COMMISSION DECISION

of 29 April 2008

allowing Member States to extend provisional authorisations granted for the new active substances cyflufenamid, FEN 560 and flonicamid

(notified under document number C(2008) 1644)

(Text with EEA relevance)

(2008/353/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 January 2003 the United Kingdom received an application from Nippon Soda Co. Ltd., for the inclusion of the active substance cyflufenamid in Annex I to Directive 91/414/EEC. Commission Decision 2003/636/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 June 2003 France received an application from Société occitane de fabrications et de technologies concerning FEN 560. Commission Decision 2004/131/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 December 2003 France received an application from Enhold B.V. concerning flonicamid (former name: IKI-220). Commission Decision 2004/686/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) 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 of 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 substances and the plant protection product in the light of the requirements laid down by that Directive.

- (5) 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 applicants. The rapporteur Member States submitted the draft assessment reports to the Commission on 30 January 2006 (cyflufenamid), 18 February 2005 (FEN 560), 24 May 2005 (flonicamid), respectively.
- (6) Following submission of the draft assessment reports by the rapporteur Member States, it has been found to be necessary to request further information from the applicants and to have the rapporteur Member States examine that information and submit their assessment. 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.
- 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 cyflufenamid, FEN 560 and flonicamid will have been completed within 24 months.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

⁽¹) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2008/45/EC (OJ L 94, 5.4.2008, p. 21).

⁽²⁾ OJ L 221, 4.9.2003, p. 42.

⁽³⁾ OJ L 37, 10.2.2004, p. 34.

⁽⁴⁾ OJ L 313, 12.10.2004, p. 21.

HAS ADOPTED THIS DECISION:

Article 1

Member States may extend provisional authorisations for plant protection products containing cyflufenamid, FEN 560 or flonicamid for a period not exceeding 24 months from the date of adoption of this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 29 April 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission