



*EFSA Info session: (Re-)Evaluating Food Additives*

# European Commission Feedback

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*The views expressed are purely those of the speaker and may not in any circumstances be regarded as stating an official position of the European Commission*

# Outline

- Recent amendments food additives legislation
- Evaluation of food additives
- Re-evaluation of food additives
- Other activities

# Summary 2023: Amendments FA legislation

- R 2023/440 – Use of carbomer (E 1210) in FS
- R 2023/447 – Authorisation of glucosylated steviol glycosides (E 960d)
- R 2023/2086 - Authorisation of buffered vinegar (E 267)
- R 2023/2108 – Review of the conditions of use and specs of nitrites (E 249-250) and nitrates (E 251-252)
- R 2023/2379 – Withdrawal of stearyl tartrate (E 483)
- R 2023/1428 – Amendments of specs of mono- and diglycerides of fatty acids (E 471)
- R 2023/1329 – Amendments of specs of glycerol (E 422), polyglycerol esters of fatty acids (E 475) and polyglycerol polyricinoleate (E 476) + extension of use of E 476 in FC 03 (edible ices) and FC 12.6 (sauces)

*Rec 2023/965 – Monitoring of FA and FF*

# 2024: Amendments FA legislation

- R 2024/346 – Authorisation of the use of trimagnesium dicitrate (E 345(i)) in food supplements
- R 2024/374 – Amendments of the title of the food categories of alcoholic beverages and the use of several additives in certain alcoholic beverages

## **Pending the adoption (voted at the PAFF in February 2024):**

- Commission Regulation (EU) amending Annex II and Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the food additives tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336), sodium potassium tartrate (E 337) and calcium tartrate (E 354)

# Evaluation of Food Additives

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# Applications discussed at WGA 24 02

- WGA 24/02/02 Acerola fruit powder (2021/01, FAD-2022-3191) - update
- WGA 24/02/02 E 960a-d New specifications for E960 produced by fermentation with *Yarrowia lipolytica* (2021/06)
- WGA 24/02/02 Sorbates in desserts (2022/07, FAD-2022-8272)
- WGA 24/02/02 E 301 in vit A preparations (2023/11, FAD-2023-15270)
- WGA 24/02/02 E 1202 in colours for eggs (2023/12, FAD-2023-18934)
- WGA 24/02/02 E491 in acrylamide reducing yeast (food enzyme) (2023/14, FAD-2023-20310)
- WGA 24/02/02 E 530 in food category 04.1.1 (2024/01, FAD-2023-21051)
- WGA 24/02/02 Extensions of use of E999 in light of the recent EFSA opinion of 6 February 2024 (2013/01, 2019/15, 2020/18 and 2023/02 FAD-2023-15592)

*WGA: Working Party of Governmental Experts on Additives, i.e. a working group of the Standing Committee on Plants Animals Food and Feed, section Novel Food and Toxicological Safety of the Food Chain*

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# Use of plant extracts rich in constituents performing a technological function



EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2018)5591112

**SUMMARY REPORT OF THE  
STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED  
HELD IN BRUSSELS ON 17 SEPTEMBER 2018  
(Section Novel Food and Toxicological Safety of the Food Chain)**

- The Standing Committee issued statements on “spinach extract containing high levels of nitrate used in sausages” in 2006 and on “the use of fermented vegetable broth, enriched with nitrite” in 2010.

# Use of plant extracts rich in constituents performing a technological function



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The Committee reached unanimously the following outcome :

1. The validity of the statements of 2006 and 2010 was reconfirmed.
2. The scope of both statements shall not be limited only to (fermented/ non-fermented) extracts containing high levels of nitrate/nitrite but it shall be **generally applicable to all plant extracts which**, when added to foods, **achieve a level** of constituents (or their precursors) capable of performing a **technological function** in foods.
3. Such use of extracts that deliver a technological function in foods to which they are added is deemed **a deliberate use as a food additive**.



# Use of plant extracts rich in constituents performing a technological function



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4. Consequently, such use is deemed to **meet the definition of a food additive** and so it shall **comply with the conditions** set out in the food additive legislation (including relevant specifications) and be **labelled** in accordance with the appropriate provisions for labelling of food additives.
5. A number of plant extracts can perform both flavouring and additive functions. When **flavourings have a technological function as food additives**, the **food additive legislation shall apply**. In this case the extracts cannot be claimed to be used as flavourings.

[https://food.ec.europa.eu/document/download/aec94f26-1584-46eb-baf2-db33771769dd\\_en?filename=reg-com\\_toxic\\_20180917\\_sum.pdf](https://food.ec.europa.eu/document/download/aec94f26-1584-46eb-baf2-db33771769dd_en?filename=reg-com_toxic_20180917_sum.pdf)

# Changes in production process or starting materials

- **Article 12** of Regulation (EC) No 1333/2008 provide the rules that are applicable when there are changes in the production process or starting materials of a food additive already included in a Community list:

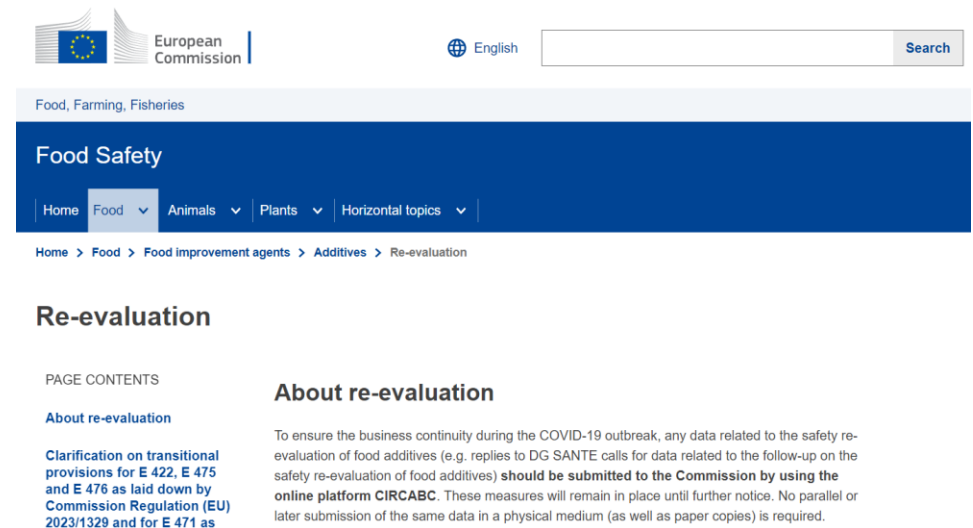
*“When a food additive is already included in a Community list and there is a **significant change** in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a **different additive** and a **new entry** in the Community lists or a **change in the specifications** shall be required **before it can be placed on the market.**”*
- The rules for adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community list are laid down in Regulation (EC) No 1331/2008 on **the common authorisation procedure**

# Re-evaluation of Food Additives

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# Re-evaluation of food additives

- Commission Regulation (EU) No 257/2010 set up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008.
- [https://food.ec.europa.eu/safety/food-improvement-agents/additives/re-evaluation\\_en](https://food.ec.europa.eu/safety/food-improvement-agents/additives/re-evaluation_en)
- Approach follow-up to the re-evaluation
- Calls for data
- Guidance on data submission to EC



The screenshot shows the European Commission website interface. At the top, there is the European Commission logo and a search bar. Below the logo, the text 'Food, Farming, Fisheries' is visible. The main navigation bar includes 'Food Safety' and a dropdown menu with options: 'Home', 'Food', 'Animals', 'Plants', and 'Horizontal topics'. Below the navigation bar, the breadcrumb trail reads: 'Home > Food > Food improvement agents > Additives > Re-evaluation'. The main heading is 'Re-evaluation'. Underneath, there is a 'PAGE CONTENTS' section with a link to 'About re-evaluation'. The 'About re-evaluation' section contains the following text: 'To ensure the business continuity during the COVID-19 outbreak, any data related to the safety re-evaluation of food additives (e.g. replies to DG SANTE calls for data related to the follow-up on the safety re-evaluation of food additives) **should be submitted to the Commission by using the online platform CIRCABC**. These measures will remain in place until further notice. No parallel or later submission of the same data in a physical medium (as well as paper copies) is required.'

# Calls for data by EC

- Call for technical data on the permitted food additives phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452)
  - Deadline: 5 March 2024
- Call for technical and scientific data on the permitted food additive sodium aluminium silicate (E 554)
  - 2-step call; data submission to be completed by June 2024
- Call for toxicological and technical data on the permitted food additives oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxypropyl starch (E 1440), hydroxypropyl distarch phosphate (E 1442), acetylated oxidised starch (E 1451) and starch aluminium octenyl succinate (E 1452)
  - 2-step call; to be published

# Risk management follow-up to the re-evaluation of hydrocolloids in food

- Locust bean gum (E 410): amendment conditions of use and specifications
- *Guar gum (E 412): ...*
- Acacia gum (E 414): amendment specifications
- Xanthan gum (E 415): amendment specifications
- Pectin (E 440i) and amidated pectin (E 440ii): amendment conditions of use and specifications
- Starch sodium octenyl succinate (E 1450): amendment conditions of use and specifications
- Celluloses (E 460(i), E 460(ii), E 461, E 462, E 463, E 464, E 465, E 466, E 468 and E 469): amendment conditions of use (E 466) and specifications

# Risk management follow-up to the re-evaluation of E 200, E 202, E 310

- Sorbic acid (E 200): amendment specifications
- Potassium sorbate (E 202): amendment specifications
- Propyl gallate (E 310): amendment specifications

# Risk management follow-up to the re-evaluation of sulphur dioxide-sulphites

- Amendment of the specifications, conditions of use, inclusion in Union list (E 226 and E 227).

## SCIENTIFIC OPINION



ADOPTED: 28 September 2022

doi: 10.2903/j.efsa.2022.7594

**Follow-up of the re-evaluation of sulfur dioxide (E 220), sodium sulfite (E 221), sodium bisulfite (E 222), sodium metabisulfite (E 223), potassium metabisulfite (E 224), calcium sulfite (E 226), calcium bisulfite (E 227) and potassium bisulfite (E 228)**



# Risk management follow-up to the re-evaluation of E 472d-f

- Tartaric acid esters of mono- and diglycerides of fatty acids (E 472d)
- Mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty acids (E 472e)
- Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids (E 472f)

Targeted stakeholder consultation



It is considered that there is no interest that the uses of E 472d,e,f as food additives in accordance with Annex II and Annex III, for which no actual use levels have been submitted under the re-evaluation or follow-up to the re-evaluation remain authorised. Consequently, these authorisation will be withdrawn

# Other activities

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# Monitoring of FA and FF

## Pilot phase by Member States

- The categorisation and prioritisation of FA and FF;
- Member States should, during the year 2024, collect data for 3 FAs and 2 FFs;
- Member States should, during the year 2025, collect data for 2 FAs and 3 FFs;
- The evaluation of the methodology.

## EFSA

- *“To develop a data collection system allowing direct data submission of monitoring data on food additives and food flavourings by Member States and other interested stakeholders. The system shall allow the collection of presence data, use levels and analytical data, including analytical data reflecting natural occurrence or presence from sources other than food additive or food flavouring use”.*
- The data model should be made available by the 1st of April 2024. The first call under the pilot phase should be launched by 1st of April 2025 and the second by 1st of April 2026.

# Establishment of EURL on FIA => FA

- Based on requests from Member States
- Different steps:
  - Adoption of a decision to establish an EURL by means of a delegated act (01/24);
  - Call for tender (03/24);
  - Preparation of the implementing act designating the EURL;
  - Launch of the EURL in 2025.

*EURL: European Union Reference Laboratory; FIA; food improvement agent*

# Delegated act revising the engineered nanomaterial definition of Regulation 2015/2283

- Essentially transposes main elements of general definition of Commission Recommendation 2022/C 229/01 (e.g. threshold of  $\geq 50\%$  of particles in the number-based size distribution)
- Addresses subjectivity in interpreting and implementing the ‘intentionally produced’ elements of the current definition
- Includes elements on its applicability as set out in the definition of Commission Recommendation 2022/C 229/01
  - the external dimension and shape of the material,
  - the exclusion from the definition of single molecules and materials with a surface to volume ratio below a certain value,
  - definitions of ‘particle’, ‘aggregate’ and ‘agglomerate’,
  - and the inclusion of only materials in solid state to exclude particles with highly dynamic external dimensions such as micelles, liposomes, or nanoscale droplets in emulsion.

# Delegated act revising the engineered nanomaterial definition of Regulation 2015/2283

- The introduction of water solubility as a criterion to exclude highly water-soluble materials from the definition.
- Transition period for applicability to allow operators sufficient time to comply
- Delegated act adopted on 14 March 2024
- 2-month scrutiny period for European Parliament and Council – no negotiation → Act is either accepted or rejected
- [Register of Commission Documents - C\(2024\)1612 \(europa.eu\)](#)

# Keep in touch



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