



Product Authorization of Ozone Applications under the BPR

Figawa Workshop

"Herausforderungen und Handlungsschritte im
Produktzulassungsverfahren für In-Situ Systeme in
der Wasseraufbereitung"

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EURO₃ZON

- EurO₃zon is an international non-profit organization under Belgian law
- EurO₃zon has filed an Active Substance Dossier for Ozone

Members of EurO₃zon

(Ozone equipment Manufactures, being in competition in the market)

- **Suez Environment (OZONIA)**
- **ProMinent**
- **Xylem (WEDECO)**
- **BWT** (presenting)

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- Two steps of legalization
- Active Substance Dossier
- Typical applications supported in Ozone Active Substance Dossier
- Authorization of Biocidal Products



Two steps of legalization

Step one

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

Step two

Thereafter the second step is the [authorization of the products](#), i.e. the biocidal applications of the ozone. In our case it is the equipment-specific ozone and NOT the equipment.

Example: Ozone treatment of cooling tower water with [ozone generated by an ozone device](#) of type X from manufacturer Y.



Active Substance Dossier



THE AS DOSSIER OF EurO₃zon

Actual state of ozone dossier

The dossier was submitted as of June 5, 2015

Evaluating CA is BAuA, Germany

Evaluation of dossier for [first step is ongoing](#)

Entity Name
LANXESS Deutschland GmbH

Country
Germany

Supplier Type
Substance Supplier

Inclusion Reason
New Active

Inclusion Date
27-Feb-15

Sodium metabisulfite

EC: 231-673-0

CAS: 7681-57-4

Product Type: 9
Micro-Pak Europe BV

Netherlands

Substance Supplier

New Active

10-Feb-15

Allyl isothiocyanate

EC: 200-309-2

CAS: 57-06-7

Product Type: 9
LM Chemicals Europe Ltd

Ireland

Substance & Product Supplier

New Active

29-May-15

YU BAO BIOTECHNOLOGY CO. Ltd.

Ireland

Substance & Product Supplier

Art.95 submission

07-Aug-15

Ozone

EC: Not allocated

CAS: 10028-15-6

Product Type: 2
EurO3zon

Belgium

Substance Supplier

New Active

02-Sep-15

Product Type: 4
EurO3zon

Belgium

Substance Supplier

New Active

02-Sep-15

Product Type: 5
EurO3zon

Belgium

Substance Supplier

New Active

02-Sep-15

Product Type: 11
EurO3zon

Belgium

Substance Supplier

New Active

02-Sep-15



THE AS DOSSIER OF EuroO₃zon

The dossier covers the following technologies for ozone generation

Ozone generation from precursors:

- from ambient air by electrical discharge
- from ambient air by UV irradiation
- from pure oxygen *) by electrical discharge
- from pure oxygen *) by UV irradiation
- from water by electrolysis

*) pure oxygen without biocidal claim



Typical applications supported in Ozone Active Substance Dossier



Applications in Ozone Dossier

BPR Definition PT 2:

Disinfectants and algaecides not intended for direct application to humans or animals

- Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.
- Usage areas include, inter alia, **swimming pools, aquariums, bathing and other waters; air conditioning systems**; and walls and floors in private, public, and industrial areas and in other areas for professional activities.



Applications in Ozone Dossier

BPR Definition PT 2:

Desinfektionsmittel und Algenbekämpfungsmittel, die nicht für eine direkte Anwendung bei Menschen und Tieren bestimmt sind

- Produkte zur Desinfektion von Oberflächen, Stoffen, Einrichtungen und Möbeln, die nicht für eine direkte Berührung mit Lebens- oder Futtermitteln verwendet werden.
- Die Anwendungsbereiche umfassen unter anderem **Schwimmbäder, Aquarien, Badewasser und anderes Wasser, Klimaanlage** sowie Wände und Böden sowohl im privaten als auch im öffentlichen und industriellen Bereich und in anderen für eine berufliche Tätigkeit genutzten Bereichen.
- ...



Applications in Ozone Dossier

Applications covered under PT 2:

- Swimming pool water
- (Sea) water for aquariums and aquacultures
- Pretreatment of filling water of process water loops (pharmaceutical industry, food industry)
- Waste water treatment
- Rinsing /washing water (e.g. bottles in beverage industry)
- Laundry water
- Water in humidifiers for air conditioning
- Room (air) sanitation



Applications in Ozone Dossier

BPR Definition PT 4: Food and feed area

- Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.
- Products used to be incorporated into materials which may enter into contact with food.



Applications in Ozone Dossier

BPR Definition PT 4: Lebens- und Futtermittelbereich

- Produkte zur Desinfektion von Einrichtungen, Behältern, Besteck und Geschirr, Oberflächen und Leitungen, die im Zusammenhang mit der Herstellung, Beförderung, Lagerung oder dem Verzehr von Lebens- oder Futtermitteln (einschließlich Trinkwasser) für Menschen und Tiere Verwendung finden.
- Produkte zur Aufnahme in Materialien, die mit Lebensmitteln in Berührung kommen können.



Applications in Ozone Dossier

Applications covered under PT 4:

- Disinfection of bottles and caps in beverage industry
- CIP (Cleaning in Place): Disinfection of fluid distribution network (food, dairy & beverage industry)



Applications in Ozone Dossier

BPR Definition PT 5: Drinking water

- Products used for the disinfection of **drinking water** for both humans and animals.



Applications in Ozone Dossier

BPR Definition PT 5: Trinkwasser

- Produkte zur Desinfektion von **Trinkwasser** für Menschen und Tiere.



Applications in Ozone Dossier

Applications covered under PT 5:

- Drinking water (tap water)
- Table water (bottled water)



Applications in Ozone Dossier

BPR Definition PT 11: Preservatives for liquid-cooling and processing systems

- Products used for the **preservation of water** or other liquids used **in cooling and processing systems** by the control of harmful organisms such as microbes, algae and mussels.



Applications in Ozone Dossier

BPR Definition PT 11: Schutzmittel für Flüssigkeiten in Kühl- und Verfahrenssystemen

- Produkte zum **Schutz von Wasser** und anderen Flüssigkeiten **in Kühl- und Verfahrenssystemen** gegen Befall durch Schadorganismen wie z. B. Mikroben, Algen und Muscheln.



Applications in Ozone Dossier

Applications covered under 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



Applications in Ozone Dossier

Limits of supported applications

- The dossier does **not cover AOP processes** itself, as this requires the simultaneous use of two active substances like O₃ / H₂O₂. (In this case a Letter of Access to the O₃ dossier and a further (?) dossier is needed.)
- Included applications are focused on **closed systems**, i.e. all ozone generated is either used or destructed by the application. No ozone emission of concern.



Authorization of Products

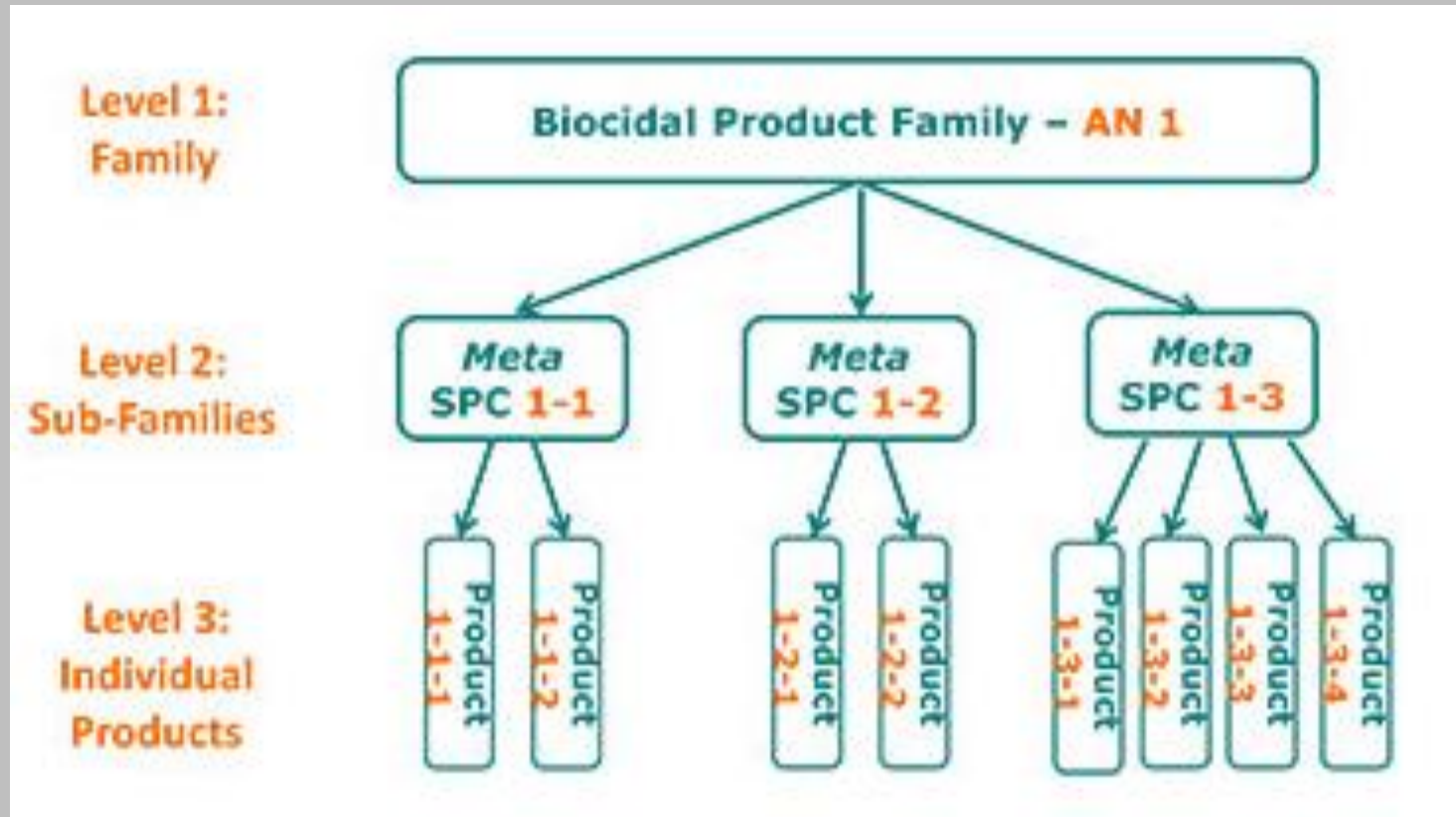


Authorization of Products

Biocidal Product Family (BPF)

- BPF means a group of biocidal products having
 - (1) similar **uses**, (= > e.g. **related applications**)
 - (2) the same active substances,
 - (3) similar composition of BP with specified variations and
 - (4) similar levels of risk and efficacy
- Characteristics of BPF described by **"Summary of Product Characteristics (SPC)"**
- Refinement of BPF: Subfamily described by **"Meta-SPC"**

Biocidal Product Family (BPF)





Authorization of Products

Level 3 is Authorization of individual product, i.e.

Uses (applications) of particular subfamily operated with ozone generated by an ozone device of type X from manufacturer Y, e.g. for professional users

- Authorization will be done by EurO₃zon, intended by "Union Authorization"
- Authorization is foreseen to include all LoA-customers => cost sharing between EurO₃zon + LoA-customers
- Intention: EurO₃zon will summarize applications in a minimum number of BPFs to keep fees low.
- Details to be discussed with eCA (BAuA) when assessment of AS-Dossier is done.

END



**Thank you
for
your attention**