



TROY

The Gold Standard for Performance

European BPR Legislation and the Boating Industry

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Topics for Discussion

- ▶ **What's the issue?**
- ▶ **Biocidal Products Regulation (BPR)**
- ▶ **Treated Articles**
- ▶ **Treated Articles in the Boating Industry**
- ▶ **European Legislation on Treated Articles**
- ▶ **Reference Materials**



Issue

- ▶ **Everyone is aware of the EU's REACH regulation but not their Biocides Product Regulation (BPR) and its potential to affect exports.**
 - ▶ How is this done?
- ▶ **Material preservatives are a fundamental tool in the manufacture of goods**
- ▶ **Material preservatives are regulated under the BPR (formerly BPD) and all goods exported to the EU must be compliant.**
 - ▶ As exporters the entity first placing the good on the market is responsible for compliance with all EU regulations
 - ▶ Materials preserved with industrial preservatives are commonplace in all parts of the world but the BPR forces us to rethink what we use, where it is used and how its labeled.
 - Like many commodities boats and associated articles fall under the BPR.



BPR

What Is It?

- ▶ **Originally begun as the Biocidal Products Directive (BPD) in 1998 (EC 98/8/EEC)**
- ▶ **Encompasses 22 different classes of products:**
 - ▶ Disinfectants
 - ▶ Materials preservatives
 - ▶ Wood preservatives
 - ▶ Paint film preservatives
 - ▶ Metalworking fluid preservatives
 - ▶ Plastic preservatives
 - ▶ Attractants
 - ▶ Insecticides
 - ▶ Piscicides
 - ▶ Etc.



BPR

What Is It?

- ▶ **Any biocidal active ingredient used in the EU must be on Annex I (approved list of actives) or have been submitted for registration in order for goods containing them to be imported into the EU.**
- ▶ **The concept of treated articles came to the forefront in 2013 once the BPR came into force. It's a different way of looking at products we see each day.**
 - ▶ Simple treated articles and;
 - ▶ Complex treated articles



Treated Article EU – Definition

Biocidal Products Regulation (BPR) : ‘biocidal product’
: any substance or mixture, **in the form in which it is supplied to the user**, 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’ means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products;



Treated Article Examples



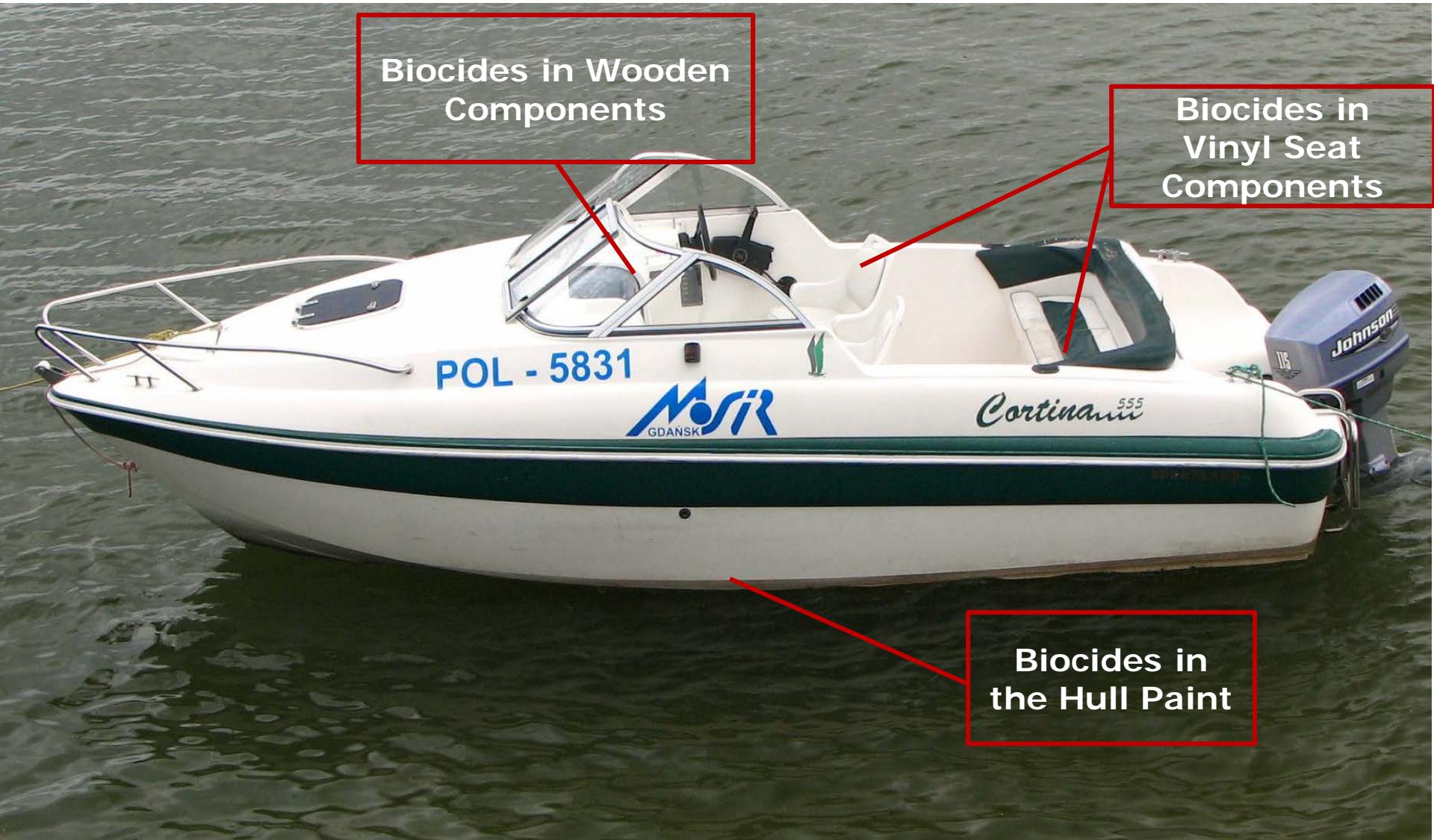


Treated Articles in the Boating Industry

Biocides in Wooden Components

Biocides in Vinyl Seat Components

Biocides in the Hull Paint





Treated Article EU – Primary Concept

- ▶ **A treated article that has a primary biocidal function shall be considered a biocidal product.....**
- ▶ **So what is meant by primary biocidal function?**



Treated Articles (TA) that are Biocidal Products in the EU:

- ▶ Mosquito nets containing insect repellents
- ▶ Insecticidal strips treated with insecticides
- ▶ Computer keyboards treated to prevent bacterial growth
- ▶ Anti-bacterial paint used in Hospital (PT2) – claim is made for an “external effect”





Primary Function

Whether a biocidal function of a treated article is a **primary** biocidal function will need to be decided **on a case-by-case basis**, taking into account all individual properties and functions, its intended use and claim of the treated article

Article 3 (3) :”The Commission may, at the request of a Member State, decide, by means of implementing acts, whether a specific product or group of products is a biocidal product or a treated article or neither.



Treated Articles BPR Requirements

BPR addresses TREATED ARTICLES which are not biocidal products (no primary biocidal function):

- ▶ **Article 58(2) provides that**
 - ▶ “A treated article shall not be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2), for the relevant product-type and use, or in Annex I, and any conditions or restrictions specified therein are met”.





BPR Guidance on Treated Articles

- ▶ **Treated Article Labeling (Mandatory) –Article 58(3) BPR**
 - ▶ Effective September 1, 2013 so no transition period
 - ▶ Statement that the article incorporates a biocidal product
 - ▶ Biocidal properties attributed to the AS contained in the article
 - ▶ Name of the active substance
 - ▶ Relevant instructions on use and/or precautions to avoid unnecessary risk to man and the environment



BPR

What Is It?

Key BPR Dates for Treated Articles:

Date	Action
September 1, 2013	Articles must containing an active ingredient must be either approved or under evaluation for a particular product type
Until Sept. 1, 2016	Transitional period for active substances not yet in the approval process
March 1, 2017	All articles coming into the EU must contain an approved active substance or an active that is under evaluation



BPR Guidance on Treated Articles

- ▶ **Specific Notes for Guidance published by EU Commission-CA-Sept13-Doc.5.1.e (2013)**
 - ▶ Document containing frequently asked questions on treated articles
 - ▶ Addressed labeling of treated articles (Article 58(3) of BPR)
 - ▶ Obligation of companies on supply chain
 - ▶ Responsibilities of person placing treated article on the market



BPR Guidance on Treated Articles

- ▶ **Obligation of Companies in the Supply Chain:**
 - ▶ Supplier of treated article -45 day information obligation to consumers on biocidal treatment of the article free of charge (like REACH on SVHC's) – Article 58(5) BPR
 - ▶ Raises the issue of complex treated articles-any article touched by a preservative or preserved material at any point in the supply chain is considered a treated article under the BPR, whether or not it is treated itself.



BPR Guidance on Treated Articles

- ▶ **2014 Commission Q&A document introduced the concept of:**
 - ▶ Simple versus complex treated articles why?
 - ▶ Initial requirement to address the incorporation of biocides into a product throughout the manufacturing process
 - ▶ Simple treated article = insecticidal strips or paint used for antifouling
 - ▶ Complex treated article = car or boat
 - ▶ Differences between the two.....



European Legislation on Treated Articles

▶ **What the BPR has done:**

- ▶ Forced to use an approved EU Biocide Supplier and;
 - Get written confirmation that its approved or that you have evidence of a letter of access (LOA)
 - Article 95 listing (published quarterly)
- ▶ Keep meticulous records on all raw materials used in production and;
- ▶ Pay closer attention to marketing claims and advertising on products exported to the EU



European Legislation on Treated Articles

- ▶ **Consequences of Non-Compliance:**
 - ▶ Disruption in trade
 - ▶ Goods seized at the port of entry
 - ▶ Fines
 - ▶ Increased scrutiny into all exports
 - ▶ Inspections at your EU facilities or distributors
 - Swedish KEMI/UBA joint exercise on internet ads
 - 60+ infractions based on ads on the internet
 - ▶ Increased efforts by EU regulators on enforcement throughout the EU.



Treated Articles Import in EU

Treated article US	Treated article EU
Intended to preserve article and registered for that use is <u>exempted</u>	Intended to preserve article is regulated under BPR Considers components upstream and downstream
Claims made should allow exemption	Claims made are regulated
No label is required	Labelling is regulated
Up to 300 active registered (April 2013 list)	From 300 US actives, only ± 100 allowed in EU in TA



Reference Materials

European Chemicals Agency Website for Treated Articles

<https://echa.europa.eu/regulations/biocidal-products-regulation/treated-articles>

Article 95 listing

<https://echa.europa.eu/information-on-chemicals/active-substance-suppliers>

U.S.EPA

<https://www.epa.gov/pesticide-registration/prn-2000-1-applicability-treated-articles-exemption-antimicrobial-pesticides>



THANK YOU

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