22 October 2013

EFSA/FIP/135-rev1

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

Minutes of the 44th plenary meeting

Held on 10-12 September 2013, Parma, Italy

(Agreed on 1st October 2013)

Participants

- **Panel Members**:
  - Birgit Dusemund, Pierre Galtier, David Gott (Vice-Chair), Ursula Gundert-Remy[1], Jürgen König, Claude Lambré (Vice-Chair), Alicja Mortensen (Chair), Pasquale Mosesso, Dominique Parent-Massin, Martin Rose, Ivan Stankovic, Paul Tobback, Ine Waalkens-Berendsen, Ruud Woutersen[2] and Matthew Wright
- **European Commission:**
  - Wim Debeuckelaere (DG Sanco E3)
  - Sirkku Heinimaa[3] (DG Health and Consumer E6)
- **EFSA:**
  - Food Ingredients and Packaging (FIP) Unit: Anna Campanini, Anna Christodoulidou, Paolo Colombo, Claudia Heppner, Georges Kass, Ana Rincon, Camilla Smeraldi and Stavroula Tasiopoulou
  - Dietetic Products, Nutrition and Allergies (NDA) Unit: Wolfgang Gelbmann
  - Corporate services Unit (CORSER): Noemi Calabrese, Francesco Ciancio
  - Additives and Products used in Animal Feed (FEEDAP) Unit: Anguita Montserrat, Paola Manini and Maria Vittoria Vettori

[1] Participated only on 10 and 11 September 2013
[2] Participated only on 10 and 11 September 2013
[3] Participated by conference call only on 11 September 2013 (5-MTHF-glucosamine salt)

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1. Welcome and apologies for absence

The Chair of the ANS Panel, welcomed all participants. Apologies for absence were received from following members of the ANS Panel Fernando Aguilar, Riccardo Crebelli, Jean-Charles Leblanc and Agneta Oskarsson.

2. Adoption of agenda

The draft agenda was first adopted without modifications.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[4] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[5], EFSA screened the Annual Declaration of interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests 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 43rd Plenary meeting held on 2-4 July 2013, Parma, Italy

The minutes of the 43rd plenary meeting were agreed by written procedure on 12 August 2013. The minutes are available on the Authority's webpage.[6]

5. Report on written procedures since 43rd Plenary meeting

No outputs were adopted by written procedure since the previous meeting.

6. Scientific outputs submitted for discussion and possible adoption

6.1 Draft opinion on Aspartame (E 951) (EFSA-Q-2011-00406)

The Chair introduced the draft opinion and moved comment by comment on the revised opinion through different sections such as Technical data, Exposure Assessment, Biological and toxicological data, Human studies. Sections of the text were discussed and clarified.

The Panel then discussed the technical report on the comments received during the public consultation on the scientific opinion on the re-evaluation of aspartame. It was clarified that Annex B of the document will contain all the scientific comments received and that the technical report will be published at the same time as the adopted opinion on the re-evaluation of aspartame.

[4] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[5] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
[6] http://www.efsa.europa.eu/en/events/event/130702-m.pdf

6.2 Draft opinion on (6S)-5-methyl-tetrahydrofolic-acid, glucosamine salt (EFSA-Q-2012-00843)

The rapporteur introduced the draft opinion to the members of the ANS Panel and outlined the revisions which were done following the suggestions made by the Panel at its 42nd plenary meeting.

The Panel stated that 5-MTHF glucosamine fully dissociates in the gastro-intestinal tract into 5-MTHF and glucosamine, which are not novel foods. Therefore the Panel addressed the safety of the compound as nutrient source and novel food. A Panel member however expressed concern that although the novel food legislation (Regulation (EC) No 258/97) had not changed this compound was being treated differently to lutein that was authorized as a novel food first.

The Panel concluded that the proposed use and use levels of 5MTHF-glucosamine when added for nutritional purposes to food supplements as a source of folate is not of safety concern.

The ANS Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The chair of the ANS Panel expressed her appreciation for the work to the members of ANS working group (WG) A.

The full opinion will be available on the Authority's webpage[7].

6.3 Draft opinion on boric acid (E284), sodium tetraborate – borax (E285); (EFSA-Q2011-00468; EFSA-Q-2011-00469)

The rapporteur introduced the draft document to the ANS Panel and explained the main issues for discussion. It has been highlighted that very similar targets (e.g. testes and kidney) among different animal species have been recorded and also considering the interspecies similar variation in toxicokinetic a limited uncertainty factor has been applied. The Panel noted that the estimated ADI considering its specific use (i.e. in caviar), consumption frequency and consumption levels, it is unlikely to be exceeded even at MPL. Attention should be paid in case of extension of the use.

The Chair expressed appreciation for the quick and accurate review of the key issues of Discussion and Conclusions made by the Panel experts and because of time constraints, proposed that the text of the draft opinion to be reviewed at the next ANS Plenary meeting.

6.4 Draft opinion on Riboflavin (E101i), riboflavin-5'-phosphate (E101ii) (EFSA-Q-2011-00361; EFSA-Q-2011-00430)

The rapporteur introduced the draft opinion to the ANS Panel summarising the key aspects of the opinion.

The Panel after having further discussed available preclinical and human data concluded that, despite the uncertainties in the database, riboflavin (E 101i) and riboflavin-5'-phosphate sodium (E 101ii) are unlikely to be of safety concern at the currently authorised uses and use levels as food additives.

The ANS Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The Chair of the ANS Panel expressed her appreciation for the work on the

[7] http://www.efsa.europa.eu/en/efsajournal/pub/3358.htm

scientific output to the members of ANS working group (WG) A and the support provided by the scientific officer of the FIP Unit.

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

7. New mandates

7.1 Isoflavones

The members oft he ANS Panel were informed that following a request from Germany, EFSA was asked to conduct a risk assessment on the intake of isolated isoflavones from food supplements in post-menopausal women. The exact Terms of Reference are currently being discussed with the requestor. The Panel agreed to set up a WG to address this request.

7.2 Steviol glycosides

The Panel was informed that the EFSA received a request for an opinion taking into account an additional use (hot beverages) of steviol glycosides (E960) as a food additive (EFSA-Q-2013-00433). This request is currently under consideration.

8. Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA, the European Commission

8.1 Scientific Committee

A meeting of the Scientific Committee was held on 16-17 July 2013 in Parma. The minutes are available on the web page.

8.2 Working Groups

8.2.1 Working Group "Botanicals in Food"

The Chair of the WG provided an update from the last two WG Meetings which were held on 26-27 August (teleconference) and 9-10 September 2013 in Parma. The WG has finalised the drafting of the opinion on Ephedra. The draft will be presented for possible adoption to the next ANS Panel Plenary meeting which will be held from 1 to 3 October 2013.

8.2.2 Working Group "Exposure"

A teleconference call had taken place on 9 July 2013 where the exposure assessments of some food additives (riboflavin, beta-cyclodextrin, polysorbates, guar gum, lecithins) were discussed.

8.2.3 Working Group "Aspartame"

A meeting of the WG took place on 2-3 September 2013 in Brussels. No additional information was provided as this item was discussed under item 6.1.

[8] http://www.efsa.europa.eu/en/efsajournal/pub/3357.htm

8.2.4 SC Working Groups of interest to ANS Panel

A member of the Panel reported on the progress of the SC WG on botanicals. The draft opinion aims to explore the use of QPS (Qualified Presumption of Safety) approach for botanicals. Good progress was made and the WG aims to deliver the draft opinion for possible adoption to the SC meeting in November 2013.

8.3 EFSA

8.3.1 General matters

The Head of the FIP Unit shortly informed the members of the ANS panel on the following topics:

- Following Catherine Geslain-Lanéelle resignation, Bernhard Url, Director of RASA, is deputising Executive Director until the Management Board of EFSA will nominate an Executive Director ad interim during its meeting on 22-23 October 2013. Marta Hugas was nominated as acting Director of RASA and Ernesto Libano as acting HoU BIOHAZ.
- The Advisory forum will meet 25 to 26 September 2013 in Lithuania and will discuss e.g. the 2014 scientific cooperation work program, receive feedback from SC away day and discuss the revised terms of reference fort he FIP network.
- FIP unit is currently recruiting a junior scientific officer (FG IV) and the call which is published on the Authority's webpage will close on 17 Sept 2013.
- In relation to indigo carmine (E132), which is currently also under evaluation as a feed additive by the FEEDAP Panel, the FIP unit was informed that the applicant for the use of the compound in feed has requested to further extend the deadline for the submission of genotoxicity data. The FIP unit proposed to also request an extension of deadline for the evaluation of indigo carmine as a food additive and the ANS Panel supported this proposal.
- The CORSER representatives made a short presentation on the new centralized unit dealing with meeting organisation and particularly pointed out what will change for members of the ANS Panel in relation with their travel organisation.
- A staff member of the FIP unit presented the feedback from observers and Panel members who attended the open 43rd ANS plenary meeting in July 2013

8.4 European Commission

The European Commission informed the members of the ANS Panel on the following matters:

- The opinions on advantame and polyvinyl alcohol-polyethylene glycol-*graft*-co-polymer recently adopted are under follow-up discussions within the Member States.
- A tender in relation with food additive monitoring data in Member States will be shortly launched. Within this tender specification it is also foreseen that data according to EFSA needs will be requested

- A technical meeting with Member States to discuss the re-evaluation programme of food additives is scheduled to take place on 4 November 2013. EFSA will be invited to this meeting.

9. Other scientific topics for information and/or discussions

9.1 Aspartame (EFSA-Q-2013-00881) – Technical report

A staff member of the FIP unit presented the final draft technical report on the outcome of the public consultation of aspartame, Respective revisions to the draft opinion on aspartame were discussed under item 6.1

9.2 Phosphates (EFSA-Q-2013-00311)

The Panel was informed about the progress made by EFSA in dealing with this request for scientific and technical assistance received from the EC. The request was the reaction to a review article that suggested a possible link between elevated phosphate serum levels and increased risk of cardiovascular disease. The preliminary conclusions of the assessment were presented and the Panel members agreed with the conclusions of EFSA. The report will undergo peer-review process and it is expected that the report will be published in November 2013.

10. Any Other Business

The members of the ANS Panel were informed that the date for the additional plenary meeting in November was fixed and will be held on 27 to 28 November 2013. The wish of the Panel to meet in Amsterdam was noted but can only be confirmed if budgetary resources would allow this.