REASONED OPINION

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Modification of the existing maximum residue level for bifenazate in soya bean

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Arysta LifeScience Great Britain Ltd submitted a request to the competent national authority in Italy to set new maximum residue level (MRL) for the active substance bifenazate in soya beans. The data submitted in support of the request were found to be sufficient to derive a MRL proposal for soya beans. Adequate analytical methods for enforcement are available to control the residues of bifenazate and its metabolite in the commodity under consideration. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of bifenazate according to the reported agricultural practice is unlikely to present a risk to consumer health.

Keywords: bifenazate, soya bean, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Arysta LifeScience Great Britain Ltd submitted an application to the competent national authority in Italy (evaluating Member State (EMS)) to set a new maximum residue level (MRL) for the active substance bifenazate in soya beans. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 8 February 2017. To accommodate for the intended use of bifenazate, the EMS proposed to lower the existing MRL from the limit of quantification (LOQ) of 0.02 mg/kg to 0.01 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) prepared under Council Directive 91/414/EEC, the Commission review report on bifenazate, the conclusion on the peer review of the pesticide risk assessment of the active substance bifenazate, the Joint Meeting on Pesticide Residues (JMPR) evaluation reports, as well as the conclusions from previous EFSA reasoned opinions on bifenazate.

The metabolism of bifenazate following foliar treatment was investigated in crops belonging to the groups of pulses/oilseeds, fruits, root crops and cereals.

The residue definition for enforcement and risk assessment for plant products was proposed as bifenazate and its metabolite, bifenazate-diazene (D3598) expressed as bifenazate. For risk assessment, confirmation that the same toxicological reference values can be used for both bifenazate and D3598 was requested during the peer review procedure.

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry detector (LC–MS/MS) are available to quantify residues in soya beans according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ). However, based on concerns related to technical feasibility of enforcement, the MRL in soybeans was recently increased to the LOQ of 0.05 mg/kg.

The available residue trials are sufficient to derive a MRL proposal of 0.01* mg/kg for soya beans. Specific studies investigating the magnitude of bifenazate residues in processed commodities are not required, as significant residues are not expected in raw agricultural commodity (RAC).

The occurrence of bifenazate residues in rotational crops was investigated in the framework of the EU pesticides peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels (> 0.01 mg/kg) are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).

A potential carry-over into food of animal origin is unlikely, as no residue in feed is expected following the intended use on soya beans. Therefore, a modification of the existing MRLs for commodities of animal origin was not considered necessary in the framework of this application.

The toxicological profile of bifenazate was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary. During the process of renewal of the approval under Regulation (EC) No 1107/2009, the same ADI was agreed while an ARfD of 0.1 mg/kg bw has been set. Although this ARfD has not yet been noted by the European Commission (EFSA, 2017), an acute dietary intake calculation considering the ARfD of 0.1 mg/kg bw has been performed. The metabolite included in the residue definition is assumed to have similar toxicity as the parent active substance, pending confirmation by the requested toxicological information.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The long-term intake of residues of bifenazate resulting from the existing and the intended uses is unlikely to present a risk to consumer health (highest theoretical maximum daily intake (TMDI) = 54.8% of the ADI, DE child). The contribution of residues in soya beans in this application to the overall exposure is negligible (TMDI = < 0.1% of the ADI, WHO cluster diet F). The short-term exposure did not exceed the ARfD for soya beans in this application (international estimated short-term intake (IESTI) = 0% ARfD).

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

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Bifenazate (sum of bifenazate plus bifenazate-diazene expressed as bifenazate)[(F)]				
0401070	Soya beans	0.05*	0.01*/0.05*	The submitted data are sufficient to derive a MRL proposal of 0.01* mg/kg for the NEU/SEU use on soya beans. However, the LOQ was recently increased to 0.05 mg/kg due to feasibility of enforcement A consumer health concern is unlikely in both cases

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

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Background

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

The applicant Arysta LifeScience Great Britain Ltd[4] submitted an application to the competent national authority in Italy, hereafter referred to as the evaluating Member State (EMS), to modify the existing MRL for the active substance bifenazate in soya beans. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the MRL regulation.

The EMS summarised the data provided by the applicant in an evaluation report which was submitted to the European Commission and forwarded to EFSA on 8 February 2017. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2017-00095 and the following subject:

Bifenazate – MRLs in soya beans.

Italy proposed to lower the existing MRL of bifenazate in soya beans from 0.02* to 0.01* mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA highlights that Annex II of Regulation (EC) No 396/2005 was amended by Regulation (EU) 2017/624[5] increasing the MRL set for bifenazate in soya beans at the LOQ of 0.02–0.05 mg/kg.

Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated LOQ for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRLs was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within three months from the date of receipt of the application.

The evaluation report submitted by the EMS (Italy, 2017) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

The active substance and its use pattern

The detailed description of the intended uses of bifenazate in soya beans, which is the basis for the current MRL application, is reported in Appendix A.

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

[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

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

[4] Arysta LifeScience Great Britain Ltd, Cheltenham Road, Brooklands Farm, WR112LS, Evesham, United Kingdom.

[5] Commission Regulation (EU) 2017/624 of 30 March 2017 amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, daminozide and tolylfluanid in or on certain products. OJ L 93, 6.4.2017, p. 30–49.

Bifenazate is the ISO common name for isopropyl 3-(4-methoxybiphenyl-3-yl)carbazate or isopropyl 2-(4-methoxybiphenyl-3-yl)hydrazinoformate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Bifenazate was evaluated in the framework of Directive 91/414/EEC with the Netherlands designated as rapporteur Member State (RMS) for the representative uses as 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 for the first approval. Nevertheless, the process of renewal of the first approval has been completed (EFSA, 2017) but not yet decided by the Commission.

Bifenazate was approved[6] for the use as acaricide on 1 December 2005.

The EU MRLs for bifenazate are established in Annexes II of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2011) and the proposed modifications have been implemented in the MRL legislation.[7] After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for bifenazate. The proposals from these reasoned opinions have been considered in regulations[6,8] for EU MRL legislation.

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Italy, 2017), the DAR prepared under Directive 91/414/EEC (Netherlands, 2003), the European Commission review report on bifenazate (European Commission, 2005), the conclusion on the peer review of the pesticide risk assessment of the active substance bifenazate (EFSA, 2017), the JMPR Evaluation report (FAO, 2006), as well as the conclusions from previous EFSA opinions on bifenazate 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,b, 2015).

For this application, the data requirements established in Regulation (EU) No 544/2011[9] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2016; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[10].

A selected list of end points of the studies assessed by EFSA in the framework of the MRL review, including the end points of studies submitted in support of the current MRL application, are presented in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of bifenazate in primary crops has been investigated on fruit crops (apples, oranges, grapes), root crops (radishes), cereals (maize) and pulses/oilseeds (cotton) during the EU pesticides peer review (EFSA, 2011, 2017). Based on the metabolic pattern depicted in all categories of crops, the residue definition for enforcement and risk assessment is proposed as the sum of bifenazate and bifenazate-diazene (D3598) expressed as bifenazate. The inclusion of bifenazate-diazene is also necessary in view of the available analytical method. Confirmation that the same

[6] 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, 22.9.2005, p. 17–19.

[7] 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, 30.1.2014, p. 9–55.

[8] Commission Regulation (EU) 2016/1 of 3 December 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, boscalid, cyazofamid, cyromazine, dazomet, dithiocarbamates, fluazifop-P, mepanipyrim, metrafenone, picloram, propamocarb, pyridaben, pyriofenone, sulfoxaflor, tebuconazole, tebufenpyrad and thiram in or on certain products. OJ L 2, 5.1.2016, p. 1–62.

[9] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for the actives substances. OJ L 155, 11.6.2011, p. 1–66.

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

toxicological reference values can be used for both bifenazate and bifenazate-diazene compound was requested during the peer review procedure (EFSA, 2017). It is highlighted that the metabolism of bifenazate in cotton indicated slow or no penetration of the applied radioactivity into the plant, and bifenazate and bifenazate-diazene metabolite occurred at negligible levels in cotton seeds (0.1% and 0.4% of the total radioactive residue (TRR), respectively), while the major part of the radioactive activity was incorporated into natural plant constituents. Therefore, it can be concluded that the information requested to confirm whether the toxicological reference values of bifenazate are also applicable to bifenazate-diazene is not relevant for the intended use under consideration.

For the intended use on soya beans, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Bifenazate is proposed to be used on soya beans that can be grown in rotation with other crops.

According to the soil degradation studies evaluated in the framework of the peer review, the period required for 90% dissipation (DT_{90}) value of bifenazate ranged from 0.3 to 12.3 days (EFSA, 2017).

In a confined rotational crops metabolism study bare soil was treated once or twice with 0.56 kg a.s./ha ^{14}C-labelled bifenazate (4.7–9.3N compared to the intended use on soya beans) and residues in succeeding carrots, lettuce and wheat were characterised. Neither parent compound nor reference metabolite could be detected, and it is unknown whether the uptake of soil specific metabolites, such as IBMHC/DDC (DT_{90} up to 154.7 days) was investigated (EFSA, 2017). However, in view of the intended use on soya beans, it can reasonably be assumed that significant individual residue compounds (> 0.01 mg/kg) are unlikely to be present in rotational crops.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of bifenazate residues was investigated in the framework of the peer review concluding that bifenazate is hydrolytically stable under standard processing conditions.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of bifenazate and bifenazate-diazene residues were assessed during the EU MRL review (EFSA, 2011).

The methods are sufficiently validated to analyse the residues of bifenazate and bifenazate-diazene (determined as bifenazate equivalents) in soya beans at the LOQ of 0.01 mg/kg for the total residue (sum of bifenazate and bifenazate-diazene) in high oil content commodities. However, following consultation with the European Union Reference Laboratories (EURL), the MRLs in soya beans set at the LOQ of 0.02 mg/kg was increased to a LOQ of 0.05 mg/kg (Reg. (EU) 2017/624[5]) based on technical feasibility.

1.1.5. Stability of residues in plants

The storage stability of bifenazate and bifenazate-diazene residues in various commodities stored under frozen conditions was investigated by JMPR (FAO, 2006) and included in the EU pesticide peer review (EFSA, 2017). Information on the storage stability of residues in frozen samples of crops classified as matrices with high starch content (cotton seed meal), high oil content (cotton seed, cotton seed refined oil) and dry matrices (cotton seed hulls) was peer reviewed (EFSA, 2017) and information on high water content matrices (cotton whole plant) was submitted with the current application (Italy, 2017). According to the JMPR assessment, residues of bifenazate and D3598 were demonstrated to be stable in cotton seeds, for at least 56 days when stored at −18°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern depicted in primary crops and the capabilities of enforcement analytical methods, the residue definition for monitoring and risk assessment was proposed as the sum of bifenazate and bifenazate-diazene (D3598), expressed as bifenazate. The same residue definitions are applicable to rotational crops and processed products. The same residue definition for enforcement is set in Regulation (EC) No 396/2005.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials performed on soya beans. The samples were analysed for the parent compound and bifenazate-diazene included in the residue definitions for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose.

Four northern GAP-compliant residue trials and four southern GAP-compliant residue trials on soya beans were provided. Samples of seeds and in some trials, also pods and remaining plants without roots were analysed. In all trials, residues of bifenazate and bifenazate-diazene were below the quantification limit of 0.01 mg/kg in soya bean seeds.

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated. A sufficient number of residue trials is available to derive a MRL of 0.01* mg/kg for soya beans.

1.2.2. Magnitude of residues in rotational crops

Based on the confined rotational crop metabolism study and considering that the total annual application rate of bifenazate is 0.12 kg a.s./ha for the intended use on soya beans and the fact that bare soil treatment was applied (interception of bifenazate residues by the primary crops is in practice expected), it can be concluded that no significant residue levels (< 0.01 mg/kg) in the edible parts of the rotated crops are expected, provided that bifenazate is applied in compliance with the GAP reported in Appendix A.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies to address the magnitude of residues for the crop under assessment are not available. However, as no significant residues are expected in soya bean seeds (total residues of bifenazate and bifenazate-diazene below the LOQ of 0.01 mg/kg), processing studies are not required.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive a MRL proposal as well as risk assessment values for soya beans (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Soya bean seeds may be used for feed purposes. However, since residues of bifenazate and bifenazate-diazene in soya bean seeds are below the LOQ of 0.01 mg/kg following the intended use, a potential carry-over into food of animal origin is unlikely.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for bifenazate used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (EFSA, 2017). The metabolite included in the risk assessment residue definition was considered provisionally to be of similar toxicity as the parent compound.

3.1. Short-term (acute) dietary risk assessment

An ARfD was not set under the first review (European Commission, 2005), but an ARfD of 0.1 mg/kg body weight (bw) was derived during the renewal of the approval procedure for bifenazate. Although this value has not yet been noted by the European Commission (EFSA, 2017) an acute intake calculation was performed considering the proposed ARfD of 0.1 mg/kg bw. The short-term exposure assessment was performed for soya beans assessed in this application in accordance with the internationally agreed

methodology (FAO, 2016) considering the highest residue (HR) derived from the supervised field trials on soya beans and the complete list of input values can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for soya beans in this application; the contribution of residues expected in soya beans to the overall exposure is negligible (international estimated short-term intake (IESTI) = 0% of the ARfD).

3.2. Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable Codex maximum residue limits (CXLs) (EFSA, 2011). EFSA updated the calculation with the relevant supervised trials median residue (STMR) value derived from the residue trials submitted in support of this MRL application for soya beans; in addition, STMRs derived in EFSA opinions published after the MRL review (EFSA, 2012a,b, 2015). The input values used in the exposure calculations are summarised in Appendix D.2. EFSA concluded that the long-term intake (highest theoretical maximum daily intake (TMDI) = 54.8% of the ADI, DE child) of residues of bifenazate resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

The contribution of residues expected in soya beans in this application to the overall long-term exposure is negligible (TMDI = < 0.1% of the ADI, WHO cluster diet F).

Conclusions and recommendations

The data submitted in support of this MRL application were found to be sufficient to derive a MRL proposal for soya beans.

Adequate analytical methods for enforcement are available to control the residues of bifenazate and bifenazate-diazene on the commodity under consideration. However, the residue definition is composed of two components and EURL recently concluded to increase the LOQ to a technically feasible level of 0.05 mg/kg.

Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of bifenazate according to the reported agricultural practice is unlikely to present a risk to consumer health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.i.	active ingredient
a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
EURL	EU Reference Laboratories (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level

MS	Member States
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number min–max	Interval between application (min)	Kg a.s./hL min–max	Water L/ha min–max	Kg a.s./ha min–max		
Soya beans	C-EU	F	*Tetranychus urticae* and *T. cinnabarinus* mites	SC	480 g/L	Spray application	BBCH 40-79/June-August	1	n.a.	0.0096–0.024	200–600	0.096–0.12	30	–
Soya beans	Italy	F	*Tetranychus urticae* and *T. cinnabarinus* mites	SC	480 g/L	Spray application	BBCH 40-79/June-August	1	n.a.	0.0096–0.024	500–1,000	0.096–0.12	30	–

SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application rate (kg a.s./ha)**	**Sampling (DAT)**
	Fruit and fruiting vegetables	Orange	1 × 0.42 and 2.24	Fruits: 43, 184, 274, and 442 Leaves: 43 and 184
		Apple	1 × 0.42 and 2.24	Fruits: 31 and 101 Leaves: 0 and 101
		Grapes	1 × 0.56 and 1.12	Fruits and leaves: 0 and 30
	Root crops	Radishes	1 × 1.12 and 2.24	Leaves and roots: 7
	Leafy crops	–	–	–
	Cereals/grass crops	Corn	1 × 0.85 and 5.6	Forage: 5 Stover and grains: 103
	Pulses/Oilseeds	Cotton	1 × 0.56 and 2.24	Leaves: 0 Seed and gin trash: 112
	Radiolabelled active substance: phenyl-UL-^{14}C-bifenazate. The results show that bifenazate is the major residue, but also D3598 occurs to different extent depending on the crop (up to 40% of TRR). Other metabolites were detected Reference: EFSA (2017)			

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application rate (kg a.i./ha)**	**PBI (days)**
	Root/tuber crops	Carrots	0.56 and 5.6	30 and 125
	Leafy crops	Lettuce	0.56 and 5.6	30 and 125
	Cereal (small grain)	Wheat	0.56 and 5.6	30, 125, 360
	Comments: label position: 1-phenyl ring. Soil was treated with a rate of 0.56 and 5.6 kg a.s./ha. Low total radioactive residues (TRR) were detected in all samples from rotational crops. 'Bound' residues made up the majority of the TRR for most samples. The extractable portion of the TRR consisted of a number of products, suggesting extensive degradation and metabolism of bifenazate. Neither bifenazate nor any of the reference metabolites were detected in any of the extracts analysed Reference: EFSA (2017)			

Processed commodities (hydrolysis study)	**Conditions**	**Investigated?**
	Pasteurisation (20 min, 90°C, pH 4)	Yes
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes
	Sterilisation (20 min, 120°C, pH 6)	Yes
	Comment: evaluated for other MRL application Reference EFSA (2012b)	

DAT: days after treatment; a.s.: active substance; a.i.: active ingredient; PBI: plant back interval.

Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring (RD-Mo)	Bifenazate and bifenazate-diazene, expressed as bifenazate (pending confirmation that the same toxicological reference values can be used for bifenazate and bifenazate-diazene)
Plant residue definition for risk assessment (RD-RA)	Bifenazate and bifenazate-diazene, expressed as bifenazate (pending confirmation that the same toxicological reference values can be used for bifenazate and bifenazate-diazene)
Conversion factor (monitoring to risk assessment)	1
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: LC–MS/MS, LOQ 0.01 mg/kg (EFSA, 2011)

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability (days)**
	High water content[a]	Cotton whole plant	≤ −18°C	37
	High oil content[b]	Cotton seed	≤ −18°C	56
	High oil content[b]	Cotton seed refined oil	≤ −18°C	28
	Dry[b]	Cotton seed hulls	≤ −18°C	52
	High starch[b]	Cotton seed meal	≤ −18°C	42
	Comment: – Reference [a]Italy (2017); [b]JMPR (FAO, 2006)			

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

Crop	Region/outdoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo}[b] (mg/kg)	$STMR_{Mo}$[c] (mg/kg)	CF[d]
Soya beans (1 × 0.12 kg as/ha, BBCH 40-79, PHI 30 days)	NEU	**Mo:** 4x < 0.01 **RA:** 4x < 0.01	–	**0.01***	0.01	0.01	–
	SEU	**Mo:** 4x < 0.01 **RA:** 4x < 0.01	–	**0.01***	0.01	0.01	–

BBCH: growth stages of mono- and dicotyledonous plants; MRL: maximum residue level; PHI: preharvest interval.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe.
(b): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.1.2.2. Conversion factors for risk assessment in plant products (to be deleted if not relevant)

Not relevant.

B.1.2.3. Residues in succeeding crops

Not relevant.

B.2. Residues in livestock

Not required.

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

Not relevant. The intended use on soya beans does not trigger the livestock exposure assessment.

B.2.1.2. Stability of residues in livestock

Not relevant.

B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

Not relevant.

B.2.2.2. Conversion factors for risk assessment in animal products

Not relevant.

B.3. Consumer risk assessment

An ARfD considered unnecessary in the initial peer review (European Commission, 2005). However, an ARfD was proposed in the framework of the renewal of the approval of bifenazate (EFSA, 2017).

ARfD	0.1 mg/kg bw (EFSA, 2017)
Highest IESTI, according to EFSA PRIMo	**Scenario 1:** Soya bean: 0.0% of ARfD
Assumptions made for the calculations	**Scenario 1:** The calculation is based on the highest residue levels expected in soya beans

ADI	0.01 mg/kg bw per day (European Commission, 2005)
Highest IEDI, according to EFSA PRIMo ver.2	**Scenario 1:** 54.8% of ADI (DE child) Contribution of crop assessed: Soya bean: < 0.1% of ADI (WHO cluster diet F)
Assumptions made for the calculations	**Scenario 1:**
	The calculation is based on the median residue levels derived for raw agricultural commodities, using the input values derived from the Article 12 MRL review (EFSA, 2011) and the subsequent reasoned opinions (EFSA 2012a, b, 2015) and the proposed value for soya beans of the current application

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Bifenazate (sum of bifenazate and bifenazate-diazene expressed as bifenazate)[(F)]				
0401070	Soya beans	0.05*	0.01*/0.05*	The submitted data are sufficient to derive a MRL proposal of 0.01* mg/kg for the NEU/SEU use on soya beans. However, the LOQ was recently increased to 0.05 mg/kg due to feasibility of enforcement A consumer health concern is unlikely in both cases

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

Appendix C – 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 per day):	0.01	ARfD (mg/kg bw):	0.1
Source of ADI:	EC	Source of ARfD:	EFSA
Year of evaluation:	2005	Year of evaluation:	2017

The ARfD was noted but not yet implemented.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
7	55
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)
54.8	DE child	21.1	Apples	8.6	Oranges	3.2	Peppers	1.5
49.2	NL child	11.1	Apples	7.6	Beans (with pods)	7.0	Oranges	3.2
38.6	FR toddler	16.6	Beans (with pods)	5.2	Peas (without pods)	4.6	Apples	0.2
37.4	IE adult	4.3	Basil	3.3	Peas (without pods)	2.6	Blackberries	0.5
35.2	WHO Cluster diet B	5.5	Peppers	5.0	Beans (with pods)	4.3	Tomatoes	0.6
30.7	FR infant	12.6	Beans (with pods)	4.4	Apples	3.9	Peas (without pods)	2.6
24.7	WHO cluster diet E	4.2	Beans (with pods)	3.4	Beans (without pods)	3.0	Wine grapes	0.5
21.2	PT General population	4.6	Wine grapes	3.8	Beans (without pods)	2.9	Peas (without pods)	0.0
20.4	UK Toddler	4.5	Oranges	4.4	Peas (without pods)	3.0	Apples	0.1
20.1	WHO regional European diet	3.5	Peas (with pods)	3.0	Beans (with pods)	2.5	Peas (without pods)	0.8
19.5	NL general	3.8	Beans (with pods)	3.3	Oranges	2.8	Peas (without pods)	0.8
19.1	UK Infant	8.6	Peas (without pods)	2.9	Oranges	2.7	Apples	0.1
19.0	ES child	4.9	Oranges	3.6	Beans (with pods)	2.0	Apples	1.6
18.6	SE general population 90th percentile	2.1	Peppers	1.8	Apples	1.7	Oranges	1.2
16.1	ES adult	3.5	Beans (with pods)	2.9	Oranges	1.7	Peppers	0.7
15.7	FR all population	7.4	Wine grapes	2.1	Beans (with pods)	0.8	Apples	0.4
12.8	IT kids/toddler	2.0	Tomatoes	1.6	Apples	1.5	Peas (without pods)	0.0
12.0	IT adult	2.3	Beans (with pods)	1.6	Tomatoes	1.4	Apples	0.0
11.8	DK child	4.1	Apples	2.5	Peppers	1.2	Pears	0.0
11.8	UK vegetarian	2.0	Peas (without pods)	1.9	Oranges	1.5	Wine grapes	0.0
11.5	WHO Cluster diet F	2.0	Oranges	1.3	Peas (with pods)	1.1	Apples	0.7
10.8	WHO cluster diet D	1.4	Tomatoes	1.2	Apples	1.2	Peppers	0.7
9.7	UK Adult	2.0	Wine grapes	1.9	Peas (without pods)	1.3	Oranges	0.0
9.6	PL general population	3.6	Apples	1.2	Tomatoes	0.9	Beans (without pods)	0.0
9.5	DK adult	2.6	Wine grapes	1.5	Peas (without pods)	1.4	Apples	0.1
7.2	LT adult	3.3	Apples	0.9	Tomatoes	0.5	Peas (without pods)	0.5
6.8	FI adult	2.2	Oranges	0.7	Apples	0.7	Beans (with pods)	0.0

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.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

The acute risk assessment is based on the ARfD.
For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
0.0	Soya bean	0.01/-	0.0	Soya bean	0.01/-	0.0	Soya bean	0.01/-	0.0	Soya bean	0.01/-
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						No of commodities for which ARfD/ADI is exceeded: ---					
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
55.1	Raspberries juice	4.6/-				9.1	Orange juice	0.9/-			
44.6	Orange juice	0.9/-				3.8	Apple juice	0.58/-			
29.6	Apple juice	0.58/-				3.2	Peach preserved with	1.6/-			
28.7	Peach juice	1.6/-				2.1	Wine	0.55/-			
22.3	Plums juice	1.6/-				0.7	Quince jelly	0.58/-			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL.
***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:
For bifenazate, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Not relevant.

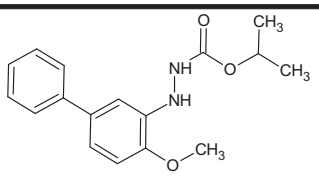
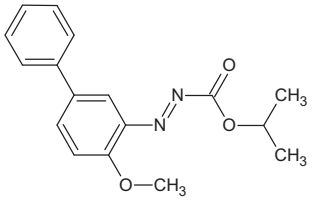
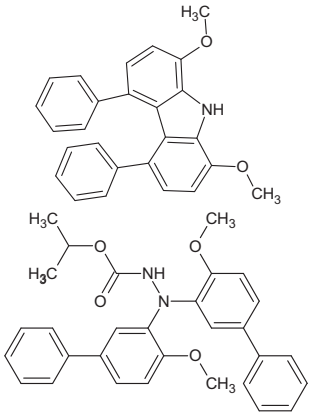
D.2. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Citrus fruits	0.23	Median residue (EFSA, 2012b)	Acute risk assessment conducted only for soya bean for which a MRL is proposed	
Tree nuts, except tree other nuts	0.03	Median residue (CXL) (EFSA, 2011)		
Pome fruits, except other pome fruit	0.18	Median residue (CXL) (EFSA, 2011)		
Apricots, cherries	0.34	Median residue (CXL) (EFSA, 2011)		
Peaches	0.34	Median residue (CXL) (EFSA, 2011)		
Plums	0.34	Median residue (CXL) (EFSA, 2011)		
Table and wine grapes	0.19	Median residue (CXL) (EFSA, 2011)		
Strawberries	0.63	Median residue (CXL) (EFSA, 2011)		
Blackberries, dewberries, raspberries	2.25	Median residue (CXL) (EFSA, 2011)		
Blueberries, cranberries, currants, gooseberries, azarole	0.23	Median residue (EFSA, 2012a, 2015)		
Tomatoes	0.14	Median residue (EFSA, 2012b)		
Peppers	1.10	Median residue (CXL) (EFSA, 2011)		
Aubergines	0.18	Median residue (CXL) (EFSA, 2011)		
Cucumbers, gherkins, courgettes	0.05	Median residue (CXL) (EFSA, 2011)		
Melons, pumpkins, watermelons	0.04	Median residue (EFSA, 2012b)		
Basil	12.90	Median residue (CXL) (EFSA, 2011)		
Beans (with and without pods), peas (with and without pods), lentils (fresh)	1.50	Median residue (CXL) (EFSA, 2011)		
Dry beans	0.01	Median residue (CXL) (EFSA, 2011)		
Soya beans	0.01	Median residue	0.01	HR
Cotton seed	0.01	Median residue (CXL) (EFSA, 2011)		
Hops (dried)	7.80	Median residue (CXL) (EFSA, 2011)		
Meat (except poultry), fat (except poultry)	0.01[(a)]	Median residue (CXL) (EFSA, 2011)		
Liver, kidney, edible offal, poultry meat and fat, eggs	0.01	Median residue (CXL) (EFSA, 2011)		

HR: highest residue; CXL: Codex maximum residue limit.

(a): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticides, STMR and HR values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat, respectively (FAO, 2016).

Appendix E – Used compound code(s)

Code/trivial name	Chemical name/SMILES notation[a]	Structural formula
Bifenazate	Isopropyl 3-(4-methoxybiphenyl-3-yl)carbazate or isopropyl 2-(4-methoxybiphenyl-3-yl) hydrazinoformate COc1ccc(cc1NNC(=O)OC(C)C)c2ccccc2	
Bifenazate-diazene D3598	Isopropyl (*E*)-(4-methoxybiphenyl-3-yl) diazenecarboxylate COc1ccc(cc1/N=N/C(=O)OC(C)C)c2ccccc2	
DDC **IBMHC/DDC**	1,8-Dimethoxy-4,5-diphenyl-9*H*-carbazole COc4ccc(c1c4nc2c1c(ccc2OC)c3ccccc3)c5ccccc5 or Isopropyl 2,2-bis(4-methoxybiphenyl-3-yl) hydrazinecarboxylate COc3ccc(cc3N(NC(=O)OC(C)C)c1cc(ccc1OC) c2ccccc2)c4ccccc4	

SMILES: simplified molecular-input line-entry system.

(a): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).