Ozone and the European Biocidal Products Regulation

Mr. Bernhard Paolini, Degrémont Technologies AG (SUEZ-OZONIA) and Chairman of EurO$_3$zon;
Dr. Tim Pühmeier, Xylem Services GmbH (WEDECO); Dr. Jörg Mielcke, Xylem Services GmbH (WEDECO);
Dr. Matthias Rothe, ProMinent; Dr. Matthias Hoffmann, BWT; Dr. Jaak Ryckeboer, Ensus Consulting BVBA

Summary

Ozone is falling as an active substance (AS) under the European Biocidal Products Regulation (EU) No 528/2012 (BPR) starting as of September 1st, 2013. In effect the BPR is considerably extending scope compared with the prior existing Biocidal Products Directive. Due to this, the AS ozone and the Biocidal Product (BP) ozone generated by a specific piece of equipment need to be authorized when there is an disinfection claim. EurO$_3$zon has submitted as of June 5, 2015 an active substance dossier (ASD) for ozone covering applications defined under biocidal product-types (PT) 2, 4, 5 and 11. The deadline for submitting active substance dossiers was September 1, 2016. Three other parties have also submitted ASDs for ozone by mid of 2016. The filing of in minimum one ASD for ozone secures that ozone can be brought to the EU market in the future. However, any party doing so needs to be in accordance with the BPR. Hence it is the main target of EurO$_3$zon to achieve that ozone is approved as an AS and listed in the EU "List of approved active substances". As soon as this is the case – somewhere second half of 2018 to our best estimation - it is then required to apply also for the authorization of the BP which is generated on-site, and is also called ozone. It is important to understand that the word "product" is not be mismatched with the ozone generating equipment but the ozone solution generated by a specific piece of equipment. Only in-situ generated ozone with a BP authorization can be brought legally correct to the EU market. This allows the further use of ozone in treatment processes in agreement with the BPR. The BP authorization can possibly most effectively be done by the actual manufacturer of such ozone equipment. However also an operator of ozone generating equipment can apply for it. In order to apply for a BP authorization the AS ozone itself needs to be approved at first and this AS dossier must be either owned or legally accessed by a letter of access (LoA). EurO$_3$zon is making Letters of Access (LoA) available to everyone who needs it. Besides, there is also another party, called EUOTA, which has submitted an ASD for ozone by mid of 2016. This organization is known also offering LoAs.

The ASD from EurO$_3$zon is now under evaluation by the Competent Authority (CA) of Germany, called BAuA. EurO$_3$zon was aware that large parts of the implementation rules of the BPR was and still is under development at the time of and after submission of the ASD. It was also discovered that some steps, such as efficacy testing, within the approval process were originally developed for stable and less reactive substances. As a consequence EurO$_3$zon is now developing adapted protocols for ozone testing in coordination with the BAuA. An additional hurdle to take is finding an agreement on adaption of the protocols with all involved parties, including all CAs.

There needs to be mentioned that in addition to the BPR requirements for ozone (only covering disinfection claims) all other ozone applications (oxidation) are potentially falling under REACH Regulation (EC) No 1907/2006. So it is very likely that REACH approval for ozone also becomes necessary in the future. Notably not only Europe is regulating the use of ozone. We know that also in the US, China, Taiwan and other countries regulatory work is in progress, which could also cover the use of ozone.

1. Regulatory Information

1.1 Situation prior to May 22, 2012

Historically, in the European Union and its meanwhile 28 Member States (MS), the European 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 regulates all biocidal products placed on market of the European Union. The BPR introduces new procedures for all EU Member States (MS) for the authorization of BPs. A system of mutual recognition among the EU MS or Union Authorization are instigated, the latter is a single EU-wide authorization which is immediately valid in all MS. 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 is also implemented in Norway, Iceland, Liechtenstein and Switzerland.

2. Important terms according to BPR, Regulation (EU) No 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 as 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 of the BPR for the use of ozone?

3.1 Ozone is declared as an existing active substance

It is important to recognize that ozone did not fall under the former Biocidal Products Directive 98/8/EC (BPD) but is now falling within the scope of the Biocidal Products Regulation 528/2012.

More specific ozone is falling under the Article 93 *"Transitional measures concerning biocidal products not covered by the scope of Directive 98/8/EC"*. However, the original publication of the Regulation 528/2012, the Article 93 has been amended in Regulation 334/2014 of the European Parliament and of the Council of 11th March 2014:

……..a Member State may continue to apply its current system or practice of making available on the market and using a biocidal product not covered by the scope of Directive 98/8/EC, but falling within the scope of this Regulation, and consisting of, containing or generating only active substances that where available on the market or used in biocidal products on 1st September 2013. The derogation shall apply until one of the following dates:

(a) Where applications for approval of all those active substances, which the biocidal product consist of, contains or generates, are submitted for the relevant product-type by 1st September 2016……or

(b) Where an application is not submitted in accordance with point (a) for one of the active substances until 1st September 2017

So the use of ozone as a biocidal AS is indeed covered by the provisions of Article 93. An AS dossier to request its approval will indeed have to be submitted by 1st September 2016 in order that it can stay on the market and still be used for biocidal purposes after 1st September 2017. The revised Article 93 does not foresee anymore an additional 180 days grace period.

EurO_3zon has submitted an ASD for ozone as of June 5, 2015 and more recently three other ASDs have been submitted too. Anyone associated to these organizations is waiving the deadlines stated above as transitional procedures apply for entities that submitted an ASD under the AS review program. At the time of writing of this text only the ASD of EurO_3zon can be found back in the public accessible ECHA Article 95 List, prepared as of 04 October 2016.

3.2 The two step authorization approach

The first step is the approval of ozone as an AS. This needs to reflect the relevant biocidal applications as defined by the

product-types. Thereafter the second step is the authorization of the BP generated by the equipment, the equipment-specific ozone. Following the approval of the AS ozone the products can then legally used in the EU territory after successful completion of the BP authorization process.

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 (see Link). The information requirements for the preparation of the AS dossier is described within Annex II of the BPR. As the first step an active substance dossier must be created, which contains all information as defined in the BPR. This dossier has 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 until September 1st, 2017.

However, if an application for ozone was filed before September 1st, 2016, ozone can still be used until the date of approval of the AS by the Commission. In case of failing the obligations under the BPR and no approval is granted, ozone cannot be anymore legally used after 1st September 2017.

Both cases as outlined above (no application / not granted authorization) would have end the legal use of ozone and as a consequence will also end the business of nearly all ozone generating equipment manufacturers who are selling equipment into the EU market. Thus also scientific work studying ozone as biocide would lose importance.

Therefore it was essential that an ASD for ozone was successfully filed before September 1st, 2016, and subsequently leading to an approval. This will be the base to ensure the further activities of the "ozone market". An application must have been filed for all product-types (PT) relevant for the ozone sector.

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

- An AS 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
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- 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 AS on the EU market, either on their own or in an BP, that have not already submitted their own dossier on the AS 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.
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- However, Article 95 does not apply for Article 93 products such as ozone generated from ambient air, water or LOX which is brought to the market without biocidal claim as long the AS ozone itself is not approved.
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- **3.4 Authorization of biocidal products**
- The BP authorization is the second important step of the biocidal legislation.
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- Before applying for an authorization for the biocidal product ozone the applicant must either own an already approved AS dossier or obtain a letter of access (LoA) to an approved AS dossier.
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- After some discussion it seems now clear that in the real world the ozone generating equipment manufacturers will apply for a BP authorization. This is also what seems to be expected by most operators. There will maybe be some operator of such equipment which decide to apply for their own product authorization. However this is a quite expensive decision and will only be economical if several pieces of equipment of the same manufacturer are operated.
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- Furthermore it is clear that the technological aspects of the equipment should not be ignored while preparing the application for the product authorization due to its impact on product quality and the risks associated with its use.
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- The understanding of EurO_3zon today is that it will be very unlikely that a LOX supplier or manufacturer will apply for any BP authorization. The costs in relation to the revenues will not be justifiable.
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- With regard to ozone from pure oxygen (LOX) supplied with a view to generate ozone for a biocidal use, the transitional measures provided for under Article 89 of the BPR are no longer applicable to pure oxygen when supplied with a view to generate ozone for a biocidal use. These BP can therefore not be placed on the market. They could however be placed on the market again subject first to the approval of the AS ozone ('ozone generated from oxygen') and second to their authorization.
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- One way to group and rationalize the BP authorization can be achieved by using a so-called "biocidal product family". EurO_3zon is working on a BP family concept in order to minimize the cost for the BP authorization in the ozone sector. Namely, an owner of a LoA issued by EurO_3zon can participate within this family concept and benefit from the cost savings.
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- We estimate that the ASD from EurO_3zon will be validated around mid-2017 and a draft assessment will be sent to all other CAs for review. However ozone will only be approved and be included into the EU list of approved substances after all submitted ASD have been validated (to our information totaling 4 AS dossiers). Thus the progress also depends on other dossiers and CAs, so an accurate date cannot be given. However the estimation is that ozone is listed somewhere by mid to end 2018. Consequently every party planning to apply for a BP authorization should be ready with its application also around mid to end 2018.
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- Another important topic in handling in-situ processes is the definition of the biocidal product. The BPR clearly points out that equipment cannot be regarded as an BP. This is not yet understood fully by the operators of ozone generating equipment. A precursor brought into the market in order to generate a biocide (e.g. liquid oxygen for the generation of ozone) have to become treated as BP. However, ambient air (a natural resource) for generating ozone is not a precursor which is placed on the market and is not treated as BP. Until September 1, 2016 to EurO_3zon's best knowledge no ASD for liquid oxygen (LOX) for the generation of ozone has been

submitted.

Ozone equipment manufacturer and operator have to 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. EurO_3zon's active substance dossier

EurO3zon is an international non-profit organization which has submitted its ASD for ozone as of June 5, 2015. It makes its active substance dossier available to the sector by means of a letter of access (LoA). Anyone in need of carrying out the biocidal product authorization can benefit regarding time and expenditure. EurO3zon offers and sells letters of access (LoA) to every interested external party.

EurO_3zon always provides detailed information about the applications covered by the dossier and about the content of the agreement between the potential customer and EurO_3zon. This is offered to potential LoA customers by EurO_3zon management in an individual meeting. Such a meeting is held without obligation and free of charge for the (potential) customer. By this way it can be ensured that the LoA interested party knows what the dossier covers related to their applications.

Contact details of EurO3zon can be found at www.euro3zon.org

The main goal is the inclusion of ozone in the EU "List of approved active substances".

The submitted ASD from EurO3zon covers the following product-types (PT):

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 ASD submitted by EUOTA covers the same product-types as above. What is covered by the other two submitted ASD is not know as of today.

The following applications are worked out in the ASD of EurO_3zon:

- Within PT 2:
  - ● Swimming pool water
  - ● (Sea) water for aquariums and aquacultures
  - ● Waste water treatment
  - ● Pretreatment of filling water of process water loops (pharmaceutical industry, food industry)
  - ● Rinsing /washing water (e.g. bottles)
  - ● Water in humidifiers for air conditioning
  - ● Room (air) sanitation
  - ● Laundry water
- Within PT 4:
  - ● Disinfection of bottles and caps in beverage industry
  - ● CIP (Cleaning in Place): Disinfection of fluid distribution network (food, dairy & beverage industry)
- Within PT 5:
  - ● Drinking water (tap water)
  - ● Table water (bottled water)
- Within PT 11:
  - ● Circulation water of cooling towers and cooling systems
  - ● Process water loops (pharmaceutical, cosmetics, food and beverage industries, …)
  - ● Other loop water, for example water used for testing of leak tightness of industrial goods

Furthermore the dossier will cover the following technologies for ozone generation:

- ● Ozone generation from air by electrical discharge
- ● Ozone generation from pure oxygen *) by electrical discharge
- ● Ozone generation from air by UV irradiation
- ● Ozone generation from pure oxygen without biocidal claim by UV irradiation
- ● Ozone generation from water by electrolysis

Not covered processes

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 ASD will be needed, of which only O_3 is covered by the dossier of EurO_3zon.

Processes with a claim to disinfect by the means of radicals are neither covered by the ASD of EurO_3zon and will require an LoA to an ASD for radicals.

What EurO_3zon will not do

- ● Selling (shared) dossier ownership

- Selling data that fall outside the requirements of the data-sharing process as described within the BPR.

5. Letter of access

In the process to obtain a Product Authorization an applicant must either own a dossier or must provide a letter of access (LoA) that grants citation rights to an existing AS dossier. The letter of access permits third parties to undertake their BP authorization obligations under the BPR without the need for writing another, own AS dossier.

A letter of access (LoA) does not include the right to have unlimited access to all data within the AS dossier. It is also not a data sharing contract in a way that the holder of the LoA have access to data. On the other hand every EU or national authority involved in the product authorization process can have the access to the data.

$EurO_3zon$'s dossier contains confidential data from its members which are not even shared between those members. Holder of a letter of access (LoA) may have a look inside the AS dossier in a controlled environment. All public data can be accessed.

If you wish to get more information about LoA it is recommended to study the ECHA Practical Guide on Biocidal Products Regulation, Special Series on Data Sharing - Letters of Access which can be downloaded from **https://echa.europa.eu/documents/10162/21742587/pg_letters_of_access_en.pdf**

5.1 Some details around $EurO_3zon$'s letter of access

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 actually available 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 MS and associated countries. Purchased LoAs for 1, 3 or 5 countries can also be upgraded later on.

$EurO_3zon$ has formulated a "Fairness Clause":
If the value of ordered LoAs before the inclusion of ozone into the EU List of Approved Active Substances is exceeding 2.25 MEUR, all surplus will be paid back and thus distributed between all owners of a LoA issued by $EurO_3zon$.

As of the time of this writing several LoAs have been sold.

Due to the unclear scenario of the authorization holders for registration of ozone as biocidal product, it is nearly impossible to provide a true estimation about the number of letter of access that could be sold. Resulting prices as shown above have been set by the $EurO_3zon$ based on assumptions of this niche LoA market and the actual and the estimated spending.

It is expected that the cost for the inclusion of ozone into the EU List of Approved Active Substances must not exceed 2.25 MEUR.

As of today the possibility to submit an own ozone AS dossier is passed by, the only possibility now is to purchase an LoA to an ASD for ozone.

6. Actual Situation

6.1 $EurO_3zon$'s active substance dossier

BAuA, the CA of Germany, is in the process of evaluation of the submitted ASD. During this evaluation the evaluating CA (eCA) can ask for more information and/or for additional tests to clarify data presented in the ASD.

It has to be understood that the procedures and even the tests are regulated within the frame of the BPR and its many guidances. Hence some historical data needs to be revalidated.

By the date of 31.05.2016, a Transitional Guidance on Efficacy Assessment for Disinfectants Product Types 1-5 was released. Besides others bacterial efficacy tests according EN 1276 and bacterial efficacy water systems tests according EN 13623 are actually conducted.

It was realized quite soon that those tests are not designed to validate the efficacy of an in-situ produced biocide which is in addition gaseous, very reactive and has a limited half life time.
Based on first test results according the procedures defined in the quoted EN Standards a discussion with the eCA was initiated. The eCA agreed with $EurO_3zon$ that those standard EN methods do not work for ozone.

$EurO_3zon$ was requested to formulate, develop and demonstrate a method appropriate for efficacy testing of ozone. All necessary resources, knowhow and equipment will be allocated for developing such a CA approved method. Once this method is agreed, the validating CA will bring the method

to the 'Working Group – Efficacy' of the BPC - for approval. The final method can then be applied also for efficacy testing of other in situ generated AS.

- It is only one unforeseen obstacle on the way to have ozone included in the EU list of approved substances. Many have already be solved and new ones may occur and will get solved alongside.
- It is expected that the eCA – BAuA – will send its report of the evaluation of EurO_3zon 's ASD to all other CA for approval by end of 2017. Thus EurO_3zon is in the position leading the initial interpretation of the data required for approval of ozone and demonstrating its leading role in the whole field of ozone and the BPR.

7. Estimated timeline

Q3-2017	validation of EurO_3zon ASD finalized
unknown	validation of the three other ASD finalized
Q3/Q4-2018	Ozone included in the EU list of approved substances
Q4-2018	Start of product authorization process

8. Miscellaneous

8.1 REACH

There needs to be mentioned that in addition to the BPR requirements for ozone - only covering disinfection claims - all other ozone applications – oxidation - are potentially falling under the REACH Regulation (EC) No 1907/2006. It is very likely that REACH approval for ozone becomes necessary in the future.

- EurO_3zon is also active in regard to ozone versus REACH and is in contact with ECHA to clarify the situation.
- In the case ozone needs a REACH approval the owners of a LoA issued by EurO3zon will be offered a LoA to the REACH dossier for a preferential price to be able to benefit most from their former investment.

8.2 Outside European Union

We know that also in the US, China, Taiwan and other countries regulatory work is in progress, which could also cover the use of ozone as a Biocide and maybe also as an oxidant.

- It seems to be absolutely necessary that every party who makes its living with selling either ozone generating or ozone related equipment starts to collect information about such work in their countries, to be able to act appropriate and to secure the future use of ozone.
- Keep in mind that the ozone ASD of EurO_3zon will be very supportive also for such non-European dossiers as the ASD is in fact a huge database covering the typical endpoints in all kind of approval dossiers.

8.3 References

- 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.
- **http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32012R0528**
- Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11th March 2014
- **http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0334**
- European Commission, 2015. Document CA-May15-Doc.5.1.a. Management of in situ generated active substances in the context of the BPR. The case of ozone.

8.4 Abbreviations

ADS:	Additional Data Set
AS:	Active Substance
ASD:	Active Substance Dossier
BP:	Biocidal Product
BPC:	Biocidal Products Committee
BPD:	Biocidal Products Directive (98/8/EC)
BPR:	Biocidal Products Regulation (528/2012)
CA:	Competent Authority
CDS:	Core Data Set
eCA:	evaluating Competent Authority
ECHA:	European Chemicals Agency
EU:	European Union
LoA:	Letter of Access
MS:	Member States
Ozone Market:	Everybody producing and/or applying ozone
PT:	Product-Type
EurO_3zon:	international non-commercial organization, that submitted a Active Substance Dossier for ozone and will sell letter of access for this dossier

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