Commission Implementing Decision (EU) 2020/1775 of 25 November 2020 allowing the Netherlands to authorise biocidal products consisting of in situ generated nitrogen for the protection of cultural heritage (notified under document C(2020) 8052) (Only the Dutch text is authentic)

COMMISSION IMPLEMENTING DECISION (EU) 2020/1775

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allowing the Netherlands to authorise biocidal products consisting of *in situ* generated nitrogen for the protection of cultural heritage

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(Only the Dutch 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(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 9 July 2020 the Netherlands 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 irremediably damaged, putting the cultural heritage at serious risk.

(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 the Netherlands, 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) As stated in the application, for more than 25 years heritage institutions in the Netherlands have implemented Integrated Pest Management strategies, turning to low-toxic approaches and moving away from the use of highly toxic substances used previously.

(9) 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.

(10) Other techniques for the control of harmful organisms are available, such as thermal shock techniques (high or low temperatures), gamma radiation. In addition, biocidal products containing other active substances can be used for that purpose. However, according to the Netherlands, each of those techniques has limitations in terms of damage that could occur to certain materials during treatment.

(11) According to the information in the application, thermal shock processes (freezing or heat treatments) have undesired effects on several materials. Low temperature treatments are not suitable for objects with a layered structure or made of anisotropic materials, due to the difference in expansion coefficients between materials or in different directions leading to stress and delamination (for example, paintings, furniture with veneer or inlays, musical instruments), and for objects containing oil, grease or wax, that may crystalize and form a white bloom on the surface of the objects.

(12) High temperature treatments can cause migration of resins and colour change in wood, softening of varnishes and changes in moisture distribution in materials. Such treatments are not suitable for objects with a layered structure or made of anisotropic

materials (for example, paintings, furniture with veneer or inlays, musical instruments), leather, materials that soften, deform or melt at increased temperatures (for example, paints, varnishes, composite objects containing plastics, waxes, resins, certain glues), natural history specimens, and objects that have been treated in the past with biocidal products containing certain active substances such as dichlorodiphenyltrichloroethane (DDT) or lindane, as the heat causes the residues to evaporate.

(13) 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 unacceptable changes such as discoloration and staining.

(14) According to the application, the use of gamma radiation could cause unwanted reactions and increased degradation of cellulosic materials such as paper, proteinaceous materials like leather, and synthetic polymers like plastics. In addition, it requires transportation of objects and collections to specific facilities for treatment.

(15) 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.

(16) As stated in the application, during the last decades several cultural institutions invested in the construction of treatment chambers and the purchase of nitrogen generators. Due to its versatility and suitability for the treatment of all materials, *in situ* generated nitrogen anoxia is very widely used in the conservation of cultural heritage.

(17) 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.

(18) 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[(5)] of the Commission expert group of Competent Authorities for Biocidal Products in 2019.

(19) 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 1487 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