COMMISSION DIRECTIVE 2006/5/EC

of 17 January 2006

amending Council Directive 91/414/EEC to include warfarin as active substance

(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) Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market [2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes warfarin.

(2) For warfarin the effects on human health and the environment has been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifiers. By Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member State for the implementation of Commission Regulation (EEC) No 3600/92 [3], Ireland was designated as Rapporteur Member State. Ireland submitted the relevant assessment report and recommendations to the Commission on 8 May 1996 in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(3) The assessment report has 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 report for warfarin.

(4) The report on warfarin and further information were also submitted to the Scientific Committee for Plants. The Committee was asked to comment on the acceptability of using clinical data generated following repeated warfarin use as an anti-coagulant in human medicine for establishing an acceptable daily intake (ADI) and an acceptable operator exposure level (AOEL). In its opinion [4], the Scientific Committee concluded that it is not necessary to allocate an ADI for warfarin. Furthermore, data available from the extensive clinical use of warfarin as an anticoagulant may confidently be expected to support the establishment of an ADI, should this be considered necessary. An AOEL can likewise be established based on human data, taking into account that in rats about 15 % of the applied dose is absorbed through the skin.

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

(6) Warfarin is used as a rodenticide. All other active substances used as rodenticides are covered by Commission Regulation (EC) No 1112/2002 of 20 June 2002 laying down the detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC [5]. Furthermore, the substance is currently subject to evaluation in the framework of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [6]. As with all substances included in Annex I to Directive 91/414/EEC, the status of warfarin could be reviewed under Article 5(5) of that Directive in the light of any new data becoming available, in particular from the assessment of similar substances or from the assessment of warfarin itself under Directive 98/8/EC.

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[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).

[2] OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 27).

[3] OJ L 107, 28.4.1994, p. 8. Regulation as last amended by Regulation (EC) No 2230/95 (OJ L 225, 22.9.1995, p. 1).

[4] Opinion of the Scientific Committee on Plants regarding the possible inclusion of warfarin in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market; SCP/WARFAR/002 final, adopted on 6 June 2000.

[5] OJ L 168, 27.6.2002, p. 14.

[6] OJ L 123, 24.4.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

(7) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties, it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the directives which have been adopted until now amending Annex I.

(8) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(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 authorisations of plant protection products containing warfarin 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 vary, replace or withdraw, as appropriate, existing authorisations 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) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(11) 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

Member States shall adopt and publish by 31 March 2007, 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 April 2007.

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

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 warfarin as an active substance by 31 March 2007. By that date, they shall in particular verify that the conditions in Annex I to that Directive, relating to warfarin, are met, with the exception of those identified in part B of the entry concerning that active substance, 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 derogation from paragraph 1, for each authorised plant protection product containing warfarin 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 30 September 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 warfarin. 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 warfarin as the only active substance, where necessary, amend or withdraw the authorisation by 30 September 2010 at the latest; or

(b) in the case of a product containing warfarin as one of several active substances, where necessary, amend or withdraw the authorisation by 30 September 2010 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 October 2006.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 17 January 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EEC

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'XX	Warfarin CAS No 81-81-2 CIPAC No 70	(RS)-4-hydroxy-3-(3-oxo-1-phenylbutyl)coumarin 3-(α-acetonyl-benzyl)-4-hydroxycoumarin	≥ 990 g/kg	1 October 2006	30 September 2013	PART A Only uses as rodenticide in the form of pre-prepared bait, if appropriate, placed in specially constructed hoppers, are authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on warfarin, and in particular Appendices I and II thereto, 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 should pay particular attention to the protection of operators, birds and non-target mammals. Risk mitigation measures should be applied where appropriate.'

(1) Further details on identity and specification of active substance are provided in the review report.