
Biocides
Services
yordas
Group

Biocides Services

Yordas Group is a leading global provider of scientific, environmental and regulatory consulting services. Yordas offers comprehensive services to the biocides industry, from the active substance approval, product planning and formulation stages to making a biocidal product available on global markets.

Our objective is to support our clients in making their biocidal products available on the market while meeting regulatory requirements in those jurisdictions. As a strategic partner, Yordas is focused on adding value to the product and helping companies maintain a competitive edge.

Biocide Regulatory Requirements

Yordas provides expert advice to determine if products fall within the scope of the relevant biocides regulation and identify the regulatory obligations associated with marketing that biocide, both within the EU and in different territories globally.

- Biocide scoping assessments
- Define biocidal products, product families and treated articles
- Preparation of regulatory submissions for:
  - **Active substance approval**
  - **Biocidal product authorisation**
  - **Biocidal product family authorisation**
  - **Mutual recognition**
  - **Simplified authorisation procedure**

Technical & Endpoint Data

Clients benefit from a highly technical team of scientific, (eco)toxicity, risk assessment and chemistry specialists who are experienced in the preparation and submission of dossiers for the approval of active substances and authorisation of biocidal products within the EU.

- Data Gap Analysis and Intelligent Testing Strategies
- Non-testing strategies as a weight of evidence approach
- Manage and coordinate new endpoint studies, as required
- Prepare hazard information and exposure assessment

Global Biocides Regulatory Services

Our chemists and regulatory experts have a wealth of experience working with clients looking to market biocidal products both in the EU and globally. Our clients benefit from the Yordas network of trusted partners, ensuring they receive the best regulatory interpretation and direct communication with non-EU regulatory authorities globally.

- Assess global regulatory requirements
- Collaborate with competent authorities globally
- Identify data requirements for regulatory submissions
- Prepare relevant regulatory submissions

Hazard Communication

The biocidal products regulations provide clear and concise requirements to disclose hazard information associated with biocidal products. Yordas provides expert advice and services concerning hazard communication, including labelling and packaging to ensure that a product is fully compliant.

- Determine classification, labelling and packaging requirements
- Conduct exposure scenarios
- Produce safety data sheets (SDS) and labels
- Translation of SDS and labels into relevant languages

Regulatory Monitoring

Yordas' regulatory experts can monitor the regulation to identify any upcoming regulatory changes that would affect an active substance or biocidal product. This monitoring allows clients to maintain a competitive edge and remain complaint with the ever-changing regulatory environments around the world.

- Monitor regulatory changes to identify new obligations
- Prepare regulatory monitoring reports
- Guidance on how changes may affect the client
- Regulatory compliance safeguards product marketability

Yordas Hive

Yordas Hive provides a comprehensive chemicals management solution that enables clients to manage their product portfolio with alerts of regulatory changes that affect their products. Hive also serves as a chemical reference tool and as a wider environmental, health and safety solution.

- Empower clients to manage their chemical compliance
- Regulatory horizon scanning
- Customised compliance updates
- Accurate regulatory information tailored to the client's products

Learn more...
yordasgroup.co.uk/hive

Route to market in the EU

The BPR ensures that eventually, only authorised biocidal products will be able to be placed on the EU market. Therefore, clients wishing to make a biocidal product available on the EU market must submit a product authorisation application following the approval of the active substances contained in the product.

There are a number of product authorisation types available:

- Union Authorisation
- National Authorisation
- Mutual Recognition
- Simplified Authorisation

These types of authorisation can apply to single biocidal products, same biocidal products and biocidal product families. Selecting the appropriate route to market will depend on a number of factors including the market throughout the EU and EEA, product-type(s) and costs.

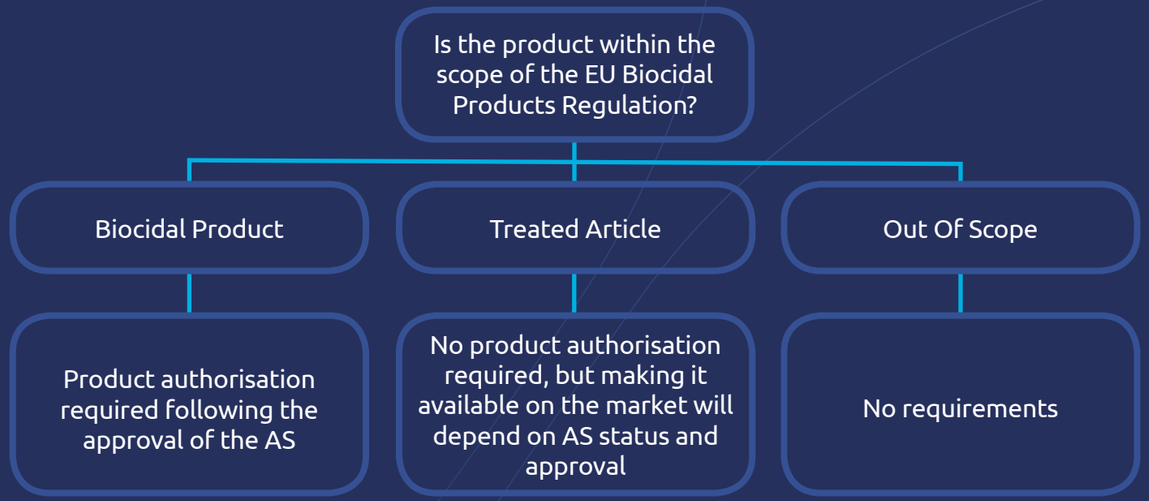

Figure 1. Product definition under the BPR

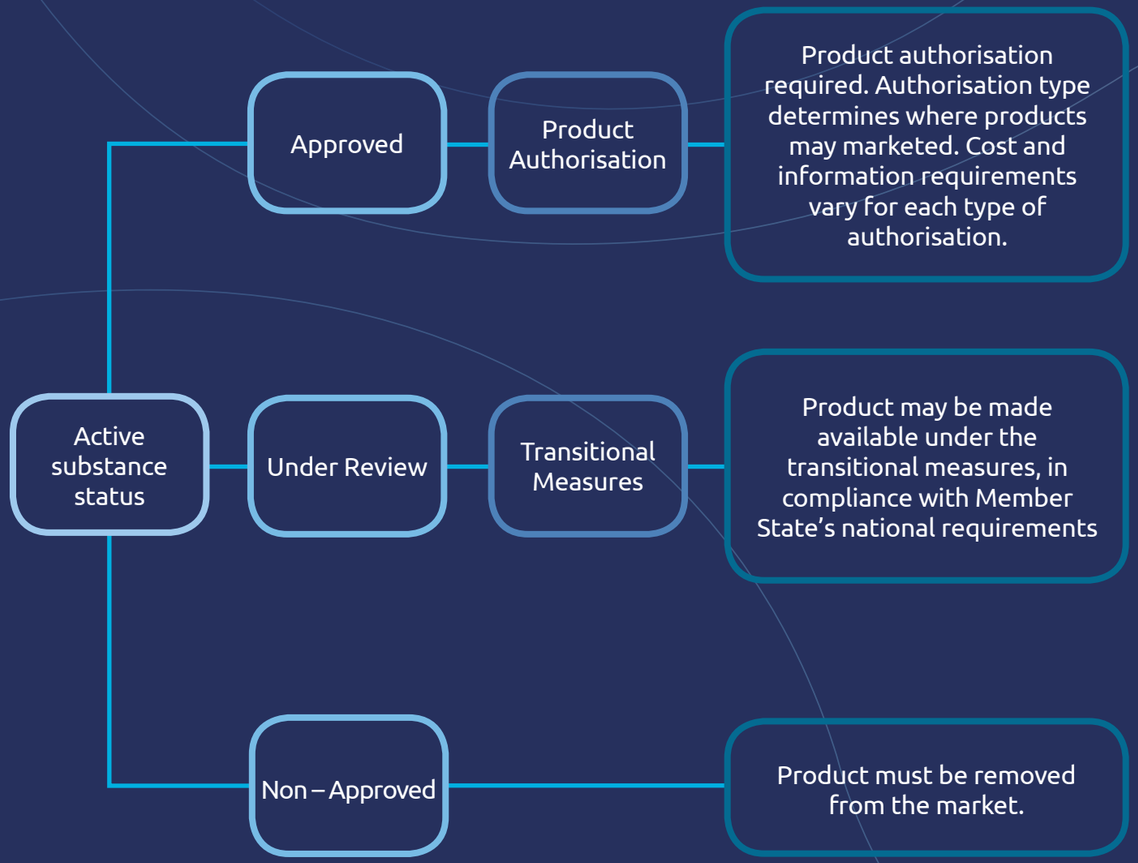

Figure 2. Status of active substance pursuant to EU BPR

EU Biocides Guide

Understanding biocidal regulatory requirements is essential to meet compliance when marketing a biocidal product on the EU market. The following guide provides definitions for key terms relating to biocides and outlines aspects of the Biocidal Products Regulation (EU) No 528/2012 (BPR).

Biocidal Products Regulation (EU) No 528/2012:

The purpose of the BPR is to protect human health and the environment by assessing the risks and efficacy of biocides placed on the EU market.

Product-types:

Biocidal products can only be authorised in relation to their product-type(s). Active substances are evaluated in relation to each product-type.

Main Group 1: Disinfectants	Main Group 2: Preservatives	Main Group 3: Pest Control	Main Group 4: Other Biocidal products
PT 1: Human Hygiene	PT 6: Preservatives for products during storage	PT 14: Rodenticides	PT 21: Antifouling products
PT 2: Disinfectants and algaecides not intended for direct application to humans or animals	PT 7: 7: Film preservatives	PT 15: Avicides	PT 22: Embalming and taxidermist fluids
PT 3: Veterinary hygiene	PT 8: Wood preservatives	PT 16: Molluscicides, vermicides and products to control other invertebrates	
PT 4: Food and feed area	PT 9: Fibre, leather, rubber and polymerised materials preservatives	PT 17: Piscicides	
PT 5: Drinking water	PT 10: Construction material preservatives	PT 18: Insecticides, acaricides and products to control other arthropods	
	PT 11: Preservatives for liquid-cooling and processing systems	PT 19: Repellents and attractants	
	PT 12: Slimicides	PT 20: Control of other vertebrates	
	PT 13: Working or cutting fluid preservatives		

Authorisation types

Different authorisation types within the EU determine where a product may be made available on the market.

Types of authorisation in the EU

Union Authorisation

Allows a biocidal product to be made available on the market throughout the entire EU

National Authorisation

Allows a biocidal product to be made available on the market throughout the entire EU

Mutual Recognition

An agreement where one or more countries recognise another country's National authorisation

Types of mutual recognition:

- In sequence
- In parallel

Simplified Authorisation

Allows a biocidal product to be marketed in all member states in the EU. Specifically for products containing active substances which pose a lower risk and are less harmful to the environment, human and animal health (Annex I of the BPR)

Article 95 Approved Supplier List:

From 1 September 2015 all manufacturers and importers who place active substances on the market either on their own or in a biocidal product must be included in the Approved Supplier List. The need for inclusion on the Article 95 list will depend on the role in the supply chain.

Classification, Labelling and Packaging Regulation (EC) No 1272/2008 (CLP):

Hazard classification, labelling and packaging of biocides in the EU is regulated by CLP to ensure harmonisation of risk management.

BPR transitional provisions:

Member states have individual requirements for suppliers looking to make their product available on the market, such as notifying the national poisons centre. While an active substance is under review at an EU level, national requirements apply until the active substance is approved, at which time BPR requirements apply in all Member States.

About Yordas

Yordas is a leading provider of scientific, environmental, human health and global regulatory consulting services. Our unique collaborative approach is designed to build strong working relationships, allowing to create a customised and integrated service specifically tailored to the needs of each individual customer.

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