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

Minutes of the 50th plenary meeting

Held on 1-3 April 2014, Parma, Italy

(Agreed on 13 05 2014)

Participants

- **Panel Members**:
  - Birgit Dusemund, Pierre Galtier, David Gott (Vice-Chair), 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:**
  - Andreia Alvarez-Porto (DG Sanco E3)
- **EFSA:**
  - Food Ingredients and Packaging (FIP) Unit: Margarita Aguilera-Gomez, Anna Christodoulidou, Paolo Colombo, Claudia Heppner, Ana Rincon, Camilla Smeraldi and Alexandra Tard
  - Dietary and Chemical Monitoring (DATA) Unit: Petra Gergelova
  - Assessment methodological support (AMU) Unit: Elisa Aiassa, Fulvio Barizzone, Laura Martino

1. Welcome and apologies for absence

The Chair, Alicja Mortensen, welcomed all participants. On the morning of 3 April in the absence of the Chair the Vice-Chair Claude Lambré chaired the meeting. Apologies for absence were received from Fernando Aguilar, Riccardo Crebelli and Ursula Gundert-Remy.

2. Adoption of agenda

The draft agenda was adopted without any modifications.

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3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[1] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[2], 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 49th ANS Plenary meeting held on 4-6 2 2013

The members of the ANS Panel revised and agreed on the draft minutes of the 49th plenary meeting. The minutes will be available on the Authority's webpage.[3]

5. Report on written procedures since 49th 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. Propyl gallate (E310) (EFSA-Q-2011-00479)

The rapporteur introduced the draft opinion to the ANS Panel summarising the key aspects. The ANS Panel concluded that despite data gaps identified in the toxicity database the available data were judged to be sufficient to establish an acceptable daily intake (ADI) for propyl gallate based on data from a sub-chronic study. The ANS Panel also concluded that there is no longer a basis for a group ADI for propyl, octyl and dodecyl gallates and that for octyl and dodecyl gallates no conclusion on the health based guidance value can be provided until the ongoing evaluations have been completed. .

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

The full opinion is available on the Authority's webpage[4].

[1] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[2] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf
[3] http://www.efsa.europa.eu/en/events/event/121204b-m.pdf
[4] http://www.efsa.europa.eu/en/efsajournal/pub/3642.htm

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

The rapporteur highlighted the key aspects of the opinion and pointed out that this food additive is currently only used in *provolone* cheese. The discussions focussed on hazard identification and characterisation, exposure assessment, risk characterisation and conclusions. Due to lack of time, and the desire of the Panel members to see the agreed modifications to the draft opinion the adoption was postponed to the next plenary meeting in May 2014.

6.3. Steviol glycosides (E960) (EFSA-Q-2013-00433)

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

The full opinion is available on the Authority's webpage[5].

6.4. 4-hexylresorcinol (E586) (EFSA-Q-2011-00485)

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

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

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

The rapporteur introduced the draft opinion and highlighted the key aspects of the safety evaluation which comprises the assessment of monomethylsilanetriol (MMST) as nutrient source and a novel food ingredient. The Panel supported the proposal made by the working group that the applicant would need to provide additional information.

7. New Mandates

Two new requests falling within the remit of the ANS Panel were received by EFSA since the last plenary: One request (application) regarding the extension of use of quillaia extract as a food additive in 'flavourings (EFSA-Q-2014-00095). As the safety assessment of quillaia within the re-evaluation programme of food additives is foreseen by 2018 and as the re-evaluation could result in a revised health based guidance value the Panel proposed to clarify with the European Commission whether both requests could be combined in one assessment and completed by 31 December 2015. The second request, also an application, was related to a safety evaluation related to a modified production method for the glutamic acid and its salts (EFSA-Q-2014-00061). This evaluation needs to be concluded by December 2014. The Panel agreed to task WG B on Food additives and nutrient sources with the preparation of the draft opinion.

[5] http://www.efsa.europa.eu/en/efsajournal/pub/3639.htm
[6] http://www.efsa.europa.eu/en/efsajournal/pub/3643.htm

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

8.1. Scientific Committee

Due to lack of time no feedback was provided.

8.2. Working groups

8.2.1. Working Group on Food Additives and nutrient sources A

Due to lack of time no feedback was provided.

8.2.2. Working Group on Food Additives and nutrient sources B

Due to lack of time no feedback was provided.

8.2.3. Working Group on Exposure Assessment

Due to lack of time no feedback was provided.

8.2.4. Working Group on Isoflavones

Due to lack of time no feedback was provided.

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

Due to lack of time no feedback 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:

At the 60th Management Board (MB) meeting which was held on 19 to 20 March 2014 the members adopted EFSA 2013 report and expressed gratitude the contributing experts and EFSA staff. In addition, the MB adopted the decision on the appointment of the members of the ANS and CEF Panels, as well as the placement of other suitable candidates in the reserve list. The publication of the composition of the new Panel members is foreseen around 20 May 2015. The inaugural meeting for both ANS and CEF will take place from 1 to 4 July 2014. The mandate of the current ANS Panel will run until 30 June 2014. Further information and the audio recording of the MB meeting is available on the Authority's webpage.[7]

In relation with FIP unit matters the Panel was informed that Dr. Margarita Aguilera-Gomez has joint the unit as national seconded expert as of 1 April 2014. Margarita will work in the area of food enzymes. In addition, a short outline of the upcoming stakeholder meeting on "Food additives re-evaluation programme according to

[7] Available at http://www.efsa.europa.eu/en/events/event/140320.htm

Commission Regulation (EU) 257/2010"[8] which will take place in Brussels on 28 April 2014 was provided.

A staff member from the FIP unit presented the satisfaction survey from observers and panel members who attended the 49th open ANS plenary meeting.

8.4. European Commission

The European Commission representative reported on two topics:

An ad hoc study in preparation of the development of a common methodology for gathering of information by the Member States on the consumption and use of food additives and flavourings in the European Union has been commissioned by DG Sanco and was awarded to the Food Chain Evaluation Consortium (FCEC). The objective is to provide a report detailing the development of a common methodology for the gathering of information by the Member States on the use of and exposure to food additives and flavourings. The needs of EFSA in relation to exposure data will be also considered. The report should be available by December 2014.

The recent proposal of a Commission Delegated Act amending the definition of "Engineered Nanomaterial" (ENM) of Regulation (EU) No 1169/2011 on the provision of food information to consumers was submitted to the Council and to the European Parliament for adoption, but was rejected by the EP due to the proposed exemption from labelling of already authorised food additives.

Some clarifications have been provided concerning the definition of ENM and the possible implication of the presence of engineered nanomaterial's ingredients in food (e.g. mandatory labelling).

EFSA's Guidance for submission for food additive evaluations[9] provides parameters for characterisation and identification of ENM. In this guidance, information in relation to nanomaterials is requested, such as chemical composition/identity; particle size; physical morphology; particle concentration; specific area and chemical reactivity/activity.

Furthermore, stability of the substance, and reaction and fate in food, including appropriate information on the chemical/physico-chemical stability of the additive during storage of the processed food is requested; this may also include information in relation to the nanoform.

Based on this Guidance, it will be possible to determine the status of food additives, in relation to the definition of ENM, namely whether the food additive used in the manufacturing process in a nanoform maintains this form in the final product.

9. Other scientific topics for information and/or discussion

9.1. Iron(III) *meso*-tartrate (EFSA-Q-2012-00924): update

The Panel discussed if additional toxicological studies are needed for the safety assessment of the complexation product of sodium tartrate with iron (III) chloride.

[8] Available at http://www.efsa.europa.eu/en/events/event/140428.htm
[9] EFSA Journal 2012;10(7):2760

9.2. Protocol for risk assessment on food supplements with isolated isoflavones

(EFSA-Q-2013-00916)

A scientific officer of the FIP unit presented a draft protocol for collection of evidence for a risk assessment of food supplements containing isolated isoflavones in peri- and post-menopausal women. This activity is in line with the EFSA strategy for evidence based scientific assessment which was to be discussed at the upcoming Scientific Committee meeting..

The ANS Panel supported the protocol, but recommended to wait with the finalisation of the protocol until all required competencies are available in the ANS WG isoflavones. The current WG had mainly the task to elaborate on data requirements and search strategies related the risk assessment of isoflavones.

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

The Chair of WG A Food additives and nutrient sources presented a conceptual framework for the risk assessment of certain food additives belonging to specific categories (e.g. authorised at *quantum satis*, charaterised by low intrinsic toxicity or with no numerical ADI). This will allow the Panel having abbreviated outputs of risk assessments falling under the re-evaluation programme and ensuring transparency and consistency across the different risk assessments. The members of the ANS Panel supported this concept and a possible adoption is foreseen at the next panel meeting.

9.4. EFSA statement on Refined Exposure Assessment for Brown HT (E155)

(EFSA-2012-00884)

A scientific officer of the DATA unit presented the outcome of the exposure estimate for brown HT which was carried out by EFSA. Data submitted via the call for usage level and concentration data (batch 1) allowed a refined exposure assessment. Three different scenario were proposed taking into consideration either the maximum permitted levels (MPLs) or different combinations with usage levels (also assuming no use for food categories without data). The refined exposure estimates were not very different from the previous assessment. An exceedance of the ADI was observed at mean exposure levels in two subgroups of the population (toddlers and children) but when considering the whole population the ADI was not exceeded. The full EFSA statement will be published on the Authority's webpage.

9.5. EFSA statement on Refined Exposure Assessment for Curcumin(E100)

(EFSA-2012-00882)

Due to lack of time no feedback was provided.

10. Any other business

No other business was raised.