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

Minutes of the 58th Plenary meeting

Held on 8-10 September 2015, Parma (Italy)

(Agreed on 27 October 2015)

Participants

a) Panel Members

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

b) European Commission and/or Member States representatives:

- Andreia Alvarez Porto (DG SANTE E7)

c) EFSA:

- Food Ingredients and Packaging (FIP) Unit: Anna Christodoulidou, Paolo Colombo, 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.

Apologies were received from Agneta Oskarsson.
2. Adoption of agenda
The agenda was adopted without any changes.

3. Declarations of Interest of Scientific Committee/Scientific Panel/ Members
In accordance with EFSA’s Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, 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. For further details on the outcome of the screening of the ADoI or the SDIo, please refer to Annex. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 57th Plenary meeting held on 9-11 June 2015, Parma (Italy)
The minutes of the 57th Plenary meeting held on 9-11 June were agreed.⁴

Report on the written procedures since 57th Plenary meeting
No scientific outputs were adopted by written procedure since the last plenary meeting.

Scientific outputs submitted for discussion and possible adoption

6.1 Risk assessment for peri and postmenopausal women taking food supplements containing isolated isoflavones (EFSA-Q-2013-00916)
The rapporteur introduced to the members of the ANS Panel the draft opinion on the risk assessment of use of isolated isoflavones in food supplement for peri and postmenopausal women 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.

The rapporteur introduced the draft opinion on the safety assessment of tocopherol extracts (E 306-308) to the members of the ANS Panel and presented the main points for discussion.

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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.

The ANS Panel has decided to include the anticipated exposure in infants (4-11 months) in the standard exposure assessment for all the remaining food additives to be re-evaluated. In addition, since the current risk assessment approach does not apply to infants below 12 weeks of age, for those food additives authorised in specific food categories (i.e. 13.1.1 and 13.1.5 (13.1.5.1 and 13.1.5.2)) an ad hoc assessment will be defined and carried out separately. This will be specified under the “Interpretation of the terms of reference” until the guidance describing the approach will be available.

6.3 Safety of the change in the specifications of Steviol Glycosides (E 960) as a food additive (EFSA-Q-2014-00002)

The draft opinion was presented by the rapporteur to the members of the ANS Panel. The need for further clarifications before finalisation was noted. Final discussion and adoption of the opinion are deferred to an upcoming plenary meeting.

6.4 Re-evaluation of E 242 Dimethyl dicarbonate (EFSA-Q-2011-00459)

This topic was not discussed because of lack of time.

6.5 Re-evaluation of E 311 Octyl gallate, Octyl ester of gallic acid; n-octyl ester of 3,4,5-trihydroxybenzoic acid (EFSA-Q-2011-00480)

The rapporteur introduced the draft opinion on the safety assessment of octyl gallate (E 311) to the members of the ANS Panel and presented the main points for discussion.

A few clarification sentences have been added with respect to the recently adopted opinion on dodecyl gallate (E 312). The conclusion of the re-evaluation of octyl gallate (E 311) as a food additive based on the toxicological database and intake calculation was the same as for the already re-evaluated dodecyl gallate (E 312) as food additive. The Panel stated that the estimated exposure to octyl gallate from the single use and use level reported would unlikely be of safety concern on a consideration of the threshold of toxicological concern (TTC) and the fact that the single use (chewing gum) reported was the only in use.

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.

6.6 Safety of the extension of use of thaumatin (E 957) as a food additive (EFSA-Q-2015-00117)

This topic was not discussed because of lack of time.
6.7 Re-evaluation of E 304(i) Ascorbyl palmitate; L-ascorbyl palmitate; 2,3-didehydro-L-threo-hexono-1,4-lactone-6-palmitate; 6-palmitoyl-3-keto-L-gulofuranolactone (EFSA-Q-2011-00473), E 304(ii) Ascorbyl stearate; L-ascorbyl stearate; 2,3-didehydro-L-threo-hexono-1,4-lactone-6-stearate; 6-stearoyl-3-keto-L-gulofuranolactone (EFSA-Q-2011-00474)

This topic was not discussed because of lack of time.

6.8 Re-evaluation of E 120 Cochineal, carminic acid, carmines (EFSA-Q-2011-00360)

The rapporteur introduced some points for discussion referring to the safety assessment of cochineal (E 120) to the members of the ANS Panel. Final discussion and adoption of the opinion are deferred to an upcoming plenary meeting.

7. New Mandates

7.1 New mandates received since the previous meeting

EFSA staff informed the members of the ANS Panel on new mandates that have been received since last Plenary meeting:

<table>
<thead>
<tr>
<th>EFSA-Q-Number</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFSA-Q-2015-00413</td>
<td>Commission request for EFSA’s scientific opinion on Calcium Phosphoryl Oligosaccharide (POs-Ca®) added for nutritional purposes to foods, food supplements and foods for special medical purposes</td>
</tr>
<tr>
<td>EFSA-Q-2015-00460</td>
<td>Commission request for EFSA’s scientific opinion on the safety in use of Trimagnesium dicitrate anhydrous (TMDC) as a food additive’</td>
</tr>
<tr>
<td>EFSA-Q-2015-00461</td>
<td>Commission request for EFSA’s scientific opinion regarding a proposed amendment of the specifications of the food additive Monosodium phosphate (E 339 i)</td>
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7.2 Valid applications since the previous meeting

Application considered suitable for the start of the assessment:

<table>
<thead>
<tr>
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<th>Valid on</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFSA-Q-2015-00413</td>
<td>Calcium Phosphoryl Oligosaccharide (POs-Ca®) added for nutritional purposes to foods, food supplements and foods for special medical purposes</td>
<td>27/08/2015</td>
</tr>
</tbody>
</table>
Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

8.1 Scientific Committee and Scientific Panel including their Working Groups

A Panel member reported on the progress made by the Scientific Committee concerning the uncertainty in the scientific assessment process. A public consultation is envisaged during the year and training sessions for experts will follow.

The representative of the ANS Panel at the Scientific Committee briefly reported on the different working groups. It was mentioned that a new Working Group will be established to address the European Commission request to consider the safety for use of food additives in food and food supplements destined for infants and young children.

8.1.1. ANS SWG on Applications

8.1.2 ANS WG Isoflavones

8.1.3 ANS SWG Re-evaluation of Food Colours

8.1.4 ANS SWG Re-evaluation of Gums and Food Additives from Natural Sources

8.1.5 ANS SWG Re-evaluation of Nitrates – Nitrites

8.1.6 ANS SWG Re-evaluation of Food Additives other than Gums & Colours

The Chairs of the aforementioned Working Groups updated the Panel members on the progress made and on the next steps.

In addition, the Chair of the Working Group Applications informed the Panel members that in order to update the guidance for the nutrient sources the establishment of an ad hoc Working Group would be envisaged.

8.2 EFSA including its Working Groups /Task Forces

None

8.3 European Commission

The European Commission representative reported about:

- The discussion held at the last Member States working group meeting, in relation to the work programme and deadlines proposed by EFSA for the evaluation of food additives used in food destined to infants and young children

- The follow-up actions to EFSA scientific opinions recently adopted concerning the extension of use of selected food additives (state of play at the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF))
Discussion is ongoing at the Commission level based on these assessments under the re-evaluation program.

- A Workshop on Regulatory challenges on innovation in food organized by the Commission will be held in Ispra (Italy) on 8-9 October 2015. Major focus on future policy-making to enable food business operators developing innovative products.

- A Workshop on the use of nitrites (E249-250) by the industry was held in Brussels on 8 September 2015 with the main aim of reviewing the results of the survey about the use of nitrites in different categories of meat products, to discuss the formation of nitrosamines (especially in situ) and also possible alternatives to the use of nitrites and/or possible levels reduction.

8. Other scientific topics for information and/or discussion

9.1 Extension of use of E 950 acesulfame K in dietary foods for young children for special medical purposes (EFSA-Q-2015-00134)

9.2 Extension of use of E 955 sucralose in dietary foods for young children for special medical purposes (EFSA-Q-2015-00135)

These topics were not discussed because of lack of time.

9. Any Other Business

The Panel experts were informed that the date for the ANS Panel meeting open to external observers in 2016 was confirmed (27-29 September).

A new Working Group will be established in the last quarter of the year to provide further support in drafting scientific opinions for food additives with legal deadline December 2016. The Working Group will be tasked to work on starches, celluloses and pectins.

In order to provide the specific expertise across different Working Groups and Panels (ANS and CEF (Food Contact Materials, Enzymes, Flavourings and Processing Aids)) for the assessment of exposure it is also proposed to establish a new Working Group able to advise in relation to outstanding exposure issues arising during the preparation of EFSA scientific outputs and to provide guidance and establish/update the exposure assessment methodologies to be applied.