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COMMISSION IMPLEMENTING DECISION (EU) 2024/1284

of 13 May 2024

concerning the extension of the action taken by the Environment Agency of Luxembourg permitting the making available on the market and use of the biocidal product Raidox 35% in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Only the French text is 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 25 August 2023, the Environment Agency of Luxembourg ('the competent authority of Luxembourg') adopted, in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012, a decision to permit until 21 February 2024 the making available on the market and use, in the isolator of the hospital 'Centre hospitalier de Luxembourg', of the biocidal product Raidox 35% ('the action'). The competent authority of Luxembourg 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 competent authority of Luxembourg, the action was necessary in order to protect public health. The biocidal product Raidox 35% is used for the disinfection of internal surfaces of the isolator in the Centre hospitalier de Luxembourg.

(3) Aseptic preparation of injectables in hospitals require sterile manufacturing processes which are carried out in safety cabinets or isolators. As indicated by the competent authority of Luxembourg, the previously existing installation in Centre hospitalier de Luxembourg (safety cabinet) became obsolete and was replaced by an isolator. The operation of isolators requires the use of biocidal products for the disinfection of internal surfaces of the isolator. The complete installation – isolator, biocidal product, vaporisation device used for the disinfection – is supplied as a package and requires a complex validation process. According to the supplier of the isolator, Raidox 35% is the only biocidal product that has been validated by the installation manufacturer for the disinfection of the isolator. As indicated by the competent authority of Luxembourg, the availability of Raidox 35% is therefore necessary to enable the operation of the isolator and the continued delivery of essential care adapted to the needs of patients. The possibility to replace Raidox 35% with another biocidal product is currently being investigated by the supplier of the isolator. The required validation of biocidal product/vaporisation device and subsequent validation on-site will still require some time.

(4) Raidox 35% is a biocidal product of product-type 2 ('disinfectants and algaecides not intended for direct application to humans or animals'), as defined in Annex V to Regulation (EU) No 528/2012. Raidox 35% contains hydrogen peroxide as an active substance and is applied by vaporisation for the disinfection of internal surfaces of isolators used in hospitals. Hydrogen peroxide is approved for use in products of product-type 2 and an application for Union authorisation of Raidox 35% is currently under evaluation.

[1] OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

(5) On 1 February 2024, the Commission received a reasoned request from the competent authority of Luxembourg 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 Raidox 35%, in the absence of alternatives to be used in the isolator at Centre hospitalier de Luxembourg, would constitute a threat to public health, given that the delivery of essential care to patients would no longer be ensured. The Commission analysed the information included in the reasoned request, as outlined above.

(6) The lack of proper disinfection of the isolator at Centre hospitalier de Luxembourg 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 competent authority of Luxembourg to extend the action for a period of 550 days.

(7) Since the action expired on 21 February 2024, this Decision should apply retroactively.

(8) 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 Environment Agency of Luxembourg may extend until 25 August 2025 the action to permit the making available on the market and use of the biocidal product Raidox 35% for the disinfection of internal surfaces of the isolator at Centre hospitalier de Luxembourg, provided that it ensures that the product is only used under its supervision.

Article 2

This Decision is addressed to the Environment Agency of Luxembourg.

It shall apply from 22 February 2024.

Done at Brussels, 13 May 2024.

For the Commission
Stella KYRIAKIDES
Member of the Commission