COMMISSION DIRECTIVE 2006/16/EC

of 7 February 2006

amending Council Directive 91/414/EEC to include oxamyl 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 Regulations (EC) No 451/2000 [2] and (EC) No 703/2001 [3] lay down the detailed rules for the implementation of the second stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish 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 oxamyl.

(2) For oxamyl, the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 451/2000 and (EC) No 703/2001 for a range of uses proposed by the notifier. Moreover, those Regulations designate the Rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 8(1) of Regulation (EC) No 451/2000. For oxamyl the Rapporteur Member State was Ireland and all relevant information was submitted on 25 August 2003.

(3) The assessment report has been peer reviewed by the Member States and the EFSA within its Working Group Evaluation and presented to the Commission on 14 January 2005 in the format of the EFSA Scientific Report for oxamyl [4]. This report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 15 July 2005 in the format of the Commission review report for oxamyl.

(4) It has appeared from the various examinations made that plant protection products containing oxamyl 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 oxamyl in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

(5) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore it is appropriate to require that oxamyl should be subjected to further testing for confirmation of the risk assessment for some issues and that such studies should be presented by the notifier.

(6) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 [5] 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.

(7) 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.

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[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 55, 29.2.2000, p. 25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p. 32).

[3] OJ L 98, 7.4.2001, p. 6.

[4] EFSA Scientific Report (2005) 26, 1-78, Conclusion on the peer review of the pesticide risk assessment of the active substance Oxamyl (finalised: 14 January 2005).

[5] 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).

(8) 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 oxamyl 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.

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

(10) 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 January 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 February 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 oxamyl as an active substance by 31 January 2007.

By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to oxamyl 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 of that Directive.

2. By derogation from paragraph 1, for each authorised plant protection product containing oxamyl 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 July 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 oxamyl. 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 oxamyl as the only active substance, where necessary, amend or withdraw the authorisation by 30 July 2010 at the latest; or

(b) in the case of a product containing oxamyl as one of several active substances, where necessary, amend or withdraw the authorisation by 30 July 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 August 2006.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 7 February 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

The following entry 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
'117	Oxamyl CAS No 23135-22-0 CIPAC No 342	N,N-dimethyl-2-methylcarbamoyloxyimino-2-(methylthio) acetamide	970 g/kg	1 August 2006	31 July 2016	PART A Only uses as nematicide and insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on oxamyl, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 July 2005 shall be taken into account. In this overall assessment, — Member States must pay particular attention to the protection of birds and mammals, earthworms, aquatic organisms, surface water, and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures, where appropriate. — Member States must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate. The concerned Member States shall request the submission of further studies to confirm the risk assessment for ground water contamination in acidic soils, birds and mammals and earthworms. They shall ensure that the notifiers at whose request oxamyl has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.'

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