Commission Implementing Regulation (EU) 2017/856 of 18 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance fluroxypyr (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/856

of 18 May 2017

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance fluroxypyr

(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) and Article 78(2) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 736/2011[(2)] approved fluroxypyr as an active substance in accordance with Regulation (EC) No 1107/2009 subject to certain conditions requiring the Member States concerned to ensure that the applicant at whose request fluroxypyr was approved provide further confirmatory information on six points, one of which concerned the relevance of the impurities present in the technical specifications.

(2) On 25 June 2012 and 5 September 2013 the applicant submitted additional information intended to address the confirmatory data requirements to the rapporteur Member State Ireland within the time period provided for its submission.

(3) Ireland assessed the additional information provided by the applicant. It submitted its own assessment, in the form of an addendum to the draft assessment report, to the other Member States, the Commission and the European Food Safety Authority, hereinafter 'the Authority', on 22 December 2014 and invited them to comment on the assessment.

(4) The Authority published a Technical Report[(3)] summarising the outcome of this consultation process for fluroxypyr on 22 July 2015.

(5) The draft assessment report, the addendum and the Technical Report were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and finalised on 23 March 2017 in the format of the Commission review report for fluroxypyr.

(6) The Commission invited the applicant to submit its comments on the Commission review report for fluroxypyr.

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/856. 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

(7) N-methyl-2-pyrrolidone (NMP) is classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council[4] as toxic for reproduction category 1B and has a general concentration limit of 0,3 %. The presence of NMP in the technical material below 3 g/kg would be highly unlikely to pose any risk to consumers. Hence the Commission has concluded that the additional information provided showed that a maximum level for the toxicologically relevant impurity NMP should be set at less than 3 g/kg (< 0,3 %) in the technical material.

(8) In order to ensure a high level of protection for consumers it is, therefore, appropriate to establish a maximum level for this impurity in the commercially manufactured active substance.

(9) The Annex to Commission Implementing Regulation (EU) No 540/2011[5] should therefore be amended accordingly.

(10) Member States should be allowed sufficient time to amend or withdraw authorisations for plant protection products containing fluroxypyr.

(11) For plant protection products containing fluroxypyr, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on 8 September 2018.

(12) 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

Amendment to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

Transitional measures

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary amend or withdraw existing authorisations for plant protection products containing fluroxypyr as the active substance by 8 September 2017 at the latest.

Article 3

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 8 September 2018 at the latest.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/856. 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 4

Entry into force

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, 18 May 2017.

For the Commission

The President

Jean-Claude JUNCKER