

## COMMISSION IMPLEMENTING REGULATION (EU) No 141/2014

of 13 February 2014

## amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance plant oils/clove oil

(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<sup>(1)</sup>, and in particular Article 13(2)(c) and Article 78(2) thereof,

Whereas:

(1) The active substance plant oils/clove oil was included in Annex I to Council Directive 91/414/EEC<sup>(2)</sup> by Commission Directive 2008/127/EC<sup>(3)</sup> in accordance with the procedure provided for in Article 24b of Commission Regulation (EC) No 2229/2004<sup>(4)</sup>. 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<sup>(5)</sup>.

(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 plant oils/clove oil<sup>(6)</sup> on 16 December 2011. The Authority communicated its view on plant oils/clove oil to the notifier. The Commission invited the notifier to submit comments on the draft review report for plant oils/clove oil. The draft review report and the view of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and the draft review report was finalised on 13 December 2013 in the format of the Commission review report for plant oils/clove oil.

(3) It is confirmed that the active substance plant oils/clove oil 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. It is, in particular, appropriate to require further confirmatory information.

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

(6) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing plant oils/clove oil.

(7) For plant protection products containing plant oils/clove oil, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire at the latest eighteen months after the date of entry into force of the regulation.

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

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

<sup>(3)</sup> Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89).

<sup>(4)</sup> 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 (OJ L 379, 24.12.2004, p. 13).

<sup>(5)</sup> 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 (OJ L 153, 11.6.2011, p. 1).

<sup>(6)</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance plant oils/clove oil. EFSA Journal 2012;10(1):2506. [43 pp.] doi:10.2903/j.efsa.2012.2506. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

HAS ADOPTED THIS REGULATION:

*Article 1*

**Amendment to Implementing Regulation (EU) No 540/2011**

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

*Article 2*

**Transitional measures**

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing

authorisations for plant protection products containing plant oils/clove oil as active substance by 6 September 2014.

*Article 3*

**Grace period**

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire on 6 September 2015 at the latest.

*Article 4*

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

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

Done at Brussels, 13 February 2014.

*For the Commission*

*The President*

José Manuel BARROSO

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## ANNEX

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 241 on the active substance plant oils/clove oil is replaced by the following:

| Number | Common Name, Identification Numbers   | IUPAC Name   | Purity  | Date of approval | Expiration of approval | Specific provisions  |
|--------|---|--|---|------------------|------------------------|--|
| 241    | Plant oils/clove oil<br>CAS No 84961-50-2 (clove oil)<br>97-53-0 (Eugenol — main component)<br>CIPAC No 906 | Clove Oil is a complex mixture of chemical substances.<br>The main component is eugenol. | ≥ 800 g/kg<br>Relevant impurity: methyl eugenol maximum 0,1 % of the technical material | 1 September 2009 | 31 August 2019         | PART A<br>Only indoor uses as post-harvest fungicide and bactericide may be authorised.<br>PART B<br>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 clove oil (SANCO/2622/2008) 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.<br>In this overall assessment Member States shall pay particular attention to the protection of operators and workers ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate.<br>The notifier shall submit confirmatory information as regards<br>(a) the technical specification;<br>(b) data comparing natural background exposure situations of plant oils/clove oil, eugenol and methyl eugenol in relation to exposure from the use of plant oils/clove oil as a plant protection product. This data shall cover human exposure.<br>The notifier shall submit to the Commission, the Member States and the Authority that information by 30 April 2016. |