REASONED OPINION

APPROVED: 11 March 2016 PUBLISHED: 31 March 2016

doi:10.2903/j.efsa.2016.4445

Modification of the existing maximum residue levels for fludioxonil in various crops

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), Italy, received an application from Syngenta Ltd to modify the existing maximum residue levels (MRLs) for the active substance fludioxonil in lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers, beans and peas (with pods) and peas (without pods). According to EFSA, the intended uses on the crops under consideration are adequately supported by residue data and an MRL proposal of 20 mg/kg was derived for the groups of lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers and an MRL proposal of 0.3 mg/kg for peas (without pods). However, no modification is proposed for lettuces, spinaches, beans (with pods) and peas (with pods), since the GAPs supported in the framework of this MRL application result in lower or similar MRL values than the MRLs currently into force in the EU legislation. Adequate analytical enforcement methods are available to control the residues of fludioxonil on the relevant crop commodities. Based on the risk assessment results, EFSA concludes that the proposed use of fludioxonil on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

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Keywords: fludioxonil, various crops, lettuce, salad plants, spinaches, herbs, edible flowers, beans, peas, MRL application, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2015-00701

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Suggested citation: EFSA (European Food Safety Authority), 2016. Reasoned opinion on the modification of the MRLs for fludioxonil in various crops. EFSA Journal 2016;14(3):4445, 20 pp. doi:10.2903/j.efsa.2016.4445

ISSN: 1831-4732

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) Italy, received an application from Syngenta Ltd to modify the existing maximum residue levels (MRLs) for the active substance fludioxonil in various crops. In order to accommodate for the intended uses of fludioxonil, Italy proposed to raise the value of the existing MRL of 15 mg/kg to 20 mg/kg in lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers; to raise the existing MRL of 1 mg/kg to 1.5 mg/kg in beans and peas (with pods) and to raise the value of 0.05 mg/kg to 0.4 mg/kg in peas (without pods). Italy 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 9 November 2015.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) and its addendum prepared under Council Directive 91/414/EEC, the Commission review report on fludioxonil, the conclusion on the peer review of the pesticide risk assessment of the active substance fludioxonil, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) evaluation reports as well as the conclusions from previous EFSA reasoned opinions, including the review of the existing MRLs for fludioxonil under Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of fludioxonil was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.37 mg/kg bw per day. No acute reference dose (ARfD) was deemed necessary.

The metabolism of fludioxonil in primary crops was investigated on the fruit, leafy and root crop groups using foliar application and on root, pulses/oilseeds and cereals crop groups using seed treatment. From these studies the peer review established the residue definition for enforcement as fludioxonil and as '*sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil*' for risk assessment. For the uses under consideration, EFSA concludes that the metabolism of fludioxonil in primary crops has been sufficiently addressed and that the residue definitions derived are applicable.

EFSA concludes that the submitted residue trials are sufficient to derive MRL proposal of 20 mg/kg for lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers extrapolated from indoor trials on lettuces and an MRL proposal of 0.3 mg/kg on peas (without pods). No modification is proposed for lettuces, spinaches, beans (with pods) and peas (with pods), since the GAPs supported in the framework of this MRL application result in lower or similar MRL proposals than the MRLs currently into force under Regulation (EC) No 396/2005. Adequate analytical enforcement methods are available to monitor the residues of fludioxonil in the commodities under consideration at the validated LOQ of 0.01 mg/kg.

Studies investigating the nature of fludioxonil residues under standard hydrolysis conditions were assessed during the peer review and showed the active substance to be hydrolytically stable. Therefore for processed commodities the same residue definition as for raw commodities (RAC) is applicable.

Specific studies investigating the magnitude of fludioxonil residues in processed commodities are not required, as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI.

Based on the available information, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the compound is used according to the proposed good agricultural practice (GAP).

Residues of fludioxonil in commodities of animal origin were not assessed, since the crops under consideration in this MRL application are normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The total chronic intake calculated accounted for up to 18% of the ADI (DE child). The contribution of residues in the crops under consideration to the total consumer exposure accounted for a maximum of 1.5% of the ADI (ES adult). An acute consumer exposure assessment was not performed, since the setting of an ARfD was concluded to be unnecessary for fludioxonil.

EFSA concludes that the proposed uses of fludioxonil on lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers, beans and peas will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a health risk to consumers.

EFSA proposes to amend the existing MRLs 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: Fludioxonil				
0251000	Lettuce and salad plants (except lettuce)	15	20	Extrapolation from indoor trials on lettuce (open leaf varieties).
0251020	Lettuces	40	40	No change. EU GAPs result in a lower MRL proposal (20 mg/kg) than the CXLs of 40 and 30 mg/kg transposed in Reg. (EU) No 2015/845.
0252010	Spinaches	30	30	
0252020	Purslanes	15	20	Extrapolation from indoor trials on lettuce (open leaf varieties).
0252030	Chards & beet leaves	15	20	
0252990	Spinaches, similar leaves	15	20	
0256000	Herbs & edible flowers	15	20	
0260010	Beans (with pods)	1	1	The submitted trials do not request a change of the existing MRL values
0260030	Peas (with pods)	1	1	
0260040	Peas (without pods)	0.05	0.3	NEU and SEU uses

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005

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Background

Regulation (EC) No 396/2005[1] establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the 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 the Regulation.

Italy, hereafter referred to as the evaluating Member State (EMS), received an application from the company Syngenta Ltd[4] to modify the existing MRLs for the active substance fludioxonil in lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers, beans and peas (with pods) and peas (without pods). 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 9 November 2015.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2015-00701 and the following subject:

Fludioxonil - Modification of existing MRLs in various crops

Italy proposed to raise the existing MRLs of fludioxonil from the value of 15 mg/kg to 20 mg/kg in lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers; from the existing value of 1 mg/kg to 1.5 mg/kg in beans and peas (with pods) and from 0.05 mg/kg to 0.4 mg/kg in peas (without pods).

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 the 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

Fludioxonil is the ISO common name for 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix C.

Fludioxonil was evaluated in the framework of Directive 91/414/EEC with Denmark designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2007/76/EC[5] which entered into force on 1 November 2008 for use as fungicide only. In accordance with

[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] Syngenta Ltd, via Gallarate 139, 20151, Milano, Italy
[5] Commission Directive 2007/76/EC of 20 December 2007 amending Council Directive 91/414/EEC to include fludioxonil, clomazone and prosulfocarb as active substances, OJ L 337, 21.12.2007, p. 100–104.

Commission Implementing Regulation (EU) No 540/2011[6] fludioxonil is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses evaluated in the peer review were foliar applications on table and wine grapes and seed treatment on wheat. The draft assessment report (DAR) has been peer reviewed by EFSA (EFSA, 2007b).

The EU MRLs for fludioxonil are established in Annex II of Regulation (EC) No 396/2005. Since the entry into force of this regulation, EFSA has issued several reasoned opinions on the modification of MRLs for fludioxonil, including the reasoned opinion on the review of the existing MRLs according to Article 12 of the abovementioned regulation (hereafter Article 12 MRL review). The MRL proposals from EFSA have been implemented in the EU legislation. The MRL changes that were reported in the EU legislation from Article 12 MRL review onwards are summarised in Table 1.

Table 1: Overview of the MRL changes after the Article 12 (Regulation (EC) No 396/2005) review of existing MRLs

Procedure[(a)]	Considered by Regulation	Remarks
Art. 12 (EFSA, 2011a)	(EU) No 79/2014	Review of existing MRLs.
Art. 10 (EFSA, 2011b)	(EU) No 79/2014	Various leafy crops.
Art. 10 (EFSA, 2012)	(EU) No 79/2014	Celery, celery leaves and radishes
Art. 10 (EFSA, 2013a)		Cucurbits inedible peel, radishes.
Art. 43 (EFSA, 2013b)	(EU) No 491/2014	Implementation of CXLs.
Art. 43 (EFSA, 2014)	(EU) No 2015/845	Implementation of CXLs.
Art. 10 (EFSA, 2016)	Not yet implemented	Pineapples

(a): Art. 10: Assessment of MRL application according to Article 6 to 10 of Regulation (EC) No 396/2005
Art. 12: Review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005
Art. 43: EFSA scientific opinion according to Article 43 of Regulation (EC) No 396/2005

Codex Alimentarius has established maximum residue limits (CXLs) for a wide range of commodities, including lettuce head (10 mg/kg), lettuce leaf (40 mg/kg), herbs (9 mg/kg), peas (with pods) (0.3 mg/kg), peas shelled (0.03 mg/kg), snap beans young pods (0.6 mg/kg) and spinach (30 mg/kg.

The details of the intended/authorised GAPs for fludioxonil are given in Appendix A.

Assessment

EFSA bases its assessment on the evaluation report submitted by the EMS (Italy, 2015), the DAR and its addendum prepared under Directive 91/414/EEC (Denmark, 2005, 2007), the Commission review report on fludioxonil (European Commission, 2007), the conclusion on the peer review of the pesticide risk assessment of the active substance fludioxonil (EFSA, 2007b), the JMPR Evaluation report (FAO, 2012, 2013) as well as the conclusions from previous EFSA opinions on fludioxonil (EFSA, 2011b, 2012, 2013a,b, 2014, 2016) including the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011a). 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 (European Commission, 1996, 1997a–g, 2000, 2010a, b, 2011, 2015; OECD, 2011).

[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.
[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.

1. Method of analysis

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

Analytical methods for the determination of fludioxonil residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (EFSA, 2007b) and reconsidered under Article 12 MRL review (EFSA, 2011a).

The multi-residue QuEChERS method using HPLC-MS/MS quantification (CEN, 2008) is considered as sufficiently validated to enforce fludioxonil in high water-, high acid-, high oil- and dry/starch content commodities at the LOQ of 0.01 mg/kg.

As lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers, peas and beans belong to the high water content commodities; EFSA concludes that a sufficiently validated analytical method is available to enforce the proposed MRLs for fludioxonil.

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 fludioxonil was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2007b). The data were sufficient to derive toxicological reference values compiled in Table 2.

Table 2: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Fludioxonil					
ADI	EFSA	2007	0.37 mg/kg bw per day	Rat, acute neurotoxicity	100
ARfD	EFSA	2007	Not necessary	-	-

(a): Table footnote

It is noted that JMPR established for fludioxonil an ADI of 0.4 mg/kg bw per day, based on the 2-year study in rat and the setting of an ARfD was also considered unnecessary (FAO, 2004).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of fludioxonil in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC (EFSA, 2007b) using foliar application on fruit crops, leafy crops and root and tuber crops as well as for seed treatment on root and tuber crops, pulses/oilseeds and cereals. An overview of the available metabolism study design is presented in Table 3.

Based on these metabolism studies, the residue definition was proposed as fludioxonil for monitoring and as '*sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3] dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil*' for risk assessment. These residue definitions apply to all crop categories for all kind of treatments.

Table 3: Summary of available metabolism studies in plants

Crop group	Crops	Application[(a)]	Sampling[(b)]	Comments
Fruit	Grape	Foliar: 3× 500 g/ha	0, 26 DAT_1, 0, 14, 35 DALA	
	Peach	Foliar: 3x 840 or 8400 g/ha	28 DALA	
		Foliar: 2x 8400 g/ha	30, 114 DALA	
	Tomato	Foliar, 3× 750 g/ha	0, 40 DALA	
Leafy	Lettuce	Foliar: 3× 200 or 600 g/ha	0, 6, 13 DALA	
Root	Spring onion	Foliar: 2x 124 or 6170 g/ha	0, 7, 14, 28 DALA	
	Potato	Seed, 2.5 g/tonne seed	0, 40, 71, 95 DAT	
Cereal	Wheat	Seed: 6.4 g/tonne (G) 7.4 g/tonne (F)	G: 11, 18, 25, 32, 39, 46, 53 DAT F: 48, 83, 106 DAT	
	Rice	Seed: 6.5 g/tonne	38, 76, 152 DAT	
Pulses/ Oilseeds	Cotton	Seed: 2.5 or 5.0 g/tonne	186 DAT	
	Soya bean	Seed: 5.0 g/tonne	28, 38, 133 DAT	

(a): circa, about; d, days; appl., applications; F, field, outdoor; G, glasshouse, indoor.
(b) DAT_1, days after 1st treatment; DAT, days after treatment; DALA, days after last administration.

For cereals, root crops and pulses/oilseeds (seed treatment) and for fruit and leafy crops (foliar treatment), a conversion factor (CF) of 1 for monitoring to risk assessment was derived reflecting that no significant concentration of metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety are expected in these crops. For root crops following foliar application, a conversion factor of 2.8 was derived from the metabolism on spring onions since higher rates of metabolites have been observed in the green plants (EFSA, 2007b).

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

For the uses on the crops under consideration, EFSA concludes that the metabolism of fludioxonil is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during the peer review are applicable.

3.1.1.2. Magnitude of residues

In support of the MRL application, sufficient GAP-compliant residue trials conducted on open leaf varieties of lettuce were submitted to derive an MRL proposal of 20 mg/kg, extrapolated to the groups lettuces and salad plants, spinaches and similar leaves and herbs and edible flowers.

In addition a sufficient number of NEU and SEU residue trials were submitted to derive MRL proposals of 1 mg/kg on beans and peas (with pods) and of 0.3 mg/kg on peas (without pods).

It is noted that the MRL proposals of 0.3 and 1 mg/kg on peas and beans are lower than the values of 0.4 and 1.5 mg/kg proposed by the EMS in its evaluation report where the northern and southern datasets were not merged together as proposed by EFSA, but where MRL proposals were derived for both EU zones separately.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 4.

The stability of fludioxonil residues in plant matrices under storage conditions prior to analysis was assessed during the peer review under Directive 91/414/EEC (EFSA, 2007b). Residues of fludioxonil were found to be stable at ≤ -18°C for up to 24 months in high water-, high acid- and high oil-content matrices as well as in dry/starch matrices. As the samples from the trials on lettuce and beans were stored for a maximum period of 8 months under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability. Storage period was not reported for pea, but since the study report for the field trials conducted on pea in 2013 and 2014 was issued by 2014, it is concluded that samples were not stored for a period longer than 2 years prior to analyses.

According to the EMS, the analytical method used to analyse the residue trial samples has been sufficiently validated and was proven to be fit for purpose (Italy, 2015).

EFSA concludes that the data are sufficient to derive the following MRL proposals:

- 20 mg/kg on the groups of lettuces and salad plants (except lettuces 40 mg/kg), spinaches and similar leaves (except spinaches 30 mg/kg), herbs and edible flowers, in NEU, SEU and indoor conditions (by extrapolation from indoor trials on lettuce),
- 0.3 mg/kg on peas (without pods) in NEU and SEU.

However, no changes are proposed for lettuces and spinaches since the submitted residue trials result in lower MRL proposals than the CXL values of 40 mg/kg and 30 mg/kg respectively, adopted by the Codex Alimentarius Commission (CAC, 2014) and transposed in the EU legislation by Regulation (EU) No 2015/845.

Similarly, no changes are proposed to the MRLs of 1 mg/kg currently set on beans (with pods) and peas (with pods) in the EU legislation, since the residue trials submitted in the framework of the current MRL application result in the same MRL proposal.

Table 4: Overview of the available residues trials data

Crop (GAPs)	Region/ Indoor[a]	Residue levels observed in the supervised residue trials[b] (mg/kg)	Recommendations/comments[c]	MRL proposal (mg/kg)	HR[d] (mg/kg)	STMR[e] (mg/kg)
Monitoring residue definition: fludioxonil **Risk assessment residue definition**: sum fludioxonil and its metabolites oxidised to CGA 192155, expressed as fludioxonil (applicable to the root crop group, inclusion of metabolites oxidised to CGA 192155 not necessary for other crop groups)						
Lettuce (open leaf) (2x 250 g/ha, PHI 7 d)	Indoor	1.97, 5.07, 5.13, 5.81, 6.44, 6.61, 7.08, 11.42	Indoor dataset significantly different from NEU and SEU outdoor datasets (H-Test, 5%). MRL, STMR and HR derived from the indoor trials. MRL_{OECD} = 16.7/20 **Extrapolation to the groups lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers**	**20**	11.42	6.13
	NEU	0.28, 0.37, 1.73, 2.40, 2.51, 3.91, 4.10, 8.59				
	SEU	0.78, 1.07, 1.70, 1.99, 2.12, 2.75, 2.86, 3.73				
Beans (with pods) (2x 375 g/ha, PHI 14 d)	NEU	0.07, 0.08, 0.15, 0.16, 0.19, 0.30, 0.38, 0.45, 0.60, 0.62	NEU and SEU datasets not significantly different (U-Test, 5%), MRL, STMR and HR derived from the merged datasets. MRL_{OECD} = 0.9/1 **Extrapolation to peas (with pods)**	**1**	0.62	0.16
	SEU	0.04, 0.07, 0.08, 0.09, 0.09, 0.13, 0.17, 0.24, 0.35				
Peas (without pods) (2x 375 g/ha, PHI 14 d)	NEU	2x<0.01, 3x0.02, 0.06, 0.07, 0.08, 0.13, 0.21	NEU and SEU datasets not significantly different (U-Test, 5%), MRL, STMR and HR derived from the merged datasets, MRL_{OECD} = 0.29/0.30	**0.3**	0.21	0.04
	SEU	0.01, 0.01, 3x0.02, 0.05, 0.07, 0.10, 0.12, 0.17				

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

(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 (2x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.10, 0.15, 0.17), Underlined values: Residue samples were taken at a PHI of 11days (lettuce), 15 days (beans (with pods) and peas (without pods), respectively).

(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values)

3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies simulating the effect on the nature of fludioxonil residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed during the peer review (EFSA, 2007b) and it was concluded that the compound is hydrolytically stable under the representative conditions. Thus, for processed commodities, the same residue definition as for raw agricultural commodities (RAC) is applicable.

Studies investigating the effect of processing on the magnitude of fludioxonil residues in processed products were assessed during the peer review and Article 12 MRL review and robust processing factors (PFs) were proposed for processed commodities for table and wine grapes, mangos and carrots only (EFSA, 2007b, 2011a). Although processing studies addressing the magnitude of residues in cooked vegetables were not provided, the contribution of the crops under consideration to the chronic intake is less than 10% of the ADI and processing studies on cooked commodities of these crops are not triggered (European Commission, 1997d).

3.1.2. Rotational crops

Studies on the nature and magnitude of fludioxonil residues in rotational crops were assessed in the framework of the peer review and it was concluded that the residue definitions set for primary crops are also applicable to rotational crops (EFSA, 2007b). Significant residues are not expected in rotational crops when the active substance is applied on primary crops up to a total annual dose rate of 750 g/ha (EFSA, 2011a). Since the same maximum annual application rate is intended for the crops under consideration in this MRL application (beans and peas), EFSA concludes that fludioxonil residues are not expected to be present in rotational crops, provided that the active substance is applied according to the proposed GAPs.

3.2. Nature and magnitude of residues in livestock

As crops under consideration and their by-products are normally not fed to livestock, the nature and magnitude of fludioxonil residues in livestock is not assessed in the framework of this application (European Commission, 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).

To estimate the chronic exposure, EFSA used the median residue values (STMRs) derived from the residue trials conducted on lettuce, beans and peas reported in Table 4, the STMR value on pineapples for which the MRL is not yet legally implemented in the EU legislation (EFSA, 2016) and the STMR values proposed during the Article 12 MRL review (EFSA, 2011a). In addition, EFSA also considered the STMR values reported in reasoned opinions related to uses notified after the Article 12 MRL review (EFSA, 2011b, 2012, 2013a) and the STMRs related to the CXLs adopted by the Codex Alimentarius Commission (FAO, 2012, 2013) and transposed in the EU legislation by Regulations (EU) No 491/2014 and (EU) No 2015/845. The 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 of fludioxonil on these crops.

An acute consumer exposure assessment was not performed, since the setting of an ARfD was concluded to be unnecessary for fludioxonil.

The input values used for the dietary exposure calculation are summarised in Table 5.

[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 5: Input values for the chronic consumer exposure assessment

Commodity	Input (mg/kg)	Comment
Risk assessment residue definition for plant commodities: sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil[(a)]		
Pineapples	2.14	STMR (whole fruit) (EFSA, 2016)
Avocados	0.05	STMR (FAO, 2013)
Mangos	0.02	$STMR_{edible\ portion}$ (FAO, 2012)
Potatoes	1.50	STMR (FAO, 2013)
Radishes	0.10	STMR × CF (2.8) (EFSA, 2013a)
Tomatoes	0.66	STMR (FAO, 2013)
Cucurbits, inedible peel	0.01	$STMR_{edible\ portion}$ (EFSA, 2013a)
Lettuces	8.3	STMR (FAO, 2013)
Lettuces & salad plants (except lettuce)	6.13	STMR (Table 4)
Spinaches	5.80	STMR (FAO, 2013)
Spinaches & similar leaves (except spinaches)	6.13	STMR (Table 4)
Herbs and edible flowers	6.13	STMR (Table 4)
Beans (without pods)	0.02	STMR (FAO, 2013)
Peas (without pods)	0.04	STMR (Table 4)
Celeries (stem vegetables)	0.32	STMR (EFSA, 2012)
Beans (dry)	0.04	STMR (FAO, 2013)
Ginseng	0.80	STMR × CF (2.8) (FAO, 2013)
Other plant and animal commodities	Input values listed in Table 4-1 and 4-2 of the reasoned opinion on the article 12 MRL review (EFSA, 2011a).	

(a): A CF of 2.8 (derived from the metabolism study on spring onions) was used for residues resulting from foliar application on root crops (EFSA, 2007b).

The estimated exposure was then compared with the toxicological reference value derived for fludioxonil (see Table 2). The results of the intake calculation are presented in Appendix B of this reasoned opinion.

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The total chronic intake calculated accounted for up to 18% of the ADI (DE child). The contribution of residues in the crops under consideration to the total consumer exposure accounted for a maximum of 1.5% of the ADI (ES adult).

EFSA concludes that the intended use of fludioxonil on lettuces and salad plants, spinaches and similar leaves, herbs and edible flowers, beans and peas will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a concern for public health.

Conclusions and recommendations

The information submitted was sufficient to propose the MRLs summarised in the table below:

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: Fludioxonil				
0251000	Lettuce and salad plants (except lettuce)	15	20	Extrapolation from indoor trials on lettuce (open leaf varieties).
0251020	Lettuces	40	40	No change. EU GAPs result in a lower MRL proposal (20 mg/kg) than the CXLs of 40 and 30 mg/kg transposed in Reg. (EU) No 2015/845.
0252010	Spinaches	30	30	
0252020	Purslanes	15	20	Extrapolation from indoor trials on lettuce (open leaf varieties).
0252030	Chards/beet leaves	15	20	
0252990	Spinaches and similar leaves (others)	15	20	
0256000	Herbs & edible flowers	15	20	
0260010	Beans (with pods)	1	1	The submitted trials do not request a change of the existing MRL values
0260030	Peas (with pods)	1	1	
0260040	Peas (without pods)	0.05	0.3	NEU and SEU uses

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex maximum residue limit (Codex MRL)
EFSA	European Food Safety Authority
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))
HPLC	high performance liquid chromatography
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
MS	Member States
MS/MS	tandem mass spectrometry detector
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – Good Agricultural Practice (GAPs)

Crop and/or situation[a]	MS or NEU/SEU 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		
Lettuces and salad plants	NEU/SEU	F/G	*Botrytis cinerea, Sclerotinia spp.*	WG	500 g/kg	Foliar spray	11-49	1-2		0.025-0.083	300-1000	0.25	7	
Spinaches and similar leaves	NEU/SEU	F/G	*Botrytis cinerea, Sclerotinia spp.*	WG	500 g/kg	Foliar spray	11-49	1-2		0.025-0.083	300-1000	0.25	7	
Herbs and edible flowers	NEU/SEU	F/G	*Botrytis cinerea, Sclerotinia spp.*	WG	500 g/kg	Foliar spray	11-49	1-2		0.025-0.083	300-1000	0.25	7	
Peas (with pods), peas (without pods)	NEU/SEU	F	*Botrytis cinerea, Sclerotinia spp.*	WG	500 g/kg	Foliar spray	51-79	1-2		0.047-0.125	300-800	0.375	14	
Beans (with pods)	NEU/SEU	F	*Botrytis cinerea, Sclerotinia spp.*	WG	500 g/kg	Foliar spray	51-79	1-2		0.047-0.125	300-800	0.375	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)

Fludioxonil			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.37**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

Prepare workbook for refined calculations

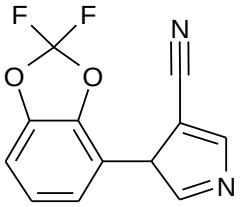
Undo refined calculations

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum	
2	18
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)
18.2	DE child	7.9	Pome fruit	6.6	Citrus fruit	1.0	Potatoes	
15.1	NL child	5.8	Citrus fruit	4.2	Pome fruit	2.4	Potatoes	
11.9	IE adult	3.8	Citrus fruit	3.6	Sweet potatoes	0.9	Potatoes	
10.0	FR toddler	3.4	Citrus fruit	2.1	Potatoes	1.8	Pome fruit	
7.4	WHO Cluster diet B	2.2	Citrus fruit	1.1	Potatoes	0.9	Pome fruit	
7.1	ES child	3.4	Citrus fruit	1.0	Pome fruit	0.9	Lettuce	
7.0	FR infant	1.8	Pome fruit	1.7	Potatoes	1.5	Citrus fruit	
6.8	UK Toddler	3.3	Citrus fruit	1.4	Potatoes	1.2	Pome fruit	
6.0	SE general population 90th percentile	2.0	Citrus fruit	1.7	Potatoes	0.9	Pome fruit	
5.9	NL general	2.7	Citrus fruit	1.1	Potatoes	0.8	Pome fruit	
5.4	ES adult	2.1	Citrus fruit	1.2	Lettuce	0.7	Pome fruit	
5.4	WHO regional European diet	1.6	Potatoes	1.2	Citrus fruit	0.8	Lettuce	
5.4	UK Infant	1.9	Citrus fruit	1.3	Potatoes	1.1	Pome fruit	
5.3	PT General population	2.2	Potatoes	1.1	Citrus fruit	0.9	Pome fruit	
4.9	WHO Cluster diet F	1.6	Citrus fruit	1.4	Potatoes	0.7	Lettuce	
4.8	WHO cluster diet E	1.6	Potatoes	1.2	Citrus fruit	0.6	Pome fruit	
4.7	DK child	1.9	Pome fruit	1.0	Potatoes	0.4	Citrus fruit	
4.0	IT kids/toddler	1.1	Citrus fruit	0.8	Pome fruit	0.7	Lettuce	
3.8	IT adult	0.8	Lettuce	0.8	Citrus fruit	0.6	Pome fruit	
3.7	WHO cluster diet D	1.6	Potatoes	0.7	Citrus fruit	0.5	Pome fruit	
3.7	PL general population	1.4	Pome fruit	1.4	Potatoes	0.2	Citrus fruit	
3.4	UK vegetarian	1.5	Citrus fruit	0.6	Potatoes	0.4	Pome fruit	
3.1	LT adult	1.3	Potatoes	1.3	Pome fruit	0.1	Citrus fruit	
3.0	FR all population	0.9	Citrus fruit	0.5	Potatoes	0.4	Pome fruit	
2.9	FI adult	1.6	Citrus fruit	0.5	Potatoes	0.3	Pome fruit	
2.6	UK Adult	1.0	Citrus fruit	0.6	Potatoes	0.3	Pome fruit	
2.2	DK adult	0.6	Pome fruit	0.6	Potatoes	0.4	Citrus fruit	

Appendix C – Used compound codes

Trivial name	Chemical name	Structural formula
Fludioxonil CGA 173506	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-pyrrole -3-carbonitrile MW: 248.2 g/mol	
CGA 192155	2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid MW: 202.1 g/mol	