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# Ozone as active substance under the Biocidal Products Regulation

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## Summary

Ozone is declared an active substance under the EU Biocidal Products Regulation No 528/2012 (BPR) starting as of September 1st, 2013. In effect the BPR is considerably extending scope compared with the prior existing directive. Due to this, the active substance ozone and the ozone generating equipment needs to be authorized. WEDECO, OZONIA, ProMinent and BWT jointly, as the "Ozone Registration Group" (ORG), are writing an active substance dossier for ozone covering applications defined under biocidal product-types (PT) 2, 4, 5 and 11. The intention of this group is to submit the active substance dossier for ozone by the end of 2014. This is a key step for anyone intending to bring ozone in the EU market. In case no such dossier is filed nobody will be able to comply with the new legislation and will be withheld from using ozone in Europe. Hence it is the main target of the "Ozone Registration Group" to achieve that the ozone gets approved as active substance and listed in the EU "List of approved active substances". Secondly, it is then required to apply also for the authorization of ozone as biocidal product, a product which is typically generated on site. This allows the further use of ozone in treatment processes in agreement with the EU law. The second step can possibly most effective be done by the actual manufacturer of such ozone equipment. In order to do so an approved active substance dossier must be owned or legally accessed by a letter of access (LoA). The ORG will make LoAs available to everyone who need it before the end of 2014.

## 1. Regulatory Information

### 1.1 Situation prior to May 22, 2012

In the European Union and its meanwhile 28 Member States (MS), the EU Biocidal Products Directive 98/8/EC (BPD) regulated all biocidal products that have been placed on the European market. This was including countries with bilateral agreements, such as Liechtenstein and Switzerland. The BPD laid the foundation for all businesses selling biocidal products, and each of these businesses had to deal with the BPD's requirements for documentation. However, several in-situ produced biocides were not regulated by the BPD (including ozone).

### 1.2 Situation as of today

On May 22, 2012 a new text was adopted by the European Parliament and the European Council called the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012), which repeals and replaces the BPD and henceforth regulate all biocidal products placed on market of the European Union. The BPR introduces new procedures for all EU countries for the authorization of biocidal products. A system of mutual recognition among EU member states is instigated, as is a single EU-wide approval, which will be in force immediately in all member states. Most significantly the in-situ generation of biocides is now embraced by the new Regulation (EU) No 528/2012. The European Chemicals Agency (ECHA) is the driving force among regulatory authorities in implementing the BPR. The BPR applies also to Norway and Iceland, while the participation of Liechtenstein and Switzerland is pending.

## 2. Important terms according to BPR, Regulation (EU) 528/2012

### 2.1 Biocidal product

A biocidal product is:
— any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,
— any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.
A treated article that has a primary biocidal function shall be considered a biocidal product.

### 2.2 Active substance
An active substance describes a substance or a micro-organism that has an action on or against harmful organisms (e.g. disinfection).

### 2.3 Existing active substance

A so called existing active substance describes a substance, which was on the market on May 14th, 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development.

## 3. What are the consequences for the use of ozone?

### 3.1 Ozone is declared as an existing active substance
It is important to recognize the ozone did not fall under the former EU Biocidal Products Directive 98/8/EC (BPD) but is now regulated under the EU Biocidal Products Regulation 528/2012.
Due to the fact that ozone was brought to the market and used as a biocide before September 1st, 2013, it is also clearly an existing active substance according to the BPR and Article 93 "Transitional measures concerning biocidal products not covered by the scope of Directive 98/8/EC" does apply. So this article regulates transitional measures for such type of substances, but in the recent published Regulation (EU) No 334/2014 this article, among others, has recently been amended.

### 3.2 The two step authorization approach
The first step is the approval of ozone as an active substance. This needs to reflect the relevant biocidal applications as defined by the product-types. Thereafter the second step is the authorization of the products generated by the equipment, the equipment-specific ozone.

### 3.3 Approval as an active substance
Active substances and therefore also ozone must be approved and listed in the EU List of approved active substances (http://ec.europa.eu/environment/chemicals/biocides/active-substances/approved-substances_en.htm). To be listed a procedure is defined within the annex of BPR. As the first step an active substance dossier must be created, which contains all information as defined in BPR. This dossier is then to be submitted for validation to an appropriate body. According to Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11th March 2014, among others, amending Article 93 of the BPR, such a dossier must be filed before September 1st, 2016.
If no application for ozone was filed in time ozone cannot be brought into the market and can only be used under transitional measures until 180 days further September 1st, 2017, which is March 1st, 2018.
However, if an application for ozone is filed before September 1st, 2016, ozone can still be used until the date of approval by the Commission. In case of failing the obligations under the BPR and no authorization is granted, ozone cannot be anymore legally used and the 180 days grace period applies.
Both cases as outlined above (no application / not granted authorization) will end the legal use of ozone and as a consequence will also end the business of nearly all ozone generating equipment manufacturer who are selling equipment into the EU market. Thus also scientific work studying ozone as biocide will lose importance.
Therefore it is essential that an active substance dossier for ozone is successfully filed before September 1st, 2016, and subsequently leading to an authorization. This will be the base to ensure the activities of the "ozone community". An application must be filed for all desired product-types (PT). The BPR defines the following product-types:

| Product-types | Examples: (Application / Relevance) |
|---|---|
| PT 1 Human hygiene | |
| PT 2 Disinfectants and algaecides not intended for direct application to humans or animals | swimming pools |
| PT 3 Veterinary hygiene | hard surfaces disinfection (agriculture) |
| PT 4 Food and feed area | bottle rinsing in beverage |
| PT 5 Drinking water | potable water |

| | |
|---|---|
| PT 6 Preservatives for products during storage<br>PT 7 Film preservatives<br>PT 8 Wood preservatives<br>PT 9 Fiber, leather, rubber and polymerized materials preservatives<br>PT 10 Construction material preservatives<br>PT 11 Preservatives for liquid-cooling and processing systems<br>PT 12 Slimicides<br>PT 13 Working or cutting fluid preservatives<br>PT 14 Rodenticides<br>PT 15 Avicides<br>PT 16 Molluscicides, vermicides and products to control other invertebrates<br>PT 17 Piscicides<br>PT 18 Insecticides, acaricides and products to control other arthropods<br>PT 19 Repellents and attractants<br>PT 20 Control of other vertebrates<br>PT 21 Antifouling products<br>PT 22 Embalming and taxidermist fluids | Cooling water treatment |

An active substance dossier must provide the following core data set (CDS) and additional data set (ADS):

- Identity
- Physical and chemical properties
- Physical hazards and respective characteristics
- Methods of detection and identification
- Effectiveness against target organisms
- Intended use and exposure
- Toxicological profile for human and animal including metabolism
- Eco-toxicological studies
- Environmental fate and behavior
- Measures necessary to protect humans, animals and the environment
- Classification, labeling and packaging.

Furthermore, it is important to know that also Article 95 of the BPR “Transitional measures concerning access to the “active substance dossier” is relevant. This article is also amended by Regulation (EU) 334/2014. Article 95 requires that all active substance manufacturers and importers (the 'substance supplier') placing active substances on the EU market, either on their own or in a biocidal product, that have not already submitted their own dossier on the active substance under the Biocidal Products Directive (BPD) or the Biocidal Products Regulation (BPR) must apply to be included on the 'active substances and suppliers (Article 95) list'. In addition to this, the amendment of the BPR also allows for 'product suppliers' (e.g. formulators) to apply to be included in this list.
However the requirements related to Article 95 only apply for Article 93 products (AS) from the date the active substance dossier of the concerned Article 93 product has been submitted. In case this active substance dossier has been submitted before 1st September 2015 then Article 95 applies from 1st September 2015 the latter is expected based on the proposed timeline and submission date of the ozone active substance dossier of the ORG.

### 3.4 Authorization of products

The biocidal product authorization is the second important part of the biocidal legislation.

Before applying for an authorization for the biocidal product ozone the applicant must either own an already approved active substance dossier or obtain a letter of access (LoA) to an approved active substance dossier.

As ozone is commonly generated in-situ, a discussion is ongoing within Europe who should be the authorization holder of the biocidal product, the manufacturer of the equipment or the end-user of the on-site generated ozone.
In other words: Who has to apply for the biocidal product authorization?

- The owner?
- The operator?
- The manufacturer of the equipment?

Imagine that every operator for each single piece of ozone generating equipment must apply for an authorization. What an administration, what a workload for the bodies of the countries who have to deal with that. As a side effect it may motivate operators of ozone generating equipment to get rid of ozone.

The discussions about this topic are still ongoing on EU level but we can expect that the manufacturer of the equipment has to hold the authorization for the in situ generated biocidal product, ozone, for the supported product-types, which allows placing on the market of the ozone generator. This would simplify significantly such a procedure.

While thinking about that, bear in mind that ozone generated by existing equipment - already installed and operated - must also comply with the new regulation and needs an authorization.

## 4. The ozone registration group

Everyone in the ozone community (manufacturers and end users) have an own opinion about the BPR and its consequences. However this situation does not permit to wait until someone might solve the situation. Hence the members of the Ozone Registration Group have jointly taken up the task for the submission of the AS ozone dossier and finally resulting in the approval of the active substance ozone under the BPR.
Ignorance in this matter would have a huge impact for the use of ozone as a biocide affecting industry, infrastructure and stopping investments for scientific work.

### 4.1 Requirements

In order to comply with the regulations it is necessary to submit a technical dossier outlining the properties of the active substance.

The creation of an active substance dossier requires

- deep technical knowhow about the generation of ozone and the effects when used in processes
- substantial amount of financial funding
- willingness and the availability of labor resources
- willingness to take some risk
- determination to be successful.

The core data set and the additional data set (see paragraph 3.3) to be delivered with an application is extensive and must be based on scientific work results (primary literature). Such a dossier may end up with 50,000 pages and more.

Once such a dossier is filed it represents also a risk. Every competent authority (CA) representing the Member States (MS) may request additional data, which may lead to additional lab and test work, which can generate substantial cost increase that are not even possible to predict.

### 4.2 The Ozone registration Group

The awareness about the impacts and the requirements to create an active substance dossier and securing their business, four ozone equipment manufacturers have joined forces which resulted in the foundation of the “Ozone Registration Group”.

These manufacturers are BWT, Degrémont Technologies (OZONIA), ProMinent and Xylem (WEDECO). To be very explicit and clear: Those four companies are and will remain to be competitors. The only topic, covered by the cooperation, is the creation of the active substance dossier. All data supplied by either company to build the dossier stays confidential towards the others.
The rationale behind this cooperation is the enormous information that needs to be collected, evaluated and lastly the financial impacts, which all cannot be managed by a single entity.

Worldwide the two greatest Ozone-Companies are part of the group supplemented by the large knowledge of each member himself make it possible to progress rapidly with the active substance dossier.

### 4.3 Active substance dossier of the Ozone Registration Group

As mentioned above, the main goal is the inclusion of ozone in the EU “List of approved active substances”. Regarding the proposed timeline to achieve the approval of ozone the active substance dossier shall be filed by the end of 2014.

The application and dossier of the Ozone Registration Group will cover the following product-types:

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

The duration for the assessment and evaluation process is estimated to last over one year but not more than two years.
The cost to reach a successful authorization of this dossier is estimated to be a minimum of two million Euros.

### 4.4 Letter of access

An applicant must either own a dossier or must provide a letter of access (LoA) that grants citation rights to an existing active substance dossier. The letter of access permits third parties to undertake their product authorization obligations under the BPR without the need for writing another, own active substance dossier.

Furthermore EC bodies are not interested having to evaluate several dossiers in different countries covering the same active substance.
The Ozone Registration Group will make available its active substance dossier by means of a letter of access (LoA). Anyone in need carrying out the biocidal product authorization and waiving the requirement of writing and submitting an own active substance dossier for ozone can benefit regarding time and expenditure. The Ozone Registration Group will offer and sell Letters of Access to any external party.

The Ozone Registration Group is in the process setting up the organization for providing letters of access to third parties. It is expected to be ready to sell LoAs before end of 2014.

For the applicants it will be a good investment to buy a LoA as they can benefit of all knowledge of the group for a minimum period of 10 years.

Regular updates about the progress and developments of the active substance dossier can be retrieved by regularly visits of the group’s website (www.ozone-registrationgroup.com).

**References**

Regulation (EU) No. 528/2012 of May 22nd, 2012 (Biocidal Products Regulation). Version 2012R0528 - EN - 23.09.2013 - 001.001 – 1
Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014
http://echa.europa.eu/

**Abbreviations**

ADS: Additional Data Set
AS: Active Substance
BP: Biocidal Product
BPD: Biocidal Products Directive (98/8/EC)
BPR: Biocidal Products Regulation (528/2012)
CA: Competent Authority
CDS: Core Data Set
ECHA: European Chemicals Agency
EU: European Union
LoA: Letter of Access
MS: Member States
ORG: Ozone Registration Group
"Ozone Community": Everybody producing and/or applying ozone.
PT: Product-Type