS), received an application from the company Syngenta[4] to modify the existing MRLs for the active substance penconazole in grapes. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission and to EFSA on 3 October 2016.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00629 and the following subject:

Penconazole: MRLs in grapes

Italy proposed to raise the existing MRL of penconazole in table and wine grapes from the value of 0.2–0.4 mg/kg.

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA proceeds with the assessment of the application and the evaluation report provided to give a reasoned opinion on the risks to the consumer associated with the application. In accordance with Article 11 of the Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months (which may be extended to 6 months if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

The evaluation report submitted by the EMS (Italy, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

The active substance and its use pattern

Penconazole is the ISO common name for (*RS*) 1-[2-(2,4-dichloro-phenyl)-pentyl]-1*H*-[1,2,4] triazole (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix B.

Penconazole has been evaluated in the framework of Directive 91/414/EEC with Germany designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2009/77/EC[5] which entered into force in January 2010 for use as a fungicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011[6], penconazole is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

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

[2] 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.

[3] 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 L 309, 24.11.2009, p. 1–50.

[4] Syngenta italia S.p.a., Via gallarate 139, 20151. Milano, Italy.

[5] Commission Directive 2009/77/EC of 1 July 2009 amending Council Directive 91/414/EEC to include chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron as active substances. OJ L 172, 2.7.2009, p. 23–33.

[6] Commission Implementing Regulation (EU) No 540/2011 of 23 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.

The draft assessment report (DAR) has been peer reviewed by EFSA (EFSA, 2008) and the representative uses evaluated in the peer review were foliar applications on cucurbits and grapes.

The EU MRLs for penconazole are established in Annexes II and IIIB of Regulation (EC) No 396/2005. Since the entry into force of this regulation, EFSA has issued one reasoned opinion on the modification of MRLs for penconazole for the use in blackberries and raspberries (EFSA, 2014). The MRL changes were implemented in the Regulation (EU) 2015/401[7].

The details of the intended Good Agricultural Practices (GAPs) for penconazole in table grapes and wine grapes are reported in Appendix A.

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Italy, 2016), the draft assessment report (DAR) and its addendum prepared under Directive 91/414/EEC (Germany, 2007, 2008), the Commission review report on penconazole (European Commission, 2010c), the conclusion on the peer review of the pesticide risk assessment of the active substance penconazole (EFSA, 2008), as well as the conclusion from a previous EFSA reasoned opinion on penconazole (EFSA, 2014). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[8] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2016; OECD, 2011).

1. Method of analysis

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

Analytical methods for the determination of penconazole residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (Germany, 2008). A liquid chromatography coupled with tandem mass spectrometry detection (LC–MS/MS) method has been validated at the limit of quantification (LOQ) of 0.01 mg/kg in high acid commodities content (grapes, strawberries); however, no independent laboratory validation (ILV) has been provided for the method (EFSA, 2008).

The multiresidue Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) (QuEChERS) method described in the European Standard EN 15662:2008 is also applicable (CEN, 2008; EFSA, 2008); the QuEChERS method with a final determination by LC–MS/MS to analyse penconazole residues has been sufficient validated at the LOQ of 0.01 mg/kg in matrices with high acid content, high water content, high oil content, high starch content and high protein content (Italy, 2016).

As grapes belong to high acid content commodity group, EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRL for penconazole in wine and table grapes.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application since grapes are not components of the EU diets for feeding livestock.

2. Mammalian toxicology

The toxicological profile of the active substance penconazole was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2008). The reference values for penconazole were set for the racemic mixture of isomers.

[7] Commission Regulation (EU) 2015/401 of 15 February 2015 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 acetamiprid, chromafenozide, cyazofamid, dicamba, difenoconazole, fenpyrazamine, fluazinam, formetanate, nicotine, penconazole, pymetrozine, pyraclostrobin, tau-fluvalinate and tebuconazole in or on certain products. OJ L 71, 14.3.2015, p. 114–156.

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

Penconazole belongs to the class of triazole fungicides, which are metabolised in plants and animals to a certain extent to common metabolites known as triazole derivative metabolites (TDMs), the major ones being the metabolites 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA). These metabolites show different toxicity than penconazole. The summary of toxicological reference values for penconazole and its metabolites are summarised in Table 1.

Table 1: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Penconazole					
ADI	European Commission	2010	0.03 mg/kg bw per day	Dog, 90-day and 1-year studies	100
ARfD	European Commission	2010	0.5 mg/kg bw	Rabbit, developmental (maternal NOAEL)	100
1,2,4-Triazole, triazole acetic acid and triazole lactic acid[(a)]					
ADI	EFSA	2011	0.02 mg/kg bw per day	Rat, multigeneration study	1,000
ARfD	EFSA	2011	0.06 mg/kg bw	Rat, developmental study	500
Triazole alanine					
ADI	EFSA	2011	0.1 mg/kg bw per day	Rat, developmental study	1,000
ARfD	EFSA	2011	0.1 mg/kg bw	Rat, developmental study	1,000

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight; NOAEL: no observed adverse effect level.
(a): EFSA PRAPeR Expert Meeting 14 agreed to apply the same toxicological reference values as for 1,2,4 triazole in the 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

The metabolism of penconazole in primary crops has been evaluated in the framework of the peer review under Directive 91/414/EEC (Germany, 2008) in the fruit crop group (tomatoes and apples).

Studies were conducted on tomatoes and apples using the ^{14}C-triazole labelled compound and on tomatoes with the ^{14}C-phenyl labelled compound (Germany, 2007; EFSA, 2008). In apple and tomato fruits, the metabolism of penconazole is showed to be similar. The TDMs resulting from the cleavage of the triazole moiety were found in the ^{14}C-triazole labelled study (EFSA, 2008).

Based on these metabolism studies and exclusively for the food commodities belonging to the fruit crop group, the residue definition has been proposed as penconazole for monitoring and as penconazole + CGA 132465 + CGA 190503 + CGA 127841 and the conjugates of the metabolites, expressed as penconazole for risk assessment (EFSA, 2008). From these metabolism studies, a risk assessment conversion factor (CF) of 6 has been derived (EFSA, 2008).

The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review. Pending the submission and assessment of the confirmatory data on TDMs requested for triazole pesticides, the residue definitions should be regarded as provisional.

It must be noted that penconazole is a racemic mixture of enantiomers. No data are available to conclude whether preferential metabolism/degradation of the constituent isomer occurs in plants. The peer review has concluded that a possible change in the isomeric composition would not significantly change the risk assessment for the representative uses (cucurbits/grapes) since sufficiently wide safety margins between the chronic and acute exposure were considered when the toxicological reference values were established (EFSA, 2008). EFSA considers that this conclusion is still valid. However, further investigations on this matter would be desirable considering the dietary exposure to grapes (see Section 4).

For the uses on grapes, EFSA concludes that the metabolism of penconazole is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed in the peer review process are applicable.

3.1.1.2. Magnitude of residues

In support of the MRL application, eight residue trials on wine grapes were provided. The trials were performed in 2014 in compliance with the critical good agricultural practices (GAP) (northern Europe (*NEU): 3× 30 g/ha, preharvest (PHI) 28 days*) in several EU independent locations. Four of the residue trials were performed as declined studies and the samples were collected at time 0, 7, 13–14, 21 and 28 days after the last application (DALA). In the rest of the cases, samples were collected at day 14 and day 27–28 after the last application.

All samples were analysed only for penconazole parent compound. Residues values ranged from the LOQ up to 0.26 mg/kg (Italy, 2016).

Based on these data set submitted, EFSA derived a MRL of 0.40 mg/kg for the intended use of penconazole in wine grapes. The residue data set can be also used to derive the same MRL of 0.4 mg/kg for the use of penconazole in table grapes.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 2.

The stability of penconazole residues in plant matrices under storage conditions prior to analysis was assessed during the peer review under Directive 91/414/EEC (EFSA, 2008). Residues of penconazole were found to be stable at $\leq -20°C$ for up to 16 months in high water (apples) and high acid (grapes) content matrices. As the trial samples were stored for a maximum period of ca 6 months under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

Table 2: Overview of the available residues trials data

Crop	Region/ indoor[a]	Residue levels observed in the supervised residue trials[b] (mg/kg)	Recommendations/ comments[c]	MRL proposal (mg/kg)	HR_{MO}[d] (mg/kg)	$STMR_{MO}$[e] (mg/kg)
Wine grapes cGAP (3× 30 g/ha, PHI 28 days)	NEU	Mo: 2× < 0.01, 0.01, 2× 0.02, 0.03, 0.04, 0.26	MRL_{OECD}: 0.39/0.40	0.40	0.26	0.02
		RA: Sample trials were only analysed for penconazole parent compound	Extrapolation from wine grapes to table grapes is acceptable (European Commission, 2016)			
		Residue definition for monitoring: penconazole	A conversion factor of 6 is applicable from monitoring to risk assessment. CF derived from plant metabolism studies in the fruit crop group evaluated in the peer-review process (EFSA, 2008)		**HR** 1.56	**STMR** 0.12
		Residue definition for risk assessment: sum of penconazole, its metabolites (CGA 132465, CGA 190503 and CGA 127841) and the conjugates of the metabolites, expressed as penconazole				

MRL: maximum residue level; cGAP: critical Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; CF: conversion factor.

*: Indicates that the MRL is proposed at the limit of analytical quantification (LOQ).

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Individual residue levels considered for MRL calculation are reported in ascending order (2× < 0.01, 0.01, 6× 0.02, 0.04, 0.08, 2× 0.10, 0.15, 0.17).
Mo: residue level according to the monitoring residue definition (see table above the residue definition for monitoring).
RA: residue level according to the residue definition for risk assessment (see table above the residue definition for risk assessment).

(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values).

(d): HR_{Mo}: Highest residue level according to residue definition for monitoring.
HR: Highest residue level according to the residue definition for risk assessment.

(e): $STMR_{Mo}$: Median residue level according to residue definition for monitoring.
STMR: Median residue level according to residue definition for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies simulating the effect on the nature of penconazole residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the conclusion of the peer review (EFSA, 2008) and it was concluded that the compound is hydrolytically stable under the representative conditions. Thus, for processed commodities, the same residue definition as for raw agricultural commodities (RAC) is applicable.

Studies investigating the effect of processing on the magnitude of penconazole residues in processed product were assessed in the conclusion on the peer review prepared under Directive 91/414/EEC and processing factors (PFs) were proposed for the use in grapes (EFSA, 2008). These PFs from grapes to the processed commodity were reported as follows with the PF value within brackets: from grapes to must (0.26), juice (0.51), wine (0.23), raisins (3.5), wet pomace (3.8) and dry pomace (18).

Additional studies were not provided in the framework of this MRL application and are not requested since the total theoretical maximum daily intake (TMDI) amounts to less than 10% of the acceptable daily intake (ADI) (European Commission, 1997d).

3.1.2. Rotational crops

As the proposed use of penconazole is on a permanent crop, the investigation of residues in rotational crops is not required and is therefore not considered in this reasoned opinion.

3.2. Nature and magnitude of residues in livestock

As grapes and their by-products are not normally fed to livestock, the nature and magnitude of penconazole residues in livestock are not assessed in the framework of this application (European Commission, 1997e).

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population[9] (EFSA, 2007).

To calculate the chronic exposure, EFSA used median residue values (STMR) derived from the residue trials conducted for grapes in this MRL application and multiplied for a factor of 6 due to risk assessment considerations (Table 2). In addition, the STMR values reported in a previous EFSA reasoned opinion under Art 10 (EFSA, 2014) and the MRLs previously implemented in the Regulation multiplied by a factor of 6 have been used to calculate the chronic exposure. For the remaining commodities of plant and animal origin for which no use has been demonstrated, the existing MRLs set at the LOQ as established in Regulation (EU) No 2015/401 were used as input values.

The acute exposure assessment was performed only with regard to grapes assuming the consumption of a large portion of table and wine grapes as reported in the national food surveys that contained residues at the highest residue level (HR) as observed in supervised field trials multiplied by the risk assessment conversion factor of 6 to consider the residue definition for risk assessment (Table 2). A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation for table grapes (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 3.

[9] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from Member States surveys are used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Table 3: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	**Comment**	**Input (mg/kg)**	**Comment**
Risk assessment residue definition: sum of penconazole and its metabolites (CGA 132465, CGA 190503, CGA 127841) and the conjugates of the metabolites, expressed as penconazole				
Table grape/wine grape	**0.12** (0.02 × 6)	$STMR_{Mo}$ × CF (Table 2)	**1.56** (0.26 × 6)	HR_{Mo} × CF (Table 2)
Raspberries/blackberries	0.21	$STMR_{Mo}$ × CF (EFSA, 2014)	Acute risk assessment undertaken only for the crops under consideration	
Pome fruits/globe artichokes	1.2	MRL × CF		
Apricots/peaches	0.6	MRL × CF		
Strawberries/currants	3	MRL × CF		
Tomatoes/aubergines	0.6	MRL × CF		
Peppers	1.2	MRL × CF		
Cucurbits – edible/inedible peel	0.6	MRL × CF		
Tea	0.6	MRL × CF		
Hops	3	MRL × CF		
Other plant and animal commodities	MRL	MRLs set at LOQ in Regulation (EU) 2015/401		

CF: conversion factor; MRL: maximum residue level; HR: highest residue level; STMR: median residue values; LOQ: limit of quantification.

The estimated exposure has been compared with the toxicological reference values derived for penconazole (Table 1).

A long-term consumer intake concerns was not identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake was calculated to be 67% of the ADI (German, children). The contribution of table grapes to the total consumer exposure accounted for less than 1% of the ADI (Poland, general population) and for less than 2% of the ADI (France, all population) in the case of wine grapes.

An acute consumer risk was not identified in relation to the MRL proposal for table and wine grapes. The highest acute consumer exposure was calculated to be around 20% of the acute reference dose (ARfD) in table grapes and around 7% of the ARfD in wine grapes.

EFSA concludes that the intended use of penconazole on table and wine grapes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a concern for public health.

EFSA emphasises that the above assessment did not take into consideration TDMs. EFSA recommends a separate risk assessment for these metabolites since can be generated by several pesticides belonging to the group of triazoles fungicides. The risk assessment should be performed as soon as the confirmatory data requested for triazole compounds have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

Conclusions and recommendations

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Penconazole[(F)]				
0151000	Table and wine grapes	0.2	0.4	NEU residue trials are sufficient to support the intended use in wine grapes. The extrapolation from wine grapes to table grapes is acceptable. No risk for consumers has been identified. However, EFSA suggests considering the risk assessment in tentative basis in view of the possible occurrence of triazole derivate metabolites (TDMs) as result of the use of penconazole

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

References

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Abbreviations

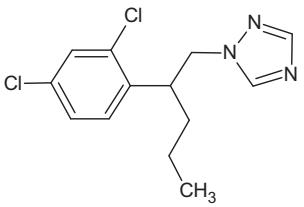
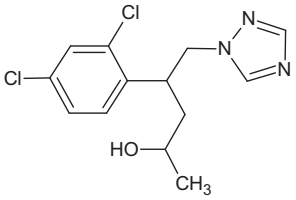
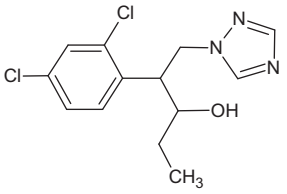
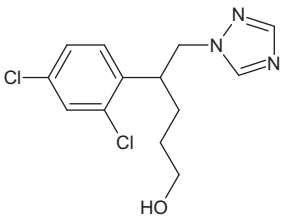
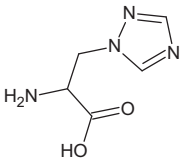
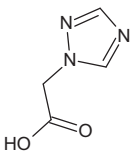
1,2,4-T	1,2,4-triazole
a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAS	Chemical Abstract Service
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
DALA	days after the last application
DAR	draft assessment report
EC	emulsifiable concentrate
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HR	highest residue
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MW	molecular weight
NOAEL	no observed adverse effect level
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
TA	triazole alanine
TAA	triazole acetic acid
TDM	triazole derivate metabolite
TLA	triazole lactic acid
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Good Agricultural Practice (GAPs)

Crop	NEU, SEU, MS or country	F G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[(d)]	Remarks
				Type [(b)]	Conc. a.s.	Method kind	Range of growth stages and season[(c)]	Number min–max	Interval between application	g/hL min–max	Water L/ha min–max	g/ha min–max		
Table grapes and wine grapes	FR, AT, CZ, HU, RO, SK, SI	NEU	*Uncinula necator*	EC	25 g/L	Foliar application	BBCH 13-85	3	Minimum 8 days		150–1,000	30	28	
Table grapes and wine grapes	DE	NEU	*Uncinula necator*	EC	25 g/L	Foliar application	BBCH 13-85	2	Minimum 8 days		100–1,600	30	28	

NEU: northern Europe; SEU: southern Europe; MS: Member State; a.s.: active substance.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – Used compound codes

Code/trivial name	Chemical name	Structural formula
Penconazole	(*RS*)-1-[2-(2,4-dichlorophenyl)pentyl]-1*H*-1,2,4-triazole Clc2ccc(C(CCC)Cn1cncn1)c(Cl)c2	
Penconazole metabolites		
CGA 132465	(2*RS*,4*RS*)-4-(2,4-dichlorophenyl)-5-(1*H*-1,2,4-triazol-1-yl)-2-pentanol Clc2ccc(C(CC(C)O)Cn1cncn1)c(Cl)c2	
CGA 190503	(2*RS*,3*RS*)-2-(2,4-dichlorophenyl)-1-(1*H*-1,2,4-triazol-1-yl)-3-pentanol OC(CC)C(Cn1cncn1)c2ccc(Cl)cc2Cl	
CGA 127841	(4*RS*)-4-(2,4-dichlorophenyl)-5-(1*H*-1,2,4-triazol-1-yl)-1-pentanol Clc2ccc(C(CCCO)Cn1cncn1)c(Cl)c2	
Triazole derivative metabolites		
1,2,4-Triazole (CGA 71019)	1*H*-1,2,4-triazole c1ncnn1	
Triazole alanine (CGA 131013)	3-(1*H*-1,2,4-triazol-1-yl)-DL-alanine NC(Cn1cncn1)C(=O)O	
Triazole acetic acid (CGA 142856)	1*H*-1,2,4-triazol-1-ylacetic acid O=C(O)Cn1cncn1	
Triazole lactic acid or Triazole hydroxy propionic acid (CGA 205369)	(2*RS*)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propanoic acid OC(Cn1cncn1)C(=O)O	