

COMMISSION DECISION

of 18 April 2001

making it possible for Member States to extend provisional authorisations granted for the new active substances flupyrsulfuron-methyl, carfentrazone-ethyl, famoxadone, prosulfuron, isoxaflutole, flurtamone, ethoxysulfuron, *paecilomyces fumosoroseus*, and cyclanilide

(notified under document number C(2001) 1090)

(Text with EEA relevance)

(2001/315/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 2000/80/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 Du Pont de Nemours submitted a dossier for the new active substance flupyrsulfuron-methyl to France on 26 October 1995.
- (3) The applicant FMC Europe NV submitted a dossier for the new active substance carfentrazone-ethyl to France on 14 February 1996.
- (4) The applicant Du Pont de Nemours submitted a dossier for the new active substance famoxadone to France on 2 October 1996.
- (5) The applicant Novartis submitted a dossier for the new active substance prosulfuron to France on 14 May 1995.
- (6) The applicant Rhone-Poulenc submitted a dossier for the new active substance isoxaflutole to the Netherlands on 6 March 1996.
- (7) The applicant Rhone-Poulenc submitted a dossier for the new active substance flurtamone to France on 15 February 1994.
- (8) The applicant AgrEvo submitted a dossier for the new active substance ethoxysulfuron to Italy on 3 July 1996.
- (9) The applicant Thermo Trilogy Corporation submitted a dossier for the new active substance *paecilomyces fumosoroseus* to Belgium on 18 May 1994.

(10) The applicant Rhone-Poulenc Agrochimie SA submitted a dossier for the new active substance cyclanilide to Greece on 27 March 1996.

(11) In accordance with the provisions of Article 6(3) of the Directive, the Commission confirmed in its Decision 97/164/EC ⁽³⁾ that the dossier submitted for flupyrsulfuron-methyl 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.

(12) In accordance with the provisions of Article 6(3) of the Directive, the Commission confirmed in its Decision 97/362/EC ⁽⁴⁾ that the dossier submitted for carfentrazone-ethyl 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.

(13) In accordance with the provisions of Article 6(3) of the Directive, the Commission confirmed in its Decision 97/591/EC ⁽⁵⁾ that the dossier submitted for famoxadone 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.

(14) In accordance with the provisions of Article 6(3) of the Directive, the Commission confirmed in its Decision 97/137/EC ⁽⁶⁾ that the dossier submitted for prosulfuron 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.

(15) In accordance with the provisions of Article 6(3) of the Directive, the Commission confirmed in its Decision 97/524/EC ⁽⁷⁾ that the dossier submitted for isoxaflutole 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.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 309, 9.12.2000, p. 14.

⁽³⁾ OJ L 64, 5.3.1997, p. 17.

⁽⁴⁾ OJ L 152, 11.6.1997, p. 31.

⁽⁵⁾ OJ L 239, 30.8.1997, p. 48.

⁽⁶⁾ OJ L 52, 22.2.1997, p. 20.

⁽⁷⁾ OJ L 220, 30.8.1996, p. 27.

- (16) In accordance with the provisions of Article 6(3) of the Directive, the Commission confirmed in its Decision 97/341/EC⁽¹⁾ that the dossier submitted for flurtamone 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.
- (17) In accordance with the provisions of Article 6(3) of the Directive, the Commission confirmed in its Decision 97/591/EC that the dossier submitted for ethoxysulfuron 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.
- (18) In accordance with the provisions of Article 6(3) of the Directive, the Commission confirmed in its Decision 97/164/EC of 17 February 1997 that the dossier submitted for *paecilomyces fumosoroseus* 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.
- (19) In accordance with the provisions of Article 6(3) of the Directive, the Commission confirmed in its Decision 97/137/EC of 3 February 1997 that the dossier submitted for cyclanilide 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.
- (20) 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 Articles 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.
- (21) For flupyrsulfuron-methyl 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 2 December 1997 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.
- (22) For carfentrazone-ethyl, 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 14 May 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.
- (23) For famoxadone, 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 5 August 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.
- (24) For prosulfuron, 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 18 January 1999 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.
- (25) For isoxaflutole, 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. The Netherlands acting as nominated rapporteur Member State submitted to the Commission on 26 February 1997 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.
- (26) For flurtamone, 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 21 May 1997 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 130, 31.5.1996, p. 20.

- (27) For ethoxysulfuron, 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. Italy acting as nominated rapporteur Member State submitted to the Commission on 20 May 1997 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.
- (28) For *paecilomyces fumosoroseus*, 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. Belgium acting as nominated rapporteur Member State submitted to the Commission on 9 December 1997 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.
- (29) For cyclanilide, 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. Greece acting as nominated rapporteur Member State submitted to the Commission on 11 February 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.
- (30) 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 respective rapporteur Member States has taken longer than three years.
- (31) Member States should be given the possibility of prolonging provisional authorisations of plant protection products containing these active substances for a period of 12 months in accordance with the provisions of Article 8 of the Directive so as to enable examination of the dossiers to continue. It is expected that within 12 months the completion of the evaluation and decision making process with respect to a decision on possible Annex I inclusion for each of the active substances concerned will have been completed.
- (32) 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 for plant protection products containing flupyrsulfuron-methyl, carfentrazone-ethyl, famoxadone, prosulfuron, isoxaflutole, flurtamone, ethoxysulfuron, *paecilomyces fumosoroseus*, and cyclanilide for a period not exceeding 12 months from the date of adoption of this Decision.

Article 2

The present Decision is addressed to the Member States.

Done at Brussels, 18 April 2001.

For the Commission

David BYRNE

Member of the Commission