Protection goals and conceptual models: How science can support risk managers on what to protect?

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TSW on Soil Risk Assessment
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INTRODUCTION TO TOPIC I

Problem Definition and Conceptual Model for Soil Risk Assessment

- Protections goals and ecological relevance
  - Setting Specific Protection Goals through ecosystem services
  - EFSA approaches and future developments

- Soil risk characterisation and environmental impact assessment.
  - Screening/lower tier: applicability of EPM
  - Higher tiers: SSD; ecological modelling
  - Current approaches (R/B/P): similarities, divergences, harmonisation
  - Update/integration of the conceptual model
GENERAL PROTECTION GOALS IN THE REGULATION

REACH & PPPR: The purpose of this Regulation is to ensure a high level of protection of ... the environment

BPR: ... improve the functioning ... whilst ensuring a high level of protection of ... the environment.

- REACH Regulation
  - Place on the market or use ... do not adversely affect ... the environment
  - Risk to the environment ... adequately controlled if the exposure levels do not exceed the PNEC

- Pesticides/ Biocides
  - Unacceptable effects on the environment:
    - Fate and distribution in the environment, contamination of water/air/soil (also following long-range environmental transport).
    - Impact on non-target organisms
    - Impact on biodiversity and the ecosystem.
UNACCEPTABLE EFFECTS ON THE ENVIRONMENT

REACH: PEC>PNEC

BIOCIDES: basic tool for decision-making is the PEC/PNEC ratio

- Non-target organisms: **PEC/PNEC ratio greater than 1**
- Soil: the *foreseeable concentration* of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in soil, has an unacceptable impact on non-target species, *unless* it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

PESTIDES: Uniform Principles define the lower tiers, unacceptable if

- Earthworms: **toxicity/exposure ratio** less than 5 (chronic); *unless* under field conditions earthworm populations are not at risk.

- Non-target soil micro-organisms: **nitrogen mineralisation processes affected** by more than 25% after 100 days; *unless* under field conditions there is no unacceptable impact on microbial activity, ..., taking account of the ability of micro-organisms to multiply.
CURRENT REGULATORY APPROACH

- General protection goals in the regulation, with limited information on acceptability

**Generic protection**

- REACH: Threshold option is clearly indicated → risk characterisation based on PNEC

**Focus on Non-target organisms**

- Pesticides: Lower tiers defined, unless clauses allows higher tier with no specific indication on level of protection
- Biocides: risk characterisation based on PNEC, but also unless clause for soil
CURRENT REGULATORY APPROACH

By compartment
- REACH: Threshold PNEC soil

Non-target organisms
- Pesticides
- Biocides

Actual levels of protection mostly defined by the scenarios and approaches described in the guidance documents (PEC estimations, AFs, RMMs, etc.)
ERA scientific challenges for regulated products

• High complexity in defining what is an “environmental harm”
  – Define environmental values to be protected
  – Acceptable level of change, location and timelines

• Variability and diversity are intrinsic elements
  – Natural vs. anthropogenic changes (spatial and temporal)
  – Expected consequences of human changes: indirect and secondary consequences, resilience, redundancy

• Particularly difficult for modified agro-ecosystems
EFSA PPR PANEL APPROACH

General vs. Specific protection goals

- **General protection goals:** overall goals to be achieved as required by the EU legislation to protect human health and the environment from unacceptable impacts of pesticides

- **Specific protection goals:** defined by:
  - the **entities** that need to be protected,
  - the **attributes** and/or **functions** of those entities,
  - the **magnitude, temporal and spatial scales** of effects on these attributes and/or functions that can be tolerated without impacting the general protection goal
  - the required **degree of certainty** with which the protection goal defined should be achieved.
ECOSYSTEM SERVICES: MAES CONCEPTUAL FRAMEWORK

- **Ecosystems**
  - functions
    - ecological processes
    - functional traits
    - biophysical structures
    - species richness
    - biotic interactions
    - genetic diversity

- **Biodiversity**
  - Present and future state

- **Ecosystem services**
  - Human well-being
    - Benefits
      - Nutrition, clean air and water
      - Health, safety, security
      - Enjoyment, ...
    - Value
      - Economic value
      - Health value
      - Shared (social) value
      - Other values
  - Drivers of change
    - Institutions, businesses
    - Policies (agriculture, forestry, fishery, environment, ...)
    - Stakeholders and users
  - Response
    - Human well-being
    - Value
    - Drivers of change
    - Ecosystem services
  - Other capital inputs

- **Socio-economic systems**
PPR PANEL APPROACH

Development of Specific protection goals

1. Ecosystem services as overarching concept
2. Identify relevant services likely to be impacted by pesticides
3. Identify **key drivers** (taxonomic or functional groups) that provide the service
4. Specify **dimensions** of protection goals for each service-driver combination
   - Define protection goal based on **tolerable effect range** and in **measurable** way
5. Identify **vulnerable representatives** for each key driver
6. Develop **risk assessment scheme**
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How to link the Ecosystem Services approach in the Risk Assessment Scheme?
INTEGRATION INTO THE RISK ASSESSMENT
- The provision of the service is relevant for the exposed area
- The service provided units may be affected by the assessed agent
- E.g. for the assessment of pesticides in the agricultural landscapes:

<table>
<thead>
<tr>
<th>Ecosystem Service category</th>
<th>In crop areas</th>
<th>Off crop areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provisioning</td>
<td>Food</td>
<td>Food</td>
</tr>
<tr>
<td></td>
<td>Fibre &amp; fuel</td>
<td>Genetic resources</td>
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<tr>
<td></td>
<td></td>
<td>Fresh water</td>
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<tr>
<td>Regulating</td>
<td>Pollination</td>
<td>Pollination</td>
</tr>
<tr>
<td></td>
<td>Pest &amp; disease regulation</td>
<td>Pest &amp; disease regulation</td>
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<td>Water regulation</td>
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<td></td>
<td>Erosion regulation</td>
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<tr>
<td></td>
<td></td>
<td>Water purification</td>
</tr>
<tr>
<td>Cultural</td>
<td>Education &amp; inspiration</td>
<td>Education &amp; Inspiration</td>
</tr>
<tr>
<td></td>
<td>Recreation &amp; ecotourism</td>
<td>Recreation &amp; ecotourism</td>
</tr>
<tr>
<td></td>
<td>Cultural heritage</td>
<td>Cultural heritage</td>
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<tr>
<td></td>
<td></td>
<td>Aesthetic value</td>
</tr>
<tr>
<td>Supporting</td>
<td>Primary production</td>
<td>Primary production</td>
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<tr>
<td></td>
<td>Photosynthesis</td>
<td>Photosynthesis</td>
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<tr>
<td></td>
<td></td>
<td>Habitat provision</td>
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<tr>
<td></td>
<td></td>
<td>Soil formation and retention</td>
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<tr>
<td></td>
<td></td>
<td>Nutrient cycling</td>
</tr>
<tr>
<td></td>
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<td>Water cycling</td>
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PPR PANEL APPROACH

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**From theory...**

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... to implementation
PROPOSED METHODOLOGY

Services → Taxa → Services → Key drivers → Dimensions → Vulnerable Species/Functions

FIVE DIMENSIONS + Degree of uncertainty

Ecological entity:
  individual – (meta)population – functional group – ecosystem

Attribute:
  behaviour – survival/growth – abundance/biomass – process – biodiversity

Magnitude:
  negligible effects – small effects – medium effects – large effects

Temporal scale:
  days – weeks – months – seasons - over one year

Spatial scale:
  in crop – edge of field – nearby off-crop – watershed/landscape
PPR PANEL APPROACH

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From the problem formulation to the SPGs conceptual model
## PROPOSED METHODOLOGY

![Diagram showing the relationship between services, taxa, key drivers, dimensions, and vulnerable species/functions.]

<table>
<thead>
<tr>
<th>Key driver</th>
<th>Ecosystem service</th>
<th>Legal requirement</th>
<th>Specific protection goal</th>
<th>Ecological entity</th>
<th>Attribute</th>
<th>Calculation of magnitude of impact</th>
<th>Spatial scale of impact</th>
<th>Temporal scale of impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbes</td>
<td>- nutrient cycling - water purification/soil remediation/waste treatment - soil formation and retention</td>
<td>no unacceptable effects</td>
<td>no unacceptable effects on functions of microbial communities</td>
<td>functional groups</td>
<td>functions</td>
<td>negligible effects to medium effects</td>
<td>field to landscape</td>
<td>weeks in fields to days in off crop areas</td>
</tr>
<tr>
<td>Non-arthropod invertebrates (terrestrial), including earthworms</td>
<td>- food - genetic resources - education an inspiration</td>
<td>no decrease of biodiversity</td>
<td>no decrease of biodiversity in the landscape, temporary impact on local populations</td>
<td>metapopulation</td>
<td>species diversity, species abundance (survival and reproduction)</td>
<td>locally small effects but negligible effects in protected areas and landscape</td>
<td>field to landscape</td>
<td>weeks in field and edge of field and no to days in protected areas and landscape</td>
</tr>
</tbody>
</table>
SPATIAL SCALE DEPEND ON THE SERVICE

Spatial and temporal scales
- Abiotic parameters (e.g., soil, climate or stream properties)
- Agronomic parameters (e.g., crop, irrigation or landscape structure)
- Biotic parameters (e.g., competition or predation)

Environmental scenario

Region
- Agricultural Landscape
  - In-Crop
    - Field margins
  - Edge of the field surface water
  - Off-Crop
    - hedges
  - Natural patches
  - Large surface water bodies
- Urban Landscape
- Industrial Landscape
- Natural Landscape
EFSA proposed approach: focus on reference tiers

1. Core toxicity data (Simple, few data)
2. Toxicity tests with additional species and/or refined exposure and Toxicodynamics-Toxicokinetics models (Intermediate Tiers)
3. Population and community experiments and models
4. Field studies and landscape level models (Higher tier)

Current approach

Proposed approach SPG
EFSA proposed approach: focus on reference tiers

Data for selection of representative reference tiers

Experimental/modelling tools available for assessing the impact on SPGs

Reference Tier

Calibration of lower tiers by reference tier

Intermediate Tier(s)

First Tier

Reference tier allows to link the ERA with specific protection goal

Data for calibrating lower tiers ensuring sufficient level of protection

General protection goal

Specific protection goal consistent with general goals

Specific protection goal
IN CONCLUSION, FOR PESTICIDES

- Ecosystem Services are used for setting Specific Protection Goals
- The aim is to ensure the protection of relevant services, including biodiversity, for the level of protection decided by risk managers
- The attributes and links are adapted to the ecological role of each non-target group as services providers
- Realistic reference tiers are used for calibration of lower tiers, offering options (e.g. recovery)
- The next step is moving to landscape assessments
First set: Protection Goals

- Relevance of setting Specific PGs under REACH and BPR for soil organisms
- Relevance of the ecosystem services approach
- Where would harmonisation of the approaches bring added value in the soil risk assessment?

Proposed issues for further discussion

- Similarities and differences
- Elements to be considered
- Foreseen adaptation needs and regulatory boundaries
- Calibration from reference tiers
PROPOSED ISSUES FOR DISCUSSION (2/3)

Second set: Analysis plan

- **Equilibrium Partitioning Method**
  - Scientific basis/uncertainty
  - When/how/to-whom?

- **Species Sensitivity Distributions**
  - Species/taxa/functions selection & integration in a PNECsoil

- **Ecological modelling**
  - Prediction of population/functional effects
  - Addressing spatial and temporal variability in exposure and response
Second set (cont.): Conceptual model

- Current approaches for linking exposure and effects (REACH/BPR/PPP):
  - Similarities, divergences
  - Harmonisation

- Updating/integration the conceptual model
Thank you

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2nd EFSA Scientific Conference
October 2015, Milano