

## REASONED OPINION OF EFSA

### Modification of the existing MRLs for fludioxonil in spinach and beet leaves (chard)<sup>1</sup>

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00210)

Issued on 4 March 2009

#### SUMMARY

Portugal received an application from Iberian Salads Agricultura SA to modify the existing MRLs for fludioxonil in spinach and beet leaves (chard). The current EC MRL for fludioxonil in these crops is set at the limit of quantification (0.05 mg/kg) and the applicant proposes to raise the MRL to 10 mg/kg by extrapolation from lettuce. The Evaluating Member State Portugal according to Article 9 of the Regulation drafted the evaluation report on this subject which was submitted to the European Commission and forwarded to EFSA on 14 January 2009.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report and the EFSA conclusion prepared in the framework of the peer review:

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.

It was concluded that the metabolic pattern is similar in all crops. The residue definition for monitoring purposes derived under the peer review is set as fludioxonil for all plant commodities. For the risk assessment the definition is set as the sum of fludioxonil and all metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety. For cereals after seed treatment, for fruits and leafy vegetables the conversion factor of 1 between residue definitions for monitoring and risk assessment was derived.

Adequate analytical methods are available to enforce an MRL in spinach and beet leaves (chard). From the supervised residue field trials data on lettuce that were submitted in support of the application, an MRL of 7 mg/kg would be required to accommodate the use of fludioxonil in Portugal. It should be mentioned that applicant proposed an MRL of 10 mg/kg. Sufficient number of trials is submitted for the extrapolation from lettuce to spinach and beet leaves (chard).

---

<sup>1</sup> For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRLs for fludioxonil in spinach and beet leaves (chard). *EFSA Scientific Report* (2009) 244, 1-23

The effect of processing on the nature of fludioxonil residues has been investigated under the peer review in hydrolysis studies. Fludioxonil is considered stable under hydrolytic processing conditions and no formation of toxicologically significant metabolites is expected. No processing data have been submitted with regard to the MRL proposal.

The metabolism in rotational crops proceeds according to the same pattern as in primary crops and no additional residue definition needs to be established. If fludioxonil is used according to the proposed GAP, no significant residues are expected in rotational crops.

Nature and magnitude of fludioxonil residues in livestock was not assessed with regard to the current application since spinach and beet leaves (chard) are not usually fed to livestock.

Consumer risk assessment was performed with the EFSA PRIMo rev.2. The chronic dietary risk assessment did not identify any consumer intake concerns for any of European diets. The contribution of spinach and beet leaves (chard) to the overall dietary intake is insignificant: 0.5 % of the ADI (FR Toddler diet) and 0.06 % of the ADI (ES adult and ES child diets) respectively. No acute intake calculations were performed since there is no ARfD value established.

It is concluded that for the proposed use no consumer intake concerns are identified and the MRL proposal of 10 mg/kg of fludioxonil in spinach and beet leaves (chard) can be supported.

### Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Spinach, beet leaves (chard)	0.05*	7 or 10 <sup>a</sup>	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses.

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

<sup>a</sup> – 10 mg/kg is the applicant's MRL proposal; 7 mg/kg is the proposal derived from the MRL calculation

**Key words: Fludioxonil, spinach, beet leaves (chard), MRL application, Regulation (EC) No 396/2005, consumer risk assessment, phenylpyrrole fungicides**

**TABLE OF CONTENTS**

Background .....	4
Terms of reference.....	4
The active substance and its use pattern.....	5
Assessment .....	6
1. Methods of analysis.....	6
1.1. Methods for enforcement of residues in food of plant origin .....	6
1.2. Methods for enforcement of residues in food of animal origin .....	6
2. Mammalian toxicology.....	6
3. Residues.....	6
3.1. Nature and magnitude of residues in plant.....	6
3.1.1. Primary crops.....	6
3.1.1.1. Nature of residues .....	6
3.1.1.2. Magnitude of residues.....	7
3.1.1.3. Effect of industrial processing and/or household preparation .....	9
3.1.2. Rotational crops.....	9
3.1.2.1. Preliminary considerations.....	9
3.1.2.2. Nature of residues .....	9
3.1.2.3. Magnitude of residues.....	9
3.2. Nature and magnitude of residues in livestock .....	10
4. Consumer risk assessment .....	10
Conclusions and recommendations .....	11
Documentation provided to EFSA .....	12
References .....	12
Appendix A – Good Agricultural Practices (GAPs) .....	13
Appendix B – Existing EC MRLs.....	14
Appendix C – Pesticide Residues Intake Model (PRIMo).....	20
Glossary / Abbreviations.....	22

**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.

Portugal, hereafter referred to as the Evaluating Member State (EMS), received an application from Iberian Salads Agricultura SA<sup>2</sup> to modify the existing MRLs for fludioxonil in spinach and beet leaves (chard). 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 14 January. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00210 and the following subject:

*Fludioxonil - Application to modify the existing MRLs for fludioxonil in spinach from 0.05\* mg/kg to 10 mg/kg and in beet leaves (chard) from 0.05\* mg/kg to 10 mg/kg.*

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

**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 data of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

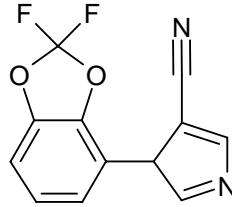
In this particular case the calculated deadline for providing the reasoned opinion is 14 April 2009.

---

<sup>2</sup> Iberian Salads Agricultura SA, Quinta dos Cativos – Boavista dos Pinheiros, 7630-033, Odemira, Portugal

## 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). The chemical structure of fludioxonil is following:



Fludioxonil belongs to the phenylpyrrole class of fungicides. The mode of action of fludioxonil is by 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 of 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 representative uses supported under the peer review cover foliar application of fludioxonil on wine and table grapes at a maximum rate of 2 x 250 g a.s./ha per year and seed treatment in wheat with 5.0 g a.s./100 kg seed.

In the European Community currently temporary MRLs are established for fludioxonil in Annex III of Regulation (EC) No 396/2005 and are summarized in Appendix B. These temporary MRLs have been derived from the MRLs that have been set at national level before Regulation (EC) 396/2005 entered into force. Codex Alimentarius has established CXLs for a wide range of commodities, but no CXLs are set for spinach and beet leaves (chard).

Portugal requested an authorization for an outdoor and indoor used of fludioxonil on spinach and beet leaves (chard) at an application rate of 2 x 0.038-0.15 kg a.s./ha. The minimum waiting period is 14 days. The interval between applications is not specified.

## ASSESSMENT

### 1. Methods of analysis

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

In the framework of the peer review of fludioxonil analytical methods were evaluated (EFSA, 2007). It was concluded that for the enforcement purposes a multi-residue method DFG-S19 (LC-MS/MS) 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 commodities with high acid and high water content, and dry commodities with an LOQ of 0.02 mg/kg.

Since spinach and beet leaves (chard) belong to the group of high water content commodities, it is concluded that adequate analytical methods exist for the enforcement of the proposed MRL.

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

Since spinach are not fed to livestock, analytical methods for food of animal origin are not considered in this evaluation.

### 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 (mg/kg bw/d)	Study relied upon	Safety factor
Fludioxonil					
ADI	EFSA	2007	0.37	2 year rat	100
ARfD	EFSA	2007	n.n.	n.n.	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 has already been assessed in the EFSA conclusion prepared in the context of the peer review (EFSA, 2007).

Metabolism studies were submitted for 5 crop groups and two different modes of application:

- fruits (grapes, tomatoes and peach- foliar application),
- root vegetables (green onions – foliar application, potatoes – seed treatment)
- leafy crops (lettuce – foliar application)
- cereals, (rice and wheat – seed treatment) and
- oilseeds (cotton and soybean – seed treatment)

It was concluded that the metabolic pattern is similar in all crops. 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 residue definition for monitoring purposes derived under the peer review is set as fludioxonil for all plant commodities. For the risk assessment the definition was set as the sum of fludioxonil and all metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety. For cereals after seed treatment, for fruits and leafy vegetables the conversion factor of 1 between residue definitions for monitoring and risk assessment was derived.

#### 3.1.1.2. Magnitude of residues

In support of the proposed GAP on spinach and beet leaves (chard), the applicant referred to the supervised residues field trials that were performed in the framework of the setting of the CXL for lettuce. In total 18 supervised residues field trials are available on different lettuce varieties. Ten trials were submitted reflecting the indoor use of fludioxonil and eight trials reflecting the outdoor use in Southern Europe (FAO/WHO, 2004). In all field trials fludioxonil was applied three times on the lettuce therefore not complying with the proposed GAP where two applications are envisaged. However, residue decline data were provided demonstrating that the most critical application regarding residue levels in the crop is the last application. Taking that into account EFSA considers that the data on supervised residues field trials are representative for the intended GAP and sufficient for deriving an MRL proposal. The residue levels measured in the indoor trials are higher than the levels measured in outdoor trials therefore the MRL proposals and risk assessment values are derived from the indoor trials. It is concluded that the residue trials on lettuce can be extrapolated to spinach and beet leaves (chard). The summary of residue field trials data and the derived MRL proposals and risk assessment values are summarized in Table 3-1. The MRL proposals were derived using the statistical methodologies agreed at European level.

The available studies submitted in the peer review of fludioxonil, demonstrate storage stability of fludioxonil in water and oil containing commodities as well as in dry commodities (EFSA, 2007). Fludioxonil residues are stable in plant samples for at least 24 months when stored at  $\leq -16^{\circ}$  C. The residue data was considered valid both in the means of analytical performance and storage stability (FAO/WHO, 2004).

It should be noted that during the evaluation process the number of applications and the PHI were modified by the EMS which resulted in new parameters of the GAP matching the available residues trials. EFSA is not in the position to judge whether the number of applications and the PHI were altered for the means of efficiency.

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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Enforcement residue definition : Fludioxonil									
Spinach, beet leaves (chard)	SEU	Outdoor	4 x <0.02; 0.04; 0.29; 2 x 1.2	4 x <0.02; 0.04; 0.29; 2 x 1.2	0.03	1.2	2.00	1.00	Trials were performed on lettuce and can be extrapolated to spinach and beet leaves (chard). MRL proposal and risk assessment values are based on the indoor use, considering that it is the most critical (indicated in bold) $R_{\text{ber (outdoor)}} = 1.9 \text{ mg/kg}$ $R_{\text{max (outdoor)}} = 2.05 \text{ mg/kg}$ $R_{\text{ber (indoor)}} = 7.45 \text{ mg/kg}$ $R_{\text{max (indoor)}} = 7.7 \text{ mg/kg}$
	EU	Indoor	0.72; 0.98; 1.1; 2.4; 2.5; 2.7; 2 x 3.4; 4.7; 6.0	0.72; 0.98; 1.1; 2.4; 2.5; 2.7; 2 x 3.4; 4.7; 6.0	<b>2.6</b>	<b>6.0</b>	<b>7 or 10</b>	1.00	

(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.

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



### 3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of fludioxonil residues has been investigated under the peer review (EFSA, 2007). Hydrolysis studies were conducted under representative hydrolytic conditions, stimulating pasteurization, baking, brewing, boiling and sterilization and demonstrate that fludioxonil is considered stable under these hydrolytic processing conditions. Formation of toxicologically significant metabolites is therefore not expected. No processing data have been submitted with regard to the current application and are not required since the contribution of spinach and beet leaves (chard) to the dietary intake is insignificant.

## 3.1.2. Rotational crops

### 3.1.2.1. Preliminary considerations

All crops supported in the framework of the current application may be grown in rotation. Under the peer review the degradation of fludioxonil in soil was investigated in laboratory and field studies (EFSA, 2007). The most critical DT<sub>90</sub> value (28-142 days) of fludioxonil was obtained based on the field study performed in Germany. Since it exceeds 100 days, rotational crop studies are necessary.

### 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). Studies indicate that TRR levels in these crops were low and depend on the application rates. It was concluded that the metabolism of fludioxonil in rotational crop proceeds according the same pattern as in primary crops.

### 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 <sup>14</sup>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 x 0.282 kg a.s./ha (U.S.) on bare soil. Lettuce, wheat, sugar beet, corn, radish, mustard and turnips were planted /sowed as rotational crops.

Studies conducted with <sup>14</sup>C- fludioxonil at application rates of 0.062, 0.124 and 0.750 kg a.s./ha resulted in very low levels of radioactive residues in rotational crops. Only cereal grain, straw and forage and only when crops were planted at 32-33 DAT contained TRR >0.01 mg/kg. In these commodities TRR were up to 0.058 mg/kg in wheat forage, 0.12 mg/kg in the mature wheat straw and 0.015 mg/kg in mature grain. TRR in all samples planted or sowed 90-120 DAT were <0.01 mg/kg. From the field study with non-radiolabelled fludioxonil applied four times to bare soil at an application rate of 0.282 kg a.s./ha, no residues exceeding 0.01 mg/kg were found in any of the samples when planted/sowed 30 DAT.

Considering that the maximum application rate with regard to the proposed GAP would be 0.3 kg a.s./ha and that a part of the applied substance is intercepted by the treated crop, it is

concluded that significant residue levels (>0.01 mg/kg) will not 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

Nature and magnitude of fludioxonil residues in livestock was not assessed with regard to the current application since spinach and beet leaves (chard) are not usually fed to livestock.

## 4. Consumer risk assessment

Consumer risk assessment was performed with the EFSA PRIMo rev.2 using the existing MRLs as established in Annex III of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use on spinach and beet leaves (chard). In addition, for several crops the STMR values were used as obtained in the previously issued EFSA reasoned opinions on fludioxonil. The input values are summarized in Table 4-1.

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
Sum of fludioxonil and all metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety				
Spinach, beet leaves (chard)	2.6	STMR	The acute risk assessment was not performed since no ARfD value is established	
Beetroot, carrots, horseradish, parsnips, parsley root, salsify	1.12	STMR*CF <sup>a</sup> (EFSA, 2009)		
Potatoes	2.8	MRL*CF (EFSA, 2009)		
Pomegranates	0.95	STMR (EFSA, 2008)		

<sup>a</sup>- conversion factor of 2.8 from enforcement definition to risk assessment definition for root and tuber vegetables

The summary of the chronic intake calculations can be found in Appendix C. The chronic dietary risk assessment did not identify any consumer intake concerns for any of European diets. The contribution of spinach and beet leaves (chard) to the overall dietary intake is insignificant: 0.5 % of the ADI (FR Toddler diet) and 0.06 % of the ADI (ES adult and ES child diets) respectively. No acute intake calculations were performed since there is no ARfD value established.

It is concluded that for the proposed use, no consumer intake concerns have been identified and the MRL proposal of 10 mg/kg for spinach and beet leaves (chard) can be supported.

## CONCLUSIONS AND RECOMMENDATIONS

Portugal received an application from Iberian Salads Agricultura to modify the existing MRLs for fludioxonil in spinach and beet leaves (chard). The current EC MRL for fludioxonil in these crops is set at the limit of quantification (0.05 mg/kg) and the applicant proposes to raise the MRL to 10 mg/kg by extrapolation from lettuce. Portugal as the Evaluating Member State drafted an evaluation report which was forwarded to EFSA on 15 December 2008.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report and the EFSA conclusion prepared in the framework of the peer review:

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.

It was concluded that the metabolic pattern is similar in all crops. The residue definition for monitoring purposes derived under the peer review is set as fludioxonil for all plant commodities. For the risk assessment the definition is set as the sum of fludioxonil and all metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety. For cereals after seed treatment, for fruits and leafy vegetables the conversion factor of 1 between residue definitions for monitoring and risk assessment was derived.

Adequate analytical methods are available to enforce an MRL in spinach and beet leaves (chard). From the supervised residue field trials data on lettuce that were submitted in support of the application, an MRL of 7 mg/kg would be required to accommodate the use of fludioxonil in Portugal. It should be mentioned that applicant proposed an MRL of 10 mg/kg. Sufficient number of trials is submitted for the extrapolation from lettuce to spinach and beet leaves (chard).

The effect of processing on the nature of fludioxonil residues has been investigated under the peer review in hydrolysis studies. Fludioxonil is considered stable under hydrolytic processing conditions and no formation of toxicologically significant metabolites is expected. No processing data have been submitted with regard to the MRL proposal.

The metabolism in rotational crops proceeds according to the same pattern as in primary crops and no additional residue definition needs to be established. If fludioxonil is used according to the proposed GAP, no significant residues are expected in rotational crops.

Nature and magnitude of fludioxonil residues in livestock was not assessed with regard to the current application since spinach and beet leaves (chard) are not usually fed to livestock.

Consumer risk assessment was performed with the EFSA PRIMo rev.2. The chronic dietary risk assessment did not identify any consumer intake concerns for any of European diets. The contribution of spinach and beet leaves (chard) to the overall dietary intake is insignificant: 0.5 % of the ADI (FR Toddler diet) and 0.06 % of the ADI (ES adult and ES child diets) respectively. No acute intake calculations were performed since there is no ARfD value established.

It is concluded that for the proposed use no consumer intake concerns are identified and the MRL proposal of 10 mg/kg of fludioxonil in spinach and beet leaves (chard) can be supported.

Table 5-1. Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Spinach, beet leaves (chard)	0.05*	7 or 10 <sup>a</sup>	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses.

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

<sup>a</sup> – 10 mg/kg is the applicant's MRL proposal; 7 mg/kg is the proposal derived from the MRL calculation

#### DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRL for fludioxonil in spinach and beet leaves (chard) according to Regulation (EC) No 396/2005 prepared by the Evaluating Member State Portugal. Received in EFSA on 15 December 2008. Updated on 27 February 2009.

#### REFERENCES

- Denmark, 2005. Draft Assessment Report on fludioxonil prepared according to Directive 91/414/EEC. January, 2005.
- EFSA, 2007. EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance fludioxonil. EFSA Scientific Report (2007) 110, 1-85.
- EFSA, 2008. Reasoned opinion prepared by Pesticides Unit (PRAPeR) on the setting of an import tolerance for fludioxonil in pomegranates. EFSA Scientific Report (2008) 199,1-19.
- EFSA, 2009. Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRL for fludioxonil in various root vegetables. EFSA Scientific Report (2009) 238, 1-27.
- FAO/WHO, 2004. Pesticides Residues in Food -2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 178

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)	Remarks
			Type (d)	Conc. of a.s.	Method	Number (range)	kg a.s./ha, where appropriate	water L/ha	kg a.s./hL, where appropriate		
Spinach, beet leaves (chard)	F/G	Fungus	WG	25 %	spray	2	0.0375 - 0.15	300-1000	0.0125-0.015	14	In mixture with cyprodinil (37.5%):0.0.01875-0.0225 kg/hl

- (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 granules (WG).

**APPENDIX B – EXISTING EC MRLS**

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
1. FRUIT FRESH OR FROZEN; NUTS	
(i) Citrus fruit	
Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	10
Oranges (Bergamot, bitter orange, chinotto and other hybrids)	7
Lemons (Citron, lemon)	7
Limes	7
Mandarins (Clementine, tangerine and other hybrids)	7
Others	7
(ii) Tree nuts (shelled or unshelled)	0,05*
Almonds	0,05*
Brazil nuts	0,05*
Cashew nuts	0,05*
Chestnuts	0,05*
Coconuts	0,05*
Hazelnuts (Filbert)	0,05*
Macadamia	0,05*
Pecans	0,05*
Pine nuts	0,05*
Pistachios	0,05*
Walnuts	0,05*
Others	0,05*
(iii) Pome fruit	5
Apples (Crab apple)	5
Pears (Oriental pear)	5
Quinces	5
Medlar	5
Loquat	5
Others	5
(iv) Stone fruit	
Apricots	5
Cherries (sweet cherries, sour cherries)	5
Peaches (Nectarines and similar hybrids)	7

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
Plums (Damson, greengage, mirabelle)	0,5
Others	0,05*
(v) Berries & small fruit	
(a) Table and wine grapes	2
Table grapes	2
Wine grapes	2
(b) Strawberries	3
(c) Cane fruit	
Blackberries	5
Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*
Raspberries (Wineberries)	5
Others	0,05*
(d) Other small fruit & berries	
Blueberries (Bilberries cowberries (red bilberries))	3
Cranberries	1
Currants (red, black and white)	3
Gooseberries (Including hybrids with other ribes species)	3
Rose hips	1
Mulberries (arbutus berry)	1
Azarole (mediteranean medlar)	1
Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	2
Others	1
(vi) Miscellaneous fruit	
(a) Edible peel	0,05*
Dates	0,05*
Figs	0,05*
Table olives	0,05*

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
Kumquats (Marumi kumquats, nagami kumquats)	0,05*
Carambola (Bilimbi)	0,05*
Persimmon	0,05*
Jambolan (java plum) (Java apple (water apple), pomegranate, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
Others	0,05*
(b) Inedible peel, small	
Kiwi	20
Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
Passion fruit	0,05*
Prickly pear (cactus fruit)	0,05*
Star apple	0,05*
American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mamme sapote)	0,05*
Others	0,05*
(c) Inedible peel, large	0,05*
Avocados	0,05*
Bananas (Dwarf banana, plantain, apple banana)	0,05*
Mangoes	0,05*
Papaya	0,05*
Pomegranate	0,05*
Cherimoya (Custard apple, sugar apple (sweetsop), litchi and other medium sized Annonaceae)	0,05*
Guava	0,05*
Pineapples	0,05*
Bread fruit (Jackfruit)	0,05*
Durian	0,05*
Soursop (guanabana)	0,05*
Others	0,05*
<b>2. VEGETABLES FRESH OR FROZEN</b>	
(i) Root and tuber vegetables	
(a) Potatoes	1

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
(b) Tropical root and tuber vegetables	0,05*
Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
Sweet potatoes	0,05*
Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
Arrowroot	0,05*
Others	0,05*
(c) Other root and tuber vegetables except sugar beet	0,05*
Beetroot	0,05*
Carrots	0,05*
Celeriac	0,05*
Horseradish	0,05*
Jerusalem artichokes	0,05*
Parsnips	0,05*
Parsley root	0,05*
Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,05*
Swedes	0,05*
Turnips	0,05*
Others	0,05*
(ii) Bulb vegetables	
Garlic	0,05*
Onions (Silverskin onions)	0,1
Shallots	0,05*
Spring onions (Welsh onion and similar varieties)	0,3
Others	0,05*
(iii) Fruiting vegetables	
(a) Solanacea	
Tomatoes (Cherry tomatoes, )	1
Peppers (Chilli peppers)	2
Aubergines (egg plants) (Pepino)	1
Okra, ladyfinger	0,5
Others	0,5

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
(b) Cucurbits - edible peel	
Cucumbers	1
Gherkins	0,5
Courgettes (Summer squash, marrow (patisson))	1
Others	0,5
(c) Cucurbits-inedible peel	0,05*
Melons (Kiwano )	0,05*
Pumpkins (Winter squash)	0,05*
Watermelons	0,05*
Others	0,05*
(d) Sweet corn	0,05*
(e) Other fruiting vegetables	0,05*
(iv) Brassica vegetables	0,05*
(a) Flowering brassica	0,05*
Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
Cauliflower	0,05*
Others	0,05*
(b) Head brassica	0,05*
Brussels sprouts	0,05*
Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
Others	0,05*
(c) Leafy brassica	0,05*
Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
Kale (Borecole (curly kale), collards)	0,05*
Others ( )	0,05*
(d) Kohlrabi	0,05*
(v) Leaf vegetables & fresh herbs	
(a) Lettuce and other salad plants including Brassicacea	10
Lamb's lettuce (Italian cornsalad)	10

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	10
Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	10
Cress	10
Land cress	10
Rocket, Rucola (Wild rocket)	10
Red mustard	10
Leaves and sprouts of Brassica spp (Mizuna)	10
Others	10
(b) Spinach & similar (leaves)	
Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	10
Beet leaves (chard) (Leaves of beetroot)	0,05*
Others	0,05*
(c) Vine leaves (grape leaves)	0,05*
(d) Water cress	0,05*
(e) Witloof	0,05*
(f) Herbs	1
Chervil	1
Chives	1
Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisel and other Apiacea)	1
Parsley	1
Sage (Winter savory, summer savory, )	1
Rosemary	1
Thyme ( marjoram, oregano)	1
Basil (Balm leaves, mint, peppermint)	1
Bay leaves (laurel)	1
Tarragon (Hyssop)	1



Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
Others	1
(vi) Legume vegetables (fresh)	
Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	1
Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,2
Peas (with pods) (Mangetout (sugar peas))	0,2
Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
Lentils	0,05*
Others	0,05*
(vii) Stem vegetables (fresh)	0,05*
Asparagus	0,05*
Cardoons	0,05*
Celery	0,05*
Fennel	0,1
Globe artichokes	0,05*
Leek	0,05*
Rhubarb	0,05*
Bamboo shoots	0,05*
Palm hearts	0,05*
Others	0,05*
(viii) Fungi	0,05*
Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
Wild (Chanterelle, Truffle, Morel, )	0,05*
Others	0,05*
(ix). Sea weeds	0,05*
3. PULSES, DRY	0,05*
Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
Lentils	0,05*
Peas (Chickpeas, field peas, chickling vetch)	0,05*
Lupins	0,05*
Others	0,05*
4. OILSEEDS AND OILFRUITS	0,05*
(i) Oilseeds	0,05*

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
Linseed	0,05*
Peanuts	0,05*
Poppy seed	0,05*
Sesame seed	0,05*
Sunflower seed	0,05*
Rape seed (Bird rapeseed, turnip rape)	0,05*
Soya bean	0,05*
Mustard seed	0,05*
Cotton seed	0,05*
Pumpkin seeds	0,05*
Safflower	0,05*
Borage	0,05*
Gold of pleasure	0,05*
Hempseed	0,05*
Castor bean	0,05*
Others	0,05*
(ii) Oilfruits	0,05*
Olives for oil production	0,05*
Palm nuts (palmoil kernels)	0,05*
Palmfruit	0,05*
Kapok	0,05*
Others	0,05*
5. CEREALS	
Barley	0,05*
Buckwheat	0,05*
Maize	0,1
Millet (Foxtail millet, teff)	0,05*
Oats	0,05*
Rice	0,05*
Rye	0,05*
Sorghum	0,05*
Wheat (Spelt Triticale)	0,2
Others	0,05*
6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i> )	0,05*
(ii) Coffee beans	0,05*
(iii) Herbal infusions (dried)	0,05*
(a) Flowers	0,05*
Camomille flowers	0,05*
Hybiscus flowers	0,05*
Rose petals	0,05*
Jasmine flowers	0,05*

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
Lime (linden)	0,05*
Others	0,05*
(b) Leaves	0,05*
Strawberry leaves	0,05*
Rooibos leaves	0,05*
Maté	0,05*
Others	0,05*
(c) Roots	0,05*
Valerian root	0,05*
Ginseng root	0,05*
Others	0,05*
(d) Other herbal infusions	0,05*
(iv) Cocoa (fermented beans)	0,05*
(v) Carob (st johns bread)	0,05*
7. HOPS (dried) , including hop pellets and unconcentrated powder	0,05*
8. SPICES	0,05*
(i) Seeds	0,05*
Anise	0,05*
Black caraway	0,05*
Celery seed (Lovage seed)	0,05*
Coriander seed	0,05*
Cumin seed	0,05*
Dill seed	0,05*
Fennel seed	0,05*
Fenugreek	0,05*
Nutmeg	0,05*
Others	0,05*
(ii) Fruits and berries	0,05*
Allspice	0,05*
Anise pepper (Japan pepper)	0,05*
Caraway	0,05*
Cardamom	0,05*
Juniper berries	0,05*
Pepper, black and white (Long pepper, pink pepper)	0,05*
Vanilla pods	0,05*
Tamarind	0,05*
Others	0,05*
(iii) Bark	0,05*
Cinnamon (Cassia )	0,05*
Others	0,05*
(iv) Roots or rhizome	0,05*
Liquorice	0,05*
Ginger	0,05*

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
Turmeric (Curcuma)	0,05*
Horse-radish	0,05*
Others	0,05*
(v) Buds	0,05*
Cloves	0,05*
Capers	0,05*
Others	0,05*
(vi) Flower stigma	0,05*
Saffron	0,05*
Others	0,05*
(vii) Aril	0,05*
Mace	0,05*
Others	0,05*
9. SUGAR PLANTS	0,05*
Sugar beet (root)	0,05*
Sugar cane	0,05*
Chicory roots	0,05*
Others	0,05*
10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	0,05*
(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*
(a) Swine	0,05*
Meat	0,05*
Fat free of lean meat	0,05*
Liver	0,05*
Kidney	0,05*
Edible offal	0,05*
Others	0,05*
(b) Bovine	0,05*
Meat	0,05*
Fat	0,05*
Liver	0,05*
Kidney	0,05*
Edible offal	0,05*
Others	0,05*
(c) Sheep	0,05*
Meat	0,05*
Fat	0,05*
Liver	0,05*
Kidney	0,05*
Edible offal	0,05*

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
Others	0,05*
(d) Goat	0,05*
Meat	0,05*
Fat	0,05*
Liver	0,05*
Kidney	0,05*
Edible offal	0,05*
Others	0,05*
(e) Horses, asses, mules or hinnies	0,05*
Meat	0,05*
Fat	0,05*
Liver	0,05*
Kidney	0,05*
Edible offal	0,05*
Others	0,05*
(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
Meat	0,05*
Fat	0,05*
Liver	0,05*
Kidney	0,05*
Edible offal	0,05*
Others	0,05*
(g) Other farm animals (Rabbit, Kangaroo)	0,05*
Meat	0,05*
Fat	0,05*
Liver	0,05*
Kidney	0,05*
Edible offal	0,05*
Others	0,05*

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
(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*
Cattle	0,05*
Sheep	0,05*
Goat	0,05*
Horse	0,05*
Others	0,05*
(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*
Chicken	0,05*
Duck	0,05*
Goose	0,05*
Quail	0,05*
Others	0,05*
(iv) Honey (Royal jelly, pollen)	0,05*
(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
(vi) Snails	0,05*
(vii) Other terrestrial animal products	0,05*

## APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

<b>Fludioxonyl</b>			
Status of the active substance:	<b>Included</b>	Code no.	<b>77</b>
LOQ (mg/kg bw):		proposed LOQ:	
<b>Toxicological end points</b>			
ADI (mg/kg bw/day):	<b>0.37</b>	ARfD (mg/kg bw):	<b>n.n.</b>
Source of ADI:	<b>EFSA</b>	Source of ARfD:	<b>EFSA</b>
Year of evaluation:	<b>2007</b>	Year of evaluation:	<b>2007</b>

For the chronic RA the input values were following: spinach, beet leaves (chard)- 2.6 mg/kg(STMR), carrots, beetroots, horseradish, parsnips, parsley roots, salsify- 1.12 mg/kg (STMR\*CF), potatoes - 2.8 mg/kg(MRL\*CF), pomegranates- 0.95 (STMR)

### Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		5                      34							
		<b>No of diets exceeding ADI:</b>		---					
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)	
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 pTMRLs were below the ADI. A long-term intake of residues of Fludioxonyl is unlikely to present a public health concern.

## GLOSSARY / 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
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
PF	processing factor
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model

RMS	Rapporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organisation