SCIENTIFIC PANEL ON FOOD ADDITIVES AND FLAVOURINGS (FAF) OPEN to Observers

46th FAF Panel meeting

29-30 April 2024
09:00-18:00 / 09:00-13:00
MINUTES (Agreed on 14 May 2024)

EUROPEAN FOOD SAFETY AUTHORITY

Location: Teleconference

Attendees:

- Panel Members:
  Gabriele Aquilina, Laurence Castle, Gisela Degen, Paul Fowler, María José Frutos Fernández, Peter Fürst, Ursula Gundert-Remy, Rainer Gürtler, Trine Husoy, Melania Manco, Wim Mennes, Peter Moldeus, Sabina Passamonti, Romina Shah, Dina (Ine) Waalkens-Berendsen, Matthew Wright and Maged Younes
- EFSA:
  Food Ingredients and Packaging (FIP) Unit: Stefania Barmaz, Valeriu Curtui, Maria Carfi, Consuelo Civitella, Borana Dino, Gabriele Gagliardi, Federica Lodi, Remigio Marano, Carla Martino, Elena Mazzoli, Agnieszka Mech, Salvatore Samuele Multari, Josef Rasinger, Ana Rincon, Laura Ruggeri, Camilla Smeraldi, Alexandra Tard, Sam Vermeiren and Panagiota Zakidou

  Methodology and Scientific Support Unit (MESE) Unit: Maria Chiara Astuto, Petra Gergelova, Sara Levorato, Daniela Maurici
- EC: Katleen Baert, Stylianos Koulouris
- Hearing Experts[1]: Mohammad Chaudhry and Jan Mast (for agenda point 8.1)
- Representatives from the European Medicines Agency (EMA): Susanne Brendler-Schwaab, Corinne De Vries, Francisca Van Doesum Wolters,
- Observers: Alquati Eleonora (CAOBISCO), Andersson Caroline (Cefic - ASASP Sector Group), Atienzar Franck (The Coca Cola Company), Boon Polly (RIVM), Buitelaar André (Unilever), Burr Mara (Consumer Brands Association), Carvalho Avelino, Cluzelle Cécile (Synpa - The French specialty food ingredients association), Cogalniceanu Elena (EAS Strategies), Collopy Patrick (Chromologics), Dammeier Jana (Chemische Fabrik Budenheim KG), Drexel Claus-Peter (Evonik Operations GmbH), Duchen Rocio (Argenta Barcelona trading as Pen & Tec Consulting SLU), FitzGerald Rex, Franklin Jenny (PQ Corporation), Gartlon Joanne (Freelance), Gatti Eva (Reckitt Benckiser), Geiser Stefanie (EAS Strategies), Gelbert Julia (Food Federation Germany), Houdeau Eric (INRAE), Hubbard Troy, Ionita Mihai (AESGP), Jaskolska Joanna (International Sweeteners Association), Kampmeyer Christopher, Kata Hejjas (Specialised Nutrition Europe), Kern Magdalena (Evonik Operations GmbH), Kildemark Niels (Haleon), Lang Gunnar (Evonik Operations GmbH), Leprêtre Christophe (Keller and Heckman LLP), Louro Henriqueta (National Institute of Health Dr. Ricardo Jorge (INSA)), Martinez Lucia (dsm-firmenich), Mavromichali Evangelia (Abbott Nutrition), McConochie Carmen (Cefic), Meier Stefanie (RDA Scientific Consultants GmbH), Mihai Ionita (AESGP), Minot de Brito Iana (NEXIRA), Montalvo Grijalva Daniela (Sciensano), Morales Patricia (Complutense University of Madrid), Mulrine Colleen (Food Standards Agency in Northern Ireland), Nolde Juergen (Grace Europe Holding GmbH), Peditto Francesca (Solvay), Pesce Francesco (EU Specialty Food Ingredients), Post Jan Dirk (Coca-Cola GmbH), Ramos José (Industrias Químicas del Ebro S.A.), Richter Dietmar (Grace GmbH), Ronsmans Stefan (Coca - Cola Services), Roosynda Merlizza (Corbion), Scarduzio Aurora (ssica), Schuster Tobias /Evonik Operations GmbH), Sergent Jacques-Aurélien (Solvay), Teoh Keng Ngee (Ajinomoto Europe), Terzi Luca (FoodDrinkEurope), Wang Si (Pepsico International)

[1] As defined in Article 34 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

CLOSED SESSION

1. Welcome and apologies for absence

Maged Younes, chair of the FAF Panel, chaired the present meeting and welcomed the Participants.
Apologies were received from Matthew Wright on 29th April.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of 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.

4. Agreement of the minutes of the 45th FAF Panel Plenary meeting held on 21-22 March 2024.

The minutes of the 45th Panel plenary meeting were agreed by written procedure on 17th April 2024.

5. Report on written procedure

Not applicable

6. Scientific output(s) submitted for discussion/adoption

6.1 Draft scientific opinion on the safety in use of soy leghemoglobin from genetically modified Pichia pastoris yeast as a food additive (EFSA-Q-2022-00031)

The FAF Panel discussed the section on identity and specifications of the draft opinion on the safety assessment the proposed new food additive soy leghemoglobin produced from a genetically modified *Pichia pastoris* yeast. The food additive application is being assessed by the FAF Panel in parallel with a request for placing on the market of Soy Leghemoglobin produced from genetically modified *Pichia pastoris* by the GMO Panel under Regulation (EC) No 1829/2003 (EFSA-Q-2019-00651). The Panel also discussed the approach for the conclusions on the safety of the proposed food additive based on the available data.

Based on the comments provided by the participants a draft document will be presented for discussion at a forthcoming FAF Panel meeting.

OPEN SESSION

7. Presentation of EFSA guidelines for observers

[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

EFSA presented the guidelines for observers for open plenary meetings.

8. Scientific output(s) submitted for discussion/adoption
Scientific output(s) submitted for discussion/adoption

8.1 Draft scientific opinion on Re-evaluation of silicon dioxide (E 551) as a 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. (EFSA-Q-2018-00526)

The technical part of the assessment of the food additive silicon dioxide (E 551) was presented. The FAF Panel discussed the assessment to toxic elements present in the food additive and the amendment of their limits in the EU specifications for E551 (Commission Regulation (EU) No 231/2012). The FAF Panel also discussed the available data on the characterisation of different synthetic amorphous silica (SAS) used as E551 regarding the constituent particle size, morphology of the aggregates and absence of coating or surface functionalisation. A preliminary description of SAS used as E551 was agreed.

The approach for the safety assessment of the food additive was discussed. In consideration of the characterisation of SAS used as E551 and in line with the EFSA Guidance on Particle – Technical Requirements (EFSA Scientific Committee, 2021a[4]), risk assessment at the nanoscale following the EFSA Guidance on Nano – Risk Assessment (EFSA Scientific Committee, 2021b[5]) will be needed, to complement the conventional risk assessment. The different steps for the screening and appraisal of the toxicity (genotoxicity) evidence were presented. Feedback from the ongoing collaboration and contribution with other EFSA Working Groups, in particular EFSA cross-cutting WG on Genotoxicity and EFSA cross-cutting WG on Nanotechnologies was also given.

The comments provided by the participants to the sections presented at the current meeting were annotated for the finalisation of the assessment.

The Chair opened the floor to the questions from the observers on this agenda item. The following one was posted in the chat:

- What do you understand by the term relative amount of "isolated particles"? Are these the aggregates as smallest dispersible units or the internal structures (constituent particles), to which the aggregates cannot be broken down?

In answer to this question, EFSA staff clarified that in several publications authors claim to identify isolated constituent particles, e.g. Khan et al. (2024)[6] indicated "*we began to identify isolated primary particles as well as primary particles within aggregate*"

- Have you been able to determine the level/amounts of toxic elemental impurities in the used test substances for the in vitro and/or in vivo genotoxicity studies? Lead and aluminium are known to be genotoxic and induce DNA damage and you showed earlier that aluminium and lead have been detected at low levels in precipitated SAS formulations.

In answer to this question, EFSA staff clarified that concentration of lead and aluminium in several SAS used as E551 have been submitted. Therefore, if any of those specific SAS were tested in the genotoxicity studies, the information is available.

[4] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6769
[5] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6768
[6] https://pubmed.ncbi.nlm.nih.gov/38175170/

8.2 Re-evaluation of saccharin (E954(i)), sodium saccharin (E954(ii)), calcium saccharin (E954(iii)) and potassium saccharin (E954(iv)) (EFSA-Q-2011-00736, EFSA-Q-2011-737, EFSA-Q-2011-738, EFSA-Q-2011-739)

The technical part (including identity/impurities and specifications, maufacturing process, methods of analysis and stabiltity) of the assessment of the food additives saccharin and its sodium, potassium and calcium salts was discussed. Despite two different manufacturing processes can be used to produce these food additives, only information from one of them has been submitted for its evaluation. Therefore, only the safety of E954i-vi produced with that specific manufacturing process can be assesed.

During the discussion, it was noted that further clarifications on the use of a reagent in the manufacturing process, under assessment, would be relevant in order to complete the assessment and avoid indicating any data gap that should need a follow-up by a further call for data from the European Commission according to its re-evaluation programme.[7]

The exposure assessment to saccharin and its sodium, potassium and calcium salts (E 954) was also discussed. The different calculated exposure scenarios were presented.

The comments provided by the participants to the presented sections were annotated for the finalisation of the assessment.

The main changes in the revised protocol were presented. These are for the acute dietary exposure to sweeteners and for the consideration of the facets for intense sweeteners and polyols. The revised protocol will be published on Zenodo on Q3 2024.

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

8.3 Self-tasking mandate proposed to EFSA by the FAF Panel for a revision of the 2012 ANS Panel "Food Additive Guidance for submission for food additive evaluations" (EFSA-Q-2023-00713)

A general information on the status of the revision of the Guidance on Food Additives was presented as well as the expected timelines for its finalisation. A public consultation of the draft revised Guidance document, endorsed by the FAF Panel, is currently forseeen between November 2024 and February 2025 and its adoption is scheduled in Q1 2025.adoption.

The Chair opened the floor to questions from the observers on this agenda item. The following questions were posted in the chat:

- With reference to slide 5, it is mentioned that the food enzyme guidance will be included in the new updated food additive guidance. I understand that this is because there are new manufacturing processes for food additives that include the use of certain enzymes, but why is it considered that the requirements for risk assessment of "food enzymes" are equivalent to those of enzymes used for manufacturing food additives, when these types of enzymes are clearly excluded from the scope of Reg. 1332/2008 on food enzymes?

In answer to this question, EFSA staff clarified that when a food enzyme is used in the manufacturing process of a food additive, the following two possible scenarios are anticipated.

1) If the food enzyme falls outside the scope of Regulation (EC) No 1332/2008, since it is used exclusively in the production of the food additive, in line with Article 2 of this

[7] https://food.ec.europa.eu/safety/food-improvement-agents/additives/re-evaluation_en

Regulation, data to perform the safety evaluation of the food enzyme should be provided within the technical dossier of the food additive, in line with the scientific criteria outlined in the EFSA scientific guidance document for the submission of dossiers on food enzymes (EFSA CEP Panel, 2021).

2) If the food enzyme falls within the scope of Regulation (EC) No 1332/2008, information as to whether the involved enzyme has been assessed or is being assessed by EFSA in the framework of Regulation (EC) No 1332/2008, should be provided by the applicant upon submission of the technical dossier of the food additive. If the assessment of the food enzyme is still ongoing, EFSA can request the extension of the deadline for the evaluation of the food additive, in line with Article 10 of Regulation (EC) No 1331/2008. At the same time the risk assessment of the enzyme in question will be prioritised by EFSA.

- Will the update to the food additive guidance include the requirement of presenting FASTA files of production organisms, as raw data for whole genome sequencing analyses? Do applicants have any chance of justifying non-presentation of FASTA files?

In answer to this question, EFSA staff clarified that the data requirements on the microorganism(s) used as production organism(s) are under revision by the EFSA Scientific Committee (SC) and are being included in the draft SC Guidance on Microorganisms used in the Food Chain, which is expected to be released for public consultation in Q4 2024. A reference to this SC guidance document will be included in the revised Guidance on Food Additive.

9. Feedback from the Scientific Committee/ Scientific Panels/EFSA/ EC

9.1 Scientific Committee including their Working groups

Feedback on the latest the Scientific Committee meeting was provided

9.2 FAF Panel Working Groups /Task Forces

The Chairs of the Working Groups of the FAF Panel provided information with respect to the status of the ongoing assessments.

9.3 European Commission

None

9.4 EFSA

None

10. New mandates

10.1 New questions received since the 45th FAF Plenary

None

10.2 Valid/accepted questions since the 45th FAF Plenary:

The following two new mandates have been considered suitable for risk assessment by EFSA since the 45th FAF Plenary meeting:

Food Sector	EFSA-Q-Number	Subject	Validity date
FA	EFSA-Q-2023-00666	Application for the authorisation of Gardenia (genipin) blue as a new food additive	10 April 2024

FA	EFSA-Q-2021-00078	Request for EFSA to perform a risk assessment and to provide a scientific opinion on the safety of a proposed amendment of the specifications of the food additive xylitol (E 967)	22 April 2024

The mandate EFSA-Q-2023-00666 will be assigned to the WG Food Additives Applications for the drafting of the scientific opinions and mandate EFSA-Q-2021-00078 will be considered together with the re-evaluation of E 967

10.3 Withdrawn questions since the 45th FAF Plenary:

None.

11. Q&A Session

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

- How is EFSA working to coordinate with other regulators like the U.S. Food and Drug Administration when it comes to food additives and flavorings?

EFSA has regular exchanges with FDA on many aspects within EFSA's remit. EFSA and FDA do not discuss specific dossiers but exchange information on risk assessment methodology, in order to understand each other's processes and align, where possible, on methodology and data needs. EFA involves them, together with many other EU and non-EU organizations, in the engagement activities around new guidance documents and preparedness activities

- Would it be possible - please - for the EFSA FAF Panel secretariat to prepare and share an exhaustive table with the tentative timelines (Q1, Q2 2024, 2025...) for the completion of each individual remaining EFSA scientific opinion to be finalized on the food additives reevaluation program (taking into account pending - or recently elapsed - EFSA-related or COM-related calls for any additional data)? It would greatly increase transparency of - and the sympathy capital for - the work of the Panel and of EFSA at large. Thank you very much in advance.

It should be acknowledged that the FAF Panel works on a number of different regulatory processes, and the re-evaluation of food additives is only one of the activities performed by the Panel. The process has been explained in detail during a dedicated Infosession held in Parma on 19-20 March 2024, and the presentations shown are all available on the EFSA website: https://www.efsa.europa.eu/en/events/info-session-re-evaluating-food-additives#presentations
As explained during that event, the FAF Panel needs to deliver opinions on:

- Food additives and flavourings new applications submitted under Regulation (EC) No 1331/2008:
  - There are currently 21 EFSA-Q-numbers in the risk assessment phase, with deadline between 2024 and 2025, corresponding to 21 opinions to be adopted by the Panel
  - There are currently 3 EFSA-Q-numbers corresponding to new food additives applications for extension of uses, that are being dealt in conjunction with the re-evaluation and for which the 9-month timeline has already expired:
    - Shellac (E 904)
    - Sucralose (E 955)
    - Pullulan (E 1204)

    - An additional EFSA-Q-number corresponding to a change to the manufacturing process has just been validated and will be dealt in conjunction with the re-evaluation of
        - Xylitol (E 967)
- Flavouring groups evaluations (FGEs)
    - There are currently 6 EFSA-Q-numbers, corresponding to 2 FGEs opinions in preparation, for possible adoption late 2024-early 2025
- Follow-up to the re-evaluation of food additives
    - There are currently 7 EFSA-Q-numbers, corresponding to 5 scientific opinions in preparation, on the follow-up to the re-evaluation of food additives permitted for use in foods for infants and young children (M-2017-00220)
        - Silicon dioxide (E 551) is being prioritised for possible adoption in 2024
    - There are currently 7 EFSA-Q-numbers, corresponding to 5-6 scientific opinions in preparation, on the follow-up to the re-evaluation of other food additives
        - Silver (E 174) is being prioritised for possible adoption in 2024
        - Gold (E 175) is being prioritised for possible adoption in 2025
- Food additives to be re-evaluated under Regulation (EU) No 257/2010
    - There are currently 20 EFSA-Q-numbers, corresponding to 12 scientific opinions on sweeteners
        - Saccharins (E 954) for possible finalisation in 2024
        - Maltitols (E 965) for possible finalisation late 2024/early 2025
        - Acesulfame K (E 950) for possible finalisation in 2025
        - Sucralose (E 955) for possible finalisation in 2025
            - Draft advanced, awaiting data
        - Neotame (E 961) for possible finalisation early 2025
            - Draft advanced, awaiting data
    - There are currently 2 EFSA-Q-numbers, corresponding to 2 scientific opinions on other food additives under preparation
        - Shellac (E 904) for possible finalisation in 2024
        - Pullulan (E 1204) for possible finalisation in 2025
    - There are currently 26 EFSA-Q-numbers, corresponding to 4-8 scientific opinions on other food additives for which assessment is starting
        - Gluconic acid and gluconates (E 574-579)
        - Ribonucleotides (E 626-635)
        - Food additives in gaseous form
    - There are currently 9 EFSA-Q-numbers, corresponding to 2-4 scientific opinions on other food additives for which calls for data are being launched during 2024
        - Malic acid and malates (E 296 ; E 350-352)
        - Fumaric acid (E 297)
        - Succinic acid (E 363)
        - Calcium disodium EDTA (E 385)
    - For all the remaining food additives, at present is really impossible to provide a clear plan for their re-evaluation, depending on the overall workload of the Panel, interconnection with other Panels, new emerging priorities.

There is a large amount of information made available on the EFSA website, including the minutes of the plenaries and of the Working Groups. All the substances under assessment are identified by an EFSA-Q-number that can be tracked in the Open EFSA website https://open.efsa.europa.eu/

- Kindly let me know the quality requirements for exporting organic food products from India
- What are all the certifications required for exporting to Europe
- How do we get the annual requirements of Moringa products like oil, powder and seeds

The answer to these questions does not fall within the remit of the FAF Panel or EFSA.

On the website of the European Commission there is a section dedicated to the information related to the import from third countries into the EU accessible at https://trade.ec.europa.eu/access-to-markets/en/home

12. AOB

None