

COMMISSION IMPLEMENTING REGULATION (EU) No 798/2013

of 21 August 2013

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance pyrethrins

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Committee on the Food Chain and Animal Health and finalised on 16 July 2013 in the format of the Commission review report for pyrethrins.

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)(c) thereof,

Whereas:

(1) The active substance pyrethrins was included in Annex I to Council Directive 91/414/EEC ⁽²⁾ by Commission Directive 2008/127/EC ⁽³⁾ in accordance with the procedure provided for in Article 24b of Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC ⁽⁴⁾. Since the replacement of Directive 91/414/EEC by Regulation (EC) No 1107/2009, this substance is deemed to have been approved under that Regulation and is listed 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 ⁽⁵⁾.

(2) In accordance with Article 25a of Regulation (EC) No 2229/2004, the European Food Safety Authority, hereinafter 'the Authority', presented to the Commission its view on the draft review report for pyrethrins ⁽⁶⁾ on 12 December 2012. The Authority communicated its view on pyrethrins to the notifier. The Commission invited it to submit comments on the draft review report for pyrethrins. The draft review report and the view of the Authority were reviewed by the Member States and the Commission within the Standing

(3) It is confirmed that the active substance pyrethrins is to be deemed to have been approved under Regulation (EC) No 1107/2009.

(4) 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 necessary to amend the conditions of approval of pyrethrins. In particular, it is appropriate to require further confirmatory information.

(5) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(6) A reasonable period of time should be allowed before the application of this Regulation in order to allow Member States, notifiers and holders of authorisations for plant protection products containing pyrethrins to meet the requirements resulting from amendment to the conditions of the approval.

(7) 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

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 1 January 2014.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ OJ L 230, 19.8.1991, p. 1.

⁽³⁾ OJ L 344, 20.12.2008, p. 89.

⁽⁴⁾ OJ L 379, 24.12.2004, p. 13.

⁽⁵⁾ OJ L 153, 11.6.2011, p. 1.

⁽⁶⁾ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance pyrethrins. EFSA Journal 2013;11(1):3032 [76 pp.] doi:10.2903/j.efsa.2013.3032. Available online: www.efsa.europa.eu/efsajournal

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

Done at Brussels, 21 August 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 246 on the active substance pyrethrins is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
246	<p>Pyrethrins: 8003-34-7 CIPAC No 32</p> <p>Extract A: extractives of <i>Chrysanthemum cinerariaefolium</i>: 89997- 63-7</p> <p>Pyrethrin 1: CAS 121- 21-1</p> <p>Pyrethrin 2: CAS 121- 29-9</p> <p>Cinerin 1: CAS 25402- 06-6</p> <p>Cinerin 2: CAS 121- 20-0</p> <p>Jasmolin 1: CAS 4466- 14-2</p> <p>Jasmolin 2: CAS 1172- 63-0</p> <p>Extract B: Pyrethrin 1: CAS 121-21-1</p> <p>Pyrethrin 2: CAS 121- 29-9</p> <p>Cinerin 1: CAS 25402- 06-6</p> <p>Cinerin 2: CAS 121- 20-0</p> <p>Jasmolin 1: CAS 4466- 14-2</p> <p>Jasmolin 2: CAS 1172- 63-0</p>	Pyrethrins are a complex mixture of chemical substances.	<p>Extract A: ≥ 500 g/kg Pyrethrins</p> <p>Extract B: ≥ 480 g/kg Pyrethrins</p>	1 September 2009	31 August 2019	<p>PART A</p> <p>Only uses as insecticide may be authorised.</p> <p>PART B</p> <p>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 pyrethrins (SANCO/2627/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to operators and workers;</p> <p>(b) the risk to non-target organisms.</p> <p>Conditions of use shall, where appropriate, include the application of adequate personal protective equipment and other risk mitigation measures.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the specification of the technical material, as commercially manufactured including information on any relevant impurities and its equivalence with the specifications of the test material used in the toxicity studies;</p> <p>(2) the risk from inhalation;</p> <p>(3) the residue definition;</p> <p>(4) the representativeness of the major component "pyrethrin 1" as regards the fate and behaviour in soil and water.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information set out in points (1) by 31 March 2014 and the information set out in points (2), (3) and (4) by 31 December 2015.'</p>