

**MINUTES OF THE 32nd PLENARY MEETING
OF THE SCIENTIFIC PANEL ON
FOOD ADDITIVES AND NUTRIENT SOURCES
ADDED TO FOOD (ANS)**

Held in Parma on 5-7 June 2012

Adopted on 2 July 2012 at the 33rd Plenary meeting

AGENDA:

1.	<i>Welcome; apologies for absence.....</i>	3
2.	<i>Adoption of the agenda.....</i>	3
3.	<i>Declarations of interest.....</i>	3
4.	<i>Adoption of the Minutes of the 31st ANS Plenary Meeting on 17-19 April 2012.....</i>	4
5.	<i>General information from EFSA, the European Commission and the Chair</i>	4
5.1.	<i>Chair</i>	4
5.2.	<i>EFSA.....</i>	4
5.3.	<i>European Commission</i>	4
6.	<i>Report from the Working Groups.....</i>	5
6.1.	<i>Working Group A on Food Additives and Nutrient Sources</i>	5
6.2.	<i>Working Group B on Food Additives and Nutrient Sources</i>	5
6.3.	<i>Working Group “Exposure assessment”</i>	5
6.4.	<i>Working Group “Chemistry and specifications”</i>	5
6.5.	<i>Working Group “Aspartame”</i>	5

6.6.	Working Group “Guidance on Food Additives”	5
7.	Food Additives	5
7.1.	Aspartame (E 951) (Question N° EFSA-Q-2011-00406)	5
7.2.	Statement on the safety assessment of the exposure to butylated hydroxyanisole (E 320) (BHA) by applying a new exposure assessment methodology (Question N° EFSA-Q-2012-00434)	5
7.3.	Shellac (E 904) (Question N° EFSA-Q-2011-00705)	6
7.4.	Guidance on submission for food additive evaluation by the Panel (Question N° EFSA-Q-2010-00675)	6
7.5.	Patent Blue V (E 131) (Question N° EFSA-Q-2011-00359)	6
7.6.	Carnauba wax (E 903) (Question N° EFSA-Q-2011-00008)	6
7.7.	Candelilla wax (E 902) (Question N° EFSA-Q-2011-00704)	6
7.8.	Borates (E 284-285) (Questions N° EFSA-Q-2011-00468; EFSA-Q-2011-00469)	6
8.	Nutrient sources	7
8.1.	Chromium(III) lactate trihydrate (Question N° EFSA-Q-2011-00043)	7
9.	Any other business	7
	Next meetings	7

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Held in Parma on 5-7 June 2012

Panel Members:

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

Apologies

Apologies for absence were noted from John Gilbert, David Gott and Jean-Charles Leblanc.

EFSA

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

European Commission

Josiane Houins-Roulet (1st and 2nd day by teleconference)

1. WELCOME; APOLOGIES FOR ABSENCE

The Chair welcomed the participants. Apologies for absence were noted.

Claudia Heppner, the new HoU of the FIP unit, introduced herself to 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 31ST ANS PLENARY MEETING ON 17-19 APRIL 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

A. Mortensen informed the Panel that she had participated in the SC plenary meeting and reported on the main outcomes.

The Panel was informed that the SC is organising a working group on emerging risks and another on nanotechnology to deal with the new EC definition on nanomaterials. Some ANS Panel members can participate in these working groups.

D. Gott has presented the guidance document at the Scientific Committee plenary meeting (21-22 May) highlighting the actions taken to address the key issues raised previously in a letter by the SC Chair, Vittorio Silano.

5.2. EFSA

The Panel was informed that for the two new applications for food additives mentioned in the 31st ANS Panel meeting, a letter concluding that data provided in the application dossier were not suitable to perform the safety assessment has been sent to the European Commission. The letters will be circulated to the Panel for information.

The Panel was informed about the start of the EFSA self-task for refined exposure assessment for the food colours already re-evaluated by the ANS Panel for which the opinion concluded that the exposure could exceed the ADI. A letter has been received from the European Commission specifying the priorities.

H. Kenigswald made a short presentation on the opinions by the FEEDAP Panel (2012) and the ANS Panel (2009) on Allura Red, highlighting the differences. The representative of the Commission indicated that a letter would be sent to EFSA on this issue.

H. Kenigswald informed the Panel that in line with the information that had been given during the April 2012 plenary meeting, the draft exposure assessment tool for food additives and its explanatory note will be circulated to the Commission and the Member States as well as to stakeholders in order to receive their feedback before finalising them.

5.3. European Commission

J. Houins-Roulet expressed the appreciation of the Commission regarding the good and impressive work done by EFSA with the support of the WG on Exposure with the preparation of the exposure assessment tool that will be made publicly available when it will be finalised. This draft tool will be presented to the Member States during a meeting that will take place on 18 June.

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 33rd Working Group A meeting held in Madrid, 29-31 May 2012.

6.2. Working Group B on Food Additives and Nutrient Sources

The Vice-Chair of Working Group B summarized the outcome of the discussions during the 23rd Working Group B meeting held in Parma, 22-24 May 2012.

6.3. Working Group “Exposure assessment”

The Vice-Chair of the Working Group on Exposure Assessment summarized the outcome of the discussions during the 17th Working Group EA meeting held in Milan, on 30 May 2012.

6.4. Working Group “Chemistry and specifications”

In the absence of the Chair of Working Group on Chemistry and Specifications, I. Stankovic summarised the outcome of the discussions during the 4th telemeeting held on 20 April 2012.

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 “Guidance on Food Additives”

No meeting of the working group has taken place since the last plenary meeting.

7. FOOD ADDITIVES

7.1. Aspartame (E 951) (*Question N° EFSA-Q-2011-00406*)

The draft opinion was discussed. Clarifications and improvements were suggested.

The Panel discussed the need to address more in details some issues concerning the degradation product diketopiperazine (DKP), mainly in relation to the calculation of the generation of DKP from aspartame, the content of DKP in food products and beverages, and the exposure of DKP from aspartame taking into account analytical and stability data. The Panel concluded that information on the food products in which DKP may be generated and the maximum levels present should be collected. EFSA will launch a public call for data to address this need.

7.2. Statement on the safety assessment of the exposure to butylated hydroxyanisole (E 320) (BHA) by applying a new exposure assessment methodology (*Question N° EFSA-Q-2012-00434*)

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

The Panel concluded that exposure to BHA from its use as food additive based on new exposure estimates using the EFSA Comprehensive Food Consumption Database does not exceed the ADI of 1 mg/kg bw/day for most groups of the population at the mean and generally does not exceed the ADI for adults at high level exposure (except Germany, where the ADI is exceeded by 12%).

The Panel noted that exposure to BHA from its use in food contact materials may contribute substantially to the total exposure to BHA and that combined exposure to BHA from its use as food additive in foods and additive to food contact material does exceed the ADI for most population groups on average and on high level consumption.

7.3. Shellac (E 904) (Question N° EFSA-Q-2011-00705)

The Panel discussed some proposals for toxicological studies received in response to the public call for data.

The Panel acknowledged that for technical reasons appropriate ADME studies are not currently possible for shellac.

Due to the technical limitations of bioanalytical methods, similar issues may arise for other complex additives and extracts from botanical sources. The issue of availability of valid bioanalytical methods should be considered by the Panel on a case by case basis.

In the absence of evidence on the actual absorption of shellac, the Panel concluded that the tests listed under the Tier 2 of the ANS Guidance on submission for food additives (adopted during this plenary meeting) would be necessary to support the safety assessment.

EFSA will communicate the outcome of the Panel discussion to the interested parties and will extend the call for data for some months in order to enable interested parties to confirm that they will commission the corresponding studies.

7.4. Guidance on submission for food additive evaluation by the Panel (Question N° EFSA-Q-2010-00675)

The Panel members discussed the remaining outstanding issues, as outlined by A. Kesisoglou. Final amendments were made and the guidance was adopted.

The technical report on the public consultation of the guidance document was also discussed and endorsed by the Panel members following minor editorial changes.

7.5. Patent Blue V (E 131) (Question N° EFSA-Q-2011-00359)

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

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

The item was not discussed due to lack of time.

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

The item was not discussed due to lack of time.

7.8. Borates (E 284-285) (Questions N° EFSA-Q-2011-00468; EFSA-Q-2011-00469)

The item was not discussed due to lack of time.

8. NUTRIENT SOURCES

8.1. Chromium(III) lactate trihydrate (*Question N° EFSA-Q-2011-00043*)

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

9. ANY OTHER BUSINESS

The meeting dates for the 2013 plenary meetings of the Panel will be discussed during the July plenary meeting based on proposals that will be circulated before.

NEXT MEETINGS

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

3 – 5 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 his ADOI/SDoI, Dr Riccardo Crebelli declared interest regarding to the agenda items «7.1. aspartame and 6.5 Working Group on Aspartame». The expert declared an interest for aspartame relate to the involvement in EFSA on aspartame (opinion of the former AFC Panel). This does not generate any potential conflict of interests with the discussion on aspartame.

In her ADOI/SDoI, Dr Birgit Dusemund declared interest regarding to the agenda items «7.8. Borates (E 284-285)». The expert declared an interest for borates that relates to past activity for her employer which is a FSO and no related activity is currently ongoing. Therefore, this does not generate any potential conflict of interests with the discussion on borates.

In her ADOI/SDoI, Dr Alicja Mortensen declared interest regarding to the agenda items «7.1. aspartame and 6.5 Working Group on Aspartame». The expert declared an interest for aspartame because it relates to past activity for her employer which is a FSO and no related activity is currently ongoing. Therefore, this does not generate any potential conflict of interests with the discussion on aspartame.

In her ADOI/SDoI, Dr D. Parent-Massin declared interest regarding to the agenda items «7.1. aspartame and 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 items «7.1. aspartame and 6.5 Working Group on Aspartame». ». 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 «7.1. aspartame and 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.