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

Minutes of the 80th Plenary meeting

Held on 13-15 March, Parma (Italy)

(Agreed on 13 April 2018)

Participants

- **Panel Members:**

  Peter Aggett, Fernando Aguilar, Riccardo Crebelli, Birgit Dusemund, Maria José Frutos Fernandez, Pierre Galtier, David Gott, Ursula Gundert-Remy, Gunter Georg Kuhnle [1], Claude Lambré, Jean-Charles Leblanc, Inger Therese Lillegaard, Peter Moldeus [2], Alicja Mortensen, Ivan Stankovic, Ine Waalkens-Berendsen, Ruud Woutersen, Matthew Wright, and Maged Younes

- **Hearing Experts:**

  Patrizia Restani for agenda item 9.1.

- **European Commission representatives:**

  DG SANTE (Health and Food Safety), E2 Food processing technologies and novel foods: Guillermo Cardon

- **EFSA:**

  FIP Unit: Anna Christodoulidou, Alessandra Giarola, Federica Lodi, Fabiola Pizzo, Ana Maria Rincon, Camilla Smeraldi, Alexandra Tard, Eleonora Alquati

  DATA Unit: Sofia Ioannidou
  COMCO Unit: Bernd Elzer

1. Welcome and apologies for absence

The Chair welcomed all participants.

Apologies were received from Metka Filipic and Agneta Oskarsson for the whole meeting, from Peter Aggett on the 13th March 2018 and from Peter Moldeus on 14th and 15th March.

Gunter Georg Kunhle did not participate in agenda point 6.1 due to a Conflict of Interest

[1] Participated by web-conference
[2] Participated by web-conference on 13.03.2018 AM

being identified for the agenda item.

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 Processes[3] and the Decision of the Executive Director on Declarations of Interest[4], EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the 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 I. 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 79th Plenary meeting held on 30 Jan-01 Feb 2018, Parma (Italy)

The minutes of the 79th Plenary meeting held on 30 Jan-01 Feb 2018 were agreed by written procedure on 2 March 2018[5].

5. Report on the written procedures since 79th 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. Safety of green tea catechins (EFSA-Q-2016-00627)

Further to the discussion on the draft scientific opinion on the safety evaluation of green tea catechins, performed under the framework of Article 8 of Regulation (EC) No1925/2006 held at the previous plenary meeting, the revised document 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 assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

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

6.2. Re-evaluation of Propane-1,2-diol (E1520) (EFSA-Q-2011-00591)

The draft scientific opinion on the re-evaluation of the already permitted food additive propane-1,2-diol (E 1520) 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 assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

[3] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[4] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf
[5] https://www.efsa.europa.eu/sites/default/files/event/180130-m.pdf

The full opinion is available on the Authority's webpage[6].

6.3. Re-evaluation of Carrageenan (E407) and processed Eucheuma seaweed (E 407a) (EFSA-Q-2011-00508; EFSA-Q-2011-00509)

Further to the discussion on the draft scientific opinion on the re-evaluation of the already permitted food additives carrageenan (E 407) and processed Eucheuma seaweed (E 407a) held at the previous plenary meeting, the revised draft document 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 assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

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

The European Commission clarified that the follow-up of the scientific opinion on Carrageenan (E407) is to be managed by EFSA under the Terms of Reference of the existing mandate (M-2017-0220) requesting EFSA to address all the data gaps specified in the recommendations made in its scientific opinions on the re-evaluation of the safety of food additives permitted in food category 13.1 (food for infants and young children) of Annex II to Regulation (EC) No 1333/2008, (see items 7.2 and 8.2.9)[7].

6.4. Silver hydrosol added for nutritional purposes to food supplements (EFSA-Q-2016-00235)

The draft scientific opinion on the evaluation of the safety of silver hydrosol added for nutritional purposes to food supplements, and on the bioavailability of silver from the proposed source, was discussed by the Panel.

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

The full opinion is available on the Authority's webpage[8].

6.5. Safety in use of curdlan as a food additive (EFSA-Q-2017-00024)

The draft opinion on the safety evaluation of the proposed new food additive curdlan was presented to the members of the ANS Panel together with the main points for discussion.

The ANS Panel considered that additional information should be requested to the applicant in order to complete the assessment. The scientific evaluation is currently suspended, awaiting submission of the additional information requested.

6.6. Safety of the proposed amendment of the specifications of the food additive Steviol glycosides (EFSA-Q-2017-00036)

The draft scientific opinion on the evaluation of the safety of the proposed amendment of the specifications of the food additive steviol glycosides (E 960), was discussed by the Panel.

[6] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5235/full
[7] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00270
[8] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5237/full

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

The full opinion is available on the Authority's webpage[9].

7. New Mandates

The Secretariat updated the members of the ANS Panel on the new mandates received since the last plenary meeting.

7.1. New questions since the previous meeting

The following new mandates have been received since the last ANS Panel Plenary meeting, still under consideration by APDESK:

Food Sector	EFSA-Q-Number	Subject	Reception date
ADD	EFSA-Q-2018-00119	Request for an opinion from the European Food Safety Authority (EFSA) as regards the safety of ethyl lauroyl arginate (E 243) as a food additive in the light of the new information provided and the proposed extension of use	16/02/2018
ADD	EFSA-Q-2018-00242	Request for EFSA to perform a risk assessment and to provide a scientific opinion on the safety of a proposed amendment of the specifications of the food additive Steviol glycosides (E 960)	09/03/2018

ADD= Food additives

7.2. Valid questions since the previous meeting

The following questions have been considered valid for the start of the assessment since the last ANS Panel Plenary meeting:

Food Sector	EFSA-Q-Number	Subject	Valid on:
NS	EFSA-Q-2018-00066	Commission request for a scientific opinion on magnesium citrate malate added for nutritional purposes to food supplements	07/03/2018

NS= Nutrient sources

The question above was assigned to the Working Group Applications.

Further to the acceptance of the mandate (M-2017-0220) from the European Commission requesting EFSA to address all the data gaps specified in the recommendations made in its scientific opinions on the re-evaluation of the safety of food additives permitted in food category 13.1 (food for infants and young children) of Annex II to Regulation (EC) No 1333/2008, the following questions have also been considered valid for the start of the assessment since the last ANS Panel Plenary meeting:

[9] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5236/full

Food Sector	EFSA-Q-Number	Subject	Valid on:
ADD	EFSA-Q-2018-00102	Re-evaluation of starch sodium octenyl succinate (E 1450) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00101	Re-evaluation of sucrose esters of fatty acids (E 473) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00100	Re-evaluation of mono-and diglycerides of fatty acids (E 471) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00099	Re-evaluation of carboxy methyl cellulose (E 466) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00098	Re-evaluation of pectins (E 440) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00097	Re-evaluation of xanthan gum (E 415) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00096	Re-evaluation of guar gum (E 412) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00095	Re-evaluation of locust bean gum (E 410) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00094	Re-evaluation of lecithins (E 322) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00093	Re-evaluation of δ-tocopherol (E 309) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00092	Re-evaluation of γ-tocopherol (E 308) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00091	Re-evaluation of α-tocopherol (E 307) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00090	Re-evaluation of tocopherol-rich extract (E 306) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00089	Re-evaluation of fatty acid esters of ascorbyl palmitate (E 304i) as a food additive in foods for infants below 16 weeks of age.	29/01/2018
ADD	EFSA-Q-2018-00088	Re-evaluation of calcium carbonate (E 170) as a food additive in foods for infants below 16 weeks of age.	29/01/2018

ADD= Food additives

The 15 questions above were assigned to the newly established Working Group Re-evaluation of food additives for use in foods for infants below 16 weeks of age (see item 8.2.9).

7.3. Withdrawn questions since the previous meeting

No applications have been withdrawn since the last ANS Plenary meeting.

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

8.1. Scientific Panel(s) including their Working Groups

Meeting of the Scientific Committee held February.

8.2. EFSA including its Working Groups /Task Forces

The Chairs of the ANS Panel Working Groups and EFSA scientific secretariat provided feedback from their latest meetings:

8.2.1. ANS Panel SWG Applications

No specific issue was brought to the attention of the Panel in addition to what already recorded in the **minutes of the WG**.

8.2.2. Re-evaluation of Gums and Food Additives from Natural Sources 2017-2018

No specific issue was brought to the attention of the Panel in addition to what already recorded in the **minutes of the WG**.

8.2.3. ANS Panel SWG on the Re-evaluation of Food Additives other than Gums and Colours

No specific issue was brought to the attention of the Panel in addition to what already recorded in the **minutes of the WG**.

8.2.4. Re-evaluation of other Miscellaneous Food Additives with 2018 deadline

No specific issue was brought to the attention of the Panel in addition to what already recorded in the **minutes of the WG**.

8.2.5. ANS Panel ad hoc WG on the Re-evaluation of Phosphates

No specific issue was brought to the attention of the Panel in addition to what already recorded in the **minutes of the WG**.

8.2.6. ANS Panel SWG Procedures under Article 8 of Regulation (EC) No 1925/2006

In addition to what already recorded in the in the **minutes of the WG**, the Panel was provided with feedback on the published opinion on the safety of hydroxyanthracene derivatives received during some post-adoption teleconferences held with interested parties and during a presentation of the scientific opinion at the European Commission meeting of the Expert Group on Food supplements and Fortified foods held in Brussels on 16 February 2018. In particular, with respect to some criticism received at the way uncertainty and weight of evidence analysis are expressed in the opinion, the Panel reflected on possible improvements to be made to the scientific opinions that will be adopted by the Panel before the start of the implementation of the new EFSA uncertainty guidance in the scientific outputs for regulated products.

8.2.7. ANS Panel WG Exposure Assessment

No specific issue was brought to the attention of the Panel in addition to what already recorded in the **minutes of the WG**.

8.2.8. ANS Panel *ad hoc* WG on the Guidance on Nutrient Sources

In addition to what already recorded in the **minutes of the WG**, the Panel was informed that following the closure of the public consultation on the draft guidance document, the document is being finalised by the WG for possible transmission to the Panel and adoption at the next plenary meeting.

8.2.9. Working Group Re-evaluation of food additives for use in foods for infants below 16 weeks of age

The Chair of this newly established Working Group presented the Panel with a brief overview of the topics for discussion during the inaugural meeting scheduled to start right after the end of the current ANS Panel plenary meeting.

8.3. European Commission

The Panel was informed on an upcoming mandate from the European Commission requesting an assessment of four studies published after the publication of the scientific opinion on the re-evaluation of titanium dioxide (E 171) as a food additive. Because this new mandate is to be addressed within a short timeframe (end of May 2018), it was proposed to reconvene the already existing WG on Re-evaluation of Food Colours 2017-2018 for the drafting of this scientific opinion.

9. Other scientific topics for information and/or discussion

9.1.Safety of monacolins in red yeast rice (EFSA-Q-2017-00138)

The ANS Panel discussed the approach to be taken for assessment of the safety of monacolins in red yeast rice. The draft opinion will be further elaborated by the WG following the recommendations from the ANS Panel.

10. Any Other Business

10.1. Orthosilicic acid-vanillin complex (OSA-VC) as a novel food pursuant to Article 26(2)(c) of Regulation (EU) No 2015/2283 – Proprietary data (EFSA-Q-2016-00004)

A scientific opinion on orthosilicic acid-vanillin complex (OSA-VC) as a novel food (NF) was adopted by the Panel on 21 November 2017.[10]

Following the entry into force of the new NF Regulation (EU) 2015/2283, the European Commission requested EFSA to evaluate whether and if so, to what extent, the requirements of Article 26(2)(c) of the NF Regulation are fulfilled, i.e. whether the NF could not have been assessed by EFSA without the scientific evidence or data requested to be protected by applicant.

The Panel noted that in elaborating its opinion on OSA-VC as a NF, the data from the manufacturing process (Section 2.1 and Appendix K of the initial application dossier, February 2014, updated in June 2014 and March 2016; and Annex 9 of the response by the applicant to the initial assessment report and the Member States' comments

[10] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5086

and objections, October 2015), the stability study (Section 2.3 and Appendix N of the initial application dossier), the particle characteristics of OSA-VC in suspension (Figure 15 of the initial application dossier and Annex 1 of the response by the applicant to the initial assessment report and the Member States' comments and objections), the data from NMR analysis on OSA-VC (Section 1.3 of the initial dossier, Annex 2,7 and 8 of the response by the applicant to the initial assessment report and the Member States' comments and objections; Annex 6 of the additional information submitted in response to a request from EFSA in April 2017) served as basis for the characterisation of the identity of the proposed NF.

The Panel considered that the conclusions on the safety of the proposed NF, OSA-VC, could not have been reached without the evidence provided by the applicant that under the conditions of simulated intestinal digestion (pH 6.8) OSA and vanillin are not associated in a complex (Annex 6 and 7 of the additional information submitted in response to a request from EFSA in April 2017), which was requested to be protected by the applicant.

On the basis of the above, the unpublished study report of acute oral toxicity in rats and sub-chronic oral toxicity in rats which have been requested to be protected by the applicant, were not considered relevant for the assessment of the safety of the proposed NF.

The unpublished study report of the bioavailability of silicon from the proposed source OSA-VC and the related supplementary information on the individual AUC results of plasma silicon concentration, which were requested to be protected by the applicant, were used by the Panel to reach conclusions on the bioavailability of silicon from the proposed new source, however they were not considered relevant for the assessment of the safety of the proposed NF.

10.2. Presentation Corporate "Guidelines for Observers"

In preparation for the coming ANS Panel plenary meeting on 15-17 May 2018 with a session open to observers, the Secretariat presented the relevant EFSA Guidelines.

Annex I

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

CONFLICT OF INTEREST: In his SDoI filled for the present meeting Mr Gunter Georg Kuhnle declared the following interest: A research project 100% funded by food industry on substances under evaluation by the Panel (agenda item 6.1). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes [11] and the Decision of the Executive Director on Declarations of Interest[12], 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 6.1 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