EFSA'S RISK ASSESSMENT ON CPs IN FOOD AND FEED

European Food Safety Authority

Presented by Martin Rose (Uni Manchester, UK) & Pim Leonards (E&H VU), member and hearing expert of the EFSA CONTAM WG on CPs

Trusted science for safe food

Outline

1. Mandate on CPs in food and feed
2. Methodology
3. Human risk assessment
4. Farm and companion animal risk assessment
5. Uncertainties
6. Recommendations
7. Next steps in the public consultation process

1. Mandate on CPs in food and feed

- In November 2016, the European Commission asked EFSA for a scientific opinion on the risks for animal and human health related to the presence of CPs in feed and food.

  - The mandate was allocated to the **EFSA Panel on Contaminants in the Food Chain** (**CONTAM Panel**).

  - A **Working Group (WG)** of experts was established to develop the draft opinion.

  - The draft opinion was endorsed by the CONTAM Panel in July 2019, and it was available at the EFSA website for **Public Consultation** (6 August-17 September).

The Opinion **was adopted by the CONTAM Panel on 17 December 2019 and published on the EFSA website on 9 March 2020**

1. Mandate on CPs in food and feed

- CPs are **complex technical mixtures of polychlorinated alkanes, with varying chain length and degree of chlorination**. The commercially available CPs are generally divided into three groups:

  SCCPs - short-chain CPs, comprising **10 to 13 carbon atoms**

  MCCPs - medium-chain CPs, comprising **14 to 17 carbon atoms**

  LCCPs - long-chain CPs, with **18 or more carbon atoms**

- Some **technical mixtures** may contain CPs from **more than one of these three group**s, and **some newer CPs do not confine themselves to these groups**.

2. Methodology

- Literature search in PubMed and Web of Science
- Conference proceedings
- Previous risk assessments by international bodies

- **Documentation provided to EFSA**:
  - Unpublished toxicity study reports provided to EFSA (EuroChlor)

- **Occurrence data in food submitted to EFSA**:
  - DE: fish samples (Krätschmer et al.)
  - UK: several foodstuff (UK-COT, 2009)

3. Human risk assessment

- Toxicokinetics
- Epidemiological studies
- Toxicity in experimental animals
- Exposure assessment (data submitted to EFSA)
- Risk characterisation

The Opinion also provides information on:

- Levels in human samples reported in the literature (e.g. human milk)
- Occurrence data in food/feed reported in the literature
- Dietary exposure studies reported in the literature
- Effects of food processing
- Non-dietary sources of exposure

Hazard identification and characterisation

- Toxicity data were retrieved only for a limited number of CP mixtures:

SCCPs

- C_{10-12}, 58% chlorination
- C_{10-13}, 56% chlorination
- C_{10-13}, 58% chlorination
- C_{12}, 60% chlorination
- C_{10-13}, 56.5% chlorination
- (carbon chain length not specified), 58% chlorination

MCCPs

- C_{14-17}, 52% chlorination
- C_{14-17}, 40% chlorination

LCCPs

- C_{22-26}, 43% chlorination
- C_{22-26}, 70% chlorination
- C_{23}, 43% chlorination

In the next slides the information will refer to these mixtures
(*for details on the specific mixture tested please refer to the Opinion*)

Hazard identification and characterisation

SCCPs tested	Lowest **BMDL10 = 2.3 mg/kg bw/day** (increased incidence of nephritis in male rats)
MCCP tested	Lowest **BMDL10 = 36 mg/kg bw/day** (increased relative kidney weight in male/female rats)

- These were considered as the **reference points** for the risk characterisation.

Hazard identification and characterisation

- The available **toxicity studies in experimental animals have been performed with only a few CPs** of different carbon chain length and different degrees of chlorination.

- The toxicokinetic studies in rats and mice indicate that the **toxicokinetics vary depending on carbon chain length, as well as on position and degree of chlorination**.

- Therefore, the toxicokinetic and toxicity studies performed with only a few CPs can in principle only provide information on the CPs investigated. **Read-across to other CPs, both within the same class as well as in other classes, is therefore problematic and will have high uncertainty**.

→ Recommendations made by the CONTAM Panel

Hazard identification and characterisation

- Due to the limitations and uncertainties in the current database, the **derivation of HBGVs (e.g. a tolerable intake) was not considered appropriate**.

- Instead, a **Margin of Exposure (MOE)** approach was applied to assess a possible health concern.

Hazard identification and characterisation

The CONTAM Panel considered that **an MOE > 1,000 might indicate that there is no health concern,**

Such MOE would take into account:

- the **variability between species** (factor of 10)
- the **variability within human individuals** (factor of 10)
- **extrapolation from sub-chronic to chronic toxicity studies** (factor of 2)
- **limitations in the database** (factor of 5)

- Toxicity data only available for a few CPs whereas the RA is covering a large number of CPs,
- Impact of the degree of chlorination, chlorine position and carbon chain length on toxicokinetics and toxicity cannot be evaluated,
- No two-generation reproductive toxicity study is available for any CP.

3. Human risk assessment

Exposure assessment

NOT POSSIBLE TO CARRY OUT A ROBUST EXPOSURE ASSESSMENT

Exposure assessment

- In order to obtain an estimate of the potential magnitude of exposure, the data submitted to EFSA on SCCPs and MCCPs in few fish species were used for a **tentative estimation of exposure resulting from 'Fish meat' consumption for fish consumers only**:

Data submitted by DE:

- 422 analytical results (184 samples)
- 'Fish meat' (salmon, tuna, catfish)
- Years: 2014-2017

Krätschmer et al – EU-RL

- No exposure could be estimated for **LCCPs** due to the lack of occurrence data.

Exposure assessment

Consumption of 'Fish meat' - fish consumers only

Uncertainty

Since it is expected that other food categories contribute to the exposure, **the exposure levels to SCCPs and MCCPs calculated in this Opinion are underestimated**

→ A recommendation was made by the CONTAM Panel

Exposure assessment

Breastfed infants

Uncertainty

The exposure of breastfed infants was estimated based on **pooled samples** from 11 European countries, showing a wide range of concentrations. Since these were pooled samples, it was **not possible to estimate specific values for highly exposed individuals.**

→ A recommendation was made by the CONTAM Panel

Exposure assessment

- Limited information is available on the **effects of food processing**.

- The presence of CPs in some common **kitchen equipment (dish cloths, hand blenders, household oven components)** has been reported. This suggests that food could become more contaminated at the preparation stage, due to either direct or secondary contact, and thus add to the dietary exposure.

- **Dust** could be an important source of exposure. Only a crude estimate was made, but it indicates that,

    - For **toddlers** exposure from dust could be in the same order of magnitude as the dietary exposure estimated from fish.

    - For **adults** the exposure from dust is lower than for children, and also lower in comparison with the exposure estimated from fish.

Preliminary risk characterisation

- Comparing the estimates of the exposure via **fish only** to the $BMDL_{10}$ calculated, **the MOEs obtained were all well >1,000**.

The CONTAM Panel concluded that these **MOEs for SCCPs and MCCPs for this limited scenario do not suggest a health concern**, while noting uncertainties because:

- **dietary exposure will be higher due to the contribution of CPs from other foods**,
- **lack of toxicokinetic data for humans**, and
- **only a few CPs have been tested in the available toxicity studies**

- For LCCPs, no risk characterisation could be performed in the absence of occurrence data and identification of a reference point.

Exposure assessment

- No data for feed were submitted to EFSA.
- The data for feed reported in the literature were too limited to attempt an exposure scenario.

Uncertainty

No risk characterisation of CPs could be performed for any farm or companion animal species

- lack of occurrence data for feed
- lack of, or limited, data on the adverse effects

A recommendation was made by the CONTAM Panel

Uncertainties

5. Uncertainties

Some of the main uncertainties are …

- The choice of **analytical instrument and quantification method** strongly influences the results. Lack of analytical standards and reference materials.
- **Exposure** is estimated by considering only occurrence levels in fish due to unavailability of occurrence data on other foodstuffs.
- No exposure could be estimated for **LCCPs** due to the lack of occurrence data.
- The exposure of **breastfed infants** was estimated based on pooled samples from 11 European countries. It was not possible to estimate specific values for highly exposed individuals.

5. Uncertainties

- Uncertainty in the **accumulation potential** of CPs.
- The lack of data on the **CP mixtures of relevance for human dietary exposure** adds to the overall uncertainty of the assessment.
- Toxicity data were retrieved only for a limited number of mixtures, and there is **uncertainty on the representativeness of the tested mixtures** towards the pattern of CPs present in food.
- The available toxicokinetic data indicate that differences among CP congeners, suggesting that read-across to other CPs as applied in this opinion, both within the same class as well as to other classes, will have high uncertainty.
- **Toxicity database for farm animals**, horses and companion animals very limited.

Recommendations

6. Recommendations

The CONTAM Panel made recommendations to improve the risk assessment for both humans and animals, and reduce the uncertainties

- Need for **validated analytical methods**, as well as **suitable standards and reference materials**.

- Needed to **identify which specific CP congeners are more relevant** in terms of occurrence in food and of relevance for human health.

6. Recommendations

The CONTAM Panel made recommendations to improve the risk assessment for both humans and animals, and reduce the uncertainties

- Need for **occurrence data in food to enable a robust human exposure assessment**.

- More data on variation of occurrence of **CPs in human milk** needed to enable a more robust exposure assessment for breastfed infants.

6. Recommendations

The CONTAM Panel made recommendations to improve the risk assessment for both humans and animals, and reduce the uncertainties

- More information on the **toxicokinetics in humans and experimental animals**, with respect to the impact of the degree of chlorination, chlorine position and carbon chain length.

- Need for **chronic toxicity studies for relevant CP mixtures**.

6. Recommendations

The CONTAM Panel made recommendations to improve the risk assessment for both humans and animals, and reduce the uncertainties

- Better understanding of the **relevance of SCCP and MCCP thyroid hormone changes in rodents and of SCCP-induced rodent thyroid tumours to humans**.

- There is a need for **developmental neurotoxicity** studies with SCCP and MCCP because of the reported changes in rodent thyroid hormone levels.

6. Recommendations

The CONTAM Panel made recommendations to improve the risk assessment for both humans and animals, and reduce the uncertainties

- Need for **occurrence data in feed**.
- Need for data on the **transfer of CPs from feed to the food of animal origin**.
- Need for **data on adverse effects of CPs in ruminants, pigs, poultry and fish. Data in horses, companion animals and fur animals** would also be needed to perform a risk assessment on these species.

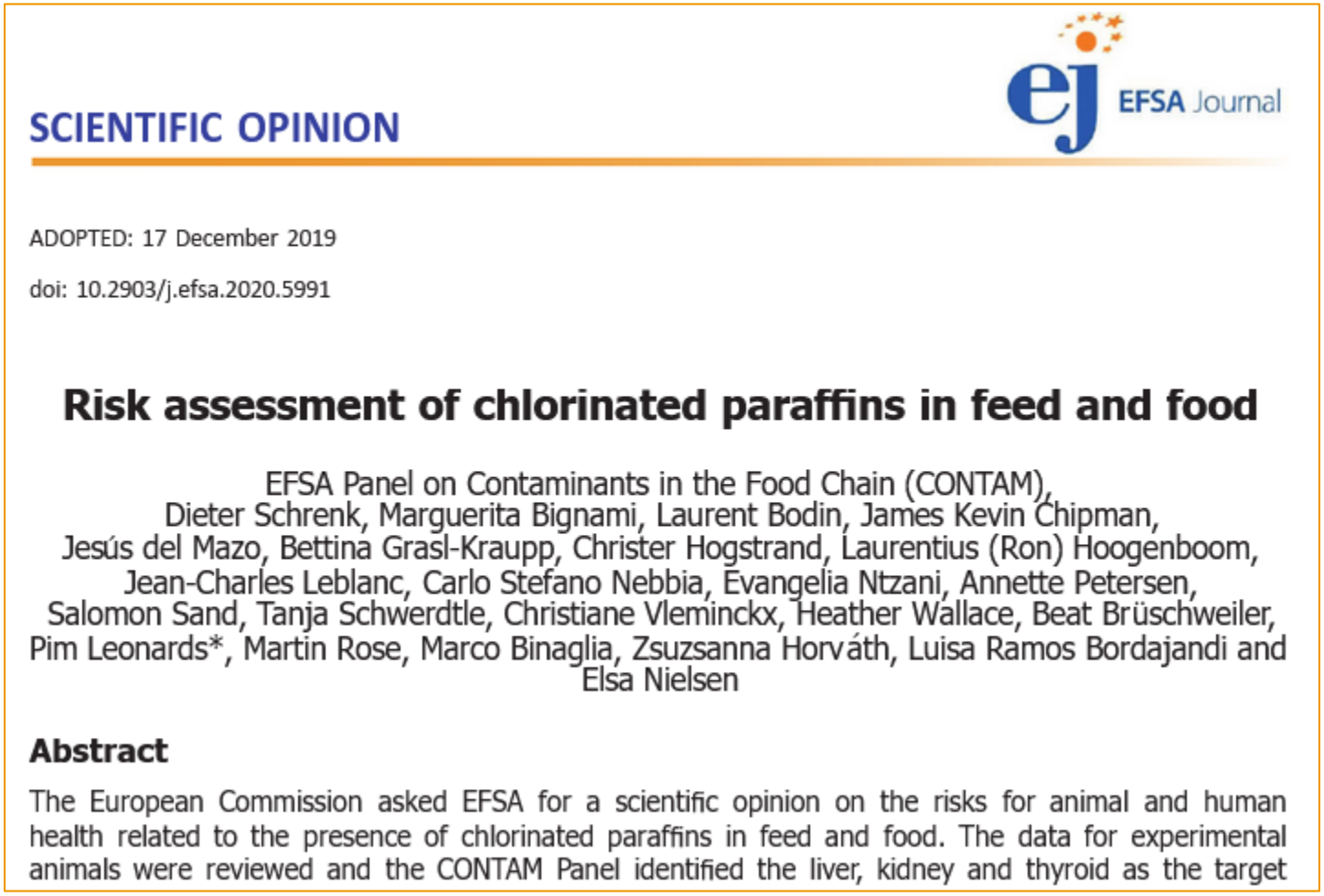
Acknowledgments

- Members of the **WG CPs in Food and feed**
- Members of the **CONTAM Panel**
- **EFSA staff** (DATA-BIOCONTAM Units)

- **European Member States/Countries**
- **Stakeholders**
  - ✓ Occurrence data
  - ✓ Consumption data
  - ✓ Toxicity study reports

Publication

Available from:
http://www.efsa.europa.eu/en/efsajournal/pub/5991



SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 17 December 2019

doi: 10.2903/j.efsa.2020.5991

Risk assessment of chlorinated paraffins in feed and food

EFSA Panel on Contaminants in the Food Chain (CONTAM),
Dieter Schrenk, Marguerita Bignami, Laurent Bodin, James Kevin Chipman,
Jesús del Mazo, Bettina Grasl-Kraupp, Christer Hogstrand, Laurentius (Ron) Hoogenboom,
Jean-Charles Leblanc, Carlo Stefano Nebbia, Evangelia Ntzani, Annette Petersen,
Salomon Sand, Tanja Schwerdtle, Christiane Vleminckx, Heather Wallace, Beat Brüschweiler,
Pim Leonards*, Martin Rose, Marco Binaglia, Zsuzsanna Horváth, Luisa Ramos Bordajandi and
Elsa Nielsen

Abstract

The European Commission asked EFSA for a scientific opinion on the risks for animal and human health related to the presence of chlorinated paraffins in feed and food. The data for experimental animals were reviewed and the CONTAM Panel identified the liver, kidney and thyroid as the target

Subscribe to
www.efsa.europa.eu/en/news/newsletters
www.efsa.europa.eu/en/rss

Engage with careers

Follow us on Twitter
@efsa_eu
@plants_efsa
@methods_efsa