Parma, 24 May 2011

EFSA/ANS/P_M23/MIN-1-5849736

MINUTES OF THE 23rd PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 12-14 April 2011

Adopted on 24 May 2011 at the 24th Plenary meeting

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MINUTES OF THE 23rd PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Parma on 12-14 April 2011

Panel Members:

Fernando Aguilar, Birgit Dusemund, Pierre Galtier, John Gilbert (1st and 2nd day), David Gott (2nd day), Rainer Gürtler, Claude Lambré, John Christian Larsen (Chair), Jean-Charles Leblanc, Alicja Mortensen, Dominique Parent-Massin, Ivonne Rietjens (Vice-Chair), Ivan Stankovic, Paul Tobback, Tatjana Verguieva, Ruud Woutersen.

Apologies

Apologies for absence were noted from Sandro Grilli and Iona Pratt.

Hearing expert:

Henk van Loveren (item 7.5)

EFSA

Hugues Kenigswald, George Kass, Majlinda Lahaniatis, Anastasia Kesisoglou, Federica Lodi, Joanne Gartlon, Ana Maria Rincon, Kim Petersen, Stavroula Tasiopoulou, Alexandra Tard (scientific staff), Maria Correa and Anna Campanini (administrative staff).

European Commission

Stéphane Brion and 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 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 and II of this document.

4. ADOPTION OF THE MINUTES OF THE 22ND ANS PLENARY MEETING ON 1-3 MARCH 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The Chair of the Panel informed the participants that the draft guidance document on food additives will be presented to EFSA Scientific Committee during its June 2011 plenary meeting. In the absence of the Chair of the Panel, I. Rietjens, Vice-Chair of the Panel and Chair of the Working Group "Guidance on Food Additives" will participate to this meeting and present the draft guidance document to the Scientific Committee on behalf of the ANS Panel.

5.2. EFSA

H. Kenigswald informed the Panel members that the Scientific Committee has endorsed the guidance on genotoxicity testing for public consultation during its April 2011 plenary meeting. It is anticipated that the public consultation will be launched soon and the guidance is foreseen to be finalised in summer or autumn 2011.

The Head of the ANS Unit reported on his participation to a public hearing at the European Parliament on 16 March related to recent publications related to aspartame, as well as the media related activities.

In addition, the Panel Members were informed on the outcome of the meeting with Stakeholders on the Programme for the Re-evaluation of approved food additives as laid down in Commission Regulation (EU) No 1333/2008, which took place on 4 April 2011.

The Panel was informed that EFSA has launched a call to renew the membership of its Scientific Committee and Panels. The call, which run from 31st March 2011 and closes on 31st May 2011, seeks to identify scientific experts who wish to join the various Panels including the ANS Panel. Experts who wish to continue working for the Panel when it is renewed again in 2014 should re-apply.

A new mandate from the Commission to re-evaluate the safety of calcium lignosulfonate as a food additive based on the additional data provided by the applicant has been received.

The Panel was informed that EFSA has received the information that a 28-day study on Sunset Yellow with emphasis on the male reproductive system is currently being carried out by interested parties. The ANS Panel established a temporary ADI for Sunset Yellow in September 2009 which

expires in September 2011. EFSA has requested that the new data are made available before August 2011 in order to enable the Panel to extend the validity of the temporary ADI until the finalisation of the assessment of the new data.

Finally the Panel was informed that EFSA has received from the European Commission a request for technical assistance to evaluate a new study on the bioavailability of aluminium from some aluminium compounds.

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 year.

The ANS Unit will provide the Panel members with the progress report.

6. REPORT FROM THE WORKING GROUPS

6.1. Working Group A on Food Additives and Nutrient Sources

The vice Chair mentioned that two web conferences have taken place since the last ANS Panel Plenary meeting. The progress achieved on advantame and calcium carbonate draft opinions was highlighted.

The Panel members were informed that the next Working Group A meeting will take place in Dublin, Ireland, on 3-4 May 2011.

6.2. Working Group B on Food Additives and Nutrient Sources

The Chair of Working Group B informed the Panel that no meeting has taken place since the last Panel Plenary meeting.

6.3. Working Group "Guidance on Food Additives"

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

6.4. Working Group "Exposure Assessment"

The Chair of the Working Group reported on the outcome of the meeting held in March 2011.

In addition, it was reported that a web conference will be soon organised focusing on the exposure assessment of calcium carbonate, when used as a food additive.

6.5. Working Group "Chemistry and specifications"

The Chair of the Working Group "Chemistry and specifications" reported on the outcome of a web conference held in March 2011, where several chemical aspects of various substances have been clarified.

7. FOOD ADDITIVES

7.1. Glycerol esters of tall oil rosin

(Question N°EFSA-2009-00880)

The draft opinion was discussed. The proposed changes to the text were noted and the opinion was adopted.

The opinion deals with the safety of glycerol esters of tall oil rosin (GETOR) when used as a food additive with the function of a stabiliser and emulsifier in certain types of drinks. GETOR are described by the petitioner as a complex mixture of mono-, di- and triglycerol esters of resin acids from tall oil rosin.

The Panel concluded that the chemical and toxicological characterisation of GETOR is not adequate and that the limitations of available toxicological data on GETOR prevent the evaluation of the safety of GETOR. Furthermore the Panel could not conclude that GETOR is chemically equivalent to the glycerol esters of wood rosin (GEWR). Therefore, the toxicological data obtained with GEWR could not be used for read across to GETOR.

The Panel concluded that the available data are too limited to conclude on the safety of GETOR as a food additive for the proposed uses and use levels.

7.2. Lutein

(Question N°EFSA-Q-2010-01491)

The draft opinion was discussed. The proposed changes to the text were noted and the opinion was adopted.

Lutein was originally re-evaluated by the Panel in 2010. The ANS Panel established an ADI of 1 mg/kg bw/day and noted that this ADI refers to lutein derived from *Tagetes erecta* containing at least 80% carotenoids. In the new opinion the Panel considered whether additional studies that were made available address the gaps identified by the Panel in the toxicological database for lutein preparations other than lutein with high concentrations of total saponified carotenoids at levels of at least 80%.

The Panel was informed that EFSA had very recently received new (corrected) use levels from CIAA that are intended to replace those provided previously by the industry that were not related to the content of pigment. This change is anticipated to have an important impact on Tier-3 exposure estimates. In order to consider the new data, the Panel decided to propose a self-task mandate for the re-evaluation of the exposure estimates and their comparison to the ADI

The Panel concluded that the additional database supports that the ADI of 1 mg/kg bw/day also refers to lutein with high concentrations of total carotenoids extracted from *Tagetes erecta* and present as esters at levels of ≥ 60%.

The Panel concluded that this ADI refers to lutein derived from *Tagetes erecta* containing ≥ 80% carotenoids consisting of lutein and zeaxanthin (79 and 5%, respectively) and to lutein with high concentrations of total carotenoids extracted from *Tagetes erecta* and present as esters at levels of ≥ 60%.

The Panel concluded that the toxicological database available is too limited to conclude that the ADI also applies to lutein preparations of lower purity or from other sources.

7.3. Patent Blue V (E 131)

(Question N° EFSA-Q-2008-231)

After a public call for genotoxicity data on Patent Blue V was launched in 2010, the industry has recently provided the requested data. The data have been considered by the rapporteur and the results of the tests were presented to the Panel.

The Panel considered the new in vitro and in vivo genotoxicity studies on Patent Blue V and noted that the tests provided were conducted according to OECD guidelines and in compliance with GLP principles.

Overall the Panel considered that the available data were not sufficient to conclude on the genotoxic potential of Patent Blue V and that further in vivo testing was necessary.

For this purpose, a new public call for data should be launched in the coming months and in relation to this call, EFSA will send to the Commission a request to extend the deadline for the finalization of the opinion to December 2012.

7.4. Calcium Carbonate (E 170)

(Question N° EFSA-Q-2003-00241)

This item was postponed because the draft opinion will be discussed in forthcoming meetings of the Working Group on Exposure Assessment and of the Working Group A on food additives and nutrient sources.

7.5. Advantame

(Question N° EFSA-Q-2010-00943)

A preliminary discussion of the draft opinion took place and proposed changes to the text were noted.

8. TECHNICAL GUIDANCE TO EXPLAIN THE TECHNICAL, EXPOSURE AND TOXICOLOGICAL DATA REQUIRED TO ESTABLISH THE SAFETY OF FOOD ADDITIVES PROPOSED FOR USE IN THE EUROPEAN UNION

(Question N° EFSA-Q-2010-00675)

The draft guidance was discussed and proposed changes to the text were noted.

9. ANY OTHER BUSINESS

The Chair of the WG on exposure assessment proposed to present the methodology followed by the Panel for exposure assessment in a Statement of the Panel. The Panel agreed and a request for a self-task mandate will be prepared, specifying the objectives and timelines for the preparation of this document.

EFSA informed the Panel that the evaluation by EFSA of the annual declaration of interests of R. Woutersen has identified a potential conflict of interests level B which according to the applicable EFSA DoI Policy does not allow him to chair the working group on "Ramazzini Institute study on aspartame in mice and methanol" and that therefore he could not be confirmed as Chair of this working group. The Chair of the Panel proposed A. Mortensen as Chair of the working group.

NEXT MEETINGS

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

24 - 26 May 2011

5 - 6 July 2011

6 - 7 July 2011

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 her ADoI/SDoI, Prof. Dr. Dominique Parent-Massin declared interest regarding to the agenda item « 7.5. Advantame». The interest declared for advantame is related to financial links of the expert with the company Ajinomoto. 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.

Annex II

INTERESTS AND ACTIONS RESULTING FROM DECLARATIONS DONE AT THE BEGINNING OF THE MEETING

In his ADOI/SDoI, Dr. Ruud Woutersen declared interest regarding to the agenda item « 7.5. 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. 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.

[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