

REASONED OPINION OF EFSA

The modification of the existing MRLs of fludioxonil in various root vegetables¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00209)

Issued on 17 February 2009

SUMMARY

The United Kingdom received an application from the Horticultural Development Council to modify the existing MRLs for fludioxonil in various root crops: carrots, beetroots, parsnips, horseradish, salsify, parsley roots, roots of herbal infusion and roots of spices.

The current EC MRL for fludioxonil in these root crops is set at the limit of quantification (0.05 mg/kg) and the applicant proposes to raise the MRL to 1 mg/kg by extrapolation from carrots.

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 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. For the root and tuber vegetables the conversion factor of 1 is not applicable since metabolism results in different ratios of the metabolites. In that regard the Rapporteur Member State Denmark in the framework of Article 12(1) of Regulation (EC) No 396/2005, derived the conversion factor of 2.8 between residue definitions for monitoring to risk assessment for several root crops, including carrots. Even though the conversion factor was derived from metabolism studies, EFSA applied it for performing the consumer risk assessment.

From the supervised residue field trials data on carrots that were submitted in support of the application, an MRL of 1 mg/kg would be required to accommodate the use of fludioxonil in

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the United Kingdom. Sufficient number of trials is submitted for the extrapolation from carrots to root crops under consideration. However, it should be noted that the GAP for which an authorization is requested covers roots of herbal infusions (valerian root, ginseng root) and roots of spices (liquorice, ginger, turmeric (curcuma), horseradish) most of which are normally grown in countries with different weather and soil conditions than in the United Kingdom. Therefore EFSA is on the opinion that residue trials on carrots performed in Northern France and Switzerland do not fully reflect the actual residue situation in these crops.

Adequate analytical methods are available to enforce an MRL in carrots, beetroots, parsnips, horseradish, salsify, parsley roots, roots of herbal infusion and roots of spices.

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.

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. From the processing studies submitted in the framework of the application, the following processing factors for enforcement of fludioxonil are recommended:

- Carrots, canned: 0.19
- Carrots, cooked: 0.11
- Carrots, juice: 0.2

Consumer intake calculations were performed using the EFSA PRIMo rev. 2. For carrots, beetroot, horseradish, parsnips, parsley root, salsify, roots of herbal infusions and roots of spices the STMR values as obtained from submitted supervised residue field trials multiplied by the conversion factor of 2.8 for the risk assessment were used as input values. Potatoes are also root vegetables having fludioxonil metabolites included in the residue definition for risk assessment and, since the STMR value is not available, EFSA applied the conversion factor of 2.8 to the current MRL for potatoes and used it as an input value. For pomegranates, the STMR value was used as obtained in the EFSA reasoned opinion on the modification of the existing MRLs for fludioxonil in pomegranates. For other commodities the existing MRLs as established in Annex III of Regulation (EC) 396/2005 were applied in the intake calculation.

No chronic intake concerns were identified for all European diets. Acute intake calculations were not performed since there is no ARfD value established. It is concluded that the MRL proposal for fludioxonil of 1 mg/kg for carrots, beetroots, horseradish, parsnips, parsley roots, salsify, roots of herbal infusions and roots of spices is acceptable with regard to consumer safety.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Fludioxonil			

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Carrots, beetroots, horseradish, parsnips, parsley roots, salsify, roots of herbal infusions, roots of spices	0.05*	1	MRL proposal is fully supported by data and no consumer intake concerns are associated with the proposed MRL

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

(F): MRL is expressed as mg/kg of fat contained in the whole product.

Key words: Fludioxonil, carrots, beetroot, parsnips, horseradish, salsify, parsley roots, roots of herbal infusion, roots of spices, MRL application, Regulation (EC) No 396/2005, phenylpyrrole

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Chapter II of the regulation, dealing with the procedure to set new MRLs or to amend existing MRLs, entered into force on 2 September 2008.

According to Article 6(2) of Regulation (EC) No 396/2005, The United Kingdom as an Evaluating Member State (EMS) received an application from the Horticultural Development Council² on the modification of the existing MRL for fludioxonil in beetroots, carrots, horseradish, parsnips, parsley roots, salsify, roots of herbal infusions (dried) and roots or rhizome of spices. On 14 January 2009, according to Article 9 of Regulation (EC) No 396/2005, the Evaluation Report prepared by the EMS on this subject was submitted to the European Commission and forwarded to EFSA.

After the receipt of the Evaluation Report, EFSA included the application in the EFSA Register of Questions with the number EFSA-Q-2009-00209 and the following subject:

Fludioxonil - Application to modify the existing MRLs for fludioxonil in beetroot from 0.05 mg/kg to 1 mg/kg, in carrots from 0.05* mg/kg to 1 mg/kg, in horseradish from 0.05* mg/kg to 1 mg/kg, in parsnips from 0.05* mg/kg to 1 mg/kg, in parsley root from 0.05* mg/kg to 1 mg/kg, in salsify from 0.05* mg/kg to 1 mg/kg, in herbal infusions (dried, roots) from 0.05* mg/kg to 1 mg/kg and in spices (roots and rhizome) from 0.05* mg/kg to 1 mg/kg.*

TERMS OF REFERENCE

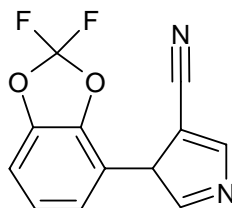
According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the Evaluating Member State, provide a reasoned opinion on the risks to the consumer and where relevant to the animals associated with the application. Particular attention shall be given to the requirements set out in that Article.

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. In this case the deadline for submission of the reasoned opinion is 14 April 2009.

² Horticultural Development Council, Bradbourne House, East Mailing, Kent, ME 196DZ, The United Kingdom

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 fludioxonil in carrots (0.7 mg/kg), but no CXLs are set for beetroots, horseradish, parsnips, parsley roots, salsify, roots of herbal infusions and roots of spices.

The applicant, the Horticultural Development Council, applied for an authorization of the use of fludioxonil on carrots, beetroot, horseradish, parsnips, parsley roots, salsify, roots of herbal infusions and roots of spices. The applicant provided supervised residue field trial data on carrots from which an extrapolation is proposed to the above mentioned root crops. The GAP for which an authorization is requested relates to an outdoor use of fludioxonil at an application rate of 3 x 0.2 kg a.s./ha, 12 days between applications. The minimum waiting period is 7 days. The GAP is given in Appendix A.

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 high acid-, high water- and dry commodities at the lowest validated fortification level of 0.02 mg/kg.

Since root and tuber vegetables referred to in the MRL application 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 the vegetables for which the applicant has requested an authorisation 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
ADI	EFSA	2007	0.37	2 year rat	100
ARfD	Considered 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. For the root and tuber vegetables the conversion factor of 1 is not applicable since metabolism results in different ratios of the metabolites. In that regard the Rapporteur Member State Denmark in the framework of Article 12(1) of Regulation (EC) No 396/2005, derived the conversion factor of 2.8 between residue definitions for monitoring to risk assessment for carrots, celeriac garlic, onions, shallots and spring onions (Denmark, 2009). The conversion factor was derived from metabolism studies.

3.1.1.2. Magnitude of residues

The applicant submitted seven residue trials on carrots for the extrapolation to beetroot, parsnips, horseradish, parsley roots, salsify, roots of herbal infusions and roots of spices (The United Kingdom, 2006). However, it should be noted that the GAP for which an authorization is requested covers roots of herbal infusions (valerian root, ginseng root) and roots of spices (liquorice, ginger, turmeric (curcuma), horseradish) most of which are normally grown in countries with different weather and soil conditions than in the United Kingdom. Therefore EFSA is of the opinion that residue trials on carrots performed in Northern France and Switzerland do not fully reflect the actual residue situation in these crops.

Supervised field trials residue data are summarized in Table 3-1.

Applicant submitted residue decline data for all trials. All trials except one demonstrated that maximum residue levels are reached on the day 7 after the last application followed by decrease with longer PHI. In all trials residue levels were in the range of 0.19 – 0.54 mg/kg. It is concluded that the submitted number of trials on carrots is sufficient for the extrapolation to root vegetables and an MRL of 1.00 mg/kg is necessary to support the proposed GAP.

The applicant did not provide data on the levels of fludioxonil metabolites (containing 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety) in carrots. For deriving the risk assessment values, EFSA applied the conversion factor of 2.8 which was derived by Denmark (see section 3.1.1.1.). Although conversion factors should be derived from residue trials, EFSA took into account this value since the dietary exposure from fludioxonil is comparatively low.

The available studies submitted in the peer review of fludioxonil, demonstrate storage stability of fludioxonil in water-, oil- containing commodities and dry commodities (EFSA, 2007). Fludioxonil residues are stable in plant samples for at least 24 months when stored at $\leq -16^{\circ}$ C. According to the data provided by the applicant, supervised residue field trial samples of carrots were stored for maximum 4 months below -18° C prior analysis, which means that the obtained analytical results can be considered acceptable with regard to storage stability (The United Kingdom, 2006).

The supervised field trial samples were analysed by the method REM-133.04 (The United Kingdom, 2006). The validated limit of quantification is 0.02 mg/kg. According to the evaluation of the EMS, the analytical method is sufficiently validated and fit for purpose.

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 ^(d)	Comments
			Enforcement	Risk assessment					
Definition for monitoring: Fludioxonil Definition for risk assessment: Fludioxonil and all metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety									
Carrots	NEU	Outdoor	0.19; 2 x 0.29; 0.4; 0.41; 0.44; 0.54	-	0.4	0.54	1	2.8	No data available for the risk assessment. Conversion factor of 2.8 derived from metabolism studies. Rber= 0.88 mg/kg Rmax= 0.76 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.

(*): 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 hydrolytic processing conditions and no formation of toxicologically significant metabolites is expected.

The applicant has submitted one balance and three follow up studies on the effects of processing on the magnitude of residues of fludioxonil in carrots (The United Kingdom, 2006). Both studies were performed with an exaggerated application rate of 3N in comparison to the GAP. The balance studies were performed for cooked carrots and bagged carrots. It shows that washing, trimming and cooking significantly decrease residue levels in carrots: from 0.37 mg/kg in raw carrots to 0.03 mg/kg in cooked carrots. From the balance studies it can be concluded that the critical points in technological process are the washing and the peeling of the carrots. The largest amount of residues remains in the waste products.

The processing factors obtained are summarized in Table 3-2.

Table 3-2. Overview of the available processing studies

Processed commodity	Number of studies	Median PF ^(a)	Median CF ^(b)	Comments
Fludioxonil				
Canned carrots	3	0.19	2.8	In the absence of data on the occurrence of fludioxonil metabolites in processed carrots it is assumed that the conversion factor for risk assessment is the same as for the raw commodities.
Cooked carrots	4	0.11		
Bagged carrots	4	0.07		
Carrot juice	3	0.2		

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

For the enforcement purposes only the processing factors derived for canned carrots, cooked carrots and carrot juice can be recommended since bagging of the carrots is not considered as a core processing procedure.

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 (Denmark, 2005). The most critical DT₉₀ 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 ¹⁴C- 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 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 ¹⁴C- 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 ¹⁴C- fludioxonil at a dosing rate of 1.117 kg a.s./ha, the highest TRR was observed 30 DAT in wheat straw (0.355 mg/kg), and radish roots (0.135 mg/kg). At 90 and 210 DAT the TRR were ≤ 0.05 mg/kg in all food crops. In cereal forage and straw, TRR were <0.2 mg/kg.
- From the field study 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 that the application rates with regard to the proposed GAP are 0.6 kg a.s./ha and that available field study demonstrates that no residues exceeding 0.01 mg/kg are present in rotational crops, it is concluded that significant residue levels in rotational crops are not expected.

3.2. Nature and magnitude of residues in livestock

According to the EU guidance document on livestock feeding studies (Appendix G, Document 7031/VI/95 rev.4) none of the crops under consideration are used as animal feedingstuff. Nature and magnitude of fludioxonil residues in livestock were therefore not assessed with regard to the current application.

4. Consumer risk assessment

Consumer intake calculations were performed using the EFSA PRIMo rev. 2. For carrots, beetroot, horseradish, parsnips, parsley root, salsify, roots of herbal infusions and roots of spices the STMR values as obtained from submitted supervised residue field trials multiplied by the conversion factor of 2.8 for the risk assessment were used as input values. Potatoes are

also root vegetables having fludioxonil metabolites included in the residue definition for risk assessment and, since STMR value is not available, EFSA applied the conversion factor of 2.8 to the current MRL for potatoes and used it as an input value. For pomegranates, the STMR value was used as obtained in the EFSA reasoned opinion on the modification of the existing MRLs for fludioxonil in pomegranates. For other commodities the existing MRLs as established in Annex III of Regulation (EC) 396/2005 were applied in the intake calculation. 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.

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
Fludioxonil				
Beetroot, carrots, horseradish, parsnips, parsley root, salsify, roots of herbal infusions, roots of spices	1.12	STMR*CF ^a	n.n.	n.n.
Potatoes	2.8	MRL*CF	n.n.	n.n.
Pomegranates	0.95	STMR (EFSA, 2008)	n.n.	n.n.

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

n.n. – not necessary

The summary of the intake calculation can be found in Appendix C. The chronic dietary risk assessment did not reveal any consumer intake concerns. The contribution of carrots to the dietary exposure only amounts for 0.8% of the ADI for French infants. For all other commodities under consideration, the contribution is below 0.3% of the ADI. Acute intake calculations were not performed since there is no ARfD value established.

It is concluded that the MRL proposal for fludioxonil of 1 mg/kg for carrots, beetroots, horseradish, parsnips, parsley roots, salsify, roots of herbal infusions and roots of spices is acceptable with regard to consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

The United Kingdom received an application from the Horticultural Development Council to modify the existing MRLs for fludioxonil in various root crops: carrots, beetroots, parsnips, horseradish, salsify, parsley roots, roots of herbal infusion and roots of spices.

The current EC MRL for fludioxonil in these root crops is set at the limit of quantification (0.05 mg/kg) and the applicant proposes to raise the MRL to 1 mg/kg by extrapolation from carrots.

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 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. For the root and tuber vegetables the conversion factor of 1 is not applicable since metabolism results in different ratios of the metabolites. In that regard the Rapporteur Member State Denmark in the framework of Article 12(1) of Regulation (EC) No 396/2005, derived the conversion factor of 2.8 between residue definitions for monitoring to risk assessment for several root crops, including carrots. Even though the conversion factor was derived from metabolism studies, EFSA applied it for performing the consumer risk assessment.

From the supervised residue field trials data on carrots that were submitted in support of the application, an MRL of 1 mg/kg would be required to accommodate the use of fludioxonil in the United Kingdom. Sufficient number of trials is submitted for the extrapolation from carrots to root crops under consideration. However, it should be noted that the GAP for which an authorization is requested covers roots of herbal infusions (valerian root, ginseng root) and roots of spices (liquorice, ginger, turmeric (curcuma), horseradish) most of which are normally grown in countries with different weather and soil conditions than in the United Kingdom. Therefore EFSA is on the opinion that residue trials on carrots performed in Northern France and Switzerland do not fully reflect the actual residue situation in these crops.

Adequate analytical methods are available to enforce an MRL in carrots, beetroots, parsnips, horseradish, salsify, parsley roots, roots of herbal infusion and roots of spices.

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.

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.

From the processing studies submitted in the framework of the application, the following processing factors for enforcement of fludioxonil are recommended:

- Carrots, canned: 0.19
- Carrots, cooked: 0.11
- Carrots, juice: 0.2

Consumer intake calculations were performed using the EFSA PRIMo rev. 2. For carrots, beetroot, horseradish, parsnips, parsley root, salsify, roots of herbal infusions and roots of spices the STMR values as obtained from submitted supervised residue field trials multiplied by the conversion factor of 2.8 for the risk assessment were used as input values. Potatoes are also root vegetables having fludioxonil metabolites included in the residue definition for risk assessment and, since the STMR value is not available, EFSA applied the conversion factor of 2.8 to the current MRL for potatoes and used it as an input value. For pomegranates, the STMR value was used as obtained in the EFSA reasoned opinion on the modification of the existing MRLs for fludioxonil in pomegranates. For other commodities the existing MRLs as established in Annex III of Regulation (EC) 396/2005 were applied in the intake calculation.

No chronic intake concerns were identified for all European diets. Acute intake calculations were not performed since there is no ARfD value established. It is concluded that the MRL proposal for fludioxonil of 1 mg/kg for carrots, beetroots, horseradish, parsnips, parsley roots, salsify, roots of herbal infusions and roots of spices is acceptable with regard to consumer safety.

Table 5-1. **Overview of the proposed EC MRLs**

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Fludioxonil			
Carrots, beetroots, horseradish, parsnips, parsley roots, salsify, roots of herbal infusions, roots of spices	0.05*	1	MRL proposal is fully supported by data and no consumer intake concerns are associated with the proposed MRL.

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

(F): MRL is expressed as mg/kg of fat contained in the whole product.

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)
			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 appropriate	
Carrots, parsnips, horseradish, salsify, parsley roots, beetroot, and roots of herbal infusions and spices	F	Fungus	WG	25 % w/w	Spray	7 days PHI	3	0.2	200 - 600	-	7

- (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 – CURRENT EC MRLS AS IN REGULATION (EC) NO 396/2005

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

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
Peaches (Nectarines and similar hybrids)	7
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), pomeac, 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), llama 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*
2. VEGETABLES FRESH OR FROZEN	

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
(i) Root and tuber vegetables	
(a) Potatoes	1
(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

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
Aubergines (egg plants) (Pepino)	1
Okra, ladyfingers	0,5
Others	0,5
(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	

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
(a) Lettuce and other salad plants including Brassicacea	10
Lamb's lettuce (Italian cornsalad)	10
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, glassworth)	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 ciselis and other Apiacea)	1
Parsley	1

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
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
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*

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
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*
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*

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
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*
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*

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
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*
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*

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
(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*
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*

Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil
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*
(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)

Fludioxonyl			
Status of the active substance:	pending	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:	DAR- DK	Source of ARfD:	DAR- DK
Year of evaluation:	2005	Year of evaluation:	2005

Input values for chronic RA - STMR of 0.4mg/kg multiplied by conversion factor of 2.8 for carrots, beetroot, horseradish, parsnips, parsley root, salsify, roots of herbal infusions, roots of spices - 1.12 mg/kg; for potatoes 2.8 mg/kg (MRL multiplied by conversion factor of 2.8); 0.95 mg/kg for pomegranates

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		2nd contributor to MS diet		3rd contributor to MS diet		pTMRLs at LOQ (in % of ADI)	
	MS Diet	(in % of ADI)	Commodity / group of commodities	(in % of ADI)	Commodity / group of commodities	(in % of ADI)	Commodity / group of commodities		
	34.0	DE child	16.3	Apples	7.2	Oranges	1.9	Potatoes	
	26.3	NL child	8.6	Apples	5.9	Oranges	4.5	Potatoes	
	15.6	FR toddler	3.8	Potatoes	3.8	Oranges	3.5	Apples	
	14.9	IE adult	2.0	Oranges	1.9	Grapefruit	1.7	Potatoes	
	13.3	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	
	11.5	FR infant	3.4	Apples	3.1	Potatoes	1.7	Oranges	
	11.0	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	
	10.3	SE general population 90th percentile	3.2	Potatoes	1.4	Apples	1.4	Oranges	
	9.8	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	
	8.5	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	
	7.4	FR all population	2.2	Wine grapes	0.9	Potatoes	0.6	Apples	
	7.2	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	
	6.5	IT adult	1.1	Apples	1.0	Lettuce	0.7	Peaches	
	6.2	LT adult	2.5	Apples	2.4	Potatoes	0.2	Pears	
	5.8	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.

Acute risk assessment /children - refined calculations

Acute risk assessment / adults / general population - refined calculations

Acute risk assessment is not necessary.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

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

Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)

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

**) pTMRL: provisional temporary MRL

***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of Fludioxonil residues is unlikely to present a public health concern.

GLOSSARY / ABBREVIATIONS

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
CXL	Codex Maximum Residue Limit
CF	Conversion Factor
DAT	Days After Treatment
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
GAP	Good Agricultural Practice
HR	Highest Residue
ILV	Independent Laboratory Validation
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOD	Limit of Detection
LOQ	Limit Of Quantification
MRL	Maximum Residue Limit
PHI	Pre Harvest Interval
PSD	Pesticide Safety Directorate, United Kingdom
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
STMR	Supervised Trials Median Residue
TRR	Total Radioactive Residue
TMDI	Theoretical Maximum Daily Intake