COMMISSION IMPLEMENTING DECISION (EU) 2022/2386

of 5 December 2022

concerning the extension of the actions 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

(notified under document C(2022) 8673)

(Only the English, Estonian, Finnish, French, German, Hungarian, Maltese, Spanish and Swedish texts are 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 31 March 2022, the French Ministry of Ecological Transition ('the French 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 for, and use by, professional users of the biocidal product Biobor JF for antimicrobial treatment of aircraft fuel tanks and fuel systems until 31 October 2022 ('the action'). The French 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) Similar actions, concerning permits granted until 31 October 2022, were taken in 7 other Member States, as follows: on 5 May 2022 by the Hungarian National Public Health Centre ('the Hungarian competent authority'), on 6 May 2022 by the Environment Agency of Luxembourg ('the Luxembourgish competent authority'), on 8 May 2022 by the Finnish Safety and Chemicals Agency ('the Finnish competent authority'), on 15 May 2022 by Malta Competition and Consumer Affairs Authority ('the Maltese competent authority'), on 21 June 2022 by the Estonian Health Board ('the Estonian competent authority'), on 1 July 2022 by the Spanish Ministry of Health ('the Spanish competent authority'), and on 25 July 2022 by the Federal Austrian Ministry of Climate Action, Environment, Energy, Mobility, Innovation and Technology ('the Austrian competent authority'). The competent authorities of those Member States informed the Commission and the competent authorities of the other Member States of the actions and the justifications for them, in accordance with Article 55(1), second subparagraph, of Regulation (EU) No 528/2012.

(3) According to the information provided by those competent authorities, the actions were necessary in order to protect public health. Microbiological growth can develop in aircraft fuel tanks, especially at the water-fuel interface, where microbiological organisms can use water for oxygen and fuel for nutrition. 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 prevention and treatment of microbiological contamination, when detected, are therefore crucial in order to avoid operational problems of aircraft.

(4) 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, namely 'preservative 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 product-type 6. As

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

those 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.

(5) On 23 May 2022, the Commission received a reasoned request from the French competent authority to allow the extension of its action in accordance with Article 55(1), third subparagraph, of Regulation (EU) No 528/2012. Similar requests were received on 27 July 2022 from the Austrian competent authority, on 24 August 2022 from the Estonian competent authority, on 25 August 2022 from the Spanish competent authority, on 29 August 2022 from the Finnish competent authority, on 9 September 2022 from the Luxembourgish competent authority, on 31 August 2022 from the Maltese competent authority and on 20 September 2022 from the Hungarian competent authority. Those reasoned requests were 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 31 October 2022 and the claim that Biobor JF is essential in order to control such microbiological contamination.

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

(7) As indicated by the concerned competent authorities, the mechanical treatment of microbiological contamination of aircraft fuel tanks and fuel systems is not always possible and 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.

(8) According to the information provided to the Commission, the manufacturer of Biobor JF has taken steps towards a future regular authorisation of the product. An application for approval of the active substances that Biobor JF contains is expected to be submitted in mid-2023. 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.

(9) 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 authorities concerned to extend their actions.

(10) As the actions expired on 31 October 2022, this Decision should apply retroactively.

(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 Estonian Health Board, the Spanish Ministry of Health, the French Ministry of Ecological Transition, the Environment Agency of Luxembourg, the Hungarian National Public Health Centre, Malta Competition and Consumer Affairs Authority, the Federal Austrian Ministry of Climate Action, Environment, Energy, Mobility, Innovation and Technology and the Finnish Safety and Chemicals Agency may extend until 4 May 2024 the actions to permit the making available on the market for, and use by, professional users of the biocidal product Biobor JF for antimicrobial treatment of aircraft fuel tanks and fuel systems.

([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).

Article 2

This Decision is addressed to:

(1) the Estonian Health Board;

(2) the Spanish Ministry of Health;

(3) the French Ministry of Ecological Transition;

(4) the Environment Agency of Luxembourg;

(5) the Hungarian National Public Health Centre;

(6) Malta Competition and Consumer Affairs Authority;

(7) the Federal Austrian Ministry of Climate Action, Environment, Energy, Mobility, Innovation and Technology;

(8) the Finnish Safety and Chemicals Agency.

It shall apply from 1 November 2022.

Done at Brussels, 5 December 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission