Commission Implementing Decision (EU) 2020/1047 of 15 July 2020 allowing Portugal to authorise biocidal products consisting of in situ generated nitrogen for the protection of cultural heritage (Only the Portuguese text is authentic)

COMMISSION IMPLEMENTING DECISION (EU) 2020/1047

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

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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 including Portugal 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 11 February 2020 Portugal 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) As stated in the application, the development in the past decades of the technique of nitrogen-based anoxia for the treatment of cultural heritage objects allowed cultural institutions (museums, archives, libraries, conservation-restoration centres, etc.) to move away from the use of highly toxic substances used previously.

(8) According to the information submitted by Portugal, 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 altering the macroscopic and molecular features of the objects. This technique can be applied for the treatment of especially sensitive materials, such as ethnographic heritage, mummies, contemporary art, for their conservation.

(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 gamma radiation, thermal shock techniques (high or low temperatures), microwaves. In addition, other active substances can be used for that purpose. However, according to Portugal, each of these techniques has limitations in terms of materials on which they can be applied.

(11) As stated in the application, other active substances are hardly used any more in cultural institutions, due to their hazard profile. After treatment with these substances, the residues on the treated objects may be progressively released to the environment, which poses a risk to human health. This is particularly relevant for cultural institutions that are open for visitors.

(12) According to the information submitted by Portugal, thermal shock processes (freezing or heat treatments) have undesired effects on several materials. Temperature increase or decrease may cause irreversible damage to cultural heritage objects, especially for organic components. Thermal processes are generally not suitable for the treatment of paintings, wax-, oil- or protein-bound polychrome objects, since during the treatment temperature-dependent properties of the materials can change causing irreversible

damage to the objects. In addition, high temperatures may cause the softening of glue in glued objects and the shrinking of materials such as leather and vellum.

(13) 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. Moreover, the point of load of the floors in some historical museum buildings might be exceeded due to the weight of the required number of cylinders. In addition, the treatment with nitrogen in cylinders would generate high costs for the cultural institutions.

(14) According to the application, during the last decades many 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.

(15) 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.

(16) 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.

(17) 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.

(18) 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. 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.

(19) The application shows that no appropriate alternatives are available in Portugal, since all the alternative techniques currently available present disadvantages either due to non-suitability for the treatment of all materials or practical disadvantages.