Implications of the EU Biocidal Products Regulation 528/2012 for cleanroom disinfectants

Biocidal products manufactured in or imported into the EU or European Economic Area must be authorised for compliance with the requirements of the EU Biocidal Products Regulation (BPR) and any relevant national legislation before being placed on the market.

BIODICAL products have been regulated in the European Union (EU) by the EU Biocidal Product Regulation 528/2012 (BPR) since 1 September 2013. The aim of BPR is to improve the consistency of the biocidal products available in the EU and ensure a high level of protection for humans and the environment via a two-stage process of active substance approval followed by biocidal product authorisation. However, the current authorisation process for hard surface disinfectants varies from country to country. For example, in the UK, a simple Safety Data Sheet (SDS) sent to the poison centre is satisfactory; whereas in the Netherlands, registration can be expensive and time consuming, requiring full microbiological, stability and safety information.

The provisions of the BPR set out to harmonise the market at EU level; simplify the approval of active substances and authorisation of biocidal products; and introduce timelines for Member State evaluations, opinion-forming and decision-making. In addition, the BPR promotes the reduction of animal testing by introducing mandatory data-sharing obligations and encouraging the use of alternative testing methods. The EU Biocides Regulation covers a diverse group of products.

The BPR acts directly in all EU Member States, meaning that local legislation does not need to be created to implement the requirements; however, due to transitional measures provided for in the Regulation, national Member State legislation, which pre-dates the introduction of the BPR and its predecessor, the Biocidal Products Directive (BPD), will still apply to some biocidal products.

Companies placing biocidal products on the market will need to take these transitional measures into consideration until December 2024, when the Review Programme for the evaluation of active substances is due to end. In addition, the Regulation has been fully implemented in Norway and Switzerland.

**Biocidal product authorisation process**

There are two consecutive steps required to gain EU BPR biocidal product authorisation:

1. The active substance(s) in the biocidal product must be approved under the appropriate product type. This process takes place at EU-level. For example, propan-2-ol, hydrogen peroxide, active chlorine.
2. Each biocidal product consisting of, containing, or generating the approved active substance(s) must then be authorised under the appropriate product type at industry-level. For example, 70 percent IPA, six percent hydrogen peroxide, branded cleanroom disinfectants.

Information and data requirements for active substance approval and biocidal product authorisation are outlined in Annex II and Annex III of the BPR.

**Biocidal product definition**

Article 3 of the BPR defines a biocidal product as, “any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organisms by...”
any means other than mere physical or mechanical action.”

In addition, the second part of the definition refers to in situ generation of active substances: “any substance or mixture, generated from substances or mixtures, which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organisms by any means other than mere physical or mechanical action.”

If the intended use of a wipe presaturated with 70 percent IPA is for surface disinfection, even if the manufacturer makes no biocidal efficacy claims, the product is classified as a biocidal product according to the BPR. Once the active substance IPA was approved under the BPR for use in product-type 2 biocidal products, a timeline was set by the EU commission whereby application for authorisation of the biocidal product (wipe) needed to be submitted by 1 July 2016. In cases where no product dossier was submitted, the biocidal product had to be removed from the market in accordance with the BPR phase-out periods.

When active substances are approved, they are listed in EU BPR Article 9: Approved List of Active Substances (Union List).

The EU BPR consists of four product groups including 22 different biocidal product types covering: disinfectants, preservatives, pest control and specialty biocides. The group relevant to life science cleanroom users is Main Group 1 Disinfectants:

- **PT1**: human hygiene products such as hand gels and hand rubs.
- **PT2**: disinfectants and algaecides not intended for direct application to humans or animals. This includes products used for the disinfection of surfaces, materials and equipment, which do not come into contact with food.
- **PT3**: veterinary hygiene products, used to disinfect materials associated with the housing or transportation of animals.

When a disinfectant has been approved under one product type it cannot be used in another product type unless approval is also granted for the second product type. For example, a hard surface disinfectant approved under product-type 2 would need a separate approval under product-type 1 to be used as hand sanitiser. For life science cleanrooms, hard surface disinfectants are categorised under product-type 2.

### Keeping track of the BPR

The active substance approval process is ongoing and is gradually replacing national regulations. Each biocidal active substance is at a different stage in the regulatory process and keeping track of the status of the active substances in your biocidal products is critical to ensure continuity of supply of the finished biocidal products.

Biocidal products which are not going through the authorisation process can no longer be placed on the market from 180 days after the date of approval of the active substance, and they can no longer be used from 365 days after the date of approval. Where the biocidal product contains more than one active substance, the relevant phase-out periods begin on the date of approval of the final active substance to be approved, or not approved.

There is currently no definitive list of authorised disinfectant products and the BPR active substance approval process is expected to still take several more years before completion.

Some common disinfectant actives used in cleanrooms – such as IPA, PAA, hypochlorites and hydrogen peroxide – have already been approved and the deadlines for submission of the product authorisation dossiers has passed. Any products for which a dossier was not submitted by the relevant deadline must remain off the EU market until authorisation is granted.

The deadline for all products containing propan-2-ol (70 percent IPA), was 1 July 2016 and for all products containing hydrogen peroxide the deadline was 1 February 2017. For products based on active chlorine or containing sodium hypochlorite, the deadline was 1 January 2019.

### Implications for users

Although no financial penalties are provided for in the BPR for an end user using an unauthorised product in their cleanrooms, it could still potentially cause problems. An unauthorised biocidal product discovered by regulators could immediately be withdrawn from the market, leaving the end user without a validated disinfectant. As a worst-case scenario, product manufacture could be delayed whilst a replacement disinfectant undergoes months of validation.

Any company about to start, or who has an ongoing disinfectant validation project, needs to ensure that the biocidal product under investigation is already, or is intended to be, authorised under the EU BPR by the manufacturer or importer.

The costs associated with the EU BPR will most likely lead to a contraction in the market, specifically in the number of biocidal products available and the diversity of active substances available for formulation. The costs to approve active substances and authorise biocidal products are significant due to the cost of generating the required supporting data and dossier preparation, as well as the evaluation fees. In broad terms, the costs to gain approval of an active substance can be several million pounds and a simple disinfectant product could potentially cost €750,000 to authorise.

Although a listing of these products is not currently publicly available, cleanroom operators should ask their disinfectant supplier about the process followed for submitting the dossiers.

This will uncover any lack of knowledge of the authorisation process and will also give the end user the opportunity to ensure their uses of the product, and usage areas, are included in the authorisation application.

If a lack of knowledge of the BPR from a manufacturer’s standpoint is apparent, cleanroom operators should start a revalidation plan to ensure continuity of a legal supply from a different manufacturer.

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**For more information on the BPR and the impact on cleanroom users, please don’t hesitate to contact us:**

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