
Demonstration of Innovative Functional food production systems based on more sustainable value chains of marine and freshwater raw materials for conscientious EU consumers

A large, stylized graphic on the left side of the slide, featuring a green leaf-like shape at the top, a blue water droplet in the center, and three blue curved lines representing waves at the bottom.

3.0 Legal requirements, policies and quality management

3.1 Novel Food regulations

Main objective

-  Define Novel Food according to regulatory definition

Learning outcomes

-  Know the definition of Novel Foods and how they are regulated in the EU
-  Understand the difference between Novel Foods and foods used traditionally in third countries
-  Understand the concept of the authorization procedure of the EU for Novel Foods

Agenda

-  Definition Novel Food
-  Regulation within the EU
-  Application procedure
-  Notification of traditional food from third countries

General Food Law - Overview

TABLE 9.1 Overview of the EU regulations for food/feed

Regulatory topic	Description
1. General Food Law Regulation	Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety • Guarantee a high level of protection of human life and health and the protection of consumers' interests. Also guarantee fair practices in food trade, taking into account animal health and welfare, plant health, and the environment • Ensure free movement of food and feed manufactured and marketed in the Union, in accordance with the General Food Law Regulation • Facilitate global trade of safe feed and safe, wholesome food by taking into account international standards and agreements when developing Union legislation, except where this might undermine the high level of consumer protection pursued by the Union

Regulatory topic	Description
2. Labeling and nutrition	• Food labeling legislation —(EU) No. 1169/2011 • Nutrition and Health Claims—(EC) No. 1924/2006 • Food supplements—Directive 2002/46/EC • Addition of vitamins and minerals—(EC) No. 1925/2006 • Food for specific groups—(EU) No. 609/2013 • <i>Trans</i> fat in food—(EC) No. 1925/2006
3. Biological and chemical safety	• Food hygiene—(EC) 852/2004 • Feed hygiene—(EC) Regulation 767/2009 • Feed additives—(EC Regulation 1831/2003) • Undesirable substances in animal feed—Council Directive 2002/32/EC. • Contaminants in foodstuff—(EC) No. 1881/2006
4. Novel food	(EU) 2015/2283 "Food business operators can place a novel food on the European Union market only after the Commission has processed an application for the authorization of a novel food, and has adopted an implementing act authorizing the placing on the market of a novel food and updating the Union list"
EU, European Union.	

Source: Markou G. (2021)

Novel Foods

Generally, foods can be placed on the European market BUT

→ New foods and ingredients, where there is no sufficient experience regarding their safety and tolerance need to be approved by the European Union.

- Including: newly developed and innovative foods, foods produced with new technologies or production processes, foods which are traditionally consumed in non-EU countries, but not in Europe.

= Novel Food

Regulated by



Regulation (EU) 2015/2283 on novel foods

11.12.2015

EN

Official Journal of the European Union

L 327/1

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 25 November 2015

on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001

(Text with EEA relevance)



**Funded by
the European Union**

Other relevant regulations

Commission implementing regulation (EU) 2017/2468

- administrative and scientific requirements concerning traditional foods from third countries

Commission implementing regulation (EU) 2017/2469

- administrative and scientific requirements for applications referred to the defined categories of novel foods

Commission implementing regulation (EU) 2017/2470

- establishing the Union list of novel foods

Commission implementing regulation (EU) 2018/456

- procedural steps of the consultation process for determination of novel food status

Definition (Regulation (EC) 2015/2283)

“Novel food” means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories.

Categories according to Art. 3 (1)

- i. Food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;
- ii. Food consisting of , isolated from or produced from microorganisms, fungi, or algae;
- iii. Food consisting of , isolated from or produced from material of mineral origin;
- iv. Food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:
 - Traditional propagating practices which have been used for food production within the Union before 15 May 1997; or
 - Non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;
- v. Food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;

Categories according to Art. 3 (1)

- vi. food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;
- vii. food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances;
- viii. food consisting of engineered nanomaterials as defined in point (f) of this paragraph;
- ix. vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:
 - a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph; or
 - they contain or consist of engineered nanomaterials as defined in point (f) of this paragraph;
- x. food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC;

Food categories - summary

-  Food with new or intentionally modified molecular structure
-  Food from microorganisms, fungi, algae, mineral origin, plants or their parts, animals or their parts
-  Food from cell or tissue cultures derived from animals, plants, microorganisms, fungi or algae
-  Food from engineered nanomaterials
-  Vitamins, minerals and other substances with a novel manufacturing process or with/from engineered nanomaterials
-  Food used exclusively in food supplements before

→ not produced in the European Union before 15 May 1997

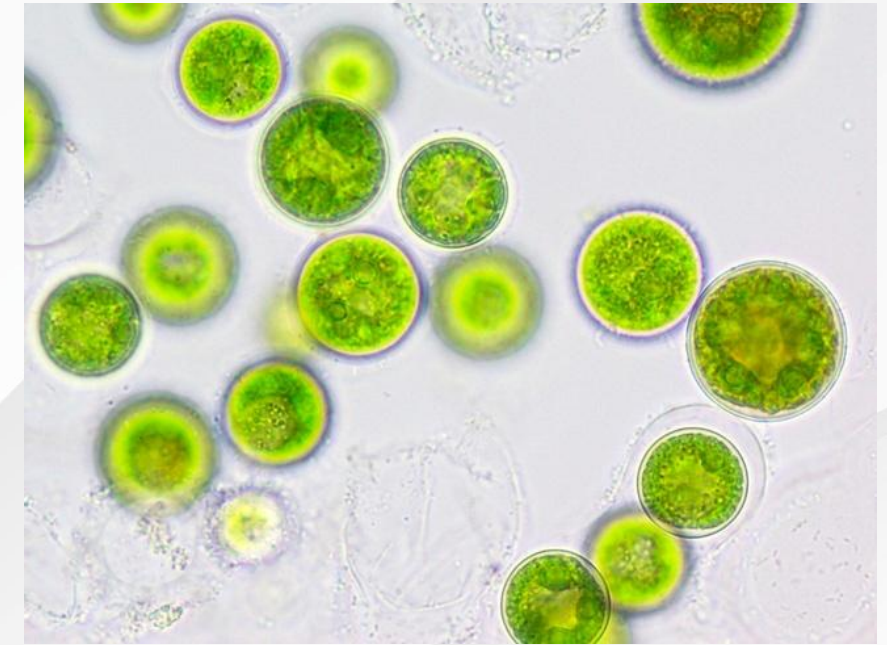
For the following food groups special regulations apply

-  GMOs for food and feed (Regulation (EC) No 1829/2003)
-  Food enzymes (Regulation (EC) No 1332/2008)
-  Food additives (Regulation (EC) No 1333/2008)
-  Flavourings (Regulation (EC) No 1334/2008)
-  Extraction solvents used in the production of food (Directive 2009/32/EC)

→ Therefore, the novel food regulation doesn't apply here.

Examples of marine and freshwater related Novel Foods

-  Algal oil from the microalgae *Ulkenia sp.*
-  Astaxanthin-rich oleoresin from *Haematococcus pluviadis* algae
-  *Odontella aurita* microalgae
-  *Schizochytrium sp.* Oil
-  Dried *Tetraselmis chuii* microalgae
-  Fish peptides from *Sardinops sagax*
-  Phosphatidylserine from fish phospholipids
-  Therapon barcoo/Scortum
-  *Calanus finmarchicus* oil
-  Antarctic Krill oil from *Euphausia superba*
-  Fucoidan extract from the seaweed *Fucus vesiculosus* and *Undaria pinnatifida*



Schizochytrium sp. (<https://www.mispecies.com/en/news/Turning-Schizochytrium-into-a-Biofactory-for-Astaxanthin-A-Breakthrough-in-Biotechnology/>)

→ Most of them are restricted to different food categories, food supplements and/or food for special purposes (e.g. medical, weight control etc.)

Novel food prototype development, Athens, Greece



Jotis S.A.
Hellenic Research and Innovation
center



Enhanced nutritional profile of
cracker

Key facts

Cracker

Product



Macroalgae

Used
species



Video

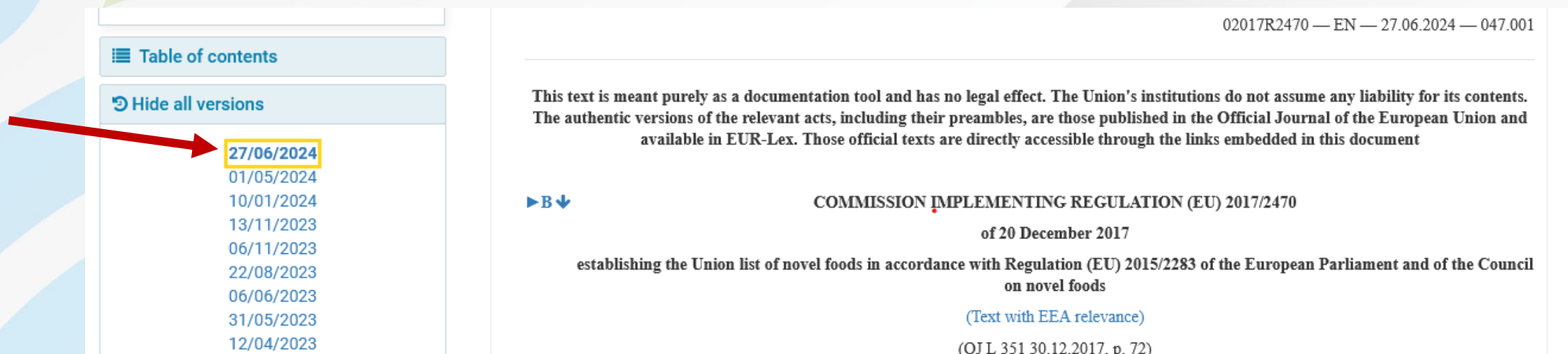


Funded by
the European Union

European Union list of Novel Foods

Commission implementing regulation (EU) 2017/2470 (establishing the Union list of novel foods)

- Positive list
 - List of all authorised novel foods
- Permission to be placed on the EU-market under the new regulation



The screenshot shows the official website for the European Union list of Novel Foods. On the left, a sidebar contains a 'Table of contents' link and a 'Hide all versions' button. Below these, a list of dates is displayed, with '27/06/2024' highlighted in yellow and indicated by a red arrow. The main content area features a disclaimer at the top, followed by the title 'COMMISSION IMPLEMENTING REGULATION (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods'. It also includes a note '(Text with EEA relevance)' and a reference to the Official Journal (OJ L 351 30.12.2017, p. 72).

How does a “novel food” get on this list?

Verification of food as Novel Food

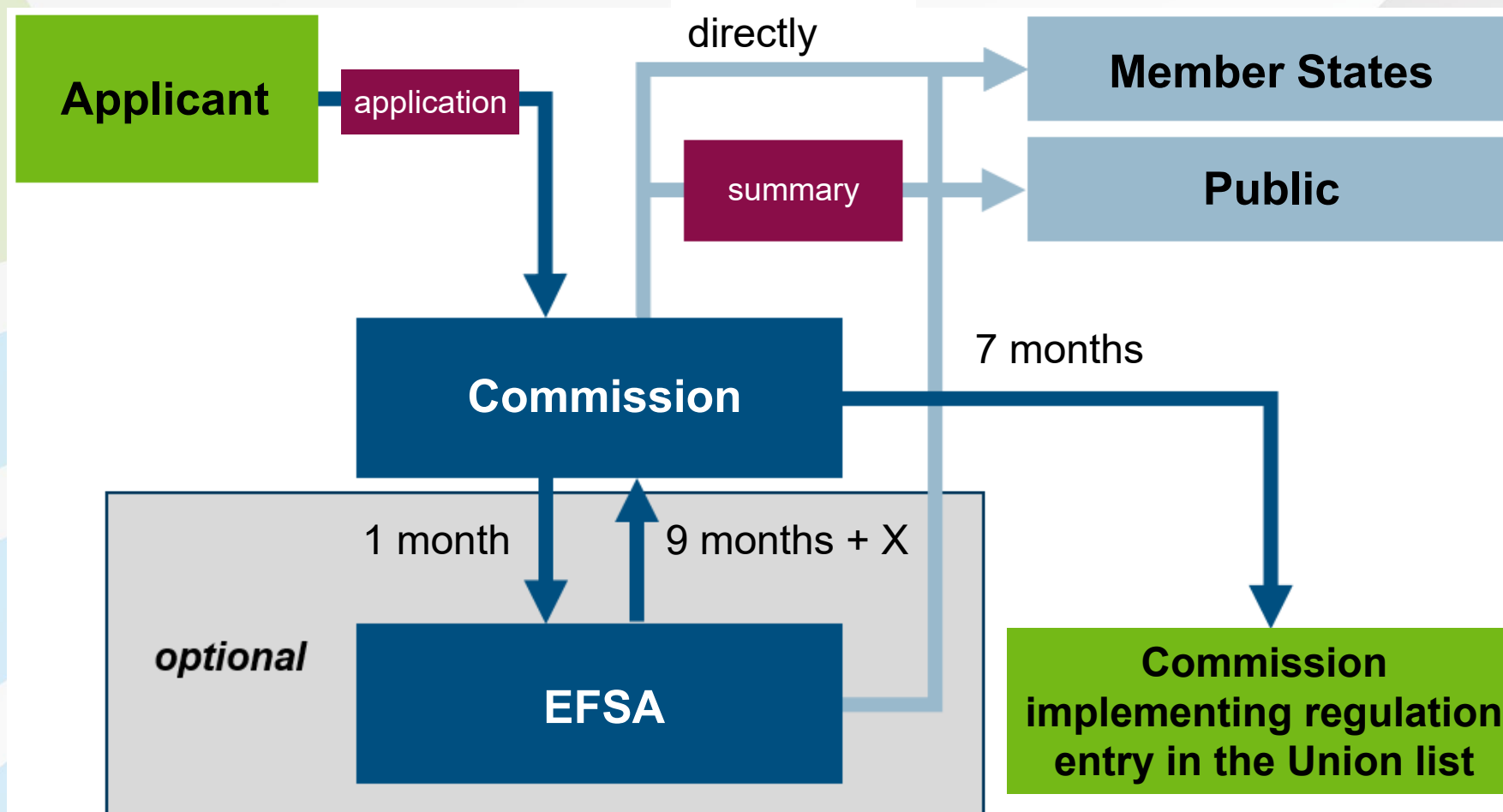
- ✓ Do the definitions in regulation (EU) 2015/2283 apply?
<https://eur-lex.europa.eu/eli/reg/2015/2283/oj>
- ✓ Is it already stated in the latest version of the Union list of novel foods
https://food.ec.europa.eu/safety/novel-food/authorisations/union-list-novel-foods_en
- ✓ Is it already in the novel food status catalogue of the European Commission (in progress / already assessed)?
<https://ec.europa.eu/food/food-feed-portal/screen/novel-food-catalogue/search>
- ✓ In case of further uncertainties:
Consultation of competent authority of the Member State
https://food.ec.europa.eu/document/download/288ca174-a585-47bf-bb9c-80fe4fc87247_en?filename=fs_novel-food_leg_list_comp_auth_reg_2018_en.pdf

Application procedure

-  Either on the commission's initiative or by application of a third party
-  **E-submission** in accordance with the new Novel Foods regulation to follow the different stages of the application
-  It is possible to request the authorisation to be valid only for the applicant for the first **5 years**.
Data protection is accepted if the scientific evidence/data is property of the applicant and the food cannot be assessed without it.
-  The EFSA prepared a guidance document and a checklist for the application:
 - <https://doi.org/10.2903/j.efsa.2021.6555>
 - <https://doi.org/10.2903/sp.efsa.2021.EN-6488>
 - And instruction videos are available on the EFSACHannel:
https://www.youtube.com/@EFSA_EU/featured

(Access: 21.08.2024)

Application procedure scheme



<https://doi.org/10.1016/j.foodres.2020.109515>
access: 07.08.2024



Authorisation occurs if...

... the applicant provides enough evidence that the food (ingredient) is:

- ✓ NOT presenting a danger or health concern to consumers
- ✓ NOT misleading consumers
- ✓ NOT giving a nutritional disadvantage for the consumer when it is intended to replace a traditional food (ingredient)

Evidence can be provided by existing scientific studies and literature evidence, or studies initiated or carried out by the applicant.

→ The application process is free of charge, but gathering sufficient information may incur costs.

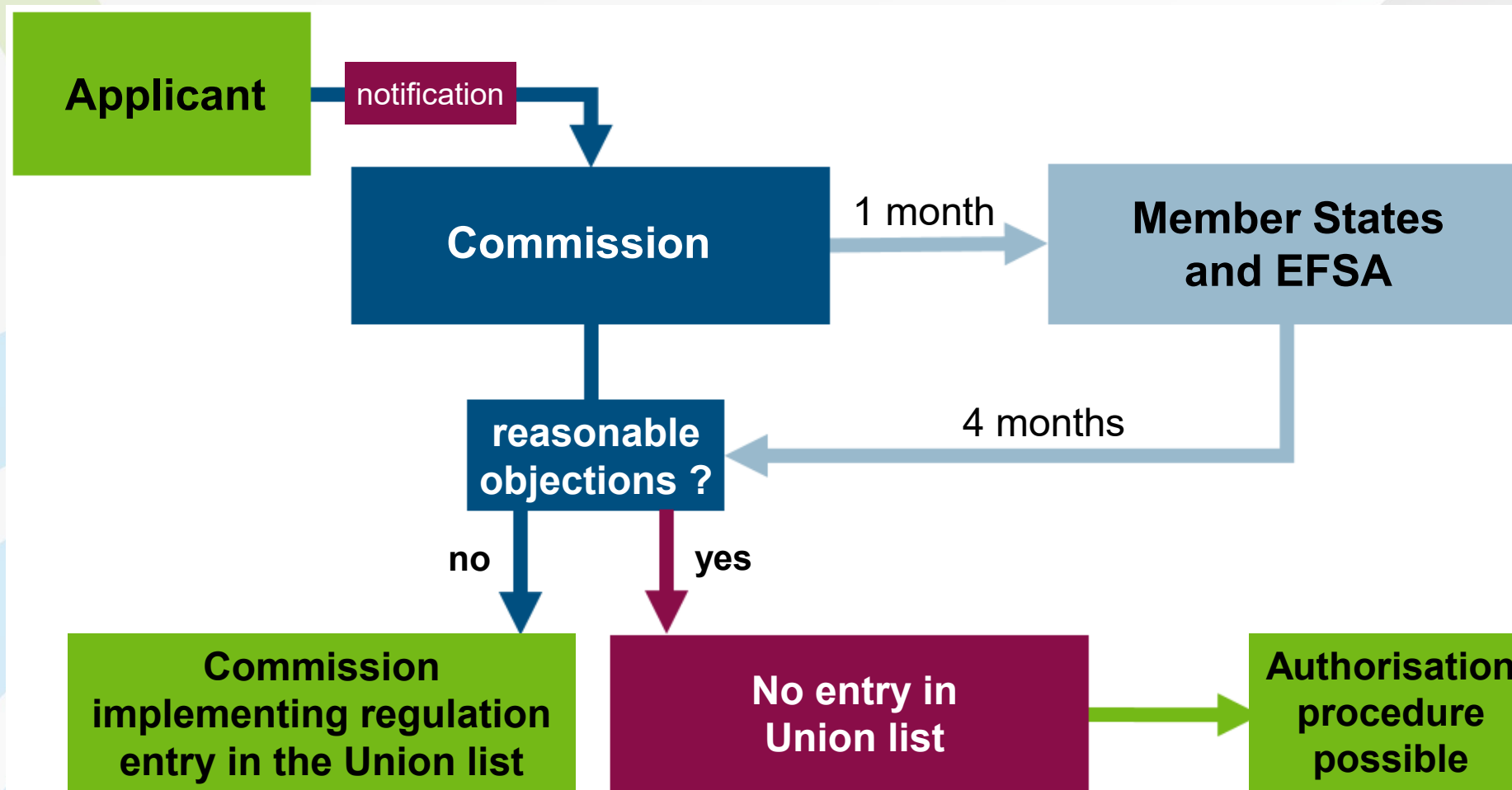
Notification of traditional food from third countries (1)

- Verification if traditional and safe use of the food is given.
- Documented data demonstrating the history of safe food use in a third country must be presented:

-  At least 25 years of safe use (safety must be confirmed by compositional data and from experience of continued use)
-  Applies to plants, animals, microorganisms, algae, fungi, and cell and tissue cultures
-  EFSA prepared a guidance document for the notification and authorisation of traditional food from third countries

<https://doi.org/10.2903/j.efsa.2021.6557> (access: 07.08.2024)

Notification of traditional food from third countries (2)



Literature

- Regulation (EU) 2015/2283 of the European Parliament and of the council of 25 November 2015 on novel foods, amending Regulation (EU) No 14169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001
- Ververis, E. (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. <https://doi.org/10.1016/j.foodres.2020.109515>
- BVL - Informationen des BVL zu neuartigen Lebensmitteln - Neuartige Lebensmittel – Novel Foods. (n.d.). https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/04_AntragstellerUnternehmen/05_NovelFood/Im_novelFood_basepage.html 19.08.2024
- Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) 2015/2283. (2021). EFSA Supporting Publications, 18(3).
- Nda, A. (2021). Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/22831 (Revision 1)2. EFSA Journal, 19(3).
- Turck, D. (2021). Guidance on the preparation and submission of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 (Revision 1)1. EFSA Journal, 19(3).
- AGES - Novel foods. (n.d.). AGES. <https://www.ages.at/en/human/nutrition-food/food-information/novel-foods?amp%3BcHash=9c2329300978445e627741437040c761&limit=all&cHash=04dd2a7522905fe3d5bd5ef50feed7f9> 19.08.2024
- Markou, G., Chentir, I., Tzovenis, I. (2021). Microalgae and cyanobacteria as food: Legislative and safety aspects. In Cultured Microalgae for the Food Industry (pp. 249-264). Academic Press. <https://doi.org/10.1016/B978-0-12-821080-2.00003-4>



Thank you very much for your attention!

Materials prepared by:
Lisa Meidl
LVA
lisa.meidl@lva.at