The EU-project ERAPharm – incentives for the further development of guidance documents?

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ERAPharm – Environmental Risk Assessment of Pharmaceuticals

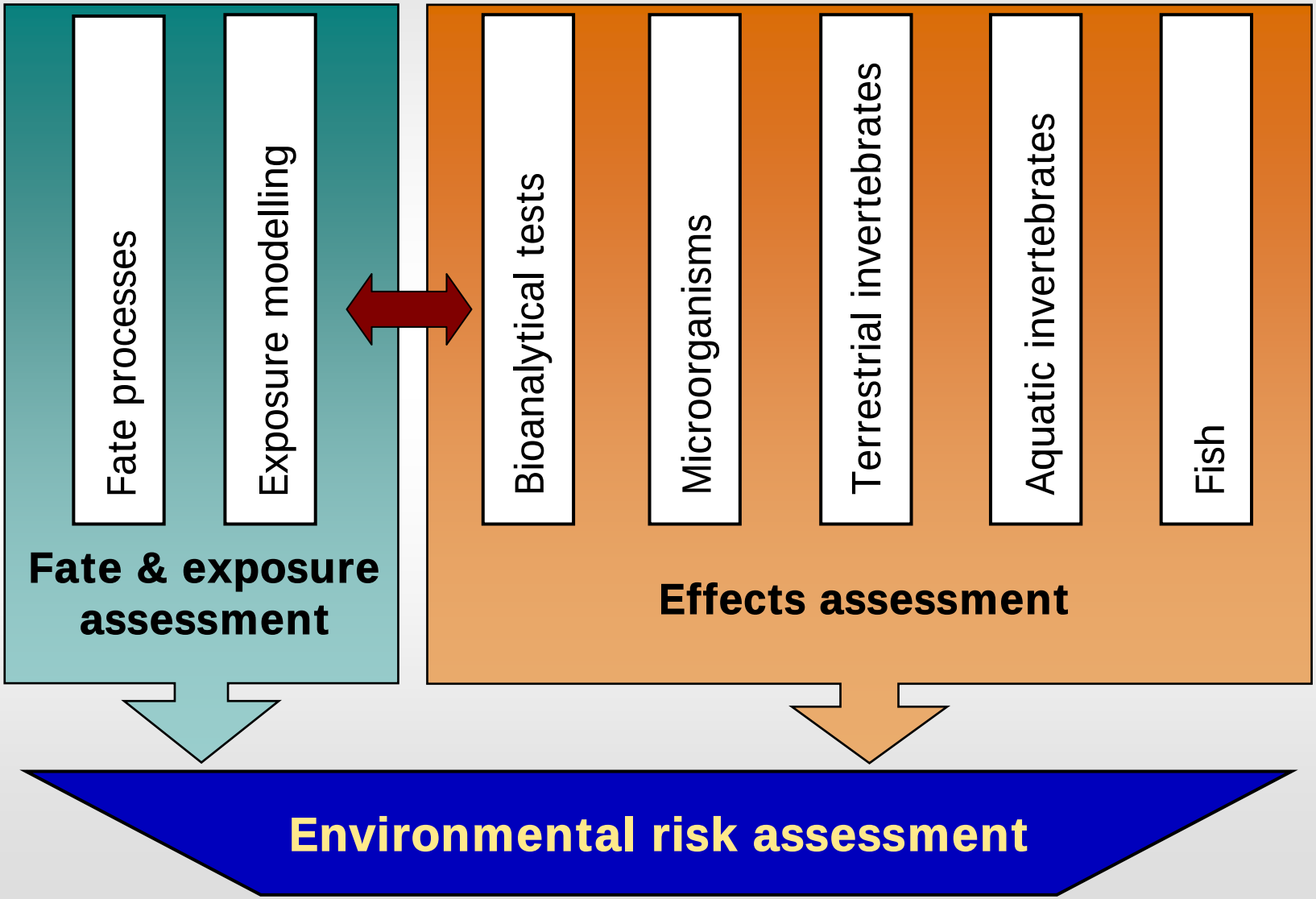
- 6th Framework Programme of the European Commission
- Specific targeted research project
- Priority 1.1.6.3 ‘Global Change and Ecosystems’
- Project duration: 3 years, starting date: 1 October 2004
- 14 Project partners from 8 different countries

The ERAPharm consortium

Overall objective of ERAPharm

To improve and complement existing knowledge and procedures for the environmental risk assessment (ERA) of human and veterinary pharmaceuticals

Structure of the project



Fate and exposure assessment (I)

- Investigation of previously unstudied major exposure routes of pharmaceuticals into the terrestrial and aquatic environment

Input from pasture animals and through application of manure and sewage sludge to land

Photo: J. Römbke

Fate and exposure assessment (II)

- Investigation of factors and processes affecting the behaviour of pharmaceuticals in water, sediment, soil and manure

  Sorption and persistence under laboratory, semi-field and field conditions

- Development of a scenario-based exposure assessment system for predicting concentrations of pharmaceuticals in soils, surface waters and sediments

  Establishment of use and exposure scenarios

  Evaluation and adaptation of process-based fate and transport models

Effects assessment (I)

- Explore the use of bioanalytical assays for initial hazard screening and mode-of-action classification:

  In vitro and low complexity bioanalytical tests covering relevant modes of action

  Test results will be used to target *in vivo* testing


Photo: EAWAG

- Evaluate whether and how information on pharmaco- and toxicodynamics in mammalian species can be used to predict effects in the environment

  Effects in mammals vs. effects in fish


Photo: Brunel University

Effects assessment (II)

- Modify / refine test methods for detecting the effects of pharmaceuticals (i.e. biologically active substances) and

  investigate the effects of environmentally relevant concentrations of pharmaceuticals in the environment

Microbial test systems for investigating the potential of antibiotics to increase the level of resistance genes

Life-cycle and multi-generation tests with aquatic organisms to detect effects of long-term, low-level exposure

Photo: K. Kronenberger

Effects assessment (III)

Tests with dung organisms for investigating the effects of parasiticides

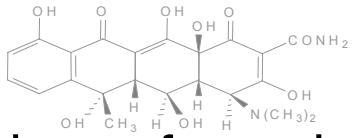
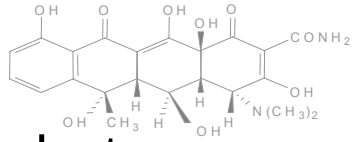
Photo: B. Förster, T. Moser

Multi-species tests with terrestrial invertebrates, e.g. terrestrial model ecosystems

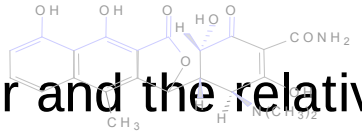
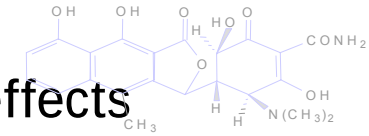
Aquatic microcosm studies

Transformation products

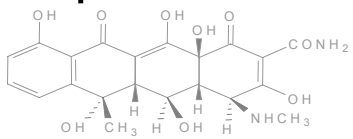
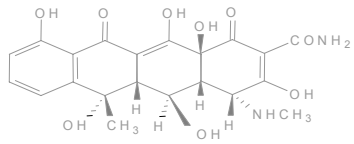
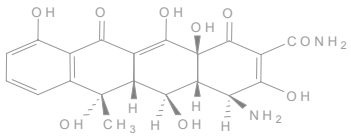
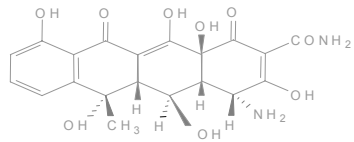
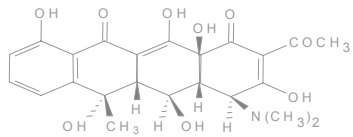
- Explore fate and effects of selected transformation products

Isolation and identification of selected transformation products

Investigation of the relative behaviour and the relative effects of selected transformation products compared to the parent compound

Transformation products of oxytetracycline, B. Halling-Sørensen

Environmental risk assessment (I)

Integration of the approaches developed within fate / exposure and effects assessment into ERA procedures

- Approaches to target the ERA

  Development of approaches to identify environmental compartments at risk

  Evaluation of action limits

  Development of approaches to identify transformation products that require testing

Environmental risk assessment (II)

- Improvement of the exposure assessment

  How to adapt current standard fate studies to more accurately assess the fate of pharmaceuticals?

  Which exposure models should be used at which stage in the ERA process?

  When should higher tier exposure studies be used? How to interpret the data?

Environmental risk assessment (III)

- Improvement of the effects assessment

  How to adapt standard effect studies to more accurately assess the effects of pharmaceuticals?

  Which uncertainty factors should be used for which tests/test endpoints?

  How to assess the significance of resistance to antibiotics?

- Pragmatic approaches for assessing transformation products

Environmental risk assessment (IV)

- Development of improved guidance on the environmental risk assessment of pharmaceuticals

  A web-based database with information on fate and effects of pharmaceuticals

  A web-based screening level risk assessment tool

  Recommendations on the ERA of human and veterinary pharmaceuticals, which will be made available to regulators, industry and the scientific community

  Further development of guidance documents related to Directives 2004/27/EC and 2004/28/EC?

Thanks to

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