




# Peer review of pesticide active substances in the EU

EFSA Scientific Conference on ERA of pesticides

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  - EU Pesticides Peer Review process
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# PESTICIDES UNIT AND PANEL ACTIVITIES




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

- **Opinions**
- **Guidance documents**
- **Ad-hoc mandates**

**Coordinates the Peer Review of active substances**

Provides **Conclusions** for single active substances to support the EU decision-makers

 **Pesticides Steering Network**  
**Pesticides Monitoring Network**

**Maximum Residue Levels & Consumers risks**

- **MRL Reasoned Opinions**
- **Annual reports: CODEX & residues monitoring**

# EU PESTICIDES PEER-REVIEW PROCESS



**Dossier submission**



## PEER REVIEW

EFSA,  
RapporteurMS,  
other MSs,  
EU Commission,  
Notifier, Public

**1. Commenting phase**

**2. Evaluation of comments**

**3. Expert's consultation**

**EFSA Conclusion**



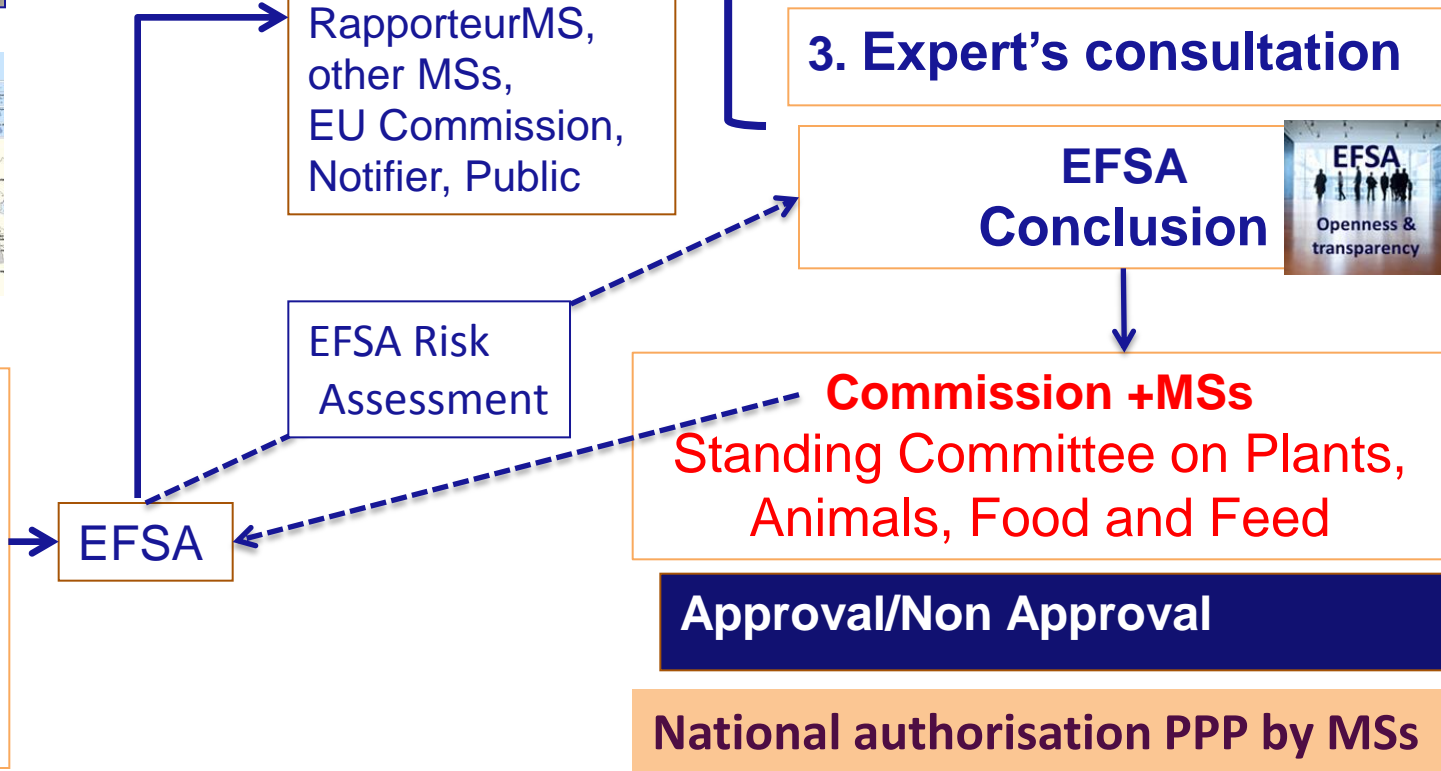
EFSA Risk Assessment

**EFSA**

**Commission +MSs**  
**Standing Committee on Plants, Animals, Food and Feed**

**Approval/Non Approval**

**National authorisation PPP by MSs**



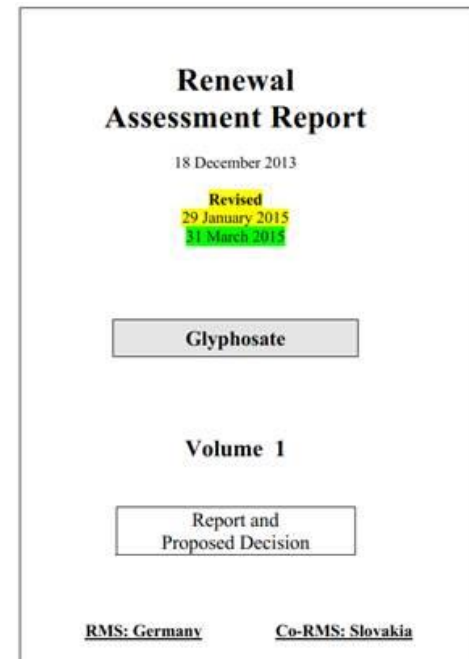


# ALL AVAILABLE EVIDENCE (RE)DISCUSSED



- Proper summary for new and old studies
- According to EFSA 2011, submission of full studies, unless lack of relevance is clear from title/abstract
- Full studies submitted/used in other evaluations

Mandatory GLP studies +  
 Scientific literature +  
 other evaluations



RMS evaluation,  
 new weight of the  
 evidence



# EFSA CONCLUSION

- Output of a scientific peer review
  - Identity and Phys/Chem properties
  - Mammalian Toxicology & Workers/Bystander/residents risks
  - Residues & Consumers risks
  - Environmental Fate and Behaviour
  - Ecotoxicology & Ecosystem risks
- Conducted by EFSA scientific staff and risk assessment experts from the Member States
- The PPR Panel is involved occasionally, e.g. request for endorsement



## EFSA PEER-REVIEW OUTPUTS

### Conclusions on Pesticides

- New active substances (Art.7)
- Applications for an amendment to the conditions of approval (Art. 7)
- Renewal of approval
  - AIR I (7 substances - finalised)
  - AIR II (29 substances - finalised)
  - AIR III (139 substances - currently ongoing)
  - AIR IV (212 substances - upcoming)
- Confirmatory data
- Review of approval (Art. 21)

### Technical reports

- Basic substances
- Confirmatory data



## SPECIFIC REQUEST FROM EC

### ■ **Recently published**

- Call for data for Risk assessment for bees
- Protocol of assessing the need of herbicides to control serious danger to plant health

### ■ **On going and new requests**

- Need to control serious danger to plant health for several herbicide a.s.
- Protocol of assessing the need of insecticides to control serious danger to plant health
- Assessment of negligible (human) exposure for several a.s.
- Updated risk of neonicotinoids/fipronil to bees
- Glyphosate: Risk for animal health / Potential endocrine activity



## NEW REQUIREMENTS UNDER REG 1107/2009

### 1. Publication of summary dossier

### 2. Scientific peer-reviewed open literature

- Review according to EFSA 2011
- Submission of the full studies
  - All relevant studies
  - Those considered relevant but not reliable
  - Those which relevance cannot be fully excluded without checking the full article
- Coverage of metabolites
  - Also those assumed not relevant by the applicant

## NEW REQUIREMENTS UNDER REG 1107/2009

### 3. Effect of water treatment processes on the nature of residues for water abstracted for drinking water

- Applicant to consider reactivity information
- In the first instance, processes of ozonation and chlorination
- Argumentations based on low concentrations at the point of extraction, should also cover metabolites predicted in groundwater and surface water
- Address differences among MS
- If novel compounds identified → risk to human or animal health through drinking water

## NEW REQUIREMENTS UNDER REG 1107/2009

### 4. Assessment of “cut-off” criteria in the EFSA conclusions

- Applicants and RMS to include explicitly the comparisons with the CLH criteria, to allow for comments on C&L proposals during public consultation
- Cooperation with ECHA on C&L proposals

### 5. New data requirements

- Expert discussions on recurrent issues in Ecotoxicology, Mammalian Toxicology; published as Technical Reports



## FINAL CONSIDERATION

### **Selection of representative uses**

- Allow the submission and EU evaluation of all relevant studies
- Ensure definitive proposals on the residue definition and a proper assessment of risk for consumers
- Facilitate a proper coverage of expected environmental fate in all relevant EU zones/areas
- Enable a proper assessment of the risk for non-target organisms, useful for all intended uses



## POSSIBLE IMPROVEMENTS: ON-GOING ACTIVITIES

- **New guidance development** on
  - Birds and mammals
  - FOCUS Repair action
  - Isomers
- Proposals for **improvements** to existing peer review process discussed in Pesticides Steering Network
- **Database** for updated List of Endpoints from Conclusions and Reasoned Opinions following EFSA assessments
- **Electronic submission** of dossier (MATRIX project)
- Final phase development **combined DAR-CLH template**

## COOPERATION ACTIVITIES ON PESTICIDES R.A.

### EU wide: Pesticide Steering Network

- plan and monitor the risk assessment process
- integrate risk assessment and MRL setting processes
- coordinate with the European Chemicals Agency (ECHA)
- give advice on prioritisation and risk assessors needs in the development and the updating of risk assessment guidance documents
- consultation with PSN on draft guidance document to ensure its fit-for-purpose



## COOPERATION ACTIVITIES ON PESTICIDES R.A.

### ■ EFSA-MSs

- Cumulative assessment, Operators-Workers, Epidemiology, microbial pesticides, co-formulants, plant-health,...

### ■ EU-Bodies

- Cooperation with ECHA on C&L, biocides, endocrine disruptors, ...
  - ECHA-EFSA Topical Scientific Workshops
- Cooperation with EU Joint Research Centre
  - Environmental variability and modelling

### ■ International organisations

- EFSA/WHO/FAO workshop on acute exposure estimations for consumers risk assessment, September 2015
- EFSA/OECD workshop on developmental neurotoxicity



# Thank you

Make a difference to Europe's food safety