Commission Implementing Regulation (EU) 2015/2033 of 13 November 2015 renewing the approval of the active substance 2,4-D 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 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/2033

of 13 November 2015

renewing the approval of the active substance 2,4-D 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

(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 Article 20(1) thereof,

Whereas:

(1) The approval of the active substance 2,4-D, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[(2)], expires on 31 December 2015.

(2) An application for the renewal of the inclusion of 2,4-D in Annex I to Council Directive 91/414/EEC[(3)] was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010[(4)] within the time period provided for in that Article.

(3) The applicant submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. The application was found to be complete by the rapporteur Member State.

(4) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter 'the Authority') and the Commission on 4 March 2013.

(5) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(6) On 7 August 2014 and 11 March 2015[(5)] the Authority communicated to the Commission its conclusion on whether 2,4-D can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/2033. 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*

presented the draft review report for 2,4-D to the Standing Committee on Plants, Animals, Food and Feed on 28 May 2015.

(7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance that the approval criteria provided for in Article 4 are satisfied. Those approval criteria are therefore deemed to be satisfied.

(8) It is therefore appropriate to renew the approval of 2,4-D.

(9) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

(10) The risk assessment for the renewal of the approval of 2,4-D is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing 2,4-D may be authorised. It is therefore appropriate not to maintain the restriction to uses as a herbicide.

(11) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

(12) This Regulation should apply from the day after the date of expiry of the approval of the active substance 2,4-D, as referred to in recital 1.

(13) 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

Renewal of the approval of active substance

The approval of the active substance 2,4-D, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

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

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Article 3

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2016.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 November 2015.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/2033. 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*

ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
2,4-D CAS No: 94-75-7 CIPAC No: 1	(2,4-dichlorophenoxy)acetic acid	≥ 960 g/kg Impurities: Free phenols (expressed as 2,4-DCP): not more than 3 g/kg. Sum of dioxins and furans (WHO-TCDD TEQ)[b]: not more than 0,01 mg/kg.	1 January 2016	31 December 2030	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 2,4-D, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, terrestrial organisms and consumers in cases of uses above 750 g/ha. Conditions of use shall include risk mitigation measures, where appropriate.

a Further details on identity and specification of active substance are provided in the review report.

b Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), expressed as World Health Organisation (WHO) toxic equivalent (TEQ) using the WHO-toxic equivalency factors (WHO-TEFs)).

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					The applicant shall submit to the Commission, the Member States and the Authority: (1) confirmatory information in the form of the submission of the complete results from the existing extended one-generation study; (2) confirmatory information in the form of the submission of the Amphibian Metamorphosis Assay (AMA) (OECD (2009) Test No 231) as to verify the potential

a Further details on identity and specification of active substance are provided in the review report.

b Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), expressed as World Health Organisation (WHO) toxic equivalent (TEQ) using the WHO-toxic equivalency factors (WHO-TEFs)).