COMMISSION IMPLEMENTING DECISION (EU) 2021/740

of 4 May 2021

concerning the extension of the action taken by the United Kingdom Health and Safety Executive permitting the making available on the market and use of the biocidal product Isopropanol Solution 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) 3037)

(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 Article 55(1), third subparagraph, thereof, in conjunction with Article 131 of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community,

Whereas:

(1) On 26 June 2020, the United Kingdom Health and Safety Executive ('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 the biocidal product Isopropanol Solution, until 23 December 2020 ('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. On 11 March 2020, the World Health Organisation (WHO) declared that the outbreak of the coronavirus disease (COVID-19) could be characterised as a pandemic. The United Kingdom Government declared the risk to the United Kingdom as 'high' and on 23 March 2020 restrictive measures came into effect. The use of alcohol-based hand disinfectants is recommended by the WHO as a preventive measure against the spread of COVID-19, as an alternative to washing hands with soap and water.

(3) Isopropanol Solution 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 hand disinfectants have been in extremely high demand in the United Kingdom, which led to unprecedented supply shortages of such products. Prior to the action, there were very few hand disinfectants authorised in the United Kingdom under Regulation (EU) No 528/2012. COVID-19 represents a serious threat to public health in the United Kingdom and additional hand disinfectants are crucial for the control of its spread.

(5) On 9 December 2020, the Commission received a reasoned request from the competent authority to extend the action in accordance with Article 55(1), third subparagraph, of Regulation (EU) No 528/2012. The reasoned request was made on the basis of concerns that public health might be endangered by COVID-19 beyond 23 December 2020 and taking into account that allowing additional hand disinfectants on the market is crucial in order to contain the danger posed by COVID-19.

(6) The infection rate has been increasing in the United Kingdom and, according to the competent authority, a further increase in the demand of hand disinfectants is expected. The extension of the action is necessary in view of the expected increase in the demand.

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

(7) The competent authority has encouraged companies that received derogations for hand disinfectants after 11 March 2020 to seek regular product authorisation as soon as possible. However, no new applications for regular product authorisation have been received by the competent authority to date.

(8) As COVID-19 continues to pose a danger to public health and the fact that such danger cannot be adequately contained in the United Kingdom, in the absence of additional hand disinfectants allowed on the market, it is appropriate to allow the competent authority to extend the action.

(9) Taking into account the end of the transition period referred to in Article 126 of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (the Withdrawal Agreement), this Decision should apply until 31 December 2020. As regards the United Kingdom in respect of Northern Ireland, however, Union law continues to apply beyond the transition period in accordance with Article 5(4) of the Protocol on Ireland/Northern Ireland to the Withdrawal Agreement. Considering that the action expired on 23 December 2020, this Decision should have retroactive effect.

(10) 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 United Kingdom Health and Safety Executive may extend the action to permit the making available on the market and use of the biocidal product Isopropanol Solution until 31 December 2020.

For the United Kingdom in respect of Northern Ireland, however, it may extend the action until 27 June 2022.

Article 2

This Decision is addressed to the United Kingdom Health and Safety Executive.

It shall apply from 24 December 2020.

Done at Brussels, 4 May 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission