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

(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 13(2) in conjunction with Article 22(1) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, CEV SA submitted to the Netherlands on 7 June 2016 an application for the approval of the active substance aqueous extract from the germinated seeds of sweet *Lupinus albus*.

(2) In accordance with Article 9(3) of Regulation (EC) No 1107/2009, the Netherlands, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') of the admissibility of the application on 18 January 2017.

(3) On 1 April 2019, 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) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of that Regulation, it requested that the applicant supplies 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 format of an updated draft assessment report on 3 March 2020.

(5) On 19 June 2020, the Authority communicated to the applicant, the Member States and the Commission its conclusion ([2]) on whether the active substance aqueous extract from the germinated seeds of sweet *Lupinus albus* 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.

(6) On 23 October 2020, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed a review report and a draft regulation regarding aqueous extract from the germinated seeds of sweet *Lupinus albus*.

(7) The applicant was given the possibility to submit comments on the review report.

(8) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular 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.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) EFSA (European Food Safety Authority), 2020. Conclusion on the peer review of the pesticide risk assessment of the active substance Aqueous extract from the germinated seeds of sweet *Lupinus albus*; *EFSA Journal* 2020;18(7):6190, 45 pp.; https://doi:10.2903/j.efsa.2020.6190. Available online: www.efsa.europa.eu.

(9) The Commission further considers that aqueous extract from the germinated seeds of sweet *Lupinus albus* is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Aqueous extract from the germinated seeds of sweet *Lupinus albus* is not a substance of concern and it fulfils the conditions set out in point 5.1 of Annex II to Regulation (EC) No 1107/2009.

(10) It is therefore appropriate to approve aqueous extract from the germinated seeds of sweet *Lupinus albus*.

(11) 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 and restrictions. It is in particular appropriate to require further confirmatory information.

(12) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ([3]) should be amended accordingly.

(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

Approval of the active substance

The active substance aqueous extract from the germinated seeds of sweet *Lupinus albus*, as specified in Annex I, is approved 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.

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, 6 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

([3]) 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).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Aqueous extract from the germinated seeds of sweet *Lupinus albus* *CAS No:* Not available for the extract *BLAD protein: 1219521-95-5* CIPAC No: Not allocated	Not applicable	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, tetrahydrohombifoline, multiflorine, sparteine*) Maximum content: provisionally set at 0,05 g/kg	27 April 2021	27 April 2036	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. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. 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; and 2. in particular, the maximum content of the quinolizidine alkaloids (*lupanine, 13α-OH-lupanine, 13α-angeloyloxylupanine, lupinine, albine, angustofoline, 13α-tigloyloxylupanine, α-isolupanine, tetrahydrohombifoline, multiflorine, sparteine*). The applicant shall submit the information referred in points 1 and 2 by 27 October 2021.

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

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 [1]	Date of approval	Expiration of approval	Specific provisions
'28	Aqueous extract from the germinated seeds of sweet *Lupinus albus* *CAS No:* Not available for the extract *BLAD protein:* *1219521-95-5* CIPAC No: Not allocated	Not applicable	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, tetrahydrohombifoline, multiflorine, sparteine*) Maximum content: provisionally set at 0,05 g/kg	27 April 2021	27 April 2036	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. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. 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; and 2. in particular on the maximum content of the quinolizidine alkaloids (*lupanine, 13α-OH-lupanine, 13α-angeloyloxylupanine, lupinine, albine, angustofoline, 13α-tigloyloxylupanine, α-isolupanine, tetrahydrohombifoline, multiflorine, sparteine*). The applicant shall submit the information referred in points 1 and 2 by 27 October 2021.'

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