Some future developments for environmental risk assessment in Europe

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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:

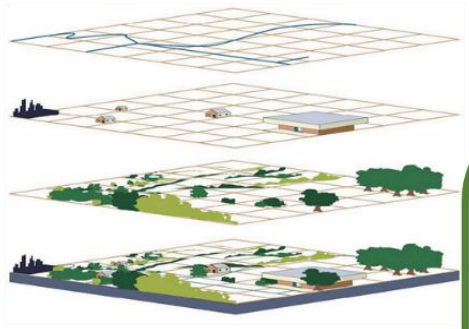
- ✓ Birds and mammals
- ✓ Aquatic organisms
- ✓ Bees and other non-target arthropods
- ✓ Soil organisms
- ✓ Terrestrial non-target plants
- ✓ Biological methods for sewage treatment

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

Roadmap for future Landscape based ERA

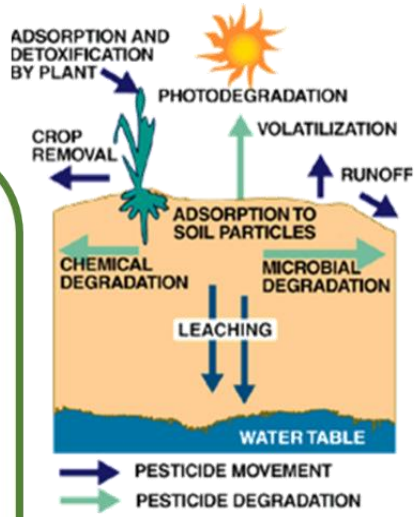
Landscape

GIS Data Layers



Multiple MS Locations

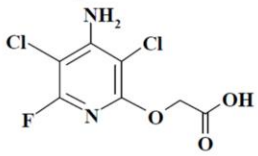
Farming Practices
& Vegetation Growth



Pesticide Fate

Weather

The pesticide



Physical-chemical properties

Environmental Fate
- Soil
- Water
- Air

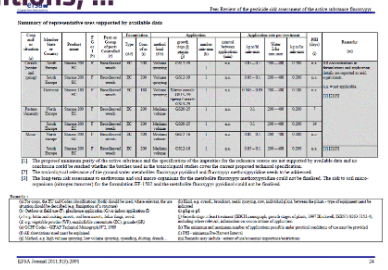
Ecotoxicity
- Mammals & birds
- Aquatic organisms
- Bees
- Non-target arthropods
- Non-target plants
- Soil organisms
- ...

List of endpoints for RA

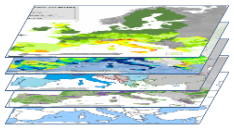
Database of validated values

INPUT MODEL: GOOD AGRICULTURAL PRACTICES

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



Environmental conditions



GIS based
EU coverage

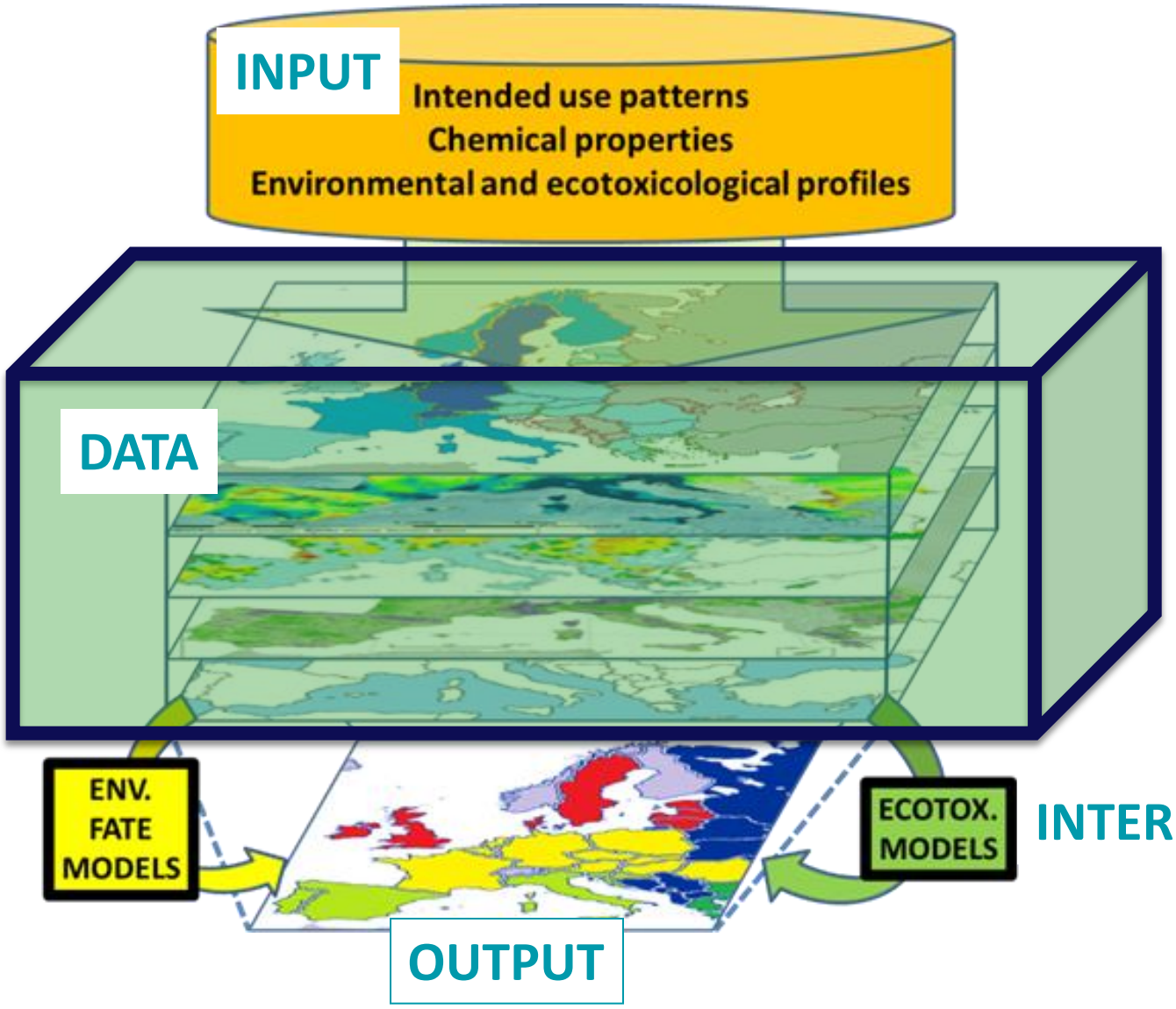
Ecological conditions

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

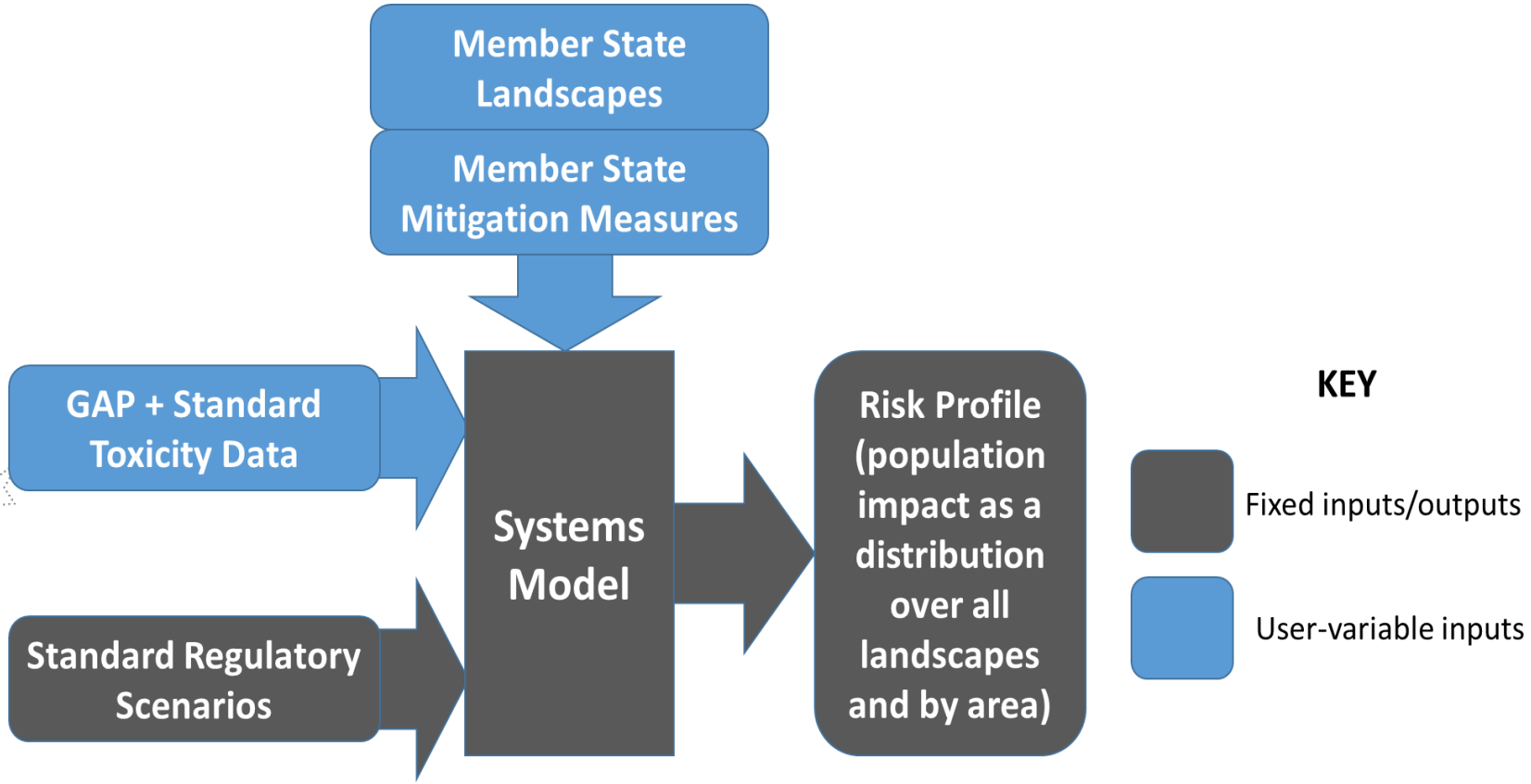
Field habitat and local conditions
- Crop & non-crop habitats
- Population in-field and off-field ecology
- Population dynamics
- Reproduction potential
- Recovery potential
- Community dynamics
- ...

Agri-cultural & land management

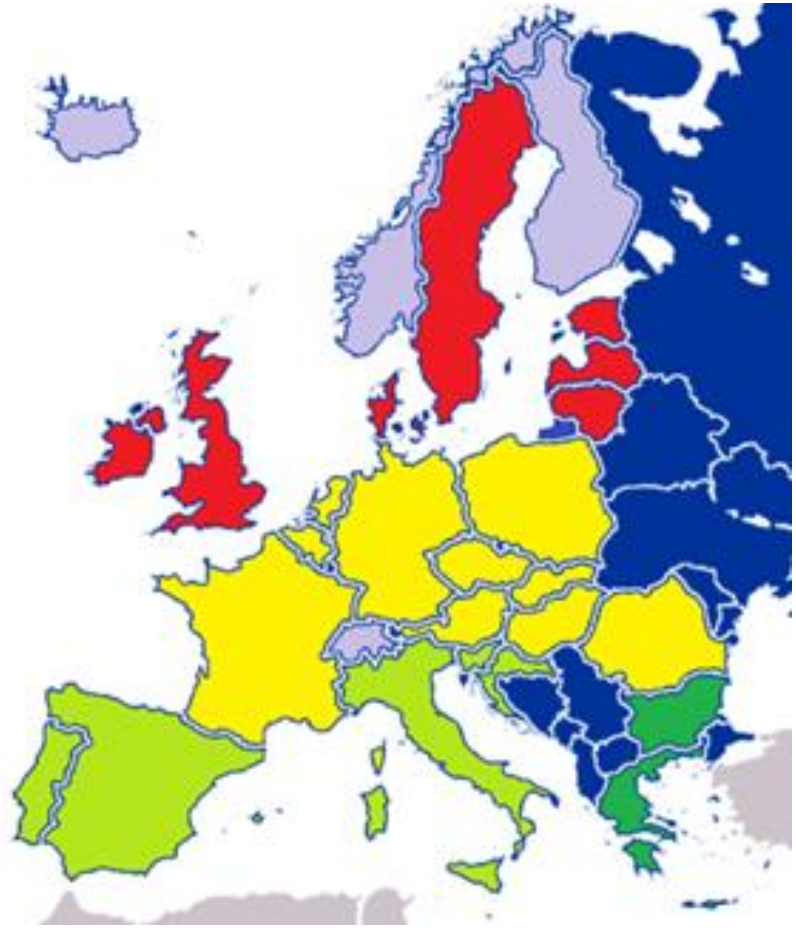
Tool development

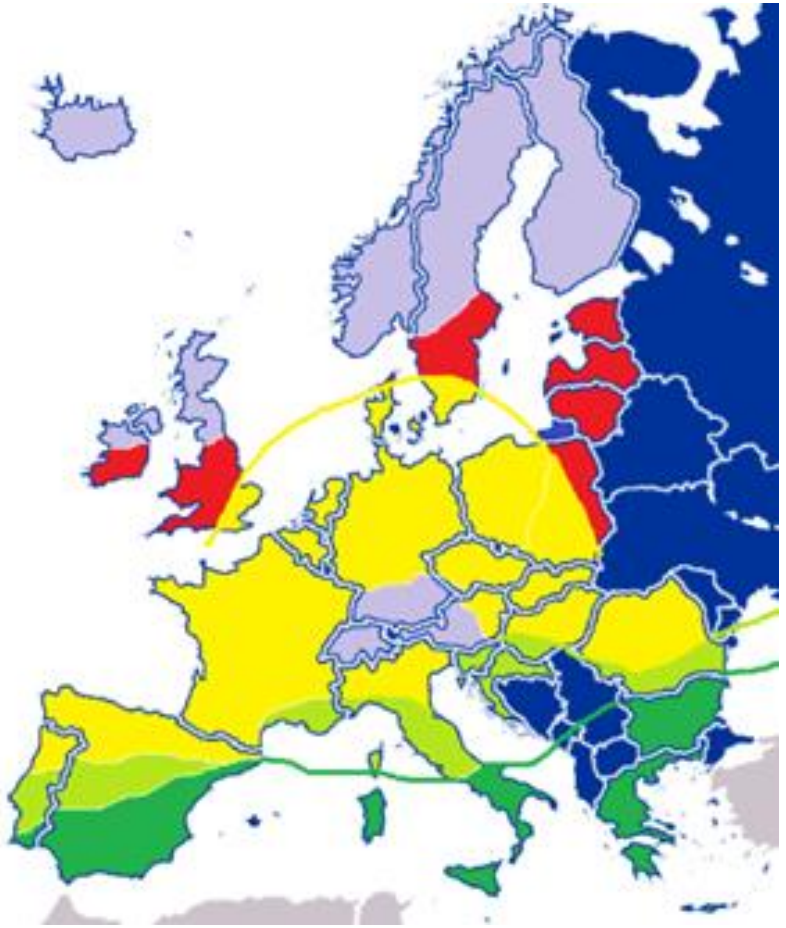


The vision for landscape ERA

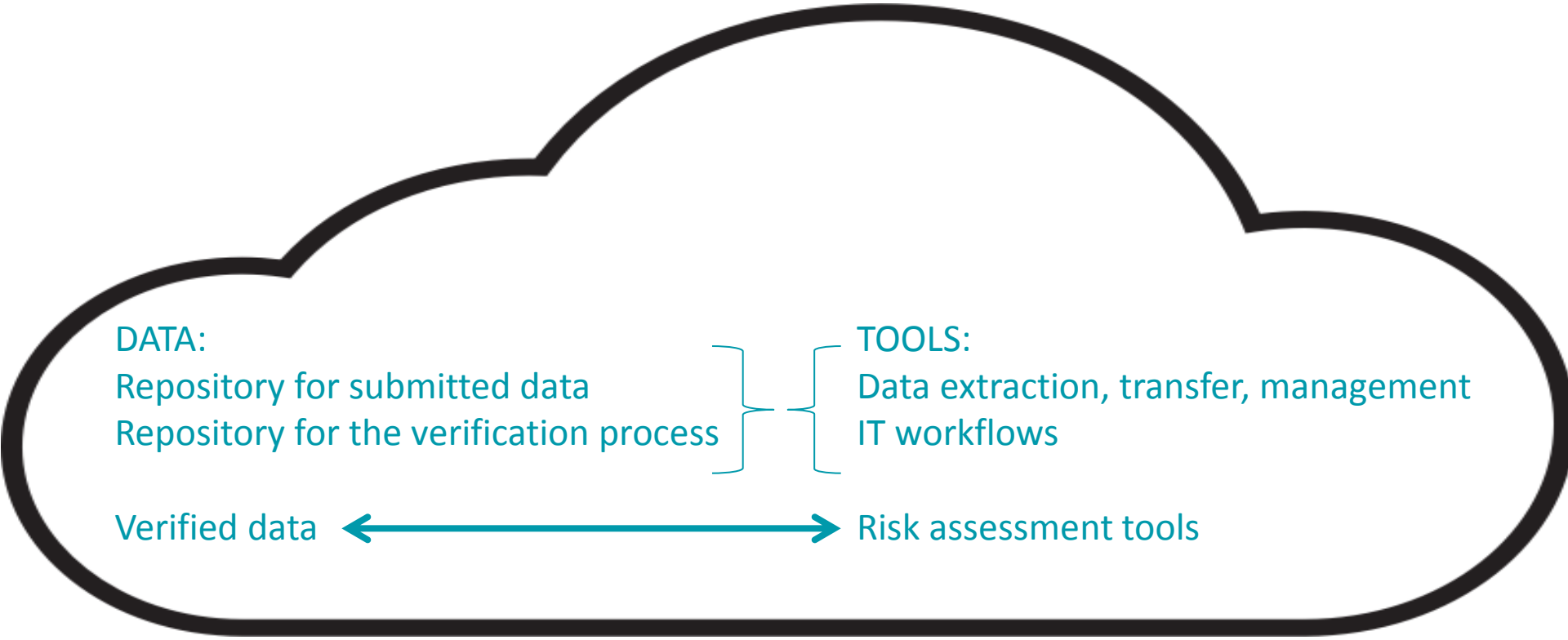


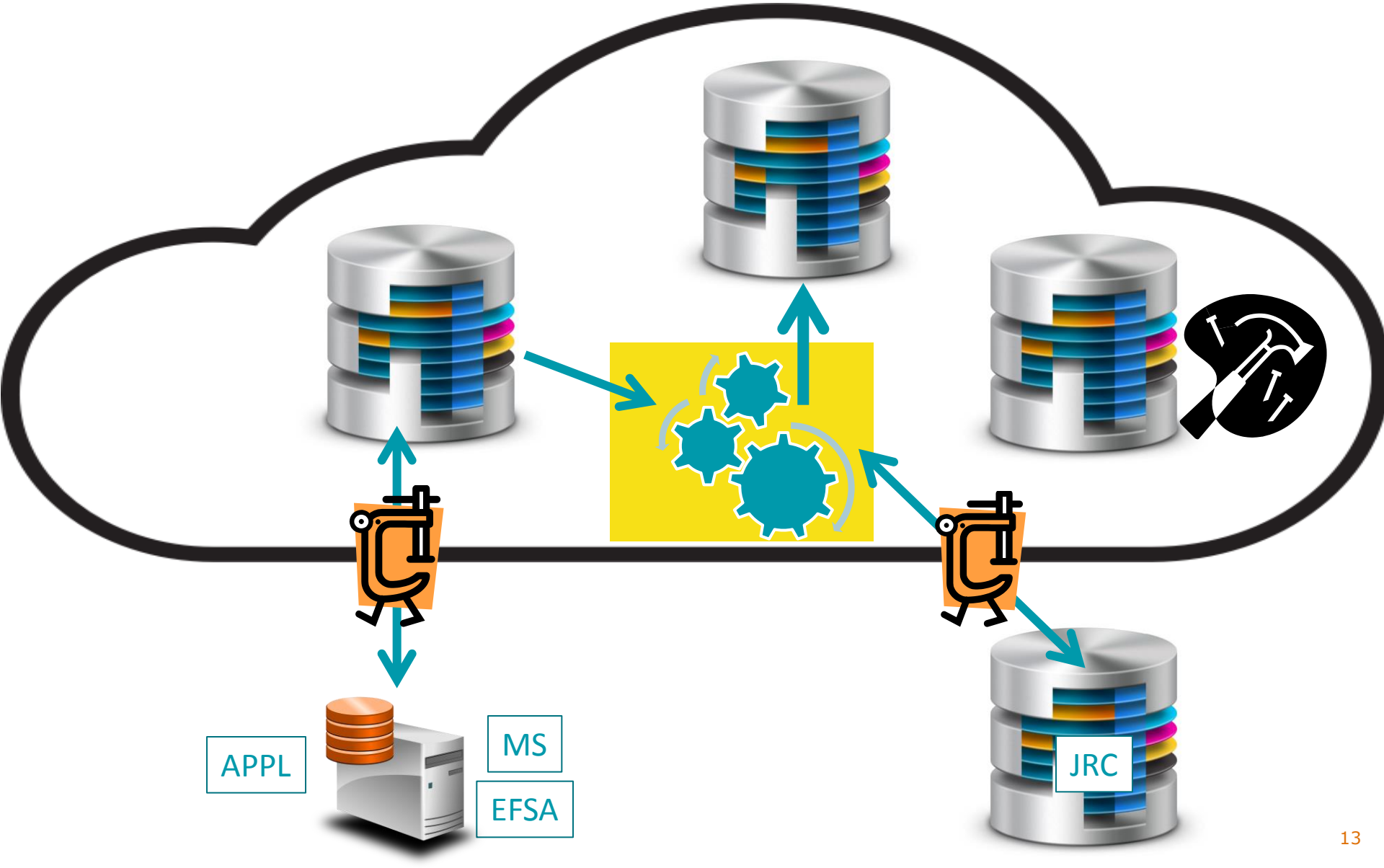
Tools supporting MS assessment and decision-making

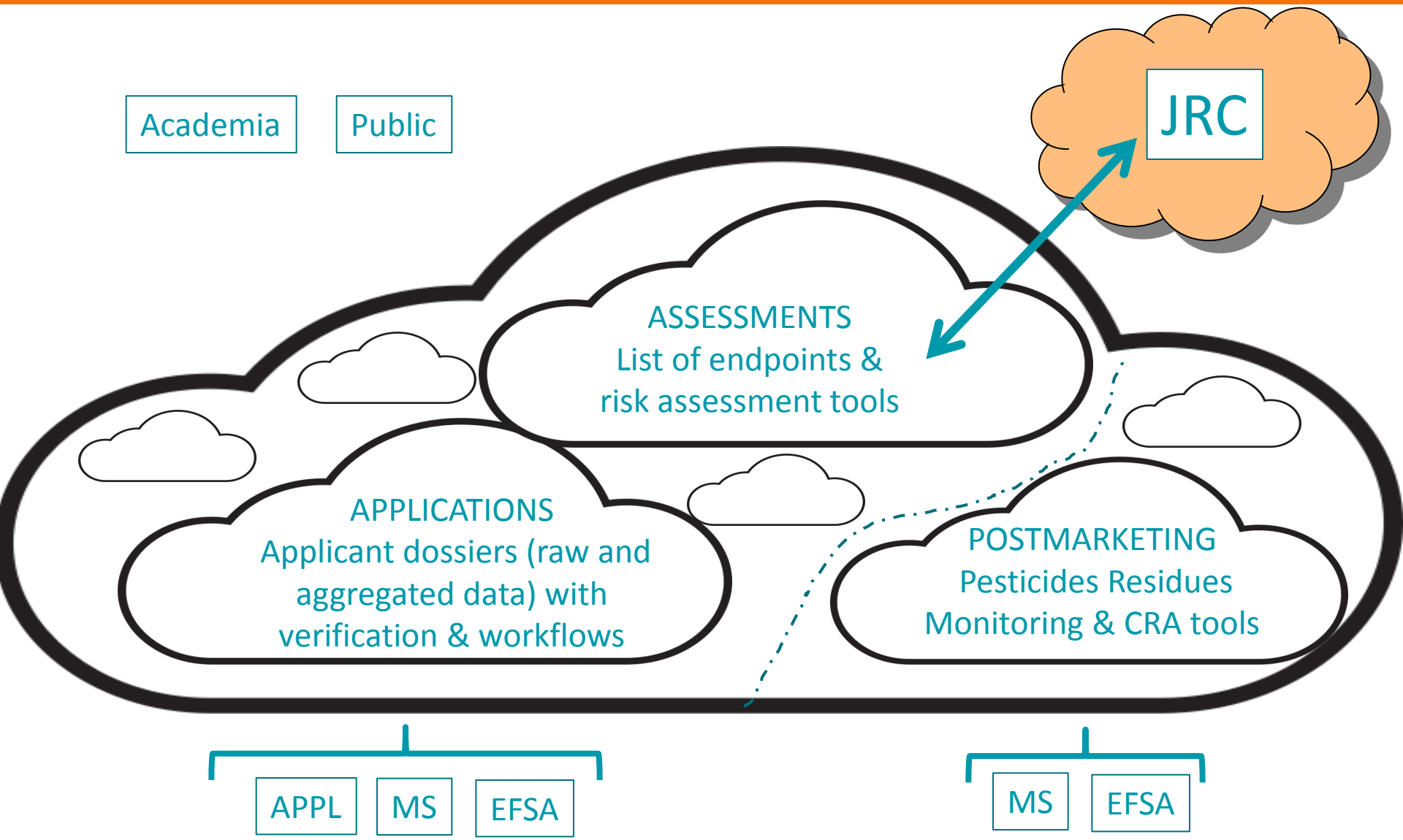


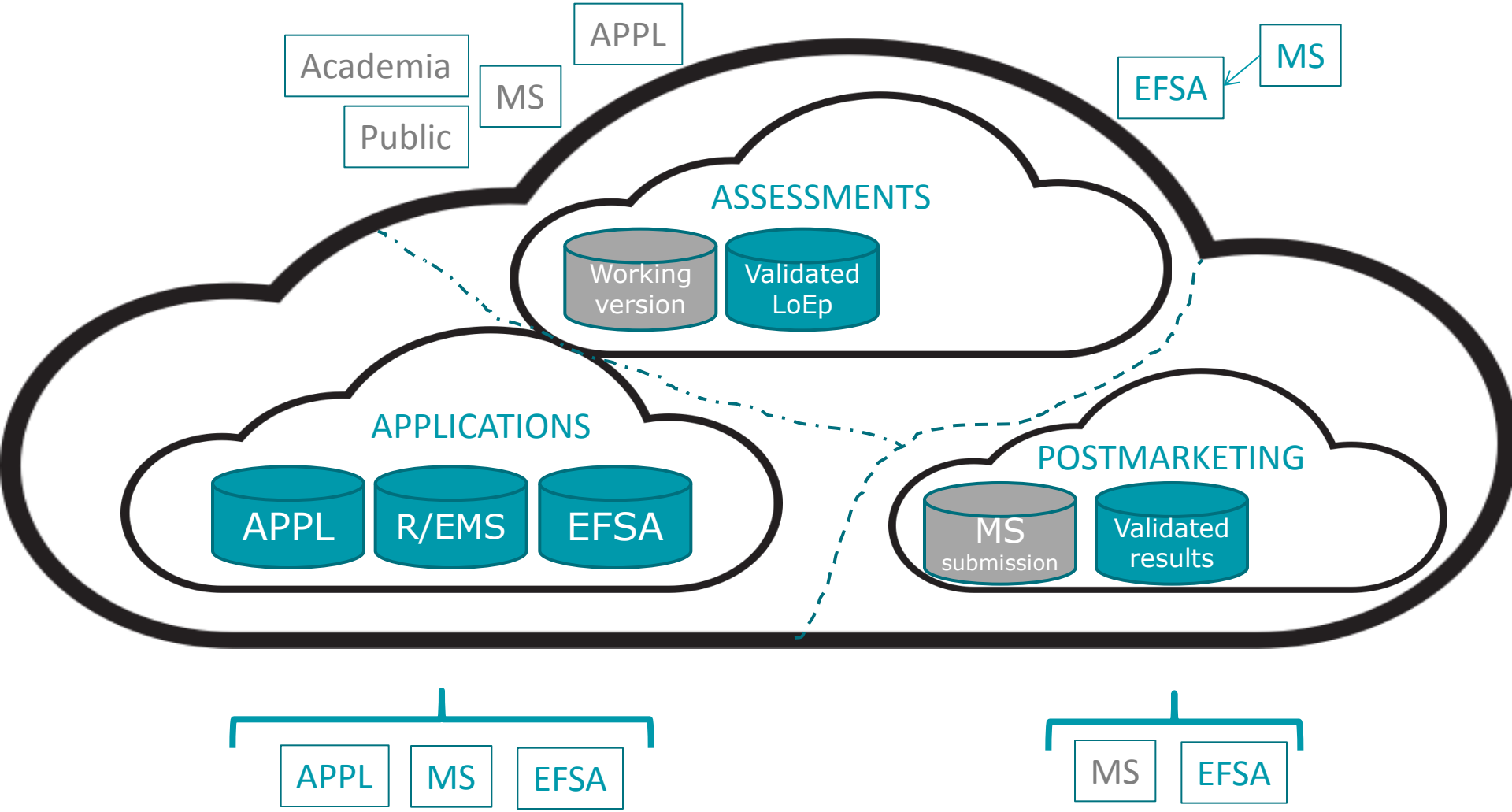


Vision for a system

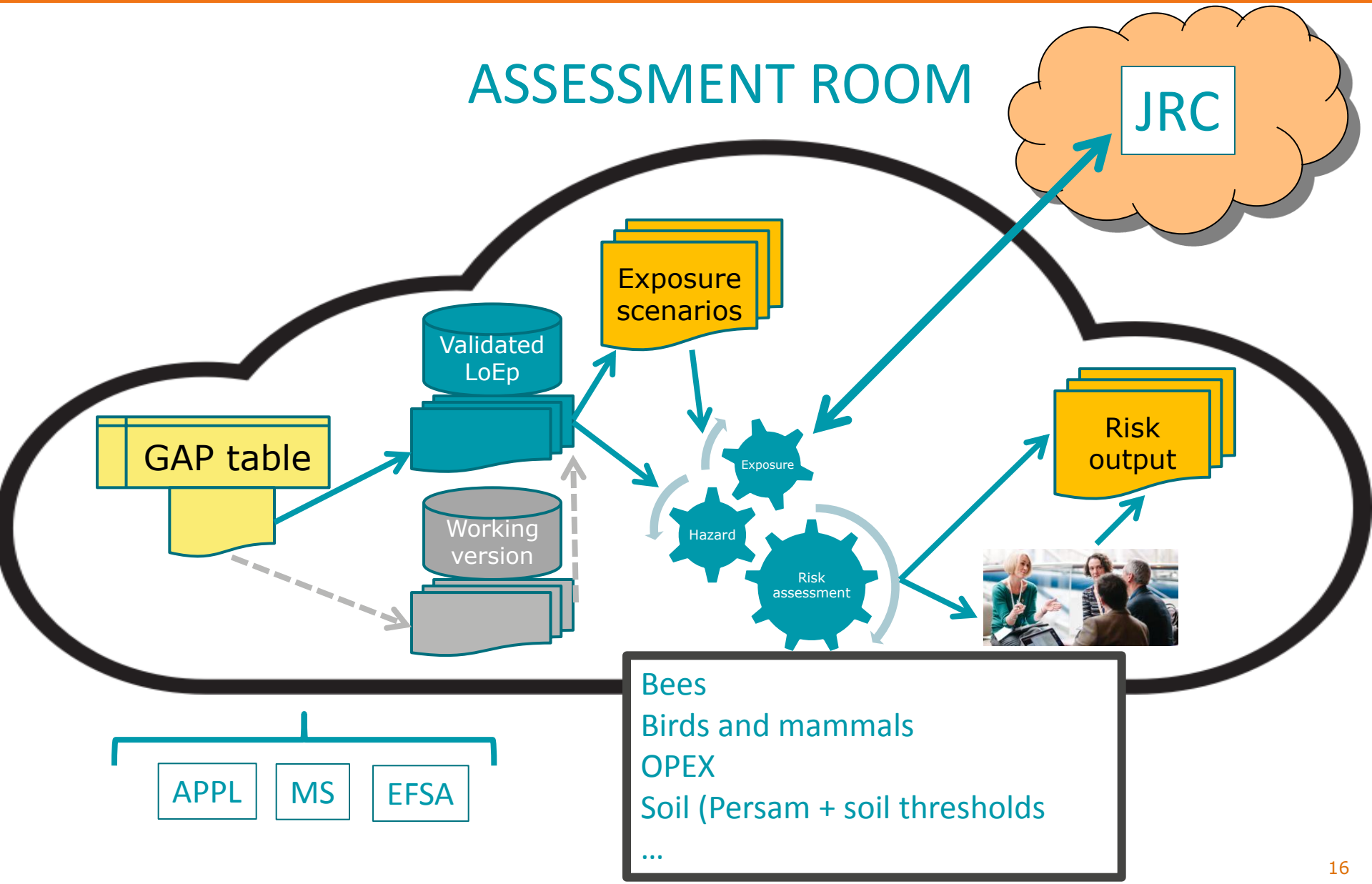



APPL
MS
EFSA
JRC


Academia
Public
JRC
ASSESSMENTS
List of endpoints &
risk assessment tools
APPLICATIONS
Applicant dossiers (raw and
aggregated data) with
verification & workflows
POSTMARKETING
Pesticides Residues
Monitoring & CRA tools
APPL
MS
EFSA
MS
EFSA


Academia
Public
MS
APPL
EFSA
MS
ASSESSMENTS
Working version
Validated LoEp
APPLICATIONS
APPL
R/EMS
EFSA
POSTMARKETING
MS submission
Validated results
APPL
MS
EFSA
MS
EFSA

ASSESSMENT ROOM



Thank you !