EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of XXX

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 Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Only the Polish text is authentic)

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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 13 March 2023, the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products ('the Polish competent authority') adopted, in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012, a decision to permit until 9 September 2023, 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 ('the action'). The Polish 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 Polish competent authority, the action was necessary in order to protect public health. Microbiological contamination of aircraft fuel tanks and fuel systems is caused by micro-organisms, such as bacteria, mould and yeast, that grow in the stagnant water and feed off the hydrocarbons in the fuel at the fuel-to-water interface. If left untreated, the microbiological contamination of aircraft fuel tanks and fuel systems can lead to malfunctions of the aircraft engine and endanger its airworthiness, thus endangering the safety of passengers and crew. The prevention of microbiological contamination and, when such contamination is detected, its treatment are therefore crucial in order to avoid operational problems in aircraft.

(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) as active substances. Biobor JF is a biocidal product of product-type 6 ('preservatives for products during storage'), as defined in Annex V to Regulation (EU) No 528/2012. 2,2'-(1-methyltrimethylenedioxy)bis-(4-methyl-1,3,2-dioxaborinane) and 2,2'-oxybis (4,4,6-trimethyl-1,3,2-dioxaborinane) have not been evaluated for use in biocidal products of

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

product-type 6. As those substances are not listed among the substance/product-type combinations included in the review programme on 17 March 2022, as set out 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 Regulation (EU) No 528/2012 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 June 2023, the Commission received a reasoned request from the Polish 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 based on concerns that air transport safety might continue to be endangered by microbiological contamination of aircraft fuel tanks and fuel systems and on the argument that Biobor JF is essential in order to control such microbiological contamination.

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

(6) As indicated by the Polish competent authority, the mechanical treatment of microbiological contamination of aircraft fuel tanks and fuel systems is not always possible and the procedures recommended by engine manufacturers require the treatment with a biocidal product even when mechanical cleaning is possible. Moreover, mechanical treatment would expose workers to toxic gases and should therefore be avoided.

(7) According to the information provided to the Commission, the manufacturer of Biobor JF has taken steps towards an authorisation of the product. An application for approval of the active substances that Biobor JF contains is expected to be submitted in the first half of 2024. The approval of the active substances and the 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 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 Polish competent authority to extend the action.

(9) Since the action expired on 9 September 2023, this Decision should apply retroactively.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

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[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).

HAS ADOPTED THIS DECISION:

Article 1

The Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products may extend until 13 March 2025 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 Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

It shall apply from 10 September 2023.

Done at Brussels,

For the Commission
Stella KYRIAKIDES
Member of the Commission