

Für Mensch & Umwelt



Sustainable chemistry conference

Sustainability of pharmaceuticals: An agency's point of view.

Prof. Dr.-Ing. Adolf Eisenträger

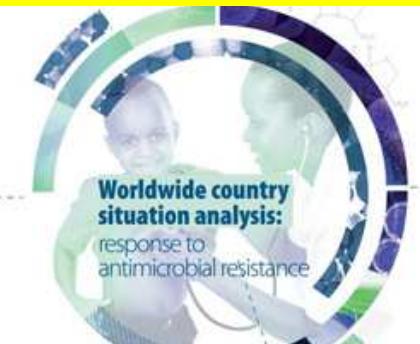
Dept. IV 2: Pharmaceuticals, Chemicals, Experimental Studies
in Div. IV: Chemical Safety

The WHO perspective



Medical Product Alert No. 4/2015:
Adverse reactions caused by
Falsified Diazepam in Central Africa

Antimicrobial resistance



Millennium Development Goals (MDGs)

MDG 1: child underweight

MDG 4: child health

MDG 4: immunization

MDG 5: maternal and reproductive health

MDG 6: HIV/AIDS

MDG 6: malaria

MDG 6: neglected tropical diseases

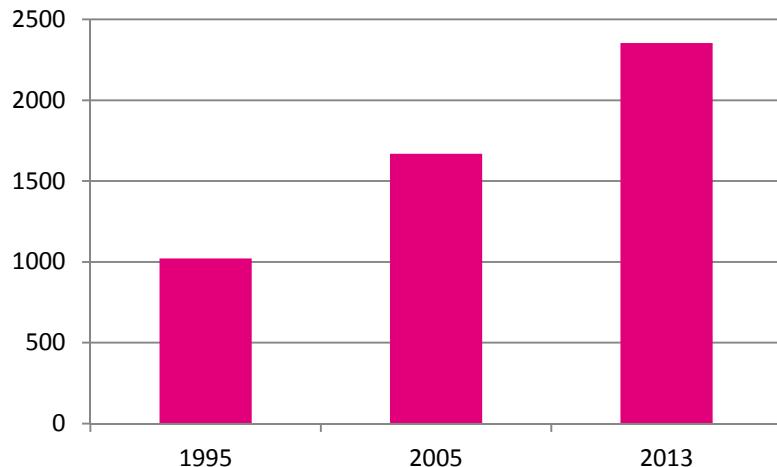
MDG 6: tuberculosis

MDG 7: water and sanitation

MDG 8: essential medicines

Availability of pharmaceuticals is one (minor) problem!

The european commission perspective



Doubling of the total expenditure on health per capita at average exchange rate (US\$)

The health sector is (too) expensive, pharmaceuticals are safe!

European medicines agency (EMA) is responsible for authorization of human, veterinary and herbal medicines

The screenshot shows the homepage of the European Medicines Agency (EMA). The header includes the text "An agency of the European Union" and the European Union flag. The main navigation menu includes Home, Find medicine, Human regulatory, Veterinary regulatory, Committees, News & events, Partners & networks, and About us. Below the menu, there are two main sections: "Search for medicines" and "Call for civil society members". The "Search for medicines" section features a search bar and a "Quick search" button. The "Call for civil society members" section features a graphic of colorful hands and text about a call for expressions of interest. The "Latest news" section lists three articles: "Public-friendly information on herbal medicines now available" (03/08/2015), "Calls for civil society members for two EMA committees" (29/07/2015), and "EMA to encourage use of scientific advice for post-authorisation safety studies" (28/07/2015). To the right, there is a sidebar with links for "Find information for..." (Patients and carers, Healthcare professionals, Animal health professionals, Pharmaceutical industry, Media professionals), a "Product emergency HOTLINE (Outside working hours)" link, and a "What's New" link.

The environmental perspective

More than 600 active pharmaceutical ingredients or metabolites and transformation products have been detected in:

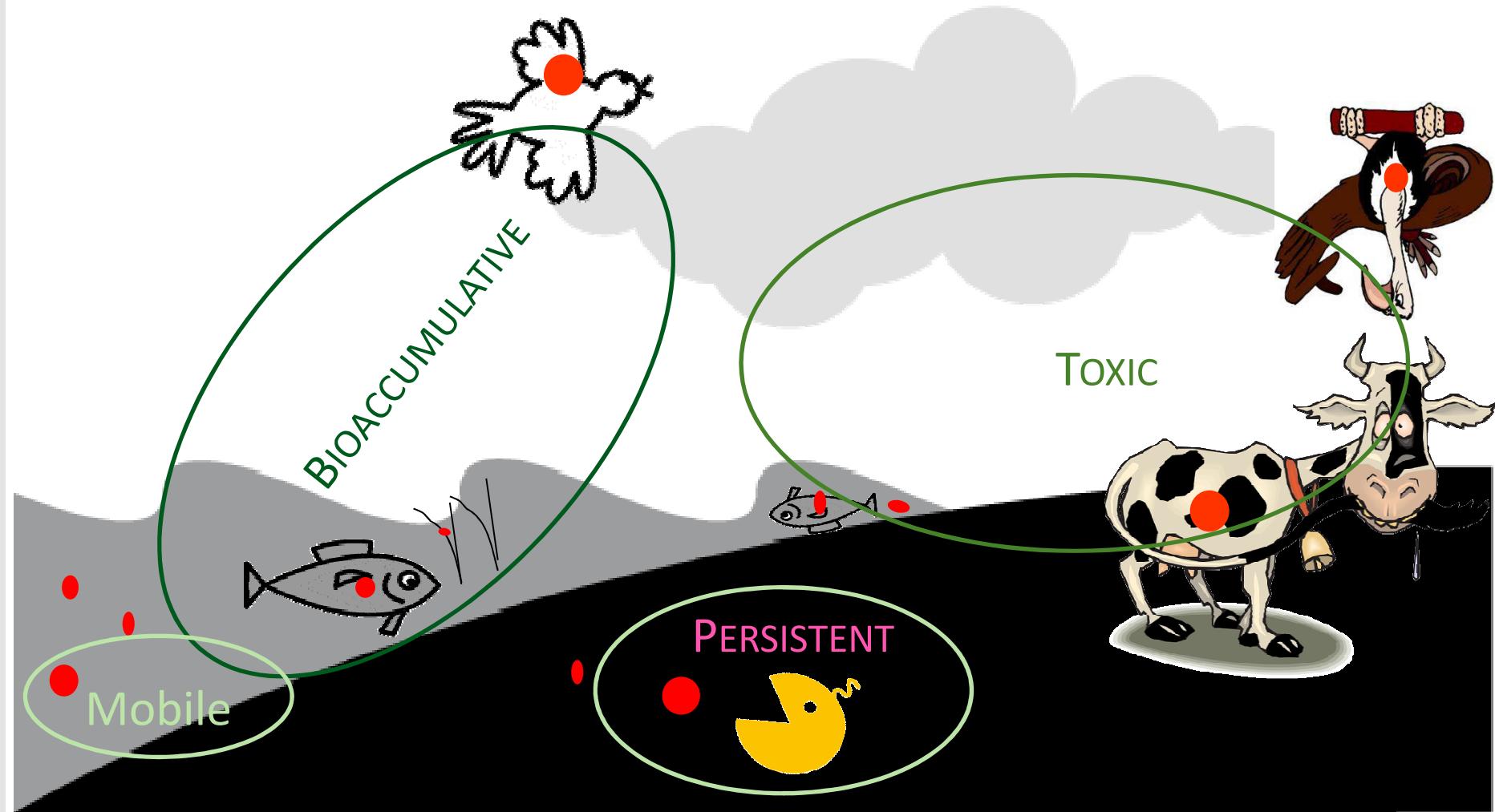
- sewage effluent,
- surfaces waters,
- groundwater,
- soil,
- manure,
- biota and even
- drinking water

in 71 countries.

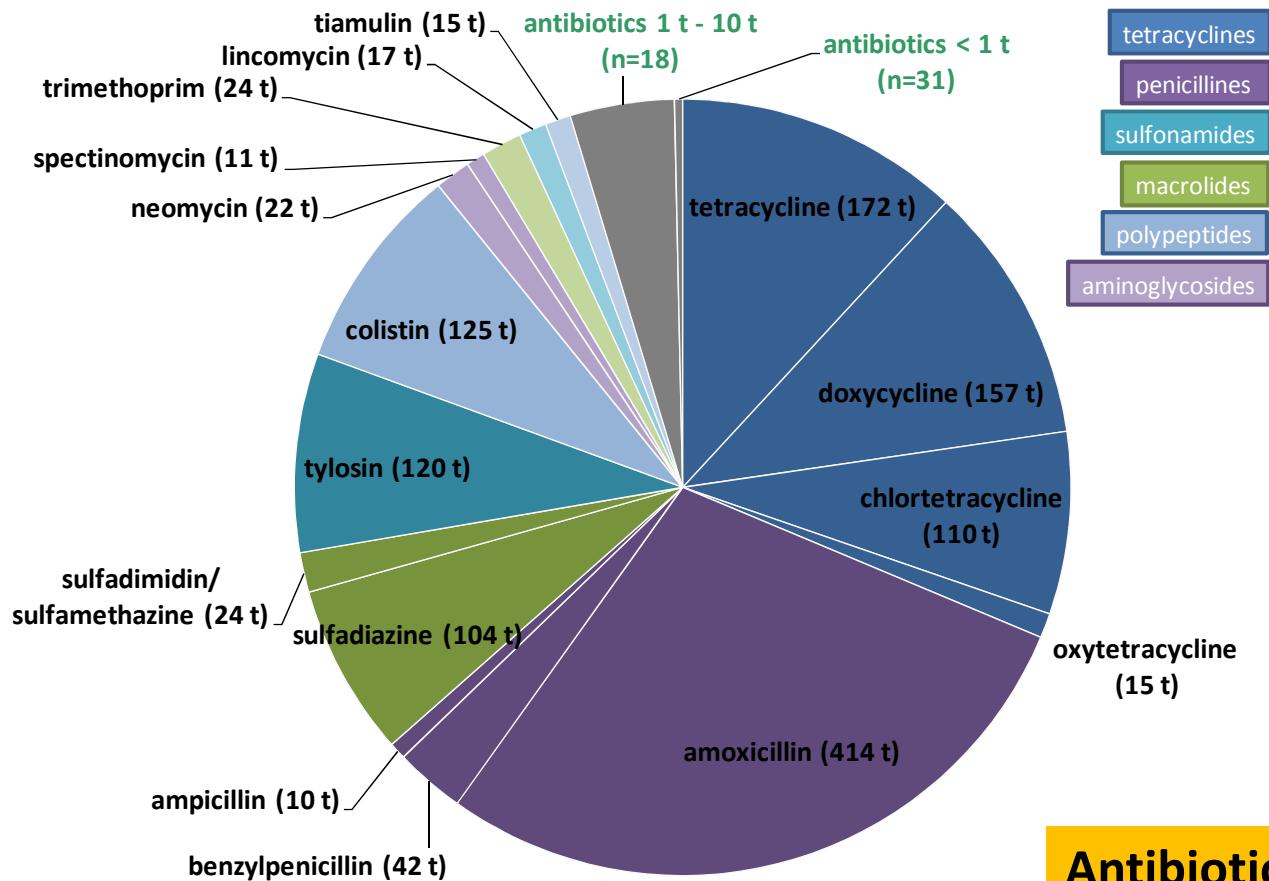
Global occurrence of pharmaceuticals in many compartments of the environment!

Result of a research project of the Federal environment agency

Intrinsic (adverse) properties of active pharmaceutical ingredients



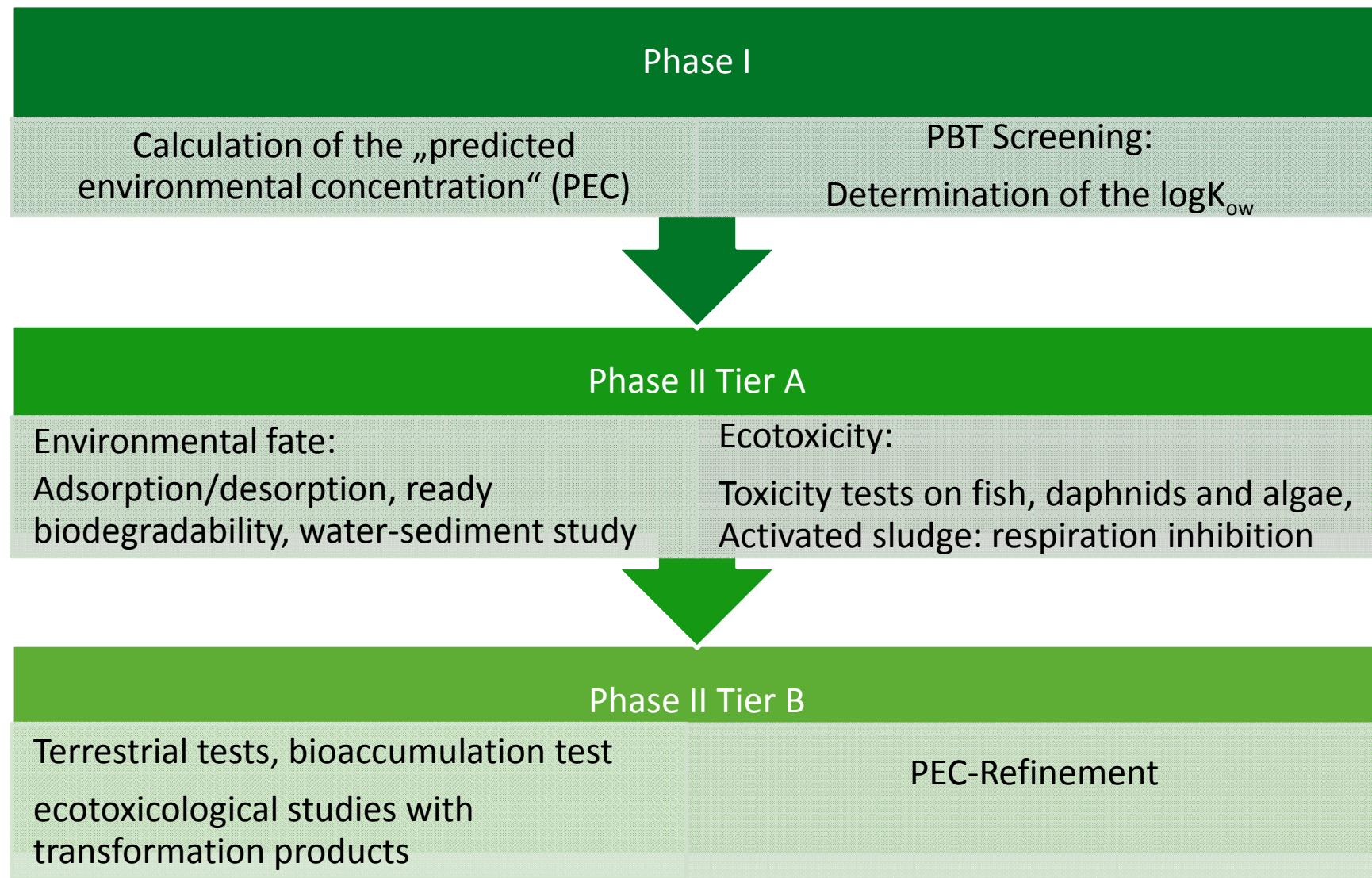
Does the current consumption of veterinary products induce antibiotic resistance?



Antibiotics for veterinary use consumed in Germany (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, 2013)

Antibiotics for veterinary use are approved active pharmaceutical ingredients!

Agency's work: Environmental risk assessment (e.g. human pharmaceuticals)



The most widely used human pharmaceuticals are „old“* substances

| Active pharmaceutical ingredient | Medical uses | Consumption [t/a [#]] |
|----------------------------------|---|----------------------------------|
| Metformin | Type 2 diabetes | 1660 (2013), + 179 % (2002-2013) |
| Ibuprofen | Pain, fever, inflammation | 1080 (2013), + 198 % (2002-2013) |
| Valsartane | High blood pressure, congestive heart failure | 103 (2013), +557 % (2002-2013) |
| Amoxicillin | Infections | 148 (2013), + 42 % (2002-2013) |
| Iomeprol | Contrast media | 243 (2013), + 144 % (2002-2013) |
| Gabapentin | Epileptic seizures, neuropathic pain, off-label use: anxiety disorder, bipolar disorder | 87 (2013), + 321 % (2002-2013) |

* market entry before 2006

#sales data for Germany, IMS Health, 2002-2013

Deficiencies

- Consumption of approved pharmaceuticals
- Authorization only for new active pharmaceutical ingredients
- Environmental risk assessment not part of benefit-risk assessment of human pharmaceuticals
- Environmental risk assessment is of lesser importance in the benefit-risk assessment of veterinary pharmaceuticals

Change to sustainable consumption is important

- **Powerful authorization process including environmental aspects:**
 - Authorization for **all** active pharmaceutical ingredients
 - Monograph-system for active pharmaceutical ingredients
 - Environmental risk assessment part of risk-benefit analysis of pharmaceuticals
- **Information about environmental risks caused by pharmaceuticals**
- **Debate on increasing use of pharmaceuticals in industrialized countries**
- **Sustainable lifestyle in industrialized countries**

Thank you!

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