COMMISSION DIRECTIVE 2001/99/EC

of 20 November 2001

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include glyphosate and thifensulfuron-methyl as active substances

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 2001/87/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]), laid down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC (hereinafter referred to as 'the Directive'). Pursuant to Regulation (EEC) No 3600/92, 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]), laid down the list of active substances of plant protection products to be assessed, with a view to their possible inclusion in Annex I to the Directive.

(2) For glyphosate and thifensulfuron-methyl 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, Germany and France were designated as rapporteur Member States for glyphosate and thifensulfuron-methyl, respectively. The rapporteur Member States submitted the relevant assessment reports and recommendations to the Commission on 1 February 1999 (glyphosate) and on 30 April 1996 (thifensulfuron-methyl) in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(3) These assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. The reviews were finalised on 29 June 2001 in the format of the Commission review reports for glyphosate and thifensulfuron-methyl.

(4) The dossiers and the information from the reviews of glyphosate and thifensulfuron-methyl were also submitted to the Scientific Committee for Plants. No specific questions were addressed to the Committee. The Committee considered that there were no issues that it wished to raise regarding the active substances in the context of a possible inclusion in Annex I to the Directive ([7]). The Committee noted that absence of comment should only be interpreted as an indication of no obvious reasons necessitating comment.

(5) 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) of the Directive, 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 substances concerned in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing the active substances concerned can be granted in accordance with the provisions of the said Directive.

(6) The Directive provides that after inclusion of an active substance in Annex I, Member States must, within a prescribed period, grant, vary or withdraw, as appropriate, the authorisations of the plant protection products containing the active substance. In particular, plant protection products should not be authorised unless account is taken of the conditions associated with the inclusion of the active substance in Annex I and the uniform principles laid down in the Directive on the basis of a dossier satisfying the prescribed data requirements.

(7) A reasonable period must be provided for 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. Moreover, after inclusion, a reasonable period is necessary to permit Member States to implement the provisions of the Directive on plant protection products containing glyphosate or thifensulfuron-methyl. In particular, Member States

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 276, 19.10.2001, p. 17.
([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]) Minutes of the plenary of the Scientific Committee on Plants from March 7, 2001 (glyphosate).
Minutes of the plenary of the Scientific Committee on Plants from June 7, 2001 (thifensulfuron-methyl)

must, within that period, review existing authorisations and, where appropriate, grant new authorisations in accordance with the provisions of the Directive. 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 the Directive. 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 the Directive.

(8) The review report is required for the proper implementation by the Member States, of several sections of the uniform principles laid down in the Directive. It is, therefore, appropriate to provide that the finalised review reports (except for confidential information) are kept available or made available by the Member States for consultation by any interested parties. If a 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 the Directive should also be amended in accordance with the Directive.

(9) 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 shall be amended in accordance with the Annex hereto.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive, by 1 January 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 authorisations for plant protection products containing glyphosate or thifensulfuron-methyl as active substance by that date.

When Member States adopt this provision, 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 deadline for amending or withdrawing authorisations for plant protection products containing glyphosate or thifensulfuron-methyl as the only active substance shall be 1 July 2006.

3. For plant protection products containing glyphosate or thifensulfuron-methyl 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.

4. Member States shall keep available the review reports for glyphosate and thifensulfuron-methyl (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

This Directive shall enter into force on 1 July 2002.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 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 Nos	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
25	Glyphosate CAS No 1071-83-6 CIPAC No 284	N-(phosphonomethyl)-glycin	950 g/kg	1 July 2002	30 June 2012	Only uses as herbicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on glyphosate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 29 June 2001 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of the groundwater in vulnerable areas, in particular with respect to non-crops uses
26	Thifensulfuron-methyl CAS No 79277-27-3 CIPAC No 452	Methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoyl-sulfamoyl) thiophene-2-carboxylate	960 g/kg	1 July 2002	30 June 2012	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on thifensulfuron-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 29 June 2001 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of groundwater, — must pay particular attention to the impact on aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures

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