Commission Implementing Regulation (EU) 2015/1201 of 22 July 2015 renewing the approval of the active substance fenhexamid 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) 2015/1201

of 22 July 2015

renewing the approval of the active substance fenhexamid 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 fenhexamid, 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 fenhexamid 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 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 30 April 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 30 June 2014 the Authority communicated to the Commission its conclusion[(5)] on whether fenhexamid can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft review

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/1201. 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*

report for fenhexamid to the Standing Committee on Plants, Animals, Food and Feed on 27 January 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 fenhexamid.

(9) 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.

(10) This Regulation should apply from the day after the date of expiry of the approval of the active substance fenhexamid, as referred to in recital 1.

(11) 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 fenhexamid, 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.

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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/1201. 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*

Done at Brussels, 22 July 2015.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/1201. 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**
Fenhexamid CAS No: 126833-17-8 CIPAC No: 603	N-(2,3-dichloro-4-hydroxyphenyl)-1-methylcyclohexanecarboxamide	≥ 975 g/kg The following relevant impurity must not exceed a certain threshold in the technical material: — toluene: max. 1 g/kg, — 4-amino-2,3-dichlorophenol: max. 3 g/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 fenhexamid, 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 protection of operators during field crop handheld operations, — the protection of workers re-entering indoor-treated crops,

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