

COMMISSION IMPLEMENTING REGULATION (EU) 2021/809

of 20 May 2021

concerning the non-approval of fermented extract from leaves of *Symphytum officinale* L. (comfrey) 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 22 January 2015, the Commission received an application from the company Greenprotech for the approval of 'comfrey steeping' as a basic substance to be used as an insect repellent and plant elicitor in fruit trees, grass and vegetables. 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 'comfrey steeping' on 28 November 2019 ⁽²⁾. Based on that technical report and the documentation provided by the applicant, it is appropriate to define the scope of the application as covering the active substance 'fermented extract from leaves of *Symphytum officinale* L. (comfrey)'.
- (3) The information provided by the applicant on the fermented extract from leaves of *Symphytum officinale* L. (comfrey) was insufficient to demonstrate 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 ⁽³⁾.
- (4) The Authority concluded that the specification of the fermented extract from leaves of *Symphytum officinale* L. (comfrey) is not well defined. The Authority also indicated that comfrey is known to contain genotoxic and carcinogenic components, and information on the concentration of genotoxic and carcinogenic compounds in the fermented extract from leaves of *Symphytum officinale* L. was not available. Consequently, it was not possible to conclude that the fermented extract from leaves of *Symphytum officinale* L. is not to be considered as a substance of concern as provided for by Article 23(1)(a) of Regulation (EC) No 1107/2009.
- (5) Moreover, the available information on the fermented extract from leaves of *Symphytum officinale* L. did not allow the Authority to finalise a non-dietary exposure risk assessment and the assessment of the risk to consumers. Furthermore, there was not sufficient information available regarding environmental exposure and the risks to non-target organisms.
- (6) 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.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA (European Food Safety Authority), 2019. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for approval of Comfrey steeping to be used in plant protection as an insect repellent and plant elicitor in fruit trees, grass and vegetables. EFSA supporting publication 2019:EN-1753. 64 pp. doi:10.2903/sp.efsa.2019.EN-1753.

⁽³⁾ 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).

- (7) The Commission presented the review report ⁽⁴⁾ and a draft Regulation to the Standing Committee on Plants, Animals, Food and Feed on 19 May 2020 and 26 January 2021, respectively, and finalised them for the meeting of that Committee on 24 March 2021.
- (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.
- (9) However, despite the arguments put forward by the applicant, the concerns related to the substance cannot be eliminated.
- (10) Consequently, it has not been established that the conditions laid down in Article 23 of Regulation (EC) No 1107/2009 are fulfilled. It is therefore appropriate not to approve fermented extract from leaves of *Symphytum officinale* L. (comfrey) as a basic substance.
- (11) This Regulation does not prevent the submission of a further application for the approval of fermented extract from leaves of *Symphytum officinale* L. (comfrey) as a basic substance in accordance with Article 23(3) of Regulation (EC) No 1107/2009 or an application for approval as active substance in accordance with Article 7 of that Regulation.
- (12) 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 fermented extract from leaves of *Symphytum officinale* L. (comfrey) 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, 20 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁴⁾ https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en