




EFSA work on Cumulative Risk Assessment of pesticides

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Content

- ❑ State of Play with the dietary cumulative risk assessment in EFSA
- ❑ Establishment of Cumulative Assessment Groups
- ❑ 2015-2018 plan

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Main title


State of play

2006 **EFSA's 7th Scientific Colloquium**

2007 to 2013 **4 Scientific Opinions and 1 guidance of the PPR Panel** with involvement of 32 experts and 3 public consultations

2009 to now **Cooperation: 4 External scientific reports** resulting from grant agreements or procurement contracts with external organisations (RIVM, ANSES, DTU, ICPS, University of London)

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Main title

State of play

We have methodologies:

- A tiered methodology for cumulative risk assessment (PPR Panel)
- A guidance for probabilistic modelling of the dietary exposure to pesticide residues (PPR Panel)
- A methodology to establish cumulative assessment groups of pesticides (PPR Panel)

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State of play

We have data:

- A first set of cumulative assessment groups (PPR Panel)
- Consumption data at individual level (EFSA comprehensive consumption database – 23 MSs covered)
- Monitoring data at sample level (Official national and EU coordinated programmes)
- Data from the peer-review

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State of play


A tool is available:

- MCRA software (Cumulative and aggregated exposure to pesticides)

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Establishment of Cumulative Assessment Groups


2 Scientific Opinions of the PPR Panel

- ❑ SO on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profiles
<http://www.efsa.europa.eu/en/efsajournal/pub/705.htm>
- ❑ SO on the relevance of dissimilar mode of action and its appropriate application for cumulative risk assessment of pesticides in food
<http://www.efsa.europa.eu/en/efsajournal/pub/1167.htm>

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Establishment of Cumulative Assessment Groups - Main conclusions of the PPR Panel

- ❑ Both similar and dissimilar modes of actions are relevant mechanisms for the combined toxicity of pesticides.
- ❑ Pesticides that produce common adverse outcomes on the same target organ/system should be grouped together in CAGs and their combined effects assessed by using the concept of dose addition as a pragmatic and conservative default approach for the purpose of assessing cumulative risks.
- ❑ Grouping methodology based on the commonality of the effect rather than on the commonality of the mode of action.

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Establishment of Cumulative Assessment Groups - Process

1. **Identification** of **specific effects** which qualify for cumulative risk assessment:

- Exclusion of local effects
- Exclusion of non adverse effects
- Exclusion of effect not relevant to humans
- Evaluation of the unambiguous nature of the effect
- Exclusion of non specific effects


2. **Characterization** of the specific effects = determination and listing of the appropriate toxicological observations (indicators)

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Establishment of Cumulative Assessment Groups - Application

Effects on the nervous and thyroid system
287 chemical active substances were screened

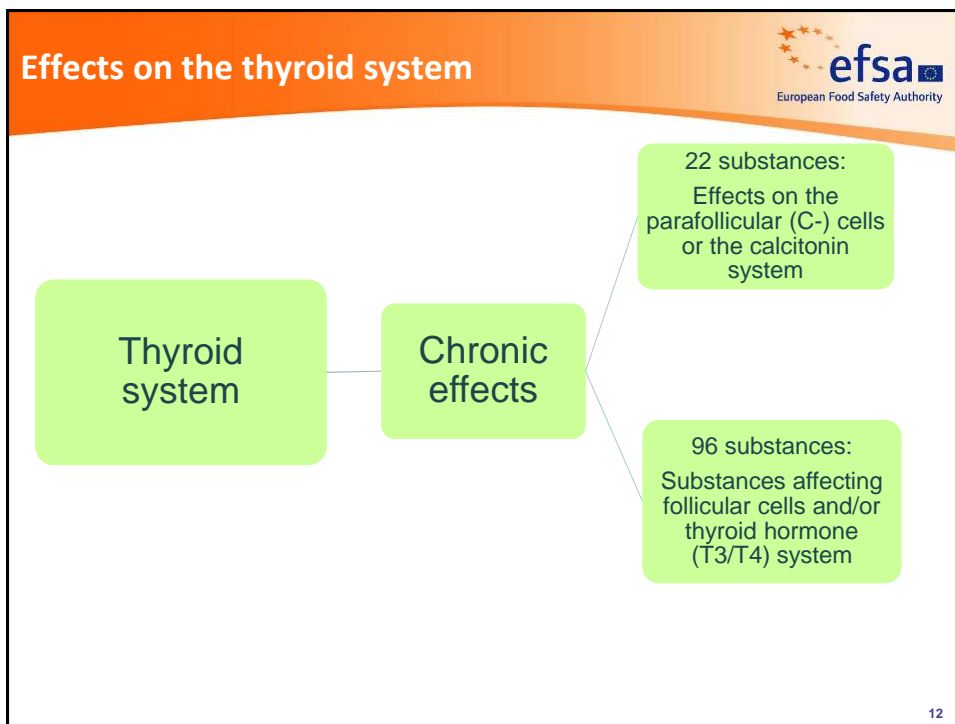
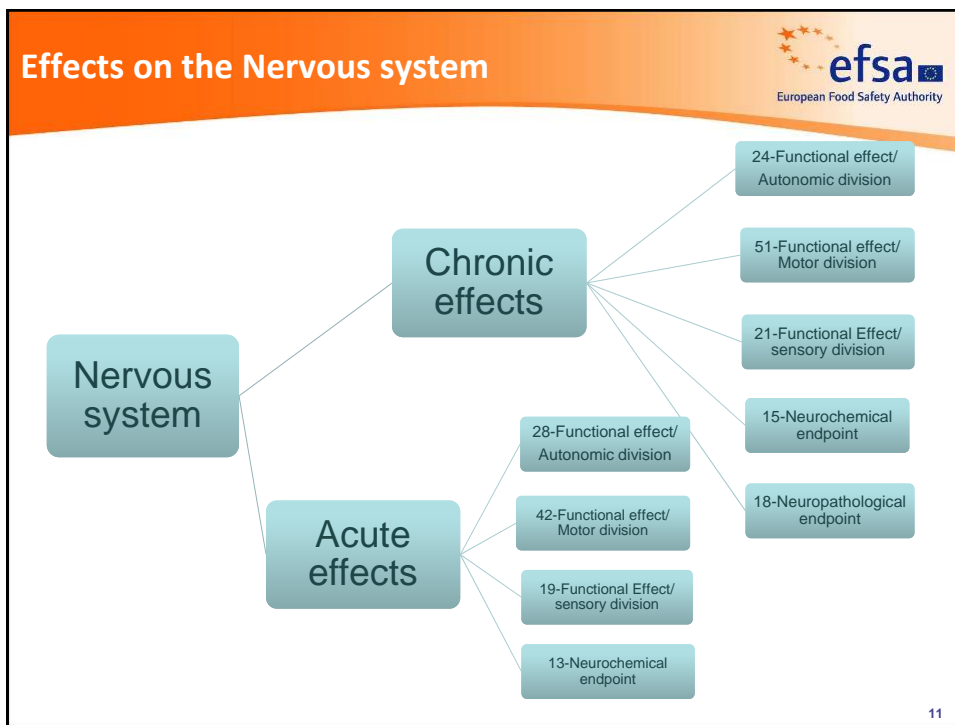


Nervous system
(65 substances with specific effects)



Thyroid system
(101 substances with specific effects)

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Establishment of Cumulative Assessment Groups – No exposure consideration

CAGs are established on the basis of the toxicological profile only.

The level of exposure was not considered for different reasons:

- Exposure is highly variable and depends of the use pattern
- Non-dietary exposure
- RMs may wish to apply different levels of protection to different types of effects

However : Cumulative risks are likely to be driven by a few pesticides/commodity combinations.

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Establishment of Cumulative Assessment Groups - One example

Effect on the follicular cells and T3/T4 system

Indicators:

- Changes in T3/T4 circulating levels
- Follicular cells hypertrophy
- Follicular cells hyperplasia
- Follicular cells neoplasia
- Increased relative thyroid weight

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Establishment of Cumulative Assessment Groups - Difficulties

High workload: large amount of data to be considered


High expertise required:

- Lack of mechanistic information
- Difficulty to conclude on the specificity of the effects in terms of nature and site of occurrence
- Interrelation of effects
- Risk communication / uncertainties

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Main title




2015-2018 Plan

EFSA programme of work on the implementation of cumulative risk assessment of pesticides for 2015-2018

- CRA for the effects on the nervous system and the thyroid
- Continuation of the work on CAGs

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Main title

2015-2018 Plan

CRA for the effects on the nervous and thyroid systems

- 2015-2016: Cumulative Exposure Assessments in the actual exposure scenario
 - With MCRA: Framework Partnership Agreement between EFSA and RIVM
 - With SAS: internal EFSA activity
- 2017: EFSA Scientific reports on the respective Cumulative Risk Assessments

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2015-2018 Plan

Continuation of the work on the establishment of Cumulative Assessment Groups

- 2014-2016: Ongoing grant agreement on a toxicological data collection and analysis to support grouping of pesticide active substances for cumulative risk assessment of effects on the nervous system, liver, adrenals, eyes, reproduction and development and thyroid system.
- 2016-2018: EFSA Scientific Reports on Cumulative Assessment Groups for the above effects.

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Thank you