

COMMISSION IMPLEMENTING DECISION

of 11 October 2011

**allowing Member States to extend provisional authorisations granted for the new active substances
benalaxyl-M, gamma-cyhalothrin and valifenalate***(notified under document C(2011) 7092)***(Text with EEA relevance)**

(2011/671/EU)

THE EUROPEAN COMMISSION,

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

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,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽²⁾, and in particular Article 80(1)(a) thereof,

Whereas:

(1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Directive 91/414/EEC shall continue to apply to active substances for which a decision has been adopted in accordance with Article 6(3) of Directive 91/414/EEC before 14 June 2011.

(2) In accordance with Article 6(2) of Directive 91/414/EEC, in February 2002 Portugal received an application from ISAGRO IT for the inclusion of the active substance benalaxyl-M in Annex I to Directive 91/414/EEC. Commission Decision 2003/35/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 accordance with Article 6(2) of Directive 91/414/EEC, in August 2001 the United Kingdom received an application from Pytech Chemicals GmbH for the inclusion of the active substance gamma-cyhalothrin in Annex I to Directive 91/414/EEC. Commission Decision 2004/686/EC ⁽⁴⁾ confirmed that the dossier was

(4) In accordance with Article 6(2) of Directive 91/414/EEC, in September 2005 Hungary received an application from ISAGRO SpA for the inclusion of the active substance valifenalate, previously referred to as valiphenal, in Annex I to Directive 91/414/EEC. Commission Decision 2006/586/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 of up to 3 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 conditions relating to the detailed assessment of the active substances and the plant protection products 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 applicants. The rapporteur Member States submitted the respective draft assessment reports to the Commission on 21 November 2003 (benalaxyl-M), on 25 January 2008 (gamma-cyhalothrin) and on 19 February 2008 (valifenalate).

(7) 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

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 309, 24.11.2009, p. 1.

⁽³⁾ OJ L 11, 16.1.2003, p. 52.

⁽⁴⁾ OJ L 313, 12.10.2004, p. 21.

⁽⁵⁾ OJ L 236, 31.8.2006, p. 31.

and it will not be possible to complete the evaluation within the time-frame provided for in Directive 91/414/EEC, read in conjunction with Commission Decisions 2009/579/EC ⁽¹⁾ (benalaxyl-M) and 2009/865/EC ⁽²⁾ (gamma-cyhalothrin).

- (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 a possible approval in accordance with Article 13(2) of Regulation (EC) No 1107/2009 for benalaxyl-M, gamma-cyhalothrin and valifenalate will have been completed within 24 months.
- (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,

HAS ADOPTED THIS DECISION:

Article 1

Member States may extend provisional authorisations for plant protection products containing benalaxyl-M, gamma-cyhalothrin or valifenalate for a period ending on 31 October 2013 at the latest.

Article 2

This Decision shall expire on 31 October 2013.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 11 October 2011.

For the Commission

John DALLI

Member of the Commission

⁽¹⁾ OJ L 198, 30.7.2009, p. 80.

⁽²⁾ OJ L 314, 1.12.2009, p. 100.