



# The Biocidal Products Regulation in the Automotive Supply Chain

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# Biocidal Products Regulation

## Purpose and Outline

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### Purpose

This presentation is intended to give a brief summary of the European Biocidal Products Regulation (BPR), and to explain the key requirements for the automotive supply chain.

### Outline

1. Overview
2. Requirements for Treated Articles
3. Compliance Steps
4. Summary

# Biocidal Products Regulation

## 1. Overview

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**ACTIVE SUBSTANCE** – *substance or micro-organism that has an action on or against harmful organisms*

- Must be **approved** (at EU level) for the appropriate **product-type**
- Companies submit dossiers for approval (comparable with REACH)
- Substances that meet REACH SVHC criteria not usually approved
- ECHA maintains a list of approved active substances & suppliers

-> *List of approved active substances:*

<http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances>

-> *Continuously updated!*

*European Commission decisions on approval and non-approval are published in the Official Journal of the European Union.*

# Biocidal Products Regulation

## 1. Overview



1. Identify AI relevant product types for articles  
→ 6 – 9, 11, 18

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

Green : AI relevant  
Red: not AI relevant



The relevance is different for production processes!

# Biocidal Products Regulation

## 1. Overview

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**BIOCIDAL PRODUCT** – *substance or mixture containing one or more active substances, with the intention of controlling harmful organisms by means other than mere physical or mechanical action*

- Must be *authorised*
- May only use active substances that are approved for the relevant *product-type (see previous slide)*

# Biocidal Products Regulation

## 1. Overview - Authorisation of biocidal products



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All biocidal products must get an **authorisation** before they can be made available on the market. Companies can choose between several alternative processes, depending on their product and the number of countries where they wish to sell it:

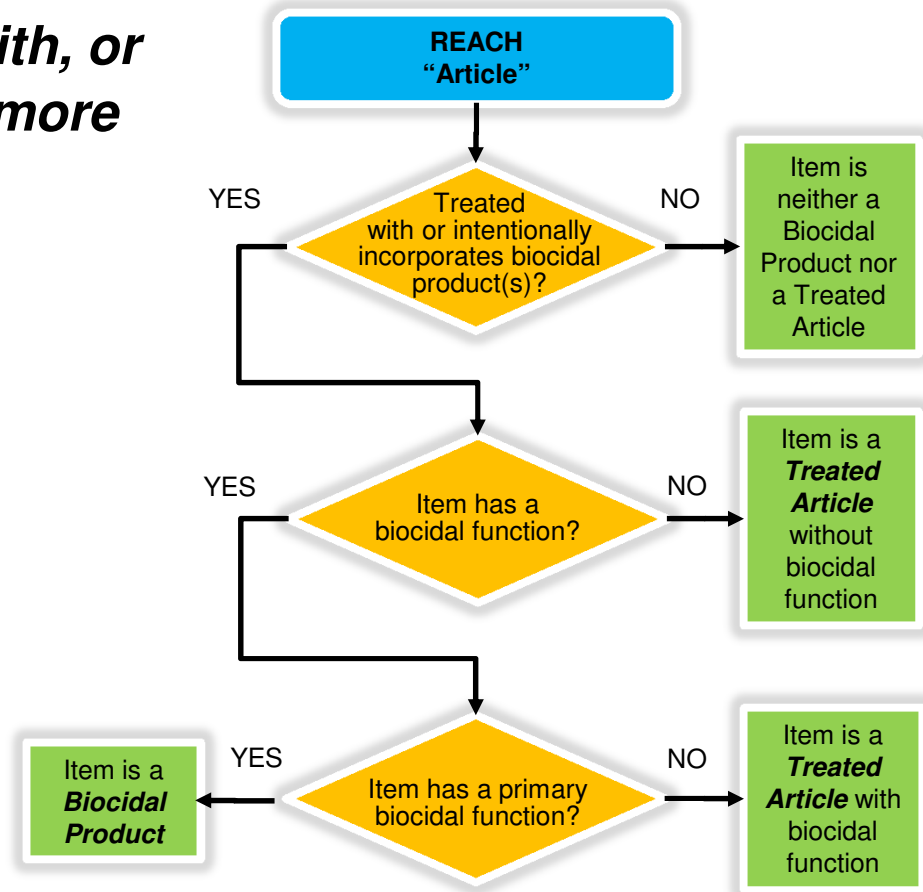
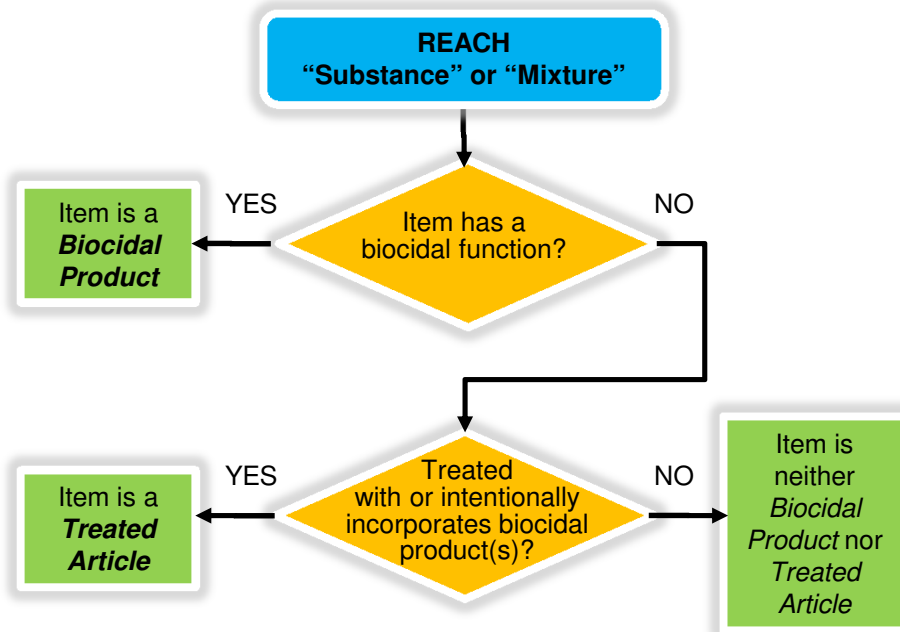
- National authorisation
  - > If the product will be placed only on a single market, authorisation from that country is sufficient.
- Mutual recognition
  - > If a company wishes to place the product on the market in several countries.
- Union authorisation
  - > For companies that wish to apply for an EU-wide authorisation in one go.
- Simplified authorisation
  - > For products which meet certain criteria specified in the regulation, e.g. do not contain any substances of concern, listed in Annex I, ....

# Biocidal Products Regulation

## 1. Overview



**TREATED ARTICLE** – *substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products*



# Biocidal Products Regulation

## 1. Overview

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### What is NOT a TA? Exemptions from the TA requirements

- Goods whose only treatment was fumigation or disinfection of premises or containers used for storage or transport, and where no residues are expected to remain
- Treated articles with primary biocidal functions – these are considered to be **biocidal products -> Authorisation Required!!!**
- Goods that intentionally incorporate biocidal products for reasons unrelated to their biocidal properties
- Goods that unintentionally incorporate biocidal products



# Biocidal Products Regulation

## 2. Requirements for Treated Articles

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### General important requirements for TAs:

- There is ***no lower threshold*** for the amount of active substance
- **Treated articles may only be placed on the market if all active substances are *approved* for the relevant product-type (or are in the approval process)**
- On request from a customer, the supplier must ***provide information*** about the biocidal treatment on the treated article, free of charge, within 45 days
- Treated articles must be ***labelled*** if either:
  - > The substance approval conditions include labelling requirements; or
  - > A claim is made about the biocidal properties

# Typical examples for claims



- 
- Antibacterial
  - Bactericidal
  - Germicidal
  - Kills pathogenic bacteria.
  - Effective against E. coli and Staphylococcus.
  - Reduces the risk of food-borne illness from bacteria.
  - Provides a germ-resistant surface.
  - Provides a bacteria-resistant surface.
  - Surface kills common gram positive and negative bacteria.
  - Surface controls both gram positive and negative bacteria.
  - Surface minimizes the growth of both gram positive and negative bacteria.
  - Reduces risk of cross-contamination from bacteria.
  - Controls allergy causing microorganisms.
  - Improves indoor air quality through the reduction of microorganisms
  - ...

# Biocidal Products Regulation

## 2. Requirements for Treated Articles

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### Labelling for Treated Articles

- Statement that the treated article incorporates biocidal products;
- Biocidal property attributed to the treated article;
- Names of all active substances contained in the biocidal products;
- Names of all nanomaterials contained in the biocidal products;
- Relevant instructions and any precautions for use.

### Labelling options – as appropriate to size/function of the treated article

- Print on the article (where possible)
- Attach to the article
- Print on the packaging
- Print on the warranty
- ***Print in the instructions / manual***

# Biocidal Products Regulation

## 2. Requirements for Treated Articles



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### Considerations for Complex Articles

*If a mixture or article has been treated with, or intentionally incorporates a biocidal product, the resulting treated article remains a treated article, even if there is no remaining biocidal product*

- Requirements for treated articles apply to the whole article (e.g. car or imported component), whether the whole article, **or only a small part or component** of the article, has been treated (and this even 5 tiers up the chain in e.g. China!) with or intentionally incorporates a biocidal product
- Treatments of components that may have occurred several tiers earlier in the supply chain might be difficult to identify – enforcement is likely to concentrate on the components where human or environmental exposure is likely.
- Unintended residues of biocidal products used in earlier production processes do not trigger the treated article requirements.
- Any biocidal claim made anywhere in product-related advertising, technical manuals, etc., and for any component, is likely to trigger the labelling requirement for the complex article.

# Biocidal Products Regulation

## 2. Requirements for Treated Articles

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### Successful Lobbying?

- *The European Commission has presented a proposal which aims to address industry concerns over the wide scope of the treated articles provisions in the BPR.*
- *Discussed at last week's meeting of the EU Biocides Competent Authorities, it excludes a range of complex articles from the provisions:*
  - > *for the purpose of Article 58 (TA Obligations), it appears reasonable to consider that only treatments of the finished goods as placed on the EU market should trigger the classification as a treated article. Treatments made on intermediate forms, or on individual components of a complex article or a mixture are thus excluded, unless these are themselves placed on the EU market.*

➡ **Much better, but still a burden!**

➡ Advise: Let your marketing people know about the requirements of the BPR as they potentially are heavily impacted!

# Biocidal Products Regulation

## 2. Requirements for Treated Articles



### Transition Arrangements for Placing Treated Articles on the Market

Active Substance / Product-Type (AS/PT) Approval Status	Placing the Treated Article (TA) on the Market	
AS is approved for the TA product-type	TA <i>may</i> be marketed without time limit	
AS is listed in Annex I		
No application for AS/PT approval made before 1 Sep 2016	TA <i>may</i> be marketed until 1 Mar 2017	TA <i>may not</i> be marketed after 1 Mar 2017, unless a new application is approved
Decision made before 1 Sep 2016 to REJECT the AS/PT application		
Decision made after 1 Sep 2016 to REJECT the AS/PT application?	TA <i>may</i> be marketed until 180 days after Rejection	TA <i>may not</i> be marketed after 180 days after Rejection
Application for AS/PT approval made before 1 Sep 2016, but no decision yet	TA <i>may</i> be marketed, pending approval decision	

➔ Based on latest information available. May change again !?

# Biocidal Products Regulation

## 3. Compliance Steps



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### (Currently) proposed compliance Steps for Treated Articles

1. Create inventory of active substances / biocidal products / treated articles / product-types at any point in the supply chain
2. Identify roles for each item on the inventory
3. Identify applications (i.e. product-types) for each item
4. Check status of active substances / PT approvals for each item
5. Identify and comply with substance approval conditions
6. Identify any claims made for marketing treated articles
7. Produce labels as required and provide them with supplied products
8. Provide information on request from customer
9. Substitute/eliminate non-approved biocidal products as needed
10. Maintain records in case required by competent authority

➔ **Based on latest information available. May change again !?**

# Biocidal Products Regulation

## 3. Compliance Steps



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### European Chemicals Agency (ECHA)

- Current and planned guidance documents focus on approval, authorisation and technical issues:

<http://echa.europa.eu/regulations/biocidal-products-regulation>

- EC issued guidance on treated articles for Competent Authorities:

<https://circabc.europa.eu/sd/d/e1adf8de-0ad6-4484-84ec-80704391a038/CA-Sept13-Doc%205.1.e%20Final-%20treated%20articles.doc>

### Automotive Task Force – Informal Sub Task Force for Biocides

- Members from ACEA, CLEPA, JAMA
- Collecting examples of automotive treated articles
- Developing industry-wide interpretations
- Main aim is development of automotive industry guidance
- Chairperson: Jonathan Swindell ([jswinde1@jaguarlandrover.com](mailto:jswinde1@jaguarlandrover.com))



# Biocidal Products Regulation

## 3. Compliance Steps

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### IMDS-Relevant Activities

- Automotive relevant active substances to be added to GADSL
- IMDS BPR FAQ under construction
- BPR – Informal TF will advise on reporting recommendations and any enhancements required to IMDS to enable compliance with this regulation.

# Biocidal Products Regulation

## 4. Summary

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- Communicate!
  - > If you (or your supplier) treat an article – ***tell your customer!***
- The BPR is already in force
  - > Communication and labelling obligations are here
  - > Active Substance approval and substitution – see timeline
- IMDS needs to catch up
  - > GADSL update - July



# THANK YOU

## Any questions, comments, or suggestions?

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