



# Update on the publication of the EFSA Dioxins risk assessment

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## MANDATE FROM 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

## 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



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

**European Food Safety Authority**

## 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 on the risks for animal and human health related to the presence of dioxins and DL-PCBs in feed and food.



# COMPREHENSIVE RISK ASSESSMENT IN FOOD AND FEED

## ■ TORs as provided by EC:



- **Evaluate the toxicity of dioxins and DL-PCBs** for farm animals and humans



- **Estimate the dietary exposure of the EU population,**



- **Estimate the exposure of the different animal species, and the levels of transfer/carry-over** from the feed to the food products of animal origin,



- **Asses the human health risks for the EU population,**

- **Asses the farm/companion animal health risks for the different animal species**



## COMPREHENSIVE RISK ASSESSMENT IN FOOD AND FEED

### ■ Set up of the CONTAM Panel Working Group:



- **13-15 external experts:** reproductive toxicology, immunotoxicology, genotoxicity, cancer, epidemiology, mode of action, toxicokinetic modelling, exposure, chemistry
- **Hearing experts:** reproductive toxicology, experts for the 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

## COMPREHENSIVE RISK ASSESSMENT IN FOOD AND FEED

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

### **PROM**oting **METH**ods for **E**vidence **U**se in **S**cience

Develop and apply a structured methodological approach for the risk assessment:

**Develop a priori the risk assessment protocol**

- ✓ **Identify** the RA sub-questions, define the approach to answer them:
  - Critical sub-questions: **Extensive literature search + appraisal**
  - Informative sub-questions: **narrative description**
- ✓ Develop **inclusion/exclusion criteria** and **data extraction** forms
- ✓ Develop **critical appraisal tools** to appraise the internal validity
- ✓ **Integration** of the lines of evidence

## COMPREHENSIVE RISK ASSESSMENT IN FOOD AND FEED

### ■ Milestones:

#### ❖ June-December 2015

Development of the Risk Assessment protocol

#### ❖ January 2016

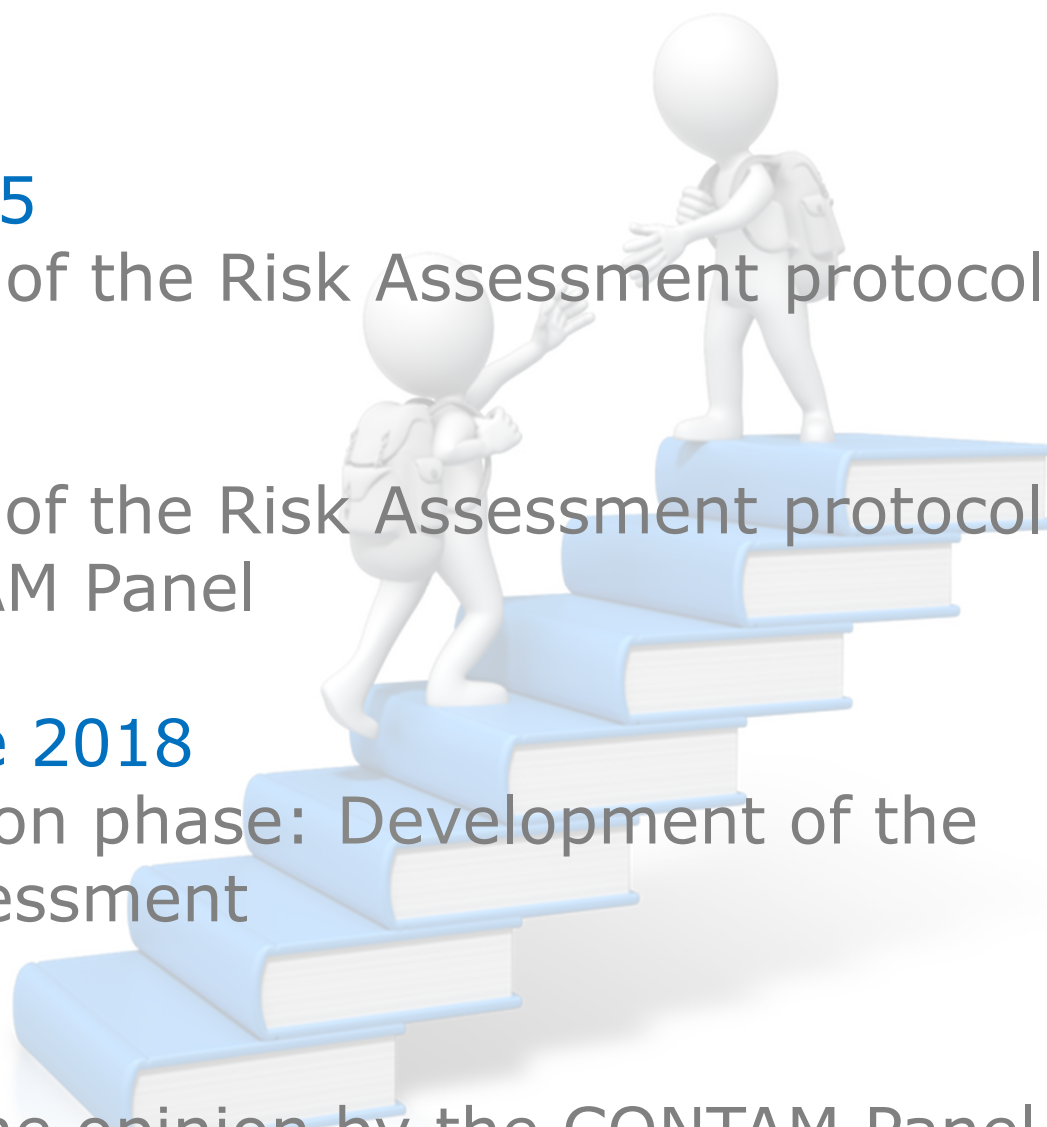
Endorsement of the Risk Assessment protocol by the CONTAM Panel

#### ❖ January 2016 - June 2018

Implementation phase: Development of the draft risk assessment

#### ❖ June 2018

Adoption of the opinion by the CONTAM Panel





# COMPREHENSIVE RISK ASSESSMENT IN FOOD AND FEED

## ■ Data for the RA:

### **Epidemiological studies**

- ✓ Extensive Literature search: 6,101
- ✓ Selection for relevance: 257
- ✓ Further selection + update literature search: 198 (appraised)



### **Studies in experimental animals**

- ✓ Extensive Literature search: 4,921
- ✓ Selection for relevance: 272
- ✓ Further selection + update literature search: 17 (appraised)



## COMPREHENSIVE RISK ASSESSMENT IN FOOD AND FEED

### ■ Data for the RA:

#### Occurrence data in food

From 24 European countries, period 2010-2016

- 19,965 food samples with all **17 PCDD/Fs + 12 DL-PCBs** determined
- 20,273 food samples with all **17 PCDD/Fs** determined
- 22,974 food samples with all **12 DL-PCBs** determined



#### Occurrence data in feed

From 12 European countries, period 2010-2016

- 1,830 feed samples with all **17 PCDD/Fs + 12 DL-PCBs** determined
- 1,844 feed samples with all **17 PCDD/Fs** determined
- 2,131 feed samples with all **12 DL-PCBs** determined

## COMPREHENSIVE RISK ASSESSMENT IN FOOD AND FEED

### ■ Exchange of views with MS:



- Given the new scientific information contained within the opinion, EFSA decided to organise an exchange of views with MS
- The adopted opinion was sent under confidentiality to the AF members on 31 August,
- AF members are invited to **provide general observations by 19 October 2018,**
- A **physical meeting in Parma will be organised the second week of November** to:
  - ✓ Present methodologies applied,
  - ✓ Present outcomes of the opinion,
  - ✓ Opportunity for an open dialogue with EFSA and the experts who worked on the opinion, and as well to provide clarifications ahead of its publication.

## COMPREHENSIVE RISK ASSESSMENT IN FOOD AND FEED

### ■ Exchange of views with MS:

- MS representatives should express their interest to attend this meeting
- Contact Persons for general observations and expressions of interest:

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