



2024/208

12.1.2024

COMMISSION IMPLEMENTING DECISION (EU) 2024/208

of 10 January 2024

postponing the expiry date of the approval of disodium tetraborate for use in biocidal products of product-type 8 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) Disodium tetraborate 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 8. Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.
- (2) 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 for use in biocidal products of product-type 8 ('the application').
- (3) 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 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 ('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.
- (6) Commission Implementing Decision (EU) 2021/1290 ⁽³⁾ postponed the expiry date of the approval of disodium tetraborate for use in biocidal products of product-type 8 to 28 February 2024, in order to allow sufficient time for the examination of the application.
- (7) On 1 September 2023, the evaluating competent authority of the Netherlands informed the Commission that the evaluation is delayed due to the need to assess additional data requested from the applicant.

⁽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⁾ 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 (OJ L 279, 3.8.2021, p. 47).

- (8) 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 further postpone the expiry date of the approval for a period of time sufficient to finalise the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority, for preparation and submission by the Agency of its opinion and the time needed for the Commission to decide whether to renew the approval of disodium tetraborate for use in biocidal products for product-type 8, the expiry date should be postponed to 31 August 2026.
- (9) After the further postponement of the expiry date of the approval, disodium tetraborate remains approved for use in biocidal products of product-type 8 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 disodium tetraborate for use in biocidal products of product-type 8 set out in Implementing Decision (EU) 2021/1290 is postponed to 31 August 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, 10 January 2024.

For the Commission
The President
Ursula VON DER LEYEN