

COMMISSION IMPLEMENTING REGULATION (EU) 2023/200**of 30 January 2023****concerning the non-approval of lemon essential oil (*Citrus limon* essential oil) 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 6 June 2020, the Commission received an application from Cugargestion Management S. L. ('the applicant') for the approval of lemon essential oil as a basic substance to be used in plant protection as an acaricide, insecticide and fungicide on citrus fruit trees. In November 2020, the Commission received a revised application, which was accompanied by the information required under Article 23(3), second subparagraph, of Regulation (EC) No 1107/2009.
- (2) The 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. As regards the lemon essential oil, an evaluation from the FEEDAP Panel of the European Food Safety Authority ('the Authority') was available ⁽²⁾. As regards the main component of lemon essential oil, namely d-limonene, the available relevant evaluations included a Conclusion on the peer review of the pesticide risk assessment issued by the Authority ⁽³⁾ as well as an opinion of the Risk Assessment Committee of the European Chemicals Agency (ECHA) ⁽⁴⁾. The outcome of these evaluations have been taken into account by the Authority as well as by the Commission.
- (3) The Commission asked the Authority for scientific assistance. The Authority provided the Commission with a technical report on lemon essential oil on 20 September 2021 ⁽⁵⁾.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Kouba M, Fašmon Durjava M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Brantom P, Chesson A, Westendorf J, Galobart J, Manini P, Pizzo F and Dusemund B, 2021. Scientific Opinion on the safety and efficacy of feed additives consisting of expressed lemon oil and its fractions from *Citrus limon* (L.) Osbeck and of lime oil from *Citrus aurantiifolia* (Christm.) Swingle for use in all animal species (FEFANA asbl). EFSA Journal 2021;19(4):6548, 55 pp. <https://doi.org/10.2903/j.efsa.2021.6548>.

⁽³⁾ EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance orange oil. EFSA Journal 2013;11(2):3090. 55 pp. <https://doi.org/10.2903/j.efsa.2013.3090>.

⁽⁴⁾ ECHA (European Chemicals Agency) Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of (R)-p-mentha-1,8-diene; d-limonene. Adopted 15 March 2019. Available at <https://echa.europa.eu/documents/10162/10c233b2-019e-4e59-e0c1-550133aed912>.

⁽⁵⁾ EFSA (European Food Safety Authority), 2021. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for approval of lemon essential oil to be used in plant protection as an acaricide, insecticide and fungicide in fruit trees (citrus). EFSA supporting publication 2021: EN-6873. 147 pp. doi:10.2903/sp.efsa.2021.EN-6873.

- (4) With regard to human health, the Authority concluded that, even though no Union harmonised classification has been established for lemon essential oil under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁶⁾ on classification, labelling and packaging of chemical substances and mixtures, the main hazard associated with lemon essential oil is its toxicity by inhalation and skin sensitisation properties. The main component of lemon essential oil, d-limonene, is classified ⁽⁷⁾ as a substance that may be fatal if swallowed and when it enters airways (Asp. Tox.1), as a skin irritant (Skin Irrit 2) and as a substance that may cause an allergic skin reaction (Skin Sens.1B). Additionally, due to the absence of data, the Authority could not conclude its assessment of non-dietary risks for operators, workers, bystanders and residents.
- (5) As regards the effect of lemon essential oil on the environment, the Authority noted that lemon essential oil is toxic to aquatic organisms. D-limonene is classified ⁽⁸⁾ as very toxic to aquatic life (Aquatic Acute 1) and as very toxic to aquatic life with long lasting effects (Aquatic Chronic 3). Moreover, the available data were not sufficient to demonstrate acceptable risk to non-target organisms.
- (6) The Commission presented the review report, concluding that the approval criteria for basic substances are not fulfilled in the case of lemon essential oil and that it is therefore not to be approved as a basic substance, as well as a draft of this Implementing Regulation to the Standing Committee on Plants, Animals, Food and Feed on 12 April 2022 and 14 October 2022, respectively.
- (7) 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 were taken into due consideration.
- (8) However, despite the arguments put forward by the applicant, the concerns related to the safety of using this substance with regard to the protection of human health and environment could not be eliminated.
- (9) Consequently, it has not been established that the conditions laid down in Article 23 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to establish that lemon essential oil is not approved as a basic substance.
- (10) This Regulation does not prevent the submission of a further application for the approval of lemon essential oil as a basic substance in accordance with Article 23(3) of Regulation (EC) No 1107/2009.
- (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

The substance lemon essential oil (*Citrus limon* essential oil) is not approved as a basic substance.

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*.

⁽⁶⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽⁷⁾ Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 188, 28.5.2021, p. 27).

⁽⁸⁾ Delegated Regulation (EU) 2021/849.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 30 January 2023.

For the Commission
The President
Ursula VON DER LEYEN
