COMMISSION IMPLEMENTING DECISION (EU) 2022/2378

of 2 December 2022

concerning the extension of the action taken by the Health and Safety Executive of the United Kingdom 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) 8678)

(Only the English 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, in conjunction with Article 5(4) of the Protocol on Ireland/Northern Ireland to the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community,

Whereas:

(1) On 28 April 2022, the Health and Safety Executive of the United Kingdom acting on behalf of the Health and Safety Executive for Northern Ireland ('the UK competent authority') adopted a decision in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012 to permit until 29 October 2022 the making available on the market and use of the biocidal product Biobor JF for antimicrobial treatment of aircraft fuel tanks and fuel systems in the United Kingdom in respect of Northern Ireland ('the action'). The UK 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 Article 55(1), second subparagraph, of that Regulation.

(2) According to the information provided by the UK 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 settled 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 and treatment of microbiological contamination, when detected, are therefore crucial in order to avoid operational problems of 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, 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 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.

([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).

(4) On 5 August 2022, the Commission received a reasoned request from the UK competent authority to allow the extension of the action in the United Kingdom in respect of Northern Ireland, 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 and the argument that Biobor JF is essential in order to control such microbiological contamination.

(5) According to the information provided by the UK competent authority 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.

(6) As indicated by the UK competent authority, the alternative procedure for treating an existing microbiological contamination is manual removal in-tank, following defueling and purging of the aircraft. However, that procedure may not always be possible to perform and would expose workers to toxic gases and therefore, it should be avoided.

(7) 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.

(8) As 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 appropriate to allow the UK competent authority to extend the action in the United Kingdom in respect of Northern Ireland.

(9) As the action expired on 29 October 2022, 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,

HAS ADOPTED THIS DECISION:

Article 1

The Health and Safety Executive of the United Kingdom, acting on behalf of the Health and Safety Executive for Northern Ireland, may extend until 2 May 2024 the permit for the making available on the market and use of the biocidal product Biobor JF for antimicrobial treatment of aircraft fuel tanks and fuel systems, in the United Kingdom in respect of Northern Ireland.

Article 2

This Decision is addressed to the Health and Safety Executive of the United Kingdom, acting on behalf of the Health and Safety Executive for Northern Ireland.

It shall apply from 30 October 2022.

Done at Brussels, 2 December 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission