Parma, 5 June 2012
EFSA/ANS/P_M31/MIN-1 out 6685520

# MINUTES OF THE 31st PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

## Held in Parma on 17-19 April 2012

## Adopted on 5 June 2012 at the 32nd Plenary meeting

**AGENDA:**

# MINUTES OF THE 31st PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

## Held in Parma on 17-19 April 2012

---

Panel Members:

Fernando Aguilar, Riccardo Crebelli, Birgit Dusemund, Pierre Galtier, John Gilbert (2nd and 3rd day), David Gott (2nd day afternoon and 3rd day), Ursula Gundert-Remy, Jürgen König, Claude Lambré, Jean-Charles Leblanc, Alicja Mortensen (3rd day), Pasquale Mosesso, Dominique Parent-Massin, Ivan Stankovic, Paul Tobback, Ine Waalkens-Berendsen, Rudolf Woutersen and Matthew Wright.

Apologies

No apologies were received.

EFSA

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

European Commission

Josiane Houins-Roulet and Jiri Sochor.

Hearing experts

Ivonne Rietjens (3rd day).

### 1. WELCOME; APOLOGIES FOR ABSENCE

The Chair welcomed the participants.

The Chair thanked the Panel members for electing her as the new Chair of the ANS Panel.

### 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 30TH ANS PLENARY MEETING ON 14-16 FEBRUARY 2012

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

No new information from the Chair, A. Mortensen. The vice chair, D. Gott, attended the plenary meeting of the Scientific Committee on behalf of A. Mortensen and reported on the main outcomes.

### 5.2. EFSA

H. Kenigswald informed the Panel that EFSA has received three new mandates from the European Commission. Two relates to new applications for food additives and are the first ones that fall under the new procedure defined in Regulation 234/2011 implementing Regulation 1331/2008: Polyvinyl alcohol-polyethylene glycol-graft-co-polymer and iron(III) meso-tartrate. The third one is a request for an exposure assessment of the food additive polyoxyethylene sorbitan monooleate (polysorbate 80, E 433) due to a request for an extension of use for this substance.

H. Kenigswald also informed the Panel that C. Heppner will become the Head of the FIP unit on the 1st June 2012.

The Panel was informed of the Scientific Colloquium organised by EFSA on low dose response in toxicology and risk assessment organised by EFSA, which will take place in June.

### 5.3. European Commission

Furthermore, the Panel was informed that the European Commission has been contacted by the Indian authorities who have indicated that they are considering to commission some toxicological studies on shellac as a response to the ongoing public call for data.

## 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 31st Working Group A meeting held in Parma, 27-29 March 2012.

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

In the absence of the Chair, the Vice-Chair of Working Group B summarised the outcome of the discussions during the 22nd Working Group B meeting held in Parma, 27-29 March 2012.

### 6.3. Working Group "Exposure assessment"

The Chair of Working Group on Exposure summarised the outcome of the two meetings that have taken place since the last meeting of the Panel.

### 6.4. Working Group "Chemistry and specifications"

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

### 6.5. Working Group "Aspartame"

The Chair of the working group reported on the progress of the work and the foreseen forthcoming meetings.

### 6.6. Working Group on guidance for food additives"

In the absence of the Chair of the Working Group on guidance for food additives, A. Kesisoglou provided feedback from the last meeting (15-16 March, Amsterdam).

## 7. FOOD ADDITIVES

### 7.1. Stigmasterol-Rich Plant Sterols (*Question N°* EFSA-Q-2011-00428)

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

The mean and 95$^{th}$ percentile exposures to stigmasterol-rich plant sterols resulting from the proposed uses and use levels were 0.01-0.2 mg/kg bw/day and 0.4-7.4 mg/kg bw/day, respectively. Using the lowest NOAEL values from the available toxicity studies of 1.54 g phytosterols/kg bw/day and 335 mg stigmasterol/kg bw/day the Panel calculated that the Margin of Safety (MOS) values amount to 7700-154 000 at the mean and 208-38500 at the 95$^{th}$ percentile for the phytosterols and to 1675-33 500 at the mean and 45-838 at the 95$^{th}$ percentile for stigmasterol.

Taking into account :

- that the mean estimated exposure resulting from the proposed use and use levels of stigmasterol-rich plant sterols (0.6-11.4 mg/day) is 132 to 4000-fold below the estimated mean daily plant sterol intake from food and food supplements (as added nutrient) (1510-2450 mg/day).

- that the estimated exposure resulting from the proposed use and use levels of stigmasterol-rich plant sterols amounts to < 0.5 % at the mean and <15% at the 97$^{th}$ percentile exposure of the estimated exposure of people using phytosterols to lower their cholesterol levels at dose levels up to 3 g/day,

- that the bioavailability of the phytosterols and phytostanols in rat is somewhat higher than that in human

- that the predicted exposures to stigmasterol-rich plant sterols are arguably large over-estimations for frozen cocktail products, and provide a worst-case scenario for potential exposure, and

- the available long-term human data,

the Panel considered these MOS values adequate. Thus, the Panel concluded that the proposed use and use levels of stigmasterol-rich plant sterols would not be of safety concern.

### 7.2. Exposure assessment of sucrose esters of fatty acids (*Question N° EFSA-Q-2011-00935*)

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

It was concluded that the current exposure estimates differ considerably from those of the original Panel opinion on the safety of sucrose esters of fatty acids prepared from vinyl esters of fatty acids and on the extension of use of sucrose esters of fatty acids in flavourings, with an observed reduction ranging from 55 to 65%, depending on the considered population. This difference in exposure estimates results from the differences in the use levels for the surface treatment for fruits which was 18 000 mg/kg fruit in the previous exposure assessment and is now 23 mg/kg fruit based on the data provided to EFSA.

The Panel concluded that the total mean and high intake of sucrose esters of fatty acids amounts to 13.1 and 22.6 mg/kg bw/day for adults and to 19.6 and 42.8 mg/kg bw/day for children, respectively. For children high level consumers the estimated intake exceeds by 7% the group ADI of 40 mg/kg bw/day for sucrose esters of fatty acids (E 473) and sucroglycerides (E 474) established by EFSA in 2004.

The Panel also concluded that the exposure to sucrose esters of fatty acids resulting from its use as a surface treatment for fruits represents less than 0.25% of the ADI. The Panel also concluded that the exposure resulting from the additional use of sucrose esters of fatty acids in clear flavoured soft drinks would only represent less than 0.1% of the ADI.

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

The guidance document was discussed, revised and provisionally endorsed by the panel.

### 7.4. Exposure assessment

The FAIM (Food Additive Intake Model) tool prepared by the working group on exposure assessment was presented to the Panel by the Chair of the Working Group on Exposure Assessment. This template will be made available to the applicants with the double objective of entering the use levels to be considered for the safety assessment and of providing estimates of the exposure.Several questions of the Panel members were addressed and clarifications were given.

### 7.5. Borates (E 284-285) (*Question N° (EFSA-Q-2011-00468 and EFSA-Q-2011-00469)*

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

### 7.6. Carnauba wax (E 903) *(Question N° EFSA-Q-2011-00008)*

The draft opinion was partially discussed due to lack of time. Clarifications and improvements on the discussed part were suggested.

### 7.7. Candelilla wax (E 902) *(Question N° EFSA-Q-2011-00704)*

This item was not discussed due to lack of time.

### 7.8. Titanium dioxide (E 171) *(Question N° EFSA-Q-2011-00348)*

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

## 8. ANY OTHER BUSINESS

The Chair noted that the length of the ANS scientific opinions has increased in recent years and asked the experts to consider options to reduce the size of opinions in the future.

## NEXT MEETINGS

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

5 – 7 June 2012

2 – 4 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 her ADOI/SDoI, Dr D. Parent-Massin declared interest regarding to the agenda item "6.5 working group on aspartame". The interest of the expert with the company Ajinomoto generates a conflict of interests level C with the discussions on aspartame. Therefore, the expert was not able to participate in these discussions and left the room during this discussion.

In her ADOI/SDoI, Dr I. Waalkens-Berendsen declared interest regarding to the agenda item "6.5 working group on aspartame" and «7.4. Advantame ». The expert declared an interest for aspartame because of the commercial relationship between her employer, TNO, and the company Ajinomoto for the realisation of studies on compounds to be used for feeding animals. This interest generates a potential conflict of interest level B for the discussions on aspartame. Therefore, the expert was not able to participate actively in the discussion on aspartame but was authorised to answer to questions addressed directly to her.

In his ADOI/SDoI, Dr. R. Woutersen declared interest regarding to the agenda items "6.5 working group on aspartame". The expert declared an interest for aspartame because of the commercial relationship between his employer, TNO, and the company Ajinomoto for the realisation of studies on compounds to be used for feeding animals. This interest generates a potential conflict of interest level B for the discussion on aspartame. Therefore, the expert was not able to participate actively in the discussion on aspartame but was authorised to answer to questions addressed directly to him.