Coupling science and regulatory needs:

Towards the integration of ecological and landscape diversity in prospective ERA

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EFSA Scientific Conference, November 2016

Background

- PPR Panel proposal: Environmental Guidance Documents are based on Specific Protection Goals (SPGs)
- SPGs require spatial dimension (e.g. in-crop, edge of field, landscape, regional, remote areas)
- The EU environmental and ecological variability is huge, playing a key role in addressing risks
- Landscape conditions are essential for assessing effects at population level and recovery
- Spatially explicit assessments offers new possibilities for risk managers
  - More realistic and protective while reducing the use of over-conservative assumptions

EXAMPLE OF CURRENT TOOLS

JOINT RESEARCH CENTRE
EUROPEAN SOIL DATA CENTRE (ESDAC)

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Resources Type

- Datasets
- Maps & Documents
- Applications & Services

Resource by

- Themes
- Networks & Cooperations
- Projects

Upcoming Events

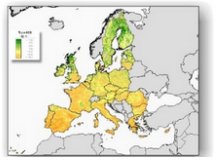
30/Sep/2015 SmartSOIL: sustainable soil management aimed at reducing threats to soils under climate change

Highlights

23 Sep 2015 Land and Soil Management Award: Deadline december 2015

7 Sep 2015 In the context of the International Ye of Soils, and the World Exposition 'Feeding the planet – Energy for life', you are cordially invited to participat to the 'Giving soils a voice' workshop the fourth meeting of European Network of Soil Awareness (ENSA)

European Food Safety Authority (EFSA) Data & PERSAM software tool



Resource Type: Datasets
Soil Projects Data

Registration is requested: Yes

Publisher: EFSA and JRC

Year: 2015

Scale: 1km

Projects: EFSA Data & Tools

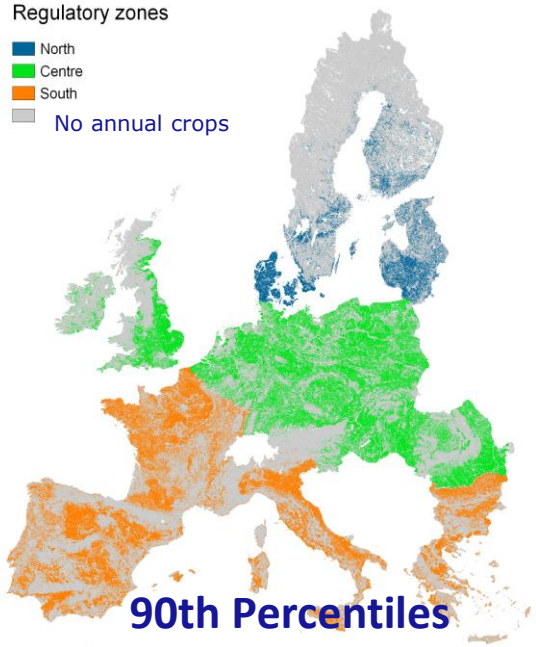
Keywords: EFSA | food safety | ECOREGION | FATE |

ment between JRC and EFSA. It contains **soil, weather and crop data** collected by JRC and organised
ftware tool PERSAM for Predicting Environmental Concentrations in soil in support of the: "EFSA
ctive substances of plant protection products and transformation products of these active substances
Guidance Document.

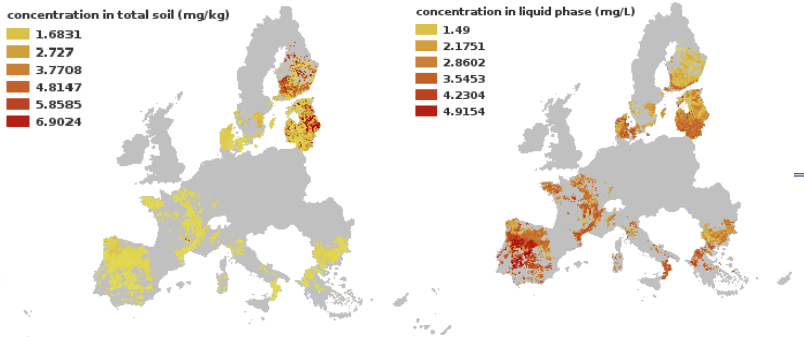
*ario Selection and Scenario Parameterisation for Permanent Crops and Row Crops on Ridges in Support of
' Their Transformation Products in Soil" (see EFSA documentation)*

ol

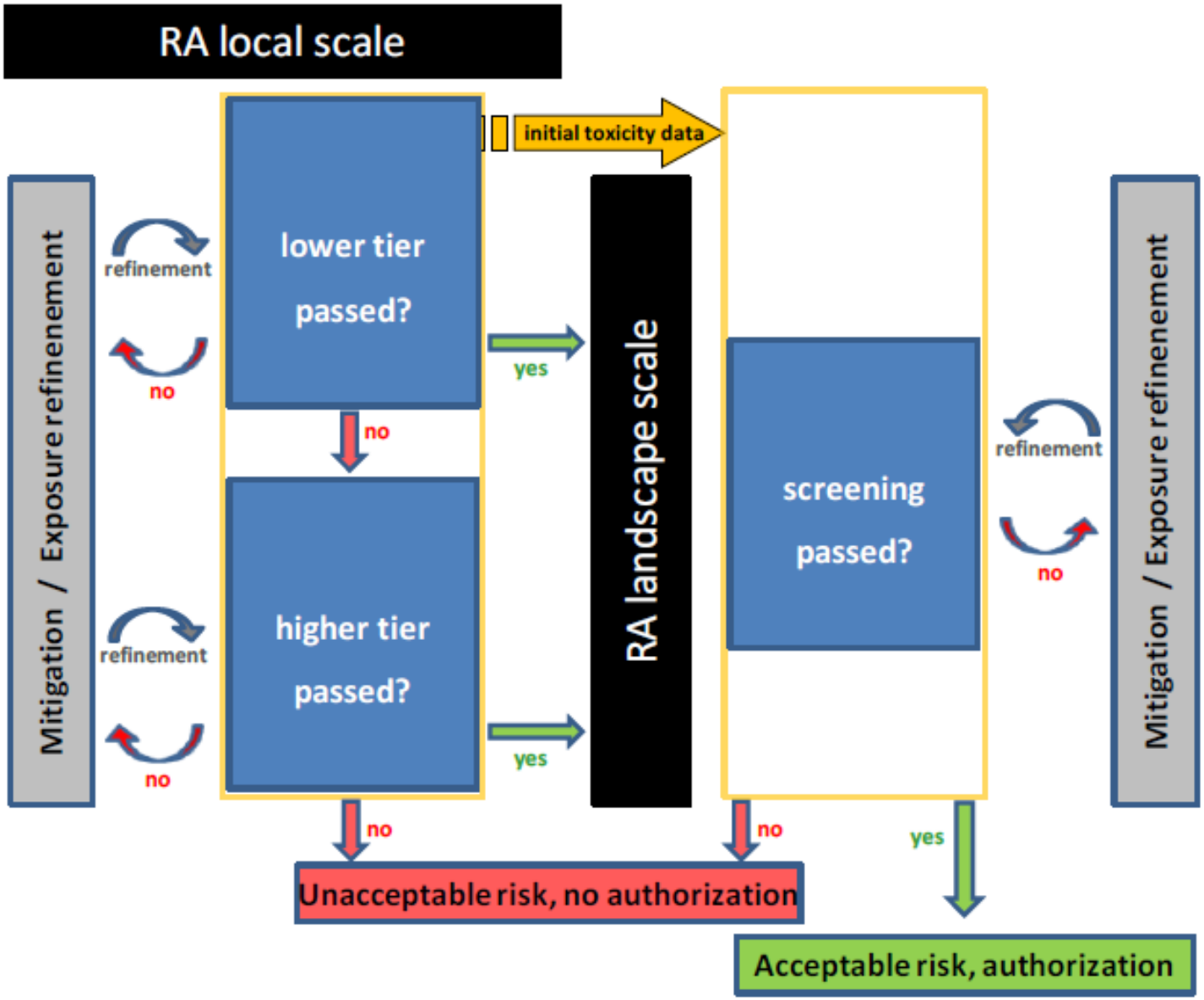
M tool (Version 1.0.3 or Version 1.0.2) with associated User Manuals, please compile the online form;
AM tool. By submitting the on-line form , you agree with the terms and conditions associated to the



90th Percentiles



Specific protection goals for non-target arthropods



EU REGULATORY SYSTEM FOR PESTICIDES

EU assessment and approval decision of the active pesticide substance

Submission
- Active substance

Risk Assessment
- Rapporteur MS
- **EFSA Peer-Review**

Decision
- EU approval

MS assessment and pre-marketing authorisation of each formulation

Submission	Submission	Submission
Risk Assessment: • Member State • Zonal process	Risk Assessment: • Member State • Zonal process	Risk Assessment: • Member State • Zonal process
Decision	Decision	Decision

Current tools

- Guidance documents for active substances and PPP
  - Tiered risk assessment methods
  - Scenarios, models, tools

EU assessment of active subst.


efsa
European Food Safety Authority

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance metobromuron[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State France, for the pesticide active substance metobromuron are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative use of metobromuron as a herbicide on potatoes. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. The consumer risk assessment should be considered provisional pending the outcome of the requested toxicological information on the metabolites included in the plant residue definitions. A high long-term risk to birds could not be excluded with the available data.

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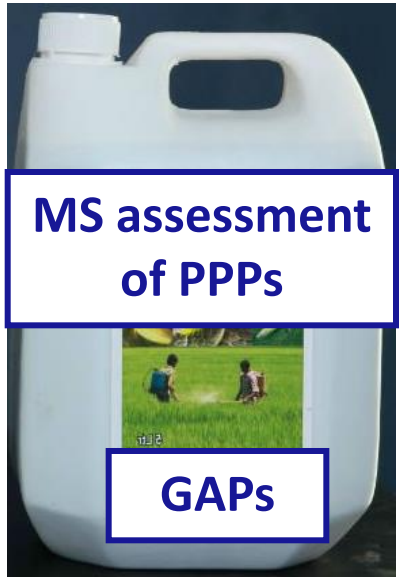
KEY WORDS

metobromuron, peer review, risk assessment, pesticide, herbicide

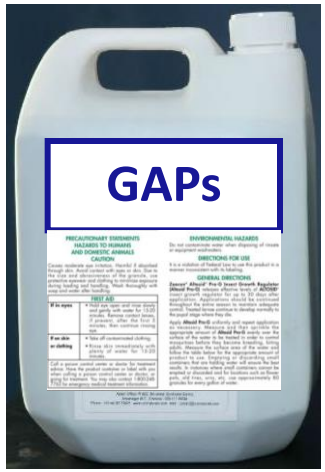
List of Endpoints

Risk envelop approach

MS assessment of PPPs



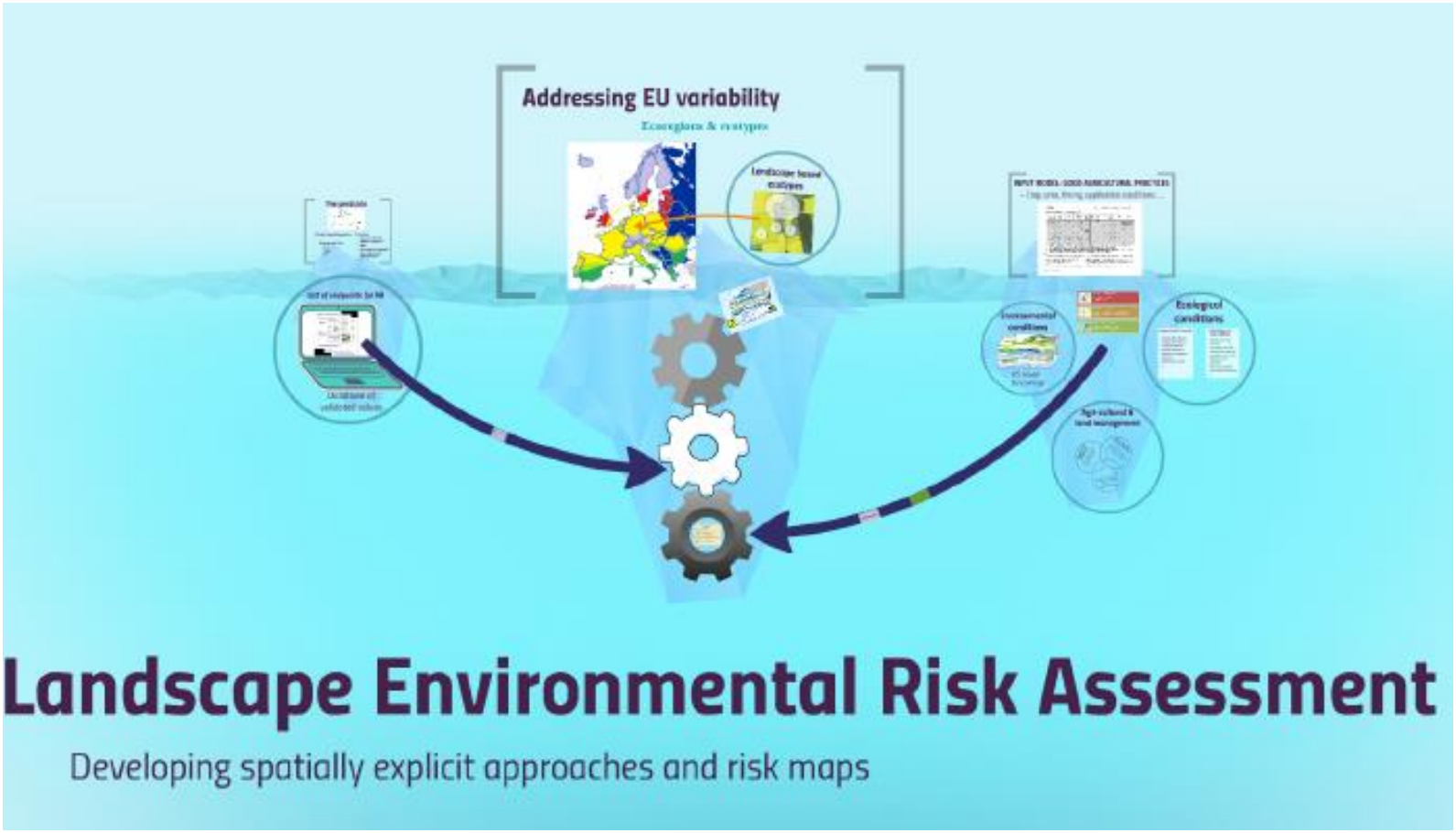
GAPs



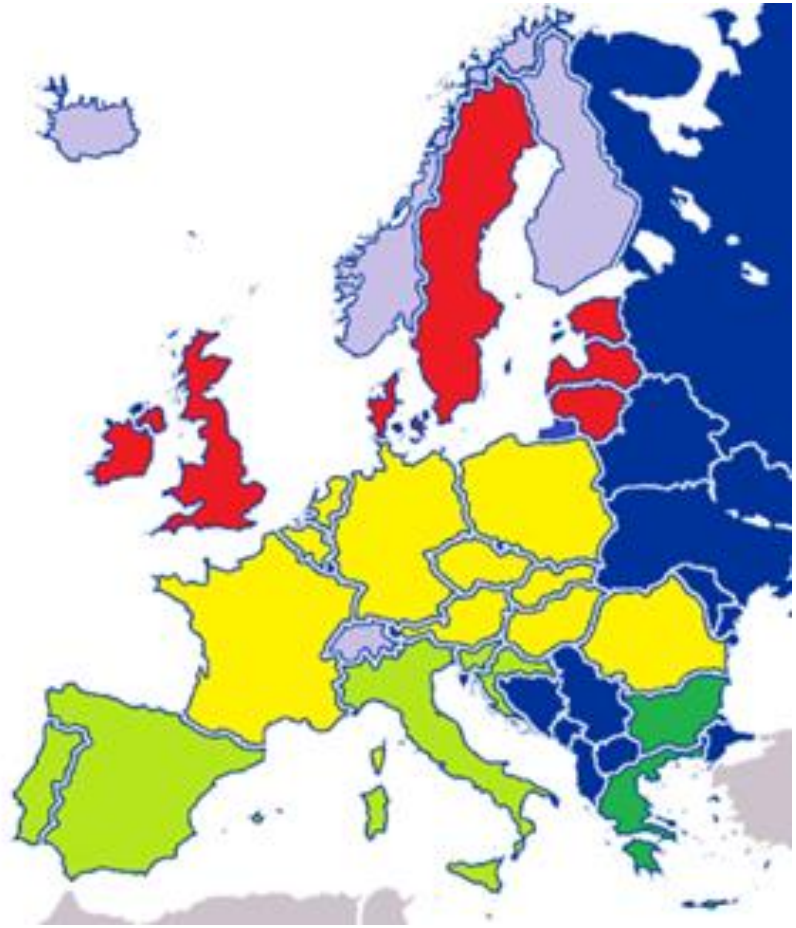
GAPs

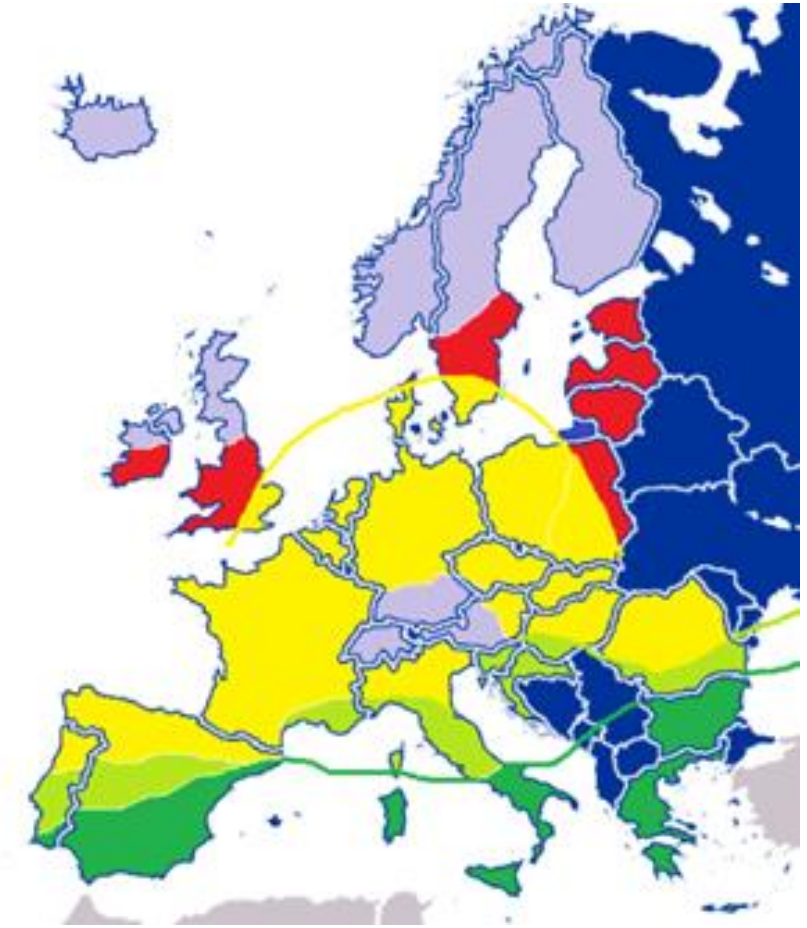
LANDSCAPE ENVIRONMENTAL ASSESSMENT

Spatial explicit risk maps addressing EU environmental variability

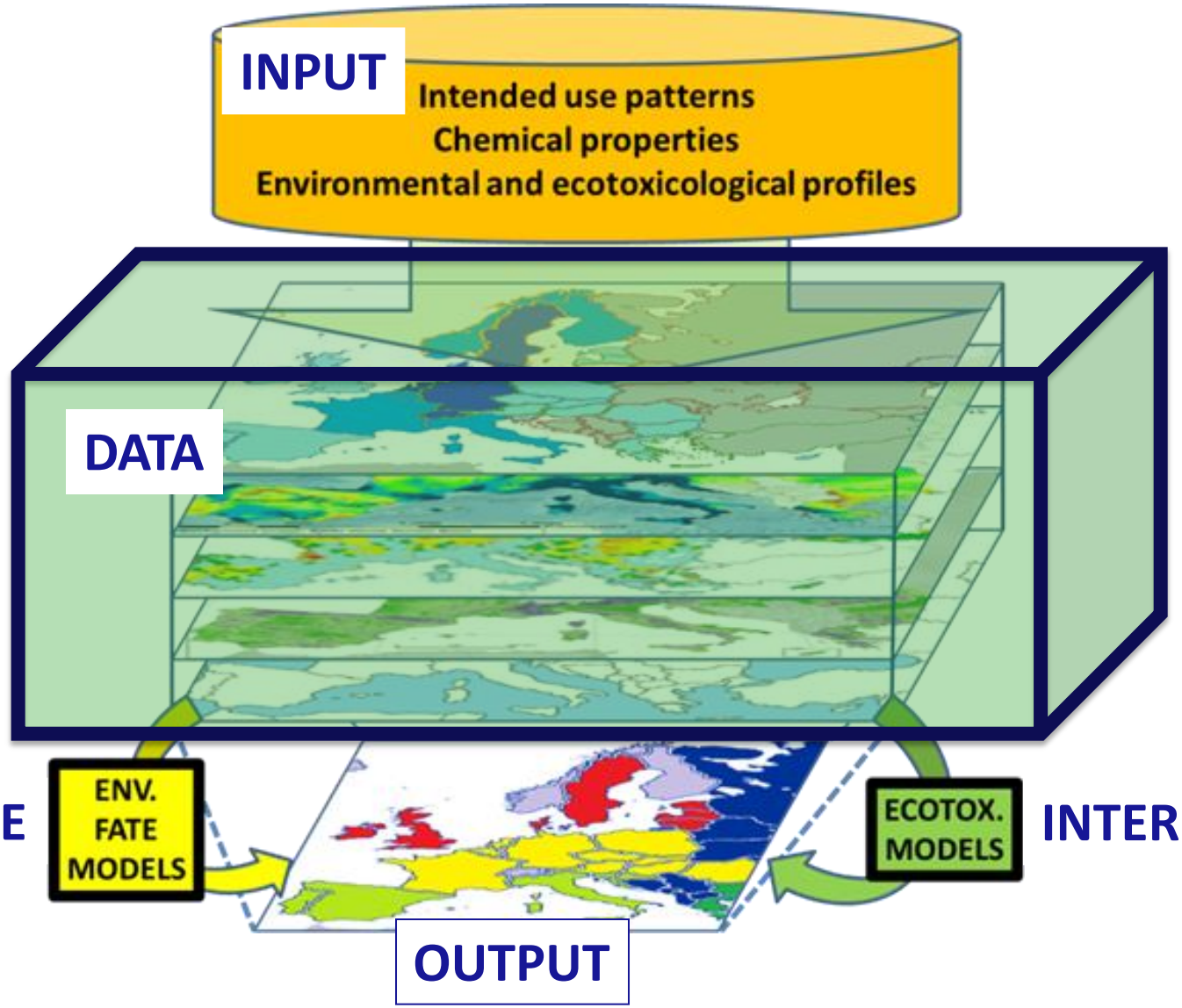


Tools supporting MS assessment and decision-making





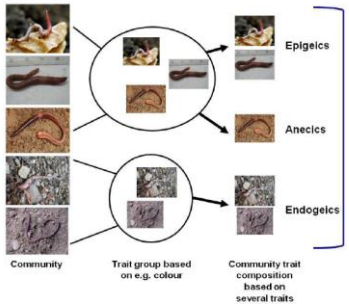
TOOL DEVELOPMENT



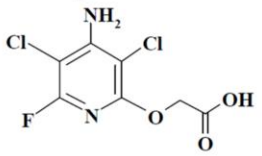
Geographical GIS-based mapping vs. other approahes

- Environmental conditions
  - GIS based, EU coverage, variable granularity
- Ecological conditions
  - GIS-Based
    - Species/habitat distribution, endemic species
    - Main ecological services and biodiversity needs
  - Field habitat and local conditions
    - Crop and non-crop habitats
    - Population in-field and off-field ecology
    - Population dynamics, reproduction potential
- Agri-cultural and land management
  - Geographical distribution crops and fields
  - Agro-technology and crop protection strategy
  - National requirements

SPATIAL SCALE DEPEND ON THE ECOSYSTEM SERVICE



The pesticide



Physical-chemical properties

Ecotoxicity
- Mammals & birds
- Aquatic organisms
- Bees
- Non-target arthropods

Environmental Fate
- Soil

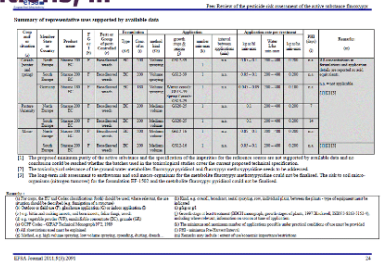
List of endpoints for RA

Database of validated values

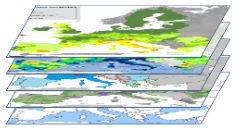
For higher tiers, includes geographical and landscape applicability

INPUT MODEL: GOOD AGRICULTURAL PRACTICES

- Crop, area, timing, application conditions, ...



Environmental conditions



GIS based
EU coverage

Ecological conditions

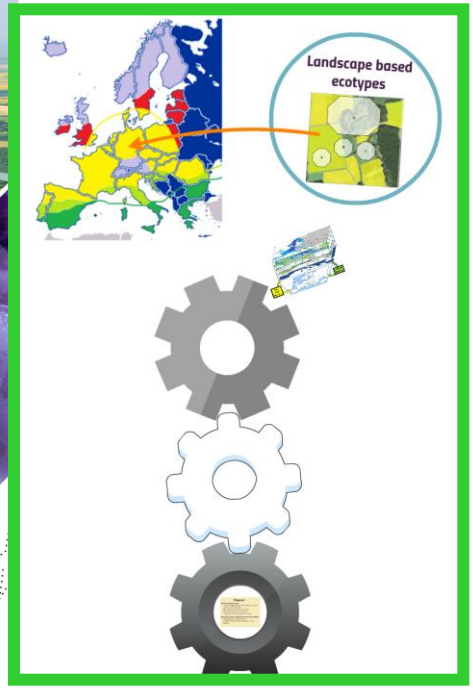
Geographical (GIS based)
- Species distribution
- Habitat distribution
- Endemic species
- Nature reservoirs
- Relevant ecosystem services
- Redundancy index
- ...

Field habitat and local conditions
- Crop & non-crop habitats
- Population in-field and off-field ecology
- Population dynamics
- Reproduction potential
- Recovery potential
- Community dynamics
- ...

Agri-cultural & land management

Considering national requirements

Conceptual frame and tool development challenges



- Addressing variability for supporting decision making
  - National/Regional assessments
  - Landscape description
  - Risk management options
- Tiered assessments
  - Calibrated EU wide lower tiers
  - Granularity adapted to the needs
- Assessments for premarketing authorisation
  - Actual use and location is a farmer decision
  - Market penetration is unknown

PPR Panel and methodological updates

Need identified
- PPR Panel
- Pesticides Steering Network

Preliminary work by EFSA
- Grants & procurements
- External report

Panel Scientific opinion
- Hearings
- Optional public consultation

Input from Risk Managers

Panel or EFSA guidance
- Hearings
- Networking
- Mandatory public consultation

Guidance ready for Risk Managers decision on enforcement

Tool ready for implementation

PPR Panel and methodological updates

Dialogue with Risk managers

Dialogue with Risk Managers

Need identified
- PPR Panel
- Pesticides Steering Network

Preliminary work by EFSA
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Panel Scientific opinion
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Panel or EFSA guidance
- Hearings
- Networking
- Mandatory public consultation

Guidance ready for Risk Managers decision on enforcement

- Academic community
- Risk assessors in MS, industry, other experiences
- Stakeholders views
- Added value & Integrative approach → IPM

Landscape ERA tool

Panel discussion: What……?

- What are the risk managers needs?
- What is the state of art?
  - Scientific knowledge and methodologies
    - Exposure, terrestrial/aquatic
    - Effects at population, recovery, integration of time events, …
  - IT technology
  - Environmental data
  - Ecological data and modelling tools for each non-target group
- What are the benefits
- What is the best way for moving ahead?

Panel discussion: How……?

- How to ensure the cooperation of regulatory and academic institutions?
- How to involve applicants and other stakeholders
- How to select risk managers priorities
- How to get an added-value from and to other related activities?
- How to identify and fulfil gaps?
  - Scientific knowledge and methodologies
  - IT technology
  - Data/information

Thank you

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