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# COMMISSION

## COMMISSION DECISION

#### of 6 September 2000

recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of RH-7281 (zoxamide), B-41; E-187 (milbemectin), BAS500F (pyraclostrobin) and AEF130360 (foramsulfuron) in Annex I to Council Directive 91/414/EEC concerning the placing of plant-protection products on the market

(notified under document number C(2000) 2285)

(2000/540/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES.

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/141/EEC of 15 July 1991 concerning the placing of plant-protection products on the market (<sup>1</sup>) as last amended by Commission Directive 2000/ 10/EC (<sup>2</sup>) and in particular Article 6(3) thereof,

Whereas:

- (1)Directive 91/414/EEC (hereinafter 'the Directive') has provided for the development of a Community list of active substances authorised for incorporation in plantprotection products.
- A dossier for the active substance RH-7281 (zoxamide) (2) was submitted by Rohm and Haas France SA to the authorities of the United Kingdom on 2 June 1999 with a view to obtaining its inclusion in Annex I to the Directive.
- A dossier for the active substance B-41; E-187 (milbe-(3) mectin) was submitted by Sankyo Company Limited to the Dutch authorities on 6 March 2000 with a view to obtaining its inclusion in Annex I to the Directive.
- A dossier for the active substance BAS500F (pyraclos-(4) trobin) was submitted by BASF AG to the German authorities on 28 February 2000 with a view to obtaining its inclusion in Annex I to the Directive.
- A dossier for the active substance AEF130360 (foram-(5) sulfuron) was submitted by Aventis GmbH to the German authorities on 30 March 2000 with a view to obtaining its inclusion in Annex I to the Directive.
- (6) The said authorities indicated to the Commission that, on preliminary examination, the dossier appears to satisfy the data and information requirements of Annex II to the Directive. Further, they believe that the dossier contains data and information required by Annex III to the Directive in respect of at least one plant-protection

product containing the active substances concerned. Subsequently, in accordance with the provisions of Article 6(2), the dossiers were submitted by the applicant to the Commission and other Member States.

- The dossier for RH-7281 (zoxamide), B-41; E-187 (7)(milbemectin), BAS500F (pyraclostrobin) and AEF130360 (foramsulfuron) were referred to the Standing Committee on Plant Health on 31 May 2000.
- (8) Article 6(3) of the Directive requires it being confirmed at the level of the Community that each dossier is to be considered as satistying 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.
- (9) 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.
- Such Decision does not prejudice the right of the (10)Commission to request the applicant to submit further data or information, to the rapporteur Member State concerned, in order to clarify certain points in the dossier, The submission of further data necessary to clarify the dossier shall not affect the time limit for the submission of the report referred to under recital 12.
- (11)The Member States and the Commission agree that the United Kingdom will pursue the detailed examination for the dossier for RH-7281 (zoxamide), that the Netherlands will pursue the detailed examination for the dossier for B-41; E-187 (milbemectin) and that Germany will pursue the detailed examination for the dosssiers BAS500F (pyraclostrobin) and AEF130360 (foramsulfuron).

<sup>(&</sup>lt;sup>1</sup>) OJ L 230, 19.8.1991, p. 1. (<sup>2</sup>) OJ L 57, 2.3.2000, p. 28.

- (12) The United Kingdom, the Netherlands and Germany will report the conclusions of their examinations accompanied by any recommendations on inclusion or noninclusion and any conditions related thereto to the Commission as soon as possible and at the latest within a period of one year from the date of publication of this Decision.
- (13) 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 at least one plant-protection product containing the active substance concerned, in Annex III to the Directive, taking into account the uses proposed:

1. the dossier submitted by Rohm and Haas France SA to the Commission and the Member States with a view to the inclusion of RH-7281 (zoxamide) as active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 31 May 2000;

- 2. the dossier submitted by Sankyo Company Limited on the Commission and the Member States with a view to the inclusion of B-41; E-187 (milbemectin) as active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 31 May 2000;
- 3. the dossier submitted by BASF AG to the Commission and the Member States with a view to the inclusion of BAS500F (pyraclostrobin) as active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 31 May 2000;
- 4. the dossier submitted by Aventis GmbH to the Commission and the Member States with a view to the inclusion of AEF130360 (foramsulfuron) as active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 31 May 2000.

### Article 2

This Decision is addressed to the Members States.

Done at Brussels, 6 September 2000.

For the Commission David BYRNE Member of the Commission