



2025/96

22.1.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/96

of 21 January 2025

approving the basic substance *Vitis vinifera* L. seed extract (grape seed extract) 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 ⁽¹⁾, and in particular Article 13(2) in conjunction with Article 23(5) thereof,

Whereas:

- (1) On 4 August 2020, the Commission received an application from Cérence (formerly Jouffray-Drillaud) for the approval of *Vitis vinifera* L. seed extract (grape seed extract) as a basic substance to be used in plant protection as a fungicide on grapevines, apples, potatoes and lettuce.
- (2) After the admissibility check, the application, as received in February 2022, was accompanied by the information required under Article 23(3), second subparagraph, of Regulation (EC) No 1107/2009.
- (3) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance pursuant to Article 23(4) of Regulation (EC) No 1107/2009. The Authority provided the Commission with a technical report on *Vitis vinifera* L. seed extract (grape seed extract) on 30 October 2023 ⁽²⁾.
- (4) The Commission presented the review report ⁽³⁾ and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed, on 21 March 2024 and 10 July 2024, respectively.
- (5) The information provided by the applicant shows that *Vitis vinifera* L. seed extract (grape seed extract) is used as food supplement and as feed additive. Moreover, it is not predominantly used for plant protection purposes, but the substance is useful in plant protection. Based on the information provided in the application and the Technical Report from the Authority, it can also be concluded that it is not a substance of concern; it does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and it is not placed on the market as a plant protection product. Consequently, *Vitis vinifera* L. seed extract (grape seed extract) fulfils the conditions set out in Article 23(1) of Regulation (EC) No 1107/2009.

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

⁽²⁾ EFSA (European Food Safety Authority), 2023. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for approval of grape seed extract as a basic substance to be used in plant protection as a fungicide on grapevines, apples, potatoes and lettuce. EFSA supporting publication 2023:EN-8435. 150 pp. doi:10.2903/sp.efsa.2023.EN-8435.

⁽³⁾ Final Review report for the basic substance *Vitis vinifera* L. seed extract (grape seed extract) finalised by the Standing Committee on Plants, Animals, Food and Feed on 5 December 2024 in view of the approval of *Vitis vinifera* L. seed extract (grape seed extract) as basic substance in accordance with Regulation (EC) No 1107/2009.

- (6) Several relevant evaluations, carried out in accordance with other Union legislation, as referred to in Article 23(2) of Regulation (EC) No 1107/2009, were available. Three Scientific Opinions from the Authority were relevant: two from the FEEDAP Panel and one from the NDA Panel ⁽⁴⁾. The outcome of those evaluations has been taken into account by the Authority as well as by the Commission.
- (7) After examination of the application and all related documents, it may be expected that *Vitis vinifera* L. seed extract (grape seed extract) satisfies, in general, the requirements laid down in Article 23 of Regulation (EC) No 1107/2009, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve *Vitis vinifera* L. seed extract (grape seed extract) as a basic substance.
- (8) The Commission invited the applicant to submit its comments on the Technical Report of the Authority and on the Commission's draft review report. The applicant submitted its comments, which have been carefully examined and taken into due consideration.
- (9) 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, however, necessary to include certain conditions for the approval.
- (10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁵⁾ should be amended accordingly.
- (11) 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 a basic substance

The substance *Vitis vinifera* L. seed extract (grape seed extract) as specified in Annex I is approved as a basic substance 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.

⁽⁴⁾ The references to these evaluations are available in the EFSA Conclusion. EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); EFSA Panel on Nutrition, Novel Foods and Food allergen (NDA). EFSA supporting publication 2023:EN-8435. 20 pp. doi:10.2903/sp.efsa.2023.EN-8435.

⁽⁵⁾ 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).

*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, 21 January 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
<i>Vitis vinifera</i> L. seed extract (grape seed extract) CAS No: Not available CIPAC No: Not available	Not available	Minimum content of 75 % of Oligomeric proanthocyanidins on the anhydrous basis	11 February 2025	<i>Vitis vinifera</i> L. seed extract (grape seed extract) shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Vitis vinifera</i> L. seed extract (grape seed extract) (PLAN/2024/800 RR rev3) and in particular Appendices I and II thereof.

⁽¹⁾ Further details on identity, specification and manner of use of the basic substance are provided in the review report.

ANNEX II

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

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
'28	Vitis vinifera L. seed extract (grape seed extract) CAS No: Not available CIPAC No: Not available	Not available	Minimum content of 75 % of Oligomeric proanthocyanidins on the anhydrous basis	11 February 2025	Vitis vinifera L. seed extract (grape seed extract) shall be used in accordance with the specific conditions included in the conclusions of the review report on Vitis vinifera L. seed extract (grape seed extract) (PLAN/2024/800 RR rev3) and in particular Appendices I and II thereof.

⁽¹⁾ Further details on identity, specification and manner of use of basic substance are provided in the review report.