EUROPEAN UNION BIOCIDAL PRODUCTS

Regulation Services

Intertek offers a single-source solution for compliance and regulatory work with the European Union's (EU) Biocides Products Regulation (BPR) No. 528/2012 for both biocidal products and articles treated with biocides.

Biocidal Product Regulation (BPR) No. 528/2012

In 2012 the European Parliament adopted Regulation (EU) No. 528/2012 (the "Biocidal Product Regulation" or "BPR"), which replaced the Biocidal Products Directive 98/8/EC. The BPR Regulation concerns the placing on the market and the use of biocidal products in the European Union (EU). Biocidal products and treated articles cover a wide range of products types due to the variety of use sectors and target organisms.

For the placing of biocidal products and treated articles on the European market, all active biocidal substances must be included in the "Union list" of approved active substances in accordance with the BPR.

The BPR applies to all manufacturers, distributors and importers of biocidal products and outlines criteria for:

- Establish a list of approved active substances which may be used in biocidal products
- Authorization process for placing on the market and the use of biocidal products within one or more Member States or the mutual recognition of authorizations within the EU
- The use of articles treated with, or intentionally incorporating, one or more biocides

Our Solutions

Our multidisciplinary team of scientists and registration specialists can assess your biocidal products and treated articles to determine their current status and future compliance requirements.

Intertek provides full technical and regulatory support including:

- Product development and strategic advice
- Regulatory support and consulting
  - Identification of compliance requirements under the BPR, including data requirements for active substances
  - Completion of data gap analysis and preliminary risk assessments (including cost estimates for completing the data package)
  - Identification of authorisation requirements of the BPR throughout the transitional periods
  - Identification of requirements for listing on Art. 95 list of active substances and products suppliers
  - Development of registration and testing strategy
- Regulatory submissions and study support
  - Dossier writing, submission and monitoring
  - Dossier preparation (IUCLID) and submission (R4BP3) according to BPR (National Authorizations and Union Authorizations) and National transitional rules (National applications prior to the approval of the active substance)
  - Post submission monitoring and liaison between competent authorities and clients
- Technical documentation support
  - Physical-chemical properties, efficacy, toxicology, ecotoxicology and fate, and behavior in the environment
  - Human health and environmental risk assessment
  - Study placement, monitoring, and design (both in-house and through partner laboratories)
  - Preparation of authorization requests for non-EU countries
  - Follow up with Competent Authorities
  - Classification and Labeling of Biocidal Products in compliance with CLP
    - Claim defense
    - Evaluation of classification requirements according to EU and non-EU Legislation
    - Safety Data Sheets (SDSs) for biocidal products and their components
  - Articles treated with biocidal products
    - Advisory on applicability of definition of "treated article"
    - Verification of labels conformity
    - Labels Preparation in accordance with the requirements of Art. 58 of the BPR Regulation

Additionally, Intertek offers global support and customised solutions for clients wishing to gain authorisation of biocides (active substance and product formulations) on the Canadian and United States markets.

The Intertek Advantage

Intertek's scientific & regulatory consultants have been successfully delivering expert advice for over 30 years. Our European office is well-positioned to liaise with the European Commission and the European Chemicals Agency on behalf of our clients.

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