COMMISSION IMPLEMENTING REGULATION (EU) 2018/1916

of 6 December 2018

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance bispyribac

(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 period of the active substance bispyribac will expire on 31 July 2021.

(3) Application for the renewal of the approval of the active substance was submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ([3]). However, the approval is likely to expire for reasons beyond the control of the applicant before a decision on the renewal of the approval has been taken. It is therefore necessary to extend the approval period 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 applications for renewal of approvals of 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.

(5) As the active substance included in this Regulation does not fall in the prioritised categories of Implementing Decision C(2016)6104, the approval period should be extended by two 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 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 period of the active substance bispyribac by two 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.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).
([3]) 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 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).

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

(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, 6 December 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

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

In the sixth column, expiration of approval, of row 1, Bispyribac, the date is replaced by '31 July 2023'.