II

(Non-legislative acts)

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/1689

of 17 September 2021

concerning the extension of the action taken by the Bulgarian Ministry of Health permitting the making available on the market and use of the biocidal products Ecolab P3-Topax 66/Еколаб P3-Топакс 66 and Ecolab BACFORCE EL 900/Еколаб БАКФОРС EL 900 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)6693)

(Only the Bulgarian 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 16 December 2020, the Bulgarian Ministry of Health ('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 products Ecolab P3-Topax 66/Еколаб P3-Топакс 66 and Ecolab BACFORCE EL 900/Еколаб БАКФОРС EL 900 as surface disinfection products until 14 June 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. On 11 March 2020, the World Health Organization declared a pandemic of the coronavirus disease (COVID-19). The use of surface disinfection products with proven virucidal activity for the disinfection of public facilities and work places was recommended by the competent authority as a preventive measure against the spread of COVID-19.

(3) Ecolab P3-Topax 66/Еколаб P3-Топакс 66 and Ecolab BACFORCE EL 900/Еколаб БАКФОРС EL 900 contain active chlorine released from sodium hypochlorite as an active substance. Active chlorine released from sodium hypochlorite is approved for use in surface disinfection biocidal products of product-type 2 (disinfectants and algaecides not intended for direct application to humans or animals) and product-type 4 (food and feed area) as defined in Annex V to Regulation (EU) No 528/2012.

(4) Ecolab P3-Topax 66/Еколаб P3-Топакс 66 and Ecolab BACFORCE EL 900/Еколаб БАКФОРС EL 900 have a proven virucidal activity against enveloped viruses according to European Standard EN 14476.

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

(5) Since the outbreak of the COVID-19, pandemic disinfection products have been in very high demand in Bulgaria, which led to unprecedented supply shortages of such products on the Bulgarian market. COVID-19 represents a serious threat to public health in Bulgaria and having sufficient disinfection products is crucial for controlling its spread.

(6) On 11 May 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 14 June 2021 and taking into account that allowing additional disinfection products on the market was crucial in order to limit the danger posed by COVID-19.

(7) According to the competent authority, COVID-19 continues to represent a danger to public health and this danger cannot yet be adequately addressed in Bulgaria, despite the measures requiring the wearing of face masks, physical distance and vaccination against COVID-19, in conditions of limited supply of vaccines.

(8) Moreover, according to the competent authority, allowing additional disinfection products on the market would also permit to maintain a diversified market for disinfection products in order to minimise risks deriving from a potential shortage of such products.

(9) As COVID-19 continues to pose a danger to public health and such danger cannot be adequately contained in Bulgaria 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 expired on 14 June 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 Bulgarian Ministry of Health may extend the permit for the making available on the market and use of the biocidal products Ecolab P3-Topax 66/Еколаб P3-Топакс 66 and Ecolab BACFORCE EL 900/Еколаб БАКФОРС EL 900 for use as surface disinfection products until 17 December 2022.

Article 2

This Decision is addressed to the Bulgarian Ministry of Health.

It shall apply from 15 June 2021.

Done at Brussels, 17 September 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission