“Evolution or Revolution – Research priorities for future risk assessment”

Putting ecological realism in environmental risk assessment

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Opening statements

Two years ago, personal view:
- ERA is **not** ... just an extension of HRA using other test species!
  - 2000000 potential targets; different protection goals
- A lot of data... **little knowledge**
- Technology-driven research without clear hypotheses is not helpful
- A lot of science... **no regulatory change?**

Now:
- Views of others... possibilities for progress
- **More than just technical progress** on RA needed

Brussels, November  2012
EU risk assessment s.l.: mainly prescription science

Exposure

- Atmospheric Deposition
- Erosion & Runoff
- Untreated discharges

Predicted Exposure Concentration (PEC)

Effects

- Laboratory studies
- Ecotoxicity tests

Predicted No Effect Concentration (PNEC)

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According to European legislation:

Chemicals shall have no unacceptable effects on the environment;

Aim is to prevent adverse effects on human health and the environment;

...etc., etc.,...

What we measure in practice:

Acute LC50s

Chronic ECx

More of the same (SSDs)

Mesocosm/semi-field effects

We need to make the protection goals operational!

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Figure 3.1 Biological levels of organization. The dimensions of time and space are less important for the investigation up to the levels of populations and biocoenoses.
Regulatory protection goals

- **Plant protection products (directive 91/414/EEC)**
  - “Unacceptable effects” can be decreases in **biodiversity** ...
  - impact on **ecosystem** functioning and functionality ...
  - disappearance of **(populations of)** species with a popular appeal...

- **Biocides (directive 98/8/EEC)**
  - (Maintain) viability of exposed organisms; ..., in practice, the focus is on **ecosystem** structure and function...

- **REACH**
  - (Protect) **(populations of)** most sensitive **species** against effects of long-term exposure

- **WFD**
  - (Maintain) quality of the structure and functioning of aquatic **ecosystems** associated with surface waters

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Something is going on…

Recent years:

- **§1. SCHENIR/SCCS/SCHER** opinion on “Addressing the new challenges for risk assessment” – 2012 –

- **§2. SCHER/SCENIR/SCCS** opinion on “Improvement of risk assessment in view of the needs of risk managers and policy makers” – 2012

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§1: From SS to communities: other endpoints

○ **Mesocosm data and SSDs** are already used successfully in ERA and are powerful tools for improving ecological realism of risk assessment.

○ Improvements are needed: e.g. development of more **standardised methods** capable to produce more reproducible results.

○ Need for their application **in regulatory ERA**:  
  - **improvement of transparency** in the evaluation of the results, reducing the need for expert judgement  
  - development of statistically-based tools capable to **quantitatively assess uncertainties**

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§1: From SS to communities: other endpoints

Single-species vs community response

Versteeg et al, 1996
§1: From SS to communities: other endpoints

Food matters for population dynamics... and tox results

Pieters et al. 2006
§1: Effects assessment for complex exposure patterns

- Currently lacking: accounting for **time and space variability** is a key issue for exposure assessment and for **effect assessment**

- Presently available: **toxicokinetic/toxicodynamic (TK/TD) models** seem to be the most suitable tool available for assessing the effects of variable exposures

- Needed: **improvement of these models** and, in particular, their **experimental validation** with organisms **representative of aquatic and terrestrial biological communities** is a priority for research

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§ 1: Lower hierarchical levels?

- Research using endpoints at the sub-individual level (e.g. biochemistry, ‘omics’ s.l.) is ever increasing field

- However, at present, the relationship between molecular effects and responses at higher hierarchical levels (population, community) is largely unknown; hence the usefulness of molecular approaches in ecological risk assessment remains to be established

- At present, they seem suitable as early warning systems, which need to calibrated against the safe levels needed to protect structure and functions of ecosystems

Brussels, November 2012
§ 1: Ecosystem vulnerability

- The relevance of **vulnerability evaluation for ecological systems** needs to be recognised.

- However, there is the need for tools **capable to express vulnerability in quantitative terms**.

- Some tools are available to quantify vulnerability to specific stress factors and in specific ecosystems (mainly rivers).

- **Research need** for the practical use in ERA: the (further) development, the application and the validation of methods capable to assess vulnerability of aquatic and terrestrial ecosystems to different kinds of stress factors.

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§ 1: Ecosystem vulnerability

Life cycle matters for community dynamics ... and tox results

Fig. 4—Abundance dynamic of two taxa having different life cycles and showing different effect-and-recovery dynamics: short-living multivoltine Chironomidae—strong immediate effect and fast recovery (A), univoltine stonefly Nemoura cinerea (B)—strong delayed effect and slow recovery. The latter species was hardly detectable during summer due to slow egg and larval development. Asterisks indicate significant ($P < 0.05$, ANOVA, confirmed by both Games–Howell and Tamhane post-hoc tests) differences from the controls.
§ 1: Indirect effects

- **Indirect effects due to ecological interactions** are a **key issue** for assessing the ‘real’ consequences of stress factors at the ecosystem level.

- Experiments and community models have demonstrated the importance of indirect effects, but overall knowledge is still poor, particularly for use in risk assessment.

- **Research need:** the development of more comprehensive studies, based on experiments, inverse statistical modelling, and ecological modelling is a key issue for assessing effects at ecosystem level.

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§ 1: Indirect effects

Predation (and competition) matters for community dynamics ... and tox results
The science behind the assessment of effects of several chemicals in combination is sufficient or proposing the introduction of mixture risk assessment in international regulations.

The knowledge on the interactions of toxic chemicals with other potential stress factors is much less developed.

Research need: urgent, considering the relevance of the issue.
Ecological models, often in combination with individual-level effect models like TK/TD or DEB (dynamic-energy budget) models, are the most promising way to fully take into account “ecology” in risk assessment.

Current modelling practice is too diverse and not transparent for regulatory risk assessment.

Good modelling practice is currently under development. A small number of models can already be used, for specific questions.

Conclusion: a concerted action is needed to agree on standard scenarios, ecologically relevant test species and endpoints, acceptance criteria of ecological models.
### § 1: Ecological modelling

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<th>Primary producers</th>
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| \[
\frac{dP_i}{dt} = T_i \cdot \sigma(t) \cdot r_i \cdot P_i \cdot \left(1 - \frac{\sum_j (\alpha_{ij} \cdot P_j)}{\sigma(t) \cdot T_i \cdot K_i}\right) - \sum_k \left(\frac{TT_k \cdot \sigma(t) \cdot g_k \cdot I_k \cdot s_{lk} \cdot P_i}{\sum_j (s_{jk} \cdot P_j) + H_k}\right) + u
\]
| with \[T_i = \left(1 + \left(\frac{c}{EC_{50,P_i}}\right)^{s_{t_i}}\right)^{-1}\] and \[TT_k = \left(1 + \left(\frac{c}{EC_{50,I_k}}\right)^{s_{k}}\right)^{-1}\] |
| and \[\sigma(t) = 1 - a \cdot \frac{2 \cdot \pi \cdot t}{365}\] |

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| \[
\frac{dI_k}{dt} = TT_k \cdot \sigma(t) \cdot e_k \cdot g_k \cdot I_k \cdot \left(\frac{\sum_j (s_{jk} \cdot P_j)}{\sum_j (s_{jk} \cdot P_j) + H_k}\right) - \sum_l \left(\frac{TTT_l \cdot \sigma(t) \cdot g_l \cdot V_l \cdot s_{lk} \cdot I_k}{s_{lk} \cdot I_k + H_l}\right) - \sigma(t) \cdot m_k \cdot I_k + u
\]
| with \[m_k = \max\left(m_{0,k} \cdot \frac{1}{d_{l,k}} \cdot \ln\left(1 + \frac{c}{LC_{50,I_k}}\right)^{s_{k}}\right)\] and \[TTT_l = \left(1 + \left(\frac{c}{EC_{50,V_l}}\right)^{s_{l}}\right)^{-1}\] |

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| \[
\frac{dV_l}{dt} = TTT_l \cdot \sigma(t) \cdot e_l \cdot g_l \cdot V_l \cdot \left(\frac{\sum_k (s_{kl} \cdot I_k)}{\sum_k (s_{kl} \cdot I_k) + H_l}\right) - \sigma(t) \cdot m_l^2 \cdot V_l + u
\]
| with \[m_l = \max\left(m_{0,l} \cdot \frac{1}{d_{V,l}} \cdot \ln\left(1 + \frac{c}{LC_{50,V,l}}\right)^{s_{l}}\right)\] |
§ 1: Ecological modelling

Brussels, November 2012

De Laender et al, 2012
§ 1: Ecological modelling

Control

Exposed to 100 µg/L Zn

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De Laender et al, 2012
§ 1: Ecological modelling
§1: Proposal for an ‘improved’ ERA approach

Current Exposure assessment
- Time variability
- Bioavailability
- Realistic scenarios
- Mixture composition

Ecosystem assessment
- Interactions between chemicals and ecosystem factors
- Ecological interactions, Vulnerability, and Indirect effects

Current Effect assessment
- Higher tier testing
- Effects of variable exposure
- Interactions with environmental factors

Dynamic exposure modelling

Ecological modelling

Ecotoxicologically realistic concentrations
- ERC

Ecologically-based safe concentrations
- EBSC

Ecologically Based Risk Characterisation
- ERC/EBSC

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§2: Opinion on “Improvement of risk assessment in view of the needs of risk managers and policy makers”

Aims:

- **reviewing** the current risk assessment (RA) practices

- exploring **what risk managers and policy makers need** from risk assessment

- identifying approaches to risk assessment that can provide results which are based on **the best available science and which are informative, consistent, transparent and easy to interpret and communicate**

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§2: Opinion on “Improvement of risk assessment in view of the needs of risk managers and policy makers”

Aims & procedure:

- Starting point: assessment, through a survey, of needs of managers and policymakers recognizing that risk assessment makes little sense unless it is effectively informing the management process.

- Working Group has also been sensitive to the continuing need to ensure that while assessment should be informed by the needs of management they should not be biased by them.
§2: Opinion on “Improvement of risk assessment in view of the needs of risk managers and policy makers”

Main conclusions:

○ Two important messages from risk managers and policymakers: **outputs of risk assessment need to be more policy and management relevant** and this ought to be facilitated by more dialogue

○ “Management relevant” risk assessments need to **inform cost/benefit analyses**

○ Considerable confusion on the needs that socio-economic analysis put on risk assessment and that to be **more useful... risk assessments should be expressed (whenever appropriate) in terms of value-relevant impacts on humans and ecosystems** rather than in terms of the somewhat technical surrogates often used in the routine risk characterizations

Brussels, November 2012
§2: Opinion on “Improvement of risk assessment in view of the needs of risk managers and policy makers”

Main conclusions:

○ A key recommendation, **express risk in terms of likely impacts on human health and ecosystem services** rather than in terms of the more prevalent risk characterizations

○ To make this change: more **dialogue between risk assessors and socio-economists**

○ Expressing risk in terms that matter for the regulators will also facilitate communication

○ Improving risk assessment reports in terms of: including the evaluation of different possible scenarios; making full characterization of the whole populations/ ecosystems at risk with clear expressions of uncertainty

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Conclusions…

- A lot of new ERA science, but unnoticed by regulatory arena...
- Some, but not all, ready for use...
- Communication effort and dialogue with users of Ras needed
- In theory... we have the right paradigm... but, we need a shift.. Now!

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