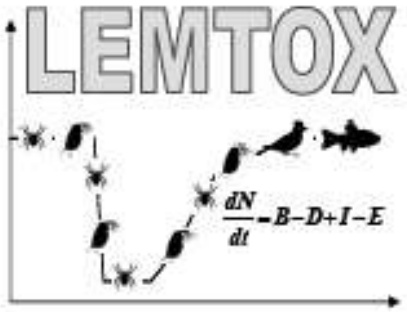
Ecological models in support of regulatory risk assessments of pesticides: Developing a strategy for the future (LEMTOX).



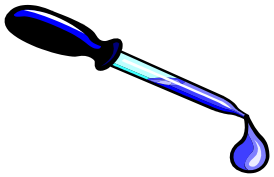
Organising Committee:
Volker Grimm (UFZ), Valery Forbes (Roskilde University), Paul van den Brink (Alterra, WUR), Fred Heimbach (RifCon), Jörn Wogram (Umweltbundesamt), Hans Thulke (UFZ), Pernille Thorbek (Syngenta)
Workshop rapporteur: Udo Hommen (Fraunhofer IME)

LEMTOX purpose and objectives

- 9-12 September 2007, Helmholtz Centre for Environmental Research – UFZ, Leipzig, Germany
- To discuss the role of ecological modeling in risk assessments used in the registration of pesticides
  - the benefits of modeling in the context of registrations,
  - the obstacles preventing ecological modeling being used routinely in regulatory submissions,
  - the actions to enable these obstacles to be overcome.
- Focus on population models such as unstructured population models, stage structured matrix models, and individual/agent-based models.

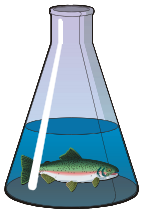
What can ecological modeling do for risk assessment?

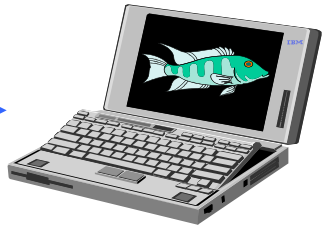
- **EM can bring more ecology into ecological risk assessment**
- **EM can provide an excellent tool for exploring the importance and interaction of ecological complexities**
- **EM can allow integrating exposure – effects – ecology**
- **Can lead to more realistic and thus, better risk assessments**



What are the benefits?

- Before/instead of creating more data.
  - For ranking compounds
  - To focus empirical studies
- For data analysis
  - Mechanistic understanding
  - Hypothesis testing
- In using/interpreting data
  - All kinds of extrapolation





What are the obstacles?

- **Uncertainty about necessary model complexity and availability of ecological parameters**
- **Lack of guidance on model analysis and communication**
  - **Lack of confidence, understanding and transparency**
  - **Time pressures to learn a new tool**
  - **Lack of user-friendly software / standardized models**
  - **Uncertainty on how to treat uncertainty**
- **Difficulty getting agreement on:**
  - **Measurable protection goals**
  - **Species of concern (generic species vs. real species?)**
  - **Geographic and temporal scale**
  - **Degree of generality, precision, and realism**

What actions are needed?

1. **Improve modeling**
   - **Provide guidance for good modeling practice**
2. **Increase confidence**
   - **Apply GMP and make the modeling transparent**
   - **Provide case studies to demonstrate benefits for ERA**
   - **Consider tiered approach starting with standardized models**
   - **Offer training**

LEMTOX Summary Published

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Ecological Models in Support of Regulatory Risk Assessments of Pesticides: Developing a Strategy for the Future

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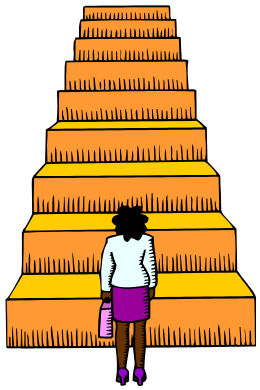
LEMTOX Full Report In Press

Thorbek P, Forbes V, Heimbach F, Hommen U, Thulke HH, van den Brink P, Wogram J, Grimm V, editors. Ecological models in support of regulatory risk assessments of pesticides: developing a strategy for the future. Pensacola, FL, USA: SETAC Press.

Challenges for future

- **We are still facing skepticism from users**
- **Lack of conviction that using models will lead to BETTER risk assessments**
- **Lack of agreement on how models should be incorporated in the overall process**
- **We are not always sure what population-level endpoints we want to protect**
- **Changing how ERAs are done is like turning a supertanker.**

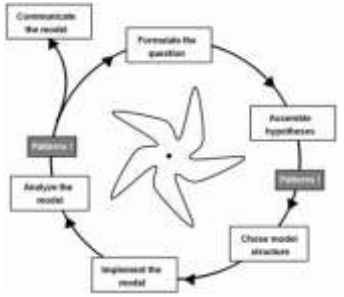


And since LEMTOX?

- **MEMoRisk: SETAC Europe Scientific Advisory Group on Mechanistic Effect Models for Ecological Risk Assessment of Chemicals has been formed.**

- **CREAM: Marie Curie Initial Training Network on Mechanistic effect models for ecological risk assessment of chemicals**

- **RUC09: Workshop on Integrating Population Modeling into Ecological Risk Assessment**



- **CREAM has:**
  - 5 mil EUR
  - A duration of 4 years (Sep 09-Sep 13)
  - 13 partners & 9 assoc. partners
- **CREAM will:**
  - fund 20 PhD students and 3 postdocs
  - formulate and test guidance for Good Modeling Practice using case studies;
  - develop a suite of well-tested and validated mechanistic ecological effect models;
  - provide world class training for the next generation of modelers.

CREAM

RUC 09 Workshop

- Held in Roskilde, DK, 23-25 August, 2009
- Sponsored by RIFM, ECETEOC and RUC
- Brought together ca. 30 stakeholders from industry, regulatory authorities and academia

RUC 09 Workshop

- Aim was to identify priority research questions that stakeholders see as critical to accepting population models as decision tools.
- Building on LEMTOX, we considered site-specific ERAs (Superfund) and REACH, as well as pesticides
- Learned Discourse on workshop submitted to IEAM
- Full workshop conclusions to be published in peer-reviewed journal.
- A ’writing group’ currently working on project proposals to address ’burning’ stakeholder questions.

Needs identified by stakeholders

- Need to know which population-level endpoints should be used for ERA
- Need help to interpret relevance of individual-level effects of e.g., EDs
- Need better inter-species extrapolation
- Need better lab-to-field extrapolation
- Need standard/generic models be developed for ERA
- Need a decision framework for using and selecting models for ERA

Conclusions

- **Population modeling can add value to ERA:**
  - **By reducing uncertainty in extrapolation**
  - **By producing outputs more closely related to protection goals**
  - **By helping to prioritize testing efforts**
  - **By providing mechanistic understanding to aid management**
  - **By providing 'value-relevant' outputs that are needed for socioeconomic analyses**