



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Fipronil

SANCO/10033/2006 final rev 1

12 March 2010¹

Review report for the active substance **fipronil**

finalised in the Standing Committee on the Food Chain and Animal Health at its meeting
on 16 March 2007
in view of the inclusion of fipronil 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 fipronil, 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⁽²⁾ 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, as last amended by Regulation (EC) No 1490/2002⁽³⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Fipronil is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EC) No 451/2000, Aventis Crop Science notified to the Commission of their wish to secure the inclusion of the active substance fipronil in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EC) No 451/2000, the Commission, designated France as rapporteur Member State to carry out the assessment of fipronil on the basis of the dossiers submitted by the notifiers. In Regulation (EC) No 703/2001⁴ the Commission specified furthermore that the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EC) No 451/2000, as well as for other parties with regard to further technical and scientific information was 30 April 2002.

¹ On 12 March 2010 the Standing Committee on the Food Chain and Animal Health has taken note of the revision of the review report after the assessment of the confirmatory data referred to in point 7 of this report (cfr. infra).

² OJ No L 55, 29.02.2000, p.25.

³ OJ No L 224, 21.8.2002, p.23.

⁴ OJ No L 98, 7.4.2001, p. 6.

Aventis CropScience SA submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. During the preparation of the draft assessment report, Fipronil was bought by BASF Aktiengesellschaft Therefore BASF was considered to be the main data submitter.

In accordance with the provisions of Article 8(1) of Regulation (EC) No 451/2000, France submitted on 10 February 2004 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 fipronil in Annex I to the Directive. Moreover, in accordance with the provisions of Article 8(2) of Regulation (EC) 451/2000, the Commission and the Member States received also the summary dossier on fipronil from BASF, on 17 March 2004.

In accordance with the provisions of Article 8 of Regulation (EC) No 451/2000, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by BASF being the main data submitters, on 15 July 2004 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 8 (7) of Regulation 451/2000 the EFSA sent to the Commission its conclusion regarding the peer review of the pesticide risk assessment of the active substance fipronil (finalised: 3 March 2006, revision of 12 April 2006)⁵. 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 8 (7) of Regulation (EC) No 451/2000, the Commission referred on 16 March 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 16 March 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 Commission Directive 2007/52/EC concerning the inclusion of fipronil in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing fipronil 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.

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

⁵ *EFSA Scientific Report* (2006) 65, 1-110

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 8(9) of Regulation (EC) No 451/2000, 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 fipronil 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 fipronil 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: 0.0002 mg fipronil/kg bw/day

ArfD: 0.009 mg fipronil/kg bw

AOEL: 0.0035 mg fipronil/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 International Estimated Daily Intake (IEDI, STMR values from maize, sunflower and animal products) for a 60 kg adult is 3 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994), and < 20% for infants and toddlers, based on the French Dietary model.

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

Estimates of acute dietary exposure of adults and toddlers revealed that the Acute Reference Dose (ARfD) would not be exceeded (NESTI based on the UK/PSD data: 2 % or 4 % for respectively adults or toddlers).

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 main identity of fipronil are given in Appendix I.

The active substance shall comply with the FAO specification and there seem not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report.

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 fipronil

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Member States must pay particular attention to:

- the packaging of the marketed products to avoid the generation of photo-degradation products of concern;
- the potential for groundwater contamination, especially from metabolites which are more persistent than the parent compound, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;

- the protection of granivorous birds and mammals, aquatic organisms, non-target arthropods and honey bees;
- the use of adequate equipment ensuring a high degree of incorporation in soil and a minimisation of spillage during application.

Conditions of authorisation should include risk mitigation measures, where appropriate.

7. List of studies to be generated

The concerned Member States shall request the submission of further studies to confirm the risk assessment for granivorous birds and mammals and honey bees, especially bee brood.

They shall ensure that the notifier at whose request fipronil has been included in this Annex provide such studies to the Commission within 1 years from the entry into force of this Directive.

On 12 March 2010 the Standing Committee on the Food Chain and Animal Health has taken note of the revision of the review report after the assessment of the above confirmatory data. This assessment has been carried out in line with the Guidance document on the procedures for submission and assessment of confirmatory data following inclusion of an active substance in Annex I of Council Directive 91/414/EEC⁶. The Committee agrees that, on the basis of the current outcome, the risk for the exposed species is acceptable. No further review by EFSA has been considered necessary.

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 (pages 46 to 48).

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

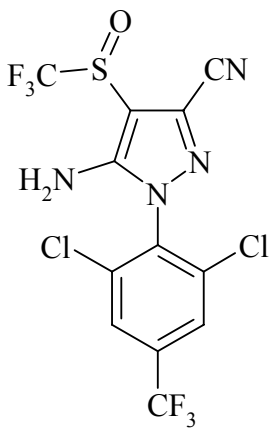
⁶ Doc. SANCO/5634/2009 rev 3, 2.10.2009.

the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for fipronil in Annex I of the Directive.

APPENDIX I

Identity

FIPRONIL

Common name (ISO)	Fipronil
Chemical name (IUPAC)	(±)-5-amino-1-(2,6-dichloro- α,α,α -trifluoro-para-tolyl)-4-trifluoromethylsulfinyl-pyrazole-3-carbonitrile
Chemical name (CA)	5-amino-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1 <i>R,S</i>)- (trifluoromethyl)sulfinyl]-1 <i>H</i> -pyrazole-3-carbonitrile
CIPAC No	581
CAS No	120068-37-3
EEC No	Not allocated
FAO SPECIFICATION	950 g/kg \pm 25 g/kg [581/TC/S/F (1998)]
Minimum purity	950 g/kg
Molecular formula	C ₁₂ H ₄ Cl ₂ F ₆ N ₄ OS
Molecular mass	437.15
Structural formula	

APPENDIX II

List of uses supported by available data

FIPRONIL

Crop and/or situation	Member State or Country	Product Name	F G or I	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					Type	Conc. of a.s.	method, kind	growth stage & season	number (range)	interval between applications (minimum)	kg a.s./hl (range)	water l/ha (range)	kg a.s./ha (range)		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)				(l)	(m)	
Sunflower	SP S FR N/S IT S	EXP80415 A	F	Soil insects and wireworms	FS	500g/l	Seed dressing	BBCH 00	1	-			0.015-0.030	140 Days	0.25-0.5 kg as/100kg seeds 6kg seeds/ha=1U U=75000 grains
Maize	GR S IT S SP S FR N/S NL/BLG N	EXP80415 A	F	Soil insects and wireworms	FS	500g/l	Seed dressing	BBCH 00	1	-			0.045-0.05	80-120 (silage) 120-140D (S) 150-180 D (N)	0.25kg as/100kg seeds 18-20 kg seeds /ha (GR-SP:20kg seeds /ha) (BLG: 40.8g/50000 seeds) (Swiss: 50 g/100 Kg seeds 18-30kg/seeds /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)	(h)	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(i)	g/kg or g/L
	(c)	e.g. biting and suckling insects, soil born insects, foliar fungi, weeds	(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on
	(d)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)		

	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		season at time of application
	(f)	Method, <i>e.g.</i> high volume spraying, low volume spraying, spreading, dusting, drench	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(g)	All abbreviations used must be explained		
			(l)	PHI - minimum pre-harvest interval
			(m)	Remarks may include: Extent of use/economic importance/restrictions