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Why is a Biocide Monitoring necessary?
- Introduction of the Regulatory Background

Ingrid Nöh, Stefanie Jäger, Silke Müller-Knoche

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23 Product Types: e.g. Pest Control Agents, Desinfectans, Material Protection Agents, Antifoulings, In Can Preservatives …



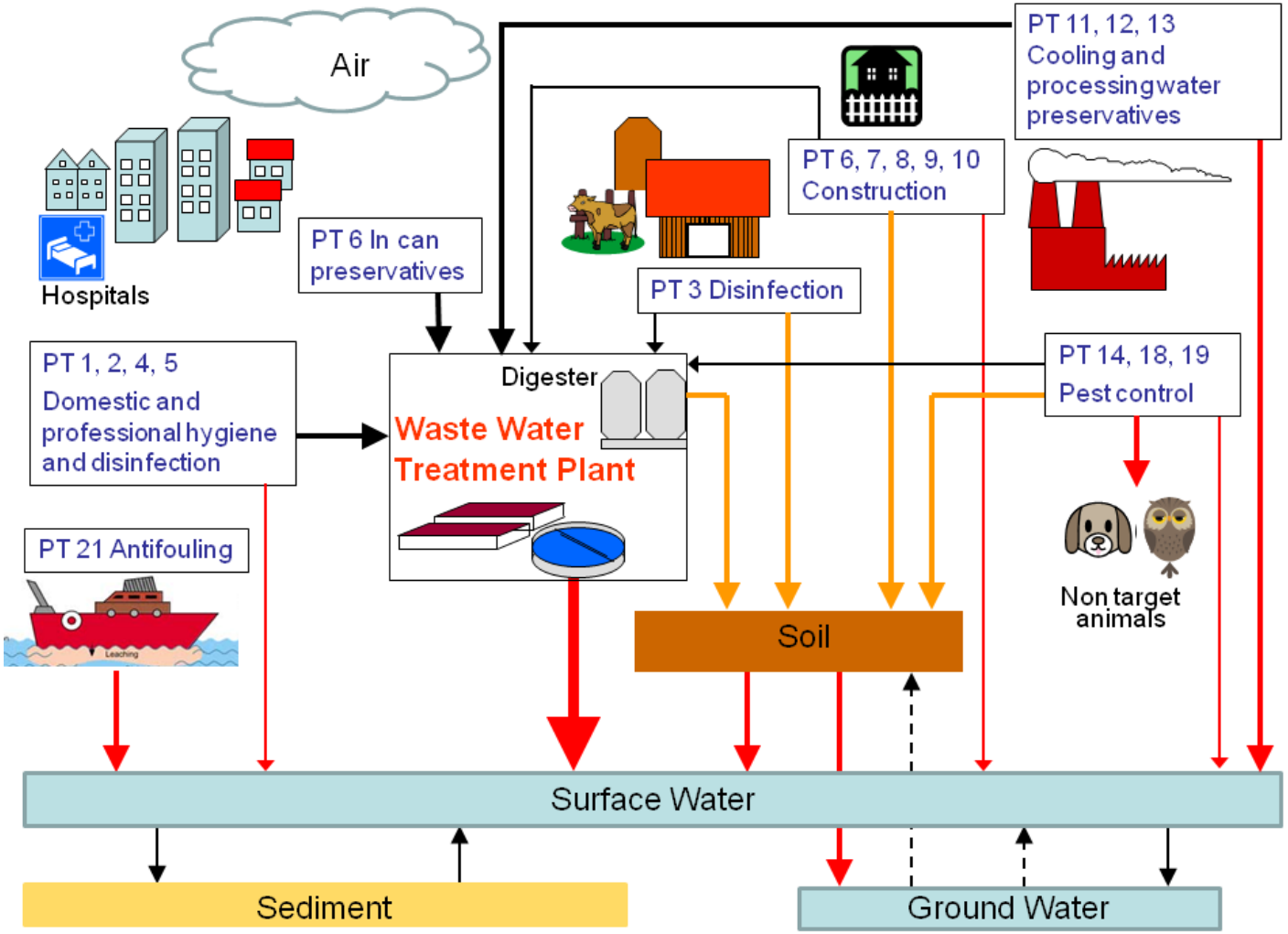







In Germany: ca. 30.000 products

Possible pathways for biocides entering the environment ...



Biocidal Product Directive 98/8/EC (BPD)

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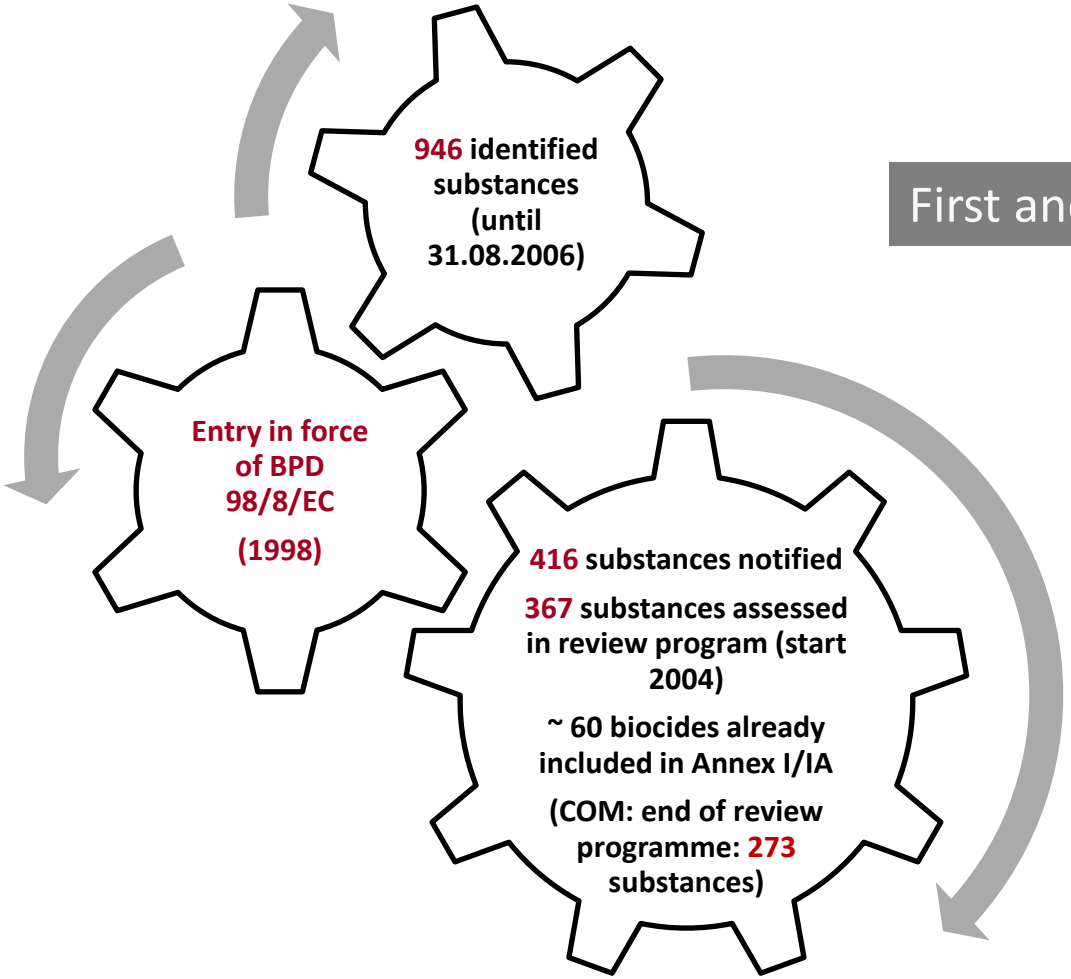
Is effect of BPD actually observable?



First and early consequences of BPD

⇒ Reduction of the total number of active substance on the market

Biocidal Product Directive 98/8/EC (BPD)

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Active substances (AS) (EU-level)	***Biocidal products (BP)*** (national level)
• Active substance dossiers • Risk assessment for the active substance and one reference product	• Biocidal product dossiers • Risk assessment for the biocidal product, i.e. active substances & substances of concern
<u>Goal:</u> Decision on Annex I / IA entry – on the further use of the AS	<u>Goal:</u> Decision on Authorisation of BP or Mutual recognition of authorisations – further use

Article 5 (IV) 98/8/EC

Member States shall authorise a biocidal product only if … the biocidal product …

iii) has no unacceptable effects itself or as a result of its residues, ***on human or animal health****,…*

iv) has no unacceptable effect itself, or as a result of its residues, ***on the environment*** *…*

The BPD will be replaced by **EU Regulation No 528/2012** which has to be applied from **September 1, 2013.**

Biocidal Product Directive 98/8/EC (BPD)

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Reduction of total number of active substances because of non-inclusion in Annex I/IA

Applications restricted due to risk mitigation measures

Further consequences of BPD/new Regulation

Disappearance of certain biocides as consequence of comparative assessment

Increasing use of certain biocides as alternative for those who lost their market authorisation or are restricted

Monitoring Data: Potential fields of application

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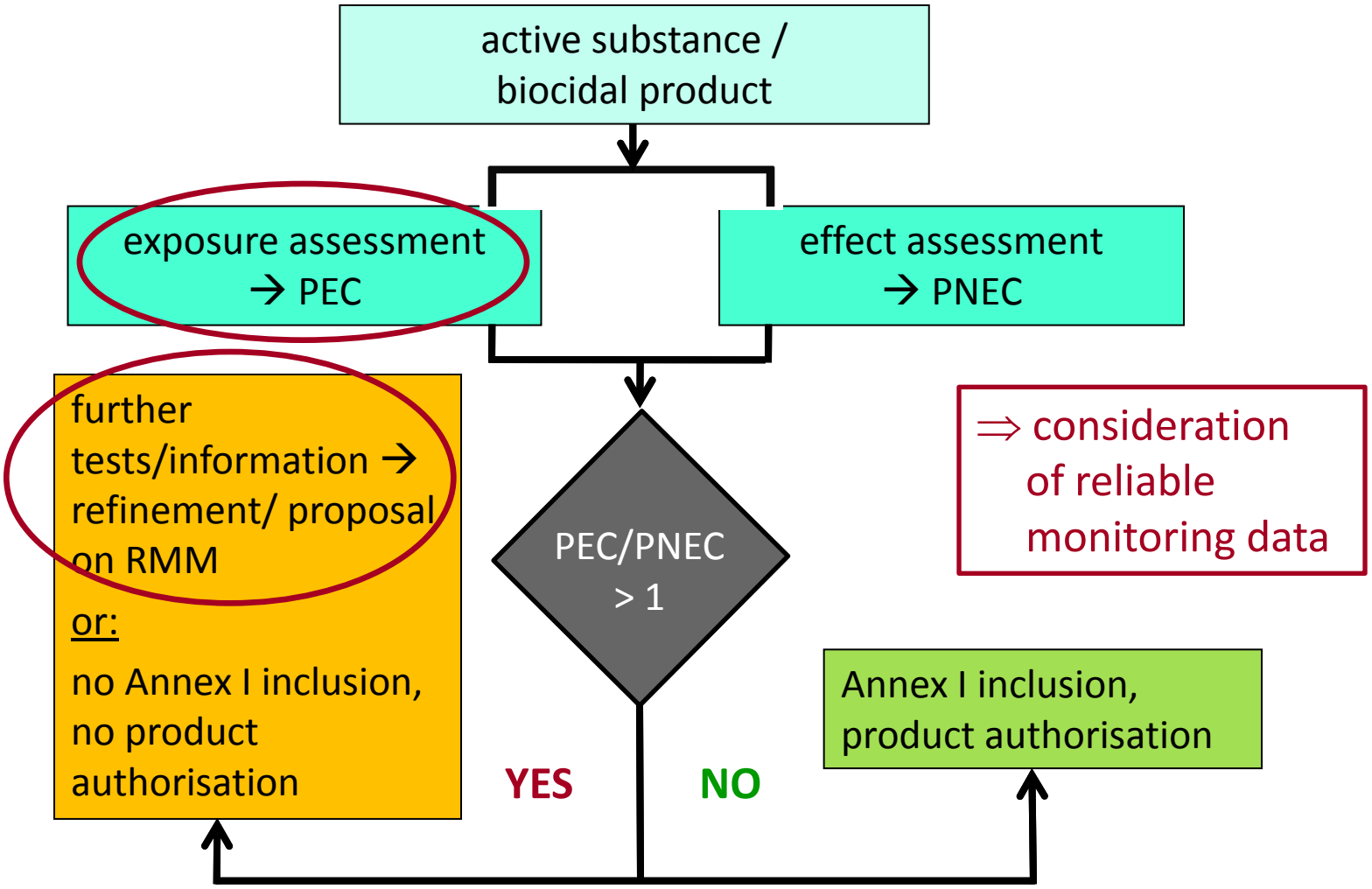
Is refinement of environmental risk assessment possible?



Potential fields for using monitoring data
-
Examples

Example 1: Check of effectiveness of RMM

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Rodenticides PT 14

- FGARs/SGARs show high risk for primary and secondary poisoning
- SGARs: all potential PBT/vPvB substances except Bromadiolone
- FGARs/SGARs: resistence already observed

⇒ Annex I inclusion not possible under BPD but …

… No adequate alternatives for rodent control as vector for human diseases - protection of human health

ANTICOAGULANTS
1. Generation *(FGAR)*[1]
Coumatetralyl
Chlorphacinon
Warfarin
2. Generation *(SGAR)*[2]
Difenacoum
Bromadiolone
Difethialon
Brodifacoum
Flocoumafen

[1]**FGAR**: first generation anticoagulant rodenticides

[2]**SGAR**: second generation anticoagulant rodenticides

Example 1: Check of effectiveness of RMM

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⇒ **shortened Annex I inclusion for 5 years**

⇒ **products authorisation only for 3 years restricted with RMM**

RMM in Germany:

- no authorisation for consumer use
- labelling of areas where rodenticides are currently used
- preventing access for non-target organisms (e.g. use of bait boxes)
- control visits to remove dead animals
- control of effectiveness and possible resistance
- professional disposal of all baits after end of control measures

→ Monitoring data for effectiveness check of RMM

Example 2: Check of exposure models

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- Sewage treatment plant (STP) - important entry pathway of biocides into the environment (especially for aquatic compartment)
- Models (e.g. Simple Treat) simulating distribution of biocides in STP are available, but not validated for all substance classes, e.g. inorganic compounds, ionizable substances

→ Possible solution in such cases:

  - Collection of available monitoring data referring to elimination potential of STP
  - Evaluation of the reliability and representativity of these data
  - Derivation of a realistic elimination potential and subsequently, of a realistic release fraction into surface water

Conclusion: Monitoring data can help ....

... to clarify sources of releases ...

- Is the substance detected actually the result of a biocidal use or other use(s)?

... to check effectiveness of RMM ...

- Is an improvement of the RMMs necessary?

... to check ...

- Are the assumptions and decisions made during environmental risk assessment correct e.g. for accumulation or exposure calculations (e.g. used exposure models)?
- Are there any pollution spots (substances/compartment) ?
- Does there actually exist a problem, e.g. ecotox. effects of rodenticides on raptors?

But ...

Concurrent use of biocidal active substances

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Simultaneous application of biocidal active substances in chemicals, plant protection products and/or pharmaceuticals

Active substance	Biocides	Pharma-ceuticals	Plant Protection Products	Chemicals
Propan-2-ole	X	X		X
Permethrin	X	X		
Deltamethrin	X	X	X	
Imidacloprid	X	X	X	
Triclosan	X	X		
Bromadiolone	X		X	

⇒ Source of release could often not clearly be determined.

Biocide Monitoring – Current situation in Germany

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- Very few data for applied amounts and emission rates of biocidal active substances in Germany
- Poor data from environmental monitoring campaigns which could actually be assigned to biocidal uses (result of UBA survey in 2011 → Rüdel, Knopf)
- Product authorisation has started without any information of the actual situation of biocide emission into environment (starting point)

Summary and Conclusions

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Needs

- Baseline of environmental exposure by biocides (observing changes)
- Monitoring strategy to improve risk assessment instruments

⇒ Effective protection of our environment

Open questions

- Are effects of BPD observable?
  - non-inclusion, RMM, occurrence of alternative substances
- Can trends be observed - towards in- or decreasing environmental concentrations due to the decisions made?
- How to include monitoring data for risk assessment (EU procedure)?

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Specific questions regarding monitoring strategies

- Is it necessary to focus on substances which are solely used in biocidal products?

- Is it possible to distinguish for some substances between entries from biocidal applications and applications of PPP, pharmaceuticals or chemicals (e.g. by applying adequate monitoring strategies)?

Outlook

Two UBA research projects dealing with monitoring of biocides:

- Prioritization of biocides (2011): FKZ 360 04 036
- Validation of prioritization conzept and development of monitoring programme (2012-2015): FKZ 3712 67 403

⇒ See presentations of Heinz Rüdel and Burkhard Knopf


Thank you for
your attention!


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