

COMMISSION IMPLEMENTING DECISION (EU) 2021/1290**of 2 August 2021****postponing the expiry date of approval of disodium tetraborate for use in biocidal products of product-type 8****(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) The active substance disodium tetraborate was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ for use in biocidal products of product-type 8, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.
- (2) The approval of disodium tetraborate for use in biocidal products of product-type 8 will expire on 31 August 2021. On 28 February 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of disodium tetraborate.
- (3) As disodium tetraborate is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽³⁾, it meets the exclusion criteria set out in Article 5(1), point (c), of Regulation (EU) No 528/2012.
- (4) On 2 July 2020, the evaluating competent authority of the Netherlands 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 Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (5) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, 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.
- (6) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the 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.
- (7) Consequently, for reasons beyond the control of the applicant, the approval of disodium tetraborate for use in biocidal products of product-type 8 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of disodium tetraborate for use in biocidal products of product-type 8 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority, for the preparation and submission of the opinion by the Agency and the period of time necessary to decide if at least one of the conditions in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is fulfilled and whether the approval of disodium tetraborate may therefore be renewed, it is appropriate to postpone the expiry date of approval to 28 February 2024.

⁽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).

⁽³⁾ 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).

- (8) Except for the expiry date of approval, disodium tetraborate remains approved for use in biocidal products of product-type 8 subject to the specifications and conditions set out in Annex 1 to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of disodium tetraborate for use in biocidal products of product-type 8 is postponed to 28 February 2024.

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 August 2021.

For the Commission
The President
Ursula VON DER LEYEN
