Novel Foods

Webinar: "Novel food: tra percezione e realtà - Scienza, Sicurezza e Normative UE"

Ivona Babic, PhD, policy officer
European Commission
DG Health and Food Safety

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

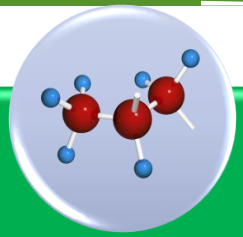
1. The Novel Food Regulation

Regulation (EU) 2015/2283)

- The purpose of novel food Regulation is to ensure the effective functioning of **the internal market** while providing a **high level of protection of human health and consumers' interests**.
- **Definition:** *Food not used for human consumption to a significant degree before 15 May 1997 and that falls under at least one of the categories:*
- **10 categories**

Novel Food Categories

New production process



New or modified molecular structure

Micro-organisms, fungi, algae

From plants or their parts

Of mineral origin

From animals or their parts

Cell or tissue cultures derived from animals/ plants/fungi/ algae

Engineered nanomaterials

EFSA source

Main requirements

European Commission

Article 7:

Main requirements - novel foods must:

- ✓ Be safe for human health
- ✓ Must not mislead the consumer, especially when the novel food is intended to replace another food
- ✓ Must not be nutritionally disadvantageous where it is intended to replace another food

2. Novel Foods authorisation process

NF authorisation process
Article 10

Application[1] or COM initiative

COM[2]

- Information made available to Member States
- Summary is published
- EFSA not consulted[3]
  - COM (7 months from the date of the valid application, impl. act)
  - Standing Committee
  - Update of Union list
- EFSA consulted (9 months)
  - Applicant & MS
  - COM (7 months from EFSA opinion, impl. act)
  - Standing Committee
  - Update of Union list [4]

[1] *Applicant may withdraw its application at any time*

[2] *COM may terminate the procedure at any stage*

[3] *When the update is not liable to have an effect on human health*

[4] *Generic authorisation, except if authorisation based on protected data*

Applications (Article 10)

- *Applicant - EU MS, non-EU MS or the interested party which may represent several interested parties*
- *Information to public – Summaries + Transparency Provisions*
- *Evaluation by the European Food Safety Authority*
- *COM and EFSA do not charge fees for managing applications*
- *Authorisation by the Commission and MS*
- *Time limits for each step*
- *Experience has shown the process to take at least 18 months (versus 3.5 years on average with the former Novel Food Regulation)*

Confidentiality

- Amended by Regulation 2019/1381 (TR)
- On request by applicant
- Confidentiality may only be granted to a limited list of elements (list in Article 39 GFL and complemented in the NF regulation) and only if disclosure is demonstrated to potentially harm the applicant's interests to a significant degree.
- Assessments to be performed by EFSA – in accordance with the Practical Arrangements
- Except where EFSA is not consulted (novel food applications without EFSA opinion), assessment to be performed by the Commission – in accordance with the NF regulation.

Data Protection

- On request by applicant
- Conditions for data protection:

  (a) the newly developed scientific evidence or scientific data was designated as proprietary;

  (b) the initial applicant had exclusive right of reference to the evidence or data; and

  (c) the novel food could not have been assessed by EFSA without the submission of the proprietary scientific evidence or scientific data.
- COM can grant the individual authorization for 5 years
- Authorization holder indicated in the Union list

3. Novel foods dossiers

Requirements

- Novel Foods Regulation (EU) 2015/2283
- Commission Implementing Regulation (EU) 2017/2469 -administrative and scientific requirements for applications
- EFSA Guidance on the scientific requirements for an application for authorisation of a novel food
- Transparency Regulation (EU) 2019/1381
- E-Submission Food Chain Platform

Transparency Regulation (EU) 2019/1381

European Commission

- requires applicants to notify EFSA of studies supporting their application before the study begins
- Timing: Studies commissioned or carried out after 27 March 2021, must be notified to EFSA before they start
- Method: Notifications are submitted via the EFSA portal (Connect)
- Purpose: To ensure EFSA is aware of all studies supporting an application, regardless of their outcome, and to prevent delays
- Consequences of non-compliance: Non-validity - the assessment of the validity of re-submitted application starts 6 months after the re-submission of application

Parts of the dossier

- Administrative Data - Identity of the novel food – name, description; Confidentiality; Data Protection; Proposed entry in the Union list – conditions of uses
- Cover letter
- Summary data
- Technical Dossier - Production process; Compositional data; Specifications; Proposed uses and use levels and anticipated intake of the novel food; ADME; Safety data

EFSA Risk assessment

- Identity of the novel food
- Production process
- Compositional data
- Specifications
- History of use of the novel food and/or of its source
- Proposed uses and use levels and anticipated intake
- Absorption, distribution, metabolism, and excretion (ADME)
- Toxicological information
- Nutritional information
- Allergenicity
- Concluding remarks

New EFSA guidance on the scientific requirements for NF applications

- Applicable as of 1 February 2025
- https://www.efsa.europa.eu/en/efsajournal/pub/8961

EFSA shall consider the following:

✓ whether the Novel Food in question is **safe**

✓ whether the composition of the food and the conditions of its use **do not pose a safety risk** to human health in the Union

✓ whether the normal consumption of the NF would be **nutritionally disadvantageous** for the consumer

4. The Union list of Novel Foods

The Union list consists of 2 tables:

- **Table 1**
  - ✓ Conditions under which the NF may be used (specified food category and Maximum levels)
  - ✓ Additional specific labelling requirements
  - ✓ Other requirements
  - ✓ Data protection, where necessary
- **Table 2**
  - ✓ Specifications

Table 1

European Commission

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
'**Magnesium L-threonate**	*Specified food category*	*Maximum levels*	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "Magnesium L-threonate". 2. The labelling of food supplements containing magnesium L-threonate shall bear a statement that the food supplements should be consumed by adults only, excluding pregnant and lactating women.		Authorised on 7 November 2024. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: AIDP Inc., 19535 East Walnut Drive South City of Industry, CA 91748, the United States. During the period of data protection, the novel food magnesium L-threonate is authorised for placing on the market within the Union only by AIDP Inc., unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of AIDP Inc. End date of the date protection: 7 November 2029'
	Food supplements as defined in Directive 2002/46/EC for adults, excluding pregnant and lactating women	250 mg/day			

Table 2

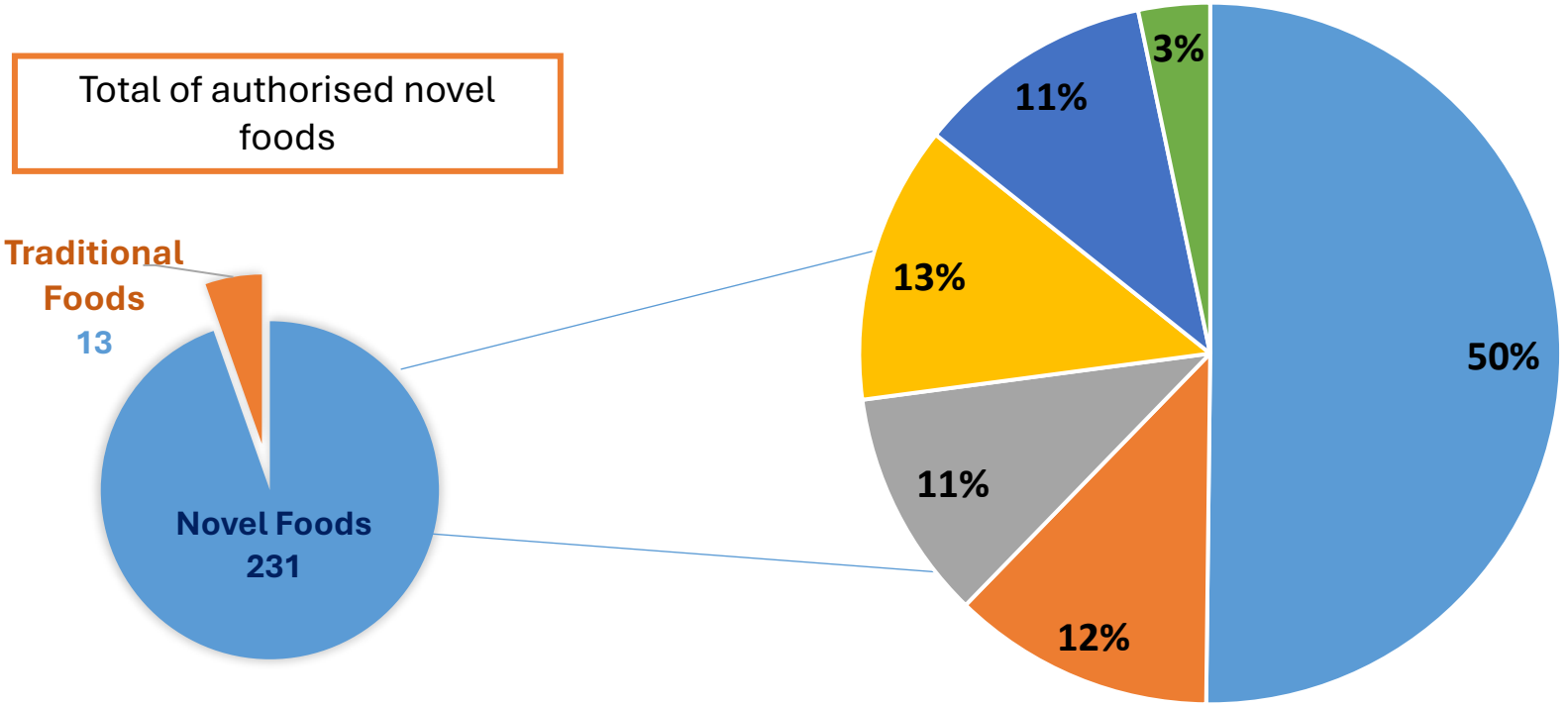
(2) in Table 2 (Specifications), the following entry is inserted:

Authorised Novel Food	Specification
'Magnesium L-threonate	**Description/Definition:** The novel food is produced by chemical synthesis and consists of magnesium L-threonate. **Chemical identity:** Chemical (IUPAC) name: Magnesium (2R,3S)-2,3,4-trihydroxybutanoate monohydrate Common name: magnesium L-threonate Molecular formula: $C_8H_{16}MgO_{11}$ CAS number: 500304-76-7 Molecular weight: 312,5 Da **Characteristics/composition:** Appearance: White powder Mg L-threonate monohydrate: 98 %–102 % Magnesium: 7,2 %–8,3 % L-Threonate: 82 %-91 % Oxalic acid: ≤ 1 % Ethanol: ≤ 5 000 ppm Loss on drying: ≤ 5,0 % **Microbiological criteria:** Total aerobic microbial count: ≤ 100 CFU/g Total yeast and moulds count: ≤ 10 CFU/g *E. coli:* Not detected in 10 g *Salmonella:* Not detected in 25 g Abbreviations: CAS: chemical abstracts service, IUPAC: International Union of Pure and Applied Chemistry, CFU: colony forming unit'

Food supplements

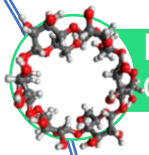
European Commission

Total of authorised novel foods



Trends in novel foods

Plant extracts and algal-based products



Novel Foods consisting of/rich in non-digestible carbohydrates

Human identical milk oligosaccharides

Alternative proteins: Insects, cell-based foods

Engineered nanomaterials

Synthetic or extracted cannabidiol

5. Consultation under Article 4 of the NFR

Determination of the NF status

- Art 4(2) NFR:
  - If FBOs are still unsure about a food as novel, they shall consult the competent authorities of the EU country where they first intend to place the food on the market.
  - the novel-status consultation: is this food novel, or not?

- Commission Implementing Regulation (EU) 2018/456

- List of MS CA: https://ec.europa.eu/food/sites/food/files/safety/docs/fs_novel-food_leg_list_comp_auth_reg_2018_en.pdf

- Run by Member States, not the Commission (Reg (EU) 2018/456 sets the procedure))

- Recipient Member State decides → Commission publishes the outcome

- A "not novel" outcome = no authorisation needed → fast, low-cost market access

Article 4 in numbers

197

consultation conclusions issued in the EU since 2018

- ✓ Novel ~ 51%
- ✓ Not novel ~ 41%
- ✓ Novel in foods but not novel in food supplements ~ 8%

Publication of consultation requests

Consultation process on novel food status

Name and description of the food concerned	Date of publication	Statement on the food concerned	Reasons justifying the statement	Where the food is novel, the most appropriate food category under which it falls in accordance with Article 3(2) of Regulation (EU) 2015/2283
A plant protein concentrate that is fermented with the mycelium of shiitake (Lentinus edades).	25 February 2019	Novel when used as or in foods.	View document EN	Category 3(2) (a)(ii)
Agaricus blazei dehydrated mycelium powder	29 October 2019	Novel when used as or in foods.	View document EN	Category 3(2) (a)(ii)
Albizia julibrissin Durazz. - flowers	8 August 2019	Novel when used as or in foods.	View document EN	Category 3(2) (a)(iv)
Alcohol extract of kudzu (Pueraria lobata (Willd.) Ohwi) root.	30 June 2020	Novel when used as or in foods.	View document EN	Category 3(2) (a)(iv)
Apricot kernel drink and Fermented apricot kernel cream	22 March 2021	Not Novel	View document EN	

6. The Novel Food Catalogue

Novel Food Catalogue - Statuses

NOT NOVEL IN FOOD - According to the information available to the Member States' competent authorities, this product was used for human consumption to a significant degree within the Union before 15 May 1997. Thus, it is not considered to be 'novel' according to the provisions of the Novel Food Regulation (EU) 2015/2283 and its access to the market is not subject to the pre-market authorisation in accordance with Regulation (EU) 2015/2283.

However, other legislation may restrict the placing on the market of this product as a food in the EU or in some Member States. Therefore, it is recommended to check with the competent authority(ies) of the Member State(s).

NOT NOVEL IN FOOD SUPPLEMENTS - According to the information available to Member States' competent authorities, this product was used in food supplements in the EU before 15 May 1997. Therefore, its use in food supplements is not considered to be novel and is not subject to the pre-market authorisation in accordance with Regulation (EU) 2015/2283.

Any other food uses of this product, other than as, or in, food supplements, might be considered to be novel and consequently might need to be authorised pursuant to the requirements of the Novel Food Regulation (EU) 2015/2283 before they can be placed as food on the EU market.

In addition, other legislation may restrict the placing on the market of this product as a food in the EU or in some Member States. Therefore, it is recommended to check with the competent authority(ies) of the Member State(s).

NOVEL FOOD - According to the information available to Member States' competent authorities, this product was not consumed in the EU to a significant degree as a food before 15 May 1997. Therefore, a pre-market authorisation in accordance with Regulation (EU) 2015/2283 is required before it can be placed as food on the EU market.

AUTHORISED NOVEL FOOD - This is an authorised novel food and it has been included in the Union list established by Commission Implementing Regulation (EU) 2017/2470.

Thank you for your attention !

Further Information:

https://food.ec.europa.eu/food-safety/novel-food_en

https://food.ec.europa.eu/food-safety/novel-food/authorisations_en

https://food.ec.europa.eu/food-safety/novel-food/legislation_en

https://food.ec.europa.eu/food-safety/novel-food/consultation-process-novel-food-status_en

https://food.ec.europa.eu/food-safety/novel-food/novel-food-status-catalogue_en