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Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS)
Minutes of the 42nd plenary meeting
Held on 14-16 May 2013, Parma, Italy
(Agreed on 2 July 2013)

Participants

- **Panel Members**:
  - Fernando Aguilar, Riccardo Crebelli,[1] Birgit Dusemund, Pierre Galtier, David Gott (Vice-Chair), Ursula Gundert-Remy, Jürgen König,[2] Claude Lambré (Vice-Chair), Jean-Charles Leblanc, Alicja Mortensen (Chair), Pasquale Mosesso, Agneta Oskarsson, Dominique Parent-Massin, Martin Rose, Ivan Stankovic, Paul Tobback, Ine Waalkens-Berendsen, Ruud Woutersen and Matthew Wright
- **European Commission:**
  - Marina Marini,[3] Jiri Sochor,[4] Wim Debeuckelaere[5]
- **EFSA:**
  - Food Ingredients and Packaging (FIP) Unit: Anna Campanini, Claudia Heppner, Georges Kass, Kim Petersen, Ana Rincon, Camilla Smeraldi, Alexandra Tard and Stavroula Tasiopoulou
  - Nutrition Unit: Wolfgang Gelbmann[6]

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

2. Adoption of agenda

The draft agenda was adopted without any modifications.

[1] Participated only on 14 and 15 May 2013
[2] Participated only on 14 and 15 May 2013
[3] Participated by conference call only on 14 May 2013
[4] Participated by conference call only on 15 May 2013
[5] Participated by conference call only on 16 May 2013
[6] Participated only on 16 May 2013

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3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[7] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests,[8] EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, as well as the Oral Declaration of Interest at the beginning of the meeting, please refer to Annex I.

4. Agreement of the minutes of the 41st Plenary meeting held on 22-24 April 2013, Parma, Italy

The members of the ANS Panel acknowledged the draft minutes of the 41st plenary meeting and proposed some minor revisions. With these revisions the ANS Panel agreed with the minutes of the 41st plenary meeting. The minutes are available on the Authority's webpage.[9]

5. Report on written procedures since 41st Plenary meeting

No outputs were adopted by written procedure.

6. Scientific outputs submitted for discussion and possible adoption

6.1. Allura Red AC (E 129) (EFSA-Q-2012-00743)

Further to the discussion at the previous Plenary meeting, the Chair of the Working Group (WG) presented an updated version of the draft statement on Allura Red AC and other sulphonated mono azo-dyes addressing the comments raised by the ANS Panel Members. The ANS Panel adopted the statement subject to incorporation of the changes suggested during the meeting. The Panel chair expressed her appreciation of the work on the scientific output by the WG on allura red and by the scientific officer of FIP unit.

6.2. (6S)-5-methyltetrahydrofolic acid, glucosamine salt (EFSA-Q-2012-00843)

The rapporteur introduced the draft document to the ANS Panel and highlighted the main issues. The Panel noted that the terms of reference asked for an evaluation of the substance as a novel food in addition to its evaluation as a nutrient source. The European Commission confirmed that the evaluation should meet the full terms of reference. It was clarified that the data package submitted for a novel food evaluation and nutrient source assessment would be identical and the safety assessment of the substance follows similar approaches but bioavailability also has to be addressed for the safety assessment as nutrient source. The Panel asked for clarification of why 5-MHTF was being treated differently to lutein. The Panel considered that scientifically it was possible to proceed with the safety evaluation but asked the WG to clarify some aspects in the assessment and elaborate further on the manufacturing process. In addition, the ANS Panel asked to receive inputs from the NUTRI Unit on the draft opinion to ensure that all the requirements for the evaluation of the substance as a novel food were considered. The Panel suggested clarification of the criteria used by EFSA to allocate mandates to Panels when several panels have the competency to address a mandate.

[7] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[8] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
[9] http://www.efsa.europa.eu/en/events/event/121204b-m.pdf

6.3. Aspartame (E 951) (EFSA-Q-2011-00406)

The Panel was informed that both the draft opinion and the draft technical report have been updated, but there was no time to discuss the revised documents and this was deferred to September ANS Panel meeting.

6.4. Advantame (EFSA-Q-2010-00943)

The rapporteur introduced the draft document to the ANS Panel and explained the main issues for discussion.

The results from subchronic studies with advantame in rodents and dogs were equivocal as regards immunotoxicity and, therefore, the Panel had requested additional studies in young rats to investigate the effects of advantame on various immunological parameters. These data were submitted to EFSA and included in the safety assessment. The panel discussed the chapter on immunotoxicity and the opinion. Some further revisions were proposed to the rapporteur, and the opinion could be presented for possible adoption during the next ANS Panel meeting. The Panel noted that the Joint FAO/WHO Expert Committee on Food Additives JECFA was considering advantame in June and EFSA and JECFA have agreed to share their respective documents.

6.5. Yohimbe (EFSA-Q-2012-00228)

The Chair of the Working Group on Botanicals presented the draft opinion on Yohimbe and sought agreement from the ANS Panel on the preliminary conclusions reached. The draft opinion would be further elaborated on the basis of the comments raised by the Panel and presented at an upcoming Plenary meeting for possible adoption.

The general view from the Panel was that botanicals and botanicals preparations for use in food supplements should be evaluated on the basis of existing data on the chemical specifications and existing toxicological data for the individual botanical or botanical preparation. In this specific situation, however, the ANS Panel noted important data gaps concerning the quantitative data on the composition and specifications, the bioavailability of active ingredients from the Yohimbe bark extract and data on the toxicity of well specified individual preparations of Yohimbe bark and the major Yohimbe bark alkaloids, especially regarding subchronic toxicity and genotoxicity.

6.6. Montan acid esters (EFSA-Q-2011-00708)

The rapporteur introduced the draft document to the ANS Panel and explained the main issues for discussion. The ANS Panel adopted the opinion subject to incorporation of the changes suggested during the meeting. The Panel chair expressed her appreciation to the WG Food Additive B for their work on the scientific output.

7. New Mandates

The ANS Panel members were informed that EFSA has been asked to provide technical assistance in relation to a renewed application on revised proposed uses of ethyl lauroyl arginate as a food additive (EFSA-Q-2013-00338). In addition, requests to evaluate the new food additive anthrapen (EFSA-Q-2013-00284) and modifications to the specifications to hydroxypropyl methylcellulose (EFSA-Q-2013-00283) were not accepted by EFSA as the submitted data were not considered suitable for risk assessment. Further information can be found on the Authority´s webpage.

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

No meeting of the Scientific Committee was held since the previous ANS Panel meeting.

8.2 Working Groups

8.2.1 Working Group "Botanicals in Food"

In addition to the discussion held under the agenda item 6.5. the Chair of the Working Group informed the Panel that a request for extension of the deadlines of the two mandates will be requested. The new proposed deadlines are end of October 2013 and end of December 2013 for the Yohimbe and Ephedra opinions, respectively.

Furthermore, the work on these two botanicals has highlighted the need to elaborate specific guidance on the genotoxicity testing of botanicals and botanicals preparations.

8.2.2 Working Group "Aspartame"

No additional information was provided after the short presentation under item 6.3.

8.2.3 SC Working Groups of interest to ANS Panel

Due to lack of time no feedback was provided on this agenda item.

8.3 EFSA

8.3.1 General matters

The Head of the FIP Unit informed the members of the ANS Panel on the following matters:

- The EFSA Consultation Stakeholder Platform meeting will take place on 12 June 2013 in Brussels where; the work of EFSA Application desk will be presented, also the harmonisation of the timelines for submission of applications to EFSA, CEFIC will give a presentation on Food Contact Materials and a member of the CEF Panel will present the work of the Panel.
- The next Advisory Forum meeting will take place on 19 and 20 June 2013 in London where the chairs of the ANS Panel and CEF Panels will be invited to present their work. In addition, the proposal to set up a network on food ingredients and packaging will be presented. The proposal will be to ask for nominations from Member States for specific areas falling within the remit of the ANS Panel such as food additives, botanical substances. The members of the ANS Panel supported this initiative.
- The next Management Board meeting will take place on 26 and 27 June 2013.
- Within EFSA, as of 16 May 2013, the Director of SCISTRAT Hubert Deluyker will become the scientific adviser to the Executive Director. Juliane Kleiner was appointed as Director of SCISTRAT. The units of the Scientific Committee and the EMRISK unit will be merged and headed by Tobin Robinson. Within the FIP unit three vacant scientist posts could be filled. Anna Christodoulidou chemist, toxicologist and long standing expertise in risk assessment on genetically modified organisms during her work in the GMO unit of EFSA will join the FIP unit as of 1.6.2013. She will work in the area of food enzymes and food additives. The names of the other two staff members will be disclosed once the administrative procedures have been finalised. In relation with the

upcoming open ANS Panel meeting which is scheduled for July 2013, the registration of observers for attendance is ongoing, with deadline 17 June 2013.

- EFSA was invited by FoodDrinkEurope to give a training course on the transmission of food additives data, particularly relating to the submission of data on use levels and the public call launched in March 2013. Some other stakeholders, non members of the FoodDrinkEurope have been also invited to participate. The training, will take place in Brussels on 30 May 2013.

8.4 European Commission

No feedback was provided by the European Commission

9. Other scientific topics for information and/or discussion

No information was provided under this agenda item.

10. Any Other Business

No other business was raised.

Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)[10]

a) **CONFLICT OF INTEREST**: In his SDoI filled for the present meeting, Dr Ivan Stankovic declared the following interests: Dr. Stankovic will participate at Joint FAO/WHO Expert Committee on Food Additives seventy-seventh meeting on Food Additives and Contaminants that will take place on 4-13 June 2013 and where advantame (agenda item 6.4) will be evaluated. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a conflict of Interest.

This resulted in the impossibility for the expert to be present when item 6.4 were discussed, voted on or in anyway processed by that concerned scientific group.

[10] The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.