Parma, 9 February 2010

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MINUTES OF THE 11th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Paris on 24-26 November 2009

Adopted on 9 February 2010 at the 12th Plenary meeting

AGENDA:

MINUTES OF THE 11th PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Held in Paris on 24-26 November 2009

PARTICIPANTS

Panel Members:

Fernando Aguilar (1st and 2nd day), Ruth Charrondiere, Birgit Dusemund (2nd and 3rd day), Pierre Galtier, John Gilbert, David Gott, Rainer Guertler (2nd and 3rd day), Jürgen König, Claude Lambré (1st and 2nd day), John Christian Larsen (Chair), Jean-Charles Leblanc, Alicja Mortensen (2nd day), Dominique Parent-Massin, Iona Pratt (Vice-Chair) (1st, 2nd day and 3rd day morning), Ivonne Rietjens (Vice-Chair), Ivan Stankovic, Paul Tobback, Tatjana Verguieva, Ruud Woutersen.

Apologies

Apologies for absence were noted from Sandro Grilli.

EFSA

Hugues Kenigswald, Kim Petersen, Stavroula Tasiopoulou and Majlinda Lahaniatis (scientific staff) – Anna Campanini (administrative staff).

European Commission

Apologies for absence were noted from Marina Marini and Olga Solomon.

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. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

4. MATTERS ARISING FROM THE 10th PLENARY MEETING HELD ON 22-24 SEPTEMBER 2009

The Secretariat had received comments that were inserted in the minutes. 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/ans090922-m.pdf

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

5.1 EFSA

The Panel was informed on three on-going public calls for scientific data:

"Call for scientific data on food additives permitted in the EU and belonging to the functional classes of preservatives and antioxidants"

"Call for scientific data on miscellaneous waxes permitted as food additives in the EU"

"Call for scientific data on food additives permitted in the EU and belonging to the functional classes of emulsifiers, stabilisers and gelling agents"

The public calls for scientific data were published on the EFSA website on 23 November 2009. The purpose is to offer interested parties the opportunity to submit any available documented information, published or unpublished, relevant to the functional groups listed above in order to support the re-evaluation of the corresponding food additives. These submissions will be done in a 2-

step process. The deadline for accomplishing the first step of registration of the contact details of the interested party and description of the information available is 23 February 2010.

A meeting between EFSA and WHO/JECFA has been held on 26 October 2009 to discuss the cooperation and exchange of information between the two organisations.

The Panel Members were also informed of the outcome of a meeting between EFSA and FDA on 5 November 2009.

The Panel was informed that the ANS Unit next year, in addition to the senior scientific officer (toxicology) who is expected to join the team in the 1st quarter of 2010, will recruit two additional scientific officers.

Finally, an updated format of the EFSA scientific outputs has been circulated in October and all the opinions published thereof should be formatted in accordance. An abstract of the opinion should also preferably be included.

5.2 Commission

A brief update on the status of nutrient sources for fortified food and food supplements was made based on the information provided by M. Marini.

5.3 Chair

The Chair informed the participants on the ongoing activities of the EFSA Scientific Committee discussed:

- The Scientific Committee discussed the use of predictive technology in risk assessment, and current and future working groups activities on 90-day feeding studies, nanotechnology, genotoxicity testing strategies and harmonisation of risk assessment terminology.
- EFSA will be organising a Workshop on “Systematic Review and Risk Assessment in food and feed safety”, which will take place in EFSA on 23, 24 and 25 February 2010. 4 Panel Members will participate to this workshop.
- A draft proposal for update on rules and procedures for the establishment and operation of the Scientific Committee and Panels and of their working group was presented.
- A meeting of the Chairs and Secretariats of the EU Commission and Agency Scientific Committees and Panels involved in risk assessment will be held in November and the following issues will be discussed: emerging risks, risk assessment terminology, uncertainty, etc.

– The first meeting of the working group on genotoxicity testing strategy was postponed and will take place in January 2010.

– A new working group on emerging risk will be established

6. REPORT FROM THE WORKING GROUPS

A brief summary of the present status of the work done by Working Groups A and B on food Additives and Nutrient Sources of the ANS Panel was presented by the Chairs.

7. FOOD ADDITIVES

7.1 Resorcinol (EFSA-Q-2006-123)

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

The Panel established an ADI of 0.12 mg resorcinol/kg bw/day based on the application of an uncertainty factor of 300 to the adjusted NOAEL of 36 mg/kg bw/day for acute neurological effects in a carcinogenicity study in rats. The conservative estimates of acute consumption of shrimps would indicate that dietary exposure to resorcinol for adults and for children would exceed the ADI when the residual concentration of resorcinol in whole raw shrimps is above 35 mg/kg. The Panel notes that this value is only applicable if other uses of resorcinol are excluded.

The Panel noted that the proposed uses for resorcinol are for all crustaceans but that only experimental data on shrimps have been reported. The current evaluation is therefore related only to the use of resorcinol on raw shrimps and dietary exposure should be re-estimated if new usages are introduced

7.2 Natamycin (EFSA-Q-2006-009)

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

The Panel considered that the available data are not sufficiently robust for the purpose of deriving an ADI because of the limitations of the database on natamycin in terms of the age and design of the animal studies, the limited number of animals used, the lack of a carcinogenicity study and the

inadequate description of the human data.

However, given that natamycin is very poorly absorbed, the Panel considers that the conservative exposure estimates would provide an adequate margin of safety from the effect level seen from the long-term studies in animals and the human study used by JECFA to establish an ADI. The Panel considered that the proposed use levels of natamycin are not of safety concern if it is only used for the surface treatment of the rind of semi-hard and semi-soft cheese and on the casings of certain sausages.

The Panel concluded that there was no concern for the induction of antimicrobial resistance.

7.3 Modified acacia gum (EFSA-Q-2008-002)

The draft opinion was discussed. The proposed changes to the text were noted and the opinion was sent back to the working group for further elaboration.

7.4 Polyglycitol syrup (EFSA-Q-2007-072)

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

The Panel considered that the chemical and toxicological data available on polyglycitol syrup were insufficient to establish an ADI, but based on the available data concludes that there was no indication of a safety concern for the proposed uses and use levels of polyglycitol syrup. The Panel considered that conservative estimates of the exposure to polyglycitol syrup, for consumers only and the general population, arising from the proposed uses and use-levels, are close to, and for children even higher than, doses associated with gastric disturbances when administered as bolus doses in human trials and as reported in recent case reports.

7.5 Basic methacrylate copolymer (EFSA-Q-2009-00452)

The draft opinion was discussed. The proposed changes to the text and need for additional information was noted and the revised opinion will be re-discussed in a forthcoming plenary meeting.

7.6 Calcium lignosulfonate (EFSA-Q-2009-00374)

Due to lack of time this item was not discussed.

7.7 Steviol glycosides (EFSA-Q-2007-071, EFSA-Q-2008-387, EFSA-Q-2008-401)

A preliminary discussion took place on the approach proposed by the working group for the structure of the draft opinion.

7.8 Lycopene (EFSA-Q-2009-00820)

Due to lack of time this item was not discussed.

8. NUTRIENT SOURCES

8.1 Ferric sodium EDTA (EFSA-Q-2007-016)

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

The Panel concluded that iron is bioavailable from ferric sodium EDTA.

The Panel also concluded that the use of ferric sodium EDTA as a source of iron in food is of no safety concern as long as it does not lead to an exposure to EDTA above 1.9 mg EDTA/kg bw/day.

The Panel further concluded that ferric sodium EDTA as a source of iron at the proposed use level in fortified food for the general population would not be of safety concern.

Finally the Panel noted that when ferric sodium EDTA is used in PARNUTS or food supplements at levels which provide 22.3 mg iron/day for an adult and 11.1 mg iron/day for a child, the corresponding exposure to EDTA would be 1.9 mg EDTA/kg bw/day for adults and 3.9 mg/kg bw/day for children.

8.2 Heme iron (blood peptonates) (EFSA-Q-2009-375)

Due to lack of time this item was not discussed.

9. ANY OTHER BUSINESS

A few matters regarding the organisation of the work in 2010 were discussed.

The organisation of the work for the preparation of the new guidance document for food additive

applications was discussed. The Chair will write to the Executive Director of EFSA to propose a self-mandate for the preparation of the guidance document. A working group was created and the Chair of the Panel officially nominated I. Rietjens as Chair of this working group. I. Rietjens accepted the nomination and D. Gott was appointed as rapporteur.

10. NEXT MEETINGS

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

9 - 11 February 2010
13 - 15 April 2010
8 – 10 June 2010
6 - 8 July 2010
5 - 7 October 2010
7 - 9 December 2010