

Scientific Panel on Food Additives and Nutrient Sources Added to Food (ANS)

Minutes of the 75th Plenary meeting

Inaugural session jointly with Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on 5 July 2017

Held on 05-06 July, 2017, Parma (Italy)

(Agreed on 20 July 2017)

Participants

■ Panel Members:

ANS: Peter Aggett, Fernando Aguilar, Riccardo Crebelli, Birgit Dusemund, Metka Filipic, Maria José Frutos Fernandez, Pierre Galtier, David Gott, Ursula Gundert-Remy, Gunter Georg Kuhnle, Claude Lambré, Jean-Charles Leblanc, Inger Therese Lillegaard, Peter Moldeus, Alicja Mortensen, Agneta Oskarsson, Ivan Stankovic, Ine Waalkens-Berendsen, Rudolf Antonius Woutersen, Matthew Wright, and Maged Younes

CEF: Claudia Bolognesi, Laurence Castle, Kevin Chipman, Jean-Pierre Cravedi, Karl-Heinz Engel, Roland Franz, Konrad Grob, Rainer Gürtler¹, Trine Husøy, Maria Rosaria Milana, Wim Mennes, Gilles Rivière, Vittorio Silano, Christina Tlustos, Karla Pfaff, Detlef Wölfle and Holger Zorn

■ Hearing Experts²:

None

■ EFSA:

Food Ingredients and Packaging (FIP) Unit: Margarita Aguilera-Gomez, Maria Anastassiadou, Magdalena Andryszkiewicz, Eric Barthélémy, Mary Carfi, Anna Federica Castoldi, Cristina Croera, Ana Gomes, Natalia Kovalkovicova, Alexandros Lioupis, Yi Liu, Joaquim Manuel Maia, Carla Martino, Claudio Putzu, Annamaria Rossi, Ellen Van Haver, Katharina Volk, Claudia Roncancio Peña, Anna Christodoulidou, Alessandra Giarola, Federica Lodi, Fabiola Pizzo, Ana Maria Rincon,

¹ Not present on 5 July AM

² 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>

Camilla Smeraldi, Alexandra Tard, Stavroula Tasiopoulou, Marco Lannutti, Maria Correia

Executive Director: Bernhard Url

Executive Directorate: Juliane Kleiner

Scientific Evaluation of Regulated Product (REPRO) Department: Guilhem de Seze

Evidence Management (DATA) Unit: Davide Arcella

Emergency Team: Davide Bernardini

External Relations Unit: James Ramsay

Risk Communications: Arthur Healy

Legal & Assurance Services Unit: Simone Gabbi, Citlali Pintado

Finance Unit: Jürgen De Maggio

Corporate Services (CORSER) Unit: Francesco Ciancio

Scientific Committee and Emerging Risk (SCER) Unit: Raquel Garcia Matas, Tobin Robinson, Bernard Bottex, Jean-Lou Dorne, Nikolaos Georgiadis, Georges Kass, Caroline Merten, Reinhilde Schoonjans

Assessment and Methodology Support (AMU) Unit: Elisa Aiassa

1. Safety Moment - Emergency Procedures

The participants were informed by D. Bernardini about the safety instructions applicable to visitors at EFSA and the emergency procedures in place.

2. Welcome and opening speech – Introduction to EFSA, Strategy and Open Risk Assessment at EFSA

The Executive Director of EFSA, B. Url, welcomed the members of the Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) and the members of the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) to this inaugural meeting. In his opening speech, he highlighted the current challenges for the existing EU risk assessment model and the key objectives of the Open EFSA strategy 2020.

3. Introduction to the Scientific Evaluation of Regulated Products Department

The Head of Scientific Evaluation of Regulated Products Department (REPRO), G. de Seze, introduced to the Panel members the existing regulatory and international frameworks under which the REPRO department and the different Units within it operate. Areas of possible overlap in the scientific assessments were brought to the attention of the experts.

4. Introduction to the Communications and External Relations

J. Ramsey from the External relations Unit presented an overview of the risk communication activities within EFSA, the tasks performed by the Advisory Forum and Scientific cooperation Unit and the mission of the External Relations Unit.

A. Healy, from the Risk Communications Unit elaborated on the aspects relating to publishing the EFSA scientific outputs in the EFSA Journal.

5. Tour de Table ANS & CEF Panel Members

All the members of both Panels were invited to give a short introduction to their scientific background and specific areas of expertise.

6. Introduction to independence, confidentiality, liability requirements

S. Gabbi from the Legal and Assurance Services gave the Panel members an introduction to the applicable legal requirements, including the EFSA policy on independence and transparency, and the existing provisions on confidentiality and data protection requirements.

7. Administrative framework for supporting experts

F. Ciancio from the CORSER Unit and J. De Maggio from the Finance Unit presented EFSA's centralised system for logistic and financial support towards the organization of the meetings and the reimbursement of the experts.

8. Trainings opportunities for EFSA Experts

R. Garcia Matas from the Scientific Committee and Emerging Risk Unit (SCER) informed the Panel members about the EFSA training courses that have been organised in 2017-2018 for experts.

9. Overview of cross-cutting guidance

T. Robinson, Head of the SCER Unit, presented the role of the Scientific Committee in developing cross-cutting guidance for the EFSA Scientific Panels. The following guidance documents, which are -finalized or in development, were presented in more detail by the responsible scientific officers of the SCER Unit: PROMoting METHods for Evidence Use in Scientific assessments (PROMETHEUS), Weight of Evidence, Biological Relevance, Uncertainty, Benchmark Dose, Infants, Genotoxicology, Nanotechnology and Chemical mixtures.

10. Exposure assessment and Food Consumption Database

D. Arcella from the DATA Unit presented a new release of the Food Additives Intake Model for estimating the exposure to food additives. The updated tool, which will allow more refined exposure estimates compared to the previous Excel version, should be available on the EFSA website in the next few months.

11. Work-programme of the ANS and CEF Panels

C. Roncancio Peña, Head of FIP Unit, presented the tasks of the FIP Unit and an overview of the rules and procedures of relevance for the Panels and Working Groups. The staff of the FIP Unit was introduced to the Panel members.

On a general note, it was acknowledged that this one-year mandate of both Panels will serve as a transition period in the light of the upcoming renewal of all the EFSA Scientific Panels in July 2018 and the transformation of the CEF Panel into the Panel on food contact materials, enzymes and processing aids (CEP) and the ANS Panel into the Panel on food additives and flavourings (FAF).

A tentative work-programme of the ANS Panel for the period July 2017-June 2018 was presented. The main focus for this one-year term of office of the Panel will be the reduction of the backlog in the re-evaluation of food additives under Regulation (EC) No 257/2010, in addition to the evaluations of new applications. Moreover, the Panel aims

at finalising those activities related to the assessment of nutrient sources and certain other substances added to food, since these tasks will be transferred to the new Panel on nutrition, novel foods and food allergens (NDA) as of July 2018.

As regards the work-programme of the CEF Panel, the Panel members were informed about the ongoing and possible future mandates that fall within the remit of the CEF Panel (food enzymes, flavourings, processing aids and food contact materials). A 6-year workplan was presented to the Panel members to address more than 300 mandates in the area of food enzymes. Majority of these mandates are enzyme applications received by EC within the legal deadline of submission (i.e., 11 March 2015).

The Panel members were informed about the EFSA decision allowing continuation of the already established Standing Working Groups of the ANS and CEF Panels for their one-year mandate 2017-2018, including confirmation of membership and the re-appointment of their respective chairs and vice-chairs as follows:

Standing working groups for the ANS Panel (**chair**/vice-chairs):

- Applications (**D. Gott**/P. Moldeus)
- Exposure assessment (**J-C. Leblanc**/C. Tlustos)
- Procedures under Article 8 of Regulation (EC) No 1925/2006 (**M. Wright**/P. Galtier)
- Re-evaluation of Food Additives other than Gums & Colours (**C. Lambré**/M. Wright)
- Re-evaluation of Food Colours (**R. Woutersen**/A. Oskarsson)
- Re-evaluation of Gums and Food Additives from Natural Sources (**B. Dusemund**/I. Stankovic)
- Re-evaluation of Starches, Celluloses and Pectins (**R. Woutersen**/ D. Gott)

Standing working groups for the CEF Panel (**chair**/vice-chairs):

- Flavourings (**W. Mennes**/T. Husoy)
- Genotoxicity (**R. Guertler**)
- Food Contact Materials (**L. Castle**/D. Wölfle)
- Recycling Plastics (**MR. Milana**/F. Poças)
- Food Enzymes (**K-H. Engel**/S. Kärenlampi)

The members who were not part of the previous Panels were asked to express their interest for joining one of the Standing working groups of their respective Panel.

The following ad-hoc Working Group of the ANS Panel was also confirmed for the one-year mandate:

- *Ad hoc* working group of the ANS Panel on Guidance on Nutrient Sources (**D. Gott**)

The inaugural joint session was closed and the Panels reconvened separately the following day for their respective plenary meetings.

12. Welcome and apologies for absence

On the second day, the Head of the FIP Unit, C. Roncancio Peña chaired this first agenda point till the election of the chair and vice-chairs, and welcomed the members of the ANS Panel in its current composition.

13. Election of Chair and Vice-Chairs of the Panel

The election took place following the procedure established by EFSA and under the supervision of Citlali Pintado (Legal & Assurances Services).

Maged Younes was elected as chair of the ANS Panel and Ursula Gundert-Remy and Ruud Woutersen were elected as vice-chairs of the ANS Panel.

14. Adoption of agenda

The agenda was adopted without any changes.

15. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the 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.

16. Agreement of the minutes of the 74th Plenary meeting held on 20-22 June 2017, Parma (Italy)

The minutes of the 74th Plenary meeting held on 20-22 June were agreed by written procedure on 30 June 2017.

17. <http://www.efsa.europa.eu/sites/default/files/event/170620-m.pdf> Report on the written procedures since 74th Plenary meeting

The ANS Panel 'Statement on the approach followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation' had been unanimously adopted subject to incorporation of changes as suggested during the written procedure ending on 30 June 2017.

The scientific output will be available on the Authority's webpage.

18. Scientific outputs submitted for discussion and possible adoption

- 18.1. Re-evaluation of celluloses: microcrystalline cellulose (460i); powdered cellulose (E 460ii), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), sodium carboxy methyl cellulose (E 466), crosslinked sodium carboxymethyl cellulose (E 468), enzymatically hydrolysed carboxymethyl cellulose (E 469)**

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

([EFSA-Q-2011-00545](#); [EFSA-Q-2011-00546](#); [EFSA-Q-2011-00547](#);
[EFSA-Q-2011-00548](#); [EFSA-Q-2011-00549](#); [EFSA-Q-2011-00550](#);
[EFSA-Q-2011-00551](#); [EFSA-Q-2011-00552](#); [EFSA-Q-2011-00553](#);
[EFSA-Q-2011-00554](#))

The draft opinion on the re-evaluation of celluloses was presented to the members of the ANS Panel together with the main points for discussion. The ANS Panel discussed the different parts of the risk assessment and suggested some revisions of the opinion before it can be adopted at the next plenary meeting.

19. New Mandates

The Secretariat informed the members of the ANS Panel that, since the last plenary meeting, the following mandate was received by EFSA and allocated to the ANS Panel:

- M-2017-0121: Request for EFSA to perform a risk assessment and to provide a scientific opinion on the safety in use of Monk fruit extract/Luo han guo (LHG) extract as a food additive (EFSA-Q-2017-00527)

The mandate is currently under consideration by the Application Desk (APDESK) Unit of EFSA.

20. Other scientific topics for information and/or discussion

20.1. Re-evaluation of food additives permitted for use in food categories 13.1.1 and 13.1.5.1 and intended for infants below 16 weeks of age

Further to the adoption of the EFSA Scientific Committee Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age, the Panel held an initial reflection on its implementation in the re-evaluation of food additives permitted for use in those food categories intended for use in this age groups. Until now the scientific opinions issued by the ANS Panel only cover the general population above 12 weeks of age as the uses in foods for infants below that age requires a specific risk assessment.

There are 32 additives to be evaluated for these specific uses. The Panel was of the opinion that an *ad hoc* WG of the Panel should implement the requirements for the specific substances and finalise their assessment in collaboration with the current and future working groups of the Panel.

20.2. Re-evaluation of food additives with deadline 31.12.2018

- Proposal for setting up a new Working Group of the ANS Panel phosphoric acid, phosphates, di-, tri- and polyphosphates (E 338-341; E 343; E 450-452) ([EFSA-Q-2011-00618](#); [EFSA-Q-2011-00619](#); [EFSA-Q-2011-00620](#); [EFSA-Q-2011-00621](#); [EFSA-Q-2011-00622](#); [EFSA-Q-2011-00623](#); [EFSA-Q-2011-00624](#); [EFSA-Q-2011-00625](#); [EFSA-Q-2011-00626](#); [EFSA-Q-2011-00628](#); [EFSA-Q-2011-00629](#); [EFSA-Q-2011-00630](#); [EFSA-Q-2011-00532](#); [EFSA-Q-2011-00533](#); [EFSA-Q-2011-00534](#); [EFSA-Q-2011-00535](#); [EFSA-Q-2011-00536](#); [EFSA-Q-2011-00537](#); [EFSA-Q-2011-00538](#); [EFSA-Q-2011-00539](#); [EFSA-Q-2011-00540](#); [EFSA-Q-2011-00541](#); [EFSA-Q-2011-00542](#); [EFSA-Q-2011-00543](#))

The Panel held an initial brainstorming discussion on how to address the re-evaluation of this group of food additives. The Panel was of the opinion that, given the similarities between the different substances, the assessment would be more efficiently addressed by an *ad hoc* Working Group, also in

consideration of the current workload of the other Standing Working group and to this end, Ursula Gundert-Remy was appointed as Chair of this new Working Group. The Panel further discussed possible areas of expertise needed for the re-evaluation of these food additives. Completion of the assessment, according to the deadline set in Regulation (EC) No 257/2010 is the end of 2018.

- Proposal for setting up a new SWG of the ANS Panel for other food additives with deadline 31.12.2018: hydrochloric acid and chlorides (E 507-509; E 511) ([EFSA-Q-2011-00657](#); [EFSA-Q-2011-00658](#); [EFSA-Q-2011-00659](#); [EFSA-Q-2011-00660](#)); stannous chloride (E 512) ([EFSA-Q-2011-00661](#)); sulphuric acid and sulphates (E 513-517) ([EFSA-Q-2011-00662](#); [EFSA-Q-2011-00663](#); [EFSA-Q-2011-00664](#); [EFSA-Q-2011-00665](#); [EFSA-Q-2011-00666](#); [EFSA-Q-2011-00667](#); [EFSA-Q-2011-00668](#)); aluminium sulphates (E 520-523) and sodium aluminium phosphate acidic (E 541) ([EFSA-Q-2013-00697](#)); ferrocyanides (E 535-536; E 538) ([EFSA-Q-2011-00676](#); [EFSA-Q-2011-00677](#); [EFSA-Q-2011-0067](#)); hydrogenated poly-1-decene (E 907) ([EFSA-Q-2011-00707](#)); polydextrose (E 1200) ([EFSA-Q-2011-00583](#)); polyvinylpyrrolidone (E 1201) ([EFSA-Q-2011-00584](#)); polyvinylpolypyrrolidone (E 1202) ([EFSA-Q-2011-00585](#)); benzylalcohol (E 1519) ([EFSA-Q-2011-00590](#))

The Panel held a further discussion on how to address the re-evaluation of a group of other food additives with deadline 31.12.2018 according to Regulation (EC) No 257/2010. These are a group of heterogeneous substances, already included in past or current calls for occurrence data. The Panel was of the opinion that the drafting of these scientific opinions should be allocated to a new Standing Working group, and to this end, Ruud Woutersen was appointed as the Chair of this new Working Group. The Panel further discussed possible areas of expertise needed for the re-evaluation of these food additives.

21. Any Other Business

The Panel tentatively agreed on the next plenary meeting dates for the 2017-2018 ANS Panel mandate, as follows:

26-28 September 2017, 21-23 November 2017 (with an open plenary session), 30 January- 1st February 2018, 13-15 March 2018, 15-17 May 2018, 26-28 June 2018.

A plenary would also be held in October 2017, with the exact dates and location still to be decided.

The Chair of the SWG on Procedures under Article 8 of Regulation (EC) No 1925/2006, sought the initial view of the ANS Panel on the approach to be followed for performing the assessment of the safety of monacolins in red yeast rice. The draft opinion will be further elaborated by the SWG following the recommendations from the ANS Panel.