COMMISSION DIRECTIVE 2001/21/EC

of 5 March 2001

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include amitrole, diquat, pyridate and thiabendazole 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 2000/80/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 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 State for the implementation of 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 amitrole, diquat, pyridate and thiabendazole 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 respective notifiers. Under Regulation (EC) No 933/94, France was designated as rapporteur Member State for amitrole, the United Kingdom for diquat, and Spain for thiabendazole. Austria was designated as rapporteur Member State for pyridate under 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. The rapporteur Member States submitted the relevant assessment report and recommendation to the Commission on 30 April 1996 (amitrole), on 2 April 1996 (diquat), on 18 November 1996 (pyridate) and 30 April 1996 (thiabendazole) in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(4) 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 12 December 2000 in the format of the respective Commission review reports for amitrole, diquat, pyridate and thiabendazole. If the review reports have to be updated to take account of technical and scientific developments, the conditions for the inclusion of the substances concerned 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 of amitrole were submitted to the Scientific Committee for Plants for consultation. In its opinion of 6 June 2000 ([8]), the Committee confirmed the acceptable operator exposure level selected and offered advice on the interpretation of the long-term studies in rodents. The recommendations were taken into consideration in this Directive and in the relevant review report.

(6) The dossier and the information from the review of diquat were also submitted to the Scientific Committee for Plants for consultation. In its opinion of 5 April 2000 ([9]), the Committee offered advice on the interpretation of the available studies on bird reproduction, on potential long-term effects of residues bound to soil particles, on the potential environmental impact of aquatic weed control, and on certain aspects of operator and consumer exposure. The Committee offered its interpretation of the bird reproduction studies available. It concluded that there are no indications that residues in soil will have unacceptable effects. Further, the Committee noted that aquatic weed control uses of diquat may pose a high risk to non-target aquatic organisms and insufficient data is available to demonstrate that efficient risk mitigation measures can be applied.

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 309, 9.12.2000, 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]) OJ L 49, 4.3.1995, p. 50.
([8]) Scientific Committee on Plants SCP/AMITR/002 final.
([9]) Scientific Committee on Plants SCP/DIQUAT/002 final.

With regard to operator exposure, the Committee advised that measures should be considered to limit exposure of non-professional users. Finally, the Committee noted that insufficient information is available to fully assess the dietary exposure of consumers related to uses as desiccant in small grain cereals. Those opinions were taken into consideration in this Directive and in the relevant review report.

(7) For pyridate also, the dossier and the information from the review were submitted to the Scientific Committee for Plants for consultation. In its opinion of 6 June 2000 [1], the Committee confirmed the validity of the acceptable operator exposure level selected within the Standing Committee on Plant Health.

(8) For thiabendazole as well, the dossier and the information from the review were submitted to the Scientific Committee for Plants for consultation. In its opinion of 22 September 2000 [2], the Committee confirmed that the intended post-harvest uses of thiabendazole for fruit and potatoes will not pose an unacceptable risk to aquatic organisms, provided that adequate risk mitigation measures are applied. This recommendation was taken into consideration in this Directive and in the relevant review report.

(9) 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.

(10) Article 5(5) of the Directive provides that the inclusion of an active substance in Annex I can be reviewed at any time if there are indications that the criteria for inclusion are no longer satisfied. Therefore, the Commission will reconsider the inclusion in Annex I of amitrole if the requested additional information as outlined in point 7 of the review report were not submitted.

(11) 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.

(12) 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 amitrole, diquat, pyridate or thiabendazole. 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.

(13) It is 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.

(14) The review reports are 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 substances in Annex I to the Directive.

(15) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health delivered on 12 December 2000,

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

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 amitrole, diquat, pyridate or thiabendazole as active substances by that date.

[1] Scientific Committee on Plants SCP/PYRID/002 final.
[2] Scientific Committee on Plants SCP/THIABEN/002-final.