FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD ADDITIVES AND FLAVOURINGS (FAF)

MINUTES OF THE 16TH PLENARY MEETING – Open for Observers

Held on 21-23 September 2020
Online meeting

14.00-18.00 on 21st September 2020 – Open session
09.00-13.00 on 22nd September 2020 – Open session
14.00-17.00 on 22nd September 2020 – Closed session
09:00-12.15 on 23rd September 2020 – Closed session

(Agreed by written procedure on 14 October 2020)

Participants

- Panel Members:

  Gabriele Aquilina, Laurence Castle, Karl-Heinz Engel, Maria José Frutos Fernandez, Peter Fürst, Ursula Gundert-Remy, Rainer Gürtler[1], Trine Husøy, Melania Manco, Wim Mennes, Peter Moldeus, Sabina Passamonti, Romina Shah[2], Dina (Ine) Waalkens-Berendsen, Detlef Wölfle, Matthew Wright and Maged Younes

- Hearing Experts:

  Ullrika Sahlin[3] participated in agenda point 6.1

- European Commission and/or Member States representatives:

  DG SANTE (Health and Food Safety), E2 Food processing technologies and novel foods: Guillermo Cardon, Miguel-Angel Granero Rosell, Milada Schulzova and Jiri Sochor

- EFSA:

  FIP Unit: Claudia Roncancio Peña, Stefania Barmaz, Ana Campos Fernandes, Maria Carfi, Consuelo Civitella, Esraa Elewa, Galvin Ndip Eyong, Alessandra Giarola, Federica Lodi, Carla Martino, Ana Maria Rincon, Camilla Smeraldi, Alexandra Tard and Giorgia Vianello

  COMMS Unit: Anthony Smith

[1] Apologies on 23rd September 2020
[2] Apologies on 22nd September AM and 23rd September 2020
[3] Attended on 21st September 2020

- Observers:

  Aya Ahmed (Start-up Company), Nicole Albrecht (Bell Flavors & Fragrances GmbH), Sharadha Arun (Reliance Industries Ltd), Michael Backes (Symrise AG), Zoltán Balázs (Leveret GmbH), Soraya Bellini (CIATI), Anne-Marie Boulanger (Bureau of Chemical Safety, Health Canada), F. Hanna Campbell (Epidaurus Telemedical), Jan Demyttenaere (EFFA - European Flavour Association), Candace Doepker (ToxStrategies, Inc), Allison Franzen (ToxStrategies), Stefanie Geiser (EAS Strategies), Nuri Gras (Subsecretaría de Agricultura, Ministerio de Agricultura de Chile), Alison Joy Hardinge (AJH Consulting), Joanna Jaskolska (International Sweeteners Association), Jens Karsten (CleanSmokeCoalition), Stefano Liparoto (Kerry Taste & Nutrition), Paul Loeven (Bureau of Chemical Safety, Health Canada), Alina-Roxana Mihai (J.S. Hamilton Romania), Mohamad Jaleel Mohamed Fari (Halal Accreditation Council), Severin Mueller (Givaudan), Manon Ombredane (International Chewing Gum Association (ICGA)), Georgios Papamokos (University of Ioannina), Thomas Reich (SCC GmbH), Rachel Serafin (AZELIS), Jitka Sosnovcova (National Institute of Public Health - Czech Republic), Paulína Strečanská (The Ministry of Agriculture - Czech Republic), Marian Verbruggen (Ruitenberg Ingredients b.v.), Pablo Andrés Villani (INAL – ANMAT), Angeliki Vlachou (FoodDrinkEurope), Benjamin Voss (proFagus GmbH), Julie Young (UK Flavour Association).

1. Welcome and apologies for absence | Open session Day 1

The Chair welcomed the participants in the meeting. Apologies were received from Paul Fowler for the whole length of the meeting.

2. Guidelines for observers attending the open session[4] | Open session Day 1

The Scientific Panel coordinator presented the rules for observers to be followed during and after the open plenary meeting. Observers were given the possibility to send questions when submitting their registration and these questions would be answered in a dedicated session at the meeting. Observers were also informed that the Chair would grant opportunity for additional questions at the end of each discussion topic.

The Chair invited the members of the Panel and staff to introduce themselves to the Observers attending online.

3. Adoption of agenda | Open session Day 1

The agenda was adopted without changes.

4. Declarations of Interest of Scientific Panel members | Open session Day 1

[4] http://www.efsa.europa.eu/sites/default/files/observersguidelines.pdf

In accordance with EFSA's Policy on Independence[5] and the Decision of the Executive Director on Competing Interest Management[6], 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.

5. Agreement of the minutes of the 15th Plenary meeting held on 30 June-2 July 2020, online meeting | Open session Day 1

The minutes of the 15th Plenary meeting held on 30 June-2 July 2020 were agreed by written procedure on 22 July 2020[7].

6. Report on written procedures since the 15th Plenary meeting | Open session Day 1

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

7. Scientific topic(s) for discussion

FLAVOURINGS

7.1. Guidance on smoke flavourings (EFSA-Q-2019-00687): endorsement of draft for public consultation | Open session Day 1 and Day 2 AM

Further to the discussion at the previous plenary meetings, the Panel discussed the proposed draft guidance document on the data to be included in applications for the authorisation of new smoke flavouring primary products, as well as for the modification or for the renewal of existing authorisations, submitted under Articles 7, 11 and 12 of Regulation (EC) No 2065/2003.
At the current meeting, the Panel reviewed the different sections of the draft guidance and unanimously endorsed the document, subject to incorporation of changes as suggested during the meeting.
The draft guidance will be released for public consultation on the Authority's webpage at the beginning of October 2020 for a period of six weeks, i.e. until mid-November 2020.

A technical hearing with the relevant stakeholders and interested parties is planned during the public consultation period on 5 November as a virtual meeting, aimed at exchanging views on the content of the draft guidance document and to discuss the comments raised during the public consultation. An on-line registration form will be made available on the EFSA website to allow the registration of interested participants.

The draft guidance, revised to take into account the comments received during the public consultation phase, will be presented to the Panel at a forthcoming plenary meeting at the beginning of 2021, with the aim of finalising it and publishing it by the end of March 2021.

[5] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[6] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
[7] http://www.efsa.europa.eu/sites/default/files/event/2020/15th-plenary-meeting-faf-panel_0.pdf

The Chair opened the floor to the questions from the observers on this agenda item.
The following questions were posed by some of the observers attending the plenary:

- What is the rationale for assessing genotoxicity endpoints with a combination of a component-based approach and a whole mixture approach as opposed to toxicity endpoints other than genotoxicity, for which only the whole mixture approach is used: why the dilution effect of individual components would have a different impact when considering genotoxicity and toxicity endpoints? What's the point in recommending testing of the individual components for the genotoxicity assessment?

  In response to these questions, it was clarified that genotoxicity of individual components may not be detected in a whole mixture testing approach. In general, it is considered that genotoxicity effects do not have a threshold.

- In the case of renewals of existing authorisations of smoke flavourings, has EFSA considered the time needed for the generation of the data required which may go beyond the deadline for the expiry of the authorisations? Will detailed study plans be considered acceptable as submissions?

  This point was noted and it was anticipated that this could be further addressed at the technical hearing foreseen on 5th November 2020.

- Would any food categories be considered in the exposure assessment of smoke flavouring primary products?

  The proposed approach for the exposure assessment, as outlined in the draft guidance, will consider all food categories in which the primary product is used or intended to be used.

7.2. FGE.69 Rev1 (EFSA-Q-2019-00742; EFSA-Q-2019-00743; EFSA-Q-2019-00744) | Open session Day 2 AM

The draft opinion on FGE.69 Rev1 was presented for the first time to the members of the Panel together with the main points for discussion.

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.

The Chair opened the floor to the questions from the observers on this agenda item.

- An update was requested by EFFA (European Flavour Association) on the timing of the finalisation of the EFSA Scientific Committee guidance on aneugenicity, that is awaited to progress with the evaluation of several FGEs.

  According to the latest information, the guidance, which has already completed the public consultation phase, is expected for finalisation by the end of April 2021.

- A clarification was sought by EFFA with respect to flavouring substance 07.027, covered by FGE.69 Rev1, for which the mTAMDI intake estimate is above the TTC for its structural class (Cramer Class I)

  As reported in the adopted opinion as a recommendation to the risk managers, for this substance more reliable data on uses and use levels would be needed to finalise its safety evaluation.

FOOD ADDITIVES

7.3. Re-evaluation of lecithins (E 322) as a food additive in foods for infants below 16 weeks of age (EFSA-Q-2018-00094) Open session Day 2 AM | Closed session Day 2 PM and Day 3

During the open session, a presentation was given to the Plenary outlining the background to this scientific opinion and the overall approach followed for the assessment of the data.

On the second day, during the closed session, the draft opinion on the follow-up to the re-evaluation of lecithins (E 322) was presented for the first time to the members of the Panel together with the main points for discussion.

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.

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

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

8.1.1. EFSA Scientific Committee

The Chair provided feedback from the 100th meeting of the EFSA Scientific Committee which took place on 16-17 September 2020. Of particular relevance to the activities of the FAF Panel were the updates on the following guidance/scientific documents under preparation that were presented during the last EFSA SC meeting:

- Draft opinion on Non-Monotonic Dose Response (NMDR)
- Draft scientific opinion on "Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals"

The Panel was also informed that the public consultation on the draft statement on EFSA approaches for the Derivation of Health Based Guidance Values (HBGV) for food additives, other regulated products and nutrients is over and that the Scientific Committee will proceed with the finalisation of this output by the end of the year.

8.2. EFSA including its Working Groups/Task Forces | Open session Day 2 AM

The Chairs of all the FAF Panel working groups provided an update on the progress made with the scientific assessments allocated to them.

8.2.1. 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**.

8.2.2. 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**.

8.2.3. 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**.

8.2.4. 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**.

8.2.5. 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**.

8.2.6. 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**.

8.2.7. 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**.

8.2.8. FAF WG on Guidance Update 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**.

8.3. European Commission | Closed session Day 3

The EC representative provided a brief update on the main upcoming changes to the submission of applications. As of March 2021, with the entry into force of the new Transparency Regulation, the FSCAP tool will be used for electronic submission of dossiers.

The new Transparency Regulation will lead to some amendments to Regulation (EC) No 1331/2008 (the so called "Common Authorisation Procedure" for the evaluation of food additives, flavourings and enzymes) and some amendments are also to be introduced in Regulation (EU) No 257/2010 on the re-evaluation of food additives.

9. New Mandates | Closed session day 3

The Scientific Panel coordinator presented an overview of the new mandates received at EFSA since the last plenary meeting at the end of June 2020. All the new mandates relate to applications submitted under the Common Authorisation Procedure for food additives and flavourings. The increase in the number of applications received is acknowledged.

9.1. Request for a scientific opinion on the proposed extension of use of pullulan (E 1204) to several food categories

This new mandate (M-2020-0130) from the European Commission covers the request for evaluation of an application for a proposed extension of use of pullulan (E 1204) to several food categories (EFSA-Q-2020-00517) and is under consideration by APDESK.

Pending confirmation of the validity of the application, the scientific assessment will be carried out by the WG Food Additives Applications.

9.2. Request for a scientific opinion on the safety in use of oligonucleotides as a food additive

This new mandate (M-2020-0131) from the European Commission covers the request for evaluation of an application for a new food additive, oligonucleotides used for food tracing purposes (EFSA-Q-2020-00518) and is under consideration by APDESK.

Pending confirmation of the validity of the application, the scientific assessment will be carried out by the WG Food Additives Applications.

9.3. Request for a scientific opinion on the safety of the new flavouring substance E-3-benzo[1,3]dioxol-5-yl-N,N-diphenyl-2-propenamide (Ref FLA 19-01)

This new mandate (M-2020-0149) from the European Commission covers the request for evaluation of an application for a new flavouring substance, E-3-benzo[1,3]dioxol-5-yl-N,N-diphenyl-2-propenamide (EFSA-Q-2020-00572) and is under consideration by APDESK.

Pending confirmation of the validity of the application, the scientific assessment will be carried out by the WG Flavourings.

9.4. Request for a scientific opinion on the safety of the new flavouring substance 2-hydroxy-4-methoxybenzaldehyde (Ref FLA 20-01)

This new mandate (M-2020-0150) from the European Commission covers the request for evaluation of an application for a new flavouring substance, 2-hydroxy-4-methoxybenzaldehyde (EFSA-Q-2020-00573) and is under consideration by APDESK.

Pending confirmation of the validity of the application, the scientific assessment will be carried out by the WG Flavourings.

9.5. Request for a scientific opinion on the safety in use of long-chain glycolipids from *Dacryopinax spathularia* as a food additive

Since the last plenary meeting, this mandate (M-2020-0102) was considered valid by APDESK on 14/07/2020 and the scientific assessment is currently in progress (EFSA-Q-2020-00433). The WG Food Additives Applications is tasked with the drafting of the scientific opinion.

9.6. Request for a scientific opinion on the safety in use of carbomer (cross-linked polyacrylic acid polymers) as a food additive

Since the last plenary meeting, this mandate (M-2020-0129) was considered valid by APDESK on 07/09/2020 and the scientific assessment is currently in progress (EFSA-Q-2020-00514). The WG Food Additives Applications is tasked with the drafting of the scientific opinion.

9.7. Request for a scientific opinion on the safety of the proposed amendment of the specifications of the food additive steviol glycosides (E 960) as regards rebaudioside D produced via enzyme-catalysed bioconversion of purified stevia leaf extract

Since the last plenary meeting, this mandate (M-2020-0133) was considered valid by APDESK on 07/09/2020 and the scientific assessment is currently in progress (EFSA-Q-2020-00520). The WG Food Additives Applications is tasked with the drafting of the scientific opinion.

10. Questions from and answers to Observers (in application of the guidelines for Observers) | Open sessions Day 1 and Day 2 AM

The Chair opened the floor to any additional question from the observers attending the meeting.

The Scientific Panel coordinator presented the questions received in advance to the current plenary and provided answers.

- Q: "From *a regulatory perspective, is the GMO status of Soya bean important for the E 322 to be used in infant foods?"*

  A: The Chair of the Panel explained that the scope of the current opinion is limited to the follow-up of the uncertainties and data gaps identified by the former ANS Panel in the context of the re-evaluation of the food additive lecithins (E 322) and to complete the safety evaluation of the food additive with respect to its uses in foods intended for infants below 16 weeks of age.

  With respect to the evaluations of GM plant materials to be used in the EU for food and/or feed uses, observers were reminded that these fall under the remit of the EFSA GMO Panel.

- Q: *"Given that according to the UL of authorised smoke flavouring primary products (Commission Implementing Regulation (EU) No 1321/2013) the smoke flavouring PP's are authorised only until end of 2023 (which is a bit more than 3 years from now) there is only a time period of three years for the producers to conduct new studies, prepare and submit the dossiers, for EFSA to complete the safety assessments (and publish all the opinions) and for the EU-Commission to adopt and publish a new regulation for the timely renewal of those authorisations in case of a favourable opinion.*
  Our experience with the ongoing safety evaluation program on flavouring substances has demonstrated us that 3 years is a rather short period for such an ambitious program. EFFA, on behalf of the producers and users of those smoke flavouring primary products is concerned that 3 years may not be sufficient to conduct all the necessary studies (according to the EFSA Guidance), and to complete the safety assessment of those products on time for the EU-Commission to publish a new regulation for the renewals before the end of the current authorisation period.
  Therefore it is of paramount importance to have the EFSA scientific guidance for the preparation of applications on smoke flavouring primary products as soon as possible, so that the companies can start commissioning the appropriate studies without delay.
  Our question is in relation to the timings: from the EFSA website we understood that the EFSA draft Guidance (after adoption by the EFSA FAF Panel on 21 September) will be open for public consultation as of 5 October. How long will the consultation period last (i.e. what will be the deadline for comments?), and after this deadline how long will it take to finalise, adopt

and publish the final version of the Guidance so that the companies know exactly what kind of scientific studies to conduct?
A: This question has been answered when introducing the presentation on agenda item 7.1.

No other general questions were raised by the observers, in addition to some clarifications on the points discussed during the open session of the plenary.

11. Other scientific topics for information and/or discussion | Open session Day 2 AM

11.1. Communication of uncertainty in scientific assessments

Anthony Smith (COM) presented the EFSA guidance document on communication of uncertainty in scientific assessments (January 2019), an EFSA output developed as complementary guidance to the Scientific Committee guidance document on uncertainty analysis (January 2018). Anthony provided background on the purpose of the communications guidance and its connection with the SC guidance.

A description was given of the key sections of the Communication GD with a focus on aspects relevant to EFSA Panels, i.e. the 'advice for assessors' described in the 'Guidance' section of the document, together with a demonstration of how the guidance was used to support communication on recent EFSA assessments, for example, two reports on cumulative risks from groups of pesticides.

12. Any other business | Notice

The Panel was reminded that the expert appointed as WG chair may be invited to participate in the role of chair or member in a given WG meeting, based on the complexity of the topics that are on the agenda. In those cases, in which the WG Chair is invited to join a meeting as a member, or his/her attendance is not required based on the topics that are on the agenda, EFSA staff will take care of coordinating the meeting.