REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for cyazofamid in grapes[1]

European Food Safety Authority[2]

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, France, hereafter referred to as the evaluating Member State (EMS), received an application from the company ISK Biosciences Europe N.V to modify the existing MRLs for cyazofamid in table and wine grapes. In order to accommodate for the intended uses of cyazofamid, France proposed to raise the existing MRLs from the value of 0.5 mg/kg to 2 mg/kg. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. According to EFSA the data are sufficient to derive MRL proposals of 2 mg/kg for the proposed uses on table and wine grapes. Adequate analytical enforcement methods are available to control the residues of cyazofamid in the commodities under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of cyazofamid on grapes will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

KEY WORDS

cyazofamid, grapes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, sulphonamide fungicide, CCIM

[1] On request from the European Commission, Question No EFSA-Q-2013-00258, approved on 27 September 2013.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, France, hereafter referred to as the evaluating Member State (EMS), received an application from the company ISK Biosciences Europe N.V to modify the existing MRLs for cyazofamid in table and wine grapes. In order to accommodate for the intended uses of cyazofamid, France proposed to raise the existing MRLs from the value of 0.5 mg/kg to 2 mg/kg. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 5 March 2013.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC, as well as the conclusions from previous EFSA opinions on cyazofamid.

The toxicological profile of cyazofamid was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.17 mg/kg bw per day. No ARfD was deemed necessary.

The metabolism of cyazofamid in primary crops was investigated in tomatoes, potatoes and grapes. In all three crops metabolic patterns were similar and the parent compound was the major residue in both fruits and foliage. The residue for enforcement and risk assessment in fruits and fruiting vegetables and root and tuber vegetables derived in the peer review was defined as cyazofamid only. EFSA concludes that the metabolism of cyazofamid in primary crops is sufficiently addressed and that the residue definitions derived are applicable.

The submitted supervised residue trials are sufficient to derive MRL proposals of 2 mg/kg for the proposed uses on table and wine grapes. Adequate analytical enforcement methods are available to control the residues of cyazofamid in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

A limited number of data on the nature of residues over processing derived from the primary crop metabolism study for grapes were available in the framework of the Article 12 review (EFSA, 2012b). According with these data some conversion of parent cyazofamid to metabolite CCIM was suggested. Additionally, some further information on levels on CCIM in wine confirms that CCIM is present in wine. Uncertainties remain on the similarity of the toxicity profile of CCIM compared to parent but this is not of major concern as the total chronic intake estimated on the basis of residues of cyazofamid in the raw agricultural commodities are <1 % of the ADI. As the residues in wine are mainly composed of the metabolite CCIM, it is proposed that the residue definition for enforcement and risk assessment in wine should be defined as sum of cyazofamid and CCIM, expressed as cyazofamid. Based on the available information EFSA is of the opinion that the following processing factor should be included in Annex VI of Regulation (EC) No 396/2005.

- Grapes to wine (white and red): • 0.13

Since the proposed use of cyazofamid is on permanent crops, investigations of residues in rotational crops are not required.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The highest long-term exposure was calculated for DE child representing 0.3 % of the ADI. Table grapes were the main contributor to the dietary burden accounting for a maximum of 0.2 % of the ADI (DE child); the contribution of wine grapes was insignificant (lower than 0.05 % of the ADI).

No acute exposure calculation was necessary because of the low toxicity of cyazofamid.

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

Thus EFSA proposes to amend the existing MRLs as reported in the summary table.

SUMMARY TABLE

Code number[(a)]	**Commodity**	**Existing EU MRL** (mg/kg)	**Proposed EU MRL** (mg/kg)	**Justification for the proposal**
Enforcement residue definition: cyazofamid				
151010	Table grapes	0.5 / 0.9[(b)]	2	The MRL proposals are sufficiently supported by data and no consumer health risk was identified for the intended uses on these crops.
151020	Wine grapes	0.5 / 0.9[(b]	2	

(a): According to Annex I of Regulation (EC) No 396/2005.
(b): Recommended MRLs under Article 12 of Regulation 396/2005 but still not adopted in EU legislation

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BACKGROUND

Regulation (EC) No 396/2005[3] establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that 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[4], repealed by Regulation (EC) No 1107/2009[5], shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

France, hereafter referred to as the evaluating Member State (EMS), received an application from the company ISK Biosciences Europe N.V[6] to modify the existing MRLs for the active substance cyazofamid in table and wine grapes. This application was notified to the European Commission and 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 who forwarded the application, the evaluation report and the supporting dossier to EFSA on the reception date 05 March 2013.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2013-00258 and the following subject:

Cyazofamid: Application to modify the existing MRLs in table and wine grapes.

France proposed to raise the existing MRLs of cyazofamid in table and wine grapes from current MRL values of 0.5 mg/kg to 2 mg/kg.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the deadline for providing the reasoned opinion is 5 June 2013

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.

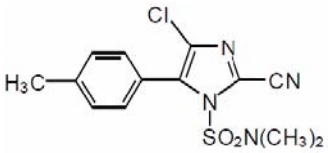
[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

[5] 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.

[6] ISK Biosciences Europe N.V, Pegasus Park, De Kleetlaan 12 B, Box 9, 1831 Diegem, Belgium.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Cyazofamid is the ISO common name for 4-chloro-2-cyano-*N*,*N*-dimethyl-5-*p*-tolylimidazole-1-sulfonamide (IUPAC).



Molecular weight: 324.8 g/mol

Cyazofamid belongs to the group of sulfonamide and imidazole compounds which are used as fungicides. It is used mainly as a protective, contact foliar acting fungicide that needs to be applied in advance of disease attack and may be expected to provide protection over a period of seven to ten days. It inhibits all stages of the life cycle of oomyctes fungi, including *Phytophthora infestans*, by specifically inhibiting respiration at the mitochondrial cytochrome *bc*1 complex.

Cyazofamid was evaluated in the framework of Directive 91/414/EEC with France being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were foliar spray on tomato (indoors) and potato (outdoors). Following the peer review, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2003/23/EC[7], entering into force on 1 July 2003. According to Regulation (EU) No 540/2011[8], cyazofamid is approved under Regulation (EC) No 1107/2009[9]. This approval is restricted to uses as a fungicide only. As EFSA was not yet involved in the peer review of cyazofamid, a conclusion of EFSA on this active substance is not available.

The EU MRLs for cyazofamid are established in Annexes II and IIIB of Regulation (EC) No 396/2005 (Appendix C). The recommendations derived by EFSA in the framework of the MRL review (EFSA, 2012b) have been presented in the SCFCAH for discussion (SANCO/11012/2013), but a decision has not yet been taken. The current MRLs for cyazofamid in table and wine grapes are set at 0.5 mg/kg. EFSA also issued a reasoned opinion on the modification of the existing MRL for cyazofamid in horseradish (EFSA, 2012a). Codex Alimentarius did not established CXLs for cyazofamid.

The details of the intended GAP for cyazofamid in gapes are given in Appendix A.

[7] Commission Directive 2003/23/EC of 25 March 2003 amending Council Directive 91/414/EEC to include imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl and cyazofamid as active substances. OJ L 81, 28.3.2003, p. 39-42.

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

[9] 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.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (France, 2013), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (France, 2001), as well as the conclusions from previous EFSA opinions on cyazofamid (EFSA, 2012a, 2012b). 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[10] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

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

Analytical methods for the determination of cyazofamid residues in plant commodities were assessed in the DAR and during the peer review under Directive 91/414/EEC (France 2001). The analytical method is based on the HPLC-UV principle, validated for the determination of cyzofamid in plant commodities with an LOQ of 0.01 mg/kg in high water content (potatoes, tomatoes) and acidic (grapes and grape processing fractions). Suitable ILV data were provided; for high water content commodities the method was validated also using HPLC-DAD (EFSA, 2012b).

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 is also applicable. The liquid chromatography coupled with tandem mass spectrometry detection (LC-MS/MS) method analyses trifloxystrobin residues in matrices with high water, high acid and dry content at the LOQ of 0.01 mg/kg (CEN, 2008)

Additionally, another analytical method for determination of cyazofamid and CCIM in grapes based on HPLC-UV has been assessed and found acceptable at the LOQ of 0.01 mg/kg (France, 2013).

Based on the information presented above, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRL for cyazofamid on grapes are available.

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 fed to livestock.

2. Mammalian toxicology

The toxicological profile of cyazofamid was assessed in the peer review under Directive 91/414/EEC and toxicological reference values were established by the European Commission (2002). The toxicological reference values are presented in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Cyazofamid					
ADI	EC	2002	0.17 mg/kg bw per d	2 yr rat	100
ARfD	EC	2002	Not necessary		

[10] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of cyazofamid was investigated for foliar application on fruits and fruiting vegetables (tomato and grape) and on root and tuber vegetables (potato) using ^{14}C-labelled cyazofamid (France, 2001). The characteristics of these studies are summarized in Table 3-1.

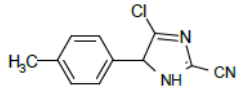
Table 3-1: Summary of available metabolism studies in plants

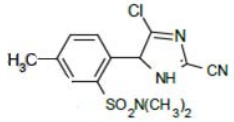
Group	Crop	Label position	Application details				
			Method, F or G[(a)]	Rate (kg/a.s/ha)	No	Sampling (DAT)	Remarks
Fruits and fruiting vegetable	Grapes	Phenyl and imidazole rings	Foliar, F	0.1	5	44 days after last treatment	-
	Tomatoes	Phenyl and imidazole rings	Foliar, F	0.1 and 0.4	4	44 days after last treatment	-
Leafy vegetables	Potatoes	Phenyl and imidazole rings	Foliar, F and G	0.1 and 0.4	2-5	7 days after last treatment	-

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

In all three crops, parent compound was found to be the major residue in both fruits and foliage. The highest TRR identified in the fruits and edible crop parts were 0.022 mg eq/kg (potato tubers), 0.29 mg eq/kg (tomatoes, of which 83 % was removed as surface wash) and 0.50 mg eq/kg (grapes). Parent comprised up to 10 % TRR (a maximum of 0.002 mg eq/kg) in potato tubers, 31-68 % TRR in the surface wash of tomatoes and 58 % TRR in grapes. The main identified metabolite was CCIM[11] resulting from hydrolysis of the parent compound (up to 3 % TRR in potatoes, 1-7 % TRR in tomatoes, 4-6 % TRR in grapes). Other metabolites, including polar metabolites, were identified in tomatoes but they were all present in small amounts (CCTS[12], <4 % of the TRR and all other metabolites present at extremely low to non-detectable levels). In grapes, other conjugated metabolites derived from CCIM were identified for a level up to 3 % TRR, but at a level lower than 0.01 mg/kg. The remaining residue in all three studies comprised radioactive carbon incorporated into natural plant sugars/acids/starch.

The studies indicate that the metabolic pathway in potatoes, tomatoes and grapes is similar in both foliage and fruits. Cyazofamid metabolism proceeds via hydrolysis of the sulphonamide group resulting in CCIM which may form conjugates. A certain number of polar compounds were formed which are strongly associated with the crop matrix or are further incorporated into natural products. However, parent cyazofamid was the major compound in all tree crops. Although CCIM was formed to some extent, the peer review decided, for the crops covered by the metabolism studies, not to

[11] CCIM: 

[12] CCTS: 

include CCIM in the residue definition. Thus, the residue definition for enforcement and risk assessment is defined as cyazofamid only (EFSA, 2012b; France, 2013)

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

3.1.1.2. Magnitude of residues

In support of the proposed GAP on grapes, the applicant provided 25[13] trials on wine grapes (13 SEU and 12 NEU). All trials were performed with 8 applications of 100 g cyazofamid/ha (±25 % deviation of application rate) with a PHI of 21 days which match the proposed GAP. The samples were analysed for parent cyazofamid and the metabolite CCIM. Wine grapes are major crop both in northern and southern Europe. The trials submitted in the support of this application were stored at -18 °C for a period of 2 to 5 months.

At harvest the residue levels in the supervised field trials ranged from 0.096 to 1.33 mg/kg for cyazofamid, while CCIM was found above LOQ level in 12 samples at a maximum level of 0.059 mg/kg.

The results of the residue trials, the related risk assessment input values (highest residue, median residue, and conversion factor) and the MRL proposals are summarised in Table 3-2.

The potential degradation of residue during storage stability was first evaluated in the framework of the peer review. The storage stability of 14C-cyazofamid was demonstrated in metabolism studies for a period of 5 months for grape foliage and pulp (high acid content). The storage temperature however was not specified. It is noted that in the grape juice samples, parent cyazofamid was found to completely converted to metabolite CCIM during storage of the frozen product for 5 months. In tomatoes, no degradation of parent cyazofamid was observed after 9 months; in potatoes, around a quarter of the parent cyazofamid was found to be degraded to CCIM after 6 months; no other timings or degradation products were observed (EFSA, 2012b).

Additionally, storage stability studies for cyazofamid in grapes (homogenized and unhomogenized) and wine were submitted under this application (France, 2013). The stability of the residues using incurred grapes was demonstrated in unhomogenized samples for at least one year when stored at - 20 °C whilst for the homogenized samples the range of recoveries was between 52-98 % after 8 days of storage. In wine samples cyazofamid residues were demonstrated to be stable for up to 3 years storage at -25 °C.

As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical method used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for the purpose (France, 2013).

EFSA concludes that the data are sufficient to derive a MRL proposal of 2 mg/kg for the intended use on grapes in NEU/SEU.

[13] A total number of 33 trials were applied by the applicant but only 25 were considered as valid because they have been stored for a maximum of one year.

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

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement RD	Risk assessment RD					
Enforcement residue definition: Cyazofamid.									
Wine grapes → table grapes	NEU	Outdoor	0.096; 0.114; 0.130; 0.131; 2x 0.180; 0.210; 0.264; 0.348; 0.368; 0.467; 0.554	See enforcement RD	0.19	0.55	0.9	1	R_{ber}=0.73 R_{max}=0.66 MRL_{OECD} = 0.85/0,9
	SEU	Outdoor	0.130; 0.131; 0.220; 0.259; 0.275; 0.310; 0.330; 0.340; 0.414; 0.738; 0.755; 1.01; 1.33	See enforcement RD	**0.33**	**1.33**	**2**	**1**	R_{ber}=1.49 R_{max}=1.46 MRL_{OECD} = 1.95/2

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.
(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of cyazofamid was investigated in the framework of the peer review. Although the applicant did not provide the standard hydrolysis studies, but studies with grapes being treated with ^{14}C-cyazofamid which were used to prepare two kinds of wine simulating commercial wine production. The process to produce 'vin de Goutte' was considered to reflect commercial production of wine. In the wine samples derived by this methodology, the TRR concentrations ranged from 0.02 to 0.3 mg/kg. Parent cyazofamid accounted for 5-11 % TRR and the major metabolite/degradation product in both wines was CCIM (28-31 % TRR). Polar compounds (14-23 %TRR) and 5-CGTC[14] (3-7.5 % TRR) were other products identified or characterised, ranging from 0.01 to 0.05 mg/kg.

In addition, four residues trials were available where grape samples were used to produce white and red wine. The unprocessed grapes were found to contain cyazofamid only (ranging from 0.18 to 0.33 mg/kg); CCIM was not detectable in grapes. In the wine, residues of CCIM were found at a level up to 0.045 mg/kg (expressed as cyazofamid equivalents); the parent compound was below the LOQ in the wine samples. Therefore for wine, it is proposed that the residue definition for risk assessment and enforcement should be the sum of cyazofamid and CCIM, expressed as cyazofamid (EFSA 2012b).

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF[(a)]	Median CF [(b)]	Comments
Enforcement residue definition: **Grape:** cyazofamid **Wine:** sum cyazofamid and CCIM expressed as cyazofamid				
wine grapes, wine (red and white)	4	0.13	1	Processing factor based on ratio of residues of cyazofamid + CCIM (expressed as cyazofamid) in wine/residues of cyazofamid in wine grapes. Two trials on red and two trials on white wine were available. Since the processing factors were comparable for the two types of wine, a global processing factor for red and white wine was derived.

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

The processing factors derived from the studies described above are considered to sufficiently robust to be recommended for inclusion in Annex VI.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Since the proposed use of cyazofamid is requested for a permanent crop, the investigation of residues in rotational crops is of no relevance.

3.2. Nature and magnitude of residues in livestock

Since grapes and their by-products are normally not fed to livestock, the nature and magnitude of cyazofamid residues in livestock is not assessed in the framework of this application (EC, 1996).

[14] 5-CGTC: 5-chloro-1--D-glucopyranosyl-4-*p*-tolylimidazole-2-carbonitrile

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population [15] (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the median residue value as derived from the residue trials on grapes (see Table 3-2) and the median residue values reported in the framework of the review of MRLs of cyazofamid under article 12 (EFSA, 2012b).

No acute consumer exposure assessment was performed, due to the low acute toxicity of cyazofamid.

The input values used for the dietary exposure calculation are summarised in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	**Chronic exposure assessment**		**Acute exposure assessment**	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: cyazofamid				
Table grapes	**0.33**	Median residue (SEU), See table 3-2	Acute risk assessment was not performed since no ARfD is necessary for cyazofamid.	
Wine grapes	**0.33x0.7[16]x0.13**	Median residue (SEU) x YF x PF		
Potatoes	0.01	Median residue (=LOQ) (EFSA 2012b)		
Horseradish	0.03	Median residue (EFSA 2012a)		
Tomatoes	0.05	Median residue (EFSA 2012b)		
Cucumbers, gherkins, courgettes	0.03	Median residue (EFSA 2012b)		
Melons, pumpkins, watermelons	0.01	Median x PF (EFSA 2012b)		

The estimated exposure was then compared with the toxicological reference values derived for cyazofamid (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The highest long-term exposure was calculated for DE child representing 0.3 % of the ADI. Table grapes were the main contributor to the dietary burden accounting for a maximum of 0.2 % of the ADI (DE child); the contribution of wine grapes was insignificant (lower than 0.05 % of the ADI).

[15] 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 MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

[16] Consumption figures in the EFSA PRIMo are expressed as wine grapes. Since it is assumed that all wine grapes are consumed as wine, the consumption is recalculated to wine using a yield factor (1 kg of wine grapes is needed to produce 0.7 kg of wine) to perform the refined intake calculation for wine grapes.

Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

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

CONCLUSIONS AND RECOMMENDATIONS

The toxicological profile of cyazofamid was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.17 mg/kg bw per day. No ARfD was deemed necessary.

The metabolism of cyazofamid in primary crops was investigated in tomatoes, potatoes and grapes. In all three crops metabolic patterns were similar and the parent compound was the major residue in both fruits and foliage. The residue for enforcement and risk assessment in fruits and fruiting vegetables and root and tuber vegetables derived in the peer review was defined as cyazofamid only. EFSA concludes that the metabolism of cyazofamid in primary crops is sufficiently addressed and that the residue definitions derived are applicable.

The submitted supervised residue trials are sufficient to derive MRL proposals of 2 mg/kg for the proposed uses on table and wine grapes. Adequate analytical enforcement methods are available to control the residues of cyazofamid in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

A limited number of data on the nature of residues over processing derived from the primary crop metabolism study for grapes were available in the framework of the Article 12 review (EFSA, 2012b). According with these data some conversion of parent cyazofamid to metabolite CCIM was suggested. Additionally, some further information on levels on CCIM in wine confirms that CCIM is present in wine. Uncertainties remain on the similarity of the toxicity profile of CCIM compared to parent but this is not of major concern as the total chronic intake estimated on the basis of residues of cyazofamid in the raw agricultural commodities are <1 % of the ADI. As the residues in wine are mainly composed of the metabolite CCIM, it is proposed that the residue definition for enforcement and risk assessment in wine should be defined as sum of cyazofamid and CCIM, expressed as cyazofamid. Based on the available information EFSA is of the opinion that the following processing factor should be included in Annex VI of Regulation (EC) No 396/2005.

Grapes to wine (white and red): 0.13

Since the proposed use of cyazofamid is on permanent crops, investigations of residues in rotational crops are not required.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The highest long-term exposure was calculated for DE child representing 0.3 % of the ADI. Table grapes were the main contributor to the dietary burden accounting for a maximum of 0.2 % of the ADI (DE child); the contribution of wine grapes was insignificant (lower than 0.05 % of the ADI).

No acute exposure calculation was necessary because of the low toxicity of cyazofamid.

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

Thus EFSA proposes to amend the existing MRLs as reported in the summary table.

SUMMARY TABLE

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: cyazofamid				
151010	Table grapes	0.5 / 0.9[(b)]	2	The MRL proposals are sufficiently supported by data and no consumer health risk was identified for the intended uses on these crops.
151020	Wine grapes	0.5 / 0.9[(b)]	2	

(a): According to Annex I of Regulation (EC) No 396/2005.
(b): Recommended MRLs under Article 12 of Regulation 396/2005 but still not adopted in EU legislation

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APPENDICES

Appendix A. Good Agricultural Practice (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number (k)	interval min max	g as/hL min max	Water l/ha min max	g a.s./ha min max		
Vineyards		F	Grape downy mildew (plasmora viticola)	SC	25 g cyazofamid & 250 g disodium phosphonate/l	Foliar application	Ripening of fruits (BBCH 81-89)	8		7.5-37.5	300-1500	112.5	21	It is recommended to use the product in resistance management programs

(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (Growth stages of mono-and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

Appendix B. PESTICIDE RESIDUE INTAKE MODEL (PRIMO)

Cyazofamid			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.17**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2002**	Year of evaluation:	**2002**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
0.3	DE child	0.2	Table grapes	0.0	Tomatoes	0.0	Potatoes	
0.2	WHO Cluster diet B	0.1	Tomatoes	0.1	Table grapes	0.0	Wine grapes	
0.2	NL child	0.1	Table grapes	0.0	Potatoes	0.0	Tomatoes	
0.2	PT General population	0.1	Table grapes	0.0	Wine grapes	0.0	Potatoes	
0.1	FR all population	0.1	Wine grapes	0.0	Table grapes	0.0	Tomatoes	
0.1	WHO cluster diet D	0.0	Table grapes	0.0	Tomatoes	0.0	Potatoes	
0.1	PL general population	0.1	Table grapes	0.0	Tomatoes	0.0	Potatoes	
0.1	IE adult	0.1	Table grapes	0.0	Wine grapes	0.0	Potatoes	
0.1	WHO cluster diet E	0.0	Table grapes	0.0	Wine grapes	0.0	Potatoes	
0.1	FR toddler	0.0	Table grapes	0.0	Potatoes	0.0	Tomatoes	
0.1	WHO regional European diet	0.0	Tomatoes	0.0	Table grapes	0.0	Potatoes	
0.1	DK child	0.0	Table grapes	0.0	Cucumbers	0.0	Tomatoes	
0.1	UK Toddler	0.0	Table grapes	0.0	Potatoes	0.0	Tomatoes	
0.1	NL general	0.0	Table grapes	0.0	Potatoes	0.0	Tomatoes	
0.1	WHO Cluster diet F	0.0	Table grapes	0.0	Potatoes	0.0	Tomatoes	
0.1	IT kids/toddler	0.0	Tomatoes	0.0	Table grapes	0.0	Potatoes	
0.1	IT adult	0.0	Tomatoes	0.0	Table grapes	0.0	Potatoes	
0.1	DK adult	0.0	Wine grapes	0.0	Table grapes	0.0	Tomatoes	
0.1	SE general population 90th percentile	0.0	Potatoes	0.0	Tomatoes	0.0	Cucumbers	
0.1	UK vegetarian	0.0	Tomatoes	0.0	Table grapes	0.0	Wine grapes	
0.1	FR infant	0.0	Potatoes	0.0	Table grapes	0.0	Courgettes	
0.1	UK Adult	0.0	Wine grapes	0.0	Tomatoes	0.0	Table grapes	
0.1	ES child	0.0	Tomatoes	0.0	Potatoes	0.0	Table grapes	
0.0	ES adult	0.0	Tomatoes	0.0	Table grapes	0.0	Wine grapes	
0.0	LT adult	0.0	Potatoes	0.0	Tomatoes	0.0	Cucumbers	
0.0	UK Infant	0.0	Potatoes	0.0	Tomatoes	0.0	Table grapes	
0.0	FI adult	0.0	Tomatoes	0.0	Potatoes	0.0	Wine grapes	

Conclusion:

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

Appendix C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLS)

(Pesticides - Web Version - EU MRLs (File created on 07/08/2013 11:39))

Code number	Groups and examples of individual products to which the MRLs apply	Cyazofamid	
		Current MRLs	Proposals EFSA 2012b
100000	1. FRUIT FRESH OR FROZEN NUTS		
110000	(i) Citrus fruit	0,01*	
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0,01*	
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,01*	
110030	Lemons (Citron, lemon, Buddha's hand (Citrus medica var. sarcodactylis))	0,01*	
110040	Limes	0,01*	
110050	Mandarins (Clementine, tangerine, mineola and other hybrids tangor (Citrus reticulata x sinensis))	0,01*	
110990	Others	0,01*	
120000	(ii) Tree nuts	0,01*	
120010	Almonds	0,01*	
120020	Brazil nuts	0,01*	
120030	Cashew nuts	0,01*	
120040	Chestnuts	0,01*	
120050	Coconuts	0,01*	
120060	Hazelnuts (Filbert)	0,01*	
120070	Macadamia	0,01*	
120080	Pecans	0,01*	
120090	Pine nuts	0,01*	
120100	Pistachios	0,01*	
120110	Walnuts	0,01*	
120990	Others	0,01*	
130000	(iii) Pome fruit	0,01*	
130010	Apples (Crab apple)	0,01*	
130020	Pears (Oriental pear)	0,01*	
130030	Quinces	0,01*	
130040	Medlar	0,01*	
130050	Loquat	0,01*	
130990	Others	0,01*	
140000	(iv) Stone fruit	0,01*	
140010	Apricots	0,01*	
140020	Cherries (Sweet cherries, sour cherries)	0,01*	
140030	Peaches (Nectarines and similar hybrids)	0,01*	
140040	Plums (Damson, greengage, mirabelle, sloe, red date/Chinese date/Chinese jujube (Ziziphus zizyphus))	0,01*	
140990	Others	0,01*	
150000	(v) Berries & small fruit		
151000	(a) Table and wine grapes	0,5	0.9
151010	Table grapes	0,5	0.9
151020	Wine grapes	0,5	0.9
152000	(b) Strawberries	0,01*	
153000	(c) Cane fruit	0,01*	
153010	Blackberries	0,01*	
153020	Dewberries (Loganberries, tayberries, boysenberries, cloudberries and other Rubus hybrids)	0,01*	
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x Rubus idaeus))	0,01*	
153990	Others	0,01*	
154000	(d) Other small fruit & berries	0,01*	
154010	Blueberries (Bilberries)	0,01*	
154020	Cranberries (Cowberries/red bilberries (V. vitis-idaea))	0,01*	
154030	Currants (red, black and white)	0,01*	
154040	Gooseberries (Including hybrids with other Ribes species)	0,01*	
154050	Rose hips	0,01*	
154060	Mulberries (Arbutus berry)	0,01*	
154070	Azarole (mediteranean medlar) (Kiwiberry (Actinidia arguta))	0,01*	
154080	Elderberries (Black chokeberry/appleberry, mountain ash, buckthorn/sea sallowthorn, hawthorn, serviceberries, and other treeberries)	0,01*	
154990	Others	0,01*	
160000	(vi) Miscellaneous fruit	0,01*	
161000	(a) Edible peel	0,01*	
161010	Dates	0,01*	
161020	Figs	0,01*	
161030	Table olives	0,01*	
161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (Citrus aurantifolia x Fortunella spp.))	0,01*	
161050	Carambola (Bilimbi)	0,01*	
161060	Persimmon	0,01*	
161070	Jambolan (java plum) (Java apple/water apple, pomerac, rose apple, Brazilean cherry, Surinam cherry/grumichama (Eugenia uniflora))	0,01*	
161990	Others	0,01*	
162000	(b) Inedible peel, small	0,01*	
162010	Kiwi	0,01*	
162020	Lychee (Litchi) (Pulasan, rambutan/hairy litchi, longan, mangosteen, langsat, salak)	0,01*	
162030	Passion fruit	0,01*	
162040	Prickly pear (cactus fruit)	0,01*	
162050	Star apple	0,01*	
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel/yellow sapote, mammey sapote)	0,01*	
162990	Others	0,01*	
163000	(c) Inedible peel, large	0,01*	
163010	Avocados	0,01*	
163020	Bananas (Dwarf banana, plantain, apple banana)	0,01*	
163030	Mangoes	0,01*	
163040	Papaya	0,01*	
163050	Pomegranate	0,01*	
163060	Cherimoya (Custard apple, sugar apple/sweetsop, ilama (Annona diversifolia) and other medium sized Annonaceae fruits)	0,01*	
163070	Guava (Red pitaya/dragon fruit (Hylocereus undatus))	0,01*	
163080	Pineapples	0,01*	
163090	Bread fruit (Jackfruit)	0,01*	
163100	Durian	0,01*	
163110	Soursop (guanabana)	0,01*	
163990	Others	0,01*	
200000	2. VEGETABLES FRESH OR FROZEN		
210000	(i) Root and tuber vegetables		
211000	(a) Potatoes	0,01*	0.01*[(b)]
212000	(b) Tropical root and tuber vegetables	0,01*	

Code number	Groups and examples of individual products to which the MRLs apply	Cyazofamid	
		Current MRLs	Proposals EFSA 2012b
212010	Cassava (Dasheen, eddoe/Japanese taro, tannia)	0,01*	
212020	Sweet potatoes	0,01*	
212030	Yams (Potato bean/yam bean, Mexican yam bean)	0,01*	
212040	Arrowroot	0,01*	
212990	Others	0,01*	
213000	(c) Other root and tuber vegetables except sugar beet		
213010	Beetroot	0,01*	
213020	Carrots	0,01*	
213030	Celeriac	0,01*	
213040	Horseradish (Angelica roots, lovage roots, gentiana roots)	0,1	0.1
213050	Jerusalem artichokes (Crosne)	0,01*	
213060	Parsnips	0,01*	
213070	Parsley root	0,01*	
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0,01*	
213090	Salsify (Scorzonera, Spanish salsify/Spanish oysterplant, edible burdock)	0,01*	
213100	Swedes	0,01*	
213110	Turnips	0,01*	
213990	Others	0,01*	
220000	(ii) Bulb vegetables	0,01*	
220010	Garlic	0,01*	
220020	Onions (Other bulb onions, silverskin onions)	0,01*	
220030	Shallots	0,01*	
220040	Spring onions and welsh onions (Other green onions and similar varieties)	0,01*	
220990	Others	0,01*	
230000	(iii) Fruiting vegetables		
231000	(a) Solanacea		
231010	Tomatoes (Cherry tomatoes, Physalis spp., gojiberry, wolfberry (Lycium barbarum and L. chinense), tree tomato)	0,2	0.6[b]
231020	Peppers (Chilli peppers)	0,01*	
231030	Aubergines (egg plants) (Pepino, antroewa/white eggplant (S. macrocarpon))	0,01*	
231040	Okra (lady's fingers)	0,01*	
231990	Others	0,01*	
232000	(b) Cucurbits — edible peel	0,1	0.2[b]
232010	Cucumbers	0,1	
232020	Gherkins	0,1	
232030	Courgettes (Summer squash, marrow (patisson), lauki (Lagenaria siceraria), chayote, sopropo/bitter melon, snake gourd, angled luffa/teroi)	0,1	
232990	Others	0,1	
233000	(c) Cucurbits-inedible peel	0,1	0.15[b]
233010	Melons (Kiwano)	0,1	
233020	Pumpkins (Winter squash, marrow (late variety))	0,1	
233030	Watermelons	0,1	
233990	Others	0,1	
234000	(d) Sweet corn (Baby corn)	0,01*	
239000	(e) Other fruiting vegetables	0,01*	
240000	(iv) Brassica vegetables	0,01*	
241000	(a) Flowering brassica	0,01*	
241010	Broccoli (Calabrese, Broccoli raab, Chinese broccoli)	0,01*	
241020	Cauliflower	0,01*	
241990	Others	0,01*	
242000	(b) Head brassica	0,01*	
242010	Brussels sprouts	0,01*	
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,01*	
242990	Others	0,01*	
243000	(c) Leafy brassica	0,01*	
243010	Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi), choi sum, Peking cabbage/pe-tsai)	0,01*	
243020	Kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0,01*	
243990	Others	0,01*	
244000	(d) Kohlrabi	0,01*	
250000	(v) Leaf vegetables & fresh herbs	0,01*	
251000	(a) Lettuce and other salad plants including Brassicacea	0,01*	
251010	Lamb's lettuce (Italian corn salad)	0,01*	
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,01*	
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curly leaf endive, sugar loaf (C. endivia var. crispum/C. intybus var. foliosum), dandelion greens)	0,01*	
251040	Cress (Mung bean sprouts, alfalfa sprouts)	0,01*	
251050	Land cress	0,01*	
251060	Rocket, Rucola (Wild rocket (Diplotaxis spp.))	0,01*	
251070	Red mustard	0,01*	
251080	Leaves and sprouts of Brassica spp, including turnip greens (Mizuna, leaves of peas and radish and other babyleaf crops, including brassica crops (crops harvested up to 8 true leaf stage), kohlrabi leaves)	0,01*	
251990	Others	0,01*	
252000	(b) Spinach & similar (leaves)	0,01*	
252010	Spinach (New Zealand spinach, amaranthus spinach (pak-khom, tampara), tajer leaves, bitterblad/bitawiri)	0,01*	
252020	Purslane (Winter purslane/miner's lettuce, garden purslane, common purslane, sorrel, glassworth, agretti (Salsola soda))	0,01*	
252030	Beet leaves (chard) (Leaves of beetroot)	0,01*	
252990	Others	0,01*	
253000	(c) Vine leaves (grape leaves) (Malabar nightshade, banana leaves, climbing wattle (Acacia pennata))	0,01*	
254000	(d) Water cress (Morning glory/Chinese convolvulus/water convolvulus/water spinach/kangkung (Ipomea aquatica), water clover, water mimosa)	0,01*	
255000	(e) Witloof	0,01*	
256000	(f) Herbs	0,01*	
256010	Chervil	0,01*	
256020	Chives	0,01*	
256030	Celery leaves (Fennel leaves, coriander leaves, dill leaves, caraway leaves, lovage, angelica, sweet cisely and other Apiacea leaves, culantro/stinking/long coriander/stink weed (Eryngium foetidum))	0,01*	
256040	Parsley (leaves of root parsley)	0,01*	
256050	Sage (Winter savory, summer savory, Borago officinalis leaves)	0,01*	
256060	Rosemary	0,01*	
256070	Thyme (Marjoram, oregano)	0,01*	
256080	Basil (Balm leaves, mint, peppermint, holy basil, sweet basil, hairy basil,	0,01*	

Code number	Groups and examples of individual products to which the MRLs apply	Cyazofamid	
		Current MRLs	Proposals EFSA 2012b
	edible flowers (marigold flower and others), pennywort, wild betel leaf, curry leaves)		
256090	Bay leaves (laurel) (Lemon grass)	0,01*	
256100	Tarragon (Hyssop)	0,01*	
256990	Others	0,01*	
260000	(vi) Legume vegetables (fresh)	0,01*	
260010	Beans (with pods) (Green bean/French beans/snap beans, scarlet runner bean, slicing bean, yard long beans, guar beans, soya beans)	0,01*	
260020	Beans (without pods) (Broad beans, flageolets, jack bean, lima bean, cowpea)	0,01*	
260030	Peas (with pods) (Mangetout/sugar peas/snow peas)	0,01*	
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,01*	
260050	Lentils	0,01*	
260990	Others	0,01*	
270000	(vii) Stem vegetables (fresh)	0,01*	
270010	Asparagus	0,01*	
270020	Cardoons (Borago officinalis stems)	0,01*	
270030	Celery	0,01*	
270040	Fennel	0,01*	
270050	Globe artichokes (Banana flower)	0,01*	
270060	Leek	0,01*	
270070	Rhubarb	0,01*	
270080	Bamboo shoots	0,01*	
270090	Palm hearts	0,01*	
270990	Others	0,01*	
280000	(viii) Fungi	0,01*	
280010	Cultivated fungi (Common mushroom, oyster mushroom, shiitake, fungus mycelium (vegetative parts))	0,01*	
280020	Wild fungi (Chanterelle, truffle, morel, cep)	0,01*	
280990	Others	0,01*	
290000	(ix) Sea weeds		
300000	3. PULSES, DRY	0,01*	
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,01*	
300020	Lentils	0,01*	
300030	Peas (Chickpeas, field peas, chickling vetch)	0,01*	
300040	Lupins	0,01*	
300990	Others	0,01*	
400000	4. OILSEEDS AND OILFRUITS		
401000	(i) Oilseeds	0,02*	
401010	Linseed	0,02*	
401020	Peanuts	0,02*	
401030	Poppy seed	0,02*	
401040	Sesame seed	0,02*	
401050	Sunflower seed	0,02*	
401060	Rape seed (Bird rapeseed, turnip rape)	0,02*	
401070	Soya bean	0,02*	
401080	Mustard seed	0,02*	
401090	Cotton seed	0,02*	
401100	Pumpkin seeds (Other seeds of Cucurbitaceae)	0,02*	
401110	Safflower	0,02*	
401120	Borage (Purple viper's bugloss/Canary flower (Echium plantagineum), Corn Gromwell (Buglossoides arvensis))	0,02*	
401130	Gold of pleasure	0,02*	
401140	Hempseed	0,02*	
401150	Castor bean	0,02*	
401990	Others	0,02*	
402000	(ii) Oilfruits		
402010	Olives for oil production	0,01*	
402020	Palm nuts (palmoil kernels)	0,02*	
402030	Palmfruit	0,02*	
402040	Kapok	0,02*	
402990	Others	0,02*	
500000	5. CEREALS	0,02*	
500010	Barley	0,02*	
500020	Buckwheat (Amaranthus, quinoa)	0,02*	
500030	Maize	0,02*	
500040	Millet (Foxtail millet, teff, finger millet, pearl millet)	0,02*	
500050	Oats	0,02*	
500060	Rice (Indian/wild rice (Zizania aquatica))	0,02*	
500070	Rye	0,02*	
500080	Sorghum	0,02*	
500090	Wheat (Spelt, triticale)	0,02*	
500990	Others (Canary grass seeds (Phalaris canariensis))	0,02*	
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*	
610000	(i) Tea	0,02*	
620000	(ii) Coffee beans	0,02*	
630000	(iii) Herbal infusions (dried)	0,02*	
631000	(a) Flowers	0,02*	
631010	Camomille flowers	0,02*	
631020	Hybiscus flowers	0,02*	
631030	Rose petals	0,02*	
631040	Jasmine flowers (Elderflowers (Sambucus nigra))	0,02*	
631050	Lime (linden)	0,02*	
631990	Others	0,02*	
632000	b) Leaves	0,02*	
632010	Strawberry leaves	0,02*	
632020	Rooibos leaves (Ginkgo leaves)	0,02*	
632030	Maté	0,02*	
632990	Others	0,02*	
633000	(c) Roots	0,02*	
633010	Valerian root	0,02*	
633020	Ginseng root	0,02*	
633990	Others	0,02*	
639000	(d) Other herbal infusions	0,02*	
640000	(iv) Cocoabeans (fermented or dried)	0,02*	
650000	(v) Carob (st johns bread)	0,02*	
700000	7. HOPS (dried)	0,02*	
800000	8. SPICES		
810000	(i) Seeds	0,02*	
810010	Anise	0,02*	
810020	Black caraway	0,02*	
810030	Celery seed (Lovage seed)	0,02*	
810040	Coriander seed	0,02*	
810050	Cumin seed	0,02*	
810060	Dill seed	0,02*	
810070	Fennel seed	0,02*	
810080	Fenugreek	0,02*	
810090	Nutmeg	0,02*	
810990	Others	0,02*	
820000	(ii) Fruits and berries	0,02*	
820010	Allspice	0,02*	
820020	Sichuan pepper (Anise pepper, Japan pepper)	0,02*	
820030	Caraway	0,02*	
820040	Cardamom	0,02*	
820050	Juniper berries	0,02*	
820060	Pepper, black, green and white (Long pepper, pink pepper)	0,02*	
820070	Vanilla pods	0,02*	
820080	Tamarind	0,02*	
820990	Others	0,02*	
830000	(iii) Bark	0,02*	
830010	Cinnamon (Cassia)	0,02*	
830990	Others	0,02*	
840000	(iv) Roots or rhizome		

Code number	Groups and examples of individual products to which the MRLs apply	Cyazofamid	
		Current MRLs	Proposals EFSA 2012b
840010	Liquorice	0,02*	
840020	Ginger	0,02*	
840030	Turmeric (Curcuma)	0,02*	
840040	Horseradish	0,1	
840990	Others	0,02*	
850000	(v) Buds	0,02*	
850010	Cloves	0,02*	
850020	Capers	0,02*	
850990	Others	0,02*	
860000	(vi) Flower stigma	0,02*	
860010	Saffron	0,02*	
860990	Others	0,02*	
870000	(vii) Aril	0,02*	
870010	Mace	0,02*	
870990	Others	0,02*	
900000	9. SUGAR PLANTS	0,01*	
900010	Sugar beet (root)	0,01*	
900020	Sugar cane	0,01*	
900030	Chicory roots	0,01*	
900990	Others	0,01*	
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	0,01*	
1010000	(i) Tissue	0,01*	
1011000	(a) Swine	0,01*	
1011010	Muscle	0,01*	
1011020	Fat	0,01*	
1011030	Liver	0,01*	
1011040	Kidney	0,01*	
1011050	Edible offal	0,01*	
1011990	Others	0,01*	
1012000	(b) Bovine	0,01*	
1012010	Muscle	0,01*	
1012020	Fat	0,01*	
1012030	Liver	0,01*	
1012040	Kidney	0,01*	
1012050	Edible offal	0,01*	
1012990	Others	0,01*	
1013000	(c) Sheep	0,01*	
1013010	Muscle	0,01*	
1013020	Fat	0,01*	
1013030	Liver	0,01*	
1013040	Kidney	0,01*	
1013050	Edible offal	0,01*	
1013990	Others	0,01*	
1014000	(d) Goat	0,01*	
1014010	Muscle	0,01*	
1014020	Fat	0,01*	
1014030	Liver	0,01*	
1014040	Kidney	0,01*	
1014050	Edible offal	0,01*	
1014990	Others	0,01*	
1015000	(e) Horses, asses, mules or hinnies	0,01*	
1015010	Muscle	0,01*	
1015020	Fat	0,01*	
1015030	Liver	0,01*	
1015040	Kidney	0,01*	
1015050	Edible offal	0,01*	
1015990	Others	0,01*	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,01*	
1016010	Muscle	0,01*	
1016020	Fat	0,01*	
1016030	Liver	0,01*	
1016040	Kidney	0,01*	
1016050	Edible offal	0,01*	
1016990	Others	0,01*	
1017000	(g) Other farm animals (Rabbit, kangaroo, deer)	0,01*	
1017010	Muscle	0,01*	
1017020	Fat	0,01*	
1017030	Liver	0,01*	
1017040	Kidney	0,01*	
1017050	Edible offal	0,01*	
1017990	Others	0,01*	
1020000	(ii) Milk	0,01*	
1020010	Cattle	0,01*	
1020020	Sheep	0,01*	
1020030	Goat	0,01*	
1020040	Horse	0,01*	
1020990	Others	0,01*	
1030000	(iii) Bird eggs	0,01*	
1030010	Chicken	0,01*	
1030020	Duck	0,01*	
1030030	Goose	0,01*	
1030040	Quail	0,01*	
1030990	Others	0,01*	
1040000	(iv) Honey (Royal jelly, pollen, honey comb with honey (comb honey))	0,01*	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*	
1060000	(vi) Snails	0,01*	
1070000	(vii) Other terrestrial animal products (Wild game)	0,01*	

(*) Indicates lower limit of analytical determination

(b)-Tentative proposal, derived from a GAP evaluated at EU level, which is not fully supported by data but no risk to consumer was identified.

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation, *French*)
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAD	Diode array detector
DAR	Draft Assessment Report
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EU	European Union
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (former GIFAP)
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
i.e.	that is (id est, *Latin*)
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development

PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RD	residue definition
RMS	rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
STMR	supervised trials median residue
TRR	total radioactive residue
UV	ultra-violet (detector)
WHO	World Health Organisation
YF	yield factor
yr	year