

A photograph of a female scientist in a laboratory. She is wearing a white lab coat, a blue surgical cap, safety glasses, and a blue face mask. She is also wearing blue nitrile gloves. She is holding a pipette in her right hand and a small vial in her left hand, appearing to be in the process of transferring liquid. In the background, there are various laboratory glassware, including test tubes in a rack and a flask, all set against a bright, blue-tinted background.

Authorisation of biocidal products in Europe

The way forward

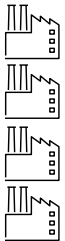
Arcadis helps companies to comply with regulations regarding biocidal products. In particular, we support our customers with upcoming BPR deadlines, obtaining an overview of and interpreting the continuously extending biocide regulatory framework.

If you manufacture, supply or use biocidal active substances or biocidal products in the EEA, you need to be aware of the EU's Biocidal Product Regulation (EU 528/2012). It is designed to make sure that the potential risk caused by biocides are in balance with their expected benefits.

Ensuring compliance with EU BPR is a resource consuming process, which requires a broad range of expertise. The Arcadis experts in Belgium can support you in understanding and meeting the obligations under the BPR and corresponding legislation (e.g., Switzerland).



- Is your company **placing** biocidal products on the **market, e.g.:**
- Do you want to ensure **market continuation** of your product?
- Are your **suppliers** meeting the current biocidal requirements?
- Is your **active substance** under review or already approved?
- Does your company manufacture articles that are treated with, or intentionally incorporate, one or more biocidal products (**treated articles**)?



- Do you want to ensure **market continuation** of your product?
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- Is your company **using** one of the above listed biocidal products / treated articles?
- Are your employees aware of the need to use authorised biocidal products only for certain **intended biocidal uses**?
- Do you have a **system** in place **tracking** all active substances, their status and the biocidal products / treated articles they are used in?

Legenda



Manufacturer



User

About Arcadis

Arcadis is the leading global Design & Consultancy firm for natural and built assets. Applying our deep market sector insights and collective design, consultancy, engineering, project and management services we work in partnership with our clients to deliver exceptional and sustainable outcomes throughout the lifecycle of their natural and built assets. We are 36,000 people, active in over 70 countries that generate €4 billion in revenues. We support UN-Habitat with knowledge and expertise to improve the quality of life in rapidly growing cities around the world.

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How can we support you:

Are you a manufacturer or importer of active substances or biocidal products?



Dossier preparation

- Active substance dossiers
 - Inclusion in **Annex I**?
- Product dossiers (**single** product or product **families**)
- Consortia for biocides
- Obtaining access to the dossier of the active substance (**Letter of Access**)
- Demonstrating **technical equivalence** when buying from a “new” source
- Gathering of data required to build the dossier: coordination of **tests**, writing **waivers**
- **Risk assessments** (ecotoxicological and toxicological expertise in-house)
- Putting together the **IUCLID** dossier



Dossier submission

Pre-submission meetings with the eCA

- What kind of submission?
 - National authorisation
 - Mutual recognitions
 - Union authorisation
- Submitting the dossier through **R4BP3**



Compliance check for the manufacturing of treated articles

- Check the **authorisation** of the **biocidal product** for the treatment of the article
- Listing of **label requirements**

Are you a user of biocidal products / treated articles?



- **BPR training** for users and regulatory teams for biocides



- Support with the interpretation of the legislation (e.g. assessment if the products are subject to another, closely related regulation e.g. MDR, PPP, REACH)



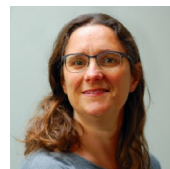
- Development and implementation of compliance strategies (e.g. via an **inventory template** for documenting compliance status of biocidal products or **process flows** for the evaluation of products used)



- Act as **helpdesk** or **Trustee**

Arcadis may provide you with just the support you need!

Contacts in Europe



Maaïke Bilau

Manager Product Stewardship and Sustainability

+32 492 73 04 89

maaïke.bilau@arcadis.com



Bart Kerré

Environmental Risk Assessor

+32 477 19 0657

bart.kerre@arcadis.com