

### **Pharmaceuticals in Soil, Sludge and Slurry**

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& Unit IV 2.2 - Pharmaceuticals, Washing and cleansing agents

#### **Federal Environment Agency of Germany**







Umwelt Bundes Amt () Für Mensch und Umwelt



### **Federal Environment Agency - UBA**



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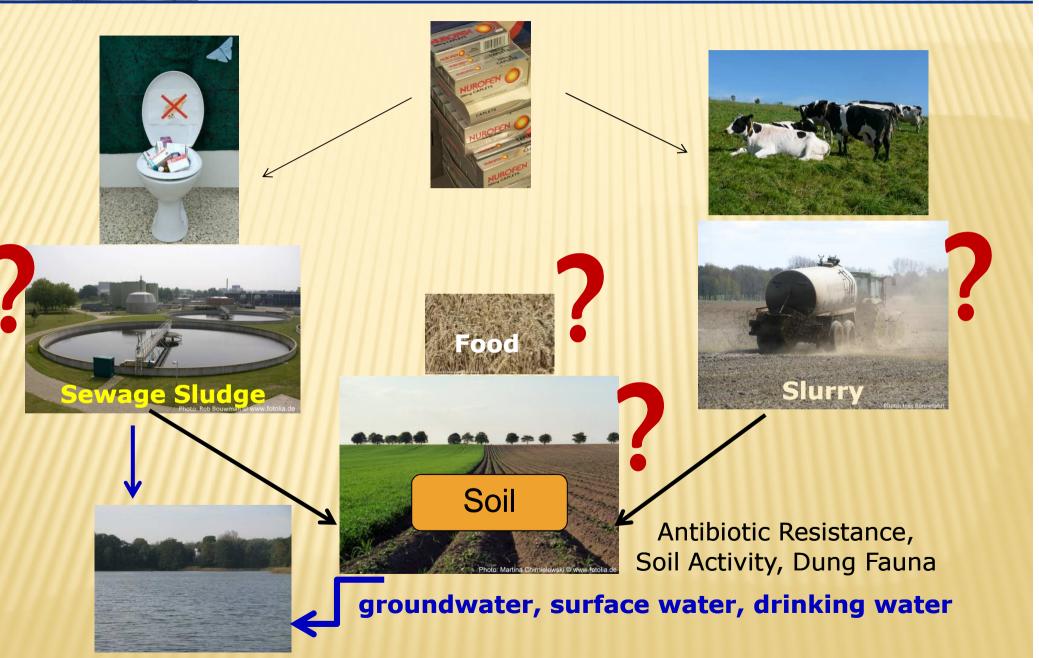
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# Routes of exposure of pharmaceuticals





### **Pharmaceuticals in the Environment**



#### **Backgrund:**

- First detection of clofibric acid in the effluent of a sewage treatment plant in the USA 1976 (Garrison et al. 1976) – in the 1990ies first detection of clofibric acid in Berlin drinking water as well as surface and ground water
- Germany: > 150 pharmaceuticals and metabolites were found in diverse environmental matrices according to a paper of Bergmann (2011) summarizing actual literature data
- Forecast: further increasing consumption of pharmaceuticals
- Lots of publications concerning pharmaceuticals in surface water and groundwater – but only few publications about pharmaceuticals in soil, sludge and slurry





#### **Pharmaceutical Regulation/ Autorization process**

Federal Environment Agency of Germany: since 1998 responsible for environmental risk assessment in the authorisation process of human- and veterinary pharmaceutical products.

UBA assessed about: VMPs 600, HMPs 1250

The environmental risk assessment of pharmaceuticals is part of EU regulations:

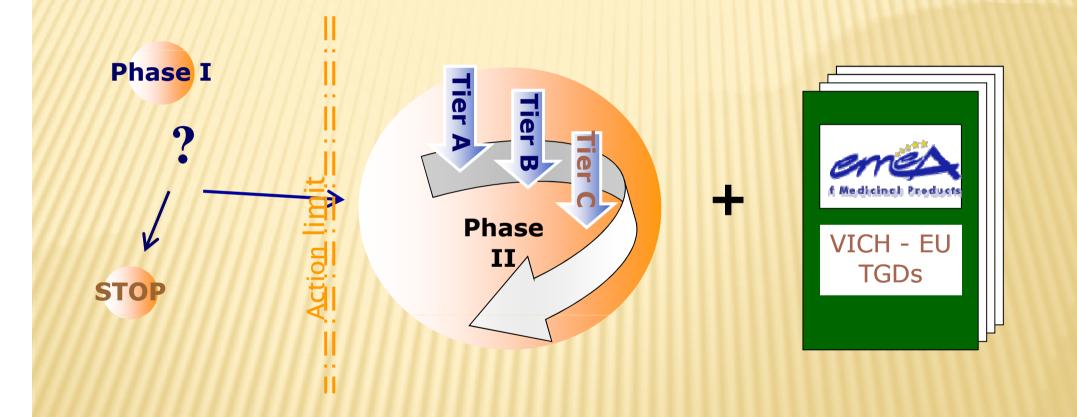
Directive 2001/82/EG (2004) Veterinary Medicinal Products 2001/83/EG (2004) Medicinal Products for Human Use

EU-wide harmonised guidelines for conducting an ERA



### Environmental risk assessment of Bundes pharmaceuticals

### **General ERA Framework** for pharmaceuticals

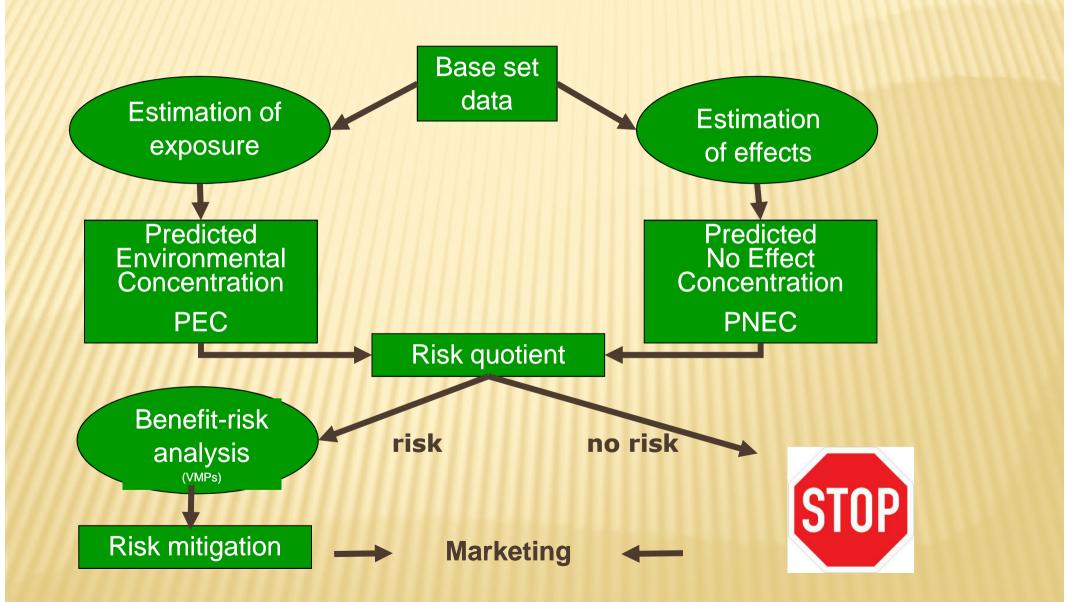


Action limit not applicable for some compounds, e.g. hormones (both) or antiparasiticides for pasture animals



#### **General ERA Scheme**



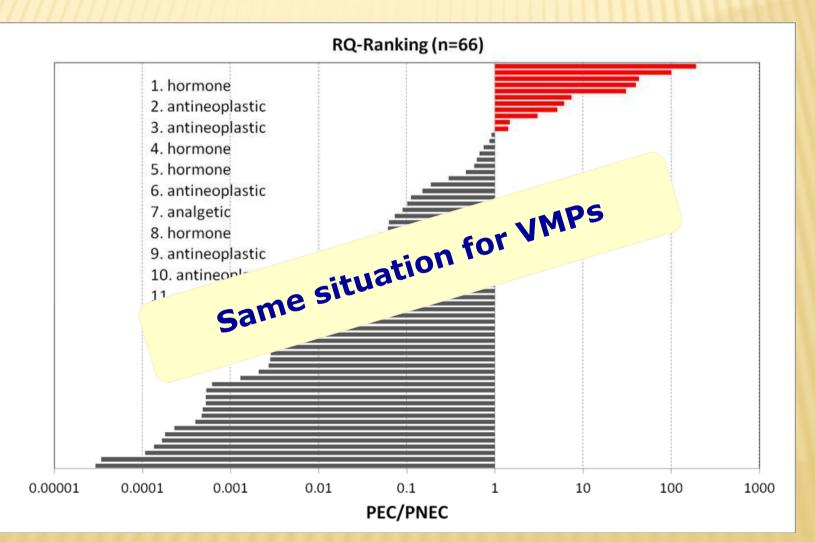




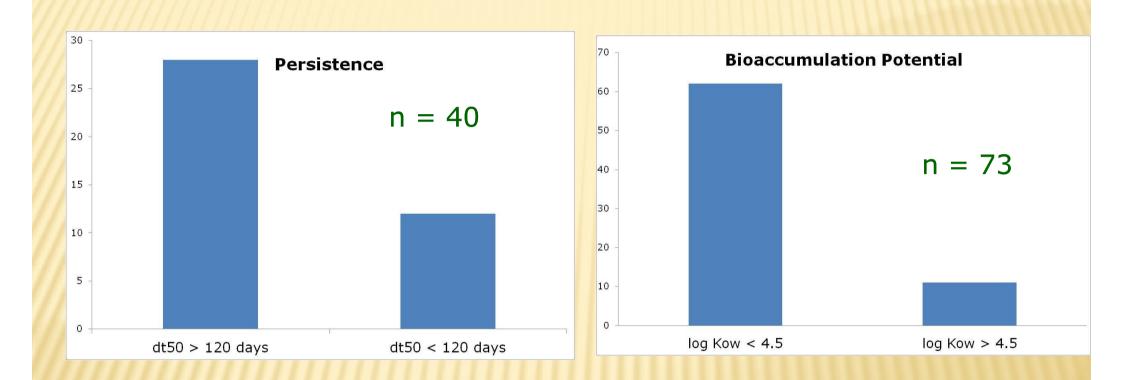
**Substances of concern** 



### Pharmaceuticals (HMPs) with identified Environmental Risk UBA results







2/3 of the substances which enter Phase II are classified as persistent (dt50 normalised to 12°C). Approximately 15 % of the active ingredients have to undergo a PBT assessment.



### Environmental risk assessment / Monitoring



No monitoring obligatory for pharmaceuticals after authorization.

Approximately 85 HMP and VMP are currently monitored in special campaigns of the Federal States of Germany

According to an expertise provided for our agency in 2011 (Bergmann et al.) more than 200 pharmaceutical substances and more than 20 metabolites were detected in diverse environmental matrices

- but for only for 15 of them an ERA was provided

There is a lack between substances found in the environment and the knowledge about them!!!





### Pharmaceuticals in soil, sludge and slurry

### Hidden danger or overestimated risk?





#### Occurrence and problems of pharmaceutical residues in soils

- ✓ Lots of data and efforts concerning pharmaceuticals in surface water Water Framework Directive
- ✓ Small data basis about pharmaceutical residues in sewage sludge and slurry
- ✓ Only few data available concerning fate, bioavailability and impact of pharmaceuticals on soil microbial community, soil fauna, enrichment in soil, reduction/recovery
- Necessity of the implementation of indicator substances for pharmaceutical residues in monitoring strategies for sewage sludge
  - $\checkmark$  At present not enough data for the estimation of risk
  - ✓ How many pharmaceuticals at which loads are concentrated in sewage sludge?
  - ✓ Are more reduction techniques necessary to reduce pharmaceutical loads?





#### Transfer in plants

- ✓ Mechanisms of transfer?
- ✓ Problems for human health?

#### Resistance to antibiotics

- ✓ Selective advantages for the growth of resistant bacteria, possibility of gene transfer
- ✓ Risk of accumulation and dissemination to animal husbandry and human-being?
- ✓ Until now no strategies for the implementation into risk assessment

#### Do parasiticides have long term effects on dung fauna?

High toxicity against dung fauna and daphnia



#### **Conference Topics**



#### Mixture Toxicity

- Until now only single substance
   assessment but mixture of lots of
   substances spread on soils!!!
- ✓ Addition of impact possible!
- Is our risk assessment protective enough?





### Pharmaceuticals in Soil, Sludge and Slurry

## Thank you very much for your attention!







10:00 - 12:30 Scientific programme

12:30 -13:30 Lunch Break

13:30 - 15:00 Scientific programme

15:00 -15:30 Break and posterwalk

15:30 - 17:15 Scientific programme

19:00 - ... Dinner "Georgengarten"









- Location: Restaurant "Am Georgengarten"
   Entry of the parc area Georgengarten coming from the city
- Start: 7 p.m.







