Cumulative and aggregate risk assessment. Activities of the PPR panel and PPR unit

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Content of the presentation:

Regulatory background

Dietary Cumulative Risk assessment:

- What has been done
- What is ongoing
- What needs to be initiated

Non dietary CRA

Regulatory background

EFSA activities on pesticides are based on 3 main legislations:

1. Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market.

- Data requirements and criteria decision making
- Role of EFSA in PEER REVIEW of ASs (Conclusions)

2. Regulation (EC) 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin

- Establishment of MRLs
- Role of EFSA in RA related to MRLs (Reasoned opinions) and in the evaluation of the overall consumer exposure (monitoring reports)

Regulatory background

3. Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food safety Authority and laying down procedures in matters of food safety.

➢Role of EFSA in Risk analysis

- Support for Community legislation and policies
- Main principles for independent, objective and transparent RAs
- Precautionary principle
- Cooperation with competent bodies
- Commission of studies
- Data search, collection and analysis

Dietary Cumulative Risk Assessment

Regulation EC 396/2005 on maximum residue levels (MRLs)

Art 14 (Decision on applications concerning MRLs):

" …account shall be taken of… the possible presence of pesticide residues arising *from sources other than current plant protection uses* of active substances, *and their known cumulative and synergistic effects*, when the methods to assess such effects are available…"

Whereas (6):

"It is also important *to carry out further work to develop a methodology to take into account cumulative and synergistic effects*. In view of human exposure to combinations of active substances and their possible aggregate and synergistic effects on human health, MRLs should be set *after consultation of the European Food Safety Authority*…"

CRA, completed activities

2006 The EFSA's 7th **Scientific Colloquium** Report –

Cumulative Risk Assessment of pesticides to human health: The Way forward

http://www.efsa.europa.eu/en/supporting/pub/117e.htm

- Underlying science
- Existing experience
- Recommendations

CRA, completed activities

2008: PPR **Scientific Opinion** to evaluate the suitability of existing methodologies and, if appropriate, the identification of new approaches to assess cumulative and synergistic risks from pesticides to human health with a view to set MRLs for those pesticides in the frame of Regulation (EC) 396/2005

http://www.efsa.europa.eu/en/efsajournal/pub/705.htm

- Review of the different types of combined toxicity: conclusion that dose addition is the most relevant for pesticide residues
- Review of the different RA methodologies for dose addition
- Description of the possible steps of a tiered approach for CRA
  - Hazard characterisation (critical effect, specific (common) effect, NOAEL, BMD)
  - Exposure assessment (deterministic, probabilistic)
  - Risk characterisation (HI, aHI,… methods based on RPFs)
- Sources of uncertainties
- Probabilistic methodology needed.

CRA: completed activities

2009 PPR **Scientific Opinion** for a selected group of pesticides from the triazole group to test possible methodologies to assess cumulative effects from exposure through food from these pesticides on human health

http://www.efsa.europa.eu/en/efsajournal/pub/1167.htm

- Support by a procurement contract with Rikilt institute (Published)
- Scenarios: Acute (developmental effect)/chronic (liver effect), pre and post normative, deterministic/probabilistic
- Conclusions:

1. The CAG should be as refined as the data allow at an early stage
2. The exposure assessments should ideally be restricted to one deterministic and one probabilistic tier.
3. Identification of issues which need to be solved: establishment of cumulative assessment groups at European level, level of protection, exposure assessment methodologies

CRA, ongoing activities

2012: PPR **Scientific Opinion** on the identification of pesticides to be included in cumulative assessment groups (CAGs) on the basis of their toxicological profile

- Opinion supported by a grant contract with the Danish Technical University (final report approved by EFSA, will be published)
- Development of a strategy to identify relevant toxicological effects of pesticides and their respective endpoints.
- Methodology based on identification of relevant phenomenological effects rather than on mechanism of action
- Proposal of respective CAGs
- Adoption of the opinion foreseen by end of 2012
- Public consultation?

CRA: ongoing activities

2013: PPR **Scientific opinion** on the relevance of dissimilar mode of action (response addition) and its appropriate application for cumulative risk assessment of pesticides in food

- Growing scientific evidence (Christiansen et al., 2008; Kortenkamp 2008; Moretto, 2008; Kortenkamp and Hass, 2009; Kortenkamp et al., 2009; Kortenkamp and Faust 2010; Jacobsen et al., 2010; Reffstrup et al., 2010)
- Opinion supported by a procurement contract with the school of Pharmacy of the University of London (Final report approved by EFSA, will be published)
- Is dissimilar mode of action relevant?
- How should it be accounted for?
- Current trend: use dose addition as a valid surrogate approach
- Adoption foreseen end 2013

CRA, ongoing activities

2012: PPR **guidance** on the use of probabilistic methodology for modelling dietary exposure to pesticide residues

- How does the cumulative exposure varies across a population of interest?
- 2 scenarios (MRL setting/authorization and actual exposure)
- Acute and chronic exposure
- Single compound exposure and cumulative exposure
- Basic and refined modelling
- 2 Public consultations, the second one being just started:

  http://www.efsa.europa.eu/en/consultations/call/120125.htm

  Deadline 07 March 2012
- Adoption by June 2012

CRA: future activities

- Definition of priorities between a possibly high number of CAGs
- Definition of the desired levels of protection
- Data collection, identification of data gaps
- Deterministic methodology
- First CRAs in 2013
- Accessible platform for CRA?

Non dietary CRA

1. Procurement contract between EFSA and FERA on a collection and assessment of data relevant for non dietary cumulative exposure to pesticides and proposal for conceptual approaches for non dietary cumulative exposure assessment.

- Development of a data collection strategy to reflect the non dietary cumulative exposure to pesticides
- Implementation of the strategy into a pilot survey
- Will focus on farmers, contract applicators, amateur users and workers in treated areas.
- Completion mid 2012

2. Future mandate for the PPR Panel on non dietary CRA and on aggregate exposure