

COMMISSION DECISION

of 5 December 1997

recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of CGA 245 704, flazasulfuron, *Spodoptera exigua* nuclear polyhedrosis virus, imazosulfuron, pymetrozine and sulfosulfuron in Annex I of Council Directive 91/414/EEC concerning the placing of plant protection products on the market

(Text with EEA relevance)

(97/865/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 Directive 97/57/EC⁽²⁾, and in particular Article 6 (3) thereof,

Whereas Directive 91/414/EEC (hereinafter 'the Directive') 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 six active substances to Member States' authorities in view of obtaining the inclusion of the active substances in Annex I of the Directive;

Whereas a dossier for the active substance CGA 245 704 was submitted by Novartis Crop Protection AG to the French authorities on 15 October 1996;

Whereas a dossier for the active substance flazasulfuron was submitted by ISK Biosciences to the Spanish authorities on 16 December 1996;

Whereas a dossier for the active substance *Spodoptera exigua* nuclear polyhedrosis virus was submitted by Biosys to the Dutch authorities on 12 July 1996;

Whereas a dossier for the active substance imazosulfuron was submitted by Urania Agrochem GmbH to the German authorities on 27 June 1996;

Whereas a dossier for the active substance pymetrozine was submitted by Novartis Crop Protection AG to the German authorities on 4 September 1996;

Whereas a dossier for the active substance sulfosulfuron was submitted by Monsanto to the Irish authorities on 24 April 1997;

Whereas the said authorities indicated to the Commission the results of a first examination of the completeness of

the dossier 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 of the Directive; whereas subsequently, in accordance with the provisions of Article 6 (2), the dossier was submitted by the applicants to the Commission and other Member States;

Whereas the dossiers for flazasulfuron, *Spodoptera exigua* nuclear polyhedrosis virus and pymetrozine were referred to the Standing Committee on Plant Health on 29 May 1997;

Whereas the dossier the CGA 245 704 was referred to the Standing Committee on Plant Health on 19 June 1997;

Whereas the decision for imazosulfuron and sulfosulfuron were referred to the Standing Committee on Plant Health on 11 July 1997;

Whereas Article 6 (3) of the Directive requires it being 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 of the Directive;

Whereas such confirmation is necessary in order to pursue the described 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 between the Member States and the Commission that France will pursue the detailed examination for the dossier for CGA 245 704, that Spain will pursue the detailed examination for the dossier for

⁽¹⁾ OJ L 230, 19. 8. 1991, p. 1.

⁽²⁾ OJ L 265, 27. 9. 1997, p. 87.

flazasulfuron, that the Netherlands will pursue the detailed examination for the dossier for *Spodoptera exigua* nuclear polyhedrosis virus, that Germany will pursue the detailed examination for the dossiers for imazosulfuron and pymetrozine and that Ireland will pursue the detailed examination for the dossier for sulfosulfuron;

Whereas France, Spain, the Netherlands, Germany and Ireland 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 this report 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 satisfy 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, taking into account the uses proposed:

1. The dossier submitted by ISK Biosciences to the Commission and the Member States with a view to the inclusion of flazasulfuron as an active substance in Annex I of Directive 91/414/EEC and referred to the Standing Committee on Plant Health on 29 May 1997.
2. The dossier submitted by Biosys to the Commission and the Member States with a view to the inclusion of *Spodoptera exigua* nuclear polyhedrosis virus as an

active substance in Annex I of Directive 91/414/EEC and referred to the Standing Committee on Plant Health on 29 May 1997.

3. The dossier submitted by Novartis Crop Protection AG to the Commission and the Member States with a view to the inclusion of CGA 245 704 as an active substance in Annex I of Directive 91/414/EEC and referred to the Standing Committee on Plant Health on 19 June 1997.
4. The dossier submitted by Urania Agrochem GmbH to the Commission and the Member States with a view to the inclusion of imazosulfuron as an active substance in Annex I of Directive 91/414/EEC and referred to the Standing Committee on Plant Health on 11 July 1997.
5. The dossier submitted by Novartis Crop Protection AG to the Commission and the Member States with a view to the inclusion of pymetrozine as an active substance in Annex I of Directive 91/414/EEC and referred to the Standing Committee on Plant Health on 29 May 1997.
6. The dossier submitted by Monsanto to the Commission and the Member States with a view to the inclusion of sulfosulfuron as an active substance in Annex I of Directive 91/414/EEC and referred to the Standing Committee on Plant Health on 11 July 1997.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 5 December 1997.

For the Commission

Franz FISCHLER

Member of the Commission