Exponent®

THOUGHT LEADERSHIP

PUBLISHED 2Q 2019

Considerations for the Successful Submission of Biocidal Product Dossiers in the EU

May 20, 2019

The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012)[1] concerns the market placement and use of biocidal products intended to protect humans, animals, materials or articles against harmful organisms. All biocidal products must receive authorisation before they enter the market.

Preparing and submitting a biocidal product dossier is a complex yet critical step in this process for product manufacturers. A dossier includes data on a biocidal product's efficacy, toxicity and physical chemistry test results, as well as assessments for human and environmental exposure. Data must support the product claims that a manufacturer seeks to place on the product label and align with the product's intended use in the market.

As the evaluation process for biocidal product dossiers can take up to three years, it is important for manufacturers to prioritise a clear preparation and submission strategy from the onset. A clear strategy can help reduce evaluation time, improve a dossier's performance at evaluation checkpoints, and facilitate prompt authorisation and faster access to the market. This article will discuss three considerations for developing a successful dossier strategy: balancing flexibility with complexity; understanding the evolving regulatory landscape; and proactively clarifying with Member States any grey areas regarding Product Type, product use, or regulatory governance.

Balancing Flexibility with Complexity:

Annex V to the BPR classifies biocidal products into 22 biocidal Product Types grouped into four main product families: disinfectants, preservatives, pest control and other biocidal products[2]. Many manufacturers mistakenly expect all their products to fall within one product family; however, the EU authorities have strict guidelines regarding what constitutes a biocidal product family. The current guidelines often require a manufacturer to subdivide the product family and/or create more than one family to accommodate the products intended for the market with a particular active substance. For example, the combination of product families is quite common for disinfectants belonging to Product Types 2 and 4.

Exponent partners with manufacturers to complete dossiers for a multitude of Product Types and has proven strategies to economise the amount of testing required. This can involve examining a manufacturer's data and evaluating opportunities to apply via read across one product's data to other products. It can also involve identifying key products within a product family for which exposure and risk assessments should be performed. These strategies can help ensure that dossiers are simple, to help expedite evaluation, while remaining protective of the use of the different products.

Understanding the Evolving Regulatory Landscape:

Since the BPR came to force in 2013, its application has been a learning process for ECHA, Member State Competent Authorities, regulatory consultants, and industry applicants. A principal challenge has been the inclusion of multiple products with different levels of

[1] https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr
[2] https://echa.europa.eu/regulations/biocidal-products-regulation/product-types

complexity and different uses. In many cases, product families have been so diverse that Member State evaluators have encountered difficulties determining whether the products included in the dossier are suitably covered.

Over the last eighteen months, an ECHA working group has focused on simplifying the BPR guidance by restricting the number of uses that can be covered within a biocidal product family. In particular, the working group has sought to better define the term "similarity of use" to help minimise differences within a biocidal product family. Preamble 36 of the BPR discusses the idea of grouping similar products together under one application[3]. While the legal definition of "similar" involves similar risks, use, and efficacy, regulatory authorities and stakeholders have interpreted this term differently in practice. This has led to differences of opinion between regulators and manufacturers.

The ECHA working group's guidance is expected to come into force in the next six to twelve months. While the guidance will likely involve a more restricted application of this concept, the expectation is that it will enable stakeholders to better balance flexibility with complexity and simplify the evaluation process for the Member State Competent Authorities.

[3] https://echa.europa.eu/regulations/biocidal-products-regulation/legislation

Proactively Clarifying Grey Areas:

Manufacturers can benefit from obtaining clarifying regulatory advice from the outset of the dossier preparation process. Grey areas can exist within Product Types, product uses, and applicable regulations. Is the product a biocide, medical device, veterinary product, cosmetic, or a pesticide? Should it be regulated under more than one regulation? Clarity is critical, as an incorrectly identified Product Type or indefensible legal claim can prompt evaluators to reject a dossier. A rejection can slow a new product's speed to market or cause the manufacturer of an existing product to forfeit up to three years of sales if the dossier's intent was to maintain the product on the market.

Our team at Exponent proactively collaborates with Member States to clarify potential grey areas before dossier preparation.

Exponent's Experience:

Exponent's team of experts in biocide regulation, chemistry, risk assessment, efficacy, environmental fate, ecotoxicology, and mammalian toxicology have decades of experience at regulatory authorities, contract research organisations, and industry. We evaluate product claims, perform exposure assessments, and prepare and submit biocidal product dossiers with an eye toward accuracy, simplicity, and speed to market.

Alison McGuire, BSc CSci CChem FRSC
Chemical Regulation & Food Safety
Senior Managing Scientist
Harrogate (UK)
+44 (0) 1314 458614 | amcguire@exponent.com

David Dillon, Ph.D.
Chemical Regulation & Food Safety
Senior Managing Scientist
Harrogate (UK)
+44 (0) 1423 853231 | ddillon@exponent.com