

# Biocide Restrictions in the European Union

Understanding the Requirements of the EU's Biocides Products  
Regulation for the Marine Industry

Dave Marlow  
Brunswick

IBEX  
2017

# Biocide Restrictions in the European Union

- Biocidal products are used to control unwanted organisms that are harmful to human or animal health, or that cause damage to human activities. These harmful organisms include pests and microorganisms.
- The EU has set up strict rules and procedures to ensure a high level of protection for human health, animal health and the environment.
- First as the Biocides Product Directive (1998) and now as the Biocides Product Regulation



# Biocide Restrictions – Basic Principles

- The Biocides Products Regulation EU 528/2012 states a biocidal product must be authorized before it can be made available on the market in the EU.
- Biocidal substances and biocidal products are produced by many industry sectors and lists 22 biocidal product types, in four main groups:
  - Disinfectants
  - Preservatives
    - Wood
    - Paint
    - Vinyl
  - Pest Control
  - Other Biocidal Products
    - Anti-fouling
- Entered into force on September 1, 2013 amid widespread controversy and confusion within the chemical industry.

# Biocide Restrictions – Basic Principles

- The Regulation allowed for a 3 year transition period to deal with many of the issues associated with finding new compliant formulations
- Articles containing non approved biocides were no longer permitted in the EU market after 1 September 2016
- Manufacturers were permitted an additional 180 days extension to file for an evaluation. This extended the final compliance date to 1 March 2017.
- There has been confusion in the industry that REACH, which was aimed at understanding the intrinsic properties of chemical substances, covered the issues associated with the requirements of the BPR.

# Biocide Restrictions – Definitions

- ‘Biocidal product’ means any substance or mixture consisting of one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of any harmful organism by any means other than mere physical or mechanical action
- Treated articles are defined as any substance, mixture, or article that has been treated with, or intentionally incorporates, one or more formulated biocidal products.
- The product is considered a Treated Article if the biocide is present only as a means to protect the article itself. Example: a wood bench treated with a preservative

# Biocide Restrictions – Requirements

- Manufacturers importing treated articles must ensure that all the active substances have been approved in the EU for that purpose.
- Boat companies must ensure compliance for the substances they manufacture or purchase from suppliers.
- However you go about securing your compliance to the BPR, be mindful you can be asked to produce and prove that due diligence.

**Boat manufacturers must have detailed records showing due diligence**

# Biocide Restrictions – Labeling

The Regulation requires manufacturers and importers of treated articles to label these when:

- a claim is made that the treated article has biocidal properties; or
- the active substance used to treat the article was approved subject to specific labelling provisions to protect human health, animal health and the environment.

Labeling is the responsibility of the person who places the product on the market in the EU.

- Treated article – must be labeled
- Complex article – need not be labeled unless claims are made towards the efficacy of a treated article

# Biocide Restrictions – Marine Industry Impact

- **Woods** - Chromated Copper Arsenate has been removed and replaced with Micronized Copper Azole. Many “treated transoms” used arsenate.
- **PVC Vinyl's/Flooring** – Proprietary chemical changes varied from supplier to supplier to eliminate the banned substances.
  - OPBA (Oxybisphenosxyarsine) is an arsenic based biocide processed in vinyl and used on boats seats, boat foam cushions and other articles. It prevents bacterial staining known as pinking.
  - Boat vinyls have been reformulated
  - Flooring manufacturers are still working through compliance options
  - Some boat manufacturers have had to discontinue flooring options for the EU.



# Biocide Restrictions – Marine Industry Impact

- **Anti-fouling Bottom Paints** – Now using approved cuprous oxide.

## Biocides Product Regulation for Antifouling Coatings. BPR advisory.

Dicopper oxide (Cuprous oxide) has now been approved for use in antifouling coatings in the EU. To assist with your potential requirement to test and register your own coating systems, now is the time to proceed toward obtaining your own product authorisation.

The dossier submittal must be complete by December 31, 2017 (with the exception of two-year storage stability study).

For a brief summary with recommendations as to how to proceed, please contact [chemical@cpgroup.co.uk](mailto:chemical@cpgroup.co.uk)

- ICOMIA is working to identify how member states will regulate the use of bottom paints.
- Article entitled, **“No or limited access to effective Anti-fouling paints may jeopardize the EU Yacht and Marine Leisure Industry”**

# Biocide Restrictions – Marine Industry Impact

## Manufacturing Complications:

- Compliance date was March 1, 2017
- Many suppliers were not ready for the transition
- Boat manufacturers still scrambling to determine production issues/CE boats
- Complications due to segregation of materials during transition
- Costs of new replacement materials can be higher
- May impact warranty if replacement biocide/product is not as effective
- Potential exposure to member state fines and penalties as prescribed
- Must have accurate record keeping on due diligence

**Ignorance is not a defense**

# QUESTIONS??

Contact Adrian Krysgman @ [rygsmaa@Troycorp.com](mailto:rygsmaa@Troycorp.com)

Contact John McKnight at [jmcknight@nmma.org](mailto:jmcknight@nmma.org)

Or last resort, you can contact me @ [dave.marlow@Brunswick.com](mailto:dave.marlow@Brunswick.com)

Treated Articles Info Link:

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