

COMMISSION IMPLEMENTING DECISION (EU) 2021/106**of 28 January 2021****concerning the extension of the action taken by the French Ministry for the Ecological Transition permitting the making available on the market and use of disinfection products containing propan-2-ol 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) 380)***(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 the third subparagraph of Article 55(1) thereof,

Whereas:

- (1) On 13 March 2020, the French Ministry for the Ecological Transition ('the competent authority') adopted, in accordance with the first subparagraph of Article 55(1) of Regulation (EU) No 528/2012, a decision (subsequently amended on 29 June 2020) to permit the making available on the market and use of disinfection products containing propan-2-ol for human hygiene (product-type 1 as defined in Annex V to Regulation (EU) No 528/2012), for a period lasting until 31 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 the second subparagraph of Article 55(1) 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 a coronavirus disease (COVID-19) pandemic. On 22 March 2020, the French parliament adopted a law declaring a public health emergency. The use of alcohol-based hand disinfectants is recommended by the WHO and by the French Ministry for Health as a preventive measure against the spread of COVID-19 disease, as alternative to washing hands with soap and water. The product formulation covered by the action is in line with the propan-2-ol-based formulation recommended by WHO.
- (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 France, which led to unprecedented supply shortages of such products. Prior to the action there were no hand disinfectants authorised in France under Regulation (EU) No 528/2012. COVID-19 represents a serious threat to public health in France and additional disinfection products are crucial for the control of its spread, considering that washing hands with soap and water is not always possible.
- (5) On 10 September 2020, the Commission received a reasoned request from the competent authority to extend the action in accordance with the third subparagraph of Article 55(1) 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 31 December 2020 and taking into account that allowing additional disinfection products on the market is crucial in order to contain the danger posed by COVID-19, which cannot be contained by other means.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

- (6) According to the competent authority, a further increase in the demand of disinfection products is expected. Despite the existence of alternatives based on ethanol, the competent authority considers it necessary to maintain a diversified offer of disinfectant products on the market, in order to minimise the risk posed by potential raw material shortages.
- (7) The competent authority has encouraged operators that benefitted from the action to seek regular product authorisation as soon as possible. One operator confirmed its intention to apply for regular authorisation of its propan-2-ol-based disinfectant.
- (8) As COVID-19 continues to pose a danger to public health and such danger cannot be adequately contained in France in the absence of additional disinfection products allowed on the market, it is appropriate to allow the competent authority to extend the action for a period not exceeding 550 days starting from the day following the expiry of the initial period of 180 days from the decision of the competent authority of 13 March 2020.
- (9) 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 French Ministry for the Ecological Transition may extend the action to permit for the making available on the market and use of disinfection products containing propan-2-ol for human hygiene until 13 March 2022.

Article 2

This Decision is addressed to the French Ministry for the Ecological Transition.

Done at Brussels, 28 January 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission
