

COMMISSION IMPLEMENTING DECISION (EU) 2021/1315**of 6 August 2021**

concerning the extension of the action taken by the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products 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) 5821)

(Only the Polish 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 6 November 2020, the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products ('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 preventive and curative antimicrobial treatment of aircraft fuel tanks and fuel systems until 5 May 2021 ('the action'). The competent authority informed the Commission and the competent authorities of the other Member States of its 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, thus putting at risk the safety of passengers and crew. The COVID-19 pandemic and the ensuing flight restrictions led to numerous aircraft being temporarily parked. The immobility of aircraft is an aggravating factor of 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), 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 them and they have to be assessed and approved before biocidal products containing them can be authorised also at national level.
- (4) On 8 March 2021, the Commission received a reasoned request from the competent authority to allow the extension of the action in accordance with the 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 5 May 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 anomalies noticed after the treatment with that product.
- (6) As indicated by the competent authority, the alternative procedure for treating an existing microbiological contamination is manual removal in-tank, following defueling and purging of the aircraft. Manual removal may however not always be possible alongside other maintenance actions that are required when an aircraft is parked or stored for long periods. Moreover, the manual cleaning of contaminated tanks would expose workers to toxic gases and should therefore be avoided.
- (7) According to the information available to the Commission, the manufacturer of Biobor JF has taken steps towards the regular authorisation of the product and an application for approval of the active substances it contains is expected to be submitted in 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) Considering that the action expired on 5 May 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 Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products may extend the action to permit the making available on the market for, and use by, professional users of the biocidal product Biobor JF for the preventive and curative antimicrobial treatment of aircraft fuel tanks and fuel systems until 6 November 2022.

Article 2

This Decision is addressed to the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

It shall apply from 6 May 2021.

Done at Brussels, 6 August 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission
