

Für Mensch & Umwelt

Umwelt   
Bundesamt

**Sustainable chemistry conference**

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

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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

### 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

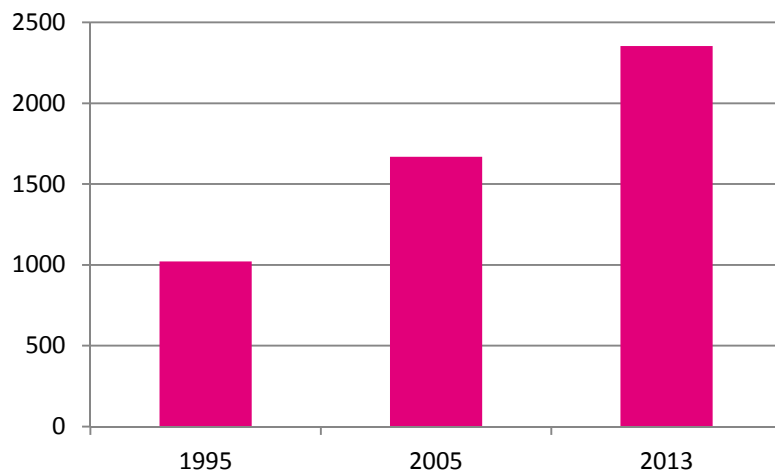
MDG 8: essential medicines

## Antimicrobial resistance



**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 official website of the European Medicines Agency (EMA). At the top, it features the EMA logo and the text 'EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH'. To the right, there is a search bar and social media links. The main navigation bar includes links for Home, Find medicine, Human regulatory, Veterinary regulatory, Committees, News & events, Partners & networks, and About us. The content area is divided into several sections: 'Search for medicines' with a search box, 'Call for civil society members' with a call to action, and 'Find information for...' with links to Patients and carers, Healthcare professionals, Animal health professionals, Pharmaceutical industry, and Media professionals. A 'Latest news' section on the left lists recent updates, including 'Public-friendly information on herbal medicines now available' and 'Calls for civil society members for two EMA committees'.

## The environmental perspective

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

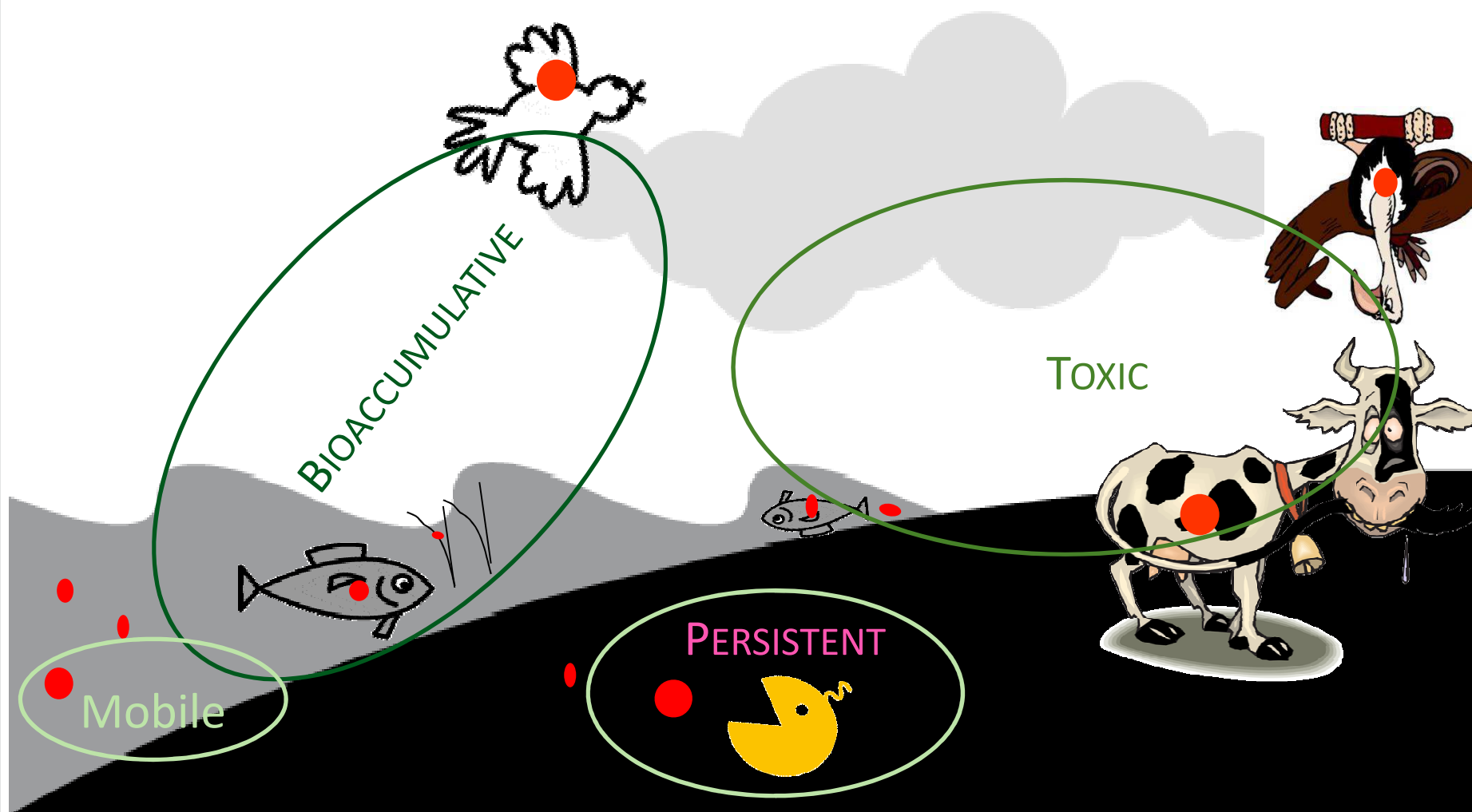
- **sewage effluent,**
- **surfaces waters,**
- **groundwater,**
- **soil,**
- **manure,**
- **biota and even**
- **drinking water**

**in 71 countries.**

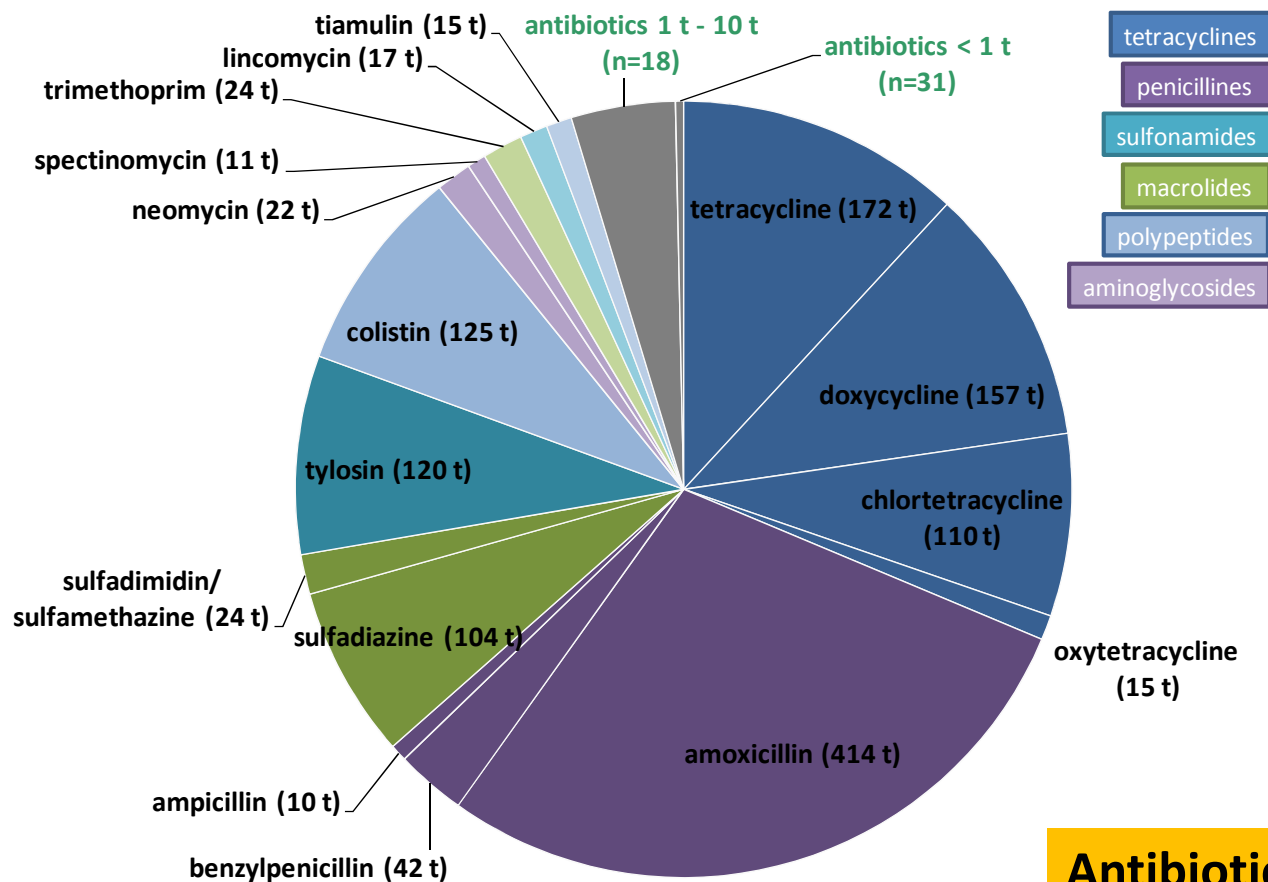
**Global occurrence of pharmaceuticals in many compartments of the environment!**

Result of a research project of the Federal environment agency

## Intrinsic (adverse) properties of active pharmaceutical ingredients



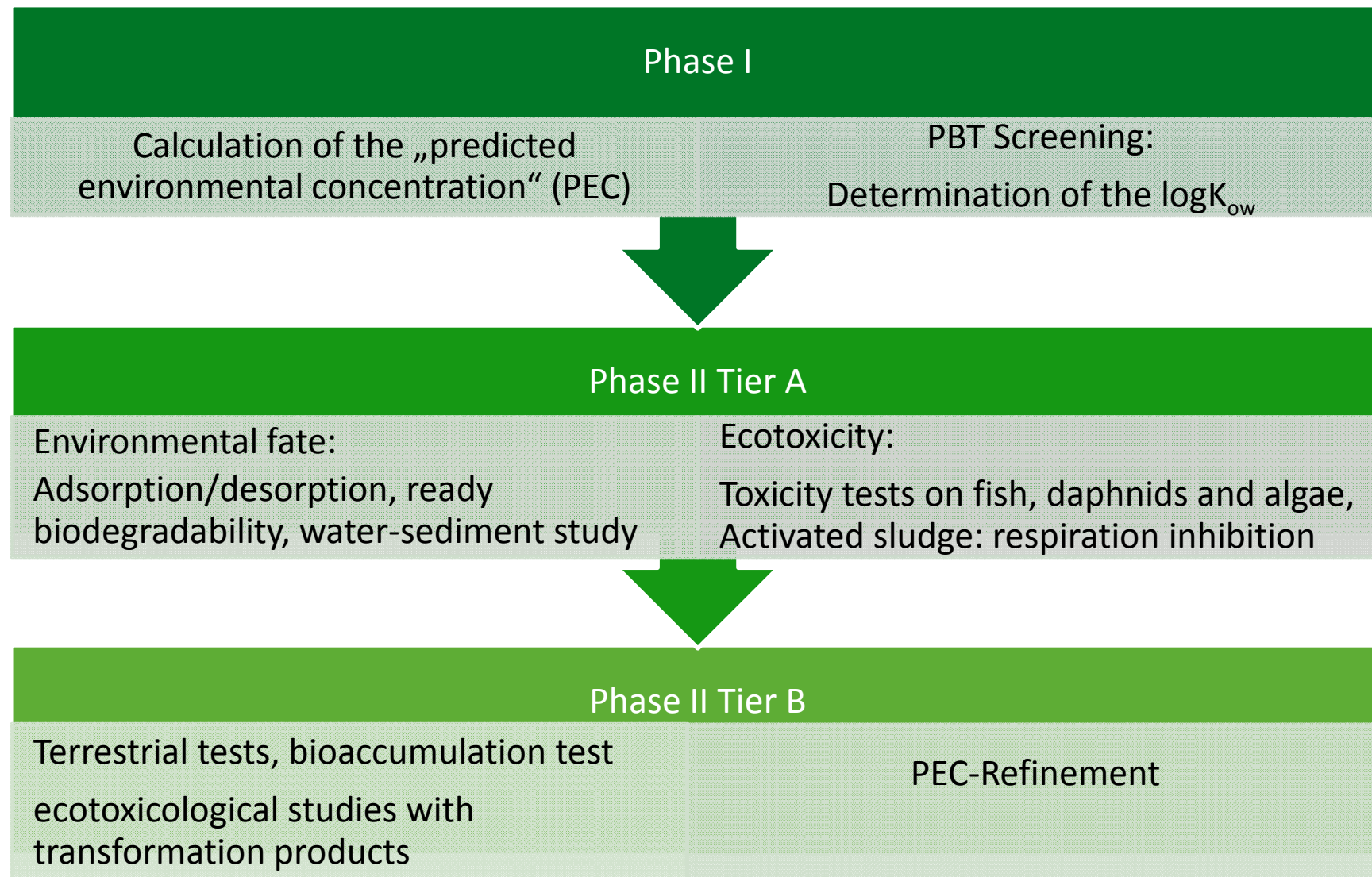
## Does the current consumption of veterinary products induce antibiotic resistance?



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)
lomeprol	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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