COMMISSION DIRECTIVE 2000/68/EC

of 23 October 2000

including an active substance (bentazone) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market

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 2000/10/EC [2], and in particular Article 6(1) and the fourth subparagraph of Article 8(2) thereof,

Whereas:

(1) Commission Regulation (EEC) No 3600/92 [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 [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 if it may be expected that neither the use of, nor residues from, plant protection products containing that active substance will have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment.

(3) Such an active substance may be included in Annex I for a period not exceeding 10 years.

(4) For bentazone 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 number of uses proposed by the notifiers. Germany was designated as rapporteur Member State under Regulation (EC) No 933/94 laying down the active substances of plant protection products and designating the rapporteur Member State for the implementation of Regulation (EEC) No 3600/92. It submitted the relevant assessment report and recommendation to the Commission on 13 November 1996, in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(5) The assessment report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. This review was finalised on 13 July 2000 in the format of the Commission review report for bentazone.

(6) The dossier and the information from the review have also been submitted to the Scientific Committee for Plants for consultation. The Scientific Committee for Plants in its opinion [7] confirmed that the substance can be used without unacceptable risk but noted that Member States should assess the leaching potential to groundwater in particularly vulnerable locations and in rice cultures.

(7) It has appeared from the assessments 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. It is appropriate therefore to include the active substance concerned in Annex I, in order to ensure that in all Member States the granting, varying or withdrawing, as appropriate, of the authorisations of plant protection products containing bentazone can be undertaken in accordance with the provisions of the Directive.

(8) Article 8(2) of the Directive provides that after inclusion of an active substance in its Annex I, Member States shall, within a prescribed period, grant, vary or withdraw, as appropriate, the authorisations of the plant protection products containing the active substance. In particular, Articles 4(1) and 13(1) of the Directive require that plant protection products are not 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 Annex VI on the basis of a dossier satisfying the data requirements laid down in its Article 13.

(9) Before inclusion, a reasonable deadline is necessary 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 for the Member States to implement the Directive and in particular to vary or withdraw, as appropriate, existing authorisations or grant new authorisations in accordance with the provisions of Directive 91/414/EEC. A longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product in accordance with the uniform principles laid down in Annex VI to the Directive. For plant protection

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 57, 2.3.2000, p. 28.
[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 inclusion of bentazone in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market (opinion expressed by the Scientific Committee on Plants on 2 December 1999).