



Recent Developments and Future Plans in the EFSA Assessments of Pesticides

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Pesticides Unit

Pesticides Unit and Panel activities



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

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

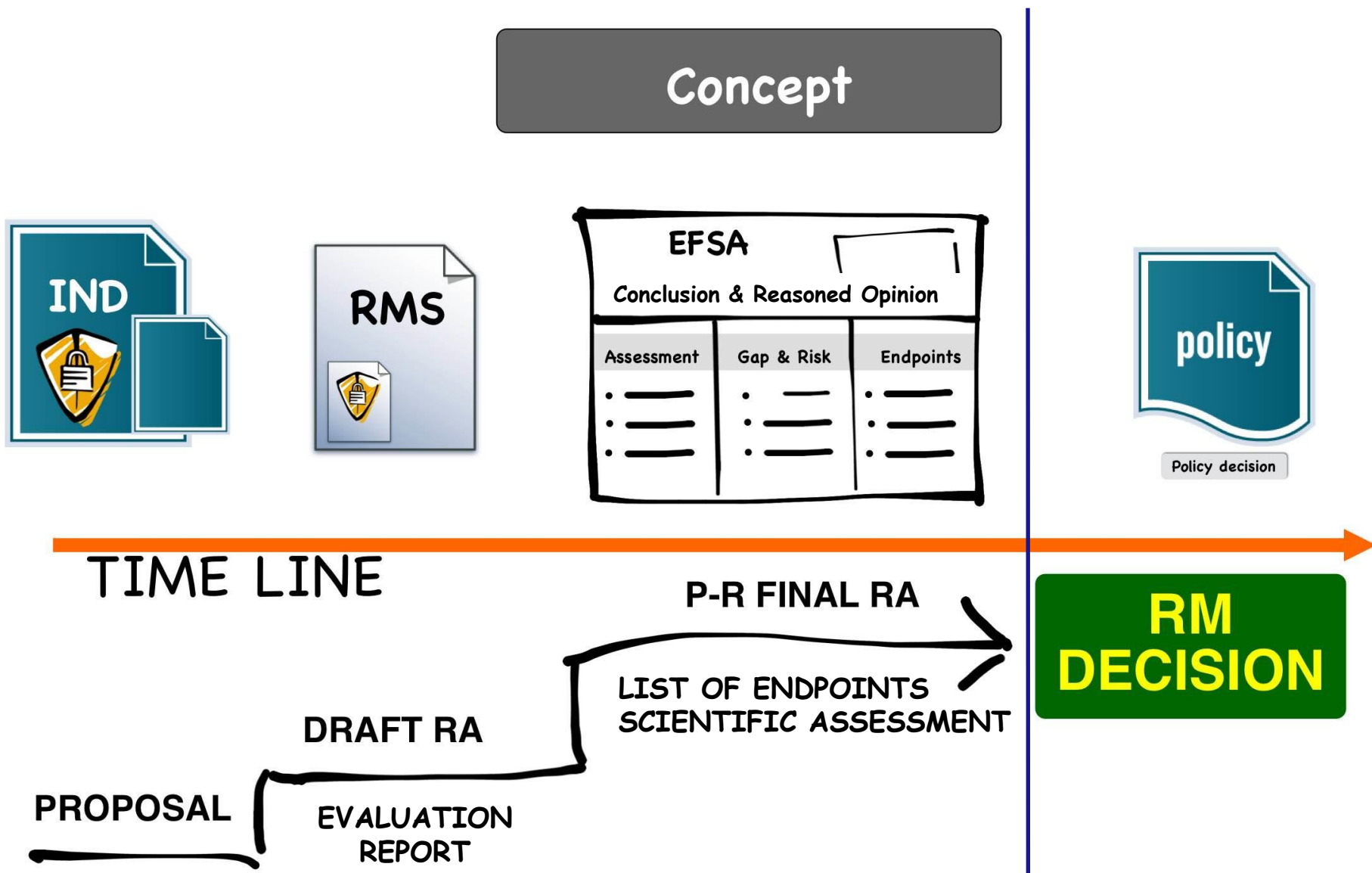


Pesticides Steering Network
Pesticides Monitoring Network

**Maximum Residue Levels
&
Consumers risks**

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

PESTICIDES PEER-REVIEW & MRL PROCESSES



CONCLUSION & REASONED OPINIONS

- 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 & Consumers risks



*Some conclusions are limited to one or more areas

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The Peer-Review Process

Dossier submission



European Union
Programme for Inclusion of Active Substances
in Annex I to Council Directive 91/414/EEC
(Articles 5 and 6 of Council Directive 91/414/EEC)



D/RAR
Draft/Review
Assessment
Report



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

EFSA PEER-REVIEW OUTPUTS

- **Conclusions on Pesticides**

- New active substances
- AIR-II and III renewals
- Confirmatory data
- Reviews under Art 21

- **Technical reports**

- Basic substances
- Confirmatory data

Assessment of Endocrine Disruption
Recurrent issues: Ecotoxicology,
Toxicology



SPECIFIC REQUEST FROM EC

■ Recently published


- Risk of neonicotinoids foliar uses to bees
- Diflubenzuron (metabolite 4-chloroaniline)
- 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 (e.g. flumioxazin)
- Protocol of assessing the need of insecticides to control serious danger to plant health
- Assessment of negligible (human) exposure for flupyrsulfuron-methyl, pymetrozine
- Updated risk of neonicotinoids/fipronil to bees
- Risk of glyphosate for animal health

HAZARD BASED APPROVAL CRITERIA

Annex II, Regulation 1107/2009

- 
- Is or has to be classified as
 - **Mutagen category 1A and 1B**
 - **Carcinogen category 1A and 1B**
 - **Toxic for reproduction category 1A and 1B**
 - Has endocrine properties which may cause adverse effects on humans
 - Is a persistent organic pollutant (POP)
 - Is persistent, bioaccumulative and toxic (PBT) or very-P and very-B (vPvB)
 - Has endocrine properties which may cause adverse effects on the environment

EXCEPTIONAL APPROVAL HAZARDOUS PESTICIDE A.S.



- 
- Carcinogen Category 1A or 1B
 - Toxic to reproduction Category 1A or 1B
 - Endocrine properties which may cause adverse effects on humans

"unless the exposure of humans under realistic proposed conditions of use, is negligible".

- Carcinogen Category 1B with threshold
- Endocrine properties which may cause adverse effects on humans or non-target organisms

"is necessary to control a serious danger to plant health which cannot be contained by other available means"

NEGLECTIBLE EXPOSURE – FIRST CASES

- 
- 
- EC mandates EFSA to provide scientific assistance as regards the consideration of whether exposure of humans to a.s. under realistic proposed conditions of use, can be considered negligible.
 - **Flupyr sulfuron-methyl** (Interim ED based on EFSA proposal)
 - **Pymetrozine** (interim ED based on EFSA proposal + harmonised)
 - ✓ Addendum on Negl. Exposure prepared by RMS
 - ✓ Procedure established (EFSA to deliver its conclusion within 3 months from the receipt of the evaluation by RMS)
 - ✓ Template for the conclusion on the NE available

ARTICLE 4(7)

- Evaluation of data concerning the necessity of the application of herbicide a.s. to control a serious danger to plant health
 - Ongoing application: flumioxazin Art. 4(7)
- EFSA established an ad hoc WG who proposed a methodology. Discussion with MS and EC (PSN, 10 March 2016).



Protocol for evaluation of data concerning the necessity of the application of herbicide a.s. to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods.

<http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2016.EN-1060/abstract>

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Scientific Cooperation: MRLs



Dossier submission



EFSA

Data gathering phase

EFSA Risk Assessment

Commenting phase

EFSA Reasoned Opinion

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

MRL setting



MRL ACTIVITIES

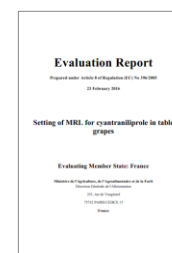
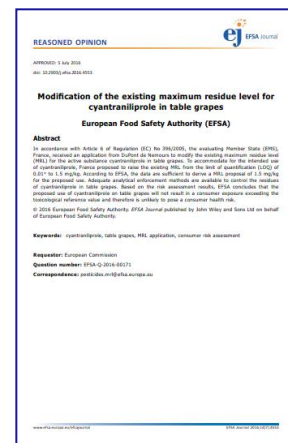
- Reasoned opinions on new proposals/modifications of existing MRL
 - Based on applications
- Reasoned opinions reviewing MRLs for approved/non-approved active substances
 - Based on work programme agreed at the PSN [Link](#)
- Reasoned opinions for ad-hoc EC Request under Art. 43
 - Dimethoathe, omethoate, coumafos, permethrin, oxytetracycline, streptomycin, flumequine, amitraz, thiabendazole, chlorpyrifos, atrazine, metalaxyl (-M), λ -cyhalothrin,...

MRL HIGHLIGHTS

- New calculators covering new data requirements
- New Templates for Reasoned Opinions

- Methods of analysis
- Residues nature and magnitude
- Consumers risk assessment
- MRL proposal

– Evaluation reports & PRIMO risk assessments published as background documents



Parameter	Value	Unit	Comment
Residue level	0.1	mg/kg	Proposed MRL
Exposure assessment	0.05	mg/kg bw/day	Calculated exposure
Toxicological reference value	0.1	mg/kg bw/day	Derived from ADI

- EFSA/FAO/WHO Workshop and Stakeholder Consultation on: Revisiting the International Estimate of Short-Term Intake (IESTI equations) used to estimate the acute exposure to pesticide residues via food

Pesticides Unit and Panel activities



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ANNUAL SCIENTIFIC REPORTS ON PESTICIDES RESIDUES

International harmonisation & Post-marketing monitoring

■ Scientific support for EU Codex Committee on Pesticide Residues (CCPR)

- General issues
- Assessment of individual substances
 - Toxicological reference values
 - Residue definitions
 - CODEC MRL proposals
 - Consumers risk assessment
- Published on Q3

■ Annual Report on Pesticides Monitoring

- ❖ Compiles and report the MS monitoring programmes

➤ Interactive report



- Results of the EU coordinated programme
- Results of the National control programme
- Dietary exposure and dietary risk assessment



COOPERATION ACTIVITIES ON PESTICIDES R.A.

- **EU wide: Pesticide Steering Network**
 - Standard and dedicated meetings
 - Documents available upon request
- **EFSA-MSs**
 - Cumulative assessment, Operators-Workers, Epidemiology, microbial pesticides, co-formulants, plant-health,...
- **EU-Bodies**
 - Cooperation with EU Joint Research Centre
 - Environmental variability and modelling
 - Cooperation with ECHA on C&L, biocides, endocrine disruptors, ...
 - ECHA-EFSA Topical Scientific Workshops
- **International organisations**
 - EFSA/WHO/FAO workshop on acute exposure estimations for consumers risk assessment, September 2015
 - EFSA/OECD workshop on developmental neurotoxicity

IN SUMMARY

Panel + Unit staff + 2 MS networks

Methodological developments

- Scientific opinions
- Guidance
- Panel statements

PPR Team

Same procedures as other EFSA units

Full scientific assessment of active substances

- Conclusions on pesticides
- Technical reports

Peer Review Teams

Specific workflows according to legal procedures involving MSs and ED decision

Ad-hoc assessments under request by EC

- Conclusions
- Statements
- Scientific reports

Proposals for setting Maximum Residue Levels (MRLs)

- Reasoned Opinions

MRL Team 1

Specific workflows & legislation involving MSs

Annual report support to CODEX on MRLs

MRL Team 2

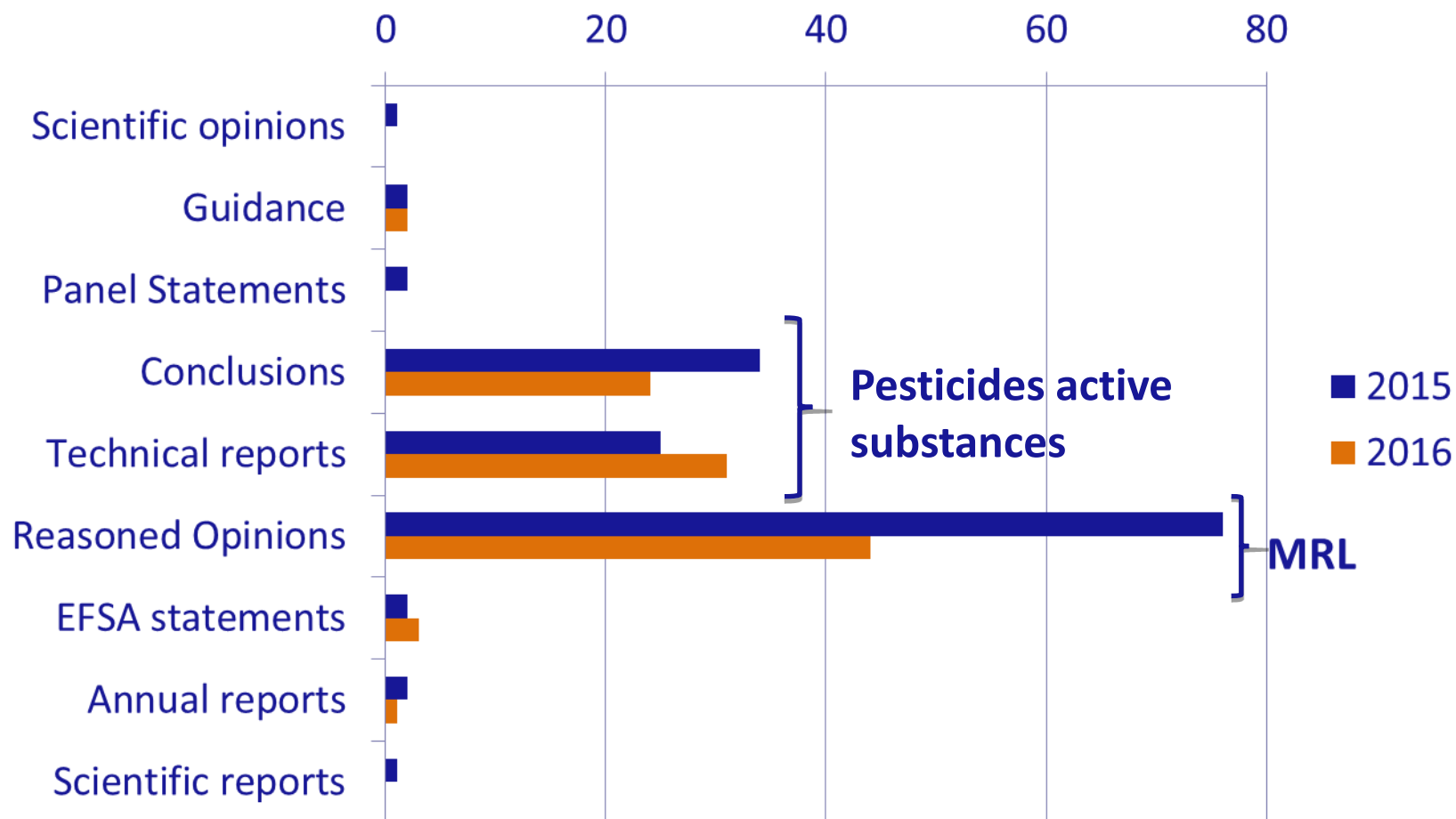
Specific annual activities

Annual Report on residues monitoring



SCIENTIFIC OUTPUTS

Adopted in 2015 - 2016 (Jan-Aug)





Thank you

Make a difference to Europe's food safety