



Case study: enforcement from an industry perspective



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Outline

Introduction

Compliance and enforcement, a shared responsibility

Why proper enforcement of the BPR is critical for industry

Potential issues for enforcement

Conclusion



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Dow Microbial Control

- 19 active substances supported
- > 100 biocidal products
- World class regulatory expertise
- Technical expertise
- First class customer service
- Supply chain excellence



■ Proper enforcement of the BPR ...

... to ensure the provisions of the BPR (and associated legislation) are applied in the field

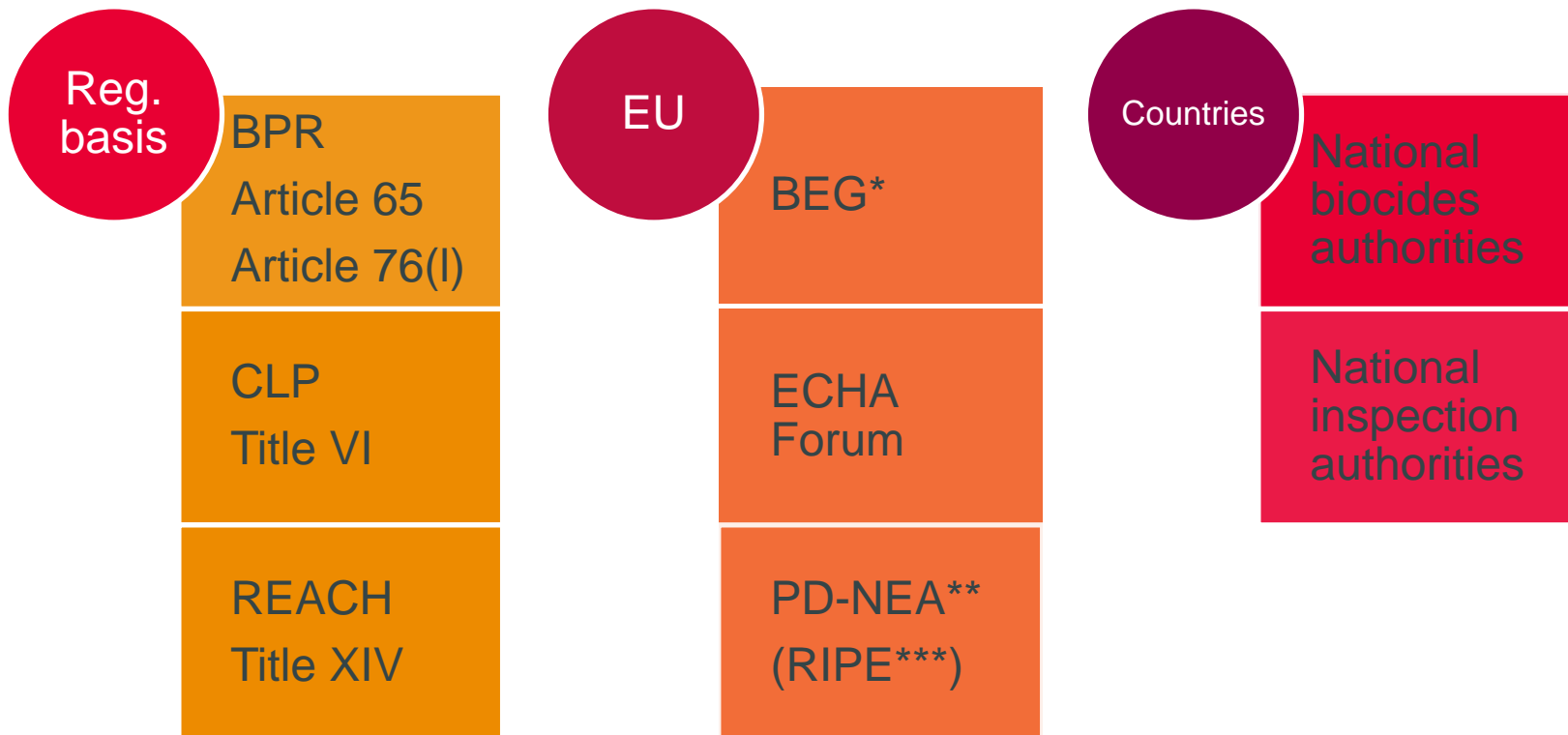
=> Compliance control

... is critical to fully achieve BPR main objectives:

- High level of protection for human and animal health and the environment
- Improvement of the free movement of biocidal products within the Union



Regulatory basis and structures for BPR enforcement



*BEG: BPR Enforcement Group

**PD-NEA: Portal Dashboard-National Enforcement Authorities

***RIPE: REACH Implementation Portal for Enforcers



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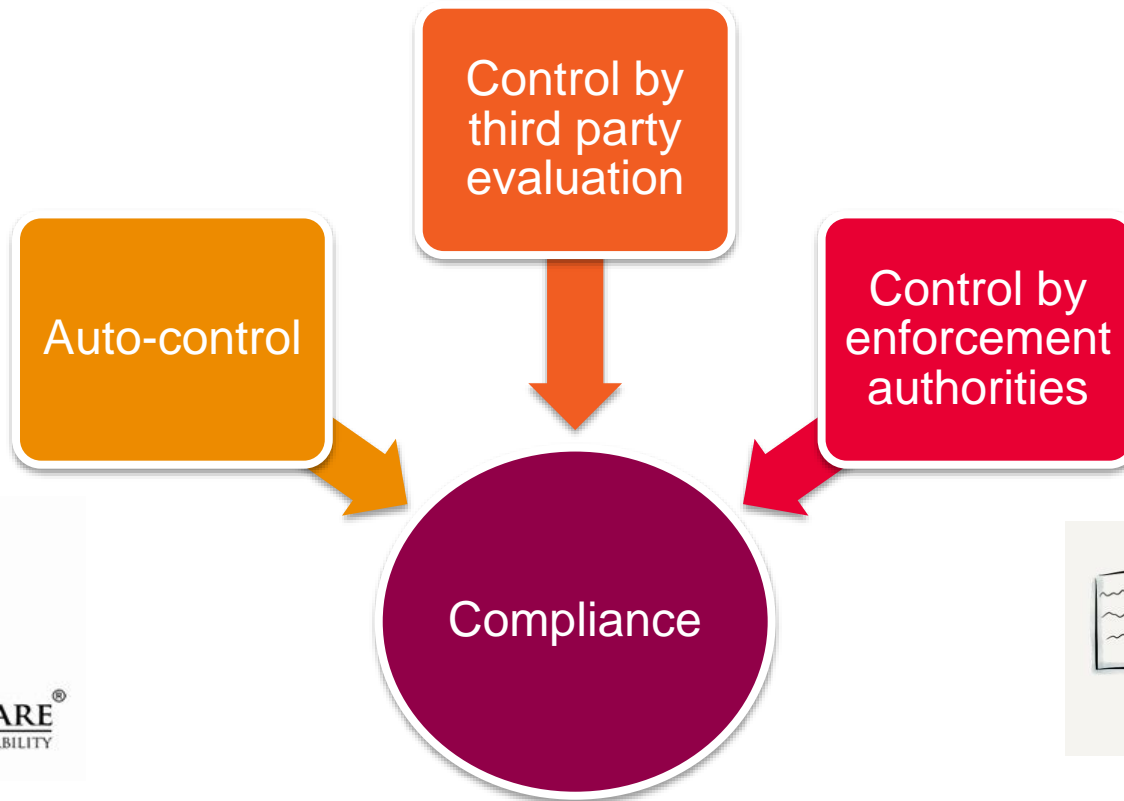
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Compliance and enforcement

Compliance is a legal obligation, but it is also an industry commitment



Reasons for non compliance

Complexity of the regulatory framework

Grey areas, lack of and constant evolution of guidances

Lack of knowledge

Changes

Lack of resources

Illegal trade



What is the situation today?



- No robust data published on BPR compliance rate
- Based on national surveys and REACH statistics, rate of non compliance may range 5-30%

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Enforcement is critical for risk management

- Non compliance with BPR would increase:
 - The risk for human health (consumers, workers)
 - The risk for animal health and the environment
 - The industrial risk (accidents, workers protection, environmental damages)
- May engage companies' liability and cause financial damages
- May affect companies'/business' reputation
- **Enforcement (self or external) is key for industry to reduce and manage all risks associated with the marketing and use of biocidal products, at all levels in the supply chain**



BPR – A huge and unprecedented cost for industry

- Cost to defend an active substance > 4 €MM
- Cost to file a product authorization dossier [200 k€ to > € 1MM]
- Need to build internal regulatory expertise or to use consultants



Hundreds of millions € should be spent by industry to comply with BPR

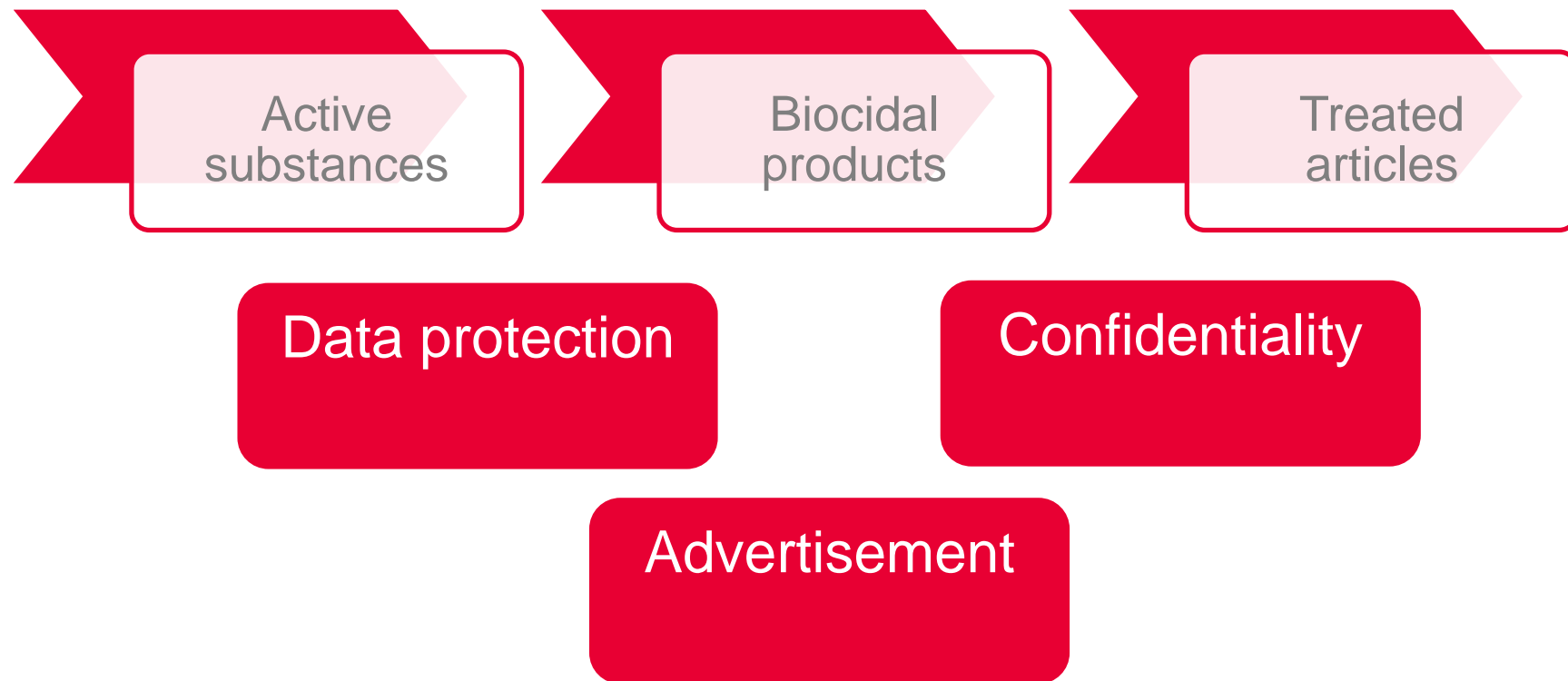
Most of industry resources are expected to be consumed by the BPR

Need for transparency and a level playing field

- Biocides market is relatively small and fragmented.
- The high BPR cost is negatively impacting the profitability and the innovation capacity of this business ...
- ...It becomes critical that all players follow the same rules and face the same hurdles
- **Enforcement is key to avoid unfair competition and maintain industry's ability to innovate.**



Levels of compliance and enforcement



Phase-out of non compliant active substances

Compliance requirements for active substances

- Approved or being reviewed under the BPR for the relevant Product Type
- Classified, labelled and packaged according to the CLP
- Supplier included in the Article 95 list for the relevant Product Type

Impact of non compliance on risk

- Use of withdrawn or non-approved active substances, potentially hazardous
- Misuse/mishandling of active substances
- **Increased/unacceptable risk**

Impact of non compliance on the market

- No compensation for companies investing in active substances support
- Unfair competition (free riding, non harmonized labelling, ...)
- Reduces the resources available to invest for innovation



Enforcement of Article 95

- Some countries with national registration scheme have imposed the need to provide a proof of compliance in different forms
- In countries without such scheme, need for physical controls
- A supplier certificate is not sufficient and should be complemented by a declaration of compliance from the biocidal product supplier
- No information on the current state of compliance.



BPR Compliance: Compliance Certificate



Dow Europe GmbH
Bachtobelstrasse 3, P.O. Box
CH-8810 Horgen
Switzerland

Customer name
Address of customer
Second line of address
Country

Horgen, **date**

Object: Dow Biocide Products compliance with Article 95 of the Regulation 528/2012 (BPR)

Dear Sir/Madam,

We hereby confirm that every active substance entering in the composition of the following Dow Microbial Control biocidal product(s), made available onto the European Market by the Dow Chemical Company, are compliant with the Article 95 of the BPR regulation 528/2012 as per the official list of BPR active substance suppliers published on the ECHA website:

http://echa.europa.eu/documents/10162/17287015/2015_active_substance_suppliers_en.pdf

Dow Microbial Control Product(s):

- Trade Name (active substances)
- Trade Name (active substances)
- Trade Name (active substances)

Rohm and Haas Europe Trading ApS, a wholly owned subsidiary of The Dow Chemical Company, has the status of participant under the Commission Delegated Regulation (EU) No 1062/2014 on the work program for the systematic examination of all existing active substances



Phase-out of non compliant biocidal products

Compliance requirements for biocidal products

- Authorized under the BPR and used according to the authorization or
- Meet the applicable regulatory requirements during the transition period
- Classified, labelled and packaged according to CLP and BPR
- Contains only REACH-compliant co-formulants

Impact of non compliance on risk

- Misuse/mishandling of biocidal products (and treated articles/fluids)
- Use of biocidal products containing potentially hazardous substances
- Efficacy failure => microbiological risk and liability
- **Increased/unacceptable risk**

Impact of non compliance on the market

- Unfair competition
- Limit the competitive advantage for companies investing in product compliance
- Wrong claims/illegal advertisement
- Reduces the resources available to invest for innovation



Phase-out of non compliant treated articles

Compliance requirements for treated articles

- Active substances approved or under review for the relevant Product Type and use
- Articles labelled according to the CLP (when applicable) and to the BPR

Impact of non compliance on risk

- Use of treated articles containing potentially hazardous substances
- Non substantiated claims (biocidal properties)
- Biocidal efficacy failure => quality issues, microbiological risk, defective products
- **Increased/unacceptable risk**

Impact of non compliance on the market

- Unfair competition
- Limit the competitive advantage for manufacturers investing in compliance
- Increase the risk of delocalization of the articles' manufacture outside EU
- No incentives for innovation

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Resources available and coordination



Member States

- Number of inspectors/lack of
- Different services involved
- Understanding the complexity of the system
- Monitoring and reporting
- Process for stakeholders to report non compliance



European Commission

- Need EU coordination
- BEG resources
- Define priorities
- Provide guidances
- Report statistics



ECHA

- Need ECHA support for coordination
- Forum/PD-NEA
- BPR vs REACH Prioritization ?
- Financing ?

Complexity of the system and grey areas

Scope

- Multiple levels in the supply chain
- Multiple scope issues unresolved (PT allocation)
- Interlinkage with other legislations

Long review period

- Different status for different products within same application
- Different rules followed for approval/authorization

Claims

- Use of products with a biocidal effect but not marketed as biocidal products
- Biocidal properties and biocidal functions for treated articles

Guidances

- Thousands of pages, multiple sources (ECHA, COM, national, ...)
- Reality of different interpretations
- Still being developed and evolving
- Who has read everything ?

Harmonization, communication and proportionality

- Considering the complexity of the BPR framework and the diversity of the national enforcement structures, harmonization is a challenge.
- Need for a central coordination
- Need to raise awareness and clarify guidances
- Need to set up a transparent, consistent framework of penalties,
- ... from simple advice to criminal complaint and fines
- covering scenarios from flagrant abuse to difficulties of interpretation/following of transitional guidance



Control of treated articles



Awareness

- Most manufacturers/importers of treated articles are likely not aware of their obligations (particularly outside EU).

Compliance

- When articles are manufactured inside EU, BPR enforcement at biocidal products level ensures compliance
- But for imported treated articles with no biocidal claim, or for complex articles it could be **very challenging** to ensure compliance
- Is enforcement possible at all for these ???

Labelling

- Different labelling rules for treated articles can create market distortion
- Overuse of treated articles labelling may be counter-productive (dilution of the message, confusion for users, failure to communicate the benefits of biocides)

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- Compliance is a shared responsibility between industry and authorities
- Enforcement is a critical step to ensure:
 - An efficient management of the risks
 - A level playing field and a fair competition for all parties
 - A return on investment and an incentive for innovation
- There are still multiple challenges to be addressed for enforcement:
 - Resources
 - Clarification and harmonization
 - Transparency and proportionality
 - Compliance of imported treated articles





— Thank You

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For more information visit www.AreYouReadyForBPR.com or contact your local sales representative.

Disclaimer

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Use Biocides Safely. Always read the label and product information before use.

