




Some future developments for environmental risk assessment in Europe


Mark Egsmose, The Pesticides Unit

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OUT-LINE

- 
- EU PPP regulation – the framework
 - List of Endpoint data-base
 - Electronic submissions - MATRIX
 - Landscape based RA
 - Integrating tools for RA – in the cloud


EU PPP REGULATION

- 
- Current procedure for PPP regulation
 - Collaborate model involving EU and MS experts
 - Dual evaluation system: EU & MS
 - Extensive guidance for harmonisation of RA
 - Transparent publication of the assessment
 - Producing guidance
 - Refit is on-going and the EC will communicate on this

LIST OF END-POINT DATA-BASE

- 
- Data-model of the LoEP is available
 - Framework for implementation of data-bases
 - Desirable to have all GAPs in EU for all PPPs included

MATRIX PROJECT

- 
- Electronic submissions of regulated products
 - Regulatory frameworks are different for regulates products in EFSA
 - Considerations to integrate with the IUCLID platform together with ECHA

Current environmental risk assessment

Environmental fate and behaviour:

- ✓ Exposure via soil
- ✓ Exposure in small surface water bodies
- ✓ Groundwater
- ✓ Air

Ecotoxicology:

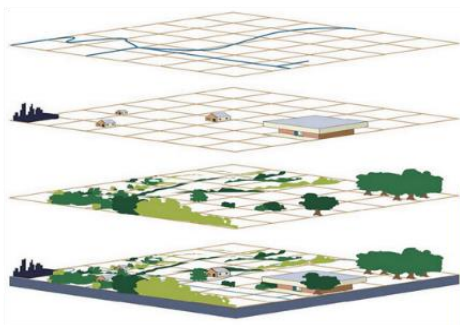
- ✓ Birds and mammals
- ✓ Aquatic organisms
- ✓ Bees and other non-target arthropods
- ✓ Soil organisms
- ✓ Terrestrial non-target plants
- ✓ Biological methods for sewage treatment

Standard guideline studies, predictive fate models, *ad hoc* higher tier studies, data from systematic literature search

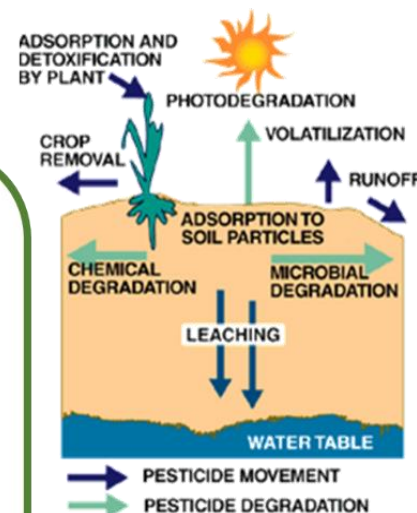
Roadmap for future Landscape based ERA

Landscape

GIS Data Layers

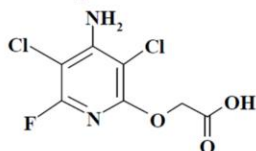


Multiple MS Locations





The pesticide



Physical-chemical properties

Environmental Fate

- Soil
- Water
- Air

Ecotoxicity

- Mammals & birds
- Aquatic organisms
- Bees
- Non-target arthropods
- Non-target plants
- Soil organisms
- ...

List of endpoints for RA



**Database of
validated values**

INPUT MODEL: GOOD AGRICULTURAL PRACTICES

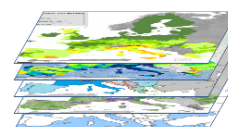
- Crop, area, timing, application conditions, ...

Summary of representative uses supported by available data

Use	Product	Formulation	Active substance	Concentration (%)	Application rate (kg/ha)	Frequency (times/year)	Area (ha)	Population (inhabitants)	Water bodies (km ²)	Soil (kg/ha)	Other	Remarks
Use 1	Product 1	Formulation 1	Active substance 1	Concentration 1 (%)	Application rate 1 (kg/ha)	Frequency 1 (times/year)	Area 1 (ha)	Population 1 (inhabitants)	Water bodies 1 (km ²)	Soil 1 (kg/ha)	Other 1	Remarks 1
Use 2	Product 2	Formulation 2	Active substance 2	Concentration 2 (%)	Application rate 2 (kg/ha)	Frequency 2 (times/year)	Area 2 (ha)	Population 2 (inhabitants)	Water bodies 2 (km ²)	Soil 2 (kg/ha)	Other 2	Remarks 2
Use 3	Product 3	Formulation 3	Active substance 3	Concentration 3 (%)	Application rate 3 (kg/ha)	Frequency 3 (times/year)	Area 3 (ha)	Population 3 (inhabitants)	Water bodies 3 (km ²)	Soil 3 (kg/ha)	Other 3	Remarks 3
Use 4	Product 4	Formulation 4	Active substance 4	Concentration 4 (%)	Application rate 4 (kg/ha)	Frequency 4 (times/year)	Area 4 (ha)	Population 4 (inhabitants)	Water bodies 4 (km ²)	Soil 4 (kg/ha)	Other 4	Remarks 4
Use 5	Product 5	Formulation 5	Active substance 5	Concentration 5 (%)	Application rate 5 (kg/ha)	Frequency 5 (times/year)	Area 5 (ha)	Population 5 (inhabitants)	Water bodies 5 (km ²)	Soil 5 (kg/ha)	Other 5	Remarks 5

EFSA Journal 2013; 9(2):204

Environmental conditions



**GIS based
EU coverage**



Ecological conditions

Geographical (GIS based)

- Species distribution
- Habitat distribution
- Endemic species
- Nature reserves
- Relevant ecosystem services
- Redundancy index
- ...

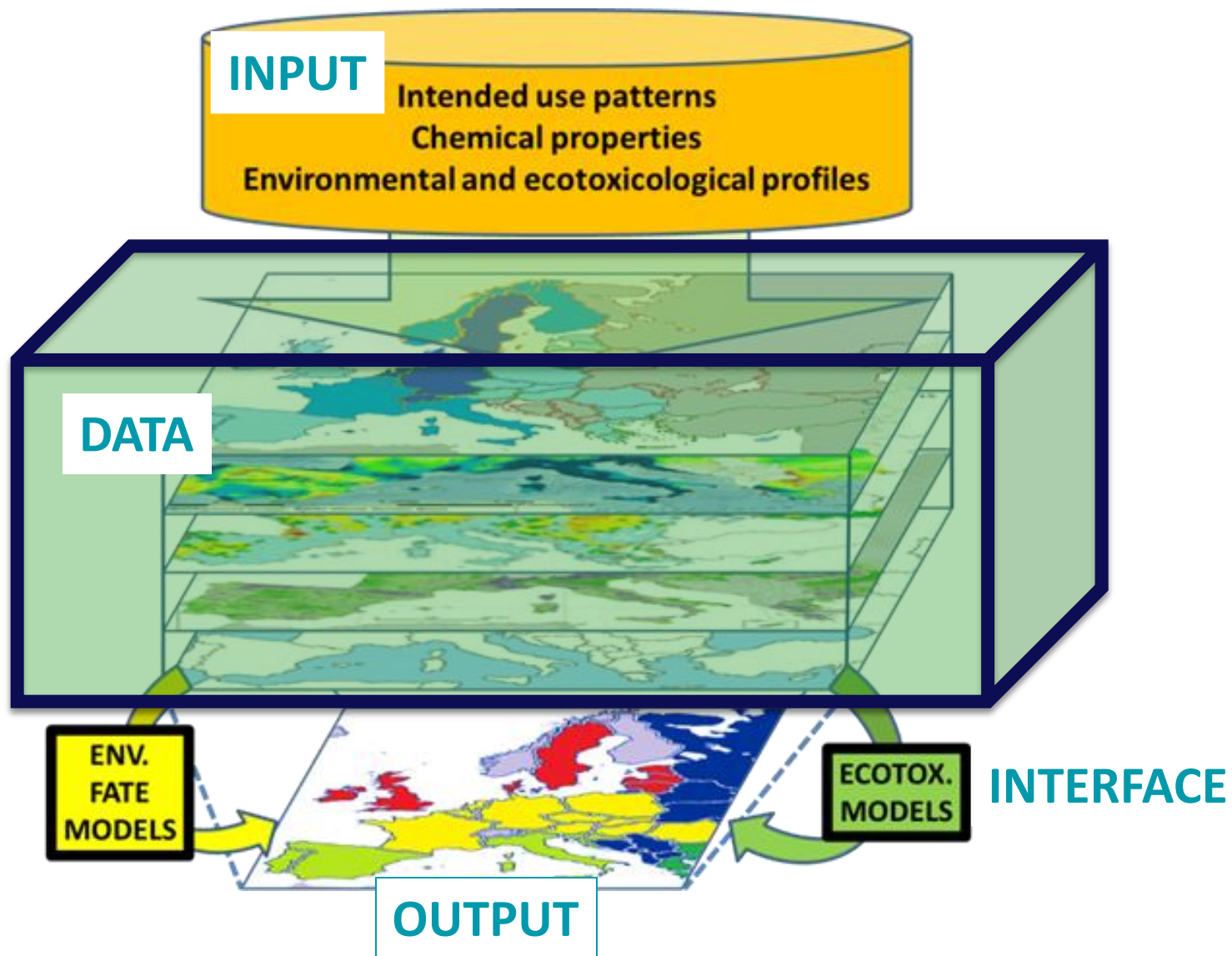
Field habitat and local conditions

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

Agri-cultural & land management

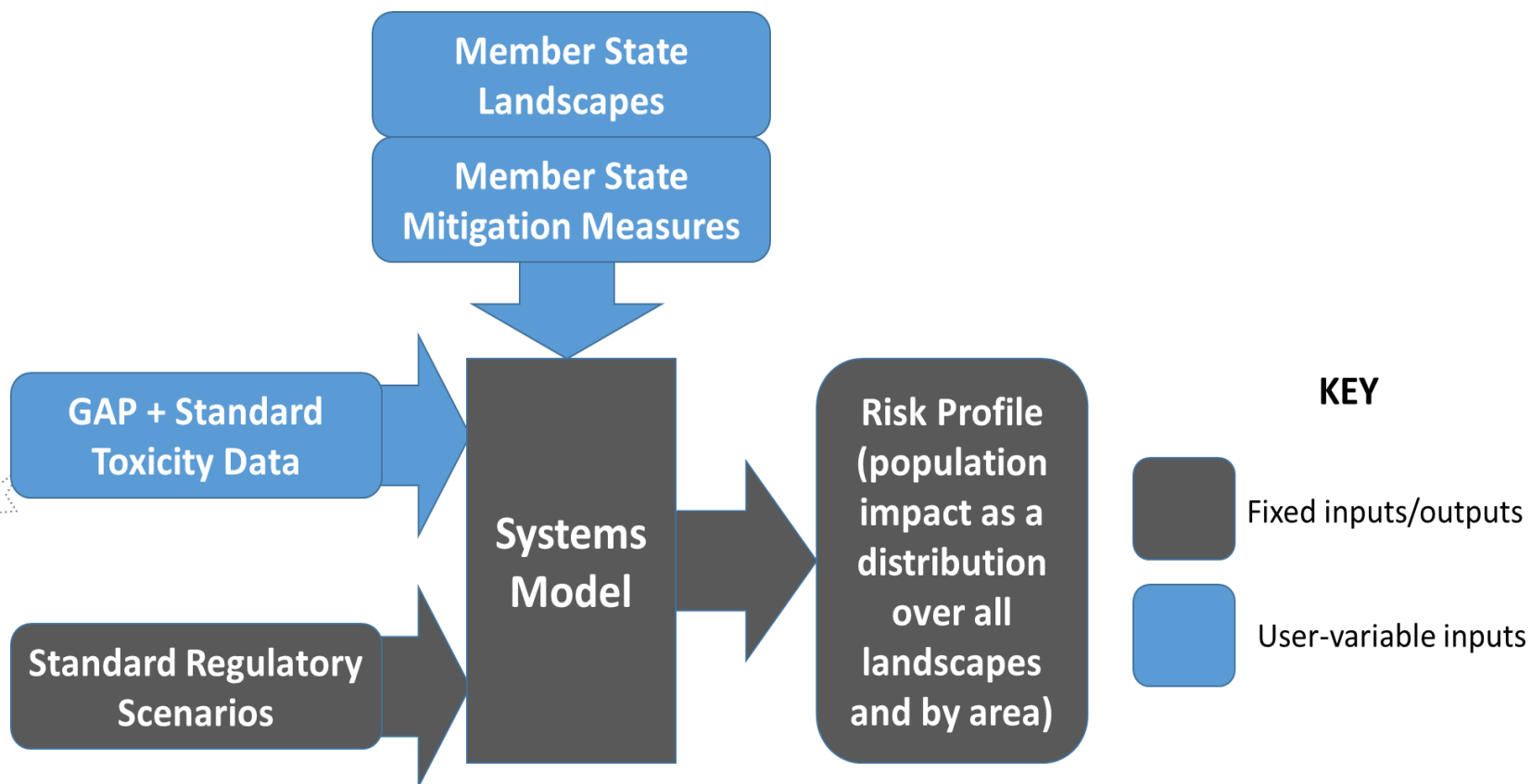


Tool development



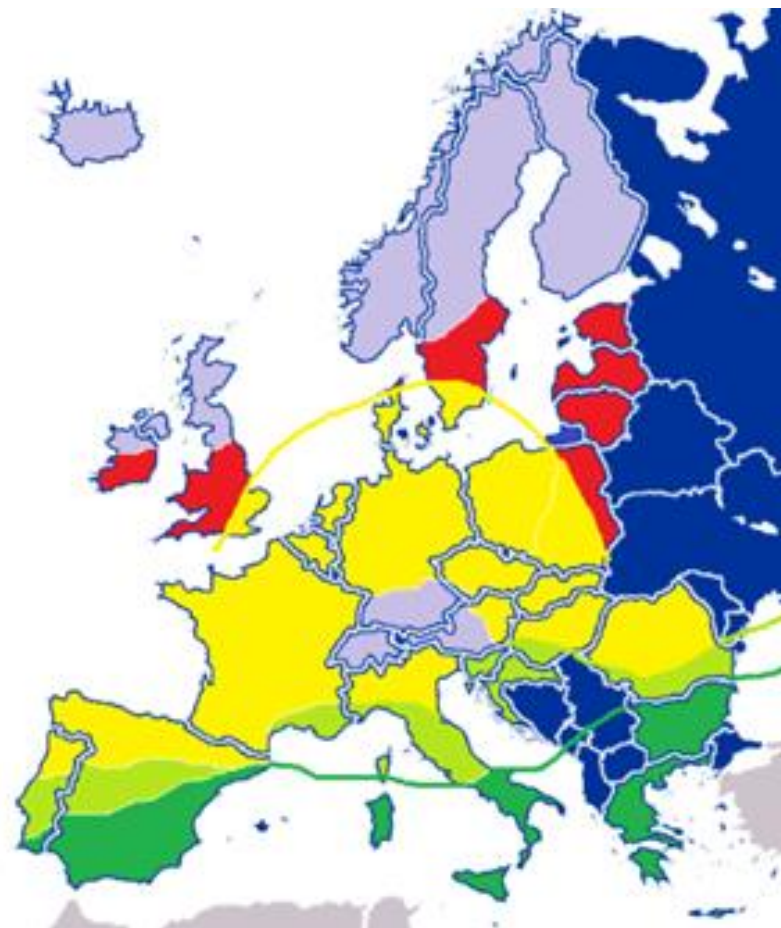


The vision for landscape ERA





Tools supporting MS assessment and decision-making



Vision for a system

DATA:

Repository for submitted data
Repository for the verification process

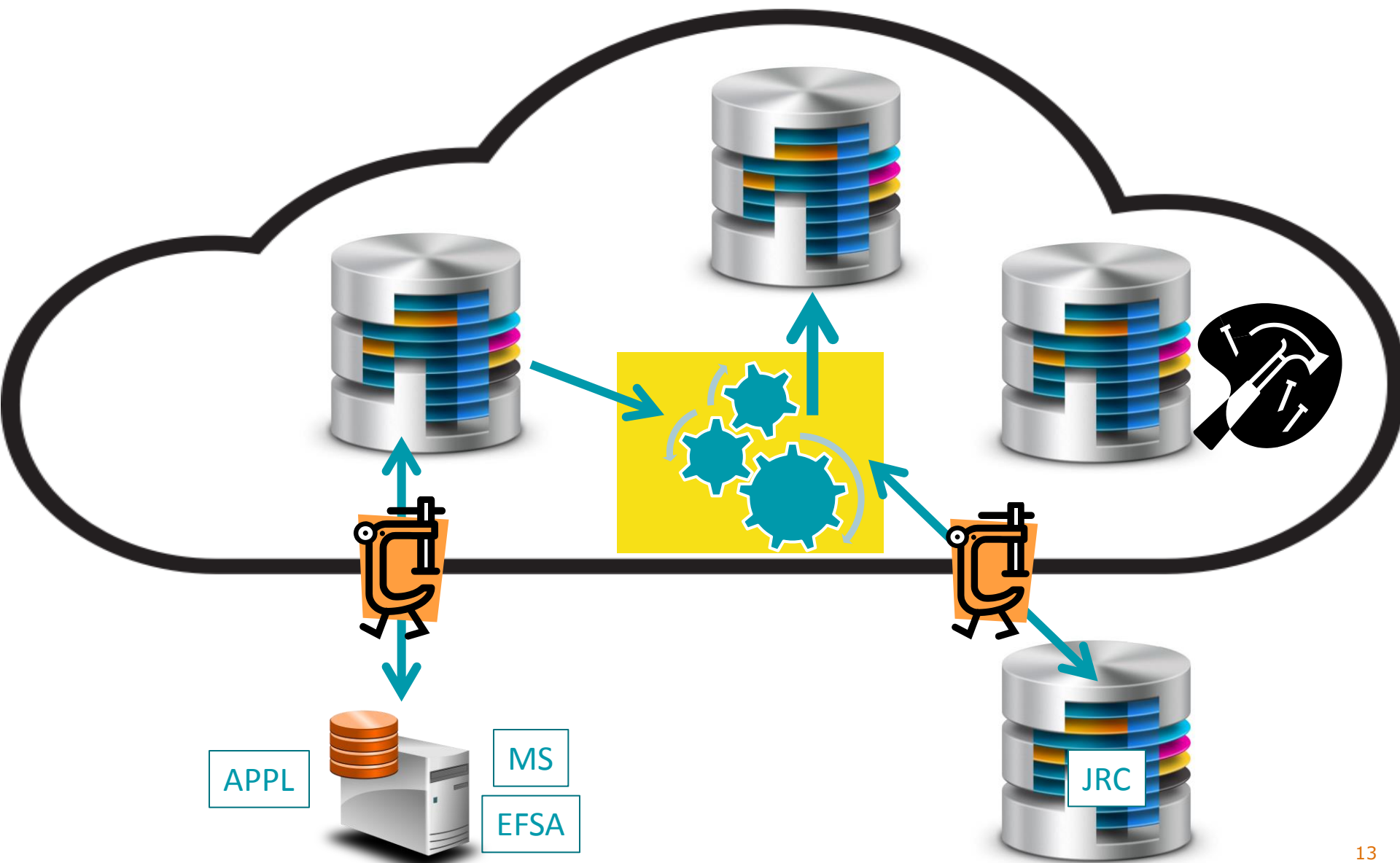
TOOLS:

Data extraction, transfer, management
IT workflows

Verified data



Risk assessment tools



Academia

Public

ASSESSMENTS
List of endpoints &
risk assessment tools

APPLICATIONS
Applicant dossiers (raw and
aggregated data) with
verification & workflows

POSTMARKETING
Pesticides Residues
Monitoring & CRA tools

JRC

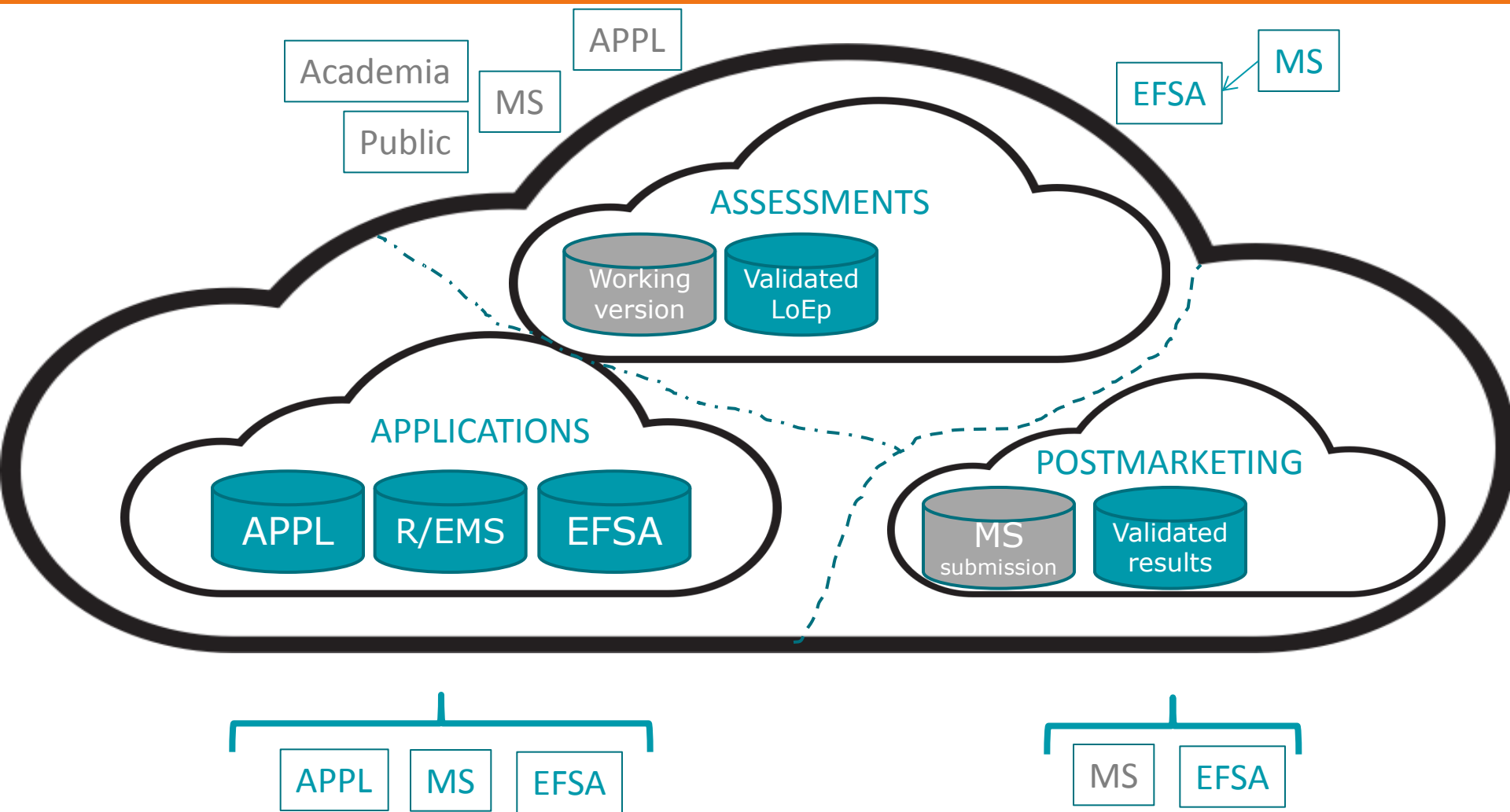
APPL

MS

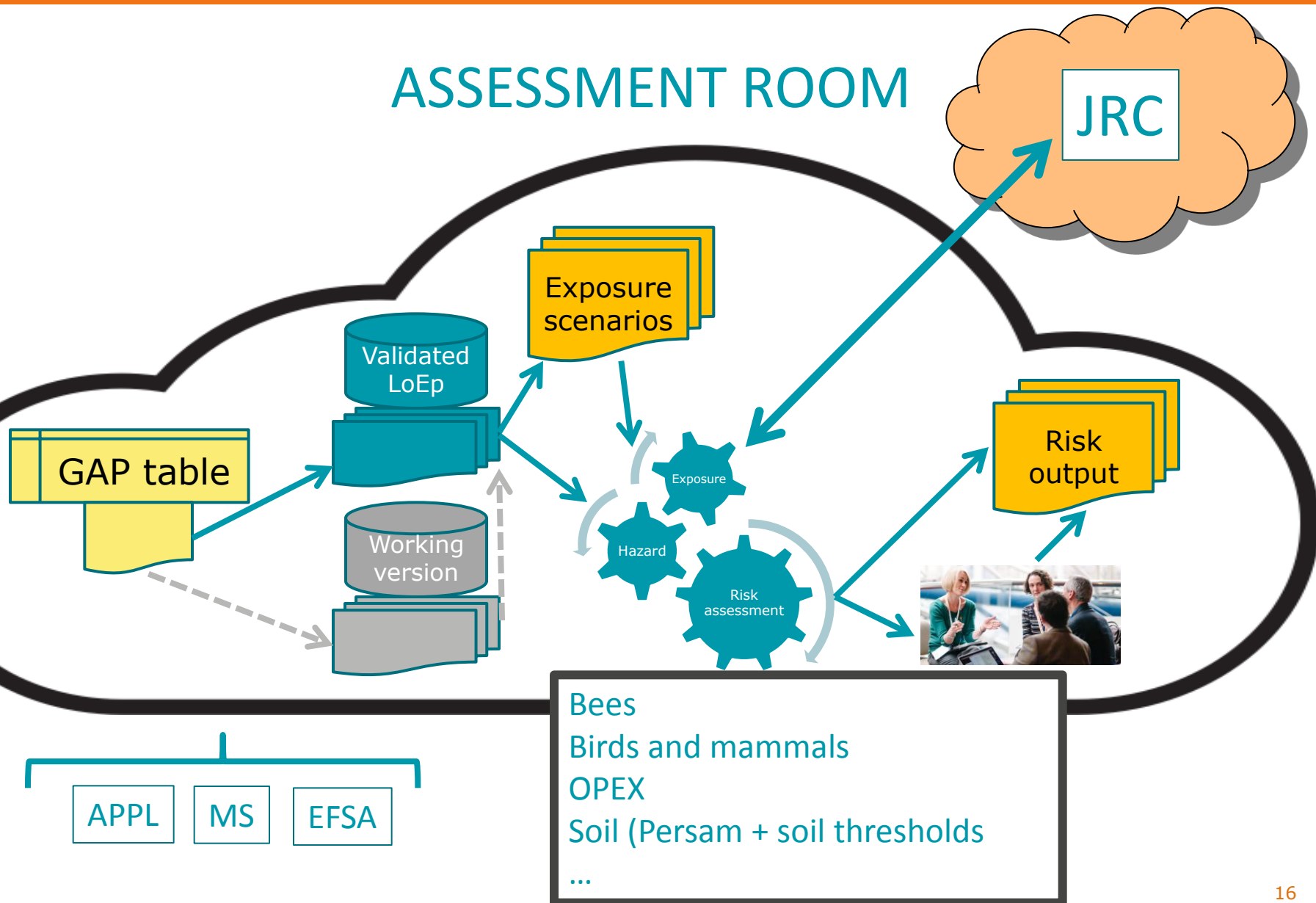
EFSA

MS

EFSA



ASSESSMENT ROOM







Thank you !