COMMISSION IMPLEMENTING DECISION (EU) 2022/2298

of 23 November 2022

postponing the expiry date of the approval of propiconazole 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) Propiconazole 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 until 31 March 2020 under that Regulation subject to the requirements set out in Annex I to Directive 98/8/EC.

(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 propiconazole for use in biocidal products of product-type 8 ('the application').

(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 that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) Commission Implementing Decision (EU) 2020/27 ([3]) postponed the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 to 31 March 2021 in order to allow sufficient time for the examination of the application.

(5) Commission Implementing Decision (EU) 2021/354 ([4]) postponed again the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 to 31 December 2022.

(6) On 2 June 2021, the evaluating competent authority submitted the assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency'). Within 270 days of receipt of a recommendation from the evaluating competent authority, 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) On 9 March 2022, the Agency adopted its opinion ([5]) on renewal of the approval of propiconazole in accordance with Article 14(3) of Regulation (EU) No 528/2012.

([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) 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).

([4]) 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 (OJ L 68, 26.2.2021, p. 219).

([5]) Biocidal Products Committee (BPC) opinion on the application for approval of the active substance: propiconazole, Product type: 8, ECHA/BPC/324/2022, adopted on 9 March 2022.

(8) 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 ([6]), and therefore meets the exclusion criterion set out in point (c) of Article 5(1) of Regulation (EU) No 528/2012. Furthermore, propiconazole is considered as having endocrine disrupting properties that may cause adverse effects in humans, and therefore meets the exclusion criterion set out in point (d) of Article 5(1) of Regulation (EU) No 528/2012. While the examination to decide whether at least one of the conditions of the first subparagraph of Article 5(2) of that Regulation is fulfilled, and whether the approval of propiconazole may therefore be renewed, is ongoing, it will not be possible to complete this examination before the current expiry of approval.

(9) 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 the approval for a period of time sufficient to complete the full procedure of the examination of the application. Taking into account the time needed 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 the time to decide whether to renew the approval of propiconazole for use in biocidal products of product-type 8, the expiry date should be postponed to 31 December 2023.

(10) After the postponement of the expiry date of the approval, propiconazole remains approved for use in biocidal products of product-type 8 subject to the requirements set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of propiconazole for use in biocidal products of product-type 8 set out in Implementing Decision (EU) 2021/354 is postponed to 31 December 2023.

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, 23 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

([6]) 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).