II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/555

of 24 March 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 and Article 78(2) 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.
- (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 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 1 year for the active substances paraffin oil/(CAS 64742-46-7), paraffin oil/(CAS 72623-86-0), paraffin oil/(CAS 8042-47-5), paraffin oil/(CAS 97862-82-3) and sulphur.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²) OJ L 153, 11.6.2011, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).
(4) Commission Implementing Decision of 28 September 2016 on the establishment of a work programme for the assessment of

⁽⁴⁾ Commission Implementing Decision of 28 September 2016 on the establishment of a work programme for the assessment of applications for the renewal of approvals of active substances expiring in 2019, 2020 and 2021 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ C 357, 29.9.2016, p. 9).

- (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 2 or 3 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 corapporteurs, and the available resources necessary for assessment and decision-making. It is therefore appropriate to extend the approval periods for 2-phenylphenol (including its salts such as the sodium salt), chlormequat, dimethachlor, etofenprox, penconazole, propaquizafop, tetraconazole, tri-allate, and zeta-cypermethrin by 2 years, and to extend the approval periods of active substances bensulfuron, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad by 3 years.
- (6) The Commission received an application for the renewal of the approval of the active substance quizalofop-P (variant quizalofop-p-ethyl) and a separate application for the renewal of the approval of the active substance quizalofop-P (variant quizalofop-p-tefuryl). Given this fact and due to the different risk profiles of quizalofop-p-ethyl and quizalofop-p-tefuryl, it is appropriate to consider them as two different active substances for the purpose of the renewal procedure. The variant quizalofop-p-ethyl does not fall in the prioritised categories in Implementing Decision C/2016/6104. Therefore, and taking into account the reasons given in recital 5, it is appropriate to extend its approval period by 2 years.
- (7) 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.
- (8) 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.
- (9) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (10) Taking into account that the approvals of some of the substances expire on 31 October 2019, and that applicants should submit supplementary dossiers 30 months before the expiry of the approval, this Regulation should enter into force as soon as possible.
- (11) 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 third 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, 24 March 2017.

For the Commission The President Jean-Claude JUNCKER

ANNEX

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in the sixth column, expiration of approval, of row 271, Bensulfuron, the date is replaced by '31 October 2022';
- (2) in the sixth column, expiration of approval, of row 272, Sodium 5-nitroguaiacolate, the date is replaced by '31 October 2022';
- (3) in the sixth column, expiration of approval, of row 273, Sodium o-nitrophenolate, the date is replaced by '31 October 2022':
- (4) in the sixth column, expiration of approval, of row 274, Sodium p-nitrophenolate, the date is replaced by '31 October 2022';
- (5) in the sixth column, expiration of approval, of row 275, Tebufenpyrad, the date is replaced by '31 October 2022';
- (6) in the sixth column, expiration of approval, of row 276, Chlormequat, the date is replaced by '30 November 2021';
- (7) in the sixth column, expiration of approval, of row 278, Propaquizafop, the date is replaced by '30 November 2021';
- (8) in the sixth column, expiration of approval, of row 281, zeta-Cypermethrin, the date is replaced by '30 November 2021';
- (9) in the sixth column, expiration of approval, of row 284, Dimethachlor, the date is replaced by '31 December 2021';
- (10) in the sixth column, expiration of approval, of row 285, Etofenprox, the date is replaced by '31 December 2021';
- (11) in the sixth column, expiration of approval, of row 287, Penconazole, the date is replaced by '31 December 2021';
- (12) in the sixth column, expiration of approval, of row 288, Tri-allate, the date is replaced by '31 December 2021';
- (13) in the sixth column, expiration of approval, of row 292, Sulphur, the date is replaced by '31 December 2020';
- (14) in the sixth column, expiration of approval, of row 293, Tetraconazole, the date is replaced by '31 December 2021';
- (15) in the sixth column, expiration of approval, of row 294, Paraffin oils, the date is replaced by '31 December 2020';
- (16) in the sixth column, expiration of approval, of row 295, Paraffin oil, the date is replaced by '31 December 2020';
- (17) in the sixth column, expiration of approval, of row 299, 2-phenylphenol (including its salts such as the sodium salt), the date is replaced by '31 December 2021';

(18) entry 279 is replaced by the following:

'279	Quizalofop-P					
	Quizalofop-P-tefuryl CAS No 119738-06-6 CIPAC No 641.226	(RS)-Tetrahydrofur- furyl (R)-2-[4-(6-chlo- roquinoxalin-2-yloxy) phenoxy]propionate	≥ 795 g/kg	1 December 2009	30 November 2019	PART A Only uses as herbicide may be authorised. PART B
	Quizalofop-P-ethyl CAS No 100646-51-3 CIPAC No 641.202	ethyl (R)-2-[4-(6-chlo-roquinoxalin-2-yloxy) phenoxy]propionate	≥ 950 g/kg	1 December 2009	30 November 2021	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 quizalofop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of nontarget plants and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of nontarget plants and ensure that conditions of use prescribe the application of adequate personal protective equipment, Che protection of nontarget plants and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate. Conditions of authorisation shall include risk mitigation measures, where appropriate.

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