29 July 2013

EFSA/FIP/110

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

Minutes of the 43rd plenary meeting

Held on 2-4 July 2013, Parma, Italy

(Agreed by written procedure on 12 August 2013)

Participants

- **Panel Members**:
  - Fernando Aguilar, Riccardo Crebelli, Birgit Dusemund, Pierre Galtier, David Gott (Vice-Chair), Ursula Gundert-Remy[1], Jürgen König, Claude Lambré (Vice-Chair), Jean-Charles Leblanc, Pasquale Mosesso, Agneta Oskarsson, Martin Rose, Ivan Stankovic, Paul Tobback, Ine Waalkens-Berendsen and Matthew Wright
- **European Commission:**
  - Andreia Alvarez-Porto (DG Sanco E3)
- **EFSA:**
  - Food Ingredients and Packaging (FIP) Unit: Anna Campanini, Anna Christodoulidou, Paolo Colombo, Claudia Heppner, Kim Petersen, Ana Rincon, Camilla Smeraldi and Stavroula Tasiopoulou
  - Dietary and Chemical Monitoring Unit: Davide Arcella[2],
  - Science Strategy and Coordination Directorate - Planning and Monitoring Team: Andras Szoradi[3]
  - Communication Directorate: Laura Smillie
- **Observers[4]:**
  - Stefanie Geiser (European Advisory Services), Inger Billeskov (INEC – Association of Producers of Carob Bean Gum), Michael D. Rogers (International Council on Amino Acid Science (ICAAS)), Frederic Martens (Prayon/Purified Phosphoric Acid

[1] Participated by conference call on 2 and 3 July 2013
[2] Participated only on 3 July 2013
[3] Participated only on 2 July 2013
[4] http://www.efsa.europa.eu/en/stakeholders/docs/observersguidelines.pdf

European Food Safety Authority – Via Carlo Magno 1/a, 43126 Parma, ITALY
Tel: (+39) 0521 036 111 • Fax: (+39) 0521 036 110 • www.efsa.europa.eu

and Phosphates Association), Karin Klingelhöller (Sachtleben Chemie GmbH), Hervé Nordmann (Ajinomoto Sweeteners Europe), Maria-Jose Saiz-Abajo (National Centre for Food Technology and Safety (CNTA)), Caroline Rey (European Food Emulsifiers Manufacturers Association (EFEMA), Roxan Hooshangi (Mission of Canada to the EU).

1. Welcome and apologies for absence

In the absence of the Chair, Alicja Mortensen, the Vice-Chair David Gott chaired the meeting and welcomed all participants including the observers. Apologies for absence were received from Alicja Mortensen (Chair), Dominique Parent-Massin and Ruud Woutersen. Due to a CEF Plenary taking place at the same time, Claudia Heppner from the FIP unit sent her apologies for the 3 July 2013.

2. Introduction of observers

A short introduction of the Panel members and the observers participating in the open plenary meeting took place.

3. Adoption of agenda

The draft agenda was adopted without modifications.

4. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[5] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[6], 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.

5. Presentation of the 'Guidelines for observers'

Andras Szoradi briefly presented the 'Guidelines for observers' to the meeting participants.

6. Agreement of the minutes of the 42nd Plenary meeting held on 14-16 May 2013, Parma, Italy

The members of the ANS Panel agreed on the draft minutes of the 42nd plenary meeting. The minutes are available on the Authority's webpage.[7]

7. Report on written procedures since 42nd Plenary meeting

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

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

8. Scientific outputs submitted for discussion and possible adoption

8.1. Draft opinion on Advantame (EFSA-Q-2010-00943)

Claude Lambré introduced the draft document to the ANS Panel and explained the main issues for discussion. The Panel established an acceptable daily intake (ADI) of 5 mg/kg bw/day by applying a 100-fold uncertainty factor to the no-observed-adverse-effect-level (NOAEL) of 500 mg/kg bw/day in maternal toxicity (gastrointestinal disturbances) in a prenatal developmental toxicity study in rabbits. Conservative estimates of advantame exposure for high level adults and children consumers were below the ADI at the proposed uses and use levels. After considering all the data on stability, degradation products, toxicology and exposure, the Panel concluded that advantame would not be of safety concern at the proposed uses and use levels as a sweetener.

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

The full opinion is available on the Authority's webpage

8.2. Draft opinion on Yohimbe (EFSA-Q-2012-00228)

The Chair of the WG Botanicals in Food introduced the draft document to the ANS Panel and highlighted the main issues. The Panel concluded that the chemical and toxicological characterisation of yohimbe bark and its preparations for use in food are not adequate to conclude on their safety as ingredients of food, e.g. in food supplements. Thus the Panel could not provide advice on a daily intake of yohimbe bark and its preparations that do not give rise to concerns about harmful effects to health. An estimate of exposure to yohimbine from food supplements was performed showing that the theoretical maximum daily intake could exceed the maximum approved daily dose of yohimbine from its use as a medicinal product.

The ANS Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The vice-chair of the ANS Panel expressed his appreciation for the work to the members of the WG botanicals in food.

The full opinion is available on the Authority's webpage

8.3. Draft opinion on Acacia gum (E 414) (EFSA-Q-2011-00513)

The rapporteur introduced the draft document to the ANS Panel and highlighted the main issues.

The ANS Panel noted that there is insufficient information on the use levels of acacia gum (E 414) to estimate its dietary exposure. Acacia gum is permitted in many foodstuffs following the quantum satis (QS) principle. Although the SCF had previously agreed to allocate an ADI "not specified" to these substances for which no usage level data was collected, the ANS Panel decided to revise this position and concluded that a safety evaluation could not be made in the absence of dietary exposure assessment. Therefore, the ANS Panel asked that a call for data on usage levels of substances permitted at QS level is launched and that once such data are available, an exposure assessment is carried out. The Panel noted that some of the described toxicological studies were not compatible with the definition of ADI "not specified" and needed to be evaluated more thoroughly.

In addition, the ANS Panel flagged the need for having a general discussion on how to handle substances where there is no numerical ADI specified, for QS authorised substances and substances which are poorly absorbed such that no observed adverse effect are unlikely to be identified even at the highest dose which can now be tested for animal welfare reasons, especially when historically such doses could potentially have affected the nutritional balance

of the experimental animals. It was proposed that a short paper will be prepared and presented to the ANS Panel for endorsement at a forthcoming meeting providing further guidance to the ANS Panel on dealing with these issues and a clear and transparent approach for its re-evaluation programme of food additives.

8.4. Draft opinion on Locust bean gum (E 410) (EFSA-Q-2011-00510)

This item was not discussed due to lack of time.

8.5. Draft opinion on Polyvinyl alcohol-polyethylene glycol-graft-co-polymer (EFSA-Q-2012-00911)

The rapporteur introduced the draft document to the ANS Panel and highlighted the main issues. The opinion was adopted.

Polyvinyl alcohol-polyethylene glycol-graft-co-polymer (PVA-PEG graft co-polymer) is a synthetic, branched, graft co-polymer primarily intended for use as a film coating for food supplements. The co-polymer is not absorbed from the gastrointestinal tract to any extent. From a feeding study in the dog a NOAEL of approximately 800 mg/kg bw/day was derived. Conservative intake estimates from food supplements for children and for adults respectively lead to a sufficient margin of safety compared to the NOAEL. The Panel concluded that the use of PVA-PEG graft co-polymer food supplements as a film coating is unlikely to be of safety concern at the proposed uses and use levels.

The ANS Panel adopted the opinion subject to incorporation of changes as suggested during the meeting. The vice-chair of the ANS Panel expressed his appreciation for the work to the members of ANS WG Food additive B.

The full opinion is available on the Authority's webpage

9. New Mandates

The ANS Panel members were informed that following a request from a Member State, the Bundesinstitut für Risikobewertung (BfR, 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 will be discussed and clarified with the BfR and the outcome shared at the next ANS Panel meeting. The Panel noted that unless the exact Terms of Reference were clarified, a general assessment of isoflavones would be an enormous task probably requiring input from several Panels and not only ANS Panel. In addition, the Panel was informed that the EFSA statement on revised proposed uses of the food additive ethyl lauroyl arginate (EFSA-Q-2013-00338) had been finalised and published.

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

10.1 Scientific Committee

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

10.2 Working Groups

10.2.1. Working Group "Botanicals in Food"

The Chair of the WG informed the Panel that a meeting of the WG had taken place on 25-26 June 2013 in Brussels, where the draft scientific opinions on *Ephedra* species and *Pausinystalia yohimbe* were discussed.

10.2.2. Working Group "A" on Food Additives and Nutrient Sources

The Chair of the WG A informed the Panel members that a meeting took place on 17-18 June 2013 in Dublin, where seven draft opinions were discussed.

10.2.3. Working Group "B" on Food Additives and Nutrient Sources

The Panel was informed that a meeting of the WG B had taken place on 18-20 June 2013 in Parma. The rapporteur informed the Panel that the draft pre-evaluation document on nitrates and nitrites as food additives addressed the extensive literature available since the last evaluation of nitrates done by SCF in 1997 based on the confirmation of the ADI established by others bodies. Therefore, for the re-evaluation of nitrates and nitrites the literature search was restricted to information published since 2002, just prior to the last major review of nitrates as food additives undertaken by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The WG sought and received agreement in principle from the Panel of this proposed approach to nitrates with the proviso that any essential specific studies published before 2002 were included.

10.2.4. Working Group "Exposure"

The Panel was informed that a meeting of the WG Exposure had taken place on 14 May 2013, where the EFSA statement related to the food additive ethyl lauroyl arginate and the EFSA statement on the refined exposure assessment of Amaranth (E 123) were discussed.

10.2.5. Working Group "Aspartame"

A meeting of the WG took place on 10-11 June 2013 in Brussels.

10.2.6. SC Working Groups of interest to ANS Panel

- A meeting of the Working Group on Botanicals/QPS was held on 28-29 May, where the applicability of a QPS and a tiered safety assessment approach for botanicals was discussed. The draft opinion on this will be soon ready for presentation.
- A meeting of the Standing Working Group on Guidance Review took place on 23-24 May 2013 in Parma, where the priorities for the development of guidance documents were discussed: 4 topics were identified where the development of guidance was deemed necessary, whereas for 2 topics an update of the current guidance is needed. In addition, development of guidance on allergy was proposed, as well as on -omics, which will be considered in the future.

10.3 EFSA

10.3.1. General matters

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

- *EFSA's Stakeholder Consultative Platform (SHP):*
  - An "open" meeting of EFSA's Stakeholder Consultative Platform (SHP) took place on 12 June 2013 in Brussels with the participation of observers. The set up of discussion groups under SHP was welcomed and ways to inform the SHP were proposed. The discussion group on chemical data collection will have its first meeting in autumn 2013. FoodDrinkEurope had organised a training course on data collection for food additives (FA) with participation of EFSA colleagues from the DCM Unit on 30 May 2013. The Head of EFSA's APDESK Unit presented an update of the activities carried out by the Unit, including the presentation on a

feasibility study for the electronic submission of dossiers for applications of regulated products. A final decision is expected by September 2013.

- EFSA presented an overview of the administrative practices followed by EFSA in the scientific risk assessment of regulated products applications, establishing a reasonable extension of the time limit for evaluations.
- CEFIC presented its view on Food Contact Materials and put forward some suggestions in view of EFSA's upcoming consultation on the revised Guidance Document on the submission of dossiers related to substances to be used in FCM to be evaluated by EFSA. A member of the CEF Panel presented work of the Panel, particularly in the area of FCM.

- *48th meeting of the Advisory Forum (19-20 June, London):*
  - The Chairs of the ANS and CEF Panel were invited to present the Panels' work, including an overview on the draft safety evaluation of aspartame and an update on BPA. The presentations were very much appreciated. The Head of the FIP unit presented a proposal for the establishment of a FIP network dealing with different topics within its remit. The members of the Advisory Forum (AF) found that clarifications in the proposed Terms of References (ToR) are needed, hence it was agreed to submit a slightly revised version for final approval.

- *57th Management Board meeting, 27 June, Parma:*
  - EFSA presented an update on EFSA's Multiannual Plan and Multiannual Staff Policy Plan (see http://www.efsa.europa.eu/en/mb130627/docs/mb130627-p5.pdf) which cannot be finalised yet due to the ongoing negotiations on the EU's Multiannual Financial Framework (MFF) (2014-2020). Both documents are likely to be tabled again at the October Management Board meeting. Raymond O'Rourke was appointed as a new member of the Board and the Board agred that Bernhard Url will become deputising officer of EFSA´s Executive Director as of 16 July 2013.

- *EFSA FIP unit:*
  - In total, 231 applications were received in response to the call launched by EFSA for the renewal of the ANS and CEF Panels, which came to closure on 1 July 2013. The eligibility check is ongoing. The aim is to have the final list of the new Panel members ready by March 2014.
  - Hanne Pedersen and Anna Campanini will move to CORSER unit which deals with central meeting organisation, as of 16 September 2013.
  - There was also the presentation of a new member of FIP Unit

10.4 European Commission

Andreia Alvarez-Porto reported on the following:

- outcome of the proposals approved in April related to the following substances: sucrose esters of fatty acids, OSA modified gum, rosemary extracts, neutral methacrylate copolymer and stigmasterol. The request related to the substance polyvinylpyrrolidone-vinyl acetate copolymer was not approved, pending clarifications regarding its specifications;
- Guidance document on descriptors

- Proposed meeting with EFSA in November on the state of play of the re-evaluation programme.

11. Questions from observers

Questions from Stefanie Geiser European Advisory Service, Belgium:

1. Latest status of food additives evaluations and opinion on aspartame
Answer:
The ANS Panel continues its re-evaluation programme on food additives. The re-evaluation of the synthetic colours has been completed and currently the Panel is focussing on natural colours, preservatives anti-oxidants, emulsifiers, stabilisers and gelling agents. The re-evaluation programme needs to be completed by 2020. As announced in an EFSA press release on 8 May 2013 following discussions with the Commission the deadline for the re-evaluation of aspartame has been extended to November 2013. This will allow the Panel to fully consider the comments received during the public consultation.

2. Status of scientific outputs on Ephedra species (EFSA-Q-2012-00106) and Yohimbe (EFSA-Q-2012-00228) which were on the last ANS meeting Agenda – and under which regulatory context have these evaluations been requested to EFSA?
Answer:
The deadlines for Yohimbe and *Ephedra* species have been postponed to the end of October and December, respectively. The regulatory context falls under Article 8 (2) of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods.

3. Latest status of activities of the SC Working Group "Botanicals in Food" (under Agenda point 10) and how this involves the ANS.
Answer:
The Working Group "Botanicals in Food" is a specific working group of the ANS Panel.

Questions from Michael Rogers, International Council on Amino Acid Science (ICASS), Belgium:

1. When is EFSA anticipating the final conclusion on the ULs for vitamins and minerals?
Answer:
The establishment of upper levels is the remit of the NDA Panel and not the ANS Panel. The ANS Panel does not set UL for food supplements but may refer to them when addressing the safety of nutrient sources.

2. Does EFSA consider the quality (i.e. specifications) of the nutrients that exist on the EU market to be sufficiently high enough to prevent adverse effects in humans?
Answer:
Specifications for a nutrient source, as proposed by the applicant, are assessed by EFSA's Panel. The panel considers if additional specifications should be established, mainly on safety grounds, and provides recommendations if additional specifications are needed. Where the opinions notes and/or recommends the importance of including additional specifications, the Commission may consider those in the respective legal measures.

3. Have any considerations been given to potential deficiencies in essential amino acids in certain groups of European citizens?
Answer:
This is of the remit of the NDA Panel and not the ANS Panel.

Questions from Karin Klingelhöller, Sachtleben Chemie GmbH, Germany:

1. Is material used for a long period (e.g. Titanium Dioxide, Silicon Dioxide) going to be skipped from the discussion about novel food and nanomaterial?

2. How will the new nanomaterial-limit (x /10 / 50% by number) be regulated for older products?
Answer to 1&2:
The presence of nanomaterials and their impact constitute an integral part of the safety assessment for all food additives carried out by the ANS Panel, irrespective of how long the food additive has been on the market. When appropriate and if needed, based on the assessment of the specification during the re-evaluation, the particle size of Food additives will be clarified in Commission Regulation (EU) No 231/2012 laying down specifications for food additives.

Questions from Caroline Rey, European Food Emulsifiers Manufacturers Association (EFEMA), Belgium:

1. We noted that a number of emulsifiers were covered by the recent call for additives usage level and/or concentration data in food and beverages intended for human consumption. We also noted in the News Story that EFSA plans to adopt "several opinions in 2014 in anticipation of the 2015 legislative deadline". Does this objective also concern all emulsifiers (for which Regulation 275/2010 fixes the deadline on 31st December 2016)?
Answer:
EFSA had launched two calls for data on emulsifiers back in 2010. For substances where insufficient data on usage levels were obtained, EFSA has decided to launch yet another call for data to ensure all information on usage levels is available to the ANS Panel to carry out the re-evaluation of the food additives specified under Regulation 275/2010. In order to meet the legal deadlines of 2015 and 2016, which affects the 33 and 47 food additives, respectively, the FIP Unit and the ANS had to start the re-evaluation process over a year ago.

2. Would EFSA accept to disclose its work programme for the re-evaluation of additives?
Answer:
EFSA in collaboration with the ANS Panel is in the process of fine-tuning the re-evaluation work programme which will be published once finalised.

12. Any Other Business

The Panel discussed the possible need for an additional plenary meeting in November 2013 for the adoption of the opinion on aspartame. It was difficult to quickly identify a suitable date and it was agreed that members would be invited to submit their availabilities on possible dates via "doodle".

In addition, the members of the ANS Panel agreed on the following meetings dates for 2014: 4-6 February, 1-3 April, 13-15 May; 1-3 July, 3 - 4 July (inauguration), 9-11 September , 28-30 October and 9-11 December. From 3 July onwards meeting dates should be considered provisional as these have to be confirmed at the inaugural meeting by the newly appointed CEF/ANS Panels (mandate 2014 to 2017).