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Abstract Title: A tour through the European Regulations for ozone treatment

Abstract:

Historically ozone has been applied in 1000s of different applications starting from early as 1904. The key drivers were based on science and applied research. Overall ozone has become a conventional treatment technology for drinking water, waste water and industrial water processes. In several countries ozone has been reflected as treatment option local laws and regulations. Today, in the European Union, users of ozone must consider additional legal requirements for the production and use of ozone. There are two key legislative acts that need to be considered, based on the ozone application.

This is:

- European Union REACH Regulation (EC) No 1907/2006 for oxidation processes
- European Union Biocides Regulation (EC) No 528/2012 for disinfection processes

In the cases of oxidative ozone treatment

The REACH regulation has been implemented to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. REACH is actually a very complex law that entered into force on 1st of June 2007.

In the original scope manufacturers and importers have been addressed as main parties being required to gather information on the properties of the particular substances in order to allow their safe handling. All required data has to be entered into a central database of the European Chemicals Agency (ECHA) in Helsinki.

In layman terms REACH follows the theme: “No data - no market” and defines in this way the role of the “industry”. In the case of ozone the requirement of data gathering is actually switched to end-users as ozone is always produced in-situ (at the location where it is consumed) instead of being delivered by chemical/supply industry. It is believed generally not feasible for most end-users to be made responsible for this data gathering. Typically they do not have the required wealth of scientific background information about ozone or the funds to fund (to finance) associated fees, studies and assessments.

Non-biocidal applications include the following applications:

- Oxidation of emerging contaminants / micro-pollutants
- Decolouration
- Taste & Odour Removal
- COD - / AOX Elimination
- Pre-oxidation
- General pollutant treatment

- Sludge-Reduction
- Pesticide, phenol removal

The applicability of the REACH regulation depends on the annual tonnage of ozone produced for non-biocidal applications. REACH assumes a risk potential based on the tonnage of particular chemicals used per year and defines three major tonnage bands with different obligations:

- above 1 ton/a
 - information about properties and uses including risk assessments and its physicochemical, toxicological and eco-toxicological properties
- above 10 tons/a
 - more detailed information about substance properties and its effects. In addition it is required to document the results of the chemical safety assessment in a chemical safety report (CSR) as defined in REACH Annex.
- above 1000 tons/a
 - the above data plus exposure scenarios regarding human health and the environment.

	REQUIRED INFORMATION ON INTRINSIC PROPERTIES FOR REGISTRATION					
	PC, toxicological and ecotoxicological information	Physico-chemical properties (PC)	Toxicological and ecotoxicological information		PC, toxicological and ecotoxicological information	Toxicological and ecotoxicological information
	All available relevant data	Annexe VII requirements	Annexe VII requirements	Annexe VIII requirements	Annexe IX requirements	Annexe X requirements
1-10 t/y	•	•	• ¹			
10-100 t/y	•	•	•	•		
100-1000 t/y	•	•	•	•	• ²	
≥ 1000 t/y	•	•	•	•	• ²	• ²

Ref: http://www.prc.cnrs.fr/reach/en/data_requirements.html

In summary the scope of the REACH regulation it is required to register ozone with ECHA in order to operate legally ozone systems in the case where the annual ozone production is exceeding the annual production rate of 1 ton. Please note that already smaller ozone systems with a capacity of 110 g/h (6 PPD) exceed one ton of ozone and therefore are falling under the registration obligation.

In the cases of ozone treatment for disinfection

In those cases where ozone is used as disinfectant or for the sanitization, ozone is falling as an active substance (AS) under the European Biocidal Products Regulation (BPR) starting as of September 1st, 2013. In effect the BPR is even considerably extending scope compared with the prior existing Biocidal Products Directive. Due to this, the AS ozone and the Biocidal Product (BP) ozone generated by a specific piece of equipment need to be authorized when there is a disinfection claim. EurO₃zon has submitted as of June

5, 2015 an active substance dossier (ASD) for ozone under specific biocidal product-types that are classifying particular ozone applications (PT) 2, 4, 5 and 11 (e.g. disinfection, cooling water treatment, etc.).

The current situation for ozone under REACH

Ozone REACH dossier is submitted on behalf of the Lead Registrant (Xylem), with EurO₃zon mandated as Third Party Representative on 22nd of February in 2018. This enables everyone bringing ozone to the EU market and subsequently filing a registration under REACH in order to produce ozone legally for oxidative processes.

EurO₃zon is offering access to the dossier by a REACH typical LoA (Letter of Access) procedure. This will generate a token that can be used by end-user/producers of ozone that falls under the regulation.

The current situation about Biocidal Product Regulation for ozone

EurO₃zon has submitted as of June 5, 2015 an active substance dossier (ASD) for ozone covering applications defined under biocidal product-types (PT) 2, 4, 5 and 11 well upfront the final deadline for submitting (September 1, 2016). The ASD from EurO₃zon is now under evaluation by the Competent Authority (CA) of Germany (BAuA).

Since 1st September 2017 any new biocides must comply with the BPR before they can be brought to the market.

Due to the timely submission of the ASD for ozone for evaluation all market players, associated to the evaluation, can benefit from the transitional period of Article 89(2) of the BPR to use and make the product available on the market, subject to national laws. Where an application was not made by market players (or on behalf of) by 1st September 2016, the products must be removed from the market by 1st September 2017.

In order to get associated with an ongoing ASD evaluation for ozone any market player can obtain a letter of access to such a dossier.

At the time of writing of this text only the ASD of EurO₃zon can be found back in the public accessible ECHA Article 95

Summary

The regulations concerning REACH- and Biocidal Products are now in full operation and a requirement for the ozone market in Europe. The resulting impacts and requirements for the market player will be outlined in the full paper and providing guidance and provide guidance to comply with the regulations.