



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants, pesticides

Fludioxonil

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THE VIEWS OF THE COMMISSION SERVICES**

Review report for the active substance **fludioxonil**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
9 October 2007

in view of the inclusion of fludioxonil in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of fludioxonil, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EC) No 451/2000⁽¹⁾ laying down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and Regulation (EC) No 1490/2002⁽²⁾, have laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. fludioxonil is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 10 of Regulation (EC) No 451/2000, Syngenta notified to the Commission of their wish to secure the inclusion of the active substance fludioxonil in Annex I to the Directive.

In accordance with the provisions of Article 6(1) of Regulation (EC) No No1490/2002, the Commission, designated Denmark as rapporteur Member State to carry out the assessment of fludioxonil on the basis of the dossiers submitted by the notifier. In Regulation (EC) No 1490/2002 the Commission specified furthermore that the deadline for the notifier with regard to the submission to the rapporteur Member States of the dossiers required under Article 7(2) of

¹ OJ No L 55, 29.02.2000, p.25.

² OJ No L 224, 21.8.2002, p.23.

Regulation (EC) No 1490/2002, as well as for other parties with regard to further technical and scientific information was 30 November 2003.

Syngenta submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore Syngenta was considered to be the sole data submitter.

In accordance with the provisions of Article 10(1) of Regulation (EC) No 1490/2002, Denmark submitted on 5 April 2005 to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of fludioxonil in Annex I to the Directive. Moreover, in accordance with the provisions of Article 10(2) of Regulation (EC) 1490/2002, the Commission and the Member States received also the summary dossier on fludioxonil from Syngenta.

In accordance with the provisions of Article 11 of Regulation (EC) No 1490/2002, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Syngenta being the sole data submitter, on 15 August 2005 by making it available.

The EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

In accordance with the provisions of Article 11 c of Regulation 1490/2002 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance fludioxonil (finalised 27 July 2007)³]. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 12 of Regulation (EC) No 1490/2002, the Commission referred on 9 October 2007 a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 9 October 2007.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive **2007/76/EC**⁴ concerning the inclusion of fludioxonil in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing fludioxonil they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

³ EFSA Scientific Report (2007) 110, 1-85.

⁴ Commission Directive 2007/76/EC (OJ L 337, 21.12.2007, p. 100)

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 13 of Regulation (EC) No 1490/2002, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing fludioxonil will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each fludioxonil containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

The following reference values have been finalised as part of this re-evaluation:

ADI 0.37 mg/kg bw/day

ARfD Allocation was not considered necessary due to the low acute toxicity of fludioxonil.

AOEL 0.59 mg/kg bw/day

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is <5 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994).

Additional intake from water and products of animal origin are not expected to give rise to intake problems.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity

The identity of fludioxonil is given in Appendix I.

At the time of the evaluation no FAO specification was allocated.

The review has established that for the active substance notified by the main data submitter none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA, and at section 3 of this report.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing fludioxonil

On the basis of the proposed uses and the supported uses (as listed in Appendix II), for uses other than seed treatment, Member States, in the framework of any authorisations to be granted, varied or withdrawn, must pay particular attention to the potential for groundwater contamination, in particular from the soil photolysis metabolites CGA 339833 and CGA 192155, in vulnerable zones and must pay particular attention to the protection of fish and aquatic invertebrates.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of fludioxonil in Annex I under the current inclusion conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. The list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Scientific report (page 34).

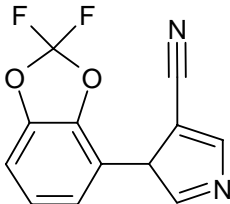
8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for fludioxonil in Annex I of the Directive.

APPENDIX I**Identity****FLUDIOXONIL**

Common name (ISO)	Fludioxonil
Chemical name (IUPAC)	<i>4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile</i>
Chemical name (CA)	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile
CIPAC No	522
CAS No	131341-86-1
EEC No	Not allocated
FAO SPECIFICATION	Not allocated
Minimum purity	950 g/kg
Molecular formula	C ₁₂ H ₆ F ₂ N ₂ O ₂
Molecular mass	248.2 g/mol
Structural formula	

APPENDIX II

List of uses supported by available data

FLUDIOXONIL

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Wheat	Southern and Northern Europe	Celest 025 FS	F	<i>Microdochium nivale</i> <i>Fusarium</i> spp. <i>Tilletia caries</i> , <i>Septoria</i> sp. <i>Helminthosporium</i> sp.	FS	25 g fludioxonil/L	Seed treatment	Not relevant	1	-	5.0 g as/100 kg seed	Undiluted -max. 1.5 L/per 100 kg of seed	0.005-0.00875	Not relevant	Sowing rate: 100-175 kg/ha

- Remarks:**
- (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 (I)
 - (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 plants - 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) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions

