EU Regulations and monitoring of food additives

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Until E2: Food processing technologies and novel foods *(until 30/9/2024)*

Unit D2: Medical products: quality, safety, innovation

DG SANTE

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

- Monitoring of food additives
- Recent amendments food additives legislation
- Outlook for 2025

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Legal context for the monitoring of food additives

Article 27 in the Regulation (EC) No 1333/2008 lays down the provisions for Monitoring of **food additive** intake:

- Member States shall maintain systems to monitor the consumption and use of food additives on a **risk-based approach** and report their findings with appropriate frequency to the Commission and the Authority.
- After the Authority has been consulted, a **common methodology** for the gathering of information by the Member States shall be adopted.

What?

Monitoring the consumption and use of food additives (FAs) and food flavourings (FFs)

- Is a post-market activity that takes place after they have been authorised. The aim is to collect national data on the use/occurrence of FAs and FFs and to assess the national dietary intake to FAs and FFs.
- Includes the verification of the data and dietary intake estimated at the time of the most recent exposure assessment of FAs and FFs.
- Dietary intake from other sources in the diet => overall dietary exposure

Methodology: 4 main parts

I. Risk-based categorisation and prioritisation of the FAs and FFs for monitoring purposes	→	Member States EFSA: preparatory work
II. Collection of data, and data submission to EFSA	→	Member States Producers and users of FF EFSA: set up data collection system
III. Estimation of dietary intake	→	EFSA
IV. Reporting of the findings	→	Member States EFSA

Methodology: 4 main parts

RECOMMENDATIONS

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of 12 May 2023

I. Risk-based categorisation and prioritisation of the FAs and FFs for monitoring purposes → Member States
EFSA: preparatory work

II. Collection of data, and data submission to EFSA → Member States
Producers and users of FF
EFSA: set up data collection system

III. Estimation of dietary intake → EFSA

IV. Reporting of the findings → Member States
EFSA

2 Mandates

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Categorisation

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For example: Food additives

- **Group 1:** Food additives with an ‘acceptable daily intake (ADI) not specified’ or for ‘there is no need for a numerical ADI’
  - .....
- **Group 2:** Food additives with numerical ADI
  - ……..
- **Group 3:** no safety concern despite missing data to establish a numerical ADI
  - .....

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Prioritisation

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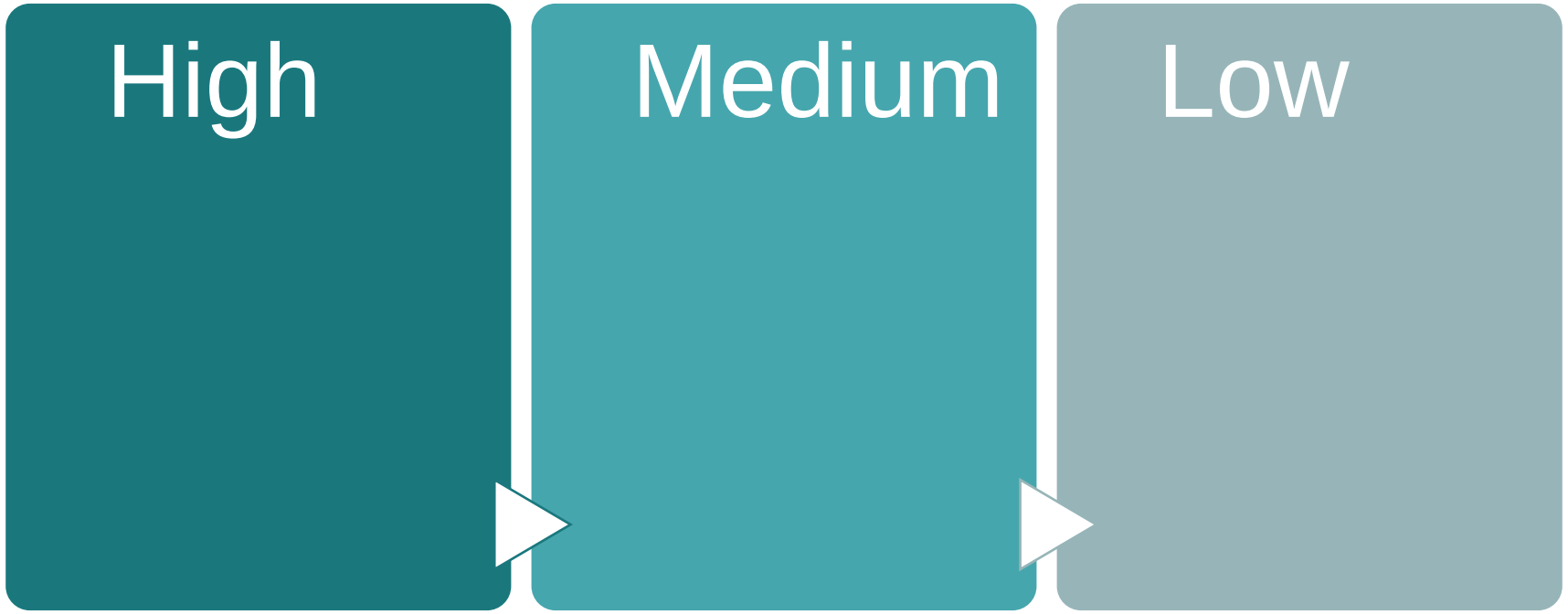

Prioritisation

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- Other **legitimate factors** can be taken into account when prioritising FAs/FFs for monitoring purposes. These may lead to an adjustment of the monitoring priority based on the general categorisation.

For example:

- dual use as FA and FF;
- the substance is also considered as an allergen;
- aspects related to differences in national consumption
- ….

II. Collection of data by the MS and data submission to EFSA

The following type of data are envisaged:

- Analytical data =>Member States
- Use levels => Member States (FA) and EFFA (FF)
- (Presence data) => Member States

Data submission to EFSA

II. Collection of data by the MS and data submission to EFSA

The following type of data are envisaged:

- Analytical data =>Member States
- Use levels => Member States (FA) and EFFA (FF)
- (Presence data) => Member States

} **Data submission to EFSA**

Member States can complement monitoring data with data originating from **official control tasks** in accordance with Regulation (EU) No 2017/625, if the latter are representative for the use of food additives or food flavouring in food available on the market.

➡ only use data from the planned control programme, no data from follow-up incidents.

III. Estimation of dietary intake

- EFSA will calculate the dietary exposure in accordance with its guidance documents using the data submitted to EFSA.
- When relevant, other sources than FA/FF use are to be taken into account.
- Estimation of the dietary intake of FA/FFs should only be performed when it brings added value.

IV. Reporting of the findings

Reporting will be done on a yearly basis.

Mandate A

Subject: **Request for scientific and technical assistance in the preparatory work for the implementation of the common methodology for the monitoring of food additives in accordance with Article 27 of Regulation (EC) No 1333/2008 and food flavourings in accordance with Article 20 of Regulation (EC) No 1334/2008**

- Task 1: To make structured information on the outcome of the risk assessments of authorised food additives available with the aim to develop in the future a structured database summarizing the outcome of the risk assessments of FAs.
- ….

Mandate B

Subject: Request for scientific and technical assistance in the collection and reporting of the data obtained by the Member States in accordance with Article 27 of Regulation (EC) No 1333/2008 and Article 20 of Regulation (EC) No 1334/2008

- Task 1: To develop a data collection system allowing direct data submission of monitoring data on FAs and FFs 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 FA or FF use.
- Task 2:
  - To collect on a yearly basis monitoring data on food additives and food flavourings.
  - To analyse the collected data and compare the newly collected data with the data used in the most recent EFSA opinion.
  - To calculate the dietary exposure.
  - To report on a yearly basis

Risk management follow-up

- The Commission should discuss an appropriate risk management follow-up taking the outcomes of the monitoring into account with the Working Party of Governmental Experts on Additives and the Working Party of Governmental Experts on Food Flavourings

- Update prioritisation and multi-annual monitoring plan.

Pilot phase

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- 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.

Sampling year	Food additives
2024	Green S (E 142) Tartrazine (E 102) Ponceau 4R, Cochineal Red A (E 124)
2025	BHT (E 321) Sorbic acid-sorbates E 200-203

Establishment of EURL on FIA

- Based on the request made by MS
- Focused on FA first
- Officially operational from January 2025 onwards

Recent amendments food additives legislation

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
- R 2024/1451 – Review of the conditions of use of tartaric acid-tartrates (E 334-337, E 354)
- R 2024/2597 – Amendments of specifications sorbates (E 200, E 202) and propyl gallate (E 310) + extension of use of (E200, E 202) in FC 16
- R 2024/2608 – Amending Annex II as regards the use of powdered cellulose (E 460(ii)) and glucono-delta-lactone (E 575) in unripened soft spreadable cheese products

2024: Amendments FA legislation

Favourable opinion at the PAFF on 20 November 2024:

- Commission Regulation (EU) amending conditions of use and specifications for celluloses (E 460-E 469)
- Commission Regulation (EU) amending conditions of use of mono-and diglycerides of fatty acids (E 471) and carnauba wax (E 903) on certain fresh fruit and cassavas and carriers in glazing agents for cassavas
- Commission Regulation (EU) amending specifications and conditions of use as regards steviol glycosides from fermentation using *Yarrowia lipolytica*

Outlook for 2025

Outlook for 2025

- Business as usual
- Specific files: authorised for use in foods for infants below 16 wks of age
- Specific files: other
- Calls for data

Outlook for 2025

- Business as usual
  - Applications
  - FA re-evaluation + follow-up to the re-evaluation
  - Interpretation questions
  - Work in the context of the Codex Alimentarius
- Specific files: authorised for use in foods for infants below 16 wks of age
- Specific files: other
- Calls for data

Outlook for 2025

- Business as usual
- Specific files: authorised for use in foods for infants below 16 wks of age
  - Hydrocolloids (i.e. locust bean gum (E 410), guar gum (E 412), gum arabic (acacia gum) (E 414), xanthan gum (E 415), pectins (E 440) and starch sodium octenyl succinate (SOSS; E 1450): amendments of specifications and conditions of use
  - Follow-up of EFSA opinions on the safety of food additives for infants and young children:
    - Ascorbyl palmitate (E 304(i));
    - Lecithins (E 322);
    - Sucrose esters of fatty acids (E 473);
    - Calcium carbonate (E 170),
- Specific files: other
- Calls for data

Outlook for 2025

- Business as usual
- Specific files: authorised for use in foods for infants below 16 wks of age
- Specific files: other
  - Quillaia extract (E 999): Amendments of specifications and extension of use
  - MOH
  - Sulphites
  - Re-evaluation of sweeteners
- Calls for data

Outlook for 2025

- Business as usual
- Specific files: authorised for use in foods for infants below 16 wks of age
- Specific files: other
- Calls for data
  - Polyvinylpyrrolidone (E 1201) and polyvinylpolypyrrolidone (E 1202)
  - Erythritol (E 968)
  - Shellac (E 904)
  - …

Thank you

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