Report on the participation in the CA 83 meeting under DG SANTE in Brussels 16/5 2019

The CA committee is the Committee of Competent Authorities for the regulation of biocides under the Reg. 528/2012 (BPR) and it is a subcommittee under the Standing Committee on Biocidal Products.

As the only "outsiders" CEO, René Luyten, B-Cat (a representative from the suppliers of in-situ generated nitrogen) and I (representing ICOM/ICOMOS) had been invited to explain each our views on the ban of insitu generated nitrogen under item 5.4 on the agenda "The in-situ generation of nitrogen for the preservation of museum objects".

I referred to the joint letter of 13 Marsh 2019 from ICOM/ICOMOS and repeated the positions stated there. With reference to the response of Director General, Anne Bucher, DG SANTE a discussion took place under which her positions were explained by the chairman, Mr. Martinus Nagtzaam and Mr. Ludovic Chatelin both from the DG SANTE.

The idea of removal of nitrogen from the list in Annex I of the BPR as suggested by ICOM/ICOMOS was supported by several memberstates but it will become rather difficult because of an EU verdict (Söll vs Tetra) where the court decision was equating all substances that would lead the eradication of organisms whatever the substance would act from direct action or indirect action. So even if everybody does acknowledge the fact that nitrogen does not act as an active biocidal substance it is judged from the end result of the process in which it takes place and hence is defined as an active substance. If used not for disinfection but for say, for preservation it is not covered by the BPR.

So, if nitrogen cannot be removed from the list in Annex I there are only two ways to go:

- We can either go for a "short term" solution where we apply for a derogation under art. 55(3) in the BPR if there are not any other suitable alternatives. "Short term" because there is a risk that this application needs to be renewed every now and then. Besides, it will not be unilateral because each country will have to apply individually and granted permission individually.
- 2) Or we could go for a more permanent solution where nitrogen provided by in-situ generators are equated with the present solution of using nitrogen from cannisters and hence added to the list in Annex I. This comprises the opening of a "dossier" collecting data on the substances, its effects and toxicity as well as assessing the method (according to the rules laid down in the BPR). Only the method assessing part has not been done yet, so it is expected to be done under a reduced procedure.

I stipulated that we needed an urgent solution and that it was very unfortunate that the cultural heritage sector had been left uninformed for so long time. I also underlined that in terms of a derogation the museums sector for years had been moving away from the use of harmful chemicals and that the reduction of our possibilities of choosing between environmentally friendly methods was under attack. As stated in the letter and the CEN standard on IPM, there are other alternatives, but nitrogen is the most compatible in every aspect – ecologically, economically and in terms of material harmlessness.

I suggested that ICOM would consider perhaps to go for both solutions at the same time. If so, I asked I we could let ICOM lead the process of urging as many member states as possible to apply in unanimous way for a derogation under art. 55(3) in order – hopefully – to get a fast and intermediate solution. Along with that, ICOM together with one or more member states could initiate the more long term process of opening a dossier for the possible addition of in-situ generated nitrogen to Annex I of the Reg. 528/2012.

The financial question of these procedures was not discussed, but as it seems that the fees for opening a dossier etc. are rather high, it can be of some importance.

There was a good atmosphere at the meeting and especially the commissions people understood the problem and recognized that this was an unfortunate juridical dilemma that would need a solution – though they had never been in a similar situation before.

Among the member states it was clear who was struck by the problem – Austria, Switzerland, Germany, Spain, Greece, The Netherlands, Lithuania, Ireland and Denmark spoke up in favor of a solution one way or the other.

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