26-28 June 2024

NOVEL FOOD GUIDANCE UPDATE: CHANGES AFTER PUBLIC CONSULTATION

(EFSA-Q-2023-00442)

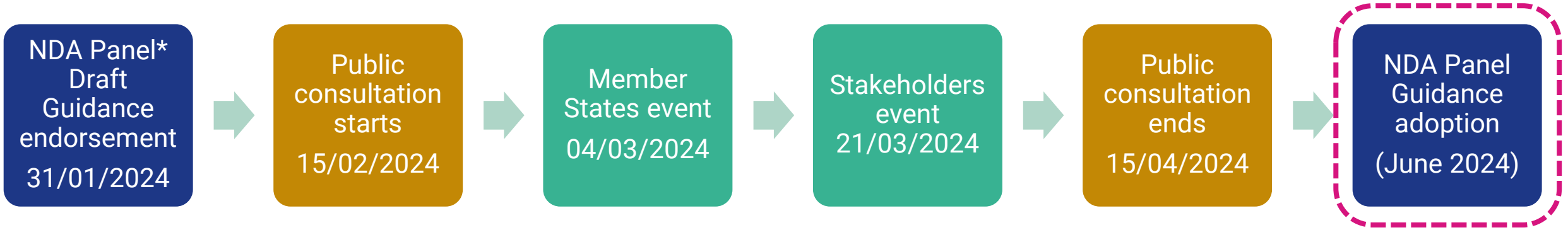
Ermolaos Ververis

Scientific Officer, Update coordinator

150th NDA Panel Plenary meeting

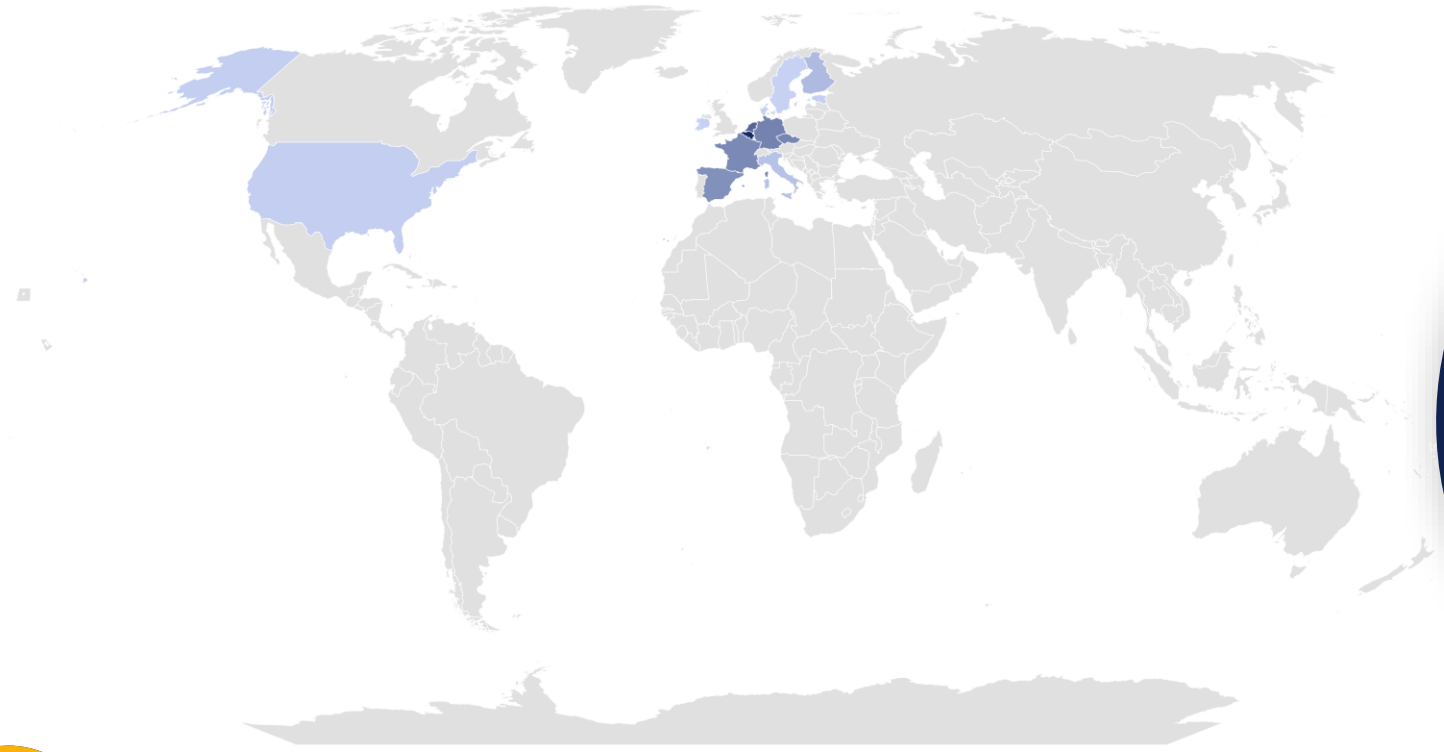
EUROPEAN FOOD SAFETY AUTHORITY

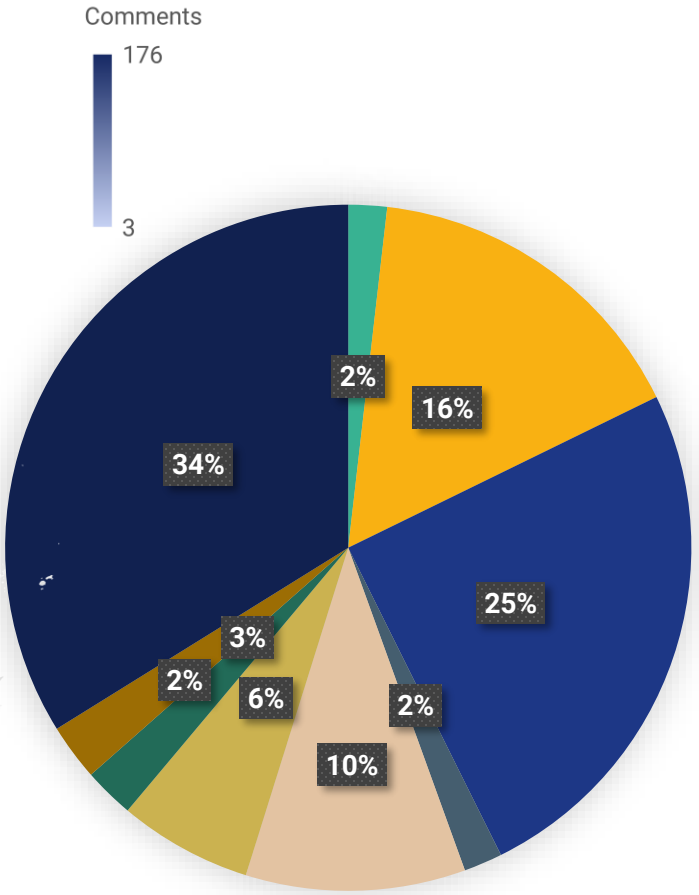
TIMELINE



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

PUBLIC CONSULTATION – 715 COMMENTS RECEIVED





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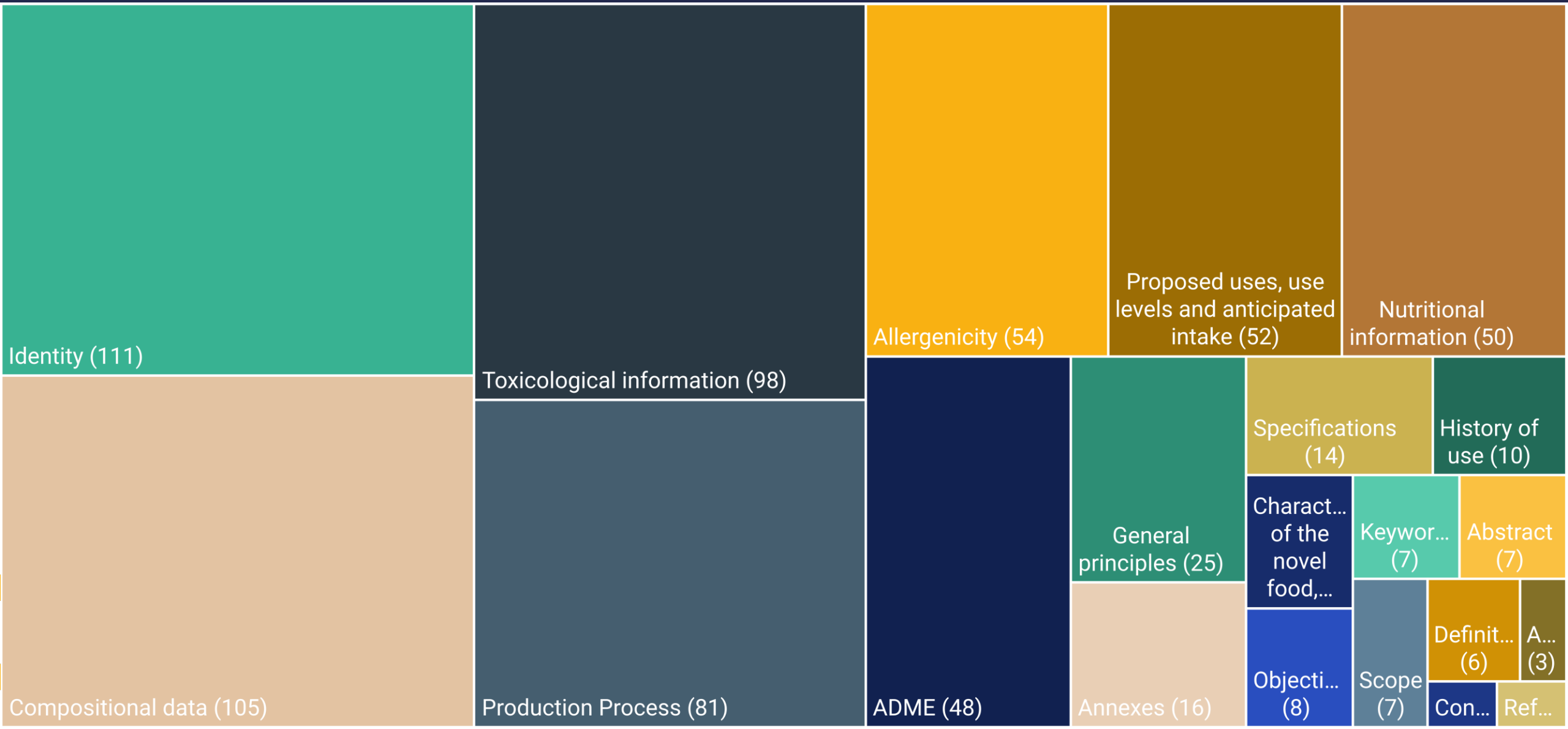

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SECTION 1

IDENTITY OF THE NOVEL FOOD

Andrea Germini

Team leader Novel foods - Product characterization

EUROPEAN FOOD SAFETY AUTHORITY

1. IDENTITY OF THE NOVEL FOOD

Main clarifications & amendments

- "**Full characterisation**" of the novel food
  Paragraph removed because redundant with the information provided in section 3.3. where the elements for the comprehensive characterisation of the composition of complex mixtures and whole foods are described.

1.1. Chemical substances, products of mineral origin and polymers

- Use of **nutritional or health claim** in the novel food name.
  Clarified that allowed when compliant EU Regulatory provisions
- Applicability of the **definition of polymers with respect to natural polymers**

  Specified that it applies to those polymers obtained from natural sources or through chemical or enzymatic synthesis or modification, and it excludes proteins

1. IDENTITY OF THE NOVEL FOOD

Main clarifications & amendments

1.2. Foods consisting of, isolated from or produced with microorganisms (and Appendix A)

- **Roles of microorganisms** in the context of novel foods

  Definition of **active agents**, **biomasses** and **production strains**, in the context of novel foods
- **Certificate of deposition**

  Clarification on the applicability to the microbial strain under assessment
- Clarifications on **antimicrobial resistance genes**

  Definition of antimicrobials of clinical relevance provided (EUCAST, 2024) in the glossary
- **QPS* approach**

  Clarification on QPS status and toxicological requirements (addressed in section 8)

*QPS: Qualified presumption of safety

1. IDENTITY OF THE NOVEL FOOD

Main clarifications & amendments

1.3. Food consisting of, isolated from or produced from plants, macroscopic fungi and macroalgae, or their parts

- Unclarity on the naming used for **algae vs microalgae**

  Algae renamed as **macroalgae** (i.e., seaweed)

- Clarification on the nature of the **non-GMO statement**

  Statement from the applicant accompanied by information on the source material

- Clarification on **reference databases** used for taxonomic identification

  Confirmation of the approach and correction of hyperlink

1.4. Food consisting of, isolated from or produced from animals or their parts

- Clarification on **hygiene and veterinary requirements**

  Reference to Regulation (EU) 2017/625 on official controls and other official activities and, where applicable, to Regulation (EC) No 853/2004 on specific hygiene rules for food of animal origin

1. IDENTITY OF THE NOVEL FOOD

Main clarifications & amendments

1.5.1. Foods consisting of, isolated from or produced from cell culture or tissue culture derived from animals

- **Hygiene and veterinary requirements** applicable to cells and tissues used for culturing

  Cross-reference to inspection requirements defined in section “1.4. Food consisting of, isolated from or produced from animals or their parts”

1.5.2 Foods consisting of, isolated from or produced from cell culture or tissue culture derived from plants, macroscopic fungi or macroalgae

- Clarifications provided to commentors but no amendments to the GD

1.6 Foods containing or consisting of engineered nanomaterials

- Clarifications provided to commentors but no amendments to the GD

1. IDENTITY OF THE NOVEL FOOD

Comments not leading to amendments

- Use of non novel ingredients in the formulation of the novel food.
- Information required for botanicals sourced from multiple sources.
- Legal classifications of GMMs*.
- Detailed description of analytical methods.
- Provision of raw WGS* data for for microorganisms used as NFs or in their production.
- Presence of viable cells and DNA (analysis; thresholds).
- Legal limits for microbial nucleic acids and endo/exotoxins.
- Need for preclinical and clinal studies for cell culture-derived foods of animal origin.
- Need for specific guidance on quality requirements for animal cells sourced from non-traditional livestock.
- Applicability of EFSA GD on nanomaterials to modified proteins obtained through precision fermentation.

*GMMs: Genetically modified microorganisms; WGS: Whole genome sequence

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SECTION 2

PRODUCTION PROCESS

Ermolaos Ververis

Scientific Officer

EUROPEAN FOOD SAFETY AUTHORITY

2. PRODUCTION PROCESS

Main clarifications & amendments

- Description of the production process: **comprehensive,** detailed enough to ensure **understanding of the critical parameters and steps** involved, enabling the **identification** of all potential **food safety hazards**.

2.1 General provisions

- Materials in contact with food vs EU compliance: requirements clarified
  (Moreover, for every material in contact with food during the production process (e.g., plastic containers), a declaration of compliance as laid down by Regulation (EC) No 1935/2004 and any other relevant EU provisions should be provided).
- Non-confidential summary: requirements added and clarified
  (If the description on the production process contains information for which a confidentiality request has been submitted, pursuant to Articles 39 to 39e of Regulation EC No 178/2002 and EFSA's Practical Arrangements concerning transparency and confidentiality, a non-confidential summary of the production process should also be provided, including all steps of the process with a general description of the operational conditions and safety-related parameters).

2. PRODUCTION PROCESS

Main clarifications & amendments

2.2 Considerations for specific production process steps

- Use of food enzymes as processing aids: framework & requirements clarified
  - *Demonstration of absence in at least three representative batches of the novel food that have been independently produced*
  - *If the enzyme is present: report enzymatic activity and potential residual (EFSA CEP Panel, 2021).*
  - *If the enzyme has been inactivated or removed: provision of inactivation/removal processes and operational conditions*
- Use of food additives in the production of a novel food: framework and provisions clarified

  […] it should be noted that such additives must be authorized and listed with conditions of use in the EU's positive list based on Regulation (EC) No 1333/2008 . Any unauthorized additives cannot be used.

2. PRODUCTION PROCESS

Main clarifications & amendments

2.3 Considerations for specific novel food categories

- Directive 2009/32/EC on extraction solvents used in the production of foodstuffs and food ingredients should be considered.
- Clarified: cell culture or tissue culture **derived from animals, plants, macroscopic fungi or macroalgae**
- **Growth factors of microbial origin**: framework & requirements clarified

The safety of growth factors of microbial origin (e.g., recombinant proteins, vitamins, amino acids) used in the production of e.g., novel foods consisting of, isolated from or produced from cell culture or tissue culture will be assessed to establish the safety of the novel food, taking into consideration the scientific requirements for the taxonomic and hazard identification of microorganisms intentionally used in the food chain, as listed in section 1.2 and Appendix A according to relevant EFSA guidance documents (EFSA FEEDAP Panel, 2018; EFSA, 2021e).

2. PRODUCTION PROCESS

Main clarifications & amendments

2.4 Considerations for specific novel food categories

- Application dossiers with analytical data **on novel food batches manufactured by different producers:** : framework & requirements clarified
- Application dossiers with analytical data **on novel food batches manufactured by processes involving steps that can be different** (e.g., drying the raw material using various methods)
- Such differences shall be described & equivalency to be substantiated

Comments not leading to amendments

- “Only a brief description of techniques used & production process steps”
- Definition of "novel aspects" of production processes.
- Eliminate requests compliance documentation, HACCP, etc.
- Alternatives to disclosing production yield to protect intellectual property.

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SECTION 3

COMPOSITIONAL DATA

Ermolaos Ververis

Scientific Officer

EUROPEAN FOOD SAFETY AUTHORITY

3. COMPOSITIONAL DATA

Main clarifications & amendments

3.1.1 Analytical methods

- Additional examples of nationally/internationally recognised validated methods
- Provision of Limited of Detection (LOD) and/or Limit of Quantification (LOQ)

3.1.2 Addressing compositional variability

- **Preferably** with independent batches of raw materials
- Analyses to be preferably performed on the same group of batches
- Batches from scales other than industrial: clarified

  It is expected that the analyzed batches are produced either at an industrial production scale or at one representative of it. Representativeness shall be duly justified.

- **Various forms of the novel food** (e.g., dried, frozen, powder): analytical requirements clarified

  all analyses must be conducted on at least five representative batches of each form, produced independently. Any deviations from this requirement must be justified.

3. COMPOSITIONAL DATA

Main clarifications & amendments

3.1.4 Compositional analytes

- the presence of metabolites of safety concern
- **Quantification of protein content**: requirements clarified
  In case the protein content of the novel food is substantial, it should also be calculated as the sum of the anhydrous amino acids, to account for the presence of non-protein nitrogen and the complete quantitative amino acid profile should be provided.

3.3 Complex mixtures and whole foods

- Additional examples of complex mixtures provided
- Substances of concern: requirements clarified
- Definition of antinutrients: provided
  Antinutrients are compounds that can interfere with the absorption of essential nutrients. Novel foods can contain antinutrients such as tannins, lectins, trypsin inhibitors, amylase inhibitors, phytic acid and phytates, oxalates or saponins, among others.
- For active agents and biomasses, the respective concentration of viable cells and non-viable cells in the novel food should be reported.

3. COMPOSITIONAL DATA

Main clarifications & amendments

3.4 Stability

- New **distinct subsection**: “Stability of the novel food”
- Requirement to include the proposed shelf-life
- Testing of a lower number of batches **should be justified by scientific arguments**
- Use of accelerated conditions in stability testing: clarified

  Accelerated conditions may be used as an alternative. Such approaches, usually conducted at higher temperature, could be applicable only in cases where chemical parameters are monitored

3. COMPOSITIONAL DATA

Comments not leading to amendments

- Additional information on laboratory accreditation and method accreditation.
- Rank analytical methods from best to least recommended.
- Reintroduce substantial equivalence for novel foods with compositions similar to existing foods.
- Reduce the requirement for at least five batches.
- Describe in more detail the data required as results of method validation.
- Additional information for sampling practices.
- Specific levels of identification required for unidentified components.
- Acceptance of ongoing stability studies.
- Clarify the requirements and methodologies for extrapolating results from accelerated conditions to intended storage conditions.
- Specific number of batches to be tested when investigating the impact of processing on novel foods when used as ingredients.

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SECTION 4

SPECIFICATIONS

Wolfgang Gelbmann & Ermolaos Ververis

Senior Scientific Officer, Scientific Officer

150th NDA Panel Plenary meeting

efsa
EUROPEAN FOOD SAFETY AUTHORITY

4. SPECIFICATIONS

Main clarifications & amendments

- Indication of the purpose of specification.
- Addition of a brief description of the novel food including elements of the identity and production process (such as the source, microbiological strain).
- Better explanation and indication of types of requested specification parameters.
- Rationale for the proposed specification parameters and their limits.

Comments not leading to amendments

- Include recommended methods for chemical, physicochemical, nutritional, and microbiological parameters.
- Recommendation for reinstatement of “Substantial Equivalence”.

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SECTION 5

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

Emanuela Turla

Senior Scientific Officer

EUROPEAN FOOD SAFETY AUTHORITY

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

Main clarifications & amendments

- Inclusion of examples of quantitative data on the consumption of the novel food.
- Inclusion of examples of handling and preparation of the novel food.
- Consider literature search covering also foods with similar chemical composition.
- Deletion of the requirement to provide full study reports of human studies.

Comments not leading to amendments

- Explain how to perform a systematic review.
- Provide examples when it is applicable to follow systematic literature review principles.

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SECTION 6

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

Emanuela Turla

Senior Scientific Officer

150th NDA Panel Plenary meeting

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6. PROPOSED USES, USE LEVELS AND ANTICIPATED INTAKE

Main clarifications & amendments

6.1 Target population

- The legal text on the target population has been reported.

6.2 Proposed uses and use levels

- When the novel food is intended to be used in food supplement, the category ‘food supplement’ in DietEx or FAIM should not be used.
- Intended use as ‘single meal replacement’ should be expressed as g of novel food in one meal replacement.

Comments not leading to amendments

- FAIM tool categories
- Use of a probabilistic intake assessment

6. PROPOSED USES, USE LEVELS AND ANTICIPATED INTAKE

Main clarifications & amendments

6.4 Combined intake considering other sources of the novel food or its main constituents

- **Overestimation of intake of a nutrient from the novel food as replacement/substitution is not permitted in the EFSA exposure tools**

→ EFSA tool cannot be modified to consider replacement/substitution.
However, the guidance has been changed to advise applicants that when replacement occurs, they should consider the potential double account which derives from the novel food and the diet.

Comments not leading to amendments

6.3 Anticipated intake of the novel food

- **The 95th percentile consumption is not representative of the average common consumption of foods**

→ When assessing the safety of a novel food, also individuals who are high consumers should be considered.

6. PROPOSED USES, USE LEVELS AND ANTICIPATED INTAKE

Main clarifications & amendments

6.5 Estimate exposure to substances of safety concern

- **Exposure to substances of safety concern from the novel food when the exposure from the background diet already exceeds health-based guidance values (HBGV)**
  → The guidance has been changed to advise applicants to consider the potential double accounting of substances of safety concern from the novel food and the diet.

Comments not leading to amendments

- Exposure to substances of safety concern from the novel food with no HBGV.

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SECTION 7

ABSORPTION, DISTRIBUTION, METABOLISM & EXCRETION (ADME)

George Kass

Team leader Novel foods - Product safety

150th NDA Panel Plenary meeting

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7. ADME

Main clarifications & amendments

7.1 General considerations

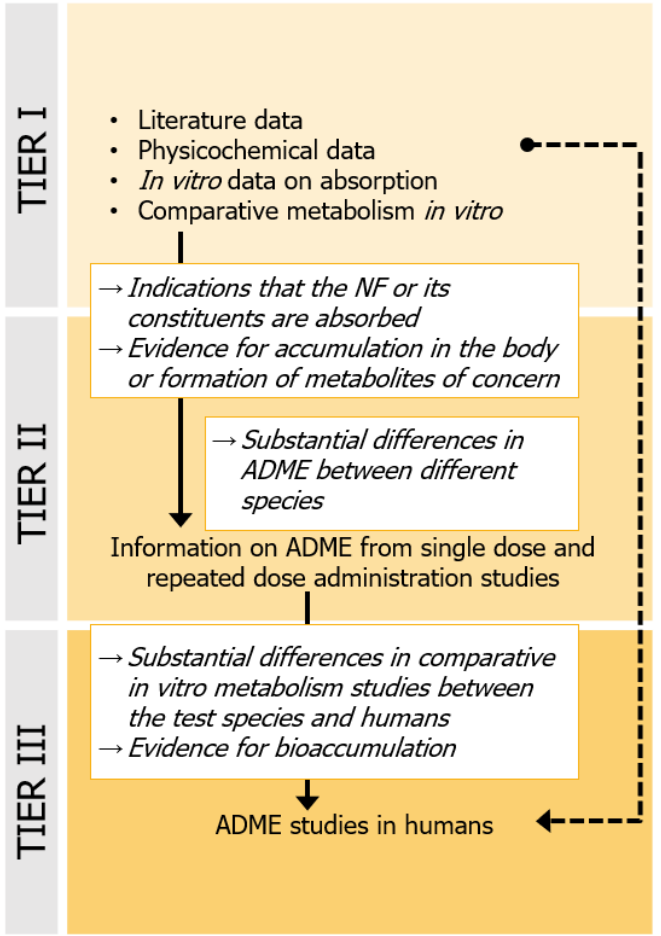
- When ADME studies should be conducted: clarified further
  While a detailed list of conditions or past examples where ADME studies would be required cannot be provided due to the heterogenous nature of novel foods, some clarifications have been provided.
  - To account for matrix and mixture effects
  - Polymers >1000Da that are resistant to degradation
  - Conventional materials containing nanoscale particles

7. ADME

Main clarifications & amendments

7.2 Tiered ADME testing approach

- Figure 1 further clarified.
- Statement that in vitro models, when shown to have similar level of predictivity, could replace in vivo models to assess absorption and metabolism.



7.3 Specific considerations for novel foods proposed as new nutrient sources

- New section added:
  For novel foods also proposed as new nutrient sources, the bioavailability of the nutrient from the new source needs to be demonstrated

  […] following the principles outlined in the EFSA Guidance on scientific principles and data requirements for the safety and relative bioavailability assessment of substances proposed as new micronutrient sources

7. ADME

Comments not leading to amendments

- Recommendation for a database of recommended alternative test laboratories.
- Further clarify substantial ADME differences between species, genders, and ages.
- Address validation and acceptance of non-validated methods for comparative metabolism studies.
- Detailed protocols for performing ADME and digestibility studies

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SECTION 8

TOXICOLOGICAL INFORMATION

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150th NDA Panel Plenary meeting

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8. TOXICOLOGICAL INFORMATION

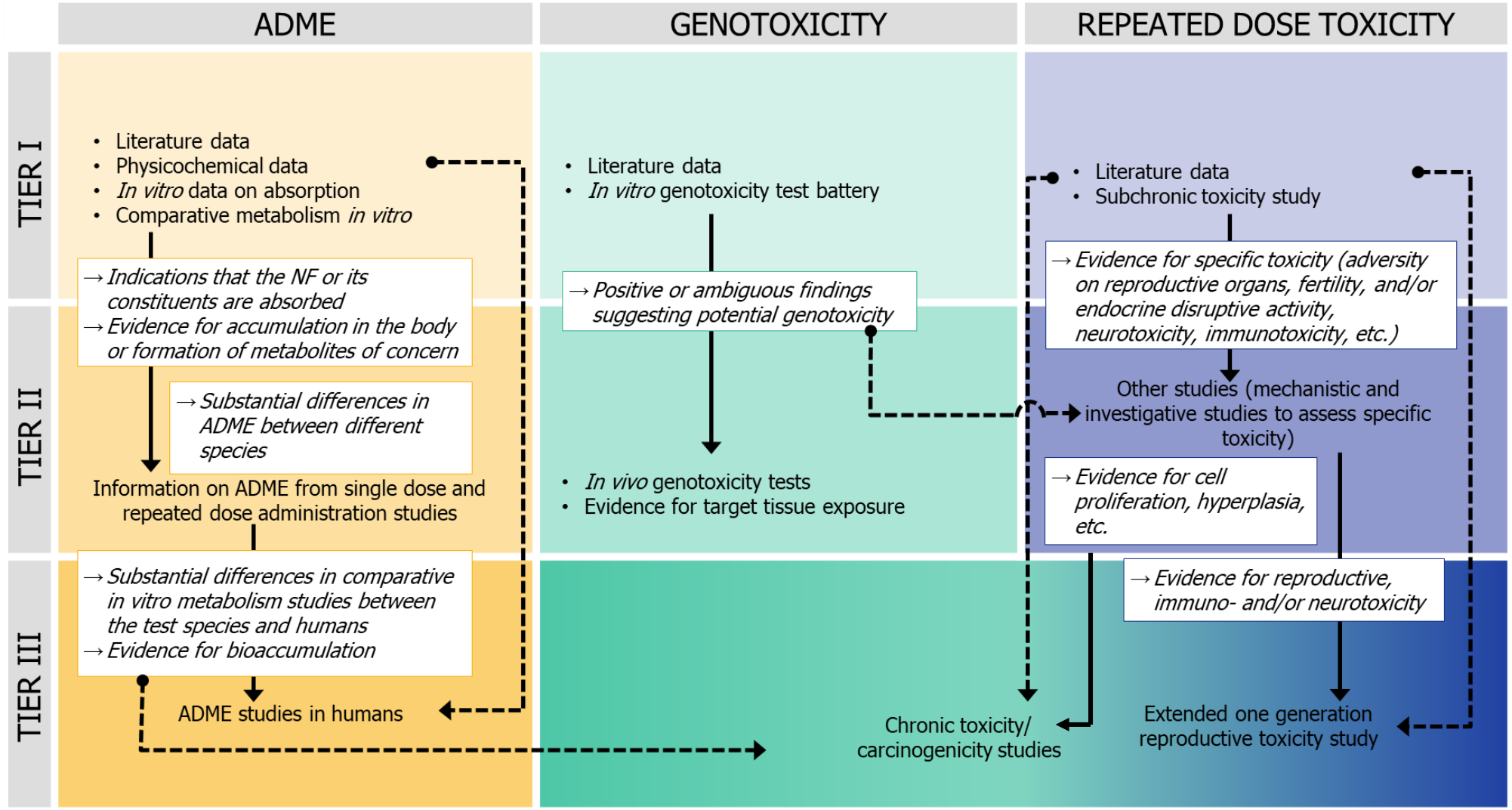
Main clarifications & amendments

8.1 General considerations

- Not referring anymore to the EFSA ANS Panel Guidance from 2012.
- Addition of referring to EFSA Guidance documents on nanomaterials and small particles from 2021.
- Addition of specifically mentioning criteria set by the EFSA's QPS approach.

8. TOXICOLOGICAL INFORMATION

8.2 Tiered approach to conduct toxicological studies



8. TOXICOLOGICAL INFORMATION

Comments received

- **Determinants** for the need of ***in vivo* studies.**
- Use of New Approach Methodologies **(NAMs).**
- **What material to test?**
- **Specify triggers** for the different tiers.
- Be more specific regarding requirements for different types of novel foods.

Important note

- Need to follow **OECD test guidelines & GLP.**

8. TOXICOLOGICAL INFORMATION

Main clarifications & amendments

8.3 Genotoxicity

- Reference to EFSA statement on genotoxicity assessment of chemical mixtures and Guidance on nanomaterials.
- Clarification provided when **genotoxicity testing of microorganisms** (viable and non-viable) is required: testing both supernatant and cell lysate.

8.3.1 Tier 1 genotoxicity testing

- Special considerations needed when the novel food is a **nanomaterial, or proteins/peptides:** clarified
  Bacterial reverse "treat and plate" methodology or mammalian gene mutation assays needed.
  In case of positive outcome of the *in vitro* micronucleus test > need to investigate aneugenicity by performing a kinetochore staining or fluorescence in situ hybridization (FISH).

8. TOXICOLOGICAL INFORMATION

Main clarifications & amendments

8.3.3 Tier 3 genotoxicity testing

- Clarification that if a novel food produces positive *in vivo* genotoxicity test results, no further testing is necessary, and the substance should be considered as genotoxic *in vivo*, has been provided.

8. TOXICOLOGICAL INFORMATION

Main clarifications & amendments

8.4 Repeated-dose Toxicological Studies

8.4.1 Tier I repeated-dose toxicological studies

8.4.1.1 Subacute

8.4.1.2 Subchronic toxicity

- Emphasis and explanation of the default uncertainty factor of 200 for reference point in a subchronic toxicity study, but deviation possible upon scientific justification.
- Considerations to employ satellite for recovery and toxicokinetics
- Considerations regarding (OECD TG408) optional/additional endpoints

Considerations when to add relevant endpoints in the 90-day study and to possibly store and keep samples from the study.

- Historical control data should be provided.

8. TOXICOLOGICAL INFORMATION

Main clarifications & amendments

8.4.2 Tier II repeated-dose toxicological studies

8.4.2.1 Reproductive, endocrine and developmental toxicity

Information can be derived by the 90-day study endpoints according to the OECD TG 408.

8.4.2.2 Other Tier II studies

8.4.3 Tier III repeated-dose toxicological studies

8.4.3.1 Extended one generation reproductive toxicity study

8.4.3.2 Chronic toxicity and carcinogenicity

Studies could be requested only in exceptional cases (e.g., accumulation of the substance, or hyperplasia observed in subchronic toxicity studies)

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SECTION 9

NUTRITIONAL INFORMATION

Ruth Roldán Torres

Scientific Officer

EUROPEAN FOOD SAFETY AUTHORITY

9. NUTRITIONAL INFORMATION

Main clarifications & amendments

- Ensure **clarity on the relevance of the paradigm for toxicological requirements**, considering ULs and DRVs: clarified in the text
- **Cross-reference** the section to toxicological information - general principles: applied

Comments not leading to amendments

- Consider **minimum intakes in vulnerable groups** (e.g., infant formula) *The Guidance considers not only potential adverse effects from nutrient intakes exceedance from the novel food **but also inadequate intakes by affecting the consumer's nutritional status**.*

- Clarify **whether nutrient excess is based on a standard consumer** diet or **different diet choices**; indicate in the Guidance "**Problems with excess of nutrient intakes under specific diets**". *As per **Regulation 2015/2283** and **Commission Implementing Regulation (EU) 2017/2469 the target population for the assessment is the general population**, including vulnerable groups (esp. in cases in which the NF is intended to be used as an ingredient in standard food categories). There is no provision in place that would allow or justify a case-by-case approach depending on specific dietary patterns.*

9. NUTRITIONAL INFORMATION

Comments not leading to amendments

9.1 Excess intake of nutrients

- Request for a "**comprehensive analysis" of all nutrients that could potentially exceed the Tolerable Upper Intake Levels (ULs) when no UL is established**.
  *For **nutrients** for which **no UL is available**, the applicant should **check whether other HBGVs are applicable** (e.g., ADI for copper, EFSA SC, 2021). The latter should be considered for the safety assessment.*

Main clarifications & amendments

- Consider **combined nutrient intakes** and cumulative exposure to nutrients from other dietary sources alongside the novel food.
  This is already addressed in the Guidance (anticipated intake). Text clarified "the combined nutrient intakes from the novel food and other sources of that nutrient (see section 6.4)

9. NUTRITIONAL INFORMATION

Comments not leading to amendments

9.2 Inadequate intakes of essential nutrients

- Request **for specific criteria or quantitative thresholds** that define what constitutes inadequacy

The risk of inadequacy of nutrient intake in populations can be assessed by comparing the estimated intake of micronutrients with DRVs for dietary requirements *(i.e. ARs) (EFSA NDA Panel 2010, DRV principles). Such an approach requires to* ***estimate total nutrient intake from the whole diet and is difficult to implement to predict the impact of specific foods****. The evaluation of the potential of the novel food to lead to inadequate intakes of essential nutrients should be* ***guided by compositional analyses and comparisons with comparable foods as described in the guidance.***

Main clarifications & amendments

9.2.1 Antinutrient content

- Clarification on antinutrient definition → Explanatory footnote included when the term is mentioned in the section “Compositional information”, alongside examples.

9. NUTRITIONAL INFORMATION

Main clarifications & amendments

9.4 Specific considerations regarding novel protein sources

- Clarify whether the 12% protein value applies to the novel food or final products.
  It refers to the novel food. However, this requirement was removed from this chapter.
- Consider **alternative methods for assessing protein digestibility** without animal trials
- Provide clear guidance on **protein quality assessment methods** and selection of control proteins: **framework & requirements clarified**
  "Methods to measure true ileal digestibility of amino acids in vivo have been established in animals and humans. In vitro methods could be proposed by applicants. Suitability of the method in consideration **will be examined during the risk assessment.** The **following minimum requirements** are proposed:
  - ✓ standardised test conditions that reflect the environment of the upper gastrointestinal tract (e.g., relevant enzymes and activity, pH, time, temperature);
  - ✓ inclusion of digestion of a blank sample (i.e., protein-free comparator) and a reference protein (e.g., casein, whey protein) ;
  - ✓ suitable methods to differentiate the absorbable and non-absorbable fraction of the digesta."

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SECTION 10

ALLERGENICITY

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Senior Scientific Officers

150th NDA Panel Plenary meeting

EUROPEAN FOOD SAFETY AUTHORITY

10. ALLERGENICITY

Main clarifications & amendments

- Indication of four “types” of NF with different requirements including a diagram:
    1. NF with no protein derived from the production process
    2. NF derived from allergenic foods subject to mandatory labelling
    3. NF derived from allergenic foods not subject to mandatory labelling
    4. NF for which the allergenic potential is unknown
- Testing requirements **clearer** for the different types of novel foods
- More weight (by specifically mentioning) on severity, prevalence and potency (10.3)
- **Tiered - approach regarding cross-reactivity/-allergenicity** for “new” proteins (10.4) taking into account comments from risk managers regarding cross-allergenicity

10. ALLERGENICITY

Main clarifications & amendments

10.4 Novel foods for which the allergenic potential is unknown

- Notion that there are no validated methods for predicting *de novo* sensitisation
- Tiered approach investigating cross-allergenicity:

Step 1
- Information on allergenicity of the source organism of the novel food based on a **comprehensive literature search** and **phylogenetic relationships** with sources containing known food allergens.

Step 2
- **Bioinformatic search** for cross allergenicity i.e., amino acid sequence (AAS) comparison and complementary approaches.

Step 3[1]
- **Human serum specific IgE binding assay** with immunoassay methods such as ELISA or electrophoresis combined with immunoblotting with serum IgE sera.

Step 4[2]
- **Human studies** e.g., skin-prick tests and an oral food challenge (preferably a double-blind placebo-controlled food challenge) in subjects with confirmed food allergy to the known food allergen.

[1]: Required only if bioinformatic analyses indicate potential cross-allergenicity to a known allergen
[2]: Required only is IgE binding assays indicate potential cross-allergenicity to a known allergen

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OTHER SECTIONS

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Scientific Officer

150th NDA Panel Plenary meeting

EUROPEAN FOOD SAFETY AUTHORITY

OTHER SECTIONS

Main clarifications & amendments

Scope

A separate EFSA guidance document is available to assist applicants in preparing an application on substances proposed as new sources of micronutrients, including new forms of micronutrients, and for the quantification of the relative bioavailability of the micronutrient from the new source

General principles

emphasised: *tests on animals should be replaced, reduced or refined (3 Rs)*

Glossary

Added

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