



1 March 2024

(24-1954)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: European Commission Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: European Commission, EU-TBT Enquiry Point, Fax: +(32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu Website: http://ec.europa.eu/growth/tools-databases/tbt/en/
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): acibenzolar-S-methyl (pesticide active substance)
5. Title, number of pages and language(s) of the notified document: Draft Commission Implementing Regulation 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) No 2016/389; (4 page(s), in English)
6. Description of content: This draft Commission Implementing Regulation provides that the approval of the active substance acibenzolar-S-methyl is withdrawn in accordance with Regulation (EC) No 1107/2009. EU Member States shall withdraw authorisations for plant protection products containing acibenzolar-S-methyl as an active substance. This decision only concerns the placing on the market of this substance and plant protection products containing it. Following withdrawal and the expiry of all grace periods for stocks of products containing this substance, separate action will likely be taken on MRLs and a separate notification will be made in accordance with SPS procedures.
7. Objective and rationale, including the nature of urgent problems where applicable: In order for an active substance to be approved in accordance with Regulation (EC) No 1107/2009 (concerning the placing of plant protection products on the market), it must be demonstrated that the substance is not harmful to human health, animal health or the environment. Criteria are listed in Article 4 of the Regulation (and also detailed in Annex II thereto) which must be met to enable approval.

During the evaluation and peer-review of acibenzolar-S-methyl, areas that could not be finalised were identified. These are detailed in the statement of the European Food Safety Authority (EFSA).

The applicant had been requested to submit information under Article 21 of Regulation (EC) No 1107/2009 by the end of June 2025. However, on 8 September 2023 the applicant informed the Commission that they will not submit such information due to their preliminary self-classification of the substance as toxic for reproduction category 1B (R1B).

Thus the substance would not be expected to meet the approval criteria under Regulation (EC) No 1107/2009 as it would meet one of the cut-off criteria provided by that Regulation (R1B). The applicant informed that for that same reason it has opted to stop further production of all plant protection products containing acibenzolar-S-methyl as active substance for EU countries.

Existing authorisations will need to be withdrawn; EU Member States must withdraw existing plant protection products containing acibenzolar-S-methyl at the latest by 6 months from the date of entry into force. A period of grace in line with Article 46 of Regulation (EC) No 1107/2009 is allowed for and shall expire at the latest 12 months from the entry into force (allowing for a final season of use); Protection of human health or safety; Protection of animal or plant life or health; Protection of the environment

8. Relevant documents:

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

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R1107>

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (*OJ L 153, 11.6.2011, p. 1-186*)

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0540>

EFSA (European Food Safety Authority), 2021. Peer review of the pesticide risk assessment of the active substance acibenzolar-S-methyl.

<https://doi.org/10.2903/j.efsa.2021.6687>

9. Proposed date of adoption: 2nd quarter 2024

Proposed date of entry into force: 20 days following publication in the Official Journal of the EU

10. Final date for comments: 60 days from notification

11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:

European Commission,
EU-TBT Enquiry Point,
Fax: + (32) 2 299 80 43,
E-mail: grow-eu-tbt@ec.europa.eu

The text is available on the EU-TBT Website : <http://ec.europa.eu/growth/tools-databases/tbt/en/>

https://members.wto.org/crnattachments/2024/TBT/EEC/24_01779_00_e.pdf