

Addressing REACH for Ozone used by municipal water works and update on Ozone under BPR

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Abstract

Ozone can be used for both chemical oxidation and disinfection. Oxidation of compounds of (raw) drinking water or wastewater is covered by the REACH (Registration, Evaluation and Authorization of Chemicals) Regulation (EC) No 1907/2006 [1,2]. If the use of ozone implies disinfection purposes, coverage of the uses will be assured by the Biocidal Products Regulation (BPR; Regulation (EU) No. 528/2012) [2].

In this paper, EurO₃zon ivzw would like to inform especially the municipal water works on the REACH regulation implementation and obligations when using ozone for oxidation purposes. Besides, an update is given on the finalisation of EurO₃zon's BPR ozone active substance dossiers.

Keywords: Ozone; REACH; municipal water works; BPR; Active Substance, Europe

Updates on Ozone under REACH

An introduction on Ozone under the REACH regulation, the substances affected, and the registration process is provided in the IOA published article 'Addressing REACH Regulation for Ozone in the EU' [3]. This article brings an update on the ozone REACH dossier supported by EurO₃zon ivzw and especially explains – as an example - the duties of the municipal water works for registering ozone used for oxidation under REACH. Namely, in the intention and purpose of the REACH regulation, the responsibility of registering in-situ generated ozone lies with the operator of ozone equipment.

Ozone production under REACH

The REACH regulation concerns the 'placing on the market and the use' of chemical substances and it aims to ensure a high

level of protection of human health and of the environment. It turns every entity operating one or more ozone generators (for oxidative purposes) into the role of a (more or less large) manufacturer of the chemical ozone. In most cases, the manufacturer of the ozone is also the user of the generated ozone. Consequently, the use of ozone for oxidation purposes requires compliance with the provisions of the REACH regulation. Even in case the generated ozone is sold on-site (i.e., placed on the market) to another entity, REACH applies. In order to comply with the regulation, all those operators/manufacturers, that are in the ozone market predominantly users, have to carry out a REACH registration.

Are municipal water works falling under REACH and what are the implications?

For an oxidative ozone application, users can easily determine

¹EurO₃zon® is a registered trademark of the non-profit association EurO₃zon ivzw

Table 1. Fees for registrations submitted under Article 6, 7 or 11 of Regulation (EC) No 1907/2006 [4]

Tonnage band [tonnes/year]	Individual registration [€]	Joint Submission [€]
below 1	No REACH registration is required	
1 - 10	1 739	1 304
10 – 100	4 674	3 506
100 – 1000	12 501	9 376
over 1000	33 699	25 274

their obligation under REACH by assessing the amount of chemicals (here ozone) being produced. Firstly, the annual ozone production needs to be determined for the water treatment and it is classified into several bands. Resulting, the user might be exempted depending on the appropriate ‘tonnage bands’, as presented in Table 1. 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.

REACH states some exemptions - Do they apply to ozone?

EurO₃zon ivzw has thoroughly investigated if ozone is falling under REACH or if it can be exempted under certain conditions [5-8]. It must be concluded that the in-situ synthesis of ozone for oxidation purposes (e.g., in drinking or wastewater treatment, etc.), if falling within mentioned tonnage bands, is falling under the scope of the REACH regulation and requires the individual registration by the user. There are only a very few ‘general’ exemptions available for ozone that do not apply to the industrial or municipal application of ozone [3]. Such scenarios are the synthesis of chemicals, whereas the end-product then must be registered under REACH.

How to purchase access rights to ozone under REACH?

Even though ozone system manufacturers themselves are not falling within the scope of the REACH regulation and the expected assumed cost for conducting and maintaining the REACH registration is amounting to exceed \$800,000 (depending on the amount of required studies and including the

assessment cost and ECHA (European CHemicals Agency) fees [4]), the non-profit association EurO₃zon ivzw has extended its mission of promoting the use of Ozone in Europe by embracing the registration requirements under the European Union REACH regulation (EC) No 1907/2006 [1]. The first steps on the REACH registration of Ozone are described in the IOA published article “Addressing REACH Regulation for Ozone in the EU” [3].

EurO₃zon ivzw decided to carry the burden of the REACH registration in order to keep the use of ozone for oxidative purposes legal. The initiated authorization process under REACH, evaluating the protection of human health and of the environment for the use of ozone, keeps these uses legal within the EEA² market. Users of ozone are now obliged to share the burden. For the practical implementation, EurO₃zon ivzw submitted on 22nd February 2018 an ozone REACH dossier on behalf of the Lead Registrant (LR), an EurO₃zon member, with EurO₃zon ivzw mandated as Third Party Representative (TPR). Purchasing Access Rights (token) to the ozone REACH dossier is possible as explained on the website <http://www.euro3zon.org>.

The EurO₃zon fee structure for purchasing Access Rights to the Joint Submission of the ozone REACH registration dossier (co-registrations) is derived from the cost sharing formula in the EurO₃zon REACH Co-Registrant Agreement whereby all members pay a pro rata share of the costs of the ozone REACH dossier. Thus, all co-registrants are required to pay for access to the ozone REACH dossier. The LoA (Letter of Access) fees are tonnage dependent and based on the principle of fair, non-discriminatory cost sharing, balancing the interests of all

²EEA = European Economic Area, the EEA includes EU countries and also Iceland, Liechtenstein and Norway. Switzerland is not an EU or EEA member, but the BPR rules apply also.

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 e.g. of Arsenic)	57	499	yes	above 100 tons
Ozonolysis	125	1095	yes	above 1000 tons
Wastewater	6.8	60	yes	above 10 tons
Wastewater	12	105	yes	above 100 tons
Industrial wastewater	0.1	0.87	no	below 1 ton
Removal of manganese in mineral water	0.4	3.50	yes	above 1 ton

co-Registrants members and of the Lead Registrant.

The purchase of Access Rights (token) to the Joint Submission of the ozone REACH registration dossier is organized in a secure and transparent way via the EurO3zon REACH 'LoA shop' (<http://www.euro3zon.org/LoA/IndexReach>) and involves nine (9) consecutive steps.

After receiving the token, the LoA-customer has to complete his own co-registration via REACH-IT at ECHA. This requires either a three-step or four-step process, as follows:

- 1) REACH-IT (ECHA) account creation;
- 2) Purchasing access to the ozone REACH dossier;
- 3) If required: submitting an Article 26 inquiry [1]. This is only relevant for co-registrants that were not pre-registered;
- 4) Completing the co-registration.

If an organization consists of more than one legal entity that produces ozone in the scope of REACH, each legal entity needs to complete a Co-Registrant Agreement and needs to pay for individual access rights to the REACH registration dossier.

If a user needs help for submitting an Article 26 inquiry and/or completing the co-registration, or wants to outsource these tasks, technical support can be delivered, including the purchase of a Data Support Package and/or consultancy services.

Information on the ozone REACH registration process can be accessed on the EurO3zon website: www.euro3zon.org or by contacting reach@euro3zon.org directly.

Conclusion

In the scope of the REACH regulation, it is required for municipal water works to register ozone used for oxidation purposes with ECHA in order to operate legally ozone systems in the case where the ozone production is exceeding the annual ozone production rate of 1 ton. It has to be noted that already smaller ozone systems with a capacity of 115 g/h (6 PPD or pounds per day) exceed one ton of ozone per year and therefore fall under the REACH registration obligation (depending on the duty cycle of the equipment).

Update on Ozone under BPR

The position of ozone (in EU redefined as 'ozone generated from oxygen') under the BPR is already explained in the articles "*Ozone Biocidal Product Authorization under the European Biocidal Products Regulation*" and "*Ozone under the European Biocidal Products Regulation - Latest updates*

from EurO3zon", which were both published in Ozone News (Volume 47, No. 3, pages 18-20 and Volume 48, No. 6, pages 16-17, resp.). Placing ozone biocidal products legally on the European market requires a two-step process, of which approval of ozone as active substance is the first step [9-10].

Evaluation process of biocidal active substances under the BPR

The evaluation process of biocidal active substances (AS) under the BPR consists of the following seven steps³.

1. The evaluating competent authority carries out the AS dossier evaluation.
2. The evaluating competent authority finalises the draft assessment report and the conclusions of its evaluation.
3. The draft assessment report is sent to the applicant through R4BP 3. The applicant has then 30 days to provide written comments.
4. The assessment report is transmitted through R4BP 3 to ECHA for peer review in the Biocidal Products Committee (BPC).
5. If the active substance is a candidate for substitution, a public consultation is launched. This gives third parties the possibility to submit relevant information, including information on alternative substances [this step is not applicable for ozone].
6. The BPC has 270 days to deliver an opinion through a peer review assessment and to submit this opinion to the Commission.
7. The Commission takes a decision on the approval of the AS.

Following a positive decision, the AS is included on the Union list of approved active substances.

Progress of approval of the active substance ozone under the BPR

Following the submission of an application for 'ozone generated from oxygen' covering the product types (PTs) 2, 4, 5 and 11⁴ by EurO3zon ivzw on 5 June 2015, the German evaluating Competent Authority submitted an assessment report and the conclusions of its evaluation to the ECHA on 9 September 2020. In order to review the assessment report and the conclusions of the evaluating Competent Authority, ECHA organised consultations via the BPC (BPC-41) and its Working Groups (WG III 2021). Revisions agreed upon were presented and the ozone assessment report and conclusions were amended accordingly.

During 2021 the Biocidal Products Committee (BPC) prepared the opinions of ECHA for approval of the active substance ozone based on the four AS dossiers submitted and supported by EurO3zon ivzw.

³ <https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/approval-of-active-substances/evaluation-process-for-active-substances>

⁴PT 2 Disinfectants and algaecides (not intended for direct application to humans or animals), PT 4 Food and feed area, PT 5 Drinking Water, and PT 11 Preservatives for liquid- cooling and processing systems.

Then, on 1 December 2021, the Biocidal Products Committee (BPC) adopted the opinions on the application for approval of the AS ‘ozone generated from oxygen’ for PTs 2, 4, 5 and 11 by consensus. The opinions are published on the following ECHA webpage: <http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval>.

In other words, the approval process of the AS ozone based on the EurO3zon’s AS dossiers reached meanwhile step 7, the final step, meaning a decision on approval of the AS ‘ozone generated from oxygen’ has now to be taken by the European Commission.

However, another application for the same AS is evaluated by the Competent Authority of the Netherlands. The evaluation of that other dossier has not yet been finalized and was not reflected in the BPC opinions mentioned above and interferes with the timeline of EurO3zon’s AS dossiers.

Progress of the ozone biocidal product authorization dossiers under the BPR

After the approval of the active substance (Step 1), the next step - for keeping ozone generating devices legally in the EEA and Swiss market – includes the successful completion of the subsequent Biocidal Product (BP) authorization dossiers covering the many different biocidal uses (Step 2) [9]. And, although the AS ozone did not receive an approval as AS yet, due to time constraints for preparing the BP dossier, EurO3zon ivzw reached an agreement with the German Competent Authority in order to support these BP dossiers prior to approval of the AS ozone. So, EurO3zon ivzw is since 2019 intensively working on the BP dossiers including several projects for proving efficacy of ozone for all relevant uses [9]. This testing is done under realistic conditions, involves the development of new testing methods and happens in cooperation with highly valued testing facilities and partners. This will result in a submission of the complete BP dossiers in due time, but again well before any deadline, once the approval date of the AS ozone is known.

Access to these BP dossiers is exclusively available for the Letter of Access (LoA)-holders and EurO3zon members. At the time of publication, EurO3zon ivzw is still offering Associate Membership for companies that are interested to work with EurO3zon ivzw for placing their ozone generating devices legally on the market, but the first commitment in this process is the purchase of a LoA (Step 1) as described in more detail under the following webpage: <https://www.euro3zon.org/Loa/IndexBpr>. The LoA price is only depending on the number of Member States the LoA covers, if not the whole EU territory is of interest.

Updates on the BPR can be found on the EurO3zon website:

www.euro3zon.org or contact bpr@euro3zon.org directly.

Disclaimer: The answers provided here are based on the best information currently available and this information does not constitute advice regarding legal or regulatory compliance. You are solely responsible for obtaining appropriate legal or regulatory advice necessary in making your own evaluation of any legal or regulatory requirements applicable to you or your organization or company.

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