



Cumulative Risk Assessment

Luc Mohimont

Deputy Head Pesticides Unit

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The cocktail effect of pesticides

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 now available

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

- Hazard assessment: Mixtures of interest
- Exposure assessment: Probabilistic modelling
- Risk characterisation: Tiered methodology

4 Scientific Opinions and 1 Guidance

5 Working Groups (30 independent experts)

Cooperation with 4 external organisations (RIVM, ICPS, ANSES, DTU)

3 public consultations

Holistic approach for the assessment of chemical mixtures

EFSA Scientific Committee

Guidance on harmonized methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals

- Endorsed by the Scientific Committee for public consultation on 28 May 2018
- The current work on pesticides is one of the options proposed by the Scientific Committee

Data are available

- Official monitoring results from national competent authorities
- National food consumption surveys
- Pesticide dossiers reviewed by EFSA

An implementation programme is in place

2018

- Nervous system
- Thyroid

2019 to 2023

- Adrenals
- Development
- Eyes
- Haematopoietic system
- Liver
- Reproduction
- Testes

Example: Nervous system

420 Active substances reviewed

- 120 acting on the motor function
- 55 acting on the sensory function
- 60 acting on the autonomic function
- 50 with neurochemical effects
- 20 with neuropathological effects

All results will be published in an EFSA scientific report

Knowledge sharing with national competent bodies

Cooperation Agreement with RIVM on the **MCRA** software (= web-based tool owned by RIVM accessible for stakeholders performing probabilistic cumulative and aggregated exposure assessments)

Long term objective is that MCRA becomes

- fully compatible with EFSA's methodologies and data
- usable autonomously by EFSA and national competent organisations for consistent and transparent regulatory assessments

Cooperation with EC and MSs

Commission WG on risk management questions related to cumulative risk assessment

- Protection goals
- Problem formulation
- Regulatory assumptions

Joint effort in **Risk Communication**

Uncertainties !