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Ozone Biocidal Product Authorization under the European Biocidal Products Regulation

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Placing ozone biocidal products legally on the European market requires a two-step process

Authorization of ozone as a biocidal product (BP) under the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012), requires two steps, the first step being the approval of ozone as an active substance (AS). Approval entails that ozone is included in the EU list of approved active substances, in which ozone is officially referred to as 'ozone generated from oxygen'. The second step is successfully completing a BP authorization. Overall, the requirements for a BP authorization dossier are similar to those for an AS dossier; physicochemical properties, efficacy, human health, environment,… are all part of such a dossier. However, at BP authorization level, individual product-specific authorization applications are required, resulting in complex data and high costs for applicants in case of authorization of multiple BPs with only small variations in composition.

Status of evaluation of the ozone active substance dossiers

In 2015, $EurO_3zon$ submitted four ozone AS dossiers, i.e. for Product Types (PTs) 2, 4, 5 and 11, which are up until now still under review by BAuA (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin), the German evaluating competent authority (eCA). During the review process, several questions were raised, related to, amongst others, oxygen as precursor, efficacy, monitoring data of disinfection by-products and endocrine properties of ozone. Assessment of endocrine properties is the consequence of a new regulation which is applicable to all active substances, even if already approved. Currently, only issues with efficacy testing are still ongoing before ozone AS can be approved.

Authorization of multiple biocidal products: Biocidal Product Family

One way to deal with the BP authorization complexity and to reduce costs for registration is grouping of several BPs under a single authorization, by creating a Biocidal Product Family (BPF) tree which is characterized by three levels (Figure 1). According to Article 3(1)(s) of the BPR, a BPF refers to a group of biocidal products having similar uses, the same active substances, similar composition within specified variations and similar levels of risk and efficacy, this is the first level. Within one BPF, BPs can be further arranged into several sub-families, the so-called meta-SPCs (SPC = Summary of Product Characteristics), this is the second level. BPs belonging to the same meta-SPC have a common set of Risk Management Measures and identical Hazard and Precautionary statements. The big advantage of such an approach is that the risk and efficacy assessment can be based on the "worst-case" scenario, thereby reducing redundant testing/costs. For example, the risk assessment for the product with the highest AS concentration within one meta-SPC ('maximum risk') will cover the risk of all other products within the same meta-SPC. Or, successful efficacy testing with the product with the lowest AS concentration within one meta-SPC ('minimum efficacy') will guarantee efficacy of the other products as well. The third level within the BPF concept is the level of the individual BPs.

In situ generated substances versus biocidal product authorization

While the three levels of the BPF concept (family, meta-SPC, individual product) may be rather straightforward for traditional BPs, a debate is still ongoing within Europe for in situ generated BPs such as ozone. For some in situ generated BPs that are generated at the place of use for direct application, the in situ generated BP may be equipment-specific, i.e. the BP is generated by an in situ device of type X from manufacturer Y. In situ devices for generating ozone can take in various concentrations of oxygen from various sources (pure O2, ambient air, water), delivering an output foreseen within the set range and within the frame of the BPF, and the result is an infinite number of ozone concentrations being generated. It is, therefore, at the moment not yet clear to what extent an applicant has to list all ozone BPs. Currently, $EurO_3zon$ and other stakeholders are discussing this issue with the national

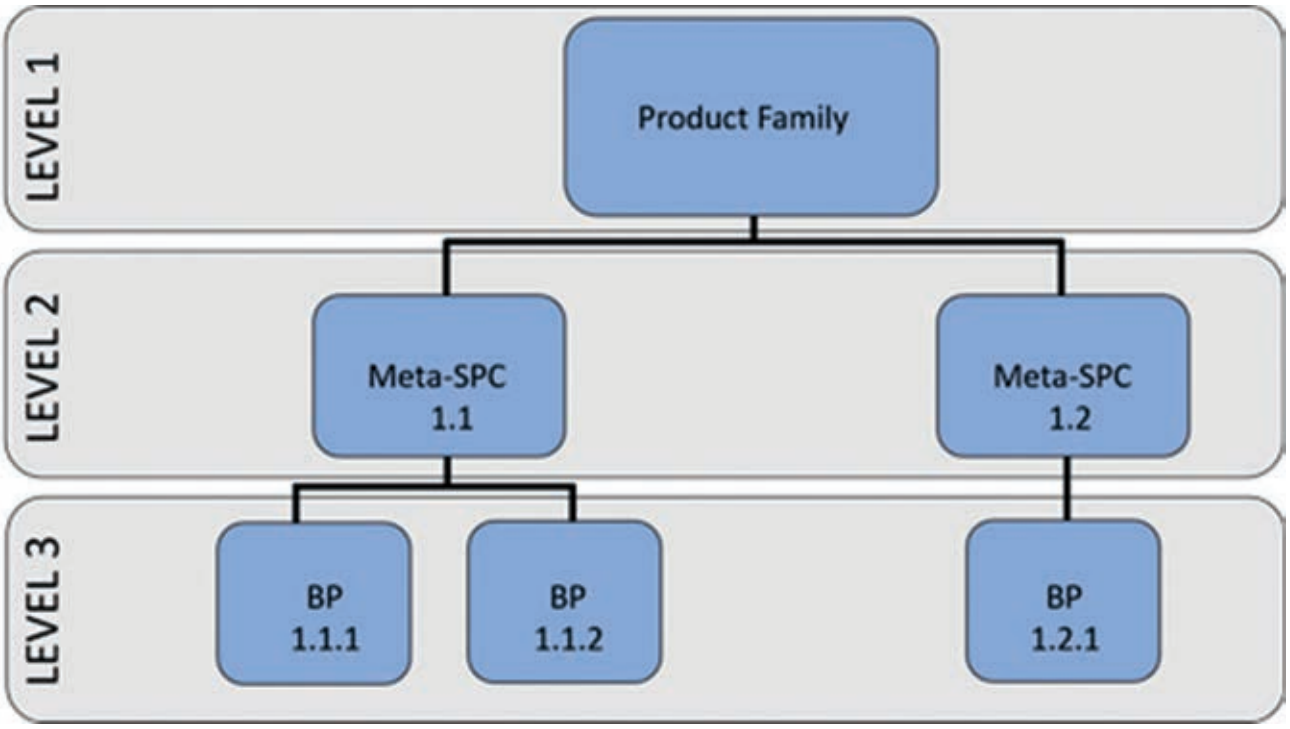

Figure 1. The three levels of the Biocidal Product Family (BPF) Concept. First level: creating a Product Family, a group of biocidal products with similar composition, similar uses, similar risk and efficacy. Second level: grouping of biocidal products in different Meta-SPC's, with biocidal products within the same meta-SPC having identical Hazard & Precautionary phrases. Third level: the level of individual biocidal products (BP's). This figure is only an example, more Meta-SPC's (= Summary of Product Characteristics, level 2) and BP's (level 3) are possible.

and European authorities regarding; to what extent is the third level of a BPF necessary, or how can the third level fit for ozone and other in situ generated products? A proposal that is actually under discussion by the Competent Authority (CA) meeting is that the authorization for ozone BPs will be granted at the meta-SPC level, i.e. characterization at the third level would not be necessary.

Union authorization

The BPR allows that BPs can be authorized at the European Union level, which is called a Union Authorization (UA). This UA provides the same rights and obligations in all the Member States as if they were granted by national authorizations, without needing a specific national authorization. In other words, one single authorization is valid for the entire European (EU/EEA) market. An important condition for UA is that the BPs have similar conditions of use across the EU, and some Product Types (PTs) are excluded.

A UA is possible for single BPs or entire BPFs. In practice, most UA applications up until now are for BPFs. Indeed, the combination of the BPF concept and UA allows high flexibility (e.g. marketing strategy across the EU) and simplification (e.g. evaluation process and costs) for the applicant when authorizing multiple BPs.

Product authorization in EFTA member states

Three of the four EFTA (EFTA = European Free Trade Association) members (Iceland, Liechtenstein and Norway) accept the rules of the BPR, because they are also member of the EEA (EEA = European Economic Area). Additionally, even the fourth EFTA state, Switzerland, orientates its requirements for legal uses of BPs closely to the BPR. Switzerland requires a transitional product authorization for ozone, a so called "ZN-Übergangszulassung" (ZN-transitional authorization), until ozone is included in the EU list of approved active substances. The request for a ZN-transitional authorization had to be submitted by a Swiss company to the Swiss authorities by 2017. To keep ozone uses in Switzerland legal, EurO_3zon commissioned the Swiss consultant PAB Management Services GmbH (Steinmaur, CH) for preparing a ZN ozone dossier based on EurO_3zon's data, and for the

subsequent submission. By meeting the deadline, the legal use of ozone in Switzerland keeps ensured. In April 2019, PAB Management received the official ZN-transitional authorization for a first group of ozone uses, so that the legality of these ozone uses is now officially confirmed for the EurO_3zon members and their end users. The final, permanent authorization of ozone uses in Switzerland later on will be in line with the EU product authorization for ozone.

Efficacy testing

One of the most comprehensive sections of a BP authorization dossier is efficacy testing. At the stage of AS approval, efficacy testing requires demonstration of the efficacy of the AS itself, which implies that the AS should be at least sufficiently effective against one claimed group of target organism (e.g. bacteria, yeast,…). In case of the ozone AS dossier, it was agreed with the evaluating authority to show efficacy against bacteria for each Product Type including PT 2, 4, 5 and 11. At this stage, one simple screening test or laboratory study with one reference organism (e.g. *Staphylococcus aureu*s) is usually sufficient. However, in case of the ozone AS dossier, also simulated use tests linked to practical conditions were requested due to the inappropriateness of the standard EN methods for testing the unstable, strongly oxidative substance ozone.

At the stage of BP authorization, requirements for efficacy testing are much more demanding. Now, biocidal activity should be demonstrated by the BP itself and against all claimed target organisms, and in accordance with the use instructions (temperature, concentration, contact time, interfering substances, …). In practice this corresponds to a minimum testing requirement of two different tests (laboratory suspension tests + simulated use tests) per reference test organism for that target group (e.g. *Staphylococcus aureus, Pseudomonas aeruginosa* and *Enterococcus hirae*), per claimed activity (e.g. bactericidal activity, PT 2). In some cases, additionally also in-use field studies are required, under actual use conditions on specific surfaces and in a real-life environment. It is clear that "worst-case" testing within the frame of the BPF concept can reduce redundant testing and, hence, limits costs considerably.

First EurO_3zon biocidal product workshop

Awaiting the AS approval date for ozone and the outcome of the BPF discussions with the authorities, EurO_3zon is currently initiating the preparations for the BP authorization dossier, of which EurO_3zon will be authorization holder. This BP authorization will include all interested LoA customers, with the intention to share/reduce costs for all consortium members. In this perspective, EurO_3zon organized a one-day workshop (April 4th 2019, Heidelberg, Germany) with its current LoA-customers in order to present the above-mentioned issues related to ozone BP authorization while giving an update on the progress of the AS approval dossier. The main goal of this workshop was to align with the LoA-customers on the BP authorization process. This included reflecting on the number of BPFs needed for ozone, and on the proposed claimed uses and target organisms; is the addition of a claim justified by the associated additional costs for efficacy testing? Once agreed between the different LoA-customers on this technical level, an efficacy testing plan can be developed. The workshop was perceived as a success by the LoA-customers and EurO_3zon members. More workshops may take place in the near future to finally agree on submitting one or more mutual ozone BP authorization dossiers are considered.

Please check BPR news section on www.euro3zon.org for further updates.

IOA-PAG ATLANTA CONFERENCE, AUGUST 27-29, 2019
TECHNICAL PROGRAM SUMMARY

The technical program has been summarized for the Atlanta conference, with approximately 45 presentations given in two parallel sessions. The session topics are listed below. For the complete technical program visit the conference website, www.ioa-pag.org or see them in the next issue of Ozone News.

Tuesday, August 27, 2019

Session 1 - Ozone Design and Operation (3 papers)
Session 2 - Reuse and Contaminants (3 papers)
Session 3 – Ozone Applications in Georgia (3 papers)
Session 4 – Biofiltration (3 papers)
Round Table Discussions and Poster Session (7 or more)

Wednesday, August 28, 2019

Session 5 – Cyanobacteria Treatment (5 papers)
Session 6 – Reuse and Contaminants (5 papers)
Session 7 – Ozone Design and Operation (6 papers)
Session 8 – Advanced Oxidation Processes and Contaminants (6 papers)

The Round Table Discussions are a continuation of the successful implementation of them at the previous Las Vegas conference. Industry experts will focus on a specific topic in time-limited sessions in a one-on-one experience with a few attendees. This can allow for more in-depth discussions and ability to respond to specific questions or issues. If you were unable to attend these in the Las Vegas conference, you should consider participating at this one.