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Update on activities of the Ozone Registration Group related to the Ozone Active Substance (AS) Dossier under the Biocidal Product Regulation (EU) 528/2012

As mentioned in the last two issues of *Ozone News*, ozone has been declared an active substance in Europe under the EU Biocidal Products Regulation No 528/2012 Starting as of September 1, 2013. A detailed description of the issues caused by the regulation starts on page 22 of *Ozone News* Vol. 42 No 4.

Following is a current update of the activities of the group. We thank Dr. Tim Pühmeier, Gloal WEDECO Product Manager for Xylem for providing this update.

The Ozone Registration Group (ORG) has now been actively working on the ozone active substance dossier since more than 2 ½ years in order to meet the requirements for the Biocidal Product Regulation and supporting ozone applications accordingly to product types (PT): 2, 4, 5 and 11.

Developments at EU level:
Despite the activities by the ORG that is working on the dossier

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there are still some open questions as policy for the belated inclusion for the in-situ products is still under discussion at EU level.

The Commission regularly organizes Competent Authorities (CA) meetings and also organized an additional *in-situ* workshop, in which the Competent Authorities of the EU Member states are discussing overall policy issues. Here are still some key questions open with regard to the *in-situ* ozone market.

One being, that the actual AS dossier requirement is putting a strong focus on describing the biocide precursors. Here the ozone community could potentially face submitting up to three dossiers (one for each ozone precursor: air, oxygen and water). Recent discussions with policy makers indicate that one AS dossier, covering all of these precursors in a single dossier, seems acceptable; and so, only one AS dossier submission being necessary (Note: The ORG is writing the dossier in that way already).

Secondly the authorization procedure contains issues that remain unclear and needs outlining who can become the authorization holder. To the view of each of the member of the ORG, the majority of all end-users, utilizing ozone generators, can never be enabled on their own to become the authorization holder. This is practically unachievable and requires more resources and knowledge from the end-users than these can typically invest (irrelevant of the size of their operations). Hence the ORG members propose a model where the ozone manufacturers can take up this role for the end-users.

Key dates:

For ozone, companies (bringing AS ozone to market in EU) have time until 1st of September 2016 to submit their dossier for substance approval. Until such a dossier has been submitted and accepted as complete, article 95 of the BPR does not apply. However, as the ORG will submit its dossier early 2015 and as soon it is accepted as complete, article 95 will also apply for ozone from 1st of September 2015 on. From beyond this point any party that can take the role of authorization holder is required having access to an ozone active substance dossier. Meanwhile, this dossier is then under evaluation by an ECA (Evaluating Competent Authority). Approximately 2 years later

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a decision is expected concerning the approval for each PT group to be included in the dossier – this is all based upon the most complete and accurate submitted dossier. Other "incomplete" dossier(s), if present, can be faced to the risk of being rejected. This also means that all the costs invested in such a dossier are lost and the stakeholders in such a dossier still have again to obtain a LoA of an approved dossier. First of all such a scenario would result in would result in extended time required for the process. This might cause defaulting on the deadlines for compliance with the BPR as set out by the EU/ECHA.

Status update - dossier writing:

The dossier work comprises mainly of tasks as outlined in the regulation (EU) 528/2012. The good news is that ozone is understood well and applied for a long time. This is combined with the exceptionally long ozone specific experience of all members and associates in the ORG. Furthermore this experience also extents to the EU regulatory system which being very helpful in structuring the dossier and the interpretation of the technical and scientific details to it. The biggest challenge and workload is due to the toxicological aspects of the use and application of ozone. This amounts to approximately 50% of the dossier work; that took a lot of effort and additional resources. Beyond the science driven work there is also a large proportion of tasks related administrative discussions with end-users, NGOs and also at EU level and with competent authorities. Altogether these efforts shall result in a very comprehensive active substance dossier for ozone (if not most extensive, if such a thing exits) that shall enable the authorities to scrutinize the aspects of "bringing ozone to the market" and finally include ozone in the list of approved substances under the BPR.

The ozone dossier is soon being finalized and it is planned to submit the dossier for approval at the beginning of 2015. Thereafter the "Letter of Access" (LoA) procedure will then be started for anyone in need. Hence as promised from the beginning this is making the dossier available to everyone for registering their ozone processes as part of the product registration. The LoA will be made available via an international non-profit association that is currently under formation.

After obtaining a LoA and subsequent to the dossier of the ORG any additional PTs can be applied for under the BPR without causing the duplication of work, even in the case that someone is bringing ozone to the EU market for special other applications (PT) than supported in the dossier that is compiled

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by the ORG.

LoA costs and cost sharing

Anyone needing access to the LoA for the AS ozone will have to compensate the consortium members for their costs that have been incurred. The costs depend on several factors including direct costs to produce the dossier as well as ECHA and ECA processing costs.

The proposed pricing structure is taking care of regional aspects as not everyone is bringing ozone to the market in all of Europe. The LoA will be available in lots for different numbers of countries, but always cover the PT groups: 2, 4, 5 and 11 and will have a validity of 10 years. Precise terms and conditions will be published by the international association being under foundation.

- 1 country
- 3 countries
- 5 countries
- all countries

However, there is no intention of gaining excessive income out of the LoA sales, as the focus is the cost recuperation and cost sharing. Therefore a large number of companies utilizing the LoA to the dossier of the ORG would dramatically reduce the individual cost.

The members of the ORG are looking forward for positive decisions made by the European Commission and the CA (Competent Authorities) meeting and also welcome feedback and discussion with anyone in need of a LoA so that fair and detailed information for sharing the dossier by LoA can be developed.

The members of the ORG can be conveniently contacted by email: **communication@ozone-registration-group.com** and will provide updates via: **http://portal.ozone-registration-group.com**.