

EU Biocidal Products Regulation: An Overview of the EU Biocide Authorization Process and Key Considerations of New Legislation

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Introduction

Following intense negotiations, the long-envisioned European Union (EU) **Biocidal Products Regulation (BPR)**, was approved by the European Parliament on 19 January 2012. This legislation will replace the Biocidal Products Directive 98/8/EC (BPD). By 1 September 2013, the BPR shall become applicable in all Member States in the European Union. The BPD will no longer be in force, with a few minor exceptions. This presentation provides an overview of the current EU biocidal product authorization process and key considerations of the new regulation.

Biocidal Product Authorization Procedures in the EU

For biocidal products that contain active substances that are not yet included on Annex I to the BPD, national registrations can be requested in the European countries of interest. Each country has their own requirements which also vary depending upon the Product Type (PT).

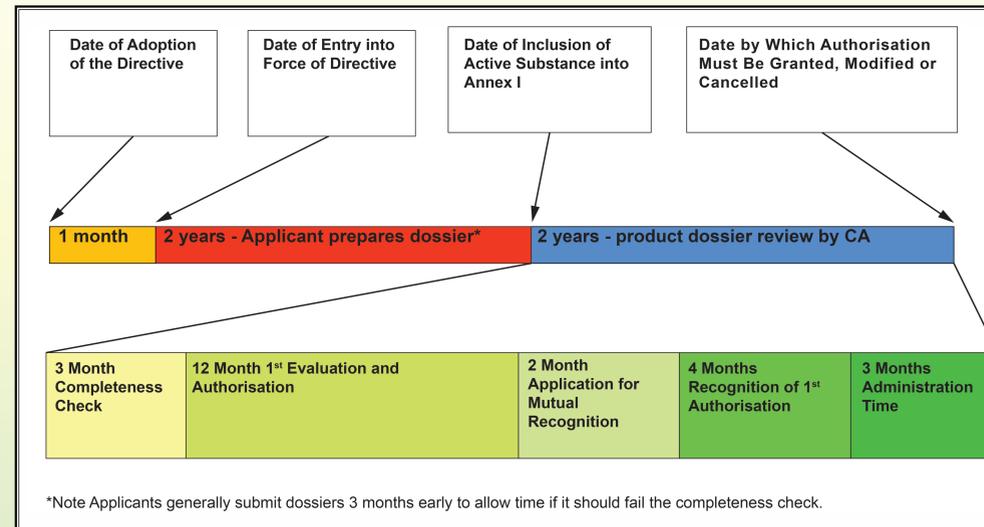
Once an active substance has been reviewed under the BPD and considered to be acceptable, the active substance is placed on Annex I by publication of the decision in the Official Journal of the European Communities (OJEC) (*Date of Entry into Force of the Directive*). At this stage, the clock starts ticking as all biocidal products containing this active substance must then be authorized. (There is an exception to this rule, where if the product contains more than one active substance, the date of inclusion of the last active substance is considered to be the key date).

From the *Date of Entry into Force of the Directive*, the applicant has 2 years in which to prepare the biocidal product dossier for product authorization. It is recommended that the dossier be submitted up to 3 months in advance of the date of formal inclusion of the active substance on to Annex I (21 months after publication in the OJEC). If a dossier is not submitted at this stage, then the biocidal products containing the active substance must be withdrawn from the EU market.

MAIN GROUP 1: Disinfectants and general biocidal products	
PT 1: Human hygiene biocidal products	PT 4: Food and feed area disinfectants
PT 2: Private area and public health area disinfectants and other biocidal products	PT 5: Drinking water disinfectants
PT 3: Veterinary hygiene biocidal products	
MAIN GROUP 2: Preservatives	
PT 6: In-can preservatives	PT 11: Preservatives for liquid-cooling and processing systems
PT 7: Film preservatives	PT 12: Silicicides
PT 8: Wood preservatives	PT 13: Metalworking-fluid preservatives
PT 9: Fibre, leather, rubber and polymerised materials preservatives	PT 14: Preservatives for liquid-cooling and processing systems
PT 10: Masonry preservatives	
MAIN GROUP 3: Pest control	
PT 15: Rodenticides	PT 18: Piscicides
PT 16: Avicides	PT 19: Insecticides, acaricides and products to control other arthropods
PT 17: Molluscicides	PT 20: Repellents and attractants
MAIN GROUP 4: Other biocidal products	
PT 21: Preservatives for food or feedstocks (removed from BPR)	PT 23: Embalming and taxidermist fluids
PT 22: Antifouling products	PT 24: Control of other vertebrates (PT 20 under BPR)

If a product has already been sold in the EU prior to the date of inclusion in Annex I, the applicant can request a certificate of exemption or similar exemption from each member state where the product is sold, to allow the product to remain on the market while the Biocidal Product review is taking place. This period is known as the "Transitional Period".

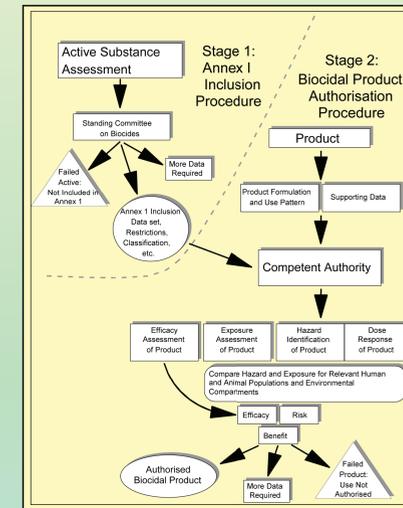
The following diagram outlines the key time points in the authorization process.



Structure of a Biocidal Product Dossier

The diagram¹ (Stage 2) shows the structure of a biocidal product dossier, required to support a product authorization request in the EU. Important points to note are the requirement to have physical chemical data and efficacy data on the actual product to be authorized. Exposure and risk assessments must be performed to assess both the risk to human health and the environment. A label and Safety Data Sheet are also required for the product.

¹Technical Notes for Guidance, European Chemicals Bureau



Mutual Recognition

A process known as mutual recognition can be applied for when a product dossier is submitted to the first Member State, known as the Reference Member State. An applicant can ask any Member State to be the Reference Member State although it is expected that in most cases the application will be made to the Member State that was either the Rapporteur for the active substance or to the Member State where the product will first be placed on the market. The applicant can indicate that they also wish to receive authorization in several other member states, known as the Concerned Member States. The European Commission has developed a community register called R4BP into which all of the product details are inserted. Each Member State has their own requirements regarding the aspects of the product dossier they would like to receive and when they wish to receive the data.

Mutual recognition aims to reduce the amount of work required by member states and has the benefit of reduced fees for the applicant. The Reference Member State conducts a thorough review of the dossier and prepares a Product Assessment Report (PAR) which is then reviewed by the other member states.

The Future: Implications of the BPR

By 1 September 2013, the BPR shall become applicable in all Member States in the European Union. The BPD will no longer be in force with a few minor exceptions.

By 1 September 2013, all biocidal product manufacturers will require either their own active substance dossier or a letter of access (LOA) to an active substance dossier even if evaluation of the active substance has not started at that date. A positive list of suppliers will be created by the European Chemicals Agency (ECHA). The list will not be Product Type (PT) specific. By 1 September 2015, all biocidal products must contain active substances which are sourced from this positive list.

The definitions for what kind of products shall be regarded as biocidal products are likely to remain more or less limited to chemical substances and mixtures as well as micro-organisms, including in exceptional circumstances some treated articles with clear biocidal functions. There will be no significant change in the type of products that are considered to be biocidal products when the BPR takes over.

Key considerations to note are that although discussion ensued for some time concerning devices for generating active substances, these products are unlikely to be covered by the new definition for a "biocidal product" while substances and mixtures generated from precursors will be regarded as biocidal products. Treated articles with a primary biocidal function controlling harmful organisms shall in the future also be considered to be biocidal products. This definition will also include substances and mixtures, which are not biocidal products but contain a biocidal product.

Union authorizations will be handled by the European Chemicals Agency (gradually taking over from the European Commission beginning with: in 2013, PTs 1, 3, 4, 5, 18 and 19; in 2016, PTs 2, 6 and 13; in 2020, all remaining categories. Union authorizations will not apply to PTs 14, 15, 17, 20 and 21.

A simplified authorization procedure will be available for low risk products. To be considered as a low risk product, the product must not be classified, not a nano material, no personal protective equipment (PPE) required and its efficacy must be adequate. There will be no requirement to have an LOA to the active substance for products that fit the requirements of the simplified authorization procedure, and the dossier can be submitted directly to ECHA where it will be evaluated by a Competent Authority (CA) within 90 days. Once the product is authorized, other Member States only need to be notified and mutual recognition procedures are not required.

For products that are very similar in composition, the concept of Biocidal Product Families can be used to reduce the workload for applicants. The requirements for creating a Biocidal Product Family are similar to those defined under the Biocidal Products Directive, for Frame Formulations.

Frame formulations were originally designed so that pigments, dyes and perfumes could be replaced, but under the BPR the types of co-formulants that can be replaced have expanded. The key points to note are that any changes made should not affect the instructions for use, classification of the formulation or reduce the efficacy of the formulation.

Recommended links for more information on the Biocidal Products Regulation: <https://www.europeanbiocides.net/> and http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/guidance-documents

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