GENERAL INTRODUCTION AND BACKGROUND

CONTAM Opinion on dioxins and DL-PCBs in food and feed

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Info Session - 13 November 2018
In 2015, EFSA received a mandate from EC asking for:

1. Scientific and technical assistance to **assess and explain the differences in health-based guidance values (HBGV) established by different organisations** as regards dioxins and DL-PCBs

2. Based on the outcome of the above, **if appropriate, carry out a comprehensive RA on the risks for animal and human health related to the presence of dioxins and DL-PCBs in feed and food**
Mandate by EC

**EFSA Statement on the differences in HBGV**

Examine the approaches taken by the SCF, JECFA and the US-EPA and how these differing approaches impact on the final derivation of a numerical value.

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**Scientific statement on the health-based guidance values for dioxins and dioxin-like PCBs**

*European Food Safety Authority*
Mandate by EC

EFSA Statement on the differences in HBGV

Examine the approaches taken by the SCF, JECFA and the US-EPA and how these differing approaches impact on the final derivation of a numerical value.

Differences related to:
- Experimental animal studies vs human data (epi studies)
- Body burden 1-compartment kinetics vs PBPK modelling
- Differences in Uncertainty factors applied

In view of the different approaches used, it would appear appropriate to undertake a comprehensive risk assessment related to the presence of dioxins and DL-PCBs in feed and food.
Mandate by EC

**EFSA Comprehensive risk assessment**

- TORs as provided by EC:
  - Evaluate the *toxicity* for humans
  - Estimate the *dietary exposure* of the EU population
  - Assess the *human health risks*

- Evaluate the *adverse effects* in farm/companion animals
- Estimate the *exposure* of the different animal species
- **Transfer** from feed to food of animal origin
- Assess the *farm/companion animal health risks*
The mandate did not include a risk-benefit assessment of fish consumption.
The Opinion

Selected as pilot opinion to implement the principles of the Prometheus framework

**PROmoting METHods for Evidence Use in Science**

Develop and apply a structured methodological approach for the RA
The Opinion

Set-up of the CONTAM Panel Working Group:

- **14 external experts**: on reproductive toxicology, immunotoxicology, genotoxicity, cancer, epidemiology, mode of action, toxicokinetic modelling, exposure, chemistry

- **Hearing experts**: on reproductive toxicology, tk modelling, two main cohorts (Seveso and Russian Children’s Study)

  - Supported by **EFSA staff** from the BIOCONTAM, DATA and AMU Units

The WG initiated its activities in June 2015
The Opinion

Milestones:

- **June-December 2015**
  Development of the Risk Assessment strategy

- **January 2016**
  Endorsement of the strategy by the CONTAM Panel

- **January 2016 - June 2018**
  Implementation phase: Development of the draft risk assessment

- **June 2018**
  Adoption of the opinion by the CONTAM Panel
The Opinion

After adoption:

- The publication of the adopted opinion was planned for 28 August 2018

- Given the new scientific information contained in the opinion and its sensitivity, EFSA decided to postpone its publication and organise an exchange of views with MS

  ✓ The adopted opinion was sent under confidentiality to the AF members on 31 August

  ✓ AF members were invited to provide general observations by 19 October 2018

  ✓ AF members were invited to an Information Session in Parma
Today’s Information Session

Objectives:

✓ Present **methodologies** applied in the EFSA Opinion
✓ Present the **main outcomes** of the opinion
✓ Opportunity for an **open dialogue** with EFSA and the experts who worked on the opinion
✓ To **provide clarifications** ahead of its publication
Today’s Information Session

The focus will be on topics raised in the comments received

- Methodology
- Occurrence data and exposure assessment
- Trends in exposure and human milk
- Studies in experimental animals
- Studies in humans
- TEF scheme
- Toxicokinetic modelling and derivation of HBGV
- Uncertainty and recommendations

- Not on the farm and companion animals risk assessment
- Not on the transfer from feed to food of animal origin
Today’s Information Session

After each block of presentations: **time for discussion**