Checklist to comply with EU Biocidal Products Regulation 528/2012

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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.

Biocidal 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 the 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.

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. It repeals and updates the Biocidal Products Directive 98/8/EEC (the BPD).

As a regulation, rather than a directive, 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.

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

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

**Article 95 of the BPR**

As well as the approval process described above, from 1 September 2015, Article 95 of the BPR has applied to active substances placed on the EU market, either on their own or in biocidal products. The provisions of Article 95 aim to make access to the market fairer via sharing of the costs associated with active substance approval. From 1 September 2015 biocidal products cannot be made available on the EU market unless the active substance is sourced from an approved supplier on the so-called Article 95 list maintained by the European Chemicals Agency (ECHA).

For example, if a wipe containing 70% IPA/30% water is imported from a manufacturer outside of the EU, either the active substance supplier or the product manufacturer or the EU importer must be listed in Article 95. If none of the above are listed in Article 95, the product cannot be sold legally in the EU as a biocidal product. It should be noted that non-EU companies can be included in the Article 95 list alongside an appointed EU representative.

**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.

Although no financial penalties are necessarily provided for in the BPR in every member state 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 whom has an on-going 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 €750k to €1m to authorise.
Step by step

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. Despite these set-backs, biocidal product users can do the following:

1. List all products being used for microbial control (these might be products not currently supplied with efficacy claims such as IPA presaturated wipes). Review the SDS for these products and note the ingredients. If unsure, confirm with the supplier the active microbiocidal ingredients in the formulation.

2. Find out the suppliers of each active substance in the disinfectant formulation. Ask the supplier to provide details of the active substance manufacturer’s inclusion on the ECHA Article 95 list. The Article 95 list is available online (https://echa.europa.eu/information-chemicals/active-substance-suppliers).

3. Ensure the active substance is listed under the correct product-type for its use.

4. If the active substance has been approved and is listed on the Union list of approved active substances, then a manufacturer of an existing biocidal product has approximately two years to submit a dossier for either National or Union Authorisation of the formulation. The list of currently approved active substances can be checked online via https://echa.europa.eu/information-chemicals/biocidal-active-substances.

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

6. For all products containing propan-2-ol (70% IPA) the deadline 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. The list of currently approved active substances and upcoming deadlines can be checked online via https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation/-union-authorisation-applications.

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.

The manufacturer should also confirm whether they are submitting a dossier for a Union Authorisation (all countries) or a National Authorisation, which may or may not be followed by Mutual Recognition applications.

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.

For more information on the BPR or to request information on Contec’s BPR authorized disinfectants, email infoeu@contecinc.com