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MINUTES OF THE 26th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 6 - 7 July 2011

Adopted on 21.09.2011 at the 27th Plenary meeting

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Held in Parma on 6 - 7 July 2011

Panel Members:

Fernando Aguilar, Birgit Dusemund, Pierre Galtier, John Gilbert, David Gott, Ursula Gundert-Remy, Juergen Koenig, Claude Lambré, Alicja Mortensen, Pasquale Mosesso, Dominique Parent-Massin, Ivonne Rietjens, Ivan Stankovic, Ine Waalkens-Berendsen, Rudolf AntoniusWoutersen and Matthew Wright.

Apologies

Apologies for absence were noted from Riccardo Crebelli, Jean-Charles Leblanc and Paul Tobback.

EFSA

Hugues Kenigswald, Anastasia Kesisoglou, Majlinda Lahaniatis, Federica Lodi, Kim Petersen, Ana Maria Rincon, Stavroula Tasiopoulou (scientific staff), Anna Campanini and Maria Correa (administrative staff)

European Commission

Josiane Houins-Roulet and Dimitrios Chrysafidis

Common information session on 6 July 2011 with the Scientific Panel on food contact materials, enzymes, flavourings and processing aids (CEF Panel)

1. WELCOME AND OPENING OF THE MEETING

The Director of the Scientific Evaluation of Regulated Products (REPRO) Directorate, Riitta Maijala, welcomed the members of the EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) and of EFSA Scientific Panel on Food Additives and Nutrient Sources added to food (ANS Panel) to the inauguration meeting.

2. INFORMATION ON THE ROLE OF THE PANEL MEMBERS AND EFSA SUPPORT

A series of general introductory presentations were given providing the experts with an overview of the organisational structure of the Authority, as well as EFSA strategies, policies and procedures.

2.1. Scientific Evaluation of Regulated Products (REPRO) Directorate: general presentation

The Director, Riitta Maijala, provided the participants with information on the activities of the REPRO Directorate.

2.2. Risk Assessment and Scientific Assistance (RASA) Directorate: general presentation

On behalf of the Director of the Risk Assessment and Scientific Assistance Directorate, Claudia Heppner, Head of the Contaminants Unit, provided the participants with information on the activities of the Risk Assessment and Scientific Assistance (RASA) Directorate, assessment methodology and exposure methodology assistance.

2.3. Scientific Strategy and Coordination (SCISTRAT) Directorate and Scientific Committee: general presentation and role

Djien Liem, Head of the Scientific Committee Unit, provided the participants with information on the activities of the SCISTRAT Directorate, on the role of the Scientific Committee and on EFSA science strategy. It was mentioned that a public consultation on the draft opinion on "Exploring options for providing preliminary advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC)" will be launched.

2.4. Legal aspects

Dirk Detken, Head of the Legal and Regulatory Affairs Unit, informed the participants on some legal aspects regarding the confidentiality and liability.

2.5. Independence- declaration of interest

Dirk Detken informed the participants on the EFSA Policy on Declarations of Interests, as well as EFSA updated processes for handling Declarations of Interest. The participants were informed that a public consultation on the "Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority" will be launched soon.

2.6. Financial aspects – expert compensation guide

Juergen De Maggio of the Finance Unit presented some aspects of the EFSA financial framework that are of interests for Panel members.

2.7. Communication – guidance for Panel members

Anne Laure Gassin, Director of Communications, provided the participants with an overview of the communications strategy.

3. THE FACET EU PROJECT (FLAVOURING, ADDITIVES AND FOOD CONTACT MATERIAL EXPOSURE TASK): DEVELOPMENTS, TOOLS AND PRACTICAL APPLICATIONS

ANS and CEF Panel members presented the following aspects of the FACET EU project:

3.1 Introduction to the project
3.2 The case of food additives
3.3 The case of flavourings
3.4 The case of food contact materials

Specific session to the ANS Panel on 7 July 2011

4. ROUND TABLE PRESENTATION OF PANEL MEMBERS AND THE ANS UNIT

Hugues Kenigswald, Head of the ANS Unit, welcomed the ANS Panel members to the specific session of the 26th Panel meeting. Apologies for absences were noted.
A round table presentation of the Panel members took place. The ANS Unit members, who were present during this meeting, introduced themselves providing information on their tasks and responsibilities within the Unit in support of the ANS Panel.

5. ELECTION OF THE PANEL CHAIR AND VICE CHAIR

The election of a Chair person and of two vice chairs for the ANS Panel took place following the procedure defined in the EFSA Management Board December 2009 decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and their working groups. Prof. dr. ir. Ivonne M.C.M. Rietjens was elected as the Chair of the ANS Panel. Dr. Alicja Mortensen and Dr. David Gott were elected as the vice Chairs. The newly elected Chair took over from the Head of the ANS Unit the chairing of this meeting.

6. WORKING PROGAMME 2011-14 AND ORGANISATION OF WORK

H. Kenigswald presented the working programme for 2011 – 2014 and the corresponding priorities. The register of questions can be seen on the EFSA website at http://registerofquestions.efsa.europa.eu/roqFrontend

7. ORGANISATION OF STANDING WORKING GROUPS INCLUDING NOMINATION OF STANDING WORKING GROUPS'S CHAIRS

The participants discussed and agreed on the structure and composition of the standing Working Groups. The chair of the Panel proposed Prof. Paul Tobback and Dr. Alicja Mortensen as new Chairs of the Working Groups A and B on food additives and nutrient sources, respectively. The Panel agreed with the proposal of the Chair. In addition, the Chair of the Panel nominated Prof. Claude Lambré and Dr David Gott as Vice-Chairs of the Working Group A and B on food additives and nutrient sources , respectively.

Following the proposal of the Chair, the following nominations were agreed by the Panel::

1. Working Group on Chemistry and Specifications: Dr John Gilbert was re-appointed as Chair and Prof. Ivan Stankovic as Vice-Chair.

2. Working Group on Exposure Assessment: Dr Jean-Charles Leblanc was re-appointed as Chair and Prof. Jürgen König as Vice-Chair.

3. Working Group on Toxicology: Dr David Gott was appointed as Chair.

4. Working Group on Guidance on food additives: Prof. dr. ir. Ivonne M.C.M. Rietjens was re-appointed as Chair.

The Head of ANS Unit proposed also the creation of a new working group on genotoxicity in order to facilitate the harmonisation and coordination between the specialists of genotoxicity participating to the working groups A and B. Several members raised objections and it was decided that the creation of this working group could be considered at a later stage if specific needs would be identified.

In a discussion on declaration of interests, in order to facilitate the identification of interests, the Panel members asked to be informed of the names of the applicants and/or interested parties for each mandate. H. Kenigswald indicated that there will soon be the possibility to automatically add this information for the specific declaration of interests in the case of new applications.

8. MEETING DATES

8.1. For the Panel

The Head of the ANS Unit informed the Panel members of the foreseen meeting dates for the ANS Panel for the rest of 2011: 20 - 22 September, 25 - 27 October and 6 - 8 December. The Panel agreed to keep these meeting dates.

The Chair of the Panel asked the Secretariat to propose meeting dates for 2012. The meeting dates should be circulated to members of the Panel during the summer. The meetings calendar 2012 will be confirmed at the next Plenary meeting in September 2011.

8.2. For the ANS Panel Working Groups

The Head of ANS Unit informed the Panel members of the meeting dates for the ANS working groups A and B for the rest of 2011: 6 - 8 September, 4 - 6 October and 15 - 17 October.

When the plenary meetings of the Panel will be set for 2012, dates should be proposed for the meetings of working groups A and B. In order to facilitate the exchanges between working groups A and B, the Panel asked that as far as possible their meetings should take place on the same days and in the same location, preferably Parma.

9. ASPARTAME (QUESTION N° EFSA-Q-2011-00189 AND EFSA-Q-2011-00406)

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 this agenda item of 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.

The Chair of the Working Group "Ramazzini Institute study on aspartame in mice and methanol" informed the Panel of the issues raised during the first meeting of this Working Group:

1. Impossibility of finalising the assessment of methanol toxicity by the December 2011 deadline as some concerns have been raised on the only two carcinogenicity studies available on oral exposure to methanol: the mouse study by Apaja (1980) and the rat study by Soffritti et al. (2002). The first study is considered as not adequate due to the lack of a control group. The validity of the results of the second study is questioned and it is necessary to wait for the outcomes of the NTP re-evaluation of the histopathological findings of several studies performed by the Ramazzini Institute including the one on methanol, which is ongoing and is foreseen to be finalised at the earliest by the end of this year.

2. Clear overlap with the new mandate related to the full re-evaluation of aspartame.

3. Difficulties to interpret the ToR with respect to the Halldorsson et al. (2010) study

In the following discussion, the Commission representative provided the rationales for the anticipated re-evaluation of aspartame by September 2012. The experts exchanged their views regarding the scientific rationales for re-evaluating aspartame within this short timeframe. D. Gott added that the on-going FSA research on aspartame might provide further insights useful for the risk assessment but that the timeline for finalising the assessment will not allow to take them into consideration. In conclusion, the Chair of the Panel considered the timeframe for completing the evaluation of aspartame too short and asked EFSA and the Commission to further explore the possibility of extending the deadline.

Regarding the Halldorsson et al. (2010) study, the Panel noted that since the study is only exploratory and furthermore not related to any specific sweetener, there is no justification in exploring possible explanatory mechanisms for aspartame including metabolites like methanol.

After discussion, the Panel concluded to propose to EFSA the withdrawal of the self-mandate on aspartame studies and methanol since the objectives of this self-mandate are covered by the mandate on the re-evaluation of aspartame requested by the European Commission on May 2011. Therefore, the Chair of the Panel will send a letter to the EFSA Executive Director providing the rationales to withdraw the mandate. Accordingly, the Working Group "Ramazzini Institute study on aspartame in mice and methanol" should stop its activities.

To support the preparation of the draft opinion on the re-evaluation of aspartame, the Panel concluded to create a new working group and the Chair of the Panel proposed to nominate Dr Ursula Gundert-Remy as Chair of this new working group. The Chair of the Panel suggested to carefully consider the nomination of the experts for this new working group. She advised the Head of ANS Unit to clarify the application of EFSA policy with regard to the question of whether involvement in previous EFSA evaluations on aspartame and the Soffitti studies would have to be considered as an interest or perhaps even as a conflict of interest. She also suggested involving new experts in the working group.

The Head of ANS Unit provided the Panel with a brief overview of the data already submitted in response to the public call for data and explained the ongoing work in EFSA and the foreseen establishment of a preparatory document summarising the data available by a contractor under a procurement contract. The preparatory document is foreseen to be finalised by the end of January 2012.

The Panel concluded that in order to be able to finalise the assessment by September 2012, the working group should start its activities as soon as possible without waiting for the preparatory document.

10. ANY OTHER BUSINESS

none

NEXT MEETINGS

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

20 - 22 September 2011

25 - 27 October 2011

6 - 8 December 2011

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. Advantame».
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 on feed products. This involvement generates a conflict of interest with the discussion by the ANS Panel on the advantame (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, 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