



Brussels, **XXX**
PLAN/2023/2650
[...] (2024) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

withdrawing 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, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Commission Implementing Regulation (EU) 2016/389

(Text with EEA relevance)

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(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/EEC¹, and in particular Article 21(3) and Article 78(2) thereof,

Whereas:

- (1) The approval of acibenzolar-S-methyl was renewed by Commission Implementing Regulation (EU) 2016/389².
- (2) Commission Regulation (EU) 2018/605³ amended Regulation (EC) No 1107/2009 by introducing new criteria to identify active substances which have endocrine disrupting properties, which became applicable on 10 November 2018. This required that the applicant should submit to the Commission, the Member States and the Authority confirmatory information as regards the endocrine-disrupting properties of acibenzolar-S-methyl.
- (3) The applicant submitted an updated dossier as well as additional information in February 2019.
- (4) On 8 July 2021, the European Food Safety Authority ('the Authority') published a peer review of the pesticide risk assessment for the active substance acibenzolar-S-methyl⁴ related to the confirmatory data submitted by the applicant, and reporting that the assessment of the endocrine-disrupting properties of acibenzolar-S-methyl could not be finalised based on the available data for both humans and non-target organisms, and identified further data that were necessary to finalise the assessment.

¹ OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

² 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 (OJ L 157, 27.5.2014, p. 96, ELI: http://data.europa.eu/eli/reg_impl/2016/389/oj).

³ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33, ELI: <http://data.europa.eu/eli/reg/2018/605/oj>).

⁴ Peer review of the pesticide risk assessment of the active substance acibenzolar-S-methyl, EFSA Journal 2021;19(7):6687 <https://doi.org/10.2903/j.efsa.2021.6687>.

- (5) The Commission therefore launched a review of the existing approval of the active substance in accordance with Article 21 of Regulation (EC) No 1107/2009. The applicant was invited to submit, by end of June 2025, additional information necessary to evaluate if acibenzolar-S-methyl still fulfils the criteria for approval laid down in point 3.6.5 of Annex II to that Regulation.
- (6) On 8 September 2023, the applicant informed the Commission of the cessation of further studies concerning the endocrine-disrupting attributes of acibenzolar-S-methyl and of its decision to self-classify that substance as toxic for reproduction category 1B (R1B) under Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁵.
- (7) Consequently, it has not been established that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. The Commission therefore considers that acibenzolar-S-methyl no longer fulfils the criteria for approval laid down in point 3.6.5 of Annex II to that Regulation.
- (8) It is therefore appropriate to withdraw the approval of acibenzolar-S-methyl.
- (9) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly and Implementing Regulation (EU) No 2016/389 should be repealed.
- (10) Member States should be provided with sufficient time to withdraw authorisations for plant protection products containing acibenzolar-S-methyl.
- (11) For plant protection products containing acibenzolar-S-methyl, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should be as short as possible and expire no later than 12 months from the date of entry into force of this Regulation.
- (12) This Regulation does not prevent the submission of a new application for the approval of acibenzolar-S-methyl pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (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

Withdrawal of approval

The approval of the active substance acibenzolar-S-methyl is withdrawn.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, row 98 on acibenzolar-S-methyl is deleted.

⁵ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing acibenzolar-S-methyl as active substance by ... [*Office of Publications: please insert date 6 months after the date of entry into force of this Regulation*].

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by ... [*Office of Publications: please insert date 12 months after the date of entry into force of this Regulation*].

Article 5

Repeal

Implementing Regulation (EU) No 2016/389 is repealed.

Article 6

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,

For the Commission

The President

Ursula VON DER LEYEN