

REASONED OPINION

Reasoned opinion on the modification of the existing MRL for cyazofamid in aubergines¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany hereafter referred to as the evaluating Member State (EMS), received an application from the company ISK Biosciences Europe N.V. to modify the existing MRL for the active substance cyazofamid in aubergines. In order to accommodate for the intended use of cyazofamid, Germany proposed to raise the existing MRL from the limit of quantification of 0.01* mg/kg to 0.2 mg/kg. Germany 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 an MRL proposal of 0.3 mg/kg for tomato, extrapolated to aubergines. Adequate analytical enforcement methods are available to control cyazofamid residues in aubergines. Based on the risk assessment results, EFSA concludes that the proposed use of cyazofamid on aubergines will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

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KEY WORDS

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

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany hereafter referred to as the evaluating Member State (EMS), received an application from the company ISK Biosciences Europe N.V.³ to modify the existing MRL for the active substance cyazofamid in aubergines. In order to accommodate for the intended use of cyazofamid, Germany proposed to raise the existing MRL from the limit of quantification of 0.01* mg/kg to 0.2 mg/kg. Germany 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 May 2014. On 10 September 2014, EFSA requested additional information to the EMS which was submitted on 18 November in an updated evaluation report.

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 acute daily intake (ADI) of 0.17 mg/kg bw per day. No acute reference dose (ARfD) was deemed necessary.

The metabolism of cyazofamid in primary crops was investigated by foliar application in the fruit (tomato, grape) and the root/tuber crop groups (potato) and the residue for enforcement and risk assessment was proposed as cyazofamid. 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 an MRL proposal of 0.3 mg/kg for tomato, extrapolated to aubergines. Adequate analytical enforcement methods are available to control cyazofamid residues in aubergines at the validated LOQ of 0.01* mg/kg. It is noted that

Specific studies investigating the magnitude of cyazofamid in processed commodities were not submitted and are not required.

The occurrence of cyazofamid residues in rotational crops was investigated in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005. Based on the available information, it is concluded that significant residues are unlikely to occur in rotational crops, provided that the compound is used on aubergines according to the proposed GAP (Good Agricultural Practice).

Residues of cyazofamid in commodities of animal origin were not assessed in the framework of this application, since the aubergines are normally not fed to livestock.

In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 a comprehensive dietary exposure assessment was performed, taking into account the existing uses for cyazofamid. EFSA now updates this risk assessment using STMR value aubergines and STMRs proposed on horseradish and grapes in previous reasoned opinions under Article 10 of Regulation (EU) 396/2005. The maximum chronic consumer intake was calculated to be 0.3 % of the ADI (DE child), the contribution of residues in aubergines to the total consumer intake being negligible (< 0.01 % of the ADI).

No acute exposure calculation was conducted as the setting of an ARfD was concluded to be unnecessary for cyazofamid.

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

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Thus EFSA proposes to amend the existing MRL 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				
231030	Aubergines	0.01*	0.3	The MRL was derived by extrapolation from trials conducted on tomato under indoor conditions and no consumer risk was identified for this use. It is highlighted that, based on the same GAP but on a different dataset, an MRL of 0.6 mg/kg has been proposed for tomato under the Article 12 review of the existing MRLs.

(a): According to Annex I of Regulation (EC) No 396/2005.

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

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BACKGROUND

Regulation (EC) No 396/2005⁴ 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/EEC⁵, repealed by Regulation (EC) No 1107/2009⁶, shall submit to a Member State, when appropriate, an application to modify an MRL in accordance with the provisions of Article 7 of that Regulation.

Germany, hereafter referred to as the evaluating Member State (EMS), received an application from the company ISK Biosciences Europe N.V.⁷ to modify the existing MRL for the active substance cyazofamid in aubergines. 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 5 May 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00317 and the following subject:

Cyazofamid - Application to modify the existing MRL in aubergines

Germany proposed to raise the existing MRL of cyazofamid in aubergines from the limit of quantification of 0.01* mg/kg to 0.2 mg/kg.

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

On 10 September EFSA required further clarification regarding three residue trials performed on tomatoes, submitted during Art 12, but not considered under the current application. Following this request the EMS sent an updated evaluation report addressed accordingly on 18 November 2014.

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 August 2014.

⁴ 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, 16.03.2005, p. 1-16.

⁵ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

⁶ 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.

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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).

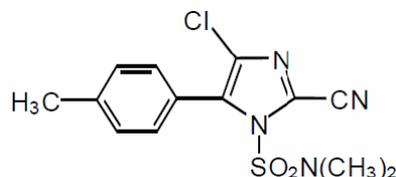


Figure 1: Structure of cyazofamid. Molecular weight: 324.8 g/mol

Cyazofamid belongs to the group of sulfonamide and imidazole compounds which are used as fungicides. It is a protective, contact foliar acting fungicide that needs to be applied in advance of disease attack and expected to provide protection over a period of seven to ten days. It inhibits all stages of the life cycle of oomycetes fungi, including *Phytophthora infestans*, by specifically inhibiting respiration at the mitochondrial cytochrome *bc1* 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 during the peer review were foliar spray on tomato (indoors) and potato (outdoors). Following the peer review, the active substance was included in Annex I to Directive 91/414/EEC by Commission Directive 2003/23/EC⁸, entering into force on 1st July 2003. According to Regulation (EU) No 540/2011⁹, cyazofamid is approved under Regulation (EC) No 1107/2009¹⁰. This approval is restricted to uses as a fungicide only. As EFSA was not involved in the peer review of cyazofamid, an EFSA conclusion is therefore not available.

The EU MRLs for cyazofamid are established in Annexes II of Regulation (EC) No 396/2005. The recommendations derived by EFSA in the framework of the Article 12 MRL review (EFSA, 2012b) were legally bound in Regulation (EU) 398/2014¹¹. The current MRL for cyazofamid in aubergines is 0.01* mg/kg. EFSA also issued reasoned opinions on the modification of the existing MRL for cyazofamid in horseradish (EFSA, 2012a) which was taken over by Regulation (EC) 897/2012. The reasoned opinion on the modification of the MRL in grapes to a value of 2 mg/kg (EFSA 2013) has not yet been considered in the EU legislation.

Codex Alimentarius did not establish CXLs for cyazofamid.

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

⁸ 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.

⁹ 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.

¹⁰ 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.

¹¹ Commission Regulation (EU) No 398/2014 of 22 April 2014 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 benthialdicarb, cyazofamid, cyhalofop-butyl, forchlorfenuron, pymetrozine and silthiofam in or on certain products. OJ L 119, 23.4.2014, p. 3-39. Pesticides - Web Version - EU MRLs check it on 28/08/2014 09:38)

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Germany, 2014), 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, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011¹² and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a,b, 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 during the peer review under Directive 91/414/EEC (France 2001). The analytical method, based on HPLC-UV quantification, was validated in high water content (potato, tomato) and acidic matrices (grapes) with an LOQ of 0.01 mg/kg. 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) analyses cyazofamid residues in with high water, high acid and dry content matrices, at the LOQ of 0.01* mg/kg (CEN, 2008).

Since the commodity under consideration belongs to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRL for cyazofamid on the aubergines.

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, since aubergines are normally 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). They 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 day	2 year rat	100
ARfD	EC	2002	Not necessary		

¹² 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 the fruit (tomato and grape) and on root/tuber (potato) crop groups (France, 2001). The metabolism studies are described in details in the previous reasoned opinion (EFSA, 2013). In all three crops, parent compound was found the major component of the residues. Therefore the residue definition for enforcement and risk assessment were proposed as cyazofamid only.

The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review.

For the uses on aubergines, 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

The applicant provided twenty residue trials on tomatoes conducted under indoor conditions, to support an extrapolation to aubergines (guidance document SANCO 7525/VI/95). Ten trials were however disregarded, since their samples were stored more than one year under frozen conditions, while cyazofamid residues were shown to be stable for no more than 12 months in high water content matrices.

A total of ten compliant trials remain valid to support this application. In each location, two different formulations (with or without adjuvant) were experimented and the highest residue value was selected for MRL calculation. Samples from these trials, were analysed for cyazofamid and its metabolite CCIM within one year after sampling. Cyazofamid residues were in the range of 0.017 to 0.13 mg/kg while, CCIM residues were all below the LOQ (0.01 mg/kg). Based on this dataset, the MRL value of 0.3 mg/kg derived from indoor trials on tomatoes, is extrapolated to aubergines.

It is highlighted that, based on similar GAPs (6×80 g/ha, *PHI 3 days*) **but on a different dataset**, an MRL of 0.6 mg/kg has already been proposed for tomatoes grown under indoor conditions during the review of the existing MRLs under Article 12. Three additional trials, conducted with a less critical GAP (3×40 g/ha *PHI 3 days*), but resulting in higher residue levels (0.05, 0.27 and 0.59 mg/kg) were reported and taken into account to derived an MRL of 0.6 mg/kg. EFSA asked for further clarifications but no information could be provided by the EMS to confirm whether these trials were referring to trials on normal size or cherry tomatoes, since Germany did not reported these three trials during the MRL review. It is therefore proposed to disregard these trials under this MRL application.

Based on the dataset submitted under current application and the additional information made available by the EMS, EFSA concluded that data are sufficient to support the MRL of 0.3 mg/kg for the use on aubergines. For tomatoes, the MRL of 0.6 mg/kg proposed, during the MRL review and implemented into EU legislation by Regulation (EU) 398/2014¹³ remains valid.

The results of the residue trials, the related risk assessment input values (HR, STMR) and the MRL proposal are summarised in Table 3-1.

¹³ Commission Regulation (EU) No 398/2014 of 22 April 2014 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 benthialvalicarb, cyazofamid, cyhalofop-butyl, forchlorfenuron, pymetrozine and silthiofam in or on certain products, OJ L 119, 23.4.2014, p. 3–39.

The stability of cyazofamid residue during storage under frozen conditions (≤ -20 °C) was reconsidered in the framework of the MRLs review under Article 12 (EFSA, 2012b). It was concluded that cyazofamid residues are stable for a maximum of 12 months in high water content (tomato), high acid content (intact grapes not homogenised) and 6 months in high starch content matrices (potato), after which cyazofamid is degraded to CCIM. Having regard to these stability study results, only trials where samples were analysed within one year after sampling, were taken into account for MRL calculation.

According to the EMS, the analytical method used to analyse the supervised residue trial samples has been sufficiently validated and were proven to be fit for the purpose (Germany, 2014).

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.3 mg/kg for the intended use on aubergines, in EU.

Table 3-1: Overview of the available residues trials data

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)	Comments (b)	MRL proposal (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
			Enforcement & risk assessment residue definition: cyazofamid				
Tomatoes	EU	Indoor	0.017; 2 × 0.04; 0.043; 0.06; 0.10; 3 × 0.11, 0.13	MRL _{OECD} = 0.24/0.3 Extrapolation to aubergines	0.3	0.13	0.08

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011).

(b): Statistical estimation of MRLs (unrounded/rounded values) according to the OECD methodology (OECD, 2011) and any useful information.

(c): HR: Highest value of the individual trial results according to the risk assessment residue definition.

(d): STMR: Median value of the individual trial results according to the risk assessment residue definition.

3.1.1.3. Effect of industrial processing and/or household preparation

Specific processing studies were not submitted and are not requested as the total theoretical maximum daily intake (TMDI) amounts to less than 10 % of the ADI (EC, 1997d).

3.1.2. Rotational crops

Aubergines can be grown in rotation with other plants thus the possible occurrence of residues in succeeding crops has to be assessed. During the MRL review under Art. 12, the behaviour of cyazofamid in rotational crops was evaluated. It was then concluded that the residue definition set for primary crops is also applicable to rotational crops and that, no residues are expected in succeeding crops when the active substance is applied according to the intended GAP at a total rate of 480 to 800 g a.s /ha (EFSA, 2012b). Since a total application rate of 480 g/ha is proposed on aubergines, it is concluded that cyazofamid residues are not expected to be present in rotational crops when the active substance is applied according to the proposed GAPs.

3.2. Nature and magnitude of residues in livestock

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

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 population¹⁴ (EFSA, 2007).

In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 a comprehensive dietary exposure assessment was performed, taking into account the existing uses for cyazofamid (EFSA, 2012b). EFSA now updates this risk assessment using for aubergines the STMR derived from the residue trials on tomatoes (see Table 3-1), the STMRs derived for horseradish and grapes in a previous reasoned opinion under Article 10 (EFSA, 2012a and 2013) and the STMR values reported in the framework of the review of MRLs of cyazofamid under article 12. The input values used for the dietary exposure calculation are summarised in Table 4-1.

No acute consumer exposure assessment was performed, since the setting of an ARfD was concluded to be unnecessary for cyazofamid.

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				
Aubergines	0.08	STMR	Acute risk assessment was not performed since no ARfD is necessary for cyazofamid	
Table grapes	0.33	STMR (EFSA 2013)		
Wine grapes	0.03	STMR×PF×YF (EFSA 2013)		
Horseradish	0.03	STMR (EFSA 2012a)		
Commodities assessed during the MRL review	See Table 4-1 in Reasoned Opinion on MRLs review (EFSA, 2012b)			

¹⁴ 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. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

The estimated exposure was then compared with the toxicological reference value 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 total calculated intake accounted for up to 0.3 % of the ADI (DE child). The contribution of cyazofamid residues in aubergines to the total consumer exposure is 0.01 % of the ADI (WHO cluster diet B).

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

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

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 acute daily intake (ADI) of 0.17 mg/kg bw per day. No acute reference dose (ARfD) was deemed necessary.

The metabolism of cyazofamid in primary crops was investigated by foliar application in the fruit (tomato, grape) and the root/tuber crop groups (potato) and the residue for enforcement and risk assessment was proposed as cyazofamid. 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 an MRL proposal of 0.3 mg/kg for tomato, extrapolated to aubergines. Adequate analytical enforcement methods are available to control cyazofamid residues in aubergines at the validated LOQ of 0.01* mg/kg. It is noted that

Specific studies investigating the magnitude of cyazofamid in processed commodities were not submitted and are not required.

The occurrence of cyazofamid residues in rotational crops was investigated in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005. Based on the available information, it is concluded that significant residues are unlikely to occur in rotational crops, provided that the compound is used on aubergines according to the proposed GAP (Good Agricultural Practice).

Residues of cyazofamid in commodities of animal origin were not assessed in the framework of this application, since the aubergines are normally not fed to livestock.

In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 a comprehensive dietary exposure assessment was performed, taking into account the existing uses for cyazofamid. EFSA now updates this risk assessment using STMR value aubergines and STMRs proposed on horseradish and grapes in previous reasoned opinions under Article 10 of Regulation (EU) 396/2005. The maximum chronic consumer intake was calculated to be 0.3 % of the ADI (DE child), the contribution of residues in aubergines to the total consumer intake being negligible (< 0.01 % of the ADI).

No acute exposure calculation was conducted as the setting of an ARfD was concluded to be unnecessary for cyazofamid.

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

RECOMMENDATIONS

Code number^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: cyazofamid				
231030	Aubergines	0.01*	0.3	The MRL was derived by extrapolation from trials conducted on tomato under indoor conditions and no consumer risk was identified for this use. It is highlighted that, based on the same GAP but on a different dataset, an MRL of 0.6 mg/kg has been proposed for tomato under the Article 12 review of the existing MRLs.

(a): According to Annex I of Regulation (EC) No 396/2005.

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

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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 min-max (k)	interval min-max	kg as/hL min-max	Water L/ha Min-max	g a.s./ha min-max		
Aubergines	Indoor	G	<i>Phytophthora infestans</i>	SC	160 g/L	Foliar spray	From BBCH 15	6	7-10 days	6.7	600-1200	40-80	3	application rates depend on crop height

Remarks:

- | | |
|---|--|
| <p>(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)</p> <p>(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> | <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</p> <p>(i) g/kg or g/l</p> <p>(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</p> <p>(k) The minimum and maximum number of application possible under practical conditions of use must be provided</p> <p>(l) PHI - minimum pre-harvest interval</p> |
|---|--|

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		ARID (mg/kg bw):		n.n.			
Source of ADI:		EC		Source of ARID:		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	pTMRs 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	IE adult	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	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	Aubergines (egg plants)		
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 pTMRs were below the ADI. A long-term intake of residues of Cyazofamid is unlikely to present a public health concern.									

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
DAD	Diode array detection
DAR	Draft Assessment Report
DAT	days after treatment
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
MS/MS	tandem mass spectrometry
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)

RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
UV	ultra-violet (detector)
WHO	World Health Organization