

EFSA: Implementation of CRA of pesticide residues

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The legal basis

Article 14 of **Regulation (EC) No 396/2005** provides that pesticide MRL setting needs to 'take account of their known cumulative and synergistic effects, when the methods to assess such effects are available'



Methodologies are available

EFSA Panel on plant protection products and their residues (2007 to 2013)

- Hazard identification/characterisation: Mixtures of interest (CAGs)
- Exposure assessment: Probabilistic modelling
- Risk characterisation: Tiered methodology
- 4 Scientific Opinions and 1 Guidance
- 5 Working Groups
- Cooperation with external organisations (RIVM, ICPS, ANSES, DTU)
- 3 public consultations



The methodology in 3 sentences

- The methodology uses cumulative assessment groups which are populated by pesticides causing a same phenomenological effect.
- The cumulative risks are calculated with the dose-addition model
- Interactions so far not considered but not expected considering the low level of exposure

The methodology offers a high level of protection and allows RMs to apply the precautionary principle.

Overall feeling that it tends to overestimate the actual risks.



Data are available

- Official monitoring results from national competent authorities
- National food consumption surveys from various institutes in EU MSs
- Pesticide dossiers reviewed by EFSA



Exposure tools are available

- EFSA SAS®-based model
 Development/validation of the probabilistic model
 Programming codes publicly available
- RIVM Monte Carlo Risk Assessment (MCRA)
 Software implementing the probabilistic model



An implementation programme started in 2014

Retrospective cumulative risk assessment

By end of June 2019 (pilot phase)

Nervous system and thyroid

From 2020

Adrenals, development, eyes, haematopoietic system, kidneys, liver, reproduction and testes



Foreseen publications (end June)

2 batches of 4 documents (Nervous system and thyroid)

- 1 EFSA SR on Cumulative Assessment Groups
- 1 RIVM SR on cumulative Exposure Assessment
- 1 EFSA SR on Cumulative Exposure Assessment
- 1 EFSA SR on cumulative Risk Assessment and uncertainty analysis

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