REG. 1107/2009
EU DUAL REGULATORY SYSTEM FOR PESTICIDES

EU assessment and approval decision of the active pesticide substance

- Active substance
- Rapporteur MS
- EFSA Peer-Review
- EU approval

MS assessment and pre-marketing authorisation of each formulation

- PPP dossier
- Member State
- Zonal process
- MS PPP authorisation
REG. 396/2005
MAXIMUM RESIDUE LEVELS AND RISK FOR CONSUMERS

EU assessment for all MRL plus combined **pre-** and **post-marketing** assessment of risk for consumers

- MRL application
- Evaluating MS
- EFSA assessment
- EU MRL
- MS to confirm compliance with EU MRLs

**EFSA Annual Report on pesticides residues**

**EFSA MRL reviews**

**EU & MS Annual Monitoring programmes**
PESTICIDES UNIT AND PANEL ACTIVITIES

Methodological developments

Scientific Panel on Plant Protection Product and their Residues (PPR) & methodological development

- Opinions
- Guidance documents
- Ad-hoc mandates

Coordinates the Peer Review of active substances

- Pesticides Steering Network
- Pesticides Monitoring Network

Maximum Residue Levels & Consumers risks

Provides Conclusions and Technical reports for single active substances to support the EU decision-makers

- MRL Reasoned Opinions
- Annual reports: CODEX & residues monitoring
SCIENTIFIC CONSISTENCY

General Scientific assessment:
Opinions & Guidance

Dossier specific assessment:

Conclusions
MRL Reasoned opinions

Reg. 396/2005
MRL setting, pesticide monitoring

Reg. 1107/2009
Evaluation of active substances including micro-organisms (representative uses)

Scientific staff working with Member States experts

PPR Panel
Opinions & Guidance documents
METHODOLOGICAL UPDATES

Need identified
- PPR Panel
- Pesticides Steering Network

Preliminary work by EFSA
- Grants & procurements
- External report

Dialogue with Risk managers

Panel Scientific opinion
- Hearings
- Optional public consultation

Guidance ready for Risk Managers decision on enforcement
- Hearings
- Networking
- Mandatory public consultation

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

Landscape ERA tool
SCIENTIFIC OUTPUTS

Overview

- Scientific Panel outputs (Methodological)
  - Scientific opinions
  - Panel Guidance
  - Panel Statements
- Unit scientific outputs in cooperation with the Panel and MS networks (Methodological)
  - EFSA Guidance
- Unit scientific outputs in cooperation with the MS networks (assessing specific substances)
  - Conclusions on Pesticides
  - Technical Reports
    - E.g. Confirmatory data and basic substances
  - Reasoned Opinions
  - EFSA Statements
  - Annual scientific report supporting CODEX (MRLs)
  - Annual Report on Pesticides Monitoring
  - Other scientific outputs
PESTICIDES PEER-REVIEW & MRL PROCESSES

Conclusion & Reasoned Opinion

EFSA

Assessment | Gap & Risk | Endpoints
--- | --- | ---

TIME LINE

IND

RMS

P-R FINAL RA

LIST OF ENDPOINTS

SCIENTIFIC ASSESSMENT

RM DECISION

PROPOSAL

DRAFT RA

EVALUATION REPORT

Policy decision
Mandatory safety studies

Studies covering one or more representative uses on a widely grown crop and at least one plant protection product containing the active substance

New studies

New weight of evidence

All relevant data from the scientific peer-reviewed open literature

The dossier submitted by the applicant must include the full report of the studies conducted as well as a summary description of them.
ALL AVAILABLE EVIDENCE DISCUSSED AND PRESENTED

RMS

Comments

EFSA

Mandatory GLP studies + Scientific literature + other evaluations

RMS evaluation, updates are highlighted

Comments, responses, meeting reports, MSs views

Critical concerns, data gaps. Validated endpoints
EFSA SCIENTIFIC ASSESSMENT

- Substance ID
- Hazard assessment
- Phys-chem. Properties
- Env. Fate properties

Classification (CLP) Hazard approval criteria

(Eco)Toxicological profile: CMR, Endocrine effects, PBT, POP

- Hazard characterisation
- Exposure assessment
- Risk characterisation

Risk based approval criteria
Conclusions on Pesticides
- Identity and Phys/Chem properties
- Mammalian Toxicology & non dietary health risks
- Residues & Consumers risks
- Environmental Fate and Behaviour
- Ecotoxicology & environmental risks

Reasoned Opinions on MRLs & Annual reports:
- Residues
- (Mammalian Toxicology)
- Consumers risks
Article 6 to 10 of Regulation (EC) No 396/2005:

An MRL application has to be submitted if

• the existing MRLs are not sufficient to cover the new use that was requested in a MS
• Residues in imported products are higher than the existing EU MRL
• An active substance shall be exempted from the need to set MRLs
• A residue definition needs to be revised
• An MRL should be lowered because the applicant considers it is posing a risk to consumers
EXTRAPOLATION

- in Regulation
  - Data requirements (Reg 283/2013; Reg 284/2013)
    - Toxicology
    - ADME
    - Medical data
  - Residues
    - Magnitude of residues in plants

- in Guidance, Scientific Opinions
PROTECTION GOALS

• Protection of biodiversity
• Protection of ecosystem services
• Ecological recovery of (non-target) populations
• Definition of target vs. non-target organisms
• Protection of endangered species

• Spatial and temporal variability
• Secondary consequences (effects & recovery)
• Relation with other stressors (cumulative effects ... and beyond)
PROTECTION GOALS - REFERENCE TIER

Data for selection of representative reference tiers

Data for calibrating lower tiers ensuring sufficient level of protection

General protection goal

Specific protection goal consistent with general goals

Specific protection goal

Reference Tier

Reference tier allows to link the ERA with specific protection goal

Intermediate Tier(s)

First Tier

Calibration of lower tiers by reference tier

1. Core toxicity data
2. Toxicity tests with additional species and/or refined exposure and Toxicodynamics-Toxicokinetics models
3. Population and community experiments and models
4. Field studies and landscape level models

Ecological realism

Simple (few data) to Complex (many data)
Spatial explicit risk maps addressing EU environmental variability
TOOL DEVELOPMENT – LANDSCAPE ERA

Input:
- Intended use patterns
- Chemical properties
- Environmental and ecotoxicological profiles

Data:

Output:

Interphase:

Env. Fate models

Ecotox. models
FROM GENERIC SCENARIOS TO MAPPING RISKS

Moving to landscape based mapping for:
- Protection goals
- Risk assessment
- Risk management options

Environmental and ecological conditions + Land use (crop dist.) = Agro-ecoregions and landscape ecotypes

Agro-ecoregions and landscape ecotypes + GAPs and use patterns = Mapping risks at EU level (individual substance and cumulative)

Substance P1: DegT50 = 15 d; \( K_{ow} \) = 15 L/kg
Concentration in pore water (mg/l)
- Non-arable
- 0 - 0.4
- 0.4 - 0.5
- 0.5 - 0.6
- 0.6 - 0.7
- > 0.7
GEOGRAPHICAL GIS-BASED MAPPING

- 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

- Agro-cultural and land management
  - Geographical distribution crops and fields
  - Agro-technology and crop protection strategy
  - National requirements
SPATIAL SCALE

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
- Urban Landscape
- Industrial Landscape
- Natural Landscape

In-Crop
- Field margins

Off-Crop
- Edge of the field surface water
- hedges
- Natural patches
- Large surface water bodies
CONCEPTUAL FRAME

- 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
QUESTIONS AND RESEARCH NEEDS

- 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?
QUESTIONS AND RESEARCH NEEDS

- 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
CHALLENGES FOR MORE REALISTIC ASSESSMENTS

Several chemical stressors:
• Pesticides
• Fertilizers
• ...
• Veterinary medicines
• Feed additives
• ...
• Contaminants in sludge
• Contaminants in compost
• ...
• Atmospheric deposition
• Waste facilities run-off

Several non-chemical stressors
• Microbial pesticides
• GMOs
• Biological hazards
• Invasive species
• Habitat destruction
• ...

Geo-based characteristics
• Climate
• Geographical features
• Soil properties
• ...

Ecological characteristics
• Species distribution
• Species relevance
• Ecosystem services
• ...

Anthropogenic alterations
• Soil properties
• Land use
• Landscape agricultural modifications
• ...
Thank you!

Make a difference to Europe’s food safety

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