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

Minutes of the 82nd Plenary meeting

Held on 25-29 June 2018, Parma (Italy)

(Agreed on 16 July 2018)

Participants

- **Panel Members:**

Peter Aggett, Fernando Aguilar[1], Riccardo Crebelli[2], Birgit Dusemund, Metka Filipic, Maria José Frutos Fernandez, Pierre Galtier[3], David Gott, Ursula Gundert-Remy, Gunter Georg Kuhnle[4], Claude Lambré, Jean-Charles Leblanc, Inger Therese Lillegaard, Peter Moldeus[5], Alicja Mortensen, Agneta Oskarsson[4], Ivan Stankovic, Ine Waalkens-Berendsen, Ruud Woutersen, Matthew Wright[4] and Maged Younes

- **Hearing Experts:**

Patrizia Restani for agenda item 6.1.

- **European Commission representatives:**

DG SANTE (Health and Food Safety), E2 Food processing technologies and novel foods: Guillermo Cardon

- **EFSA:**

FIP Unit: Claudia Roncancio Peña, Eleonora Alquati, Anna Christodoulidou, Dimitrios Chrysafidis, Alessandra Giarola, Federica Lodi, Fabiola Pizzo, Ana Maria Rincon, Camilla Smeraldi, Alexandra Tard

COMCO Unit: Elzer Bernd
DATA: Zsuzsanna Horvath
NUTRI Unit: Andrea Germini

1. Welcome and apologies for absence

The Chair welcomed all participants to this last plenary meeting of the ANS Panel.

[1] Apologies on 25, 28 and 29 June 2018
[2] Apologies on 25 and 29 June 2018
[3] Apologies on 28 June 2018
[4] Apologies on 29 June 2018
[5] On the 28 June 2018 partial attendance in the morning

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[6] and the Decision of the Executive Director on Declarations of Interest[7], EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the 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 81st Plenary Open for Observers meeting held on 15-17 May 2018, Parma (Italy)

The minutes of the 81st Plenary Open for Observers meeting held on 15-17 May 2018 were agreed by written procedure on 7 June 2018[8].

5. Report on the written procedures since 81st 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. Scientific opinion on the safety of monacolins in red yeast rice (EFSA-Q-2017-00138)

Following a request from the European Commission (EC) to EFSA, the ANS Panel was asked to provide a scientific opinion on the safety of monacolins from red yeast rice (RYR). This risk assessment was carried out in the framework of the procedure under Article 8(2) of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods, for monacolins from RYR, initiated by the EC.

Further to the initial discussion at the previous plenary meeting, the draft opinion on the evaluation of the safety of monacolins in red yeast rice was discussed by the Panel.

The ANS Panel discussed the different parts of the assessment modified since the last plenary and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

6.2. Scientific opinion on the proposed amendment to the authorisation of ferric sodium EDTA as a novel food ingredient and evaluation of the proposed use of ferric sodium EDTA as a source of iron in foods for specific groups (EFSA-Q-2017-00696)

Following a request from the European Commission (EC) to EFSA, the ANS Panel was asked to provide a scientific opinion on the evaluation of proposed amendments to the existing specifications and conditions of use of ferric sodium EDTA of its proposed use as a source of iron in processed cereal-based foods and baby foods. The draft opinion on the evaluation on the proposed amendment to the authorisation

[6] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[7] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
[8] https://www.efsa.europa.eu/sites/default/files/event/180515-m.pdf

of novel food ingredient ferric sodium EDTA and its proposed use as a source of iron in foods for specific groups was presented to the ANS Panel for the first time.

The ANS Panel discussed the different parts of the assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

In performing this assessment, the Panel reviewed the toxicological database on the basis of which the currently applicable acceptable daily intake (ADI) for EDTA was set, based on the information provided by the applicant in the dossier supporting this application. The Panel noted that the current ADI for EDTA was calculated on the basis of the current ADI for calcium disodium EDTA (E 385), a permitted food additive in the EU, whose re-evaluation, as foreseen in Regulation (EC) No 257/2010, is still ongoing.

The current assessment highlighted certain shortcomings in the available toxicity database, in particular with respect to data on reproductive and developmental toxicity, which would need to be addressed prior to the re-evaluation of calcium di sodium EDTA (E 385) as a food additive.

In order to progress with the re-evaluation of this food additive EFSA will be launching soon a public call for data to gather available information from interested parties.

In the context of the current assessment, the Panel also held a more general reflection on the assessment of substances intentionally added to food (hence, these considerations were not limited to food additives) and containing essential nutrients (usually minerals) and on the need to develop toxicological nutritional risk assessments addressing chronic high dietary intakes. The Panel was of the opinion that this topic would possibly be of interest for the EFSA Scientific Committee.

6.3. Scientific opinion regarding four new studies on the potential toxicity of titanium dioxide used as a food additive (E171) (EFSA-Q-2018-00271)

Further to the initial discussion held at the last ANS Panel plenary meeting, the draft opinion on the evaluation of four studies published after the re-evaluation of titanium dioxide (E171) on the potential toxicity of titanium dioxide was discussed by the Panel for the first time.

Panel members were reminded of the background to this mandate from the EC, triggered by a note sent by France to the European Commission on 15 February 2018, and requesting the adoption of interim protective measures provided for by Article 53 of Regulation (EC) No 178/2002. In that note, France had mentioned as justification for this request, the four studies on the potential toxicity of titanium dioxide published after the adoption of the 2016 ANS Panel Opinion on the re-evaluation of titanium dioxide (E171) as a food additive[9].

The ANS Panel discussed the different parts of the assessment, which also takes into account the information exchanged with the authors of the four studies before and during the technical hearing held on 16 May 2018, and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion is available on the Authority's webpage[10].

[9] https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_toxic_20180417_sum.pdf
[10] http://www.efsa.europa.eu/en/efsajournal/pub/5366

The Panel expressed its gratitude to the authors of the four studies for the availability and cooperation demonstrated during this assessment.

In addition to the assessment of the four studies included in the mandate received by the EC, the ANS Panel also took the opportunity for discussing two additional studies on titanium dioxide nanoparticles (Rompelberg et al., 2016; Heringa et al., 2018) related to the publication by Heringa et al. (2016) which had been provided by the National Institute for Public Health and the Environment (RIVM) during the re-evaluation of titanium dioxide (E 171) as a food additive in 2016 (EFSA ANS Panel, 2016). At the time, the three studies (Heringa et al., 2016; Rompelberg et al., 2016; Heringa et al. 2018, referenced in the 2016 scientific opinion as 'Documentation provided to EFSA No 11, 17 and 18') were still unpublished and therefore not described in the scientific opinion. However, these studies were evaluated along with the whole dataset and taken into account during the assessment. The Panel recommended that, once the final manuscripts were publicly available, further considerations by the Panel on these RIVM studies would be performed.

The results of these publications were also presented by one of the authors (Dr Oomen) during the ANS Open Plenary meeting (16 May 2018)[11].

The Heringa et al. (2016) study has been evaluated under the latest mandate received from the European Commission (22 March 2018) and included in the scientific opinion adopted at the current plenary meeting.

In the study by Rompelberg et al. (2016), the oral intake of TiO_2 and its NPs from food, food supplements and toothpaste in the Dutch population (aged 2 to over 70 years) was estimated by combining data on food consumption and supplement intake. For children (2–6 years), additional intake via ingestion of toothpaste was estimated. The Panel noted that the estimated intake of TiO_2 from the Rompelberg et al. (2016) study is lower than the estimated exposure calculated by EFSA for TiO_2 (E 171), which is most probably due to the different concentration levels of TiO_2 assumed in food products. In addition, the food categories considered in both the exposure assessments were different. With respect to the calculation of exposure to TiO_2 nanoparticles, it was noted that the ANS Panel considered that 3.2% (by mass) of the TiO_2 (E 171) were nanoparticles, according to information provided by industry (EFSA ANS Panel, 2016), whereas in the Rompelberg et al. (2016) study the percentage of nanoparticles in TiO_2 was considered to be 0.31% (by mass).

In the Heringa et al. (2018) study, post-mortem samples were analysed and the concentration of titanium and titanium dioxide particles were measured. This latest manuscript was not yet available at the time of the EFSA assessment in 2016, since the validation of the analytical method was still ongoing.

The total amount of titanium and the amount of TiO_2 particles were measured in 15 post-mortem samples (liver and spleen) of humans (6 men and 9 women who died at the age of 56 to 104 years), by inductively coupled plasma high-resolution mass spectrometry and single particle inductively coupled plasma high-resolution mass spectrometry, respectively. In addition to these techniques, electron microscopy was used to characterise the particles. TiO_2 particles were above detection limit in 7 of the 15 liver samples and in 13 of the 15 spleen samples. The concentrations of total titanium varied from 0.02 to 0.09 mg/kg tissue for liver, and from 0.02 to 0.4 mg/kg tissue for spleen. The authors considered that, on average, 51% and 67% of total titanium was present as TiO_2 particles in the liver and the spleen, respectively. The dimensions of the detected TiO_2 particles (including aggregates and agglomerates) were in the range of 85 nm (the LOD) to 720 nm.

[11] https://www.efsa.europa.eu/en/events/event/180515

The Panel noted that no information on the history of the donors (e.g. medical/occupational/environmental exposure) of the post-mortem samples was provided. The authors made the assumption that most of titanium and TiO_2 particles detected came from the oral exposure, with inhalation or dermal routes of exposure very limited or null.

The Panel further noted that TiO_2 is produced industrially in large quantities and that, in addition to its use as a food additive, it has many non-food applications (e.g. in paints, plastics, cosmetics, toothpaste, drugs excipients). The Panel, therefore, considered that the sources of the TiO_2 particles detected in the post-mortem samples of liver and spleen cannot be traced. Additionally, the Panel noted that TiO_2 was not detected in post-mortem samples (4) of subjects aged below approximately 79 year-old. In this respect, the Panel considered that there may be alternative explanations for this difference between samples from older and younger subjects such as the fact that the elderly may take more medicines that can contain TiO_2 as an excipient.

Considering the limitation of the study concerning the human donors (i.e. no data on exposure nor exposure route), the Panel considered that although TiO_2 particles may be accumulated in the liver and spleen, the relevance of this observation cannot be assessed for the risk assessment of titanium dioxide (E 171) as a food additive.

Overall, the Panel concluded that the results of these three studies do not change the conclusions of the existing opinion of EFSA (2016) related to the safety of titanium dioxide (E 171) as a food additive.

6.4. Re-evaluation of the safety of silicates (E 552-553a,b) as food additives (EFSA-Q-2011-00679; EFSA-Q-2011-00680; EFSA-Q-2011-00681; EFSA-Q-2011-00682)

The ANS Panel was presented for the first time with a draft scientific opinion on the re-evaluation of the already permitted food additives calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) together with the main points for discussion.

The ANS Panel discussed the different parts of the assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

6.5. Re-evaluation of the safety of glycerol esters of wood rosin (E 445) as food additive (EFSA-Q-2011-00531)

The ANS Panel was presented for the first time with a draft scientific opinion on the re-evaluation of the already permitted food additive glycerol esters of wood rosin (E 445) together with the main points for discussion.

The ANS Panel discussed the different parts of the assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

6.6. Re-evaluation of the safety of propane-1,2-diol alginate (E 405) as food additive (EFSA-Q-2011-00506)

The ANS Panel was presented for the first time with a draft scientific opinion on the re-evaluation of the already permitted food additive propane-1,2-diol alginate (E 405) together with the main points for discussion.

The ANS Panel discussed the different parts of the assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

6.7. Refined exposure assessment of extracts of rosemary (E392) (EFSA-Q-2013-00691)

The ANS Panel was presented for the first time with a draft scientific opinion on the refined exposure assessment of the permitted food additive extracts of rosemary (E 392) together with the main points for discussion.

The ANS Panel discussed the refined exposure assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

6.8. Re-evaluation of the safety of ferrocyanides (E 535-536; 538) as food additives (EFSA-Q-2011-00676; EFSA-Q-2011-00677; EFSA-Q-2011-00678)

The ANS Panel was presented for the first time with a draft scientific opinion on the re-evaluation of the already permitted food additives sodium ferrocyanide (E 535), potassium ferrocyanide (E 536) and calcium ferrocyanide (E 558) together with the main points for discussion.

The ANS Panel discussed the different parts of the assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

6.9. Re-evaluation of the safety of aluminium sulphates (E 520-523) and sodium aluminium phosphate acidic (E 541) as food additives (EFSA-Q-2013-00697)

The ANS Panel was presented for the first time with a draft scientific opinion on the re-evaluation of the already permitted food additives aluminium sulphate (E 520), aluminium sodium sulphate (E 521), aluminium potassium sulphate (E 522), aluminium ammonium sulphate (E 523) and sodium aluminium phosphate acidic (E 541) together with the main points for discussion.

The ANS Panel discussed the different parts of the assessment and unanimously adopted the opinion, subject to incorporation of changes as suggested during the meeting.

The full opinion will be available on the Authority's webpage.

After the completion of the ongoing assessment of aluminium silicates (E 554-555), the last two remaining aluminium-containing food additives to be re-evaluated in the frame of Regulation 257/2010, EFSA should produce a report summarising the overall intake of aluminium resulting from the permitted uses of food additives containing this element.

The Panel was of the view that any future update of the risk assessment for aluminium should be performed using a holistic approach and covering all sources of exposure.

7. New Mandates

7.1. New questions since the previous meeting

The following new mandates have been received since the last Plenary meeting, still under consideration:

Food Sector	EFSA-Q-Number	Subject	Reception date
ADD	EFSA-Q-2018-00415	Request for the EFSA to perform a risk assessment and to provide a scientific opinion on the safety of a proposed amendment of the specifications of the food additive Lecithins (E 322) and a proposed use in Cocoa and Chocolate products	17/05/2018

7.2. Valid questions since the previous meeting

The following questions have been considered valid for the start of the assessment since the last Plenary meeting:

Food Sector	EFSA-Q-Number	Subject	Valid on
ADD	EFSA-Q-2018-00242	Request for EFSA to perform a risk assessment and to provide a scientific opinion on the safety of a proposed amendment of the specifications of the food additive Steviol glycosides (E 960)	23/05/2018
ADD	EFSA-Q-2018-00119	Request for an opinion from the European Food Safety Authority (EFSA) as regards the safety of ethyl lauroyl arginate (E 243) as a food additive in the light of the new information provided and the proposed extension of use	12/06/2018

These questions will be assigned to the new FAF Panel.

7.3. Withdrawn questions since the previous meeting

No applications have been withdrawn since the last ANS Plenary meeting.

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

8.1. Scientific Panel(s) including their Working Groups

This item was not discussed due to lack of time.

8.2. EFSA including its Working Groups /Task Forces

The Chairs of the ANS Panel Working Groups and EFSA scientific secretariat provided feedback from their latest meetings. With the end of the term of office of the current ANS Panel, its WGs will be closed and new ones will be created under the new Food Additives and Flavourings (FAF) Panel.

8.2.1. ANS Panel SWG Applications

The Chair of the Working Group provided an overview of the ongoing assessments that will need to be handed over to a new WG to be established under the new FAF Panel.

The following draft opinions on the evaluation of nutrient sources, currently on hold pending receipt of additional information, will be handed over to the NDA Panel for finalisation:

- Scientific opinion on selenium triglycerides (EFSA-Q-2015-00343)
- Scientific opinion on Inositol-Stabilized Arginine Silicate (EFSA-Q-2017-00071)

8.2.2. Re-evaluation of Gums and Food Additives from Natural Sources 2017-2018

The mandate of this Working Group has been accomplished, with the exception of the draft opinion on the re-evaluation of shellac (E 904), which was put on hold pending receipt of additional information. The drafting of this opinion will be handed over to one of the WGs that will be established under the new FAF Panel for finalisation.

8.2.3. ANS Panel SWG on the Re-evaluation of Food Additives other than Gums and Colours

The Chair of the Working Group provided an overview of the ongoing assessments that will need to be handed over to a new WG to be established under the new FAF Panel.

8.2.4. Re-evaluation of other Miscellaneous Food Additives with 2018 deadline

The Chair of the Working Group provided an overview of the ongoing assessments that will need to be handed over to a new WG to be established under the new FAF Panel.

8.2.5. ANS Panel ad hoc WG on the Re-evaluation of Phosphates

The Chair provided an overview of the preliminary assessment performed by the Working Group. A presentation on the draft opinion will be given to the inaugural plenary meeting of the new FAF Panel.

8.2.6. ANS Panel SWG Procedures under Article 8 of Regulation (EC) No 1925/2006

The mandate of this Working Group has been accomplished. Future assessments to be performed under Article 8 of Regulation (EC) No 1925/2006 will be assigned to the NDA Panel.

8.2.7. ANS Panel WG Exposure Assessment

EFSA staff presented an overview of the activities performed by this Working Group.

8.2.8. ANS SWG on Re-evaluation of Food Colours

With the adoption of the opinion on titanium dioxide (see agenda item 6.3), the mandate of this Working Group has been accomplished.

8.2.9. Re-evaluation of food additives for use in foods for infants below 16 weeks of age

The Chair provided an overview of the preliminary assessment performed by the Working Group which will lead to the publication of several specific calls for data. In addition the Panel was informed that the follow-up of silicon dioxide (E 551) and acacia gum (E 414) will also be covered by this Working Group.

8.3.European Commission

This item was not discussed due to lack of time.

9. Other scientific topics for information and/or discussion

10. Any Other Business

Feedback received from Observers at the 81st ANS Plenary meeting – Open for Observers – 16-17 May 2018.