Commission Implementing Regulation (EU) 2017/1186 of 3 July 2017 withdrawing the approval of the active substance repellents by smell of animal or plant origin/tall oil crude, 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 Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1186

of 3 July 2017

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(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 the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2008/127/EC[(2)] included repellents by smell of animal or plant origin/tall oil crude as active substance in Annex I to Council Directive 91/414/EEC[(3)]. Commission Implementing Regulation (EU) No 637/2012[(4)] required that Member States concerned ensure that the notifier at whose request repellents by smell of animal or plant origin/tall oil crude has been included provide further confirmatory information on the equivalence between the specifications of the technical material as commercially manufactured and those of the test material used in the toxicity dossiers and on the toxicological profile of the substance by 1 May 2013 and 31 May 2014 respectively.

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[(5)].

(3) In April 2013, the notifier submitted information, with a view to complying with the obligation to submit further information as referred to in recital 1, to the rapporteur Member State, Greece.

(4) Greece assessed the information submitted by the notifier including some further information related to the initial submission that was submitted during the evaluation process. It submitted its assessment, in the form of addenda to the draft assessment

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/1186. 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*

report, to the other Member States, the Commission and the European Food Safety Authority, herein after 'the Authority' in November 2014 and November 2015.

(5) The Member States, the applicant and the Authority were consulted and asked to provide comments on the assessment of the rapporteur Member State. The Authority published a Technical Report summarising the outcome of this consultation for tall oil crude on 27 March 2015[6].

(6) In the light of the information provided by the notifier, the evaluation of this information by the rapporteur Member State and the comments submitted on the evaluation by Member States and EFSA, the Commission considers that the confirmatory information is not sufficient to conclude on the equivalence between the specifications of the technical material as commercially manufactured, and those of the test material used in the toxicity dossiers nor on the toxicological profile of the substance.

(7) The Commission invited the notifier to submit its comments on the considerations of the Commission.

(8) However, despite the arguments put forward by the notifier, the Commission has come to the conclusion that the information submitted is incomplete and does not allow a conclusion on the equivalence between the specifications of the technical material as commercially manufactured and those of the test material used in the toxicity dossiers nor on the toxicological profile of the substance to be made.

(9) Consequently, it is appropriate to withdraw the approval of that active substance.

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

(11) Member States should be provided with time to withdraw authorisations for plant protection products containing that active substance.

(12) For plant protection products containing that active substance, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on 24 October 2018.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Withdrawal of approval

The approval of the active substance repellents by smell of animal or plant origin/tall oil crude is withdrawn.