COMMISSION IMPLEMENTING DECISION (EU) 2021/2165

of 3 December 2021

concerning the extension of the action taken by the Ministry of Health of the Czech Republic permitting the making available on the market and use of the biocidal product Biobor JF 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) 8684)

(Only the Czech 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 15 April 2021, the Ministry of Health of the Czech Republic ('the competent authority') adopted a decision to permit, in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012, the making available on the market for, and use by, professional users of the biocidal product Biobor JF for the antimicrobial treatment of aircraft fuel tanks and fuel systems until 12 October 2021 ('the action'). The competent authority informed the Commission and the competent authorities of the other 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 competent authority, the action was necessary in order to protect public health, as the microbiological contamination of aircraft fuel tanks and fuel systems can lead to malfunctions of the aircraft engine and endanger its airworthiness, thereby putting at risk the safety of passengers and crew. The COVID-19 pandemic and the ensuing flight restrictions have led to numerous aircraft being temporarily parked. The immobility of aircraft is an aggravating factor in microbiological contamination.

(3) Biobor JF contains 2,2'-(1-methyltrimethylenedioxy)bis-(4-methyl-1,3,2-dioxaborinane) (CAS number 2665-13-6) and 2,2'-oxybis (4,4,6-trimethyl-1,3,2-dioxaborinane) (CAS number 14697-50-8), which are active substances for use in biocidal products of product-type 6 as 'preservatives for products during storage', as defined in Annex V to Regulation (EU) No 528/2012. As those active substances are not listed in Annex II to Commission Delegated Regulation (EU) No 1062/2014 [2], they are not included in the work programme for the systematic examination of all existing active substances contained in biocidal products, referred to in Regulation (EU) No 528/2012. Article 89 of that Regulation therefore does not apply to those active substances and they have to be assessed and approved before biocidal products containing them can be authorised also at national level.

(4) On 7 July 2021, the Commission received a reasoned request from the competent authority to allow the extension of 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 air transport safety might continue to be endangered by microbiological contamination of aircraft fuel tanks and fuel systems after 12 October 2021 and the claim that Biobor JF is essential in order to control such microbiological contamination.

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

[2] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

(5) According to the information provided by the competent authority, the only alternative biocidal product recommended by aircraft and engine manufacturers for the treatment of microbiological contamination (Kathon™ FP 1.5) was withdrawn from the market in March 2020 due to severe engine behaviour anomalies that were noticed after the treatment with that product.

(6) As indicated by the competent authority, there are no alternatives to the treatment of microbiological contamination of aircraft fuel tanks and fuel systems with Biobor JF.

(7) According to the information available to the Commission, the manufacturer of Biobor JF has taken steps towards the regular authorisation of the product. It also appears that an application for approval of the active substances that Biobor JF contains is expected to be submitted by mid-2022. The approval of the active substances and subsequent authorisation of the biocidal product would constitute a permanent solution for the future, but a significant amount of time would be needed for the completion of those procedures.

(8) The lack of control of microbiological contamination of aircraft fuel tanks and fuel systems might endanger the air transport safety and that danger cannot be adequately contained by using another biocidal product or by other means. It is therefore appropriate to allow the competent authority to extend the action.

(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 Ministry of Health of the Czech Republic may extend until 16 April 2023 the action to permit the making available on the market for, and use by, professional users of the biocidal product Biobor JF for the antimicrobial treatment of aircraft fuel tanks and fuel systems.

Article 2

This Decision is addressed to the Ministry of Health of the Czech Republic.

Done at Brussels, 3 December 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission