Parma, 3 May 2013

EFSA/FIP/56 rev. 3

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

**Minutes of the 40th plenary meeting**

**Held on 12-14 03 2013, Parma, Italy**

**(Agreed on 24 04 2013)**

## Participants

- **Panel Members**:
  - Fernando Aguilar[1], Birgit Dusemund, Pierre Galtier, David Gott (Vice-Chair), Ursula Gundert-Remy, Jürgen König[2], Claude Lambré (Vice-Chair), Alicja Mortensen (Chair), Pasquale Mosesso, Agneta Oskarsson, Martin Rose[2], Ivan Stankovic, Paul Tobback[3], Ine Waalkens-Berendsen, Ruud Woutersen and Matthew Wright[2].
- **European Commission:**
  - Wim Debeuckelaere[4].
- **EFSA:**
  - Food Ingredience and Packaging (FIP) Unit: Anna Campanini, Claudia Heppner, Georges Kass, Kim Petersen, Ana Rincon, Camila Smeraldi, Alexandra Tard and Stavroula Tasiopoulou.

## 1. Welcome and apologies for absence

The Chair welcomed the participants to the 40th ANS Panel meeting.

Apologies were received from Riccardo Crebelli, Jean-Charles Leblanc and Dominique Parent-Massin.

Fernando Aguilar did not participate in agenda item 1-8, 9.2-9.4. and 10.

Jürgen König did not participate in agenda item 7, 8, 9.2-9.4 and 10.

Martin Rose did not participate in agenda item 6.4, 7, 8, 9.2-9.4 and 10.

Matthew Wright did not participate in agenda item 6.4, 7, 8, 9.2-9.4 and 10.

Wim Debeuckelaere did not participate in agenda item 1 to 6.1.

Paul Tobback did not participate in agenda item 1 to 6.1.

[1] Participated by conference call on 13 March 2013.
[2] Participate on 12 and 13 March 2012.
[3] Participated on 13 and 14 March 2013.
[4] Participated by conference call on 13 and 14 March 2013.

## 2. Adoption of agenda

The agenda was adopted.

## 3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs)[5] and the Decision of the Executive Director implementing this Policy[6], 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. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at in the Oral Declaration of interest (ODoI) at the beginning of this meeting.

## 4. Agreement of the minutes of the 39th Plenary meeting held on 19-21 February 2013, Parma, Italy

The members of the ANS Panel acknowledged the draft minutes of the 39th plenary meeting and proposed some minor revisions. With these revisions the ANS Panel agreed the minutes of the 39th plenary meeting. The minutes are available on the Authority's webpage[7].

## 5. Report on written procedures since 39th Plenary meeting

No outputs were adopted by written procedure.

## 6. Scientific outputs submitted for discussion and possible adoption

### 6.1. Draft opinion on allura red (E 129) (EFSA-Q-2012-00743)

The Chair of the ANS Working Group (WG) allura red provided an update on the progress made in relation with the draft opinion on allura red. The feedback provided by the ANS Panel at its February plenary was discussed by the WG. The WG acknowledged that more time and availability of genotoxicity experts is required to further reflect on the draft recommendations to be included in the draft opinion. The Panel supported to request an extension of the deadline for this self-task mandate. The ANS Panel was also informed that an update on allura red was given by the Chair of the WG during the FEEDAP Panel in March 2013.

### 6.2. Draft opinion on anthocyanins (E 163) (EFSA-Q-2011-00349)

The rapporteur introduced the draft opinion to the ANS Panel and highlighted the main issues. The ANS Panel adopted the opinion on the re-evaluation of anthocyanins (E 163) as a food additive subject to incorporation of changes as suggested during the meeting. The Chair of the ANS Panel expressed her appreciation for the work done by the ANS WG B Food additives and nutrient sources.

### 6.3. Gallates (E 310-312) (EFSA-Q-2011-00479; EFSA-Q-2011-00480; EFSA-Q-2011-00481)

The rapporteur outlined the challenges in the safety evaluation of gallates. The ANS Panel provided steering on the approach to take and, based on the feedback received, the opinions will be further discussed and amended by ANS WG B Food additives and nutrient sources. The Panel agreed that the toxicological database for propyl gallate is sufficient for its

[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/130219b.htm

evaluation. New data from the public call for submission of usage levels will end in July 2013 and these data will be considered before the opinion can be finalised. For octyl and dodecyl gallate the available database is too limited for the risk assessment and a new public call for toxicological data will be launched.

### 6.4. Draft opinion on sodium stearoyl-2-lactylate (E 481) and calcium stearoyl-2-lactylate (E 482) (EFSA-Q-2012-00698)

The rapporteur introduced the draft document to the Panel and presented the main issues for discussion. The ANS Panel adopted the opininon on the re-evaluation of stearoyl-2-lactylate (E 481) and calcium stearoyl-2-lactylate (E 482) as food additives subject to incorporation of changes as suggested during the meeting. The Chair of the ANS Panel expressed her appreciation for the work done by the ANS WG B Food additives and nutrient sources.

### 6.5. Draft opinion on microcrystalline wax (E 905) (EFSA-Q-2011-00706)

The rapporteur introduced the draft document to the Panel and outlined the main issues. The ANS Panel adopted the opininon on the re-evaluation of microcrystalline wax (E 905) as a food additive subject to incorporation of changes as suggested during the meeting. The Chair of the ANS Panel expressed her appreciation for the work done by the ANS WG B Food additives and nutrient sources.

## 7. New Mandates

The Panel members were informed that since the last plenary meeting no new mandates have been received and the acceptability assessment for authorisation of Kopal (EFSA-Q-2013-00238) as food additives is still under consideration by APDESK.

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

No specific information was provided by the Chair.

### 8.2. Working Groups

#### 8.2.1. Working Group “Aspartame”

No additional information was provided due to the discussions which took place under item 9.1.

#### 8.2.2. Working Group “Allura Red”

The outcome of this WG was discussed under item 6.1. No additional information was provided.

### 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 Advisory Forum met on 6 to 7 March 2013 in Dublin and commented on the multi-annual plan (2014 to 2016), discussed proposals on projects suitable for new grants scheme, endorsed the recommendation of the self-review of EFSA´s scientific networks and agreed to consider the terms of reference for a network in the area of FIP at its next meeting, supported EFSA’s initiative on transparency and willingness to participate in further discussion groups, committed itself to reinforce the use of the

information exchange platform and exchange of work priorities as a standing item in the AF and Focal point agendas.

- EFSA will publish a call for expressions of interest for membership in ANS and CEF Panel on 15 April 2013. Within this context the Panel members were invited to share their experience gained to colleagues in the communication directorate, asked if a member would like to attend a focal point meeting in Romania in May to talk about their experience as a Panel member and asked to express their interest, in testing a mock up version of a new tool for applications. The FIP secretariat will send more information by email.
- The ANS Panel was informed that EFSA was invited to attend a public hearing on aspartame organised by MEP Mme Lepage on 27 March 2013.

### 8.3.2. SC Guidance documents

The members of the ANS Panel went through a document provided by the Scientific Committee (SC) WG on guidance documents summarising all the guidance documents issued by the Scientific Committee. The ANS Panel was asked to provide information i) if the Panel knows these SC guidance documents, and ii) in case the Panel is not using these SC guidance documents to provide a reasoning. In addition, the Panel was invited to express its view on new guidance documents which would need to be developed by the SC. The FIP secretariat will communicate the outcome of this assessment to the SC secretariat.

### 8.3.3. Feedback stop the clock

The Director of REPRO directorate noted that different timelines for submission of additional information during the risk assessment process is applied by scientific Panels of EFSA. In order to harmonise the “stop-the clock mechanism” standard common timelines for certain data submissions are proposed by EFSA. All scientific Panels in the regulated area are invited to comment on the proposed timelines. The ANS Panel discussed the document and proposed changes regarding the timelines for submitting information to EFSA. The FIP secretariat will communicate the outcome of this assessment to the REPRO directorate.

## 8.4. European Commission

European Commission (EC) reported back from the 45th session of joint FAO/WHO Food Standards programme CODEX committee on food additives held on 18-22 March 2013 in Beijing, China. EC thanked EFSA for the support provided commenting on the discussion paper on the revision of the guidelines for the simple evaluation of food additive intake and the dietary exposure to aluminium-containing food additives (E 523 - aluminium ammonium sulphate, 541 (i, ii) - sodium aluminium phosphates (acidic and basic), E 554 - sodium aluminosilicate, E 556 - calcium aluminium silicate, E 559 - aluminium silicate).

The EC also outlined that a new mandate in relation with phosphate was recently sent to EFSA.

## 9. Other scientific topics for information and/or discussion

## 9.1. Aspartame (EFSA-Q-2011-00406; EFSA-Q-2012-00881)

The Panel discussed the first set of scientific comments (e.g. methanol) received during the public consultation process on the draft opinion on re-evaluation of aspartame. In addition, the Panel was informed that parts of the draft opinion were directly quoted from a review paper. The Panel regret that this happened and stressed that this should not have happened and asked to revise this part of the opinion. In addition, the Panel was informed about the

upcoming meeting with stakeholders who submitted comments on the draft aspartame opinion which will take place on 9 April 2013.

### 9.2. Advantame (EFSA-Q-2010-00943)

The results of a study investigating the potential immunotoxic effects of dietary administered advantame in male and female young Wistar rats which was requested by EFSA were presented to the Panel. The Panel agreed to continue with the evaluation of this substance and further discussion will take place at the next meeting of the ANS WG on Toxicology (April 2013).

### 9.3. Sunset yellow (EFSA-Q-2013-00248)

The EC has asked EFSA to evaluate the results from a 28-day extended study on Sunset Yellow FCF (E110) which was requested by the ANS Panel earlier. In addition, EFSA was also asked in a separate request to carry out a revised exposure assessment where a call for usage level data will be launched by January 2014. The ANS Panel proposed that only one assessment is carried out and to ask for an extension of the deadline to March 2014.

### 9.4. Sign off the food additives re-evaluation programme 2013-2014

The Panel members agreed on the 2013 and 2014 workprogramme including the launch for call for usage level data on the re-evaluation programme for food additives which was prepared by the FIP Secretariat. EFSA is aiming to launch the calls for usage level data by end of March 2013.

## 10. Any Other Business

No other business was raised.