COMMISSION DIRECTIVE 2001/103/EC

of 28 November 2001

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include 2,4-dichlorophenoxy acetic acid (2,4-D) as an 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]), as last amended by Commission Directive 2001/1999/EC ([2]), 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 ([3]), as last amended by Regulation (EC) No 2266/2000 ([4]), provides for the adoption of a list of certain active substances of plant protection products to be assessed with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list is contained in Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member States for the implementation of Commission Regulation (EEC) No 3600/92 ([5]), as last amended by Regulation (EC) No 2230/95 ([6]), and includes 2,4-dichlorophenoxy acetic acid ('2,4-D').

(2) For 2,4-D the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifiers. Under Regulation (EC) No 933/94, Greece was designated as rapporteur Member State for 2,4-D. The rapporteur Member State submitted the relevant assessment report and recommendations to the Commission on 17 January 1997 in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(3) This assessment report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. The review was finalised on 2 October 2001 in the format of the Commission review report for 2,4-D.

(4) The dossiers and the information from the review of 2,4-D were also submitted to the Scientific Committee for Plants. In its opinion ([7]) of 21 May 2001 the Committee commented on the selection of a suitable animal model to be used for human risk assessment. The recommendation was taken into consideration in formulating this Directive and the relevant review report.

(5) It has appeared from the various examinations made that plant protection products containing 2,4-D 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 the active substance concerned in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant protection products containing 2,4-D can be granted in accordance with the provisions of Directive 91/414/EEC.

(6) A reasonable period should be provided for before an active substance is included in Annex I to Directive 91/414/EEC in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion. Moreover, Directive 91/414/EEC provides that after inclusion of an active substance in Annex I thereto, Member States must, within a prescribed period, review and grant, vary or withdraw, as appropriate, the authorisations of the plant protection products containing the active substance. It is therefore necessary to stipulate such a period. A longer period should be provided for the submission and assessment of the complete dossier of each plant protection product in accordance with the uniform principles laid down in Directive 91/414/EEC. For plant protection products containing several active substances, the complete evaluation on the basis of the uniform principles can only be carried out when all the active substances concerned have been included in Annex I to Directive 91/414/EEC.

(7) The review report is required for the proper implementation by the Member States, of several sections of the uniform principles laid down in Directive 91/414/EEC. The finalised review report, except for confi-

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 304, 21.11.2001, p. 14.
([3]) OJ L 366, 15.12.1992, p. 10.
([4]) OJ L 259, 13.10.2000, p. 27.
([5]) OJ L 107, 28.4.1994, p. 8.
([6]) OJ L 225, 22.9.1995, p. 1.

([7]) Opinion of the Scientific Committee on Plants regarding the evaluation of 2,4-dichlorophenoxy acetic acid (2,4-D) in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market — SCP/2,4d/002-final.