Biocidal Products Regulation – 'cleaning' up the marketplace

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Your guide and important insight into the new regulations covering bio-decontamination claims and processes in Europe.

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EU regulation 528/2012 Biocidal Products Regulation (BPR)

Applying to all biocidal products, EU regulation 528/2012 Biocidal Products Regulation (BPR)[1] came into force in September 2013. The regulation is designed to control the selling or 'placing on the market' of biocidal products. It involves the analysis of a biocidal product's performance (efficacy), toxicity, environmental fate and risk during use. This paper aims to summarise some of the key points raised when sourcing BPR approved products.

Authorisation as an 'Active'

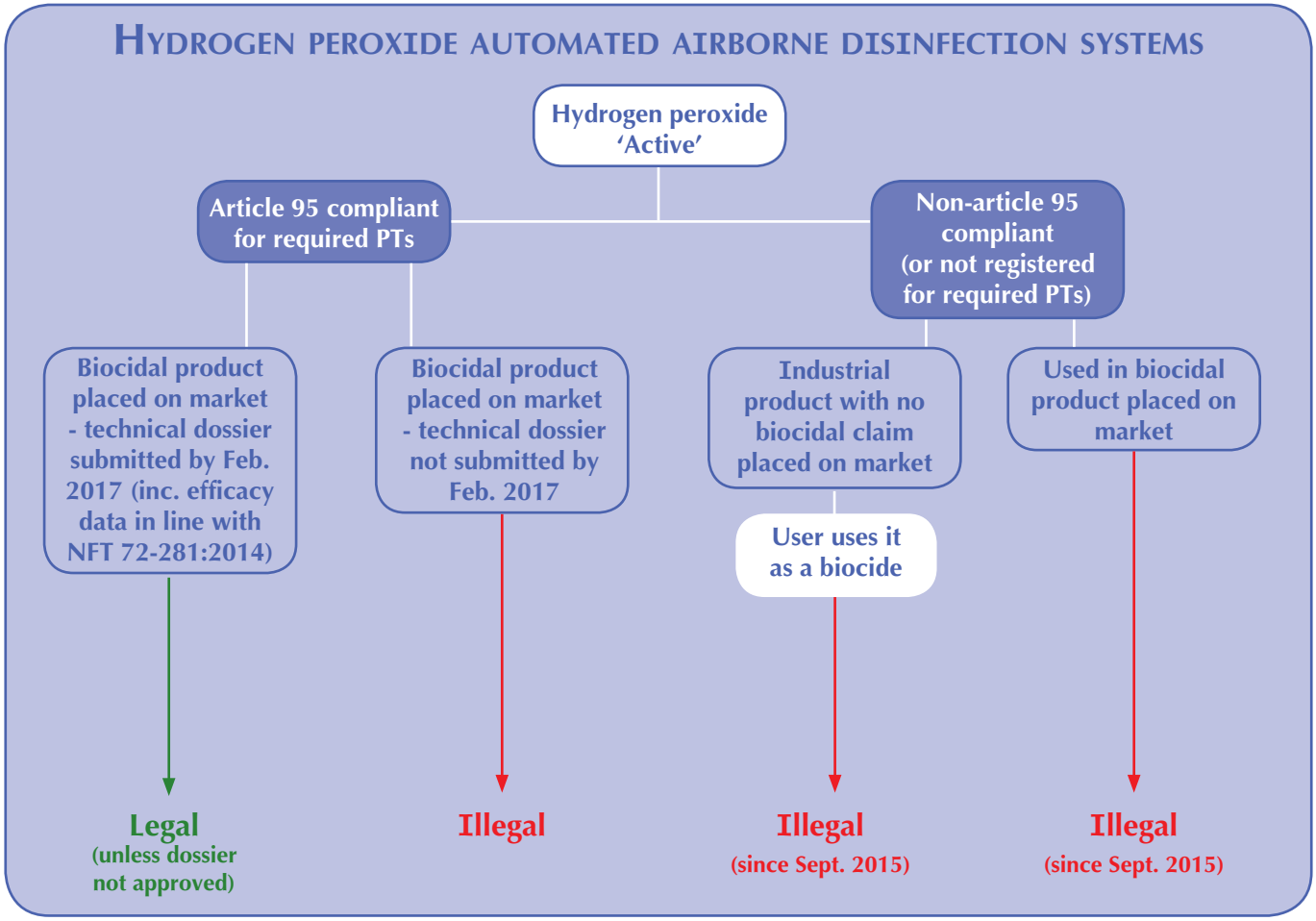
The BPR is a two-step process. Firstly, biocidal active ingredients must be authorised as 'Actives'. An important factor in BPR product/'Active' assessment is the manner in which a biocidal product is intended to be used. The biocidal product/'Active' must be authorised for use in accordance with specific categories - called Product Types (PTs). There are twenty-two different PTs. These range from PT1 'Human hygiene' through to PT22 'Embalming fluids'.

To be marketed for a certain application, biocidal products must be authorised for use within a specific PT. For example, hydrogen peroxide vapour (HPV) use within an animal research facility would require PT3 'Veterinary' authorisation. If a biocidal 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 'Public Area' authorisation. Biocidal products are likely to possess authorisations for a number of PTs (or use areas). Users should always ensure that a disinfectant product or system is authorised for their specific intended use.

Proving performance (efficacy)

Next is the second step. Once an 'Active' has been authorised, manufacturers of biocidal products/systems using or containing that 'Active' are required to submit a technical dossier to a European Competent Authority (CA) by a specified deadline. This technical dossier is to include evidence for supporting the use, risk, toxicity and efficacy claims and must also indicate the process parameters used to support such claims – including where applicable the application equipment used and contact times. In other words, compliance with the BPR requires that both the biocide (in this case the hydrogen peroxide aqueous solution) and the equipment (in this case the vapour generator or nebulising/aerosolising machine) are tested together to support any efficacy claims. In the case of hydrogen peroxide, the deadline for technical dossier submission is February 2017.

If a manufacturer of a biocidal product/system does not submit their dossier by the specified deadline, it is considered an unauthorised biocidal product/system and it shall be illegal to market that product/system.



The role of Article 95 in the BPR

In September 2015, Article 95 of the BPR came into force. Article 95 states that a supplier of any 'Active' intended for use within a biocidal product/system must be registered under the BPR process. The supplier of the 'Active' must be present on a list called 'The Article 95 List'. Producers of disinfectant products/systems may only use 'Actives' sourced from suppliers who are compliant with Article 95 (i.e. they are on the list) and may only market their product for a specific use if that use or 'Product Type' is associated with the 'Active' on the Article 95 list. Products marketed as disinfectants / biocides utilising biocidal 'Actives' from a non-Article 95 compliant source are illegal.

In practice, a number of hydrogen peroxide-based decontamination systems are able to utilise hydrogen peroxide sourced from a number of different manufacturers/sources. An example of a commonly used supply is Merck's industrial hydrogen peroxide. Here this manufacturer places its industrial hydrogen peroxide on the market for use as an industrial product – with no intention for it to be used as part of a biocidal process.

"Bioquell's 35% hydrogen peroxide is obtained from an Article 95 compliant source."

If a user chooses to use such hydrogen peroxide for a disinfection purpose then the product is considered to be a biocide and as the active does not come from an Article 95 compliant source, it is an illegal use. Companies using industrial hydrogen peroxides as biocides should review their regulatory position and assess the risks to their business operations.

Users should also be aware that a biocidal product claiming to be compliant with the BPR, based on the fact that their biocidal product contains an 'Active' from an Article 95 compliant supplier, may not necessarily remain compliant with the BPR in the future. Compliance with Article 95 is only a first step on the path to a product/system that is in full compliance with the BPR. Biocidal products (using their delivery system) must also undergo authorisation by one or more European Competent Authorities (CA), which involves assessment of use, risk, toxicity and efficacy. For manufacturers of decontamination systems that deliver biocides via an airborne route (such as HPV/fogging systems), regulators require the submission of efficacy data produced using the standard NF T 72-281 (2014).

"Hydrogen peroxide was given an authorisation as an 'Active' in 2015 for a range of Product Types (PTs)."

Airborne disinfection systems – efficacy requirements and the role of standard NF T 72-281 (2014)

Bio-decontamination systems that distribute a biocide via an automated spray, mist, fog, vapour, etc. are considered 'airborne automated disinfection systems'. Here the biocidal product/'Active' (i.e. in the case of hydrogen peroxide-based systems, the hydrogen peroxide liquid) must be tested in combination with its application device/system. The European Chemicals Agency (ECHA) has produced a detailed guidance document on the efficacy assessment requirements for biocidal products, particularly in Product Types (PTs) 1-5[2]. Airborne disinfection systems such as Bioquell's must be tested against NF T 72-281 (2014) in accordance with the PT use scenarios claimed by the biocidal product.

NF T 72-281 is a challenging test against a wide range of microbiological organisms including bacteria, viruses, fungi, yeasts, spores, mycobacteria and bacteriophage, with soiling conditions relevant to the claimed use scenario.

For example, a hydrogen peroxide-based system intended to be used in a hospital without any qualifications, must pass the 'Human Health' section of the test, which stipulates:

- 5-log reduction of the specified bacterial strains (such as *Pseudomonas aeruginosa*)
- 4-log reduction of yeasts & fungi
- 3-log reduction of spores
- 4-log reduction of viruses and
- 4-log reduction of Mycobacterium.

The NF T 72-281 test methodology attempts to assess real-world application of the biocide via its associated delivery system or generator. The organisms are dried onto stainless steel tokens, which are located on the opposite side of the room to the generator/equipment, facing away from it. The biocidal liquid must be tested in combination with the specified manufacturer's generator. The dose of hydrogen peroxide, and its contact time required to achieve the stipulated reductions, should be described.

NF T 72-281 is being used as the basis for a new European standard method for all airborne disinfection systems – this is why NF T 72-281 is being used as the standardised test for product / system registration under the BPR.

"For hydrogen peroxide, the entry date onto the Union list of approved substances of the BPR is 1st February 2017."

Implications for purchasers of airborne disinfection systems

To best future-proof processes and procedures, users of all airborne disinfection systems and facilities looking to purchase such systems should question manufacturers as to whether their systems have been tested to and passed NF T 72-281 (2014).

If the NF T 72-281 (2014) test has been passed, users should request the following information:

1. The concentration of the biocide used in the test (often given as a percentage) e.g. Bioquell uses 35% hydrogen peroxide; and
2. The contact time used to kill the organisms specified (usually given in hours and minutes).
3. The organisms killed (i.e. *Aspergillus brasiliensis*)
4. The level of kill achieved (i.e. >log 5 reduction)

These figures can then be compared with other suppliers who have also passed the NF T 72-281 (2014) test.

All airborne disinfection system suppliers should be working to provide a validated and approved biocidal product under the BPR over the next few months. If suppliers are planning to meet the regulations by providing a 'new' biocidal product to replace an existing product, or supply a new product derived from a biocidal 'Active' sourced from a new supplier, then biocidal/bio-decontamination processes currently conducted by users may need to be revalidated. Should a new biocidal product be 'introduced' as a 'replacement' just as the new regulations come into force in 2017, there could easily be a bottleneck delay in the user business as all the relevant standard operating procedures (SOPs) may need to be rewritten en masse.

To avoid such issues and to build a system that will be future-proofed in 18 months' time, come and talk to Bioquell. If you have any questions or would like to discuss the implications of the BPR with one of our experts in this area, feel free to drop Bioquell a note or call one of our global offices.

References

1. http://echa.europa.eu/regulations/biocidal-products-regulation
2. https://echa.europa.eu/documents/10162/13564/draft_tg_vol_iib_efficacy_pt1-5_ca_en.pdf

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