COMMISSION DIRECTIVE 2006/10/EC

of 27 January 2006

amending Council Directive 91/414/EEC to include forchlorfenuron and indoxacarb as active substances

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], and in particular Article 6(1) thereof,

Whereas:

(1) In accordance with Article 6(2) of Directive 91/414/EEC Spain received on 7 December 1998 an application from SKW Trostberg AG (on behalf of the Taskforce SKW Trosberg AG (Degussa AG) and Kyowa Hakko Kogyo Co.Ltd.) for the inclusion of the active substance forchlorfenuron in Annex I to Directive 91/414/EEC. Commission Decision 2000/181/EC [2] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(2) The Netherlands received an application under Article 6(2) of Directive 91/414/EEC on 6 October 1997 from DuPont de Nemours for the inclusion of the active substance indoxacarb in Annex I to Directive 91/414/EEC. Commission Decision 1998/398/EC [3] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) For those active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The designated rapporteur Member States submitted draft assessment reports concerning the substances to the Commission on 2 March 2001 (forchlorfenuron) and 7 February 2000 (indoxacarb).

(4) The draft assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 23 September 2005 in the format of the Commission review reports for forchlorfenuron and indoxacarb.

(5) The review of forchlorfenuron did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants or of the European Food Safety Authority which has taken over the role of that Committee.

(6) For indoxacarb, two questions were submitted to the Scientific Committee on Plants (SCP). The SCP was asked to comment on the NOEL (No observed effect level) for effects on red blood cells in rats and on the adequate basis for the derivation of an Acute Reference Dose (ARfD) for indoxacarb.

In its opinion [4] the SCP stated that the changes observed in some Red Blood Cells parameters were generally slight and not accompanied by significant reticulocytosis, giving the overall picture of a mild haemolytic effect. While a clear NOEL could not be established, the SCP concluded on a dose up to which the effects observed are not adverse.

The SCP furthermore replied that the general and non-specific signs of toxicity observed in the acute neurotoxicity study in rats can be used as a basis for the derivation of the ARfD.

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/6/EC (OJ L 12, 18.1.2006, p. 21).
[2] OJ L 57, 2.3.2000, p. 35.
[3] OJ L 176, 20.6.1998, p. 34.
[4] Opinion of the Scientific Committee on Plants on specific questions from the Commission concerning the evaluation of indoxacarb (SCP/Indoxa/002-Final); opinion adopted by the Scientific Committee on Plants on 18 July 2002).

(7) The recommendations of the SCP were taken into account during the further review by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health, in this Directive and in the Review Report. This evaluation established the relevant endpoints (ARfD and Acceptable daily intake = ADI) on the basis of the exposure levels identified by the SCP.

(8) It has appeared from the various examinations made that plant protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1) (a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review reports. It is therefore appropriate to include forchlorfenuron and indoxacarb in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances may be granted in accordance with the provisions of that Directive.

(9) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing provisional authorisations of plant protection products containing forchlorfenuron or indoxacarb to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should transform existing provisional authorisations into full authorisations, amend them or withdraw them in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.

(10) The inclusion of forchlorfenuron in Annex I to Directive 91/414/EEC is based on a dossier covering the use of this active substance on kiwi fruits. Other uses are currently not adequately supported by data from the notifier and not all of the risks from such uses have shown to be adequately addressed under the criteria required by Annex VI to that Directive. If Member States are to grant authorisations for other uses, they should therefore require the data and information necessary to prove that the uses are compatible with the criteria in Directive 91/414/EEC, in particular concerning the effect on human consumers and the environment.

(11) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish by 30 September 2006 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 October 2006.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing forchlorfenuron or indoxacarb as active substances by 30 September 2006. By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to forchlorfenuron and indoxacarb, respectively, are met, with the exception of those identified in part B of the entry concerning those active substances, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing forchlorfenuron or indoxacarb as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 March 2006 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning forchlorfenuron and indoxacarb, respectively. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

(a) in the case of a product containing forchlorfenuron or indoxacarb as the only active substance, where necessary, amend or withdraw the authorisation by 30 September 2007 at the latest; or

(b) in the case of a product containing forchlorfenuron or indoxacarb as one of several active substances, where necessary, amend or withdraw the authorisation by 30 September 2007 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 4

This Directive shall enter into force on 1 April 2006.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 27 January 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

In Annex I to Directive 91/414/EEC the following rows are added at the end of the table

No	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
'119	Forchlorfenuron CAS No 68157-60-8 CIPAC No 633	1-(2-chloro-4-pyridinyl)-3-phenylurea	≥ 978 g/kg	1 April 2006	31 March 2016	PART A Only uses as plant growth regulator may be authorised. PART B In assessing applications to authorise plant protection products containing forchlorfenuron for uses other than in kiwi plants, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorization is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on forchlorfenuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 September 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied where appropriate.
120	Indoxacarb CAS No 173584-44-6 CIPAC No 612	methyl (*S*)-*N*-[7-chloro-2,3,4a,5-tetrahydro-4a-(methoxycarbonyl) indeno[1,2-*e*][1,3,4]oxadiazin-2-ylcarbonyl]-4′-(trifluoromethoxy) carbanilate	TC (Technical Material): ≥ 628 g/kg indoxacarb	1 April 2006	31 March 2016	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on indoxacarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 September 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of aquatic organisms. Conditions of use should include risk mitigation measures, where appropriate.'

[1] Further details on identity and specification of active substances are provided in the review report.