Commission Implementing Decision (EU) 2020/1050 of 15 July 2020 allowing Spain to authorise biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage (Only the Spanish text is authentic)

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allowing Spain 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 Spain 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 19 November 2019 Spain 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 Spain, 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 Spain, 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 barely used in cultural institutions due to their hazard profile. After treatment with these substances, the residues on the treated objects can be progressively released to the environment, which poses a risk to human health. This is particularly relevant for the cultural institutions that are open for visitors.

(12) According to the application, the use of gamma radiation could generate DNA alterations in objects such as mummies or objects in natural history museums, whereas their further study and analysis require preserving their genetic material intact. Moreover, the use of gamma radiation would require the creation of special radioactive facilities, equipping the space in a specific way in order to meet safety requirements

and training and monitoring of staff exposed to ionising radiations. Such arrangements are hardly feasible in cultural institutions.

(13) According to the information in the application, thermal shock processes (freezing or heat treatments) have undesired effects on several materials. High temperature treatments can cause modifications on the surface of organic materials, softening of glues and lipid crystallisation. According to Spain, high-temperature based treatments are barely applied in the cultural heritage conservation field, since many of the materials found in movable cultural heritage have a lipid or protein nature (e.g. oil paintings, tempera, wax sculptures). Moreover, a temperature increase might trigger undesired chemical reactions. Similarly, low temperature treatments could affect the surface treatments and coverings as well as generate condensation inside the treatment spaces.

(14) As stated in the application, microwave treatments may generate heat, causing microscopic and macroscopic alterations in cultural objects.

(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 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.

(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, on Commission's request, 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.