

Parma, 12 April 2011  
EFSA/ANS/P\_M22/MIN-5708742

**MINUTES OF THE 22<sup>nd</sup> PLENARY MEETING  
OF THE SCIENTIFIC PANEL ON  
FOOD ADDITIVES AND NUTRIENT SOURCES  
ADDED TO FOOD (ANS)**

**Held in Brussels on 1-2 March 2011**

**Adopted on 12 April 2011 at the 23<sup>rd</sup> Plenary meeting**

**AGENDA:**

---

1.	<i>Welcome; apologies for absence</i> .....	3
2.	<i>Adoption of the agenda</i> .....	3
3.	<i>Declarations of interest</i> .....	3
4.	<i>Adoption of the Minutes of the 21<sup>st</sup> ANS Plenary Meeting on 1-3 February 2011</i> .....	4
5.	<i>General information from EFSA, the European Commission and the Chair</i> .....	4
5.1.	<i>Chair</i> .....	4
5.2.	<i>EFSA</i> .....	4
5.3.	<i>European Commission</i> .....	4
6.	<i>Report from the Working Groups</i> .....	5
6.1.	<i>Working Group A on Food Additives and Nutrient Sources</i> .....	5
6.2.	<i>Working Group B on Food Additives and Nutrient Sources</i> .....	5
6.3.	<i>Working Group “Guidance on Food Additives”</i> .....	5
6.4.	<i>Working Group “Exposure assessment”</i> .....	5
6.5.	<i>Working Group “Chemistry and specifications”</i> .....	5

7.	<i>Food Additives</i> .....	5
7.1.	<i>Aspartame</i> .....	5
7.2.	<i>Lutein</i> .....	6
	(Question N°EFSA-Q-2010-01491) .....	6
8.	<i>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</i> .....	6
9.	<i>Any other business</i> .....	6
	<i>Next meetings</i> .....	6

**MINUTES OF THE 22<sup>nd</sup> PLENARY MEETING  
OF THE SCIENTIFIC PANEL ON  
FOOD ADDITIVES AND NUTRIENT SOURCES  
ADDED TO FOOD (ANS)**

**Held in Brussels on 1-2 March 2011**

---

**Panel Members:**

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

**Apologies**

Apologies for absence were noted from Sandro Grilli.

**EFSA**

Joanne Gartlon, George Kass, Hugues Kenigswald, Majlinda Lahaniatis (scientific staff), and Maria Correa (administrative staff).

**European Commission**

Wim Debeuckelaere (1<sup>st</sup> day) 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 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 21<sup>ST</sup> ANS PLENARY MEETING ON 1-3 FEBRUARY 2011**

The draft minutes were discussed and some changes were suggested. The adopted minutes can be seen on:

<http://www.efsa.europa.eu/en/events/event/ans110201.htm>

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

##### **5.1. Chair**

The Chair informed the participants on the new mandates that fall within the remit of the ANS Panel, as well as ongoing work carried out by EFSA.

The Chair informed the participants that the request of the ANS Panel dated 15 November to prepare under self-tasking a safety assessment for the re-evaluation of lutein preparations other than lutein with high concentrations of total saponified carotenoids at levels of at least 80% used as a food additive, has been approved by the EFSA's Mandate Review Committee and that the EFSA Executive Director has formally agreed with the proposed timeframe for the execution of this self-mandate.

The Chair summarised the outcome of the Scientific Committee meeting, 9-10 February 2011.

##### **5.2. EFSA**

The Panel was informed about:

- a hearing in the European Parliament on recent publications related to aspartame on 16 March 2011, and
- a meeting with Dr M. Soffritti with EFSA on 23 March 2011 to discuss the carcinogenicity study in mice published in 2010.

Following the publication of the EFSA Statement on the “Revised exposure assessment for steviol glycosides for the proposed uses as a food additive” approved on 13 January 2011<sup>1</sup>, some Panel members made comments on the approach followed. It was clarified that the Panel had been previously informed of the fact that the revised exposure assessment would be prepared by the ANS Unit, with the support of the working group on exposure assessment, in the form of an EFSA statement and that the Panel had agreed. It was also clarified that the EFSA statement adhered strictly to the methodology used by the Panel in its opinion. The Panel members were also informed that some Member States have been performing their own exposure calculations for steviol glycosides.

##### **5.3. European Commission**

The Commission explained the comments it received from some applicants about the exposure assessment. Applicants complained that the assessment is not transparent, has not been peer reviewed, is not sufficiently refined and is using a database which is not accessible to them. Also some Member States have raised questions about the exposure assessment, in particular as they do not understand the levels of conservativeness. Some Member States have reported that their national exposure assessment

---

<sup>1</sup> Revised exposure assessment for steviol glycosides for the proposed uses as a food additive. Available from : <http://www.efsa.europa.eu/en/efsjournal/doc/1972.pdf>

indicates lower exposure than in the EFSA assessment. The exposure experts indicated that the exposure assessments performed by the Panel aim at covering the whole European market and that the exposure can vary widely between Member States.

The exposure experts clarified that the exposure calculations performed by the Panel for food additives are not particularly conservative. It was also highlighted that if further discussions on the exposure assessment approaches and their harmonisation between Panels are needed, they should take place in a working group of the Scientific Committee.

The participants also discussed on the access to the food consumption databases for EFSA, Panel experts and the applicants for exposure assessment purposes. The Chair of the WG on “Exposure Assessment” highlighted the need to provide access to the EFSA comprehensive database in order to further refine the assessment. H. Kenigswald clarified that in a near future, the ANS Unit should be provided with the necessary access rights to the database. Another issue to be considered is to provide the applicants with templates for performing their own exposure assessment for new products to be authorised within the European Union.

## **6. REPORT FROM THE WORKING GROUPS**

### **6.1. Working Group A on Food Additives and Nutrient Sources**

The Chair mentioned that the 21<sup>st</sup> meeting of the Working Group A will take place on 3 March 2011. Advantame and benzoates, as food additives, will be discussed during this meeting.

### **6.2. Working Group B on Food Additives and Nutrient Sources**

No meeting has taken place since the last ANS 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”**

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

### **6.5. Working Group “Chemistry and specifications”**

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

## **7. FOOD ADDITIVES**

### **7.1. Aspartame**

The Chair summarised the key activities of EFSA regarding the evaluation of the Soffritti et al. (2010) and Halldorsson et al. (2010) studies.

The Panel proposed to undertake a detailed analysis of the study results reported by Soffritti et al. (2010), as well as the suggested implications of methanol in the toxicity of aspartame as suggested by Soffritti et al. (2010) and Halldorsson et al. (2010). A request for a self-task mandate will be sent to EFSA by the Chair.

In order to support the preparation of the scientific opinion, the Panel decided to create a new ad hoc working group. The Chair proposed to nominate Dr. Ruud Woutersen as the Chair of this WG. EFSA will proceed with administrative steps once the EFSA's Mandate Review Committee and the Executive Director have formally agreed with the self-task mandate proposed by the Panel and the corresponding timeframe for its execution.

H. Kenigswald informed the Panel that a statement on the chronic dietary exposure to methanol should be adopted by the UK Committee on Toxicology in the coming months.

## **7.2. Lutein**

*(Question N°EFSA-Q-2010-01491)*

This item was not discussed due to lack of time.

## **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**

This was the first time that the draft guidance was discussed by the Panel. The rapporteur presented the draft document and acknowledged the input of the members of the WG Guidance on Food Additives and the EFSA Secretariat.

The content of the various sections of the document were discussed in detail and the rationale for the various approaches proposed were given.

## **9. ANY OTHER BUSINESS**

none

## **NEXT MEETINGS**

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

12 - 14 April 2011	20 - 22 September 2011
24 - 26 May 2011	25 - 27 October 2011
5 - 7 July 2011	6 - 8 December 2011

## Annex I

### **INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ADOI OR SDOI<sup>s</sup>**

In her ADoI/SDoI, Prof. Dr. Dominique Parent-Massin declared interest regarding to the agenda items « 7.1. Aspartame ». The interest declared for aspartame is related to financial links with Ajinomoto, a company that produces aspartame and is also involved in other sweeteners. This involvement generates a conflict of interest with the discussion by the ANS Panel on the aspartame (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.