



2026/1209

10.6.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/1209

of 9 June 2026

concerning the non-approval of *Capsicum* oleoresin as a basic substance 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

(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 15 November 2021, the Commission received an application from Concept Nature Bio ('the applicant') for the approval of *Capsicum* oleoresin as a basic substance to be used in plant protection as a mammal repellent for uses applied to seeds of wheat, maize, pea and sunflower and to crops of maize, oilseed rape, cabbage, sunflower, sugar beet, wheat and grassland via foliar spray.
- (2) On 31 March 2023, the Commission received a revised version of the application solving some requested modifications and clarifications in Section 2 'Identity of the substance', Section 3 'Uses of the substance for plant protection', Section 4 'Classification of the substance and notification of studies'.
- (3) On 11 August 2023, the Commission confirmed the validity of the application for further evaluation.
- (4) 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 *Capsicum* oleoresin on 7 August 2025 ⁽²⁾.
- (5) *Capsicum* oleoresin is available on the Union market for use as food additive (E160c), feed additive (4d11) and as riot control substance. 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 when the Authority provided its scientific assistance ⁽³⁾. The Authority and the Commission have both taken the outcome of those evaluations into account.
- (6) With regard to the identity of the substance, the Authority stated that the composition of the substance is not clear and the maximum content of capsaicinoids is not specified. Moreover, when *Capsicum* oleoresin is used as a food additive, one of its components, capsaicin, is only allowed in concentrations of less than 250 mg/kg (< 0,025 %) in accordance with Commission Regulation (EU) No 231/2012 ⁽⁴⁾. When *Capsicum* oleoresin is used as food flavouring, capsaicin is not to be added as such to food, in accordance with Article 6(1) of Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁽⁵⁾.

⁽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), 2025. *Overall conclusions on the application for approval of Capsicum oleoresin as a basic substance to be used in plant protection as a mammal repellent applied via seed treatment and foliar spray on various crops and seed types*, EFSA supporting publication 2025:EN-9621, 153 p., available online : <https://doi.org/10.2903/sp.efsa.2025.EN-9621>.

⁽³⁾ Appendix F: Literature search carried out by EFSA targeting impact on human and animal health, fate and behaviour in the environment and effects on non-target organisms, <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00550>.

⁽⁴⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 (OJ L 83, 22.3.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/231/oj>).

⁽⁵⁾ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34, ELI: <http://data.europa.eu/eli/reg/2008/1334/oj>).

- (7) With regard to human health, the Authority found, based on the Opinion of the Scientific Committee on Food concerning capsaicin ⁽⁶⁾, that capsaicinoids are known to be genotoxic *in vivo* and *in vitro* and adverse health effects are known to occur following their oral intake by humans. Therefore, in May 2025, the Commission mandated the Authority to issue a scientific opinion on the health risks related to the presence of capsaicin in foods ⁽⁷⁾. Furthermore, the Authority identified a data gap as regards genotoxicity assessment and could not finalise the non-dietary risk assessment, nor the consumer risk assessment because the respective toxicological reference values were not available. Consequently, the Commission concludes that it is not possible to demonstrate the fulfilment of the condition set out in Article 23(1), points (a) and (b), of Regulation (EC) No 1107/2009, that an active substance is not a substance of concern, and that it does not have an inherent capacity to cause endocrine-disrupting, neurotoxic or immunotoxic effects.
- (8) With regard to the intended uses, the Authority noted uncertainties in the application rates and the conditions of use. The Authority concluded that an exact recipe for preparation and final dilutions required for application of the substance was lacking.
- (9) Additionally, the Authority highlighted that there was insufficient toxicity data for terrestrial vertebrates, aquatic invertebrates, algae, macrophytes, non-target terrestrial plants, honey bees and non-target arthropods other than bees, and insufficient information to finalise the exposure assessment for non-target organisms.
- (10) The Commission presented its review report and a draft of this Implementing Regulation to the Standing Committee on Plants, Animals, Food and Feed on 10 December 2025 and 11 March 2026, respectively.
- (11) The Commission invited the applicant to submit its comments on the technical report of the Authority and on the Commission's review report. The applicant submitted its comments, which have been carefully examined.
- (12) However, despite the arguments put forward by the applicant, the concerns related to the risk to consumers, operators, workers, bystanders and residents and with regard to the protection of the environment could not be eliminated.
- (13) By email of 30 April 2026, Concept Nature Bio withdrew its application for the approval of *Capsicum* oleoresin as basic substance. Due to the withdrawal of the application, *Capsicum* oleoresin should not be approved pursuant to Article 23 of Regulation (EC) No 1107/2009.
- (14) This Regulation does not prevent the submission of a further application for the approval of *Capsicum* oleoresin as a basic substance in accordance with Article 23(3) of Regulation (EC) No 1107/2009.
- (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

The substance *Capsicum* oleoresin is not approved as a basic substance.

⁽⁶⁾ Opinion of the Scientific Committee on Food on Capsaicin; Scientific Committee on Food SCF/CS/FLAV/FLAVOUR/8, 26 February 2002.

⁽⁷⁾ Further details and related timelines available in OpenEFSA: <https://open.efsa.europa.eu/questions/EFSA-Q-2025-00304?search=capsaicin>.

Article 2

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, 9 June 2026.

For the Commission
The President
Ursula VON DER LEYEN