

## Joint Research Centre (JRC)

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***Past, Current and Futures Issues  
in the Environmental Risk Assessment of Biocides***

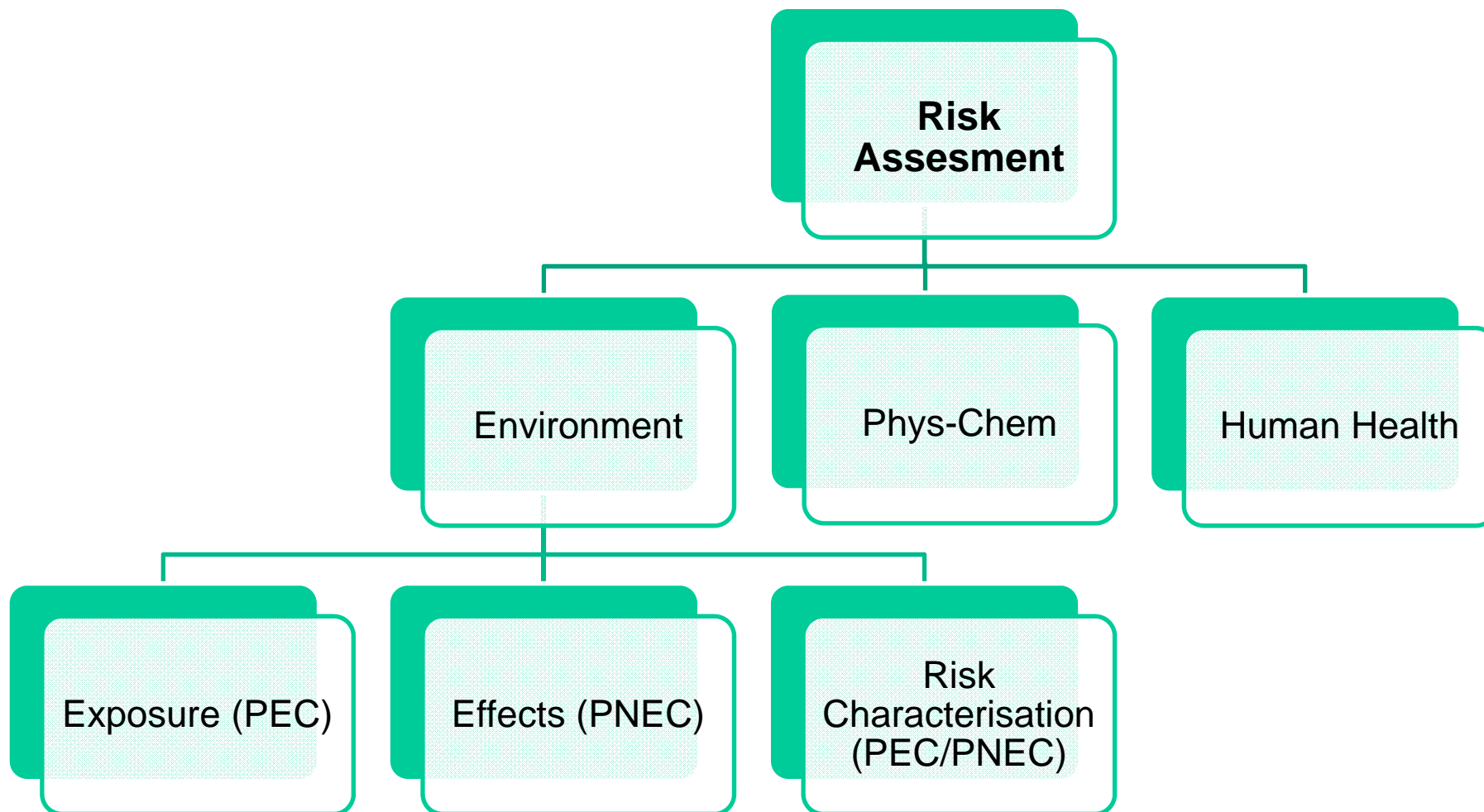


**IHCP - Institute for Health and Consumer Protection**

*Ispra - Italy*

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

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



**So the BPD was created to:**

**Improve the protection of human health and environment  
Harmonise the EU market: positive list (Annex I) followed  
by product authorisation including mutual recognition**

**EU legislation on pesticides 91/414 served as a template  
for the BPD but substance definition is taken from  
legislation on industrial chemicals**



Wood  
preservatives  
PT 08

## Rodenticides PT 14



Insecticides  
PT 18

## Various uses against various pests



**Repellents and  
attractans**

**PT 19**

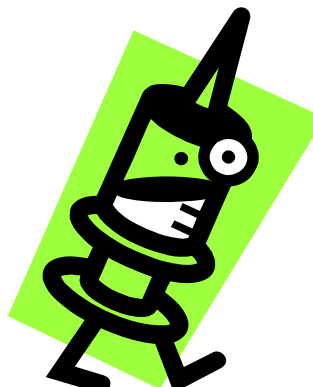
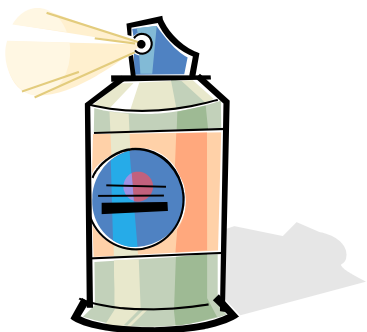
**Antifoulings**

**PT 21**



**Embalming fluids**

**PT 22**



## Simple worst case Scenario

- Article 5.1 (BPD) + Annex VI

## OECD ESDs + EUBEES ESDs

- Simple and harmonised approach
- Set of Assumptions



**Exposure Assessment**  
**=**  
**Complex process**



## The Issues

Default parameters need to be harmonised within PTs

ESDs' parameters should reflect REALITY

Missing scenarios should be developed or adapted

The other “agreements”: CA decisions

## Harmonization within PTs

### PT 21

Simultaneous discussions at TM level

Harmonization of exposure parameters

## Harmonization among PTs

### Use of localised Exposure for particular PTs

#### PT 7, 9, 10

For the receiving soil compartment a depth of 50 cm should be used

#### PT18

For the receiving soil compartment a depth of 10 cm in case of no mixing (urban areas) and 20 cm in case of mixing (rural areas) should be used

## Missing Scenarios???

### PT 8

No exposure scenario for **Professional in-situ spraying** exists in the current ESD of the OECD

This scenario has been developed in the revised PT 08 ESD (to be endorsed by the TFB)

## Reality

### PT 18: household and professional uses

#### Number of houses:

For outdoor use: a number of 2500 households

For indoor use a number of 4000 households

#### Number of commercial buildings:

For both indoor and outdoor use, 300 will be used as default

#### Number of hospitals:

No separate assessment for hospitals will be included. The number of commercial buildings of 300 is considered to include also hospitals

## Reality

### PT 18: household and professional uses

#### Surface of a standard house:

A surface area of a standard house of 130 m<sup>2</sup> is considered as default for general treatment.

A wet cleaning zone leading to a release to the STP of 38.5 m<sup>2</sup> will be used.

#### Surface of commercial buildings

For the surface area to be treated for general treatment the default value is 609 m<sup>2</sup>.

## The other “agreements”

### PT 18: household and professional uses

#### Focus Scenarios for Groundwater:

How many scenarios showing no unacceptable risk should be considered for Annex I inclusion?

### PT 21: Antifoulings

#### “Wider Environment” scenario:

What are the protection goals?

Can Annex I proposal being accepted when marinas show unacceptable risk?

## **The Manual of Technical Agreements MOTA**

**MOTA** is an information document that intends to provide the agreements of the Technical Meetings (TMs) in a concise format

The intention of this document is to make the TMs and the decision-making process more transparent.

It is expected that the users will include applicants as well as Member State Competent Authorities (CA).



## **The Manual of Technical Agreements**

### **MOTA**

**MOTA** is not a legally binding document. It is not an authoritative source of information, and when in doubt, the original documents should always be checked.

The main sources for the **MOTA** are the adopted minutes of the TM, and in all cases, a reference is given to the TM where the agreement was reached.

This document is intended to create a general database of questions that have already been handled and where agreement was reached at the TM. The **MOTA** is publicly available at the biocides web-site of JRC-IHCP.

## **The Manual of Technical Agreements**

### **MOTA**

**MOTA** does not require a formal endorsement by the CA meeting or the TM. It is a living document that will be updated constantly with new additions, in principle after each TM. Any mistakes found in the text can be corrected at any time by reporting the error to the chair of the TM.

The text will be updated regularly by uploading an addendum on CIRCA as a separate document for a commenting period of 6 weeks. After the commenting period, JRC will insert the new text into the MOTA, edit an existing paragraph, or delete the text, as relevant.

- ✓ Guidance on the relevance of the manufacturing process when carrying out the risk assessment under the BPD;
- ✓ Guidance on rapidly degrading substances;
- ✓ Guidance on the use of PPP DAR and existing substances risk assessment reports under the BPD;
- ✓ Guidance on the relevance of REACH guidance for dossier evaluation under the BPD;
- ✓ Guidance on leaching rate estimation for PT 07, 09 and 10

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

**Exposure driven  
waiving**

**Long range transport**

**Synergistic effects**

**Challenges**

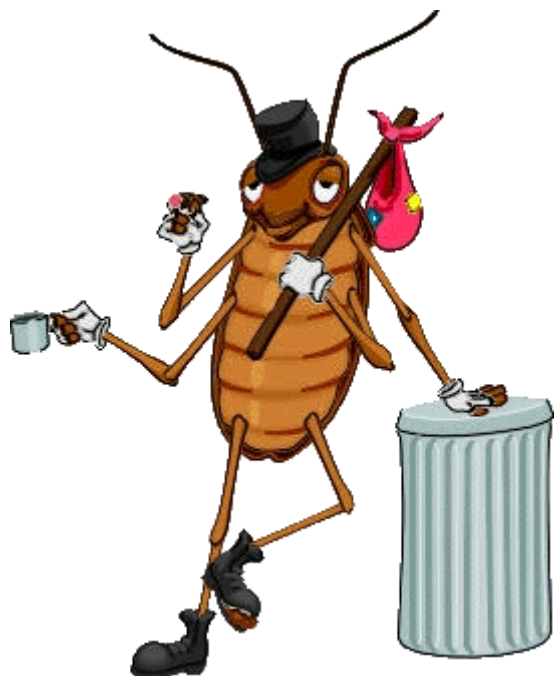
**Cumulative effects**

**Exclusion criteria**

**Substitution criteria**

# To take home:

- Exposure assessment is complex!
- Lots of **EXPERIENCE** is being gained as we move in the Review programme
- Close **COOPERATION** is needed:
  - Scientist
  - Industry
  - Regulators



**Thank you for  
your attention!!!**

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**[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/)**