

COMMISSION IMPLEMENTING DECISION (EU) 2023/1085

of 2 June 2023

postponing the expiry date of the approval of *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ as an active substance for use in biocidal products of product-type 18. Pursuant to Article 86 of Regulation (EU) No 528/2012, it is therefore considered approved under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.
- (2) The approval of *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 for use in biocidal products of product-type 18 ('the approval') is to expire on 30 September 2023. On 30 March 2022, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval ('the application').
- (3) On 2 February 2023, the evaluating competent authority of Italy informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (4) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.
- (5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.
- (6) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority and for preparation and submission by the European Chemicals Agency of its opinion, and the time needed to decide whether the approval of *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 for use in biocidal products for product-type 18 may be renewed, the expiry date should be postponed to 31 March 2026.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

- (7) After the postponement of the expiry date of the approval, *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 remains approved for use in biocidal products of product-type 18 subject to the conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 for use in biocidal products of product-type 18 set out in Annex I to Directive 98/8/EC is postponed to 31 March 2026.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 2 June 2023.

For the Commission
The President
Ursula VON DER LEYEN
