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Ministry of Health

DEPARTMENT OF PROGRAMMING, MEDICAL DEVICES,
DRUGS AND POLICIES IN FAVOUR OF THE HEALTH SERVICE
NATIONAL
GENERAL DIRECTORATE OF MEDICAL DEVICES AND PHARMACEUTICALS
OFFICE 8 *BIOCIDES AND COSMETICS*
I.5.i.d./41
THE DIRECTOR OF THE OFFICE

HAVING REGARD TO Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012, relating to the making available on the market and use of biocidal products;

HAVING REGARD TO Commission Regulation (EC) No 1451/2007 of 4 December 2007 concerning the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market;

HAVING REGARD to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Regulation (EEC) No 3922/9;

HAVING REGARD to Article 55(1) of Regulation (EU) No 528/2012, according to which a competent authority, by way of derogation from Articles 17 and 19, may permit, for a maximum period of 180 days, the making available on the market or the use of biocidal products which do not comply with the conditions for authorisation laid down in this Regulation, for limited and controlled use and under the supervision of the competent authority, where this is made necessary by a danger threatening human health public, animal health or the environment and which cannot be combated by other means;

HAVING SEEN its decrees, transmitted with notes prot. 64763 of 14/09/2021, 80418 of 10/11/2021, 95784 of 29/12/2022, 50323 of 14/06/2023, 102815 of 10/12/2024 and 4559 of 2001/2025, with which, to ensure the safety of flight operations, pursuant to Article 55, paragraph 1, of Regulation (EU) 528/2018, the authorization to import the product ***"Biobor JF"*** of the Company Hammonds Fuel Additivies, Inc, 6951 W Little York D – Houston, Texas (USA) was issued;

CONSIDERING that requests for authorization to use the product ***"Biobor* JF"** are received from multiple operators ;

CONSIDERING that, at the current state of affairs, it is not possible to import the product ***"Biobor JF"*** by Società Servizi Aerei SpA;

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CONSIDERING that the recognition of the possibility of using the product ***"Biobor JF"*** it appears necessary to protect public health as:

- microbiological contamination of aircraft fuel tanks and fuel systems is caused by microorganisms, such as bacteria, moulds and yeasts, which grow in the settling water and feed on the hydrocarbons contained in the fuel at the fuel-water interface;

- if left untreated, microbiological contamination of aircraft fuel tanks and fuel systems can cause aircraft engine malfunctions and compromise their airworthiness, thus endangering the safety of passengers and crew;

- the prevention and treatment of microbiological contamination, if detected, are therefore essential to avoid aircraft operational problems;

WHEREAS ***"Biobor* JF",** a biocidal product of product-type 6 ('product preservatives during storage'), as defined in Annex V to Regulation (EU) No 528/2012, contains 2,2'-[(1-methylpropan-1,3-diyl)bis(oxy)]bis[4-methyl-1,3,2-dioxaborinan] (CAS number 2665-13-6) and 2,2'-oxybis[4,4,6-trimethyl-1,3,2-dioxaborinan] (CAS number 14697-50-8) as active substances;

WHEREAS 2,2'-[(1-methylpropan-1,3-diyl)bis(oxy)]bis[4-methyl-1,3,2-[dioxaborinan] and 2,2'-oxybis[4,4,6-trimethyl-1,3,2-dioxaborinan] have not been evaluated for use in biocidal products of product-type 6 and which, being not listed among the active substance/product-type combinations included in the review programme of 17 March 2022 referred to in Annex II to Commission Delegated Regulation (EU) No 1062/2014, these substances 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;

CONSIDERING, therefore, that Article 89 of Regulation (EU) No 528/2012 does not apply to the above-mentioned active substances, which must be evaluated and approved before biocidal products containing them can also be authorised at national level;

CONSIDERING that there are no alternative products available that are suitable for combating microbiological contamination of aircraft fuel tanks and fuel systems;

WHEREAS, as reported in the European Commission Implementing Decisions 2025/485 and 2025/489 of 17 March 2025, the manufacturer of the product ***"Biobor JF"*** has taken measures to obtain regular authorisation of the product, and the application for prior approval of the related active substances should be imminent;

CONSIDERING that the subsequent authorization of the product ***"Biobor JF"*** would constitute a definitive solution for the future, but implies the passage of a long time for the completion of the underlying procedures;

CONSIDERING that the lack of control of microbiological contamination of aircraft fuel tanks and fuel systems could endanger the safety of air transport and that such danger cannot be adequately contained by the use of another biocide or by other means;

WHEREAS pursuant to Regulation (EU) 2018/1139 aircraft and engine manufacturers provide officially approved procedures and instructions to aircraft operators to properly maintain aircraft and that the approved and implemented procedures include the treatment of aviation fuel with the biocide ***"Biobor JF"*** to prevent the proliferation of microorganisms;

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CONSIDERING that, in order to enable the safe operation of aircraft, aircraft operators should be able to follow procedures and instructions officially approved by aircraft or engine manufacturers;

HAVING ACKNOWLEDGED, for the purposes of assessing the existence of the requirements for the adoption of a measure pursuant to art. 55 of Regulation (EU) 528/2012, the existence of numerous current derogation authorisations for the product in question in other Member States;

CONSIDERING it necessary to adopt a measure which, on the basis of the derogation provided for by art. 55 of Regulation (EU) 528/2012, allows the importation and use of the biocide ***"Biobor JF"*** on Italian territory;

CONSIDERING it necessary, given the multiple parties interested in using the product, to adopt a single provision which, on the basis of the derogation provided for by art. 55 of Regulation (EU) 528/2012, allows the importation and use of the biocide ***"Biobor JF"*** on Italian territory;

DECREE

For a period not exceeding 180 days starting from 28 June 2025, the importation into Italy of the product ***"Biobor JF"*** by Hammonds Fuel Additivies, Inc., 910 Rankin Road, Houston, Texas 77073 (USA) is authorised for exclusive use on aircraft for the antimicrobial treatment of fuel and fuel systems by professional users.

Operators who intend to use the aforementioned product ***"Biobor JF"*** on Italian territory pursuant to this decree are required to give prior notice to the Ministry of Health, Department of Programming, Medical Devices, Medicines and Policies in favor of the National Health Service, General Directorate of Medical Devices and Medicines, Office 8 Biocides and Cosmetics, by certified email (dgfdm@postacert.sanita.it). The notification allows you to take advantage of the exemption, without the need for further verification by the same Office.

The notifying operator shall provide the same office, using the same methods, with immediate communication of the cessation of the importation and use of the aforementioned product within the expiry of the period indicated above.

Against this act, a judicial appeal may be lodged with the competent Regional Administrative Court within sixty days, or an extraordinary appeal to the Head of State within one hundred and twenty days.

Rome 13 June 2025

THE DIRECTOR OF THE OFFICE
Dr. Raffaella Perrone
Signed Raffaella Perrone