FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD ADDITIVES AND FLAVOURINGS (FAF)

MINUTES OF THE 25TH PLENARY MEETING

Held on 10 November 2021
09.00-17.00

Online meeting

(Agreed by written procedure on 29 November 2021)

Participants

- Panel Members:

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

- European Commission and/or Member States representatives:

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

- EFSA:

  FIP Unit: Claudia Roncancio Peña, Maria Carfi, Consuelo Civitella, Antonio Rivas Cornejo, Christina Kyrkou, Marcello Laganaro, Federica Lodi, Carla Martino, Ana Maria Rincon, Camilla Smeraldi, Alkiviadis Stagkos-Georgiadis, Alexandra Tard, Giorgia Vianello

  FEED Unit: Paola Manini

  SCER Unit: Daniela Maurici, Reinhilde Schoonjans, José Vicente Tarazona

1. Welcome and apologies for absence

The Chair welcomed the participants in the meeting. No apologies were received for the whole length of the meeting.

[1] Apologies on AM

2. Adoption of agenda

The agenda was adopted without changes.

3. 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 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.

4. Agreement of the minutes of the 24th Plenary – Open for Observers meeting held on 29-30 September 2021, as online meeting

The minutes of the 24th FAF Plenary – Open for Observers meeting held on 29-30 September 2021 were agreed by written procedure on 20 October 2021[4].

5. Report on written procedures since 24th Plenary – Open for Observers meeting

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

6. Scientific topic(s) for discussion

FLAVOURINGS

6.1. Update of EFSA guidance on the data required for the risk assessment of flavourings (EFSA-Q-2021-00289)

The view of the Panel was sought with respect to the approach that is being elaborated by the Working Group on the Guidance Update on Flavourings, in particular for what concerns the principles to be applied for the safety evaluation of flavouring substances for the following three main aspects:

- **Applicability of the Threshold of Toxicological Concern (TTC) approach to the evaluation of flavouring substances with a low estimated exposure.**
- **Toxicological data needed for the evaluation of flavouring substances if the estimated exposure is above the TTC**
- **Use of read-across principle in the assessment of food flavourings**

[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/en/events/event/24th-plenary-meeting-faf-panel-proposed-be-open-observers

Based on the discussion held at the current plenary meeting, the WG will further elaborate the draft guidance document aiming at presenting a revised version at a forthcoming plenary meeting. According to the current timetable, the revised guidance should undergo a period of public consultation in the second quarter of 2022, with a view to finalise it by November 2022.

7. Other scientific topics for information and/or discussion

7.1. Re-evaluation of sucrose esters of fatty acids (E 473) as a food additive in foods for infants below 16 weeks of age (EFSA-Q-2018-00101)

The food additive sucrose esters of fatty acids (E 473) did not undergo a full re-evaluation under Regulation (EC) No 257/2010 because this food additive had already been re-evaluated by EFSA in 2006[5]. A later opinion was issued in 2012 on the safety of sucrose esters of fatty acids prepared from vinyl esters of fatty acids and on the extension of use of sucrose esters of fatty acids in flavourings[6]. The latest scientific assessment completed in 2018 by the Panel on Food Additives and Nutrients (ANS Panel) was limited to a refined exposure assessment of the food additive[7].

A first call for data[8] had been launched by EFSA to gather information relevant to the re-evaluation of the use of E 473 in infants below 16 weeks of age, however no responses were received from interested business operators confirming the use of the food additive (E 473) in the food categories (FC) 13.1.1 (Infant formulae as defined Directive 2006/141/EC) and 13.1.5.1 (Dietary foods for infants for special medical purposes and special formulae for infants).

The call for data however did not include a request for data to address the presence of impurities of toxicological concerns regarding the potential presence of impurities carried over and/or developed from the food oils and fats used in the manufacturing processes that have been identified in the re-evaluation of other food additives (e.g. E 471, E 472a-f) that are related to E 473.

The Panel was therefore informed on the need for gathering additional information on technical data for the risk assessment of any impurity of toxicological concern, and as a next step an additional call for data on the food additive E 473 will be launched.

The call will also provide a last opportunity for interested business operators to confirm whether the food additive sucrose esters of fatty acids (E 473) is used in food categories 13.1.1 and 13.1.5.1 and to provide relevant information. If no information on these uses is received, the safety of the use of the food additive for infants below 16 weeks of age will not be addressed the scientific opinion under development.

[5] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2004.106
[6] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2658
[7] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5087
[8] https://www.efsa.europa.eu/it/consultations/call/181129

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

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

No meetings of the EFSA Scientific Committee were held since the last plenary meeting.

8.1.1 EFSA Scientific Committee

8.1.1.1 Info-session on the latest EFSA Scientific Committee guidance documents applicable to the assessment of food additives and flavourings

EFSA staff from the Scientific Committee and Emerging Risk (SCER) Unit provided a presentation on the latest scientific guidance documents adopted and published by the EFSA Scientific Committee between March and October 2021, namely:

- Statement on the derivation of Health-Based Guidance Values (HBGVs) for regulated products that are also nutrients
- Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles
- Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health
- Guidance on aneugenicity assessment
- Opinion on the impact of non-monotonic dose responses on EFSA's human health risk assessments

The presentation of these scientific guidance documents was followed by a discussion on their possible practical applicability to ongoing assessments.

In particular, with respect to the implementation of the "Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles", the Panel noted that this will require, for several ongoing assessments, additional requests for data from applicants/interested parties to confirm that an assessment of the fraction of small particles including nanoparticles is not needed for the substance under assessment, or that is already covered in the safety assessment process following the conventional sectorial guidance.

With respect to the follow-up on the re-evaluation of tocopherols (E 306-309), the Panel noted that upper intake levels of vitamin E are currently under revision by EFSA and therefore following the approach outlined in the "Statement on the derivation of Health-Based Guidance Values (HBGVs) for regulated products that are also nutrients", the assessment of the food additive should be completed only after the intake level of the nutrient has been set. The current deadline for the NDA Panel to deliver its opinion on the upper intake level of vitamin E is March 2023.

8.1.2. FAF Panel Working Groups

In addition to what is already recorded in the minutes of the existing FAF Panel WG meetings, the Panel held a discussion on the need to set-up a new Working Group to handle

the current workload originating from the mandates for the follow-up of food additives re-evaluation opinions received from the European Commission.

Currently, the following assessments are currently ongoing at the level of a Working Group:

Mandate number	EFSA-Q-number	Food additive(s) (E number)	FAF Panel Working Group
M-2017-0220	2018-00088	Calcium carbonate (E 170)	WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age
			WG on Specifications of Food Additives
M-2017-0220	2018-00090	Tocopherol-rich extract (E 306)	WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age
	2018-00091	α-tocopherol (E 307)	
	2018-00092	γ-tocopherol (E 308)	
	2018-00093	δ-tocopherol (E 309)	
M-2017-0220	2018-00095	Locust bean gum (E 410)	WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age
M-2017-0220	2018-00096	Guar gum (E 412)	WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age
M-2017-0220	2018-00097	Xanthan gum (E 415)	WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age
M-2017-0220	2018-00099	Carboxy methyl cellulose (E 466)	WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age
M-2017-0220	2018-00101	Sucrose esters of fatty acids (E 473)	WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age
M-2017-0220	2018-00270	Carrageenan (E 407)	WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age
M-2017-0220	2018-00526	Silicon dioxide (E 551)	WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age
			WG on Specifications of Food Additives
M-2017-0220	2021-00674	Citric acid esters of mono- and diglycerides of fatty acids (E 472c)	WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age
M-2019-0220	2019-00815	Glycerol (E 422)	WG on Specifications of Food Additives
M-2021-00025	2021-00110	Sulfur dioxide and sulphites (E 220-224; 226-228)	WG on Specifications of Food Additives
			WG on Sulphur dioxide-Sulphites (E220-228)
M-2021-00036	2021-00178	Iron oxides (E172)	WG on Specifications of Food Additives
M-2021-00037	2021-00178	Indigotine, indigo carmine (E 132)	WG on Specifications of Food Additives

Mandate number	EFSA-Q-number	Food additive(s) (E number)	FAF Panel Working Group
Mandate under registration	2021-00560	Silicates and talc (E 552, E 553a,b)	WG on Specifications of Food Additives
Mandate under registration	2021-00559	Polyglycerol polyricinoleate (E 476)	WG on Specifications of Food Additives
Mandate under registration	2021-00563	Polyglycerol esters of fatty acids (E 475)	WG on Specifications of Food Additives
Mandate under registration	2021-00564	Glycerol esters of wood rosins (E 445)	WG on Specifications of Food Additives
Mandate under registration	2021-00562	Gold (E 175)	WG on Specifications of Food Additives

In the case of some mandates, currently assigned to the WG on Specifications of Food Additives, the assessment is not limited to the evaluation of technical data but, once the characterisation of the food additive is completed, it will require also an evaluation of biological and toxicological data on the food additive (E 132; E 172; 175; E 445; E 552-553a,b). This would also be the case for those assessments that were initiated under the WG on the re-evaluation of food additives permitted in foods for infants below 16 weeks of age and later handed over to the WG on Specifications of Food Additives because of the expertise needed for assessing the data on the characterisation of the food additives (E 170, E 551) and that, depending on the conclusions on the characterisation, may require an assessment of the fraction of small particles including nanoparticles in line with the applicable EFSA SC Guidance documents.

In addition, the Panel noted that other similar new mandates could be received in the future from the European Commission as soon as the data requested to the interested business operators have been generated as part of the follow-up program managed by the European Commission[9] and therefore the scope of the new Working Group would not be limited to the food additives listed above.

In the light of the above, the Panel agreed on the proposal from the FIP Unit to set up a new Working Group tasked with the preparation of scientific opinions on the follow-up of the food additives re-evaluation opinions requiring an assessment of safety data further to the evaluation of the technical data performed by the WG Specifications.

The Panel member Ursula Gundert-Remy was proposed as Chair of this new WG.

8.2. EFSA including its Working Groups/Task Forces

This agenda item was not discussed.

8.3. European Commission

This agenda item was not discussed.

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

9. New mandates

The Panel was informed of the following new application dossiers/mandates received since the last plenary meeting and still under validation:

- **Application for the authorisation of a new food additive under Regulation (EC) No 1331/2008: buffered vinegar** EFSA-Q-2021-00595

  Pending confirmation of the validity of the application, the Panel noted that the present assessment will be carried out by the WG on Food Additives Applications.

The Panel was informed of the following new application dossiers/mandates considered valid since the last plenary meeting.

- **Application for a modification of an already authorised smoke flavouring under Regulation (EC) 2065/2003: Scansmoke PB 1110 (SF-001)** EFSA-Q-2021-00561

  This mandate (M-2021-00648) from a Member State refers to a request for the change of the authorisation holder of the smoke flavouring primary product Scansmoke PB1110. Since this request concerns only the change of administrative data, an opinion of the Panel is not needed.

10. Any Other Business

None