21 March 2024

EFSA'S STAKEHOLDER WEBINAR ON THE NOVEL FOOD GUIDANCE UPDATE

EUROPEAN FOOD SAFETY AUTHORITY

HOUSEKEEPING RULES

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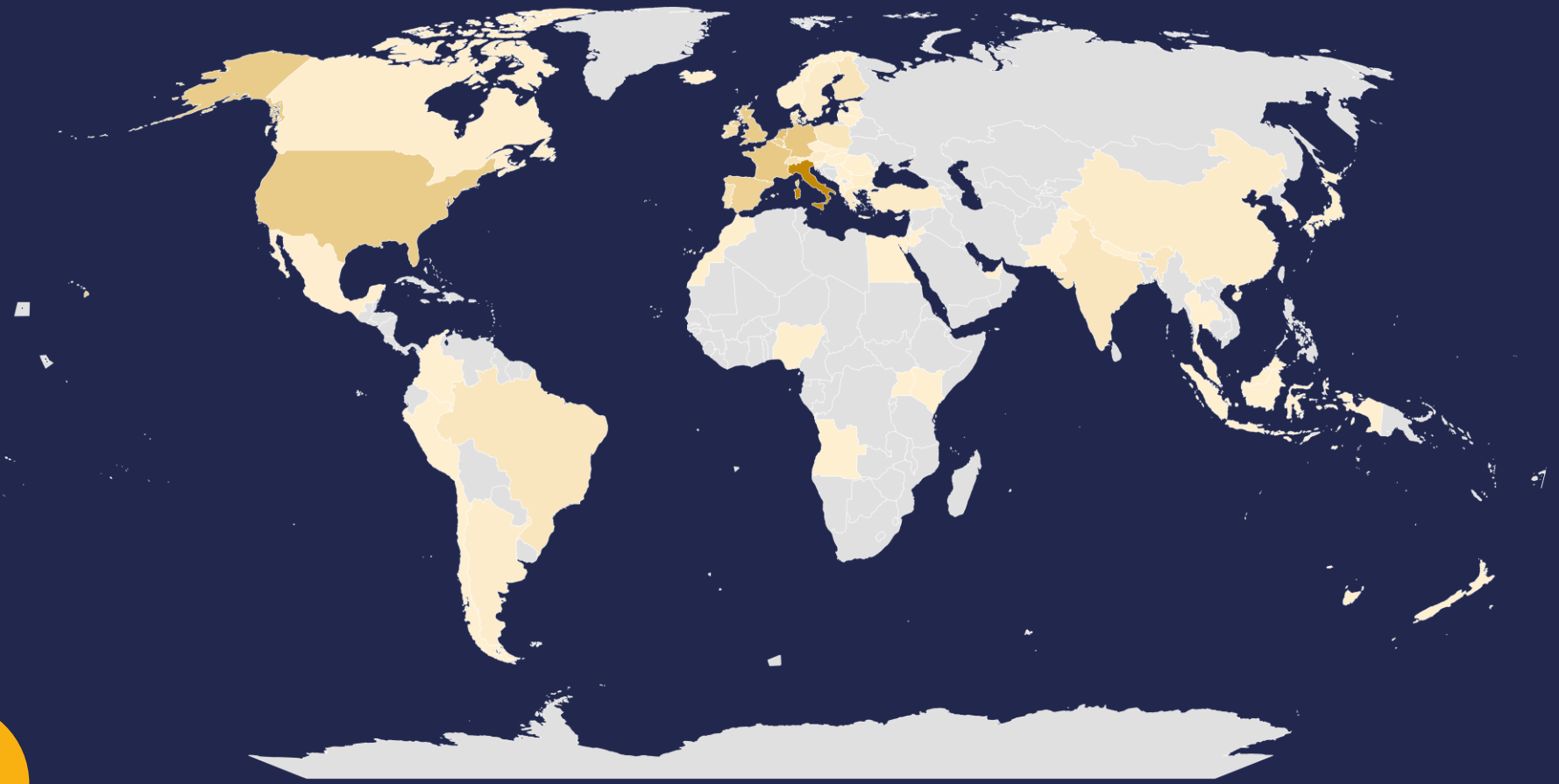
- The event is held in **English**.
- The event is being **recorded**, and the recording will be published on EFSA's website, along with the presentations.
- After the event, attendees will receive a link to a **survey** to evaluate EFSA's event services.

EFSA'S STAKEHOLDER WEBINAR ON THE NOVEL FOOD GUIDANCE UPDATE



844 registrants
from **62** countries

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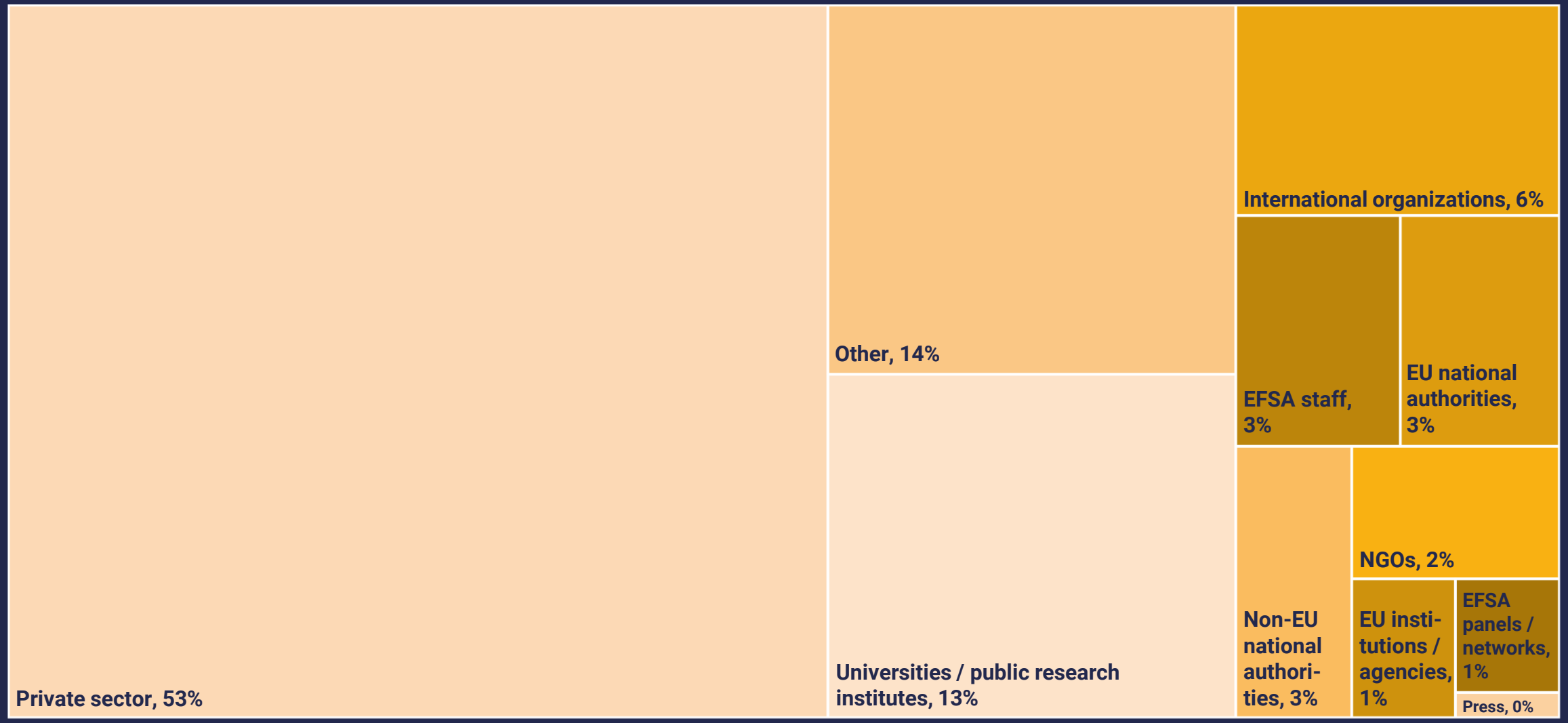


OBJECTIVES OF THE WEBINAR

- Explaining **the main elements of novelty** in the updated guidance document
- Illustrating the **ongoing public consultation** and providing guidance on how stakeholders can contribute input
- Starting to **address questions and requests for clarification** received* from stakeholders regarding the draft guidance document.

** The webinar will address relevant questions or clarification needs submitted by registrants until 10 March 2024.*

TODAY'S MODERATOR AND SPEAKERS

Ana Afonso
Head of Unit
Nutrition &
Food Innovation Unit

Andrea Germini
Team leader
Novel Foods
Product characterization

Ermolaos Ververis
Scientific Officer
Novel Foods
Product characterization

Emanuela Turla
Senior Scientific Officer
Novel Foods
Product characterization

George Kass
Team leader
Novel Foods
Product safety

Wolfgang Gelbmann
Senior Scientific Officer
Novel Foods
Product safety

AGENDA

15:10-15:25
Risk assessment of Novel Foods by EFSA
Andrea Germini

15:25-15:45
Update of the Novel Food Guidance: purpose & overview of proposed changes
Ermolaos Ververis

15:45-15:55
Break

15:55-17:55
Questions & Answers
Wolfgang Gelbmann, Andrea Germini, George Kass, Emanuela Turla and Ermolaos Ververis

17:55-18:00
Close of the webinar
Ana Afonso

RISK ASSESSMENT OF NOVEL FOODS BY EFSA

Andrea Germini

Team leader

Novel Foods - Product characterization

Nutrition & Food Innovation Unit

EFSA's Stakeholder Webinar
on the Novel Food Guidance Update

EUROPEAN FOOD SAFETY AUTHORITY

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

- Phenylcapsaicin
- Non-sticky base for chewing gum
- Ice-structuring protein

New synthetised or isolated compounds


- Krill oil
- Lycopene from *Blakeslea trispora*
- Yellow mealworms (*Tenebrio molitor*)

New sources


- UV-treated yeast or mushrooms
- Milk products fermented with *B. xylanisolvens*

New processes & technologies


- Haskap berries
- Cacao pulp
- Coffee leaves

Traditional foods (non-EU countries)


NOVEL FOOD CATEGORIES | REGULATION (EU) 2015/2283

- 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

9 months

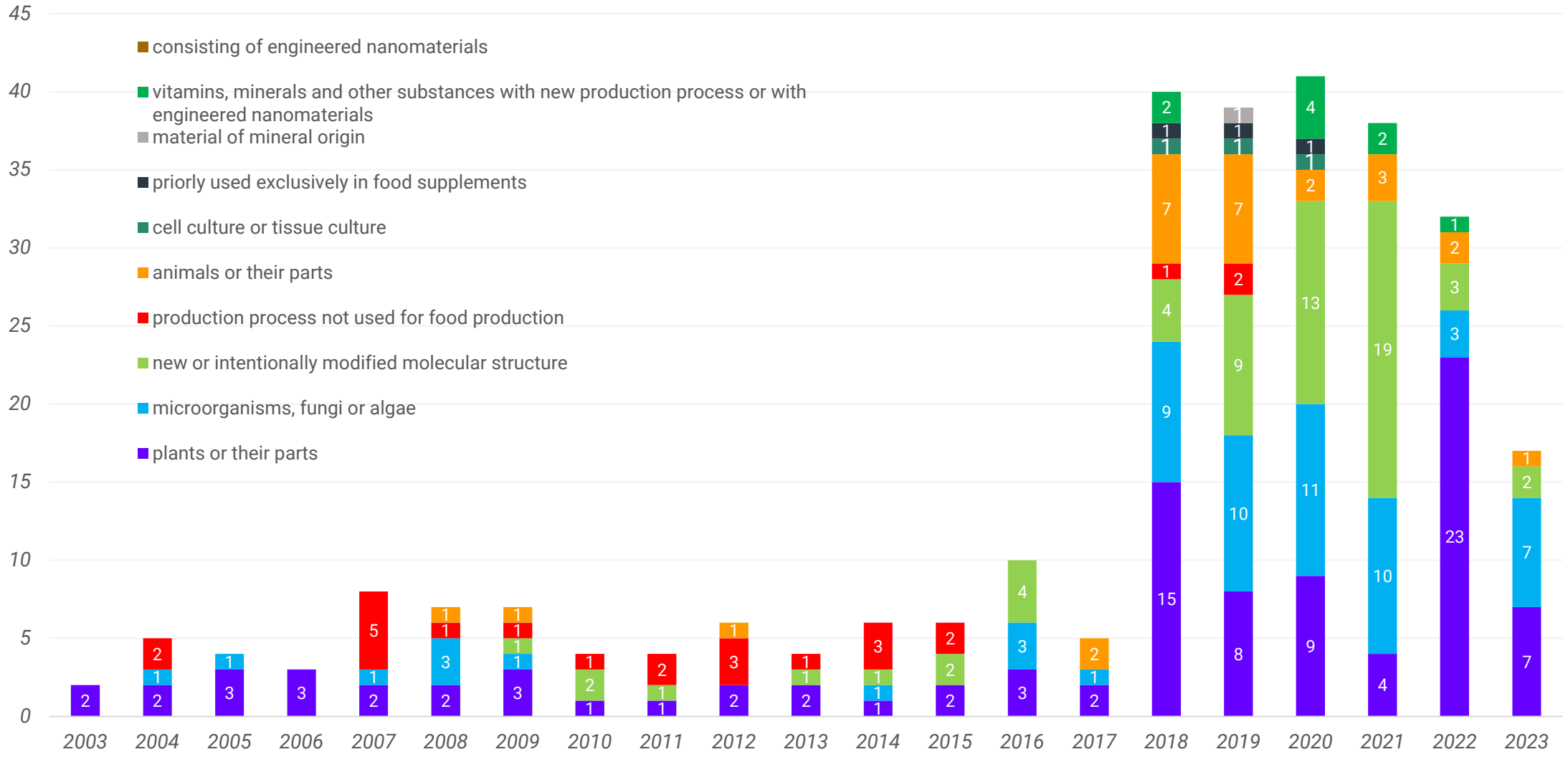
Submit a dossier according to the Novel Food (NF) Guidance

Validate the dossier
Mandate EFSA to carry out the risk assessment

Carry out the risk assessment
May request additional information to the applicant

Decide on market authorisation
Integration to the Union List of authorized novel foods

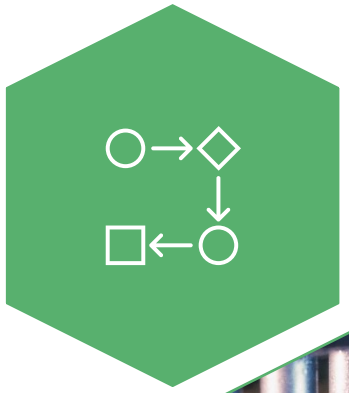
NOVEL FOOD APPLICATIONS ENTERED EFSA'S RISK ASSESSMENT



Number of Novel Food dossiers validated for EFSA's Risk Assessment

Adapted from: Ververis et al. (2020), Novel foods in the European Union: Scientific requirements and challenges of the risk assessment process by the European Food Safety Authority. *Food Research International*, 137, 109515.

TRENDS IN THE NOVEL FOODS AREA

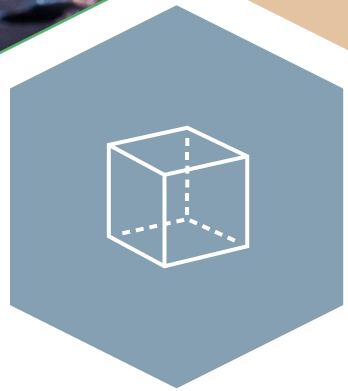


Novel carbohydrates

Novel proteins and their sources

New processes

Nanomaterials



Plant extracts

NOVEL PROTEINS AND THEIR SOURCES

Insects

Plants

Algae

By-products

Fungi

Cell/tissue culture-derived

Traditional sources & novel processing*

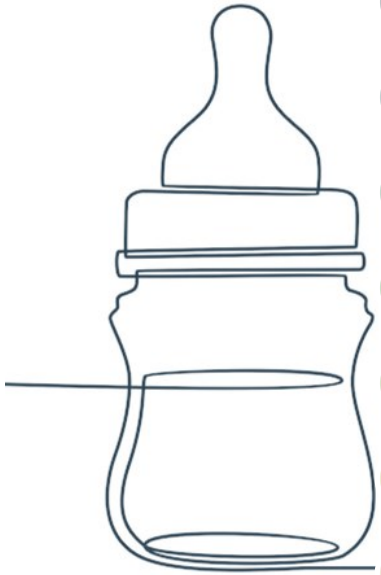
Novel sources

**Food processes not used within the EU before 15/05/1997, with a potential significant impact on the product*

Sugars replacers

- Isomaltulose
- Isomalto-oligosaccharide
- Galacto-oligosaccharides
- Allulose
- Cellobiose
- D-tagatose

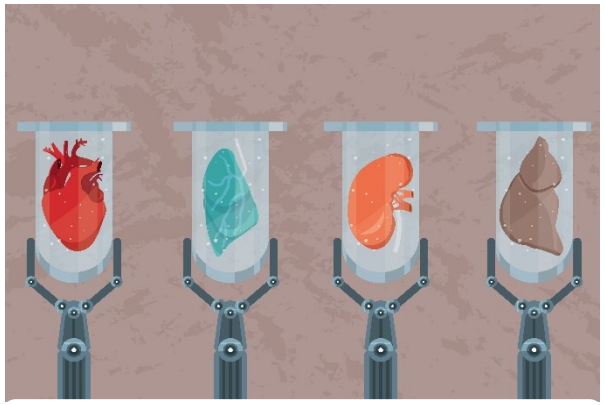
Human identical Milk Oligosaccharides (HiMOs)



- *2'-O-fucosyllactose (2'-FL)*
- *Lacto-N-neotetraose (LnNT)*
- *3'-sialyllactose (3'-SL) sodium salt*
- *N-acetyl-D-neuraminic acid (NANA)*
- *Lacto-N-tetraose (LNT)*
- *6'-sialyllactose (6'-SL) sodium salt*
- *Difucosyllactose (DFL)*

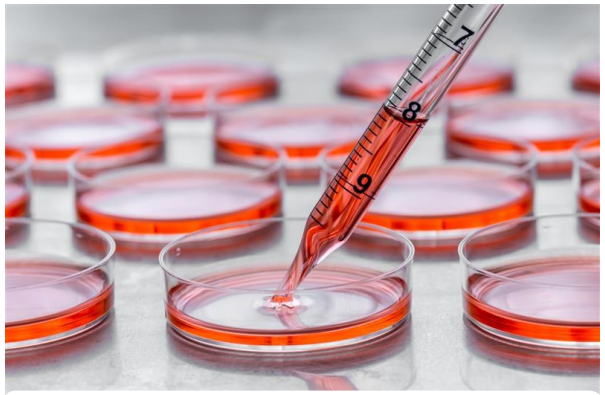
NOVEL CARBOHYDRATES

CELL CULTURE-DERIVED FOODS OF ANIMAL/PLANT ORIGIN

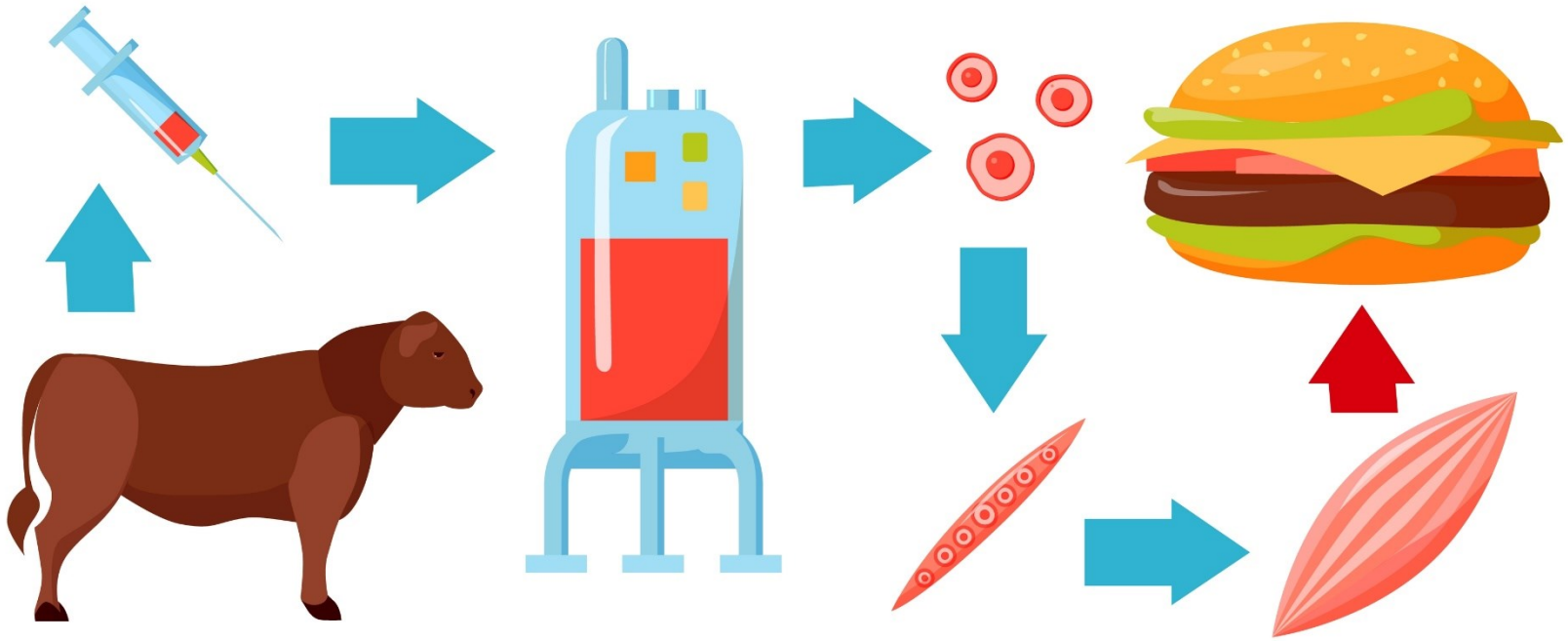


Tissue engineering

+



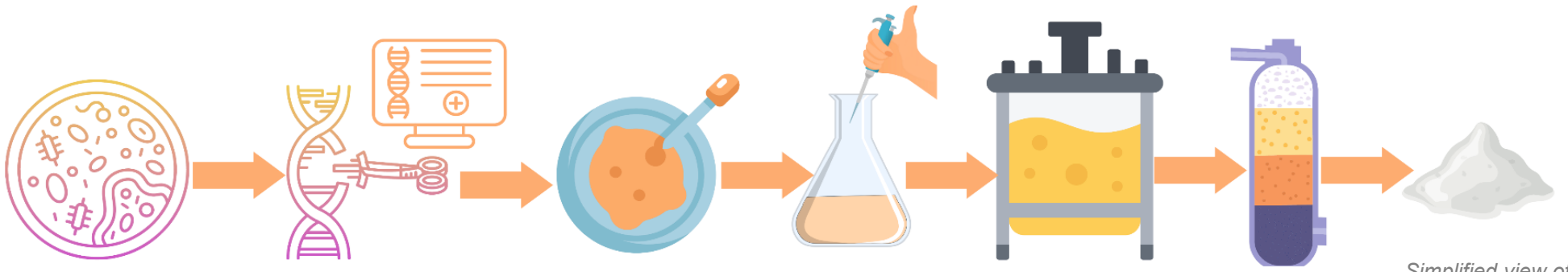
Cell culture



Simplified view of the production process

Source: shuttestock.com

PRECISION FERMENTATION



Simplified view of the production process

Absence of a regulatory definition
Engineered microbial cell factories in the production of food ingredients

Pre-market authorisation under **different regulatory frameworks** (e.g., novel foods, food additives and flavourings, GMOs, etc.

EFSA’s SCIENTIFIC COLLOQUIUM 27

EFSA’s Scientific Colloquium 27 “Cell culture-derived foods and food ingredients”

11 May 2023, 09.00 - 12 May 2023, 12.30 (CEST)

Brussels, Belgium and online

Share:

CELL CULTURE-DERIVED FOODS

PRECISION FERMENTATION

- Identify relevant sectors in the agri-food system
- Review state of the art of relevant concepts, technologies, and derived products
- Discuss emerging safety and methodological aspects and their impact on EFSA’s risk assessment approaches

- https://www.efsa.europa.eu/en/events/efsas-scientific-colloquium-27-cell-culture-derived-foods-and-food-ingredients
- EFSA’s Scientific colloquium report

21 March 2024

UPDATE OF THE NOVEL FOOD GUIDANCE: PURPOSE & OVERVIEW OF PROPOSED CHANGES

Ermolaos Ververis

Scientific Officer

Novel Foods - Product characterization

Nutrition & Food Innovation Unit

EUROPEAN FOOD SAFETY AUTHORITY

EFSA's Stakeholder Webinar
on the Novel Food Guidance Update

EFSA GUIDANCE ON NOVEL FOODS -UPDATE

EFSA Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283

- Mandate from EC received & accepted by EFSA: June 2023
- Deadline: June 2024
- Considerations:
  - Regulatory Updates: Implementing Regulation (EU) 2017/2469
  - EFSA's experience in assessing novel foods
  - Advances in science and technologies

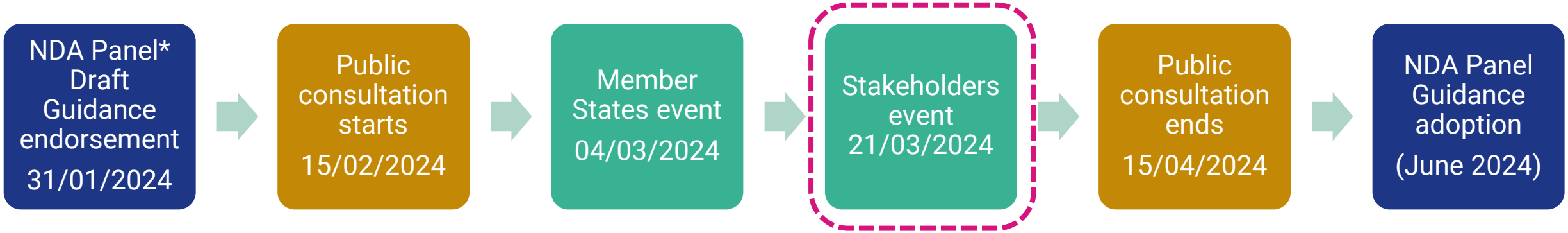
***Administrative guidance** for the preparation of applications on novel foods: parallel update*

EFSA's experience

- Centralised assessment of multiple & heterogeneous novel food dossiers
- 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 GUIDANCE ON NOVEL FOODS -UPDATE

Current Timeline



* NDA Panel: EFSA Panel on Nutrition, Novel foods and Food Allergens

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 from **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
  - from animals
  - from plants, macroscopic fungi or algae
- containing or consisting of **engineered nanomaterials**

IDENTITY OF THE NOVEL FOOD

- New identifiers
- Insights into identification methods/techniques
- Suitable comparators
- ECHA guidance (identification & naming)

- The role of microorganisms in the NF production
- GM production strains: purpose, characterisation & structure of genetic modification(s)
- Viable cells & DNA of production strains
- QPS*, genes of concern, WSG**

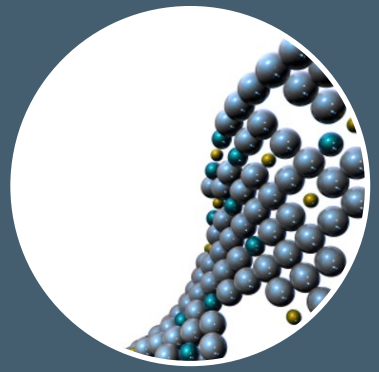
- Experimental verification of the identity
- Identity vs growing region(s)
- Identify vs harvesting season
- Non-GMO statement

*Qualified presumption of Safety; ** Whole Genome Sequencing

IDENTITY OF THE NOVEL FOOD

- Verification of the identity
- Suitability for human consumption
- Animals' health status
- Origin of initial livestock
- Non-GMO statement

- Creation of two subsections
- Requirements for established cell lines and primary cells
- Compliance with inspection requirements & absence of zoonotic agents
- Information on whether the cells or tissues sourced from a non-GM source have been **genetically modified**



- EFSA Guidance on risk assessment of nanomaterials to be applied in the food and feed chain (2021).
- ≠ small particles (including nanoparticles)

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*

COMPOSITIONAL DATA

Explanation on the role of compositional data in the risk 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

SPECIFICATIONS

Specifications encompass chemical, physicochemical, nutritional, and microbiological parameters defining the identity and safety of novel foods.

- Role in Risk Management
- Inclusion of key descriptors, source names, microbial strains, and production process details.
- Major constituents, proximate analytes, characteristic components, safety parameters, and quality/stability indicators.
- Applicants must justify each parameter and its limits, supported by compositional and stability analysis data.
- Specifications should be verifiable using the indicated analytical techniques, with information on method’s sensitivity provided.

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

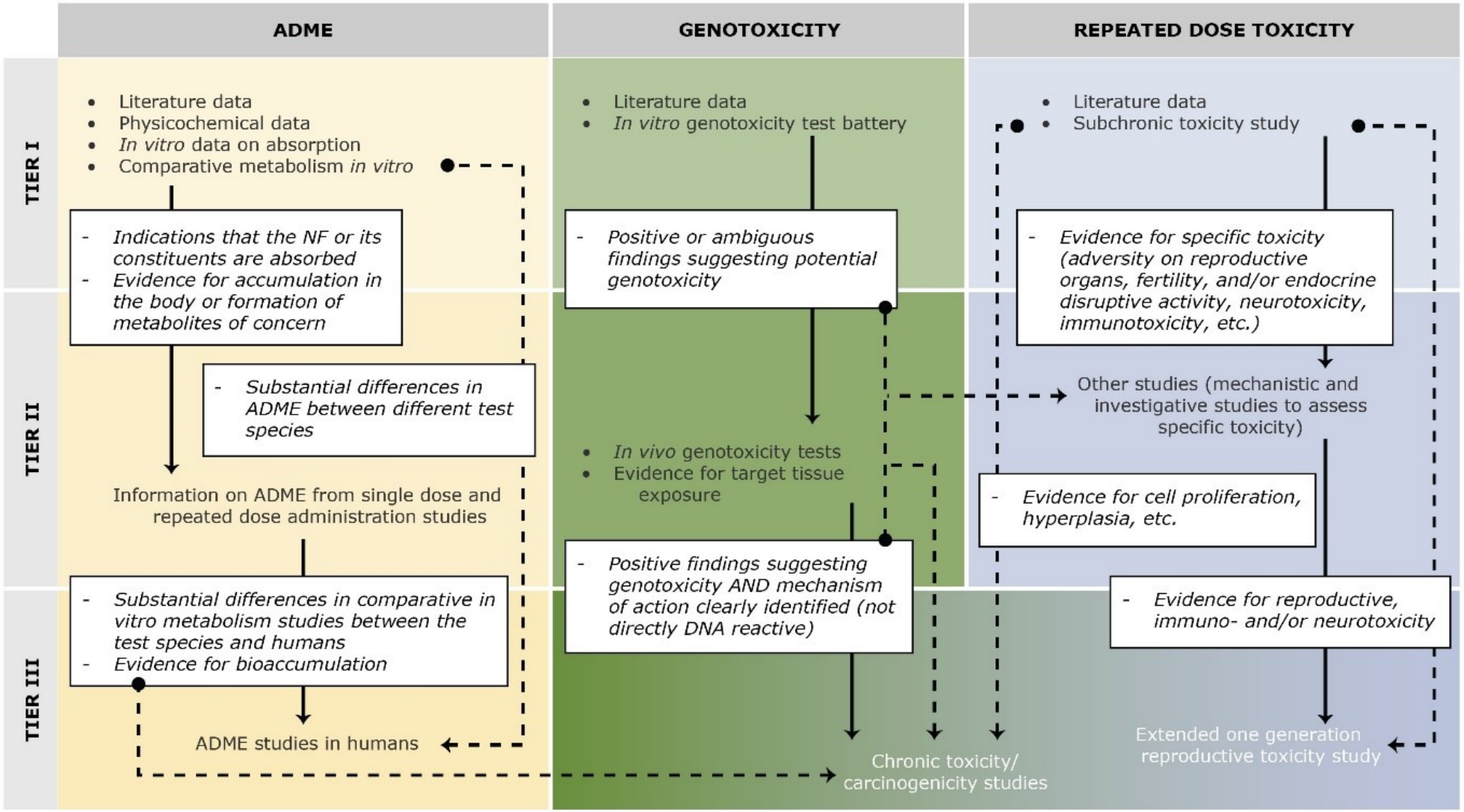
Anticipated Intake of the novel food

DietEx, FAIM tool

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

Estimated exposure to undesirable substances

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 new sources of micronutrients for novel foods proposed as new sources of vitamins and minerals*

Specific considerations for novel protein sources

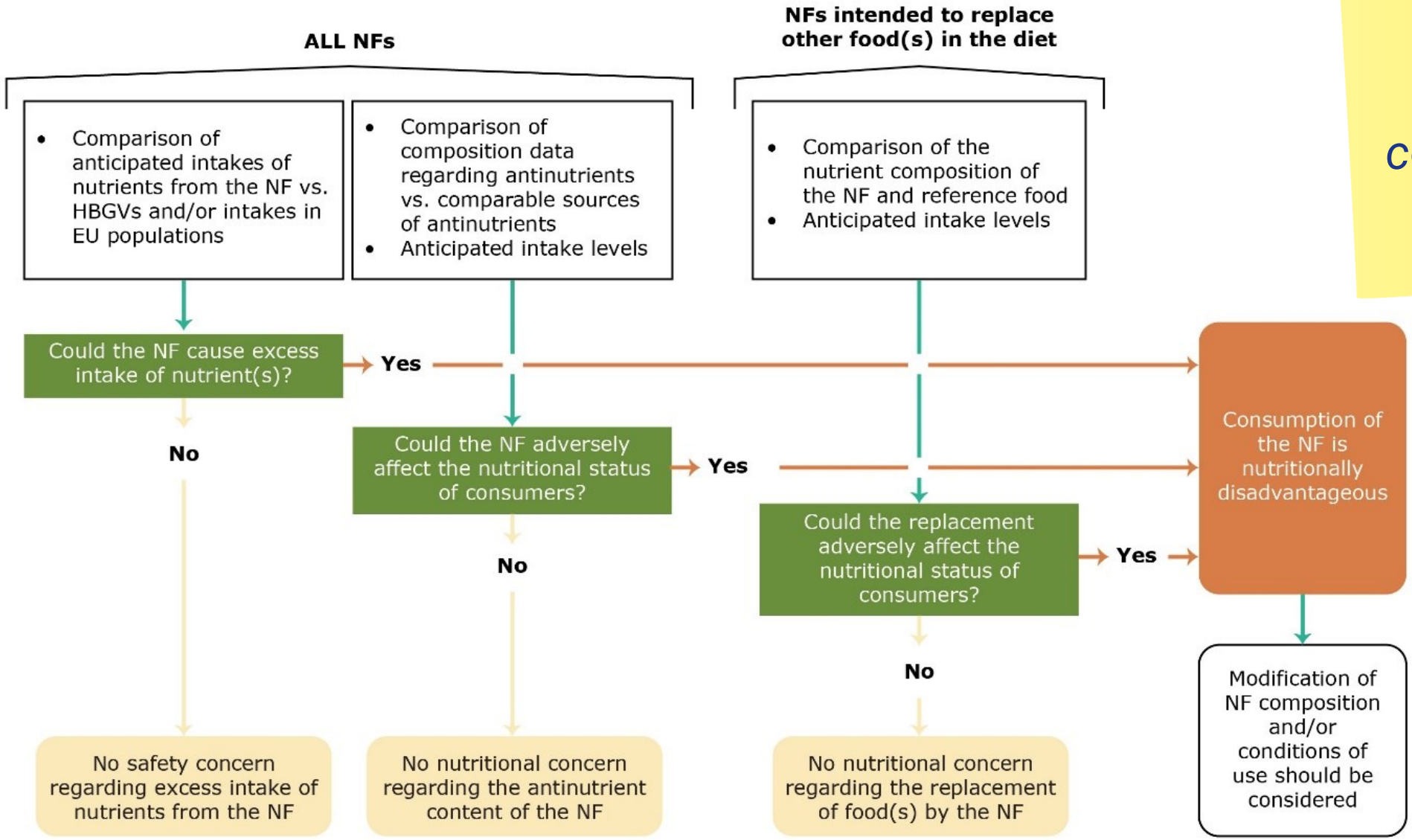
- *Protein quality (ileal digestibility & indispensable amino acids); Digestible Indispensable Amino Acid Score (DIAAS)*

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



ALLERGENICITY

- (a) **to inform risk managers** about the allergenic properties of a NF which may serve them for their marketing authorisation decisions including those with regards to possible labelling requirements and
- (b) **to collect the available evidence** related to the allergenicity of a NF and **to generate a limited set** of data in order gain some knowledge about the respective properties of the NF.

NF divided in four sub-categories

1. NF with NO protein content derived from the production process
2. NF derived from allergenic foods subject to MANDATORY ALLERGEN LABELLING with no proteins from other sources
3. NF derived from allergenic foods NOT subject to mandatory allergen labelling
4. NF for which the allergenic potential is UNKNOWN
   - Single protein & simple protein mixtures
   - Complex protein mixtures and whole foods

Each NF subcategory has different data requirements.

21 March 2024

QUESTIONS & ANSWERS

Wolfgang Gelbmann, Andrea Germini, George Kass, Emanuela Turla & Ermolaos Ververis

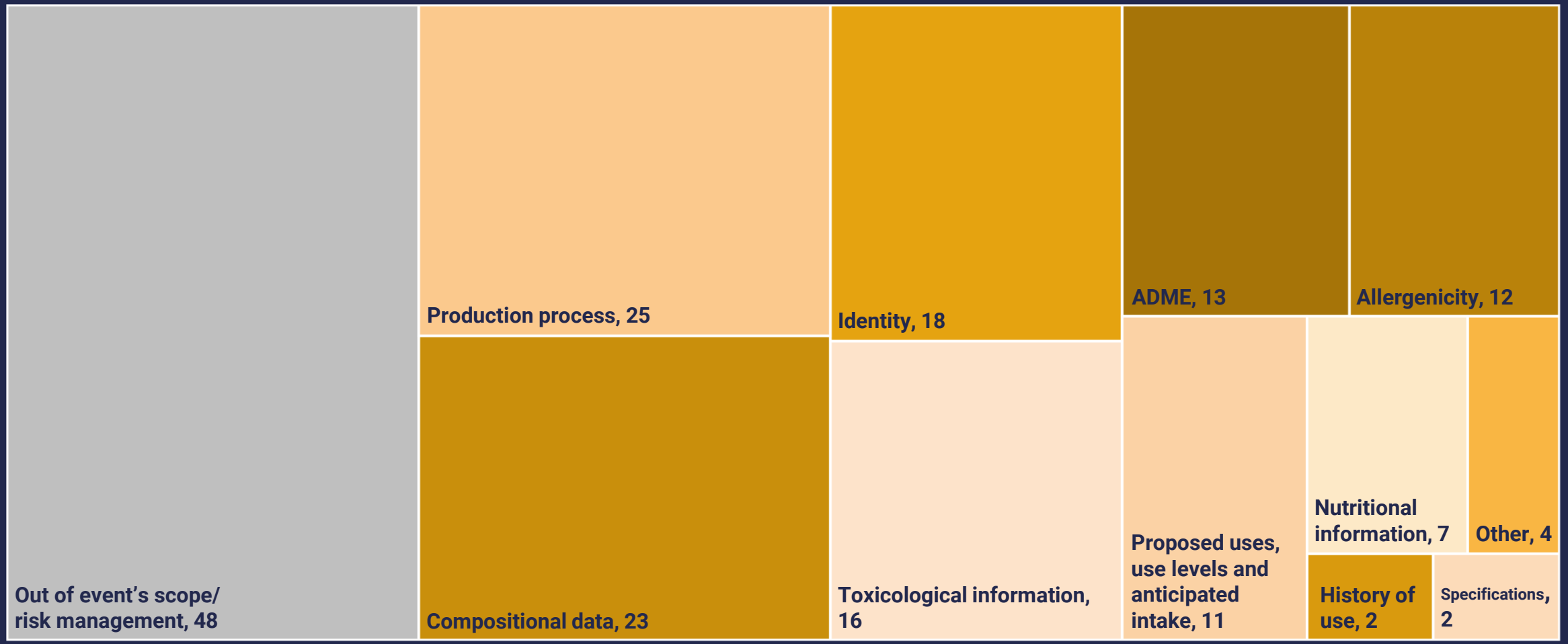
Nutrition & Food Innovation Unit

EFSA's Stakeholder Webinar
on the Novel Food Guidance Update

EUROPEAN FOOD SAFETY AUTHORITY

QUESTIONS & COMMENTS RECEIVED

181 questions submitted by **76** registrants



IDENTITY

Topics raised by registrants

- Status of products produced using **multiple (novel or not) sources**
- The role of **non-novel components** in the product to be assessed
- Novel Food **origin – EU or global**?
- Identity vs **Whole Genome Sequencing**
- Established accepted **purity levels**
- Taxonomy
- Use of **GM- microorganisms** in the production of novel foods – requirements & additional testing
- Demonstration of **non-GM status**
- Engineered **nanomaterials vs nanoparticles**

PRODUCTION PROCESS

Topics raised by registrants

- Required **level of details** in the production process description
- The role of food safety **management systems**, HACCP etc.
- Food contact material **compliance**
- Information on **raw material**
- Use of **food enzymes** in the risk assessment
- Production process **scale**
- **Changes in the production process** during risk assessment/after authorisation

COMPOSITIONAL DATA & SPECIFICATIONS

Topics raised by registrants

- The **role of compositional data** in the NF Risk Assessment
- At least **five batches** independently produced to be analysed
- Use of **omics** in the compositional characterisation
- Components **not previously used for food** production
- Compositional **variability** among batches
- **Thoroughness** of the compositional characterisation
- **Sources** for hazard identification
- Analytical **methods accepted**
- Appropriate (compositional) **comparators**
- **Interrelationship** of compositional data and specifications
- **Specifications** vs generic authorisations

HISTORY OF USE & PROPOSED USES, USE LEVELS, INTAKE

Topics raised by registrants

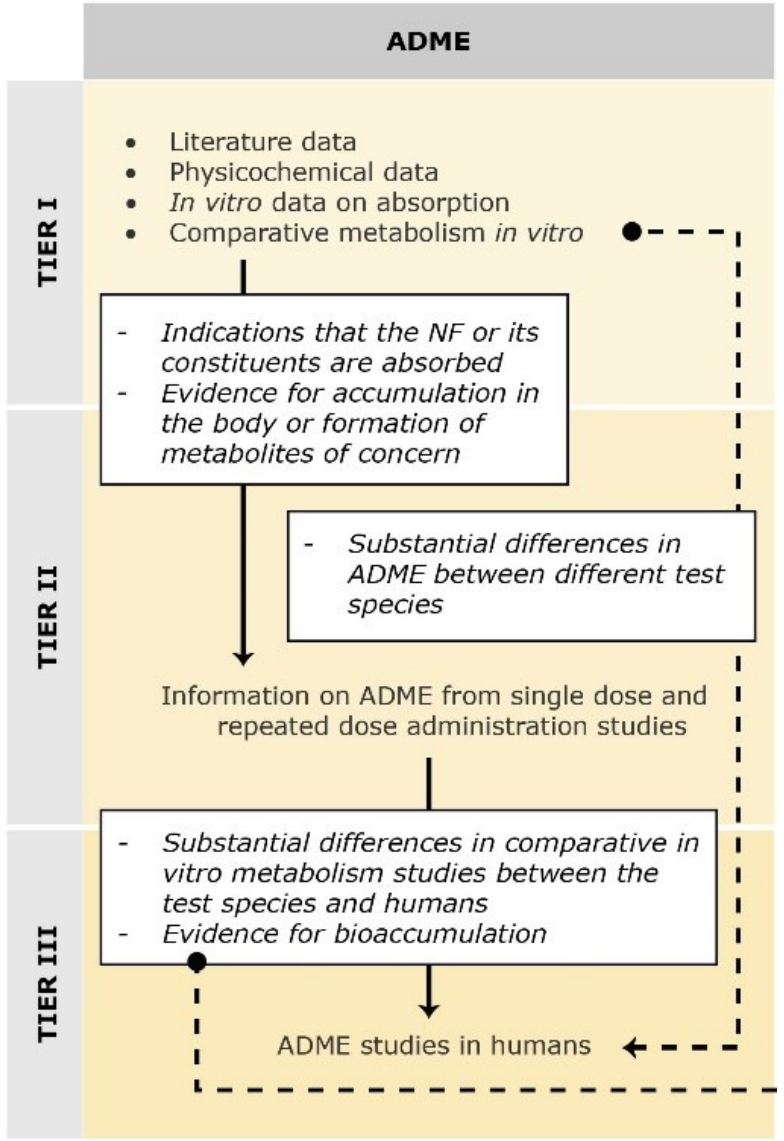
- **Documenting** the history of use

- EU dietary exposure **tools available**
- Conducting the **exposure assessment** – applicant vs EFSA
- Authorised uses: **novel foods vs food additives**
- Use of **national dietary survey** food consumption data/background diet
- **Combined exposure** of authorised uses and new intended uses
- Exposure to **undesirable substances**

ABSORPTION, DISTRIBUTION, METABOLISM, EXCRETION (ADME)

Topics raised by registrants

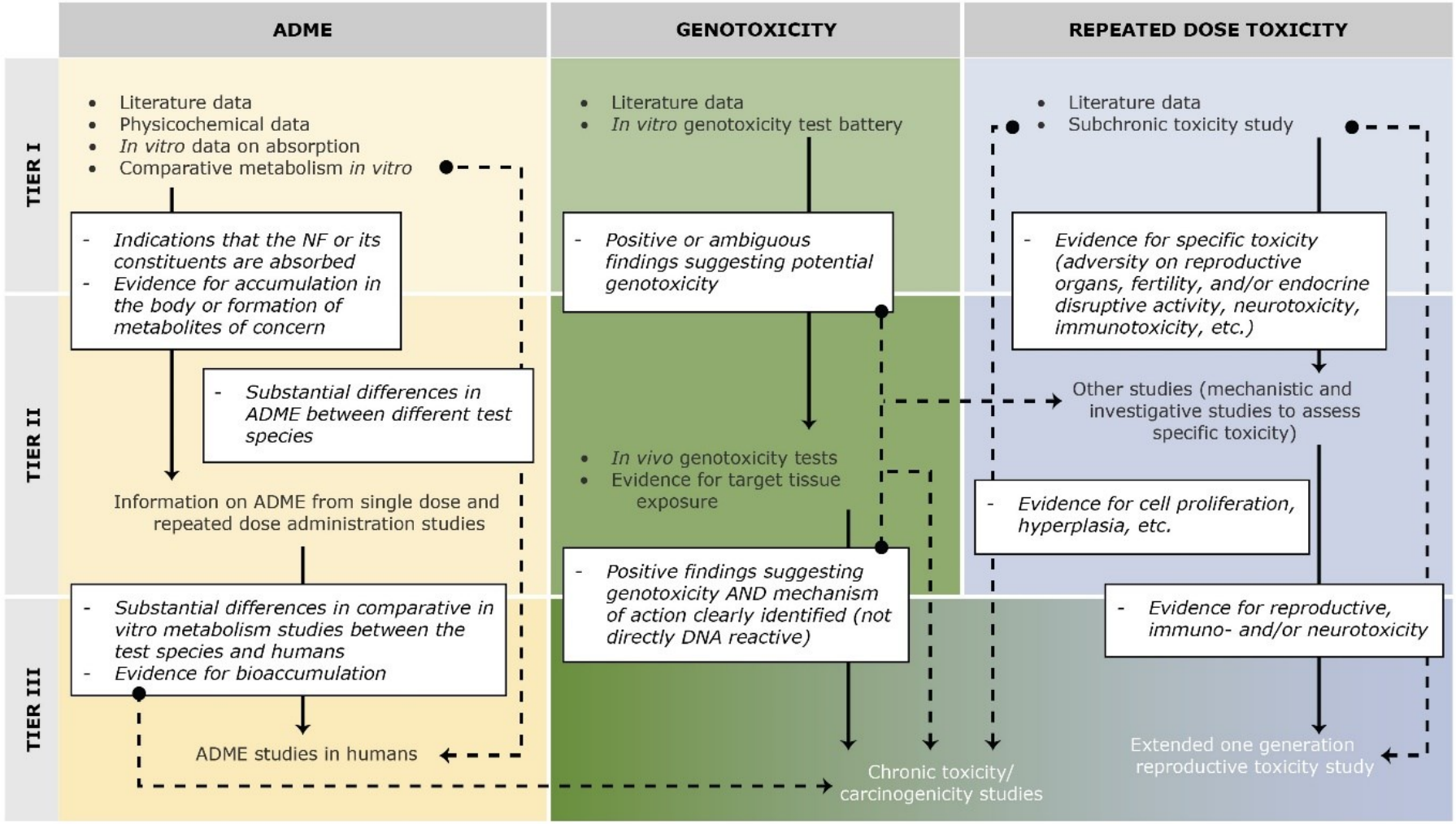
- **Need** for ADME studies
- **Determinants** for the need of **in vivo studies:** identity, compositional data, special NF groups
- **In vitro and in vivo studies: Protocols** for conducting the studies
- **NAMs for ADME:** validated approaches



TOXICOLOGICAL INFORMATION

Topics raised by registrants

- **Determinants** for the need of **in vivo studies**
- Use of New Approach Methodologies **(NAMs)**
- **What to test?**
- **Triggers** between TIERs
- Need to follow **OECD test guidelines & GLP**



NUTRITIONAL INFORMATION

Topics raised by registrants

- The concept of **nutritionally disadvantageous**
- **Antinutrient-**related considerations
- **Protein digestibility**: Use of in vivo vs in vitro studies
- Nutritional assessment: appropriate **food comparators**

ALLERGENICITY

Topics raised by registrants

- The role of **literature data** in addressing allergenicity aspects
- **Standard protocols** for allergenicity assessment
- Adequacy of **in silico comparison** of NF to know allergens
- Approach for **“major” vs. “minor” allergens**
- **Tiered approach** for investigating allergenicity
- Use of **in silico models**
- Analyzing **complex protein mixtures and whole foods**
- **Follow-Up Analysis** for potential cross-allergenicity
- Investigating **food intolerances**
- **Dose-response**

THANK YOU FOR ATTENDING OUR WEBINAR!

The written public consultation on the draft updated novel food guidance remains open **until 14 April**

The recording and presentations from this webinar will be made available on EFSA's website in the coming days

Please take a few minutes to complete the satisfaction survey that you will receive by email

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