

ZEBET's Role as the National Focal Point for Stakeholders: Perspectives of the Federal Ministry of the Environment, Nature Conservation and Nuclear Safety and the Federal Environment Agency

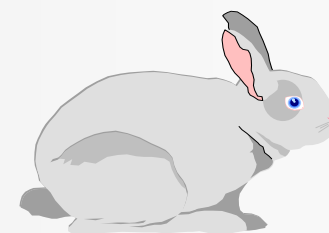
Petra Greiner
Federal Environment Agency, UBA

Retrospectives....

- ...congratulation ZEBET!
- ...thanks for continued efforts and contributions to implement and strengthen the 3 R-principle in regulatory toxicology
- ...

....demanding challenges

- Increased need for assessing hazards and risks of chemicals through life cycle for human health and the environment
- ...requires data and information on substances - majority of (existing) testmethods for toxicological effects with animal tests.



....demanding challenges

➡ Regulations require both: high level of chemicals safety -i.e. increased information on hazard and risks - reduced animal testing

- - REACh (many chemicals)
- - Biocides Directive, New regulation on PPP (new elements)

Role of Zebet

Retro/perspective...

- ...development of alternative / in vitro methods , OECD TGs (human skin models, phototoxicity Test)
- ...coordination and performance of validation studies
- ...“alternatives“ research (incl fundraising, proposals)
- ...Forum for information exchange among Stakeholders - „Bridging role“

3 R's in Environmental toxicology... Role of Zebet

- ...National board for ecotoxicological testing and assessment methods (UBA)
- ...ZEBET participation of the validation study and further development of the Fish Embryo toxicity (FET) test

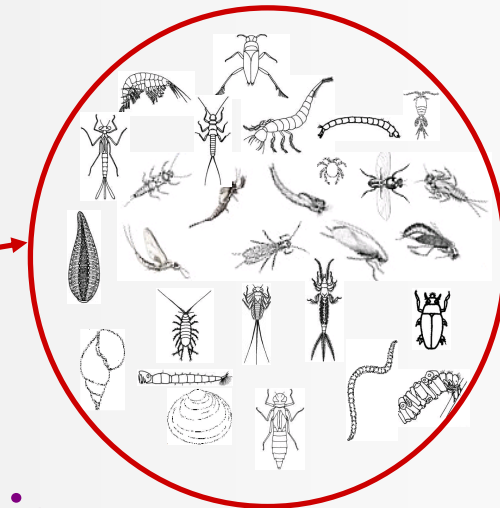
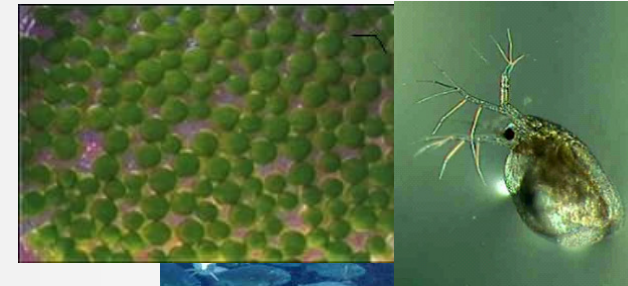
Principles and strategies in the environmental risk assessment

- Usually assessment of individual substances
- Related to environmental compartments (Water, soil, sediments (air))
- Model-assumptions and Labtests extrapolated for expected environmental conditions

Protection goal: ecosystem, protection of species population, maintain biodiversity

Ecotoxicological Effects Assessment

- Tests with single species as surrogate for the biocenosis
- akut / chronic / life cycle



- => *Safety factor for biocenosis*

Need for replacing/refining/reducing vertebrate tests in regulatory ecotoxicology?

- Highest priority: alternative to the acute toxicity tests with fish (OECD TG 203), REACh at 10 t level, Fish embryotests with zebrafish, DE-lead country at OECD TGP, Test prescribed in German waste water legislation

Need for replacing/refining/reducing vertebrate tests in regulatory ecotoxicology?

- Bioaccumulation study with fish (OECD TG 305), REACH at 100 t, PBT-assessment , cut-off criterion new PPP-Regulation.
DE co-lead for revision, a.o. reduced animals due to reduced testdesign.
- Complex challenges: *higher tier* studies
- Endocrine Effects, cut-off criteria PPP regulation, Screening Assays with fish.

Contributions to reduce Animal Tests in regulatory toxicology beyond 3 R's

- Better Use of all available information and data on chemicals incl. across regulations,
- Sharing data among companies to avoid any duplication of animal testing,
- Further development of QSARs, testing strategies and guidance for harmonised assessment and use of data and results



Perspective

Effective Protection of health and environment on adequate Database



Continued replacement of vertebrate animal tests

Delivery of missing data as effective as possible