Scientific Panel on Food Additives and Flavourings (FAF)

Minutes of the 1st Plenary meeting

Held on 04-05 July 2018, Parma (Italy)

(Agreed on 24 July 2018)

Participants

- **Panel Members:**

Gabriele Aquilina, Laurence Castle, Maria José Frutos Fernandez, Fürst Peter, Ursula Gundert-Remy, Rainer Gürtler, Trine Husøy, Wim Mennes[1], Peter Moldeus, Agneta Oskarsson, Sandra Rainieri, Romina Shah, Ine Waalkens-Berendsen, Detlef Wölfle and Maged Younes

- **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

COM Unit: Bernd Elzer

1. Welcome and apologies for absence

Head of the FIP Unit welcomed the participants in the meeting.
Apologies were received from Karl-Heinz Engel and Paul Fowler for the whole meeting.

The Panel members were invited to give a short introduction to their scientific background and specific areas of expertise.

This followed by an introduction of the all the EFSA staff supporting the work of the Panel.

2. Election of Chair and Vice-Chairs of the Panel

The election took place following the procedure established by EFSA and under the supervision of Claudia Roncancio Peña (Head of FIP Unit).
Maged Younes was elected as Chair of the FAF Panel and Wim Mennes and Maria José Frutos Fernandez were elected as Vice-Chairs of the FAF Panel.

3. Adoption of agenda

The agenda was adopted without any changes.

[1] Apologies on 5 July 2018

4. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[2] and the Decision of the Executive Director on Declarations of Interest[3], EFSA screened the Annual 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.

5. Work-programme of the FAF Panel 2018-2021

A tentative work-programme of the FAF Panel for the period July 2018-June 2021 was presented.

5.1. Re-evaluation of food additives

EFSA staff presented an overview of the work-programme for the re-evaluation of food additives already permitted in the EU as of January 2009 (all falling under the EFSA Mandate number M-2011-0160), the different timelines foreseen in Regulation (EC) No 257/2010 for the completion of the programme and the applicable processes of public calls for the gathering of data for the assessment from the interested parties.

With reference to the tentative work-programme published at the beginning of this year[4], it was noted that the previous ANS Panel had managed to adopt 12 scientific opinions of the 22-26 provisionally scheduled for the current year. During the initial months of the new FAF Panel, the work should continue aimed at finalising the re-evaluation for the remaining food additives with deadline 2018 for which assessment had already started at the level of the Working Groups previously set under the former ANS Panel.

With the closure of the public call for technical and toxicological data on 30 June 2018, the work on the re-evaluation of sweeteners should also start, with the aim of finalising it by the end of 2020, as foreseen in Regulation (EC) No 257/2010. To this end the Panel agreed to set-up a small Working Group tasked with the development of a general strategy for the assessment of sweeteners and providing steer for the preparatory activities to be undertaken by the FIP Unit.

Panel members were also informed about the remaining substances with original deadline 31.12.2018 according to Regulation (EC) No 257/2010 for which work has not yet started and therefore are likely to require a renegotiation with the European Commission for their completion.

It was further explained to the Panel that based on the conclusions and recommendations contained in the scientific opinions issued by the Panel, the European Commission (EC) has set up a number of follow-up activities aimed at gathering the data identified as missing during the re-evaluation procedure. As some of these data are being generated by interested parties, it is anticipated that several mandates for the follow-up of scientific opinions will be received in the coming years, requesting assessment by the Panel.

[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
[4] http://www.efsa.europa.eu/sites/default/files/foodaddtentativewp18.pdf

Finally it was highlighted that some of these follow-up activities have also been delegated by the EC to EFSA, namely for those food additives (falling under EFSA Mandate M-2017-0220) that are still to be evaluated for their safety in use in foods for infants below 16 weeks of age.

5.2. Evaluation of food additives applications under Regulation (EC) No 1331/2008

EFSA staff presented an overview of the procedure and the scientific approach used for the evaluation of applications for food additives submitted under Regulation (EC) No 1331/2008, the stop-the-clock mechanism foreseen in the Regulation in order to comply with the 9-month timeframe for the assessment and of the currently ongoing dossiers.

5.3. Evaluation of flavourings according to Regulation (EC) No 1565/2000, Regulation (EC) No 872/2012, Regulation (EC) No 1334/2008 and Regulation (EC) No 1331/2008 and evaluation of smoke flavourings according to Regulation (EC) No 2065/2003

EFSA staff presented an overview of the procedure and the scientific approach used for the evaluation of flavourings according to the different Regulations and the status of the ongoing evaluations, together with a tentative timeplan for their completion.

Some scientific issues that have emerged during the evaluation of these substances were brought to the attention of the Panel, in particular the evaluation of mixtures of substances and the approach for the follow-up of substances showing in vitro aneugenicity.

For the latter, it was highlighted that this issue is possibly affecting a number of substances under evaluation, and is not limited to flavourings. The Panel was therefore of the opinion to bring this issue to the attention of the relevant WG of the scientific committee in order to have some steering with respect to the most appropriate testing strategy to be followed for those cases in which in vitro testing demonstrate an aneugenic mode of action.

With respect to the former, the Panel was informed about the ongoing public consultation on the draft statement "Genotoxicity assessment of chemical mixtures" launched by the EFSA's Scientific Committee. The Panel was invited to provide feedback to this statement and to the related draft guidance on harmonised methodologies for assessing combined exposure to multiple chemicals.[5]

6. Establishment of Working Groups of the FAF Panel

In accordance with the applicable procedure (EFSA SOP_006), the ongoing mandates handed over from the ANS and the CEF Panels to the new FAF Panel were verified, and the need for establishing Working Groups was identified by the Chair of the Panel in consultation with the Head of the FIP Unit.
As a general principle, it was agreed on the need to ensure some continuity between the work carried out by the Working Groups previously established under the ANS and CEF Panels, respectively, in particular for those scientific opinions that are expected to be completed by the end of the current year.

The ongoing mandates were allocated as follows to the newly established Working Groups of the FAF Panel:

[5] http://www.efsa.europa.eu/en/press/news/180626

- **WG on Flavourings (Multiple mandates)**
  - All flavourings to be evaluated according to Regulation (EC) No 1565/2000, Regulation (EC) No 872/2012, Regulation (EC) No 1334/2008 and Regulation (EC) No 1331/2008
- **WG Food Additives Applications (Multiple mandates)**
  - Steviol glycosides (E 960) (EFSA-Q-2016-00689)
  - Curdlan (EFSA-Q-2017-00024)
  - Monk fruit extract/Luo han guo (LHG) (EFSA-Q-2017-00527)
  - Ethyl lauroyl arginate (E 243) (EFSA-Q-2018-00119)
  - Steviol glycosides (E 960) (EFSA-Q-2018-00242)
- **WG on Phosphates (M-2011-00160)**
  - Re-evaluation of phosphoric acid, phosphates, di-, tri- and polyphosphates as food additives (E 338-341; E 343; E 450-452)
- **WG on the re-evaluation of remaining food additives other than colours and sweeteners (M-2011-00160)**
  - Tartaric acid and tartrates (E 334-337) [combined with new application EFSA-Q-2017-00827]
  - Acid esters of mono- and diglycerides of fatty acids (E 472a-f)
  - Propane-1,2-diol esters of fatty acids (E477)
  - Thermally oxidised soya bean oil interacted with mono- and diglicerides of fatty acids (E 479b)
  - Stearyl tartrate, Distearyl tartrate, Dipalmityl tartrate (E 483)
  - Aluminium silicates (E 554-E555)
  - Dimethyl polysiloxane (E900)
  - Quillaia extract (E 999) [combined with new application EFSA-Q-2014-00095]
- **WG on Miscellaneous (re-evaluation of miscellaneous food additives (M-2011-00160)**
  - Hydrochloric acid and chlorides (E 507-511)
  - Sulphuric acid and sulphates (E 513-517)
  - Shellac (E 904)
  - Hydrogenated poly-1-decene (E 907)
  - Polydextrose (E 1200)
  - Polyvinylpyrrolidone (E 1201)
  - Polyvinylpolypyrrolidone (E 1202)
  - Benzyl alcohol (E 1519)
- **WG on Sweeteners (M-2011-00160)**
  - Strategy for the re-evaluation of polyols [sorbitols (E 420); mannitols (E 421); isomalt (E 953); maltitols (E 965); lactitol (E 966); xylitol (E 967); erythritol (E 968)] and other sweeteners [acesulfame K (E 950); cyclamates (E 952); saccharins (E 954); sucralose (E 955); thaumatin (E 957); neohesperidine DC (E 959); neotame (E 961); salt of aspartame-acesulfame (E 962)]

- **WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age (M-2017-00220)**
    - Calcium carbonate (E 170)
    - Fatty acid esters of ascorbyl palmitate (E 304i)
    - Tocopherol-rich extract (E 306)
    - α-, β-, δ-tocopherol (E 307-309)
    - Lecithins (E 322)
    - Carrageenan (E 407)
    - Locust bean gum (E 410)
    - Guar gum (E 412)
    - Acacia gum (E 414)
    - Xanthan gum (E 415)
    - Pectins (E 440)
    - Carboxy methyl cellulose (E 466)
    - Mono-and diglycerides of fatty acids (E 471)
    - Sucrose esters of fatty acids (E 473)
    - Silicon dioxide (E 551)
    - Starch sodium octenyl succinate (E 1450)

6.1. Rules of procedure of Working Groups, Rapporteurs and EFSA Staff

A presentation was given by EFSA Staff to explain the rules of procedure of Working Groups, the roles of Rapporteurs and EFSA scientific officers supporting the different Working Groups.

6.2. Appointment of Chairs of the Working Groups

Following consultation between the Chair of the Panel and the FIP Head of Unit, the following Panel members were appointed as Chairs of the Working Groups:

- **WG on Flavourings:**
    - Wim Mennes
- **WG Food Additives Applications**
    - Laurence Castle
- **WG on Phosphates**
    - Ursula Gundert-Remy
- **WG on the re-evaluation of remaining food additives other than colours and sweeteners**
    - Peter Moldeus
- **WG on Miscellaneous (re-evaluation of miscellaneous food additives)**
    - Maria José Frutos Fernandez
- **WG on Sweeteners**
    - Maged Younes

- **WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age**
  - Ursula Gundert-Remy

7. Scientific outputs submitted for discussion and possible adoption

7.1. Re-evaluation of phosphoric acid, phosphates, di-, tri- and polyphosphates (E 338-341; E 343; E 450-452) (EFSA-Q-2011-00618; EFSA-Q-2011-00619; EFSA-Q-2011-00620; EFSA-Q-2011-00621; EFSA-Q-2011-00622; EFSA-Q-2011-00623; EFSA-Q-2011-00624; EFSA-Q-2011-00625; EFSA-Q-2011-00626; EFSA-Q-2011-00628; EFSA-Q-2011-00629; EFSA-Q-2011-00630; EFSA-Q-2011-00532; EFSA-Q-2011-00533; EFSA-Q-2011-00534; EFSA-Q-2011-00535; EFSA-Q-2011-00536; EFSA-Q-2011-00537; EFSA-Q-2011-00538; EFSA-Q-2011-00539; EFSA-Q-2011-00540; EFSA-Q-2011-00541; EFSA-Q-2011-00542; EFSA-Q-2011-00543)

The FAF Panel discussed the different parts of the preliminary assessment and the approach followed by the Working Group for developing the draft scientific opinion.

The Panel was further informed about the ongoing public consultation (closing date 13 July 2018) targeting health professionals in the fields of nephrology, mineral metabolism, cardiovascular and nutrition medicine and aimed at gathering their feedback on a number of questions on phosphates food additives re-evaluation which will help the Working Group in progressing with the assessment.

The scientific opinion will be further elaborated by the Working Group and an updated draft will be presented at the coming FAF Panel plenary meeting for discussion.

8. Other scientific topics for information and/or discussion

9. Any Other Business

The dates of the next plenary meetings will be agreed in writing among the Panel members.