COMMISSION IMPLEMENTING DECISION (EU) 2020/1266

of 9 September 2020

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

(notified under document C(2020) 6030)

(Only the Danish 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 Denmark 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 29 April 2020 Denmark 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 in the application, 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. According to Denmark, it is the method with the least known negative and potentially damaging effects on the materials and combinations of materials of which cultural heritage objects are made.

([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).

(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) and use of biocidal products containing other active substances. However, according to Denmark, each of those techniques has limitations in terms of materials on which they can be applied.

(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 into the environment, which poses a risk to human health and environment. This is particularly relevant for the cultural institutions that are open for visitors and also for the people who work with and handle cultural heritage objects. Furthermore, the use of some active substances can cause changes in colour and appearance of cultural heritage objects.

(11) According to the information in the application, thermal shock processes (freezing or heat treatments) have undesired effects on several materials. After heating treatments, oils from impregnation treatments of wooden objects can protrude to the surface leaving stains, thus changing the appearance of the objects. Waxes and resins can melt during heat treatments. Similarly, low temperature treatments could affect painted surfaces and materials containing shellac, alkyds and acrylics. The method of low temperature is considered inconvenient and less sustainable since all objects need to be tightly packed in plastic foil to avoid condensation after treatment.

(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. Furthermore the storage of cylinders poses a security challenge. The treatment with nitrogen in cylinders would also generate high costs for the cultural institutions.

(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. In addition, discontinuing the use of facilities and equipment acquired for *in situ* generated nitrogen anoxia would result in a loss of previous investments.

(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 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.

(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 Denmark, since all the alternative techniques currently available present disadvantages either due to non-suitability for the treatment of all materials or practical disadvantages.

([5]) 83rd, 84th, 85th and 86th meetings 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

(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 Denmark and that no appropriate alternatives are available. Denmark 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:

Article 1

Denmark 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 Denmark.

Done at Brussels, 9 September 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission