

## Ozone under the European Biocidal Products Regulation- Latest updates from EurO<sub>3</sub>zon

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### Abstract

This paper is a continuation of our former article "Ozone Biocidal Product Authorization under the European Biocidal Products Regulation" which was published in Ozone News (Volume 47, No 3, pages 18-20). Our latest news update includes the fact that the draft Competent Authority Report (CAR) for 'ozone generated from oxygen' has been concluded by the eCA (evaluating Competent Authority) BAuA (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin) and submitted to ECHA (the European Chemicals Agency) for further treatment, that three LoA (Letter of Access) holders became Associate Members of EurO<sub>3</sub>zon, and that EurO<sub>3</sub>zon ivzw has become one of ECHA's accredited stake holders.

### Status of Assessment report of the active substance dossier for 'ozone generated from oxygen'

As of the 9<sup>th</sup> September 2020, the assessment report, the so-

called draft CAR of the active substance (AS) dossiers for 'ozone generated from oxygen' (further called 'ozone') of EurO<sub>3</sub>zon has been completed successfully by the eCA BAuA. This draft CAR is covering the Product Types (PT) PT2, PT4, PTS and PT11\*\* and has now been transmitted through the *Register for Biocidal Products* (R4BP 3) to ECHA (the European Chemicals Agency) for peer review in the Biocidal Products Committee (BPC)

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

On 9 October 2020 ECHA confirmed then that the draft CAR for the active ozone has passed the accordance check. The AS dossiers were then assigned to ECHA's Process Flow 39. The details and deadlines for the further steps of the review process of the AS dossiers are specified in the "Timelines for the peer review of active substance evaluations", which can be downloaded from the website of the **BPC** ([https://echa.europa.eu/documents/10162/4221979/revised\\_timeline\\_as\\_app\\_en.pdf/ba57583d\\_b081-4b6e-8632-3d8a5bfe0028](https://echa.europa.eu/documents/10162/4221979/revised_timeline_as_app_en.pdf/ba57583d_b081-4b6e-8632-3d8a5bfe0028)).

This represents a key milestone and achievement resulting of all the work performed by EurO<sub>3</sub>zon during the past years and a huge step towards the approval of ozone as a biocidal AS within Europe. This is also very important for making decisions by potential buyers of LoA's, who can now join the next step, the subsequent BP authorization dossiers that cover many different biocidal uses of ozone and which are required to keep ozone generating devices legally in the EEA\*\*\* market. This feature is exclusively available for members of EurO<sub>3</sub>zon.

\*\*PT 2 Disinfectants and algacides (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.

\*\*\* EEA = 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.

### Associate Membership within EurO<sub>3</sub>zon

On 9 December 2019 the new statutes of EurO<sub>3</sub>zon ivzw were published allowing Associate Membership within EurO<sub>3</sub>zon, a service that is available for LoA holders to the ozone AS dossiers of EurO<sub>3</sub>zon in order to cooperate easily for BP authorisation. Membership is reserved to and limited to entities having legal personality, being producers of devices generating or using Ozone (O<sub>3</sub>) or having developed methods based on the use of ozone (O<sub>3</sub>), and to Research institutes, federations and to individuals having an interest in the 'in situ' generation

of ozone (O<sub>3</sub>). On 20 December 2019 all necessary documentation for Associate Membership and BP authorisation cooperation was available for interested LoA holders. On 8 June 2020 EurO<sub>3</sub>zon ivzw welcomed the LoA holder companies Hydro-Elektrik GmbH (Germany), Industrie De Nora SpA (Italy) and Primozone Production AB (Sweden) as Associate Members.

*Industrie De Nora SpA* (<https://www.denora.com/>), through De Nora Water Technologies, has been developing and delivering ozone generation systems for municipal disinfection and advanced oxidation process (AOP) for industrial applications, supporting customers from design to commissioning and after sales.

*Hydro-Elektrik GmbH*, founder and owner of HydroGroup (<https://www.hydrogroup.biz>), has improved water treatment technologies through research with focus on the field of drinking water treatment. Hydro-Elektrik's portfolio includes oxidative processes with ozone, the optimisation of classical multilayer filtration, ozone biofiltration and ozone-membrane hybrid processes.

*Primozone Production AB* (<https://www.primiozone.com>) is a complete partner in ozone solutions devoted to its customers with efficient ozone generators and ozone treatment systems and providing knowledge about ozone for e.g. different industrial water treatment applications.

The founding and associate members of EurO<sub>3</sub>zon ivzw represent more than 75% of the ozone market and practically all relevant disinfection applications in Europe and worldwide.

The three associate members have meanwhile also joined forces with the founding members of EurO<sub>3</sub>zon for completing the BP Authorisation dossiers, which are in progress since early 2019. More information on these dossiers can be found in our former article in Ozone News (Volume 47, No 3, pages 18-20).

Please regularly check EurO<sub>3</sub>zon's website ([www.euro3zon.org](http://www.euro3zon.org)) for learning more about the progress of EurO<sub>3</sub>zon's AS and BP dossiers.

### **EurO<sub>3</sub>zon becomes one of ECHA's accredited stakeholders**

On 2 October 2020 EurO<sub>3</sub>zon has become one of ECHA's accredited stakeholders. As a representative of the sector of in situ generated ozone and other in situ generated active substances, EurO<sub>3</sub>zon has an important role in ensuring that important information from its area of expertise is brought to the attention of EC HA. In this role EurO<sub>3</sub>zon seeks to be further involved in the development of the guidance on in situ generated active substances under the

BPR. EurO<sub>3</sub>zon will participate in bodies and networks such as the BPC, Forum for Exchange of Information on Enforcement, and for Updating of guidance documents related to REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), CLP (Classification, Labelling and Packaging of substances and mixtures) and Biocides.

With this measure, EurO<sub>3</sub>zon ivzw takes up its responsibility to actively support the biocide regulatory processes at European level and to represent the interests of ozone users and ozone equipment manufacturers.



*Ozone Dossier accepted for evaluation.*



*Bernard Paolini discusses EurO<sub>3</sub>zon at IOA conference*

ERRATUM

Erratum to “Ozone under the European Biocidal Products Regulation - Latest updates from EurO<sub>3</sub>zon” Ozone News  
Volume 48, No 6, pages 16-17

**Page 16, first column, author list:**

‘Dr. Bart Kem’ *should read* ‘Dr. Bart Kerré’

‘Dr. Jorg Mielcke’ *should read* ‘Dr. Jörg Mielcke’

**Page 16, second column, first paragraph, line 5:**

‘PTS’ *should read* ‘PT5’

**Page 16, second column, second paragraph, lines 8-10:**

‘the BPC

[https://echa.europa.eu/documents/10162/4221979/\\_revised  
\\_timeline\\_as\\_app  
\\_en.pdf/ba57583d\\_b081-4b6e-8632-3d8a5bfe0028](https://echa.europa.eu/documents/10162/4221979/_revised_timeline_as_app_en.pdf/ba57583d_b081-4b6e-8632-3d8a5bfe0028).’

*should be replaced by:*

‘the BPC

[https://echa.europa.eu/documents/10162/4221979/revised\\_t  
imeline\\_as\\_app\\_en.pdf/ba57583d-b081-4b6e-8632-  
3d8a5bfe0028](https://echa.europa.eu/documents/10162/4221979/revised_timeline_as_app_en.pdf/ba57583d-b081-4b6e-8632-3d8a5bfe0028)

**Page 17, first column, fourth paragraph, line 21:**

‘(<https://www.primiozone.com>)’ *should read:*

‘(<https://www.primiozone.com>)’

**Page 17, first column, fifth paragraph:**

The founding and associate members of EurO<sub>3</sub>zon ivzw represent more than 75% of the ozone market and practically all relevant disinfection applications in Europe and worldwide.

*should be replaced by:*

“The founding and associate members of EurO<sub>3</sub>zon ivzw assume representing more than 75% of the ozone market for water based applications and practically all relevant disinfection applications in Europe and worldwide.”

**Page 17, first column, ninth paragraph, 3<sup>rd</sup> last line:**

‘EC HA’ *should read:* ‘ECHA’

We apologize for the errors that were present in this document.