7 11 2013

EFSA/FIP/156 rev.2

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

Minutes of the 45th plenary meeting

Held on 1-3 10 2013, Parma, Italy

(Agreed on 6 11 2013)

Participants

- **Panel Members**:
  - Fernando Aguilar[1], Riccardo Crebelli, Birgit Dusemund, Pierre Galtier, David Gott (Vice-Chair), Claude Lambré (Vice-Chair), Jean-Charles Leblanc, Alicja Mortensen (Chair), Pasquale Mosesso, Dominique Parent-Massin[2], Agneta Oskarsson, Martin Rose, Ivan Stankovic, Paul Tobback, Ine Waalkens-Berendsen, Ruud Woutersen and Matthew Wright[3]
- **European Commission:**
  - Jiri Sochor (DG Sanco E3)
- **EFSA:**
  - Food Ingredients and Packaging (FIP) Unit: Anna Christodoulidou, Paolo Colombo, Claudia Heppner, Georges Kass, Ana Rincon, Camilla Smeraldi and Stavroula Tasiopoulou
  - Dietary and Chemical Monitoring (DCM) Unit: Davide Arcella

1. Welcome and apologies for absence

The Chair of the ANS Panel, welcomed all participants. Apologies for absence were received from the following members of the ANS Panel: Ursula Gundert-Remy and Jürgen König.

2. Adoption of agenda

The draft agenda was adopted.

[1] Participated by teleconference only on 2 October 2013
[2] Participated only on 2 and 3 October 2013
[3] Participated only on 1 and 2 (morning) October 2013

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

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 44th Plenary meeting held on 10-12 September 2013, Parma, Italy

The minutes of the 44th plenary meeting held on 10 to 12 September 2013 were discussed and agreed. The minutes are available on the Authority's webpage[6].

5. Report on written procedures since 44th Plenary meeting

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

6. Scientific outputs submitted for discussion and possible adoption

The Chair of the ANS Panel expressed her appreciation for the work on the scientific outputs discussed at this meeting, to the Working Groups Food additives and nutrient sources A and B, Exposure Assessment, Botanicals in food, Aspartame and to the EFSA staff members involved in each Working Group.

6.1 Draft opinion on Ephedra (E951) (EFSA-Q-2012-00106)

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

The ANS Panel discussed in detail the sections "Discussion" and "Conclusions" of the opinion and agreed on the risk characterisation and conclusions. However the ANS Panel was not able to finalise the whole opinion during the 45th plenary meeting and proposed to defer this task to the forthcoming ANS Plenary meeting which will be held on 6-7 November 2013.

6.2 Draft opinion on Aspartame (E951) (EFSA-Q-2011-00406)

The Chair introduced the draft opinion on aspartame and the Panel members discussed in the light of the comments received during the public consultation the revised sections related to human studies, biological and toxicological data on methanol and degradation products.

[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/130910.htm

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

The rapporteur briefly introduced the draft opinion related to the re-evaluation of the safety of boric acid (E 284) and sodium tetraborate (borax) (E 285) as food additives in the EU. The ANS Panel established group ADI (acceptable daily intake) of 0.16 mg boron/kg body weight per day based on a NOAEL of 9.6 mg boron/kg bw/day, derived from a developmental toxicity study in rats, and an uncertainty factor of 60. The highest average exposure estimate to boron across European Member States from its use as food additive is 0.04 mg boron/kg bw/day for children, and 0.01 mg boron/kg bw/day for adults. Exposure estimates to boron from its use as food additive at the 95th percentile for consumers only are 0.56 mg boron/kg bw/day or children, and 0.13 mg/kg bw/day for adults. The Panel concluded that it is unlikely that a regular exceedance of the ADI occurs even for high consumers only.

The ANS Panel adopted the opinion subject to incorporation of changes as suggested during the meeting..

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

6.4 Draft opinion on Beetroot red (E162) (EFSA-Q-2011-00350)

This item was not discussed due to lack of time and deferred to a future meeting of the ANS Panel.

6.5 Iron III meso-tartrate (EFSA-Q-2012-00924)

The Chair of WG Food additive A presented the outcome of the draft opinion related to a safety assessment of iron III meso-tartrate as food additive. The members of the ANS Panel could not conclude on the safety of this compound based on the results of a sub chronic rodent study. Therefore, and as stated in the Guidance for submission for food additive evaluation of the ANS Panel (EFSA 2012) [8] further *in vivo* testing would be required (Tier 2) before the ANS Panel can conclude on the safety of iron III meso-tartrate.

7. New mandates

7.1 Isoflavones

The final draft Terms of Reference for a risk assessment on the possible health risks associated with the intake of isolated isoflavones in food supplements by peri- and post menopausal women have been sent to the requestor (Bundesinstitut für Risikobewertung, Germany). The Panel agreed to set up a separate WG as well as nominated a Panel member as WG chair.

7.2 Steviol glycosides

Further clarification on the request the additional use (hot beverages) of steviol glycosides (E960) as a food additive (EFSA-Q-2013-00433) is awaited from the European Commission.

[7] http://www.efsa.europa.eu/en/efsajournal/pub/3407.htm
[8] http://www.efsa.europa.eu/en/events/event/120921.htm

Once the registration is complete the ANS WG exposure will be asked to prepare the draft opinion. The ANS WG Food Additives A or B will assist if needed.

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

8.1 Scientific Committee

The 63rd Scientific Committee meeting was held on 16-17 September 2013. The Head of the FIP unit replaced the chair of the ANS Panel and reported the following:

- Prioritisation for revising of guidance documents issued by the SC were discussed and it was agreed to start with the following i) the use of weight of evidence approach in risk assessment and ii) biological relevance (adaptive vs adverse response). The internal mandates will be prepared and it is anticipated that two new WGs will be set up.
- EFSA's work in the area of emerging risks for chemicals was presented, in particular a procedure for the identification of emerging chemical risks, an update on biological emerging risks and an update on emerging risks activities were provided.
- The preliminary outcome of the draft opinion on Qualified Presumption of safety (QPS) approach for botanicals was shared and discussed
- The Head of the Legal and Regulatory Affairs Unit gave a presentation regarding access of documents which EFSA receives in an increasing number. It was pointed out that all documents prepared or handled by EFSA can be subject to disclosure (e.g. internal notes, preparatory documents (e.g. draft opinions), internal and external correspondence (including e-mails), documents of Member States).

8.2 Working Groups (WG) of the ANS Panel

8.2.1 WG 'A' Food additives and nutrient sources

The chair of the WG informed the members of the ANS Panel that a meeting of the WG took place on 16-18 September 2013 in Parma and the following draft opinions were discussed: Iron (III) meso-tartrate, tragacanth (E413), sorbic acid (E200), potassium sorbate (E202) and calcium sorbate (E203), lecithins (E322) and xanthan gum (E415).

8.2.2 WG 'B' Food additives and nutrient sources

The chair of the WG informed the members of the ANS Panel that a meeting of the WG took place on 24-26 September 2013 in Parma and the following draft opinions were discussed: ascorbic acid and its salts (E300-302), paprika extract, capsanthin, capsorubine (E160c), dimethyl dicarbonate (E242), beta-cyclodextrin (E459) and polyoxyethylene sorbitans (E432–E436).

8.2.3 WG on Aspartame

The chair of the WG informed the members of the ANS Panel that a meeting of the WG took place on 30 September and 1 October 2013 in Parma. Revisions of some chapters

of the draft opinion on aspartame were discussed and finalised as presented during the 45th ANS Panel meeting.

8.2.4 SC Working Groups of interest to ANS Panel

Due to lack of time no feedback from SC WGs of interest to the ANS Panel was provided.

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:

- An additional plenary meeting has been fixed in Parma for the 6-7 November 2013 to allow progression of the aspartame opinion that needs to be finalized by the next Panel of 27-28 November 2013. Consequently the two WG (Food additives A and B) will be shortened by one day. The ANS plenary meeting foreseen at beginning of December is proposed to be cancelled.
- The members of the Panel were informed about comments received during the pre-notification of the opinion on riboflavin (E101i) and ribo), riboflavin-5'-phosphate (E101ii) (EFSA-Q-2011-00361; EFSA-Q-2011-00430). The ANS Panel agreed to revise the respective sentence to provide further clarity.

8.4 European Commission

The European Commission informed the members of the ANS Panel that a tender in relation with food additive monitoring data in Member States has been launched. The outcome of the project is considered to provide also useful information for the food additive re-evaluation program for EFSA.

9. Other scientific topics for information and/or discussions

9.1 EFSA statement on Refined Exposure Assessment for amaranth (E123) (EFSA-Q-2012-00883)

A scientific officer of the FIP unit presented the refined exposure assessments for amaranth (E123) as the exposure which was used in the opinion of the ANS Panel in 2010 was exceeding the health based guidance value. The current refined exposure estimates showed considerably lower exposure in comparison with the 2010 opinion. The EFSA statement will be published by mid October 2013.

9.2 ANS decision tree on the risk assessment of food additives with ADI "not specified" and QS use

The background and the rationale for the preparation of a decision tree was presented by a member of the ANS Panel to the Panel. The Panel appreciated the

initiative to ensure transparency and consistency in the risk assessment process and generally agreed on the approach taken. However, further discussions and refinement is needed to define e.g. low toxicity. The members of the ANS Panel indicated to welcome a document outlining presented decisions tree for further discussions at the Panel. In addition, it was suggested to test the decision tree with additives belonging to different categories.

9.3 Update on Food Additive re-evaluation programme

This item was not discussed due to lack of time but the FIP unit informed the Panel members that a presentation is available related to submitted usage level and/or concentration data of “batch 1” (call closed on 15 September 2013).

10. Any Other Business

No any other business was raised.