SERVICE SHEET

ARCADIS Design & Consultancy for natural and built assets

AUTHORISATION OF BIOCIDAL PRODUCTS IN EUROPE

The way forward

The Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, by the action of the active substances contained in the biocidal product. It entered into force on 1 September 2013.

Being compliant with this Regulation is the legal prerequisite that allows marketing of your biocidal products in Europe or Switzerland, which has implemented similar provisions in the framework of the Ordinance on Biocidal Products (OBP). However, obtaining an authorisation for marketing your biocidal products is not the only concern - under the BPR also treated articles are regulated.

Obtaining compliance with the BPR is often a time consuming and costly process demanding various kinds of expertise.

HOW CAN ARCADIS HELP YOU?

Imagine you are a producer of human hygiene products and household disinfectants, or preservation and disinfecting products in the food industry, and you wonder whether you are compliant with the BPR, or you even need to be. Or you are a producer of paints that contain preservation agents and you have not dealt with regulations on biocidal products before.

First, you will need to establish if your products are biocidal products or treated articles and if they actually fall within the scope of the BPR and are not subject to another, closely related, legislation covering for instance Human Medicinal Products or Plant Protection Products. Determining this may not be as easy as it seems!
Secondly, you will need to check whether the active substances in your products or treated articles are or will be included in Annex I (IA or IB). Do you have a tracking system in place to monitor this and to follow up on the evaluation timelines and approval dates for the active substances in the products or treated articles you are placing on the market?

Once you have established a system tracking all the active substances, their status and the biocidal products or treated articles they are used in, you should evaluate your inventory:

- Are there any uses that are not compliant anymore?
- Are all active substances expected to be available for your use in the future?
- Is sufficient information available from the suppliers?
- For which products do you need to apply for a product authorisation? Shall any products be phased-out?

Once you have established for which products an authorisation shall be applied for, you need to start compiling the biocidal product dossiers as required under the BPR. At this stage in the process, you should ask yourself:

- whether you have access to the dossier of the active substances (Letter of Access) in your products or whether you need to demonstrate technical equivalence when buying an active substance from a “new” source (meaning a different manufacturing process, manufacturing location or manufacturer)?
- which data are required to build the biocidal product dossier, and what about product families, data sharing and the Register for Biocidal Products (R4BP)?
- whether you have the required in-house (eco)toxicological expertise to deal with the elaborate exposure and risk assessment?

Are you seeking for regulatory and/or technical support in the rather complex process of getting your biocidal products authorised?
Arcadis may provide you with just the support you need!

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 withour clients to deliver exceptional and sustainable outcomes throughout the lifecycle of their natural and built assets. We are 27,000 people active in over 70 countries that generate more than €3.3 billion in revenues.

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