

COMMISSION DECISION

of 31 May 1999

recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of ZA 1296 (mesotrione), Iodosulfuron-methyl-sodium (AEF 115008) Silthiopham (MON 65500) and *Gliocladium catenulatum* in Annex I to Council Directive 91/414/EEC concerning the placing of plant-protection products on the market

(notified under document number C(1999) 1400)

(Text with EEA relevance)

(1999/392/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC⁽¹⁾ of 15 July 1991 concerning the placing of plant-protection products on the market as last amended by Commission Directive 1999/1/EC⁽²⁾ and in particular Article 6(3) thereof,

- (1) Whereas Directive 91/414/EEC (hereinafter 'the Directive') has provided for the development of a Community list of active substances authorised for incorporation in plant-protection products;
- (2) Whereas applicants have submitted dossiers for four active substances to Member States' authorities in view of obtaining inclusion of the active substances in Annex I to the Directive;
- (3) Whereas a dossier for the active substance ZA 1296 (mesotrione) was submitted by Zeneca Agrochemicals to the United Kingdom authorities on 23 April 1998;
- (4) Whereas a dossier for the active substance Iodosulfuron-methyl-sodium (AEF 115008) was submitted by Hoechst Schering Agroevro GmbH to the German authorities on 14 December 1998;
- (5) Whereas a dossier for the active substance Silthiopham (MON 65500) was submitted by Monsanto Crop Protection to the Irish authorities on 14 December 1998;
- (6) Whereas a dossier for the active substance *Gliocladium catenulatum* was submitted by Kemira Agro Oy to the Finnish authorities on 19 May 1998;
- (7) 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 to the Directive; whereas subsequently, in accordance with the provisions of Article 6(2), the dossiers were submitted by the applicant to the Commission and other Member States;

- (8) Whereas the dossiers for ZA 1296 (mesotrione), Iodosulfuron-methyl-sodium (AEF 115008), Silthiopham (MON 65500) and *Gliocladium catenulatum* were referred to the Standing Committee on Plant Health on 11 February 1999;
- (9) 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 to the Directive;
- (10) 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 authorisation 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;
- (11) 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;

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 21, 28.1.1999, p. 21.

- (12) Whereas it is understood between the Member States and the Commission that the United Kingdom will pursue the detailed examination for the dossier for ZA 1296 (mesotrione), that Germany will pursue the detailed examination for the dossier for Iodosulfuron-methyl-sodium (AEF 115008), that Ireland will pursue the detailed examination for the dossier for Silthiopham (MON 65500), and that Finland will pursue the detailed examination for the dossier for *Gliocladium catenulatum*;
- (13) Whereas the United Kingdom, Germany, Ireland and Finland 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 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;
- (14) Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plant Health,
1. The dossier submitted by Zeneca Agrochemicals to the Commission and the Member States with a view to the inclusion of ZA 1296 (mesotrione) as an active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 11 February 1999.
 2. The dossier submitted by Hoechst Schering Agrevo GmbH to the Commission and the Member States with a view to the inclusion of Iodosulfuron-methyl-sodium (AEF 115008) as an active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 11 February 1999.
 3. The dossier submitted by Monsanto Crop Protection to the Commission and the Member States with a view to the inclusion of Silthiopham (MON 65500) as an active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 11 February 1999.
 4. The dossier submitted by Kemira Agro Oy to the Commission and the Member States with a view to the inclusion of *Gliocladium catenulatum* as an active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 11 February 1999.

HAS ADOPTED THIS DECISION:

Article 1

The following dossiers satisfy 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, taking into account the uses proposed:

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 31 May 1999.

For the Commission

Franz FISCHLER

Member of the Commission
