Scientific Panel on Food Additives and Nutrient Sources added to Food

Minutes of the 39th plenary meeting of the

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

Held on 19-21 02 2013, Parma

(Agreed on 13 03 2013)

Participants

- **Panel Members**:
  - Fernando Aguilar, Riccardo Crebelli, Birgit Dusemund, Pierre Galtier, David Gott (Vice-Chair), Ursula Gundert-Remy, Jürgen König, 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:**
  - Wim Debeuckelaere.
- **EFSA:**
  - Food Ingredients and Packaging (FIP) Unit: Maria Correia, Claudia Heppner, Georges Kass, Anastasia Kesisoglou, Kim Petersen, Ana Rincon, Camilla Smeraldi, Alexandra Tard and Stavroula Tasiopoulou.
  - Executive Office Unit: Roy Kirby.

1. Welcome and apologies for absence

The Chair welcomed the participants to the 39th ANS Panel meeting. A round table presentation of the Panel members and FIP members took place to introduce the new ANS Panel members.

Fernando Aguilar did not participate in agenda item 6.6, 6.7, 8.1-8.2, 8.3.1-8.3.3, 8.4 and 9[1].

Jürgen König did not participate in agenda item 6.6, 6.7, 8.1-8.2, 8.3.1-8.3.3, 8.4 and 9[1].

Wim Debeuckelaere did not participate in agenda item 1 to 6.3, 6.5, 6.8 and 8.3.4[2].

Jean-Charles Leblanc did not participate in agenda item 7, 8.2, 8.3.1 (second bullet point), 8.3.2, 8.3.3 and 9.

[1] Present on 19 and 20 February 2013.
[2] Participated by conference call on 20 and 21 February 2013.

2. Adoption of agenda

It was proposed to insert in the agenda an additional item under agenda point 8.3 on the "Horizon 2020 Framework Programme for Research and Innovation" that had been distributed to the ANS Panel on 11 February 2013.

The agenda was adopted with the above amendment.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs)[3] and the Decision of the Executive Director implementing this Policy[4], 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 38th plenary meeting held on 19-20 December 2012, Schiphol, Netherlands

The members of the ANS Panel acknowledged the draft minutes of the 38th plenary meeting and proposed some minor revisions. With these revisions the ANS Panel agreed on the minutes of the 38th plenary meeting. The minutes are available on the Authority's webpage[5].

5. Report on written procedures since 38th plenary meeting

No outputs were adopted by written procedure.

6. Scientific outputs submitted for discussion and possible adoption

6.1. Draft opinion on ethyl esters of iodized fatty acids (EFSA-Q-2011-00034)

The ANS Panel adopted the opinion on ethyl esters of iodized fatty acids 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 Working Group (WG) B Food Additives and nutrient sources 2011-2014.

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

The Panel held a first discussion on the draft scientific output prepared by the ANS WG on Allura Red. The background to this self-task mandate, the strategy followed by the Working Group in performing this risk characterisation and the preliminary conclusions were illustrated to the Panel, alongside possible recommendations. The Panel overall agreed with the proposed outline of the scientific output, which will undergo further drafting at the final meeting of the Working Group scheduled for 6-7 March 2013. The opinion will be on the agenda for possible adoption by the ANS Panel at the next plenary meeting.

Furthermore, the work on this self-task mandate has highlighted the need for clarification on the interpretation of genotoxicity results outlined in the Scientific Committee Opinion on genotoxicity testing strategies applicable to food and feed safety assessment[6] since it may lead to different interpretations by different EFSA Panels. The Chair of the ANS Panel was asked by the members of the ANS Panel to raise this point at the 60th meeting of the Scientific Committee and a short information paper was prepared.

[3] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[4] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
[5] http://www.efsa.europa.eu/en/events/event/121219b-m.pdf
[6] http://www.efsa.europa.eu/en/efsajournal/pub/2379.htm

6.3. 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 clarified that the ANS Panel was requested to perform an exposure assessment considering an extension of the uses of sodium stearoyl-2-lactylate. It was noted that sodium stearoyl-2-lactylate (E 481) and calcium stearoyl-2-lactylate (E 482) are included in the re-evaluation program of the food additives in application of Article 6(3) of the Commission Regulation (EU) No 257/2010 with a legal deadline for their re-evaluation by 31st December 2016 and, therefore, the current assessment is not focused on the full risk assessment.

The ANS Panel adopted the statement on the exposure assessment of sodium stearoyl-2-lactylate (E 481) and calcium stearoyl-2-lactylate (E 482) including exposure resulting from extension of the authorisation of sodium stearoyl-2-lactylate 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 on Exposure.

6.4. Draft opinion on β-apo-8'-carotenal (E 160e) (EFSA-Q-2012-01001)

Based on a request from the EC the ANS Panel was asked to assess new toxicological information on β-apo-8'-carotenal (E 160e). It was noted that there were not sufficient data on usage levels for this compound available to EFSA and hence the ANS Panel supported launching a call for usage data as soon as possible to allow the ANS Panel to update risk assessment on β-apo-8'-carotenal (E 160e). This means that the original set deadline can not be met and EC will be asked for an extension of the deadline.

6.5. Draft opinion on erythritol (E 968) (EFSA-Q-2012-00910)

The rapporteur introduced the draft document to the Panel and clarified that ANS Panel was requested to perform an exposure assessment considering an extension of the use of erythritol and the safety of the new proposed use.

The ANS Panel adopted the statement on the exposure assessment of erythritol (E 968) taking into account additional data provided 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 on Exposure.

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

The rapporteur introduced the draft document to the Panel and explained the main issues for discussion. The main points and conclusions of the safety evaluation were discussed and it was agreed to present the document for possible adoption to the forthcoming ANS Panel meeting.

6.7. Draft opinion on hexamethylene tetramine (E 239) (EFSA-Q-2011-00458)

The rapporteur introduced the draft document to the Panel and explained the main issues for discussion. The Panel was informed that the FEEDAP Panel is currently working on the same substance and agreed to consider the timelines of that Panel.

6.8. Draft opinion on riboflavin (E 101i) and riboflavin-5'-phosphate sodium (E 101ii) (EFSA-Q-2011-00361; EFSA-Q-2011-00430)

The rapporteur introduced the draft document to the Panel and explained the main issues for discussion. A thorough discussion took place on the approach to be followed for its safety assessment. In addition, the Panel was informed that the FEEDAP Panel is currently also assessing these substances. Based on the suggestions made by the Panel the document will be discussed in the forthcoming WG A Food Additives and nutrient sources 2011-2014 meeting.

7. New Mandates

The Panel was informed that EFSA has received a mandate to revise the temporary ADI of Sunset Yellow FCF (E 110) based on the new information provided following the request for clarification of the effects of Sunset Yellow FCF on the testis, sperm morphology and sperm mobility in a 28-day study performed according to the recently updated OECD test guideline 407 as indicated in the ANS opinion (2009). The request was allocated to ANS Panel. The legal deadline for the evaluation is November 2013.

An application for the authorisation of Kopal as a food additive was received by EFSA and APDESK is currently addressing the acceptability of this application.

In the course of the public consultation on aspartame, EFSA has received a new report on the association of aspartame with diabetes. The Panel was informed that EFSA proposed to take new studies into account until the closing data of public consultations which means for the aspartame opinion until the 15 February 2013. EFSA also provided guidance that new scientific information which might arise after the closing data of public consultations should only be taken into account in the case it would lead to a revision of the outcome of the evaluation. The Panel was informed that EFSA has an external contract in place monitoring the upcoming scientific literature on aspartame.

A new mandate on caffeine has been allocated to the NDA Panel but the participation of some experts from the ANS Panel in the NDA WG might be asked by NUTRI Unit.

The Panel was informed of a letter drafted by several members of the Advisory Forum was sent to the EFSA proposing that EFSA takes a lead in co-ordinating the work on safety assessments of botanical substances.

A letter from the applicant of glycerol esters of gum rosin (GEGR), an opinion on which was adopted by the ANS Panel in 2010, as well as a letter from a MEP on the same subject were addressed to EFSA. EFSA with the participation of the European Commission held a teleconference with the applicant on GEGR in February to clarify further EFSA position indicating that the identity of the GEGR was not demonstrated in the application dossier and that the applicant has to re-submit a new application dossier addressing this point.

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

8.1 Scientific Committee

No specific information was provided by the Chair.

8.2 Working Groups

8.2.1 Working Group “Botanicals in Food”

The chair of the WG on Botanicals informed the ANS Panel about the outcome of the meeting that took place on 18th February 2013 and the minutes are published on the Authority’s webpage[7].

8.2.2 Working Group “Allura Red”

No further information was provided due to the discussions which took place under item 6.2.

8.2.3 Working Group “A” on Food Additives and Nutrient Sources

This item was not discussed due to lack of time and deferred to the next meeting.

[7] http://www.efsa.europa.eu/en/fipwgs/documents/BotanicalsinFood.pdf

8.2.4 Working Group "B" on Food Additives and Nutrient Sources

This item was not discussed due to lack of time and deferred to the next meeting.

8.2.5 Working Group "Exposure assessment"

During its 24th meeting, on 14th February 2013, the WG EA discussed the approach to be followed for the exposure assessment of food additives (included in the re-evaluation program) with no ADI set (ADI "not specified" previously allocated by other bodies) and which are authorised at *quantum satis* for the majority of the food categories.

- When no information or limited relevant information on the use level has been made available to EFSA, then no exposure section will be presented. Some text will be provided for clarity purposes.
- When relevant information is available to EFSA on several foodstuffs (usage levels data from industries, monitoring data from MS or any other source (e.g. Codex), then the exposure section will follow the current guidelines.

8.3 EFSA

8.3.1 General matters

- Presentation on Implementation of Quality Management.

  The Panel was presented with the strategic objectives, the implementation and how the verification of the quality management system is taking place by EFSA.

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

  The draft management plan for 2014 and a multi annual management plan will be presented for the first time to the EFSA Management Board in March 2013.

  As expressed at the a previous plenary meeting a specialised training on risk assessment for Panel members is in place and the ANS Panel members were invited to participate.

  A specific contract for preparatory documents on silver (E 174) and gold (E 175) was launched.

  EFSA consultative stakeholders Platform workshop is scheduled for March 2013 and at this meeting a proposal for setting up a discussion group related to chemical data collection including food additives is proposed.

  Georges Kass is the deputy HoU of FIP Unit since the beginning of January 2013. Anastasia Kesisoglou will leave the FIP Unit and EFSA at the end of the month to take up a new assignment. The Panel appreciated Anastasia's support during the last four years, particularly related to the new guidance document on food additives as well as the recently related to the WG Botanicals and wished her all the best for her future career.

  The "Horizon 2020 Framework Programme for Research and Innovation" was briefly presented and the ANS Panel concluded that assessment of mixtures and the use of new techniques such as in vitro in combination with PBK modeling, omics technologies in risk assessment are important initiatives under the framework programme.

  The ANS Panel was invited by the Scientific Committee WG on guidance documents to provide feedback on the current guidance documents developed by the SC over the last years and outline if these guidance documents are applied by the ANS Panel, or if not why as well as provide feedback if a revision of respective guidance

documents is proposed. Due to lack of time it was agreed to address this questionnaire at the next ANS Panel meeting in March 2013.

8.3.2 Work programme re-evaluation of food additives

The objectives, procedure, approach to take and a proposal for a work program for 2013 and 2014 for the remaining food additives falling within the re-evaluation programme were presented by the FIP Unit to the members of the ANS Panel. The Panel members appreciated the overview of the re-evaluation of food additives programme, noted the challenges and current achievement. The Panel members agreed that in order to meet the legal deadlines specified in legislation EU Regulation No 257/2010 that a revamp of the approach to take is needed. The Commission explained the re-evaluation procedure laid down in Article 4 of that Regulation and clarified this procedure does not require a systematic full re-evaluation. The Panel members agreed that access to scientific information is critical and supported to enhance co-operation with stakeholders having access to relevant information of the safety assessment (e.g. data on usage levels, toxicological data), requesting access to applications for feed additives which are also assessed as food additives to respective applicants, communicating the 2013 and 2014 work programme to stakeholders and e.g. on the EFSA webpage and supported a structured way of public calls for data. The Commission confirmed that, when needed, it will support EFSA in order to assure that all interested business operators are informed in a timely manner of requests for data. In addition, the Panel agreed that substances with no ADI set and which are allowed as *quantum satis* are not subject to a call for usage level data as well as have further discussions in e.g. the WG toxicology how to address substances where there was no ADI specified by previous committees. It was proposed that further discussions will take place at the next plenary meeting.

8.3.3 Feedback public consultation on aspartame

The FIP Unit provided an overview of the comments received during the public consultation process on the draft opinion on re-evaluation of aspartame which closed on 15 February 2013. It was reported that different national food safety bodies, industry associations, NGOs, and others have provided comments on various parts of the safety evaluations, and many comments related to the toxicological part. The comments will be discussed at the next meeting of the Working Group “Aspartame” which will take place in March 2013.

8.3.4 Energy drinks

EFSA has commissioned an external study on the consumption of energy drinks and the external scientific report is now finalised. EFSA plans to communicate for the first time on an external scientific report. The Panel was invited, appreciating that the Panel was not made available the full report of this external scientific report, whether the data provided would necessitate the revisiting of the exposure scenarios used in the ANS Panel’s opinion on taurine and D-glucuronolactone from energy drinks from 2009[8]. The ANS Panel noted that the dietary exposure estimates for adults in the 2009 opinion are higher than the exposure estimates presented in the external report. As the 2009 opinion did not show a safety concern for the adult population, these results do not provide a basis for revising the safety assessment. The Panel noted some possible weaknesses in the methodology used in the study and it was proposed that this should be reported to the relevant Unit of EFSA. In addition, the ANS Panel agreed to look more closely into the outcome of this external scientific report with regards to energy drinks consumption by children and adolescents once the external scientific report is published.

[8] http://www.efsa.europa.eu/en/efsajournal/pub/935.htm

8.4 European Commission

No specific information was provided.

9. Other scientific topics for information and/or discussion

9.1 Gaseous chlorine dioxide (EFSA-Q-2012-00748)

EFSA has rejected an application in relation with gaseous chlorine dioxides to be used as food additive in cold storage areas as the data provided by the applicant were considered not suitable for the risk assessment of this compound by EFSA. The members of the Panel confirmed that the suitability of the data provided by the applicant for the authorisation of gaseous chlorine dioxide as preservative which is slowly released are not suitable for the assessment of the gaseous chlorine dioxide as food additive.

10. Any Other Business

No other business was raised.