DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/762

of 6 May 2021

concerning the extension of the action taken by the Irish Department of Agriculture, Food and the Marine permitting the making available on the market and use of biocidal products containing propan-2-ol for use as human hygiene products in accordance with Article 55(1) of Regulation (EU)

No 528/2012 of the European Parliament and of the Council

(notified under document C(2021) 3127)

(Only the English 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 the third subparagraph of Article 55(1) thereof,

Whereas:

- (1) On 18 September 2020, the Irish Department of Agriculture, Food and the Marine ('the competent authority') adopted a decision in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012 to permit the making available on the market and use of biocidal products containing propan-2-ol for use as human hygiene products until 16 March 2021 ('the action'). The competent authority informed the Commission and the competent authorities of the other Member States about 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, the action was necessary in order to protect public health. The use of alcohol-based hand disinfectants has been recommended by the World Health Organization (WHO) as a preventative measure against the spread of COVID-19, as an alternative to washing hands with soap and water.
- (3) Propan-2-ol-based formulation recommended by WHO contains propan-2-ol as an active substance. Propan-2-ol is approved for use in biocidal products of product-type 1 (human hygiene) as defined in Annex V to Regulation (EU) No 528/2012.
- (4) Since the outbreak of the COVID-19 pandemic disinfection products have been in extremely high demand in Ireland, which led to unprecedented supply shortages of such products on the Irish market. COVID-19 represents a serious threat to public health in Ireland and having sufficient disinfection products is crucial for controlling its spread.
- (5) According to the conditions in the action, companies intending to make available on the market such products need to submit specific information on the products to the competent authority, which will decide whether to grant permission to make the products available on the market.
- (6) On 5 February 2021, the Commission received a reasoned request from the competent authority to be allowed to extend the action in accordance with Article 55(1), third subparagraph, of Regulation (EU) No 528/2012. The request was made on the basis of concerns that public health might be endangered by COVID-19 beyond 16 March 2021 and taking into account that allowing additional disinfection products on the market is crucial in order to limit the danger posed by COVID-19.

- (7) According to the competent authority, the demand for disinfection products for human hygiene remains extremely high due to the continued incidence of COVID-19 in Ireland.
- (8) The competent authority has encouraged all companies that made their products available on the market under the action to seek regular product authorisation as soon as possible, in order to minimise gaps in marketing of the products. Some companies applied for national authorisation of their products. However, a considerable amount of time is needed for the evaluation of the applications.
- (9) As COVID-19 continues to pose a danger to public health and such danger cannot be adequately contained in Ireland in the absence of additional disinfection products allowed on the market, it is appropriate to allow the competent authority to extend the action.
- (10) Considering that the action has lapsed since 17 March 2021, this Decision should have retroactive effect.
- (11) 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 Irish Department of Agriculture, Food and the Marine may extend the permit for the making available on the market and use of biocidal products containing propan-2-ol for use as human hygiene products until 18 September 2022.

Article 2

This Decision is addressed to the Irish Department of Agriculture, Food and the Marine.

It shall apply from 17 March 2021.

Done at Brussels, 6 May 2021.

For the Commission Stella KYRIAKIDES Member of the Commission