COMMISSION IMPLEMENTING DECISION (EU) 2020/1049

of 15 July 2020

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

(notified under document C(2020) 4715)

(Only the French 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 than more hazardous chemicals. 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 also 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 France 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 14 January 2020 France 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 these 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 France, 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 at a reasonable cost.

(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, gamma radiation. In addition, other active substances can be used. However, according to France, 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 France, as regards the technique of cold disinfestation there are doubts as to its suitability for all collections of fine arts and decorative arts. In the case of works in laminated materials (painted, varnished or waxed works, inlaid works or works with incrustation threads) this technique may pose a risk of damaging those objects. However, with respect to the preservation of cultural heritage included in the national inventory, such doubts are not allowed, in accordance with the national conservation policies applicable to institutions holding public collections.

(11) As stated in the application, disinfestation by raising the temperature is not widely used by cultural heritage institutions. As in the case of cold disinfestation, there are concerns about the impact of heat treatment on stratified materials. Moreover, with heat treatment there are additional risks of loss of adhesion for adhesives, softening of the wax-containing elements and resurfacing of previously used chemicals, which generates spots on the surface of the objects.

(12) According to the information in the application, the technique of gamma radiation requires specific equipment meeting specific safety requirements for the implementation of the technique and require advanced skills. It is thus a costly and difficult to replicate technique. Moreover, this technique is not suitable for transparent or translucent materials, which tend to become opaque or to stain in response to gamma radiation.

(13) The application demonstrates that the use of biocidal products containing other active substances available on the market in France leaves residues on the works treated, that can be released into the environment and can pose a risk to human health. Moreover, these substances have significant disadvantages in terms of physical conservation of cultural works since many of them can induce changes in colour, oily or tacky exudations, surface crystallisations or alterations of the DNA of materials of animal origin.

(14) In recent decades, in the context of an IPM for protection of cultural heritage, a growing number of cultural heritage institutions sought solutions to move away from the use of potentially hazardous chemicals and turned to techniques – such as anoxia – which are gentler to cultural heritage collections and less detrimental to the persons working with them.

(15) 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 and economic disadvantages. The limited quantities in cylinders require frequent transport and a separate storage facility. The storage of a large number of cylinders poses security risks due to the presence of gas under pressure. The anoxia using in-situ generated nitrogen results in lower costs for cultural heritage institutions compared to the use of nitrogen in cylinders. Beyond the initial investment in treatment chamber and in-situ nitrogen generator it does not generate any other costs.

(16) 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 make it more complicated for them to reach the objective of moving away from the use of more hazardous active substances in their IPM.

(17) Discussions related to a possible derogation pursuant to Article 55(3) for in-situ generated nitrogen took place in several meetings ([5]) of the Commission expert group of Competent Authorities for Biocidal Products in 2019.

(18) 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.

(19) 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.

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

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

(22) 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

France 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 French Republic.

Done at Brussels, 15 July 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission

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