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EFSA/FIP374 rev.2

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

Minutes of the 51st plenary meeting

Held on 13-15 May 2014, Parma, Italy

(agreed by written procedure on 19 June 2014)

Participants

- **Panel Members**:
  - Fernando Aguilar, Riccardo Crebelli, Birgit Dusemund, Pierre Galtier, David Gott (Vice-Chair), Ursula Gundert-Remy[1], Jürgen König[2], Claude Lambré (Vice-Chair), Jean-Charles Leblanc[1], Alicja Mortensen (Chair), Pasquale Mosesso, Agneta Oskarsson, Dominique Parent-Massin, Martin Rose, Ivan Stankovic, Paul Tobback, Ine Waalkens-Berendsen, Ruud Woutersen[1] and Matthew Wright.
- **European Commission:**
  - Wim Debeuckelaere (DG Sanco E3)[2].
- **EFSA:**
  - Food Ingredients and Packaging (FIP) Unit: Anna Christodoulidou, Paolo Colombo, Claudia Heppner, Ana Rincon, Camilla Smeraldi, Alexandra Tard and Stavroula Tasiopoulou.

1. Welcome and apologies for absence

The Chair, Alicja Mortensen, welcomed all participants. No apologies for absence were received.

2. Adoption of agenda

The revised draft agenda was adopted.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[3] and the Decision of the Executive Director implementing this Policy regarding

[1] Participated on 14 and 15 May 2014
[2] Participated on 13 and 14 May 2014
[3] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

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Declarations of Interests[4], 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 50th ANS Plenary meeting held on 1-3 04 2014

The members of the ANS Panel revised and agreed on the draft minutes of the 50th plenary meeting. The minutes will be available on the Authority's webpage.[5]

5. Report on written procedures since 50th 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 (WG) A and B on Food additives and nutrient sources, Exposure Assessment, and to the EFSA staff members involved in each Working Group.

6.1. Hexamethylene Tetramine (E239) (EFSA-Q-2011-00458)

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

The full opinion is available on the Authority's webpage[6].

6.2. Indigotine, indigo carmine (E132) (EFSA-Q-2011-00358)

The rapporteur introduced the draft opinion highlighting the main points for discussion. The full toxicological database and the shortcomings noted in a recent sub-chronic toxicological study were discussed. Further clarifications and improvements were requested and will be carried out by the WG A on Food additives and nutrient sources before the opinion is reconsidered for possible adoption.

6.3. Propionic acid and propionates (E280-283) (EFSA-Q-2011-00464, EFSA-Q-2011-00465, EFSA-Q-2011-00466, EFSA-Q-2011-00467)

The draft opinion was presented by the rapporteur to the members of the ANS Panel. The Panel agreed on the approach taken and the draft conclusions. However, to due lack of time it was not possible to review the full draft opinion and consequently adoption was deferred to a future plenary meeting.

6.4. Sunset yellow (E110) (EFSA-Q-2013-00248)

The rapporteur briefly presented the draft opinion to the members of the ANS Panel. Dietary exposure estimates based on maximum permitted levels scenario were presented and discussed. Due to lack of time the Panel agreed to adopt the opinion by

[4] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
[5] http://www.efsa.europa.eu/en/events/event/121204b-m.pdf
[6] http://www.efsa.europa.eu/en/efsajournal/pub/3696.htm

written procedure since the rest of the draft opinion had already been discussed and presented at an earlier plenary meeting.

6.5. Polyoxyethylene sorbitans (E432-436) (EFSA-Q-2011-00523, EFSA-Q-2011-00524, EFSA-Q-2011-00525, EFSA-Q-2011-00526, EFSA-Q-2011-00523, EFSA-Q-2012-00740)

The members of the ANS Panel provided some further steering to the draft opinion on polyoxyethylene sorbitants and requested that WG B on Food additives and nutrient sources to carry out further revisions before the draft opinion is presented for possible adoption.

7. New Mandates

This item was not discussed due to lack of time

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

8.1. Scientific Committee and other Scientific Panel(s)

No meeting of the Scientific Committee (SC) took place since the previous ANS Panel meeting.

8.2. Working groups

8.2.1. Working Group A on Food Additives and nutrient sources

This item was not discussed due to lack of time.

8.2.2. Working Group B on Food Additives and nutrient sources

This item was not discussed due to lack of time.

8.2.3. Working Group on Exposure Assessment

This item was not discussed due to lack of time.

8.2.4. Working Group on Isoflavones

This item was not discussed due to lack of time.

8.2.5. Scientific Committee Working Groups of interest to the ANS Panel

A member of the ANS Panel reported that the SC WG on guidance documents is preparing an editorial for the EFSA journal which will outline the rationale by which Panels might reach divergent risk assessment outcomes for the same substance.

8.3. EFSA

8.3.1. General matters

The Acting Executive Director and the Head of REPRO directorate joined the Panel on 14 May 2014 to thank the Panel members for the committed work done in the three years period from 2011-2014. In addition, the Head of the FIP Unit expressed her gratitude for the dedicated work of the members of ANS Panel and its Working Groups in providing scientifically sound scientific advice in the area of food additives and nutrition to risk managers over the last three years. The ANS Panel with the mandate 2014-2017 will start its mandate from 1st July 2014 onwards.

8.3.2

An EFSA staff member of the FIP unit summarised the main outcomes of the stakeholder workshop on the re-evaluation programme of food additives which was held by EFSA in Brussels on 28 April 2014. The workshop was a proper platform to exchange views with all interested parties to further enhance co-operation and data submission in relation to the re-evaluation programme on food additives. An event report and all the presentations which were given during this meeting is available at the EFSA website[7].

8.4. European Commission

The European Commission representative reported on three topics:

As a follow up of to the EFSA opinion on montan acid esters the European Commission is finalising a draft measure to remove montan acid esters (E912) from the Union list of food additives.

A workshop, organised by the national food safety authority in the Netherlands, on "the monitoring of the consumption and the use of the food additives and flavourings" had been held in Brussels on 8 May 2014. According to Art. 27 of Regulation 1333/2008 Member States shall maintain systems to monitor the consumption and use of food additives on a risk-based approach report their findings with appropriate frequency to the Commission and the Authority. Thus Member States can play a crucial role in requesting food industries to provide data, particularly within the re-evaluation programme. EFSA has to elaborate how to make the best use of analytical data on food additives provided by Member States.

The "Green week 2014" promoted by European Commission will be held in Brussels on 3-5 June 2014. The theme will include how technological and social innovation can support efforts to strengthen food sustainability and to reduce food waste. DG Sanco will be involved to illustrate the role of food additives and possible innovations.

9. Other scientific topics for information and/or discussion

9.1. Steviol glycosides (EFSA-Q-2014-00002): update

The Panel was requested to provide a scientific opinion on the safety of a proposed amendment of the specifications of steviol glycosides (E960) in accordance with Regulation (EC) No. 1331/2008.

[7] http://www.efsa.europa.eu/en/supporting/pub/605e.htm

The Panel discussed briefly the available information on toxicokinetic and genotoxicity for the respective steviol derivative (rebaudioside M) and asked the WG on Chemistry to evaluate the potential impact that quali-quantitative differences on chemical structure and steviol extract composition might have compared to authorized steviol glycosides.

9.2. Conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) 257/2010 (EFSA-Q-2014-0194)

The Rapporteur introduced the draft document and highlighted the revisions which were made since the last Panel meeting. After discussion, the ANS Panel adopted the statement subject to incorporating changes agreed during the meeting.

The scientific statement is available on the Authority's webpage[8].

9.3. EFSA statement on refined exposure assessment of curcumin (E100) (EFSA-Q-2012-00884)

A staff member of the FIP unit presented the draft outcome of the exposure estimates for curcumin (E100). Further to the last call for data, concentration data (uses levels and analytical data) were received which allowed a refined exposure estimate to be undertaken. The draft output prepared by EFSA will now undergo peer review prior to publication on the Authorities webpage.

9.4. Organic silicon (EFSA-Q-2013-00874)

The rapporteur summarised the present status of the draft opinion and the content of the reply letter of the applicant in answer to the request by EFSA for additional information on the biological and toxicological data provided in the application dossier. The members agreed with the proposal of the rapporteur to discuss the content of the reply letter in the next meeting of the working group.

9.5 Hydroxypropyl methylcellulose (E464) (EFSA-Q-2013-00283)

EFSA had been asked to assess the safety of Hydroxypropyl methylcellulose (HPMC - E464) in relation to a request for a change in specifications of the food additive. Short and long-term toxicity studies and genotoxicity assays were briefly presented and the members of the ANS Panel discussed whether additional data were required for the safety assessment of HPMC.

10. Any other business

No other business was raised.

[8] http://www.efsa.europa.eu/en/efsajournal/pub/3697.htm