



2025/951

26.5.2025

COMMISSION IMPLEMENTING DECISION (EU) 2025/951

of 22 May 2025

postponing the expiry date of the approval of polyvinylpyrrolidone iodine for use in biocidal products of product-types 1 and 3 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) Polyvinylpyrrolidone iodine was approved as an active substance for use in biocidal products of product-types 1, 3, 4 and 22 by Commission Implementing Regulation (EU) No 94/2014 ⁽²⁾ subject to the conditions set out in the Annex to that Regulation.
- (2) The approval of polyvinylpyrrolidone iodine for use in biocidal products of product-types 1, 3, 4 and 22 ('the approval') is to expire on 31 August 2025. On 28 February 2024, two applications were submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of polyvinylpyrrolidone iodine for product-types 1 and 3 ('the applications'), while there was no application submitted for the renewal of the approval of polyvinylpyrrolidone iodine for product-types 4 and 22.
- (3) On 19 April 2024, the evaluating competent authority of Sweden informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the applications 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 use in biocidal products of product-types 1 and 3 for a period of time sufficient to enable the examination of the applications. Taking into account the time-limits for evaluation by the evaluating competent authority, for preparation and submission by the European Chemicals Agency of its opinions and the time needed for the Commission to decide whether to renew the approval, the expiry date for use in biocidal products of product-types 1 and 3 should be postponed to 29 February 2028.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>.

⁽²⁾ Commission Implementing Regulation (EU) No 94/2014 of 31 January 2014 approving iodine, including polyvinylpyrrolidone iodine, as an existing active substance for use in biocidal products for product-types 1, 3, 4 and 22 (OJ L 32, 1.2.2014, p. 23, ELI: http://data.europa.eu/eli/reg_impl/2014/94/oj).

- (7) After the postponement of the expiry date of the approval, polyvinylpyrrolidone iodine remains approved for use in biocidal products of product-types 1 and 3 subject to the conditions set out in the Annex to Implementing Regulation (EU) No 94/2014,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of polyvinylpyrrolidone iodine for use in biocidal products of product-types 1 and 3 set out in the Annex to Implementing Regulation (EU) No 94/2014, is postponed to 29 February 2028.

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, 22 May 2025.

For the Commission
The President
Ursula VON DER LEYEN
