

Parma, 12 May 2016
EFSA/CONTAM/2732

Scientific Panel on Contaminants in the Food Chain
Minutes of the 78th plenary meeting
Meeting open to Observers
Held on 10-12 May 2016, Brussels (Belgium)
(Agreed on 27-05-2016)

Participants

• **Panel Members:**

Jan Alexander, Lars Barregard¹, Margherita Bignami, Sandra Ceccatelli, Bruce Cottrill, Mike Dinovi², Lutz Edler, Bettina Grassl-Kraupp, Christer Hogstrand, Ron Hoogenboom, Helle Knutsen, Carlo Nebbia³, Isabelle Oswald⁴, Annette Petersen, Martin Rose, Tanja Schwerdtle, Christiane Vleminckx, Günter Vollmer and Heather Wallace.

• **Hearing Experts⁵:**

Peter Hollman (for item 9.1)⁶

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

Frank Swartenbroux¹ and Frans Verstraete⁴ (European Commission, DG Health and Food Safety, unit E2), Maila Puolamaa (European Commission, DG Internal Market, Industry, Entrepreneurship and Small and Medium –Sized Enterprises)⁶, Matthias Gehling (Bundesinstitut für Risikobewertung (BfR), for item 9.1)⁶

• **EFSA:**

• **BIOCONTAM Unit:**

Katleen Baert, Marco Binaglia, Mari Eskola, Marta Hugas, Karen Mackay, Luisa Ramos Bordajandi², Ruth Roldán Torres², Hans Steinkellner² and Mathijs Van Manen².

• **DATA Unit:**

José Ángel Gómez Ruiz (for item 9.4) and Sofia Ioannidou² (for item 9.2).

¹ Present on 10-11 May only

² Attendance by audio-web conference

³ Attendance by audio-web conference on 10-11 May only

⁴ Present on 11-12 May only

⁵ 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>

⁶ Present on 11 May only

- **EXREL Unit:**
Stephen Pagani
- **Executive Directorate:**
Hubert Deluyker

- **Observers⁷:**
Herve Lafforgue (Danone Company), Dirk Hoegaerts (Agilent Technologies Inc.), Stefano Del Frate (GB Foods), Johan Robbens (Institute of Agricultural and Fisheries Research, ILVO), William Munro (Food Standards Scotland), Vic Wyman (EU Food Policy), Lucia Klauser (Swiss Federal Food Safety and Veterinary Office) and Karine Vandermeiren (Veterinary and Agrochemical Research Centre, CODA-CERVA)

- **Others:**
Not Applicable

1. Welcome

The CONTAM Panel Chair welcomed the participants.

2. Apologies for absence

Apologies were received from Alain-Claude Roudot and Vera Maria Rogiers (CONTAM Panel) and Marina Marini (European Commission, DG Health and Food Safety, unit D1)

3. Introduction of Panel Members and Observers

The Panel Chair welcomed the observers and the meeting participants introduced themselves.

4. Adoption of agenda

The agenda was adopted without changes.

5. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁸ and the Decision of the Executive Director on Declarations of Interest⁹, EFSA screened the Annual Declarations of Interest and the Specific 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 have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

⁷ <http://www.efsa.europa.eu/en/stakeholders/observers.html>

⁸ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁹ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

6. Presentation of the EFSA Guidelines for Observers

The CONTAM Team Leader presented the EFSA Guidelines for Observers attending the open plenary meetings.

7. Agreement of the minutes of the 77th Plenary meeting held on 1-3 March 2016, Parma (Italy)

The minutes of the 77th Plenary meeting held on 1 – 3 March 2016 were agreed¹⁰ on 20 April 2016.

8. Report on the written procedures since 77th Plenary meeting

Not applicable

9. Scientific outputs submitted for discussion and/or possible adoption

9.1 Draft statement on the presence of microplastics and nanoplastics in food with particular focus on seafood (EFSA-Q-2015-00159)¹¹

The Chair of the WG on Plastic microparticles and nanoparticles in food presented the draft statement in which BfR asked EFSA to identify the main data gaps to be filled to perform a risk assessment related to the presence of microplastics and nanoplastics in food. The CONTAM Panel adopted the statement subject to incorporation of minor changes as suggested during the meeting. The chair of the CONTAM Panel expressed her appreciation to the members of the WG and the EFSA staff.

9.2. Draft Scientific Opinion on the risks for human health related to the presence of malachite green in food of animal origin (EFSA-Q-2014-00815)¹²

The chair of the Standing WG (SWG) on non-allowed pharmacologically active substances in food and feed and their reference points for action presented the draft opinion on malachite green in food for discussion and possible endorsement. The CONTAM Panel endorsed the opinion subject to incorporation of minor changes as suggested during the meeting. The CONTAM Panel agreed that the opinion is ready for adoption pending the clarification on the potential scientific divergence identified with BfR on the approaches applied for the characterization of the carcinogenic and genotoxic hazard.

9.3 Draft Scientific Opinion on the risks to human and animal health related to the presence of deoxynivalenol and its acetylated and modified forms in food and feed (EFSA-Q-2013-00721)¹³

The Chair of the WG on Fusarium toxins presented the approach proposed for the hazard characterization of acute and chronic effects of deoxynivalenol and its acetylated and modified forms in humans and in farm and companion animals. In particular the discussion was focused on the use of human data, including biomonitoring data, for the establishment of a human Acute Reference Dose and the application of the benchmark

¹⁰ <http://www.efsa.europa.eu/en/contam/contammeetings.htm>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00159>

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00815>

¹³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00721>

dose modeling for the establishment of the chronic Tolerable Daily Intake. A revised approach for the human and animal exposure assessment for the deoxynivalenol and its acetylated and modified forms was also presented.

9.4 Draft Scientific Opinion on the risks to human and animal health related to the presence of erucic acid in food and feed (EFSA-Q-2015-00027)¹⁴

The Chair of the WG on erucic acid in food and feed presented the draft opinion on the presence of erucic acid in food and feed for discussion. The Panel discussed the opinion and, subject to some minor revisions, endorsed the following sections: 1. Introduction, 2. Data and methodologies, 3.1. Occurrence data and 3.2. Dietary exposure assessment. The opinion will be presented for discussion and possible endorsement of selected sections at the 79th CONTAM Panel meeting.

10. Table of contents and length of CONTAM opinions

The CONTAM Panel discussed the proposal for a standard table of contents to be used as a basis for the CONTAM scientific opinions taking into account the template endorsed by the EFSA Scientific Committee in 2014. The Panel agreed on the proposal subject to minor modifications and provided that sufficient flexibility will be allowed to adapt the table of content in case of specific needs. The CONTAM Panel also discussed the possibility to reduce the length of its scientific opinions. In general the majority of Panel Members agreed that there is room for reducing the length of the Scientific Opinions and indicated possible options and approaches to achieve this objective. Namely, more tables could be used to summarise information, and some sections could be more focused to the information needed for the risk assessment, whereas supplementary information could be included in the appendices. It was agreed that it is the responsibility of the WG Chair to consider these aspects and to convey these messages in the WG of the Panel. Finally, the CONTAM Panel agreed while it can be beneficial to deliver more concise Scientific Opinions, a sufficient level of information must be maintained to allow the utmost transparency of the approaches and decisions taken to perform the assessments.

11. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

11.1. European Commission

The European Commission representative gave feedback on the activities of the European Commission in relation to the issued scientific opinions of the CONTAM Panel. Several amendments for current legislation are under discussion with the Member States as an outcome of the CONTAM Panel scientific opinions. In addition, several recommendations to the Member States are under preparation by the European Commission based on CONTAM opinions.

11.2. CONTAM Panel Working Groups

11.2.1. Working Group on Fusarium toxins

See item 9.3

¹⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00027>

11.2.2. Standing Working Group on Non-allowed pharmacologically active substances in food and feed and their reference points for action

See item 9.2

11.2.3. Working Group on dioxins in food and feed

The Chair of the WG on Dioxins in food and feed informed the members of the CONTAM Panel that the draft opinion on dioxins and DL-PCBs in food and feed is progressing well. Since the draft strategy for the risk assessment developed under the framework of the Prometheus project was endorsed by the CONTAM Panel at its 76th Plenary meeting, the WG has started with its implementation.

11.2.4. Working Group on Erucic acid in food and feed

See item 9.4

11.2.5. Update from WG on Group HBGV for mycotoxins

The Chair of the WG reported that the work was progressing well. A WG meeting was held on 25 – 26 April. An additional literature search was carried out to gather further toxicity data on T2/HT2 metabolites. The additional evidence will be discussed at the next WG meeting.

11.2.6. Update from WG on Plastic microparticles

See item 9.1.

11.2.7 Update from WG on Zearalenone in feed

The Chair of the WG on Zearalenone in feed informed the members of the CONTAM Panel that the draft opinion on zearalenone and its modified forms in feed is progressing well. The CONTAM Panel was reminded that it had selected this opinion to test the draft SC guidance on uncertainty and variability, and an initial exercise in this respect took place during a training session on the draft guidance. More discussion on the uncertainty analysis will take place at the next WG meeting.

11.2.8. Update from WG on Previous cargoes

The Chair of the WG on Previous cargoes informed the members of the CONTAM Panel that the draft opinion on the evaluation of substances as acceptable previous cargoes for edible fats and oils is progressing well. A presentation with the proposed approach to follow in this opinion was given. The Panel agreed that the criteria used in the previous opinions¹⁵ on the evaluation of substances as acceptable previous cargoes should be maintained. The Panel also discussed the assessment of substances with insufficient information on the impurity profile and proposed to specify under which conditions these substances could meet the criteria for acceptability as previous cargo..

11.2.9. Update from WG on Perfluoroalkylated substances (PFASs) in food

The Chair of the WG on PFAS in food informed the members of the CONTAM Panel that the draft opinion on PFAS in food is progressing well. The substances to be included in the assessment were discussed and it was agreed that the WG will include 27 substances previously covered in EFSA external report on an extensive literature search on toxicokinetic, toxicity and human data for PFAS, and an EFSA scientific report on occurrence and dietary exposure to PFAS. It was agreed that per-/poly-fluorinated substances used in the manufacture of food contact materials, under evaluation by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and

¹⁵ <http://www.efsa.europa.eu/en/press/news/121218>

Processing Aids (CEF), will not be covered in the CONTAM Panel opinion. The draft layout of the opinion was also discussed.

11.2.10. Update from WG on Furan in food

The Chair of the WG on furan in food informed the members of the CONTAM Panel that a first meeting was held in April. At this meeting the literature search was discussed. The draft structure and content of the draft opinion has been agreed. The opinion will address furan and also 2-methylfuran and 3-methylfuran, and the WG will check whether other furan analogues (e.g. 2,5-dimethylfuran) might be relevant for inclusion in the opinion.

11.3. EFSA

11.3.1. Advisory Forum

The CONTAM Team Leader informed the Panel on relevant items discussed at the 59th Advisory Forum meeting (8-9 March 2016). In particular the scientific divergence with BfR and the Hellenic Food Authority (EFET) on the assessment on cyanogenic glycosides in apricot kernels, the scientific divergence with BfR on the assessment on chloramphenicol and the potential scientific divergence with BfR on the assessment on malachite green were discussed. The former case was closed and a joint BfR-EFET-EFSA report was published at the end of April 2016¹⁶. A meeting with BfR is being organised to discuss the assessments on chloramphenicol and malachite green. Additional information on the 59th Advisory Forum meeting is available on the EFSA website¹⁷.

11.3.2. Management Board

The CONTAM Team Leader informed the Panel on relevant items discussed at the 68th Management Board meeting (16 March 2016). In particular the proposal to change the mandates of the CEF, ANS and NDA Panels and the concurrent realignment for the renewal of the ANS and CEF Panels with the other EFSA Panels and Scientific Committee was discussed. Additional information on the 68th Management Board meeting is available on the EFSA website¹⁸

11.3.3. Other

The CONTAM Team Leader informed the Panel that amongst the measures to improve the transparency of the EFSA risk assessment processes, EFSA aims to include more details in the Panel plenary meeting minutes and to publish them within ten working days after the meetings.

11.4 Scientific Committee and its Working Groups of interest to the CONTAM Panel

The CONTAM Panel Chair highlighted the main items discussed in the 78th plenary meeting of the Scientific Committee (SC) held on 20-21 April 2016. The draft statement on non-monotonic dose response of substances for human risk assessment, based on the outcome of an EFSA external report, was discussed. The SC opinion on priority for the development of risk assessment guidance by the EFSA SC in 2016-2018 was discussed and will be subjected to adoption by written

¹⁶ <http://www.efsa.europa.eu/sites/default/files/4424ax1.pdf>

¹⁷ <http://www.efsa.europa.eu/it/events/event/160308b>

¹⁸ <http://www.efsa.europa.eu/en/mb/mbmeetings>

procedure. Christer Hogstrand was nominated WG Chair of a new WG on chemical mixtures and CONTAM Panel members were invited to express their interest for a new WG on nanotechnologies. Finally, the SC agreed to have a discussion on emerging risks regularly held in all the EFSA Scientific Panels. More information is available on the EFSA website¹⁹.

The respective CONTAM Panel members who are members of the SC WGs of interest to the CONTAM Panel informed about current status of these WGs, namely the WG on Weight of evidence, WG on Biological relevance, WG on Benchmark Dose (BMD) approach and SWG on Genotoxicity. Updates were also provided on the Assessment and Methodology Unit WG on Prometheus and the WG on Hazard analysis and critical control points (HACCP) of the Panel on Biological Hazards.

12. Other scientific topics for information and/or discussion

12.1. Present status of current outsourcing activities of the CONTAM Team (BIOCONTAM Unit)

For the Article 36 grant on the combined bioaccumulation/toxicity study on a broad mixture of mineral oil saturated hydrocarbons relevant to the human dietary exposure (signed with Institut national de la recherche agronomique (INRA, France) and Norwegian Institute of Public Health (NIPH, Norway) in September 2013), the project deadline has been extended to the end of January 2016. The final meeting took place in the first half of February 2016 and the final report is under preparation.

For the Article 36 grant on occurrence of tropane alkaloids in food, the contract was signed with the appointed beneficiaries (Stichting Dienst Landbouwkundig Onderzoek (RIKILT, The Netherlands)), Institut de Recerca i Tecnologia Agroalimentàries (IRTA, Spain), Fera Science Ltd. (UK) and Vysoka Skola Chemicko-Technologicka V Praze (VSCHT, Czech Republic). The second interim meeting took place in January 2016 (12 months from the start of the project), where the second interim report was discussed. A three month extension to the project is in preparation, and as a result the new timeline for both the submission of the draft final report and the final meeting will be September 2016.

For the Article 36 grant on occurrence data on citrinin in food, the contract was signed with the appointed beneficiaries (RIKILT, The Netherlands), Netherlands Food and Consumer Product Safety Authority (NVWA, The Netherlands), Università Cattolica del Sacro Cuore (UCSC, Italy), IRTA (Spain) and National Institute of Public Health – National Institute of Hygiene (NIPH-NIH, Poland) in August 2015. The first interim report was submitted to EFSA in April 2016 and the first interim meeting was held on 4 May 2016. The final report should be available by the end of 2016.

For the Article 36 grant on in vivo toxicity and genotoxicity of beauvericin and enniatins, the kick-off meeting with the appointed beneficiaries (Consortium of Istituto Superiore di Sanità (ISS), Italian National Agency for New Technologies, Energy and Sustainable Economic Development (ENEA) and French Agency for Food, Environmental and Occupational Health and Safety (ANSES) was held on 1 April. The next meeting will be held on 7 October (discussion of the 1st interim report). Total duration of the project is 18 months, the final report should be available by October 2017.

For the reopening competition under the multiple framework contract for an extensive literature search on furan and its methyl analogues, 2-methylfuran and 3-methylfuran,

¹⁹ <http://www.efsa.europa.eu/en/panels/scientific-committee>

a contract has been signed with the Technical University of Denmark (DTU). The activities started in April and will finish in June 2016.

For the reopening competition under the multiple framework contract for an extensive literature search on fumonisins and their modified forms, two offers have been received which are currently being evaluated. The start of activities is foreseen for June and as the project duration is four months a final report should be available by October 2016.

For the two negotiated procedures on the extensive literature search, selection for relevance and data extraction of studies related to the toxicity of PCDD/Fs and DL-PCBs in humans and in experimental animals, offers have been received for both procedures and are currently being evaluated. The start of activities is foreseen for June 2016.

13. Answers to questions from Observers (in application of the EFSA Guidelines for Observers)

The chair of the CONTAM Panel answered to the written questions submitted by the observers.

Question 1: In the future, how will you address the mixture of mycotoxins for assessing the risk ?

Answer to question 1: In specific cases the CONTAM Panel has already addressed the risks of mixture of mycotoxins sharing a common mode of action (e.g. recent opinions on modified mycotoxins in food and feed and adequacy of a group Health Based Guidance Value for zearalenone and its modified forms, on-going opinion on deoxynivalenol). More broadly, the issue of risk assessment of chemical mixtures is a key topic for various EFSA's Panels and activity is on-going to develop a harmonised approach applicable to assess the combined exposure to multiple chemicals.

Question 2: The carcinogenicity of furan mediated by genotoxic mechanism is challenged. Do you think that the establishment of a safe threshold could be possible?

Answer to question 2: The CONTAM Panel has recently received a mandate from EC to deliver a scientific opinion on the risk to public health related to the presence of furan and methylfurans in food. A Panel WG has been established to work on this opinion and at the moment the review of the available data is on-going.

Question 3: Considering the process contaminants issue, do you think it's possible that EFSA develops a global framework, a stepwise procedure and decision tree to validate the safety of food processing?

Answer to question 3: Following clarifications asked to the submitter, the Panel Chair noted that the requested activities would require considerations on risk management and therefore they would not fall under the responsibility of EFSA. The EC officer present at the meeting confirmed this interpretation and noted that the development of such strategies and tools would principally require active involvement of the food industry.

14. Any other business

Not applicable