



2025/1177

17.6.2025

**COMMISSION IMPLEMENTING REGULATION (EU) 2025/1177**

**of 16 June 2025**

**approving the active substance lysate of *Willaertia magna* as a low-risk active substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending 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 <sup>(1)</sup>, and in particular Article 13(2) in conjunction with Article 22(1) thereof,

Whereas:

- (1) On 18 June 2020, Austria received an application pursuant to Article 7(1) of Regulation (EC) No 1107/2009 from AMOEBA SA for the approval of the active substance lysate of *Willaertia magna* C2c Maky.
- (2) In accordance with Article 9(3) of that Regulation, Austria, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 4 November 2020 of the admissibility of the application.
- (3) On 29 July 2022, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (4) In accordance with Article 12(1) of Regulation (EC) No 1107/2009, the Authority circulated the draft assessment report to the applicant and to the other Member States and made it available to the public.
- (5) In accordance with Article 12(3) of Regulation (EC) No 1107/2009, the Authority requested the applicant to supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the form of an updated draft assessment report on 4 June 2024.
- (6) On 13 December 2024 the Authority communicated to the applicant, the Member States and the Commission its conclusion <sup>(2)</sup> on whether the active substance lysate of *Willaertia magna* C2c Maky can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.
- (7) The Authority confirmed that, based on the available evidence, the scientific conclusions on the lysate of *Willaertia magna* strain C2c Maky are also applicable to *Willaertia magna* as a species. In order to reduce the administrative burden and the risk of resistance building, it is therefore appropriate not to limit the approval to the strain *Willaertia magna* C2c Maky but to approve the active substance as lysate of the species *Willaertia magna*.

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

<sup>(2)</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance lysate of *Willaertia magna* C2c Maky, EFSA Journal 2025; 23:e9194; <https://doi.org/10.2903/j.efsa.2025.9194>.

- (8) The Commission presented to the Standing Committee on Plants, Animals, Food and Feed a review report and a draft Regulation regarding the lysate of *Willaertia magna* on 11 March 2025 and 14 May 2025, respectively.
- (9) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 13(1) of Regulation (EC) No 1107/2009, on the review report. The applicant submitted its comments, which have been carefully examined.
- (10) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance lysate of *Willaertia magna*, and in particular with respect to the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (11) The Commission further considers that lysate of *Willaertia magna* is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. The lysate of *Willaertia magna* is not a substance of concern and fulfils the conditions set in Annex II, point 5, to Regulation (EC) No 1107/2009. Lysate of *Willaertia magna* is an active substance for which a low-risk for humans, animals and the environment is expected, its components are naturally-occurring, and it is readily biodegradable.
- (12) It is therefore appropriate to approve lysate of *Willaertia magna* as a low-risk active substance.
- (13) In accordance with Article 13(2) 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 in order to ensure quality control during the manufacturing process and during the use of plant protection products containing lysate of *Willaertia magna*.
- (14) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 in conjunction with Article 22(2) thereof, Commission Implementing Regulation (EU) No 540/2011 <sup>(3)</sup> should be amended accordingly.
- (15) 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

#### Approval of the active substance

The active substance lysate of *Willaertia magna*, as specified in Annex I, is approved, subject to the conditions laid down in that Annex.

<sup>(3)</sup> 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, ELI: [http://data.europa.eu/eli/reg\\_impl/2011/540/oj](http://data.europa.eu/eli/reg_impl/2011/540/oj)).

*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**

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, 16 June 2025.

*For the Commission*

*The President*

Ursula VON DER LEYEN

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Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
Lysate of <i>Willaertia magna</i>	Not applicable	No relevant impurities	7 July 2025	7 July 2040	<p>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 lysate of <i>Willaertia magna</i>, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"><li>— the guarantee by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the adherence of the limits on microbiological contamination as set in the OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No 65 <sup>(2)</sup>,</li><li>— the suspensibility of plant protection products containing lysate of <i>Willaertia magna</i>, which may require continuous stirring during their loading and use.</li></ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

<sup>(1)</sup> Further details on identity and specification of active substance are provided in the review report.

<sup>(2)</sup> Organisation for Economic Co-operation and Development (2014), OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products, Series on Pesticides and Biocides, No 65, OECD Publishing, Paris, <https://doi.org/10.1787/9789264221642-en>.

ANNEX II

In Part D of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
'53	Lysate of <i>Willaertia magna</i>	Not applicable	No relevant impurities	7 July 2025	7 July 2040	<p>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 lysate of <i>Willaertia magna</i>, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"><li>— the guarantee by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the adherence of the limits on microbiological contamination as set in the OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No 65 <sup>(2)</sup>,</li><li>— the suspensibility of plant protection products containing lysate of <i>Willaertia magna</i>, which may require continuous stirring during their loading and use.</li></ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

<sup>(1)</sup> Further details on identity and specification of active substance are provided in the review report.

<sup>(2)</sup> Organisation for Economic Co-operation and Development (2014), OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products, Series on Pesticides and Biocides, No. 65, OECD Publishing, Paris, <https://doi.org/10.1787/9789264221642-en>.’