COMMISSION DIRECTIVE 2000/80/EC

of 4 December 2000

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, so as to consolidate that Annex and include a further active substance (lambda-cyhalothrin)

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 2000/68/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 that Regulation, 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) In accordance with Article 5(1) of the Directive, an active substance should be included in Annex I for a period not exceeding 10 years if it may be expected that neither the use of, nor residues from, plant protection products containing the active substance will have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment.

(3) For lambda-cyhalothrin 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. Sweden was designated as rapporteur Member State under Commission Regulation (EC) No 491/95 ([7]) amending Regulation (EEC) No 3600/92 and Regulation (EC) No 933/94, in particular with regard to the integration of the designated public authorities and the producers in Austria, Finland and Sweden in the implementation of the first stage of the programme of work referred to in Article 8(2) of the Directive. Sweden submitted the relevant assessment report and recommendation to the Commission on 12 June 1996, in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(4) That assessment report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. That review was finalised on 19 October 2000 in the format of the Commission review report for lambda-cyhalothrin. If the review report has to be updated to take account of technical and scientific developments, the conditions for the inclusion of lambda-cyhalothrin in Annex I to the Directive will also need to be amended in accordance with the Directive.

(5) The dossier and the information from the review have also been submitted to the Scientific Committee on Plants for consultation. In its opinion of 28 January 2000 ([8]), the Committee noted that an acute dietary risk assessment for consumers should be conducted and an acute reference dose should be defined. Further, with regard to the protection of the environment, the Committee emphasised that appropriate risk mitigation measures must be applied to avoid unacceptable effects on aquatic organisms and non-target arthropods including bees. Those recommendations were taken into consideration in the measures provided for in this Directive and in the relevant review report.

(6) It has appeared from the various examinations made that plant protection products containing the active substance 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 review report. It is therefore appropriate to include the active substance concerned in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing the active substance concerned can be granted in accordance with the provisions of the said Directive.

(7) 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

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 276, 28.10.2000, p. 41.
([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]) OJ L 49, 4.3.1995, p. 50.

([8]) Scientific Committee on Plants, 28.1.2000.

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.

(8) 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 lambda-cyhalothrin. In particular, Member States 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.

(9) It is appropriate to provide that the finalised review report (except for confidential information) is kept available or made available by the Member States for consultation by any interested parties.

(10) 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, where those principles refer to the evaluation of the data which were submitted for the purpose of the inclusion of the active substance in Annex I to the Directive.

(11) A number of substances have been included in Annex I to the Directive by a series of Commission Directives, namely Directive 97/73/EC [1], 98/47/EC [2], 1999/1/EC [3], 1999/73/EC [4], 1999/80/EC [5], 2000/10/EC [6], 2000/49/EC [7], 2000/50/EC [8]. For the sake of clarity and rationality, the details concerning those substances should be set out in tabular form and those Directives should be repealed without prejudice to the obligations of the Member States concerning the time limits for transposition and application set out in Annex II.

(12) To ensure consistency and uniform application, it is appropriate to provide that the finalised review report on each substance should be taken into account in applying the uniform principles for the evaluation and authorisation of plant protection products under Annex VI to the Directive. Similarly, all review reports (except for confidential information) should be kept available or made available by the Member States for consultation by any interested parties.

(13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health delivered on 19 October 2000,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is replaced by the text in Annex I to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 July 2002 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 lambda-cyhalothrin as an active substance by that date.

When Member States adopt those 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 deadline for amending or withdrawing authorisations for plant protection products containing lambda-cyhalothrin as the only active substance shall be 1 January 2006.

3. For plant protection products containing lambda-cyhalothrin 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 includes the last of those substances in Annex I.

[1] OJ L 353, 24.12.1997, p. 26.
[2] OJ L 191, 7.7.1998, p. 50.
[3] OJ L 21, 28.1.1999, p. 21.
[4] OJ L 206, 5.8.1999, p. 16.
[5] OJ L 210, 10.8.1999, p. 13.
[6] OJ L 57, 2.3.2000, p. 28.
[7] OJ L 197, 3.8.2000, p. 32.
[8] OJ L 198, 4.8.2000, p. 39.

Article 3

The Directives listed in the third column of Annex II are hereby repealed without prejudice to the obligations of the Member States concerning the transposition deadline and the specific provisions set out in Annex II.

Article 4

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

The provisions in Article 2 concerning the active substance lambda-cyhalothrin together with the inclusion of this active substance in Annex I to Directive 91/414/EEC apply from 1 January 2002.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 4 December 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

'ANNEX I

ACTIVE SUBSTANCES AUTHORISED FOR USE IN PLANT PROTECTION PRODUCTS

General provisions applying to all substances listed in this Annex:

For the implementation of the uniform principles of Annex VI in relation to each substance, the conclusions of the review report on it, and in particular the Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on the date indicated under "specific provisions" for that substance shall be taken into account.

Member States shall keep available all review reports (except for confidential information within the meaning of Article 14 of the Directive) for consultation by any interested parties or shall make it available to them on specific request.

Number	Common name, identification numbers	IUPAC name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
1	Imazalil CAS No 73790-28-0, 35554-44-0 CIPAC No 335	(±)-1-(β-allyloxy-2,4-dichlorophenyle-thyl)imidazole or (±)-allyl 1-(2,4-dichloro-phenyl)-2-imidazol-1-ylethyl ether	975 g/kg	1.1.1999	31.12.2008	Only uses as fungicide may be authorised For the following uses the following particular conditions apply: — post harvest fruit, vegetable and potato treatments may only be authorised when an appropriate decontamination system is available or a risk assessment has demonstrated to the authorising Member State that the discharge of the treatment solution does not have an unacceptable risk to the environment and in particular to aquatic organisms, — post harvest treatment of potatoes may only be authorised when a risk assessment has demonstrated to the authorising Member State that the discharge of the processing waste from treated potatoes does not have an unacceptable risk to aquatic organisms, — outdoor foliar uses may only be authorised when a risk assessment has demonstrated to the authorising Member State that the use has no unacceptable effects on human and animal health and the environment Date of Standing Committee on Plant Health at which the review report was finalised: 11.7.1997.
2	Azoxystrobin CAS No 131860-33-8 CIPAC No 571	Methyl (E)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy] phenyl}-3-metho-xyacrylate	930 g/kg (Z isomer max. 25 g/kg)	1.7.1998	1.7.2008	Only uses as fungicide may be authorised In the decision-making according to the uniform principles, particular attention should be given to the impact on aquatic organisms. Authorisation conditions should include appro-priate risk mitigation measures Date of Standing Committee on Plant Health at which the review report was finalised: 22.4.1998

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
3	Kresoxim-methyl CAS No 143390-89-0 CIPAC No 568	Methyl (E)-2-methoxyimino-2-[2-(o-tolyloxymethyl) phenyl] acetate	910 g/kg	1.2.1999	31.1.2009	Only used as fungicide may be authorised In their decision-making according to the uniform principles, Member States shall pay particular attention to the protection of groundwater under vulnerable conditions Date of Standing Committee on Plant Health at which the review report was finalised: 16.10.1998
4	Spiroxamine CAS No 1181134-30-8 CIPAC No 572	(8-tert-Butyl-1,4-dioxaspiro [4.5] decan-2-ylmethyl)-ethyl-propylamine	940 g/kg (diastereomers A and B combined)	1.9.1999	1.9.2009	Only uses as a fungicide may be authorised In their decision-making according to the uniform principles, Member States: — must pay particular attention to operator safety and must ensure that the conditions of authorisation include appropriate protective measures, and — must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Date of Standing Committee on Plant Health at which the review report was finalised: 12.5.1999
5	Azimsulfuron CAS No 120162-55-2 CIPAC No 584	1-(4,6-dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-pyrazol-5-ylsulfonyl]-urea.	980 g/kg	1.10.1999	1.10.2009	Only uses as herbicide may be authorised Aerial application may not be authorised In their decision making according to the uniform principles, Member States must pay particular attention to the impact on aquatic organisms and terrestrial non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures (e. g. in rice cultivation minimum holding periods for water prior to discharge) Date of Standing Committee on Plant Health at which the review report was finalised: 2.7.1999
6	Fluroxypyr CAS No 69377-81-7 CIPAC No 431	4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid	950 g/kg	1.12.2000	30.11.2010	Only uses as herbicide may be authorised In their decision-making according to the uniform principles, Member States: — shall take into account the additional information requested in point 7 of the review report, — must pay particular attention to the protection of groundwater, — must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Member States shall inform the Commission if the requested additional trials and information as outlined in point 7 of the review report were not submitted by 1.12.2000 Date of Standing Committee on Plant Health at which the review report was finalised: 30.11.1999