

## COMMISSION DECISION

of 29 July 2009

**allowing Member States to extend provisional authorisations granted for the new active substances acequinocyl, aminopyralid, ascorbic acid, benalaxyl-M, mandipropamid, novaluron, proquinazid, spirodiclofen and spiromesifen**

(notified under document number C(2009) 5582)

(Text with EEA relevance)

(2009/579/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 <sup>(1)</sup>, 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 March 2001 the United Kingdom received an application from Makhteshim Agan Ltd. for the inclusion of the active substance novaluron in Annex I to Directive 91/414/EEC. Commission Decision 2001/861/EC <sup>(2)</sup> 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 accordance with Article 6(2) of Directive 91/414/EEC, in August 2001 the Netherlands received an application from Bayer AG, Germany for the inclusion of the active substance spirodiclofen in Annex I to Directive 91/414/EEC. Commission Decision 2002/593/EC <sup>(3)</sup> 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 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 <sup>(4)</sup> 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 accordance with Article 6(2) of Directive 91/414/EEC, in April 2002 the United Kingdom received an application from Bayer AG for the inclusion of the active substance spiromesifen in Annex I to Directive 91/414/EEC. Commission Decision 2003/105/EC <sup>(5)</sup>

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) In accordance with Article 6(2) of Directive 91/414/EEC, in March 2003 the Netherlands received an application from Agro-Kanesho Co. Ltd for the inclusion of the active substance acequinocyl in Annex I to Directive 91/414/EEC. Commission Decision 2003/636/EC <sup>(6)</sup> 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.
- (6) In accordance with Article 6(2) of Directive 91/414/EEC, in January 2004 the United Kingdom received an application from DuPont (UK) Ltd for the inclusion of the active substance proquinazid in Annex I to Directive 91/414/EEC. Commission Decision 2004/686/EC <sup>(7)</sup> 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.
- (7) In accordance with Article 6(2) of Directive 91/414/EEC, in September 2004 the Netherlands received an application from Citrex Nederland BV for the inclusion of the active substance ascorbic acid in Annex I to Directive 91/414/EEC. Commission Decision 2005/751/EC <sup>(8)</sup> 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.
- (8) In accordance with Article 6(2) of Directive 91/414/EEC, in September 2004 the United Kingdom received an application from Dow AgroSciences for the inclusion of the active substance aminopyralid in Annex I to Directive 91/414/EEC. Commission Decision 2005/778/EC <sup>(9)</sup> 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.

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1.

<sup>(2)</sup> OJ L 321, 6.12.2001, p. 34.

<sup>(3)</sup> OJ L 192, 20.7.2002, p. 60.

<sup>(4)</sup> OJ L 11, 16.1.2003, p. 52.

<sup>(5)</sup> OJ L 43, 18.2.2003, p. 45.

<sup>(6)</sup> OJ L 221, 4.9.2003, p. 42.

<sup>(7)</sup> OJ L 313, 12.10.2004, p. 21.

<sup>(8)</sup> OJ L 282, 26.10.2005, p. 18.

<sup>(9)</sup> OJ L 293, 9.11.2005, p. 26.

- (9) In accordance with Article 6(2) of Directive 91/414/EEC, in December 2005 Austria received an application from Syngenta Limited for the inclusion of the active substance mandipropamid in Annex I to Directive 91/414/EEC. Commission Decision 2006/589/EC <sup>(1)</sup> 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.
- (10) Confirmation of the completeness of the dossiers was necessary in order to allow those active substances 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 those active substances, 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.
- (11) For those 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 respective rapporteur Member States submitted the draft assessment reports to the Commission on 21 November 2003 (benalaxyl-M), on 9 March 2004 (spiromesifen), on 21 April 2004 (spirodiclofen), on 8 March 2005 (acequinocyl), on 14 March 2006 (proquinazid), on 22 August 2006 (aminopyralid), on 30 November 2006 (mandipropamid), on 12 January 2007 (novaluron) and on 10 September 2007 (ascorbic acid).
- (12) Following submission of the draft assessment report by the rapporteur Member State concerned, in each case 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 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, in the cases of novaluron read in conjunction with Commission Decision 2007/404/EC <sup>(2)</sup>, of spirodiclofen, spiromesifen and benalaxyl-M with Commission Decision 2007/333/EC <sup>(3)</sup> and of proquinazid with Commission Decision 2008/56/EC <sup>(4)</sup>.
- (13) As the evaluations so far have 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 inclusion in Annex I to that Directive for acequinocyl, aminopyralid, ascorbic acid, benalaxyl-M, mandipropamid, novaluron, proquinazid, spirodiclofen and spiromesifen will have been completed within 24 months.

- (14) At the same time Decisions 2007/333/EC, 2007/404/EC and 2008/56/EC should be repealed, since they have become obsolete.
- (15) 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 acequinocyl, aminopyralid, ascorbic acid, benalaxyl-M, mandipropamid, novaluron, proquinazid, spirodiclofen or spiromesifen for a period ending 29 July 2011 at the latest.

*Article 2*

Decisions 2007/333/EC, 2007/404/EC and 2008/56/EC are repealed.

*Article 3*

This Decision shall expire on 29 July 2011.

*Article 4*

This Decision is addressed to the Member States.

Done at Brussels, 29 July 2009.

*For the Commission*

Androulla VASSILIOU

*Member of the Commission*

<sup>(1)</sup> OJ L 240, 2.9.2006, p. 9.

<sup>(2)</sup> OJ L 151, 13.6.2007, p. 45.

<sup>(3)</sup> OJ L 125, 15.5.2007, p. 27.

<sup>(4)</sup> OJ L 14, 17.1.2008, p. 26.