COMMISSION IMPLEMENTING REGULATION (EU) No 797/2011

of 9 August 2011

approving the active substance spiroxamine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 [1], and in particular Article 13(2) and Article 78(2) thereof,

Whereas:

(1) In accordance with Article 80(1)(b) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC [2] is to apply to active substances listed in Annex I to Commission Regulation (EC) No 737/2007 of 27 June 2007 on laying down the procedure of the renewal of the inclusion of a first group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances [3], with respect to the procedure and the conditions for approval. Spiroxamine is listed in Annex I to Regulation (EC) No 737/2007.

(2) The approval of spiroxamine, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances [4], expires on 31 December 2011. A notification was submitted in accordance with Article 4 of Regulation (EC) No 737/2007 for the renewal of the inclusion of spiroxamine in Annex I to Directive 91/414/EEC within the time period provided for in that Article.

(3) That notification was found to be admissible by Commission Decision 2008/656/EC of 28 July 2008 on the admissibility of the notifications concerning the renewal of the inclusion in Annex I to Council Directive 91/414/EEC of the active substances azimsulfuron, azoxystrobin, fluroxypyr, imazalil, kresoxim-methyl, prohexadion-calcium and spiroxamine, and establishing the list of the notifiers concerned [5].

(4) Within the time period provided for in Article 6 of Regulation (EC) No 737/2007, the notifier submitted the data required in accordance with that Article together with an explanation as regards the relevance of each new study submitted.

(5) The rapporteur Member State prepared an assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter 'the Authority') and the Commission on 17 September 2009. In addition to the assessment of the active substance, that report includes a list of the studies the rapporteur Member State relied on for its assessment.

(6) The Authority communicated the assessment report to the notifier and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the assessment report available to the public.

(7) At the request of the Commission, the assessment report was peer reviewed by the Member States and the Authority. The Authority presented its conclusion on the peer review of the risk assessment of spiroxamine [6] to the Commission on 1 September 2010. The assessment report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 17 June 2011 in the format of the Commission review report for spiroxamine.

(8) It has appeared from the various examinations made that plant protection products containing spiroxamine may be expected to continue to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular as regards the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve spiroxamine.

[1] OJ L 309, 24.11.2009, p. 1.
[2] OJ L 230, 19.8.1991, p. 1.
[3] OJ L 169, 29.6.2007, p. 10.
[4] OJ L 153, 11.6.2011, p. 1.
[5] OJ L 214, 9.8.2008, p. 70.
[6] Conclusion on the peer review of the pesticide risk assessment of the active substance spiroxamine. *EFSA Journal* 2010; 8(9)1719 [102 pp.], doi:10.2903/j.efsa.2010 1719. Available online: www.efsa.europa.eu

(9) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions not provided for in the first inclusion in Annex I to Directive 91/414/EEC.

(10) Without prejudice to the conclusion that spiroxamine should be approved, it is, in particular, appropriate to require further confirmatory information.

(11) A reasonable period should be allowed to elapse before approval in order to permit Member States and interested parties to prepare themselves to meet the new requirements resulting from the approval.

(12) Without prejudice to the obligations provided for by Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009 the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing spiroxamine. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the update of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.

(13) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market [1] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.

(14) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance spiroxamine, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing spiroxamine as an active substance by 30 June 2012.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in Part B of the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing spiroxamine as either the only active substance or as one of several active substances all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 31 December 2011 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account Part B of the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

(a) in the case of a product containing spiroxamine as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2015 at the latest; or

(b) in the case of a product containing spiroxamine as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 2015 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or substances, whichever is the latest.

[1] OJ L 366, 15.12.1992, p. 10.

Article 3

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 4

Entry into force and application

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2012.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 August 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Spiroxamine CAS No 1181134-30-8 CIPAC No 572	8-*tert*-butyl-1,4-dioxaspiro[4.5] decan-2- ylmethyl(ethyl) (propyl)amine (ISO)	≥ 940 g/kg (diastereomers A and B combined)	1 January 2012	31 December 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spiroxamine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (1) the risk to operators and workers and ensure that conditions of use include the application of adequate personal protective equipment; (2) the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (3) the risk to aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) the possible impact on the worker, the consumer and the environmental risk assessment of the potential stereo-selective degradation of each isomer in plant, animals and the environment; (b) the toxicity of the plant metabolites formed in fruit crops and the potential hydrolysis of fruit crop residues in processed commodities; (c) the groundwater exposure assessment for metabolite M03 (2); (d) the risk to aquatic organisms. The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) by two years after the adoption of specific guidance and the information set out in points (b), (c) and (d) by 31 December 2013.

(1) Further details on identity and specification of active substance are provided in the review report.
(2) M03: [(8-tert-butyl-1,4-dioxaspiro[4.5]dec-2-yl)methyl]ethyl(propyl)amine oxide.

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, the entry relating to spiroxamine is deleted;

(2) in Part B, the following entry is added:

'7	Spiroxamine CAS No 1181134-30-8 CIPAC No 572	8-*tert*-butyl-1,4-dioxaspiro [4.5]decan-2-ylmethyl(ethyl) (propyl)amine (ISO)	≥ 940 g/kg (diastereomers A and B combined)	1 January 2012	31 December 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spiroxamine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (1) the risk to operators and workers and ensure that conditions of use include the application of adequate personal protective equipment; (2) the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (3) the risk to aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) the possible impact on the worker, the consumer and the environmental risk assessment of the potential stereo-selective degradation of each isomer in plant, animals and the environment; (b) the toxicity of the plant metabolites formed in fruit crops and the potential hydrolysis of fruit crop residues in processed commodities; (c) the groundwater exposure assessment for metabolite M03 (*);

						(d) the risk to aquatic organisms. The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) by two years after the adoption of specific guidance and the information set out in points (b), (c) and (d) by 31 December 2013.

(*) M03: [(8-tert-butyl-1,4-dioxaspiro[4.5]dec-2-yl)methyl]ethyl(propyl)amine oxide.'