



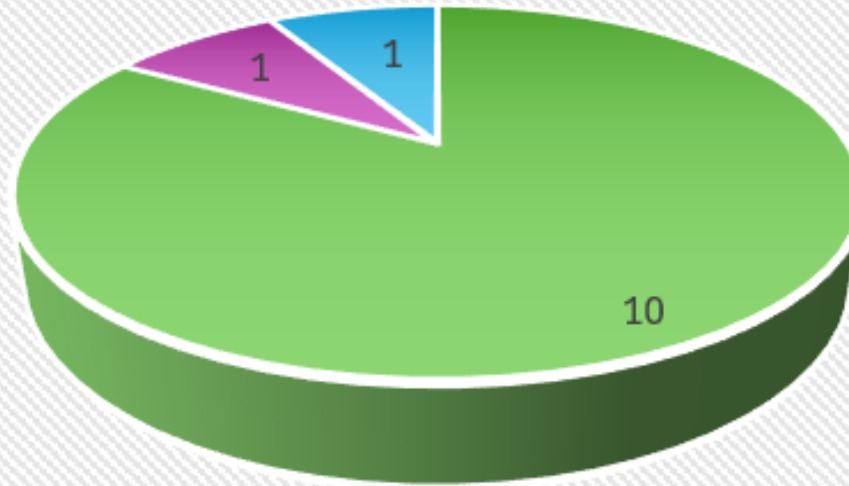
# UPDATE ON THE EVALUATION OF NEW FOOD ADDITIVE APPLICATIONS SUBMITTED UNDER REGULATION (EC) NO 1331/2008

67<sup>th</sup> FAF Panel meeting  
2<sup>nd</sup> July 2026

# NEW FOOD ADDITIVES (FA) APPLICATIONS IN THE RISK ASSESSMENT PHASE

All information available at Open EFSA

Number of new FA applications currently in risk assessment phase

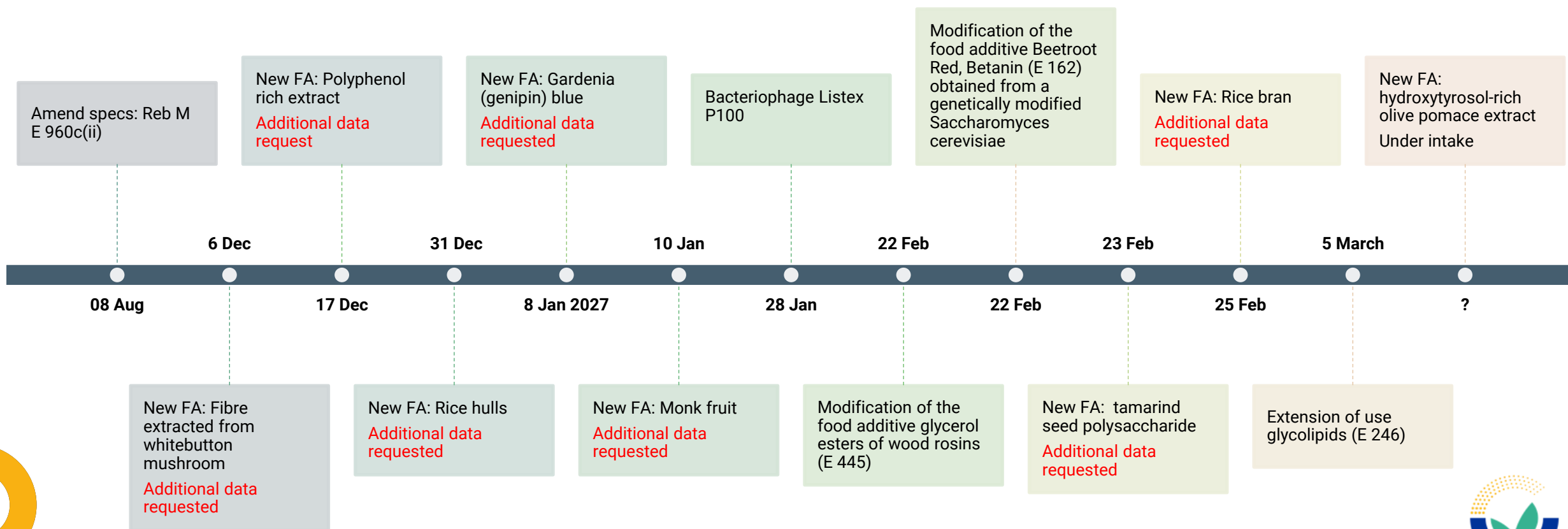


- New food additives from botanical sources
- Amendments of specifications of E 960 (a-d)
- Decontaminant substance/new food additive

# 2026-2027 PLAN: NEW FA APPLICATIONS

Status of the new food additive applications in the risk assessment phase and the associated legal deadline

Data updated as of yesterday...



# KEY CHALLENGES ACROSS THE NEW FOOD ADDITIVE APPLICATIONS

**Physico-chemical characterisation** of the food additive is the first pivotal step of the risk assessment.

- Technical **data requirements depend on the type of proposed food additive** (e.g. single substance, complex mixture, containing or derived from microorganisms).
- However, especially for the mixture, identification and quantification of the components can be challenging. If the FA is a mixture (like the FA from botanical sources), the following is necessary:
  - ✓ **concentration of the major classes** of components (e.g. carbohydrates, proteins, lipids)
  - ✓ concentration of **characteristic components** (e.g. polyphenols)
  - ✓ concentration of other **identified components of potential concern** (e.g. substance listed in the [EFSA of Botanicals](#))
  - ✓ justification of the choice of analysed compounds.
  - ✓ proportion of the **unidentified fraction**

The assessment of the presence of small particles including nanoparticles, especially for complex mixture, can be a challenge



# KEY CHALLENGES ACROSS THE NEW FOOD ADDITIVE APPLICATIONS

## Strategy to establish whether the conventional risk assessment is sufficient

- **Evidence to demonstrate** whether the proposed food additive can be assessed following **the conventional risk assessment**, or whether **nano-specific aspects** should be addressed are required.

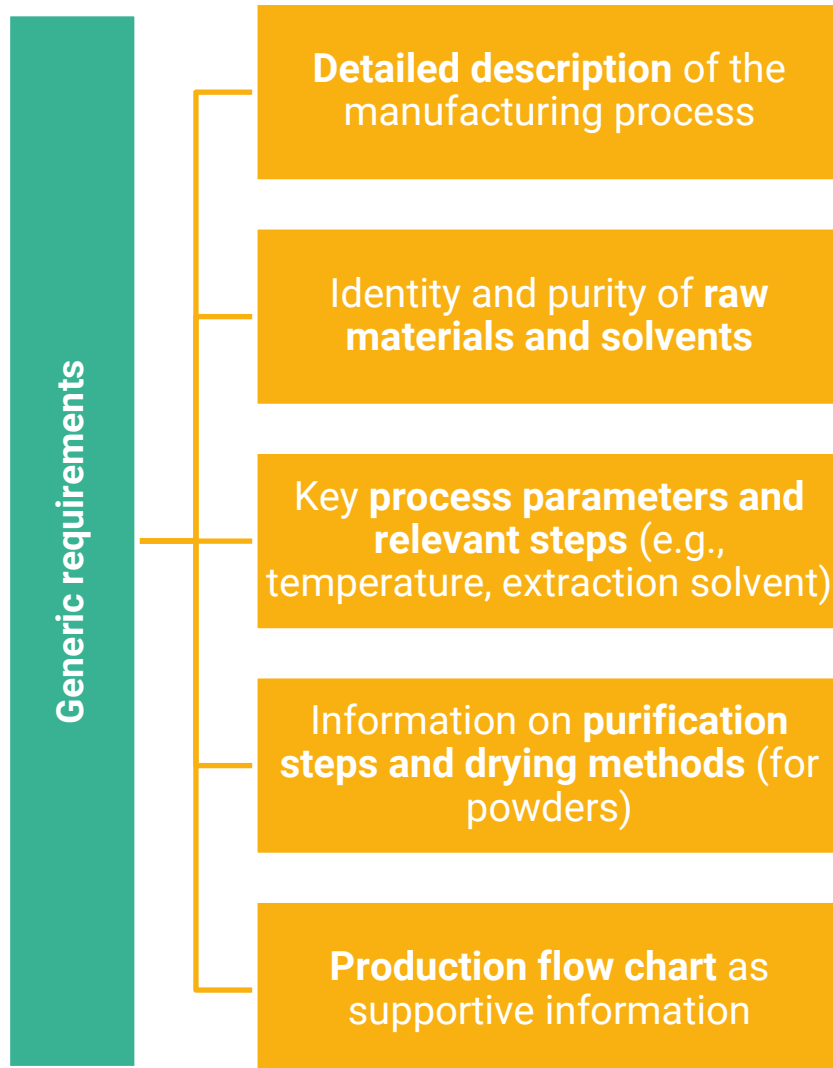
Applicable guidance:

- EFSA Scientific Committee 'Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles' (Guidance on Particle-TR) explains the process to take a decision whether nano specific considerations should be provided.
- If nano-specific considerations are required, data should be provided taking into account the requirements established in the EFSA Scientific Committee Guidance on risk assessment of nanomaterials (EFSA Scientific Committee, 2021).



# KEY CHALLENGES ACROSS THE NEW FOOD ADDITIVE APPLICATIONS

## MANUFACTURING PROCESS



The **use of an enzyme** in the manufacturing process may represent an issue in case the falls outside the scope of Regulation (EC) No 1332/2008 as it is when enzymes are used exclusively in the production of the proposed food additive, **data related to the safety evaluation of the enzyme(s) should be provided and assessed in the context of the food additive application**



# KEY CHALLENGES ACROSS THE NEW FOOD ADDITIVE APPLICATIONS

Toxicological assessment:

- **Test material** → Toxicological studies should be carried out with the test material manufactured according to the **manufacturing process** as specified in the technical dossier and in compliance with the **proposed specifications** of the food additive
- **Food additives consisting of mixtures** → when toxicological data are not available on the **whole mixture**, safety data on **functional components** and/or on **components of toxicological concerns** (if applicable) should be provided.

For **genotoxicity assessment** specific considerations apply: the components of the mixture should be identified and quantified as much as possible → the identified components should be assessed individually with respect to their genotoxic potential, using all available data. Conclusions on genotoxicity are required for all identified components → **component-based approach**





# KEY CHALLENGES ACROSS THE NEW FOOD ADDITIVE APPLICATIONS

- **Botanicals** → a “**presumption of safety**” may be applied to botanicals used as food additives when they are derived from conventional food sources with a **long-term history of safe use** and if data on exposure show that **no significant increase of intake** compared to historical levels is to be expected due to the intended use levels ([EFSA SC, 2009](#)). Of note:
  1. ‘**significant increase of intake compared to historical dietary intake**’ is to be judged on **case-by-case basis** depending on the chemical composition of the botanical;
  2. **extraction/manufacturing processes** differing from the traditional methods of food preparation **may lead to compositional differences** and concentrate undesirable components;
  3. for a botanical with a potential to contain **toxic, addictive, psychotropic substances**, the presumption of safety is applied only if it can be demonstrated that these undesirable substances are absent in the source material or significantly reduced/inactivated during the processing. The [EFSA Compendium of Botanicals](#) database should be consulted.
- **Allergenicity:** allergenicity should be addressed following [Guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation \(EU\) 2015/2283](#)







**ANY QUESTIONS?**



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