EFSA’ activities on risk assessment of endocrine disruptors with a special emphasis on pesticides

Hans Steinkellner, Panel on Plant Protection Products and their Residues (PPR), European Food Safety Authority (EFSA)

8th BfR Forum on Consumer Protection: When substances affect the endocrine system - Possible health risks of endocrine disruptors
Berlin, 19-20 April 2010
EFSA’s role is to assess and communicate risks associated with the food chain.

Requests for scientific assessments are received from the European Commission, the European Parliament and EU Member States. EFSA also undertakes scientific work on its own initiative, so-called self-tasking.

EFSA’s gives advice on European legislation on food or feed safety (approval of pesticides and food/feed additives) and develops guidance documents and gives support for regulatory frameworks in the field of food and feed safety.
EFSA’s tasks

EFSA provides independent scientific advice and risk assessments but is not involved directly in any risk management processes.

EFSA’s scientific work is mainly carried out by its Scientific Panels, consisting of independent experts serving a 3-year mandate.

Their output is usually published in form of "Scientific opinions" in the on-line "EFSA Journal".
EFSA’s structure

Risk Assessment Directorate

- AHAW - Animal health and welfare
- ANS - Food additives and nutrient sources added to food
- BIOHAZ - Biological hazards
- CEF - Food contact materials, enzymes, flavourings and processing aids
- CONTAM - Contaminants in the food chain
- FEEDAP - Additives and products or substances used in animal feed
- GMO – Genetically modified organisms
- NDA - Dietetic products, nutrition and allergies
- PLH - Plant health
- PPR - Plant protection products and their residues
- SC – Scientific committee
- AFC - Former Panel on additives, flavourings, processing aids and materials in contact with food
EFSA’s structure

Scientific Cooperation and Assistance Directorate

- AMU – Assessment methodology
- DATEX – Data collection and exposure
- EMRISK – Emerging risks
- PRAPeR – Pesticide risk assessment peer review
- SCO – Scientific cooperation
- Zoonoses – Zoonoses data collection
Pesticides

PRAPeR – Pesticides Risk Assessment Peer Review
• assessment of PPPs under Directive 91/414/EEC
• setting of MRL’s under Regulation EC 396/2005

PPR - Plant Protection Products and their Residues
• scientific advice on risk assessment of PPPs for risk managers
• updating existing and developing new guidance documents
• support of PRAPeR risk assessments

- Extensive data requirements for authorisation of PPPs (developmental studies in 2 species, multigeneration study, chronic/carcinogenicity studies in 2 species)

- Endocrine effects are not specifically addressed

...requires a specific toxicological evaluation of substances for endocrine disrupting properties, applicable from 14 June 2011 onwards.
An active substance shall only be approved if it is not considered to have endocrine disrupting properties unless the exposure of humans is negligible.

By 14 December 2013, the Commission shall present a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties.

Pending the adoption of these criteria, substances that are or have to be classified as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties.

In addition, substances such as those that are or have to be classified as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.
OECD

- development of guidance documents, test guidelines and a conceptual framework for the assessment of endocrine disruptors
Activities joined by PPR

EU Member States

• BfR activities on the establishment of criteria for endocrine disrupting properties under the EU Plant Protection Product Regulation
EU Commission - DG ENV

• lead on endocrine disruptors in regard to future regulatory measures in the EU

• analysis of regulatory relevance of the scientific debate on EDs in context with the Community Strategy on EDs, the OECD conceptual framework, approaches in different national and international bodies

• drawing conclusions on the future assessment of EDs in the EU
Regulation EC 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

“.. account shall be taken of… the possible presence of pesticide residues ..and their known cumulative and synergistic effects, when the methods to assess such effects are available…”

“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..”
Cumulative Risk Assessment

2008: Opinion of the Scientific Panel on Plant Protection products and their Residues 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

2009: Scientific Opinion on Risk Assessment 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

2010-2011: Opinion on Cumulative Assessment Groups of pesticides
   Compilation of a pesticide data base (structure & activity), identification of specific and non-specific effects, identification of mechanisms of toxic action, identification of “Common Assessment Groups”
According to OECD guidance document on the definition of Residue (Series on Pesticides, No. 31; Series on Testing and Assessment, No. 63, 2006)

“toxicologically relevant” metabolites should be included in residue definition for dietary risk assessment
Toxicity of pesticide metabolites

2009-2011: Scientific opinion on approaches to evaluate the toxicological relevance of metabolites and degradates of pesticide active substances in dietary risk assessment

2011-2012: Guidance document on the establishment of the residue definition for risk assessment in food commodities
Commissioned work for opinion

- Applicability of the Thresholds of Toxicological concern (TTC) concept
- Impact of metabolic processes on the toxicological properties of active substances
- Applicability of (Q)SAR analyses
CEF - Food contact materials, enzymes, flavourings and processing aids

2006: Opinion related to Bisphenol A

2008: Opinion on the toxicokinetics of Bisphenol A

Currently: Mandates for evaluations of
- a study on high and low-dose neurodevelopmental effects of BPA
- recent literature on toxicity of BPA, focused on low dose effects

A global opinion is expected for May 2010
ANS - Food additives and nutrient sources added to food

• Risk assessment for authorisations

The approach for the evaluation of potential endocrine effects will be one of the issues considered for the preparation of the guidance on submissions for food additive evaluations that will replace the current guidance established by the SCF in 2001 (*SCF/CS/ADD/GEN/26 Final*).
Authorisations for feed additives are carried out under Regulation (EC) No. 1831/2003 on additives for use in animal nutrition.

Maximum levels for certain contaminants in feed (and provisions for their monitoring) are provided in Directive 2002/32/EC on undesirable substances (e.g.

Monitoring for contaminants and impurities in feed additives should be consistent with existing legislation (e.g. Directive 2002/32/EC) or recommendations from internationally recognised sources if available (e.g. JECFA, Commission recommendations)
CONTAM - Contaminants in the food chain

- risk assessment of unauthorised substances not covered by other EFSA Panels
2005: Opinion related to the presence of non dioxin-like polychlorinated biphenyls (PCB) in feed and food

2006: Opinion related to hexachlorobenzene as undesirable substance in animal feed

2006: Advice related to relevant chemical compounds in the group of brominated flame retardants for monitoring in feed and food

2006: Opinion related to DDT as an undesirable substance in animal feed

2006: Opinion to assess the health risks to consumers associated with exposure to organotins in foodstuffs

2007: Opinion related to hormone residues in bovine meat and meat products

2007: Chlordane as undesirable substance in animal feed

2008: Glucosinolates as undesirable substances in animal feed

2008: Scientific opinion on perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts
AMU - Assessment Methodology

EFSA Scientific Cooperation (ESCO) Working Group on Isoflavones

- Identification and characterisation of potential hazards/health benefits associated with consumption of isoflavones
- Report is expected for end of 2010
EFSA activities

NDA - Dietetic products, nutrition and allergies

• dietary reference values
• health claims (e.g. iodide, isoflavones)
• dietary products
• assessment of novel foods

2009: Opinion on the safety of ‘Alfalfa protein concentrate’ as food
EFSA activities

SC - Scientific Committee

Current activities:

• Scientific Opinion on exploring options for providing preliminary advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC)

• Leads EFSA‘s Internal Task Torce on EAS involving concerned Units in order to develop a common strategy towards endocrine active substances in regard to EFSA‘s remit in food and feed safety issues
  - identification of trends and developments in assessment of EAS and risk communication and perception issues
  - technical report on EAS clarifying the state of play and giving recommendations for scientific and communication issues
Communications Directorate

Press releases & web stories so far focussed on individual substances (Bisphenol A, Dioxins, PCBs, PFOS/PFOA)

- Analysis of occurrence of relevant terms in media and public debate
- Overall approach to the issue (e.g. terminology - Endocrine active Substances-EAS vs. Endocrine Disrupting Substances-EDS)
- Scientifically sound but understandable communication
http://www.efsa.europa.eu/de/
Thank you for your attention!