LIMITATIONS OF REGULATORY RISK ASSESSMENTS OF CHEMICALS

The example of biocidal active substances in households
Biocidal active substances

= active substances with a controlling effect on any harmful organism by any means other than mere physical or mechanical action (according to European Biocidal Products Regulation (EU) 528/2012 (BPR))
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= active substances with a controlling effect on any harmful organism by any means other than mere physical or mechanical action (according to European Biocidal Products Regulation (EU) 528/2012 (BPR))

→ exemptions e.g. for plant protection products, human or veterinary pharmaceuticals, personal care products
Biocidal active substances

= active substances with a controlling effect on any harmful organism by any means other than mere physical or mechanical action (according to European Biocidal Products Regulation (EU) 528/2012 (BPR))

Main group 1: Disinfectants
Biocidal active substances

= active substances with a controlling effect on any harmful organism by any means other than mere physical or mechanical action (according to European Biocidal Products Regulation (EU) 528/2012 (BPR))

Main group 1: **Disinfectants**

Main group 2: **Preservatives**
Biocidal active substances

= active substances with a controlling effect on any harmful organism by any means other than mere physical or mechanical action (according to European Biocidal Products Regulation (EU) 528/2012 (BPR))

Main group 1: **Disinfectants**

Main group 2: **Preservatives**

Main group 3: **Pest control**
Biocidal active substances

= active substances with a controlling effect on any harmful organism by any means other than mere physical or mechanical action (according to European Biocidal Products Regulation (EU) 528/2012 (BPR))

Main group 1: Disinfectants

Main group 2: Preservatives

Main group 3: Pest control

Main group 4: Other biocidal products
Environmental risk assessment

RISK or no RISK?
Environmental risk assessment

Predicted environmental concentration = PEC

Predicted no effect concentration = PNEC

RISK or no RISK?
Environmental risk assessment

Predicted environmental concentration = PEC

Predicted no effect concentration = PNEC

RISK or no RISK?
Biocides

Emissions of biocidal active substances from households can originate from several product categories:

Biocidal active substances according to Biocidal Products Regulation 528/2012
Biocides

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Biocidal active substances according to Biocidal Products Regulation 528/2012

Biocidal Products (Regulation 528/2012)
Biocides

Emissions of biocidal active substances from households can originate from several product categories:

- Biocidal Products (Regulation 528/2012)
- Plant Protection Products (Regulation 1107/2009)

Biocidal active substances according to Biocidal Products Regulation 528/2012
Biocides

Emissions of biocidal active substances from households can originate from several product categories:

- Biocidal Products (Regulation 528/2012)
- Plant Protection Products (Regulation 1107/2009)
Biocides

Emissions of biocidal active substances from households can originate from several product categories:

- Biocidal Products (Regulation 528/2012)
- Plant Protection Products (Regulation 1107/2009)
- Washing and Cleaning Agents (Regulation 648/2004)
Biocides

Emissions of biocidal active substances from households can originate from several product categories:

- Biocidal Products (Regulation 528/2012)
- Plant Protection Products (Regulation 1107/2009)
- Washing and Cleaning Agents (Regulation 648/2004)
- Personal Care Products (Regulation 1223/2009)
Biocides

Emissions of biocidal active substances from households can originate from several product categories:

- Biocidal Products (Regulation 528/2012)
- Plant Protection Products (Regulation 1107/2009)
- Washing and Cleaning Agents (Regulation 648/2004)
- Personal Care Products (Regulation 1223/2009)
- Treated Materials (Regulation 528/2012)
Goal

Describe cases where biocidal active substances might enter the sewage system without falling under the Biocidal Products Regulation

Minimize the release of hazardous chemicals (6.3)

Environmentally sound management of chemicals (12.4)
Methods

- Interviews with standardised questionnaires (not part of this presentation)

- Barcode scans:
  - all products for the control of pests
  - all washing and cleaning products
  - certain personal care products with high release to wastewater
Study areas

Rural neighbourhood
(Main study site)

Intermediate neighbourhood

Urban neighbourhood

n=92 households

n=19 households

n=20 households
Results

- Scan of almost 3,000 products

- Retrieved:
  - Names of 96 % of the scanned products
  - Ingredients of 93 % of the scanned products

- 214 biocidal active substances detected that were at least identified under the old Biocidal Products Directive 98/8/EC

- Results only include information regarding 79 active substances currently under review or approved active substances
Results

- Households with biocidal active substances: 100%
- Households with biocidal products: 75%
- Average number of biocidal products per household: 1.7
- 9 product types present in the households
Results: Product categories

- 1,411 Washing and Cleaning Agents
- 275 Pest Control Products
- 1,277 Personal Care Products
Results: Product categories

- 1,411 Washing and Cleaning Agents
- 220 Biocidal Products
- 275 Pest Control Products
- 1,277 Personal Care Products
- 26 Plant Protection Products
- 3 Veterinary Pharmaceuticals
- 12 Pharmaceuticals/Medical products
- 14 products: Not identified

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01.06.2017
Results: Substances found in the products

Number of products containing substances

- Washing and Cleaning Agents
- Personal Care Products
- Pest Control Products
Results: Uses not falling under Biocidal Products Regulation

— 64 % do not fall under the risk assessment of BPR because:

- 1488 Assessed uses (36%)
- 562 Washing and Cleaning Agents (14%)
- 2023 Personal Care Products (49%)
- 33 Other Pest Control Products (0.8%)
Results: Uses not falling under Biocidal Products Regulation

- 64% do not fall under the risk assessment of BPR because:

- Use in a washing and cleaning agent without being assessed as in-can-preservatives (product type 6)
Results: Uses not falling under Biocidal Products Regulation

- 64% do not fall under the risk assessment of BPR because:
  - Use in a washing and cleaning agent without being assessed as in-can-preservatives (product type 6)
  - Use in a personal care product
Results: Uses not falling under Biocidal Products Regulation

— 64% do not fall under the risk assessment of BPR because:
  
  — Use in a washing and cleaning agent without being assessed as in-can-preservatives (product type 6)
  
  — Use in a personal care product
  
  — Use in another pest control product than biocidal product
Discussion

— Personal care products and washing and cleaning agents clearly outnumber biocidal products as emission sources of active substances in wastewater
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— Risks might be underestimated because not all emission sources are considered during PEC calculation (no aggregated exposure assessment)
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— Personal care products and washing and cleaning agents clearly outnumber biocidal products as emission sources of active substances in wastewater

— Risks might be underestimated because not all emission sources are considered during PEC calculation (no aggregated exposure assessment)

— Not all monitoring results of biocidal active substances can be explained by product inventory → emissions from building materials
Conclusions

1. Households are a **possible emission source** for certain biocidal active substances in wastewater

2. Risk assessments and risk mitigation measures have to consider **products from other regulatory backgrounds**

3. Too **complex** for existing risk assessment concepts?

→ Sustainable use of biocides
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Contact

Leuphana Universität Lüneburg
Institute for Sustainable and Environmental Chemistry
Dipl.-Ing (FH) Stefanie Wieck, M.A.
Scharnhorststr. 1
21335 Lüneburg
Fon 04131.677-2918
Fax 04131.677-2848
wieck@leuphana.de
www.leuphana.de

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Literature


Product categories

— All washing and cleaning agents;
— Certain personal care product types with high release to wastewater: shampoo, body wash, bath additives, conditioner, soap, toothpaste, mouthwash, body lotion, hand cream, hair styling products, hair dye and make-up remover
— Products for the control of pests: plant protection products, disinfectants, wood preservatives, construction material preservatives, rodenticides, insecticides, repellents, embalming fluids, products against fleas and lice
Sampling site
Substances

- Analysis of 15 selected biocidal active substances:
  - Benzalkonium chloride
  - Benzisothiazolinone (BIT)
  - Carbendazim
  - Chloromethylisothiazolinone (CMIT)
  - Dichlorooctylisothiazolinone (DCOIT)
  - N,N-Diethyl-meta-toluamide (DEET)
  - Diuron
  - Icaridine
  - Octylisothiazolinone (OIT)
  - Piperonyl butoxide
  - Salicylic acid
  - Tebuconazole
  - Terbutryn
  - Tetramethrin
  - Triclosan