Addressing REACH regulation for Ozone in the EU

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Abstract

REACH is an European regulation for mitigating the risk originating from chemicals. However the use of ozone governed for many applications and operators by this new regulation with the obligation to register their production of ozone. This regulation does not necessary affect every end-user as there are some limited exemptions available. EurO_3zon is now in process to create a substance dossier for the REACH registration.

This publication does not aim to replace any official EU guidance, but rather to provide focus and overview to REACH and its relationship to the substance ozone. Additionally to extent and share the knowledge about the boundaries of the registration requirements relates to ozone applications.

Keywords

Ozone; REACH; Registration; Europe; Legislation;

Introduction

The REACH (Registration, Evaluation and Authorization of CHemicals) regulation has been introduced 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 and is set out to be implemented over a period of 12 years.

This regulation is directly in force without delay since its implementation and therefore must not pass local governments in all member states in the EU. It is

actually replacing more than 40 national and European laws. Resulting, all European member states adjusted their national laws and regulations allowing implementing REACH procedures and empowering public authorities for its enforcement.

REACH is a chemicals regulation.

In the original scope of the law the EU-based manufacturers and importers (of chemicals) in amounts of one ton or more per year are required to gather information on the properties of the particular substances in order to allow their safe handling and submit hazard information to the European Chemicals Agency (ECHA) in Helsinki and then entered into a central database.

REACH is applicable to all 28 European member states and including: Overseas France, Azores, Madeira and Canary Islands and the European Economic Area (EEA): Island, Liechtenstein and Norway (Switzerland is not part of the EEA).

In layman terms REACH follows the theme:

“No data - no market” and defines in this way the role of the “industry”.

Substances under REACH

REACH regulation is including in principal all substances in the form of isolates, mixtures and as part of other products.

However, there are several exemptions possible where no registration is necessary (e.g. low amount of substances being below 1 t/a, isolated intermediates, polymers (but monomers are in scope), waste, specific substances named in Annex IV [1] with a low risk such as sugar and oxygen.

REACH is only offering several scenarios where no registration is required. See excerpt of exemption options below:

1. Low amounts of substances brought to the EU market
2. In case the substance is regulated under a different regulation such as the Biocidal Products Regulation (BPR) [2] there is no requirement for additionally fulfil REACH requirements.
3. There is an exemption foreseen within REACH for equipment testing- or research purposes.
4. The last exemption applies for the synthesis of compounds using a substance as an intermediate reaction partner. However, in such cases the resulting new compounds must be fully registered under REACH.

REACH Registration Process

The REACH registration consists of an extensive electronic dossier of information submitted via the REACH-IT platform that is operated by ECHA. The information requirement is strictly dependent upon the tonnage band produced.

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.

The general data requirement encompasses physico-chemical, toxicology, health and environmental properties. In case such information is not readily available, then the registrant must either generate this test data or even conduct additional studies accordingly to current guidelines. All this information is gathered in the registration dossier in order to gain approval by ECHA after submission. A standard registration fee is payable to ECHA when the registration is made (see Table 1).

Once a dossier has been submitted to the ECHA, the agency will conduct a completeness check to make sure that the required information it is completed correctly. This check will be followed by an evaluation of the dossier a Competent Authority of an EU Member State and ask questions of the registrant on technical and other aspects of the dossier.

Table 1 Fees for registrations submitted under Article 6, 7 or 11 of Regulation (EC) No 1907/2006 [3]

Tonnage band [tonnes/year]	Individual registration [€]	Joint Submission [€]
1 - 10	1,739	1,304
10 – 100	4,674	3,506
100 – 1000	12,501	9,376
over 1000	33,699	25,274

The case of Ozone and REACH

The REACH regulation is imposing the role as chemical manufacturer towards any operator/owner of ozone systems that cannot benefit from exceptions.

Ozone applications and its production in the EU

Ozone is being in use for over one hundred years, it can be found as part of many oxidative processes and is produced on-site for purposely design treatment targets. In practice as ozone cannot be produced, bottled and shipped the REACH regulation turns every entity operating one or more ozone generators (for oxidative purposes) into the role of a (small or large) chemical manufacturer 'bringing ozone to the EU market'. In order to comply with the regulation all those operators have to carry out a REACH registration. These operators are in the ozone market predominately end-users.

The big question - is "my" process falling under REACH and what are the details?

In case of an oxidative ozone application, end-users can easily determine their obligation under REACH. Firstly the annual ozone production needs to be determined. This step defines if the end-user is exempted or if the user falls into one of the tonnage bands highlighted above. It is important to know that any legal-entity that operates one or several ozone plants must be added by their capacity for the assessment (even if such ozone generators are located at different sites). A summary is shown in Table 2.

Table 2 Typical ozone applications and associated annual production rates.

Application	Ozone Capacity [kg/h]	Annual Ozone Production [t/a]	REACH is applicable	REACH Tonnage Band
Decolorization	1,2	11	yes	above 10 tons
Removal of pharmaceuticals	5	44	yes	above 10 tons
Pulp bleaching	190	1664	yes	above 1000 tons
Drinking water (Disinfection, Microbiological barrier)	114	999	no (falls under BPR)	n/a
Drinking water (Oxidation eg. of Arsenic)	57	499	yes	above 10 tons
Ozonolysis	125	1095	yes	above 1000 tons
Waste water	6,8	60	yes	above 10 tons
Waste water	12	105	yes	above 100 tons
Industrial waste water	0,1	0,87	no	below 1 ton
Removal of manganese in mineral water	0,4	3,50	yes	above 1 ton

Is there a way out – REACH states exemptions! Do they apply to ozone?

EurO_3zon has thoroughly investigated if ozone is falling under REACH or if it can be exempted under certain conditions. This process was undertaken by involving several specialist REACH consultants and direct intervention with ECHA and competent authorities [4-7]. It must be concluded that the in-situ synthesis of ozone for oxidation purposes (e.g. in wastewater treatment, pulp bleaching, decolonization, etc.), if falling within mentioned tonnage bands are falling under the scope of the REACH regulation and requires the individual registration by the end-user.

There are only a very few 'general' exemptions available for ozone that have limited reach for the industrial or municipal application of ozone, see outlined below:

a. In cases of ozone production not exceeding 1 ton per year there is no requirement for the operator to engage in the registration process. For example this would allow the operation of one or many small ozone systems for oxidation purposes with a total ozone production capacity below 110g/h (6 PPD) in 24/7 operation or any equivalent if operated otherwise per rata.
b. In the case where ozone is used as a disinfectant. However in such cases the biocidal products regulation (BPR) must be fulfilled. It is rather easy to identify whether an ozone treatment process falls under REACH or BPR. Any ozone application aiming at the oxidation of substances (e.g. removal of pharmaceuticals, color or recalcitrant organic compounds) falls under REACH. Whilst any disinfection processes and claims (e.g. drinking water disinfection, cooling water treatment) is regulated by the BPR. The differentiation between oxidation and disinfection is important due to the reason that the BPR takes over for the latter scenario.
c. Ozone systems used in research can be exempted.
d. The synthesis of compounds where ozone is an intermediate reaction partner, but this required that the resulting new compounds must be registered under REACH.

Who is now going to register ozone under REACH?

The authors believe that this task and obligation for this data gathering is not feasible for most end-users that are responsible. Typically they do not have the required wealth of scientific background information for ozone or the funds to invest into associated registration fees for the required dossiers, studies and additional assessments. It is important to stress that in case of the unavailability of an ozone dossier there is no registration possible. The expected assumed cost for conducting the REACH registration is likely amounting to exceed $800,000; depending on the amount of required studies and including assessment cost and ECHA fees.

Since the legal passing of the REACH regulation in 2007, there has been no activity observed in the ozone market to take up the registration process for ozone in order to fulfil legal requirements. This might have been due to the individual judgement and assumption of end-users that certain exemptions for registration would be applicable for ozone and waving its registration requirements.

Even though as ozone system manufacturers are generally not falling in the scope of the REACH regulation, the non-profit association EurO_3zon has now extended their mission of promoting the use of Ozone in Europe by embracing the registration requirements under European Union REACH regulation (EC) No 1907/2006 [1].

REACH registration of ozone

Ozone qualified as a phase-in substance as it's a known substance and listed in the EINECS (European INventory of Existing Commercial chemical Substances).
Therefore ozone can benefit from the delayed implementation timetable (see Figure 1).

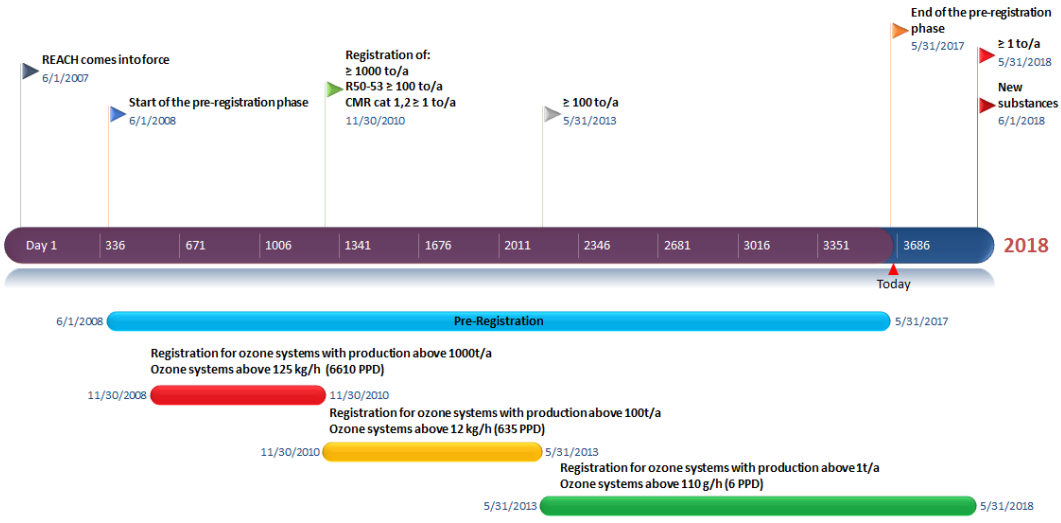

Figure 1 The major milestones of the REACH chemical regulation for ozone

Many users of ozone equipment have already made use of the pre-registration under ECHAs REACH-IT platform as part of a pre-SIEF (Substance Information Exchange Forum) and counting 137 members and 29 inactive ones.

Following interaction with the pre-SIEF members, Xylem IP Management is the company who has accepted to take over the role of Lead Registrant (LR). Communication with the LR will continue to be done through EurO_3zon, the appointed Third Party Representative (TPR) (see contact details below) and is proceeding the tasks for the preparation and registration of the ozone dossier (Ozone, EC 233-069-2, CAS 10028-15-6) as outlined below.

All pre-registrants will be contacted to organize data/cost sharing and respective responsibilities in the substance exchange forum for ozone (SIEF), according to the

principles of fairness, transparency and non-discrimination prescribed by REACH. The pre-registrants who have responded that they own relevant data will be contacted directly to assess the relevance of this data for the registration.

The key stages in the registration process are the outline below. However these are not necessary to be carried out in parallel rather than in a strictly serial order:

1. Collection of pre-registrants' feedback on their status, their information requirements according to their respective tonnage band, and data they may own Literature research and data gathering.
2. Data evaluation, review and data gap analysis
3. Classification and labelling information strategy
4. Determination of Exposure scenarios
5. Preparation of joint technical dossier

Summary

In 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 system with a capacity of 110 g/h (6 PPD) exceed one ton of ozone and therefore falling under the registration obligation.

In the spirit and purpose of the REACH regulation the responsibility of registering in-situ generated ozone lies with the operator of ozone equipment. However EurO_3zons intentions are to secure and support the legal operation of ozone system effectively under the REACH regulation in the ozone market.

Regular updates about the progress and developments REACH registration process can be accessed on the EurO_3zon website: www.euro3zon.org or contact reach@euro3zon.org directly.

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