Commission Implementing Regulation (EU) No 154/2014 of 19 February 2014 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance extract from tea tree (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 154/2014

of 19 February 2014

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance extract from tea tree

(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)(c) and Article 78(2) thereof,

Whereas:

(1) The active substance extract from tea tree 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[(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[(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 extract from tea tree[(6)] on 16 December 2011. The Authority communicated its views on extract from tea tree to the notifier. The Commission invited it to submit comments on the draft review report for extract from tea tree. 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 finalised on 13 December 2013 in the format of the Commission review report for extract from tea tree.

(3) It is confirmed that the active substance extract from tea tree 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.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 154/2014. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(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 extract from tea tree.

(7) For plant protection products containing extract from tea tree, where Member States grant any period of grace in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire at the latest 18 months from the date of entry into force of this 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,

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 extract from tea tree as active substance by 12 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 12 September 2015 at the latest.

Article 4

Entry into force

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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 154/2014. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Done at Brussels, 19 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 228 on the active substance extract from tea tree is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity[a]	Date of approval	Expiration of approval	Specific provisions
‘228	Extract from tea tree CAS No Tea Tree Oil 68647-73-4 Main components: terpinen-4-ol 562-74-3 γ-terpinene 99-85-4 α-terpinene 99-86-5 1,8-cineole 470-82-6 CIPAC No 914	Tea Tree Oil is a complex mixture of chemical substances.	Main components: terpinen-4-ol ≥ 300 g/kg γ-terpinene ≥ 100 g/kg α-terpinene ≥ 50 g/kg 1,8-cineole ≥ 1 g/kg Relevant impurity: Methyl eugenol: maximum 1 g/kg of the technical material	1 September 2009	31 August 2019	PART A Only uses as fungicide in greenhouse 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 extract from tea tree (SANCO/2609/2008 final) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13

a Further details on identity and specification of active substance are provided in their review report.

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						December 2013 shall be taken into account. 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; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;

a Further details on identity and specification of active substance are provided in their review report.