

Use of ozone: A legal sword of Damocles?

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Abstract

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Ozone can be used for both disinfection and oxidation. If ozone is used for disinfection purposes, the application is subjected to the Biocidal Products Regulation (BPR; Regulation (EU) No 528/2012) [1]. The oxidation of e.g. water contaminants in drinking water production or wastewater treatment falls under the REACH Regulation (Registration, Evaluation and Authorisation of Chemicals) (EC) No 907/2006 [2].

All users of ozone must comply with both regulations if they want to use ozone in existing or projected installations in a legally compliant way within the EU. This article explains what needs to be considered.

Biocidal Products Regulation (BPR) or REACH?

Both regulations are provisions of chemicals law and have the task of ensuring a high level of protection for human health and the environment. In addition, they serve to harmonize the European market with regard to the legal framework for handling chemicals. As a result, all chemicals produced, imported, or used in the European Economic Area are subject to the same requirements for assessing their usefulness, efficacy and risk to humans and the environment.

Biocidal Products Regulation (BPR)

As the name suggests, the BPR refers to products that contain biocidal active substances and whose declared purpose is to destroy or otherwise control harmful organisms. To this end, such products must undergo a two-stage testing and approval/authorisation process, in which first the active substance and then the biocidal product placed on the market are tested for their efficacy and risks, and finally authorised under the BPR after evaluation by a national notified body/authority. Even if, in the case of ozone, the active substance and the product are identical, this two-step process must be followed.

The responsibility for this approval process can be assumed by anyone in the entire chain between production and use. Generally, the manufacturer or importer will face the authorisation process, since the financial and technical effort would by far exceed the capacities of a typical end-user.

Within Europe, two consortia already handle the authorisation of ozone, so users only need to be careful to use ozone generation equipment from manufacturers that have access to one of the two authorisation dossiers. However, there are differences in the uses for which the consortia seek authorisation. Here, users should ask the manufacturer of their ozone generation equipment for clarification as to whether the particular use is covered by the dossiers of the manufacturer's consortium.

REACH

All uses of ozone with non-biocidal claims are covered by REACH. The requirements of REACH are based on the annual quantity (tonnage ranges) of ozone produced by the user.

In municipal water treatment, this applies to process steps in which ozone is used for oxidation. Some examples are the decolorization of water, the removal of odour, the oxidation of anthropogenic micropollutants such as pharmaceutical and pesticide residues, or the oxidation of undesirable metal ions such as iron, manganese, or even arsenic.

Unlike the BPR, the responsibility for approval lies with the manufacturer or importer of the chemical, and no one else can assume this obligation.

For the purposes of REACH, any company that operates ozone generation equipment becomes a manufacturer, to a greater or lesser extent, of the chemical ozone, and thus has the obligation to review any authorization requirements. In most cases, the manufacturer of the ozone is also the user of the ozone produced, as the ozone production facility is owned by the same legal entity as the one in which it is used. Only in special cases, such as “operator models” in which the ozone generation plant belongs to someone else and the latter sells the generated ozone, the obligation of approval is not with the end-user.

Distinction between the two regulations

"But isn't disinfection also a kind of oxidation?" Yes, of course, this is true for all oxidative disinfectants and thus also for ozone. Nevertheless, there is no choice as to which regulation one wishes to follow. The question of disinfection or oxidation is based solely on the essential purpose(s) of the use of ozone, the “claim(s)”. If the essential purpose is the establishment of a microbiological barrier, then automatically only the biocide regulation applies, even if one or the other micro pollutant is oxidized at the same time. However, if the ozone is essentially used to oxidize micro pollutants or other substances, it does not matter that germs are also rendered harmless in the process, then REACH applies. If e.g. a water treatment system has two ozonation stages, one for oxidation and a second for disinfection, the first falls under REACH and the second under BPR. Table 1 presents some examples of the differentiation of various uses between BPR and REACH.

Table 1: REACH or BPR? A comparison of typical ozone applications.

Application	Ozone demand [kg/h]	Annual ozone production [t/a]	REACH-obligation	REACH tonnage range
Decolourisation	1.2	11	yes	> 10 t
Removal of micropollutants	5	44	yes	> 10 t
Paper/pulp bleaching	190	1,664	yes	> 1000 t
Drinking water (disinfection, microbiological barrier)	114	999	no (BPR applies)	-
Drinking water (oxidation e.g. of arsenic)	57	499	yes	> 100 t
Ozonolysis	125	1,095	yes	> 1000 t
Municipal waste water	6.8	60	yes	> 10 t
Waste water	12	105	yes	> 100 t
Industrial waste water	0.1	0.9	no	< 1 t
Removal of manganese in mineral water	0.4	3.5	yes	> 1 t

Does my application fall under the REACH regulation, and what are the implications?

In the case of an oxidative ozone use, users can easily check their obligations under REACH by assessing the amount of chemical ozone produced. In contrast to the BPR, REACH has a minimum quantity rule, only above which there is an obligation to register. The amount of data required for registration, and therefore the amount of fees for testing, is determined by tonnage ranges of annual production volume as shown in Table 2.

It is important to note that any legal entity operating one or more ozone production facilities must add up all individual ozone outputs in the assessment, even if the ozone production facilities are located at different sites. For example, if a company owns three small water plants, each producing only 0.4 tons of ozone per year, they are still subject to REACH because they produce a total of 1.2 tons of ozone per year and thus fall within the tonnage band of 1-10 tons/year. However, if the three plants are operated by three individual subsidiaries, which are to be regarded as legal entities, and none of the subsidiaries produces 1.0 t or more of ozone per year, none of the companies will be subject to REACH.

Table 2: Fees for registrations under the REACH Regulation [4]

Tonnage band [t/year]	Fee (ECHA) [€]
< 1	-
1 – 10	1.304,-
10 – 100	3.506,-
100 – 1.000	9.376,-
> 1.000	25.274,-

REACH provides for some exemptions - do they apply to ozone?

In fact, there are very few exemptions to the registration requirement for ozone under REACH, but these are not applicable to municipal uses of ozone [3]. An exceptional scenario is, for example, the synthesis of chemicals in which ozone is involved in one of possibly several reaction steps. Here, however, the newly generated end product must be registered under REACH in a clearly defined manner.

How to get the REACH registration?

Even though the obligation to register lies with the operators and not the manufacturers of ozone generation equipment, a group of equipment manufacturers as members of the non-profit organization EurO₃zon ivzw, based in Belgium, have been pushing for registration. Already in 2018, EurO₃zon submitted an ozone REACH dossier on behalf of one of its members to the European Chemicals Agency (ECHA), giving that member lead registrant status [3].

As provided for by the REACH Regulation, all further registrations must relate to this lead notification. The background to this regulation is that, on the one hand, the reviewing authority ECHA should not be overburdened by hundreds of dossiers, but that, on the other hand, a fair and transparent distribution of the notification costs among all applicants must be ensured. Therefore, the REACH Regulation ensures that the costs of preparing all the studies and data required for the notification dossier - in the case of ozone this amounts to around € 850,000 - are kept small for each party by sharing them among all co-registrants.

The cost of acquiring access rights to submit the ozone REACH registration dossier (Co-Registration) is derived from the cost sharing calculation method as foreseen in the EurO₃zon REACH Co-Registrant Agreement that applicants may enter into with EurO₃zon. A proportional share of the ozone REACH dossier costs is provided for all registrants, based on volume, on the principle of fair, non-discriminatory cost sharing that takes into account the interests of all co-registrants and the lead registrant.

For the purchase of the access rights (token/proof) for the submission of the ozone REACH registration dossier, EurO₃zon has set up an online LoA (letter-of-access) shop [6]. The current costs for the access certificate are also listed there. After receiving the token, the operator of an ozone generation facility must perform his own co-registration via REACH-IT at ECHA or mandate a service provider to do this for him.

In the case of larger organizations such as a water association consisting of more than one legal entity (e.g., different municipal utilities) producing ozone within the scope of REACH, each legal entity must enter into a co-registration agreement and complete the registration, including associated costs.

The whole registration process takes place online, but at the same time requires experience in dealing with the corresponding portals of the European Chemicals Agency ECHA (e.g. REACH-IT). Depending on the experience of the user/co-registrant, external assistance from a service provider may be useful during registration; EurO₃zon can provide advisory support and/or recommend experts here within the scope of its statutes.

Further information on the REACH registration process for ozone as well as contact details can be found on the EurO₃zon website [5].

Summary

Ozone can only be used in compliance with the law if its production and use are in conformity with the Biocidal Products Regulation (BPR; Regulation (EU) No. 528/2012) [1] or the REACH Regulation (Registration, Evaluation and Authorization of Chemicals) (EC) No. 907/2006 [2].

If ozone is used for disinfection, an authorization according to the Biocide Regulation must be obtained, which is already taken care of by manufacturers of ozone generation plants.

If ozone is used for oxidation, e.g. of anthropogenic micropollutants, of metals such as iron, manganese or arsenic, for decolorization, for odor elimination, etc., every operator of an ozone generation plant with an annual production of 1 t or more is obliged to register under REACH. However, he does not have to submit to a completely new registration process but can refer to the already submitted dossier of a lead registrant against a fair and transparent cost sharing.

Operators of ozone generation facilities may also fall under both regulations, depending on the intended use of the ozone.

Disclaimer: The answers provided herein are based on the best information currently available and do not constitute legal or regulatory compliance advice. It is the readers' sole responsibility to seek appropriate legal or regulatory advice to evaluate for themselves the legal or regulatory requirements applicable to them or their organization or business.

References

- [1] REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products
- [2] REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency
- [3] Paolini, B., Pühmeier, T., Mielcke, J., Rothe, M., Hoffmann, M., Ryckeboer., J. (2017). Addressing REACH regulation for Ozone in the EU. International Ozone Association (IOA). Ozone News Vol 45, No. 6, 11-14.
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- [5] Website EurO₃zon: <http://www.euro3zon.org>.
- [6] Online shop for REACH registration: <http://www.euro3zon.org/LoA/IndexReach>.

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