COMMISSION IMPLEMENTING REGULATION (EU) 2015/1106

of 8 July 2015

amending Implementing Regulations (EU) No 540/2011 and (EU) No 1037/2012 as regards the conditions of approval of the active substance isopyrazam

(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) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 1037/2012 ([2]) approved isopyrazam as active substance in accordance with Regulation (EC) No 1107/2009, provided that the applicant for approval, Syngenta Crop Protection AG ('the applicant'), submits confirmatory information as regards the relevance of the metabolites CSCD 459488 and CSCD 459489 for groundwater, and listed it in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([3]). The confirmatory information was to be submitted to the Commission, the Member States and the European Food Safety Authority ('the Authority') by 31 March 2015.

(2) In February 2014, the applicant informed the Commission that it was expected that not all the confirmatory information required would be available by the deadline set out in Implementing Regulations (EU) No 540/2011 and (EU) No 1037/2012. The applicant stated that this delay was due to the need to develop appropriate testing protocols and submitted a working plan for the generation of that information.

(3) The United Kingdom as the rapporteur Member State for isopyrazam assessed the information submitted by the applicant and informed the Commission in September 2014 that it considered the request of the applicant to extend the deadline for the submission of confirmatory information to be reasoned and that the working plan submitted by the applicant is realistic and appropriate.

(4) Therefore, it appears that the request is justified in order to allow the applicant to generate the necessary data within a reasonable timeline.

(5) On 30 March 2015, the applicant submitted a summary document reporting the information generated so far and setting out a final working plan for the generation of the outstanding information.

(6) It is therefore appropriate to amend the approval of isopyrazam and extend the deadline for the submission of confirmatory information until 31 July 2017.

(7) Implementing Regulations (EU) No 540/2011 and (EU) No 1037/2012 should therefore be amended accordingly.

(8) Given the fact that the deadline for submitting confirmatory information related to isopyrazam has already expired, this Regulation should enter into force on the day following that of its publication.

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

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Implementing Regulation (EU) No 1037/2012 of 7 November 2012 approving the active substance isopyrazam, 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 308, 8.11.2012, p. 15).

([3]) 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).

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) No 540/2011

In the column 'Specific provisions' of row 27, isopyrazam, of Part B of the Annex to Implementing Regulation (EU) No 540/2011, the last paragraph is replaced by the following:

'The applicant shall submit to the Commission, the Member States and the Authority this information by 31 July 2017.'

Article 2

Amendments to Implementing Regulation (EU) No 1037/2012

In the column 'Specific provisions' of the Annex to Implementing Regulation (EU) No 1037/2012, the last paragraph is replaced by the following:

'The applicant shall submit to the Commission, the Member States and the Authority this information by 31 July 2017.'

Article 3

Entry into force

This Regulation shall enter into force on the 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, 8 July 2015.

For the Commission
The President
Jean-Claude JUNCKER