Commission Implementing Regulation (EU) 2016/389 of 17 March 2016 renewing the approval of the active substance acibenzolar-S-methyl 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) 2016/389

of 17 March 2016

renewing the approval of the active substance acibenzolar-S-methyl 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 acibenzolar-S-methyl, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[(2)], expires on 30 June 2016.

(2) An application for the renewal of the inclusion of acibenzolar-S-methyl 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 1 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.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/389. 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*

(6) On 8 May 2014[5] the Authority communicated to the Commission its conclusion on whether acibenzolar-S-methyl 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 report for acibenzolar-S-methyl to the Standing Committee on Plants, Animals, Food and Feed on 12 December 2014.

(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 of Regulation (EC) No 1107/2009 are satisfied. Those approval criteria are therefore deemed to be satisfied.

(8) It is therefore appropriate to renew the approval of acibenzolar-S-methyl.

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

(10) 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 necessary to include certain conditions. It is, in particular, appropriate to require further confirmatory information.

(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) Commission Implementing Regulation (EU) 2015/1885[6] extended the expiry date of acibenzolar-S-methyl to allow the renewal process to be completed before the expiry of its approval. However, given that a decision on renewal has been taken ahead of the extended expiry date, this Regulation should apply from 1 April 2016.

(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 acibenzolar-S-methyl, 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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/389. 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 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 April 2016.

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

Done at Brussels, 17 March 2016.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/389. 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**
Acibenzolar-S-methyl CAS No 135158-54-2 CIPAC No 597	S-methyl benzo[1,2,3]thiadiazole-7-carbothioate	970 g/kg Toluene: max. 5 g/kg	1 April 2016	31 March 2031	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 acibenzolar-S-methyl, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk for consumers via food intake; (b) the protection of operators and workers; (c) the risk to aquatic organisms.

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

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/389. 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*

					Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall by 1 June 2017 submit to the Commission, the Member States and the Authority confirmatory information as regards the relevance and reproducibility of the morphometric changes observed in the cerebellum of foetuses linked to exposure to acibenzolar-S-methyl and whether these changes may be produced via an endocrine mode of action. The information to be submitted shall include a systematic review of the available evidence assessed on the basis of available guidance (e.g. EFSA GD on Systematic

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