

# Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS)

## Minutes of the 63<sup>rd</sup> Plenary meeting

Held on 8-10 March 2016, Parma (Italy)

(Agreed on 26 April 2016)

### Participants

#### a) Panel Members

Fernando Aguilar,<sup>1</sup> Riccardo Crebelli,<sup>2</sup> Alessandro Di Domenico, Birgit Dusemund, Maria José Frutos, Pierre Galtier, David Gott, Ursula Gundert-Remy, Claude Lambré, Jean-Charles Leblanc, Oliver Lindtner, Peter Moldeus,<sup>3</sup> Alicja Mortensen, Pasquale Mosesso, Agneta Oskarsson,<sup>1</sup> Dominique Parent-Massin, Ivan Stankovic, Ine Waalkens-Berendsen, Rudolf Antonius Woutersen, Matthew Wright, Maged Younes

#### b) Hearing experts<sup>4</sup>

Paul Tobback<sup>5</sup>

#### c) European Commission:

- Wim Debeuckelaere (DG SANTE E2)

#### d) EFSA:

- Food Ingredients and Packaging (FIP) Unit: Dario Battacchi, Anna Christodoulidou, Paolo Colombo, Juho Lemmetyinen, Federica Lodi, Ana Maria Rincon, Claudia Roncancio Peña, Camilla Smeraldi, Alexandra Tard, Stavroula Tasiopoulou

### 1. Welcome and apologies for absence

The Chair welcomed all participants.

In the partial absence of the Chair, Alicja Mortensen, the Vice-Chair Claude Lambré was requested to chair the meeting (agenda items 6.3, 6.7 and 6.8).

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<sup>1</sup> Participated on 8 PM, 9 and 10 March 2016

<sup>2</sup> Participated via teleconference

<sup>3</sup> Participated on 8 and 9 March 2016

<sup>4</sup> As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>5</sup> Participated via teleconference on 9 PM March 2016 (agenda item 6.8)

## 2. Adoption of agenda

The agenda was adopted without any changes.

## 3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>6</sup> and the Decision of the Executive Director on Declarations of Interest,<sup>7</sup> EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the Scientific Panel Members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

## 4. Agreement of the minutes of the 62<sup>nd</sup> Plenary meeting held on 26-28 January 2016, Parma (Italy)

The minutes of the 62<sup>nd</sup> Plenary meeting held on 26-28 January 2016 were agreed.<sup>8</sup>

## 5. Report on the written procedures since 62<sup>nd</sup> Plenary meeting

No scientific outputs were adopted by written procedure since the last plenary meeting.

## 6. Scientific outputs submitted for discussion and possible adoption

### 6.1 Re-evaluation of E 210 Benzoic acid ([EFSA-Q-2011-00001](#)), E 211 Sodium benzoate ([EFSA-Q-2011-00002](#)), E 212 Potassium benzoate ([EFSA-Q-2011-00003](#)) and E 213 Calcium benzoate ([EFSA-Q-2011-00004](#))

The rapporteur introduced the draft opinion on the safety assessment of benzoic acid (E 210) and benzoates (E 211-213) to the members of the ANS Panel and presented the main points for discussion. The ANS Panel discussed the different parts of the risk assessment and adopted the opinion subject to incorporation of changes as suggested during the meeting.

The full opinion is available on the [Authority's webpage](#).

### 6.2 Re-evaluation of E220 Sulphur dioxide ([EFSA-Q-2011-00445](#)), E221 Sodium sulphite ([EFSA-Q-2011-00446](#)), E222 Sodium bisulphite ([EFSA-Q-2011-00447](#)), E223 Sodium metabisulphite ([EFSA-Q-2011-00448](#)), E224 Potassium metabisulphite ([EFSA-Q-2011-00449](#)), E226 Calcium sulphite ([EFSA-Q-2011-00450](#)), E227 Calcium bisulphite ([EFSA-Q-2011-00451](#)), E228 Potassium bisulphite ([EFSA-Q-2011-00452](#))

The rapporteur introduced the draft opinion on the safety assessment of sulphur dioxide (E 220) and sulphites (E 221-224, 226-228) to the members of the ANS Panel and presented the main points for discussion. The ANS Panel discussed the different parts of the risk assessment and adopted the opinion subject to incorporation of changes as suggested during the meeting.

<sup>6</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>7</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>8</sup> <https://www.efsa.europa.eu/en/events/event/160126>

The full opinion is available on the [Authority's webpage](#).

**6.3 Request for EFSA opinion regarding a proposed extension of use of E 160a carotenes in dietary foods for young children for special medical purposes ([EFSA-Q-2015-00136](#))**

The rapporteur introduced the draft opinion on the safety of the proposed extension of use of carotenes (E 160a) in food for special medical purposes (FSMP) to the members of the ANS Panel and presented the main points for discussion. The ANS Panel discussed the different parts of the opinion and adopted it subject to incorporation of changes as suggested during the meeting.

The full opinion is available on the [Authority's webpage](#).

**6.4 Request for EFSA opinion regarding a proposed extension of use of E 950 acesulfame K in dietary foods for young children for special medical purposes ([EFSA-Q-2015-00134](#))**

The rapporteur introduced the draft opinion on the safety of the proposed extension of use of acesulfame K (E 950) in food for special medical purposes (FSMP) to the members of the ANS Panel and presented the main points for discussion. The ANS Panel discussed the different parts of the opinion and adopted it subject to incorporation of changes as suggested during the meeting.

The full opinion is available on the [Authority's webpage](#).

**6.5 Safety of the proposed amendment of the specifications for basic methacrylate copolymer (E 1205) as a food additive ([EFSA-Q-2015-00223](#))**

This item was not discussed because of lack of time.

**6.6 Re-evaluation of E 416 Karaya gum ([EFSA-Q-2011-00515](#))**

This item was not discussed because of lack of time.

**6.7 Safety of potassium polyaspartate (A-5D K/SD) for use as a stabiliser in wine ([EFSA-Q-2015-00222](#))**

The rapporteur introduced the draft opinion on the safety of the proposed use of potassium polyaspartate (A-5D K/SD) as a stabiliser in the wine to the members of the ANS Panel and presented the main points for discussion. The ANS Panel discussed the different parts of the opinion and adopted it subject to incorporation of changes as suggested during the meeting.

The full opinion is available on the [Authority's webpage](#).

The Panel acknowledged that it was the first case of a dossier for a new food additive being submitted and evaluated according to the current 'Guidance for submission for food additive evaluations' (EFSA, 2012).<sup>9</sup> A more general discussion was held about the use of *in vitro* models, particularly Caco-2 cells, for the evaluation of absorption in Tier 1 testing. Considering the whole body of evidence generated within Tier 1, and the physicochemical characteristics of potassium polyaspartate, the Panel deemed that this was sufficient in this specific case. The Panel reiterated the need for case-by-case

<sup>9</sup> [http://www.efsa.europa.eu/sites/default/files/scientific\\_output/files/main\\_documents/2760.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2760.pdf)

evaluation in the design and interpretation of toxicokinetic studies, as already foreseen by the existing guidance.

**6.8 Safety of organic silicon (monomethylsilanetriol, MMST) as a novel food ingredient for use as a source of silicon in food supplements (EFSA-Q-2013-00874)**

The rapporteur introduced the draft opinion on the safety of the novel food ingredient monomethylsilanetriol (MMST) to the members of the ANS Panel and presented the main points for discussion. The ANS Panel discussed the different parts of the opinion and adopted it subject to incorporation of changes as suggested during the meeting.

The full opinion is available on the [Authority's webpage](#).

The Panel expressed concerns that the current guidance (SCF, 2001)<sup>10</sup> on requirements for bioavailability data of nutrient sources does not require adequate comparison of internal doses of nutrients from different sources. The Panel considered that to decrease this uncertainty this should be addressed in the forthcoming revision of the nutrient sources guidance.

**6.9 Re-evaluation of E 160b Annatto, bixin, norbixin (EFSA-Q-2011-00362) (EFSA-Q-2008-395)**

This item was not discussed because of lack of time.

**6.10 Re-evaluation of E 444 Sucrose acetate isobutyrate (EFSA-Q-2011-00530)**

This item was not discussed because of lack of time.

## **7. New Mandates**

The update on mandates is deferred to the next Plenary meeting.

## **8. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission**

### **8.1 Scientific Committee and Scientific Panel including their Working Groups**

None.

#### **8.1.1. ANS SWG Re-evaluation of Starches, Celluloses and Pectins**

#### **8.1.2. ANS SWG Re-evaluation of Gums and Food Additives from natural sources**

#### **8.1.3. ANS SWG on Applications**

<sup>10</sup> [http://ec.europa.eu/food/fs/sc/scf/out100\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out100_en.pdf)

#### **8.1.4. ANS SWG Re-evaluation of Food Additives other than Gums & Colours**

#### **8.1.5 ANS SWG of Nitrates and Nitrites**

#### **8.1.6 ANS SWG on Exposure Assessment**

The agenda items 8.1 were not discussed because of lack of time.

### **8.2 EFSA including its Working Groups /Task Forces**

#### **8.3 European Commission**

No specific topics were reported by the European Commission representative.

## **9. Other scientific topics for information and/or discussion**

### **9.1 Re-evaluation of E 410 Locust bean gum ([EFSA-Q-2011-00510](#))**

This item was not discussed because of lack of time.

### **9.2 Safety of Calcium Phosphoryl Oligosaccharide (POs-Ca®) added for nutritional purposes to foods, food supplements and foods for special medical purposes ([EFSA-Q-2015-00413](#))**

This item was not discussed because of lack of time.

### **9.3 Protocol for the systematic review of nitrosamines and nitrosamides**

The Panel discussed the draft protocol for a systematic review of the literature on the levels of nitrosamines and nitrosamides in food products found in the European market to which nitrates/nitrites have been added.

## **10. Any Other Business**

None.

## Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS)

## Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)

### JOINT SESSION

10 March 2016, Parma

#### Participants

- **ANS Panel Members:**

- Fernando Aguilar, Riccardo Crebelli,<sup>11</sup> Alessandro Di Domenico, Birgit Dusemund, Maria José Frutos, Pierre Galtier, David Gott, Ursula Gundert-Remy, Claude Lambré, Jean-Charles Leblanc, Peter Moldeus, Alicja Mortensen, Pasquale Mosesso, Agneta Oskarsson, Dominique Parent-Massin, Ivan Stankovic, Ine Waalkens-Berendsen, Rudolf Antonius Woutersen, Matthew Wright, Maged Younes

- **FEEDAP Panel Members:**

- Gabriele Aquilina, Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Georges Bories, Andrew Chesson, Pier Sandro Cocconcelli, Gerhard Flachowsky, Jürgen Gropp, Boris Kolar, Maryline Kouba, Secundino López Puente, Marta López-Alonso, Alberto Mantovani, Baltasar Mayo, Fernando Ramos, Guido Rychen, Maria Saarela, Roberto Edoardo Villa, Robert John Wallace and Pieter Wester.

- **Hearing Experts:**

- Not applicable

- **European Commission and/or Member States representatives:**

- Wim Debeuckelaere (DG SANTE E2)

- **EFSA:**

- **FEED Unit:** Manuela Tiramani, Jaume Galobart, Matteo Lorenzo Innocenti, Gloria López-Gálvez, Paola Manini and Maria Vittoria Vettori.
- **Food Ingredients and Packaging (FIP) Unit:** Dario Battacchi, Anna Christodoulidou, Paolo Colombo, Juho Lemmetyinen, Federica Lodi, Ana Maria Rincón, Claudia Roncancio Peña, Camilla Smeraldi, Alexandra Tard, Stavroula Tasiopoulou.

- **Others:**

- Not applicable

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<sup>11</sup> Via teleconference.

## **1. Welcome and apologies for absence**

The Chairs of the Panels welcomed all the participants to the joint session of the ANS and FEEDAP Panels. Apologies were received from Peter Moldeus (ANS Panel).

## **2. Adoption of the agenda**

The agenda was adopted without changes.

## **3. Introduction of Panel members**

The members of the two Panels briefly introduced themselves giving a short summary of their background and areas of expertise.

## **4. Legislative background and relevant guidance documents**

Members of the FIP and FEED units gave an overview of the legislative framework under which each Panel operates as well as of the different guidance documents.

## **5. Work plan and common areas of work**

The Chairs of the WGs, which share common areas between the two Panels, presented the workplan for the next years, with emphasis on those substances which will be assessed for both food and feed use.

## **6. Lessons learnt from the past**

Members of the FIP and FEED Units explained the past and current activities which are in place to address cross-cutting issues between the two Panels.

## **7. Open discussion: Future collaboration**

Some proposals to further strengthen cooperation between the two Panels were preliminarily discussed.

## **8. Any other business**

The chairs closed the meeting thanking all the participants for the interesting discussion and expressing the willingness to have another joint meeting in the future.