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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

DECISIONS

COUNCIL DECISION (EU) 2021/3

of 23 November 2020

on the position to be taken, on behalf of the European Union, at the reconvened sixty-third session of the Commission on Narcotic Drugs, on the scheduling of cannabis and cannabis-related substances under the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 83(1), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The United Nations (UN) Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol (the 'Convention on Narcotic Drugs'), entered into force on 8 August 1975.

(2) Pursuant to Article 3 of the Convention on Narcotic Drugs, the Commission on Narcotic Drugs (CND) may decide to add substances to the Schedules of that Convention. It can make changes to the Schedules only in accordance with the recommendations of the World Health Organization (WHO), but it can also decide not to make the changes recommended by the WHO.

(3) The UN Convention on Psychotropic Substances of 1971 (the 'Convention on Psychotropic Substances') entered into force on 16 August 1976.

(4) Pursuant to Article 2 of the Convention on Psychotropic Substances, the CND may decide to add substances to the Schedules of that Convention or to remove them, on the basis of the recommendations of the WHO. The CND has broad discretionary powers to take into account economic, social, legal, administrative and other factors, but it may not act arbitrarily.

(5) Changes to the Schedules of the Convention on Narcotic Drugs and of the Convention on Psychotropic Substances have direct repercussions on the scope of application of Union law in the area of drug control. Council Framework Decision 2004/757/JHA ([1]) applies to substances listed in the Schedules of those Conventions. Therefore, any change to the Schedules of those Conventions is directly incorporated into common Union rules.

(6) The CND, at its reconvened sixty-third session, which is scheduled to take place from 2 to 4 December 2020 in Vienna, is to adopt decisions concerning cannabis and cannabis-related substances, which are already being controlled on the basis of the Convention on Narcotic Drugs or the Convention on Psychotropic Substances.

([1]) Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335, 11.11.2004, p. 8).

(7) The Union is not a party to the Convention on Narcotic Drugs or the Convention on Psychotropic Substances. It has an observer status in the CND, where 12 Member States are members with the right to vote at its reconvened sixty-third session. It is therefore necessary for the Council to authorise those Member States to express the position of the Union on the scheduling of substances under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances since decisions on the international scheduling of substances under those Conventions fall within the competence of the Union.

(8) On 24 January 2019, the WHO issued six recommendations following the critical review at the 41st meeting of its Expert Committee on Drug Dependence (the 'WHO Expert Committee') concerning cannabis and cannabis-related substances. Those recommendations do not aim to authorise the recreational use of cannabis or cannabis-related substances.

(9) According to the assessment of the WHO Expert Committee, cannabis and cannabis resin are not particularly liable to produce ill-effects similar to the effects of the other substances in Schedule IV of the Convention on Narcotic Drugs. In addition, oral preparations of cannabis have shown therapeutic potential for the treatment of pain and other medical conditions such as epilepsy and spasticity associated with multiple sclerosis.

(10) The WHO considered that cannabis and cannabis resin should be scheduled at a level of control that will prevent harm caused by cannabis use and at the same time will not act as a barrier to access and to research and development of cannabis-related preparations for medical use. Therefore, the WHO concluded that the inclusion of cannabis and cannabis resin in Schedule IV of the Convention on Narcotic Drugs is not consistent with the criteria for a drug to be included in that Schedule.

(11) That recommendation implies no change in the level of international control of cannabis and cannabis resin. It duly takes into account scientific developments in the field since the first inclusion of cannabis and cannabis resin in the Convention on Narcotic Drugs. The deletion of cannabis and cannabis resin from Schedule IV of the Convention on Narcotic Drugs could be beneficial to the advancement of collective knowledge of the therapeutic utility as well as any associated harms of cannabis.

(12) Therefore, the position of the Union should be to delete cannabis and cannabis resin from Schedule IV of the Convention on Narcotic Drugs.

(13) According to the assessment of the WHO Expert Committee, *delta*-9-tetrahydrocannabinol and its active stereoisomer dronabinol, especially in high-purity illicitly derived forms, can produce ill-effects, dependence, and abuse potential that is at least as great as for cannabis, which is included in Schedule I of the Convention on Narcotic Drugs. A substance liable to similar abuse and productive of similar ill-effects as that of a substance already scheduled in the Convention on Narcotic Drugs would normally be scheduled in the same way as that substance. As *delta*-9-tetrahydrocannabinol is liable to similar abuse as cannabis and has similar ill-effects, it meets the criteria for inclusion in Schedule I of the Convention on Narcotic Drugs.

(14) The WHO understood that including *delta*-9-tetrahydrocannabinol under the same Convention and in the same schedule as cannabis, namely, Schedule I of the Convention on Narcotic Drugs, would greatly facilitate the implementation of the control measures of the Convention on Narcotic Drugs and the Convention on Psychotropic Substances in Member States. Therefore, the WHO recommended that *delta*-9-tetrahydrocannabinol and its active stereoisomer dronabinol be included in Schedule I of the Convention on Narcotic Drugs and, if that recommendation is adopted, be deleted from Schedule II of the Convention on Psychotropic Substances.

(15) That recommendation implies no change in the level of international control of *delta*-9-tetrahydrocannabinol and its active stereoisomer dronabinol. It could also facilitate the implementation of the control measures in Member States.

(16) Therefore, the position of the Union should be to add *delta*-9-tetrahydrocannabinol and its active stereoisomer dronabinol to Schedule I of the Convention on Narcotic Drugs and, if that recommendation is adopted, to delete them from Schedule II of the Convention on Psychotropic Substances.

(17) According to the assessment of the WHO Expert Committee, tetrahydrocannabinol (isomers of *delta*-9-tetrahydrocannabinol), which is included in Schedule I of the Convention on Psychotropic Substances, does not have abuse and ill-effects similar to those associated with *delta*-9-tetrahydrocannabinol but, due to the chemical similarity of each of the six isomers of *delta*-9-tetrahydrocannabinol, it is very difficult to differentiate any of those six isomers from *delta*-9-tetrahydrocannabinol using standard methods of chemical analysis. Moreover, including those six isomers under the same Convention and in the same Schedule as *delta*-9-tetrahydrocannabinol, namely, Schedule I of the Convention on Narcotic Drugs, would facilitate the implementation of international control of *delta*-9-tetrahydrocannabinol, and would assist Member States in the implementation of control measures at national level. Therefore, the WHO recommended that tetrahydrocannabinol (isomers of *delta*-9-tetrahydrocannabinol) be added to Schedule I of the Convention on Narcotic Drugs, subject to the adoption by the CND of the recommendation to add dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) to Schedule I of the Convention on Narcotic Drugs, and, if that recommendation is adopted, be deleted from Schedule I of the Convention on Psychotropic Substances.

(18) That recommendation implies no change in the level of international control of tetrahydrocannabinol (isomers of *delta*-9-tetrahydrocannabinol). It is in line with principles of better regulation and could facilitate the implementation of the control measures in Member States.

(19) Therefore, the position of the Union should be to add tetrahydrocannabinol (isomers of *delta*-9-tetrahydrocannabinol) to Schedule I of the Convention on Narcotic Drugs, subject to the adoption by the CND of the recommendation to add dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) to Schedule I of the Convention on Narcotic Drugs, and, if that recommendation is adopted, to delete them from Schedule I of the Convention on Psychotropic Substances.

(20) In order to ensure the coherence of the scheduling of *delta*-9-tetrahydrocannabinol and its active stereoisomer dronabinol as well as of tetrahydrocannabinol (isomers of *delta*-9-tetrahydrocannabinol), and to avoid the risk that any of those substances are scheduled under the Convention on Narcotic Drugs as well as under the Convention on Psychotropic Substances, it should be possible for the Member States that are members of the CND to express the position of the Union regarding the scheduling of those substances in a joint vote.

(21) According to the assessment of the WHO Expert Committee, the variability in psychoactive properties of extracts and tinctures of cannabis, as laid down in the Convention on Narcotic Drugs, is due principally to varying concentrations of *delta*-9-tetrahydrocannabinol contained in those extracts and tinctures. Some extracts and tinctures of cannabis without psychoactive properties and including predominantly cannabidiol have promising therapeutic applications. The fact that diverse preparations with a variable concentration of *delta*-9-tetrahydrocannabinol are controlled within the same entry 'Extract and Tinctures' and are included in the same schedule, is a challenge for responsible authorities that implement control measures in countries. Moreover, the definition of preparations under the Convention on Narcotic Drugs may cover all products that are extracts and tinctures of cannabis as 'preparations' of cannabis, and also, if the recommendation of the WHO Expert Committee to move dronabinol to Schedule I of the Convention on Narcotic Drugs were followed, as 'preparations' of dronabinol and its stereoisomers. Therefore, the WHO recommended that extracts and tinctures of cannabis be deleted from Schedule I of the Convention on Narcotic Drugs.

(22) The information provided by the WHO after the issuance of that recommendation and the analysis of the impact of that recommendation by the International Narcotics Control Board (INCB) clarify that that recommendation does not entail any change in the level of international control of extracts and tinctures of cannabis and that that recommendation is not expected to have any impact on the control or reporting obligations of Member States. In addition, the deletion of extracts and tinctures of cannabis from Schedule I of the Convention on Narcotic Drugs would bring about greater certainty in the control of products derived without the use of a solvent but by application of heat and pressure.

(23) Therefore, the position of the Union should be to vote for the recommendation to delete extracts and tinctures of cannabis from Schedule I of the Convention on Narcotic Drugs.

(24) According to the assessment of the WHO Expert Committee, cannabidiol is found in cannabis and cannabis resin but does not have psychoactive properties and has no potential for abuse and no potential to produce dependence. It does not have significant ill-effects. Moreover, cannabidiol has been shown to be effective in the management of certain treatment-resistant, childhood-onset epilepsy disorders.

(25) The WHO noted that medicines without psychoactive effects that are produced as preparations of the cannabis plant will contain trace amounts of *delta*-9-tetrahydrocannabinol and acknowledged that chemical analysis of *delta*-9-tetrahydrocannabinol to an accuracy of 0,15 % may be difficult for some Member States. Therefore, the WHO recommended that a footnote be added to the entry for cannabis and cannabis resin in Schedule I of the Convention on Narcotic Drugs, to read 'Preparations containing predominantly cannabidiol and not more than 0.2 percent of *delta*-9-tetrahydrocannabinol are not under international control.'.

(26) However, that recommendation would lower the current control level for those preparations. Moreover, the establishment of that limit of 0,2 percent of *delta*-9-tetrahydrocannabinol is not sufficiently supported by scientific evidence, the wording of that recommendation does not exclude possible divergent interpretations concerning the way of calculating that limit of 0,2 percent of *delta*-9-tetrahydrocannabinol, and the technical implementation of that recommendation will be difficult for reasons of technical and administrative capacity. The differentiated treatment of cannabidiol compared to other cannabinoids is not in line with the existing structure of the Schedules of the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. That recommendation, as it has been drafted, does not offer the necessary legal certainty.

(27) Therefore, the position of the Union should be to vote against the recommendation to add a footnote concerning 'preparations containing predominantly cannabidiol and not more than 0.2 percent of *delta*-9-tetrahydrocannabinol' to the entry for cannabis and cannabis resin in Schedule I of the Convention on Narcotic Drugs.

(28) However, the Union would welcome further consultation with all relevant stakeholders on a recommendation on the appropriate level of international control for cannabis preparations with a low *delta*-9-tetrahydrocannabinol content, while ensuring the protection of public health and welfare, taking into consideration the existing structure of the international drug control system for cannabis as well as the technical and administrative capacity that is needed for the implementation of such recommendation.

(29) According to the assessment of the WHO Expert Committee, medicines containing *delta*-9-tetrahydrocannabinol are not associated with problems of abuse and dependence and they are not diverted for the purpose of non-medical use. Moreover, the WHO recognised that such preparations are formulated in a way that they are not likely to be abused and there is no evidence of actual abuse or ill-effects to an extent that would justify the current level of control associated with Schedule I of the Convention on Narcotic Drugs or the level of control associated with Schedule II of the Convention on Psychotropic Substances. Therefore, the WHO recommended that preparations produced either by chemical synthesis or as preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that *delta*-9-tetrahydrocannabinol cannot be recovered by readily available means or in a yield which would constitute a risk to public health, be added to Schedule III of the Convention on Narcotic Drugs.

(30) However, the wording of that recommendation concerning pharmaceutical preparations is not based on any defined term in the Convention on Narcotic Drugs. Moreover, that recommendation could bring about additional regulatory burden on Member States, which would need to define the concepts used in that recommendation to ensure its uniform application and would have to ascertain whether the condition of not being recoverable by readily available means is or is not fulfilled for each product.

(31) Therefore, the position of the Union should be to vote against the recommendation to add preparations produced either by chemical synthesis or as preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that *delta*-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health, to Schedule III of the Convention on Narcotic Drugs.

(32) It is appropriate to establish the position to be taken on the Union's behalf in the CND with regard to changes to the scheduling of cannabis and cannabis-related substances, as the decisions on scheduling as regards the above-mentioned cannabis and cannabis-related substances will directly affect the content of Union law, namely, Framework Decision 2004/757/JHA.

(33) The position of the Union is to be expressed by the Member States that are members of the CND, acting jointly in the interest of the Union.

(34) Denmark is bound by Framework Decision 2004/757/JHA and is therefore taking part in the adoption and application of this Decision.

(35) Ireland is bound by Framework Decision 2004/757/JHA and is therefore taking part in the adoption and application of this Decision,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf by the Member States at the reconvened sixty-third session of the Commission on Narcotic Drugs (CND), which is scheduled to take place from 2 to 4 December 2020, when that body will be called upon to adopt decisions on the addition of substances to, or their deletion from, the Schedules of the United Nations Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the United Nations Convention on Psychotropic Substances of 1971, shall be in accordance with that set out in the Annex to this Decision.

Article 2

The position referred to in Article 1 shall be expressed by the Member States that are members of the CND, acting jointly in the interest of the Union.

Article 3

This Decision is addressed to the Member States in accordance with the Treaties.

Done at Brussels, 23 November 2020.

For the Council
The President
M. ROTH

ANNEX

Position to be taken by the Member States that are members of the Commission on Narcotic Drugs (CND), acting jointly in the interest of the Union, at the reconvened sixty-third session of the CND, which is scheduled to take place from 2 to 4 December 2020:

(1) cannabis and cannabis resin are to be deleted from Schedule IV of the Convention on Narcotic Drugs ([1]);

(2) dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) are to be added to Schedule I of the Convention on Narcotic Drugs and, if that recommendation is adopted, to be deleted from Schedule II of the Convention on Psychotropic Substances;

(3) tetrahydrocannabinol (isomers of *delta*-9-tetrahydrocannabinol) is to be added to Schedule I of the Convention on Narcotic Drugs, subject to the CND's adoption of the recommendation to add dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol) to Schedule I of the Convention on Narcotic Drugs, and, if that recommendation is adopted, is to be deleted from Schedule I of the Convention on Psychotropic Substances;

(4) the term 'extracts and tinctures' is to be deleted from Schedule I of the Convention on Narcotic Drugs;

(5) the footnote reading 'Preparations containing predominantly cannabidiol and not more than 0.2 percent of *delta*-9-tetrahydrocannabinol are not under international control.' is not to be added to the entry for cannabis and cannabis resin in Schedule I of the Convention on Narcotic Drugs;

(6) preparations produced either by chemical synthesis or as preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that *delta*-9-tetrahydrocannabinol (dronabinol) cannot be recovered by readily available means or in a yield which would constitute a risk to public health, are not to be added to Schedule III of the Convention on Narcotic Drugs.

In order to ensure coherence of the scheduling and to avoid the risk that a substance is scheduled under the Convention on Narcotic Drugs as well as under the Convention on Psychotropic Substances, the Member States that are members of the CND can accept a joint vote on the recommendations concerned.

([1]) They continue to be listed in Schedule I of that Convention.

DECISION (EU) 2021/4 TAKEN BY COMMON ACCORD BETWEEN THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES

of 9 December 2020

on the location of the seat of the European Cybersecurity Industrial, Technology and Research Competence Centre

THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 341 thereof,

Whereas:

(1) The establishment of the European Cybersecurity Industrial, Technology and Research Competence Centre ('the Competence Centre') is envisaged on the basis of the proposal submitted by the Commission to the European Parliament and to the Council on 12 September 2018.

(2) The location of the seat of the Competence Centre should be determined,

HAVE ADOPTED THIS DECISION:

Article 1

The European Cybersecurity Industrial, Technology and Research Competence Centre shall have its seat in Bucharest, Romania.

Article 2

This Decision shall enter into force on the date of its publication in the *Official Journal of the European Union*.

Article 3

This Decision shall be published in the *Official Journal of the European Union*.

Done at Brussels, 9 December 2020.

The President
P. LOURTIE

POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2021/5

of 15 December 2020

on the appointment of the EU Force Commander for the European Union military operation in Bosnia and Herzegovina and repealing Decision (CFSP) 2019/783 (BiH/31/2020)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular Article 38 thereof,

Having regard to Council Joint Action 2004/570/CFSP of 12 July 2004 on the European Union military operation in Bosnia and Herzegovina ([1]), and in particular Article 6(1) thereof,

Whereas:

(1) Pursuant to Article 6(1) of Joint Action 2004/570/CFSP, the Council authorised the Political and Security Committee (PSC) to take the relevant decisions on the appointment of the EU Force Commander for the European Union military operation in Bosnia and Herzegovina (the 'EU Force Commander').

(2) On 30 April 2019 the PSC adopted Decision (CFSP) 2019/783 ([2]) appointing Brigadier General Reinhard TRISCHAK as EU Force Commander.

(3) The EU Operation Commander has recommended the appointment of Major General Alexander PLATZER as the new EU Force Commander to succeed Brigadier General Reinhard TRISCHAK from 15 January 2021.

(4) The EU Military Committee agreed to the recommendation of the EU Operation Commander on 23 October 2020.

(5) Decision (CFSP) 2019/783 should therefore be repealed.

(6) In accordance with Article 5 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark does not participate in the elaboration and the implementation of decisions and actions of the Union which have defence implications.

(7) On 12 and 13 December 2002, the Copenhagen European Council adopted a declaration stating that the 'Berlin plus' arrangements and the implementation thereof will apply only to those Member States of the Union which are also either NATO members or parties to the 'Partnership for Peace', and which have consequently concluded bilateral security agreements with NATO,

HAS ADOPTED THIS DECISION:

Article 1

Major General Alexander PLATZER is hereby appointed EU Force Commander for the European Union military operation in Bosnia and Herzegovina as from 15 January 2021.

Article 2

Decision (CFSP) 2019/783 is hereby repealed.

([1]) OJ L 252, 28.7.2004, p. 10.

([2]) Political and Security Committee Decision (CFSP) 2019/783 of 30 April 2019 on the appointment of the EU Force Commander for the European Union military operation in Bosnia and Herzegovina and repealing Decision (CFSP) 2018/355 (BiH/28/2019) (OJ L 127, 16.5.2019, p. 11).

Article 3

This Decision shall enter into force on 15 January 2021.

Done at Brussels, 15 December 2020.

For the Political and Security Committee
The Chairperson
S. FROM-EMMESBERGER

POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2021/6

of 15 December 2020

on the appointment of the EU Mission Force Commander of the European Union military mission to contribute to the training of the Malian Armed Forces (EUTM Mali) and repealing Decision (CFSP) 2020/603 (EUTM Mali/2/2020)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular Article 38 thereof,

Having regard to Council Decision 2013/34/CFSP of 17 January 2013 on a European Union military mission to contribute to the training of Malian Armed Forces (EUTM Mali) ([1]), and in particular Article 5 thereof,

Whereas:

(1) Pursuant to Article 5(1) of Decision 2013/34/CFSP, the Council authorised the Political and Security Committee (PSC) to take the relevant decisions concerning the political control and strategic direction of EUTM Mali, including decisions on the appointment of subsequent EU Mission Force Commanders.

(2) On 16 April 2020, the PSC adopted Decision (CFSP) 2020/603 ([2]) appointing Brigadier General František RIDZÁK as EU Mission Force Commander of EUTM Mali.

(3) On 25 September 2020, Spain proposed the appointment of Brigadier General Fernando Luis GRACIA HERREIZ to succeed Brigadier General František RIDZÁK as the EU Mission Force Commander of EUTM Mali as from 12 January 2021.

(4) On 23 November 2020, the EU Military Committee supported that proposal.

(5) A decision on the appointment of Brigadier General Fernando Luis GRACIA HERREIZ as the EU Mission Force Commander of EUTM Mali as from 12 January 2021 should be taken.

(6) Decision (CFSP) 2020/603 should be repealed.

(7) In accordance with Article 5 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark does not participate in the elaboration and the implementation of decisions and actions of the Union which have defence implications. Consequently, Denmark is not participating in the adoption of this Decision and is neither bound by it nor subject to its application,

HAS ADOPTED THIS DECISION:

Article 1

Brigadier General Fernando Luis GRACIA HERREIZ is hereby appointed as the EU Mission Force Commander of the European Union military mission to contribute to the training of the Malian Armed Force (EUTM Mali) as from 12 January 2021.

Article 2

Decision (CFSP) 2020/603 is hereby repealed.

([1]) OJ L 14, 18.1.2013, p. 19.

([2]) Political and Security Committee Decision (CFSP) 2020/603 of 16 April 2020 on the appointment of the EU Mission Force Commander of the European Union military mission to contribute to the training of the Malian Armed Forces (EUTM Mali) and repealing Decision (CFSP) 2019/2096 (EUTM Mali/1/2020) (OJ L 139, 4.5.2020, p. 65).

Article 3

This Decision shall enter into force on 12 January 2021.

Done at Brussels, 15 December 2020.

For the Political and Security Committee
The Chairperson
S. FROM-EMMESBERGER

COMMISSION IMPLEMENTING DECISION (EU) 2021/7

of 5 January 2021

concerning the extension of the action taken by the Finnish Safety and Chemicals Agency 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) 7)

(Only the Finnish 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 6 May 2020 the Finnish Safety and Chemicals Agency ('the competent authority') adopted a decision in accordance with Article 55(1) first subparagraph of Regulation (EU) No 528/2012 to permit until 2 November 2020 the making available on the market and use by professional users of the biocidal product Biobor JF for the antimicrobial treatment of fuel tanks and fuel systems of aircraft ('the action'). The 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 competent authority, the action was necessary in order to protect public health. 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 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 included in the work programme laid down in Annex II to Commission Delegated Regulation (EU) No 1062/2014 ([2]) for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012, they have to be assessed and approved before biocidal products containing them can be authorised at national or Union level.

(4) On 4 September 2020, the Commission received a reasoned request from the competent authority to extend the action in accordance with the third subparagraph of Article 55(1) 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 the expiry of the temporary permit and the argument 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 was withdrawn from the market in March 2020 on account of severe engine behaviour anomalies noticed after the treatment with that product.

(6) As indicated by the competent authority, the mechanical treatment of microbiological contamination of aircraft fuel tanks and fuel systems is not always possible and agreed aviation procedures 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 by the competent authority, 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 early 2021. The approval of the active substances and subsequent authorisation of the biocidal product would represent a permanent solution for the future, but a significant amount of time will be needed for the completion of these procedures.

(8) As the lack of control of microbiological contamination of aircraft fuel tanks and fuels 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 competent authority to extend the action for a period not exceeding 550 days starting from the day following the expiry of the initial period of 180 days permitted in the decision of the competent authority of 6 May 2020.

(9) Considering that the action has lapsed since 3 November 2020, 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 Finnish Safety and Chemicals Agency may extend until 7 May 2022 the action to permit the making available on the market and use by professional users of the biocidal product Biobor JF for the antimicrobial treatment of fuel tanks and fuel systems of aircraft.

Article 2

This Decision is addressed to the Finnish Safety and Chemicals Agency.

It shall apply from 3 November 2020.

Done at Brussels, 5 January 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

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LUXEMBOURG

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