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⁽¹⁾ Text with EEA relevance.

EN

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.

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II

(Non-legislative acts)

DECISIONS

POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2021/2162**of 25 November 2021****extending the mandate of the Head of Mission of the European Union CSDP mission in Niger
(EUCAP Sahel Niger) (EUCAP Sahel Niger/1/2021)**

THE POLITICAL AND SECURITY COMMITTEE,

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

Having regard to Council Decision 2012/392/CFSP of 16 July 2012 on the European Union CSDP mission in Niger (EUCAP Sahel Niger) ⁽¹⁾, and in particular Article 9(1) thereof,

Whereas:

- (1) Pursuant to Decision 2012/392/CFSP, the Political and Security Committee (PSC) is authorised, in accordance with the third paragraph of Article 38 of the Treaty, to take the relevant decisions for the purpose of exercising the political control and strategic direction of the European Union CSDP mission in Niger (EUCAP Sahel Niger), including the decision to appoint a Head of Mission.
- (2) On 7 September 2020, the Council adopted Decision (CFSP) 2020/1254 ⁽²⁾, amending Decision 2012/392/CFSP and extending the mandate of EUCAP Sahel Niger until 30 September 2022.
- (3) On 16 December 2020, the PSC adopted Decision (CFSP) 2021/22 ⁽³⁾ appointing Ms Antje PITTELKAU as Head of Mission of EUCAP Sahel Niger from 16 January 2021 to 15 January 2022.
- (4) The High Representative of the Union for Foreign Affairs and Security Policy has proposed to extend the mandate of Ms Antje PITTELKAU as Head of Mission of EUCAP Sahel Niger from 16 January 2022 to 30 September 2022.

HAS ADOPTED THIS DECISION:

Article 1

The mandate of Ms Antje PITTELKAU as Head of Mission of the European Union CSDP mission in Niger (EUCAP Sahel Niger) is hereby extended from 16 January 2022 to 30 September 2022.

⁽¹⁾ OJ L 187, 17.7.2012, p. 48.⁽²⁾ Council Decision (CFSP) 2020/1254 of 7 September 2020 amending Decision 2012/392/CFSP on the European Union CSDP mission in Niger (EUCAP Sahel Niger) (OJ L 294, 8.9.2020, p. 3).⁽³⁾ Political and Security Committee Decision (CFSP) 2021/22 of 16 December 2020 on the appointment of the Head of Mission of the European Union CSDP mission in Niger (EUCAP Sahel Niger) (EUCAP Sahel Niger/2/2020) (OJ L 9, 12.1.2021, p. 1).

Article 2

This Decision shall enter into force on the date of its adoption.

It shall apply from 16 January 2022.

Done at Brussels, 25 November 2021.

For the Political and Security Committee
The Chairperson
D. PRONK

POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2021/2163**of 25 November 2021****extending the mandate of the Head of Mission of the European Union Monitoring Mission in Georgia (EUMM Georgia) (EUMM GEORGIA/1/2021)**

THE POLITICAL AND SECURITY COMMITTEE,

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

Having regard to Council Decision 2010/452/CFSP of 12 August 2010 on the European Union Monitoring Mission in Georgia, EUMM Georgia ⁽¹⁾, and in particular Article 10(1) thereof,

Whereas:

- (1) Pursuant to Decision 2010/452/CFSP, the Political and Security Committee (PSC) is authorised, in accordance with the third paragraph of Article 38 of the Treaty, to take the relevant decisions for the purpose of exercising the political control and strategic direction of the European Union Monitoring Mission in Georgia (EUMM Georgia), including the decision to appoint a Head of Mission.
- (2) On 11 February 2020, the PSC adopted Decision (CFSP) 2020/200 ⁽²⁾ appointing Mr Marek SZCZYGIEŁ as Head of Mission of EUMM Georgia from 15 March 2020 to 14 December 2020.
- (3) On 3 December 2020, the Council adopted Decision (CFSP) 2020/1990 ⁽³⁾ extending the mandate of EUMM Georgia to 14 December 2022.
- (4) On 8 December 2020, the PSC adopted Decision (CFSP) 2020/2048 ⁽⁴⁾ extending the mandate of Mr Marek SZCZYGIEŁ as Head of Mission of EUMM Georgia from 15 December 2020 to 14 December 2021.
- (5) The High Representative of the Union for Foreign Affairs and Security Policy has proposed to extend the mandate of Mr Marek SZCZYGIEŁ as Head of Mission of EUMM Georgia from 15 December 2021 to 14 December 2022,

HAS ADOPTED THIS DECISION:

Article 1

The mandate of Mr Marek SZCZYGIEŁ as Head of the European Union Monitoring Mission in Georgia (EUMM Georgia) is hereby extended from 15 December 2021 to 14 December 2022.

Article 2

This Decision shall enter into force on the date of its adoption.

It shall apply from 15 December 2021.

⁽¹⁾ OJ L 213, 13.8.2010, p. 43.

⁽²⁾ Political and Security Committee Decision (CFSP) 2020/200 of 11 February 2020 on the appointment of the Head of Mission of the European Union Monitoring Mission in Georgia (EUMM Georgia) and repealing Decision (CFSP) 2018/2075 (EUMM Georgia/1/2020) (OJ L 42, 14.2.2020, p. 15).

⁽³⁾ Council Decision (CFSP) 2020/1990 of 3 December 2020 amending Decision 2010/452/CFSP on the European Union Monitoring Mission in Georgia, EUMM Georgia (OJ L 411, 7.12.2020, p. 1).

⁽⁴⁾ Political and Security Committee Decision (CFSP) 2020/2048 of 8 December 2020 extending the mandate of the Head of Mission of the European Union Monitoring Mission in Georgia (EUMM Georgia) (EUMM GEORGIA/2/2020) (OJ L 420, 14.12.2020, p. 21).

Done at Brussels, 25 November 2021.

For the Political and Security Committee
The Chairperson
D. PRONK

COMMISSION IMPLEMENTING DECISION (EU) 2021/2164**of 3 December 2021****allowing Belgium to authorise biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage***(notified under document C(2021) 8670)***(Only the Dutch and French 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(3) thereof,

After consulting the Standing Committee for Biocidal Products,

Whereas:

- (1) Annex I to Regulation (EU) No 528/2012 contains active substances which have a more favourable environmental or human or animal health profile. Products containing these active substances may therefore be authorised under a simplified procedure. Nitrogen is included in Annex I to Regulation (EU) No 528/2012, subject to the restriction that it is used in limited quantities in ready-for-use canisters.
- (2) Pursuant to Article 86 of Regulation (EU) No 528/2012, nitrogen is approved as active substance for use in biocidal products of product-type 18, insecticides ⁽²⁾. Biocidal products consisting of nitrogen as approved are authorised in several Member States and are supplied in gas cylinders ⁽³⁾.
- (3) Nitrogen can also be generated in-situ from ambient air. In-situ generated nitrogen is currently not approved for use in the Union and it is neither listed in Annex I to Regulation (EU) No 528/2012, nor inserted in the list of active substances included in the review programme of existing active substances in biocidal products in Annex II to Commission Delegated Regulation (EU) No 1062/2014 ⁽⁴⁾.
- (4) Pursuant to Article 55(3) of Regulation (EU) No 528/2012, on 30 July 2021 Belgium submitted to the Commission an application for derogation from Article 19(1)(a) of that Regulation asking to allow it to authorise biocidal products consisting of nitrogen generated in-situ from ambient air for the protection of cultural heritage ('the application').
- (5) Cultural heritage can be damaged by a wide range of harmful organisms, from insects to microorganisms. The presence of those organisms not only can lead to the loss of the cultural good itself, but also poses the risk of those harmful organisms being spread to other objects nearby. Without an appropriate treatment, objects could be irretrievably damaged, putting the cultural heritage at serious risk.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Directive 2009/89/EC of 30 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include nitrogen as an active substance in Annex I thereto (OJ L 199, 31.7.2009, p. 19).

⁽³⁾ List of authorised products available at <https://echa.europa.eu/fr/information-on-chemicals/biocidal-products>.

⁽⁴⁾ 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).

- (6) In-situ generated nitrogen is used to create a controlled atmosphere with a very low concentration of oxygen (anoxia) in permanent or temporary sealed treatment tents or chambers for the control of harmful organisms on cultural heritage objects. Nitrogen is separated from the ambient air and is pumped into the treatment tent or chamber, where the nitrogen content of the atmosphere is increased to 99 % approximately and consequently oxygen is almost completely depleted. The humidity of the nitrogen pumped into the treatment area is set according to the demands of the object to be treated. Harmful organisms cannot survive under the conditions created in the treatment tent or chamber.
- (7) According to the information submitted by Belgium, the use of in-situ generated nitrogen appears to be the only effective technique for the control of harmful organisms that can be used for all types of materials and combinations of materials present in cultural institutions without damaging them and is effective against all developmental stages of pests in cultural heritage.
- (8) The method of anoxia or modified or controlled atmosphere is listed in the standard EN 16790:2016 'Conservation of cultural heritage – Integrated pest management (IPM) for protection of cultural heritage' and nitrogen is described in this standard as 'most used' for creating anoxia.
- (9) Other techniques for the control of harmful organisms are available, such as thermal shock techniques (high or low temperatures). In addition, biocidal products containing other active substances can be used for that purpose. However, according to Belgium, each of those techniques has limitations in terms of damage that could occur to certain materials during treatment.
- (10) As stated in the application, other active substances are seldom used in cultural institutions due to their hazard profile. After treatment with those substances, the residues on the treated objects can be progressively released to the environment, which poses a risk to human health. Moreover, those substances may react with the materials of the heritage objects causing irreversible changes, especially of their surface.
- (11) According to the information in the application, the use of nitrogen in cylinders is not an appropriate alternative for cultural institutions, as it presents practical disadvantages. The limited quantities in cylinders require frequent transport and a separate storage facility. The treatment with nitrogen in cylinders would also generate high costs for the cultural institutions.
- (12) Requesting cultural institutions to use several techniques to control harmful organisms – each of them suitable for specific materials and objects – instead of using one technique already used and suitable to all materials, would involve additional costs for cultural institutions and make it more complicated for them to reach the objective of moving away from the use of more hazardous active substances in their IPM. In addition, the abandonment of facilities and equipment acquired for in-situ generated nitrogen anoxia would represent a loss of previous investments.
- (13) Discussions related to a possible derogation pursuant to Article 55(3) of Regulation (EU) No 528/2012 for in-situ generated nitrogen took place in several meetings ⁽ⁱ⁾ of the Commission expert group of Competent Authorities for Biocidal Products in 2019.
- (14) In addition, at the request of the Commission, following the first, similar application for derogation for products consisting of in-situ generated nitrogen from Austria, the European Chemicals Agency conducted a public consultation on that application, allowing all interested parties to provide their views. The vast majority of the 1 487 comments received were in favour of the derogation. Many contributors outlined the disadvantages of the alternative techniques available: thermal treatments may damage certain materials; the use of other active substances leaves toxic residues on artefacts that are progressively released to the environment; the use of nitrogen in cylinders does not allow the control of the relative humidity in the treatment area, which is needed for the treatment of some materials.

⁽ⁱ⁾ 83rd, 84th, 85th and 86th meeting of the Commission Expert Group of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012, held in May 2019, July 2019, September 2019 and November 2019, respectively. The minutes of the meetings are available at https://ec.europa.eu/health/biocides/events_en#anchor0

- (15) Two international organisations representing museums and cultural heritage sites – International Council of Museums and International Council on Monuments and Sites – have expressed their intention to submit an application for inclusion of in-situ generated nitrogen in Annex I to Regulation (EU) No 528/2012, which would allow Member States to authorise products consisting of in-situ generated nitrogen without the need for a derogation in accordance with Article 55(3) of that Regulation. The submission of the application is expected in the second half of 2021. However, performing the evaluation of such an application, including the substance into Annex I to Regulation (EU) No 528/2012 and obtaining product authorisations require time.
- (16) The application shows that no appropriate alternatives are available in Belgium, since all the alternative techniques currently available present disadvantages either due to non-suitability for the treatment of all materials or practical disadvantages.
- (17) Based on all those arguments it is appropriate to conclude that in-situ generated nitrogen is essential for the protection of cultural heritage in Belgium and that no appropriate alternatives are available. Belgium should therefore be allowed to authorise the making available on the market and use of biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage.
- (18) The possible inclusion of in-situ generated nitrogen into Annex I to Regulation (EU) No 528/2012 and the subsequent authorisation by Member States of products consisting of in-situ generated nitrogen requires time. It is therefore appropriate to allow a derogation for a period that would allow the completion of the underlying procedures,

HAS ADOPTED THIS DECISION:

Article 1

Belgium may authorise the making available on the market and use of biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage until 31 December 2024.

Article 2

This Decision is addressed to the Kingdom of Belgium.

Done at Brussels, 3 December 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2021/2165**of 3 December 2021****concerning the extension of the action taken by the Ministry of Health of the Czech Republic 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) 8684)***(Only the Czech 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,

Whereas:

- (1) On 15 April 2021, the Ministry of Health of the Czech Republic ('the competent authority') adopted a decision to permit, in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012, 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 until 12 October 2021 ('the action'). The 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 competent authority, the action was necessary in order to protect public health, as the 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 COVID-19 pandemic and the ensuing flight restrictions have led to numerous aircraft being temporarily parked. The immobility of aircraft is an aggravating factor in 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), which are 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 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.
- (4) On 7 July 2021, the Commission received a reasoned request from the 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 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 12 October 2021 and the claim 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 (Kathon™ FP 1.5) was withdrawn from the market in March 2020 due to severe engine behaviour anomalies that were noticed after the treatment with that product.
- (6) As indicated by the competent authority, there are no alternatives to the treatment of microbiological contamination of aircraft fuel tanks and fuel systems with Biobor JF.
- (7) According to the information available to the Commission, the manufacturer of Biobor JF has taken steps towards the regular authorisation of the product. It also appears that an application for approval of the active substances that Biobor JF contains is expected to be submitted by mid-2022. 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) 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 authority to extend the action.
- (9) 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 Ministry of Health of the Czech Republic may extend until 16 April 2023 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 Ministry of Health of the Czech Republic.

Done at Brussels, 3 December 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2021/2166**of 3 December 2021****on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Teknol Aqua 1411-01 in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council***(notified under document C(2021) 8694)***(Text with EEA relevance)**

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 36(3) thereof,

Whereas:

- (1) On 14 September 2018, the company Teknos A/S ('the applicant') submitted to the competent authorities of several Member States, including Germany, an application for mutual recognition in parallel in accordance with Article 34 of Regulation (EU) No 528/2012 of the biocidal product Teknol Aqua 1411-01, containing the active substances 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (propiconazole) and 3-iodo-2-propynyl butyl carbamate (IPBC) ('the biocidal product'). The biocidal product is intended to be used for preservation of wood used indoor (use class 2 ⁽²⁾) and for preservation of wood used outdoors not in contact with the ground (use class 3 ⁽²⁾). Denmark is the reference Member State responsible for the evaluation of the application as referred to in Article 34(1) of Regulation (EU) No 528/2012.
- (2) The biocidal product contains very low concentrations of three non-active substances which are residual monomers of the silicon emulsion added as anti-foaming agent during the production process: octamethylcyclotetrasiloxane (D4) in concentration of 0,000024 % weight by weight (w/w), decamethylcyclopentasiloxane (D5) in concentration of 0,000054 % (w/w) and dodecamethylcyclohexasiloxane (D6) in concentration of 0,00008 % (w/w). D4, D5 and D6 have been identified ⁽³⁾ as persistent, bio-accumulative and toxic (PBT) and very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽⁴⁾.
- (3) On 5 November 2020, pursuant to Article 35(2) of Regulation (EU) No 528/2012, Germany referred objections to the coordination group, indicating that the biocidal product does not meet the conditions laid down in Article 19(1), point (b) (iv), of that Regulation for use class 3. The referral was discussed in the coordination group on 25 November 2020.
- (4) As no agreement was reached in the coordination group, on 5 January 2021 Denmark referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. Denmark provided the Commission with a detailed statement of the matter on which Member States were unable to reach agreement and the reasons for their disagreement. The statement was forwarded to the Member States concerned and to the applicant.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ The use classes are defined in the European standard CEN EN 335 – Durability of wood and wood-based products – Use classes: definitions, application to solid wood and wood-based products.

⁽³⁾ ECHA Decision ED/61/2018: <https://echa.europa.eu/documents/10162/61ac8d81-6ea2-6ad0-ffef-95037c9182ce>

⁽⁴⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

- (5) Germany considers that the application of point 48 of Annex VI to Regulation (EU) No 528/2012 should lead the evaluating body to conclude that the biocidal product does not meet the condition laid down in Article 19(1), point (b)(iv), of that Regulation. Point 48 of Annex VI to Regulation (EU) No 528/2012 indicates that the evaluating body is to conclude that the biocidal product does not comply with criterion laid down in Article 19(1), point (b)(iv), of that Regulation if the biocidal product contains any substance of concern fulfilling the criteria for having PBT or vPvB properties in accordance with Annex XIII to Regulation (EC) No 1907/2006, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect. Germany considers that D4, D5 and D6 are substances of concern as defined in Article 3(1), point (f), of Regulation (EU) No 528/2012 and that, since for PBT and vPvB substances no safe threshold value can be derived below which the release to the environment can be considered acceptable, any release of these substances to the environment is to be considered as having an unacceptable effect. Consequently, Germany argues that since a partial leaching of the biocidal product in the environment is expected due to the weathering of the wood as regards the use class 3, that use should not be authorised.
- (6) Denmark argues that since the concentrations of D4, D5 and D6 in the biocidal product are very low (combined concentration of all three of them is 0,000158 % (w/w)), their presence in the product does not result in unacceptable effects on the environment. Moreover, according to the information provided by the applicant, currently there are no appropriate alternatives to the anti-foaming agent containing these impurities for the production of the biocidal product.
- (7) Article 56(1) and (2) of Regulation (EC) No 1907/2006 sets out the authorisation requirement for substances included in Annex XIV to that Regulation. Annex XIV to Regulation (EC) No 1907/2006 includes also substances which are PBT and vPvB. However, Article 56(6) of that Regulation establishes that the authorisation requirement does not apply to substances identified as PBT or vPvB when those substances are present in mixtures in concentration below 0,1 % (w/w).
- (8) Furthermore, the Guidance on Regulation (EC) No 1907/2006, Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB assessment ⁽⁵⁾ of the European Chemicals Agency, provides that constituents, impurities and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of at least 0,1 % (w/w). According to that guidance document, the limit of 0,1 % (w/w) is based on a well-established practice recognised in Union legislation to use this limit as a generic limit. In the same guidance document it is also noted that this threshold value may be elevated or reduced on a case-by-case basis.
- (9) The Guidance on the Biocidal Products Regulation, Volume V, Guidance on applications for technical equivalence ⁽⁶⁾ of the European Chemicals Agency provides that PBT and/or vPvB properties of impurities are normally assessed when the impurities are present in concentration of at least 0,1 % (w/w), and only above that threshold value the impact of the PBT and/or vPvB properties of the impurities is considered.
- (10) It follows that a concentration limit of 0,1 % (w/w) is applied for the purpose of technical equivalence assessment with regard to PBT and/or vPvB properties of impurities under Regulation (EU) No 528/2012 and for determining whether constituents, impurities and additives are relevant for the PBT/vPvB assessment under Regulation (EC) No 1907/2006.
- (11) Article 3(1), point (f), of Regulation (EU) No 528/2012 provides a definition of a substance of concern, stating in particular that the substance is present or is produced in a biocidal product in sufficient concentration to present risks.
- (12) As set out in a note for guidance ⁽⁷⁾ presented to the competent authorities of the Member States for the implementation of Regulation (EU) No 528/2021 in June 2021, the Commission considers that, for reasons of coherence with the approach followed for the technical equivalence assessment with regard to PBT and/or vPvB properties of impurities under Regulation (EU) No 528/2012 and for determining whether constituents, impurities

⁽⁵⁾ Version 3.0 of June 2017 https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

⁽⁶⁾ Version 2.0 of July 2018 https://echa.europa.eu/documents/10162/2324906/guidance_applications_technical_equivalence_en.pdf/18f72d37-98b6-47c8-98bb-941afeff6968

⁽⁷⁾ Draft note for agreement by Member States' competent authorities for biocidal products. Categorisation of a biocidal product containing a non-active substance meeting the criteria for being PBT or vPvB (CA-June21-Doc.4.3_final), <https://circabc.europa.eu/w/browse/534d6f76-bbfd-432b-b99b-d567d7f827f1>

and additives are relevant for the PBT/vPvB assessment under Regulation (EC) No 1907/2006, the same concentration limit of 0,1 % (w/w) should be applied to determine whether a substance identified as having PBT and/or vPvB properties in accordance with Annex XIII to Regulation (EC) No 1907/2006 and contained in a biocidal product, is a substance of concern. This implies that a substance identified as having PBT and/or vPvB properties and contained in a biocidal product should be considered as substance of concern if its concentration is higher than or equal to 0,1 % (w/w) in the biocidal product. Where the biocidal product contains multiple substances identified as having PBT and/or vPvB properties in individual amounts of less than 0,1 % (w/w), the concentration limit should be considered to apply for the group of substances. The competent authorities agreed with the Commission's position.

- (13) The total concentration of D4, D5 and D6 in the biocidal product is considerably lower than 0,1 % (w/w). Those non-active substances should therefore not be considered as substances of concern for the assessment of the biocidal product. As the substances D4, D5 and D6 are neither substances of concern, nor relevant metabolites, breakdown or reaction products, point 48 of Annex VI to Regulation (EU) No 528/2012 does not apply as regards the evaluation of the biocidal product in relation to the presence of those substances.
- (14) On 9 August 2021, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The applicant provided comments which the Commission, subsequently, has taken into account.
- (15) 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

This Decision applies to the biocidal product identified by the case number BC-FB042589-47 in the Register for Biocidal Products.

Article 2

The presence of the non-active substances octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) in a total concentration lower than 0,1 % (w/w) in the biocidal product referred to in Article 1 does not imply that the biocidal product has unacceptable effects on the environment within the meaning of Article 19(1), point (b)(iv) of Regulation (EU) No 528/2012.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 3 December 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

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