COMMISSION DECISION

of 6 April 2010

allowing Member States to extend provisional authorisations granted for the new active substance FEN 560

(notified under document C(2010) 1974)

(Text with EEA relevance)

(2010/206/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union.

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 June 2003 France received an application from Société occitane de fabrications et de technologies for the inclusion of the active substance FEN 560 in Annex I to Directive 91/414/EEC. Commission Decision 2004/131/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) Confirmation of the completeness of the dossier was necessary in order to allow that active substance 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 that active substance, 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.
- (3) For that active substance, 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 applicant. The rapporteur Member State submitted the draft assessment report to the Commission on 18 February 2005.
- (4) Following submission of the draft assessment report by the rapporteur Member State, it has been found to be

necessary to request further information from the applicant and to have the rapporteur Member State examine that information and submit its assessment. Therefore, the examination of the dossier is still ongoing and it will not be possible to complete the evaluation within the timeframe provided for in Directive 91/414/EEC, read in conjunction with Commission Decision 2008/353/EC (3).

- (5) 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 substance 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 dossier to continue. It is expected that the evaluation and decision-making process with respect to a decision on a possible inclusion in Annex I to that Directive for FEN 560 will have been completed within 24 months.
- (6) At the same time Decision 2008/353/EC, should be repealed, since it has become obsolete.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Member States may extend provisional authorisations for plant protection products containing FEN 560 for a period ending on 6 April 2012 at the latest.

Article 2

Decision 2008/353/EC is repealed.

Article 3

This Decision shall expire on 6 April 2012.

⁽³⁾ OJ L 117, 1.5.2008, p. 45.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 37, 10.2.2004, p. 34.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 6 April 2010.

For the Commission

John DALLI

Member of the Commission