

# SCIENTIFIC PANEL ON FOOD ADDITIVES AND FLAVOURINGS (FAF)

## MINUTES OF THE 12<sup>TH</sup> PLENARY MEETING

**Held on 28-30 January, Parma**

**(Agreed on 13 February 2020)**

### Participants

■ Panel Members:

Gabriele Aquilina<sup>1</sup>, Laurence Castle, Karl-Heinz Engel, Paul Fowler, Maria José Frutos Fernandez, Peter Fürst, Rainer Gürtler<sup>2</sup>, Ursula Gundert-Remy, Trine Husøy, Wim Mennes, Peter Moldeus, Romina Shah<sup>3</sup>, Dina (Ine) Waalkens-Berendsen, Detlef Wölfe and Maged Younes

■ European Commission and/or Member States representatives:

DG SANTE (Health and Food Safety), E2 Food processing technologies and novel foods: Guillermo Cardon

■ EFSA:

FIP Unit: Claudia Roncancio Peña, Stefania Barmaz, Esraa Elewa, Brian Flynn, Alessandra Giarola, Federica Lodi, Carla Martino, Ana Maria Rincon, Camilla Smeraldi, Alexandra Tard and Giorgia Vianello

REPRO Department: Guilhem de Seze

DATA Unit: Davide Arcella

### 1. Welcome and apologies for absence

The Chair welcomed the participants in the meeting.

The Panel was informed of the resignation of Agneta Oskarsson from her role as member due to personal reasons with effect as of 1<sup>st</sup> January 2020. The FIP Unit is proceeding with the identification of candidates from the reserve list of the EFSA Scientific Panels for possible replacement.

<sup>1</sup> Participated by web-conference on 28 and 29 January PM and 30 January 2020

<sup>2</sup> Participated by web-conference on 28 and 29 January PM and 30 January 2020

<sup>3</sup> Participated by web-conference on 28 and 29 January 2020 PM



## 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<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 11th Plenary meeting held on 10-12 December 2019, Parma

The minutes of the 11th Plenary meeting held on 10-12 December 2019 were agreed by written procedure on 13 January 2020<sup>6</sup>.

## 5. Report on written procedures since 11th Plenary meeting

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

## 6. Scientific topic(s) for discussion

### FOOD ADDITIVES

#### 6.1. Proposed amendment to the specifications of the food additive steviol glycosides (E 960) ([EFSA-Q-2019-00063](#))

The draft opinion on the safety evaluation of the proposed amendment of the specification of the food additive steviol glycosides was presented for the first time to the members of the Panel together with the main points for discussion.

The Panel considered that additional information should be requested from the applicant in order to complete the assessment. The scientific evaluation will therefore be suspended, awaiting submission of the additional information requested.

#### 6.2. Re-evaluation of sweeteners – Public consultation on the Protocol for the exposure assessment as part of the safety assessment of sweeteners under the food additives re-evaluation programme: Sorbitols (E 420 i,ii); Mannitol (E 421 i, ii); Acesulfame K (E 950); Isomalt (E 953); Sucralose (E 955); Thaumatin (E 957); Neohesperidine DC (E 959); salt of aspartame-acesulfame (E 962); Lactitol (E 966); Xylitol (E 967); Erythritol (E 968); Cyclamates (E 952 i, ii, iii); Saccharin Na, Ca, K (E 954 i, ii, iii, iv); Neotame

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>6</sup> <https://www.efsa.europa.eu/sites/default/files/event/faf-11-m.pdf>



**(E 961); Maltitol (E 965 ([EFSA-Q-2011-00644](#); [EFSA-Q-2011-00645](#)); ([EFSA-Q-2011-00646](#); [EFSA-Q-011-00647](#)); ([EFSA-Q-2011-00721](#)); ([EFSA-Q-2011-00723](#)); ([EFSA-Q-2011-00724](#)); ([EFSA-Q-2011-00725](#)); ([EFSA-Q-2011-00726](#)); ([EFSA-Q-2011-00727](#)); ([EFSA-Q-2011-00728](#)); ([EFSA-Q-2011-00729](#)); ([EFSA-Q-2011-00730](#)); ([EFSA-Q-2011-00733](#); [EFSA-Q-2011-00734](#); [EFSA-Q-2011-00735](#)); ([EFSA-Q-2011-00736](#); [EFSA-Q-2011-00737](#); [EFSA-Q-2011-00738](#); [EFSA-Q-2011-00739](#)); ([EFSA-Q-2011-00740](#)) ([EFSA-Q-2011-00755](#); [EFSA-Q-2017-00490](#); [EFSA-Q-2019-00645](#)))**

The Panel discussed the protocol for the assessment of dietary exposure to the sweeteners under re-evaluation, and the revisions made according to the comments received during the public consultation, and unanimously endorsed the protocol, subject to incorporation of changes as suggested during the meeting, for its implementation.

The Panel also discussed the technical report on the outcome of the public consultation on this protocol, which addressed the comments received during the public consultation, and unanimously endorsed the document, subject to incorporation of changes as suggested during the meeting.

Both documents will be available on the Authority's webpage.

**6.3. Re-evaluation of tartaric acid-tartrates (E 334-337, 354) ([EFSA-Q-2011-00612](#); [EFSA-Q-2011-00613](#); [EFSA-Q-2011-00614](#); [EFSA-Q-2011-00615](#); [EFSA-Q-2011-00616](#); [EFSA-Q-2011-00617](#); [EFSA-Q-2011-00637](#))**

Further to the previous discussion held at the plenary meeting in December 2019, a revised draft scientific opinion on the re-evaluation of the safety of tartaric acid (E 334), sodium (E 335), potassium (E 336), potassium sodium (E 337) and calcium tartrate (E 354) as food additives was presented to the FAF Panel.

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.

**6.4. Re-evaluation of metatartaric acid (E 353) ([EFSA-Q-2011-00636](#))**

The draft opinion on the re-evaluation of the safety evaluation of metatartaric acid (E 353) as a food additive was presented for the first time to the members of the Panel, along with a presentation on 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.

**6.5. Acid esters of mono- and diglycerides of fatty acids (E 472a-f) ([EFSA-Q-2011-00584](#); [EFSA-Q-2011-00585](#))**

Further to the previous discussion held at the plenary meeting in September 2019, a revised draft scientific opinion on the re-evaluation of the safety of acetic acid, lactic acid, citric acid, tartaric acid, mono- and diacetyltartaric acid, mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acid (E472a-f) as food additives was presented to the FAF Panel.

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.

#### **6.6. Re-evaluation of stearyl tartrate (E 483) ([EFSA-Q-2011-00570](#))**

Further to the previous discussion held at the plenary meeting in December 2019, a revised draft scientific opinion on the re-evaluation of the safety of stearyl tartrate (E 483) as a food additive was presented to the FAF Panel.

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.

#### **6.7. Re-evaluation of hydrogenated poly-1 decene (E 907) ([EFSA-Q-2011-00707](#))**

Further to the previous discussion held at the plenary meeting in November 2019, a revised draft scientific opinion on the re-evaluation of the safety of hydrogenated poly-1-decene (E 907) as a food additive was presented to the FAF Panel.

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.

### **FLAVOURINGS**

#### **6.8. FGE.72 Rev2 ([EFSA-Q-2018-00822](#); [EFSA-Q-2018-00831](#); [EFSA-Q-2018-00832](#); [EFSA-Q-2018-00833](#); [EFSA-Q-2018-00834](#); [EFSA-Q-2018-00835](#); [EFSA-Q-2018-00836](#); [EFSA-Q-2018-00837](#))**

The draft opinion on FGE.72 Rev2 was presented for the first time to the members of the Panel together with the main points for discussion. The current revision covered eight aliphatic, branched-chain  $\alpha,\beta$ -unsaturated alcohols and aldehydes, previously evaluated with respect to genotoxicity in FGE.200Rev1 ([FL-no: 05.114]) and FGE.201Rev2 ([FL-no: 02.174, 05.033, 05.090, 05.095, 05.105, 05.107 and 05.126]).

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.

## **7. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission**

### **7.1. Scientific Committee and Scientific Panel(s) including their Working Groups**

#### **7.1.1. 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](#).

#### **7.1.2. 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](#).



### **7.1.3.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](#).

### **7.1.4.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](#).

### **7.1.5.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](#).

### **7.1.6.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](#).

### **7.1.7.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](#).

### **7.1.8.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](#).

## **7.2. EFSA including its Working Groups/Task Forces**

### **7.2.1.New expert compensation scheme, extension of current Panel mandate and mutual assessment of EFSA staff and experts**

The Head of the REPRO Department attended the Plenary meeting to inform the Panel about the changes introduced by the New Transparency Regulation and the implication to the Scientific Committee and Panels, in particular in relation to the Panel mandate extension, the increase in expert indemnity, expert mutual assessment and timeline.

## **7.3. European Commission**

The Panel was informed about the plan of the European Commission to send a new mandate to EFSA to follow-up on the conclusions from the latest scientific opinion on the proposed change in the specifications of the food additive titanium dioxide (E 171), issued by the FAF Panel in June 2019<sup>7</sup>. In that opinion, the Panel had concluded that based on the proposed change in the specifications, revisiting the toxicological database on titanium dioxide (E 171) as a food additive should consequently be conducted in line with the data requirements specified in the 2018 EFSA Scientific Committee Guidance on nanotechnology<sup>8</sup>. An initial

<sup>7</sup> EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), Younes, M, Aquilina, G, Castle, L, Engel, K-H, Fowler, P, Frutos Fernandez, MJ, Gürtler, R, Gundert-Remy, U, Husøy, T, Mennes, W, Agneta Oskarsson, PM, Rainieri, S, Shah, R, Waalkens-Berendsen, I, Wölflé, D, Gaffet, E, Mast, J, Peters, R, Rincon, AM and Fürst, P, 2019. Scientific opinion on the proposed amendment of the EU specifications for titanium dioxide (E 171) with respect to the inclusion of additional parameters related to its particle size distribution. EFSA Journal 2019;17(7):5760. <https://doi.org/10.2903/j.efsa.2019.5760>

<sup>8</sup> EFSA Scientific Committee, Hardy A, Benford D, Halldorsson T, Jeger MJ, Knutsen HK, More S, Naegeli H, Noteborn H, Ockleford C, Ricci A, Rychen G, Schlatter JR, Silano V, Solecki R, Turck D, Younes M, Chaudhry Q, Cubadda F, Gott D, Oomen



discussion took place with the aim of clarifying the possible scope of the new mandate and timelines for its completion, that should take into account the expected submission of new data from the ongoing toxicological studies that are being performed by interested food business operators as a follow-up to the re-evaluation of titanium dioxide (E 171) by the ANS Panel in 2016 as well as any new relevant data that may have become available since then.

## 8. New mandates

### 8.1. Request for evaluation of additional information in order to complete the evaluation of the 9 sulfur-containing flavouring substances, represented by the substance 2-methyl-4-oxopentane-2-thiol [FL 12.169] and belonging to FGE.74 (namely substances with FL-no: 12.169 and 12.241) and FGE.91 (namely substances with FL-no: 12.038, 12.085, 12.137, 12.138, 12.145, 12.252, and 12.259)

This new mandate (M-2020-0004) covers a request from the European Commission to complete the evaluation of the above mentioned 9 flavouring substances with an assessment of a 90-day toxicological study carried out on the representative substance [FL-no: 12.169] and updated poundage data for substances included in both FGE.74 and FGE.91. The new mandate will be addressed in the context of the ongoing revision (Rev3) of FGE.91. The preparatory work for this assessment will be carried out by the existing WG Flavourings.

## 9. Other scientific topics for information and/or discussion

No other scientific topics were presented for information and/or discussion.

## 10. Any Other Business

In preparation for the coming FAF Panel plenary meeting on 24-26 March 2019, with a session open to observers, the Secretariat presented the relevant EFSA Guidelines for Observers<sup>9</sup>

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A, Weigel S, Karamitrou M, Schoonjans R and Mortensen A, 2018. Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health. EFSA Journal 2018; 16(7): 5327. <https://doi.org/10.2903/j.efsa.2018.5327>

<sup>9</sup> <http://www.efsa.europa.eu/en/stakeholders/observers>