

1

Superfoods, food supplements, novel foods

Regulation (EU) 2015/2283



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**HEALTH, FOOD CHAIN SAFETY
AND ENVIRONMENT**



Superfoods?



Noni fruit or leaves



Chia seeds



Moringa oleifera



Hoodia parviflora



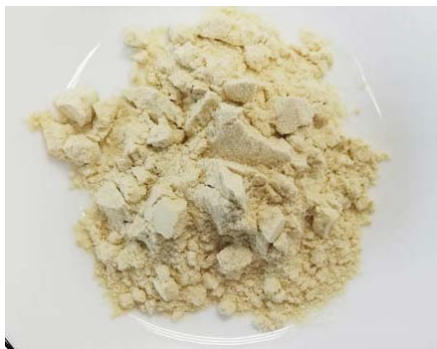
Baobab dried fruit pulp

“new” products?
Exotic!
Super?
Special properties?

Claim regulation
1924/2006 : non-specific
health claim



New/alternative protein sources



Mung bean protein
from *Vigna radiata*



Rapeseed Protein



Mealworm *Tenebrio molitor*




Chlamydomonas reinhardtii
dried biomass powder
(not authorised yet)



Dried mycelium
powder
of *Rhizopus oligosporus*





**What is
a novel food?**

When a food/ingredient is considered as novel?

1. No significant human consumption in the EU before 15th of May 1997

AND

2. Within one of the 10 described categories of EU 2015/2283

History of significant consumption in FOOD (including Food Supplements),
not as additive, flavouring, enzyme, GMO, solvent extraction (own regulations)
<-> Feed, biocides, cosmetics, medical devices, medicine (other legislations)



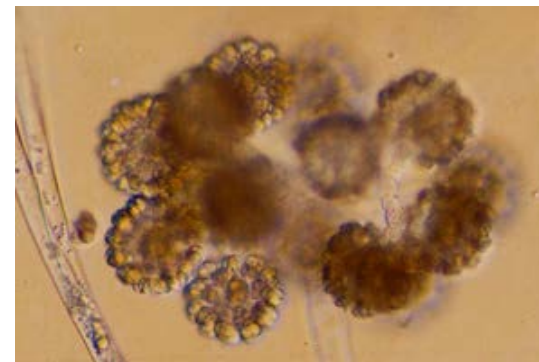
Which categories are potentially novel food?

Foods with a new or intentionally modified molecular structure



D-Tagatose

Foods consisting of or isolated or produced from microorganisms, fungi or algae



Micro-algae oil



Which categories are potentially novel food?

Foods consisting of, isolated from or produced from **plants** or their parts, (...)



Noni juice

Food consisting of, isolated from or produced from **animals** or their parts, (...)



Krill oil



insects



Which categories are potentially novel food?

Foods resulting from a **production process** not used before 1997

where that process gives rise to significant changes in the composition or structure of the foods which affect **their nutritional value, metabolism or level of undesirable substances**

Combination of process and product counts!



UV treatment producing vitamin D
DUV treatment producing vitamin D



Vitamin D mushroom powder (source of vitamin D...)



Which categories are potentially novel food?

- food consisting of, isolated from or produced from material of **mineral origin**
- food consisting of, isolated from or produced from **cell culture or tissue culture**_derived from animals, plants, micro-organisms, fungi or algae
- food consisting of **engineered nanomaterials**
- food **used exclusively in food supplements (NOT NFS)** within the Union before 15 May 1997, where it is **intended to be used in foods** other than food supplements



Which ingredients/foods are potentially novel?

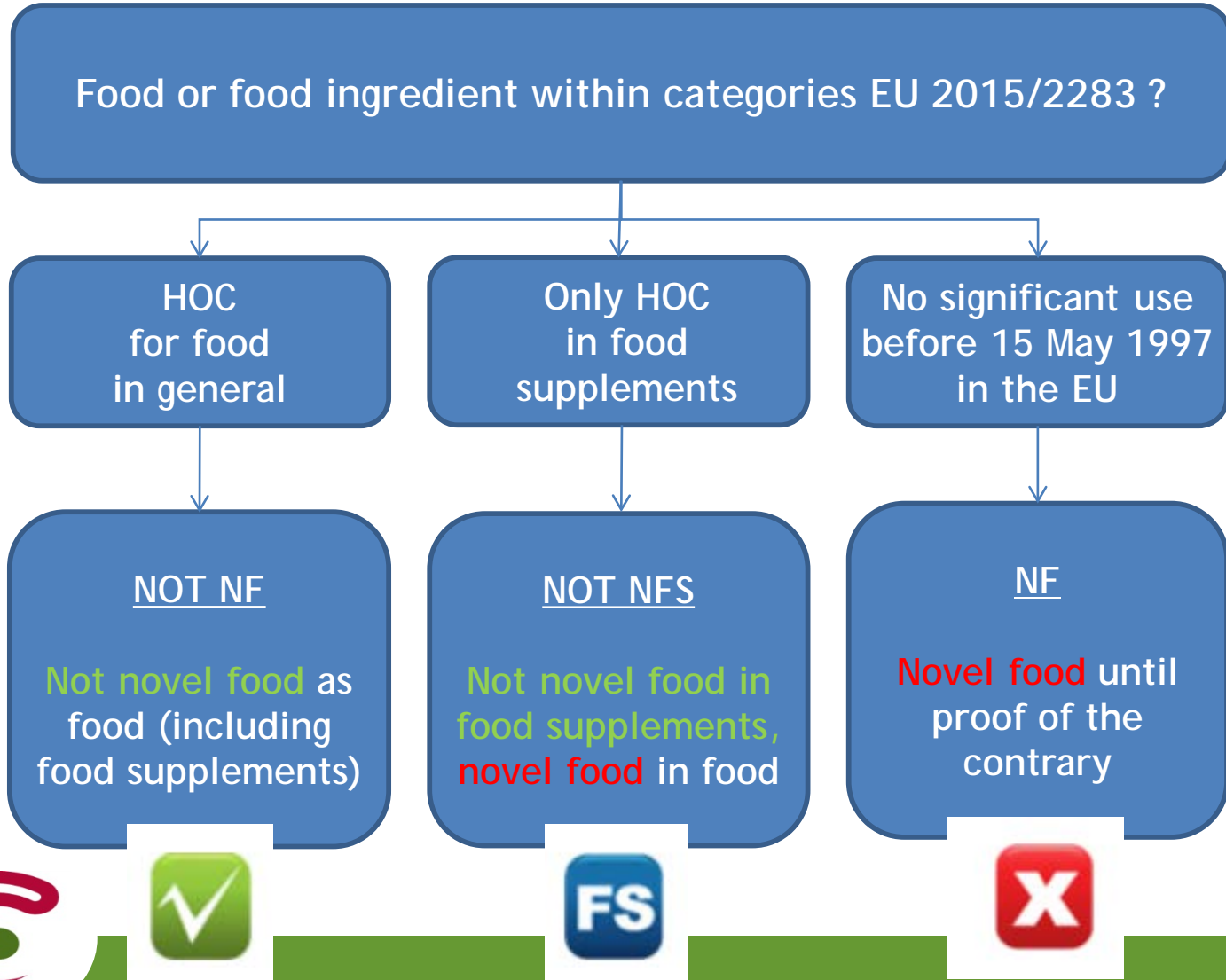
- No exhaustive database on what is *novel* or *not novel*

it is always the responsibility of the operator to prove the ingredient/food is not novel

- *Useful tool: catalogue of the European Commission*

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





EU Novel food catalogue

You can use the search engine or the alphabetical catalogue to see the list of products.

Product Name

Quick search



A B C D E F G H I J K L M N O P Q R S T U V W X Y Z ALL

Undaria pinnatifida

Undaria pinnatifida

Common Names

Wakame (DE), Japanese kelp (EN), undaria pierzastodzielna (PL), wakame (FI) (DK), hnědá řasa wakame (CZ), tengeri mustár, makróalga (HU), vrsta alge (SL), Alga Wakame (PT), lehtadru (liigid perekonnast Undaria) (ET)

Description

Brown Algae native to Japan, Korea and parts of China.


Novel Food Status



[What does it mean?](#)

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





**Authorisations
novel food**

Novel foods may only be placed on the market after their authorisation

Novel foods may only be authorized if:

- a) do not pose a **safety risk** to human health;
- b) the food's intended use does **not mislead the consumer**, especially when the food is intended to replace another food and there is a significant change in the nutritional value;
- c) where the food is **intended to replace another food**, it should not be **nutritionally disadvantageous** for the consumer.



Novel foods may only be placed on the market after their authorisation

- Centralised procedure at European level
- Risk assessment by EFSA
- Authorisation / rejection by Commission and EUMS
- Generic authorisations, or for one operator only if proprietary data
- Simplified procedure for traditional foods from third countries



Simplified procedure for traditional products from third countries

Coffee leaves infusion
 Sorghum syrup
 Hascap berries
 Cacao pulp and juice
 ...



Centralised procedure



Home Food ▾ Animals ▾ Plants ▾ Horizontal topics ▾

European Commission > Food Safety > Food > Novel Food > e-submission in accordance with the new Novel Foods regulation

e-submission in accordance with the new Novel Foods regulation

Applications must be submitted through the electronic submission system: [E-Submission Food Chain Platform](#)

The electronic submission system allows applicants to submit applications online. With this system applicants are able to follow-up their applications from the submission until the outcome.

Training and support on the E-submission Food Chain Platform is available on DG SANTE's [dedicated webpage](#) EN.

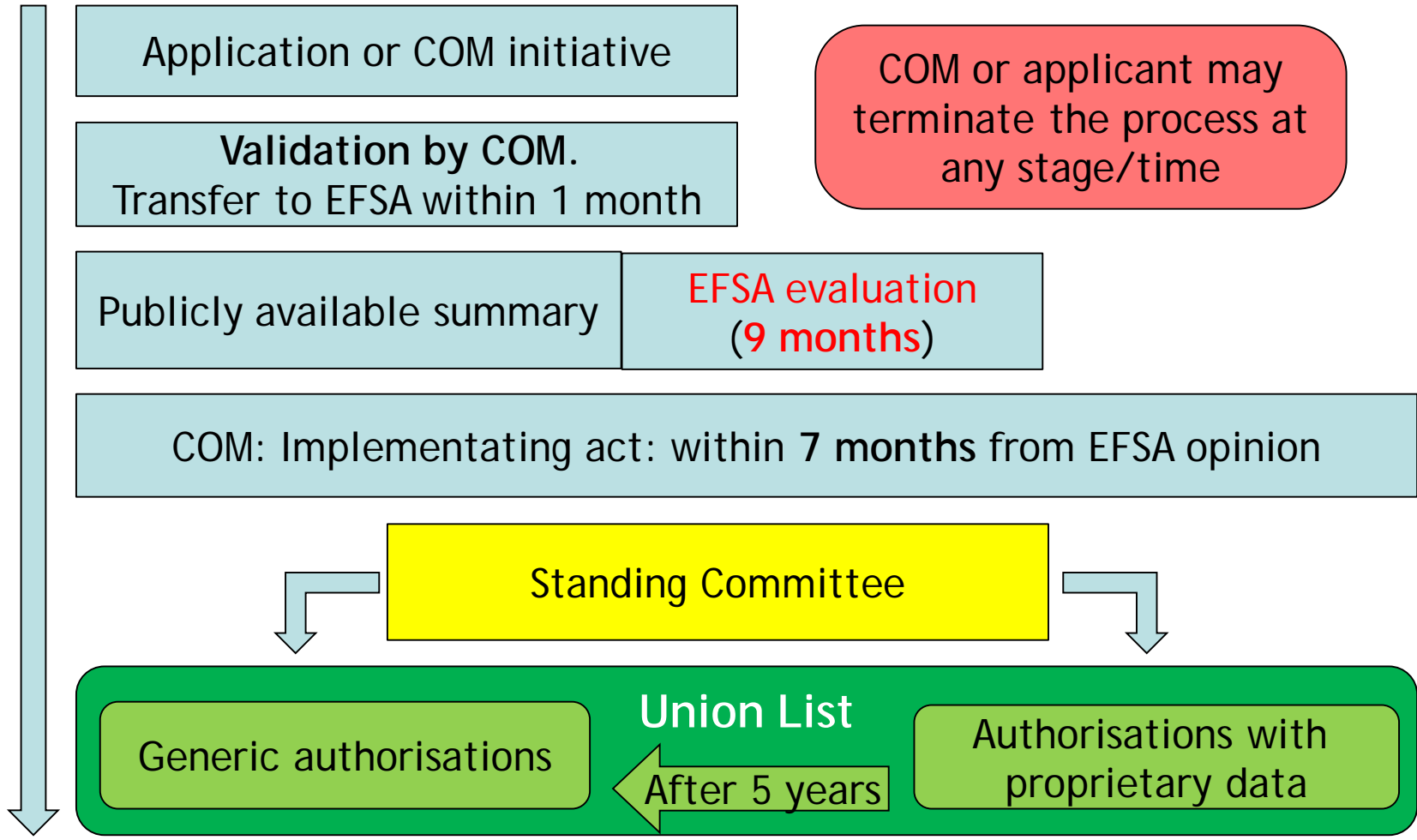
Applicants that have formally submitted dossiers under the former e-submission system before 26 March 2021, 18:00 CET will still be able to continue to follow up and be informed of the progress of the relevant processes.

[Go to the former e-submission system](#) and access the [e-submission user guide corresponding to the former e-submission system](#) EN.

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



Authorisation process and updating of Union List



GUIDANCE

doi:10.2903/j.efsa.2021.6555

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 Panel on Dietetic Products, Nutrition and Allergies (NDA),³
Dominique Turck, Jean-Louis Bresson, Barbara Burlingame, Tara Dean,
Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf,
Harry J McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka,
Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Daniel Tomé,
Marco Vinceti, Peter Willatts, Karl-Heinz Engel, Rosangela Marchelli, Annette Pöting,
Morten Poulsen, Seppo Salminen, Josef Schlatter, Davide Arcella, Wolfgang Gelbmann,
Agnès de Sesmaisons-Lecarré, Hans Verhagen and Hendrik van Loveren



Content of the application

- Description of the Novel Food
- Production process
- Compositional data - Stability
- Specifications
- History of use of the Novel Food and of its source
- Proposed uses and use levels and anticipated intake
- Absorption, distribution, metabolism, and excretion (ADME)
- Nutritional information
- Toxicological information
- Allergenicity

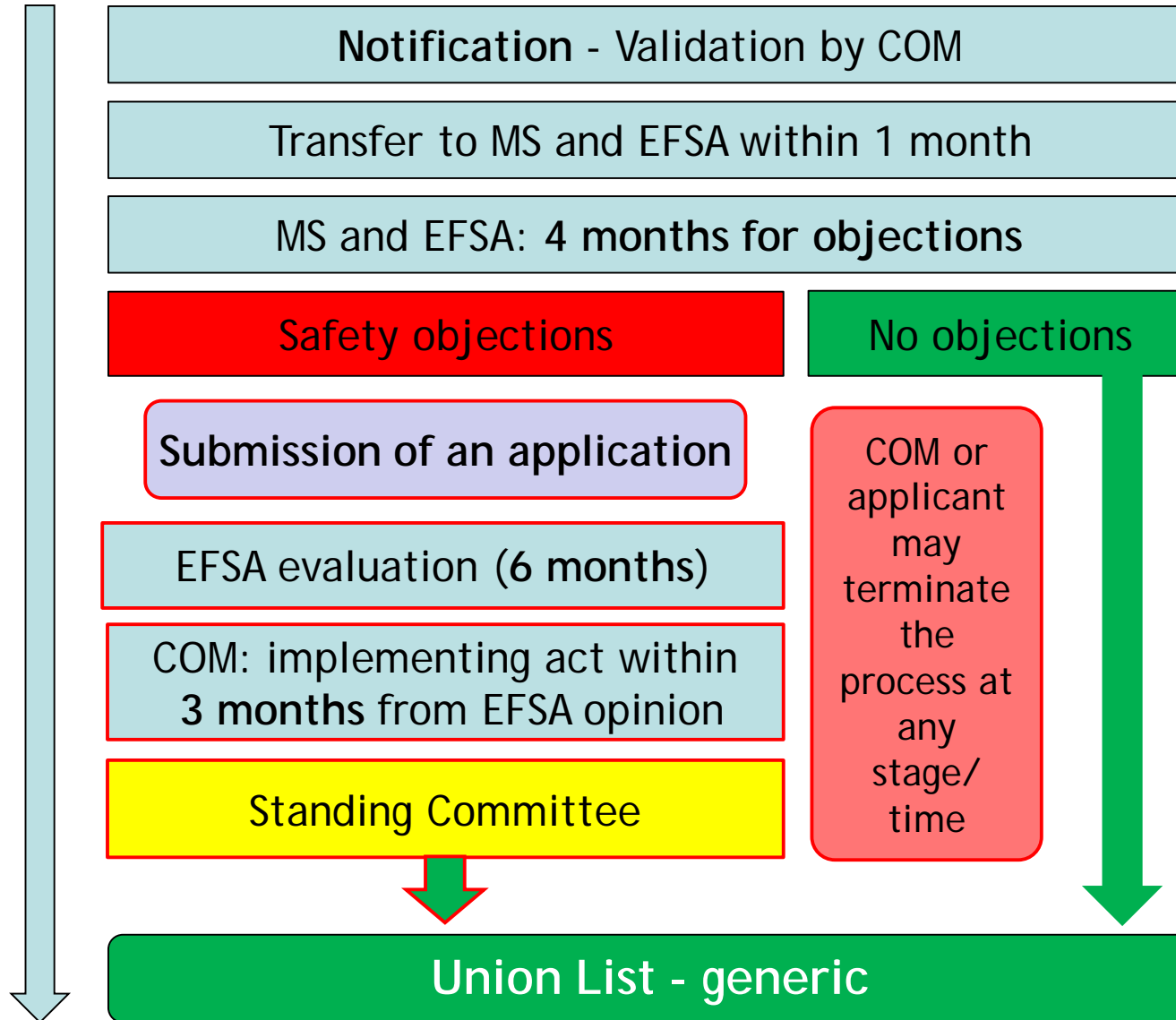


Traditional food from a third country

Criteria:

- Primary production: from plants, animals, micro-organisms, fungi or algae (processed or unprocessed)
- Safely used in the customary diet
- At least 25 years prior to the notification
- By significant number of people





Content of the notification

- Description of the Traditional Food
- Production process
- Compositional data - Stability
- Specifications
- Data from experience of use
 - Extent of use
 - Characteristics of the population group(s) of consumers
 - Role of the Traditional Food in the diet
 - Precautions for preparation and restrictions of use
 - Human data
- Proposed conditions of use in the EU market



Summary of applications and notifications

PAGE CONTENTS

[Summary of applications](#)

[List of the summaries of the applications:](#)

[Summary of notifications](#)

[List of the summaries of the notifications:](#)

Summary of applications

Summary of the applications submitted within the meaning of Article 10(1) of Regulation (EU) 2015/2283

In accordance with the requirements laid down in the [Novel Food regulation](#) {EN | ...}, the European Commission will make the summary of the application publicly available based on the information concerning the name and address of the applicant, the name and description of the novel food and scientific evidence demonstrating that the novel food does not pose a safety risk to human health.

List of the summaries of the applications:

- [2'-Fucosyllactose \(2'FL\)](#) {EN | ...}
- [2'-Fucosyllactose](#) {EN | ...}*
- [2'-Fucosyllactose](#) {EN | ...}
- [2'-fucosyllactose](#) {EN | ...}*
- [2'-Fucosyllactose/Difucosyllactose](#) {EN | ...}*
- [3'-Sialyllactose sodium salt](#) {EN | ...}*
- [3'-sialyllactose sodium salt \(3'-SL\)](#) {EN | ...}*
- [3-fucosyllactose](#) {EN | ...}*
- [3-fucosyllactose](#) {EN | ...}*
- [3-Fucosyllactose](#) {EN | ...}*

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



Union list of novel foods

<https://ec.europa.eu/food/safety/novel-food/authorisations>

PAGE CONTENTS

About the Union list

Updates to the Union list of novel foods

Updates - 2018

Updates - 2019

Updates - 2020

Updates - 2021

Updates - 2022

About the Union list

The [Implementing Regulation](#) ^{EN} establishing the list of novel foods compiles all the authorised novel foods in the European Union to date. It includes their conditions of use, labelling requirements, and their specifications. All authorisations are generic and the Union list serves as a reference for economic operators who wish to place in the market an authorised novel food unless data protection is requested by the applicant. The Union list is updated by the Commission to add newly authorised novel foods.

Under the old Regulation (EC) No 258/97 on novel foods, 228 applications have been submitted to the EU countries pursuant to Article 4 and more than 400 notifications pursuant to Article 5 of that Regulation. As a result of this legal commitment, the initial Union list contains 125 entries.

- [Union list of authorised novel foods \(Commission Implementing Regulation \(EU\) 2017/2470\)](#) ^{EN}
- [Commission Implementing Regulation \(EU\) 2018/1023](#) ^{EN} of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods
- [Commission Implementing Regulation \(EU\) 2019/1272](#) ^{EN} of 29 July 2019 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods and Implementing Decision (EU) 2017/2078 authorising an extension of use of yeast beta-glucans as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council
- [Commission Implementing Regulation \(EU\) 2020/478](#) ^{EN} of 1 April 2020 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods
- [Commission Implementing Regulation \(EU\) 2020/1559](#) ^{EN} of 26 October 2020

Use latest consolidated version!



Table 1: Authorised novel foods

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Chia oil from <i>Salvia hispanica</i>	Specified food category	Maximum levels	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chia oil (<i>Salvia hispanica</i>)'	
	Fats and oils	10 %		
	Pure chia oil	2 g/day		
	Food Supplements as defined in Directive 2002/46/EC	2 g/day		


Table 2: Specifications

Authorised Novel Food	Specification
Chia oil from <i>Salvia hispanica</i>	<p>Description/Definition: Chia oil is produced from Chia (<i>Salvia hispanica</i> L.) seeds (99,9 % pure) by cold-pressing. No solvents are used and, once pressed, the oil is held in decantation tanks and a filtration process employed to remove impurities. It can also be produced by extraction with supercritical CO₂.</p> <p>Production process: Produced by cold pressing. No solvents are used and, once pressed, the oil is held in decantation tanks and a filtration process employed to remove impurities.</p> <p>Acidity expressed as oleic acid: ≤ 2,0 % Peroxide value: ≤ 10 meq/kg Insoluble impurities: ≤ 0,05 % Alpha linolenic acid: ≥ 60 % Linoleic acid: 15-20 %</p>



**How to proof
a food
is not novel?**

Basic criteria: history of consumption (HOC)

- significant consumption → European guidelines
- consumption as a food
→ not as medicines, cosmetics or feed
- in the EU 
- prior to May 15th 1997

= date of entry into force of EC 258/97
Date remains unchanged in EU 2015/2283



Acceptable proofs of significant consumption

- Materials that can prove a human consumption of a significant degree in the EU prior to 15/5/1997:
 - Declarations or certificates of other EU member states (novel food status confirmation)
 - Sales invoices
 - Import documents
 - Price lists
 - FAO statistics
 - Literature
 - Labels with date
 - cookbooks
 - ...

on their own: not always enough
⇒ a combination of several documents
to prove a HOC



Elements to take into account

- Clear link between the documents and the food
- Invoices to companies with different activities: proof of consumption as food
Invoices to pharmacies: proof necessary that it is a food supplement, not a medicine
- HOC as medicine, feed, additive, flavoring or enzyme not relevant
- Literature: real consumption, **not just scientific studies on effects**



31

Elements to take into account

- Plant part is important!
- Extracts:
 - aqueous extracts: HOC of the plant/plant part
 - Other (selective) extracts (alcoholic, CO₂,...): HOC of the specific extract needed
- proof of notification in other EUMS
 - = not an authorisation! novel food status validated?





Interesting links

References and interesting links

Website European Commission

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

Website EFSA

<https://www.efsa.europa.eu/en/topics/topic/novel-food>



Questions?

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