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Ensuring the safety of emerging protein sources:

How EFSA's updated Novel Food Guidance protects consumer health and supports innovation in the EU agrifood sector

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EUROPEAN FOOD SAFETY AUTHORITY

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NOVEL/NEW/ALTERNATIVE PROTEINS: CURRENT INTEREST

New technologies

Innovation

Environmental sustainability

Ethics/Animal welfare

Health considerations

Nutrient Composition

KEEPING FOOD SAFE IN THE EUROPEAN UNION

KEEPING FOOD SAFE IN THE EUROPEAN UNION

EFSA was established under EU law in 2002 following a series of food crises

TO

- **Improve** the EU food safety system
- **Help ensure** a high level of consumer protection
- **Restore and maintain** confidence in the EU food supply
- **Clearly separate** risk assessment and risk management functions

WHAT IS A NOVEL FOOD IN THE EUROPEAN UNION?

Foods or ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997

- New production process
- New or modified molecular structure
- From microorganisms, fungi or algae
- From plants or their parts
- Vitamins and minerals from new process / nanomaterials
- Of mineral origin
- From animals or their parts
- Cell or tissue cultures derived from the living
- Engineered nanomaterials
- Exclusive use in food supplements prior to May 1997

NOVEL FOOD AUTHORISATION PROCEDURE IN THE EU

European Commission

efsa EUROPEAN FOOD SAFETY AUTHORITY

European Commission

Submit a dossier according to the Novel Food (NF) or Traditional Food (TF) Guidance

Validate the dossier

Mandate EFSA to carry out the risk assessment (NF only)

NF: 9 months
TF: 4 months

Carry out the risk assessment (NF)

May request additional information to the applicant (NF) or raise duly reasoned safety objections (TF)

Decide on market authorisation

Integration to the Union List of authorized novel foods

EFSA'S MISSION & RESPONSIBILITIES IN THE NOVEL FOOD AREA

WHAT EFSA DOES NOT DO

- Develop food safety policies and legislation
- Adopt regulations, authorise marketing of new products, define labelling
- Enforce food safety legislation

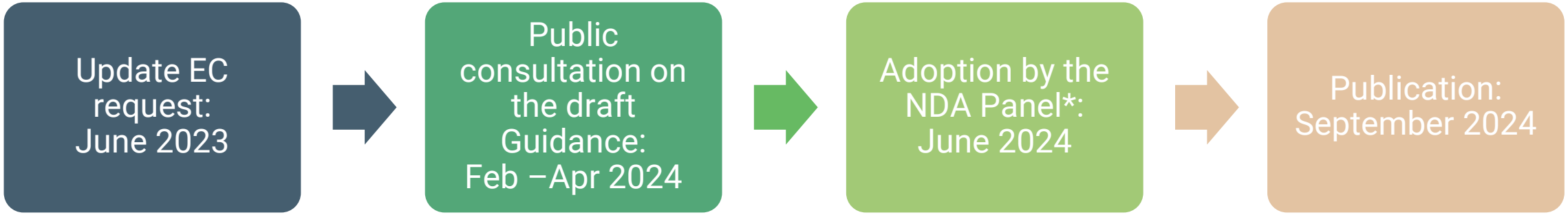
WHAT EFSA DOES

- Provide independent scientific advice and support for EU risk managers and policy makers on safety
- Develop and provide up-to-date Guidance
- Communicate independently and timely on risks associated with the food chain
- Promote scientific cooperation

EFSA'S MISSION & RESPONSIBILITIES IN THE NOVEL FOOD AREA

Develop and provide up-to-date Guidance

UPDATED EFSA NOVEL FOOD SCIENTIFIC GUIDANCE



Considerations for the update:

- Regulatory Updates: Implementing Regulation (EU) 2017/2469
- Advances in science and technologies
- EFSA's experience in assessing novel foods

EFSA's experience

- Centralised assessment of multiple & heterogeneous novel food dossiers (since 2018)
- New EFSA cross-cutting guidance applicable
- Risk assessment methodological advances
- New EFSA tools
- Engagement & feedback from stakeholders *(e.g., EFSA Scientific colloquium in cell culture-derived foods)*

* EFSA Panel on Nutrition, Novel Foods and Food Allergens

FUNDAMENTAL PRINCIPLES OF NOVEL FOOD RISK ASSESSMENT

The novel food shall be safe under the proposed conditions of use

The novel food cannot be nutritionally disadvantageous

The efficacy of the novel food is not assessed

UPDATED EFSA NOVEL FOOD SCIENTIFIC GUIDANCE

- Introduction
- Identity of the novel food
- Production process
- Compositional data
- Specifications
- History of use of the novel food and its source
- Proposed uses and use levels, anticipated intake
- Absorption, distribution, metabolism, excretion
- Toxicological information
- Nutritional information
- Allergenicity
- Conclusions

NEW Administrative guidance for the preparation of novel food applications

Adopted: 27 June 2024
DOI: 10.2903/j.efsa.2024.8961

GUIDANCE

**Guidance on the scientific requirements for an ap
authorisation of a novel food in the context of Re
2015/2283**

**EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) | Domini
Torsten Bohn | Jacqueline Castenmiller | Stefaan de Henauw | Karen Ildi
Alexandre Maciuk | Inge Mangelsdorf | Harry J. McArdle | Androniki Naska | Kristina Pentieva | Alfonso Siani | Frank Thies | Sophia Tsabouri | Marco Vinceti | Margarita Aguilera Gómez | Francesco Cubadda | Thomas Frenzel | Marina Heinonen | Monika Neuhäuser-Berthold | Carmen Peláez | Morten Poulsen | Miguel Prieto Maradona | Josef Rudolf Schlatter | Alexandros Siskos | Henk van Loveren | Reinhard Ackerl | Océane Albert | Domenico Azzollini | Antonio Fernández Dumont | Wolfgang Gelbmann | Andrea Germini | Maria Glymenaki | Georges E. N. Kass | Eirini Kouloura | Marcello Laganaro | Leonard Matijevic | Vânia Mendes | Estefanía Noriega Fernández | Irene Nuin Garciarena | Gabriela Precup | Ruth Roldán Torres | Annamaria Rossi | Emanuela Turla | Silvia Valtueña Martinez | Ermolaos Ververis | Helle Katrine Knutsen**

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Abstract
The European Commission requested EFSA to update the scientific guidance for the preparation of applications for authorisation of novel foods, previously developed following the adoption of Regulation (EU) 2015/2283 on novel foods. This guidance document provides advice on the scientific information needed to be submitted by the applicant towards demonstrating the safety of the novel food. Requirements pertain to the description of the novel food, production process, compositional data, specifications, proposed uses and use levels and anticipated intake of the novel food. Furthermore, information needed in sections on the history of use of the novel food and/or its source, absorption, distribution, metabolism, excretion, toxicological information, nutritional information and allergenicity is also described. The applicant should integrate and interpret the data presented in the different sections to provide their overall considerations on how the information supports the safety of the novel food under the proposed conditions of use. Where potential health hazards have been identified, they are to be discussed in relation to the anticipated intake of the novel food and the proposed target populations. On the basis of the information provided, EFSA will assess the safety of the novel food under the proposed conditions of use.

KEYWORDS
authorisation, EFSA guidance, food innovation, food safety, hazard characterisation, hazard identification, novel foods, risk assessment

IDENTITY OF THE NOVEL FOOD

EXPANDING/EXPLAINING THE FOLLOWING ASPECTS:

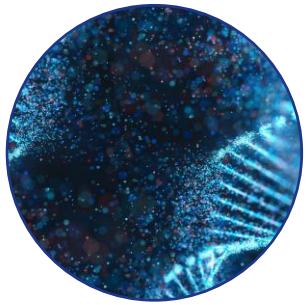
- **What is the Novel Food** (NF)
- When are **non-novel ingredients** considered part of the NF
- **Nomenclature** of NFs

SUBSECTIONS

- \- **chemical** substances,
  \- of **mineral origin**,
  \- **polymers**
- consisting of, isolated from or produced with **microorganisms**
- consisting of, isolated from or produced from **plants, macroscopic fungi and algae**, or their parts
- consisting of, isolated from or produced from **animals** or their parts
- from **cell culture or tissue** culture derived from animals, plants, macroscopic fungi or algae
- containing or consisting of **engineered nanomaterials**







PRODUCTION PROCESS

General provisions

- *input material; materials' compliance; production yield; novel aspects of the process; quality and safety assurance; standardization criteria*

Considerations for specific production process steps

- *description of conditions/farming practices; culture conditions; biological agents; post-harvest handling procedures; inactivation/removal of food enzymes; status of enzymes*

Considerations for specific novel food categories

- *plant, fungi, algae, or animal – derived; chemical synthesis – derived; microorganism-employed production processes; cell culture or tissue culture - derived*

Additional considerations

- *multiple producers; changing the production process during the risk assessment/after the eventual authorization*

Novel proteins and sources thereof

Various production processes – various forms (examples)

- Whole foods
- Protein concentrates
- Protein isolates
- Protein hydrolysates

"novel" status due to:

- Novel processing
- Novel sources
- Combination of the above

COMPOSITIONAL DATA

Role of compositional data in the assessment

Subsections

General requirements

- Analytical methods
- Addressing compositional variability
- Sampling practices
- Compositional analytes

Single substances and simple mixtures

Complex mixtures and whole foods

Stability

Impact of processing on the novel food in the proposed-for-use matrices

Protein - specific requirements

Protein Quantification

Primary Method: nitrogen-to-protein conversion factor (6.25)

Additional Calculation:

- If protein content is substantial, calculate as sum of anhydrous amino acids.
- Accounts for non-protein nitrogen.

Amino Acid Profile Characterisation

Protein Characterization – when?

- foods with specific/enriched proteins or peptides, provide details on individual protein/peptide profiles (e.g., sequence, degree of hydrolysis).

Allergenicity Considerations:

- Additional analyses may be needed for allergenicity assessment

HISTORY OF USE OF THE NOVEL FOOD AND/OR ITS SOURCE

of the novel food

- Use of the novel food as food in countries outside the EU
- Non-food uses
- Extent of use
- Population groups for which it's been a dietary component
- Its role in the diet
- Handling and preparation methods

of the source

- Information on composition
- Information on production
- Experience from the use of products from the source

PROPOSED USES AND USE LEVELS AND ANTICIPATED INTAKE OF THE NOVEL FOOD

Subsections

Target Population

The target population is the general population when no labelling restrictions can be applied

Proposed uses & use levels

Requirements for food ingredients, whole foods, food supplements and particular food categories

Anticipated Intake of the novel food

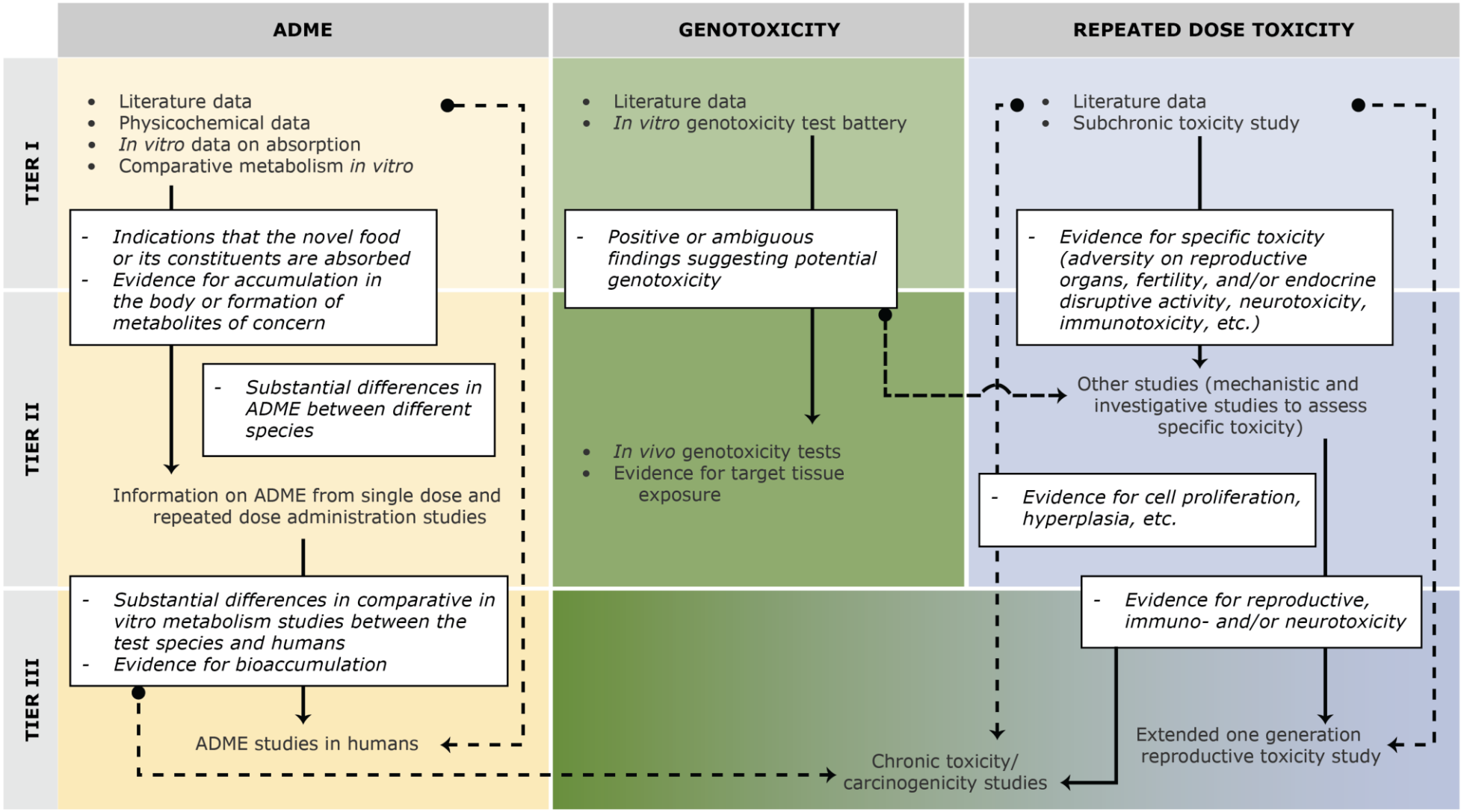
DietEx tool *, FAIM tool **

Combined intake considering other sources of the NF or its main constituents

Estimated exposure to substances of safety concern

* Dietary Exposure Tool
** Food Additives Intake Model

ADME & TOXICITY TESTING - TIERED APPROACH



Human Studies: guidance on the use of existing evidence & conducting of new studies

NUTRITIONAL INFORMATION

*Explaining the concept of **"nutritionally disadvantageous"** in the novel food risk assessment*

Excess intake of nutrients

- *Tolerable Upper Intake Levels (ULs) or HBGVs if ULs not available; background diet*

Inadequate intake of essential nutrients

- *antinutrient content; replacement of foods in the diet; essential nutrients*

Specific considerations for novel foods proposed as new sources of micronutrients

- *EFSA guidance on scientific principles and data requirements for the safety and relative bioavailability assessment of new micronutrient sources*

Specific considerations for novel protein sources

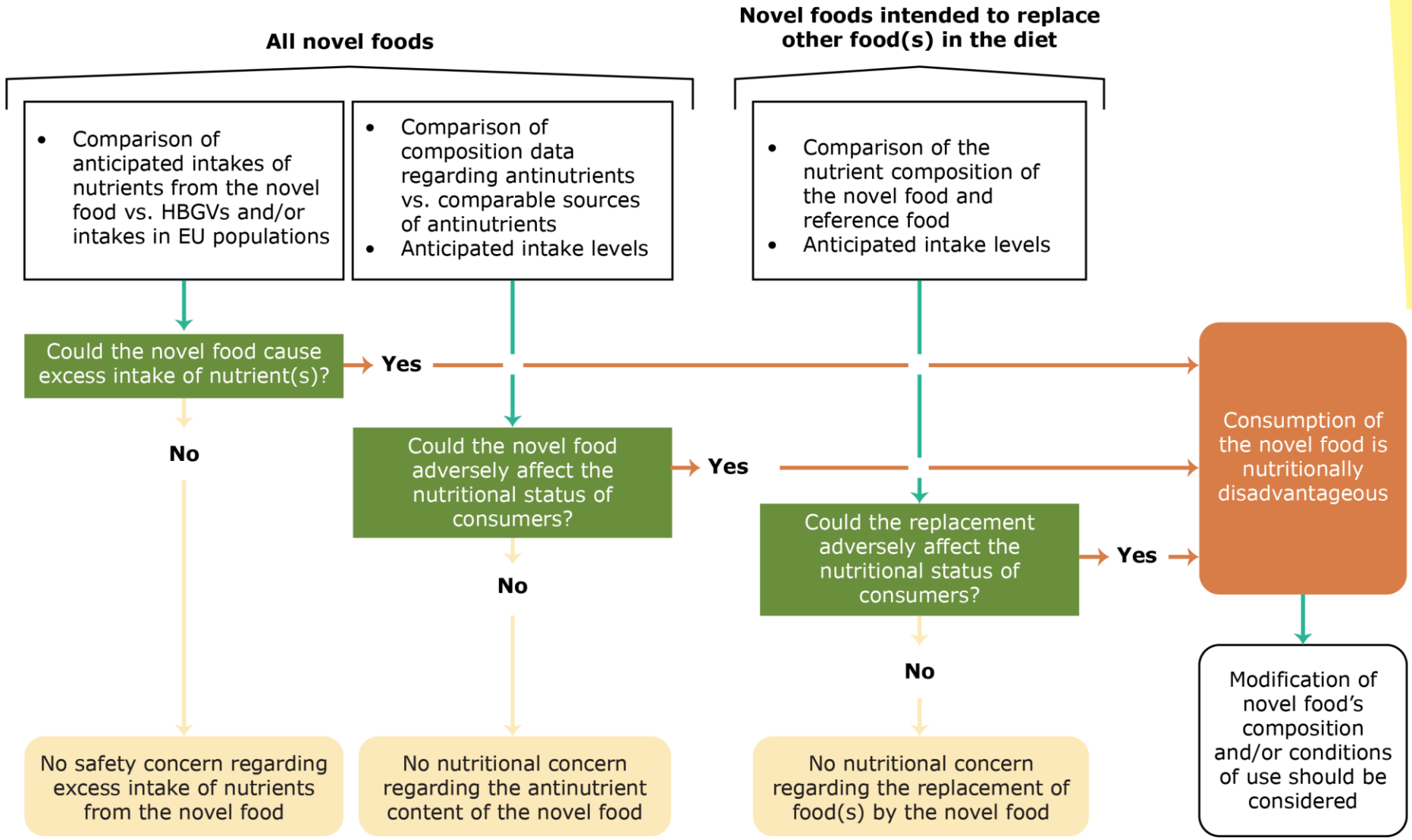
- *Protein quality (ileal digestibility & indispensable amino acids); Digestible Indispensable Amino Acid Score (DIAAS)*

Additional information

- *in vitro, in silico, animal models, and/or human studies (interaction of NF/diet/nutrients)*

INVESTIGATING THE NUTRITIONAL IMPACT OF THE NOVEL FOOD

Under the proposed conditions of use



NUTRITIONAL INFORMATION – PROTEIN QUALITY

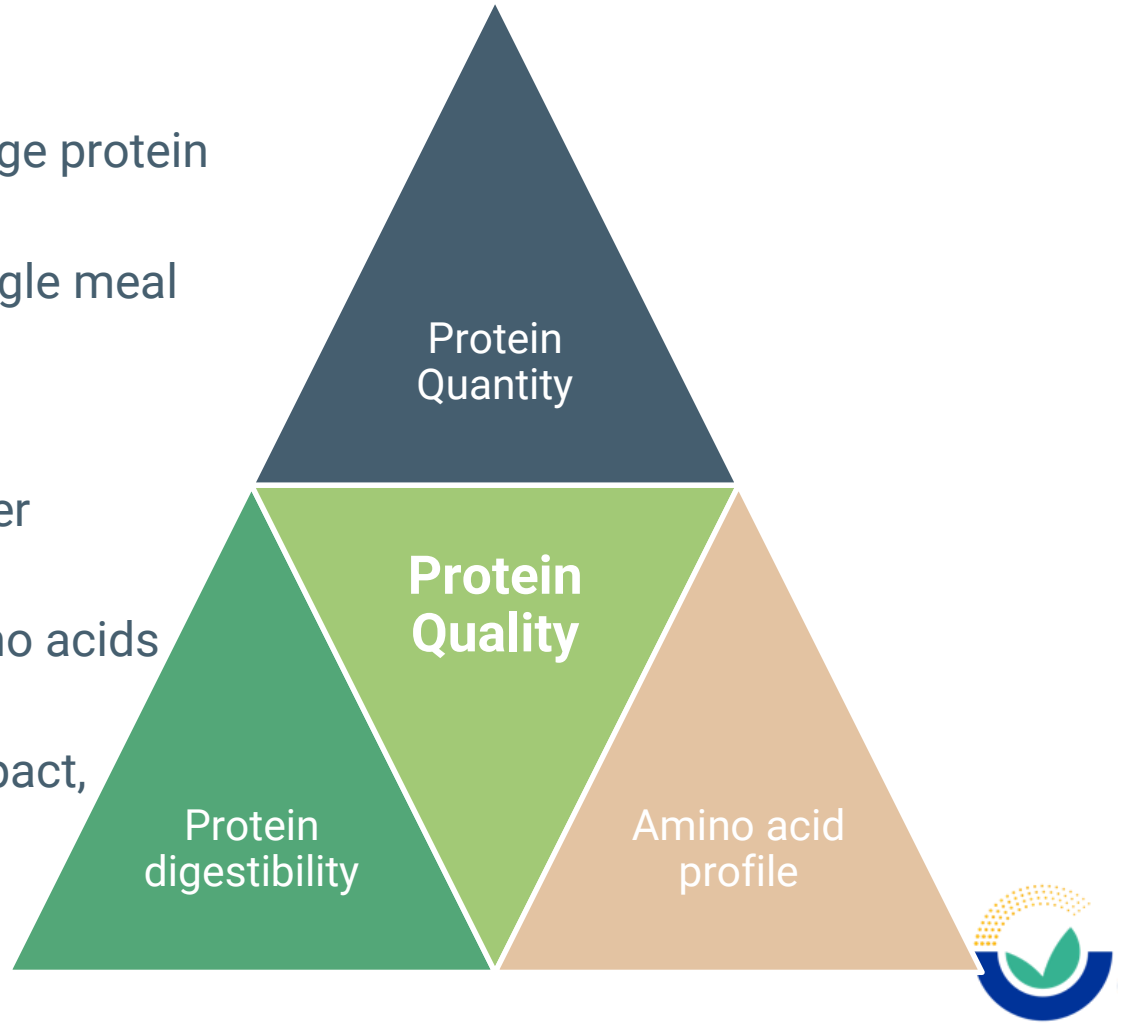
Specific considerations regarding novel protein sources

When?

- novel food provides **≥15%** of population-specific average protein requirement (AR)
- novel food serves as the **main protein source** (e.g., single meal replacements, special medical foods).

How?

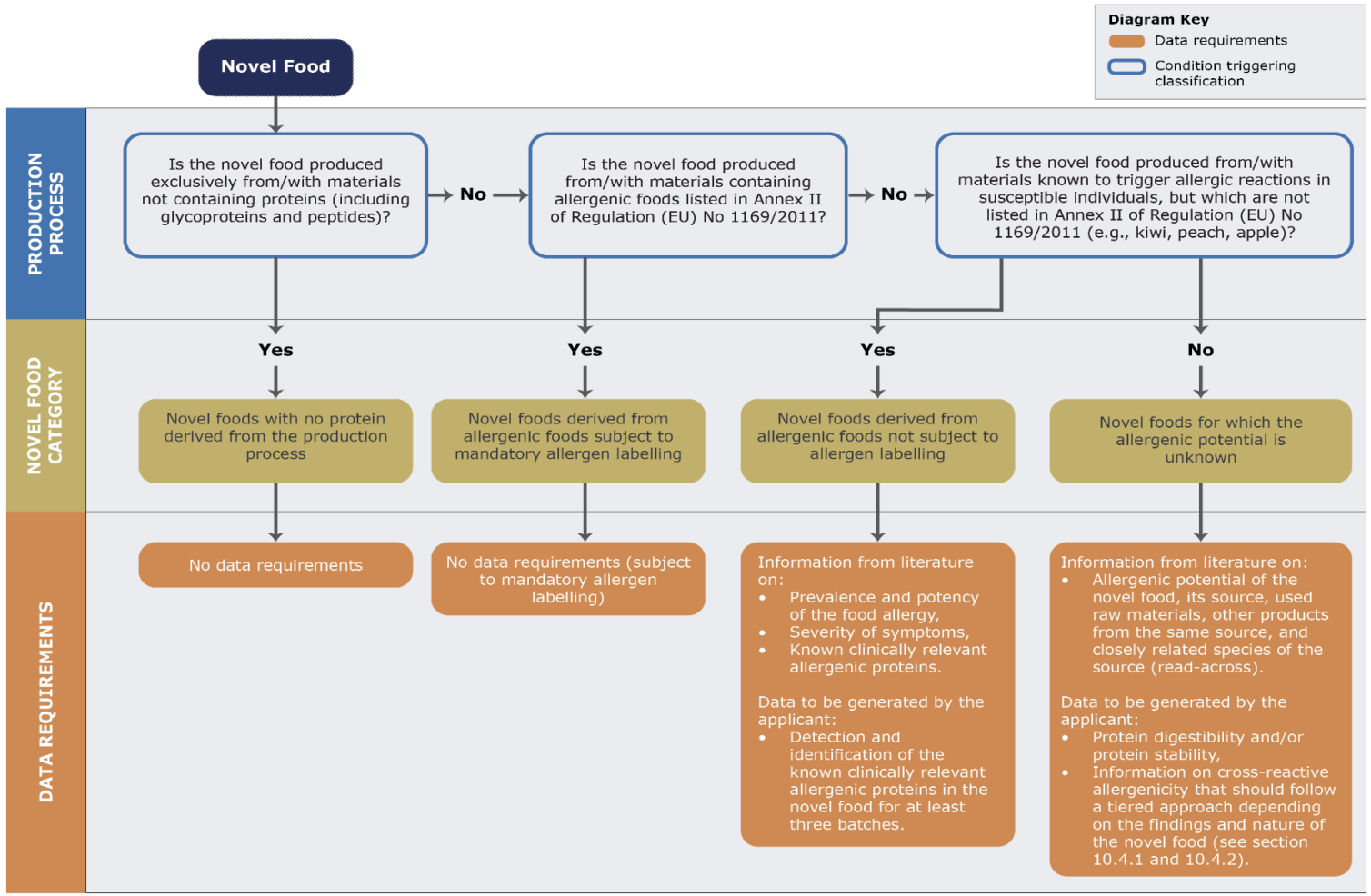
- **DIAAS** (Digestible Indispensable Amino Acid Score), per FAO/IAEA (2024) guidelines.
- Combines **true ileal digestibility** of indispensable amino acids (IAAs) with **age-specific** reference patterns.
- IAAs composition, antinutrient content, processing impact, batch variability.
- Minimum in vitro **method requirements** outlined



ALLERGENICITY

Tiered testing approach considering

- the production process
- the source
- tailored data requirements
- clinically relevant allergenic proteins
- protein stability
- cases in which the allergenic potential is unknown



WRAP-UP: KEY TAKEAWAYS

- **EFSA's Novel Food Scientific Guidance:** **advice for applicants** on preparing novel food application dossiers, with **flexibility to tailor** to specific products.
- **Guidance Update highlights:** reflect recent **regulatory changes, advances** in food science, and EFSA's **experience** in novel food risk assessment.
- **Novel proteins and sources thereof:** **diversity considered** (e.g., plant, animal, microbial, cell/tissue culture-derived).
- **Risk assessment backbone:** **compositional analysis**: includes nutrient profile, microbiological aspects, contaminants, and substances of concern.
- **Impact of EFSA's Guidance & Safety Assessment:** support food chain **resilience, diversity, and safety** by providing **science-based advice** for potential EU market approvals.
- **"Safe by design":** aligning innovation with EFSA's data requirements, early integration of safety into product development, simplifying/speeding-up pre-market authorization

CALL FOR INTEREST OPEN!

Join EFSA's new stakeholder community on applications for food and feed products!

Express your interest by
10 January 2025

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THANK YOU!