

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

Minutes of the 72nd Plenary meeting

Held on 4-6 April 2017, Parma (Italy)

(Agreed on 27 April 2017)

Participants

■ Panel Members:

Fernando Aguilar,¹ Riccardo Crebelli, Alessandro Di Domenico, Birgit Dusemund,² Maria José Frutos, Pierre Galtier, David Gott, Ursula Gundert-Remy, Claude Lambré, Jean-Charles Leblanc,³ Peter Moldeus, Alicja Mortensen, Pasquale Mosesso, Agneta Oskarsson,⁴ Dominique Parent-Massin,⁵ Ivan Stankovic, Ine Waalkens-Berendsen, Rudolf Antonius Woutersen, Matthew Wright,⁶ and Maged Younes.⁴

■ Hearing Experts:⁷

Paul Tobback (for item 6.5)

■ European Commission representatives:

DG SANTE (Health and Food Safety), E2 Food processing technologies and novel foods: Wim Debeuckelaere, Jiri Sochor

■ EFSA:

FIP Unit: Anna Christodoulidou, Federica Lodi, Fabiola Pizzo, Ana Maria Rincon, Claudia Roncancio Peña, Camilla Smeraldi, Alexandra Tard, Stavroula Tasiopoulou.

AMU Unit: Ana Garcia

DATA Unit: Andrea Altieri, Petra Gergelova

NUTRI Unit: Andrea Germini

RISCOM Unit: Bernd Elzer

Executive Directorate: Juliane Kleiner

¹ Participated via teleconference on 04-06 April 2017

² Participated via teleconference on 04 April 2017

³ Participated via teleconference on 06 April 2017

⁴ Apologies on 04 April AM

⁵ Participated via teleconference on 04 April 2017 (PM), on 05 April 2017 (PM) and 06 April 2017

⁶ Apologies on 04 April, participated via teleconference on 05-06 April 2017

⁷ 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>.

1. Welcome and apologies for absence

The Chair welcomed all participants.

Apologies were received from Oliver Lindtner for the whole meeting.

2. Adoption of agenda

The agenda was adopted without any changes.

3. 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 Interest,⁹ 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.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex.

Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 71st Plenary meeting held on 28 Feb-02 Mar 2017, Parma (Italy)

The minutes of the 71st Plenary meeting held on 28 Feb-02 Mar were agreed by written procedure on 14 March 2017.¹⁰

5. Report on the written procedures since 71st Plenary meeting

No scientific outputs were adopted by written procedure since the last plenary meeting.

6. Scientific outputs submitted for discussion and possible adoption

6.1. Request for a scientific opinion from the European Food Safety Authority in relation to a new study on the carcinogenic potential of the food additive sucralose (E 955) ([EFSA-Q-2016-00251](#))

The draft statement on the new study on the carcinogenic potential of the food additive sucralose (E 955) 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 adopted the statement, subject to incorporation of changes as suggested during the meeting.

The statement will be available on the Authority's webpage.

6.2. Re-evaluation of potassium nitrite (E 249) and sodium nitrite (E 250) ([EFSA-Q-2011-00460](#); [EFSA-Q-2011-00461](#))

The draft opinion on the re-evaluation of the safety of potassium nitrite and sodium nitrite (E 249, E 250) was presented to the members of the ANS Panel together with the main points for discussion.

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

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

¹⁰ <https://www.efsa.europa.eu/en/events/event/170228>

The ANS Panel discussed the different parts of the risk assessment and adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

6.3.Re-evaluation of sodium nitrate (E 251) and potassium nitrate (E 252) ([EFSA-Q-2011-00462](#); [EFSA-Q-2011-00463](#))

The draft opinion on the re-evaluation of the safety of sodium nitrate and potassium nitrate (E 251, E 252) 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 adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

6.4.Re-evaluation of tragacanth (E 413) ([EFSA-Q-2011-00512](#))

The draft opinion on the re-evaluation of the safety of tragacanth (E 413) 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 adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

6.5.Re-evaluation of fatty acids (E 570) ([EFSA-Q-2011-00683](#))

The draft opinion on the re-evaluation of the safety of fatty acids (E 570) 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 adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

6.6.Re-evaluation of sorbitans (E 491-495); new mandate on amendment of the specifications ([EFSA-Q-2011-00571](#); [EFSA-Q-2011-00572](#); [EFSA-Q-2011-00573](#); [EFSA-Q-2011-00574](#); [EFSA-Q-2011-00575](#); [EFSA-Q-2014-00875](#))

The draft opinion on the re-evaluation of the safety of sorbitan monostearate, sorbitan tristearate, sorbitan monolaurate, sorbitan monooleate and sorbitan monopalmitate (E 491-495) and of a proposed amendment of the specifications of sorbitan monostearate, sorbitan tristearate and sorbitan monopalmitate 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 adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

7. New Mandates

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

- M-2017-0027: Request for a scientific opinion on Inositol-Stabilized Arginine Silicate (EFSA-Q-2017-00071)
- M-2017-0068: Request for EFSA to perform a risk assessment and to provide a scientific opinion on the safety in use of Glucosylated steviol glycosides as a food additive (EFSA-Q-2017-00247)
- M-2017-0067: Request for EFSA's scientific opinion as regards a proposed amendment of the specifications of the food additive Steviol glycosides (E 960) (EFSA-Q-2017-00036)

The three mandates are currently under consideration by the Application Desk (APDESK) Unit of EFSA.

The Secretariat also informed the members of the ANS Panel about the following applications, considered valid since the previous meeting:

- M-2017-0042: Request for an opinion of the European Food Safety Authority (EFSA) as regards the extension of use of lycopene (E 160d) to certain meat preparations, meat products and fruit and vegetable preparations (EFSA-Q-2017-00098)
- M-2017-0067: Request for an opinion of the European Food Safety Authority (EFSA) as regards the safety of nisin (E 234) as a food additive in the light of new toxicological data and the proposed extension of use (EFSA-Q-2017-00097)

The ANS SWG on Applications has been tasked with the drafting of the scientific opinions.

In addition, the following mandate under Article 8 of Regulation (EC) No 1925/2006 was received:

- M-2017-0053: Commission request for a scientific opinion on the safety of monacolins in red yeast rice (EFSA-Q-2017-00138)

The ANS SWG on Procedures under Article 8 of Regulation (EC) No 1925/2006 has been tasked with the drafting of the scientific opinion.

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

8.1. Scientific Committee WG Uncertainty in Risk Assessment

The ANS Panel discussed the application of the Guidance Document on Uncertainty to the draft opinion on the re-evaluation of the safety of fatty acids (E 570), which had been previously selected as a case study for testing this new guidance.

8.2. EFSA

8.2.1. Titanium dioxide (E 171)

The re-evaluation of titanium dioxide (E 171) for use as a food additive had been completed by the ANS Panel in June 2016, and a scientific opinion published in September 2016.

At the current meeting, the Panel received an update from EFSA on the activities that had been ongoing since the publication of a new experimental animal study conducted by the French "Institut national de la recherche agronomique" (INRA) on titanium dioxide (E 171) in Scientific Reports in January 2017 (Bettini et al., 2017). The authors of this study reported possible harmful effects on the immune system and the development of pre-neoplastic colonic lesions associated with intake of titanium dioxide (E 171). EFSA became aware that this new scientific information

was going to be assessed by the French Food Safety Agency (ANSES), also in the context of a more general review of the safety of nanomaterials in food. During the past weeks EFSA has been in close contact with ANSES with respect to their ongoing assessment, following the provisions of Article 30(1) and (2) of the Regulation EC N. 178/2002, in order to identify at an early stage any potential source of divergence between the EFSA and ANSES opinions of the experts. On 9th March 2017, EFSA staffs, two experts from the ANS Panel and one expert from the FEEDAP Panel were invited to take part in a technical hearing organised by ANSES with the authors of the study, and to the joint scientific discussion between ANSES and EFSA that followed. The Panel was informed that the outcome of this assessment and the main conclusions by the ANSES WG experts will be included in a scientific opinion of ANSES, which is expected to be published in the coming weeks. The Panel noted the publication by Bettini et al. (2017) and overall agreed that this would not merit reopening the EFSA Opinion on titanium dioxide (E 171). Further feedback was given on the ongoing FEEDAP evaluation and on the follow up activities from the European Commission, including the call for data on Titanium dioxide (E 171).

8.2.2. Feedback from 72nd EFSA Management Board meeting

The ANS Panel was presented with a feedback from the latest EFSA Management Board meeting held on 22 March 2017.

The Panel was informed that the Management Board approved the nomination of 42 scientific experts to re-establish two of EFSA's Scientific Panels: the Scientific Panel on Food Additives and Nutrient Sources Added to Food (ANS) and the Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids CEF). The new term will commence on 1 July 2017 and will terminate on 30 June 2018. As of July 2018, the ANS Panel will be re-established as the Panel on Food Additives and Flavourings (FAF) following the renewal of EFSA's Scientific Panels in 2018. The new Panel will take over responsibility for the evaluation of flavourings from the current CEF Panel and will hand over responsibility for evaluation of nutrient sources to the NDA Panel.

The ANS Panel was also informed that, in preparation for the 2018 renewals, the Management Board had endorsed changes to the way EFSA's Scientific Committee, its Scientific Panels and Working Groups are established and operate. The Panel learnt that the number of Scientific Panel members will range from 15 to 25 and that an expert can serve a maximum of three terms of office on the same Scientific Panel and a maximum of two terms as Chair of the same Scientific Panel or in the Scientific Committee. It was clarified that a period shorter than 18 months is not considered a term of office.

Further, the Panel learnt that according to the new rules Experts taking part in the adoption of a scientific output need to express their views either for or against it.

8.3. European Commission

The EC representative briefly updated the Panel on some of the activities undertaken as a follow-up of scientific opinions previously adopted by the Panel.

9. Other scientific topics for information and/or discussion

9.1. Request for a scientific opinion on di-magnesium malate ([EFSA-Q-2016-00115](#))

Upon request from the WG Applications, the ANS Panel discussed the possible approach for the exposure assessment to be followed in the scientific opinion on the

safety evaluation of di-magnesium malate as a novel food ingredient proposed for use as a source of magnesium in foods for the general population, food supplements, total diet replacement for weight control and food for special medical purposes. The exposure section of the draft opinion will be further elaborated by the WG following the recommendations from the ANS Panel.

9.2.Guidance on safety evaluation of sources of nutrients or other ingredients and bioavailability of nutrient or other ingredient from the sources ([EFSA-Q-2016-00150](#))

Two members of the ANS Panel were invited to join the meeting of the Panel on Dietetic Products, Nutrition and Allergies (NDA) on 6 April 2017 to present the progress made on the drafting of the guidance and to receive comments from the NDA Panel prior to the finalisation of the draft guidance and its release for public consultation.

At the current meeting, the ANS Panel received feedback from the discussion with the NDA Panel. The Panel was informed that the NDA Panel welcomed the possibility to be involved at this stage of the process, especially in the light of the fact that the NDA Panel will take over responsibility for the evaluation of nutrient sources added to food from the current ANS Panel following the renewal of EFSA's Scientific Panels in 2018.

The ANS Panel noted that more time would be needed from the NDA Panel to consolidate their views and comments and therefore agreed to revise the self-task mandate and to extend the originally planned deadline (end of June 2017) in order to accommodate this longer period of consultation with NDA Panel.

9.3.Guidance on the characterisation of microorganisms used as feed additives or as production organisms ([EFSA-Q-2016-00069](#))

The ANS Panel was informed about changes to the plan for finalisation of this guidance, which would require further elaboration by the FEEDAP Working Group on Guidance Update.

10.Any Other Business

The Panel was consulted on the need for a correction to be implemented in the Scientific Opinion on the re-evaluation of paprika extract (E 160c) as a food additive, adopted by the Panel on 19 November 2015 and published on the EFSA journal on 10 December 2015. The Panel noted that an error was identified in Appendix B of the opinion. This error did not have an impact on the final outcome of the opinion. The updated opinion correcting the error will be re-published on the EFSA journal.

Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

CONFLICT OF INTEREST: In the ADoI or in the SDoI filled for the present meeting Dr Claude Lambré declared the following interest: Member of the ANSES (Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail) Working Group on Exposure to nanoparticles of TiO₂ in food as of February 2017. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹¹ and the Decision of the Executive Director on Declarations of Interest¹², and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in exclusion of the expert from any discussion, voting or other processing of item 8.2.1 by the concerned scientific group.

¹¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

¹² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>