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Novel Food legislation


Regulation (EU) 2015/2283



Isabelle LAQUIERE
Jean POTTIER
Regulatory expert

novelfood@health.fgov.be





**What is
a novel food?**

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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), but not as additive, flavouring, enzyme, GMO, solvent extraction (own regulations)

<-> Food, biocides, cosmetics, medical devices, medicine

(other legislations)



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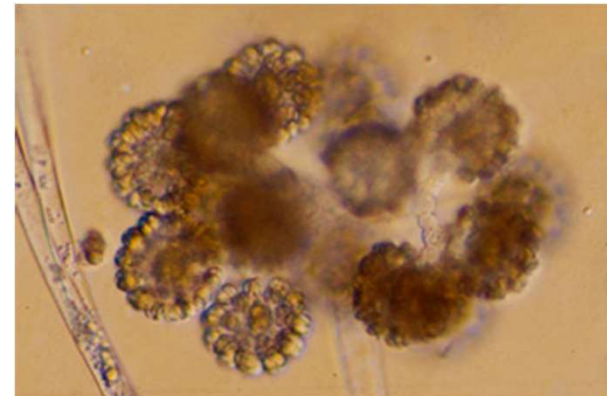
Which categories are potentially novel food?

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



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Which categories are potentially novel food?

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

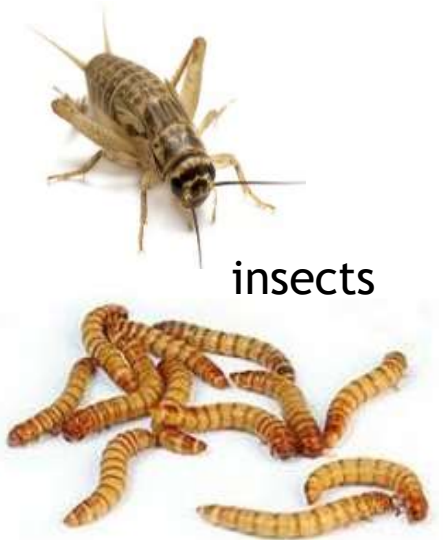


Noni juice

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



Krill oil



insects



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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**



UV treatment
producing
vitamin D



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What categories are potentially novel?

- 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** within the Union before 15 May 1997, where it is **intended to be used in foods**_other than food supplements



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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



Regulation (EU) 2015/2283

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?](#)



European
Commission

**Authorisations of
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.



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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



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

- Simplified procedure for traditional products from third countries in case of a safe history of consumption as food



Coffee leaves
infusion

Sorghum syrup

Cacao pulp and
juice

Hascap berries



Transitional measures

Foods covered by the definition of 2015/2283 which were not covered by Regulation 258/97:

→ may continue to be placed on the market until a decision is taken if:

- lawfully placed on the market by 1 January 2018 ; and
- an application/notification is submitted by 01/01/2019

-> applicable for certain insects!



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Novel foods can only be put on the market after their authorisation...



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Centralised procedure



European
Commission

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



.be

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



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'-Siallylactose 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



SCIENTIFIC OPINION

ADOPTED: 24 November 2020

doi: 10.2903/j.efsa.2021.6343

Safety of dried yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283

EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA),
Dominique Turck, Jacqueline Castenmiller, Stefaan De Henauw, Karen Ildico Hirsch-Ernst,
John Kearney, Alexandre Maciuk, Inge Mangelsdorf, Harry J McArdle, Androniki Naska,
Carmen Pelaez, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri, Marco Vinceti,
Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Rosangela Marchelli,
Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter,
Henk van Loveren, Ermolaos Ververis and Helle Katrine Knutsen

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	Data protection
Dried <i>Tenebrio molitor</i> larva (yellow mealworm)	<i>Specified food category</i>	<i>Maximum levels</i>	1. The designation of the novel food in the labelling of the foodstuff containing it shall be “Dried <i>Tenebrio molitor</i> larva (yellow mealworm)”		Authorised on 22 June 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: SAS EAP Group, 35 Boulevard du Libre Échange, 31650 Saint-Orens-de-Gameville, France.
	Dried <i>Tenebrio molitor</i> larva, whole or in powder		2. The labelling of the foodstuffs containing dried <i>Tenebrio molitor</i> larva (yellow mealworm) shall bear a statement that this ingredient may cause allergic reactions to consumers with		During the period of data protection, the novel food is authorised for placing on the market within the Union only by SAS EAP Group, unless a subsequent applicant obtains authorisation for that 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 SAS EAP Group.
	Protein products	10 g/100 g			
	Biscuits	10 g/100 g			
	Legumes-based dishes	10 g/100 g			
	Pasta-based products	10 g/100 g	products thereof, and to dust mites. This statement shall appear in close proximity to the list of ingredients.		End date of the data protection: 22 June 2026.’

- Entry name
- The conditions of use (food categories + maxima)
 - designation = legal name
 - Specific labelling requirements
- Warning regarding allergic reactions
- Data protection granted during 5 years (with deadline)

Belgian transitional measures (status April 2022) 4 insects benefiting from this:

- *Acheta domesticus* (house cricket)
- *Locusta migratoria* (African migratory grasshopper)
- *Tenebrio molitor* (yellow mealworm from yellow meal beetle)
- *Alphitobius diaperinus* (lesser mealworm)

*already authorised with data protection under specific conditions

~~*Grylloides sigillatus* (banded cricket): withdrawn~~



A graphic featuring a teal background with rounded corners. In the center is a large purple circle with a thick white border. The text "Interesting links" is written in a bold, black, sans-serif font across the middle of the purple circle.

Interesting links

<https://www.health.belgium.be/nl/voeding/voedselveiligheid/nieuwe-voedingsmiddelen/wat-een-nieuw-voedingsmiddel>



federale overheidsdienst

VOLKSGEZONDHEID, VEILIGHEID VAN DE VOEDSELKETEN EN LEEFMILIEU



E-DIENSTEN

PUBLICATIES EN ONDERZOEK

NIEUWS

AGENDA

OVER ONS

- ▶ Informatiebrochure Novel Food: [Reglementering en procedures](#)

Nuttige links en documenten

Informatienota's:

- ▶ [Vragen en antwoorden omtrent de toepassing van de wetgeving "Novel Food" met betrekking tot insecten bestemd voor menselijke consumptie](#) (versie april 2022); [English version](#)



References and interesting links

Website of the European Commission

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

Website EFSA

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



Questions?

Isabelle Laquiere
Jean Pottier

novelfood@health.fgov.be

Tel 02 524 73 64
73 62

