COMMISSION DECISION

of 2 June 1998

recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of BAS 615H, KBR 2738 (fenhexamid), oxadiargyl and DPX-KN128 (indoxacarb) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market

(notified under document number C(1998) 1447)

(Text with EEA relevance)

(98/398/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 97/73/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 authorised for incorporation in plant protection products;

Whereas applicants have submitted dossiers for four active substances to Member States' authorities in view of obtaining the inclusion of the active substances in Annex I to the Directive;

Whereas a dossier for the active substance BAS 615H was submitted by BASF plc to the United Kingdom authorities on 28 April 1997;

Whereas a dossier for the active substance KBR 2738 (fenhexamid) was submitted by Bayer plc to the United Kingdom authorities on 8 May 1997;

Whereas a dossier for the active substance oxadiargyl was submitted by Rhône Poulenc Agro SpA to the Italian authorities on 16 June 1997;

Whereas a dossier for the active substance DPX-KN128 (indoxacarb) was submitted by Du Pont de Nemours France SA to the Dutch authorities on 6 October 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 to 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 BAS 615H, KBR 2738 (fenhexamid), oxadiargyl and DPX-KN128 (indoxacarb) were referred to the Standing Committee on Plant Health on 18 February 1998;

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;

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;

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 the United Kingdom will pursue the detailed examinations for the dossiers for BAS 615H and KBR 2738 (fenhexamid), that Italy will pursue the detailed examination for the dossier for oxadiargyl and that the Netherlands will pursue the detailed examination for the dossier for DPX-KN128 (indoxacarb);

⁽¹) OJ L 230, 19. 8. 1991, p. 1. (²) OJ L 353, 24. 12. 1997, p. 26.

Whereas the United Kingdom, Italy and the Netherlands 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 at least one plant protection product containing the active substance concerned, in Annex III to the Directive, taking into account the uses proposed.

The dossier submitted by BASF plc to the Commission and the Member States with a view to the inclusion of BAS 615H as active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 18 February 1998.

- The dossier submitted by Bayer plc to the Commission and the Member States with a view to the inclusion of KBR 2738 (fenhexamid) as active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 18 February 1998.
- 3. The dossier submitted by Rhône Poulenc Agro SpA to the Commission and the Member States with a view to the inclusion of oxadiargyl as active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 18 February 1998.
- 4. The dossier submitted by Du Pont de Nemours France SA to the Commission and the Member States with a view to the inclusion of DPX-KN128 (indoxacarb) as active substance in Annex I to Directive 91/414/EEC and which was referred to the Standing Committee on Plant Health on 18 February 1998.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 2 June 1998.

Franz FISCHLER

Member of the Commission