REASONED OPINION

Reasoned opinion on the modification of the existing MRL for ametoctradin in hops[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany, hereafter referred to as the EMS, received an application from BASF SE to modify the existing maximum residue level (MRL) for the active substance ametoctradin in hops. In order to accommodate for the intended use of ametoctradin, Germany proposed to raise the existing MRL from the value of 15 mg/kg to 100 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 of 100 mg/kg for the proposed use on hops. However, EFSA is of the opinion that the analytical method is not fully validated for dried hops and therefore, additional data have to be provided to confirm that the proposed analytical method is suitable to enforce ametoctradin residues in dried hops. Based on the risk assessment results, EFSA concludes that the proposed use of ametoctradin on hops will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

KEY WORDS

ametoctradin, hops, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, triazole pyrimidines, fungicides

[1] On request from the European Commission, Question No EFSA-Q--2014-00222, approved on 22 October 2014.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany, hereafter referred to as the EMS, received an application from BASF SE to modify the existing maximum residue level (MRL) for the active substance ametoctradin in hops. In order to accommodate for the intended use of ametoctradin, Germany proposed to raise the existing MRL from the value of 15 mg/kg to 100 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 9 March 2014.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR/its addendum) prepared under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance ametoctradin, the joint meeting on pesticide residues JMPR Evaluation report, as well as the conclusions from the previous EFSA opinion on ametoctradin.

The toxicological profile of ametoctradin 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 10 mg/kg bw per day. No acute reference dose (ARfD) was deemed necessary.

The metabolism of ametoctradin in primary crops was investigated during the peer review in the fruit, leafy and root/tuber groups and the residue definition for enforcement and for risk assessment were proposed as ametoctradin. These residue definitions are applicable to hops.

EFSA concludes that the submitted supervised residue trials are sufficient to derive an MRL of 100 mg/kg for the proposed use on hops. However, EFSA is of the opinion that the analytical method is not fully validated for dried hops and therefore, additional data have to be provided to confirm that the proposed analytical method is suitable to enforce ametoctradin residues in dried hops.

Processing studies were provided and the data were sufficient to derive a processing factor for beer, which is recommended to be included in Annex VI of Regulation (EC) No 396/2005:

- Hops, beer: 0.00045

Since the proposed use of ametoctradin is on permanent crop and is not fed to livestock, investigations of residues in rotational crops and in commodities of animal origin are not required.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of chronic exposure, EFSA used the median residue value derived from the residue trials on hops. For the other commodities of plant and animal origin, the existing MRLs, including the Codex MRL (CXLs) taken into account in the EU legislation were considered. The maximum total chronic intake was estimated to be 0.7 % of the ADI (NL child).

EFSA concludes that the proposed use of ametoctradin on hops will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk. 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: ametoctradin				
700000	Hops	30	100	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. Additional data to confirm that the proposed analytical method is suitable to enforce ametoctradin residues in dried hops are required.

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

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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 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 BASF SE[6] to modify the MRL for ametoctradin in hops. 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 3 April 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00222 and the following subject:

Ametoctradin – Application to modify the existing MRL in hops

Germany proposed to raise the existing MRL of ametoctradin in hops from 15 mg/kg[7] to 100 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 3 July 2014.

[3] 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.

[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.

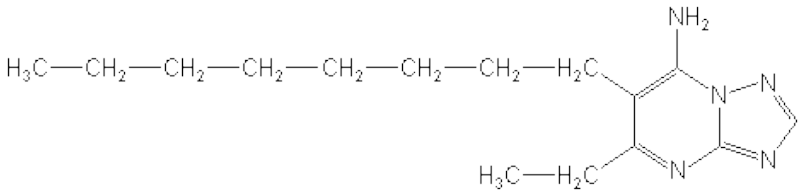
[5] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

[6] BASF SE, P.O. Box 120, 67114, Limburgerhof, Germany.

[7] After the submission of the MRL application, the MRL for hops was increased from 15 to 30 mg/kg by Regulation (EU) No 491/2014 of 5May 2014.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Ametoctradin (under developmental code as BAS 650F) is the provisionally approved ISO common name for 5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine (IUPAC). The chemical structure of the compound is reported below:



Molecular weight: 275.4 g/mol

Ametoctradin acts on *Peronosporomycetes (oomycete*) fungi. It belongs to the chemical class of triazole pyrimidine. The compound has preventive properties and inhibits zoospore development and zoospore and zoosporangium infection of host plants.

Ametoctradin was evaluated in the framework of Council Directive 91/414/EEC with the Netherlands designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Regulation (EU) No 200/2013[8] which entered into force on the 1st of August 2013 as fungicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011[9] ametoctradin is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The representative uses evaluated in the peer review were foliar applications on potatoes and tomatoes. The Draft Assessment Report (DAR) of ametoctradin has been peer reviewed by EFSA; therefore, an EFSA conclusion is available (EFSA, 2012b).

The EU MRLs for ametoctradin are established in Annexes IIIA of Regulation (EC) No 396/2005. Several uses were evaluated by EFSA in MRL applications under Article10 of Regulation 396/2005 that were implemented by the Regulations (EU) 750/2010[10] and 34/2013[11]. Additionally, CXLs established by Codex Alimentarius Commission in 2012 have been taken over in EU legislation by Regulation (EU) 491/2014[12], among these, the CXL for hops set at 30 mg/kg.

The details of the intended GAP for ametoctradin on hops are given in Appendix A.

[8] Commission Implementing Regulation (EU) No 200/2013 of 8 March 2013 approving the active substance ametoctradin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011, OJ L 67, 09.03.2013, p. 1–5.

[9] 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, 11.06.2011, p. 1-186.

[10] Commission Regulation (EU) No 750/2010 of 7 July 2010 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products OJ L 220, 21.08.2010, p. 1–56.

[11] Commission Regulation (EU) No 34/2013 of 16 January 2013 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-phenylphenol, ametoctradin, Aureobasidium pullulans strains DSM 14940 and DSM 14941, cyproconazole, difenoconazole, dithiocarbamates, folpet, propamocarb, spinosad, spirodiclofen, tebufenpyrad and tetraconazole in or on certain products. OJ L 25, 26.01.2013, p. 1–48.

[12] Commission Regulation (EU) No 491/2014 of 5 May 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 ametoctradin, azoxystrobin, cycloxydim, cyfluthrin, dinotefuran, fenbuconazole, fenvalerate, fludioxonil, fluopyram, flutriafol, fluxapyroxad, glufosinate-ammonium, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penthiopyrad, spinetoram and trifloxystrobin in or on certain products. OJ L 146, 16.05.2014, p. 1–91.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Germany, 2014), the Draft Assessment Report (DAR/its addendum) prepared under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of ametoctradin (EFSA, 2012b), the JMPR Evaluation report (FAO, 2012) as well as the conclusions from the previous EFSA opinion on ametoctradin (EFSA, 2012a). 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[13] 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 ametoctradin residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (NL, 2009; EFSA, 2012b). A method based on methanol/water extraction, clean up and final quantification by HPLC-MS/MS was proposed for enforcement purposes. The method was validated for the determination of ametoctradin residues in high water content (tomato, potato), high acid content (orange) and dry commodities (wheat), at the limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2008).

Validation data for determination of ametoctradin in hops using the analytical method describe above, were submitted under this application (Germany, 2014). Recoveries were found to be acceptable for green cone analysis, but low recoveries (31 %) were observed in one study for dried cones. EFSA is therefore of the opinion that the analytical method is not fully validated for dried hops and that additional data have to be provided to confirm that the proposed analytical method is suitable to enforce ametoctradin residues in dried hops.

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 hops are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance ametoctradin was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2012b). The data were sufficient to derive toxicological reference values for ametoctradin which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Ametoctradin					
ADI	EFSA	2012	10 mg/kg bw per day	Overall NOAEL	100
ARfD	EFSA	2012	Not necessary		

It is noted that JMPR has concluded that the setting of an ADI and ARfD was not necessary for ametoctradin (FAO, 2012).

[13] 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

In the framework of the peer review under Directive 91/414/EEC, the metabolism of ametoctradin was investigated in primary crops in the fruit (tomato), leafy (lettuce) and root/tuber (potato) groups. From these studies, EFSA established the residue definitions for monitoring and risk assessment as ametoctradin (EFSA, 2012b).

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 use on hops (leafy crop), EFSA concludes that the metabolism of ametoctradin is sufficiently addressed and the residue definitions agreed in the peer review are applicable.

3.1.1.2. Magnitude of residues

In support of the MRL application, the EMS submitted four residue trials conducted in 2009-2010 in Germany, according to the proposed GAP *(2x800 g/ha; PHI 10 days)*. Green and dried cone samples were analysed for ametoctradin. Since low recoveries (31 %) were observed in one study for the analysis conducted on dried cones, the EMS proposed to use the residue levels measured in the green cones, corrected by a dehydration factor of 4.5. The dehydration factor was calculated considering water content of 80 % and 10 % in fresh and dried cones respectively (Germany, 2014).

Since dried hops is a difficult matrix to be analysed and low recoveries for dried hops were observed in a study related to two residue trials, EFSA agreed with the approach proposed by the EMS, to derive the MRL value from the analysis conducted on green cones, corrected by the dehydration factor (Germany, 2014). Therefore, EFSA concluded that the analytical method for green cones was fully validated, in contrast on dried hops, additional validation data are required.

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

The storage stability of ametoctradin in primary crops was investigated in the DAR under Directive 91/414/EEC (NL, 2010). Ametoctradin residues are stable during frozen storage for 2 years in potato, lettuce (high water content matrices), wheat forage, straw and grain (dry commodities) and for 3 years in tomatoes (high water content matrix). 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.

EFSA concludes that the data are sufficient to derive a MRL proposal of 100 mg/kg for the intended use on hops in NEU.

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

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg) Enforcement & Risk assessment (ametoctradin)	STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
Ametoctradin								
Hops	NEU	Outdoor	Dried cones: 8.7; 15.0; 31.0; 36.0 (Underlined values: Low analytical recoveries; 31 %)					MRL derived from the calculated dried cone levels.
			Green cones: 3.2; 6.6; 9.1; 10.0 Dried cones: 14.0, 29.7; 41.0; 45.0 (calculated) (calculated levels derived from green cone levels considering a dehydration factor of 4.5)	35.4	45.0	100	Not applicable	Rber=88 Rmax=103 MRLOECD = 98/100

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011).
(b): STMR: Median value of the individual trial results according to the risk assessment residue definition.
(c): HR: Highest Residue of the individual trial results according to the risk assessment 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).

3.1.1.3. Effect of industrial processing and/or household preparation

Ametoctradin was shown to be stable under conditions simulating pasteurisation, baking/brewing/boiling and sterilisation, and thus for processed commodities the same residue definitions as in primary plant commodities are applicable.

Specific studies on the magnitude of ametoctradin residues in processed commodities are not required as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10 % of the ADI (EC, 1997d). However, processing studies were submitted under this application and the results are summarized in the table below:

Table 3-2: Overview of the available processing studies

Processed commodity	**Number of studies**	**Median PF** [(a)]	**Median CF**[(b)]	**Comments** (individual PF)
Enforcement residue definition: ametoctradin				
Hops, extracted	3	0.34	n.a.	(0.22; 0.34; 0.53)
Beer	3	$<4.55 \times 10^{-4}$	n.a.	$(<4.35; <4.55; <7.14) \times 10^{-4}$

(a): The median processing factor (PF) is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor (CF) for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study. (n.a.: not applicable)

EFSA recommends the inclusion of the derived processing factor for beer in Annex VI of Regulation (EC) No 396/2005.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

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

3.2. Nature and magnitude of residues in livestock

Since hops are not normally fed to livestock, the nature and magnitude of ametoctradin 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 population [14] (EFSA, 2007).

For the calculation of chronic exposure, EFSA used the median residue value as derived from the residue trials on hops (see Table 3-1). For the remaining commodities of plant and animal origin, the existing MRLs, as established in Annex IIIA of Regulation (EC) No 396/2005, including the CXLs transposed into EU legislation, were used as input values.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been

[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 one regional and four 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).

treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

No acute exposure assessment was performed as no ARfD was deemed necessary for this active substance. 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	
	Input value (mg/kg)	**Comment**
Risk assessment residue definition: ametoctradin		
Hops dried (calculated)	35.4	STMR
Other commodities of plant and animal origin	MRLs	Existing MRLs implemented by Regulation (EU) 491/2014[15]

The estimated exposure was then compared with the toxicological reference value derived for ametoctradin (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 0.7 % of the ADI (NL child). The contribution of residues in hops to the total consumer exposure was negligible (lower than 0.01 % of the ADI.

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

[15] Commission Regulation (EU) No 491/2014 of 5 May 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 ametoctradin, azoxystrobin, cycloxydim, cyfluthrin, dinotefuran, fenbuconazole, fenvalerate, fludioxonil, fluopyram, flutriafol, fluxapyroxad, glufosinate-ammonium, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penthiopyrad, spinetoram and trifloxystrobin in or on certain products OJ L 146, 16.05.2014, p. 1–91.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of ametoctradin 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 10 mg/kg bw per day. No acute reference dose (ARfD) was deemed necessary.

The metabolism of ametoctradin in primary crops was investigated during the peer review in the fruit, leafy and root/tuber groups and the residue definition for enforcement and for risk assessment were proposed as ametoctradin. These residue definitions are applicable to hops.

EFSA concludes that the submitted supervised residue trials are sufficient to derive an MRL of 100 mg/kg for the proposed use on hops. However, EFSA is of the opinion that the analytical method is not fully validated for dried hops and therefore, additional data have to be provided to confirm that the proposed analytical method is suitable to enforce ametoctradin residues in dried hops.

Processing studies were provided and the data were sufficient to derive a processing factor for beer, which is recommended to be included in Annex VI of Regulation (EC) No 396/2005:

- Hops, beer: 0.00045

Since the proposed use of ametoctradin is on permanent crop and is not fed to livestock, investigations of residues in rotational crops and in commodities of animal origin are not required.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of chronic exposure, EFSA used the median residue value derived from the residue trials on hops. For the other commodities of plant and animal origin, the existing MRLs, including the Codex MRL (CXLs) taken into account in the EU legislation were considered. The maximum total chronic intake was estimated to be 0.7 % of the ADI (NL child).

EFSA concludes that the proposed use of ametoctradin on hops 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: ametoctradin				
700000	Hops	30	100	The MRL proposal is sufficiently supported by data and no consumer health risk was identified. Additional data to confirm that the proposed analytical method is suitable to enforce ametoctradin residues in dried hops are required.

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

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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	kg a.s./ha Min-max		
Hops	DE	F	Downy mildew	SC	0.3	spraying		1-2	(≥8 days)	0.005-0.081*	1000-4000	0.8	10	*spraying **atomizing
										0.007-0.116**	700-2800			

Remarks:
(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)

Ametoctradin			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**10**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**RMS**	Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
0	1
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)
0.7	NL child	0.2	Spinach	0.1	Scarole (broad-leaf endive)	0.1	Kale	
0.7	WHO Cluster diet B	0.2	Lettuce	0.1	Wine grapes	0.1	Tomatoes	
0.6	FR toddler	0.4	Spinach	0.0	Leek	0.0	Broccoli	
0.5	IT adult	0.2	Lettuce	0.1	Other lettuce and other salad plants	0.1	Spinach	
0.5	FR all population	0.2	Wine grapes	0.1	Other lettuce and other salad plants	0.0	Lettuce	
0.4	ES adult	0.3	Lettuce	0.0	Beet leaves (chard)	0.0	Spinach	
0.4	NL general	0.1	Spinach	0.1	Lettuce	0.1	Scarole (broad-leaf endive)	
0.4	WHO regional European diet	0.2	Lettuce	0.1	Head cabbage	0.0	Tomatoes	
0.4	IE adult	0.1	Wine grapes	0.1	Wine grapes	0.0	Lettuce	
0.4	IT kids/toddler	0.1	Lettuce	0.1	Other lettuce and other salad plants	0.0	Beet leaves (chard)	
0.4	SE general population 90th percentil	0.1	Chinese cabbage	0.1	Head cabbage	0.0	Spinach	
0.4	DE child	0.1	Spinach	0.1	Table grapes	0.0	Lettuce	
0.4	FR infant	0.3	Spinach	0.0	Broccoli	0.0	Leek	
0.4	ES child	0.2	Lettuce	0.0	Spinach	0.0	Beet leaves (chard)	
0.4	WHO cluster diet D	0.1	Chinese cabbage	0.0	Kale	0.0	Head cabbage	
0.4	WHO cluster diet E	0.1	Wine grapes	0.0	Lettuce	0.0	Head cabbage	
0.3	WHO Cluster diet F	0.2	Lettuce	0.0	Head cabbage	0.0	Chinese cabbage	
0.2	UK vegetarian	0.1	Lettuce	0.0	Wine grapes	0.0	Spinach	
0.2	PT General population	0.1	Wine grapes	0.0	Tomatoes	0.0	Table grapes	
0.2	UK Adult	0.1	Wine grapes	0.1	Lettuce	0.0	Spinach	
0.2	DK child	0.1	Lettuce	0.0	Cucumbers	0.0	Head cabbage	
0.1	DK adult	0.1	Wine grapes	0.0	Head cabbage	0.0	Chinese cabbage	
0.1	PL general population	0.1	Head cabbage	0.0	Table grapes	0.0	Tomatoes	
0.1	UK Toddler	0.0	Spinach	0.0	Table grapes	0.0	Head cabbage	
0.1	FI adult	0.0	Lettuce	0.0	Chinese cabbage	0.0	Wine grapes	
0.1	LT adult	0.1	Head cabbage	0.0	Lettuce	0.0	Tomatoes	
0.1	UK Infant	0.0	Cauliflower	0.0	Brussels sprouts	0.0	Head cabbage	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Ametoctradin 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
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
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
i.e.	that is (id est, *Latin*)
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	Member States
MS/MS	tandem mass spectrometry
NEU	northern European Union
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development
PF	processing factor

PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
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
STMR	supervised trials median residue
WHO	World Health Organization
yr	year