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MINUTES OF THE 27th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 20-22 September 2011

Adopted on 25 October 2011 at the 28th Plenary meeting

AGENDA:

MINUTES OF THE 27th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 20-22 September 2011

Panel Members:

Fernando Aguilar, Riccardo Crebelli, Birgit Dusemund, Pierre Galtier, David Gott, Ursula Gundert-Remy, Jürgen König, Claude Lambré (1st and 2nd day), Alicja Mortensen, Pasquale Mosesso, Dominique Parent-Massin, Ivonne Rietjens, Ivan Stankovic, Paul Tobback, Ine Waalkens-Berendsen, Rudolf Woutersen and Matthew Wright (1st and 2nd day).

Apologies

Apologies for absence were noted from John Gilbert.

EFSA

Hugues Kenigswald, Majlinda Lahaniatis, Federica Lodi, Kim Petersen, Ana Maria Rincon, (scientific staff), Maria Correa and Maud Paques (administrative staff).

European Commission

Josiane Houins-Roulet (1st day) and Wim Debeuckelaere.

1. WELCOME; APOLOGIES FOR ABSENCE

The Chair welcomed the participants. Apologies for absence were noted.

2. ADOPTION OF THE AGENDA

The agenda was adopted without changes.

3. DECLARATIONS OF INTEREST

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declarations of interest (ADoIs) and Specific Declarations of interest (SDoIs) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the ADoIs and SDoIs, please refer to the Annex I of this document.

4. ADOPTION OF THE MINUTES OF THE 26TH ANS PLENARY MEETING ON 6-7 JULY 2011

The draft minutes were discussed and some changes were suggested. The adopted minutes can be seen on: http://www.efsa.europa.eu/en/science/

5. GENERAL INFORMATION FROM EFSA, THE EUROPEAN COMMISSION AND THE CHAIR

5.1. Chair

Alicja Mortensen reported on the last plenary meeting of the Scientific Committee to which she has participated on behalf of the Chair of the Panel. During this meeting which took place in September 2011 the draft "*EFSA guidance on repeated-dose 90-day oral toxicity study on whole food"*, the draft "*EFSA opinion on genotoxicity testing strategies*", the draft science strategy and a draft mandate for new risk assessment approaches were among the items discussed.

5.2. EFSA

Hugues Kenigswald informed the Panel members that Majlinda Lahaniatis will no longer be working for the ANS unit from 1 October 2011 when she will take a new position in EFSA. George Kass will become the Deputy Head of the ANS Unit.

5.3. European Commission

Josiane Houins-Roulet informed the Panel of the progress made on the implementation measures for amending the legislations on authorised food additives and nutrient sources as a follow up of the opinions adopted by the ANS Panel in the previous months.

6. REPORT FROM THE WORKING GROUPS

6.1. Working Group A on Food Additives and Nutrient Sources

The Chair of Working Group A summarised the outcome of the discussions during the 27th Working Group A meeting held as in Parma on 6-8 September 2011.

6.2. Working Group B on Food Additives and Nutrient Sources

The Chair of Working Group B summarised the outcome of the discussions during the 18th Working Group B meeting held as in Parma on 6-8 September 2011.

6.3. Working Group "Exposure assessment"

The Chair of the Working Group "Exposure assessment" summarised the outcome of the discussions during the last meeting held in Parma on 8 September 2011.

6.4. Working Group "Chemistry and specifications"

No meeting has taken place since the last Panel Plenary meeting.

6.5. Working Group "Guidance on Food Additives"

No meeting has taken place since the last Panel Plenary meeting.

7. FOOD ADDITIVES

7.1. Guidance on submission for food additive evaluations by the Panel (Question N° EFSA-Q-2010-00675)

The guidance document was discussed for the first time by the new ANS Panel. The rapporteur gave a brief presentation of the content, highlighting the main issues. Various issues were addressed (e.g. genetic predispositions, (non)absorption, genotoxic compounds with carcinogenicity, etc), , and discussed. Further clarifications and modifications were suggested. The Annexes were also discussed for the first time and extensive modifications were proposed. The comments received on the document by the Scientific Committee were also addressed and discussed.

The Chair, I. Rietjens, asked the ANS Unit to finalise (i.e. scientific contributions and clarifications, editorial, formatting, etc) the document with all the changes agreed and also produce a graph, based on the presentation, to complement the document. It is foreseen that the document will be endorsed at the next plenary meeting, enabling a publication for public consultation in November 2011. EFSA briefly outlined the procedure involved for launching a public consultation for the document.

7.2. E153 Vegetable carbon *(Question N° EFSA-Q-2011-00355)*

The rapporteur introduced the main changes in the draft document. Further clarifications and improvements based on the comments provided by the participants were noted. Subject to these revisions a new draft document will be scheduled for discussion in a forthcoming ANS Panel Plenary meeting.

7.3. E120 Cochineal carminic acid carmines *(Question N° EFSA-Q-2011-00360)*

The draft opinion was discussed. Further clarifications and improvements were suggested.

The Panel noted the case reports of allergic reactions following consumption of carmine containing foodstuffs and that the reactions were related to the protein residues present in the commercial products. Since no threshold can be established for this hazard, limiting the maximum protein residues in the specifications will not eliminate the risk.

Given the absence of a threshold, it was acknowledged by the Panel that allergenicity cannot be used for establishing an ADI.

However, the Panel would like to seek the advice from the Scientific Committee on how to take the risk for allergenicity into account when evaluating the safety of cochineal, carminic acid and carmine as a food additive and more generally on how allergenicity can be dealt with in a safety evaluation of a chemical substance and/or its impurities.

Secondly, it was agreed that the EU Commission should provide EFSA with information from other cases where a food additive with allergenic impurities has been authorised as food additives.

Thirdly, the interested parties should be contacted and asked to provide information on incidences observed in the general population and particular in children and on the possibility to reduce the residual protein content in cochineal, carminic acid and carmine. In order to support the refined exposure assessment the interested parties should also provide usage levels according to the new food classification system as well as to the old system.

7.4. E 320 Butylated hydroxyanisole (BHA) *(Question N° EFSA-Q-2011-00343)*

The draft opinion was discussed. Further clarifications and improvements were suggested and the opinion was adopted.

The Panel concluded that the available database does give reason to revise the ADI of 0.5 mg/kg bw/day.

The Panel considered that forestomach hyperplasia in rodents may no longer be considered relevant for human risk assessment.

Based on a NOAEL of 100 mg/kg bw/day for growth retardation, increased mortality and behavioural effects in rat pups at higher dose levels, and using an uncertainty factor of 100 the Panel established an ADI of 1.0 mg/kg bw/day.

Exposure estimates to BHA at Tier 2 for children and the adult population at both the average and high level exposures are unlikely to exceed the ADI of 1.0 mg/kg bw/day.

7.5. E 321 Butylated hydroxytoluene (BHT) *(Question N° EFSA-Q-2011-00344)*

This item was not discussed due to lack of time.

7.6. Montan acid esters *(Question N° EFSA-Q-2011-00708)*

The draft opinion was discussed. Further clarifications and improvements were suggested.

8. DRAFT OPINION OF THE SCIENTIFIC COMMITTEE ON "EXPLORING OPTIONS FOR PROVIDING PRELIMINARY ADVICE ABOUT POSSIBLE HUMAN HEALTH RISKS BASED ON THE CONCEPT OF THRESHOLD OF TOXICOLOGICAL CONCERN (TTC)(QUESTION N° EFSA-Q-2011-00855)

The Panel discussed the draft note to the Scientific Committee compiling the comments received from the Panel members on the draft opinion of the Scientific Committee. The note was finalised and will be sent by the ANS Unit to the Scientific Committee Unit on behalf of the Panel.

The Panel also decided that when the opinion of the Scientific Committee on "*Exploring options for providing preliminary advice about possible human health risks based on the concept of Threshold of Toxicological Concern"* will be adopted a meeting of the ANS working group on Toxicology should be organised in order to discuss its implications on the toxicological risk assessments made by the ANS Panel.

9. DRAFT OPINION OF THE SCIENTIFIC COMMITTEE ON THE "DEFAULT ASSUMPTIONS USED BY THE EFSA SCIENTIFIC PANELS AND COMMITTEE, AND EFSA UNITS IN THE ABSENCE OF ACTUAL MEASURED DATA" (QUESTION N° EFSA-Q-2011-00852)

The Panel discussed the draft note to the Scientific Committee compiling the comments received from the Panel members on the draft opinion of the Scientific Committee. The note was finalised and will be sent by the ANS Unit to the Scientific Committee Unit on behalf of the Panel.

The Panel also decided that when the opinion of the Scientific Committee on "*Default assumptions used by the EFSA Scientific Panels and Committee, and EFSA Units in the absence of actual*

measured data" will be adopted a meeting of the ANS working group on Toxicology should be organised in order to discuss its implications on the toxicological risk assessments by the ANS Panel.

10. ANY OTHER BUSINESS

The Chair of the Working Group on aspartame informed the Panel of the foreseen organisation of the working group and timeframe for finalisation of the opinion.

The following areas of expertise are considered for the constitution of the working group: epidemiology, histopathology, carcinogenicity, genotoxicity, toxicokinetics and exposure assessment. The first meeting should take place in October or November 2011 and the first draft of the opinion is foreseen to be ready by March 2012. Accordingly, it is foreseen that the draft opinion could be discussed by the Panel for the first time in June 2012.

NEXT MEETINGS

The next Plenary meetings of the ANS Panel will take place on the following dates:

25 - 27 October 2011	5-7 June 2012
6 - 8 December 2011	3-5 July 2012
14- 16 February 2012	11 – 13 September 2012
17-19 April 2012	23 – 25 October 2012
	4 – 6 December 2012