COMMISSION DIRECTIVE 2000/10/EC

of 1 March 2000

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

(Text with EEA relevance)

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 1999/80/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 1972/1999 [4], has 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) Those active substances should be included in that Annex when it may be expected that there will not be any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment.

(3) Such inclusion should be made for a period not exceeding 10 years.

(4) The Directive, at Article 8(2), provides that after inclusion of an active substance in Annex I to the Directive, 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 Article 13.

(5) For fluroxypyr 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, acting as designated rapporteur Member State under Regulation (EC) No 933/94, submitted to the Commission on 27 September 1996 the relevant assessment report.

(6) The submitted report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. This review was finalised on 30 November 1999 in the format of the Commission review report for fluroxypyr. It may be necessary to update this report to take account of technical and scientific developments. In such case the conditions for the inclusion of fluroxypyr in Annex I to Directive 91/414/EEC will also need to be amended pursuant to Article 6(1) of that Directive. The dossier and the informaiton from the review have also been submitted to the Scientific Committee for Plants for consultation.

(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. Therefore it is necessary 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 fluroxypyr can be organised in accordance with the provisions of the Directive, and to ensure that this activity is not further delayed.

(8) The Scientific Committee for Plants in its opinion identified the need to confirm by additional data the environmental safety of certain breakdown products of fluroxypyr occurring in soil and water.

(9) Article 5(5) of Directive 91/414/EEC 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 if the results of the requested additional trials as outlined in point 7 of the review report were to indicate potential adverse effects, or if the requested additional data results and information were not submitted.

(10) Before inclusion a reasonable deadline is necessary to permit Member States and the interested parties to prepare themselves for 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

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 210, 10.8.1999, p. 13.
[3] OJ L 366, 15.12.1992, p. 10.
[4] OJ L 244, 16.9.1999, p. 41.
[5] OJ L 107, 28.4.1994, p. 8.
[6] OJ L 225, 22.9.1995, p. 1.