sagentia
REGULATORY
formerly TSG CONSULTING

EUROPEAN REGULATION

Biocides – Regulatory affairs

The Biocidal Products Regulation (BPR, Regulation (EU) No 528/2012) concerns market access and use of biocidal products in the European Union. The regulation covers a diverse group of products including disinfectants, preservatives, pest control, anti-fouling and embalming products.

Successfully gaining authorisation for a biocidal product/family, or approval of an active substance, is a complex process requiring expertise from several disciplines including toxicologists, ecotoxicologists and chemists.

The BPR presents opportunities to biocide producers, including:

- Single EU-wide authorisation for certain groups of biocidal products
- Collective (family) authorisation for similar products with similar uses
- Centralised coordination by the European Chemical Agency (ECHA)

However, certain restrictions and obligations are imposed by the Regulation, including:

- Non approval of active substances meeting the exclusion criteria (CMR categories 1A or 1B, endocrine disruptors, vPvB)
- Active substances – candidates for substitution
- Increased focus on the presence of nano materials in products
- Regulation of articles treated with biocidal products

Our services

- Strategic advice and guidance
- Construction of product families
- Dossier preparation and submission (R4BP)
- Task force management
- Preparation of product labels and SDS
- Preparation of expert reports/ waivers
- Study design and monitoring
- Transitional national registration in every EU Member State
- EU-wide notification to Poison Control Centres (Article 45 of the CLP)
- Data Gap Analysis (completeness checks)
- Union Authorisation, Mutual Recognition, Same Product Authorisation and Simplified Authorisation
- Inclusion in Article 95 of approved suppliers
- Liaison with regulatory authorities
- Human health and environmental risk assessments
- Training

How Sagentia Regulatory can help

Sagentia Regulatory's consultants, supported by our multidisciplinary team of scientists and registration specialists, have the necessary expertise to help companies understand the opportunities and challenges brought about by the Biocidal Products Regulation.

We have a proven track record of securing regulatory approval for biocidal active substances and product authorisations across the EU. Our success is built on the preparation, submission and defence of high-quality dossiers, supported by deep expertise in Union Authorisation and mutual recognition processes.

About Sagentia Regulatory

For over 35 years, Sagentia Regulatory (formerly TSG Consulting) has provided companies around the world with regulatory guidance and scientific expertise. Our experts are highly knowledgeable in the core sciences and the public policy decisions that are used to structure and implement environmental and chemical regulations. By combining this knowledge with our industry experience, we provide companies with comprehensive services from the early stages of product development to marketplace entry and ongoing compliance.

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info@sagentiaregulatory.com
sagentia.com/regulatory