

Parma, 22 June 2010  
EFSA/ANS/P\_M14/MIN-1-4957008

**MINUTES OF THE 14<sup>th</sup> PLENARY MEETING  
OF THE SCIENTIFIC PANEL ON  
FOOD ADDITIVES AND NUTRIENT SOURCES  
ADDED TO FOOD (ANS)**

**Held in Parma on 13-15 April 2010**

**Adopted on 22 June 2010 at the 15<sup>th</sup> Plenary meeting**

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**PARTICIPANTS**

Panel Members:

Fernando Aguilar, Birgit Dusemund, Pierre Galtier, David Gott (1<sup>st</sup> and 2<sup>nd</sup> day), Sandro Grilli, 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 (2<sup>nd</sup> and 3<sup>rd</sup> day).

Apologies

Apologies for absence were noted from John Gilbert.

EFSA

Hugues Kenigswald, Ana Maria Rincon, Kim Petersen, Stavroula Tasiopoulou, Majlinda Lahaniatis, Anastasia Kesisoglou (1<sup>st</sup> day), Joanne Gartlon (1<sup>st</sup> day) (scientific staff) and – Anna Campanini, Maria Correia (administrative staff).

European Commission

Wim Debeuckelaere 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. 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. ADOPTION OF THE MINUTES OF THE 13TH ANS PLENARY MEETING ON 9-11 MARCH 2010**

The participants were asked to confirm the minutes of the 13<sup>th</sup> Plenary meeting of the ANS Panel. The draft minutes were discussed and adopted. The adopted draft minutes will be made available on the EFSA public web site: <http://www.efsa.europa.eu/en/events/event/ans100309-m.pdf>

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

#### **5.1. Chair**

The Chair informed the Panel that no meetings of the Scientific Committee have taken place since the last ANS Plenary meeting. In addition, the Chair informed that the EFSA Executive Director has accepted the self-task mandate for guidelines on submission for food additives evaluations.

#### **5.2. EFSA**

A few matters regarding the organisation of the work were briefly discussed.

#### **5.3. Commission**

Josiane Houins-Roulet, who replaces Marina Marini in her coordination role between the Panel and DG SANCO, was introduced to the Panel members. She will attend the Panel meetings in the future.

Commission Regulation 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives has been published. The regulation has been circulated to the Panel.

### **6. INFORMATION SESSION ON THE OPINIONS OF THE SCIENTIFIC COMMITTEE ON TRANSPARENCY**

Djien Liem, Head of the Scientific Committee and Advisory Forum Unit, informed the participants that EFSA has published two guidance documents related to transparency, one in 2006 related to

process transparency and another in 2009 related to science transparency issues. The recent publication and its main conclusions were presented. The publication is available on the EFSA website:

<http://www.efsa.europa.eu/en/scdocs/scdoc/1051.htm>

In addition, the participants were informed about recent activities of the Scientific Committee and Advisory Unit.

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

The Chair of the Working Group A reported on the outcome of the 14<sup>th</sup> meeting of this Group.

No meeting of the Working Group B has taken place since the last Plenary.

## **8. FOOD ADDITIVES**

### **8.1. Re-evaluation of food additives**

The draft strategy of the Panel for the re-evaluation of the food additives was discussed. The proposed changes to the text were noted and the strategy was adopted. It can be found as an Annex to the minutes of this meeting.

### **8.2. Amaranth (E 123)**

*(Question N°EFSA-Q-2008-227)*

The Rapporteur introduced the draft opinion. Proposed revisions based on the comments provided by the Panel members were noted. Subject to these revisions the draft opinion will be scheduled for discussion in a forthcoming meeting of the Working Group on Amaranth.

### **8.3. Litholrubine (E 180)**

*(Question N° EFSA-Q-2008-257)*

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

Litholrubine BK (E180) is a red mono-azo dye that has been previously evaluated by the JECFA and the SCF. JECFA was unable to establish an ADI, considering that there were limited histopathological examinations in two long-term studies in mice and rats that did not allow an unequivocal no-effect level to be determined. The SCF established an ADI of 0-1.5 mg/kg bw/day.

The Panel concluded that the basis for the establishment of the existing SCF ADI of 0-1.5 mg/kg bw/day based on a reported NOAEL of 150 mg/kg bw/day identified in a long-term rat study is unclear.

The Panel was unable to identify a suitable NOAEL, LOAEL or BMD to establish an ADI and concluded that the existing SCF ADI of 0-1.5 mg/kg bw/day should be withdrawn.

The Panel noted that the highest anticipated exposure to Litholrubine BK is 1700-fold lower than the identified effect level of 100 mg/kg bw/day in female rats. Therefore, the Panel considers that it is unlikely there would be a significant safety concern for humans from the current single authorised use of Litholrubine BK in edible cheese rinds.

The Panel further noted that the specifications for Litholrubine BK need to be updated with respect to the percentage of material not accounted for that may represent calcium chloride and/or calcium sulphate as the principal uncoloured components.

The Panel notes that the JECFA specification for lead is < 2 mg/kg, whereas the EC specification is < 10 mg/kg.

#### **8.4. Allyl isothiocyanate**

*(Question N°EFSA-Q-2009-00377)*

The Rapporteur introduced the document, as well as the main issues to be discussed. A preliminary discussion took place. The draft opinion will be revised by the working group.

#### **8.5. Erythrosine**

*(Question N°EFSA-Q-2008-229)*

Due to lack of time this item was not discussed.

#### **8.6. Green S**

*(Question N°EFSA-Q-2008-236)*

The Rapporteur introduced the draft opinion. Proposed revisions based on the comments provided by the Panel members were noted. Subject to these revisions the draft opinion will be scheduled for discussion in a forthcoming Plenary meeting.

## **8.7. Curcumin**

*(Question N° EFSA-Q-2008-220)*

Due to lack of time this item was not discussed.

## **9. NUTRIENT SOURCES**

### **9.1. Heme Iron (blood peptonates)**

*(Question N° EFSA-Q-2009-00375)*

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

The Panel concluded that iron from heme iron (blood peptonates) is bioavailable and absorbed to a significantly higher extent than iron from non-heme sources. The bioavailability of iron from heme iron sources may be 2- to 7-fold higher than that of iron from non-heme sources.

The Panel concluded that the available data are insufficient to demonstrate the safety of the proposed use and use levels of heme iron (blood peptonates) as a source of iron for nutritional purposes in foods intended for the general population, including food supplements.

### **9.2. Ferrous ammonium phosphate**

*(Question N° EFSA-Q-2009-00590)*

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

The Panel noted that the bioavailability of iron from ferrous ammonium phosphate (FAP) is comparable to that from the other iron salts and specifically, less than that from ferrous sulphate and greater than that from ferric pyrophosphate.

The Panel noted that FAP dissociates at low pH to its respective ferrous, ammonium and phosphate ions. Given the previous evaluations of ferrous, ammonium and phosphate salts as food additives and as nutrient sources, and that the available information on their toxicity did not identify toxicological effects, the Panel considers that additional toxicological data on FAP are not required.

The Panel noted that, at the proposed use levels, the corresponding exposure to iron from FAP does not exceed the guidance value for supplemental intake of iron of 17 mg/day recommended by the

EVM. Likewise, the corresponding exposure to phosphorus from FAP does not exceed the ULs defined by the IOM and the ammonia exposure is negligible compared to its endogenous production level.

Therefore the Panel concluded that the use of FAP as a source of iron in PARNUTS and in foods intended for the general population (including food supplements), at the proposed use levels, is not of safety concern provided that established upper safety limits for iron are not exceeded.

## **10. ANY OTHER BUSINESS**

The Panel was informed that a working group of the Scientific Committee on statistical methods will be established. F. Aguilar volunteered to participate in this group. I. Rietjens volunteered to participate in the working group of the Scientific Committee on terminology in Risk Assessment.

The Panel agreed to create three new working groups. The three working groups will be respectively devoted to chemistry and specifications, exposure assessment, and toxicology. The Chair of the Panel designated:

- For the working group on chemistry and specifications: J. Gilbert as Chair and P. Tobback as Vice-Chair
- For the working group on exposure assessment: J.-C. Leblanc as Chair and J. König as Vice-Chair
- For the working group on toxicology: I. Pratt as Chair and R. Woutersen as Vice-Chair.

## **NEXT MEETINGS**

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

22 - 24 June 2010

6 - 8 July 2010

5 - 7 October 2010

7 - 9 December 2010

## **Strategy of the ANS Panel for the re-evaluation of food additives**

Adopted on 13 April 2010

### **a. Objectives**

The objectives of the present strategy for the re-evaluation of permitted food additives are the following:

- To re-evaluate the additives in accordance with the Regulation 257/2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives
- To re-evaluate the additives per group according to the main functional class to which they belong, in order to ensure, as far as possible, consistency within a group.
- To re-evaluate the additives according to currently applicable risk assessment practice.

### **b. Procedure**

The re-evaluation procedure comprises the following steps:

1. Public call for data. The timetable for data submission in the call for data should allow the interested business operator and/or any other interested party to meet this duty.
2. Preparation of pre-evaluation documents for a given group of food additives
3. Appointment of the rapporteur when the pre-evaluation document for a food additive is ready.
4. Preparation of a draft opinion including the identification of any data gaps.
5. Discussion of the draft opinion with the working group and/or the Panel. The working group and/or the Panel will decide on the need to request additional data.
6. If necessary, call for specific additional data. The request will specify the data required and the deadline for their supply.
7. Preparation of the final opinion taking into account the data available including, if applicable, the additional data submitted after the call for specific additional data.

The Panel will conclude the opinion on the basis of the data available at the time of the discussion. Where a significant concern related to the safety is identified from available information, or when the database is considered insufficient to support the safety, the Panel may withdraw the ADI.

### **c. Criteria for scheduling the evaluation among a functional class of additives**

1. The priorities set in Regulation 257/2010 setting up the re-evaluation programme
2. The existence of new scientific evidence or technical information made available since the last evaluation which may affect the assessment of the safety of a food additive;
3. The time since the last evaluation of a food additive by the SCF or by EFSA;
4. The case where for a food additive an Acceptable Daily Intake (ADI) could not be established or a temporary ADI was established by the SCF or the basis for the ADI established by the SCF was unclear.