Commission Implementing Decision (EU) 2020/1265 of 9 September 2020 allowing Germany to authorise biocidal products consisting of in situ generated nitrogen for the protection of cultural heritage (notified under document C(2020) 6028) (Only the German text is authentic)

COMMISSION IMPLEMENTING DECISION (EU) 2020/1265

of 9 September 2020

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

(notified under document C(2020) 6028)

(Only the German 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 including Germany 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 24 April 2020 Germany 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 Germany, 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.

(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 low temperature treatment, heat treatment, humidity controlled warm air treatment. In addition, other active substances can be used for that purpose. However, according to Germany, each of those techniques has limitations in terms of materials on which they can be applied.

(10) As stated in the application, treatment with biocidal products containing other active substances leaves residues on the treated objects that may be progressively released into the environment and pose a risk to human health. This is particularly relevant in the case of cultural objects exhibited in museums and documents available for consulting in archives and libraries.

(11) According to the information submitted by Germany, thermal shock processes (freezing or heat treatments) have undesired effects on a number of materials. Temperature increase or decrease may cause irreversible damage to cultural heritage objects.

(12) 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 weight capacity 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 does not allow the control of the

relative humidity in the treatment area, which is needed for the treatment of some materials.

(13) 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.

(14) 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.

(15) 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 not allow the control of the relative humidity in the treatment area, which is needed for the treatment of some materials.

(16) 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.

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

(18) Based on all those arguments it is appropriate to conclude that *in situ* generated nitrogen is essential for the protection of cultural heritage in Germany and that no appropriate alternatives are available. Germany 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.

(19) 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: