Ecological Risk Assessment in the EU, including EUFRAM

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Ecological Risk Assessment Workshop,
Beijing (China), September 2012
Contents

1. Introduction
2. General Risk Assessment
3. European Union
4. Tiered Approach
5. Environmental Risk Assessment
6. Mathematical Modeling
7. Effect Assessment
8. Conclusions
The difference between RISK and HAZARD

Hazard

Risk management

Zero risk?

...impossible!

No animals were harmed in the making of this cartoon.
General Risk Assessment

Exposure estimation

Data evaluation

Hazard identification
Dose-response assessment

Data set

Emission rates

Environmental distribution

Exposure levels, concentrations, intakes

Toxicity data single species

Extrapolation

No-effect levels

Risk characterisation

(P)EC/PNEC, MOS, TER
Areas of Application

● Industrial Chemicals (REACH), tool: EUSES

● Pesticides, tools: FOCUS and Guidance Documents

● Biocides (non-agricultural): tools: EUSES and ESDs

● Veterinary medicines (environmental side effects)

● Human medicines (environmental side effects)

● Ballast Water (human, environment, ship)
Types of Risk Assessment

- Relation application and characteristics related to:
  - Public health
  - Private applicant
  - Professional applicant
  - Bystanders
  - Environment

- Active substance/organism, metabolites and the product

- Taking into account:
  - Type of product (spray liquid, seed dressing, granulate, gas)
  - Mode of application (spraying, pouring)
  - Time of application (spring, autumn; use phase, application phase, waste phase)
  - Place of application (crop, home, greenhouse, other)
Protection Target Groups

● **Environment**
  - Aquatic ecosystem
  - Terrestrial ecosystem
  - Sediment ecosystem
  - Predators (through worms and fish)
  - Micro-organisms in STP

● **Human**
  - Direct at the workplace
  - Direct through use of consumer products
  - Indirectly via the environment
Topics

Compartments:

- Soil
- Groundwater
- Surface water
- Air

Organisms:

- Aquatics organisms
- Terrestrial vertebrates
- Soil microflora
- Earthworms
- Non-target arthropods
- Honeybees
- Non-target higher plants
Environmental distribution

- CROPS
- AIR
- SOIL
- SURFACE WATER
- GROUND WATER
- DRINKING WATER
- Distribution
Environmental distribution and exposure to organisms

- Air
- Soil
- Surface water
- Ground water
- Crops
- Bees/insects
- Terrestrial organisms
- Birds/mammals
- Humans
- Drinking water

Distribution → Exposure
Emission – Distribution – Exposure

Emission

- AIR
- SOIL
- SURFACE WATER
- GROUND WATER

Distribution

- CROPS
- BEES/INSECTS
- TERRESTRIAL ORGANISMS
- WATER ORGANISMS
- DRINKING WATER

Exposure

- BIRDS/MAMMALS
- HUMANS
- TERRESTRIAL ORGANISMS

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Including emissions, example pesticides

- SPRAY
- SEED TREATMENT
- GRANULES
- AIR
- SOIL
- SURFACE WATER
- GROUND WATER
- CROPS
- BEES/INSECTS
- BIRDS/MAMMALS
- TERRESTRIAL ORGANISMS
- HUMANS
- WATER ORGANISMS
- DRINKING WATER

Emission → Distribution → Exposure

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European Union

- Pesticide Legislation
  - 1991: placing pesticides on the market: 91/414/EC
    - Examples:
      - FOCUS Groundwater Scenarios (2001)
      - Guidance on Aquatic Ecotoxicology (2001)
      - Guidance on Terrestrial Ecotoxicology (1999)

- Active Substances centralized, Products by Member States
Three zones in the EU, Regulation 1107/2009

● Zone A — North
The following Member States belong to this zone:
  – Denmark, Estonia, Latvia, Lithuania, Finland, Sweden

● Zone B — Centre
The following Member States belong to this zone:
  – Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom

● Zone C — South
The following Member States belong to this zone:
  – Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal
FOCUS

*FO*rum for the *Co-ordination of pesticides fate models and their USE*

- **EU initiative (DG SANCO)**
  - PECs based on community level validated models
- **Support: Commission and ECPA**
- **Participation:**
  - Registration Authorities
  - Academia & Research
  - Industry
- **Limited to exposure analysis**
- **Purpose: PEC estimation for Annex I listing**
- **Products: Guidance documents**
Environmental Risk Assessment

Modeling Tiers

I
Simple screening model, key environmental fate, and maximum label use rate

II
Process-based model; standard exposure scenarios with regional representation

III
Process-based model; spatial/temporal exposure evaluation

IV
Combined modeling and monitoring to meet specific regulatory needs

Cost/data increase
Conservatism increase
Tiered System

- **STEP 1:** single application, fixed scenario
- **STEP 2:** Multiple application, regional variation in Europe
- **STEP 3:** Advanced modelling specific European Scenarios
- **STEP 4:** Site specific calculation
Example RA

- **Assessment of surface water**
  - Exposure
    - Emission
    - Distribution
    - Concentrations

- **Assessment of aquatic organisms**
  - Hazard
    - Single species
    - Extrapolation
    - No effect concentrations

- **Comparison**
Data Set

- Application
- Physico-chemical characteristics
- Fate and behaviour (tiered)
- (Eco)toxicity (tiered)
- Residues (crops)
- Quality (GLP, GIGO)
- Evaluation (choosing RA data)
- Scenarios (protection goals)
Application

- Active Substance
- Dose
- Frequency
- Interval
Emission

Distance from crop to top of bank
Distance from top of bank to water
Width of water body
Distance from crop to far edge of water
Distance from crop to near edge of water

Drift

DOSE

Soil

Crop-

inter

cep-
tion

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### Fixed characteristics

#### Dimensions

<table>
<thead>
<tr>
<th>Type of water body</th>
<th>Width (m)</th>
<th>Total length (m)</th>
<th>Distance from top of bank to water (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ditch</td>
<td>1</td>
<td>100</td>
<td>0.5</td>
</tr>
<tr>
<td>Pond</td>
<td>30</td>
<td>30</td>
<td>3.0</td>
</tr>
<tr>
<td>Stream</td>
<td>1</td>
<td>100</td>
<td>1.0</td>
</tr>
</tbody>
</table>

#### Sediment Characteristics

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration of suspended solids in water column (mg.L⁻¹)</td>
<td>15</td>
</tr>
<tr>
<td>Sediment layer depth (cm)</td>
<td>5</td>
</tr>
<tr>
<td>Organic carbon content (%)</td>
<td>5</td>
</tr>
<tr>
<td>Dry Bulk density (kg.m⁻³)</td>
<td>800</td>
</tr>
<tr>
<td>Porosity (%)</td>
<td>60</td>
</tr>
</tbody>
</table>
Interaction of Models

1. **FOCUS**
   SWASH

2. **FOCUS**
   Spray Drift Calculator

3. **FOCUS**
   MACRO

4. **FOCUS**
   PRZM

5. **FOCUS**
   TOXSWA

6. Output file
Output Exposure Assessment

PEC
- PEC0 = Initial PEC
- PEC1
- PEC2
- PEC4
- PEC7
- PEC14
- PEC21
- PEC28
- PEC42
- PEC50
- PEC100

TWAEC
- ---
- TWAEC1
- TWAEC2
- TWAEC4
- TWAEC7
- TWAEC14
- TWAEC21
- TWAEC28
- TWAEC42
- TWAEC50
- TWAEC100

short

long
Exposure Example

PEC Calculation F-D2-S-A

PEC (microgram/L or /kg)

PEC water
TWAEC water
PEC sediment
TWAEC sediment

Days

PEC (microgram/L or /kg)

0 20 40 60 80 100 120

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Tier 1: Aquatic Effect Assessment

Acute
● 96-h EC50 algae
● 48-h EC50 daphnids
● 96-h LC50 fish

Chronic
● 4-d NOEC algae
● 21-d NOEC daphnids
● 28-d NOEC fish
Aquatic Effect Assessment (2)

- Tier 2
  - Laboratory
    - More single species studies
    - Early Life Stage test
    - Full Life Cycle test
  - Semi field
    - Microcosm studies
    - Mesocosm studies
  - Field
    - Field studies
    - Monitoring
    - Recolonization studies
    - Recovery studies

Endpoint?
Extrapolation

- Species
- Community
- Ecosystem
- Safety factor or Assessment factor
  - Intraspecies (10)
  - Interspecies (10)
  - Lab to field (10)
- Safe concentration
  - i.e. $\text{PNEC}_{\text{ecosystem}}$ or $\text{PNEC}_{\text{species}}$

$10 \times 10 \times 10$
Assessment Factors (EU, PPP)

<table>
<thead>
<tr>
<th># of Aquatic tests</th>
<th>AF</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 short term L(E)C50 (fish, <em>Daphnia</em>, algae)</td>
<td>100</td>
</tr>
<tr>
<td>3 long term NOECs (fish, <em>Daphnia</em>, algae)</td>
<td>10</td>
</tr>
<tr>
<td>Field data (*)</td>
<td>Case-by-case</td>
</tr>
</tbody>
</table>

(*) proposals by HARAP (1999) and CLASSIC (2001)
# Assessment Factors (TGD)

<table>
<thead>
<tr>
<th># of Aquatic/Terrestrial Tests</th>
<th>AF</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 short term L(E)C50 (fish, <em>Daphnia</em>, algae)</td>
<td>1000</td>
</tr>
<tr>
<td>1 long term NOEC (either fish or <em>Daphnia</em>)</td>
<td>100</td>
</tr>
<tr>
<td>2 long term NOECs (from 2 trophic levels)</td>
<td>50</td>
</tr>
<tr>
<td>3 long term NOECs (from 3 trophic levels)</td>
<td>10</td>
</tr>
<tr>
<td>Field data</td>
<td>Case-by-case</td>
</tr>
</tbody>
</table>
Predicted No-Effect Concentration (PNEC)

- Acute and/or chronic
- Most sensitive species
- Related to duration of study
- Example (hypothetical):
  - Fish: 96h-LC50=0.5 and 0.15 mg/L
  - 28d-NOEC=0.01 and 0.06 mg/L
  - Daphnia: 48h-EC50=0.13 mg/L
  - 21d-NOEC=0.05 mg/L
  - Algae: 96h-EC50=100 mg/L
  - 96h-NOEC=40 mg/L
Formulae

**Acute**

\[ \text{PNEC}_{\text{acute}} = \frac{L(E)C50}{\text{AF}_{\text{acute}}} \]

**Chronic**

\[ \text{PNEC}_{\text{chronic}} = \frac{\text{NOEC}}{\text{AF}_{\text{chronic}}} \]

With: \( \text{AF}_{\text{acute}} = 100 \) and \( \text{AF}_{\text{chronic}} = 10 \)
Output Effect Assessment

- $L(E)_{50}^{\text{most sensitive species}}$
  \hspace{1cm} 48h-EC50($Daphnia$) = 0.13 mg/L

- $\text{PNEC}_{\text{acute}}$
  \hspace{1cm} = 0.0013 mg/L

- $\text{NOEC}_{\text{most sensitive species}}$
  \hspace{1cm} 28d-NOEC(fish) = 0.01 mg/L

- $\text{PNEC}_{\text{chronic}}$
  \hspace{1cm} = 0.001 mg/L

- $\text{PNEC}_{\text{ecosystem}}$
  \hspace{1cm} = 0.0001 mg/L
Risk Characterisation

- Comparison of estimated concentration and effect concentration
- Risk ratios:
  - PEC/PNEC (OECD)
  - TER (EU)
  - Acute
  - Chronic

\[
\frac{\text{InitialPEC}}{\text{PNEC}_{\text{acute}}} < 1
\]

\[
\frac{TWAEC}{\text{PNEC}_{\text{chronic}}} < 1
\]
Decisive Ratios

\[
\frac{PEC_{\text{acute}}}{PNEC_{\text{acute}}} = \frac{\text{InitialPEC}}{L(E)C50} < 0.01
\]

\[
\frac{PEC_{\text{chronic}}}{PNEC_{\text{chronic}}} = \frac{\text{TWAEC}^{4,21,28}}{\text{NOEC}^{4,21,28}} < 0.1
\]
Risk management & Risk Mitigation

- Exposure assessment
  - More realistic modelling (assumptions)
  - Monitoring

- Hazard assessment
  - Micro- or mesocosm studies

- Mitigation measures
  - No crop zones (drift reduction)
  - Limit use area (emission reduction)
  - Additional toxicity data (assessment factor reduction)
  - Probabilistic risk assessment (increase of realism)
Conclusions

- Straightforward with possibilities for increasing realism
- Clear decision making criteria
- Well documented and scientifically sound
- Still some gaps identified
  - Compartment air
  - Terrestrial ecosystem
- State of the art
- Mechanism for updating
- Widely accepted in EU
Information

http://viso.ei.jrc.it/focus/index.html
EUFRAM

- EU-funded “concerted action” project
- Project consortium comprises 29 organizations including regulatory authorities, government research institutes, agrochemical companies, consultancy companies and universities
- Aim is to assist the implementation of probabilistic methods for assessing the environmental risks of plant protection products in Europe
- Output
  - a framework of basic principles and methods for probabilistic assessment, together with selected examples, providing more detail on selected aspects of probabilistic approaches,
  - detailed case studies developed or evaluated during the project
- EUFRAM does not have a formal status in relation to Directive 91/414/EEC; the report should not be regarded as formal guidance
What is probabilistic risk assessment?

- EUFRAM defines probabilistic risk assessment as:
  - Risk assessments that use probabilities or probability distributions to quantify one or more sources of variability and/or uncertainty in exposure and/or effects and the resulting risk
  - and subsequently:
    - Variability is defined as *Real variation in factors that influence risk*
    - Uncertainty is defined as *Limitations in knowledge about factors that influence risk*
    - Probability is defined as its *Frequency in repeated independent trials that it will occur and expressed as a proportion*
    - Probability distribution is a *graph showing the relative probabilities of different values of a variable*
    - Probabilistic risk assessment is defined as *the process of using probabilities and probability distributions to take account of variability and uncertainty in risk assessment*
The basic steps of a probabilistic assessment

● Define the objective of the assessment and decide what form of probability or distribution is required for the assessment output;

● Identify one or more inputs to the risk assessment, for which variability and/or uncertainty is to be considered, and quantify them using appropriate probabilities or distributions;

● Use appropriate methods to combine the different input distributions and produce the distribution for the assessment output, showing the variability and uncertainty of the predicted impacts.

● Interpret and communicate the results
Potential benefits of quantifying variability

- Increased realism through representing more fully variation in the real world and its influence on the risk
- The opportunity to replace worst-case assumptions with more realistic ones
- May be a more cost-effective option for refining the assessment than conducting higher tier laboratory or field studies
- Makes more use of the available data (i.e. variances or individual data points).
Potential benefits of quantifying uncertainty

- Provides an objective basis for discussions about reducing uncertainty factors (e.g. the TER thresholds of 10 and 100) when additional data is provided
- Provides an indication of the combined influence of the quantified uncertainties on the assessment outcome
- By identifying major sources of uncertainty, it may help the targeting of higher tier studies so as to maximize their cost-effectiveness in reducing uncertainty
Potential disadvantages of probabilistic approaches

- A lack of reliable information for specifying distributions of many input parameters,

- Concerns about the validity of assumptions (e.g. representativeness of tested species),

- The lack of common standard methods for the statistical calculations
Potential Output (1)

CDF for hazard, SSD

16% of species have no-effect concentrations at or below the predicted environmental concentration of 316 µg/l

i.e. this PEC will affect 16% of species
Potential Output (2)

CDF for exposure

84% of water bodies have predicted environmental concentrations equal to or less than the no-effect level of 100 μg/l

So, by subtraction, 16% of water bodies have PECs greater than the NOEC
Potential Output (3)

Two CDFs, one for exposure and one for effects

92% of water bodies have equal to or less than 10% of species affected (i.e. exposed above their NOEC)

So, 8% of water bodies have more than 10% of species affected
Potential Output (4)

Single CDF for “risk” or impacts

10% of water bodies have equal to or less than 10% of species affected (i.e. exposed above their NOEC)

So, 90% of water bodies have more than 10% of species affected
Conclusions

- EUFRAM shows the possibilities of Probabilistic Risk Assessment
- Method is still under development
- Not adopted as an official tool in the EU
- Hesitations by decision makers about the usefulness and status of development