EU specialty food ingredients

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SAFETY ASSESSMENT OF FOOD ADDITIVES – REVIEWING PROCEDURE PROGRESS

EFSA INFO SESSION: (RE-) EVALUATING FOOD ADDITIVES
19-20 MARCH 2024, PARMA

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INTRODUCTION TO EU SPECIALTY FOOD INGREDIENTS

SAFETY ASSESSMENT OF FOOD ADDITIVES – REVIEWING PROCEDURE PROGRESS

CONCLUSION

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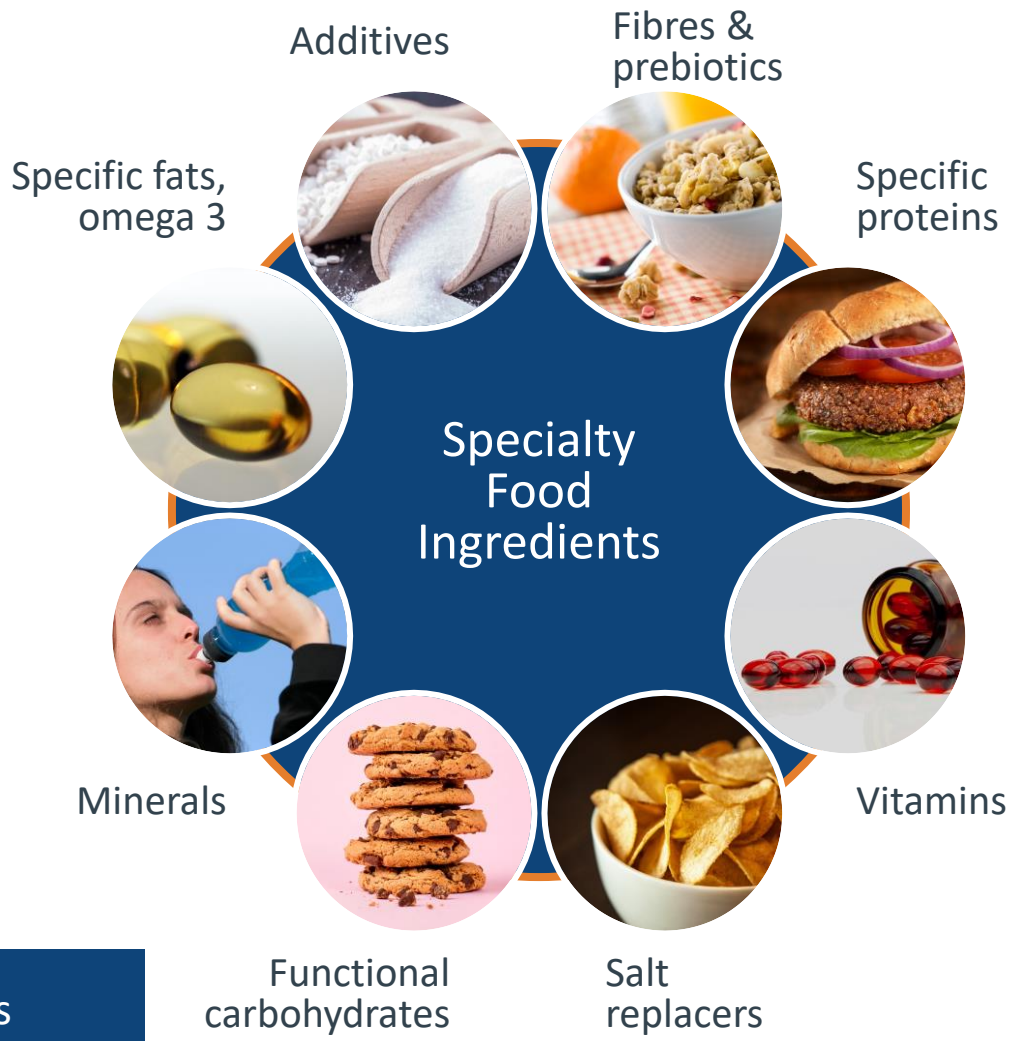
OUR CONTRIBUTION

Specialty food ingredients are present in almost all processed foodstuffs, thus contributing to the competitiveness of the European food and drink industry
→ EU food and drinks industry annual turnover:
€ 1 trillion, making it the largest manufacturing sector in the EU in terms of annual turnover.

Specialty food ingredients have technological and/or functional benefits that are essential in providing today's consumer with a wide range of tasty, safe, healthy, affordable, qualitative and sustainably produced foods.



The industry contributes over
€ 40 billion
to annual turnover of EU food and drinks industry

The industry invests
3-8%
of turnover in R&D (depending on sector)

44 MEMBERS

ASSOCIATIONS

COMPANIES

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TRANSPARENCY REGULATION

- More narrow scope of studies to be notified (Update of EFSA Q&A on Practical Arrangements)
- Training materials

- Burdensome
- Additional costs
- Delays of scientific output's adoption

- Has the aim of EFSA "*acquiring greater legitimacy in the eyes of the consumers and general public in pursuing its mission, increases their confidence in its work* " been met?

GENERAL SNAPSHOT (1)

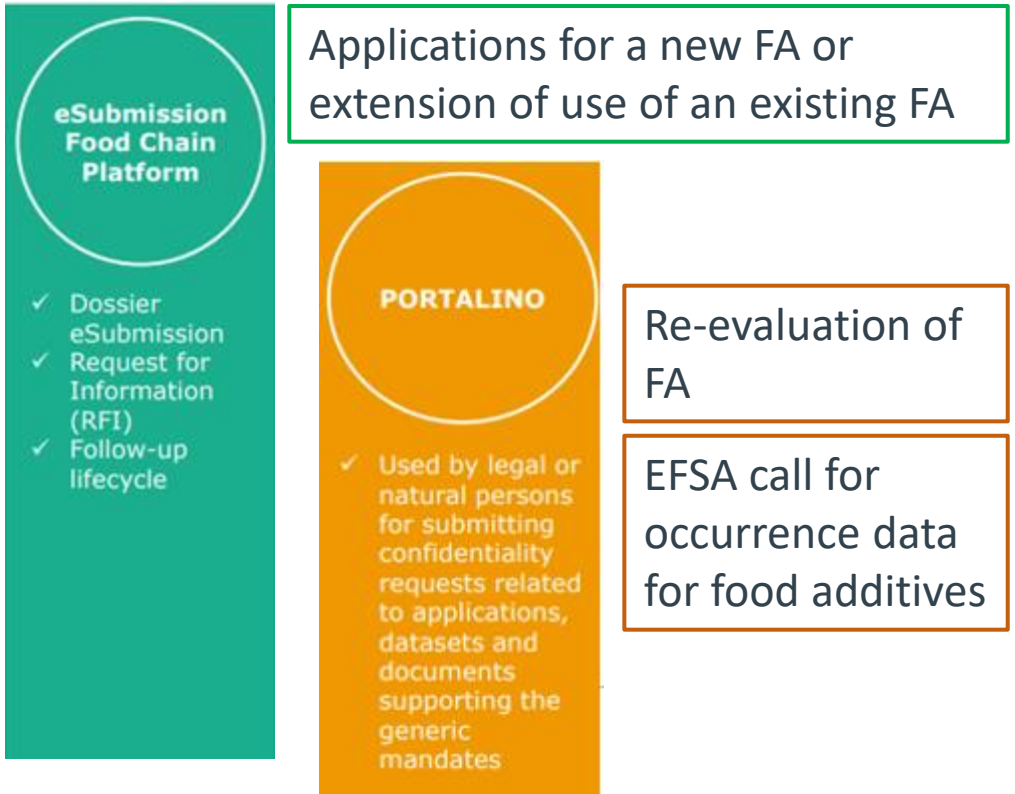
- Update of the guidance on food additives
  - One stop-shop vs the current maze of multiple guidance documents potentially applicable
  - Consultation on draft guidance

- Additional scientific requirements? Proportionality?
- Once adopted, applicable to applications in the intake & risk assessments steps?

GENERAL SNAPSHOT (2)

- Information on yearly work programmes
- Revised strategy (more targeted calls for re-evaluation)
- Valuable expert platforms
  - Discussion Group on Food Chemicals Occurrence Data
  - *Ad hoc* group “Knowledge exchange on data collection with industry”
- Reasonable flexibility regarding deadlines

- Confidentiality requests



GENERAL SNAPSHOT (3)

- Pilot partnership with Member States
  - Division of risk assessment work in tasks to be allocated to different partners, put together by EFSA into a draft scientific opinion to be reviewed by FAF Panel

RE-EVALUATION - CALLS FOR DATA AND DATA SUBMISSION

Food additives	1st call	2nd call	3rd call
Gluconic acid /gluconates (E 574-579)	**2012** Scientific data	**2016** Usage level and/or concentration data	**2023** Targeted call
Ribonucleotides (E 626-635)	**2010** Scientific data	**2016** Usage level and/or concentration data	**2023** Targeted call

- For a given FA, there can be more than 10 years between 1st calls & follow-up call(s) for data!
  - Changes in companies, associations & their consultancies (staff, merges...) => uneasy follow-up on data originally provided
  - It contributes to perception of a never-ending re-evaluation process

SUITABILITY CHECK OF APPLICATIONS

- **Increased intake phase for applications**
  (Transparency Regulation)

Suitability
>>> 30 days

Risk assessment
9 months

Risk management
9 months

Access to market

RISK ASSESSMENT (1)

- Observed increase in number of Technical Hearings with industry experts in WGs

- Invitation to (kick-off) Technical Hearings should be systematic

- “Nice to have” vs “must have” questions

e.g., quality management related questions

RISK ASSESSMENT (2)

Methodologies

- Update of EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles - Annex “Degradation/dissolution rate under acidic conditions”

Methodologies

- Need for proactive communication on updates via the EFSA website

RISK ASSESSMENT (3)

Moving targets = lack of predictability

- Implementation of draft guidance documents that have not been yet adopted in their final form

Example – Re-evaluation of the safety of polydextrose

14/10/20: the EFSA WG on Specifications of Food Additives, when assessing the data provided by the applicants, *"considered the proposed decision criteria described in the EFSA "Draft guidance on technical requirements for regulated food and feed product applications", published for public consultation, to decide whether additional data are needed to demonstrate that consumers will not be exposed to small particles of polydextrose when used as E 1200"*.

03/08/21: publication of the EFSA adopted guidance

RISK ASSESSMENT (4)

Moving targets = lack of predictability

- Requirements for additional studies according to EFSA new or updated guidance documents not in place at the time of the application

Example – Re-evaluation of the safety of sorbitols
20/06/18: closure of EFSA call for data

10-11/05/23: FAF Panel meeting: *"the preliminary assessment of the available genotoxicity data and **the dataset was considered adequate with respect to the current standards [...]** However, following a full assessment of the reliability and relevance of the available genotoxicity studies, performed according to the criteria stipulated in the protocol on hazard identification and characterization of the sweeteners* [**living document]** *and the approach for assessing genotoxicity studies, the need for additional genotoxicity data has been identified. [...] **Thus, as a follow-up to this meeting, the Panel agreed to launch another open call for data** […]".*

RISK ASSESSMENT (5)
TRANSPARENCY

FAF plenary meeting 10-11/05/23

6.3. Re-evaluation of Sorbitols (E 420) (EFSA-Q-2011-00644; EFSA-Q-2011-00645)
Further to the initial discussion held at the 23rd Panel Plenary meeting in June 2021, the hearing experts and members of the Panel WG on Sweeteners, Riccardo Crebelli and Kevin Chipman, joined the current plenary meeting for this agenda point to address questions from the Panel concerning an updated assessment of the genotoxicity data available for the re-evaluation of the sweetener sorbitols (sorbitol, E 420i and sorbitol syrup, E420ii).
The preliminary assessment of the available genotoxicity data had not highlighted the need for additional data and the dataset was considered adequate with respect to current standards, as previously discussed by the FAF Panel. However, following a full assessment of the reliability and relevance of the available genotoxicity studies for sorbitols (E 420 i,ii), performed according to the criteria stipulated in the protocol on hazard identification and characterisation of the sweeteners and the approach for assessing genotoxicity studies, the need for additional genotoxicity data has been identified. In particular, a new *in vitro* micronucleus (MN) assay according to OECD guidelines will be requested for the completion of the *in vitro* basic test battery, in accordance with the current guidelines. Thus, as a follow-up to this meeting, the Panel agreed to launch an additional open call for data to invite interested business operators and other interested parties to submit the requested information to fill the data gaps identified during the re-evaluation of sorbitols (E 420i,ii).

FAF WG re-evaluation 29-30/01/24

Call for data on modified starches

The European Commission is considering a call for 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) and an exchange took place.

GMOs WG Food & Feed applications – meeting 19/06/23

EFSA-GMO-NL-2019-162 (Soy Leghemoglobin)
The sub-Working group discussed the application. Further discussion is needed.

FAF WG Food Additives applications – meeting 16-17/11/23

Draft opinion Soy leghemoglobin (EFSA-Q-2022-00031)

Additional information provided by the applicant in response to an earlier request from EFSA were discussed by the WG. The exposure and the biological and toxicological sections of the application were addressed. The need for additional information was identified. The WG will provide feedback to the FAF Panel on the progress of this application at the next plenary meeting.

SCIENTIFIC OUTPUT (1)
ARTICULATION WITH THE REGULATORY FRAMEWORK

Table 14. Proposal for a revised version of the existing EU Specifications for calcium carbonate E 170

	Commission Regulation (EU) No 231/2012	Comment/justification for revision
Definition	Calcium carbonate is the product obtained from ground limestone or by the precipitation of calcium ions with carbonate ions	To be included that: – E 170 calcium is not an engineered nanomaterial and is not coated or functionalised or with chemically modified surfaces. – the source of calcium ions used for the precipitation of calcium carbonate shall be limestone.

ENM regulatory definition under revision

Alignment of risk assessment & regulatory definitions

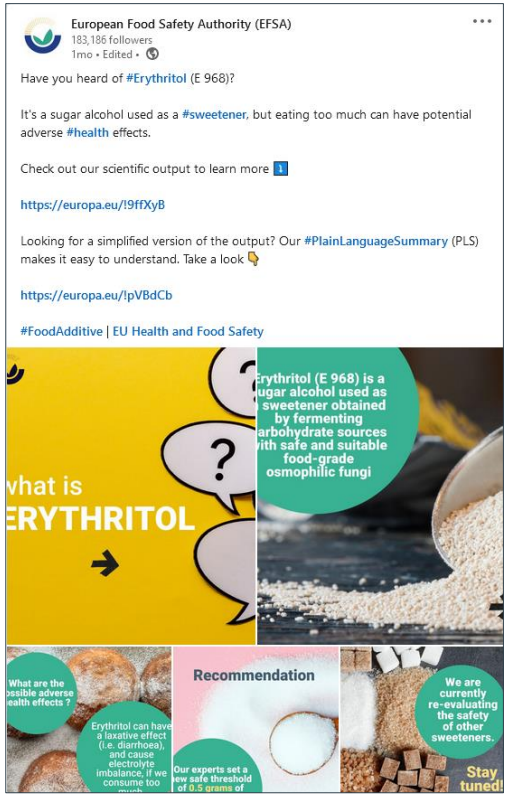
SCIENTIFIC OUTPUT (2)
COMMUNICATIONS

- Pre-notification of the opinion under embargo

- Pre-notification of the opinion under embargo: 36 hours too short
- Still no publicly available decision criteria re. EFSA specific communications published together with a specific Opinion
- Still no pre-notification under embargo of EFSA Communications
  ➔ **This is as important as the pre-notification of the opinion!**

SCIENTIFIC OUTPUT (3)
COMMUNICATIONS

- Plain Language Summary



- **Social networks are not adapted to complex scientific communications: by definition, they convey reductive messages**

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- **Direct dialogue with applicants & data providers is a win/win**
- **Focus on “must have” questions**
- **IUCLID standard data format, as part of the 1S1A approach?**
  Please give time to time! The implementation of the Transparency Regulation still means a lot to process for applicants & data providers

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