November 18, 2020

Regulatory Alert

EU Biocidal Products Regulation (EU BPR) 528/2012

Country: European Union Countries

Please see the Disclaimer at the end of the alert

INTENDED AUDIENCE

European Union countries "end-users" of biocidal products

EXECUTIVE SUMMARY

Even though the European regulation described in this regulatory alert was published in 2012 and does not correspond to the "emerging" regulation definition, several IAEG members expressed an interest to provide awareness and a general summary of its requirements.
It should also be noted that there are other regulations covering biocidal substances beyond Europe (e.g., USA - regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), China, Australia, Japan…).

Overview of the EU BPR

The European Union (EU) Biocidal Products Regulation 528/2012 (EU BPR), made effective September 2013, regulates a diverse group of "active substances" and biocidal products, including disinfectants, pest control products, anti-fouling paints, embalming fluids, preservatives, etc. The EU BPR replaced the previously existing Biocidal Products Directive (Directive 98/8/EC). The EU BPR aims to harmonize the market at European Union level; streamline and simplify the approval of "active substances" and authorisation of biocidal products; and introduce timelines for EU Member State evaluations, opinion-forming and decision-making. It also promotes the reduction of animal testing by introducing mandatory data sharing obligations and encouraging the use of alternative testing methods.

Link to Regulations: https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr

Practical Guide on BPR: https://echa.europa.eu/documents/10162/21742587/pg_on_bpr_en.pdf

Definitions:

- Active substance: a substance or a micro-organism that has an action on or against harmful organisms
- Biocidal product: any substance or mixture, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action
- Treated article: any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products (a treated article that has a primary biocidal function shall be considered a biocidal product)

The basic principle in the EU BPR is that a biocidal product must be authorised before it can be made available on the market or used in the European Economic Area (EEA) and Switzerland. This takes place in two consecutive steps:

1. The active substance is evaluated and, provided the criteria are fulfilled, is then approved for a specified product-type. Active substance approvals are granted for a limited time, typically 10 years. Once an active substance is approved, it is placed on the European Union List of approved active substances.

2. The authorisation of each biocidal product consisting of, containing or generating the approved active substance(s), once all active substances in the product have been approved. There are multiple routes for product authorisation, including Union Authorisation and National Authorisation. The most relevant route for a company is dependent upon a number of factors including intended market coverage and resources. Note that, treated articles, unlike biocidal products, do not require product authorisation, however, they must abide by Article 58 of the BPR.

It is possible in some circumstances to market biocidal products containing active substances that have not yet been approved. This is the case for so-called 'existing active substances' which are in the EU Review Programme. Any biocidal product which contains an active substance in the Review Programme may be marketed in Member States (subject to national laws) under the transitional provisions laid down in Article 89 of the BPR pending the final decision on the approval of the active substance. Annex II part 1 of the Review Programme Regulation lists those active substances which are under evaluation. The initial notification, application, and review stages for a petitioned "active substance" to become accepted and included on the Union List.[1] The regulatory status of a given active substance as 'new' or 'existing' can also be found on ECHA's website. Products containing new active substances that are still under evaluation may also be allowed on the market where a provisional authorisation is granted, however this is at the discretion of the individual Member States.

In addition to product authorisation, companies making biocidal products available on the European market must ensure that either their active substance/product suppliers or they themselves are included on the Article 95 list of approved active substances and suppliers. Article 95 aims to ensure the equal treatment of persons placing active substances on the EU market. From September 1st 2015, a biocidal product cannot be made available on the EU market unless either the active substance supplier or the product supplier is included on the Article 95 list for the product type to which the product belongs.

Link to the ECHA "information on biocides" website:
https://echa.europa.eu/information-on-chemicals/biocidal-active-substances

Link to ECHA's BPC's Published Opinions:
https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval

Link to Article 95 - Approved List of active substance and suppliers:
https://www.echa.europa.eu/documents/10162/27434452/art_95_list_en.pdf/c752c5ae-358c-e84b-652a-fb98106dfe8e

[1] It should be noted that the Union List approved list is not a "lifetime" designation, but rather the approval of an "active substance" is granted for a defined number of years, not exceeding ten years, after which time the approval process must repeated.

ECHA's What you need to know about treated articles:
https://echa.europa.eu/documents/10162/26065889/treated_articles_inbrief_en.pdf/

APPLICABILITY

End User Obligations

"End users" of biocidal products have certain obligations. They must ensure that the biocidal products that they use (including "treated articles") contain active substances that are either approved or are under evaluation in the Review Programme for the relevant product type[2]. Information on the active substance(s) contained within a product can often be found on that product's safety data sheet (SDS) or can be identified by contacting the manufacturer. End users should also review the Article 95 list, ensuring that either the active substance supplier or the product supplier is included on the list for the relevant product type.

Examples of items that falls into scope of biocidal products relevant for A&D industry

Product type	Biocidal product examples	Treated article examples
PT6 – Preservatives for products during storage	Preservatives/biocides for fuels, lubricants, aqueous formulations	Fuel, lubricants, aqueous based paints, varnishes, adhesives
PT7 – Film preservatives	Paints, sealants, adhesives designed to prevent algal or microbial surface growth (mildew, mold, algae, bacteria	Items coated with paints, sealants, adhesives, coating designed to prevent algal or microbial growth
PT9 – Fiber, leather, rubber and polymerized materials preservatives	Preservatives/biocides for textiles, leather, rubber and polymers (plastics)	Upholstery, carpet, plastics, interiors
PT11 – Preservatives for liquid cooling & processing systems	Biocides and fungicides for liquid processing/coolant system including cleaning	Biocide-treated liquids in coolant/liquid systems
PT13 – Working or cutting fluid preservatives	Biocides and fungicides for cutting fluids, metal working fluids	Metal working fluids, cutting fluids, cutting oils
PT21 – Antifouling products	Marine antifouling coatings and paints	Vessels & equipment coated with or containing antifouling product

Defense exemptions:

Member states may allow for exemptions in specific cases for certain Biocidal Products on their own or in treated articles in the interests of defense (art. 2.8 BPR). No universal exclusion of the BPR duties for defense products - Industry should apply for an exemption on a case-by-case basis

RELEVANT DATES

As indicated above, the "active substance" and biocidal product evaluation process has many different stages and, on a rolling basis, numerous substances or products are being reviewed and approved/rejected at any given time. If the European Commission makes a decision of non-approval (i.e., rejection) for an eligible active substance, Article 89(2)(b) of the BPR indicates that a Member State may continue to apply its current system or practice of making

[2] Certain Member States may have their own publicly-available approval lists/registers, which need to be checked as well if the products are being used in those countries, including Austria, Belgium, Czechia, France, Germany, Ireland, Netherlands, and Switzerland).

biocidal products available on the market for up to 12 months after the date of the decision, and may continue to apply its current system of practice of using biocidal products for up to 18 months after that decision.

Link to Published Accepted Notifications and Associated Formal Application Submission Deadlines:
https://www.echa.europa.eu/documents/10162/27434452/list_of_notifications_en.pdf/0ad3b68a-1e01-304e-722d-f4a8457842c3

For example, the Part II of the table provided in the above link identifies substances that are no longer supported under the review programme, resulting in a "non-approval" decision by ECHA. These "active substances"/"product type" combinations, if currently being used, must be phased out by end-users within 18 months of the decision at the discretion of individual Member States.

REGULATORY OBLIGATIONS

As a matter of good practice, the "end user" should maintain adequate records to document their internal biocidal product review process. For example, SDS records identifying a product's "active substance" with a cross reference to the approval/authorisation listing (including the applicable product type). In some countries, professional products need to have a certificate to be used (DE, UK, FR …). No formal reporting is required for "end users"; however, documentation should be made available in the event of a regulatory audit.

RISKS TO AEROSPACE AND DEFENSE

Business Risk: Potential chemical obsolescence issues; an unregistered product discovered by regulators will immediately be withdrawn from the market leaving the "end user" without a validated product, causing potential business disruptions.

Moderate to low regulatory enforcement likelihood for end user.

USEFUL LINKS

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Link to Article 95 Approved List:
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DISCLAIMER