

COMMISSION DECISION

of 19 October 2005

allowing Member States to extend provisional authorisations granted for the new active substances boscalid, indoxacarb, spinosad and *Spodoptera exigua* nuclear polyhedrosis virus

(notified under document number C(2005) 4002)

(Text with EEA relevance)

(2005/743/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⁾, and in particular the fourth subparagraph of Article 8(1) thereof,

Whereas:

- (1) In accordance with Article 6(2) of Directive 91/414/EEC, in April 2001 Germany received an application from BASF AG for the inclusion of the active substance boscalid (former name: nicobifen) in Annex I to Directive 91/414/EEC. Commission Decision 2002/268/EC ⁽²⁾ confirmed that the dossier was complete and could be considered as satisfying, in principle, the data and information requirements of Annex II and Annex III to that Directive.
- (2) In October 1997 the Netherlands received an application from DuPont de Nemours concerning indoxacarb (former name: DPX-KN128). Commission Decision 98/398/EC ⁽³⁾ confirmed that the dossier was complete and could be considered as satisfying, in principle, the data and information requirements of Annex II and Annex III to that Directive.
- (3) In July 1999 the Netherlands received an application from Dow Agrosciences concerning spinosad. Commission Decision 2000/210/EC ⁽⁴⁾ confirmed that the dossier was complete and could be considered as satisfying, in principle, the data and information requirements of Annex II and Annex III to that Directive.
- (4) In July 1996 the Netherlands received an application from Biosys concerning *Spodoptera exigua* nuclear polyhedrosis virus. Commission Decision 97/865/EC ⁽⁵⁾

confirmed that the dossier was complete and could be considered as satisfying, in principle, the data and information requirements of Annex II and Annex III to that Directive.

- (5) Confirmation of the completeness of the dossiers was necessary in order to allow them to be examined in detail and to allow Member States the possibility of granting provisional authorisations, for periods up to three years, for plant protection products containing the active substances concerned, while complying with the conditions laid down in Article 8(1) of Directive 91/414/EEC and, in particular, the condition relating to the detailed assessment of the active substance and the plant protection product in the light of the requirements laid down by that Directive.
- (6) For these active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the respective applicants. The rapporteur Member States submitted the draft assessment reports to the Commission on 22 November 2002 (boscalid), 7 February 2000 (indoxacarb), 5 March 2001 (spinosad) and 19 November 1999 (*Spodoptera exigua* nuclear polyhedrosis virus).
- (7) Following submission of the draft assessment reports by the rapporteur Member States, it has been necessary to request further information from the applicants and to have the Rapporteur Member States examine that information and submit their assessments. Therefore, the examination of the dossiers is still ongoing and it will not be possible to complete the evaluation within the timeframe provided for in Directive 91/414/EEC.
- (8) As the evaluation so far has not identified any reason for immediate concern, Member States should be given the possibility of prolonging provisional authorisations granted for plant protection products containing the active substances concerned for a period of 24 months in accordance with the provisions of Article 8 of Directive 91/414/EEC so as to enable the examination of the dossiers to continue. It is expected that the evaluation and decision-making process with respect to a decision on possible Annex I inclusion for each of the active substances concerned will have been completed within 24 months.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2005/34/EC (OJ L 125, 18.5.2005, p. 5).

⁽²⁾ OJ L 92, 9.4.2002, p. 34.

⁽³⁾ OJ L 176, 20.6.1998, p. 34.

⁽⁴⁾ OJ L 64, 11.3.2000, p. 24.

⁽⁵⁾ OJ L 351, 23.12.1997, p. 67.

- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

Article 2

This Decision is addressed to the Member States.

HAS ADOPTED THIS DECISION:

Article 1

Done at Brussels, 19 October 2005.

Member States may extend provisional authorisations for plant protection products containing boscalid, indoxacarb, spinosad or *Spodoptera exigua* nuclear polyhedrosis virus for a period not exceeding 24 months from the date of adoption of this Decision.

For the Commission
Markos KYPRIANOU
Member of the Commission
