

Parma, 30 September 2019
EFSA/CONTAM/3801

Scientific Panel on Contaminants in the Food Chain

Minutes of the 100th Plenary meeting

**Held on 24-26 September 2019, Parma (Italy)
(Agreed on 17 October 2019)**

Participants

- **Panel Members:**

Margherita Bignami, Laurent Bodin, Kevin Chipman, Jesús Del Mazo, Bettina Grasl-Kraupp¹, Ron Hoogenboom, Jean-Charles Leblanc², Carlo Nebbia¹, Elsa Nielsen, Evangelia Ntzani, Annette Petersen, Salomon Sand, Dieter Schrenk, Tanja Schwerdtle and Heather Wallace.

- **Hearing Experts³:**

Andy Hart (for Item 6).

- **European Commission and/or Member States representatives:**

Frans Verstraete² (European Commission, DG Health and Food Safety, Unit E2).

- **EFSA:**

- **BIOCONTAM Unit:**

Katleen Baert, Marco Binaglia, Anna Christodoulidou, Ernesto Liebana Criado, Karen Mackay, Kelly Niermans, Luisa Ramos Bordajandi, Elena Rovesti and Hans Steinkellner.

¹ Attendance on 24-25 September only.

² Attendance by audioweb-conference.

³ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest:

<http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

- **DATA Unit:**
Claudia Cascio (for Items 7.1 and 8), Francesca Riolo (for Item 7.2), Petra Gergelova (for Item 7.3) and Zsuzsanna Horvath (for Item 7.4).
- **Transformation Unit:**
Claudia Paoletti (for Item 10).
- **RASA Department:**
Juliane Kleiner (for Item 10.2).
- **Observers:**
Not applicable.
- **Others:**
Not applicable.

1. Welcome and apologies for absence

The Chair of the CONTAM Panel welcomed the participants.

Apologies were received from Christer Hogstrand and Christiane Vleminckx (CONTAM Panel), Veerle Vanheusden (European Commission, DG Health and Food Safety, Unit E2) and Marina Marini (European Commission, DG Health and Food Safety, unit D1).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA screened the Annual Declarations of Interest filled in by the Scientific Panel Members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting had been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

⁴ <https://www.efsa.europa.eu/it/corporate/pub/policyonindependence>

⁵ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

4. Agreement of the minutes of the 99th Plenary meeting held on 9-11 July 2019

The minutes of the 99th Plenary meeting held on 9-11 July 2019 were agreed on 30 July 2019.

5. Report on written procedures since 99th Plenary meeting

The Scientific opinion on the health risks related to the presence of chlorinated paraffins in feed and food was presented for possible endorsement for public consultation by written procedure. The draft opinion was endorsed by written procedure on 31 July 2019.

6. Introduction to the Guidance on uncertainty analysis in risk assessment

A presentation on the main principles of the guidance on uncertainty analysis in risk assessment was given, including an overview of the case studies prepared for the forthcoming training of the CONTAM Panel on the guidance.

7. Scientific outputs submitted for discussion

7.1. Draft scientific opinion on the risks for animal and human health related to the presence of quinolizidine alkaloids in feed and food, in particular in lupins and lupin-derived products (EFSA-Q-2016-00239)⁶

The Chair of the WG on Quinolizidine alkaloids introduced the changes implemented in the opinion based on the comments received during the public consultation. The CONTAM Panel adopted the opinion including the proposed changes and endorsed the public consultation report that will be published together with it. The Chair of the Panel thanked the WG and EFSA staff for their work.

7.2. Draft Scientific opinion on the risks for animal and human health related to the presence of glycoalkaloids in feed and food, in particular in potatoes and potato-derived products (EFSA-Q-2016-00240)⁷

The Chair of the WG on Glycoalkaloids presented the draft opinion for discussion and possible endorsement of the sections on supporting information for the assessment, toxicokinetics, toxicity in experimental animals and Mode of action. The Panel proposed revisions to the section on toxicokinetics and acute and

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00239>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00240>

repeated dose toxicity in experimental animals. The Panel also discussed the overall approach for the risk assessment. The Chair of the WG will bring the comments back to the WG which will take them into account and continue with the development of the draft opinion.

7.3. Draft Scientific opinion on the risks for public health related to the presence of aflatoxins in food (EFSA-Q-2018-00698)⁸

The Chair of the WG on Aflatoxins in food presented for discussion and possible endorsement for public consultation the draft opinion on aflatoxins in food. The Panel discussed the draft opinion and, pending insertion of minor changes, endorsed it for public consultation that will indicatively take place between the beginning of October and mid-November 2019.

7.4. Draft Scientific opinion on the risks for public health related to the presence of ochratoxin A in food (EFSA-Q-2018-00699)⁹

The Chair of the WG presented the draft opinion on ochratoxin A in food for possible endorsement for public consultation. The Panel discussed the draft opinion in particular the sections introduced after the last discussion of the opinion at the previous Panel meeting. The Panel proposed minor revisions to several sections and endorsed most of the sections of the opinion. The Panel asked the WG for a re-evaluation of the section on exposure assessment of breast-fed infants which will be re-discussed together with Abstract, Summary and Conclusions at the next Plenary meeting.

8. Draft report on exposure assessment to Δ^9 -THC in food

The approach proposed for the exposure assessment to Δ^9 -THC in food was presented for discussion. The CONTAM Panel agreed with the proposed approach. The draft report will be peer-reviewed and presented for possible endorsement to the CONTAM Panel.

9. Comments on the derivation of the Acute Reference Dose for Δ^9 -THC

The CONTAM Panel discussed the comments and information received from the European Hemp Industry Association (EHIA) in relation to their proposal for a revision of the Acute Reference Dose (ARfD) of 1 μg Δ^9 -THC/kg bw, established by the CONTAM Panel in 2015¹⁰.

The EHIA stated that a single dose of 2.5 mg/day identified as the LOAEL in the CONTAM Panel opinion is questionable and that the uncertainty factors (UFs) applied were excessive, i.e. a total UF of 30, based on extrapolation of a NOAEL

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00698>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00699>

¹⁰ <https://www.efsa.europa.eu/it/efsajournal/pub/4141>

from the LOAEL (3) and interindividual differences (10). The EIHA proposed an ARfD of 7 µg Δ⁹-THC/kg bw based on a total dose of 5 mg/day (2 x 2.5 mg/day) and a UF of 10 for interindividual differences.

Following discussion on this issue, the CONTAM Panel agreed that 2.5 mg/day should still be considered as the LOAEL, as adverse effects on the central nervous system were observed in the human studies used in the 2015 assessment even following a single dose and therefore the application of an UF of 3 for extrapolation from LOAEL to NOAEL, as well as an UF of 10 for interindividual differences, are appropriate.

In conclusion, the CONTAM Panel confirmed that the ARfD of 1 µg Δ⁹-THC/kg bw, derived in the 2015 CONTAM Panel assessment, should be retained.

10. Feedback from the Scientific Committee/ Scientific Panels, CONTAM Working Groups, EFSA, the European Commission

10.1. European Commission

The European Commission representative gave an update on the activities of the European Commission in relation to the scientific opinions of the CONTAM Panel. Several amendments of current legislation are under discussion with the Member States as an outcome of the CONTAM Panel scientific opinions.

10.2. CONTAM Panel Working Groups

- **Update from WG on Chlorinated paraffins in food and feed**

An overview of the comments received during the public consultation on the draft Scientific opinion on Chlorinated Paraffins in feed and food was presented to the Panel. The WG will address the comments and present a revised version of the opinion for possible adoption at the upcoming Panel meetings.

- **Update from WG on Ochratoxin A in food**

See Item 7.4.

- **Update from WG on Aflatoxins in food**

See Item 7.3.

- **Update from the WG on Glycoalkaloids in food and feed**

See Item 7.2.

- **Update from WG on Quinolizidine alkaloids in food and feed**

See Item 7.1.

- **Update from WG on Perfluoroalkyl substances in food**

The WG Chair provided an overview of the discussion from the meeting of the Cross-cutting WG on Benchmark Dose, following a request made by the CONTAM Panel for guidance in relation to BMD modelling of immune endpoints.

- **Update from WG on Brominated flame retardants in food**
The EFSA coordinator of the WG informed that the work is progressing well. The next WG meeting will be held 15-16 October.
- **Update from WG on Nitrites and Nitrates in feed**
The EFSA coordinator informed that the WG is progressing on the re-evaluation of the previous findings, taking into consideration the new literature identified.
- **Update from WG on previous cargoes**
The vice Chair of the WG presented to the Panel the possible approach to take for the assessment of calcium lignosulfonate as acceptable previous cargo and the limitations of this approach. Following the advice of the Panel, the draft opinion will be presented at the next Panel meeting. The next WG meeting will be held on 16 October.
- **Update of the WG on Nickel in food**
The Chair of the WG informed the Panel that the WG on Nickel in food has started its activities. A first WG meeting took place in September and the WG discussed the collection of literature and the approach for the risk assessment.

10.3. EFSA

The CONTAM Team Leader informed that the CONTAM Panel Statement on Pyrrolizidine alkaloids will be resubmitted to the Panel for correction by written procedure.

10.4. Scientific Committee and Working Groups of interest to the CONTAM Panel

The main points discussed at the 95th meeting of the EFSA Scientific Committee¹¹ were reported by the CONTAM Panel Chair. In particular, the activity of the CONTAM Panel was presented to the Scientific Committee and the EFSA Technical Report on animal dietary exposure, already endorsed by the CONTAM Panel at the 99th Panel meeting, was endorsed by the Scientific Committee. In addition, the discussions on the draft guidance on the appraisal and integration of evidence from epidemiological studies in scientific assessment, the guidance on protocol development for non-application scientific assessments and the guidance on aneugenicity assessment, were reported. Updates were provided on the WG on Genotoxicity and on Non-monotonic dose-response.

10. EFSA Architecture Transformation (ART) Programme

The Programme manager of the EFSA Architecture Transformation Programme presented an overview of the programme in relation to the changes in the Regulation (EC) 178/2002.

¹¹ <https://www.efsa.europa.eu/it/events/event/190219>

11. Any other business

Not applicable.