COMMISSION

COMMISSION DECISION

of 5 December 2000

making it possible to extend provisional authorisations granted for the new active substances FOE 5043 (flufenacet — earlier name fluthiamide) and flumioxazine

(notified under document number C(2000) 3658)

(Text with EEA relevance)

(2000/767/EC)

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 8(1) fourth subparagraph thereof,

Whereas:

(1) Directive 91/414/EEC (hereinafter 'the Directive') has provided for the development of a Community list of active substances authorised for use in plant protection products.

(2) The applicant Bayer SA submitted a dossier for the new active substance FOE 5043 (flufenacet) (previously known as fluthiamide) to France on 1 February 1996.

(3) The applicant Cyanamid submitted a dossier for the new active substance flumioxazine to France on 2 May 1994.

(4) In accordance with the provisions of Article 6(3) of the Directive, the Commission confirmed in its Decision 97/362/EC [3] that the dossier submitted for FOE 5043 (flufenacet) 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.

(5) In accordance with the provisions of Article 6(3) of the Directive, the Commission confirmed in its Decision 97/631/EC [4] that the dossier submitted for flumioxazine 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.

(6) Such confirmation of data and information is necessary to permit a detailed examination of the dossier and to allow Member States the possibility to grant provisional authorisations, for a period up to three years, for plant-protection products containing the active substance concerned, while complying with the conditions laid down in Article 8(1) of the Directive and, in particular, the condition relating to the detailed assessment of the active substance and the plant protection product in the light of the requirements laid down by the Directive.

(7) For FOE 5043 (flufenacet) the effects on human health and the environment are being assessed, in accordance with the provisions of Article 6(2) and (4) of the Directive, for the uses proposed by the applicant. France acting as nominated rapporteur Member State submitted to the Commission on 6 January 1998 the draft assessment report concerned. The submitted report is being reviewed by the Member States and the Commission within the framework of the Standing Committee on Plant Health and in working groups thereof.

(8) For flumioxazine, the effects on human health and the environment are being assessed, in accordance with the provisions of Article 6(2) and (4) of the Directive, for the uses proposed by the applicant. France acting as nominated rapporteur Member State submitted to the Commission on 20 January 1998 the draft assessment report concerned. The submitted report is being reviewed by the Member States and the Commission within the framework of the Standing Committee on Plant Health and in working groups thereof.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 276, 28.10.2000, p. 41.
[3] OJ L 152, 11.6.1997, p. 31.
[4] OJ L 262, 24.9.1997, p. 7.

(9) It will not be possible to complete the evaluation of the dossiers within three years of the adoption of the decisions on completeness referred to above because the examination of the dossiers after submission of the draft assessment reports by the rapporteur Member State, France, have been subject to longer time periods than the Community average for new active substance evaluation.

(10) The evaluation processes for both applications have been examined according to a set of assessment criteria. From this analysis it would appear that the longer time periods for the Community evaluation have been due to factors essentially not due to the two applicants referred to above.

(11) To enable the assessment of the FOE 5043 (flufenacet) and flumioxazine to continue, and to permit plant-protection products containing these active substances to continue to be made provisionally available for use in agriculture, Member States should therefore be permitted to prolong authorisations of plant protection products containing these active substances granted under Article 8(1) of the Directive.

(12) An extension of 12 months is proposed in both cases, as this should be sufficient to allow the completion of the evaluation and decision making process with respect to a decision on possible Annex I inclusion.

(13) Such provisions to extend the possible time limits for provisional authorisations should be seen as a temporary measure. The Commission has already taken steps to improve the efficiency of the evaluation system with a view to complete the evaluation of a new active substance within a period of three years from the date of publication of the completeness.

(14) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DECISION:

Article 1

Member States may extend provisional authorisations already granted for plant-protection products containing FOE 5043 (flufenacet) and flumioxazine for a period not exceeding 12 months from the date of adoption of this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 5 December 2000.

For the Commission

David BYRNE

Member of the Commission