REASONED OPINION

EFSA Journal

ADOPTED: 9 June 2015

PUBLISHED: 16 June 2015

doi:10.2903/j.efsa.2015.4143

Modification of the existing maximum residue level (MRL) for fluoxastrobin in shallots

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), United Kingdom, received an application from Bayer CropScience S.A.S. to modify the existing maximum residue level (MRL) for the active substance fluoxastrobin in shallots. In order to accommodate for the intended use of fluoxastrobin, the United Kingdom proposed to set the MRL at 0.04 mg/kg. According to EFSA the data are sufficient to derive a MRL proposal of 0.04 mg/kg for the intended use on shallots in northern Europe. Adequate analytical enforcement methods are available to control the residues of fluoxastrobin and its Z-isomer in the commodity under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of fluoxastrobin on shallots will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

Keywords: fluoxastrobin, shallots, MRL application, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2015-00073

Correspondence: pesticides.mrl@efsa.europa.eu

Suggested citation: EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the existing maximum residue level (MRL) for fluoxastrobin in shallots. EFSA Journal 2015;13(6):4143, 19 pp. doi:10.2903/j.efsa.2015.4143

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from Bayer CropScience S.A.S. to modify the maximum residue level (MRL) for the active substance fluoxastrobin in shallots. In order to accommodate for the intended use of fluoxastrobin, the United Kingdom proposed to set the MRL at 0.04 mg/kg. The United Kingdom 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 28 January 2015.

EFSA bases its assessment on the evaluation report, the draft assessment report (DAR) and its final addendum prepared under Council Directive 91/414/EEC, the Commission review report on fluoxastrobin, EFSA conclusions on the peer review of the pesticide risk assessment of the active substance and on the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of fluoxastrobin was assessed in the framework of the peer review under Council Directive 91/414/EEC. The data were sufficient to derive an acceptable daily intake (ADI) of 0.015 mg/kg bw per day and an acute reference dose (ARfD) of 0.3 mg/kg bw.

During the peer review, the metabolism in primary crops was investigated in wheat only and therefore the residue definition for enforcement and risk assessment proposed as the sum fluoxastrobin and its Z-isomer was limited to the cereal group only. Thereafter, additional metabolism studies on the fruit and pulses crop groups not reviewed by EFSA were submitted and assessed at national level only and it was concluded that the residue definition proposed cereals only is applicable to all plants commodities. A detailed review of these metabolism studies at EU level would be desirable. By the time and since shallots is a minor crop at EU level, EFSA concludes that the proposed residue definitions are applicable to shallots.

EFSA concludes that the extrapolation to shallots of the MRL of 0.04 mg/kg derived from residue trials conducted on onions is acceptable. Adequate analytical enforcement methods are available to control the residues of fluoxastrobin and its Z-isomer on the commodity under consideration at the validated LOQ of 0.01 mg/kg.

Specific studies investigating the magnitude of fluoxastrobin residues in processed commodities are not required as significant residues are not expected in the raw agricultural commodity (RAC).

Based on the available information, EFSA concludes that significant residue levels of fluoxastrobin are unlikely to occur in rotational crops, provided that the compound is used on shallots according to the proposed good agricultural practice (GAP).

Residues of fluoxastrobin in commodities of animal origin were not assessed in the framework of this application, since shallot is not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the review of the existing MRLs for fluoxastrobin according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses of fluoxastrobin at EU level supported by data. EFSA updated this chronic risk assessment adding the median residue level (STMR) derived for shallots from the supervised trials on onions.

Under the assumption that the MRLs will be amended as proposed in the Article 12 review, no long-term or acute consumer intake concerns were identified. The highest calculated chronic intake accounted for 5 % of the ADI (Dutch child), the highest acute exposure for shallots being less than 0.01 % of the ARfD.

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

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

Summary Table

Code[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)		Comment/Justification
			Art. 12[b]	Art. 10	
Enforcement residue definition: Fluoxastrobin[c]					
0220030	Shallots	0.05*	0.01*	0.04	Extrapolation from NEU trials on onions.

(*) Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a) Commodity code according to Annex I of Regulation (EC) 396/2005.
(b) Lowering of the MRL to the LOQ of 0.01 mg/kg was proposed in the framework of the MRL review (EFSA, 2012).
(c) Current residue definition limited to fluoxastrobin under Regulation 'EC) No 396/2005. However, the MRL proposal was derived according to the residue definition "sum of fluoxastrobin and its Z-isomer" proposed in the framework of the MRL review (EFSA, 2012).

Table of contents

Background

Regulation (EC) No 396/2005[1] establishes the rules governing the setting of pesticide MRLs at European Union (EU) 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,[2] repealed by Regulation (EC) No 1107/2009,[3] 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.

United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from the company Bayer CropScience S.A.S.[4] to modify the existing MRL for the active substance fluoxastrobin in shallots. 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 Regulation. After completion, the evaluation report was submitted to the European Commission and to EFSA on 28 January 2015.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2015-00073 and the following subject:

Fluoxastrobin - Setting new MRLs in shallot.

United Kingdom proposed to set the existing MRL of fluoxastrobin in shallots at 0.04 mg/kg.

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

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the EMS, 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 if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

The active substance and its use pattern

Fluoxastrobin is the ISO common name for (*E*)-{2-[6-(2-chlorophenoxy)-5-fluoropyrimidin-4-yloxy]phenyl}(5,6-dihydro-1,4,2-dioxazin-3-yl)methanone *O*-methyloxime (IUPAC). The active substance used in the pesticide formulations contains also the *Z*-isomer at much lower level (approximately 2 %). The chemical structures of the active substance (E-isomer) and its Z-isomer are reported in Appendix C. Fluoxastrobin belongs to the group of strobilurin compounds which are used as fungicides.

Fluoxastrobin was evaluated in the framework of Council Directive 91/414/EEC with United Kingdom designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Commission Directive 2008/44/EC[5] which entered into force on 01 August 2008 for use as fungicide. In accordance with Commission Implementing Regulation (EU) No 540/2011[6] fluoxastrobin is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses supported for the peer review process were two foliar applications on cereals up to 200 g a.s./ha and 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, 16.03.2005, 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, 19.08.1991, 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] Bayer CropScience S.A.S., 16 Rue Jean Marie Leclair, Cedex 09, 69009 Lyon, France.
[5] Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* and prothioconazole as active substances. OJ L 94, 05.04.2008, p. 13–20.
[6] 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.

PHI of 35 days. The draft assessment report (DAR) of fluoxastrobin has been peer reviewed by EFSA (EFSA, 2007b).

The EU MRLs for fluoxastrobin are established in Annex IIIA of Regulation (EC) No 396/2005. Since the entry into force of the abovementioned regulation, EFSA has issued a reasoned opinion for fluoxastrobin which reviewed all uses authorised at EU level according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2012). Modifications of the existing MRLs were proposed for several crops, including the lowering to the LOQ of 0.01 mg/kg for shallots, which are currently under discussion at the Standing Committee on Plants, Animals, Food and Feed (SCPAFF) (draft Regulation SANCO/11739/2013).

No CXLs are established for fluoxastrobin.

The details of the intended GAP for fluoxastrobin in northern Europe (NEU) is given in Appendix A.

Assessment

EFSA bases its assessment on the evaluation report submitted by the EMS (United Kingdom, 2014), the DAR and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2003, 2007, 2012), the Commission review report on fluoxastrobin as revised after the assessment of the confirmatory data (EC, 2012), EFSA conclusions on the peer review of the pesticide risk assessment of the active substance fluoxastrobin and on the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2007b, 2012). 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[7] 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 fluoxastrobin and its Z-isomer (the relevant residues for enforcement) in plant commodities were assessed in the framework of the peer review and the Article 12 review. EFSA concluded that adequate analytical methods are available to monitor residues in high water content commodities, to which group shallot belongs, and in dry/high starch content commodities with a LOQ of 0.01 mg/kg for fluoxastrobin and 0.002 mg/kg for its Z-isomer (EFSA, 2012).

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 shallots are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance fluoxastrobin was assessed in the framework of the peer review under Council Directive 91/414/EEC (EFSA, 2007b). The data were sufficient to derive toxicological reference values for fluoxastrobin which are compiled in Table 1.

Table 1: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Fluoxastrobin					
ADI	European	2012	0.015 mg/kg bw per day	Dog, 1-year study	100
ARfD	Commission	2012	0.3 mg/kg bw	Dog, 1st week of 90-day and 1-yr studies	100

[7] 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.

Based on the results of mammalian toxicity studies conducted with different isomer ratios, the peer review concluded that it is unlikely that the Z-isomer is more toxic than the E-isomer of fluoxastrobin (EFSA, 2007b). Hence, the ADI and the ARfD are applicable to the proposed risk assessment residue definition which includes both the E- and Z-isomers of fluoxastrobin (EFSA, 2012).

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 Council Directive 91/414/EEC, the metabolism of fluoxastrobin in primary crops was evaluated after seed treatment and foliar applications in the cereal group only (EFSA, 2007b). The overview of the metabolism study design is presented in Table 2.

Table 2: Summary of available metabolism studies in plants

Crop group	Crops	Application[(a)]	Sampling	Comments
Cereals	Wheat	Seed; 35 g/ha + Foliar; 2× 300 g/ha, BBCH 32-69 (Cph, Mtx, Py)	32-36, 83-98 and 121-152 days after planting	(EFSA, 2007b)

(a) BBCH: growth scale for monocotyledonous and docotyledonous plants.
U-^{14}C-chlorophenyl (Cph), 2-^{14}C-pyrimidine (Py), U-^{14}C-methoxyiminotolyl (Mtx) labelled fluoxastrobin.

Based on the metabolism study on wheat, the residue definition for enforcement and risk assessment was proposed for the cereal group only as sum of fluoxastrobin and its Z-isomer in the conclusion of the peer review (EFSA, 2017b). The current residue definition for enforcement set in Regulation (EC) No 396/2005 refers to fluoxastrobin only.

After the peer review, metabolism of fluoxastrobin was also investigated in tomatoes, peanuts and rape seeds (representing two additional crop groups: fruit and pulses/oilseeds) following seed treatment and/or foliar applications. These studies were evaluated by The Netherlands on behalf of the RMS, but not assessed by EFSA. EFSA takes note that according to the United Kingdom and The Netherlands the metabolic pattern was considered to be similar to that observed in cereals, and therefore, that the residue definition proposed for cereals in the conclusion of the peer review is expected to be applicable to all plants commodities. However, EFSA pointed out that a detailed peer review of these metabolism studies at EU level has not been done and would be desirable (EFSA, 2012).

By the time and considering that shallot is a minor crop at EU level, EFSA concludes that the residue definition for enforcement and risk assessment proposed in the framework of the peer review for cereals (EFSA, 2007b) and the Article 12 review (EFSA, 2012) is applicable for the setting of an MRL on shallots.

3.1.1.2. Magnitude of residues

No specific residue trials on shallots have been submitted. It is proposed to extrapolate to shallots the MRL of 0.04 mg/kg derived on bulb onions from the NEU residue trials conducted according to the proposed GAP and already assessed in the framework of the Article 12 MRL review (EFSA, 2012). Extrapolation from onions to shallots is possible as the GAPs are comparable (EC, 2011).

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

Samples were analysed for residues of fluoxastrobin and its Z-isomer separately (United Kingdom, 2014).The supervised residue trial samples were already assessed by EFSA and considered as valid with regards to storage stability and the analytical determination of residues (EFSA, 2012).

EFSA concludes that sufficient information was provided to extrapolate to shallot the MRL of 0.04 mg/kg derived from the residue trials conducted on onion in NEU.

Table 3: Overview of the available residues trials data

Crop (Trial GAP)	**Region/ Indoor**[a]	**Individual residue levels** (mg/kg)[b]	**Recommendations/comments**[c]	**MRL proposals** (mg/kg)	**HR** (mg/kg) [d]	**STMR** (mg/kg) [e]
Onions (4× 125 g/ha, PHI 14 d)	NEU	8× <0.02; 0.03	Trials on onions previously assessed (EFSA, 2012). MRL_{OECD}: 0.03/0.04 **Extrapolation to shallots**.	0.04	0.03	0.02

(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.
(b) Individual residue levels considered for MRL calculation are reported in ascending order.
(c) Any information/comment supporting the decision and OECD MRL calculation (e.g. MRL_{OECD}: unrounded/rounded 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 available information on the nature of fluoxastrobin residues, EFSA concluded that the compound is hydrolytically stable under the representative processing conditions (EFSA, 2007b). Thus, for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable (EFSA, 2012).

Specific studies to assess the magnitude of residues of fluoxastrobin and its Z-isomer during the processing of shallots are not necessary as the residue levels in RAC did not exceed the trigger value of 0.1 mg/kg (EC, 1997d).

3.1.2. Rotational crops

Shallots can be grown in rotation with other plants. Since fluoxastrobin degradation in soil is above the trigger value of 100 days (EFSA, 2012), the possible occurrence of residues in succeeding crops resulting from the use of fluoxastrobin on primary crops has to be assessed (EC, 1997c).

The nature and magnitude of fluoxastrobin residues in rotational crops was investigated in the course of the peer review (EFSA, 2007b). EFSA concluded that the residue definitions set for primary crops are applicable to rotational crops and that significant residues of fluoxastrobin and its Z-isomer are not expected in rotational crops (except in straw), when the active substance is applied on primary crops up to the maximum dose rate of 680-850 g/ha (EFSA, 2007b, 2012).

Since the intended application rate for shallots is limited to a maximum total application rate of 520 g/ha (4 × 130 g/ha), EFSA concludes that significant residues are unlikely to occur in rotational crops provided that the active substance is applied according to the proposed GAP.

3.2. Nature and magnitude of residues in livestock

As shallots are not normally fed to livestock, the nature and magnitude of fluoxastrobin 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[8] (EFSA, 2007a).

In the framework of the review of the existing MRLs for fluoxastrobin according to Article 12 of Regulation (EC) No 396/2005 a comprehensive long-term exposure assessment was performed taking into account the existing uses of fluoxastrobin at EU level supported by data. Those food commodities for which no uses were reported in the framework of the Article 12 review were excluded from the exposure calculation assuming that there is no use on these crops (EFSA, 2012). EFSA updated the chronic risk assessment performed under the Article 12 review with the median residue value (STMR) derived from the residue trials conducted on onion and extrapolated to shallots (see Table 3).

The acute exposure assessment was performed only with regard to the commodity under consideration assuming the consumption of a large portion of the food item as reported in the national food surveys and considering highest residue level (HR) observed in supervised field trials (EFSA, 2007a).

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

[8] 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, 2007a).

Table 4: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Risk assessment residue definition: Sum of fluoxastrobin and its Z-isomer				
Shallots	0.02	STMR (onion, NEU)	0.03	HR (onion, NEU)
Other commodities of plant and animal origin	STMR	See Table 4-1 in Reasoned opinion on the review of the existing MRLs according to Art. 12 of Reg. (EC) No 396/2005 (EFSA, 2012).	Acute risk assessment was undertaken only with regard to the crop under consideration.	

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

Under the assumption that the MRLs will be amended as proposed in the Article 12 review, 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 5 % of the ADI (Dutch child), the contribution of the residues in shallots to the total exposure accounting for a maximum of 0.01 %.

No acute consumer risk was identified in relation to the MRL proposal for shallots, the highest calculated acute exposure being less than 0.01 % of the ARfD.

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

Conclusions and recommendations

The submitted information was sufficient to derive the MRL proposal summarised in the table below.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)		Comment/Justification
			Art. 12[(b)]	**Art. 10**	
Enforcement residue definition: Fluoxastrobin [(c)]					
0220030	Shallots	0.05*	0.01*	0.04	Extrapolation from NEU trials on onions.

(*) indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a) Commodity code according to Annex I of Regulation (EC) 396/2005.
(b) Lowering of the MRL to the LOQ of 0.01 mg/kg was proposed in the framework of the Art. 12 MRL review (EFSA, 2012).
(c) Current residue definition limited to fluoxastrobin under Regulation 'EC) No 396/2005. However, the MRL proposal was derived according to the residue definition "sum of fluoxastrobin and its Z-isomer" proposed in the framework of the MRL review (EFSA, 2012).

References

European Commission, 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95-rev.4.

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realisation of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414). SANCO/3029/99-rev.4.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8.1.

European Commission, 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9.

European Commission, 2012. Review report for the active substance fluoxastrobin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 22 January 2008 in view of the inclusion of fluoxastrobin in Annex I of Council Directive 91/414/EEC. SANCO/3921/07 - final, revised 28 September 2012, 8 pp.

EFSA (European Food Safety Authority), 2007a. Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs. The EFSA Journal 2007, 32r, 1-1141. doi:10.2903/j.efsa.2007.32r

EFSA (European Food Safety Authority), 2007b. Conclusion on the peer review of the pesticide risk assessment of the active substance fluoxastrobin (rev 2007). EFSA Scientific Report 2007, 102r, 1-84, doi:10.2903/j.efsa.2005.102r

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for fluoxastrobin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(12):3012, 42 pp. doi:10.2903/j.efsa.2012.3012

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. Available online: http://www.oecd.org/env/pesticides under Pesticide Publications/Publications on Pesticide Residues.

United Kingdom, 2003. Draft assessment report on the active substance fluoxastrobin prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, August 2003.

United Kingdom, 2007. Final addendum to the draft assessment report on the active substance fluoxastrobin prepared by the rapporteur Member State United Kingdom in the framework of Council Regulation (EC) No 33/2008, compiled by EFSA, April 2007.

United Kingdom, 2012. Addendum 8 to the Report and Proposed Decision of the United Kingdom made to the European Commission under Article 8(1) of 91/414/EEC, April 2012.

United Kingdom, 2014. Evaluation report on the modification of MRLs for fluoxastrobin in shallots prepared by the evaluating Member State the United Kingdom under Article 8 of Regulation (EC) No 396/2005, 03 December 2014, 29 pp.

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
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
d	day
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
EC	emulsifiable concentrate
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
HR	highest residue
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue level
NEU	northern Europe
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
SCPAFF	Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH)
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WHO	World Health Organization
yr	year

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/hL min-max	Water L/ha min-max	g/ha min-max		
Shallots	NEU	F	fungi	EC	100 g/L	Foliar spraying	Up to BBCH 47	4	5-10	-	-	130	14	

Remarks:

(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the usage 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), water-soluble granule (WG)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) all abbreviations must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants. type of equipment used must be indicated
(i) g/kg or µg/L
(j) Growth stage at last treatment (Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forestry, Braunschweig, Germany, 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

Appendix B – Pesticide Residue Intake Model (PRIMo)

Fluoxastrobin			
Status of the active substance:	**approved**	Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.015**	ARfD (mg/kg bw):	**0.3**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2007, 2013**	Year of evaluation:	**2007, 2013**

Risk assessment residue definition: Sum of fluoxastrobin and its Z-isomer

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
0	5
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)
5.5	NL child	3.9	Milk and milk products: Cattle	0.6	Wheat	0.4	Potatoes	5.4
3.9	FR infant	3.4	Milk and milk products: Cattle	0.3	Potatoes	0.1	Wheat	3.9
2.9	DE child	1.9	Milk and milk products: Cattle	0.5	Wheat	0.2	Potatoes	2.9
2.8	ES child	1.7	Milk and milk products: Cattle	0.6	Wheat	0.2	Bovine: Meat	2.8
2.5	SE general population 90th percentile	1.7	Milk and milk products: Cattle	0.4	Wheat	0.3	Potatoes	2.5
2.2	WHO Cluster diet B	1.1	Wheat	0.4	Milk and milk products: Cattle	0.2	Potatoes	2.1
2.1	WHO cluster diet D	0.9	Wheat	0.6	Milk and milk products: Cattle	0.3	Potatoes	2.0
1.9	WHO Cluster diet F	0.5	Milk and milk products: Cattle	0.5	Wheat	0.2	Potatoes	1.7
1.8	WHO regional European diet	0.6	Milk and milk products: Cattle	0.4	Wheat	0.3	Potatoes	1.7
1.7	WHO cluster diet E	0.5	Wheat	0.4	Milk and milk products: Cattle	0.3	Potatoes	1.5
1.7	NL general	0.9	Milk and milk products: Cattle	0.3	Wheat	0.2	Potatoes	1.6
1.7	DK child	0.7	Wheat	0.6	Rye	0.2	Potatoes	1.5
1.5	IE adult	0.4	Milk and milk products: Cattle	0.3	Barley	0.3	Wheat	1.0
1.4	ES adult	0.7	Milk and milk products: Cattle	0.3	Wheat	0.1	Barley	1.3
1.3	LT adult	0.5	Milk and milk products: Cattle	0.2	Potatoes	0.1	Rye	1.2
1.0	FR all population	0.4	Wheat	0.4	Milk and milk products: Cattle	0.1	Potatoes	1.0
1.0	IT kids/toddler	0.9	Wheat	0.1	Potatoes	0.02	Onions	1.0
1.0	PT General population	0.5	Wheat	0.4	Potatoes	0.05	Onions	0.9
0.9	FR toddler	0.3	Wheat	0.3	Potatoes	0.2	Bovine: Meat	0.9
0.8	UK Toddler	0.5	Wheat	0.2	Potatoes	0.03	Onions	0.8
0.7	UK Infant	0.3	Wheat	0.2	Potatoes	0.1	Oats	0.6
0.6	IT adult	0.6	Wheat	0.04	Potatoes	0.01	Onions	0.6
0.6	DK adult	0.3	Wheat	0.1	Potatoes	0.1	Rye	0.6
0.4	UK vegetarian	0.3	Wheat	0.1	Potatoes	0.03	Onions	0.4
0.4	UK Adult	0.2	Wheat	0.1	Potatoes	0.02	Onions	0.3
0.4	FI adult	0.1	Wheat	0.1	Rye	0.1	Potatoes	0.3
0.3	PL general population	0.2	Potatoes	0.04	Onions		FRUIT (FRESH OR FROZEN)	0.3

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Fluoxastrobin 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)
0.003	Shallots	0.03 / -	0.003	Shallots	0.03 / -	0.002	Shallots	0.03 / -	0.002	Shallots	0.03 / -
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)	
0.2	Potato puree (flakes)	0.05 / -		0.03	Bread/pizza	0.02 / -	
0.1	Wheat flour	0.02 / -		0.01	Potato uree (flakes)	0.05 / -	
0.0	Fried potatoes	0.05 / -		0.01	Fried potatoes	0.05 / -	

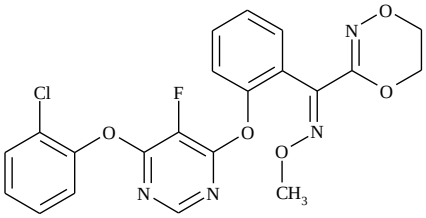
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Fluoxastrobin 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 C – Used compound codes

Trivial name/Code	Chemical name	Structural formula
Fluoxastrobin HEC 5725	(E)-{2-[6-(2-chlorophenoxy)-5-fluoropyrimidin-4-yloxy]phenyl}(5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime	
Z isomer of fluoxastrobin	(Z)-{2-[6-(2-chlorophenoxy)-5-fluoropyrimidin-4-yloxy]phenyl}(5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime