Commission Implementing Regulation (EU) 2019/291 of 19 February 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, azoxystrobin, fluazifop p, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, prochloraz, prohexadione, spiroxamine, tefluthrin and terbuthylazine (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/291

of 19 February 2019

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, azoxystrobin, fluazifop p, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, prochloraz, prohexadione, spiroxamine, tefluthrin and terbuthylazine

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

(2) The approval periods of the substances 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, azoxystrobin, fluazifop p, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, prochloraz, prohexadione, spiroxamine, tefluthrin and terbuthylazine will expire on 31 December 2021.

(3) 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 is likely to 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.

(4) In view of the time and resources necessary for completing the assessment of the applications for the renewal of approval of a large number of active substances the approvals of which will expire 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

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/291. 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*

animal health or the environment as provided for in Article 18 of Regulation (EC) No 1107/2009.

(5) 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 the Member States acting as rapporteurs and co-rapporteursand the available resources necessary for assessment and decision-making, that period should be of one year for the active substance prohexadione.

(6) For the 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 current date of expiry, the fact that in accordance with Article 6(3) of Implementing Regulation (EU) No 844/2012, the supplementary dossier for an active substance is to be submitted no later than 30 months before the expiry of the approval, taking into account the need to ensure a balanced distribution of responsibilities and work among the 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 the active substances 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, fluazifop p, prochloraz and spiroxamine by two years, and to extend the approval periods of the active substances azoxystrobin, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, tefluthrin, terbuthylazine by three 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) 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:

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/291. 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*

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, 19 February 2019.

For the Commission

The President

Jean-Claude JUNCKER