

REASONED OPINION

Modification of the existing MRL for fludioxonil in celeriac¹

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SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, France, hereafter referred to as the Evaluating Member State (EMS), received an application from Syngenta Agro S.A.S. to modify the existing MRL for fludioxonil in celeriac. In order to accommodate the intended GAP in France, the applicant proposes to raise the existing MRL of 0.05 mg/kg (set at the LOQ) to 0.2 mg/kg. France as the Evaluating Member State (EMS) drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 29 May 2009. Originally, the applicant also applied for the amending MRLs on carrots, salsify and celery. On 12 August 2009, the applicant withdrew the application on celery. The MRL requests for carrots and salsify have been dropped as well because they have been assessed by EFSA before.

EFSA derives the following conclusions regarding the application for celeriac, based on the above mentioned evaluation report, the EFSA conclusion on the peer review of Fludioxonil, as well as the Draft Assessment Report prepared by the RMS Denmark.

The toxicological profile of the active substance was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.37 mg/kg bw/d. An ARfD was considered not necessary.

The metabolism of fludioxonil in plants was investigated under the peer review in five crop categories. The peer review concluded that the metabolic pattern is qualitatively similar in all crop groups investigated, but differences were noted regarding the quantities of metabolites occurring. The risk assessment residue definition was set as the sum of fludioxonil and all metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety. The enforcement residue definition was set as parent fludioxonil for all plant commodities. For cereals, fruits and leafy vegetables the conversion factor of 1 between residue definitions for monitoring and risk assessment is applicable. For the root vegetables which are the representative crop group for celeriac, a conversion factor of 2.8 was derived by the RMS Denmark in the framework of Article 12(1) of Regulation (EC) No 396/2005. Even though the conversion factor was derived from metabolism studies, EFSA applied it for performing the consumer risk assessment for celeriac. It is concluded that metabolism of fludioxonil in celeriac is addressed and no additional metabolism studies are required. Adequate analytical methods are available for the control of the compliance of the proposed MRL in celeriac.

The submitted supervised residues field trials indicate that the current MRL of 0.05 mg/kg does not accommodate the intended GAP in France and a higher MRL of 0.2 mg/kg would be necessary.

1 On request from the European Commission, Question No EFSA-Q-2009-00634, issued on 7 October 2009.

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Since for celeriac crop rotation is relevant, the occurrence of fludioxonil residues in rotational crops was also investigated. It is concluded that significant fludioxonil residues will not occur in rotational crops provided that the active substance is applied according to the proposed GAP. Celeriac is not used as a livestock feed therefore the nature and magnitude of fludioxonil residues in commodities of animal origin was not investigated. Fludioxonil is stable under core processing conditions. No processing studies have been submitted for celeriac and such are not necessary considering the insignificant consumer exposure to fludioxonil residues from the intake of celeriac.

Consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment the MRLs as established in Annex III of Regulation (EC) No 396/2005 as well as the STMR value derived for the intended use on celeriac multiplied by the conversion factor of 2.8 were used as input values. For root, tuber and bulb crops for which the MRLs are set above the LOQ, available STMR values or MRL values multiplied by the conversion factor of 2.8 were used as input values. For several crops the STMR values were available to refine the intake calculations. Acute intake assessment was not undertaken since no ARfD is established for fludioxonil.

Consumer intake calculations did not identify long-term intake concerns for any of European diets. The total calculated intake values ranged from 4.7 to 34.1% of the ADI. The contribution of celeriac to the total dietary intake was insignificant, accounting only for a maximum of 0.007% of the ADI.

Consequently EFSA concludes that the intended use of fludioxonil on celeriac is acceptable as it will not raise any concerns to consumer health. MRL proposal is presented in the table below:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: fludioxonil			
Celeriac	0.05*	0.2	The MRL proposal is supported by data and no risk for consumers was identified for the proposed use. The MRL proposal is based on the NEU use. No residue data are available for the Southern use.

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

KEY WORDS

Fludioxonil, celeriac, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, phenylpyrrole fungicide

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

France, hereafter referred to as the evaluating Member State (EMS), received an application from Syngenta AGRO S.A.S.³ to modify the existing MRLs for the active substance fludioxonil in several crops. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 29 May 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00634 and the following subject:

Fludioxonil - Application to modify the existing MRLs for fludioxonil in various root crops.

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

On 8 July 2009 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. Information addressing those data requirements was submitted by the EMS on 14 August 2009 and taken into consideration by EFSA for finalization of this reasoned opinion.

TERMS OF REFERENCE

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

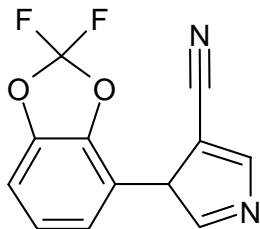
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 3 October 2009.

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THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Fludioxonil is the ISO common name for 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-pyrrole-3-carbonitrile (IUPAC):



MW: 248.2 g/mol

Fludioxonil belongs to the phenylpyrrole chemical class of fungicides. Its mode of action is inhibition of a mitogen-activated protein (MAP) kinase in signal transduction of osmo-regulation (glycerol synthesis). Fludioxonil is used as foliar and seed treatment application to control diseases caused by fungi in the class of *Ascomycetes*, *Basidiomycetes* and *Fungi imperfecti*.

Fludioxonil was peer reviewed according to Directive 91/414/EEC with Denmark being the designated Rapporteur Member State. It was included in Annex I to this Directive by Directive 2007/76/EC which entered into force on 1 November 2008. The Annex I inclusion is restricted to the use as a fungicide only. The peer review is completed and an EFSA conclusion was issued on 27 July 2007. The representative uses supported under the peer review cover foliar application of fludioxonil on wine and table grapes and seed treatment of wheat grain.

In the European Community temporary MRLs are established for fludioxonil in Annex III of Regulation (EC) No 396/2005 and are summarized in Appendix C. These temporary MRLs have been derived from the MRLs that have been set at national level before Regulation (EC) 396/2005 entered into force. For pomegranates, spinach and beet leaves as well as for various root vegetables (carrots, beetroots, salsify, horseradish, parsnips, parsley roots, roots of herbal infusions and roots of spices) MRL requests were recently assessed by EFSA (EFSA, 2008, 2009a, 2009b) and Annex III of Regulation (EC) No 396/2005 has been amended according to the EFSA recommendations. Codex Alimentarius has established CXLs for a wide range of commodities, but no CXLs are set for celeriac.

Originally, the applicant Syngenta AGRO S.A.S. requested an authorization in France for an outdoor use of fludioxonil on carrots, salsify, celeriac and celery. On 12 August 2009, the applicant informed EFSA that it withdraws the application regarding intended use on celery as it cannot satisfy the data requirements set by EFSA on 8 July 2009. Also an MRL requests for carrots and salsify have been dropped because the MRL applications for these crops have been assessed by EFSA before.

The intended outdoor use of fludioxonil on celeriac refers to an application of the active substance twice per growing season at a rate of 0.25 kg a.s./ha (Appendix A). The minimum waiting period is 14 days.

Taking into account the above mentioned, in this reasoned opinion EFSA will consider the MRL request for fludioxonil on celeriac only.

ASSESSMENT

1. Methods of analysis

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

The availability of analytical methods for enforcement was investigated in the framework of the peer review of Directive 91/414/EEC (Denmark, 2005). It was concluded that for the enforcement purposes a multi-residue method DFG-S19 is applicable. The extraction of fludioxonil is performed with acetone or acetone/acetonitrile. Extracts are cleaned up by gel permeation chromatography (GPC) and determined by LC-MS/MS. The method was validated for high acid-, high water- and dry commodities at the lowest validated fortification level of 0.02 mg/kg.

Since celeriac belongs to the group of high water content commodities, it is concluded that adequate analytical methods exist for the control of the compliance of the proposed MRL.

1.2. Methods for enforcement of residues in food of animal origin

Celeriac is not used as a livestock feeding stuff. Therefore availability of analytical methods for the determination of fludioxonil residues in food of animal origin was not investigated under the current application.

2. Mammalian toxicology

Toxicological reference values for fludioxonil were derived at Community level during the peer review under Directive 91/414/EEC (EFSA, 2007). They are compiled in Table 2-1.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Fludioxonil					
ADI	EFSA	2007	0.37 mg/kg bw/d	Rat, acute neurotoxicity	100
ARfD	EFSA	2007	n.n.		

n.n.- not necessary

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of fludioxonil in primary crops was investigated in the context of the peer review of Directive 91/414/EEC (Denmark, 2005). Metabolism studies have been provided for five crop groups following two different modes of application:

- fruits and fruiting vegetables: grapes, tomatoes and peach (foliar application)

- root vegetables: seed treatment of potatoes (tuber vegetables) and foliar application on green onions (bulb vegetables). Both crops belong to the group of root and tuber vegetables according to EU Guidance document 7028/VI/95 rev.3 (European Commission, 1997)
- leafy vegetables: lettuce (foliar application)
- cereals: rice and wheat (seed treatment)
- oilseeds: cotton and soybean (seed treatment)

Fludioxonil is metabolised mainly through oxidation followed by conjugation of metabolites with sugars. Cleavage of the pyrrole ring results in the formation of 2,2-difluoro-benzo[1,3]dioxole metabolites. The peer review concluded that the metabolic pattern is qualitatively similar in all crop groups investigated, but in root vegetables (study with spring onions) after foliar application higher rates of metabolites have been observed.

In the peer review the enforcement residue definition was set as fludioxonil for all plant commodities. Risk assessment residue definition was set as the sum of fludioxonil and its metabolites oxidised to metabolite CGA 192155 (2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid).

For cereals (seed treatment), for fruits and leafy vegetables the conversion factor of 1 between residue definitions for monitoring and risk assessment was derived which reflects the fact that no significant concentrations of metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety are expected. For the root vegetables after foliar application the conversion factor of 1 is not applicable since metabolism demonstrated that relevant metabolites are expected in significant concentrations (see 3.1.1.2.).

EFSA concludes that metabolism of fludioxonil in celeriac is sufficiently addressed and no additional metabolism studies are required.

3.1.1.2. Magnitude of residues

In support of the intended GAP in France, the applicant submitted four supervised residue field trials on celeriac. All trials were performed in the Northern France. Since France according to the EU Guidance document 7525/VI/95 is divided into Southern and Northern part (European Commission, 2008) and the intended GAP refers to the use of fludioxonil in both parts, at least four trials should be submitted for the each growing area (SEU and NEU). However, France confirmed that the production of celeriac is mainly located in the Northern parts of France. EFSA considered the available data for deriving the MRL proposal based on the NEU use.

Trials provide residue data in celeriac 14 and 20/21 days after the treatment. In three trials the measured fludioxonil residue was higher with a longer PHI of 20 or 21 day PHI. These higher values have been selected to derive the MRL proposal. Residues trials data are summarized in Table 3-1. The samples were only analyzed for the parent compound but not for the metabolites included in the residue definition for risk assessment. Celeriac belongs to the group of root vegetables for which fludioxonil related metabolites are expected in significant concentrations (see 3.1.1.1.). Since for celeriac no specific conversion factors from enforcement to risk assessment residue definition could be derived from supervised field trials data, EFSA proposes to use a generic conversion factor of 2.8 which was derived for other root vegetables by Denmark (Denmark, 2008) in the framework of Article 12(1) of Regulation (EC) No 396/2005. Although conversion factors should be derived from residue trials, EFSA took into account this value since the dietary exposure from fludioxonil residues is low. It is noted that fludioxonil will undergo full risk assessment in the framework of Article 12(1) of Regulation (EC) No 396/2005.

The storage stability of fludioxonil was investigated in the framework of the peer review and results demonstrate that fludioxonil is stable in water and oil containing commodities as well as in dry commodities for at least 24 months when stored deep frozen (Denmark, 2005). Celeriac samples prior analyses were stored deep frozen for a maximum period of 105 days not exceeding the demonstrated storage stability period of fludioxonil.

Fludioxonil residues in supervised residue trial samples were determined by GC-MS/MS with the LOQ of 0.01 mg/kg. According to the EMS, analytical method used for analysing supervised residue trial samples is considered sufficiently validated.

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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STM (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement (Fludioxonil)	Risk assessment (sum of fludioxonil and all metabolites containing the 2,2- difluoro- benzo[1,3]dioxole-4 carboxylic moiety)					
Celeriac	NEU	Outdoor	0.064*; 0.071; 0.077*; 0.10*	-	0.074	0.1	0.2	2.8	No data available for the risk assessment. Conversion factor of 2.8 derived from metabolism studies. R _{ber} =0.19 mg/kg R _{max} =0.16 mg/kg

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

* Residue value taken at longer PHI of 20 or 21 day

3.1.1.3. Effect of industrial processing and/or household preparation

Under the peer review of Directive 91/414/EEC the effects of processing on the nature of fludioxonil was investigated in a hydrolysis study by simulating pasteurization, baking, brewing, boiling and sterilisation processes (Denmark, 2005). The studies demonstrate that fludioxonil does not undergo degradation.

No studies on the effects of processing on the magnitude of fludioxonil residues have been submitted with regard to celeriac. Such, however, are not required considering the insignificant contribution of celeriac to the total dietary intake.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Celeriac can be grown in crop rotation. Under the peer review the degradation of fludioxonil in soil was investigated in laboratory and field studies (Denmark, 2005). The most critical DT₉₀ value (28-142 days) for fludioxonil was obtained based on the field study performed in Germany. In this case the occurrence of fludioxonil residues in rotational crops has to be investigated.

3.1.2.2. Nature of residues

Under the peer review five rotational crop studies were submitted on lettuce, winter wheat, sugar beets, corn, mustard, turnips, radishes (Denmark, 2005). The identified metabolites were consistent with those found in primary crops. Metabolic pathway of fludioxonil in plants proceeds according to a similar pathway as in primary plants: oxidation of pyrrole ring, hydrolysis of the nitrile moiety, opening of the pyrrole ring and further degradation to yield the final metabolite CGA 192155. Studies indicate that TRR levels in these crops were low and depend on the application rates.

From the studies with ¹⁴C-fludioxonil at application rates of 0.124 kg a.s./ha and 0.062 kg a.s./ha, TRR in radish, turnip and mustard samples 33 DAT were below <0.01 mg/kg and samples were not further analyzed. In both studies the TRR was higher in fractions of wheat (straw, forage and grain), but did not exceed 0.12 mg/kg of the TRR (mature wheat straw). Parent fludioxonil was not detected at levels > 0.01 mg/kg. From the study with application rate of 0.124 kg a.s./ha, other metabolites as tentatively identified CGA 265378⁴, CGA 192155, CGA 308103⁵, CGA 340351⁶, CGA 227731⁷ and CGA 260766⁸ did not account for >0.05 mg/kg each.

From the study with ¹⁴C-fludioxonil at an application rate of 1.1 kg a.s./ha, in all crop samples (radish, wheat and mustard), the parent fludioxonil accounted for 0.2% to 11.8 % (mature radish tuber 30 DAT) of TRR. Metabolite CGA 192155 (2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid) was the major metabolite and accounted for a maximum of 38.3% TRR in mature radish tuber (90 DAT) and 28% of the TRR in mature mustard leaves (90 DAT) (WHO/FAO, 2004).

It was concluded that the metabolism of fludioxonil in rotational crops proceeds according the same pattern as in primary crops and the same residue definitions are applicable.

⁴ CGA 265378: 4-(2,2-difluoro-benzol[1,3]dioxol-4-yl)-2,5-dioxo-2,5-dihydro-1H-pyrrole-3-carbonitrile

⁵ CGA 308103: 2-(2,2-difluoro-benzol[1,3]dioxol-4-yl)-2-hydroxy-acetamide

⁶ CGA 340351: 2,2-difluorobenzol[1,3]dioxole-4-carboxylic acid amide

⁷ CGA 227731: 6-hydroxy-2H-chromeno[3,4-c]pyrrol-4-one

⁸ CGA 260766: 3-(2,2-difluorobenzol[1,2]dioxol-4-yl)-4-hydroxy-pyrrole-2,5-dione

3.1.2.3. Magnitude of residues

Under the peer review five rotational crop studies were submitted (Denmark, 2005). Four of them were conducted by applying either pyrrole or phenyl labelled ^{14}C - fludioxonil on a bare soil at an application rates of 0.750 kg a.s./ha (Switzerland), 0.124 kg a.s./ha, 0.062 kg a.s./ha, 1.100 kg a.s./ha (U.S.) and one field study with non radio labelled fludioxonil applied at an application rate of 4 times 0.282 kg a.s./ha (U.S.) on a bare soil. Lettuce, wheat, sugar beet, corn, radish, mustard and turnips were planted /sowed as rotational crops (Denmark, 2005).

For drafting this opinion, EFSA considered only those rotational crop studies that have been performed at the same or at higher application rates as in the proposed GAP:

- The study in Switzerland was performed with pyrrole labelled ^{14}C - fludioxonil applied to bare soil at an application rate of 0.750 kg a.s./ha. The lettuces were planted 90 days after application, but winter wheat, sugar beets and corn were sown 140, 320 and 345 DAT. No residues exceeding 0.01 mg/kg were detected in any sample at any DAT.

- In the U.S. study with ^{14}C - fludioxonil at a dosing rate of 1.117 kg a.s./ha (2 N seasonal application rate), the highest TRR was observed 30 DAT in wheat straw (0.355 mg/kg), and radish roots (0.135 mg/kg). In mature crops 90 DAT and 210 DAT no residues exceeded 0.01 mg/kg. Only in radish tubers (30 DAT) and mature wheat straw (30 DAT) residues were >0.01 mg/kg: fludioxonil accounted for 0.016 mg/kg in radish tubers and CGA 192155 accounted for 0.015 mg/kg in straw.

- From the field study (4 times 0.282 kg a.s./ha) with non-radiolabelled fludioxonil, no residue levels >0.01 mg/kg were found in any of the samples when planted/sowed 30 DAT (Denmark, 2005).

Considering the results from the rotational crop study which was performed with a similar application rate (0.75 kg a.s./ha) to the intended one on celeriac (0.5 kg a.s./ha) it is concluded that significant fludioxonil residues will not occur in rotational crops provided that the active substance is applied according to the intended GAP.

3.2. Nature and magnitude of residues in livestock

Celeriac is not used as a livestock feed therefore the nature and magnitude of fludioxonil residues in livestock was not investigated under the current application.

4. Consumer risk assessment

Consumer intake calculations were performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment, as input values EFSA used the existing MRLs as well as the STMR value for celeriac as derived from the supervised residue field trials multiplied with the conversion factor of 2.8 for risk assessment. In addition, for crops which have been evaluated by EFSA recently, EFSA used available risk assessment values as derived in the previously issued EFSA reasoned opinions (EFSA, 2008, 2009a, 2009b). For root, tuber and bulb crops for which the MRLs are set above the LOQ, available STMR values or MRL values were multiplied by the conversion factor of 2.8 and used as input values. This correction was performed to take into account the metabolites included in the residue definition for risk assessment. It should be noted that the use of the existing MRL values in the intake calculation overestimates the actual consumer exposure as it is assumed that all crops for which no information on the STMR values is available will contain residues at the MRL.

Acute intake assessment was not undertaken because no ARfD value is established.

Input values are summarized in the table below.

Table 4-1. Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition for risk assessment: sum of fludioxonil and all metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety				
Celeriac	0.21	STMR*CF ^a	Acute intake assessment was not performed sine there is no ARfD established for fludioxonil.	
Potatoes	2.8	MRL*CF ^a		
Beetroot, carrots, horseradish, parsnips, parsley root, salsify	1.12	STMR*CF ^a (EFSA, 2009a)		
Pomegranate	0.95	STMR (EFSA, 2008)		
Spinach, beet leaves (chard)	2.6	STMR (EFSA, 2009b)		
Spring onions	0.84	MRL*CF ^a		
Onions	0.06	STMR*CF (Denmark, 2008)		

^a – the conversion factor of 2.8 from “fludioxonil” to “fludioxonil and the sum of 2,2-difluoro-benzo[1,3]dioxole metabolites”

Summary of consumer intake calculations is available in Appendix B.

Consumer intake calculations did not identify long-term intake concerns for any of European diets. The total calculated intake values ranged from 4.7 to 34.1% of the ADI. The contribution of celeriac to the total dietary intake was insignificant, accounting only for up to 0.007% of the ADI.

Consequently EFSA concludes that the intended use of fludioxonil on celeriac is acceptable as it will not raise any concerns to consumer health.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The metabolism of fludioxonil in plants was investigated under the peer review in five crop categories. The peer review concluded that the metabolic pattern is qualitatively similar in all crop groups investigated, but differences were noted regarding the quantities of metabolites occurring. The risk assessment residue definition was set as the sum of fludioxonil and all metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety. The enforcement residue definition was set as parent fludioxonil for all plant commodities. For cereals, fruits and leafy vegetables the conversion factor of 1 between residue definitions for monitoring and risk assessment is applicable. For the root vegetables which are the representative crop group for celeriac, a conversion factor of 2.8 was derived by the RMS Denmark in the framework of Article 12(1) of Regulation (EC) No 396/2005. Even though the conversion factor was derived from metabolism studies, EFSA applied it for performing the consumer risk assessment for celeriac. It is concluded that metabolism of fludioxonil in celeriac is addressed and no additional metabolism studies are required. Adequate analytical methods are available for the control of the compliance of the proposed MRL in celeriac.

The submitted supervised residues field trials indicate that the current MRL of 0.05 mg/kg does not accommodate the intended GAP in France and a higher MRL of 0.2 mg/kg would be necessary.

Since for celeriac crop rotation is relevant, the occurrence of fludioxonil residues in rotational crops was also investigated. It is concluded that significant fludioxonil residues will not occur in rotational crops provided that the active substance is applied according to the proposed GAP. Celeriac is not used as a livestock feed therefore the nature and magnitude of fludioxonil residues in commodities of animal origin was not investigated. Fludioxonil is stable under core processing conditions. No processing studies have been submitted for celeriac and such are not necessary considering the insignificant consumer exposure to fludioxonil residues from the intake of celeriac.

Consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment the MRLs as established in Annex III of Regulation (EC) No 396/2005 as well as the STMR value derived for the intended use on celeriac multiplied by the conversion factor of 2.8 were used as input values. For root, tuber and bulb crops for which the MRLs are set above the LOQ, available STMR values or MRL values multiplied by the conversion factor of 2.8 were used as input values. For several crops the STMR values were available to refine the intake calculations. Acute intake assessment was not undertaken since no ARfD is established for fludioxonil.

Consumer intake calculations did not identify long-term intake concerns for any of European diets. The total calculated intake values ranged from 4.7 to 34.1% of the ADI. The contribution of celeriac to the total dietary intake was insignificant, accounting only for a maximum of 0.007% of the ADI.

Consequently EFSA concludes that the intended use of fludioxonil on celeriac is acceptable as it will not raise any concerns to consumer health.

RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: fludioxonil			

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Celeriac	0.05*	0.2	The MRL proposal is supported by data and no risk for consumers was identified for the proposed use. The MRL proposal is based on the NEU use. No residue data are available for the Southern use.

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

REFERENCES

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and/or situation (a)	F or G (b)	Pest or group of pests controlled (c)	Formulation rate per treatment		Application			Application rate per treatment			PHI (days) (k)	Remarks: (l) e.g. minimum realistic PHI
			Type (d-f)	Conc. of a.s. (i)	method, kind, if other than spray (f-h)	growth stage (j)	number (range)	kg a.s./ha, where appropriate	water L/ha	kg a.s./hL, where appropri.		
Celeriac	F		WG	25% w/w	Low volume spraying		2	0.250			14	

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure).
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application.
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds.
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
- (e) GCPF Codes – GIFAP Technical Monograph No 2, 1989.
- (f) All abbreviations used must be explained.
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated.
- (i) g/kg or g/L.
- (j) Growth stage at 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.
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use.
- (l) PHI – minimum pre-harvest interval.
- (m) Remarks may include: extent of use/economic importance/restrictions.

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Fludioxonil			
Status of the active substance:	Included	Code no.	77
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

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		5 34							
		No of diets exceeding ADI:		---					
	Highest calculated TMDI values in % of ADI	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	pTMRs at LOQ (in % of ADI)	
	MS Diet								
	34.1	DE child	16.3	Apples	7.2	Oranges	1.9	Potatoes	
	26.6	NL child	8.6	Apples	5.9	Oranges	4.5	Potatoes	
	16.1	FR toddler	3.8	Potatoes	3.8	Oranges	3.5	Apples	
	15.0	IE adult	2.0	Oranges	1.9	Grapefruit	1.7	Potatoes	
	13.4	WHO Cluster diet B	2.0	Potatoes	1.6	Oranges	1.4	Apples	
	11.8	UK Toddler	3.7	Oranges	2.6	Potatoes	2.3	Apples	
	11.8	FR infant	3.4	Apples	3.1	Potatoes	1.7	Oranges	
	11.1	ES child	4.1	Oranges	1.5	Apples	1.4	Potatoes	
	10.5	PT General population	4.0	Potatoes	1.4	Apples	1.3	Wine grapes	
	10.4	SE general population 90th percentile	3.2	Potatoes	1.4	Apples	1.4	Oranges	
	9.9	NL general	2.8	Oranges	2.1	Potatoes	1.6	Apples	
	9.6	DK child	3.1	Apples	1.8	Potatoes	0.9	Pears	
	9.6	UK Infant	2.5	Potatoes	2.5	Oranges	2.1	Apples	
	9.2	WHO cluster diet E	2.9	Potatoes	1.1	Apples	0.9	Wine grapes	
	8.8	WHO regional European diet	3.0	Potatoes	1.0	Lettuce	0.9	Oranges	
	8.7	ES adult	2.4	Oranges	1.4	Lettuce	1.0	Apples	
	8.2	WHO Cluster diet F	2.6	Potatoes	1.6	Oranges	0.9	Apples	
	7.5	FR all population	2.2	Wine grapes	0.9	Potatoes	0.6	Apples	
	7.3	IT kids/toddler	1.2	Apples	0.9	Oranges	0.8	Lettuce	
	7.1	PL general population	2.8	Apples	2.6	Potatoes	0.4	Pears	
	7.0	WHO cluster diet D	3.1	Potatoes	0.9	Apples	0.5	Oranges	
	6.6	IT adult	1.1	Apples	1.0	Lettuce	0.7	Peaches	
	6.2	LT adult	2.5	Apples	2.4	Potatoes	0.2	Pears	
	5.9	UK vegetarian	1.6	Oranges	1.0	Potatoes	0.8	Apples	
	4.8	FI adult	1.8	Oranges	0.9	Potatoes	0.5	Apples	
	4.7	DK adult	1.1	Potatoes	1.1	Apples	0.8	Wine grapes	
	4.7	UK Adult	1.1	Oranges	1.1	Potatoes	0.6	Wine grapes	

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

APPENDIX C – EXISTING EC MRLs

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	10.00
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	7.00
110030	Lemons (Citron, lemon)	7.00
110040	Limes	7.00
110050	Mandarins (Clementine, tangerine and other hybrids)	7.00
110990	Others	7.00
120000	(ii) Tree nuts (shelled or unshelled)	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	5.00
130010	Apples (Crab apple)	5.00
130020	Pears (Oriental pear)	5.00
130030	Quinces	5.00
130040	Medlar	5.00
130050	Loquat	5.00
130990	Others	5.00
140000	(iv) Stone fruit	
140010	Apricots	5.00
140020	Cherries (sweet cherries, sour cherries)	5.00
140030	Peaches (Nectarines and	7.00

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
	similar hybrids)	
140040	Plums (Damson, greengage, mirabelle)	0,5
140990	Others	0,05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	2.00
151010	Table grapes	2.00
151020	Wine grapes	2.00
152000	(b) Strawberries	3.00
153000	(c) Cane fruit	
153010	Blackberries	5.00
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries)	5.00
153990	Others	0,05*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	3.00
154020	Cranberries	1.00
154030	Currants (red, black and white)	3.00
154040	Gooseberries (Including hybrids with other ribes species)	3.00
154050	Rose hips	1.00
154060	Mulberries (arbutus berry)	1.00
154070	Azarole (mediteranean medlar)	1.00
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries, and other treeberries)	2.00

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
154990	Others	1.00
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomereac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	
162010	Kiwi	20.00
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammeey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	3.00
163060	Cherimoya (Custard apple, sugar	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
	apple (sweetsop), llama and other medium sized Annonaceae)	
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	1.00
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	1.00
213020	Carrots	1.00
213030	Celeriac	0,05*
213040	Horseradish	1.00
213050	Jerusalem artichokes	0,05*
213060	Parsnips	1.00
213070	Parsley root	1.00
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	1.00
213100	Swedes	0,05*
213110	Turnips	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
213990	Others	0,05*
220000	(ii) Bulb vegetables	
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,1
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,3
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	1.00
231020	Peppers (Chilli peppers)	2.00
231030	Aubergines (egg plants) (Pepino)	1.00
231040	Okra, lady's fingers	0,5
231990	Others	0,5
232000	(b) Cucurbits - edible peel	
232010	Cucumbers	1.00
232020	Gherkins	0,5
232030	Courgettes (Summer squash, marrow (patisson))	1.00
232990	Others	0,5
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicaceae	10.00
251010	Lamb's lettuce (Italian cornsalad)	10.00
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	10.00
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	10.00
251040	Cress	10.00
251050	Land cress	10.00
251060	Rocket, Rucola (Wild rocket)	10.00
251070	Red mustard	10.00
251080	Leaves and sprouts of Brassica spp (Mizuna)	10.00
251990	Others	10.00
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	7.00
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel,	10.00

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
	glasswort)	
252030	Beet leaves (chard) (Leaves of beetroot)	7.00
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	1.00
256010	Chervil	1.00
256020	Chives	1.00
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	1.00
256040	Parsley	1.00
256050	Sage (Winter savory, summer savory,)	1.00
256060	Rosemary	1.00
256070	Thyme (marjoram, oregano)	1.00
256080	Basil (Balm leaves, mint, peppermint)	1.00
256090	Bay leaves (laurel)	1.00
256100	Tarragon (Hyssop)	1.00
256990	Others	1.00
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	1.00
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,2
260030	Peas (with pods) (Mangetout (sugar peas))	0,2
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,1
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel,)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	0,05*
401000	(i) Oilseeds	0,05*
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	0,05*
500020	Buckwheat	0,05*
500030	Maize	0,1
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,2
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	1.00
633010	Valerian root	1.00

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
633020	Ginseng root	1.00
633990	Others	1.00
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	1.00
840010	Liquorice	1.00
840020	Ginger	1.00
840030	Turmeric (Curcuma)	1.00
840040	Horseradish	1.00
840990	Others	1.00
850000	(v) Buds	0,05*
850010	Cloves	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	0,05*
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,05*
*-indicates lowest limit of analytical quantification		

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
Bw	body weight
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
GAP	good agricultural practice
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LC	liquid chromatography

LC-MS	liquid chromatography-mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMO	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SEU	Southern European Union
SG	water soluble granule
SL	soluble concentrate
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WG	water dispersible granule
WHO	World Health Organisation