

**COMMISSION IMPLEMENTING DECISION (EU) 2021/354****of 25 February 2021****postponing the expiry date of approval of propiconazole 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 <sup>(1)</sup>, and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) The active substance propiconazole was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council <sup>(2)</sup> 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) On 1 October 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of propiconazole.
- (3) On 8 February 2019, the evaluating competent authority of Finland 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. The evaluating competent authority has requested the applicant to provide sufficient data to carry out the evaluation in accordance with Article 8(2) of that Regulation.
- (4) As the competent authority is carrying out a full evaluation of the application, in accordance with Article 14(3) of Regulation (EU) No 528/2012, 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 within 270 days of receipt of the recommendation from the evaluating competent authority.
- (5) Considering that propiconazole is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council <sup>(3)</sup>, and therefore meets the exclusion criterion set out in point (c) of Article 5(1) of Regulation (EU) No 528/2012, further examination is necessary to decide whether at least one of the conditions of the first subparagraph of Article 5(2) of Regulation (EU) No 528/2012 is fulfilled, and whether the approval of propiconazole may therefore be renewed.
- (6) The expiry date of approval of propiconazole has been postponed to 31 March 2021 by Commission Implementing Decision (EU) 2020/27 <sup>(4)</sup> in order to allow sufficient time for the examination of the application. This examination is still not finalised and the evaluating competent authority has not yet submitted its assessment report and the conclusions of its evaluation to the Agency.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> Commission Implementing Decision (EU) 2020/27 of 13 January 2020 postponing the expiry date of approval of propiconazole for use in biocidal products of product-type 8 (OJ L 8, 14.1.2020, p. 39).

- (7) Consequently, for reasons beyond the control of the applicant, the approval of propiconazole 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 propiconazole for use in biocidal products of product-type 8 for a period of time sufficient to enable the examination of the application.
- (8) Considering the period necessary for the preparation and submission of the opinion by the Agency, the period necessary to assess if at least one of the conditions of the first subparagraph of Article 5(2) of Regulation (EU) No 528/2012 is fulfilled and whether the approval of propiconazole may therefore be renewed, it is appropriate to postpone the expiry date of approval to 31 December 2022.
- (9) Except for the expiry date of approval, propiconazole remains approved for use in biocidal products of product-type 8 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

*Article 1*

The expiry date of approval of propiconazole for use in biocidal products of product-type 8 is postponed to 31 December 2022.

*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, 25 February 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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