BIOCIDE

PRODUCT REGISTRATION: AN E-GUIDE

charles river

Introduction

In the EU, biocidal products are only allowed on the market if they've been authorised by the competent authorities in the Member States in which they will be marketed.

Per the EU Regulation No. 528/2012 (also known as BPR), obtaining authorisation to make a biocide available on the market is a two-step process:

1. Approval of the active substance/product-type combination at EU level
2. Approval of the biocidal product at the Member State level

Important: New biocidal products that contain active substance/product type combinations that have already been approved by the BPR active substance procedure always require authorisation under the BPR before being put on the market in one or more Member States.

Biocidal products that contain active substance/product–type combinations that are still in the BPR review procedure require authorisation or notification according to the (transitional) national procedure of the Member State under consideration.

Following the approval of the respective active substance/product-type combinations, such biocidal products need to be authorized under the BPR. In order for a product to stay on the market during the product evaluation procedure under the BPR *an application for authorization under the BPR needs to be submitted before the official approval date of the active substance/product type combination*.

Efficacy + Environmental Risk + Human Exposure = Biocidal Product Dossier => Dossier Evaluation and Approval by Competent Authorities

Dossier Preparation

It is up to you, the applicant, to assess and prove a biocide's safety and efficacy:

01

Demonstrate efficacy

- against the relevant target organisms – claim on the label
- for the desired use type
- at concentrations that are safe for humans and environment
- under realistic use conditions

02

Evaluate environmental risk

- How does the product enter the environment?
  - via STP
  - direct discharge
- Distribution between different environmental compartments and environmental fate
- Demonstrate the absence of risk to relevant populations

03

Characterise human exposure

- Define all exposure scenarios
  - primary
  - secondary
  - indirect via residues in food
  - combined (in case of several active substances or products used in combination with each other)
- Define all exposed user groups (professional, consumers, children/infants etc.)
- Demonstrate the absence of risk for each exposure scenario for all relevant user groups

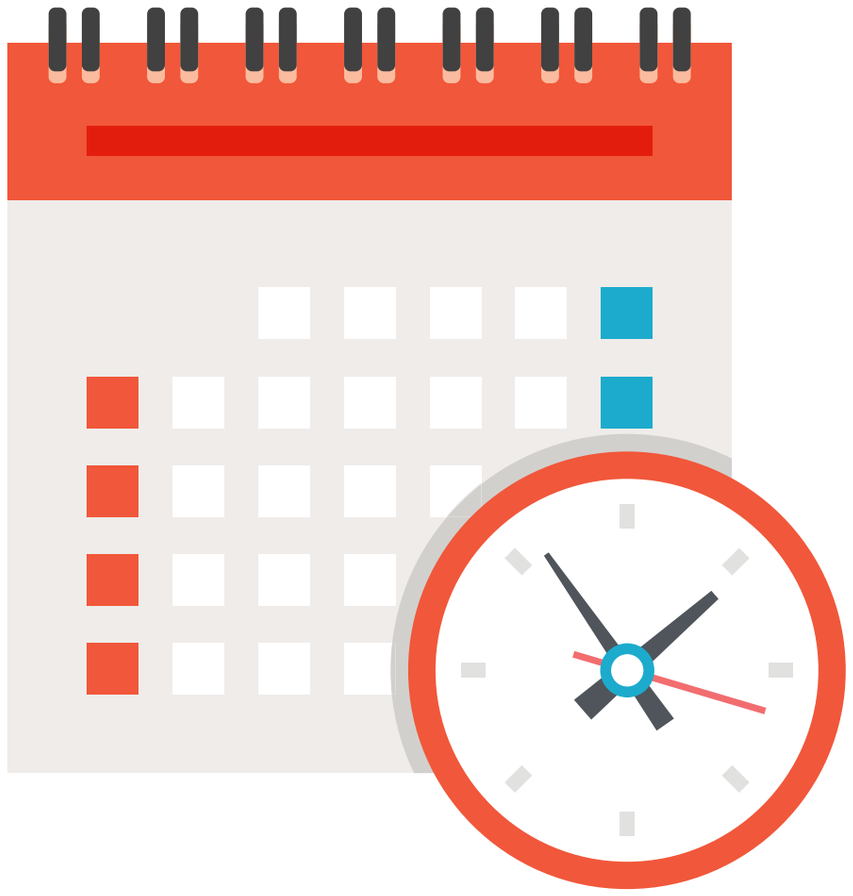
This proof is one of the most important parts of the biocidal product dossier.

Timing and Budget Matters

Study lead times and performance of the required assessments may take longer than originally planned, impacting your ability to meet deadlines and stay within budget with regard to your biocidal product(s).

Timeline

For the biocidal products which are already on the market under transitional law, from the moment of the publication of the Inclusion Regulation of the relevant active substance/product-type combination you have:



~ **2 years** for product dossier preparation and performance of required product studies according to BPR requirements. This requires careful planning and best use of resources to complete tasks and fulfil data requirements (including a full risk assessment demonstrating (a) safe (use(s)) on time.

3 years (at a maximum) for authorities to review your dossier; authorization is then granted, or proposal is modified or cancelled.

Market Matters

Where you plan to market your biocidal product will determine whether you need to apply for a single country authorisation (and mutual recognition) or for EU-wide (Union) authorisation for the product authorisation (NOTE: Union authorization is not possible for all product types!).

The following possibilities of authorization of biocidal products exist under the BPR:

- **National authorization** and **mutual recognition**

- **Union authorisation**
  The Biocidal Products Regulation has introduced this new alternative for companies that wish to apply for an EU-wide authorisation in one step. Please note that this option is not available for all product types.

- **Simplified authorisation**
  There is also a simplified procedure for products which meet certain criteria specified in the regulation (products containing active substances included in Annex I of the BPR, provided they meet a number of requirements).

- **Same biocidal product authorisation**
  This option is available if your biocidal product is identical to an already authorised biocidal product or one that currently has an ongoing application for authorisation.

- **Biocidal product family authorization**
  Products with similar uses and the same active substances can be authorized as a biocidal product family.

- **National authorisation and mutual recognition renewal**
  An authorization is granted for a limited time period (normally 10 years). Before the expiry date of the authorization, the authorisation holder has to apply for the renewal of an authorisation to the Member State competent authority (MSCA) who granted the authorisation.

7-Step Approach to Register Your Biocidal Product

1. **Perform scoping assessment:** confirm EU status of active substance/product type combination, availability of the CAR, use and product type, LoA.
2. **Conduct data gap analysis:** review existing data for the biocidal product to determine whether they fulfill the legal data requirements.
3. **Finalize your strategy:** set the right registration strategy for your product. The competent authorities offer to potential applicants a possibility to have a pre-submission meeting to discuss the critical parts of the product dossier. This is a very useful opportunity to discuss your registration strategy in advance.
4. **Complete data requirements:** conduct required studies, consider waiving opportunities where relevant.
5. **Prepare product dossier (IUCLID and product assessment report (PAR)):** include study summaries, exposure and risk assessments and summary of product characteristics (SPC).
6. **Finalise dossier:** fill in application forms and submit via R4BP3.
7. **Follow up:** perform after-care, including post-submission discussion with competent authorities.

Helpful Tips Before You Begin (and as You Go)

1. Plan ahead!
2. Talk with your active substance suppliers with regard to their Article 95 status..
3. Check the active substance /PT combination approval date or monitor the agenda of Biocidal Product Committee meetings.
4. Investigate the preferred authorisation way.
5. Check available Guidances (e.g. ECHA) and watch for updates.
6. Communicate with authorities on their fees, capacity, etc.
7. Familiarize yourself with IUCLID, PAR and SPC.
8. Create your personal account in R4BP3 for the actual product dossier submission.
9. After submission, keep track of your R4BP3 account to be aware of requests from authorities.

Indeed, there is much to do before you even get started. If you're feeling overwhelmed, consider outsourcing. But remember, your choice of partner can positively, or negatively, impact your success.

Partnering with a Preferred CRO

Unforeseen delays in this complex process can mean valuable time to market is lost. When selecting your development partner you should ensure that they have:

- A thorough understanding of the regulations as they relate to your situation
- The scientific expertise needed to ensure your compliance
- The capability to provide full support, from inventory and data gap analysis to the preparation and submission of a complete dossier and post-submission care
- The capacity to perform required studies and supply accurate, timely data

Have more questions?

We're here to help. Our team of scientists and regulatory experts are ready with advice and answers to all of your biocidal product registration questions. We would be happy to discuss your specific needs, and put you on the path to a successful authorisation.

Contact us

Send an email to askcharlesriver@crl.com or visit us at www.criver.com/biocides-eguide.

References

Click on the links below for additional resources and contact information.

- **ECHA Guidance Documents:**
  Information requirements – Annex III of Biocidal Product Registration:
  - physicochemical properties
  - human health
  - environment
  - efficacy

- **Assessment and evaluation: Guidance on assessment and evaluation of human health, environment and efficacy**

- **Guidance on the assessment of SoCs** (Doc 5.11)

- **List of preferred models per product type for human health risk assessment**

- **Guidance documents for emission scenarios**

Related Acronym Glossary

a.s. – Active Substance

BPR – Biocidal Product Registration

CAR – Competent Authority Report

IUCLID – International Uniform Chemical Information Database

LoA – Letter of Access

PAR – Product Assessment Report

R4BPR – Register for Biocidal Products

SPC – Summary of Product Characteristics

STP – Sewage Treatment Plant

charles river

www.criver.com