DECISIONS

COMMISSION IMPLEMENTING DECISION

of 2 August 2011

allowing Member States to extend provisional authorisations granted for the new active substances acequinocyl, *Adoxophyes orana* granulovirus, aminopyralid, flubendiamide, mandipropamid, metaflumizone, phosphane, pyroxsulam and thiencarbazone

(notified under document C(2011) 5321)

(Text with EEA relevance)

(2011/490/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,

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 March 2003 the Netherlands received an application from Agro-Kanesho for the inclusion of the active substance acequinocyl in Annex I to Directive 91/414/EEC. Commission Decision 2003/636/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 November 2004 Germany received an application from Andermatt Biocontrol GmbH for the inclusion of the active substance *Adoxophyes orana* granulovirus in Annex I to Directive 91/414/EEC. Commission Decision 2007/669/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 accordance with Article 6(2) of Directive 91/414/EEC, in April 2004 the United Kingdom received an application from Dow AgroSciences Ltd for the inclusion of the active substance aminopyralid in Annex I to Directive 91/414/EEC. Commission Decision 2005/778/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) In accordance with Article 6(2) of Directive 91/414/EEC, in March 2006 Greece received an application from Bayer CropScience AG for the inclusion of the active substance flubendiamide in Annex I to Directive 91/414/EEC. Commission Decision 2006/927/EC [6] 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 December 2005 Austria received an application from Syngenta Ltd for the inclusion of the active substance mandipropamid in Annex I to Directive 91/414/EEC. Commission Decision 2006/589/EC [7] 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.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 309, 24.11.2009, p. 1.
[3] OJ L 221, 4.9.2003, p. 42.
[4] OJ L 274, 18.10.2007, p. 15.
[5] OJ L 293, 9.11.2005, p. 26.
[6] OJ L 354, 14.12.2006, p. 54.
[7] OJ L 240, 2.9.2006, p. 9.

(7) In accordance with Article 6(2) of Directive 91/414/EEC, in November 2005 the United Kingdom received an application from BASF SE for the inclusion of the active substance metaflumizone in Annex I to Directive 91/414/EEC. Commission Decision 2006/517/EC [1] 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 October 2007 Germany received an application from S&A GmbH for the inclusion of the active substance phosphane in Annex I to Directive 91/414/EEC. Commission Decision 2008/566/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.

(9) In accordance with Article 6(2) of Directive 91/414/EEC, in February 2006 the United Kingdom received an application from Dow AgroSciences GmbH for the inclusion of the active substance pyroxsulam in Annex I to Directive 91/414/EEC. Commission Decision 2007/277/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.

(10) In accordance with Article 6(2) of Directive 91/414/EEC, in April 2007 the United Kingdom received an application from Bayer CropScience AG for the inclusion of the active substance thiencarbazone in Annex I to Directive 91/414/EEC. Decision 2008/566/EC 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.

(11) 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.

(12) 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 15 March 2005 (acequinocyl), on 13 August 2008 (*Adoxophyes orana* granulovirus), on 22 August 2006 (aminopyralid), on 1 September 2008 (flubendiamide), on 30 November 2006 (mandipropamid), on 15 April 2008 (metaflumizone), on 24 February 2010 (phosphane), on 20 March 2008 (pyroxsulam) and on 17 December 2008 (thiencarbazone).

(13) 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 time-frame provided for in Directive 91/414/EEC, read in conjunction with Commission Decisions 2009/579/EC [4] (acequinocyl, aminopyralid and mandipropamid) and 2009/865/EC [5] (metaflumizone).

(14) 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 acequinocyl, *Adoxophyes orana* granulovirus, aminopyralid, flubendiamide, mandipropamid, metaflumizone, phosphane, pyroxsulam and thiencarbazone will have been completed within 24 months.

(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, *Adoxophyes orana* granulovirus, aminopyralid, flubendiamide, mandipropamid, metaflumizone, phosphane, pyroxsulam and thiencarbazone for a period ending on 31 July 2013 at the latest.

Article 2

This Decision shall expire on 31 July 2013.

[1] OJ L 201, 25.7.2006, p. 34.
[2] OJ L 181, 10.7.2008, p. 52.
[3] OJ L 116, 4.5.2007, p. 59.
[4] OJ L 198, 30.7.2009, p. 80.
[5] OJ L 314, 1.12.2009, p. 100.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 2 August 2011.

For the Commission
John DALLI
Member of the Commission