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COMMISSION IMPLEMENTING DECISION (EU) 2025/1074

of 2 June 2025

not approving ethylene oxide as an existing active substance for use in biocidal products of product-type 2 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 89(1), third subparagraph, thereof,

Whereas:

(1) Annex II to Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes ethylene oxide (EC No: 200-849-9, CAS No: 75-21-8) for product-type 2.

(2) Ethylene oxide has been evaluated for use in biocidal products of product-type 2 (private area and public health area disinfectants and other biocidal products), as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which corresponds to product-type 2 (disinfectants and algaecides not intended for direct application to humans or animals), as described in Annex V to Regulation (EU) No 528/2012. Norway was designated as the rapporteur Member State ('the evaluating competent authority').

(3) On 1 December 2009, an application was submitted to request the inclusion of ethylene oxide for use in biocidal products of product-type 2 ('the application') into Annex I to Directive 98/8/EC. In the application, the applicant submitted a sole representative biocidal product supported for the industrial sterilisation of single-use medical devices before those are placed on the market. In accordance with Article 90(2), first subparagraph, of Regulation (EU) No 528/2012, the evaluating competent authority proceeded with the assessment of the application under that Regulation.

(4) On 5 March 2020, the evaluating competent authority submitted the assessment report on the application together with the conclusions of its evaluation to the European Chemicals Agency ('the Agency). The Agency discussed the assessment report and the conclusions in technical meetings.

(5) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee is to prepare the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of the Agency on 3 December 2020 ([4]), having regard to the conclusions of the evaluating competent authority.

([1]) OJ L 167, 27.6.2012, p. 1., ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1, ELI: http://data.europa.eu/eli/reg_del/2014/1062/oj).
([3]) 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, ELI: http://data.europa.eu/eli/dir/1998/8/oj).
([4]) Biocidal Products Committee Opinion on the application for approval of the active substance: ethylene oxide, Product type: 2, ECHA/BPC/272/2020, adopted on 3 December 2020.

(6) In its opinion, the Agency concludes that ethylene oxide fulfils the criteria set in Article 5(1), points (a), (b) and (c), of Regulation (EU) No 528/2012, and that ethylene oxide in product-type 2 should normally not be approved, unless at least one of the conditions for derogation set in Article 5(2) of that Regulation is met.

(7) After the adoption of the opinion of the Agency, the applicant asked the Commission whether the representative product and use presented in the application fall under the scope provided for in Article 2 of Regulation (EU) No 528/2012, considering Regulation (EU) 2017/745 of the European Parliament and of the Council ([5]).

(8) Regulation (EU) 2017/745 entered into force on 25 April 2017 and most of its provisions applied as of 26 May 2021, bringing modification or clarification of the scope of the Union legislation on medical devices. Ethylene oxide is a substance that is used for sterilisation, as part of the manufacturing process, of medical devices which are afterwards placed on the market in a sterile condition. This use of ethylene oxide is covered by Regulation (EU) 2017/745. Consequently, the representative product included in the application is used for a process that is within the scope of Regulation (EU) 2017/745.

(9) Pursuant to Article 2(2), point (b), of Regulation (EU) No 528/2012, that Regulation is not to apply to biocidal products or treated articles that are within the scope of Council Directives 90/385/EEC ([6]) and 93/42/EEC ([7]), which have been repealed and replaced by Regulation (EU) 2017/745.

(10) Consequently, the representative product included in the application was not within the scope of Regulation (EU) No 528/2012.

(11) On 21 June 2022, the Commission contacted the applicant to inquire as to whether it would be interested in submitting another representative biocidal product for the evaluation of ethylene oxide for use in biocidal products of product-type 2 that would fall within the scope of Regulation (EU) No 528/2012.

(12) On 30 June 2022 and 25 August 2022, the applicant informed the Commission about its interest in other representative biocidal products for the evaluation of ethylene oxide for use in biocidal products of product-type 2 within the scope of Regulation (EU) No 528/2012: (i) for the sterilisation of medicinal products; (ii) for the sterilisation of packaging intended for medicinal products, but without the product itself being present during sterilisation, and (iii) for the sterilisation of 'combination products'. The applicant asked the Commission whether such uses are within the scope of Regulation (EU) No 528/2012.

(13) Medicinal products are regulated by Regulation (EC) No 726/2004 ([8]), Directive 2001/83/EC ([9]) and Regulation (EU) 2019/6 ([10]) of the European Parliament and of the Council ('the Union legislation on medicinal products').

([5]) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj).

([6]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17, ELI: http://data.europa.eu/eli/dir/1990/385/oj).

([7]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1, ELI: http://data.europa.eu/eli/dir/1993/42/oj).

([8]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj).

([9]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/oj).

([10]) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43, ELI: http://data.europa.eu/eli/reg/2019/6/oj).

(14) The Union legislation on medicinal products contains provisions on the manufacturing of medicinal products, and in particular it establishes that the holder of a manufacturing authorisation is to comply with the principles and guidelines of good manufacturing practice, including with respect to the use of ethylene oxide for the sterilisation of certain medicinal products. Consequently, the intended uses of the applicant for ethylene oxide for the sterilisation of medicinal products and for the sterilisation of packaging intended for medicinal products, but without the product itself being present during sterilisation, whenever those activities are performed on a site holding a manufacturing authorisation in accordance with Article 40 of Directive 2001/83/EC and Article 88 of Regulation (EU) 2019/6, are covered by the scope of the Union legislation on medicinal products.

(15) In accordance with Article 2(2), point (c), of Regulation (EU) No 528/2012, that Regulation is not to apply to biocidal products or treated articles that are within the scope of Regulation (EC) No 726/2004, Directive 2001/83/EC, and Directive 2001/82/EC which has been repealed and replaced by Regulation (EU) 2019/6.

(16) Consequently, the intended uses of the applicant for ethylene oxide for the sterilisation of medicinal products and for the sterilisation of packaging intended for medicinal products, but without the product itself being present during sterilisation, are not within the scope of Regulation (EU) No 528/2012.

(17) As regards the use of ethylene oxide for the sterilisation of 'combination products', which contain elements specified in both Regulation (EU) 2017/745 and the Union legislation on medicinal products, Article 1(8) and (9) of Regulation (EU) 2017/745 set out the circumstances in which a product that combines a medical device and a medicinal product falls within the scope of Regulation (EU) 2017/745 or within the scope of the Union legislation on medicinal products.

(18) Consequently, the intended use of the applicant for ethylene oxide for the sterilisation of 'combination products' is not within the scope of Regulation (EU) No 528/2012.

(19) In conclusion, pursuant to Article 2(2), points (b) and (c), of Regulation (EU) No 528/2012, the use of ethylene oxide included in the application and the additional uses intended to be supported by the applicant for use in biocidal products of product-type 2 are not within the scope of Regulation (EU) No 528/2012, but they are considered within the scope of the Union legislation on medicinal products or Regulation (EU) 2017/745.

(20) Since no use of ethylene oxide supported or intended to be supported by the applicant is within the scope of Regulation (EU) No 528/2012, it is appropriate to not approve ethylene oxide as an active substance for use in biocidal products of product-type 2.

(21) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Ethylene oxide (EC No: 200-849-9, CAS No: 75-21-8) is not approved as an active substance for use in biocidal products of product-type 2.

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, 2 June 2025.

For the Commission
The President
Ursula VON DER LEYEN