

# COMMISSION

## COMMISSION DECISION

of 21 May 1997

**recognizing in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of carfentrazone-ethyl, fosthiazate and fluthiamide in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market**

(Text with EEA relevance)

(97/362/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<sup>(1)</sup>, as last amended by Commission Directive 96/68/EC<sup>(2)</sup>, and in particular Article 6(3) thereof,

Whereas Directive 91/414/EEC has provided for the development of a Community list of active substances authorized for incorporation in plant protection products;

Whereas applicants have submitted dossiers for three active substances to Member States authorities in view of obtaining the inclusion of the active substances in Annex I to Directive 91/414/EEC;

Whereas a dossier for the active substance carfentrazone-ethyl was submitted by FMC Europe NV to the French authorities on 14 February 1996;

Whereas a dossier for the active substance fosthiazate was submitted by ISK Biosciences Division to the United Kingdom authorities on 5 March 1996;

Whereas a dossier for the active substance fluthiamide was submitted by Bayer SA to the French authorities on 1 February 1996;

Whereas the said authorities indicated to the Commission the results of a first examination of the completeness of the dossiers with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active

substance concerned, in Annex III to the Directive; whereas subsequently, in accordance with the provisions of Article 6(2), the dossiers were submitted by the applicants to the Commission and other Member States;

Whereas the dossiers for carfentrazone-ethyl, fosthiazate and fluthiamide were referred to the Standing Committee on Plant Health on 19 December 1996;

Whereas Article 6(3) of the Directive requires it to be confirmed at the level of the Community that each dossier is to be considered as satisfying in principle the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive;

Whereas such confirmation is necessary in order to pursue the detailed examination of the dossier as well as in order to open to Member States the possibility of granting provisional authorization for plant protection products containing this active substance in due respect of the conditions laid down in Article 8(1) of the Directive, and in particular the condition to make a detailed assessment of the active substances and the plant protection products with regard to the requirements of the Directive;

Whereas such decision does not prejudice that further data or information may be requested from the applicant where it would appear during the detailed examination that such information or data are required for a decision to be taken;

Whereas it is understood by the Member States and the Commission that France will pursue the detailed examination for the dossiers for carfentrazone-ethyl and fluthiamide and that the United Kingdom will pursue the detailed examination for the dossier for fosthiazate;

<sup>(1)</sup> OJ No L 230, 19. 8. 1991, p. 1.

<sup>(2)</sup> OJ No L 277, 30. 10. 1996, p. 25.

Whereas France and the United Kingdom will report the conclusions of their examinations accompanied by any recommendations on the inclusion or non-inclusion and any conditions related thereto, to the Commission as soon as possible and at the latest within a period of one year; whereas on receipt of these reports the detailed examination will be continued with the expertise from all Member States within the framework of the Standing Committee on Plant Health;

Whereas 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*

The following dossiers are considered as satisfying in principle the data and information requirements provided for in Annex II and, for a plant protection product containing the active substance concerned, in Annex III of the Directive:

1. the dossier submitted by FMC Europe NV to the Commission and the Member States with a view to the inclusion of carfentrazone-ethyl as active substance in

Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 19 December 1996;

2. the dossier submitted by ISK Biosciences Division to the Commission and the Member States with a view to the inclusion of fosthiazate as active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 19 December 1996;
3. the dossier submitted by Bayer SA to the Commission and the Member States with a view to the inclusion of fluthiamide as active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 19 December 1996.

*Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 21 May 1997.

*For the Commission*

Franz FISCHLER

*Member of the Commission*