BPR Compliance
What does it mean for your Hydrogen Peroxide Disinfection System?

EU regulation 528/2012 Biocidal Products Regulation (BPR) (http://echa.europa.eu/regulations/biocidal-products-regulation) applies to all biocidal products. The regulation is designed to control the distribution and use of biocidal products and involves the evaluation of a products performance (efficacy), toxicity, environmental fate and risk during use. The manner in which a product is intended to be used is an important factor in BPR product assessment and products must be authorised for use in accordance with specific categories called Product Types (PTs). There are 22 different PTs ranging from PT1 "Human hygiene" through to PT22 "Embalming fluids".

The BPR is a two step process. Firstly, biocidal active ingredients must be authorised as "Actives". Hydrogen peroxide was given an authorisation in 2015 for a range of PTs. Once an active has been authorised, manufacturers of biocidal products containing that active are required to submit a technical dossier to a European Competent Authority (CA) by a specified deadline. In the case of hydrogen peroxide this deadline was the 1st February 2017. If a manufacturer of a product did not submit their dossier by the specified deadline, the product is considered an unauthorised biocidal product and it is illegal to use or market that product. A dossier for Bioquell HPV-AQ was submitted in January 2017 and an approval opinion was received from the European Chemicals Agency (ECHA) Biocidal Product Committee (BPC) for an EU wide authorisation in October 2021. The approval opinion covers the use of the Bioquell technology in PTs 2 (Public Area), 3 (disinfection of animal cages / racks in biomedical and research facilities) and 4 (Food & Feed Areas). Official publication of the approval opinion by the European Commission is expected imminently.

Bioquell's hydrogen peroxide vapour (HPV) disinfectant and associated vaporisation systems have received an approval opinion from the European Chemicals Agency (ECHA) Biocidal Product Committee (BPC) for an EU wide Union Authorisation. The approval opinion covers the use of the Bioquell technology in PTs 2 (Public Area), 3 (disinfection of animal cages/racks in biomedical and research facilities) and 4 (Food & Feed Areas).

Biocidal products must be authorised for use within a specific PT to be marketed and used for that application – for example if a product is authorised solely for use in PT1 (Human Hygiene) applications, it cannot be used as a disinfectant for hospital surfaces, which requires a PT2 authorisation.

Users should ensure that a disinfectant product or system is authorised for their specific intended use.

AUTOMATED AIRBORNE DISINFECTION SYSTEMS – EFFICACY REQUIREMENTS

Bio-decontamination systems that distribute a biocide via an automated spray, mist, vapour, etc are considered "airborne automated disinfection systems" and the biocidal product (i.e. in the case of hydrogen peroxide based systems, the hydrogen peroxide liquid) must be tested in combination with its application technology / system. The disinfectant product registration will specify the specific parameters or characteristics of the delivery system that can be used with the product. For example, a product tested with an aerosol-based delivery system may only be used with an aerosol delivery system with the same performance characteristics – the product could not be used with a vaporisation or misting based delivery system, or an aerosol system that did not have performance characteristics in line with the product authorisation. Users of automated airborne disinfection systems should ensure that the product disinfectant / delivery system combination they are using will be compliant with this requirement under the BPR. Bioquell's HPV-AQ disinfectant has received an approval opinion for use with Bioquell's range of vapour-based delivery systems.

The ECHA has produced a detailed guidance document on the efficacy assessment requirements for biocidal products (https://echa.europa.eu/documents/10162/2324906/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/2c42983a-ee0b-9e35-c596-b172fee61115?t=1644567032606). Automated airborne disinfection systems such as Bioquell's should be tested against EN 17272:2020 in accordance with the product type (PT) use scenarios claimed by the product.

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EN 17272 is a challenging test against a wide range of microbiological organisms including bacteria, viruses, fungi, yeasts, spores, mycobacteria and bacteriophage. It is based on the long-standing French standard NFT 72-281, but includes additional requirements such as a distribution test and claims for small enclosures. The soiling conditions used during the test must be relevant to the claimed use scenario. For example, a hydrogen peroxide-based system intended to be used in a hospital, must pass the relevant "Human Health" sections of the test, which stipulates a 5 log reduction of the specified bacterial strains (such as *Acinetobacter baumannii*), 4 log reduction of yeasts & fungi, 4 log reduction of spores, 4 log reduction of viruses and 4 log reduction of Mycobacterium. A biocidal product may only be marketed and used for the disinfection of surfaces in accordance with the microorganism groups for which it has been authorised. For example, a product tested and authorised for use against bacteria, yeasts and spores is not authorised to be used against viruses, fungi, etc. It is very important for users of disinfectant products to discuss their efficacy requirements with product manufacturers to ensure that the products that they are using or intending to use are authorised for use against the microorganisms they are targeting.

The EN 17272 test methodology intends to assess the application of the biocide via its associated delivery system or generator in standardised conditions that allow regulators to understand a systems performance and users to compare technologies. The organisms are dried onto stainless steel tokens, which are located on the opposite side of the enclosure to the generator, facing away from it. In the distribution part of the test, the tokens are placed in the corners of the enclosure facing the walls and ceiling / floor to test the efficacy of the disinfectant at the extremities of the enclosure and the effects of environmental parameters such as gravity on the products dispersion. The distribution and efficacy tests are required to be performed in both large (30 – 150m^3) and small (0.25 – 4m^3) enclosures depending on the manufacturers intended use. For example, a product intended to be used solely in enclosures greater than 4m^3 does not require testing in a small enclosure and its regulatory authorisation under the BPR will not cover use in small enclosures. The product dose and its required time in contact with the surfaces (dwell time) to achieve the necessary microbial reductions should be described. In accordance with both EN 17272 and ECHA guidance, automated airborne disinfection system cycles must be validated or verified in the actual enclosure where the disinfection is taking place using appropriate biological or calibrated chemical indicators. Biological indicators comprising *Geobacillus stearothermophilus* are the industry standard performance indicator for oxidation-based automated airborne disinfection systems such as Bioquell's.

Bioquell's HPV-AQ Union Authorisation approval opinion covers the use of Bioquell's technology in large and small enclosures for PTs 2,3 (animal cage/rack bio-decontamination) & 4 against the broad spectrum of microorganisms including, bacteria, mycobacteria, spores, yeast, fungi, viruses and bacteriophage. It's 35% hydrogen peroxide solution combined with its Bioquell microcondensation process results in rapid and efficacious cycles. Bioquell's validated cycle times based on EN 17272 standardised testing have dwell (contact) times of 35 minutes, compared to competitor technologies such as Steris Vaprox (3 to 6 hour dwell time[1]) and Phileas 02Safe (2 to 3 hour dwell time[2]).

Users of automated airborne disinfection systems and facilities looking to purchase such systems should question manufacturers as to the status of their product authorisations under the BPR and request specific details of the products authorised use (such as approved enclosure size, microorganisms, PTs, cycle contact times, etc).

Please contact your local Ecolab representative for further information on the application and use of Bioquell's technology.

1 Steris Vaprox BPR SPC (Ireland) - https://echa.europa.eu/ documents/10162/77d06b18-6e78-7a1b-1614-0162b0b86d25
2 Phileas 02Safe BPR SPC (Ireland) - https://echa.europa.eu/documents/10162/d76c72ba-7d4c-4fa0-f52e-4f7b8cad139b

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John Chewins is an expert in the application and use of peroxygen based automated airborne disinfection systems. He is the Scientific and Regulatory Director and has worked for Bioquell UK for over 20 years. John is the Deputy Chairman of the British Standard Institutes (BSI) CH 216 disinfectants and antiseptics standards writing committee as well as the Chairman of the BSI UV automated disinfection standard writing committee. He is a member of ISO/TC 198 (sterilization of healthcare products) and actively participates in a number of working groups including aseptic processing, biological indicators and chemical indicators. John is an expert in the application of the European Biocidal Products Regulation to automated airborne disinfection systems and often presents on this subject.

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