European Food Safety Authority

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REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for bifenazate in blueberries, cranberries, gooseberries and azaroles (kiwiberries)[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, Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing maximum residue levels (MRLs) for the active substance bifenazate in blueberries, cranberries, gooseberries and azaroles (based on the intended use on kiwiberries). In order to accommodate for the intended uses of bifenazate, Belgium proposed to raise the existing maximum residue limits (MRLs) from the limit of quantification (LOQ) to 0.7 mg/kg. Belgium 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 a MRL proposal of 0.7 mg/kg for the intended indoor use on blueberries, cranberries, gooseberries and kiwiberries (azaroles). The intended outdoor use in Belgium is not supported by residue data. Adequate analytical enforcement methods are available to control the residues of bifenazate in the commodities under consideration. Based on the risk assessment results, EFSA concludes that the proposed uses of bifenazate on blueberries, cranberries, gooseberries and kiwiberries (azaroles) will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

KEY WORDS

bifenazate, small berry fruits, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, carbazate acaricide, bifenazate-diazene

[1] On request from the European Commission, Question No EFSA-Q-2014-00599, approved on 10 March 2015.

[2] Correspondence: pesticides.mrl@efsa.europa.eu

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing maximum residue levels (MRLs) for the active substance bifenazate in blueberries, cranberries, gooseberries and azaroles (based on the intended use on kiwiberries). In order to accommodate for the intended uses of bifenazate, Belgium proposed to raise the existing maximum residue limits (MRLs) from the limit of quantification (LOQ) to 0.7 mg/kg. Belgium 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 1 September 2014.

EFSA bases its assessment on the Evaluation report, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC, the Commission Review Report, the JMPR Reports and previous EFSA reasoned opinions, including the reasoned opinion on the review of the existing MRLs for bifenazate under Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of bifenazate was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg bw per day. No acute reference dose (ARfD) was deemed necessary.

The metabolism of bifenazate in primary crops was investigated in the fruit crop group only, on orange, apple and grape. EFSA proposed to define the residue for both enforcement and risk assessment in the fruit crop group as bifenazate, sum of bifenazate and bifenazate-diazene, expressed as bifenazate. The residue definition for enforcement proposed by EFSA has been recently implemented in the EU legislation and applies to the small berry fruits under consideration.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.7 mg/kg for the intended indoor use on blueberries, cranberries, gooseberries and kiwiberries (azaroles). The intended outdoor use in Belgium is not supported by residue data. Adequate analytical enforcement methods are available to control the residues of bifenazate in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

Since bifenazate was hydrolytically stable under standard hydrolysis conditions representative of pasteurisation, boiling/cooking and sterilisation, the same residue definition as for raw agricultural commodities (RAC) is applicable for processed commodities. Specific studies investigating the magnitude of bifenazate residues in processed commodities are not required considering the low contribution of residues in these small berry fruits to the total chronic consumer exposure.

Since the proposed use of bifenazate is on permanent/semi-permanent crops, investigations of residues in rotational crops are not required.

Residues of bifenazate in commodities of animal origin were not assessed in the framework of this application, since small berry fruits are not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA updated the most recent long-term consumer exposure assessment performed in the framework of a previous MRL application with the supervised trials median residue (STMR) derived from the trials conducted on currants. Those food commodities for which no uses of bifenazate were reported in the framework of the Article 12 review and in the subsequent reasoned opinions or for which no safe Codex maximum residue limits (CXLs) were identified, were excluded from the exposure calculation, assuming that there is no uses on these crops. No acute consumer exposure assessment was performed as the setting of an ARfD was not necessary for bifenazate.

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 65 % of the ADI (German child). The

contribution of residues in the small berry fruits under consideration to the total consumer exposure accounted for a maximum of 0.07 % of the ADI for blueberries (Finnish adult).

EFSA concludes that the proposed uses of bifenazate on blueberries, cranberries, gooseberries and kiwiberries (azaroles) 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 MRLs as reported in the summary table.

SUMMARY TABLE

Code[(a)]	**Commodity**	**Existing EU MRL** (mg/kg)	**Proposed EU MRL** (mg/kg)	**Comment/Justification**
Enforcement residue definition: Bifenazate (sum of bifenazate plus bifenazate-diazene expressed as bifenazate) (F) (A)				
0154010	Blueberries	0.01*	0.7	Supported by extrapolation from indoor trials on red currats. Outdoor use in NEU is not supported by residue data. To support the use on kiwiberries, the MRL of 0.7 mg/kg is proposed on the food commodity azaroles (code 0154070), since under Regulation (EU) No 752/2014, the MRL for kiwiberries is still covered by azaroles until 1 January 2017. By this date, the MRL for kiwiberries will be covered by the MRL on table grapes (code 0151010). It is noted that the current MRL on table grapes under Regulation (EC) No 396/2005 is 0.7 mg/kg.
0154020	Cranberries	0.01*	0.7	
0154040	Gooseberries (green, red and yellow)	0.01*	0.7	
0154070	Azaroles/Mediterranean medlars	0.01*	0.7	

(a): According to Annex I of Regulation (EC) No 396/2005.
(A): The European Union reference laboratories identified the reference standard for bifenazate-diazene as commercially not available. When re-viewing the MRL, the Commission will take into account the commercial availability of the reference standard referred to in the first sentence by 22 March 2015, or, if that reference standard is not commercially available by that date, the unavailability of it.
(F): Fat-soluble.
* The MRL is set at the limit of analytical quantification.

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BACKGROUND

Regulation (EC) No 396/2005[3] establishes the rules governing the setting of pesticide maximum residue levels (MRL) 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.

Belgium, hereafter referred to as the EMS, compiled an application to modify the existing MRLs for bifenazate in certain small fruits and berries. This application was notified to the European Commission and EFSA and was subsequently evaluated 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 1 September 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00599 and the following subject:

Bifenazate - Application to modify the existing MRLs in blueberries, cranberries, gooseberries and azaroles.

Belgium proposed to raise the existing MRLs of bifenazate in blueberries, cranberries, gooseberries and on azaroles (kiwiberries), based on the intended use on kiwiberries, from the LOQ of 0.01 mg/kg to 0.7 mg/kg. At time of the submission of the application, a specific code number was not allocated in Annex I of Regulation (EC) No 396/2005 to kiwiberries, the MRL for kiwiberries being covered by the MRL set on the food commodity azaroles (code 0154070). Meanwhile, kiwiberries have been reclassified by Commission Regulation (EU) No 752/2014[6] under the food commodity table grapes (code 0151010). However, it is highlighted that until 1 January 2017, the MRL on azaroles applies to kiwiberries.

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 1 December 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] Commission Regulation (EU) No 752/2014 of 24 June 2014 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council. OJ L 208, 15.07.2014, p. 1-71.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Bifenazate is the ISO common name for isopropyl 2-(4-methoxybiphenyl-3-yl)hydrazinoformate (IUPAC). The chemical structure of the compound is reported below.

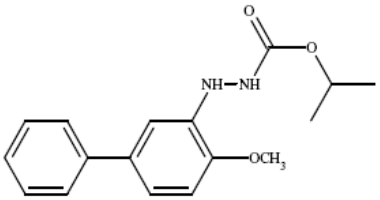

Figure 1: Structure of bifenazate. Molecular weight: 300.4 g/mol

Bifenazate is a non-systemic active substance which belongs to the group of carbazate acaricides. The mode of action is based on the post-synaptic inhibitory of the γ-aminobutyric acid (GABA) receptor in the nervous system of spider mites.

Bifenazate 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 Commission Directive 2005/58/EC[7] which entered into force on 1 December 2005 for use as acaricide. In accordance with Commission Implementing Regulation (EU) No 540/2011[8] bifenazate is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses supported by the applicant for the approval of the active substance were foliar applications on ornamentals in glasshouse. The Draft Assessment Report (DAR) of bifenazate was not peer reviewed by EFSA, therefore no EFSA conclusion is available.

The EU MRLs for bifenazate are established in Annex II of Regulation (EC) No 396/2005. All MRLs have been reviewed in the framework of Article 12 of Regulation (EC) No 396/2005 and afterwards amended two times, taking into account the recommendations of EFSA (EFSA, 2011, 2012a, 2012b). The existing EU MRLs for bifenazate on the crops under consideration are set at the LOQ of 0.01 mg/kg. Codex Alimentarius has established CXLs for several commodities, but no CXLs have been set for the crops under consideration.

The details of the intended good agricultural practices (GAPs) for bifenazate are given in Appendix A.

ASSESSMENT

EFSA bases its assessment on the Evaluation report submitted by the EMS (Belgium, 2014), the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (the Netherlands, 2003), the Commission Review Report on bifenazate (EC, 2005), the JMPR Reports (FAO, 2006, 2008, 2010) and previous EFSA Reasoned opinions, including the Reasoned opinion on the review of the existing MRLs for bifenazate under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011, 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[9] 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).

[7] Commission Directive 2005/58/EC of 21 September 2005 amending Council Directive 91/414/EEC to include bifenazate and milbemectin as active substances. OJ L 246, 22.09.2005, p. 17-19.

[8] 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.

[9] 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.

1. Method of analysis

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

Analytical methods for the determination of residues of bifenazate in plant commodities were assessed in the framework of the review of the existing MRLs for bifenazate under Article 12 of Regulation (EC) No 396/2005. EFSA concluded that adequate analytical methods are available to monitor bifenazate residues in high water, high acidic and high oil content and in dry commodities at the LOQ of 0.01 mg/kg (EFSA, 2011).

Since the commodities under consideration belong to the group of high acid content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for bifenazate 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 the crops under consideration are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance bifenazate was assessed under Council Directive 91/414/EEC (EC, 2005). The data were sufficient to derive toxicological reference values for bifenazate which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Bifenazate					
ADI	EC	2005	0.01 mg/kg bw per day	90 d & 12 mo oral dog, 104 wk oral rat	100
ARfD	EC	2005	Not necessary.		

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

As the representative uses supported for the peer review process were uses on ornamentals, no data on the residue behaviour of bifenazate in plants were reported in the DAR. The metabolism of bifenazate has been assessed in the framework of the Article 12 MRL review, in the fruit crop group only (orange, apple and grape) and considering a single foliar application.

The characteristics of these studies are summarised in Table 3-1 below and detailed assessment is available in the EFSA reasoned opinion on the review of the existing MRLs under Article 12 (EFSA, 2011).

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

Crop group	Crop	Application and sampling				
		Method	**Rate (g/ha)**	**No**	**Sampling (DAT)(a)**	**Remarks**
Fruit	Orange	Foliar	420 & 2240	1	43, 184, 274, 442	-
	Apple	Foliar	420 & 2240	1	0 (leaf), 101	
	Grape	Foliar	560 & 1120	1	0, 30	

(a): DAT: Day after treatment

Based on these metabolism studies, EFSA proposed to define the residue for both enforcement and risk assessment in the fruit crop group as bifenazate (sum of bifenazate plus bifenazate-diazene, expressed as bifenazate). The residue definition for enforcement previously set as bifenazate under Regulation (EC) No 396/2005 has been recently amended by Commission Regulation (EU) No 79/2014[10] to take over the recommendation of the Article 12 MRL review and to define the residue for monitoring as bifenazate (sum of bifenazate plus bifenazate-diazene, expressed as bifenazate).

For the crops considered, EFSA concludes that the metabolism of bifenazate is sufficiently addressed and the residue definitions for enforcement and risk assessment are applicable

3.1.1.2. Magnitude of residues

Outdoor (NEU). No residue trials were submitted. To support the intended use either a sufficient number of field residue trials or the evidence that the outdoor use is less critical for residues compared to the indoor use should be provided.

Indoor. Belgium proposes to extrapolate to blueberries, cranberries, gooseberries and azaroles (kiwiberries), the MRL value of 0.7 mg/kg derived from four indoor decline trials conducted on red currants and already assessed by EFSA in a previous MRL application (EFSA, 2012a). According to EU guidance document, extrapolation from data on currant is possible and four trials are sufficient when extrapolating to another minor crop of the same group (EC, 2011). Although slightly underdosed, but within the 25 % tolerance[11], the data are considered supporting the MRL proposal of 0.7 mg/kg for the intended indoor use.

It is highlighted that according to Commission Regulation (EU) No 752/2014 and until 1 January 2017, the MRL for kiwiberries is covered by the MRL set on azaroles (code 0154070). Therefore, to cover the intended use on kiwiberries, the MRL is proposed for the food commodity azaroles. By this date, kiwiberries MRL will be covered by the food commodity table grapes (code 0151010). It is noted that the current MRL for table grapes under Regulation (EC) No 396/2005 is 0.7 mg/kg.

The results of the residue trials, the related risk assessment input values (HR, STMR) and the MRL proposal are summarised in Table 3-2.

Based on the available information, EFSA concluded that residues of bifenazate (sum of bifenazate and bifenazate-diazene, expressed as bifenazate) were stable for at least six months in a large range of commodities with high water and high acid content (EFSA, 2011). The samples from the supervised residue trials on currants were considered valid with regard to storage stability and analysed using an appropriate analytical method (EFSA, 2012a; Belgium, 2014).

[10] Commission Regulation (EU) No 79/2014 of 29 January 2014 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, chlorpropham, esfenvalerate, fludioxonil and thiobencarb in or on certain products. OJ L 27, 30.01.2004, p. 9-55

[11] Except the 2nd application (-26 %) of one of the four trials, the application rates were about 20 to 25 % lower than the intended application rate.

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.7 mg/kg for the intended indoor use on blueberries, cranberries, gooseberries and azaroles.

The intended outdoor use on these crops in Belgium is not adequately supported by residue data and no MRL proposal can be therefore derived.

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

Crop (trial GAP)	**Region/ Indoor** (a)	**Individual trials results** (mg/kg) (b)	**Recommendations/comments** (c)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (d)	**STMR** (mg/kg) (e)
Red currants (2× 106 to 115 g/ha)	NEU	No data available.		-	-	-
	Indoor	0.12; 2× 0.23; 0.<u>26</u>	Data already assessed by EFSA (EFSA, 2012a). Trials slightly underdosed (supported GAP 2× 144 g/ha). <u>Underlined</u>: value measured at a longer PHI (3 days) than the PHI of the intended GAP. MRL_{OECD}: 0.63/0.7 **Extrapolation to blueberries, cranberries, gooseberries and azaroles**.	**0.7**	0.26	0.23

(a): **NEU:** Outdoor trials conducted in northern Europe, **SEU:** Outdoor trials conducted in southern Europe, **Indoor:** indoor EU trials or **Country code:** if non-EU trials (EC, 2011).
(b): Individual residue levels considered for MRL calculation are reported in ascending order.
(c): Any information/comment supporting the decision and OECD MRL calculation, unrounded values.
(d) **STMR:** Median value of the individual trial results according to residue definition for risk assessment.
(e): **HR**: Highest value of the individual trial results according to the residue definition for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

Based on the results of a standard hydrolysis study assessed in the framework of a previous reasoned opinion (EFSA, 2012b), EFSA concluded that the compound is hydrolytically stable under the representative processing conditions. Thus, for processed commodities the same residue definition as for RAC is applicable.

Studies investigating the magnitude of bifenazate residues in processing were not submitted and are not required because of the low contribution of residues in the berries under consideration to the total chronic consumer exposure.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Since the proposed use of bifenazate is on permanent/semi-permanent crops, investigations of residues in rotational crops are not required.

3.2. Nature and magnitude of residues in livestock

Since berries are not normally fed to livestock, the nature and magnitude of bifenazate residues in livestock is not assessed in the framework of this application.

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[12] (EFSA, 2007).

For the calculation of the chronic exposure, EFSA updated the most recent long-term consumer exposure assessment performed in the framework of a previous MRL application including the STMR value derived from the residue studies on currants for the crops under consideration (see Table 3-2). Those food commodities, for which no uses of bifenazate were reported in the framework of the Article 12 review (EFSA, 2011) and in the subsequent reasoned opinions (EFSA 2012a, 2012b) or for which no safe CXLs were identified (EFSA, 2011), were excluded from the exposure calculation, assuming that there is no uses on these crops.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all the food items consumed have been treated with the active substance under consideration. In reality, it is not likely that the food consumed will contain residues at levels of the STMR 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 consumer exposure assessment was performed as the setting of an ARfD was not necessary for bifenazate.

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

[12] 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).

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

Commodity	Chronic exposure assessment	
	Input value (mg/kg)	**Comment**
Risk assessment residue definition: Bifenazate (sum bifenazate and bifenazate-diazene expressed as bifenazate)		
blueberries	0.23	STMR (currant, indoor)
cranberries	0.23	STMR (currant, indoor)
gooseberries	0.23	STMR (currant, indoor)
azaroles (kiwiberries)	0.23	STMR (currant, indoor)
Other commodities of plant and animal origin	See Table 4.1 of the EFSA Reasoned opinion on the modification of the existing MRLs for bifenazate in citrus fruit, pome fruit, stone fruit, grapes, hops, strawberries, tomatoes, peppers, aubergines, melons and watermelons (EFSA, 2012b).	

The estimated exposure was then compared with the toxicological reference value derived for bifenazate (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 65 % of the ADI (German child). The contribution of residues in the small berry fruits under consideration to the total consumer exposure accounted for a maximum of 0.07 % of the ADI for blueberries (Finnish adult).

EFSA concludes that the intended uses of bifenazate on blueberries, cranberries, gooseberries and azaroles 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

CONCLUSIONS

The toxicological profile of bifenazate was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg bw per day. No acute reference dose (ARfD) was deemed necessary.

The metabolism of bifenazate in primary crops was investigated in the fruit crop group only, on orange, apple and grape. EFSA proposed to define the residue for both enforcement and risk assessment in the fruit crop group as bifenazate, sum of bifenazate and bifenazate-diazene, expressed as bifenazate. The residue definition for enforcement proposed by EFSA has been recently implemented in the EU legislation and applies to the small berry fruits under consideration.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.7 mg/kg for the intended indoor use on blueberries, cranberries, gooseberries and kiwiberries (azaroles). The intended outdoor use in Belgium is not supported by residue data. Adequate analytical enforcement methods are available to control the residues of bifenazate in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

Since bifenazate was hydrolytically stable under standard hydrolysis conditions representative of pasteurisation, boiling/cooking and sterilisation, the same residue definition as for raw agricultural commodities (RAC) is applicable for processed commodities. Specific studies investigating the magnitude of bifenazate residues in processed commodities are not required considering the low contribution of residues in these small berry fruits to the total chronic consumer exposure.

Since the proposed use of bifenazate is on permanent/semi-permanent crops, investigations of residues in rotational crops are not required.

Residues of bifenazate in commodities of animal origin were not assessed in the framework of this application, since small berry fruits are not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA updated the most recent long-term consumer exposure assessment performed in the framework of a previous MRL application with the supervised trials median residue (STMR) derived from the trials conducted on currants. Those food commodities for which no uses of bifenazate were reported in the framework of the Article 12 review and in the subsequent reasoned opinions or for which no safe Codex maximum residue limits (CXLs) were identified, were excluded from the exposure calculation, assuming that there is no uses on these crops. No acute consumer exposure assessment was performed as the setting of an ARfD was not necessary for bifenazate.

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 65 % of the ADI (German child). The contribution of residues in the small berry fruits under consideration to the total consumer exposure accounted for a maximum of 0.07 % of the ADI for blueberries (Finnish adult).

EFSA concludes that the proposed uses of bifenazate on blueberries, cranberries, gooseberries and kiwiberries (azaroles) will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

RECOMMENDATIONS

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: Bifenazate (sum of bifenazate plus bifenazate-diazene expressed as bifenazate) (F) (A)				
0154010	Blueberries	0.01*	0.7	Supported by extrapolation from indoor trials on red currats. Outdoor use in NEU is not supported by residue data. To support the use on kiwiberries, the MRL of 0.7 mg/kg is proposed on the food commodity azaroles (code 0154070), since under Regulation (EU) No 752/2014, the MRL for kiwiberries is still covered by azaroles until 1 January 2017. By this date, the MRL for kiwiberries will be covered by the MRL on table grapes (code 0151010). It is noted that the current MRL on table grapes under Regulation (EC) No 396/2005 is 0.7 mg/kg.
0154020	Cranberries	0.01*	0.7	
0154040	Gooseberries (green, red and yellow)	0.01*	0.7	
0154070	Azaroles/Mediterranean medlars	0.01*	0.7	

(a): According to Annex I of Regulation (EC) No 396/2005.
(A): The European Union reference laboratories identified the reference standard for bifenazate-diazene as commercially not available. When re-viewing the MRL, the Commission will take into account the commercial availability of the reference standard referred to in the first sentence by 22 March 2015, or, if that reference standard is not commercially available by that date, the unavailability of it.
(F): Fat-soluble.
* 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. a.s. (i)	Method kind (f-h)	Growth stage & season (j)	number min-max (k)	interval min-max	g as/hL min-max	Water L/ha min-max	g a.s./ha min-max		
Blueberries, Gooseberries, Cranberries	Belgium	F	Spider mite	SC	240 g/L	spraying	BBCH 10-97	2	7 days			144	1	
		I												
Kiwiberries	Belgium	F	Spider mite	SC	240 g/L	spraying		2	7 days			144	1	
		I												

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)

Bifenazate			
Status of the active substance:	**approved**	Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2005**	Year of evaluation:	**2005**

Chronic risk assessment - refined calculations

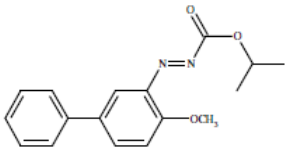
TMDI (range) in % of ADI
minimum - maximum
7 65

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)
65.1	DE child	21.1	Apples	10.3	Citrus fruit	8.6	Oranges	1.5
58.3	NL child	11.1	Apples	9.1	Citrus fruit	7.6	Beans (with pods)	3.2
43.9	FR toddler	16.6	Beans (with pods)	5.3	Citrus fruit	5.2	Peas (without pods)	0.2
43.4	IE adult	6.0	Citrus fruit	4.3	Basil	3.3	Peas (without pods)	0.5
38.6	WHO Cluster diet B	5.5	Peppers	5.0	Beans (with pods)	4.3	Tomatoes	0.6
33.1	FR infant	12.6	Beans (with pods)	4.4	Apples	3.9	Peas (without pods)	2.6
26.5	WHO cluster diet E	4.2	Beans (with pods)	3.4	Beans (without pods)	3.0	Wine grapes	0.5
25.6	UK Toddler	5.2	Citrus fruit	4.5	Oranges	4.4	Peas (without pods)	0.1
24.3	ES child	5.3	Citrus fruit	4.9	Oranges	3.6	Beans (with pods)	1.6
23.7	NL general	4.2	Citrus fruit	3.8	Beans (with pods)	3.3	Oranges	0.8
22.9	PT General population	4.6	Wine grapes	3.8	Beans (without pods)	2.9	Peas (without pods)	0.0
22.1	UK Infant	8.6	Peas (without pods)	3.0	Citrus fruit	2.9	Oranges	0.1
21.9	WHO regional European diet	3.5	Peas (with pods)	3.0	Beans (with pods)	2.5	Peas (without pods)	0.8
21.7	SE general population 90th percentile	3.1	Citrus fruit	2.1	Peppers	1.8	Apples	1.2
19.3	ES adult	3.5	Beans (with pods)	3.3	Citrus fruit	2.9	Oranges	0.7
17.1	FR all population	7.4	Wine grapes	2.1	Beans (with pods)	1.5	Citrus fruit	0.4
14.5	IT kids/toddler	2.0	Tomatoes	1.7	Citrus fruit	1.6	Apples	0.0
14.2	UK vegetarian	2.4	Citrus fruit	2.0	Peas (without pods)	1.9	Oranges	0.0
14.0	WHO Cluster diet F	2.5	Citrus fruit	2.0	Oranges	1.3	Peas (with pods)	0.6
13.3	IT adult	2.3	Beans (with pods)	1.6	Tomatoes	1.4	Apples	0.0
12.5	DK child	4.1	Apples	2.5	Peppers	1.2	Pears	0.0
11.8	WHO cluster diet D	1.4	Tomatoes	1.2	Apples	1.2	Peppers	0.6
11.2	UK Adult	2.0	Wine grapes	1.9	Peas (without pods)	1.6	Citrus fruit	0.0
10.1	DK adult	2.6	Wine grapes	1.5	Peas (without pods)	1.4	Apples	0.1
9.8	PL general population	3.6	Apples	1.2	Tomatoes	0.9	Beans (without pods)	0.0
9.3	FI adult	2.5	Citrus fruit	2.2	Oranges	0.7	Apples	0.0
7.4	LT adult	3.3	Apples	0.9	Tomatoes	0.5	Peas (without pods)	0.5

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

Appendix C. List of metabolites and related structural formula

Trivial name/Code	Chemical name	Structural formula
bifenazate-diazene (D3598)	diazenecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-, 1-methylethyl ester	

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
CXL	Codex Maximum Residue Limit
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
GABA	γ-aminobutyric acid
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
HR	highest residue
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
(k)g	(kilo)gram
L	litre
LOQ	limit of quantification
mo	month
MRL	maximum residue level
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RAC	raw agricultural commodity
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
STMR	supervised trials median residue

TMDI	theoretical maximum daily intake
WHO	World Health Organization
wk	week
yr	year