



PARMA SUMMER SCHOOL 2023 INNOVATIVE FOOD PRODUCTS

The EU legislative framework on novel foods and food innovation

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The views expressed are purely those of the speakers and may not in any circumstances be regarded as stating an official position of the European Commission

Content of the presentation

1. The Novel Food Regulation
2. NF authorisation process (Art. 10)
3. TF authorisation process (Art. 14)
4. The Union list of novel foods
5. Interaction between the NFR and other EU regulations
6. The Novel Food Catalogue and Food Information Portal
7. Consultation under Article 4 of the NFR
8. Termination of the NF procedure
9. Novel Foods and Innovation



Regulation (EU) 2015/2283 of the European Parliament and of the Council

"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.**"



Regulation (EU) 2015/2283 (art.7)

Novel foods must:

- Be safe
- Not mislead the consumer, especially when the novel food is intended to replace another food
- Not be nutritionally disadvantageous where it is intended to replace another food



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Definition and categories

Definition: Food not used for human consumption to a significant degree before 15 May 1997 and that falls under at least one of the following categories:

10 categories in total

- (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*
- (vi) Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae*
- (viii) Food consisting of engineered nanomaterials*

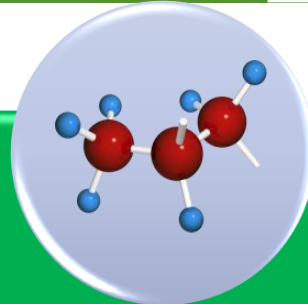
1. Novel Food Regulation



Novel Food categories



New production process



New or modified molecular structure



Micro-organisms, fungi, algae



From plants or their parts



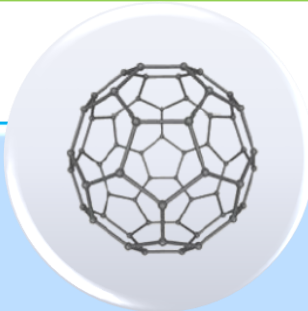
Of mineral origin



From animals or their parts



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



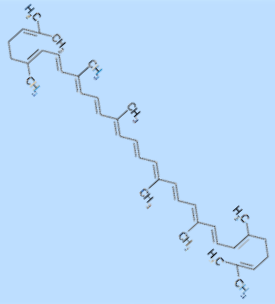
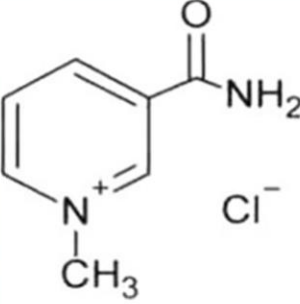
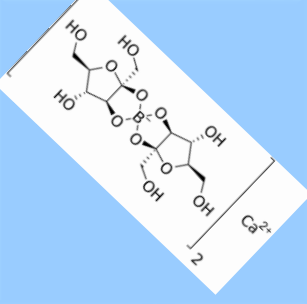
Engineered nanomaterials

1. Novel Food Regulation

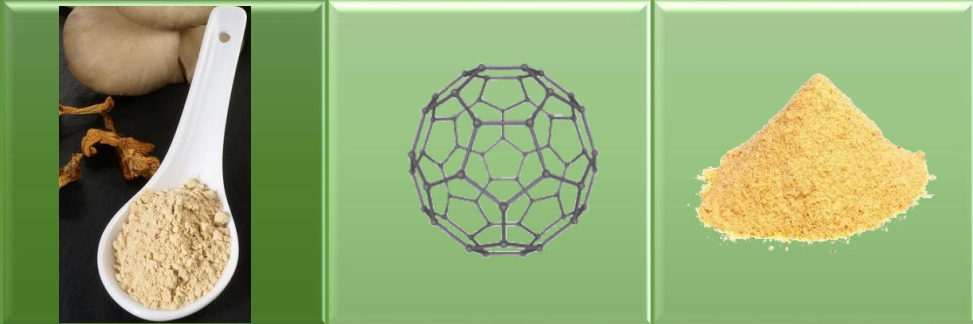


Examples of novel foods in FS

newly synthesized/
isolated compounds

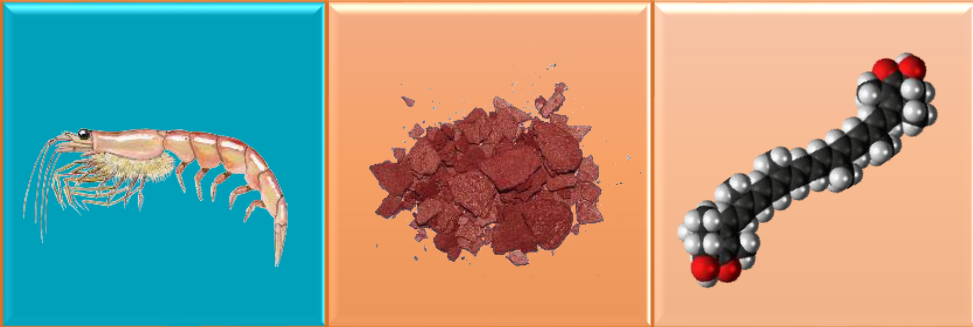
| | | |
|---|---|--|
|  |  |  |
| <p>Synthetic Lycopene</p> | <p>1-Methylnicotinamide chloride</p> | <p>Calcium fructoborate</p> |

new processes



| | | |
|-----------------------------------|--|--------------------------------|
| <p>Vitamin D2 mushroom powder</p> | <p>Iron hydroxide adipate tartrate</p> | <p>UV-treated bakers yeast</p> |
|-----------------------------------|--|--------------------------------|

new sources



| | | |
|--|--|---|
| <p>Antarctic Krill oil from <i>Euphausia superba</i></p> | <p>Lycopene from <i>B.trispora</i></p> | <p>Astaxanthin from <i>H. pluvialis</i></p> |
|--|--|---|



Novel Food applications (Article 10)

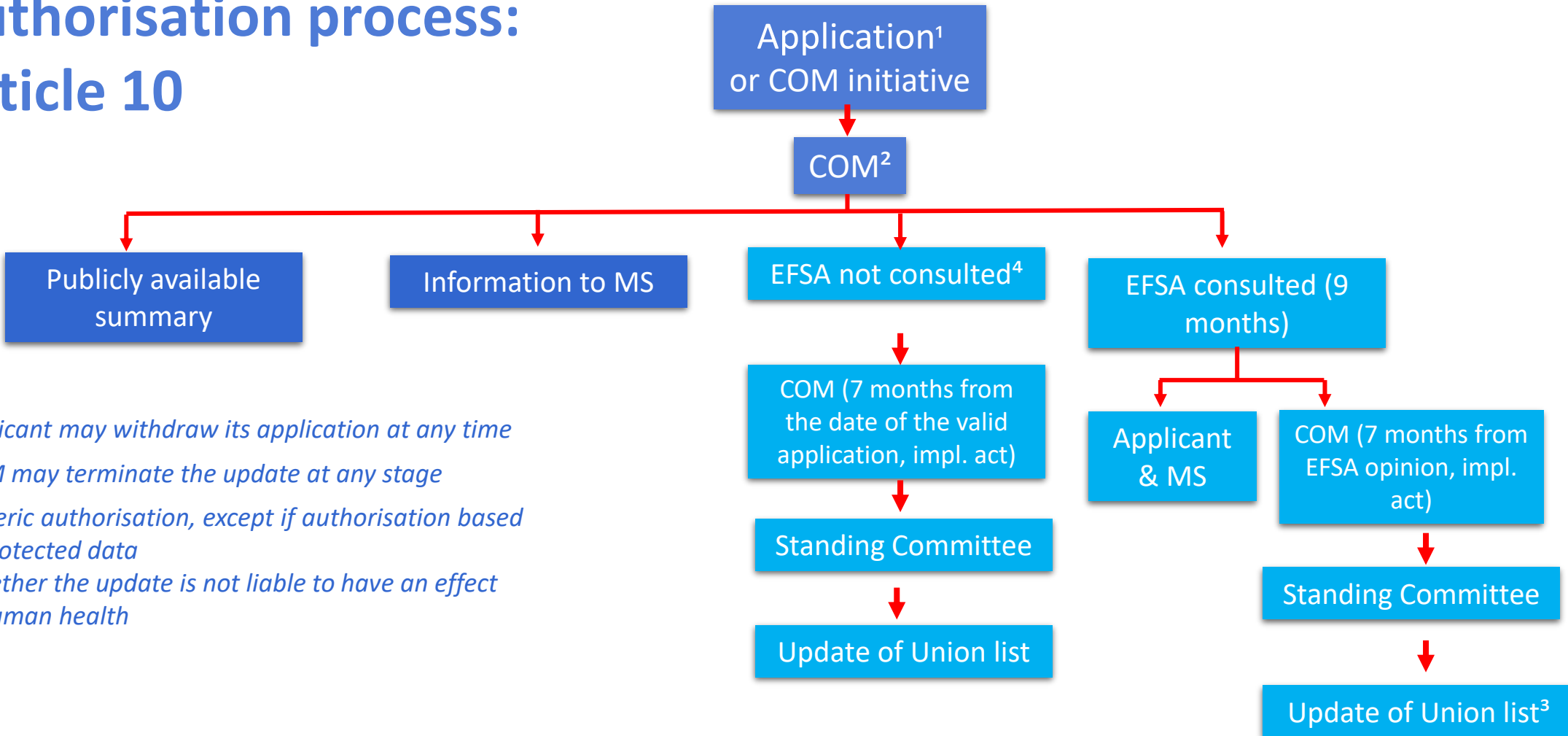
- Applicant - EU MS, non-EU MS or the interested party which may represent several interested parties
- Information to public – Summaries + Transparency Provisions
- Evaluation by the European Food Safety Authority
- COM and EFSA do not charge fees for managing applications
- Authorisation by the Commission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

2. NF authorisation process (Art 10)



European Commission

Authorisation process: Article 10



¹Applicant may withdraw its application at any time

²COM may terminate the update at any stage

³Generic authorisation, except if authorisation based on protected data

⁴Whether the update is not liable to have an effect on human health



EFSA Risk assessment of Novel Foods

- Identity of the novel food
- Production process
- Compositional data
- 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

EFSA Guidance:

<https://www.efsa.europa.eu/en/efsajournal/pub/6555>

Summary of applications and 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](#), 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.

The summaries are listed in chronological order.

Applications - 2018

- [Egg membrane](#) {EN | ...}* - Biova, LLC
- [Whole and ground Alphitobius diaperinus \(lesser mealworm\) larvae products](#) {EN | ...}* - ProtiFarm Holding NV
- [Acheta domesticus \(house cricket\)](#) {EN | ...} - Belgian Insect Industry Federation (BiiF)
- [Whey protein isolate obtained from cow's milk](#) {EN | ...} - Armor Protéines S.A.S
- [Zeaxanthin](#) {EN | ...} - DSM Nutritional Products Europe
- [Eurycoma longifolia \(Tongkat ali\) root extract](#) {EN | ...}* - Biotropics Malaysia Berhad

PAGE CONTENTS

Summary of applications

Applications - 2018

Applications - 2019

Applications - 2020

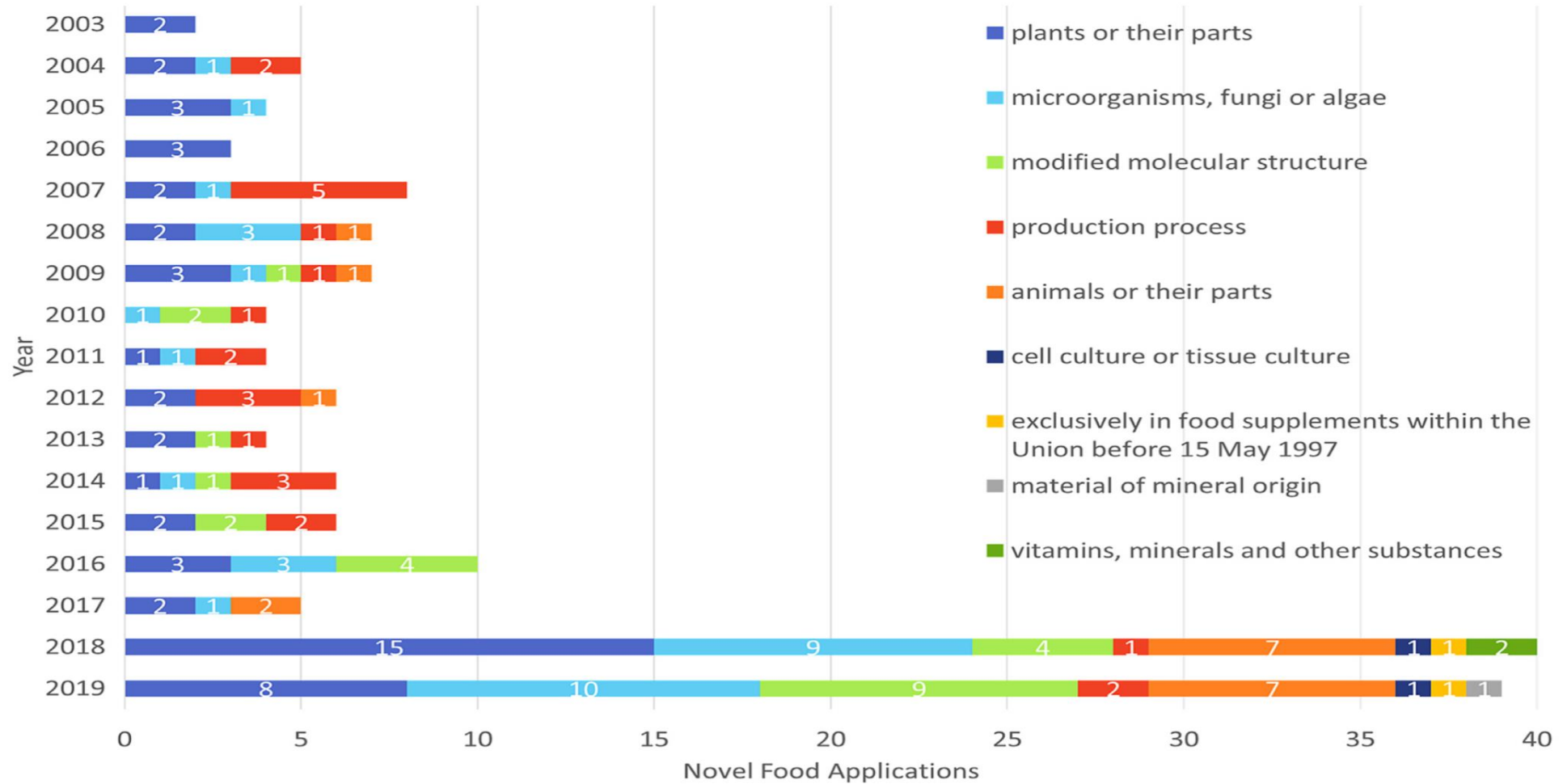
Applications - 2021

Applications - 2022



European Commission

Novel food applications by category





Traditional food from a third country

Traditional food from a third country is a food derived from primary production with a history of safe use in a third country.

➤ Traditional food can be

- ✓ *Produced from plants/animals/micro-organisms etc. (juice of the fruit of *Morinda citrifolia* L, decorticated grains of *Digitaria exilis*)*
- ✓ *From primary production (chia seeds, Haskap berries)*
- ✓ *Processed or unprocessed (baobab dried fruit, syrup from *Sorghum bicolor*)*




➤ Traditional food cannot be

- ✓ *New molecules; from mineral origin; from a new process; from engineered nanomaterial; already authorised vitamins; minerals for which a new process has been applied or contains engineered nanomaterials; food used only in food supplements*

3. TF authorisation process (Art 14)



traditional foods
from non-EU countries

| | | |
|--|---|---|
|  |  |  |
| Chia seeds | Baobab fruit | Noni Juice |



Traditional food from a third country

Authorisation

Based on history of safe food use in a third country

➤ *Fast and simplified*

- *Notification evaluated by MS and EFSA*
- *If no duly reasoned safety objections, the COM updates the Union list **without delay** and the product may be placed on the market*

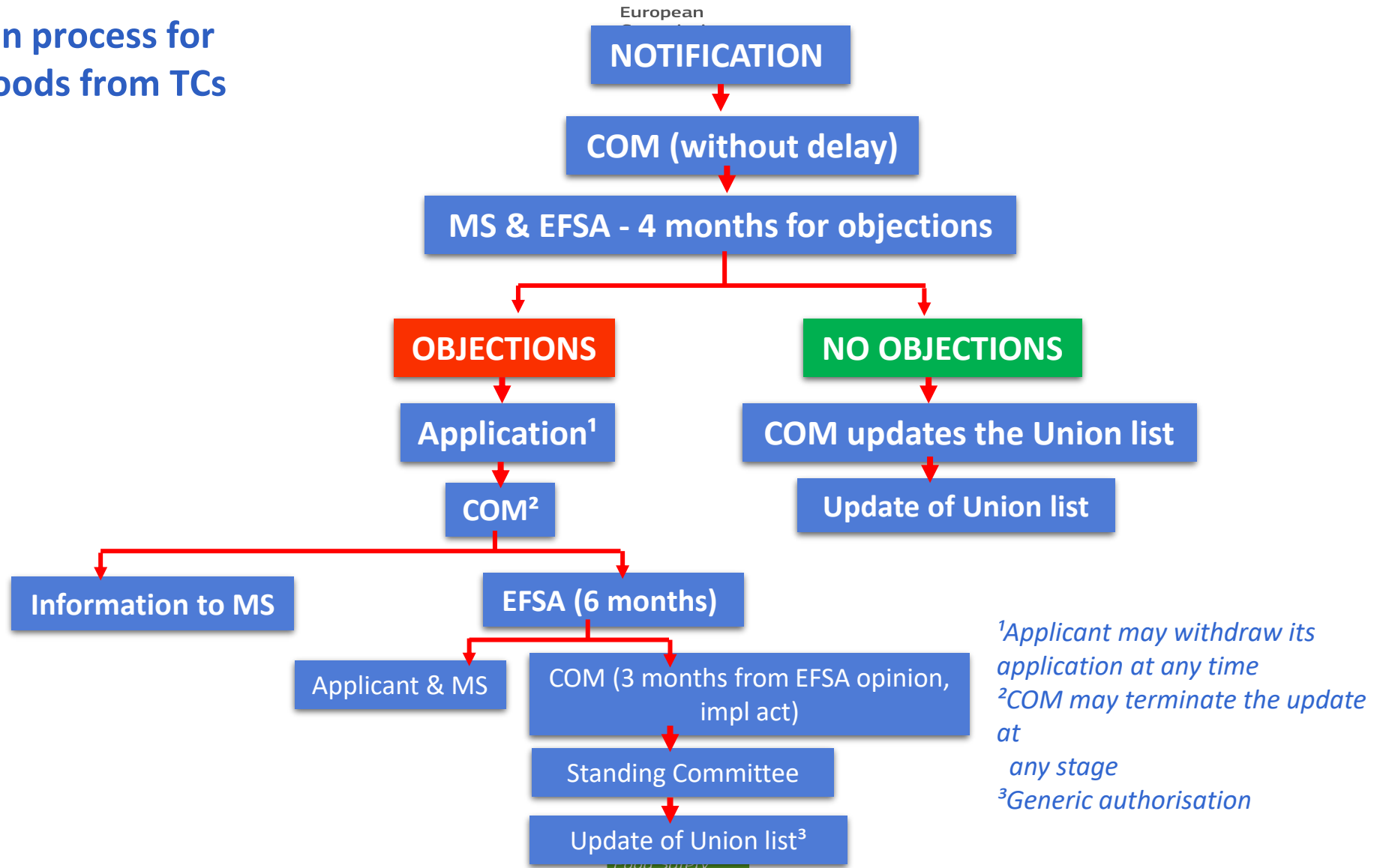
➤ *In case of duly reasoned safety objections*

- *the COM shall not authorise the TF and inform the applicant*
- *the notification may be turned into an application, evaluated by EFSA and authorised by COM*

3. TF authorisation process (Art 14)



Authorisation process for traditional foods from TCs



Summary of applications**Applications - 2018****Applications - 2019****Applications - 2020****Applications - 2021****Applications - 2022****Summary of notifications****Notifications - 2018****Notifications - 2019****Notifications - 2021****Notifications - 2022**

Summary of notifications

Summary of the notifications of traditional foods from non-EU countries submitted within the meaning of Article 14 of Regulation (EU) 2015/2283.

In line with the European Commission's transparency policy, a short summary of the notification from a non EU-country will be published. This summary will include the name and address of the applicant, the name and description of the traditional food and a brief description demonstrating the history of safe food use in the non-EU country.

The summaries are listed in chronological order.

Notifications - 2018

- [Digitaria exilis \(Fonio\)](#) {EN | ...} - Obà Food Srl
- [Berries of Lonicera caerulea L. \(Haskap\)](#) {EN | ...} - Soloberry Ltd
- [Sorghum Syrup](#) {EN | ...} - Sorghum Zrt.

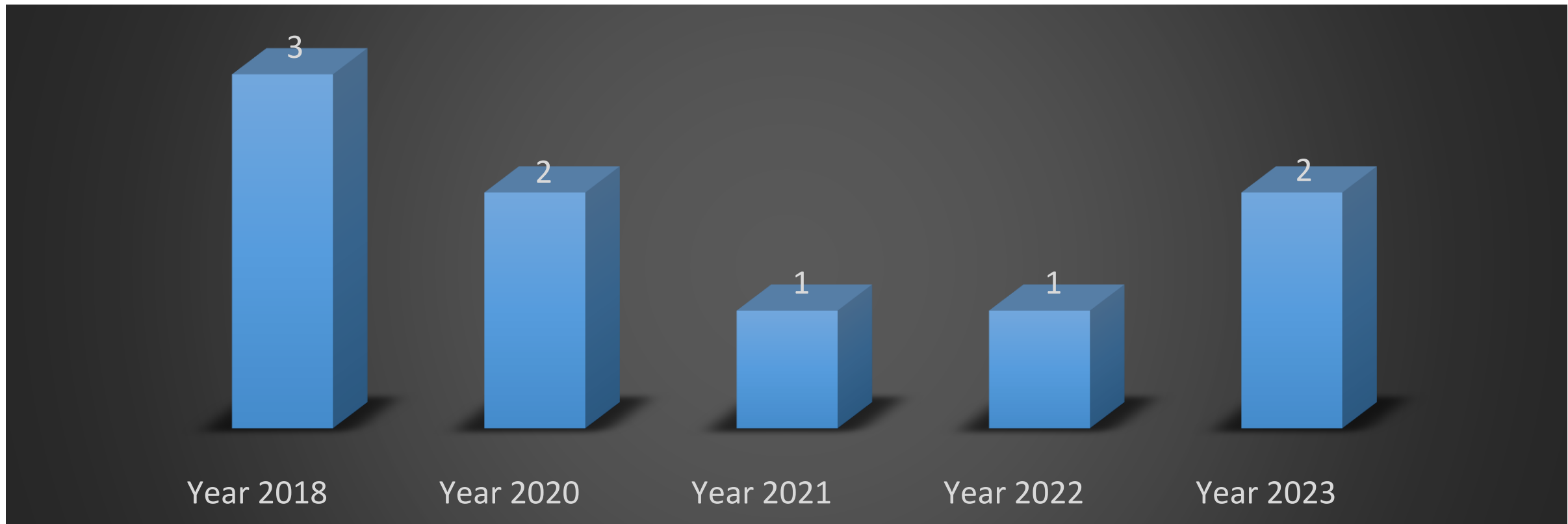
Notifications - 2019

- [Cacao fruit pulp](#) {EN | ...} - Cabosse Naturals NV
- [Cocoa pulp and products thereof](#) {EN | ...} - Nestec York Ltd.
- [Herbal infusion made from coffee leaves](#) {EN | ...} - AM Breweries
- [Powder of Maquiberry \(Aristotelia chilensis\)](#) {EN | ...} - South Am Freeze Dry S.A.
- [Leaf powder of Moringa stenopetala](#) {EN | ...} - Mrs Laura Manzano Outeiral
- [Roasted sacha inchi seeds](#) {EN | ...} - Promperu, Agroindustrias Osho SAC, Amazon Health Products SAC, Comercio Alternativo de Productos No Tradicionales y Desarrollo para Latino América Perú (Candela) and Shanantina SAC

3. TF authorisation process (Art 14)



Authorised Traditional Foods from Third countries in the EU per year



4-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 (notifications for traditional foods, novel food applications without EFSA opinion), assessment to be performed by the Commission – in accordance with the 'TR' and the NF regulation.

4-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
- Does not apply to traditional foods from third countries



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

4. The Union list of novel foods



Table 1

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 |
|------------------------|---|----------------|---|--------------------|--|
| | Specified food category | Maximum levels | | | |
| Calcium fructoborate | Food supplements as defined in Directive 2002/46/EC for the adult population, excluding food supplements for pregnant and lactating women | 220 mg/day | <ol style="list-style-type: none"> 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'calcium fructoborate'. 2. The labelling of food supplements containing calcium fructoborate shall bear a statement that those food supplements should not be consumed by population under 18 years of age and by pregnant and lactating women. | | <p>Authorised on 23 December 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: VDF FutureCeuticals, Inc., 300 West 6th Street Mokenca, Illinois 60954, the United States.</p> <p>During the period of data protection, the novel food calcium fructoborate is authorised for placing on the market within the Union only by VDF FutureCeuticals, 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 VDF FutureCeuticals, Inc.</p> <p>End date of the date protection: 23 December 2026'</p> |

4. The Union list of novel foods



Table 2

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

| 'Authorised Novel Food | Specifications |
|--------------------------------|---|
| Calcium fructoborate | <p><i>Description/Definition</i> The novel food is calcium fructoborate, a calcium salt tetrahydrate of a bis(fructose) ester of boric acid in the form of a powder, represented by $\text{Ca}[(\text{C}_6\text{H}_{10}\text{O}_6)_2\text{B}]_2 \cdot 4\text{H}_2\text{O}$, with a molecular mass of 846 Da. The novel food is produced by chemical synthesis whereby fructose is combined with boric acid in water to produce a bis(fructose) ester of boric acid through various heating and mixing processes. Calcium carbonate is then added to produce a solution containing the calcium salt of fructoborate (tetrahydrate). The solution is freeze-dried, ground to produce the final powdered product, and then packaged and stored under representative storage conditions ($22 \pm 1^\circ\text{C}$ RH 55-60 %).</p> <p><i>Characteristics/composition</i> Free moisture: < 5,0 % Calcium: 4,5-5 % Boron: 2,5-2,9 % Fructose: 80-85 % Ash: 15-16 %</p> <p><i>Heavy metals</i> Arsenic: $\leq 1 \text{ mg/kg}$</p> <p><i>Microbiological criteria</i> Total plate count: $\leq 1\,000 \text{ CFU/g}$ ^(a) Yeast and mould: < 100 CFU/g Coliforms: $\leq 10 \text{ CFU/g}$ <i>Escherichia coli</i>: < 10 CFU/g <i>Salmonella</i> spp.: Absence in 25 g Coagulase-positive staphylococci: Absence in 1 g</p> |
| (a) CFU: colony forming units' | |

4. The Union list of novel foods



Union list of novel foods

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.

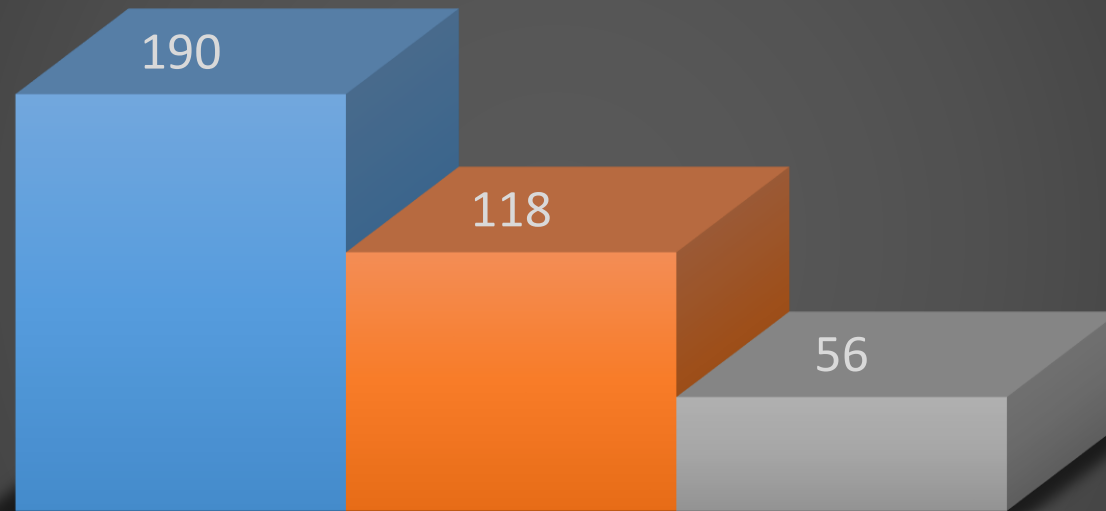
Under the old Regulation (EC) No 258/97 on novel foods, 228 applications have been submitted to the EU countries pursuant to Article 4 and more than 400 notifications pursuant to Article 5 of that Regulation. As a result of this legal commitment, the initial Union list contains 125 entries.

- [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 amending Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods

Updates to the Union list of novel foods *(To date, 108 times)*

- [Commission Implementing Regulation \(EU\) 2018/460](#) ^{EN|...} of 20 March 2018 authorising the placing on the market of *Ecklonia cava* phlorotannins as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470
- [Commission Implementing Regulation \(EU\) 2018/461](#) ^{EN|...} of 20 March 2018 authorising an extension of use of taxifolin-rich extract as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470
- [Commission Implementing Regulation \(EU\) 2018/462](#) ^{EN|...} of 20 March 2018 authorising an extension of use of L-ergothioneine as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470
- [Commission Implementing Regulation \(EU\) 2018/469](#) ^{EN|...} of 21 March 2018 authorising the placing on the market of an extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470
- [Commission Implementing Regulation \(EU\) 2018/991](#) ^{EN|...} of 12 July 2018 authorising the placing on the market of hen egg white lysozyme hydrolysate as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470
- [Commission Implementing Regulation \(EU\) 2018/1011](#) ^{EN|...} of 17 July 2018 authorising an extension of use levels of UV-treated mushrooms as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470

4. The Union list of novel foods



■ Total authorised NF ■ NF authorised in FS ■ NF only in FS

5. Interaction between the NFR and other EU regulations



The NF Regulation does not apply to:

- a) genetically modified foods falling within the scope of Regulation (EC) No 1829/2003;*
- b) foods when and in so far as they are used as:
 - (i) food enzymes falling within the scope of Regulation (EC) No 1332/2008;*
 - (ii) food additives falling within the scope of Regulation (EC) No 1333/2008;*
 - (iii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;*
 - (iv) extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive 2009/32/EC.**



Substances authorised under the FA regulation and the NF regulation

Lycopene

FA: E 160 d (colour)

3 sources (synthetic, from red tomatoes and from *Blakeslea trispora*)

NF: 4 entries authorised in 2006 and 2009 (synthetic, from tomatoes, from *Blakeslea trispora* and oleoresin from tomatoes). Used as a NFI and in FS

Lactitol

FA: E 966 (sweetener)

NF: Com Impl Dec 2017/450. To be used in FS

Health Claim: Com Impl Reg 2017/676: Lactitol contributes to normal bowel function by increasing stool frequency. The claim may be used only for FS which contain 10 g of lactitol in a single daily quantified portion.

Methyl cellulose

FA: E 461 (other than colours and sweeteners)

NF: Authorised by UK FSA in 2013 to be used as NFI. Same specs as a FA.

6. The Novel Food Catalogue



Food Safety

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[Plants](#) ▾

[Horizontal topics](#) ▾

[European Commission](#) > [Food Safety](#) > [Food](#) > [Novel food](#) > [Novel food catalogue](#)

Novel food catalogue

The **Novel Food Catalogue** lists products of animal and plant origin and other substances subject to the Novel Food Regulation, based on information provided by the EU Member States.

It is a non-exhaustive list and serves as orientation on whether a product will need an authorisation under the Novel Food Regulation. EU countries may restrict the marketing of a product through specific legislation. For information, businesses should address their national authorities.

In some cases, it shows information on the history of use of food supplements and ingredients used exclusively in food supplements in the EU countries. If foods and/or food ingredients were used exclusively in food supplements, new uses in other foods require authorisation under the Novel Food Regulation.

6. The Novel Food Catalogue



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 (EU) 2015/2283. 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.

Different status in the Current novel food catalogue



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.

6. The Novel Food Catalogue





Different status in the new novel food catalogue

 **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, Member States' competent authorities, this product belongs to one of the categories of Article (3)(2)(a) of the Novel Food Regulation (EU) 2015/2283 and 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 consequence before the EU market

 **Novel food not yet authorised** - According to the information available to Member States' competent authorities or the conclusion reached by "name of the Member State competent authority" in response to a request under Commission Implementing Regulation (EU) 2018/456 (https://ec.europa.eu/food/safety/novel_food/consultation-process_en), 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.

 **Subject to a consultation request** - This product is currently the subject of a consultation request to a Member State submitted pursuant to the requirements of [Implementing Regulation \(EU\) 2018/456](https://ec.europa.eu/food/safety/novel_food/consultation-process_en) on the procedural steps of the consultation process for determination of novel food status. The outcome of the request will be made publicly available on this website (https://ec.europa.eu/food/safety/novel_food/consultation-process_en).

6. The Novel Food Catalogue



EU Novel food catalogue

(Future layout)

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

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

| | |
|-------------------------|--|
| Abies alba | Abies alba What does it mean? |
| Abies balsamea | |
| Abies pectinata | |
| Acacia arabica | |
| Acacia nilotica | |
| Acacia rigidula | |
| Acacia senegal | |
| Acacia sp. | |
| Acacia verek | |
| Acanthopanax senticosus | |

| |
|---|
| Common Names |
| EN: European silver fir, Silver fir, Whitewood, NL: Gewone zilverspar, Grote spar, Zilverspar, FR: Sapin pectiné, Sapin blanc, Sapin argenté, FI: Saksanpihta, DE: Weiß-Tanne, Abies pectinata |
| Description |
| The extracts of the following parts (bark, branch, needle, seed and resin) of the plant are not considered novel in food supplement. Abies alba is a fir native to the mountains of Europe from the Pyrenees north to Normandy, east to the Alps and the Carpathians, and south to southern Italy and northern Serbia. |

6. The Novel Food Catalogue

Future layout for the entries



European
Commission

Novel Food Status Catalogue

Agaricus blazei

The entry only concerns the mushroom *Agaricus blazei* and the *Agaricus blazei* dehydrated mycelium (vegetative part) powder.

Synonyms: *Agaricus subrufescens*, *Agaricus brasiliensis* or *rufotegulis*

Common names: Hime-matsutake, Almaond Portobella, amandel paddestoel (NL), pieczarka brazylijska (PL), Murill gomba (HU), Mandelpilz (DE), vrsta kukmaka (SL), žampion mandlový (CZ), Brazīlijas atmatene (LV), Champignon art (SE)

Description for *Agaricus blazei* (mushroom)

Agaricus blazei is a mushroom originating from Brazil

Status

- **Mushroom**



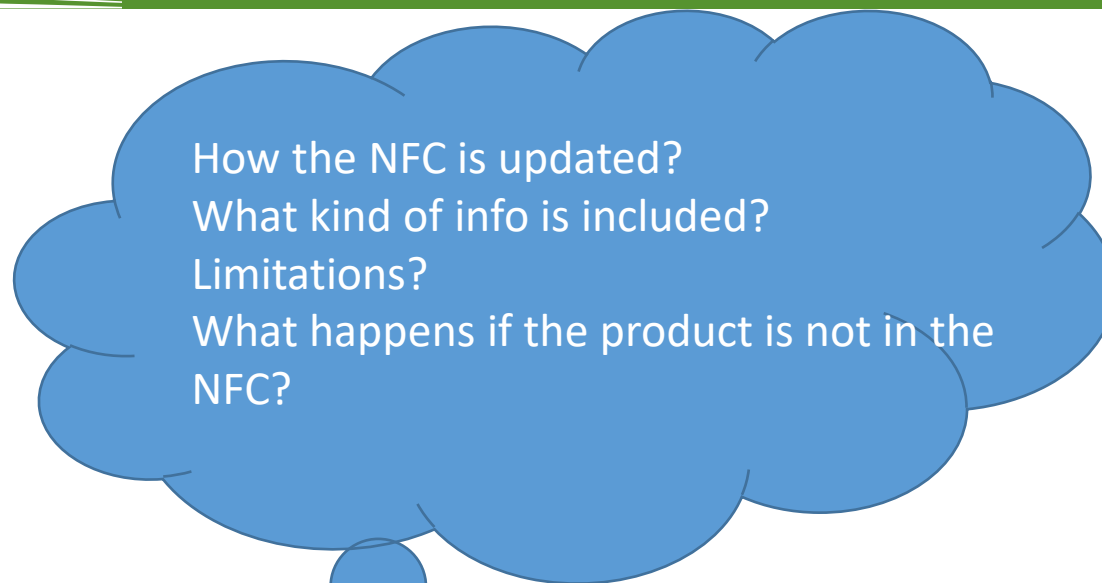
According to the information available to the Member States' competent authorities, this product was used for human consumption to a significant degree within the Union before 15 May 1997. Thus, it is not considered to be 'novel' according to the provisions of the Novel Food Regulation (EU) 2015/2283 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 [national competent authority\(ies\)](#) of the Member State(s).

- **Dehydrated mycelium powder**

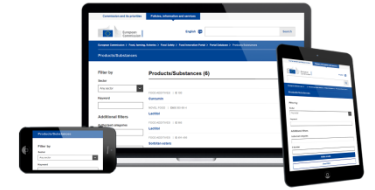


According to the conclusion reached by Spain in response to a request under Commission Implementing Regulation (EU) 2018/456 (https://ec.europa.eu/food/safety/novel_food/consultation-process_en), this product was not consumed in the EU to a significant degree as a food before 15 May 1997. Therefore, a pre-market authorisation in accordance with Regulation (EU) 2015/2283 is required before it can be placed as food on the EU market





Food Information Portal



SAVE TIME

Allow **stakeholders and public** to **save time**, as the portal will integrate and provide a single point of entry for the food sectors.

USE EXISTING FOOD DATA EFFICIENTLY

Make more **efficient** the use of Commission **resources** and **data**.

IMPROVE TRANSPARENCY

Published information to improve the visibility and the transparency on the food sector information for all the **stakeholders** and **general public**

Food and Feed Information Portal Database

European Commission > Food > Food and Feed Information Portal

Food Additives

This database is a searchable tool informing about the food additives approved for use in food in the EU and their conditions of use. It is based on the Union list of approved food additives laid down in Annex II to Regulation (EC) No 1333/2008.

- [Search for Additives](#)
- [Browse by categories](#)
- [European Legislation on Food Additives](#)
- [Information documents](#)
- [Disclaimer](#)

Food Flavouring

This database is a searchable tool informing about the flavouring substances approved for use in food in the EU and their conditions of use. It is based on the Union list of approved flavourings and source materials laid down in Annex I to Regulation (EC) No 1334/2008.

- [Search for food flavouring](#)
- [Browse by categories](#)
- [European Legislation on Food flavourings](#)
- [Information documents](#)
- [Disclaimer](#)

Health Claims

The search tool only allows searches for health claims, and not nutrition claims.

- [EU Register of Health Claims](#)
- [Some health claims subject to the individual authorisation procedure](#)
- [Download the complete dataset of nutrition and health claims in the following formats: Excel | PDF](#)

To be extended to

NOVEL FOODS

- [Search for Novel Foods](#)
- [Browse by categories](#)
- [European legislation on Novel Foods](#)
- [Novel Food Catalogue](#)



Determination of the NF status: Consultation

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.

[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



Consultation process on novel food status

To date, 86 NF status published

| 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 (<i>Lentinus edodes</i>). | 25 February 2019 | Novel when used as or in foods. | View document <small>EN ...</small> | Category 3(2) (a)(ii) |
| Agaricus blazei dehydrated mycelium powder | 29 October 2019 | Novel when used as or in foods. | View document <small>EN ...</small> | Category 3(2) (a)(ii) |
| Albizia julibrissin Durazz. - flowers | 8 August 2019 | Novel when used as or in foods. | View document <small>EN ...</small> | Category 3(2) (a)(iv) |
| Alcohol extract of kudzu (<i>Pueraria lobata</i> (Willd.) Ohwi) root. | 30 June 2020 | Novel when used as or in foods. | View document <small>EN ...</small> | Category 3(2) (a)(iv) |
| Apricot kernel drink and Fermented apricot kernel cream | 22 March 2021 | Not Novel | View document <small>EN ...</small> | |



Termination of the NF authorisation procedure

NFR: '**Valid**' in respect to an application or a notification means an application or a notification which falls within the scope of this Regulation and contains the information required for risk assessment and authorisation procedure.

If the application is not considered valid, the Commission shall indicate the reasons why it is not valid.

- ✓ Falls outside the scope of the NFR
- ✓ It does not fulfil the requirements set out in Article 10(2) of the NFR and Articles 3 to 5 of Implem Reg (EU) 2017/2469
- ✓ Studies that have not been previously notified (Art 32b of GFL)



Food innovation

- **Key driver to political priorities under the European Union Green Deal and Farm to Fork Strategy**
- **Food safety, security and 'sustainability' key elements**
- **Dietary shifts, healthy diets**
- **Environmental, social, ethical elements**



Challenges and expectations - 1

- **Food innovation can be seen as both**
 - **Creative** : shift to more sustainable, 'green' food production and consumption systems
 - **Disruptive** : may challenge some well embedded traditional, cultural and for some ethical codes
- **Carry high expectations and challenges for and from civil society, food businesses, and regulators**

Challenges and expectations - 2

- For **civil society**
 - Offer new taste experience, alternative foods
 - Address environmental/ecological/climate needs, ethical/moral/religious requirements, animal welfare, address specific dietary needs
 - May be seen as not natural, could be perceived as 'Frankenstein food'
 - Questioning the current paradigms of food production systems, established culture around food production
 - Must be proven to be safe, nutritious, wholesome and tasty (acceptance element)
 - Price versus 'established' foods
 - Taste and texture of 'established foods'
- For **food businesses**
 - A solid regulatory framework – As quick as possible entry to market
 - Technical and scientific challenges of scaling up and production
 - Data supporting safety and sustainability

Challenges and expectations - 3

- For **regulators**
 - The legal framework will deal with safety, which is a first essential step is there
 - Need very solid data on safety
 - Depending on the novelty and innovative nature of the products, close scrutiny on each and every element concerning safety and nutrition is to be expected
 - Address civil society and food business expectations so that innovative foods find their way to the EU market under win-win conditions for all



Regulation (EU) 2015/2283

- Conceived with a forward looking, anticipatory mode on upcoming food innovation
- Categories of novel foods: balance between the specific and the general to account for future developments
- Insects, alternative proteins, newly synthesised, innovative foods, and food supplements
- Fermentation products ('precision fermentation'), laboratory grown meat ('cultured meat') are/will be covered as long as they do not fall under the GMO Regulation (1829/2003)



European Commission, DG Health and Food Safety website
https://ec.europa.eu/food/safety/novel_food_en

Functional mailbox: SANTE-NOVELFOODS@ec.europa.eu