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<http://ihcp.jrc.ec.europa.eu/>

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## IPSC - IHCP - IES – Ispra, Italy

Institute for the Protection and the Security of the Citizen

**Institute for Health and Consumer Protection**

Institute for Environment and Sustainability

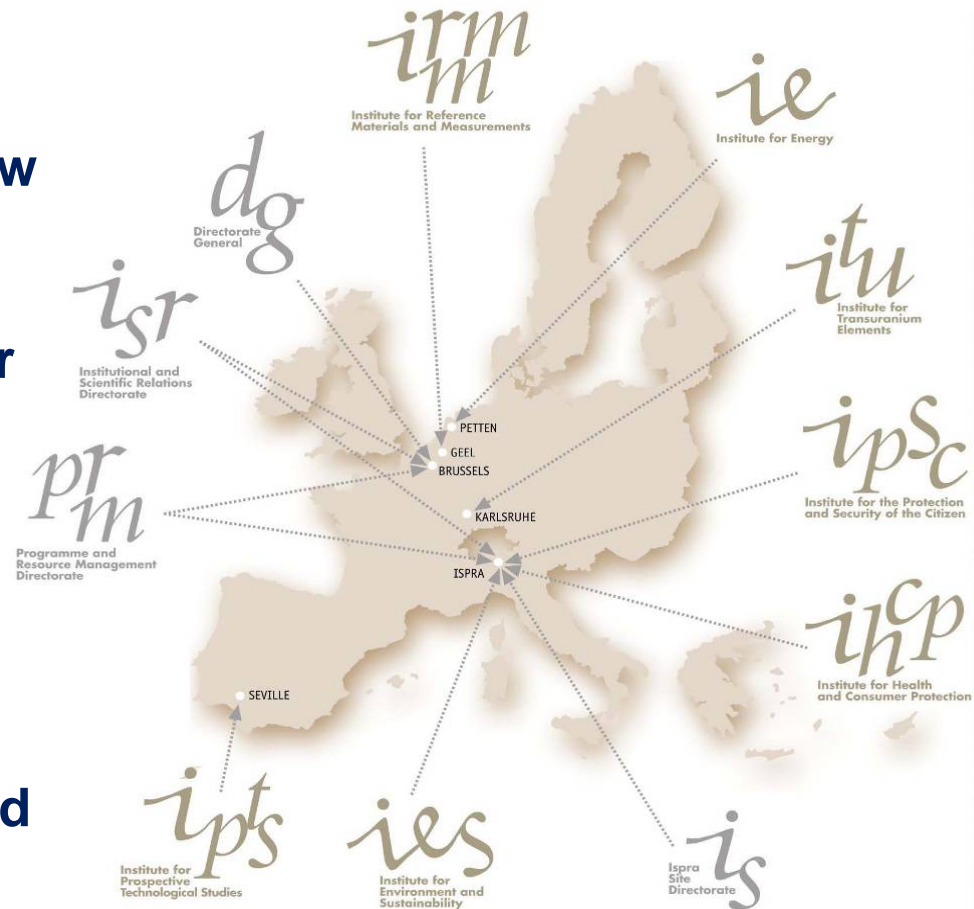
**Chemical Assessment and Testing Unit:**

➤ **Biocides sector**



## Biocides sector:

- **Coordination of Biocides Review Programme**
- **Technical Meetings 4 times/year**
- **Support of DG Environment**
- **Development and updating of guidance documents**
- **Helpdesk for Member States and Industry**



## Background and regulatory challenges for:

- **Biocidal Products Directive (98/8/EC)**
  - Environmental risk assessment
  
- **Product Authorisation**
  
- **Biocidal Products Regulation, entry into force mid-2012**

# **Biocides**

**(uses against various targets)**

**Rodenticides**

**Disinfectants**

**Anti-fouling  
agents**

**Insecticides**

**Wood  
preservatives**

# **Biocides**

**(various application types)**

**Sprays**

**Paints**

**Granules**

**Fumigants**

**Coils**

**Sticky strips**

## **Compare with Plant Protection Products (PPP):**

- **Different targets, but in the majority of cases the application type is via overspray.**

### **Additionally:**

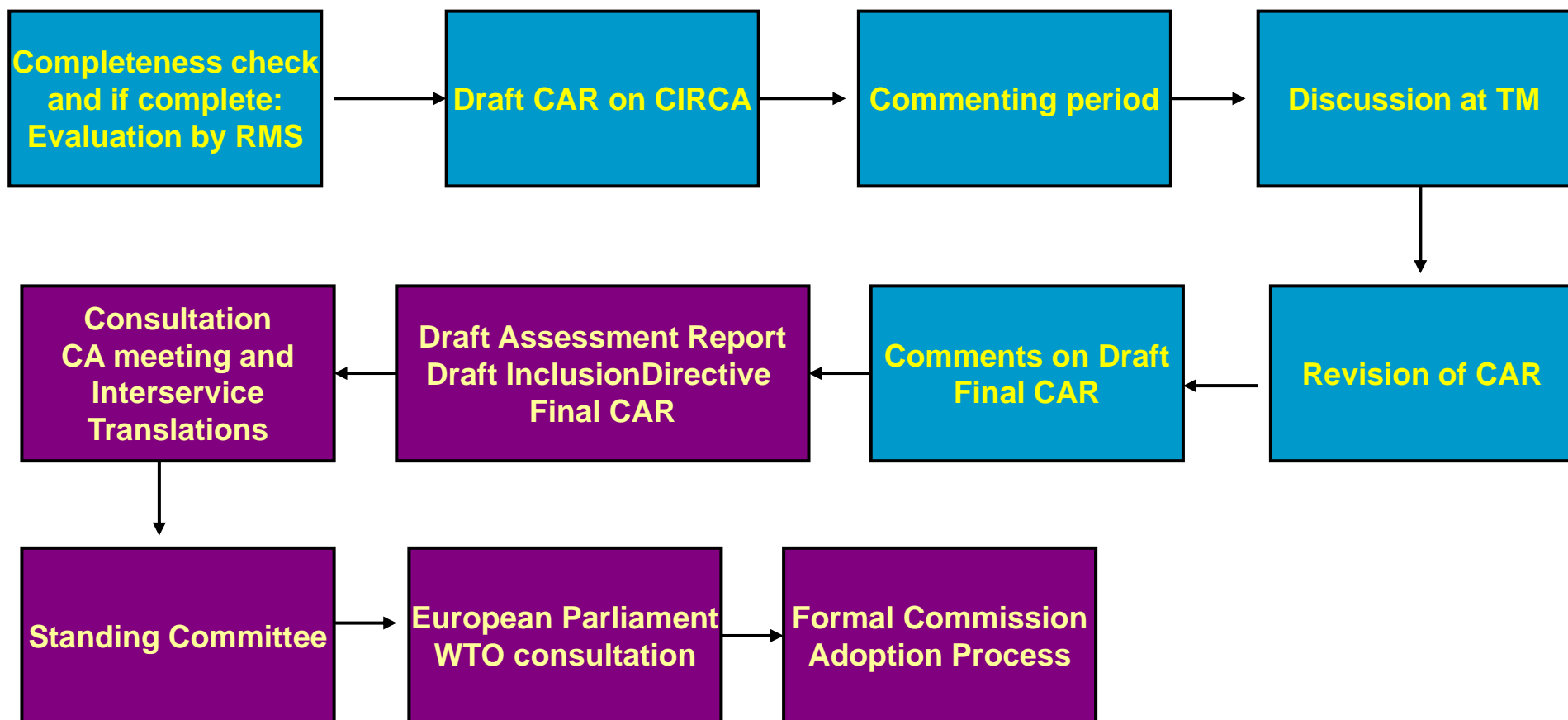
- **1/4 of PPP-market**
- **330.000 tonnes a.s./year**

**The Biocidal Product Directive (BPD) aims to harmonise the European market for biocidal products and their active substances. At the same time it aims to provide a high level of protection for humans, animals and the environment.**

- **Tiered Approach:**
- **active substance (a.s.) at the Community level.**
- **a.s. on Annex I than products will be evaluated and authorised on Member State level.**



## Review process up to Annex I inclusion



## Scope can be a regulatory challenge:

- **Are we assessing a biocide within the framework of the BPD?**
- **Borderline substances, for instance biocides/medical/veterinary substance (for instance disinfectants or repellents).**

## Basic risk assessment overview

- **Exposure assessment**      **PEC**
- **Effect assessment**      **PNEC**
- **Risk Characterisation**      **PEC/PNEC <1 ?**

**Looks easy enough...or?**

## Exposure assessment active substance:

- **Emission Scenario Documents (ESD) for each use associated to a class of substances.**
  - **Calculations based on the intended use and the type of formulation.**
  - **Model calculations, for instance FOCUS.**
- 
- **PEC (Predicted Environmental Concentration)**

## Challenge:

- **Missing ESDs for several PTs (for instance PT19 and PT23).**
- **Updating of ESDs (for instance PT8).**
- **Adaptation of existing ESD for different PT, such as PT 2 which is used for PT 19.**
- **Validation of existing ESDs, for instance through monitoring real usage releases or comparison with usage/sales data.**

## Exposure assessment:

- **Physical/chemical properties determine the fate of a chemical.**
- **Solubility in water, lipophilicity, boiling point, etc, determined under realistic environmental conditions or corrected to “standard” European situations (T=12°C).**
- **QSARs**
- **Partition coefficients (air, water, solids).**
- **Abiotic and biotic degradation rates (hydrolysis, photolysis, biodegradation).**

## Challenge:

- **Is there a standard Europe? For instance  $T=12^{\circ}\text{C}$**
- **Would it be appropriate to apply a zonal approach for biocidal substances?**

## Example: PT 18 (Insecticides)

**Gel formulation used against cockroaches  
in cracks and crevices of kitchens**

<b>kitchen floors</b>	<b>→</b>	<b>wet cleaning</b>
<b>cleaning water</b>	<b>→</b>	<b>sewer</b>
<b>STP</b>	<b>→</b>	<b>sludge &amp; water</b>



## Gel application to treated surface, via

Therefore, emissions during gel applications are mainly due to emissions to treated surface:

$$E_{application, treated, 2} = Q_{prod, point} \times N_{point} \times F_{AI} \times AREA_{treated, 2} \times F_{application, treated, 2} \times N_{appl, building, 2} \times 10^{-3}$$

## Emission from treated surface to waste water

- Emission from floor/treated:

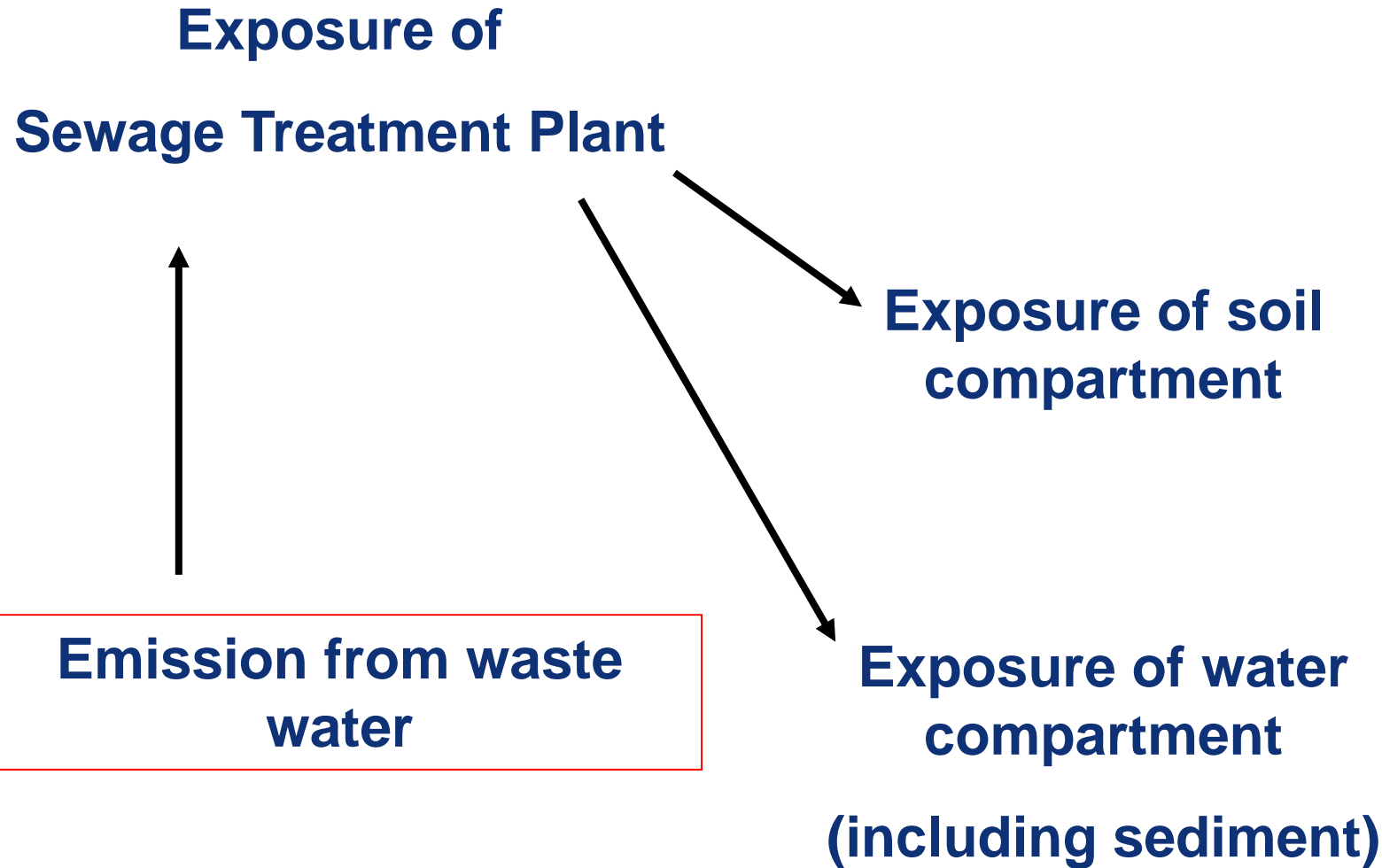
$$E_{treated, ww} = (E_{prep, floor} + E_{application, floor} + E_{application, treated}) \times F_{ww} \times F_{CE}$$

## Emission from waste water to sewage treatment plant, via

$$C_{local_{water, time x}} = \left( \frac{E_{water}}{V_{water}} \times \frac{1}{k} \right) \times \left[ 1 - \left( \frac{1 - e^{-TAU_{wway} \times k}}{k \times TAU_{wway}} \right) \right]$$

and

$$C_{local_{eff}} = C_{local_{inf}} \cdot F_{stp_{water}}$$



**Sewage Treatment Plant**

**concentration in STP  
→ risk?**

**Sludge to soil**

**concentration in soil  
→ risk?**

**Effluent water to surface water**

**concentration in water  
and sediment  
→ risk?**

## Effects Assessment active substance:

- **Aquatic ecosystem (freshwater, marine water)**
  - **Terrestrial ecosystem**
  - **Sediment ecosystem (freshwater, marine water)**
  - **Predators (through worms and fish)**
  - **Micro-organisms in STP**
  - ***Air compartment***
- 
- **PNEC (Predicted No Effect Concentration)**

## Challenge:

- **Protection goal is the ecosystem.**
- **However, is our definition of the protection goals sufficient?**

## Effects assessment for the aquatic compartment

Species from 3 trophic levels:



## First and higher tier testing, inserting “realism”:

- **First tier; standard tests performed in a laboratory setting.**
- **Second tier; standardised tests performed in a more “natural” setting (for instance microcosm or mesocosm studies)**
- **Higher tier, for instance field studies.**
- **With increase of realism, assessment factor will decrease.**



## Challenge:

- **Higher tier testing, how representative are PPP-studies for the biocidal use?**

Table 16 Assessment factors to derive a  $PNEC_{aquatic}$

Available data	Assessment factor
At least one short-term L(E)C50 from each of three trophic levels of the base-set (fish, Daphnia and algae)	1000 <sup>a)</sup>
One long-term NOEC (either fish or Daphnia)	100 <sup>b)</sup>
Two long-term NOECs from species representing two trophic levels (fish and/or Daphnia and/or algae)	50 <sup>c)</sup>
Long-term NOECs from at least three species (normally fish, Daphnia and algae) representing three trophic levels	10 <sup>d)</sup>
Species sensitivity distribution (SSD) method	5-1 (to be fully justified case by case) <sup>e)</sup>
Field data or model ecosystems	Reviewed on a case by case basis <sup>f)</sup>

## **Effects assessment for microorganisms in sewage treatment plants (STP)**

- **Major exposure pathway**
- **Important degradation pathway**

## Effects assessment for the sediment compartment:

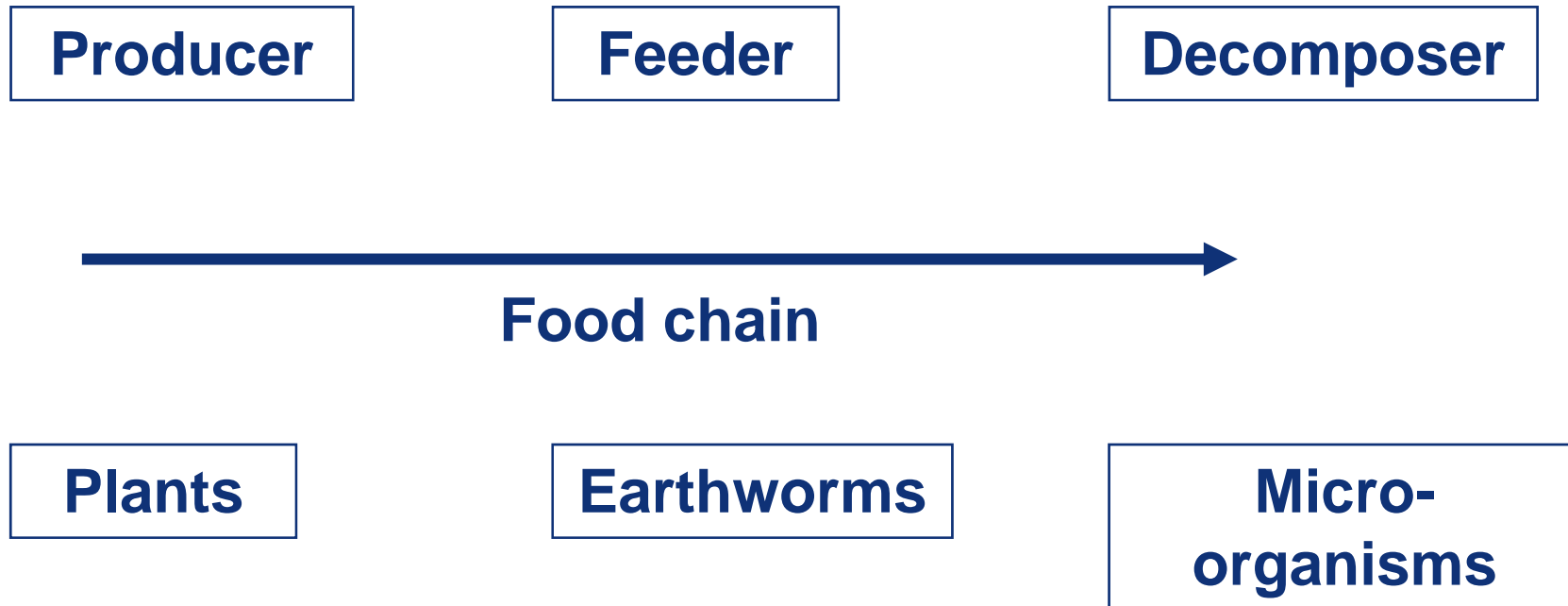
- **Tests performed with sediment dwelling organisms**
- **or derived from aquatic organisms using equilibrium partitioning**

## Equilibrium partitioning:

$PNEC_{\text{sediment}} =$

$K_{\text{suspended matter}} / RHO_{\text{suspended matter}} * PNEC_{\text{aquatic}} * 1000$

# Effects assessment for the terrestrial compartment



## Effects assessment for the air compartment:

- **only a qualitative assessment and no quantitative assessment can be performed, because of lack of toxicity data.**
- **Biotic effects (data issue)**
- **Abiotic effects (i.e. global warming, ozone, acidification)**

## Assessment of secondary poisoning:

- **Treated target species (mice, rats) eaten by predators (birds and mammals).**
- **Uptake through contaminated fish**
- **Uptake through contaminated earthworms**



## PBT assessment:

- **P = Persistence**  
(half-life in water, sediment and soil (REACH))
- **B = Bioaccumulation**  
(BCF>2000 or logKow>4.5, or vB if BCF>5000, )
- **T = Toxicity**  
(NOEC <0.01 mg/L, CMR, endocrine disruption)
- **(T screening)**                      **(L(E)C50<0.1 mg/L)**

## Risk characterisation + consequences

### Annex I inclusion

### Annex I exclusion + refinements

- how many refinements can we accept? or,
- is it acceptable to withdraw all uses except a niche-use?
- How sure are we that label instructions are followed?

## Product Authorisation

- **Is performed by the Member state where the applicant wants to enter the market.**

## Challenge:

- **The review programme is still ongoing, product authorisation has started, timelines.**
- **Mutual recognition**

## Other Challenge:

- **Products are often mixtures.**
- **How to deal with cumulative assessment?**

## How to deal with cumulative assessment?

- **What is “cumulative”?**
- **Do we combine releases of a substance from all different frameworks?**
- **Combine releases from different PTs?**
- **What are the consequences? It will be virtually impossible to assign a certain risk to a certain producer...**

## More challenges:

- *Free-riders*
- **Development of alternative/safer products.**

## **Biocidal Product Directive (BPR)**

- **Triggered by the evaluation of the BPD**
- **Progress:**
- **2<sup>nd</sup> reading and subsequent discussions**
- **Entry into force, mid 2012**



## Challenge:

- **Nanobiocides**
- **Mandatory data sharing**

## Mandatory data sharing,

- How to compensate data owners?

## Alternative methods to reduce animal testing:

- Data waiving using,
  - Read-across
  - QSAR

## Other challenges:

- **Exposure driven waiving**
  
- **Substitution criteria**

## Data requirements, changes after the BPD?

- **How to deal with the BPD-substances after BPR enters into force? Will we have two parallel systems?**

**It will be a challenge to have BPD-substances meet the BPR-criteria.**

## Others:

- **Guidance documents, development and updating will continue, for instance rapidly degrading substances.**
- **The use of peer-reviewed scientific data.**

## A big challenge is further Harmonisation

- **Between Member states, for product authorisation.**
- **Between frameworks, for instance how to make use of higher tier PPP data for biocides.**
- **Between regulators, academia and industry.**

**Thank you very much for your attention!**

**Additional information:**

- **[http://ihcp.jrc.ec.europa.eu/our\\_activities/health-env/risk\\_assessment\\_of\\_Biocides](http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides)**
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