COMMISSION DIRECTIVE 2001/28/EC

of 20 April 2001

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include KBR 2738 (fenhexamid) as an active substance

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 2001/21/EC [2], and in particular Article 6(1) thereof,

Whereas:

(1) In accordance with Article 6(2) of Directive 91/414/EEC (hereinafter referred to as 'the Directive') the United Kingdom received on 8 May 1997 an application from Bayer plc ('the applicant') for the inclusion of the active substance KBR 2738 (fenhexamid) in Annex I to the Directive.

(2) In accordance with the provisions of Article 6(3) of the Directive the Commission confirmed in its Decision 98/398/EC [3] that the dossier submitted for KBR 2738 (fenhexamid) could be considered as satisfying, in principle, the data and information requirements of Annex II and for a plant protection product containing this active substance, of Annex III to the Directive.

(3) 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, or 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.

(4) For KBR 2738 (fenhexamid), the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of the Directive, for the uses proposed by the applicant. The United Kingdom acting as nominated rapporteur Member State, submitted a draft assessment report concerning the substance to the Commission on 15 October 1998.

(5) That assessment report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. The review was finalised on 19 October 2000 in the format of the Commission review report for KBR 2738 (fenhexamid). If the review report has to be updated to take account of technical and scientific developments, the conditions for the inclusion of KBR 2738 (fenhexamid) in Annex I to the Directive will also need to be amended in accordance with the Directive.

(6) The dossier and the information from the review were submitted to the Scientific Committee on Plants for opinion on 31 March 2000. This Committee has given its opinion on 20 July 2000 in the minutes of the meeting (SCP/REPT/021 final) [4] where it was stated that the Committee did not wish to raise any issues with regard to this active substance. The Committee also noted that national authorisations would involve specific risk management in line with Annex VI [5] (Uniform principles) of the Directive.

(7) 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), (b) and (3) 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 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.

(8) After inclusion, a reasonable period is necessary to permit Member States to implement the provisions of the Directive on plant protection products containing KBR 2738 (fenhexamid) and in particular to review, within this period, existing provisional authorisations or to grant, by the end of this period at the latest, new authorisations in accordance with the provisions of the Directive. A longer period may also be required for plant protection products containing KBR 2738 (fenhexamid) and other active substances included in Annex I.

(9) It is appropriate to provide that the finalised review report (except for confidential information in the meaning of Article 14 of the Directive) 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 Annex VI to 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.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 69, 10.3.2001, p. 17.
[3] OJ L 176, 20.6.1998, p. 34.
[4] Minutes of the 21st meeting of the Scientific Committee on Plants, Brussels, 20 July 2000.
[5] OJ L 265, 27.9.1997, p. 87.