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

Minutes of the 70th Plenary meeting

Held on 24-26 January 2017, Parma (Italy)

(Agreed on 7 February 2017)

Participants

a) Panel Members

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

b) European Commission and/or Member States representatives:

Guillermo Cardon (DG SANTE E2)

c) EFSA:

- FIP (Food Ingredients and Packaging) Unit: Anna Christodoulidou, Federica Lodi, Adamantia Papaioannou, Fabiola Pizzo, 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 Riccardo Crebelli.

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[4] and the Decision of the Executive Director on Declarations of Interest,[5] 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

[1] Participated physically on 25-26 January 2017
[2] Participated physically on 24-25 January 2017
[3] Participated via web-conference on 24-26 January 2017
[4] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[5] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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 69th Plenary meeting held on 05-08 December 2016, Parma (Italy)

The minutes of the 69th Plenary meeting held on 05-08 December 2016 were agreed by written procedure on 03 January 2017.[6]

5. Report on the written procedures since 69th 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 potassium nitrite (E 249) and sodium nitrite (E 250) (EFSA-Q-2011-00460) (EFSA-Q-2011-00461)

This topic was not discussed, since the changes suggested by the Panel for the revision to the draft opinion on the safety of nitrates (E 251-252) (see 5.2) did not require further changes to the scientific opinion on the safety of nitrites (E 249-250). As previously agreed, the draft scientific opinion will be shared with the EFSA CONTAM (Contaminants in the Food Chain) Panel and the EFSA Scientific Committee to gather comments in cross-sectional issues advance to the next meeting. Final discussion and adoption by the ANS Panel are deferred to an upcoming ANS Plenary meeting.

6.2 Re-evaluation of sodium nitrate (E 251) and potassium nitrate (E 252) (EFSA-Q-2011-00462) (EFSA-Q-2011-00463)

Further to the discussion at the previous plenary meeting, a revised section on discussion, conclusions and recommendations of the draft opinion on the safety of nitrates (E 251-252) was presented to the members of the ANS Panel. The opinion will be revised taking into account the changes suggested during the current meeting and, as previously agreed, it will be shared with the EFSA CONTAM Panel and the Scientific Committee to gather comments in cross-sectional issues advance to the next meeting. Final discussion and adoption by the ANS Panel are deferred to an upcoming ANS Plenary meeting.

6.3 Proposed amendment of the specifications of the food additive microcrystalline cellulose (E 460(i)) (EFSA-Q-2016-00199)

The draft opinion on the safety evaluation of proposed changes to the specifications of the authorised food additive microcrystalline cellulose (E 460(i)) was presented to the members of the ANS Panel together with 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 will be available on the Authority's webpage.

6.4 Re-evaluation of glycerol (E 422) (EFSA-Q-2011-00519)

The draft opinion on the re-evaluation of the safety of glycerol (E 422) was presented to the members of the ANS Panel together with 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 will be available on the Authority's webpage.

[6] http://www.efsa.europa.eu/sites/default/files/event/161205-m.pdf

6.5 Re-evaluation of E 426 soybean hemicellulose (EFSA-Q-2011-00521)

The draft opinion on the re-evaluation of the safety of soybean hemicellulose (E 426) was presented to the members of the ANS Panel together with 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 will be available on the Authority's webpage.

6.6 Re-evaluation of E 322 lecithins (EFSA-Q-2011-00500)

The main points for discussion on the identity of the substance, exposure assessment, and biological and toxicological data on the re-evaluation of the safety of lecithins (E 322) were presented to the members of the ANS Panel, together with the overall conclusions and recommendations.

Final discussion and possible adoption of the scientific opinion are deferred to the next ANS Panel Plenary meeting.

7. New Mandates

The Secretariat informed the members of the ANS Panel that since the last plenary meeting, the following mandates were received by EFSA and allocated to the ANS Panel.

- M-2016-0247: Request for EFSA to perform a risk assessment and to provide a scientific opinion on the safety in use of low-substituted hydroxypropyl cellulose (L-HPC)
- M-2017-0005: Request for EFSA to perform a risk assessment and to provide a scientific opinion on the safety in use of curdlan as a food additive (EFSA-Q-2017-00024)

The two mandates are currently under consideration by the Application Desk (APDESK) Unit of EFSA.

The Secretariat also informed the members of the ANS Panel about the following application, considered valid since the previous meeting:

- M-2016-0214: Request for EFSA's scientific opinion as regards a proposed amendment of the specifications of the food additive Steviol glycosides (E 960) (EFSA-Q-2016-00689)

The ANS SWG on Applications has been tasked with the drafting of the scientific opinion.

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

8.1 Scientific Committee and Scientific Panels including their Working Groups

8.1.1 EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel)

The Secretariat updated the Panel on the new Guidance Document on the characterisation of microbial strains and feed additives obtained by them, currently being developed by the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) with the participation of relevant experts from the EFSA Panel on Food Contact Materials, Enzymes,

Flavourings and Processing Aids (CEF Panel), EFSA Panel on Genetically Modified Organisms (GMO Panel) and ANS Panel and their Working groups. It was explained that this new guidance will cover products consisting on non-genetically modified (non-GM) microorganisms (e.g. probiotics) and products obtained by fermentation of microorganisms (both genetically modified and non-GM). The document will cover the characterisation of the strain and of those aspects of the product linked to the production strain, but will not cover the safety of the product as such. With respect to fermentation products obtained from GM production strains, the guidance will provide indications on the methodologies to detect the possible presence of recombinant DNA from the production strains, which are the criteria to decide whether a product is considered a genetically modified organism. It is anticipated that the guidance will impact on the characterisation of different types of regulated products, and for what concerns the remit of the ANS Panel, it may have an impact on the characterisation of new food additives made with GM microorganisms. Therefore, the different Panels concerned will be requested to endorse the corresponding section of the document regarding the detection of recombinant DNA in products. To this end, the Panel will be given an opportunity to comment on the draft document prior to its release for public consultation, and was encouraged to provide feedback to the particular section of the document to be endorsed. The Panel suggested that this guidance document should also take into consideration its compatibility with the current Guidance for submission for food additive evaluations, adopted by the ANS Panel in 2012.

8.1.2 ANS SWG on Procedures under Article 8 of Regulation (EC) No 1925/2006

The Chair of the ANS Panel appointed Pierre Galtier as vice-chair of the newly established Standing Working Group on Procedures under Article 8 of Regulation (EC) No 1925/2006.

8.2 EFSA including its Working Groups /Task Forces

None

8.3 European Commission

None

9. Other scientific topics for information and/or discussion

9.1 Guidance on safety evaluation of sources of nutrients or other ingredients and bioavailability of nutrient or other ingredient from the sources (EFSA-Q-2016-00150)

The Panel received a presentation on the guidance document that is currently being developed as a self-task mandate, in order to define the data required for the assessment of the safety of substances proposed for use as sources of nutrients (and of other ingredients) and for the assessment of bioavailability of the nutrients (or other ingredients) from the sources. The guidance that is currently being developed is aimed at updating a pre-existing guidance issued by the Scientific Committee on Food (SCF) in 2001 by making reference to available, updated applicable guidance documents, such as the one on the safety evaluation of food additives adopted by the ANS Panel in 2012 and the recently published guidance on Novel Foods adopted by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) in 2016. The proposed step-wise approach for demonstrating bioavailability of a nutrient from a source was presented to the Panel members to gather their feedback. Overall the Panel agreed with the approach devised in the draft guidance document. Feedback will also be gathered from the NDA Panel at

its coming plenary meeting, prior to the finalisation of the draft guidance by the Working Group.

The draft scientific opinion will be presented to one of the upcoming Plenary meetings, for possible endorsement, prior to its release for public consultation.

10. Any Other Business

The panel members were informed that the calendar of open plenary meetings had been published on the EFSA website and that according to it the ANS Panel will be holding its open plenary meeting in November 2017 and not in February, as previously announced.