SCIENTIFIC PANEL ON FOOD ADDITIVES AND FLAVOURINGS (FAF)

40th FAF Panel meeting

24-26 October 2023
13:00-18:00 / 09:00-18:00 / 09:00-13:00
MINUTES (Agreed on 14 November 2023)

Location: Starhotels du Parc, Parma

Attendees:

- FAF Panel Members:
Laurence Castle, Gisela Degen, Karl-Heinz Engel, María José Frutos Fernández, Paul Fowler, Ursula Gundert-Remy, Rainer Gürtler, Trine Husoy, Melania Manco, Wim Mennes, Peter Moldeus, Sabina Passamonti, Romina Shah, Dina (Ine) Waalkens-Berendsen and Matthew Wright, Maged Younes

- EFSA:
Food Ingredients and Packaging (FIP) Unit: Stefania Barmaz, Valeriu Curtui, Maria Carfi, Consuelo Civitella, Gabriele Gagliardi, Federica Lodi, Gloria Lopez Galvez, Carla Martino, Agnieszka Mech, Salvatore Samuele Multari, Vasantha Palaniappan, Ana Rincon, Laura Ruggeri, Camilla Smeraldi, Alexandra Tard and Panagiota Zakidou

  Nutrition & Food Innovation Unit (NIF): Océane Albert, Andrea Germini, Annamaria Rossi and Ermolaos Ververis

- European Commission: Katleen Baert, Olga Goulaki

- Hearing Experts: Thor Halldorsson and Polly Boon (for agenda point 6.2)

- Observers: Altieri Ilaria (Istituto Superiore di Sanità, ISS), Andersson Caroline (European Chemical Industry Council, CEFIC), Atanasova-Pancevska Natalija (Faculty of Natural Sciences and Mathematics), Baffigo Marta (Cargill R&D Centre Europe), Bogner Hanna (Jungbunzlauer), Buitelaar André (Unilever), Cassar Mark (Malta Competition & Consumer Affairs Authority, MCCAA) - Technical Regulations Division (TRD), Chappuis Eric (Cargill), Coppens Patrick (Food Supplements Europe), Dämgen Jessica (Jungbunzlauer International AG), Demyttenaere Jan (EFFA - EUROPEAN FLAVOUR ASSOCIATION), Díaz Pérez Francisco Jesús (Tecnológico Nacional de México campus Tuxtepec), Dorioz Camille (Foodwatch), Duchen Rocio (Pen & Tec Consulting), Fornasiero Lidia (Brunswick Group), Franzen Allison (ToxStrategies, LLC), Fuentes Sol (Freelancer Interpreter), Gartlon Joanne (Freelance), Geiser Stefanie (EAS Strategies), Hejjas Kata (Specialised Nutrition Europe), Herve Maryse (EU Specialty Food Ingredients), Ismail Mohammed (Gaziantep University), Japp Britta (Palsgaard A/S), Le Thanh-Blicharz Joanna (Institute of Agricultural and Food Biotechnology – State Research Institute, IBPRS-PIB), Lee Yeonkyu (CJ CheilJedang Corporation), Lepretre Christophe (ICGA-Europe), Litti Agnese (EUTECA), McConochie Carmen (Cefic), Meier Stefanie (RDA Scienfitic Consultants), Mensik Petr (European Association of Polyol Producers, EPA), Müller Severin (Givaudan), O'Hagan Sue (PepsiCo International), Pesce Francesco (International Sweeteners Association), Phipps Kirt (Intertek), Rimondi Foulquet Cosmea (CARAGUM INTERNATIONAL), Rizzo Davide, Roosynda Merlizza (Corbion), Schotanus Anna Trijntje, Serafin Rachel (Azelis), Sipahioglu Oya (Turkish Ministry of Agriculture and Forestry), Stelmaszczyk-Kusz Agnieszka (Institute of Agricultural and Food Biotechnology -State Research Institute-IBPRS-PIB), Teoh Keng Ngee (Ajinomoto Europe), Terzi Luca (FoodDrinkEurope), Ukkonen Anne (Biosafe Ltd), Vintilă Iuliana (University "Dunărea de Jos" Galați, Wang Si (PepsiCo International)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Peter Fürst and Gabriele Aquilina for the whole duration of the plenary and from Paul Fowler for the morning of 25th October 2023.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence1 and the Decision of the Executive Director on Competing Interest Management2, 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.

4. Agreement of the minutes of the 39th FAF Panel meeting held on 26-28 September 2023, in Parma.

The minutes of the 39th FAF Panel meeting were agreed on 5th October 2023.

5. Report on written procedures since 39th Plenary meeting

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

6. Scientific outputs submitted for discussion and possible adoption

CLOSED SESSION on 24/10/2023

6.1. Scientific opinion on the safety of a proposed amendment of the specifications of the food additive steviol glycosides (E 960): new production process using genetically modified *Yarrowia lipolytica* (EFSA-Q-2021-00356)

The FAF Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

OPEN SESSION on 25/10/2023

6.2. Scientific opinion on the re-evaluation of the safety of erythritol (E 968) as a food additive (EFSA-Q-2011-00730) and on the laxative effects of erythritol under the currently authorised conditions of use for erythritol used in food in the EU (EFSA-Q-2022-00219)

Further to the initial discussion held at the 37th Plenary meeting in June 2023[3], the revised draft opinion on the re-evaluation of erythritol (E 968) as a food additive and on the laxative effects of

[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/2023-07/200623-m.pdf

erythritol under the currently authorised conditions of use was presented to the members of the Panel together with the main points for discussion. The FAF Panel discussed all parts of the draft opinion. The opinion was unanimously adopted, subject to the incorporation of changes as suggested during the meeting and editorial changes.

The Chair opened the floor to the questions from the observers on this agenda item. The following one had been received from one of the observers in advance to the meeting:

- With regards re-evaluation of erythritol, is it planned to include Moliniella in the list of QPS species? If so, are data brought during re-evaluation submission sufficient to do so?

In answer to this question, the Panel clarified that according to the 2007 EFSA Scientific Opinion on the introduction of qualified presumption of safety (QPS) approach for assessment of microorganism referred to EFSA4, QPS status cannot be recommended for filamentous fungi.
The exclusion was later reconfirmed in the EFSA QPS update of 20205, in which the following is mentioned: *"While knowledge of fungal secondary metabolites has grown substantially, information on their toxic effects on humans and animals is evolving at a much slower rate. Therefore, it was decided that until further notice, **filamentous fungi** would be excluded from the QPS evaluations. …"*
This principle was reiterated also included in the latest EFSA QPS Opinion issued in 20236: *"**Filamentous fungi** are excluded from the QPS assessments based on the potential presence of harmful traits in strains of the taxonomic unit. The assessment needs to be carried out at the strain level, by the relevant EFSA Unit and Scientific Panel."*

More information on the updated QPS status is available in the dedicated page of the EFSA website7. Moreover, an Excel file listing all the "microbiological agents as notified to EFSA" through an application for market authorization is available for consultation. The latest update is from January 20238. In that document you can see that Moniliella pollinis and Moniliella megachilensis are included in the microbiological group of "Filamentous fungi", they have been evaluated for QPS status but not included in the QPS list.

In addition, the following question was asked by an observer attending the plenary:

- In the opinion adopted it is stated that detailed information on the production strains characterisation was provided. Does the present opinion summarise this information in a specific section, e.g., mention to characterisation based on WGS, 18S rRNA etc.?

In answer to this question, EFSA staff clarified that once the opinion is adopted it will be subject to editorial review to prepare it for publication (generally within a period of approximately one month after adoption). All the relevant information described in the technical section of the opinion will be available in the full text of the opinion published.

6.3. Re-evaluation of citric acid esters of mono-and diglycerides of fatty acids (E 472c) as a food additive in foods for infants below 16 weeks of age: approach to be followed in the safety assessment (EFSA-Q-2021-00674)

Steering from the Panel was sought with respect to the approach to be followed for the safety assessment of the food additive citric acid esters of mono-and diglycerides of fatty acids (E 472c) in the population of infants below 16 weeks of age. As already done for other food additives assessed under this mandate (e.g. lecithins and mono- and diglycerides of fatty acids), the proposal from the Working Group tasked with the preparation of the draft opinion would be to

[4] The EFSA Journal (2007) 587, 1-16
[5] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.5966
[6] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2023.7747
[7] https://www.efsa.europa.eu/en/topics/topic/qualified-presumption-safety-qps
[8] https://zenodo.org/records/7554079

compare the exposure to the different components of hydrolysis products of E 472c, i.e. palmitic and stearic acid, citric acid and glycerol, with the corresponding exposure based on the quantified levels in breast milk. The FAF Panel supported the proposed approach, which will be followed by the Working Group to continue drafting the scientific opinion.

The Chair opened the floor to the questions from the observers on this agenda item, but no questions were raised by any of the attendees.

6.4. Self-task mandate for an update of the 2012 ANS Panel "Food Additive Guidance for submission for food additive evaluations" (EFSA-Q-2023-00713)

At the 38th Plenary meeting in July 2023[9], the FAF Panel had identified the need to update the 2012 ANS Panel "Food Additive Guidance for submission for food additive evaluations". Following on from the initial discussion, a self-task mandate (M-2023-00130) was prepared and sent to the EFSA Executive Director for approval.

At the current meeting the self-task mandate was presented to the FAF Panel alongside with initial elements identified from the experience accrued over the years with the assessment of new food additive application dossiers, as in need for an update or better elaboration. The overall aim of the update of the guidance would be to improve the completeness and the clarity of the initial submissions and therefore limiting the need for requesting additional information during the risk assessment. Also, the recent experience with the preparation of the two guidance documents on smoke flavourings and food flavourings will also be considered.

The proposed deadline for the completion of the revision of the guidance is the end of 2024 and a tentative prospective plan was presented to the FAF Panel. According to this initial plan, the draft updated guidance should be presented for endorsement before the launch of the public consultation at the next FAF Panel plenary meeting open to observers, currently planned for the end of April 2024. Finalisation and adoption of the revised guidance will then be handed over to the FAF Panel in its revised composition after July 2024.

The WG Food Additives Applications will be consulted regularly during the drafting of the updated guidance.

The Chair opened the floor to the questions from the observers on this agenda item. The firs two had been received from one of the observers in advance to the meeting:

- What is the flexibility of the Panel to consider non-animal approaches on a case-by-case basis in their safety assessment for situations where a specific study involving animals is prescribed in the guidance, when the non-animal approach is equally or more informative? Would additional guidance, to understand criteria for alternative approaches early, be helpful for the applicant on this aspect?

In answer to this question, the Panel clarified that all the applicable guidance documents already allow for some flexibility with respect to the use of non-animal models, provided that the approach is duly justified and the scientific rationale is well documented in the application dossier.

- When a re-evaluation is ongoing for a food additive, and an application for modification of the current authorisation is received for that same additive (e.g., due to a new manufacturing method proposed), can the applicant expect EFSA to take longer to issue an opinion on the modification (.e.g. until the re-evaluation is ready), as compared to modification applications for already re-evaluated additives?

In answer to this question, EFSA staff clarified that applications for modification of the current authorisation of a food additive are submitted under Regulation (EC) No 1331/2008 which states

[9] https://www.efsa.europa.eu/sites/default/files/2023-07/050723-m.pdf

that EFSA shall respect the deadline of 9 months to deliver a scientific opinion. However, when such new applications are received for food additives that are undergoing re-evaluation or follow-up assessment under Regulation (EU) No 257/2010, the evaluation cannot be completed until the re-evaluation or the follow-up assessments are also completed. For example in the case of modifications to the permitted uses, the evaluation cannot proceed until an updated dietary exposure assessment is available to compare it with the new proposed uses. It is acknowledged therefore that the timeframe needed for completing the re-evaluation is usually longer than the 9 months period to complete the evaluation of new applications and therefore the latter usually require an extension of the deadline for completing the evaluation of the new application.

The following additional questions on this topic were asked by observers attending the plenary:

- Will the re-evaluation program of food additives be fully completed by December 2024 and entry into force of the new guidance?

EFSA staff clarified that the two evaluations performed by the Panel are conducted under different legislative frameworks, i.e. Regulation (EU) No 257/2010 applicable to the re-evaluation of food additives that were already permitted in the EU as of 20 January 2009 and Regulation (EC) No 1331/2008 also known as the Common Autorisation Procedure for food additives, food flavourings and enzymes. The ongoing revision of the guidance is meant to facilitate the preparation of dossiers submitted under the Common Autorisation Procedure.
The food additive re-evaluation programme will continue to progress independently from this update and it won't be completed before the end of next year.

- Is our understanding correct that the new guidance should preferably apply for new reviews of FA and only after the final adoption/publishing of such guidance?

EFSA staff clarified that this is indeed the case and that indeed the revised guidance will apply only to those dossiers that will be prepared after its publication. Nonetheless, it should be noted that a significant part of the revision will concern the update of the references to the applicable horizontal guidance documents issued by the EFSA Scientific Committee since the publication of the 2012 ANS Panel guidance on food additives. These horizontal guidance documents are already being considered in the assessments carried out by the FAF Panel and its Working Groups.

- In the context of a food additive application, for characterisation of production microorganisms, best to follow the Food Enzyme guidance of 2021, rather than the Microorganism characterisation guidance of 2018, correct?

EFSA staff confirmed that this is correct. For instance, this has already been indicated in the latest calls for data for the re-evaluation of food additives published by EFSA (as an example see point 2.B of the call for data on ribonucleotides[10]).

7. Feedback from the Scientific Committee/Panel(s), EFSA, European Commission

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

No new meeting of the Scientific Committee has taken place since the previous FAF Plenary meeting.

7.2. FAF Panel Working Groups /Task Forces

[10] https://www.efsa.europa.eu/en/call/call-data-re-evaluation-ribonucleotides-e-626-635-food-additives

The Chairs of the Working Groups of the FAF Panel were consulted with respect to the status of the ongoing assessments with a view to identify possible agenda items for the coming Panel plenary meetings.

A tentative plan for the plenary meetings planned for the remaining months of 2023 was agreed.

7.3. EFSA

The EFSA staff Gloria López-Gálvez, scientific officer responsible for the coordination of the CSS (Chemicals Strategy for Sustainability) implementation in EFSA gave an overview of the strategy. The presentation focused on the one substance one assessment (1S1A), the main objective of the CSS impacting EFSA. Several activities are being conducted in EFSA towards the implementation of the 1S1A. The 'Early identification of *cross-cutting substances*' —chemicals to be assessed by EFSA but are also under evaluation of have been evaluated by other EU Agencies or by MSs— will allow to start a liaison with the partnering institution when the mandate is received by EFSA. Within the '*Piloting of the 1S1A approach in selected assessment*' some specific chemicals which are assessed by EFSA and by other Agencies are being followed; some gaps, which would preclude an efficient 1S1A implementation, have been identified. EFSA has commissioned a '*Study to map the data requirements and risk assessment methodologies across the various EU chemical regulatory frameworks'*; the mapping will detect misaligned areas and where intervention might be needed to reach coherence. The 1S1A foresees the '*Establishment of an EU-Common data platform on chemicals*' (EU-CDPC), to which EFSA will contribute; the EU-CDPC will facilitate the sharing, access and re-use of information on chemicals coming from all sources, and will be hosted by ECHA. The 1S1A will be supported by various legal proposals which are currently being prepared.

The FAF Panel warmly thanked EFSA for this presentation and raised several comments and questions on the ongoing activities.

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

- Who will conduct the hazard assessment? How the synchronised assessments will be managed?

In answer to this question, EFSA clarified that, according to the 1S1A, it is foreseen that the tasks related to substance(s) assessments will be allocated to Agencies according to their expertise; it is also foreseen that there will be a so-called "Coordination mechanism" which will support the synchronization and coordination of risk assessments.

7.4. European Commission

The EC staff Katleen Baert presented the ongoing and planned activities for the implementation of the monitoring of food additives in accordance with Article 27 of Regulation (EC) No 1333/2008 and food flavourings in accordance with Article 20 of Regulation (EC) No 1334/2008.

The methodology that is being developed to set up the monitoring programme is made of four parts: I. Risk-based categorisation and prioritisation of the FAs and FFs for monitoring purposes ; II. Collection of reliable and representative data, and data submission to EFSA ; III. Estimation of dietary intake ; IV. Reporting of the findings.

The EC has already sent two mandates to EFSA requesting scientific and technical assistance in the preparatory work for the implementation of the common methodology for the monitoring of food additives and food flavourings (EFSA-Q-2023-00026) and in the collection and reporting of the data obtained by the Member States (EFSA-Q-2023-00028).

The first two pilot data collections should take place in 2024 and in 2025 with data collection for 3 food additives and two food flavourings in the year 2024 and for two food additives and three food

flavourings in the following year. The pilot phases should allow for an evaluation of the methodology and introducing adjustments if needed.

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

- For the monitoring data (step 2 in methodology) EFSA has to set up a data collection system: will that be a general system for both food additives and food flavourings or will there be different data collection systems, one specific to food flavourings and one specific to food additives?

In answer to this question related to the preparatory work currently ongoing, EFSA clarified that EFSA is currently developing a data model that should allow direct data submission of monitoring data on both food additives and food flavourings by Member States and other interested stakeholders. The data model is currently being developed by the iDATA Unit of EFSA, that has been identified as the leading unit for these activities. A consultation with the stakeholders is foreseen prior to the finalisation of the data model.

- For the Pilot study and the analysis of the two flavouring substances caffeine & theobromine, how will the Member States differentiate between the use as flavouring versus the use for another application (e.g. use of caffeine as stimulater in energy drinks, or presence in coffea & similar drinks), or natural occurrence (not due to flavourings)?

In answer to this question, EC staff clarified that given the labelling requirements for flavourings, there are cases for which the distinction between use as a flavouring versus another use cannot be made based on the label information. However, the monitoring also aims at collecting information related to the overall exposure (including exposure from sources other than food additive and food flavouring use).

8. New mandates

8.1. New questions received since the 39th FAF Plenary

The following two new mandates have been received since the 39th FAF Plenary meeting and are undergoing validity check with the FDP Unit:

Food Sector	EFSA-Q-Number	Subject	Reception date
FA New	EFSA-Q-2023-00666	Application for the authorisation of Gardenia (genipin) blue as a new food additive	11.10.2023
FA New	EFSA-Q-2023-00672	Application for the modification of the food additive low-substituted hydroxypropyl cellulose (E 463a)	16.10.2023

8.2. Valid/accepted questions since the 39th FAF Plenary:

The following two new applications have been considered suitable for risk assessment by EFSA since the 39th FAF Plenary meeting:

Food Sector	EFSA-Q-Number	Subject	Validity date
FA Ext use	EFSA-Q-2023-00505	Application for the extension of use of the food additive quillaia extract	25.10.2023

FA New	EFSA-Q-2022-00463	Application for the authorisation of acerola fruit powder as a new food additive	25.10.2023

Both mandates will be assigned to the WG Food Additives Applications for the drafting of the scientific opinions.

8.3. Withdrawn questions since the 39th FAF Plenary:

None.

9. Other scientific topics for information and/or discussion

Nothing to report.

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

In addition to the questions related to the specific agenda items, the following questions were received from the observers during the registration phase:

- When producing food additive or processing aids, can non-food grade chemicals can be used? For example, can single chemical substance(sold as non-food grade) can be used as ingredient for manufacturing food additive? It can be deleted in final product or it can be remained in the final product.

During the manufacturing process of a food additive, any chemical can be used. For the safety assessment of the food additive, information on the nature and amount of the impurities including those as carry-over from the raw materials used in its production is needed. If a raw material (e.g. glycerol) used for the production of a food additive meets the specifications of the substance used as food additive (e.g. E422), no concern on carry-over impurities because these would be regulated by specifications of the food additive by Regulation 231/2012; however if the raw material does not meet the specifications of the food additive, there is uncertainty on the presence of other potential impurities and therefore more data should be submitted for the assessment.

- What is standard for chlorate for food additive and flavourings? Does all food additive and flavourings should compliance to chlorate as 0.01 ppm?

In the European Union, purity criteria for food additives are set in Regulation (EU) No 231/2012 whereas in the case of food flavourings purity limits are set in Regulation (EC) No 1334/2008. There are no specific limits set for chlorate in either food additives or flavourings. Having said that, any undesirable substance that can be present in a certain amount in the food additives or flavourings, is considered an impurity. Some of the impurities may be of toxicological concern. The level of the impurity in the food additive combined with the estimated intakes of the food additive, would result in an exposure to the impurity which can be compared with a reference point or a health-based guidance value for the undesirable impurity. This would help to determine whether there is a possible health concern if the impurity is present at a certain level in the food additive.

- What is food additive which presently safe and not safe

In the European Union, for food additives to be permitted for use in foods, they must undergo a safety assessment. The list of food additives permitted for use in foods in the EU is found in Regulation (EC) No 1333/2008.

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

- Will EFSA be performing an urgent re-evaluation of aspartame (following the EU Parliament question to the Commission of 12 Oct 23 - E-003022/2023) and how is this expected to affect the planning of the sweeteners re-evaluation? And, if possible, could the Panel provide a brief update on opinions on sweeteners re-evaluation close to be published (this or next year) apart the one of erythritol?

In answer to this question it was clarified that EFSA is currently re-assessing the safety of those sweeteners that were already permitted for use in foods as of 20 January 2009 under Regulation (EU) No 257/2010, among the food additives that remain to be re-evaluated is the salt of acesulfame and aspartame (E 962) for which the assessment is still ongoing. The sweetener aspartame (E 951) has been already re-evaluated by EFSA in 2013 and the acceptable daily intake (ADI) set at the time has been recently reconfirmed by JECFA. In the context of the re-evaluation of E 962 any new relevant publication on aspartame will be considered, however at the moment it is not possible to indicate a date for the completion of the assessment. Several requests for additional data and delays with the submission of the requested data have had a significant impact on the overall progress of the re-evaluation of these food additives. At the moment, the Working Group Sweeteners is aiming at finalising the scientific opinion on the re-evaluation of saccharins (E 954) for adoption in 2024. The scientific opinion on the re-evaluation of neotame (E 961) is also in an advanced stage and was in fact originally planned for adoption in 2023, however in this case submission of some requested data is still pending and therefore the assessment could not be finalised. Work continues in parallel on all the other sweeteners and, as with all the other Working Groups of the FAF Panel, the progress can be followed through the published minutes.

11. Any other business

None.