



2025/119

27.1.2025

**COMMISSION IMPLEMENTING REGULATION (EU) 2025/119**

**of 24 January 2025**

**amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the low-risk active substance aqueous extract from the germinated seeds of sweet *Lupinus albus***

(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 21(3) and Article 78(2) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2021/567 <sup>(2)</sup> approved aqueous extract from the germinated seeds of sweet *Lupinus albus* as a low-risk active substance in accordance with Regulation (EC) No 1107/2009. That approval was made subject to certain conditions, in particular the submission of confirmatory information by the applicant as regards the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification. In particular, that confirmatory information concerned the maximum content of the quinolizidine alkaloids (*lupanine*, *13α-OH-lupanine*, *13α-angeloyloxylupanine*, *lupinine*, *albino*, *angustofoline*, *13α-tigloyloxylupanine*, *α-isolupanine*, *tetrahydrorhombifoline*, *multiflorine*, *sparteine*).
- (2) In accordance with that requirement, the applicant submitted an updated dossier in October 2021, which was evaluated by the rapporteur Member State, the Netherlands, in the form of a revised draft assessment report.
- (3) On 9 December 2022, the Netherlands circulated the revised draft assessment report to the other Member States, the applicant and the European Food Safety Authority ('the Authority') for comments. On 22 September 2023, the Authority, added its scientific views on the specific points raised during the commenting. On 5 December 2023, the Authority published a technical report <sup>(3)</sup> summarising the outcome of the consultation process for aqueous extract from the germinated seeds of sweet *Lupinus albus*.
- (4) In its review report for aqueous extract from the germinated seeds of sweet *Lupinus albus* of 23 May 2024 <sup>(4)</sup>, the Commission considered the need to remove the indication that the specification of the technical material is provisional, as established in Annex I to Implementing Regulation (EU) 2021/567.

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

<sup>(2)</sup> Commission Implementing Regulation (EU) 2021/567 of 6 April 2021 approving the low-risk active substance aqueous extract from the germinated seeds of sweet *Lupinus albus* 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 118, 7.4.2021, p. 6, ELI: [http://data.europa.eu/eli/reg\\_impl/2021/567/oj](http://data.europa.eu/eli/reg_impl/2021/567/oj)).

<sup>(3)</sup> Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for the aqueous extract from the germinated seeds of sweet *Lupinus albus* in light of confirmatory data (<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2023.EN-8500>).

<sup>(4)</sup> Review report for the active substance aqueous extract from the germinated seeds of sweet *Lupinus albus*.

- (5) Furthermore, based on the confirmatory information received, the maximum content of the quinolizidine alkaloids (*lupanine*, *13α-OH-lupanine*, *13α-angeloyloxylupanine*, *lupinine*, *albine*, *angustofoline*, *13α-tigloyloxylupanine*, *α-isolupanine*, *tetrahydrorhombifoline*, *multiflorine*, *sparteine*) should be maintained at a level of 0,05 g/kg. Additionally, based on the outcome of the assessment, the Commission considers that *lupanine* is to be set as a marker of those quinolizidine alkaloids, and the maximum content of this compound is considered to be set at a level of 0,035 g/kg.
- (6) The Commission invited the applicant to submit its comments on the review report and the Commission carefully examined them.
- (7) In order to ensure a high level of protection for consumers, it is appropriate to establish a maximum level for the relevant impurities in the technical specification of the active substance. The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (8) Member States should be allowed sufficient time to amend or withdraw authorisations for plant protection products containing aqueous extract from the germinated seeds of sweet *Lupinus albus* which do not comply with the specification of the technical material as commercially manufactured.
- (9) For plant protection products containing aqueous extract from the germinated seeds of sweet *Lupinus albus*, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should expire, at the latest, 15 months after the entry into force of this Regulation.
- (10) 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*

#### **Amendment to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

#### *Article 2*

#### **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, 24 January 2025.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX

In Part D of the Annex, row 28, aqueous extract from the germinated seeds of sweet *Lupinus albus*, is amended as follows:

- (1) the column 'Purity' is replaced by the following:

'The minimum purity is not relevant for the extract.

BLAD protein content: 195–210 g/kg.

The following relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured were identified:

Total quinolizidine alkaloids (QA): (*lupanine*, *13α-OH-lupanine*, *13α-angeloyloxylupanine*, *lupinine*, *albine*, *angustofoline*, *13α-tigloyloxylupanine*, *α-isolupanine*, *tetrahydrorhombifoline*, *multiflorine*, *sparteine*)

Maximum content: set at 0,05 g/kg.

Level of *lupanine*, as a marker compound: set at 0,035 g/kg.;

- (2) the column 'Specific provisions' is replaced by the following:

'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 aqueous extract from the germinated seeds of sweet *Lupinus albus*, and in particular Appendices I and II thereto, shall be taken into account.

In this overall assessment, Member States shall pay particular attention to the necessary labelling instructions concerning the measures to address foaming and stability of dilutions of the formulation.'

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