SCIENTIFIC PANEL ON FOOD ADDITIVES AND FLAVOURINGS (FAF)

MINUTES OF THE 9TH PLENARY MEETING

Held on 24-26 September 2019, Parma

(Agreed on 16 October 2019)

Participants

- Panel Members:

  Gabriele Aquilina, Laurence Castle, Karl-Heinz Engel, Maria José Frutos Fernandez, Peter Fürst, Rainer Gürtler Ursula Gundert-Remy, Trine Husøy, Wim Mennes, Peter Moldeus, Agneta Oskarsson, Romina Shah, Ine Waalkens-Berendsen, Detlef Wölfle and Maged Younes

- Hearing Experts:

  Jean-Charles Leblanc and Oliver Lindtner have participated via web-conference on 25th September 2019, in agenda point 6.5

- European Commission and/or Member States representatives:

  DG SANTE (Health and Food Safety), E2 Food processing technologies and novel foods: Guillermo Cardon and Miguel-Angel Granero Rosell (via web-conference)

- EFSA:

  FIP Unit: Claudia Roncancio Peña, Stefania Barmaz, Maria Carfi, Esraa Elewa, Brian Flynn, Alessandra Giarola, Federica Lodi, Carla Martino, Ana Maria Rincon, Camilla Smeraldi, Alexandra Tard and Giorgia Vianello

  DATA Unit: Davide Arcella, Petra Gergelova and Francesca Riolo

  LA Unit: Simone Gabbi

1. Welcome and apologies for absence

The Chair welcomed the participants in the meeting. Apologies were received from Paul Fowler.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration(s) of Interest made at the beginning of the meeting, please refer to the Annex.

4. Agreement of the minutes of the 8th Plenary meeting held on 26-27 June 2019, Parma

The minutes of the 8th Plenary meeting held on 26-27 June 2019 were agreed by written procedure on 15 July 2019[3].

5. Report on written procedures since 6th Plenary meeting

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

6. Scientific topic(s) for discussion

FOOD ADDITIVES

6.1. Scientific opinion on the safety in use of Monk fruit extract/Luo han guo (LHG) extract as a food additive (EFSA-Q-2017-00527)

At the current meeting, the Panel discussed the different parts of the assessment on the safety of Monk fruit extract proposed as a new food additive.

On the basis of the comments received during the current plenary meeting the draft opinion will be further elaborated by the Working Group and will be tabled for possible adoption at a forthcoming Plenary meeting.

6.2. Scientific opinion on the safety of a proposed amendment of the specifications of the food additive Steviol glycosides (E 960) (EFSA-Q-2018-00242)

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

[3] https://www.efsa.europa.eu/sites/default/files/event/190626-m_0.pdf

The 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.

6.3. Re-evaluation of acetic acid, lactic acid, citric acid, tartaric acid, mono- and diacetyltartaric acid, mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acid (E472a-f) (EFSA-Q-2011-00558; EFSA-Q-2011-00559; EFSA-Q-2011-00560; EFSA-Q-2011-00561; EFSA-Q-2011-00562; EFSA-Q-2011-00563)

The FAF Panel was presented for the first time with a draft scientific opinion on the re-evaluation of acetic acid, lactic acid, citric acid, tartaric acid, mono- and diacetyltartaric acid, mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acid (E472a-f) as food additives.

At the current plenary meeting, the Panel discussed and endorsed the technical, biological and toxicological sections of the draft opinion and the exposure assessment. However, the Panel was informed that the draft opinion on the re-evaluation of tartaric acid and tartrates (E 334-337; E 354) is still under preparation, pending receipt of additional information that has been requested from interested parties. Because the two scientific opinions are closely related, the Panel considered appropriate to postpone the adoption of the scientific opinion on the re-evaluation of acetic acid, lactic acid, citric acid, tartaric acid, mono- and diacetyltartaric acid, mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acid (E 472a-f) as food additives until finalisation of the re-evaluation of tartaric acid and tartrates (E 334-337; E 354).

On the basis of the comments received during the current plenary meeting the draft opinion will be further elaborated by the Working Group and will be tabled for possible adoption at a forthcoming Plenary meeting.

6.4. Re-evaluation of sulphuric acid and sulphates (E 513-517) (EFSA-Q-2011-00662; EFSA-Q-2011-00663; EFSA-Q-2011-00664; EFSA-Q-2011-00665; EFSA-Q-2011-00666; EFSA-Q-2011-00667; EFSA-Q-2011-00668)

The 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. Draft protocol for exposure assessment for the re-evaluation of sweeteners: Sorbitols (E 420 i,ii); Mannitol (E 421 i, ii); Acesulfame K (E 950); Isomalt (E 953); Sucralose (E 955); Thaumatin (E 957); Neohesperidine DC (E 959); salt of aspartame-acesulfame (E 962); Lactitol (E 966); Xylitol (E 967); Erythritol (E 968); Cyclamates (E 952 i, ii, iii); Saccharin Na, Ca, K (E 954 i, ii, iii, iv); Neotame (E 961); Maltitol (E 965 i, ii) (EFSA-Q-2011-00644; EFSA-Q-2011-00645); (EFSA-Q-2011-00646; EFSA-Q-011-00647); (EFSA-Q-2011-00721); (EFSA-Q-2011-00723); (EFSA-Q-2011-00724); (EFSA-Q-2011-00725); (EFSA-Q-2011-00726); (EFSA-Q-2011-00727); (EFSA-Q-2011-00728); (EFSA-Q-2011-00729); (EFSA-Q-2011-00730); (EFSA-Q-2011-00733; EFSA-Q-2011-00734; EFSA-Q-2011-00735); (EFSA-Q-2011-00736; EFSA-Q-2011-00737; EFSA-Q-2011-00738; EFSA-Q-2011-00739); (EFSA-Q-2011-00740) (EFSA-Q-2011-00755; EFSA-Q-2017-00490)

Further to the discussion at the previous plenary meeting, the Panel discussed the proposed draft protocol to be applied to the re-evaluation of sweeteners in the context of Regulation (EC) No 257/2010. The protocol presented is aimed at describing in detail the methodology that will be applied to cover the exposure assessment.

At the current meeting, the Panel discussed the different sections of the draft protocol and unanimously endorsed the document, subject to incorporation of changes as suggested during the meeting.

The draft protocol will be released for public consultation on the Authority's webpage for a period of at least 6-8 weeks.

Steer from the Panel was sought with respect to exposure assessment to be performed for the re-evaluation of the food additive salt of aspartame-acesulfame (E 962). Since the exposure assessment will comprise total dietary exposure to the two moieties, aspartame and acesulfame, the Panel was consulted with respect to the data to be used to estimate total exposure to aspartame. It was acknowledged that an exposure assessment was already conducted for aspartame (E 951) in the context of its re-evaluation completed by the ANS Panel in 2013[4], however for the current re-evaluation of the salt of aspartame-acesulfame (E 962) the Panel was of the opinion that an updated dataset of occurrence level of aspartame (E 951) would be desirable in order to have a better estimate of total dietary exposure from both sweeteners (E 951, E 962). To this end, the Panel recommended the launch of a public call for concentration data (use and use levels) for aspartame (E 951) that could complement the data already received for the salt of aspartame acesulfame (E 962) in response to the previous call issued in 2018[5].

During the current plenary, the Panel also received an update on the other protocol on hazard identification and characterisation that had been subject to a public consultation phase. The Panel heard that the public consultation, launched on 5 July 2019 was extended until 19 September 2019. The Working Group is currently reviewing the comments received with the aim of consolidating a revised draft for possible discussion and agreement by the Panel at the coming meeting.

6.6. Scientific opinion on the follow-up from the re-evaluation of starch sodium octenyl succinate (E 1450) as a food additive, including use in foods for infants below 16 weeks of age (EFSA-Q-2018-00102)

Further to the discussion held at the 7th Plenary meeting in June 2019, a revised draft opinion has been elaborated by the Working Group and presented at the current meeting for possible adoption.

The 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. Re-evaluation of benzyl alcohol (E 1519) (EFSA-Q-2011-00590)

The 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.

[4] https://www.efsa.europa.eu/en/efsajournal/pub/3496
[5] http://www.efsa.europa.eu/en/consultations/call/180122

FLAVOURINGS

6.8. FGE.215 Rev1 – Subgroup 3.2 (EFSA-Q-2015-00180; EFSA-Q-2015-00181; EFSA-Q-2015-00182; EFSA-Q-2015-00183; EFSA-Q-2015-00184; EFSA-Q-2015-00185; EFSA-Q-2015-00186)

The 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.

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

7.1. Scientific Committee and Scientific Panel(s) including their Working Groups

The Chair of the Panel provided feedback from the latest meeting of the Scientific Committee, held on 12-13 September 2019, in particular on the draft guidance on aneugenicity assessment. The guidance, that should provide advice on the most appropriate *in vivo* follow-up for substances that are aneugenic *in vitro*, was presented for discussion at the last Scientific Committee plenary. After further elaboration by the SC WG on Genotoxicity, the draft guidance should be tabled for possible endorsement for public consultation at the December 2019 SC plenary. The Panel noted that finalisation of the guidance, which is extremely relevant for the finalisation of some of the outstanding flavourings evaluations, is expected by mid 2020.

In addition, the Panel was informed about an ongoing assessment of the FEEDAP Panel on botanically defined flavourings, including curcumin, for which advice has been sought from the SC WG on Genotoxicity. The Panel was reminded that curcumin (E 100) had been previously re-evaluated for use as a food colour by the former ANS Panel in 2010.

Feedback was also provided on the progress made by the Scientific Committee on the draft framework for protocol development for EFSA's non-application scientific assessments and on the guidance that is being prepared by the SC Working Group on appraisal and integration of evidence from epidemiological studies.

7.1.1. FAF WG Food Additives Applications

No additional issues were brought to the attention of the FAF Panel further to what is already recorded in the **minutes of the WG**.

7.1.2. FAF WG on the re-evaluation of miscellaneous food additives

No additional issues were brought to the attention of the FAF Panel further to what is already recorded in the **minutes of the WG**.

7.1.3. FAF WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age

No additional issues were brought to the attention of the FAF Panel further to what is already recorded in the **minutes of the WG**.

7.1.4. FAF WG on the re-evaluation of remaining food additives other than colours and sweeteners

No additional issues were brought to the attention of the FAF Panel further to what is already recorded in the **minutes of the WG**.

7.1.5. FAF WG on Sweeteners

No additional issues were brought to the attention of the FAF Panel further to what is already recorded in the **minutes of the WG**.

7.1.6. FAF WG on Flavourings

No additional issues were brought to the attention of the FAF Panel further to what is already recorded in the **minutes of the WG**.

7.1.7. FAF WG on Specifications of Food Additives

No additional issues were brought to the attention of the FAF Panel further to what is already recorded in the **minutes of the WG**.

7.2. EFSA including its Working Groups/Task Forces

7.2.1. Feedback from EFSA Assurance Working Group on Independence

A presentation was given to the Panel on the report on Independence related activities prepared by the Legal & Assurance Services (LA) Unit of EFSA covering the implementation of the policy on Declaration of Interests.

7.3. European Commission

The Panel was informed about an upcoming mandate from the European Commission, requesting EFSA to update and compile existing guidance applicable to the evaluation of new applications and the renewal of smoke flavourings primary products into a single comprehensive document. The updated guidance should take into account the applicable cross-sectional guidance documents issued by the EFSA Scientific Committee and the relevant updated version of the OECD Test Guidelines applicable to toxicological studies.

The Panel was of the opinion that, should this mandate be accepted by EFSA, a new WG of the Panel should be tasked with the preparation of this document and to this end the Chair of the Panel proposed Prof Karl Heinz Engel as possible Chair of this new Working Group.

8. New mandates

Food Additives

8.1. Request for EFSA's scientific opinion as regards a proposed amendment of the specifications of the food additive Steviol glycosides (E 960) - enzymatic conversion of highly purified rebaudioside A and/or stevioside from stevia leaf extract to minor glycosides that are present in the leaf, including rebaudioside AM

This new mandate (M-2019-0157) covers a request for assessment of an application for a proposed amendment of the specifications of the authorised food additive steviol glycosides (E 960) (EFSA-Q-2019-00499).

At the current plenary meeting the Panel was informed that the new application was still under consideration by the APDESK Unit. The Panel agreed that, in case the application is considered to be valid, the preparatory work for this assessment will be carried out by the existing WG Food additives applications.

Flavourings

8.2. New smoke flavouring primary product (Prosmoke BW 01) application for authorisation

This new mandate (M-2019-0145) covers a request for assessment of an application for a proposed amendment of the specifications of the authorised food additive steviol glycosides (E 960) (EFSA-Q-2019-00441).

At the current plenary meeting the Panel was informed that the new application was still under consideration by the APDESK Unit. The Panel agreed that, in case the application is considered to be valid, the preparatory work for this assessment will be carried out by the existing WG Flavourings.

9. Other scientific topics for information and/or discussion

No other scientific topics were presented for information and/or discussion.

10. Any Other Business

The Panel took note of a position paper sent by the European Flavour Association (EFFA) as a follow-up to the Technical meeting with stakeholders on applications for food enzymes organized by EFSA in June 2019.

Annex

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

With regard to this meeting, Dr Trine Husøy declared the following interest: current involvement in a grant application as project leader on the sweeteners, i.e. call funded by Nord Forsk (governmental organisation under the Nordic Council of Ministers). In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf