COMMISSION IMPLEMENTING DECISION

of 25 April 2013

allowing Member States to extend provisional authorisations granted for the new active substances acequinocyl, aminopyralid, ascorbic acid, flubendiamide, gamma-cyhalothrin, ipconazole, metaflumizone, orthosulfamuron, *Pseudomonas* sp. strain DSMZ 13134, pyridalil, pyroxsulam, spiromesifen, thiencarbazone and topramezone

(notified under document C(2013) 2246)

(Text with EEA relevance)

(2013/205/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 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 ([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 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 ([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 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 ([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.

(7) In accordance with Article 6(2) of Directive 91/414/EEC, in March 2007 the United Kingdom received an application from Kureha GmbH for the inclusion of the active substance ipconazole in Annex I to Directive 91/414/EEC. Commission Decision 2008/20/EC ([8]) 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 293, 9.11.2005, p. 26.
([5]) OJ L 282, 26.10.2005, p. 18.
([6]) OJ L 354, 14.12.2006, p. 54.
([7]) OJ L 313, 12.10.2004, p. 21.
([8]) OJ L 1, 4.1.2008, p. 5.

(8) 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.

(9) In accordance with Article 6(2) of Directive 91/414/EEC, in July 2005 Italy received an application from Isagro SpA for the inclusion of the active substance orthosulfamuron in Annex I to Directive 91/414/EEC. Commission Decision 2006/806/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.

(10) In accordance with Article 6(2) of Directive 91/414/EEC, in August 2008 the Netherlands received an application from Sourcon-Padena GmbH & Co KG for the inclusion of the active substance *Pseudomonas* sp. strain DSMZ 13134 in Annex I to Directive 91/414/EEC. Commission Decision 2008/599/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.

(11) In accordance with Article 6(2) of Directive 91/414/EEC, in March 2006 the Netherlands received an application from Sumitomo Chemical Agro Europe SAS for the inclusion of the active substance pyridalil 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.

(12) 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 [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.

(13) In accordance with Article 6(2) of Directive 91/414/EEC, in April 2002 the United Kingdom received an application from Bayer CropScience AG for the inclusion of the active substance spiromesifen in Annex I to Directive 91/414/EEC. Commission Decision 2003/105/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.

(14) 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. Commission Decision 2008/566/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.

(15) In accordance with Article 6(2) of Directive 91/414/EEC, in May 2003 France received an application from BASF SE for the inclusion of the active substance topramezone in Annex I to Directive 91/414/EEC. Commission Decision 2003/850/EC [8] 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.

(16) 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 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.

(17) 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 15 March 2005 (acequinocyl), on 10 September 2007 (ascorbic acid), on 22 August 2006 (aminopyralid), on 1 September 2008 (flubendiamide), on 13 September 2012 (gamma-cyhalothrin), on 29 May 2008 (ipconazole), on 15 April 2008 (metaflumizone), on 19 July 2012 (orthosulfamuron), on 3 November 2009 (*Pseudomonas* sp. strain DSMZ 13134), on 13 January 2009 (pyridalil), on 20 March 2008 (pyroxsulam), on 9 March 2004 (spiromesifen), on 17 December 2008 (thiencarbazone) and on 26 July 2007 (topramezone).

(18) 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

[1] OJ L 201, 25.7.2006, p. 34.
[2] OJ L 329, 25.11.2006, p. 74.
[3] OJ L 193, 22.7.2008, p. 14.
[4] OJ L 274, 18.10.2007, p. 15.
[5] OJ L 116, 4.5.2007, p. 59.
[6] OJ L 43, 18.2.2003, p. 45.
[7] OJ L 181, 10.7.2008, p. 52.
[8] OJ L 322, 9.12.2003, p. 28.

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, read in conjunction with Commission Implementing Decisions 2011/490/EU [1] (acequinocyl, aminopyralid, flubendiamide, metaflumizone, pyroxsulam and thiencarbazone), 2011/252/EU [2] (ascorbic acid, ipconazole, *Pseudomonas* sp. strain DSMZ 13134, spiromesifen and topramezone) and 2011/671/EU [3] (gamma-cyhalothrin).

(19) 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, aminopyralid, ascorbic acid, flubendiamide, gamma-cyhalothrin, ipconazole, metaflumizone, orthosulfamuron, *Pseudomonas* sp. DSMZ 13134, pyridalil, pyroxsulam, spiromesifen, thiencarbazone and topramezone will have been completed within 24 months.

(20) 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, flubendiamide, gamma-cyhalothrin, ipconazole, metaflumizone, orthosulfamuron, *Pseudomonas* sp. DSMZ 13134, pyridalil, pyroxsulam, spiromesifen, thiencarbazone or topramezone for a period ending on 30 April 2015 at the latest.

Article 2

This Decision shall expire on 30 April 2015.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 25 April 2013.

For the Commission
Tonio BORG
Member of the Commission

[1] OJ L 201, 4.8.2011, p. 16.
[2] OJ L 106, 27.4.2011, p. 11.
[3] OJ L 267, 12.10.2011, p. 19.