Is your biocidal product safe and legal?

The BPR and its importance

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The Biocidal Products Regulation (BPR)

Biocidal products aim to protect human, animals and materials against harmful organisms such as pests or bacteria, by destroying or inactivating them. Due to their mode of action, those products can be dangerous if they enter the market with insufficient or no vigorous testing. Since September 2013, the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) acts as a legal framework with the aim to control and harmonize the rules delimiting the marketing and use of biocidal products in the European Union.

The BPR is set under the precautionary principle, and its intent is to safeguard the health of humans and the environment. All biocidal products in the EU require approval under this Regulation prior to marketing; manufacturers who overlook this requirement are operating illegally. Before acquiring any biocidal products, it is highly recommended to verify their registration under the BPR.

Registration with the BPR

Full compliance with the BPR has to be done in two stages. First is the registration and authorization of a "Biocidal active substance". Second is the review of a technical dossier supporting the various claims made by the manufacturer. This is to ensure that any biocidal product is tested and authorized for its specific intended usage.

The BPR categorizes biocidal products in 22 different types, grouped in four areas (disinfectants, preservatives, pest control, others). For the first stage, biocidal active substances have to be registered under at least one product type. It is usual for manufacturers to group their products under a general area, because the usage of biocidal active substances is restricted to the product type they are registered under. Ozone is regulated as a biocidal active substance since September 2013.

Once a biocidal active substance has been authorized for a particular usage, manufacturers have to provide the documents needed to support their various claims. This technical dossier must contain efficacy data from approved tests; a label claim and instructions for use of their product; and any other information on possible occurrence of resistance, tolerance, or related topics. In addition to support their efficacy claims, the manufacturers must also demonstrate the safety of their product from both the user and the environment's standpoint. It is the product type and the mode of application that define the standardized tests. Products from STERISAFE are categorised as disinfectants, to use for whole room disinfection purposes.

Approval of biocidal substances through the BPR happens at both, or either the Member State and/or the EU levels. Depending on the type of the biocidal product and the intended number of countries they wish to sell it to, companies have the choice between alternative screening processes, leading to national or EU-wide authorizations. STERISAFE applied for their products to be registered in the whole Union, and is now part of what is known as the Article 95 list.

Compliance with Article 95

The Article 95 list records all accepted biocidal active substances along with their authorized supplier. As of September 2015, every manufacturers marketing a biocidal product must ensure that their substance, suppliers, or themselves are recorded in the

Article 95 list. While an appearance on this list is but a step towards full compliance with the BPR, it is an essential phase of the authorization process, and an important indicator of the reliability and credibility of the manufacturer. Compliance with Article 95 and inclusion on the list allows manufacturers to legally market their products.

To be included in the Article 95 list, airborne disinfection systems such as STERISAFE's products need to be tested against the NF T 72-281 standard, developed by the French standardisation body AFNOR. The NF T 72-281 is the starting point for the development of a new European Standard (EN) for the airborne disinfection of surfaces (EN 17272), and evaluates the efficacy of disinfectants in a semi-field method, applied either by vaporisation or spraying. The level of exigence for this standard is high, and it tests for bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculicidal sporicidal and virucidal activity, including bacteriophages. Products are tested as per their intended use, and full compliance with the standard is only given after passing biocidal activity requirements, which can go from 3-log (spores) up to 5-log (some bacterial strains) reduction. STERISAFE follows the NF T 72-281 standards when submitting its technical dossier to the BPR.

STERISAFE

STERISAFE is part of the European Ozone Trade Association (EuOTA), a group composed of manufacturers of ozone generators. The EuOTA's aim is to consolidate ozone-based knowledge amongst companies, and duly register ozone and ozone generators under the BPR. The EuOTA and its members present all guarantees of compliance with the BPR in regard to the use and marketing of ozone generators for biocidal purposes, and as such are included in the Article 95 list. As STERISAFE upholds its products to the highest standards, it can guarantees their efficacy and safety.

References:

1. ECHA (2019). *Understanding BPR*. European Chemicals Agency, accessed October 2019. <https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr>
2. European Parliament and Council of the European Union (2012). *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*. EUR-Lex, accessed October 2019. <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1570624754588&uri=CELEX:02012R0528-20140425>