COMMISSION IMPLEMENTING DECISION (EU) 2022/1495

of 8 September 2022

postponing the expiry date of the approval of medetomidine for use in biocidal products of product-type 21 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) Medetomidine was approved as an active substance for use in biocidal products of product-type 21 by Commission Implementing Regulation (EU) 2015/1731 ([2]) subject to the specifications and conditions set out in the Annex to that Regulation.

(2) The approval of medetomidine for use in biocidal products of product-type 21 ('the approval') is to expire on 31 December 2022. On 27 June 2021, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval ('the application').

(3) On 10 December 2021, the evaluating competent authority of Norway 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 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.

(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 a period of time sufficient to enable the examination of the application. Taking into account the time-limits for the evaluation by the evaluating competent authority and for preparation and submission by the European Chemicals Agency of its opinion, and the time needed to decide whether the approval of medetomidine for use in biocidal products for product-type 21 may be renewed, the expiry date should be postponed to 30 June 2025.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Implementing Regulation (EU) 2015/1731 of 28 September 2015 approving medetomidine as an active substance for use in biocidal products for product-type 21 (OJ L 252, 29.9.2015, p. 33).

(7) After the postponement of the expiry date of the approval, medetomidine remains approved for use in biocidal products of product-type 21 subject to the specifications and conditions set out in Implementing Regulation (EU) 2015/1731,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of medetomidine for use in biocidal products of product-type 21 set out in Implementing Regulation (EU) 2015/1731 is postponed to 30 June 2025.

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, 8 September 2022.

For the Commission
The President
Ursula VON DER LEYEN