Parma, 6 December 2011

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MINUTES OF THE 28th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 25-27 October 2011

Adopted on 6 December 2011 at the 29th Plenary meeting

AGENDA:

MINUTES OF THE 28th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 25-27 October 2011

Panel Members:

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

Apologies

Apologies for absence were noted from Fernando Aguilar, Jürgen König and Jean-Charles Leblanc.

EFSA

Hugues Kenigswald, Georges Kass, Federica Lodi, Ana Maria Rincon, Kim Petersen, Alexandra Tard, Maria Luisa Escudero Hernandez (scientific staff), Maria Correa (administrative staff)

European Commission

Wim Debeuckelaere, Josiane Houins-Roulet

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 Declaration of interest (ADoI) and Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the ADoI and SDoI, please refer to the Annex I of this document.

4. ADOPTION OF THE MINUTES OF THE 27TH ANS PLENARY MEETING ON 20-21 SEPTEMBER 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

The Chair informed the Panel that in application of the decisions taken during the September plenary meeting she has sent in October to the Scientific Committee two letters asking for the views of the Scientific Committee on genotoxic and carcinogenic residuals and on the way to take into account in the risk assessment allergenic by-products.

5.2. EFSA

H. Kenigswald updated the Panel on the progress of the actions related to the re-evaluation of aspartame.

5.3. European Commission

W. Debeuckelaere presented to the Panel the new database of the Commission on food additives, as well as a video clip to remind the consumers that food additives are evaluated and controlled.

The database is accessible at the following address:
https://webgate.ec.europa.eu/sanco_foods/main/?event=display

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 28th Working Group A meeting held in the form of a teleconference on 5 October 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 19th Working Group B meeting held in Parma, 4-6-October 2011.

6.3. Working Group "Guidance on Food Additives"

No meeting has taken place since the last plenary meeting of the Panel.

6.4. Working Group "Exposure assessment"

In the absence of the Chair and Vice-Chair of the working group, H. Kenigswald summarised the issues discussed during the 11th meeting of the Working Group on Exposure Assessment held in Brussels, 19 – 20 October 2011.

6.5. Working Group "Chemistry and specifications"

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

7. FOOD ADDITIVES

7.1. Aspartame (*Question N° EFSA-Q-2011-00406*)

Draft selection criteria for scientific data consideration for the re-evaluation of aspartame were discussed. Clarifications and improvements were suggested and the Panel agreed on the criteria that are presented in Annex 2 to the present minutes.

The panel discussed the issue of potential conflicts of interests in the context of their work on the reevaluation of aspartame. U. Gundert-Remy acknowledged the level of public interest in this evaluation and declined to chair the working group for personal reasons. The Panel thanked her for her contribution to the establishment of the working group. Following discussions on who could chair the working group, the Panel raised the issue of possible conflicts of interests linked to the involvement of several members in previous assessment by EFSA of studies related to aspartame. The Panel asked to discuss this issue with the Senior Management of EFSA during its next plenary meeting in December 2011.

7.2. Indigo Carmine (E 132) (*Question N° EFSA-Q-2011-00358*)

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

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

The draft guidance document was discussed. The rapporteur introduced the document highlighting some key issues. Following the discussion, minor modifications were made and the Panel endorsed the draft guidance for public consultation.

The public consultation is foreseen to start on 15 November 2011 and run until 15 January 2012.

7.4. Vegetable carbon (E 153) *(Question N° EFSA-Q-2011-00355)*

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

7.5. Chlorophylls (E 140 i) (*Question N° EFSA-Q-2011-00357*)

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

7.6. Shellac (E 904) *(Question N° EFSA-Q-2011-00705)*

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

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

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

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

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

8. ANY OTHER BUSINESS

H. Kenigswald informed the Panel that the audited draft report of a 28-day extended study on the food colour Sunset Yellow FCF has been provided to EFSA by the International Association of Color Manufacturers. Considering that this study corresponds to the data requested by the Panel in its opinion on the re-evaluation of Sunset Yellow FCF adopted in September 2009, the Panel agreed to extend the temporary ADI of 1 mg/kg bw/day established in this opinion until the finalisation of its assessment after evaluation of the new data provided.

NEXT MEETINGS

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

6 - 8 December 2011

14 – 16 February 2012

17 – 19 April 2012

5 – 7 June 2012

3 – 5 July 2012

11 –13 September 2012

23 – 25 October 2012

4 - 6 December 2012

Annex I

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOI OR SDOIs

In his ADOI/SDoI, Dr. Rudolf Antonius Woutersen declared interest regarding to the agenda item « 7.1. Aspartame». The interest declared by the expert on advantame is related to the financial links of the Institution where the expert is employed with the company Ajinomoto for the realisation of studies for products used in feed. This involvement generates a conflict of interest with the discussion by the ANS Panel on aspartame (level B). In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest (level B). Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest, the said expert incurs in the limitations identified under point C.III.b[1] that is: the expert concerned addresses orally or in written questions during the evaluation of the substance, but cannot draft assessment report or parts of them. In addition, the expert cannot participate in the final discussion. However, he can be present to answer questions addressed specifically to him.

In her ADOI/SDoI, Dr. Ine Waalkens-Berendsen declared interest regarding to the agenda item « 7.1. Aspartame».
The interest declared by the expert on advantame is related to the financial links of the Institution where the expert is employed with the company Ajinomoto for the realisation of studies for products used in feed. This involvement generates a conflict of interest with the discussion by the ANS Panel on aspartame (level B). In accordance with EFSA's Policy on Declarations of Interests and Implementing documents thereof, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest (level B). Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest, the said expert incurs in the limitations identified under point C.III.b[2] that is: the expert concerned addresses orally or in written questions during the evaluation of the substance, but cannot draft assessment report or parts of them. In addition, the expert cannot participate in the final discussion. However, she can be present to answer questions addressed specifically to her.

In her ADoI/SDoI, Prof. Dr. Dominique Parent-Massin declared interest regarding to the agenda item « 7.1. Advantame». The interest declared for advantame is related to financial links of the expert with the company Ajinomoto for the participation to a selection committee for the Ajinomoto scientific prize in France. This involvement generates a conflict of interest with the discussion by the ANS Panel on the advantame (level C). Pursuant to EFSA's Procedure on Identifying and Handling Declarations of Interest, the said expert was excluded from participating in EFSA activities concerned by the potential conflict in question.

[1] Implementing act to the policy on declaration of interests procedure for identifying and handling potential conflicts of interest. http://www.efsa.europa.eu/cs/BlobServer/General/mb_annex_procedure_doi_en%20221008,0.pdf?ssbinary=true

[2] Implementing act to the policy on declaration of interests procedure for identifying and handling potential conflicts of interest. http://www.efsa.europa.eu/cs/BlobServer/General/mb_annex_procedure_doi_en%20221008,0.pdf?ssbinary=true

ANNEX 2

SELECTION CRITERIA FOR SCIENTIFIC DATA CONSIDERATION FOR THE RE-EVALUATION OF ASPARTAME

The selection criteria for scientific data consideration for the re-evaluation of aspartame described in this report will be applied to the existing published and unpublished scientific literature. The literature database will include scientific peer reviewed papers and relevant non-peer reviewed papers (such as technical reports and published conference proceedings) identified through exhaustive literature searches performed using commercial databases and providers (e.g. ISI Web of Knowledge, PubMed), available from previous evaluations by EFSA and SCF or obtained as a result or EFSA's recent public call for scientific data on aspartame (closure: 30 September 2011).

Types of studies that will be considered within the criteria for inclusion in the selection process.

a) Experimental studies
b) Epidemiological studies in humans
c) Case reports supported by medical evidence

Table 1: Source and Type of information available that may fall in these categories:

Peer-reviewed	Not peer-reviewed
Published papers	Unpublished study reports
Meeting abstracts (conference proceedings)	Papers in non-peer reviewed journals or non-peer reviewed e-papers
Published case reports	Meeting abstracts
	Case reports in non-peer reviewed journals

Tiered Approach for the Selection Process

Tier 1. Criteria to be used for the inclusion of scientific papers and reports in the selection process:

1. All studies provided by the applicants (including unpublished study reports non peer-reviewed) with the original application dossier.

2. All studies on the safety and use of aspartame commissioned by national authorities.

3. Papers and reports that have been subject to an independent scientific peer-review process (i.e. process that scientific journals use to ensure that the articles to be published represent the best scholarship available in terms of solid scientific soundness and quality control) and have been subsequently published in a scientific journal.

4. For non independently peer reviewed papers and reports assessment based on the quality control procedures applied and the study designs used with reference to validated standards (e.g. OECD protocols and GLP Guidelines).

Tier 2. Criteria to be used for the rejection of papers and reports in the selection process:

1. Insufficient details provided on the performance or outcome of the studies (EFSA, 2009).

2. Insufficient information to assess the methodological quality of the studies (EFSA, 2009).

References

EFSA, 2009. Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA. Part 2: General principles. The EFSA Journal 1051, 1-22.