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COMMISSION IMPLEMENTING DECISION (EU) 2025/495

of 17 March 2025

concerning the extension of the action taken by the Belgian Federal Public Service Health, Food Chain Safety and Environment permitting the making available on the market and use of the biocidal product Interox SG 35 Plus in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Only the Dutch and French texts are authentic)

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 55(1), third subparagraph, thereof,

Whereas:

(1) On 30 April 2024, the Belgian Federal Public Service Health, Food Chain Safety and Environment ('the Belgian competent authority') adopted, in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012, a decision to permit until 27 October 2024 the making available on the market for, and use of the biocidal product Interox SG 35 Plus for the disinfection of the isolators at Ghent University Hospital (UZ Ghent) ('the action'). The Belgian competent authority informed the Commission and the competent authorities of the other Member States of the action and the justification for it in accordance with Article 55(1), second subparagraph, of that Regulation.

(2) According to the information provided by the Belgian competent authority, the action was necessary in order to protect public health. The biocidal product Interox SG 35 Plus is used for the disinfection of the isolators at UZ Ghent. The operation of hospital isolators requires biocidal products for the disinfection of their internal surfaces and their disinfection must be validated by the supplier of the isolators. The disinfection of the isolators is needed in order to ensure the preparation of sterile, therefore safe, end products for patients.

(3) The validated disinfection method for the isolators in place at UZ Ghent implies the use of the biocidal product Interox SG 35 Plus by automated vaporisation. The availability of Interox SG 35 Plus is therefore necessary to enable the operation of the isolators and the continued delivery of essential care adapted to the needs of patients. Discontinuing the use of Interox SG 35 Plus for the validated disinfection of the isolators would mean that isolators would have to be disinfected manually. Manual disinfection entails a significantly increased risk for patients due to potential non-sterile preparations and – given the role of UZ Ghent as tertiary care hospital – for public health.

(4) The biocidal product Interox SG 35 Plus contains hydrogen peroxide as an active substance and is applied by automated vaporisation for the disinfection of the internal surfaces of the isolators. A Union authorisation for Interox SG 35 Plus has been granted, as part of the biocidal product family 'Interox Biocidal Product Family 1' ([2]). However, the product is authorised for disinfection of enclosures of at least 15 m^3, while the volume of the isolators at UZ Ghent is 1,5 m^3. The temporary permit granted by the Belgian competent authority allows the use of the Interox SG 35 Plus under different conditions than those included in the authorisation.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) Commission Implementing Regulation (EU) 2022/1232 of 13 July 2022 granting a Union authorisation for the biocidal product family 'INTEROX Biocidal Product Family 1' (OJ L 190, 19.7.2022, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2022/1232/oj).

(5) On 21 October 2024, the Commission received a reasoned request from the Belgian competent authority to allow the extension of the action in accordance with Article 55(1), third subparagraph, of Regulation (EU) No 528/2012. The reasoned request included the same information provided already when the action was taken and was based on concerns that the discontinued use of Interox SG 35 Plus, in the absence of validated alternatives to be used in the isolators at UZ Ghent, would constitute a threat to public health, given that the delivery of essential sterile products adapted to the needs of patients would no longer be ensured. The Commission analysed the information included in the reasoned request, as outlined above.

(6) The Belgian competent authority advised UZ Ghent to contact the holder of the Union authorisation for Interox SG 35 Plus and request them to apply for a change concerning the instructions for use, which include the volume of the enclosure to be disinfected. Such change, if authorised, would constitute a permanent solution for the future use of the product at UZ Ghent.

(7) The lack of proper disinfection of the isolators at UZ Ghent might endanger public health and that danger cannot be adequately contained by using another biocidal product or by other means. It is therefore appropriate to allow the Belgian competent authority to extend the action for a period of 550 days.

(8) As the action expired on 27 October 2024, this Decision should apply retroactively.

(9) 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

The Belgian Federal Public Service Health, Food Chain Safety and Environment may extend until 1 May 2026 the action to permit the making available on the market and use of the biocidal product Interox SG 35 Plus for the disinfection of the isolators at Ghent University Hospital provided that it ensures that the product is only used under its supervision.

Article 2

This Decision is addressed to the Belgian Federal Public Service Health, Food Chain Safety and Environment.

It shall apply from 28 October 2024.

Done at Brussels, 17 March 2025.

For the Commission
Olivér VÁRHELYI
Member of the Commission