

# **EFSA' activities on risk assessment of endocrine disruptors with a special emphasis on pesticides**

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**When substances affect the endocrine system - Possible health risks of endocrine disruptors**

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# **EFSA's tasks**

**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 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" .**

## 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

## 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

## 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



## **Council Directive 91/414/EEC concerning the placing of plant protection products on the market (91/414/EEC)**

- **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**

**Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC**

**...requires a specific toxicological evaluation of substances for endocrine disrupting properties, applicable from 14 June 2011 onwards.**



# Relevant text from Reg. (EC) 1107/2009

**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**

## 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..**”

**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**

**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*).**

## **FEEDAP - Additives and products or substances used in animal feed**



**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)**

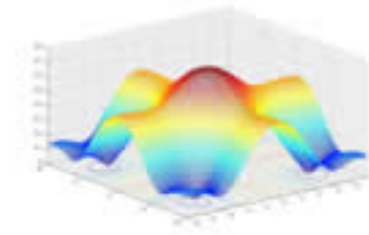
## CONTAM - Contaminants in the food chain



- **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**

## **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**



## 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 Force 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



EFSA JOURNAL

**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/>



The screenshot shows the German homepage of the European Food Safety Authority (EFSA). The browser window title is "Die Europäische Behörde für Lebensmittelsicherheit (EFSA) - der Sicherheit der Lebensmittel in - EFSA - Internet Explorer". The address bar shows "http://www.efsa.europa.eu/de". The website features the EFSA logo and a banner image of a child eating watermelon. A navigation menu on the left includes "Home", "Über die EFSA", "Partner & Netzwerke", "Wissenschaftliche Dokumente", "Gremien & Referate", "Themen A-Z", "Aufforderungen & Konsultationen", "Nachrichten", "Veranstaltungen & Sitzungen", and "Kontakt". The main content area is titled "Europäische Behörde für Lebensmittelsicherheit (EFSA)" and contains a search bar, a "Subscribe to our newsletters" button, and a section for "EFSA JOURNAL". A news item titled "EFSA veröffentlicht europaweiten Überblick über Dioxinkonzentrationen in Lebensmitteln und Futtermitteln" is visible. The footer shows the URL "http://www.efsa.europa.eu/en/events/event/ef100423.htm" and the Windows taskbar.

**Thank you for your attention!**