FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD ADDITIVES AND FLAVOURINGS (FAF)

MINUTES OF THE 32nd PLENARY MEETING – Day 2 OPEN to Observers by teleconference

Held on 8-9 November 2022 in Parma
(Agreed by written procedure on 30 November 2022)

Participants

- Panel Members:

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

- European Commission and/or Member States representatives:

  DG SANTE (Health and Food Safety), E2 Food processing technologies and novel foods: Katleen Baert, Stylianos Kolouris and Jiri Sochor

- EFSA:

  FIP Unit: Valeriu Curtui, Maria Carfi, Consuelo Civitella, Lorenzo D'Angelo, Christina Kyrkou, Federica Lodi, Carla Martino, Agnieszka Mech, Salvatore Samuele Multari, Ana Maria Rincon, Laura Ruggeri, Camilla Smeraldi, Alkiviadis Stagkos-Georgiadis, Alexandra Tard.

  MESE Unit: Bruno Dujardin

  NIF Unit: Marcello Laganaro

- Hearing Experts: Polly Boon (for agenda item 6.3)

- Observers (on 9 November 2022): Ilaria Altieri (National institute of health Italy Istituto Superiore di Sanità), Nancy Baka (FoodDrinkEurope), Desiree Bertagnolli, Francesca Bot (University of Parma), Olivier Bove (Nexira), Paul Brown (The University of the West Indies), Neepa Choksi (ToxStrategies), Cécile Cluzelle (Synpa), Jan Demyttenaere (European Flavour Association), Rocio Duchen (Pen & Tec Consulting), Sylvain Etter (Firmenich S.A.), Allison Franzen (ToxStrategies), Stefanie Geiser (EAS Strategies), Severin Givaudan, Agnieszka Gruszecka-Kosowska (AGH University of Science and Technology), Kata Héjjas (Specialised Nutrition Europe (SNE), Maryse Hervé (EU Specialty Food Ingredients), Joanna Jaskolska (International Sweeteners Association), Christophe Lepretre (ICGA Europe), Lucia Martinez (DSM Nutritional Products), Georgios Ntouros (University of Parma), Caroline Rey (Efema), Mireia Romagosa (Pen&Tec consulting S.L.U), Lorenza Romanese (European Industrial Hemp Association), Aurora Scarduzio (University of Parma), Jürgen Schnabel (Givaudan International AG), Aref Sepehr (Padova University), Christina Sloat (Awareness), Roberto Suarez (Gourmey), Sean Taylor (International Organization of the

[1] In Teleconference

Flavor Industry), Keng Ngee Teoh (Ajinomoto Europe), Luca Terzi (FoodDrinkEurope), Viviane Vijverman (Firmenich)

OPEN SESSION

1. Welcome and apologies for absence

The Chair welcomed the participants and Observers to this meeting.

2. Introducing participants and presentation of the guidelines for Observers

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

3. Adoption of agenda

The agenda was adopted without changes.

4. Declarations of Interest of Scientific Panel members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Panel 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, and no interests were declared orally by the members at the beginning of this meeting.

5. Agreement of the minutes of the 31st Plenary meeting held on 27-29 September 2022, as online meeting

The minutes of the 31st FAF Plenary meeting held on 27-29 September 2022 were agreed by written procedure on 19th October 2022[4].

[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] https://www.efsa.europa.eu/sites/default/files/2022-10/270922-m.pdf

6. Report on written procedures since 31st Plenary meeting

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

CLOSED SESSION

7. Scientific topic(s) for discussion

FOOD FLAVOURINGS

7.1. Scientific opinion on FGE.76 Rev2 EFSA-Q-2014-00675 to -00679, EFSA-Q-2014-00682 and EFSA-Q-2014-00683 – Closed Session

At the current plenary meeting the FAF Panel was presented for the first time with a draft scientific opinion on Flavouring Group Evaluation 76, Revision 2 (FGE.76 Rev2): Consideration of sulphur-containing heterocyclic compounds, evaluated by JECFA, structurally related to thiazoles, thiophenes, thiazoline and thienyl derivatives from chemical group 29 and miscellaneous substances from chemical group 30 evaluated by EFSA in FGE.21Rev5.
The Panel held an initial discussion on the different parts of the assessment and endorsed the text of the draft scientific opinion. Because this scientific opinion is closely related to FGE.21Rev6, still under preparation by the Working Group on Flavourings, the Panel considered it appropriate to postpone its adoption until the finalisation of the assessment of FGE.21Rev6.

On the basis of the comments received during the current plenary meeting the draft opinion on FGE.76Rev2 will be further elaborated by the Working Group on Flavourings and will be tabled for possible adoption at a forthcoming Plenary meeting.

OPEN SESSION ON 09.11.2022

FOOD ADDITIVES

7.2. Opinion on the re-evaluation of carboxy methyl cellulose (E 466) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups. EFSA-Q-2018-00099 – Open Session

Further to the initial discussions held at the previous meetings, the revised draft opinion on the re-evaluation of carboxy methyl cellulose (E 466) as food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation as food additive for uses in foods for all population groups as a food additive, was presented 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 but no questions were received on this topic.

FOOD FLAVOURINGS

7.3. Scientific Guidance on the data required for the risk assessment of flavourings to be used in or on foods (EFSA-Q-2021-00289) and technical report on the public consultation (EFSA-Q-2022-00619) – Open Session

Further to a public consultation phase held on the draft guidance between April and June 2022, a revised document was distributed for possible adoption.

At the current meeting, the FAF Panel discussed the amendments made to the revised document and unanimously adopted the scientific guidance.

The final guidance document will be available on the Authority's webpage.

Its publication will be accompanied by an EFSA technical report detailing the comments received during the public consultation and how they have been addressed in the adopted output. The Panel endorsed the draft technical report prepared by EFSA.

The Chair opened the floor to the questions from the observers on this agenda item but no questions were received on this topic.

8. Other scientific topics for information and/or discussion

8.1. Food additives re-evaluation under Regulation (EU) No 257/2010

8.1.1. Progress update on the re-evaluation of food additives

The Scientific Panel coordinator presented an update on the status of the re-evaluation of food additives that were already permitted for use in the EU as of 20 January 2009 and therefore requiring a re-evaluation by EFSA according to Regulation (EU) No 257/2010.

The programme, which should have been completed by the end of 2020 according to the deadline given in the Regulation, is running late and so far has covered approximately 70% of the more than 300 substances included. During the last two years the process has further slowed down, and re-evaluation could be completed for only two food additives, thaumatin (E 957) in 2021 and neohesperidine dihydrochalcone (E 959) in 2022. For the rest of the substances for which draft opinions are under preparation by the FAF Panel Working Groups, significant delays have been experienced with the submission of additional data/information requested during assessment, with important repercussions on the planning.

There are currently 15 scientific opinions under preparation, mainly concerning the re-evaluation of sweeteners. In some cases the re-evaluation of these food additives is being assessed jointly with applications for extension of the permitted uses or other types of applications.

In addition to the food additives under re-evaluation, the FAF Panel is currently facing an increase in its workload (see item 8.2), also due to the fact that for many of the food additives for which the re-evaluation has been completed, follow-up opinions need to be issued (see for example agenda item 6.2). During the year 2022, the FAF Panel has so far adopted 5 scientific opinions on the follow-up to the re-evaluation, with 13 still under preparation at the level of the Working Groups and more mandates expected before the end of the year.

On the basis of the experience accrued with food additive re-evaluations, and acknowledging the amount of time needed to complete this type of assessment, often requiring the launch of more than one call for data and subsequent requests for additional information or clarification, the Panel held a reflection on the substances that remain to be re-evaluated and on possible actions that could streamline this complex process for assessment.

Having looked at the substances that remain to be re-evaluated, the Panel strongly supported the need to group their assessment as much as possible, with a view to reduce the number of scientific opinions to be prepared and adopt. Grouping of the substances will follow considerations on the similarities of the chemical properties of the substances, their common metabolic pathways and role in human physiology. Since many of the food additives that remain to be re-evaluated are normal components of the body or the diet (e.g. acetic acid and acetates, lactic acid, citric acid) the dietary exposure resulting from their use as food additives will require comparison with the exposure resulting from their natural occurrence in food. For some of the acids to be re-evaluated, it is anticipated that information on their concentration in foods may be of significant relevance, e.g. to assess local irritant effects. Estimation of chronic dietary exposure remains an integral part of the risk assessment, however the Panel agreed that in some cases it could be possible to simplify this step, e.g. using the FAIM tool outputs to estimate the regulatory maximum scenario for those food additives with numerical maximum permitted levels in a limited number of food categories.

With respect to the requirement, Regulation (EU) No 257/2010 requires EFSA to identify any relevant literature published since the last evaluation of each food additive, the Panel acknowledges that this requirement in the legislation may be particularly challenging for substances that are commonly found in nature and for which extensive literature searches (such as those applied to the re-evaluation of sweeteners, see agenda item 8.1.2) would return an unmanageable volume of records, possible of very little relevance for the safety assessment. The Panel agreed that for these types of substances a different strategy for the identification of relevant literature will have to be devised.

For many of the food additives still to be re-evaluated, calls for data have already been launched in the past, covering many substances at the time, and some data have already been submitted to EFSA but not yet pre-assessed. However, the experience so far has shown that nearly for all the food additives that have been re-evaluated, the need for additional data or information is identified after the start of the assessment, in many cases owing to the evolution of new development of scientific guidance or to the need for reducing uncertainties. The Panel therefore agreed that, prior to the start of the drafting of the scientific opinions on the food additives that remain to be re-evaluated, an inventory of the data already provided to EFSA in response to the earlier calls for data should be performed so to inform the preparation and the launch of more targeted calls for data, fit for the purpose of the scientific opinion under development.

This approach will be tested for the preparation of the next two scientific opinions on the re-evaluation of i) gluconic acid-gluconates (E 574-579) and ii) ribonucleotides (E 626-635), identified as of priority for re-evaluation in Regulation (EU) No 257/2010. The Panel will consider the information already available to EFSA at a forthcoming plenary meeting and will provide advice on the missing data to be requested by means of a call for data

The Panel further noted that among the food additives still to be re-evaluated are a group of substances that are used in gaseous form (i.e.: carbon dioxide, E 290; helium, E 938; nitrogen, E 941; nitrous oxide, E 942; butane, E 943a; isobutane, E 943b; propane, E 944; oxygen, E 948; hydrogen, E 949) which may require a different approach for their safety re-evaluation. Also for these food additives a tailored call for data will be prepared on the basis of the information already available and discussed with the FAF Panel prior to its launch. The focus will be, in the first instance, on the actual uses of these gases as food additives and on their manufacturing processes. In some cases, information on reaction with food matrices may also be needed.

The first draft calls for data will be scheduled for discussion at a forthcoming plenary meeting in early 2023.

8.1.2. Revision of the protocol for the assessment of hazard identification and characterisation of sweeteners

The original protocol for the assessment of hazard identification and characterisation of the sweeteners was approved by the Panel on 17 January 2020 and originally published, as an EFSA supporting publication of the technical report on the "Outcome of the public consultation on a draft protocol for the assessment of hazard identification and characterisation of sweeteners", on 18 February 2020[5]. During the implementation phase of this protocol, some revisions and further elaborations were introduced to define in more details some of the steps of the systematic approach, to reflect what has been applied in the adopted scientific opinions on thaumatin (E 957)[6] and neohesperidine DC (E 959)[7] or in the other ongoing scientific opinions.

At the current meeting, the Panel discussed and endorsed the new parts of the amended protocol. This revised protocol will be made publicly available on the EFSA Knowledge Junction platform (Zenodo repository[8]).

An update on the status of the re-evaluation of sweeteners and on the indicative timelines was also presented to the Panel.

The Chair opened the floor to the questions from the observers on this agenda item and the following question was received on this topic:

- When evaluating the reliability of in vitro genotoxicity trials (OECD 471, OECD 487), which are supposed to be GLP, does EFSA also consider for scoring, if the preparation of the test item has been performed under GLP? I.e. if the additive is not used per se for the genotox trial, but instead a supernatant or cell lysate, etc. as appropriate, and the

[5] https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fsp.efsa.2020.EN-1803&file=efs31803e-sup-0001-annex.pdf
[6] https://www.efsa.europa.eu/en/efsajournal/pub/6884
[7] https://www.efsa.europa.eu/it/efsajournal/pub/7595
[8] https://zenodo.org/communities/efsa-kj?page=1&size=20

product manufacturer prepares the test item under non-GLP conditions, but sends to a GLP lab for genotox testing, will the non-GLP sample preparation condition invalidate the reliability of the trial for EFSA safety assessment?

In answer to this question, the Panel clarified that compliance with GLP is not the sole criterion used for evaluating reliability of genotoxicity studies.

8.2. 2023 Workplan FAF Panel

The Scientific Panel coordinator presented a tentative workplan for the coming year, highlighting the workload generated by the evaluation of new applications for food additives and flavourings, submitted under the Common Authorisation Procedure of Regulation (EC) No 1331/2008 and the peak of work related to the assessment of renewal applications for eight smoke flavourings to be completed by the end of September 2023.

Over the past months, planning of Working Group meetings and Panel plenaries has been significantly affected by the many and significant delays reported by applicants and interested parties in submitting additional data requested during assessment or missing information for new applications still in the validity check stage.

For this reason, the plenary originally planned towards the end of January 2023 most likely will have to be cancelled and additional dates will instead be explored for Panel plenaries to be held between May 2023 and September 2023 to cope with the workload generated by the new applications and the renewals of smoke flavourings.

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

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

Nothing to report.

Nothing to report in addition to what was already included in the minutes of the FAF Panel WG meetings.

9.3. EFSA including its Working Groups/Task Forces

Nothing to report.

9.4. European Commission

Nothing to report.

10. New mandates

The Panel was informed of a new mandate received from the European Commission since the last plenary meeting in September 2022:

- Request for a scientific opinion from the European Food Safety Authority as regards the specifications of the food additive vegetable carbon (E 153) (EFSA-Q-2022-00830)

As a first step the mandate above will be allocated to the WG Specifications for the assessment of the data submitted by the interested business operators in response to the call issued by the European Commission in December 2020[9].

11. Questions from and answers to Observers (in application of the guidelines for Observers)

The Chair introduced the following questions from the observers received during the registration phase:

- In case of applications for the modification of specifications of already approved food additives, must applicants consider the 2021 'Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles' if the specification for particle size will not be affected and/or where specific measuring techniques are included in the available specification? e.g. for E463a: by laser diffraction method — Not less than 45 µm (not more than 1 % in weight of particles of less than 45 µm) and not more than 65 µm by size-exclusion chromatography (SEC) — Average (D50) particle size between 47,3 µm and 50,3 µm; D90 value (90 % below given value) between 126,2 µm and 138 µm.

In principle, the EFSA Scientific Committee Guidance on technical requirements on nanoparticle is applicable since the date of its publication in August 2021. The guidance is aimed at confirming if a conventional risk assessment, such as the one already existing for the substance for which an application for modification of existing specifications, is submitted is sufficient. Applicability of the guidance will depend on the nature of the proposed changes to the specifications.

Prospective applicants are invited to consult the dedicated section on the EFSA website: https://www.efsa.europa.eu/en/applications/food-improvement-agents

- How to find a place where all information all resources related to food sector is available online and at some location with ability to experiment new things and learn existing processes?

The requestor was directed to the EFSA website, from which different resources can be accessed. In addition to the page above, for example, a wide range of data (e.g. dietary consumption data), repositories (e.g. OpenFood Tox) and assessment calculations tools (e.g. FAIM) can be accessed through the following link: https://www.efsa.europa.eu/en/data-tools

- EFSA has recently advocated for the use for benchmark dose or BMD. When could we expect this to be mandatory for all applications? Will this be considered for the next

The Chair of the Panel clarified that use of BMDR modelling is already an established practice that the FAF Panel has implemented it in its scientific opinions, in particular in several opinions

[9] https://food.ec.europa.eu/system/files/2020-12/fs_food-improvement-agents_reeval_call_20201215_e153_data.pdf

on flavourings, whenever the toxicity data show a dose–response relationship for at least one endpoint.

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

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.

12. Any Other Business

Nothing to report