Commission Implementing Regulation (EU) 2017/195 of 3 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of several active substances listed in Part B of the Annex to Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/195

of 3 February 2017

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of several active substances listed in Part B of the Annex to Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme)

(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 first paragraph of Article 17 thereof,

Whereas:

(1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[(2)] sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009. Part B of the Annex to Implementing Regulation (EU) No 540/2011 sets out the active substances approved under Regulation (EC) No 1107/2009.

(2) Applications for the renewal of the approval of the active substances included in this Regulation were submitted in accordance with Commission Implementing Regulation (EU) No 844/2012[(3)]. However, the approval of those substances may expire for reasons beyond the control of the applicant before a decision has been taken on the renewal of their approval. It is therefore necessary to extend their approval periods in accordance with Article 17 of Regulation (EC) No 1107/2009.

(3) In view of the time and resources necessary for completing the assessment of applications for the renewal of approvals of the large number of active substances the approvals of which are expiring between 2019 and 2021, Commission Implementing Decision C(2016)6104[(4)] established a work programme grouping together similar active substances and setting priorities on the basis of safety concerns for human and animal health or the environment as provided for in Article 18 of Regulation (EC) No 1107/2009.

(4) The presumed low risk substances should be prioritised in accordance with Implementing Decision C(2016)6104. The approval of those substances should

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/195. 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*

therefore be extended by a period as short as possible. Taking into account the distribution of responsibilities and work among Member States acting as rapporteurs and co-rapporteurs and the available resources necessary for assessment and decision-making, that period should be of one year for the active substances aluminium ammonium sulphate, aluminium silicate, blood meal, calcium carbonate, carbon dioxide, extract from tea tree, fat distilation residues, fatty acids c7 to c20, garlic extract, gibberellic acid, gibberellin, hydrolysed proteins, iron sulphate, kieselgur (diatomaceous earth), pepper dust extraction residue (PDER), plant oils/rape seed oil, potassium hydrogen carbonate, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, repellents by smell of animal or plant origin/tall oil crude, repellents by smell of animal or plant origin/tall oil pitch, sodium aluminium silicate, straight chain lepidopteran pheromones, and urea.

(5) For active substances which do not fall in the prioritised categories in Implementing Decision C(2016)6104, the approval period should be extended by either two or three years, taking into account the present date of expiry, the fact that according to Article 6(3) of Implementing Regulation (EU) No 844/2012 the supplementary dossier for an active substance shall be submitted no later than 30 months before expiry of the approval, the need to ensure a balanced distribution of responsibilities and work among Member States acting as rapporteurs and co-rapporteurs and the available resources necessary for assessment and decision-making. It is therefore appropriate to extend the approval periods for bifenthrin, cymoxanil and metazachlor by two years, and to extend the approval periods of active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aclonifen, aluminium phosphide, calcium carbide, calcium phosphide, denathonium benzoate, dodemorph, ethylene, imidacloprid, magnesium phosphide, metamitron, plant oils/citronella oil, plant oils/clove oil, plant oils/spear mint oil, pyrethrins, and sulcotrione by three years.

(6) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where no supplementary dossier in accordance with Implementing Regulation (EU) No 844/2012 is submitted no later than 30 months before the respective expiry date laid down in the Annex to this Regulation, the Commission will set the expiry date at the same date as before this Regulation or at the earliest date thereafter.

(7) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where the Commission will adopt a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed because the approval criteria are not satisfied, the Commission will set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later. As regards cases where the Commission will adopt a Regulation providing for the renewal of an active substance referred to in the Annex to this Regulation, the Commission will endeavour to set, as appropriate under the circumstances, the earliest possible application date.

(8) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

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(9) 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

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*.

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

Done at Brussels, 3 February 2017.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

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

(A) Part A is amended as follows:

(1) in the sixth column, expiration of approval, of row 215, Aclonifen, the date is replaced by '31 July 2022';

(2) in the sixth column, expiration of approval, of row 216, Imidacloprid, the date is replaced by '31 July 2022';

(3) in the sixth column, expiration of approval, of row 217, Metazachlor, the date is replaced by '31 July 2021';

(4) in the sixth column, expiration of approval, of row 218, Acetic acid, the date is replaced by '31 August 2022';

(5) in the sixth column, expiration of approval, of row 219, Aluminium ammonium sulphate, the date is replaced by '31 August 2020';

(6) in the sixth column, expiration of approval, of row 220, Aluminium silicate, the date is replaced by '31 August 2020';

(7) in the sixth column, expiration of approval, of row 222, Blood meal, the date is replaced by '31 August 2020';

(8) in the sixth column, expiration of approval, of row 223, Calcium carbide, the date is replaced by '31 August 2022';

(9) in the sixth column, expiration of approval, of row 224, Calcium carbonate, the date is replaced by '31 August 2020';

(10) in the sixth column, expiration of approval, of row 225, Carbon dioxide, the date is replaced by '31 August 2020';

(11) in the sixth column, expiration of approval, of row 226, Denathonium benzoate, the date is replaced by '31 August 2022';

(12) in the sixth column, expiration of approval, of row 227, Ethylene, the date is replaced by '31 August 2022';

(13) in the sixth column, expiration of approval, of row 228, Extract from tea tree, the date is replaced by '31 August 2020';

(14) in the sixth column, expiration of approval, of row 229, Fat distilation residues, the date is replaced by '31 August 2020';

(15) in the sixth column, expiration of approval, of row 230, Fatty acids C7 to C20, the date is replaced by '31 August 2020';

(16) in the sixth column, expiration of approval, of row 231, Garlic extract, the date is replaced by '31 August 2020';

(17) in the sixth column, expiration of approval, of row 232, Gibberellic acid, the date is replaced by '31 August 2020';

(18) in the sixth column, expiration of approval, of row 233, Gibberellin, the date is replaced by '31 August 2020';