COMMISSION IMPLEMENTING DECISION

of 4 July 2012

allowing Member States to extend provisional authorisations granted for the new active substances bixafen, *Candida oleophila* strain O, fluopyram, halosulfuron, potassium iodide, potassium thiocyanate and spirotetramat

(notified under document C(2012) 4436)

(Text with EEA relevance)

(2012/363/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 October 2008 the United Kingdom received an application from Bayer CropScience AG for the inclusion of the active substance bixafen in Annex I to Directive 91/414/EEC. Commission Decision 2009/700/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 July 2006 the United Kingdom received an application from Bionext SPRL for the inclusion of the active substance *Candida oleophila* strain O in Annex I to Directive 91/414/EEC. Commission Decision 2007/380/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 June 2008 Germany received an application from Bayer CropScience AG for the inclusion of the active substance fluopyram in Annex I to Directive 91/414/EEC. Commission Decision 2009/464/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 May 2005 Italy received an application from Nissan Chemical Europe SARL for the inclusion of the active substance halosulfuron in Annex I to Directive 91/414/EEC. Commission Decision 2006/586/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 September 2004 the Netherlands received an application from Koppert Beheer BV for the inclusion of the active substance potassium iodide in Annex I to Directive 91/414/EEC. Commission Decision 2005/751/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 September 2004 the Netherlands received an application from Koppert Beheer BV for the inclusion of the active substance potassium thiocyanate in Annex I to Directive 91/414/EEC. Decision 2005/751/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.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 309, 24.11.2009, p. 1.
[3] OJ L 240, 11.9.2009, p. 32.
[4] OJ L 141, 2.6.2007, p. 78.
[5] OJ L 151, 16.6.2009, p. 37.
[6] OJ L 236, 31.8.2006, p. 31.
[7] OJ L 282, 26.10.2005, p. 18.

(8) In accordance with Article 6(2) of Directive 91/414/EEC, in October 2006 Austria received an application from Bayer CropScience AG for the inclusion of the active substance spirotetramat in Annex I to Directive 91/414/EEC. Commission Decision 2007/560/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) 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.

(10) 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 16 December 2009 (bixafen), on 5 February 2008 (*Candida oleophila* strain O), on 30 August 2011 (fluopyram), on 30 March 2008 (halosulfuron), on 27 July 2007 (potassium iodide and potassium thiocyanate) and on 29 April 2008 (spirotetramat).

(11) 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 2010/457/EU [2] (*Candida oleophila* strain O, potassium iodide and potassium thiocyanate) and 2010/671/EU [3] (spirotetramat).

(12) 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 bixafen, *Candida oleophila* strain O, fluopyram, halosulfuron, potassium iodide, potassium thiocyanate and spirotetramat will have been completed within 24 months.

(13) 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 bixafen, *Candida oleophila* strain O, fluopyram, halosulfuron, potassium iodide, potassium thiocyanate or spirotetramat for a period ending on 31 July 2014 at the latest.

Article 2

This Decision shall expire on 31 July 2014.

Article3

This Decision is addressed to the Member States.

Done at Brussels, 4 July 2012.

For the Commission
John DALLI
Member of the Commission

[1] OJ L 213, 15.8.2007, p. 29.
[2] OJ L 218, 19.8.2010, p. 24.
[3] OJ L 290, 6.11.2010, p. 49.