COMMISSION IMPLEMENTING DECISION (EU) 2020/1048

of 15 July 2020

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

(notified under document number C(2020) 4724)

(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 Austria 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 26 June 2019 Austria 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'). Further information on the use of *in situ* generated nitrogen by museums and the absence of appropriate alternatives was provided by Austria in a letter of 3 September 2019.

(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.

([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).

(7) According to the information submitted by Austria, 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 museum collections and exhibitions and cultural heritage sites without damaging them and is effective against all known harmful organisms to cultural heritage objects at all stages of development.

(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 biocidal active substances can be used. However, according to Austria, each of these techniques has limitations in terms of damage that could occur to certain materials during treatment and, therefore, none of them can be used alone for the treatment of all types of materials and combinations of materials.

(10) According to the information submitted by Austria, thermal processes, i.e. freezing or heat treatments, are not suitable for the treatment of a variety of objects, among which paintings, wax-, oil- or protein-bound polychrome objects, glued objects, leather or vellum objects, photo materials, new untreated wooden objects, newly restored objects, objects under tension. In addition, due to the different thermal conductivity and thermal expansion of different materials, mechanical stress caused by dilation can endanger fragile objects made of mixed materials.

(11) The application demonstrates that the use of biocidal products containing other active substances available on the market in Austria can modify the objects in a chemical way and may damage the objects, depending on the sensitivity of materials.

(12) At the same time, in the context of an IPM for protection of cultural heritage, museums intend to move away from the use of more hazardous active substances.

(13) According to the information in the application, the use of nitrogen contained in cylinders is not an appropriate alternative for museums and cultural heritage sites as it presents practical disadvantages. The limited quantities in cylinders require frequent transport and a separate storage facility. Moreover, according to the information in the application, 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.

(14) Requesting museums and cultural heritage sites 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 museums and cultural heritage sites and makes it more complicated for those users to reach the objective of moving away from the use of more hazardous active substances in their IPM.

(15) 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.

(16) In addition, on request of the Commission, the European Chemicals Agency conducted a public consultation on the 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 leave 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.

(17) 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 and obtaining product authorisations require time.

([5]) 83rd, 84th, 85th and 86th meeting 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) The application and further information submitted by Austria show that currently no appropriate alternatives are available in Austria, since all the alternative techniques currently available present disadvantages either in terms of non-suitability for the treatment of all materials or practical disadvantages.

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

(20) 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 time period that would allow the completion of the underlying procedures,

HAS ADOPTED THIS DECISION:

Article 1

Austria 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 Austria.

Done at Brussels, 15 July 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission