

**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.

dential information, should be kept available or made available by the Member States for consultation by any interested parties. If the review report has to be updated to take account of technical and scientific developments, the conditions for the inclusion of the substance concerned in Annex I to Directive 91/414/EEC should also be amended in accordance with that Directive.

- (8) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant 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 keep available the review report for 2,4-D, except for confidential information within the meaning of Article 14 of Directive 91/414/EEC, for consultation by any interested parties or shall make it available to them on specific request.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive, by 1 April 2003 at the latest. They shall forthwith inform the Commission thereof.

In particular they shall, in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing author-

isations for plant protection products containing 2,4-D as active substance by that date.

When Member States adopt these 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. With regard to evaluation and decision-making pursuant to 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 thereto, the time limit for amending or withdrawing authorisations for plant protection products containing 2,4-D as the only active substance shall be 1 October 2006.

3. For plant protection products containing 2,4-D together with another active substance which is in Annex I to Directive 91/414/EEC, the period for amending or withdrawing authorisations shall expire four years after the entry into force of the Directive which amended Annex I so as to add the last of those substances to it.

Article 4

This Directive shall enter into force on 1 October 2002.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 28 November 2001.

For the Commission

David BYRNE

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 (!)	Entry into force	Expiration of inclusion	Specific provisions
'27	2,4-D CAS No 94-75-7 CIPAC No 1	(2,4-dichlorophenoxy) acetic acid	960 g/kg	1.10.2002	30.9.2012	<p>Only uses as herbicide may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on 2,4-D, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 2 October 2001 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions — must pay particular attention to the dermal absorption — must pay particular attention to the protection of non-target arthropods and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures

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