

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/640****of 12 May 2020****concerning the non-approval of propolis extract 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 <sup>(1)</sup>, and in particular Article 23(5) in conjunction with Article 13(2) thereof,

Whereas:

- (1) On 20 December 2016, the Commission received an application from the company Pollenergie for the approval of propolis extract as a basic substance for post-harvest treatment in plant protection as fungicide or bactericide on fruits with non-edible peel. That application was accompanied by the information required under the second subparagraph of Article 23(3) of Regulation (EC) No 1107/2009.
- (2) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance. The Authority provided the Commission with a technical report on propolis extract on 11 October 2018 <sup>(2)</sup>. The Commission presented the review report <sup>(3)</sup> and the draft of this Regulation on the non-approval of propolis extract to the Standing Committee on Plants, Animals, Food and Feed on 5 December 2019.
- (3) The information provided by the applicant on the propolis extract under evaluation was insufficient to demonstrate clearly that it fulfils the criteria of a foodstuff as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(4)</sup>.
- (4) The Authority identified propolis extract as a skin sensitiser (H317 'may cause an allergic skin reaction'). Although no other specific concerns were identified, the information provided was not sufficient to demonstrate the absence of genotoxic potential and of endocrine activity and to conclude an assessment of the risk to consumers. Moreover, the available information on propolis extract did not allow to establish a safe limit for the use of that substance.
- (5) No relevant evaluation, carried out in accordance with other Union legislation as referred to in Article 23(2) of Regulation (EC) No 1107/2009, was available.
- (6) 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.
- (7) However, despite the arguments put forward by the applicant, the concerns related to the substance cannot be eliminated.
- (8) Consequently, as laid down in the Commission's review report, it has not been established that the requirements laid down in Article 23 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to approve propolis extract as a basic substance.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> EFSA (European Food Safety Authority), 2018. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for propolis extract (admissibility accepted when named water-soluble extract of propolis) for use in plant protection as fungicide and bactericide. EFSA supporting publication 2018:EN-1494. 56 pp. doi:10.2903/sp.efsa.2018.EN-1494.

<sup>(3)</sup> <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>.

<sup>(4)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (9) This Regulation does not prejudice the submission of a further application for the approval of propolis extract as a basic substance in accordance with Article 23(3) of Regulation (EC) No 1107/2009.
- (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*

The substance propolis extract 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*.

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

Done at Brussels, 12 May 2020.

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

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