

#### **Biological hazards and contaminants Unit (BIOCONTAM Unit)**

Parma, 22 December 2014 EFSA/CONTAM/2330

#### Scientific Panel on Contaminants in the Food Chain Minutes of the 68<sup>th</sup> plenary meeting Held on 25-27 November, 2014, Parma (Italy) (Agreed on 8 January 2015)

#### **Participants**

#### • Panel Members:

Diane Benford, Bruce Cottrill, Sandra Ceccatelli<sup>1</sup>, Michael Dinovi<sup>2</sup>, Eugenia Dogliotti<sup>3</sup>, Lutz Edler, Peter Farmer, Ron Hoogenboom, Helle Knutsen, Anne-Katrine Lundebye, Antonio Mutti, Carlo Nebbia<sup>3</sup>, Michael O'Keeffe, Annette Petersen, Dieter Schrenk, Hendrik Van Loveren<sup>4</sup>, Christiane Vleminckx and Pieter Wester

#### Hearing Expert<sup>5</sup>:

Chiara Dall'Asta<sup>6</sup> (for item 6.1)

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

Frans Verstraete (European Commission, DG Health and Consumers, unit E3)

#### EFSA:

#### • **BIOCONTAM Unit:**

Katleen Baert, Marco Binaglia, Bianca Bottoni, Gina Cioacata, Barbara Dörr, Nicklas Gustavsson, Ernesto Liebana Criado, Karen Mackay, Luisa Ramos Bordajandi, Ruth Roldán Torres, Hans Steinkellner and Natalie Thatcher

#### DATA Unit:

José Ángel Gómez Ruiz (for item 6.2), Davide Arcella (for item 9.1) and Fanny Héraud (for items 6.1, 9.2 and 9.3)

#### • Observers<sup>7</sup>:

Not Applicable

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<sup>&</sup>lt;sup>1</sup> Present by tele-web on 25 November – 26 November 2014, morning only.

<sup>&</sup>lt;sup>2</sup> Present by tele-web on 25-27 November 2014.

<sup>&</sup>lt;sup>3</sup> Present on 25 and 26 November only.

<sup>&</sup>lt;sup>4</sup> Present on 25 November – 26 November 2014, morning only.

<sup>&</sup>lt;sup>5</sup> 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.

<sup>&</sup>lt;sup>6</sup> Present on 25 November 2014 only.

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



#### Others:

Not Applicable

#### 1. Welcome and apologies for absence

The chair welcomed the participants, and particularly she welcomed the new CONTAM Panel members Annette Petersen and Antonio Mutti. The meeting participants gave a brief introduction on themselves. Apologies were received from Peter Fürst (CONTAM Panel), Manfred Metzler (CONTAM Panel), Marina Marini (European Commission, DG Health and Consumers, unit 03), Frank Swartenbroux (European Commission, DG Health and Consumers, unit E3), Leonidas Palilis (Hellenic Food Authority) and Mari Eskola (BIOCONTAM Unit, EFSA).

#### 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 Processes<sup>8</sup> and the Decision of the Executive Director on Declarations of Interest<sup>9</sup>, 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.

#### 4. Agreement of the minutes of the 67<sup>th</sup> Plenary meeting held on 16-18 July 2014, Parma (Italy)

The minutes of the 67<sup>th</sup> Plenary meeting held on 30 September – 2 October 2014 were agreed by written procedure on 9 November 2014<sup>10</sup>.

#### 5. Report on the written procedures since 67<sup>th</sup> Plenary meeting

The draft opinion on chloramphenicol in food and feed (EFSA-Q-2013-00925) was adopted by written procedure by the CONTAM Panel on 5 November 2014.

#### 6. Scientific outputs submitted for discussion and/or possible adoption

#### 6.1. Discussion and possible adoption of the draft opinion on metabolites and masked or bound forms of certain mycotoxins in food and feed (EFSA-Q-2013-00720)11

The chair of the CONTAM WG on Masked mycotoxins in food and feed presented the draft opinion (EFSA-Q-2013-00720) in which the European Commission had asked EFSA to assess the risk for human and animal health related to the presence of metabolites and

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

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

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

<sup>11</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2013-00720



masked or bound forms of certain mycotoxins in food and feed. The CONTAM Panel discussed the draft opinion and adopted it subject to incorporation of minor changes as suggested during the meeting. The CONTAM Panel decided to change the term "masked mycotoxins" to "modified mycotoxins" in the opinion and thus the title of the adopted opinion is "opinion on modified mycotoxins in food and feed". The chair of the CONTAM Panel expressed her appreciation to the members of the WG and the EFSA staff.

#### 6.3. Discussion on the draft opinion on nickel in foodstuffs (EFSA-Q-2012-00378)<sup>12</sup>

The chair of the CONTAM WG on Chromium and nickel in food presented the draft opinion (EFSA-Q-2012-00378) in which the Hellenic Food Authority had asked EFSA to assess the risk for human health related to the presence of nickel in foodstuffs. The members of the CONTAM Panel discussed the draft opinion and provided their suggestions, in particular with respect to the approach taken for the dose response 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. The draft opinion on nickel in foodstuffs will be presented for discussion and possible adoption at the 69<sup>th</sup> meeting of the CONTAM Panel (20–22 January 2015).

#### 7. New mandates

7.1. Request for a risk assessment on the presence of malachite green in food of animal origin (EFSA-Q-2014-00815)

The CONTAM Panel discussed the request and agreed that the requested scientific opinion will be developed in the SWG on Non-allowed pharmacologically active substances in food and feed and their reference points for action.

- 8. Feedback from the Scientific Committee/the Scientific Panel, EFSA, the European Commission
  - 8.1. Scientific Committee and Scientific Panel(s) including their Working Groups
    - 8.1.1 Scientific Committee and its Working Groups of interest to CONTAM Panel

The chair of the CONTAM Panel highlighted the main items discussed in the 70<sup>th</sup> plenary meeting of the Scientific Committee (SC) held on 11-12 November 2014. The comments received from the public consultation on the draft on EFSA guidance on statistical reporting were discussed. A draft SC statement on the risks and benefits of fish/seafood consumption as regards methylmercury was discussed. This draft statement is of interest to the CONTAM Panel because it relates to the follow up of the scientific opinion of the CONTAM Panel on mercury and methyl mercury in food, the CONTAM Panel chair informed the members of the CONTAM Panel on the approach taken for the preparation of the statement. In addition, the SC discussed the preliminary programme of the Scientific Conference in the context of Expo 2015 and new advanced training courses for scientific panel members. More information is available on the EFSA website<sup>13</sup>.

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 standing WG on Emerging Risks (SC), the standing WG on Guidance review (SC), the standing Working

13 http://www.efsa.europa.eu/en/panels/scer.htm?wtrl=01

http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2012-00378



Group on Genotoxicity (SC), the WG on Uncertainty in Risk Assessment (SC), and the WG on Safety risks from insects as food and feed (SC).

#### 8.2. CONTAM Panel Working Groups

#### 8.2.1. Working Group on Acrylamide in food

The vice-chair of the WG on Acrylamide in food informed the members of the CONTAM Panel that the WG has started the discussion how to address the comments received during the public consultation period. See item 9.3.

#### 8.2.2. Working Group on Chromium and nickel

See item 6.3.

#### 8.2.3. Working Group on Fusarium toxins

The chair of the WG on *Fusarium* toxins informed the members of the CONTAM Panel that the draft opinion on deoxynivalenol, metabolites of deoxynivalenol and masked deoxynivalenol in food and feed (EFSA-Q-2013-00721) is progressing well.

#### 8.2.4. Working Group on Masked mycotoxins in food and feed

See item 6.1.

#### 8.2.5. Working Group on Nickel in feed

The chair of the WG on Nickel in feed informed the members of the CONTAM Panel that the draft opinion on nickel in feed (EFSA-Q-2013-00766) is progressing well. The draft opinion will be presented to the CONTAM Panel for a discussion at the 69<sup>th</sup> meeting of the CONTAM Panel (20–22 January 2015).

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

The chair of the SWG on Non-allowed pharmacologically active substances in food and feed and their reference points for action informed the members of the CONTAM Panel that the draft opinion on nitrofurans and their metabolites in food (EFSA-Q-2014-00066) is progressing well.

## 8.2.7. Working Group on Tetrahydrocannabinol (THC) in milk and other products of animal origin

In the absence of the chair and vice-chair of the WG on THC in milk and other products of animal origin the scientific officer of the BIOCONTAM Unit informed the members of the CONTAM Panel that the draft opinion on tetrahydrocannabinol (THC) in milk and other products of animal origin (EFSA-Q-2013-00787) is progressing well. In addition, an update on the opinion, including points still to be addressed by the WG, was presented to the CONTAM .The draft opinion will be presented to the CONTAM Panel for a further discussion of the approach at the 69<sup>th</sup> meeting of the CONTAM Panel (20–22 January 2015).

#### 8.2.8. Working Group on Chlorate in food

The chair of the WG on Chlorate in food informed the members of the CONTAM Panel that the WG started to work on the draft opinion on chlorate in food (EFSA-Q-2014-00534).



#### 8.2.9. Working Group MCPD and glycidyl esters

The chair of the WG on MCPD and glycidyl esters informed the members of the CONTAM Panel that the WG started to work on the draft opinion on presence of 2- and 3-monochloropropane-1,2-diol (2- and 3-MCPD) fatty acid esters and glycidyl fatty acid esters in food (EFSA-Q-2014-00535).

#### 8.2.10. Working Group on Phorbol esters in Jatropha kernel meal

The vice-chair of the WG on Phorbol esters in Jatropha kernel meal informed the members of the CONTAM Panel that the WG started to work on the draft opinion on phorbol esters in Jatropha kernel meal (EFSA-Q-2014-00445).

#### 8.3. EFSA

#### 8.3.1. Advisory Forum

The last Advisory Forum (AF) meeting took place on 24-25 September 2014 in Venice, Italy. There has been no AF meetings since the September meeting. The next meeting will be on 10-11 December 2014. More information on the AF and its meeting is available on the EFSA website<sup>14</sup>.

#### 8.3.2. Management Board

The last Management Board (MB) meeting took place on 23 October 2014 in Parma, Italy. New MB members were appointed by the Council of the European Union following an open call for expressions of interest. The list of candidates was drawn by the European Commission following consultation with the European Parliament. The term on the MB will run till 30 June 2018. At its meeting the MB elected Sue Davies as MB chair and Piergiuseppe Facelli and Jaana Husu-Kallio as vice-chairs. Among the agenda items, priorities for EFSA's Strategy 2020 and the future functioning, role and responsibilities of the MB were discussed. In addition, the MB discussed three ongoing improvement initiatives of EFSA, namely the Quality Management project aiming at creating a comprehensive and coherent quality management system across EFSA, the project and resource management approach of EFSA and the Prometheus project aiming at strengthening EFSA's methodological transparency in scientific assessments and increasing consistency and harmonisation across EFSA methods using evidence. More information on the MB and its meeting is available on the EFSA website<sup>15</sup>.

#### 8.3.3. Other

As in the previous CONTAM Panel meetings since May 2014, the CONTAM Panel noted again that in its process for adoption of the scientific opinions, extensive peer review of the text drafted by external experts and Panel members is regularly performed. The contributions of the resigned CONTAM Panel member Ivonne Rietjens to the draft opinion on metabolites and masked or bound forms of certain mycotoxins in food and feed were also discussed, in view of the new interest situation identified earlier in Spring 2014. It was concluded that all the contributions drafted by Ivonne Rietjens in the aforementioned scientific outputs have been thoroughly discussed by WG members and subsequently peer reviewed by the members of the CONTAM Panel. This process ensures that the information provided is transparently considered.

<sup>14</sup> http://www.efsa.europa.eu/en/af/afmeetings.htm

<sup>15</sup> http://www.efsa.europa.eu/en/mb/mbmeetings.htm



The acting head of the BIOCONTAM Unit presented the latest revisions of the Decision of the Executive Director on Declarations of Interest in relation to implementing rules of DOIs. The Decision of the Executive Director came into force on 31 July 2014 and is available on the EFSA website<sup>16</sup>.

The acting team leader of the CONTAM Team of the BIOCONTAM Unit informed the members of the CONTAM Panel on the following matters:

A draft report reflecting the outcome of the consultation with ANSES and BfR on the draft opinion on perchlorate was shared with the two national risk assessment bodies for approval and will be published as a joint report documenting the resolution of the diverging scientific views on the risk assessment of perchlorate in food. The achievements of the CONTAM Panel 2014 were presented. In total six CONTAM Panel meetings were held, five scientific opinions were adopted and one draft opinion was endorsed for public consultation. An outline on the future work programme was also given. The members of the CONTAM Panel were thanked for their valuable work during the past year and seasonal greetings were expressed. In addition, the chair of the CONTAM Panel thanked the Panel members for their contributions during the year and looked forward to meet the new challenges in 2015.

#### 8.4. 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 have been made by the European Commission based on CONTAM opinions. The representative of the European Commission also indicated that requests on the toxicity of dioxins and a re-evaluation of their health based guidance value, on the risks from erucic acid in vegetable oils and fats in food and feed, on the influence on public health of possible deregulating pectenotoxins in bivalve molluscs, and on the evaluation of certain substances as acceptable previous cargoes will be submitted to EFSA by the end of 2014/beginning of 2015. In addition, the representative of the European Commission outlined the plan of the European Commission for the other new requests within the remit of the CONTAM Panel in 2015-2016. The plan on new requests included among others requests on nitrates in food, on furan in food (depending on the availability of new studies), on assessment on new substances as acceptable previous cargoes and on perfluoroalkylated substances (PFAS) in food. Furthermore he indicated that a regulatory framework setting acceptability criteria for detoxification of contaminated feed is in discussion. It is foreseen that EFSA will be requested by the Commission to assess the safety and effectiveness of detoxification processes.

#### 9. Other scientific topics for information and/or discussion

### 9.1. Presentation on a new release of the EFSA Comprehensive food consumption database

The scientific officer of the DATA Unit presented the new release of the EFSA Comprehensive food consumption database. The CONTAM Panel provided some comments and their appreciation of the new more comprehensive food consumption database.

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<sup>&</sup>lt;sup>16</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



#### 9.2. Presentation on a probabilistic approach for acute exposure assessments

The scientific officer of the DATA Unit presented the probabilistic approach for the acute exposure assessments which will be used in the opinions of the CONTAM Panel. The CONTAM Panel provided some further comments and their appreciation for the availability of the probabilistic exposure assessment method for the future acute exposure assessments.

## 9.3. Detailed presentation on the comments received in the public consultation for the draft opinion on acrylamide in food (EFSA-Q-2013-00007)<sup>17</sup> and proposal from the WG how to address them

The scientific officer of the BIOCONTAM Unit and the vice-chair of the WG on Acrylamide in food presented the comments received through the public consultation (1 July–15 September 2014) of the draft opinion on acrylamide in food (EFSA-Q-2013-00007) to the members of the CONTAM Panel. In addition, the preliminary proposals by the WG on how to address some of the comments were presented. The CONTAM Panel discussed the comments and the vice-chair of the WG will bring the feedback received back to the WG which will take them into account. In addition, the members of the CONTAM Panel were informed about the "Follow-up meeting on the public consultation on acrylamide in food" (10 December 2014, Brussels), where the comments received during the public consultation will be discussed with the contributing stakeholders and other relevant parties to ensure a full understanding of the comments received. The agenda of the meeting with the stakeholders is available at the EFSA website<sup>18</sup>.

# 9.4. Presentation on the outcome of the CONTAM project on extensive literature search and provision of summaries on oral toxicity of perfluoroalkylated substances (PFASs), their precursors and potential replacements in experimental animals and humans (EFSA-Q-2012-00896)

The scientific officer of the BIOCONTAM Unit presented to the members of the CONTAM Panel the outcome of the CONTAM procurement on an extensive literature search and provision of summaries on studies related to the oral toxicity of perfluoroalkylated substances (PFASs), their precursors and potential replacements in experimental animals and humans (EFSA-Q-2012-00896). The CONTAM Panel discussed whether the outcome of the project and the latest occurrence data reports on PFAS issued by the EFSA DATA Unit could provide the basis to refine the previous scientific opinion of the CONTAM Panel on perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts in food published in 2008. The CONTAM Panel discussed this as a possible self-tasking topic. The CONTAM Panel decided that the new evidence for PFOS and PFOA since the last CONTAM assessment in 2008, as well as the data available for a series of PFAS other than PFOA and PFOS would warrant issuing an update of the previous opinion. The CONTAM Panel also noted that since some of these substances may also have application as food contact materials, the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) would have to be consulted for the development of the scientific opinion. The CONTAM Panel agreed that the update of the previous opinion could be handled as a self-tasking mandate. However, the representative of the European Commission pointed out that PFASs in food is a potential topic for a future external mandate to EFSA from the European Commission (see item 8.4).

18 http://www.efsa.europa.eu/en/panels/contam.htm

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<sup>17</sup> http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00007



## 9.5. Presentation on the outcome of the CONTAM project on combined toxicokinetic and *in vivo* genotoxicity study on *Alternaria* toxins (EFSA-Q-2012-00433)

The senior scientific officer of the BIOCONTAM Unit presented the outcome of the CONTAM project on combined toxicokinetic and *in vivo* genotoxicity study on *Alternaria* toxins (EFSA-Q-2012-00433) to the members of the CONTAM Panel. The CONTAM Panel discussed whether the outcome of the project could provide the basis to refine the previous scientific opinion of the CONTAM Panel on *Alternaria* toxins in food and feed (issued in 2011). The CONTAM Panel agreed that the outcome of the project did neither give complete reassurance with regard to potential *in vivo* genotoxicity of *Alternaria* toxins nor it increased any concerns with that regard. Therefore an update of the previous opinion was considered not necessary at the moment.

## 9.6. Presentation on the outcome of the CONTAM project on *in vivo* genotoxicity studies on nivalenol and deoxynivalenol (EFSA-Q-2013-00674)

The scientific officer of the BIOCONTAM Unit presented on the outcome of the CONTAM project on *in vivo* genotoxicity studies on nivalenol and deoxynivalenol (EFSA-Q-2013-00674) to the members of the CONTAM Panel. The CONTAM Panel discussed the outcome of the project. The results on deoxynivalenol will be used in the development of the draft opinion on deoxynivalenol, metabolites of deoxynivalenol and masked deoxynivalenol in food and feed. The CONTAM Panel also discussed whether the outcome of the project could provide the basis to refine the previous scientific opinion of the CONTAM Panel on nivalenol in food and feed (issued in 2013) and decided that it was not necessary to update the scientific opinion on nivalenol.

## 9.7. Discussion on a request for clarification on the acceptability of calcium nitrate solution as acceptable previous cargo received from the European Commission

The acting team leader of the CONTAM Team of the BIOCONTAM informed the CONTAM Panel members on the letter received by EFSA from the European Commission requesting for clarification on the acceptability of calcium nitrate solution as acceptable previous cargo. The CONTAM Panel discussed the content of the letter and decided that a re-evaluation of the various forms of calcium nitrate solutions proposed as acceptable previous cargoes is not warranted since the different degrees of hydration have no influence on the toxicology and chemical reactivity of the substance. EFSA will detail the conclusions of the CONTAM Panel in a reply letter to the European Commission.

### 9.8. 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 INRA (France) and NIPH (Norway) in September 2013), the first interim report is due in July 2014.

For the Article 36 grant to collect occurrence data on sterigmatocystin in food (signed with RIKILT (the Netherlands), Unicatt (Italy), Fera (United Kingdom), BPI (Greece) and NVWA (the Netherlands) in September 2013), the second interim report was submitted in August 2014. The final report is due in January 2015.



For the Article 36 grant on occurrence data of pyrrolizidine alkaloids in food (signed with RIKILT (the Netherlands), BfR (Germany) and IRTA (Spain) in September 2013), the second interim report was submitted in September 2014. The final report is due in May 2015.

For the Article 36 grant on deoxynivalenol biomarkers in urine (signed with ISS (Italy), Unicatt (Italy), NVI (Norway), NIPH (Norway) and UoH (UK) in December 2013), the first interim report was submitted in August 2014. The final report is due in February 2015.

For the Article 36 grant on occurrence of tropane alkaloids in food, the contract was awarded to RIKILT (the Netherlands), IRTA (Spain), FERA (United Kingdom), and ICT (Czech Republic). The kick-off meeting will be held in January 2015.

#### 10. Any other business

Not Applicable