Ozone as active substance under the Biocidal Products Regulation

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REGULATORY INFORMATION

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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).

REGULATORY INFORMATION

Situation as of today (1 of 2)

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.

REGULATORY INFORMATION

Situation as of today (2 of 2)

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, Iceland, Liechtenstein and Switzerland.

On the 60th meeting of Representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012, held on 20-21 May 2015, important decisions were taken concerning the "Management of in situ generated active substances in the context of the BPR - The case of ozone"

IMPORTANT TERMS

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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

IMPORTANT TERMS

Active substance

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

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

Active Substance Dossier

ACTIVE SUBSTANCE DOSSIER

Ozone, 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

→Ozone was brought to the market and used as a biocide before September 1st, 2013

→Ozone is 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

ACTIVE SUBSTANCE DOSSIER

The two steps

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. In our case the equipment-specific ozone and NOT the equipment.

ACTIVE SUBSTANCE DOSSIER

Step 1

Approval as an active substance

→Active substances / ozone must be approved and added to the EU List of approved active substances
http://ec.europa.eu/environment/chemicals/biocides/active-substances/approved-substances_en.htm

→Defined procedure within the BPR:

- → Active substance dossier to be created, containing all information as defined in BPR
- → Dossier to be submitted for validation to an appropriate body

Deadline for filing:

before September 1st, 2016

ACTIVE SUBSTANCE DOSSIER

Possible scenarios

- No application for ozone was filed in time
  - ozone cannot be brought into the market and can only be used under transitional measures until September 1st, 2017
- Application for ozone is filed before September 1st, 2016
  - ozone can still be used until the date of approval by the Commission.
  - If no authorization is granted, ozone cannot be anymore legally used after September 1, 2017

ACTIVE SUBSTANCE DOSSIER

Worst case

- Both cases outlined before (no application / not granted authorization) would end the legal use of ozone and as a consequence would 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 would lose importance

Content of an Active Substance Dossier

CONTENT OF AN AS DOSSIER

Requested data for an active substance dossier

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

CONTENT OF AN AS DOSSIER

An application must be filed for all desired product-types (PT).

Product types

22 product types are defined within the BPR.

For your information all PTs are listed in the congress paper.

Let’s focus on the most important ones in regard to the use of ozone:

Authorization of Products

AUTHORIZATION OF PRODUCTS

Step 2

- Biocidal product authorization is the second important part of the biocidal legislation
- Before applying for an authorization the applicant must either own an already approved active substance dossier or obtain a letter of access (LoA) to an approved active substance dossier

AUTHORIZATION OF PRODUCTS

- Who can be the authorization holder of the biocidal product?
- Who can to apply for the biocidal product authorization?

The answer to both of these questions is

- The owner/operator
- The oxygen supplier (precursor supplier)
- The manufacturer of the equipment

AUTHORIZATION OF PRODUCTS

In real life it is estimated that in most cases the manufacturer of the ozone generating equipment will be the authorization holder.

Cases where an owner/operator wants to be authorization holder may happen but will stay exceptions because of the investments resp. costs linked to this.

The same - and also mainly based on cost - is expected for oxygen suppliers. Only about 0.1% of all oxygen produced is used in ozone generation.

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.

The Ozone Registration Group

THE OZONE REGISTRATION GROUP

- The Ozone Registration Group has taken up the task for the creation of the AS ozone dossier and ensuring the approval of the active substance ozone
- The awareness about the impacts and the requirements to create an active substance dossier and to secure their business, four ozone equipment manufacturers have joined forces which resulted in the foundation of the "Ozone Registration Group".
- **These manufacturers are BWT, Suez Environment (OZONIA), ProMinent and Xylem (WEDECO)**

THE OZONE REGISTRATION GROUP

- 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 impact, which all cannot be managed by a single entity

Worldwide the two largest 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

EurO$_3$zon

EURO$_3$ZON

- is an international non-profit organization under Belgian law and was established as of May 7, 2015.
- has filed an Active Substance Dossier as of June 5, 2015
- Will make available LoA to this AS Dossier

EurO_3zon will provide detailed information about the applications covered by the dossier and about the content of the contract between the potential customer and EurO_3zon. This will be offered to potential LoA customers by EurO_3zon's management in an individual meeting. Such a meeting will be without obligation and free of charge for the (potential) customer.

www.EurO3zon.org / info@EurO3zon.org

The Active Substance Dossier of $EurO_3zon$

THE AS DOSSIER OF EURO$_3$ZON

- The Dossier was submitted as of June 5, 2015

The following product types are covered:

- 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 AS DOSSIER OF EURO$_3$ZON

The dossier covers the following technologies for ozone generation:

from air by electrical discharge

from air by UV irradiation

from pure oxygen by electrical discharge

from water by electrolysis

The dossier does **not** cover AOP processes itself, as this requires the simultaneous use of two active substances like O_3 / H_2O_2. Firstly, AOP processes are mostly exploited for other reasons than disinfection and if disinfection is claimed at least access to two or even more active-substance dossiers will be needed, of which only O_3 is covered by the dossier of EurO_3zon.

THE AS DOSSIER OF EURO$_3$ZON

Cost and duration of assessment and evaluation

Cost to reach successful authorization

→2.225 MEUR

Duration of assessment and evaluation

→> 1year ≤ 2 years

Especially the topics "*Toxicological profile for human and animal including metabolism*" and "*Eco-toxicological studies*" have been heavily underestimated. This is mainly due to the well researched area of ozone in many aspects. There are over 1,000 publications ranging from human to environmental effects. Resulting that many more scientific papers than initially planned had to be analyzed and accessed if these are relevant or not. At this stage the workload peaked and more personnel had to be contracted

Letter of Access

to the AS Dossier of

$EurO_3zon$

LETTER OF ACCESS

→ An applicant for a product authorization 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 without the need for writing another, own active substance dossier

An owner of a LoA from EurO_3zon will

- have access to all public data contained therein
- have no access to confidential data
- may have a look inside the dossier in a controlled environment

LETTER OF ACCESS

Guarantee to sell LoA

→ $EurO_3zon$ will offer and sell letters of access to any party

Difficulties

→Estimation of the number of LoA sold is very difficult

→Estimated cost until successful authorization is 2.225 MEUR

Duration of Validity of LoA

From date of LoA purchase to 10 years from approval of the AS-dossier (inclusion of ozone into the Union List of Approved Active Substances)

LETTER OF ACCESS

Fairness clause

If the value of ordered LoA **before** the inclusion of ozone into the EU List of Approved Active Substances is exceeding 2.225 MEUR, all surplus will be paid back and thus distributed between all LoA-owners.

- LoAs will be offered including all 4 covered PTs and its applications. It will be independent of the tonnage of ozone generated by the ozone devices sold or operated by the customer. The price level strongly depends on the number of countries the LoA is given for

1 country	75,000 Euro
3 countries	150,000 Euro
5 countries	225,000 Euro
All countries	350,000 Euro

The countries can be freely selected by the customer from all EU-members and associated countries

Summary

SUMMARY

Article 95 of the BPR "Transitional measures concerning access to the active substance dossier"

→Article 95 requires that all active substance manufacturers and importers placing active substances on the EU market, 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'.

SUMMARY

Article 95 of the BPR “Transitional measures concerning access to the active substance dossier”

NEW situation for ozone

On the last Competent Authority meeting (20-21 May 2015) it was decided that for

(1) ozone generated from ambient air, water or pure oxygen (LOX, GOX) supplied **without** the intention to generate ozone for a biocidal use, the provisions of Article 95 do not apply

(2) ozone generated from pure oxygen (LOX, GOX) supplied **with** the intention to generate ozone for a biocidal use Article 95 of the BPR will only apply from the time of authorization of these biocidal products.

SUMMARY

Situation for the AS ozone

- AS Dossier for ozone is filed
- Declaration of completeness is pending
- EurO$_3$zon is setting up the selling of the LoAs

Recommendations for next steps

- Definition of your needs
- Ordering of the LoA
- To own a LoA latest by June 5, 2016 to secure your business

Thank you for your attention