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

Minutes of the 78th Plenary meeting

Held on 21-23 November 2017, Parma (Italy)

Meeting open to Observers

(Open session: 22 November 2017, 09:00-18:00h
23 November 2017, 09:00-15:00h)

(Agreed on 18 December 2017)

Participants

- Panel Members:
  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

- Hearing Experts:
  Agenda item 6.1 & 10.4: Paul Tobback¹
  Agenda item 10.5: Pasquale Mosesso²

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

- EFSA:
  FIP Unit: Claudia Roncancio Peña, Anna Christodoulidou, Alessandra Giarola, Federica Lodi, Adamantia Papaioannou, Fabiola Pizzo, Ana Maria Rincon, Camilla Smeraldi, Alexandra Tard
  COMMS Unit: Edward Bray, Bernd Elzer
  DATA Unit: Claudia Cascio, Zsuzsanna Horvath

¹ Participated by web-conference
² Participated only on the 22 November
Observers:

Attending physically in Parma:

Cristine Bradley (Intern. Special Dietary), Marilia Campanaro Costa (Nutricia Danone), Alberto Celada (Dow Chemical Co. - 23 Nov), Patrick Coppens (Food Supplements Europe), Stefanie Geiser (EAS Strategies), Alison Joy Harding (Marinalg), Ruggero Luca Lamacchia (GBFoods), Anastasia Lazidu (Danone Trading), Federica Manini (Soremartec Italia), Evangelia Mavromichali (Specialised Nutrition EU), Petr Mensik (EU Specialty Food Ingredients), Leo Meunier (Danone), Manon Ombredane (Intern. Chewing Gum Association), Kaori Ono (Ajinomoto Foods Europe), Miguel Angel Prieto Arranz (CEFIC), Caroline Rey (EFEMA), Fatih Serdaroglu (Ministry of Food Agriculture and Livestock, Turkey), Cindy van Bommel (Mead Johnson Nutrition), Angeliki Vlachou (FooDrinkEurope)

Attending via webstreaming:

Cinzia Ballabio (ASSOERBE), Fabiana Bariselli (SISTE), Claire Bertin (URGOTECH), Friederike Buehre-Weck (Evonik Resource Efficiency GmbH), Alberto Celada (Dow Chemical Co. - 22 Nov), Elena Cogalniceanu (EAS Strategies), Nora Debraise (CEFIC), Sara Deledda (Davines SpA), Veyret Elodie (Synadiet), Sandra Fernandez (EHPM), Wolf Goertz (self-employed-press/media), Pieter Hooyenga (Mead Johnson Nutrition), Michael Horn (Ortis SA), Madgalena Kern (Evonik Resource Efficiency GmbH), Klavdija Kmetič (AESGP), Simone Koenig (Bayer Consumer Care AG), Valerie Moise (Cabot Corporation), Eiichiro Shibata (Kao Corporation), Andrea Taft (EMA), Maria-Laurence Trameson (Laboratories Super Diet), Nico Van Belzen (Int'l Dairy Federation)

1. Welcome and apologies for absence

The Chair welcomed all participants.

Peter Moldeus and Agneta Oskarsson did not participate in the morning session on 21 November 2017.

Peter Aggett did not participate in the afternoon session on 23 November 2017

Birgit Dusemund did not participate in agenda point 10.5 due to a Conflict of Interest 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 and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Panel Members invited for the present meeting.

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

---


4 Physically present on 22 November 2017. Attended via webstream on 23 November 2017


4. Agreement of the minutes of the 77th Plenary meeting held on 23-24 October 2017, Amsterdam (Netherlands)

The minutes of the 77th Plenary meeting held on 23-24 October were agreed by written procedure on 13 November 2017.

5. Report on the written procedures since 77th 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. Orthosilicic acid-vanillin complex (OSA-VC) as a novel food ingredient and as a source of silicon added for nutritional purposes to food supplements (EFSA-Q-2016-00004)

The draft opinion on the evaluation of the safety of orthosilicic acid-vanillin complex (OSA-VC) as a novel food ingredient proposed as a source of silicon to be used in food supplements, and on the bioavailability of silicon 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.

OPEN SESSION
22 November 2017, 09:00-18:00h
23 November 2017, 09:00-15:00h

7. Welcome

The Chair welcomed all observers who attended the open session of the plenary.

8. Brief introduction of Panel members and Observers

A tour de table followed the Chair’s welcome to enable the participants physically attending the plenary meeting to introduce themselves.

9. Presentation of the EFSA Guidelines for Observers

The Head of FIP Unit presented the rules for observers to be followed during and after the open plenary meeting. Observers were given the possibility to send questions when submitting their registration and these questions would be answered in a dedicated session at the meeting. Observers were also informed that the Chair would grant opportunity for additional questions at the end of each discussion topic.

---

7 http://www.efsa.europa.eu/sites/default/files/event/171023-m.pdf
10. Scientific outputs submitted for discussion and/or possible adoption

10.1. Refined exposure assessment for sucrose esters of fatty acids (E 473) (EFSA-Q-2013-00692)

The draft opinion on the refined exposure assessment of the permitted food additive sucrose esters of fatty acids (E 473) was presented to the members of the ANS Panel together with the main points for discussion. The ANS Panel discussed the refined exposure 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 webpage10.

10.2. Re-evaluation of polyglycerol esters of fatty acids (E475) (EFSA-Q-2011-00564)

The draft opinion on the re-evaluation of the already permitted food additive polyglycerol esters of fatty acids (E475) 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 is available on the Authority’s webpage11.

10.3. Draft Guidance on Nutrient Sources (EFSA-Q-2016-00150)

The Chair of the ad hoc Working Group tasked with the preparation of this output as a self-task mandate from the ANS Panel presented an overview of the content of the guidance. The Panel was informed that the draft document had been revised by the Working Group further to comments received from the Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) between February and June 2017.

In order to allow the time for consultation with the NDA Panel a request for extension of the mandate was requested and granted until 30 June 2018, corresponding with the end of the term of office of the ANS Panel in its current composition and the handover of the evaluations of nutrient sources added to food to the NDA Panel. At the current meeting, the ANS Panel discussed the different sections of the guidance and unanimously endorsed the document, subject to incorporation of changes as suggested during the meeting.

The draft guidance will be released for public consultation on the Authority’s webpage for a period of 6-8 weeks.

10.4. Re-evaluation of silicon dioxide (E 551) (EFSA-Q-2011-00576)

Further to the initial discussion on the on the re-evaluation of the already permitted food additive silicon dioxide (E 551) held at the previous plenary meeting, the revised draft opinion 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.

### 10.5. Scientific opinion on the safety of hydroxyanthracene derivatives (EFSA-Q-2016-00562)

Further to the initial discussion on the safety evaluation of hydroxyanthracene derivatives, performed under the framework of Article 8 of Regulation (EC) No 1925/2006 held at the previous plenary meeting, the revised draft opinion 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.

### 10.6. Re-evaluation of carrageenan (E 407) and processed Eucheuma seaweed (E 407a) (EFSA-Q-2011-00508; EFSA-Q-2011-00509)

On 22 November 2017, the Chair of the Working Group Gums and Food Additives from Natural Sources had sought advice from the ANS Panel with respect to the preliminary conclusions reached on the re-evaluation of the already permitted food additives carrageenan (E 407) and processed Eucheuma seaweed (E 407a) and highlighted the sections of the draft opinion which would warrant further elaboration by the Working Group.

During the open plenary session, the Rapporteur gave a presentation on the main considerations based on the assessment so far completed by the Working Group.

The draft opinion will be further elaborated by the WG following the recommendations received from the ANS Panel.

The revised draft opinion will be scheduled for discussion and possible adoption at the next plenary meeting.

### 11. New Mandates

The Secretariat informed the members of the ANS Panel that no new mandates were received since the last plenary meeting.

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

#### 12.1. Scientific Panel(s) including their Working Groups

The Chair of the Panel reported relevant outcomes from the last Scientific Committee meeting held on 15-16 November 2017.

The Panel was informed about the endorsement for public consultation of the draft Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed and the adoption of a scientific opinion issued on request of the European Commission and providing clarification and consideration of several aspects related to the assessment of genotoxicity.

Of relevance to the work of the ANS Panel was also the adoption of a new concise Guidance on Uncertainty Analysis in Scientific Assessment accompanied by a another opinion detailing principles and methods behind the guidance document.
12.2. EFSA including its Working Groups /Task Forces

In accordance with EFSA’s standard operating procedure, a possible update of the Guidance for submission for food additive evaluations adopted by the ANS Panel in 2012 was initially discussed. While maintaining the validity of the Guidance, the Panel acknowledged the possible need to update some of its references, with particular respect to the latest scientific developments (for instance, the ongoing work of the Scientific Committee on guidance on nanotechnologies, update of guidance on GMM, new guidance for infants and young children).

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

12.2.1. 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.

12.2.2. 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.

12.2.3. 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.

12.2.4. 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.

12.2.5. ANS Panel ad hoc WG on the re-evaluation of phosphates
In addition to what already recorded in the minutes of the WG, on 22 November 2017, the Chair of the WG had sought advice from the ANS Panel with respect to a possible approach to be followed for the re-evaluation of this group of food additives and with respect to the possible structure of the single scientific opinion, which is intended to cover all the 25 E-numbers phosphates and polyphosphates.

During the open plenary session it was further explained that the re-evaluation of these additives will also be covering the safety assessment for their use in infants below 12 weeks of age, when their use is already permitted in food category 13.1.

12.2.6. ANS Panel SWG Procedures under Article 8 of Regulation (EC) No 1925/2006
In addition to what already recorded in the minutes of the WG, the Chair anticipated that the draft scientific opinion on the safety of green tea catechins will be brought to the ANS Panel for discussion at the coming plenary meeting in January 2018.

12.2.7. 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.
12.3. European Commission

As already anticipated at the previous plenary meeting in October 2017, the European Commission representative confirmed a mandate was being finalised. The mandate aims at 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 1333/2008, as part of EFSA’s work in completing its risk assessments concerning the use of food additives in food for infants below 12 weeks of age.

13. Other scientific topics for information and/or discussion
None

14. Questions from and answers to Observers (in application of the guidelines for Observers)

During this session the questions received from the observers in advance to the meeting and grouped according to their topics were answered by the ANS Panel and the EFSA secretariat.

Questions on the re-evaluation of food additives: work-plan for 2018 and beyond

- Could you indicate which Opinions are expected to be finalised in 2018?
- Which is roughly the expected timeline for finalization of the currently on-going assessments? And for those included in the next batch.
- Could you please provide an indicative timeline of the next call for data (additive use levels) and which additives would be included?

The work-plan for the re-evaluation of food additives 2018 will be published early next year on the EFSA’s website. It was anticipated that work will be concentrated on those scientific opinions carried over from the previous years and those with deadline 31.12.2018 which are already being drafted by the currently established Working Groups of the Panel. The 2017 work-plan has been nearly achieved by the ANS Panel during the current year, with the exception of the following four scientific opinions that are expected for completion in 2018:

- Re-evaluation of carrageenan and processed euchema seaweed (E 407-407a)
- Re-evaluation of salts of fatty acids (E 470a-b)
- Re-evaluation of mono and diglycerides of fatty acids (E 472a-f)
- Re-evaluation of quillaia (E 999)

The work-plan for next year will also include those food additives with deadline 2018 and for which work has already started at the level of the Working Groups. Among these, priority will be given to the re-evaluation of phosphoric acid, phosphates and polyphosphates (E 338-341; E 343; E 450-452) aiming at completing their re-evaluation by the end of the year (see item 12.2.5 and below).

Observers were reminded that, as of July 2018, the ANS Panel will no longer exist as such but will be replaced by the new Food Additives and Flavourings (FAF) Panel. It can be expected that the change in remit and composition of the Panel may lead to a period of disruption of the work, which may eventually affect execution of the work-plan.

The next call for the collection of use levels will be launched at the beginning of next year and it will include all the sweeteners included in the re-evaluation programme for completion by the end of 2020. The inclusion in the call of other food additives possibly to be re-evaluated in the period 2019-2020 is still under consideration.
Overall, EFSA and the Panel acknowledged that whilst a lot has been achieved in the past years, it would be unfeasible to foresee that the re-evaluation programme could be completed on time. In particular, there are approximately 68 food additives with deadline 2018 for which work has not yet started (e.g. have not yet been included in calls for data, nor have been assigned to a working group for assessment).

EFSA will put forward a proposal for re-negotiating timelines with the European Commission for these remaining food additives, whilst aiming at maintaining the end of 2020 as the deadline for the completion of the re-evaluation of sweeteners.

**Questions on the re-evaluation of phosphates**

- Can the Panel provide further specific insights on the workplan, timeline, etc of the “EFSA phosphate ad-hoc WG”?
- How does the Panel intend to carry out the exposure assessment for those additives that from a scientific/technical point of view could be grouped (e.g. phosphates) - as a “group of substances” or on an individual basis?
- Is the recent call for data intended to identify the data available for young infants? If not, will there be a separate call for data once the ad hoc working group starts?

An answer to some aspects raised by these questions was provided also under the discussion of the agenda item 12.2.5. In addition it was further confirmed that the Panel is aiming at completing this re-evaluation by its original deadline 31.12.2018.

Exposure assessment for phosphates will be performed not for every E number separately but as a group exposure to all phosphates. Estimates will be derived for phosphate exposure from food additives and phosphate exposure from "naturally occurring" phosphates in the diet, provided that the submitted data are suitable to this.

The EFSA Call for technical and toxicological data on phosphates authorised as food additives in the EU already includes the group of infants below 16 weeks of age as the opinion will include the evaluation for this specific use as well. Therefore interested parties were invited to respond to this call by providing or express their intention to provide data following the EFSA Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age. If necessary the WG on phosphates will formulate specific requests as a follow-up of the data received through the call.

**Questions on the re-evaluation of food additives in infants and young children**

- Could EFSA provide more information on the process and timelines of the re-evaluation of the 33 additives?
- What is EFSA’s approach for prioritizing the 33 additives?
- For the additives already assessed for which EFSA proposed no ADI (e.g. sources of nutrients) and no gap was part of the conclusion for all population, does EFSA go through a re-evaluation? Will there be an additional call for data for additives on which opinions were recently published and concluded that the evaluation could not be concluded?
- For additives used in foods for special medical purposes (FSMPs) for young children where EFSA concluded that more data is required will EFSA issue a separate call?"  
- Will there be an (additional) call for data for additives on which opinions were recently published and concluded that the evaluation could not be concluded (Locust Bean Gum/ Guar Gum/OSA starch)?
- Will EFSA use different levels of scrutiny depending on whether or not the substances are used as technological additives or sources of nutrients (addition of which is mandatory)?
Will EFSA issue a call for data for the additives proactively before starting the evaluation and when can we expect such call for data?

What will be the timelines afforded to interested parties to reply to the call for data and to provide additional data?

Is there information on when the ad hoc working group on safety assessments on additives for young infants will start? And will this working group issue a separate call for data that may be required?

At the moment EFSA is awaiting receipt of a mandate 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 1333/2008, as part of EFSA’s work in completing its risk assessments concerning the use of food additives in food for infants below 12 weeks of age. Following the acceptance of the mandate, EFSA will be able to launch a general call for data for the interested parties and to establish an *ad hoc* WG that will proceed with this evaluation as well as defining a strategy for assessment and prioritisation.

For those food additives with deadline 31.12.2018 and for which assessment at the level of Working Group has only recently started (i.e. phosphoric acid, sodium, potassium and calcium phosphates (E 338-341) and hydrochloric acid (E507), the safety of their use in these specific age groups will be addressed in the opinions that are currently being prepared.

**15. Any Other Business**

None.