DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2022/137

of 28 January 2022

concerning the extension of the action taken by the Health and Safety Executive of the United Kingdom permitting the making available on the market and use of the biocidal product Mydis in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2022) 408)

(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 5(4) of the Protocol on Ireland/Northern Ireland to 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 11 March 2021, the Health and Safety Executive of the United Kingdom acting on behalf of the Health and Safety Executive for Northern Ireland ('the UK 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 in Northern Ireland of the biocidal product for hand disinfection Mydis, until 21 August 2021 ('the action'). The UK competent authority informed the Commission and the competent authorities of the 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 UK competent authority, the action was necessary in order to protect public health. On 11 March 2020, the World Health Organization (WHO) declared that the outbreak of the coronavirus disease (COVID-19) could henceforth be characterised as a pandemic. The Government of the United Kingdom 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) Mydis contains active chlorine released from hypochlorous acid as an active substance. Active chlorine released from hypochlorous acid is approved for use in biocidal products of product-type 1, namely 'human hygiene', as defined in Annex V to Regulation (EU) No 528/2012.

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

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

(5) On 17 August 2021, the Commission received a reasoned request from the UK competent authority to allow the extension of the action in the United Kingdom in respect of Northern Ireland, 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 21 August 2021 and taking into account that allowing additional hand disinfectants on the market is crucial in order to contain the dangers posed by COVID-19.

(6) According to the UK competent authority, the demand for hand sanitisers remains high, therefore an extension of the action in the United Kingdom in respect of Northern Ireland is needed.

(7) Companies that have received derogations for hand disinfectants in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012 after the WHO declaration on the pandemic have been encouraged to seek regular product authorisation as soon as possible. However, no new applications for regular product authorisation have been received by the UK competent authority to date.

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

(9) Considering that the action expired on 21 August 2021, 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 Health and Safety Executive of the United Kingdom, acting on behalf of the Health and Safety Executive for Northern Ireland, may extend until 23 February 2023 the action to permit the making available on the market and use of the biocidal product Mydis, in the United Kingdom in respect of Northern Ireland.

Article 2

This Decision is addressed to the Health and Safety Executive of the United Kingdom, acting on behalf of the Health and Safety Executive for Northern Ireland.

It shall apply from 22 August 2021.

Done at Brussels, 28 January 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission