

Ministeriet for Fødevarer, Landbrug og Fiskeri Fødevarestyrelsen



Danmarks Erhvervsfremmebestyrelse



24 March 2022

# Theme day on novel food



# Novel food regulation

A consumer protection mechanism

March 2022 Maja Effersøe Khan, Hanne Boskov Hansen and Mette Fangel Juda

### **Disposition**

- ✓ What is novel food?
- ✓ How do you clarify whether a food is novel food?
- ✓ How will a novel food be approved?
- ✓ Special topics: seaweed, microbial cultures, insects, hemp
- ✓ Questions

## What is novel food?

Any food that was **not** used for human consumption to a significant degree within the Union **before 15 May 1997.** 

Genetically modified foods, food enzymes with a technological purpose, food additives, food flavourings and extraction solvents is regulated by other regulation.

The food should moreover fall within at least one of the 10 categories.

### **Novel food categories**

and examples of approved products

1. Food with a new modified molecular structure E.g. D-Tagatose = new sugar molecule

2. Food consisting of, isolated from or produced from microorganisms, fungi or algae; E.g. DHA- or EPA rich oil from the microalgae *Schizochytrium* sp. or microbial enzymes used with a nutritional purpose (in food supplements)

3. Food consisting of, isolated from or produced from material of mineral origin. E.g. Clinoptilolite/zeolite

4. Food consisting of, isolated from or produced from plants or their parts E.g. new plant specie, new parts of a plant, that have not been use as food before (e.g. roots, stems or leaves), or new extracts (alkohol-extracts) leading to an increased content of certain substances.

5. Food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices E.g. insects

6. Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae E.g. artificial meat

7. Food resulting from a production process, which gives rise to significant changes in the composition, affecting its nutritional value, metabolism or level of undesirable substances E.g. UV-treated mushrooms, milk or yeast with increased vitamin D content

8. Food consisting of engineered nanomaterials E.g. vitamins or minerals containing intentionally produced nanomaterials

9. Vitamins, minerals and other substances with a new production process E.g. synthetically produced substance that used to be produced from natural sources.

10. Food used exclusively in food supplements, where it is intended to be used in foods An ingredient can be not-novel in food supplement, but novel in ordinary foods Is an ingredient not-novel in ordinary foods is it also not-novel in food supplement

## How do you clarify whether a food is novel food?

EU-novel food catalogue is a living database containing the NF status of many but not all foods. The list is regularly updated by the EU Commission. It's not legally binding but the best list to use.

**DVFA plant liste** – guide to Danish, edible wild and a few cultivated plants

### Novel food catalogue

#### Food Safety

European Commission > Food, farming, fisheries > Food > Food Safety > Novel food > Novel food catalogue > Search

#### 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

L-alpha-glycerylphosphorylcholine	Lablab purpureus
L-citrulline malate	
L-fucose	Common Names
L-Theanine	Hydright been beneviet been lableb been Indian been Equation been (EN) Lableb (BC) Histophanne (DK, NO) Keelibeen (NL)
Lablab purpureus	Hyacinth bean, bonavist bean, lablab bean, Indian bean, Egyptian bean (EN), Lablab (BG), Hjelmbønne (DK, NO), Koeliboon (NL), Hyasinttipapu (FI), Dolique d'Egypte, dolique lab-lab (FR), Helmbohne, Lablabbohne (DE), Hjálmbaun (IS), Cucurbita lagenaria,
Lactarius deliciosus	zucca lagenaria (IT), Feijoeiro-bravo, feijão-cutelinho (PT), Fasolnik egipski (PL), Fríjol jacinto, fríjol dólico, judía de Egipto (ES),
Lactarius deterrimus	Hjälmböna (SE), Dolichos lablab, Dolichos purpureus
Lactarius rufus	Description
Lactarius torminosus	The information evaluates (Function NETTON Direct List) as many the seads (deviced from the wed) of ( other numerous
Lactarius trivialis	The information available (EuroFIR-NETTOX Plant List) concerns the seeds (derived from the pod) of Lablab purpureus.
Lactarius utilis	Lablab purpureus (syn. Dolichos lablab L., Dolichos purpureus L., L. niger Medikus, L. lablab (L.) Lyons, Vigna aristata Piper, and L.
Lactulose	vulgaris (L.) Savi), commonly known as the hyacinth bean, Indian bean or Egyptian bean, a species of bean in the family Fabaceae (Leguminosae, subfam. Papilionoideae), is widespread as a food crop throughout the tropics, especially in Africa, India and
Laminaria digitata	Indonesia. Sometimes the outer peel of the seed is taken out and the inner soft part is used for a variety of dishes.
Laminaria japonica	
Laminaria longicruris	Novel Food Status
Laminaria saccharina	What does it mean?
Langermannia gigantea	

https://ec.europa.eu/food/safety/novel\_food/catalogue\_en

### **Status - Novel food catalogue**

#### Statuses



This product was on the market as a food or food ingredient and consumed to a significant degree before 15 May 1997. Thus its access to the market is not subject to the Novel Food Regulation (EC) No. 258/97. However, other specific legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities.



According to information available to Member States competent authorities this product was used only as or in food supplements before 15 May 1997. Any other food uses of this product have to be authorised pursuant to the Novel Food Regulation.

There was a request whether this product requires authorisation under the Novel Food Regulation. According to the information available to Member States' competent authorities, this product was not used as a food or food ingredient before 15 May 1997. Therefore, before it may be placed on the market in the EU as a food or food ingredient a safety assessment under the Novel Food Regulation is required.



There was a request whether this product requires authorisation under the Novel Food Regulation. Further information is required.

# How do you clarify whether a food is novel food?

**EU-novel food catalogue** is a living database containing the NF status of many but not all foods. The list is regularly updated by the EU Commission. It's not legally binding but the best list to use

**DVFA plant liste – guide to Danish, edible wild and a few cultivated plants** 

#### **DVFA plant liste**

Her finder du en samlet oversigt over planter og plantedele på plantelisten til erhvervsmæssig brug .

Planterne og plantedelene på plantelisten er kategoriseret efter, om de er tilladt at markedsføre til fødevarebrug, om de kun tillades markedsført til fødevarebrug i små mængder, om de skal novel food godkendes inden markedsføring eller slet ikke tillades markedsført til fødevarebrug.

Nedenfor kan du læse mere om de fire kategorier. Du kan vælge, om du vil se hele plantelisten til erhvervsmæssig brug ved at folde alle kategorier ud, eller du kan folde den kategori ud, du er interesseret i at læse mere om.

v	<ul> <li>Tilladt til fødevarebrug</li> </ul>	$\oplus$
!	Tilladt i begrænsede mængder	$(\neq)$
!	Skal novel food godkendes inden markedsføring til fødevarebrug	$(\neq)$
x	Ikke tilladt udover dokumenteret risikofri dosering	(+)
Ηv	ad siger reglerne om markedsføring af vilde og nye dyrkede planter?	$(\neq)$
Sa	mlet oversigt over planteliste til erhvervsmæssig brug	$\oplus$

#### Example of plans that must be novel food approved before marketing

Plantenavn	Latinsk plantenavn	Plantedel
Bibernelle	Sanguisorba minor Scop.	Roden 🗹
Bøg	<i>Fagus sylvatica</i> L.	Blade 🗹
Douglasgran	<i>Pseudotsuga menziesii</i> (Mirb) Franco	<u>Nåle/skud</u>
Fuglegræs, almindelig	Stellaria media (L.) Vill.	Roden 🗹
Gederams	Epilobium angustifolium L.	Blomster 🖸
Guldnælde	<i>Lamium galeobdolon</i> (L.) Ehrend. & Polatschek	Overjordiske dele 🗹
Gul snerre	Galium verum L.	Blomster 🖸
Gyvel, almindelig	Cytisus scoparius (L.) Link	Blomster 🗹

# **Article 4:**

### **Procedure for determination of novel food status**

Consultation of Member States in case of doubt about Novel Food status.

Food business operators shall provide the necessary information to the Member State to enable it to determine whether it is novel or not.

Information to be submitted is described in Commission implementing regulation (EU) 2018/456

In Denmark the request should be submitted to the DVFA per e-mail to 29@fvst.dk.

The member state makes the decision on novel food status and informs the Commission and the other member states.

The result on the article 4 Procedure is published on the Commission webpage.

#### **Conclusions for article 4 procedure**

۲ ک

Food S	Safety			
Home	Food ~	Animals <b>~</b>	Plants 🗸	Horizontal topics ~

European Commission > Food Safety > Food > Novel Food > Consultation process on novel food status

#### **Consultation process on novel food status**

Name and description of the food concerned	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).	Novel when used as or in foods.	View document	Category 3(2)(a(ii))
Agaricus blazei dehydrated mycelium powder	Novel when used as or in foods.	View document	Category 3.2 (a)(ii)
	Novel when used as or	View document	

https://ec.europa.eu/food/safety/novel\_food/consultation-process\_en

### What kind of documentation can be used?

- Documentation from competent EU authorities about history of consumption
- Invoices showing sales as a food before 15 May 1997 (use as additive, flavouring, technological enzyme, cosmetics, medicine etc. do not count)
- Import documents
- Price lists/product catalogues
- Statistical information (e.g. from Danmarks Statistik or FAO)
- Literature showing use as an ingredient in food or food supplements
- Labels or packaging with production date before 15 May 1997
- Recipes or cook books mentioning the ingredient
- Other relevant documentation
- Must be documentation from within EU

# Two kinds of approval procedures

The ordinary approval procedure for novel foods

A simplified approval procedure, which apply to traditional foods from a third country

# Two kinds of approval procedures

The ordinary approval procedure for novel foods

A simplified approval procedure, which apply to traditional foods from a third country

#### Ordinary authorization procedure



The authorization process around 18 months (clock-stop can prolong the process significantly)

Submission of an application is free of charge. See **EFSA-guidance for applicants**.

The authorization is generally valid for all food operators. In case of data protection the authorization is restricted to the product from the specific applicant for 5 years. After that it becomes generic.

### **General conditions for novel food approval**

In order for a food to be novel food approved in the ordinary approval procedure, the following general criteria must be met:

- □ Must be safe
- □ Must not mislead the consumer
- □ Cannot be nutritionally disadvantageous compared to the food it is intended to replace

### **Documentation**

#### **Technical data:**

- Name and description of the food including technical and chemical specifications
- Description of the production process
- Information of former use or intake of the food
- Expected intake/degree of use
- Precaution and restrictions for use
- Nutritional data
- Toxicological data
- Conclusion on safety based on collected data

### Approval procedure with data protection

The applicant has exclusive rights to market the food for up til 5 years.

- □ Newly developed scientific data
- □ Applicant has the exclusive rights to refer to the scientific documentation or data, and
- □ The food could not be risk assessed and approved, if the applicant had not presented the scientific data

After 5 years, everyone can use the novel food authorization.

### **Transparency Regulation (EU) 2019/138**

Article 32b: Business operators shall notify EFSA of any study carried out to support an application

#### This to guarantee that companies submit all relevant information and do not hold back unfavorable studies

The Regulation aims at increasing the transparency of the EU risk assessment, and strengthening the reliability of the studies used by EFSA

> Transparency and sustainability of the EU risk assessment in the food chain (europa.eu)

Video: e-submission food chain platform: Introduction to the system

### **Confidential treatment**

- Confidential treatment of certain information in the application is possible if disclosure of such information may harm the applicants competitive position

- The necessity for confidentiality must be substantiated and verifiable justification shall be given.

- After the assessment by the EU Commission applicants may withdraw their application within three weeks

# Two kinds of approval procedures

The ordinary approval procedure for novel foods

A simplified approval procedure, which apply to traditional foods from a third country

# Simplified procedure for traditional foods from a third country

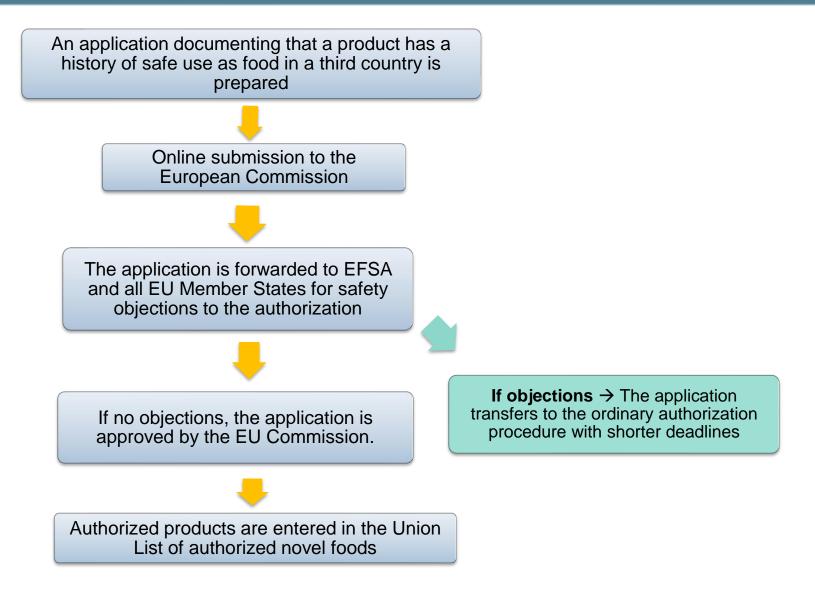
Food from primary production which have a history of safe food use in a third country.

Requirements:

"History of safe food use" outside the EU:

The food should have been consumed in **at least one third country** for at least **25 years** as a part of the **customary diet** of a **significant number** of people.

#### Authorization procedure for traditional foods from third countries



The authorization process takes around 6 months (but clock-stop can prolong the process significantly)

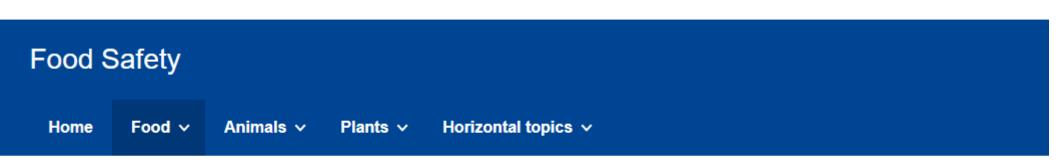
Submission of an application is free of charge. See EFSA-guidance for applicants.

The authorization is valid for all food operators

Data used for the traditional approval procedure cannot be data protected.







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

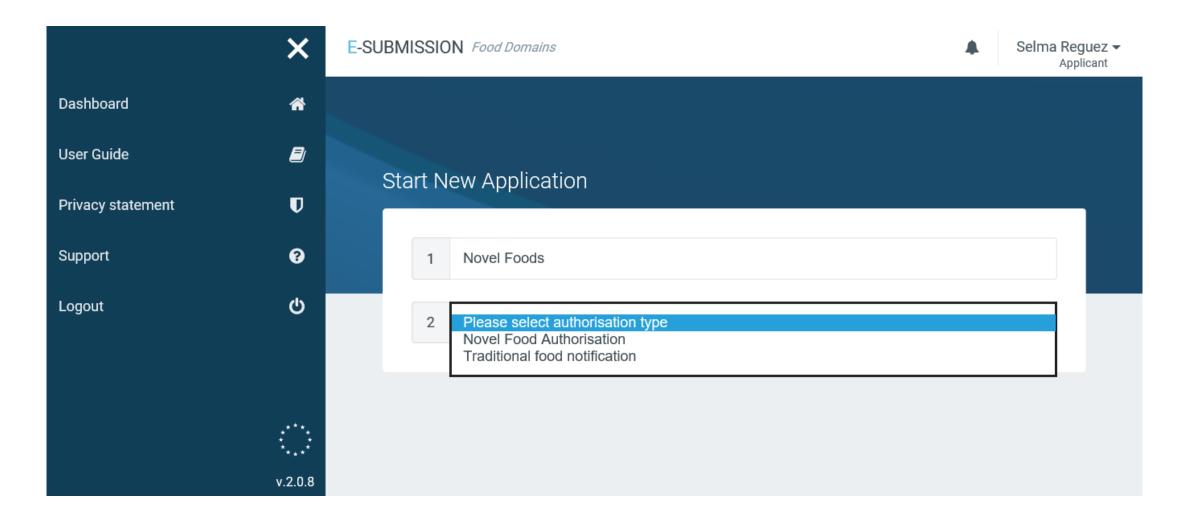
#### e-submission in accordance with the new Novel Foods regulation

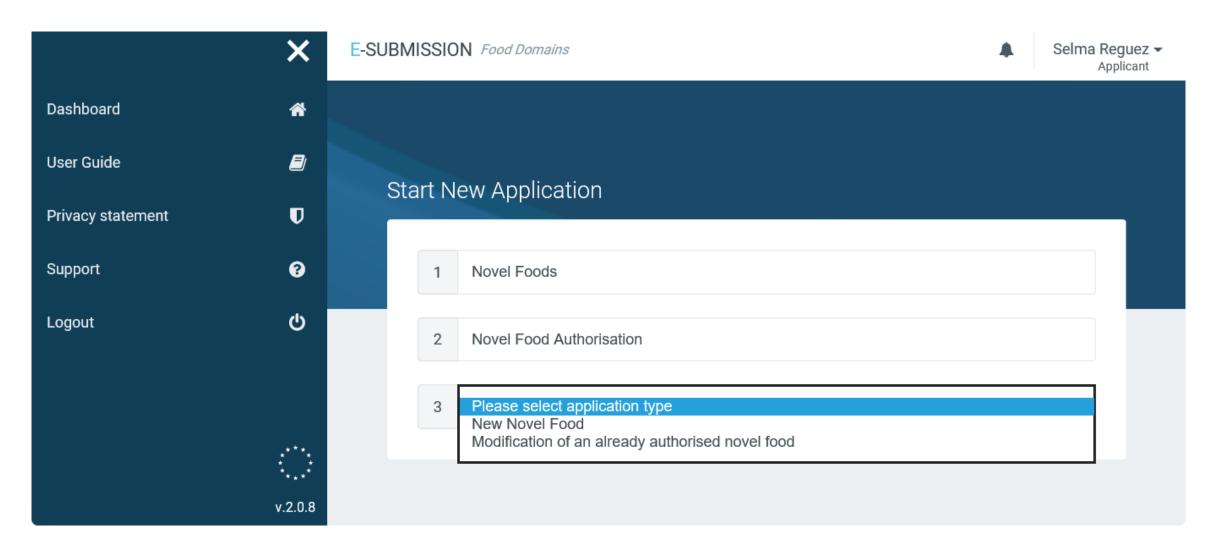
Applications must be submitted through the electronic submission system: <u>E-Submission Food</u> Chain Platform

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  $\langle EN | \bullet \bullet \bullet \rangle$ .

<sup>1</sup>/<sub>29</sub> https://ec.europa.eu/food/safety/novel\_food/e-submission\_en





<u>ش</u> 31

		A sein
		Cancel Submit
Administrative Data		Dossier saved at 12:47:28
1. Identity of the novel food to be author	sed	
Name *		
B I		
		0
Description *		
Enter identity description here		
Novel Food category *		
Please select Food Category type		-

#### **Administrative data**

5. Confidentiality

Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283

○ Yes ● No

#### 6. Data Protection

Where appropriate, state whether the application includes a request for the protection of proprietary data according to Article 26 of Regulation (EU) 2015/2283

○ Yes ● No

#### Administrative data

		Selma Reguez Applican
Conditions of uses		
Food Category *		
<sup>0</sup> All categories of foods excluding foods for infants and young children, except where specific	cally provided for	
1 Dairy products and analogues		
1.1 Unflavoured pasteurised and sterilised (including UHT) milk		
1.2 Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding s	sterilised buttermilk) r	on-heat-treated
1.3 Unflavoured fermented milk products, heat-treated after fermentation		
1.4 Flavoured fermented milk products including heat-treated products		
1.5 Dehydrated milk as defined by Directive 2001/114/EC		
1.6 Cream and cream powder		

#### **User Guide: E-Submission Food Chain platform (europa.eu)**

#### Summary of applications and notifications

#### PAGE CONTENTS Summary of applications Summary of applications Summary of the applications submitted within the meaning of Article List of the summaries of the 10(1) of Regulation (EU) 2015/2283 applications: Summary of notifications 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 List of the summaries of the concerning the name and address of the applicant, the name and description of the novel food and notifications: 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 INNING <u>2'-Fucosyllactose</u> {EN | ••• }\* 2'-Fucosyllactose (EN | \*\*\*) <u>2'-fucosyllactose</u> { EN | ••• }\* 2'-Fucosyllactose/Difucosyllactose EN I ···· \* <u>3'-Siallylactose sodium salt</u> {EN | ••• \* <u>3'-sialyllactose sodium salt (3'-SL) {EN | •••</u> 3-fucosyllactose { EN | •••• \* <u>3-fucosyllactose</u> {EN | •••• \* 3-Fucosyllactose (EN | ••••)\* <u>3'-sialyllactose sodium salt</u> (EN | ••• )\*

https://ec.europa.eu/food/safety/novel\_food/authorisations/summary-applications-and-notifications\_en

### **The Union list**

- Contains all the approved novel foods
- Updated when new novel food is approved
- Approvals are by default generic (if not data protected up to 5 years)

<u>EUR-Lex - 02017R2470-20220203 - EN - EUR-Lex</u> (europa.eu)

#### ►B

#### **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

	(Text w	Table 1: Authorised novel foods					
	(OJ L 35	Authorised novel food	novel food Conditions under which the novel food may be used Additional specific la		Additional specific labelling requirements	Other requirements	► <u>M29</u> Data Protection ◄
		v-Acetyl-D-neur- minic acid	Specified food category	Maximum levels	The designation of the novel food on the labelling of the foodstuffs		
			Infant and follow-on formulae as defined by Regulation (EU) No 609/2013 ( <sup>1</sup> )	0,05 g/L of reconstituted formula	containing it shall be 'N-acetyl-D- neuraminic acid' Food supplements containing N- acetyl-D-neuraminic acid shall bear a stratement that the food supplement		
			Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013	0,05 g/kg for solid foods	a statement that the food supplement should not be given to infants, young children and children under 10 years of age where they consume breast milk or other foods with added <i>N</i> -acetyl-D-neuraminic		
			Foods for special medical purposes for infants and young children as defined by	In accordance with the particular nutritional requirements of the	acid within the same twenty four hour period.		
Table 2: Specifications							
Authorised Novel Food			Specifications				
N-A Defi Che IUP N-A 5-A Syn Sial Che C <sub>11</sub> I	actiption: Acetyl-D-neuraminic acid is a white t finition: emical name: PAC names: Acetyl-D-neuraminic acid (dihydrate) acetamido-3,5-dideoxy-D-glycero-D-gr tonyms: lic acid (dihydrate) emical formula: H <sub>19</sub> NO <sub>9</sub> (acid) H <sub>23</sub> NO <sub>11</sub> (C <sub>11</sub> H <sub>19</sub> NO <sub>9</sub> * 2H <sub>2</sub> O) (dihy	alacto-non-2-ulopyrane					

<u>ن</u> 38 ع

### **Baobab fruit pulp**

Authorised novel food	Conditions under which the novel food may be used	Additional specific labelling requirements
Adansonia digitata (Baobab) dried fruit pulp	Not specified	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Baobab fruit pulp'

### **Baobab fruit pulp - specifications**

Adansonia digitata (Baobab) dried	Description/Definition:				
fruit pulp	The Baobab ( <i>Adansonia digitata</i> ) fruits are harvested from trees. The hard shells are cracked open and the pulp is separated from the seeds and the shell. This is milled, separated into coarse and fine lots (particle size 3 to 600 $\mu$ ) and then packaged.				
	Typical nutritional components:				
	Moisture (loss on drying) (g/100 g): 4,5-13,7				
	Protein (g/100 g): 1,8-9,3				
	Fat (g/100 g): 0-1,6				
	Total carbohydrate (g/100 g): 76,3-89,5				
	Total sugars (as glucose): 15,2-36,5				
	Sodium (mg/100 g): 0,1-25,2				
	Analytical specifications:				
	Foreign matter: Not more than 0,2 %				
	Moisture (loss on drying) (g/100 g): 4,5-13,7				
	Ash (g/100 g): 3,8-6,6				

### Alfalfa protein

Authorised novel food	Conditions under which the	he novel food may be used	Additional specific labelling requirements
Lucerne leaf extract from Medicago sativa	Specified food category	labelling of the foodstuffs containi	
	Food supplements as defined in Directive 2002/46/EC	10 g/day	shall be 'Lucerne (Medicago sativa) pro- tein' or 'Alfalfa (Medicago sativa) protein'.

### **Flavonoids from licorice root**

Authorised novel food	Conditions under which the nov	rel food may be used	Additional specific labelling requirements	Other requirements	► <u>M29</u> Data Protection ◄	
Flavonoids from Glycyrrhiza glabra	Specified food category	Maximum levels of flavonoids from Glycyrrhiza glabra	1. The designation of the novel food on the labelling of the foodstuffs	Beverages containing flavonoids shall		
	Beverages based on milk	120 mg/day	containing it shall be 'Flavonoids from <i>Glycyrrhiza glabra L</i> .'	be presented to the final		
	Beverages based on yoghurt		2. The labelling of the foods where the product was added as a novel	the product was added as a novel single	ded as a novel single portions.	
	Beverages based on fruit or vegetables food ingredient shall bear statement that:					
	Food Supplements as defined in Directive 2002/46/EC	120 mg/day	<ul> <li>(a) the product should not be consumed by pregnant and breast feeding women,</li> </ul>			
		children and young adoles-				
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	120 mg/day	<ul> <li>(b) people taking prescription drugs should only consume the product under medical supervision;</li> </ul>			
			(c) a maximum of 120 mg of flavonoids per day should be consumed.			
			<ol> <li>The amount of flavonoids in the final food shall be indicated on the labelling of the food containing it.</li> </ol>			

#### **Chia seeds**

---

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	► <u>M29</u> Data Protection ◄
H H H	Specified food category	Maximum levels	<ol> <li>The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chia seeds (Salvia hispanica)'</li> <li>Pre-packaged Chia (Salvia hisp- anica) seeds shall carry ad- ditional labelling to inform the consumer that the daily intake is no more than 15 g.</li> </ol>		
	Bread products	5 % (whole or ground chia seeds)			
	Baked products	10 % whole chia seeds			
	Breakfast cereals	10 % whole chia seeds			
	Fruit, nut and seed mixes	10 % whole chia seeds			
	Fruit juice and fruit/vegetable blend beverages	15 g/day for addition of whole, mashed or ground chia seeds			
	Pre-packaged Chia seed as such	15 g/day whole chia seeds			
	Fruit spreads	1 % whole chia seeds			
	Yoghurt	1,3 g whole chia seeds per 100 g of yoghurt or 4,3 g whole chia seeds per 330 g of yoghurt (portion)			
	Sterilised ready to eat meals based on cereal grains, pseudocereals grains and/or pulses	5 % whole chia seeds			

### **Microbial cultures**

Microbial cultures are not regulated separately in the EU and are therefore covered by the novel food regulation (if not a food additive)

In connection to the forthcoming update of Novel Food Catalogue microbial cultures will be included in the list

#### **Seaweed and algae**

The EU Commission **Joint Rearch Center** has mapped the use of seaweed and algae in the EU.

EU's novel food catalogue will be updated with the new information about the use of macroalgae (seaweed) in particular.



https://www.eumofa.eu/documents/20178/8 4590/Blue+bioeconomy\_Final.pdf

## Insects

Insects legally market in the EU before 1. of January 2018, could still be marketed until the company had submitted an application for this food, and it had been evaluated whether the product can be novel food approved.

An application for approval had to be submitted to the EU-commission before 1. of January 2019

### **Application insects**

The following insects which are under approvel in the EU, can be marketed as food in Denmark according to the transitional measures in the novel food regulation:

Yellow mealworm larvae (Tenebrio molitor)
Grashopper (Locusta migratoria)
Banded cricket (Gryllodes sigillatus)
House cricket (Acheta domesticus)
Buffalo worm larvae ( <i>Alphitobius diaperinus</i> )
Black soldier fly larvae (Hermetia Illucens)

Insects — farming and use as feed and food in Denmark and the EU — what's allowed and what is not?



https://www.foedevarestyrelsen.dk /Leksikon/Sider/Insekter.aspx

Content

# The European Commission has authorized the consumption of yellow mealworms in the EU



Carlos Galán Feced and Qayyah Moynihan, Business Insider España Updated May 6, 2021, 2:44 PM

(f) 🖾 (\*



### **Cannabidiol - CBD**

#### - CBD is novel food

- 130+ applications for approval is submitted. Of this 3 concern synthetic CBD
- CBD from *Cannabis sativa* is not covered by the rules on narcotics unless the product contains THC
- CBD is mostly categorized as medicinal products in Denmark.

#### Cannabinoids

#### Common Names

The hemp plant (*Cannabis sativa* L.) contains a number of cannabinoids and the most common ones are as follows: delta-9-tetrahydrocannabinol ( $\Delta$ 9-THC), its precursor in hemp, delta-9-tetrahydrocannabinolic acid A ( $\Delta$ 9-THCA-A), delta-9-tetrahydrocannabinolic acid B ( $\Delta$ 9-THCA-B), delta-8-tetrahydrocannabinol ( $\Delta$ 8-THC), cannabidiol (CBD), its precursor in hemp cannabidolic acid (CBDA), cannabigerol (CBG), cannabinol (CBN), cannabichromene (CBC), and delta-9-tetrahydrocannabivarin ( $\Delta$ 9-THCV). Without prejudice to the information provided in the novel food catalogue for the entry relating to *Cannabis sativa* L., extracts of *Cannabis sativa* L. and derived products containing cannabinoids are considered novel foods as a history of consumption has not been demonstrated. This applies to both the extracts themselves and any products to which they are added as an ingredient (such as hemp seed oil). This also applies to extracts of other plants containing cannabinoids. Synthetically obtained cannabinoids are considered as novel

Status



Question for e-submission and applications must be directed to EU Commission at <u>SANTE-FOODSYSTEMS@ec.europa.eu</u>

Question regarding novel food can be sent to: <a href="mailto:novelfood@fvst.dk">novelfood@fvst.dk</a>



Ministeriet for Fødevarer, Landbrug og Fiskeri Fødevarestyrelsen



Danmarks Erhvervsfremmebestyrelse



## Thank you! Questions?