GENERAL INTRODUCTION AND BACKGROUND

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

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Info Session - 13 November 2018

efsa
European Food Safety Authority

Mandate by EC

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.

SCIENTIFIC REPORT

EFSA Journal

APPROVED: 28 May 2015

PUBLISHED: 29 May 2015

doi:10.2903/j.efsa.2015.4124

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**

Mandate by EC

EFSA Comprehensive risk assessment

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 **METH**ods for **E**vidence **U**se in **S**cience

Develop and apply a structured methodological approach for the RA

The Opinion

Set-up of the CONTAM Panel Working Group:

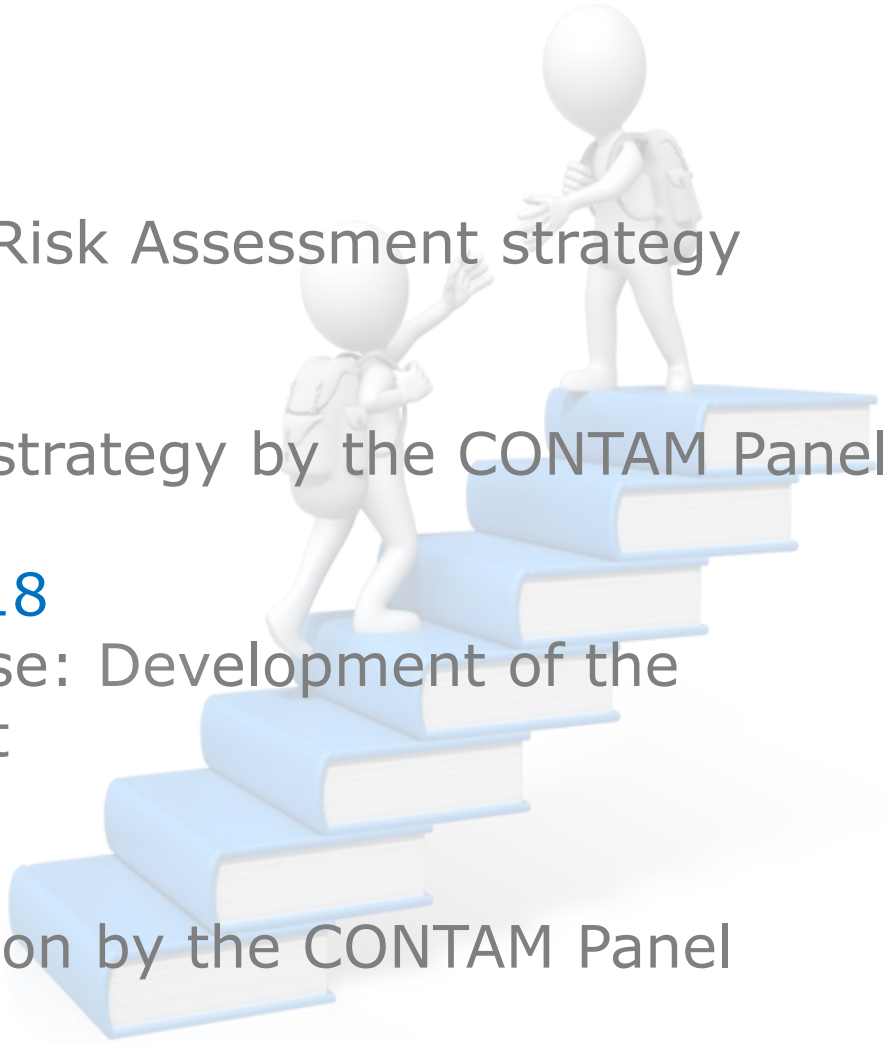
- **14 external experts**: on reproductive toxicology, immunotoxicology, genotoxicity, cancer, epidemiology, mode of action, toxicokinetic modelling, exposure, chemistry
- **Hearing experts**: on reproductive toxicology, tk modelling, two main cohorts (Seveso and Russian Children's Study)
- Supported 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**