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Special Issue : *Novel Foods*

What is Novel Food in EU?

A novel food is defined as newly developed, innovative food, food produced using new technologies and production processes, or that has been traditionally eaten outside of the EU but has not been consumed to a significant degree in the EU before May 15, 1997.[1]

Categories of Novel Foods

- Food consisting of, isolated from or produced from
  - ✓ New or intentionally modified molecular structure
  - ✓ Microorganisms, fungi or algae
  - ✓ Material of mineral origin
  - ✓ Plants or their parts obtained by non-traditional propagating practices if significant changes in the composition or structure of the food affect its nutritional value, metabolism or level of undesirable substances.
  - ✓ Animals or their parts obtained by non-traditional breeding techniques
  - ✓ Cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae.
  - ✓ Engineered nanomaterials
- Food resulting from a new production process if significant changes in the composition or structure of the food affect its nutritional value, metabolism or level of undesirable substances.
- Vitamins and minerals obtained by a new food production process or containing engineered nanomaterials.
- Food used exclusively in food supplements within the EU before May 15, 1997, intended to be used in foods other than food supplements.
- Food from clones but not offspring also fall within the scope of Novel Foods.

Principles underpinning Novel Food in the European Union

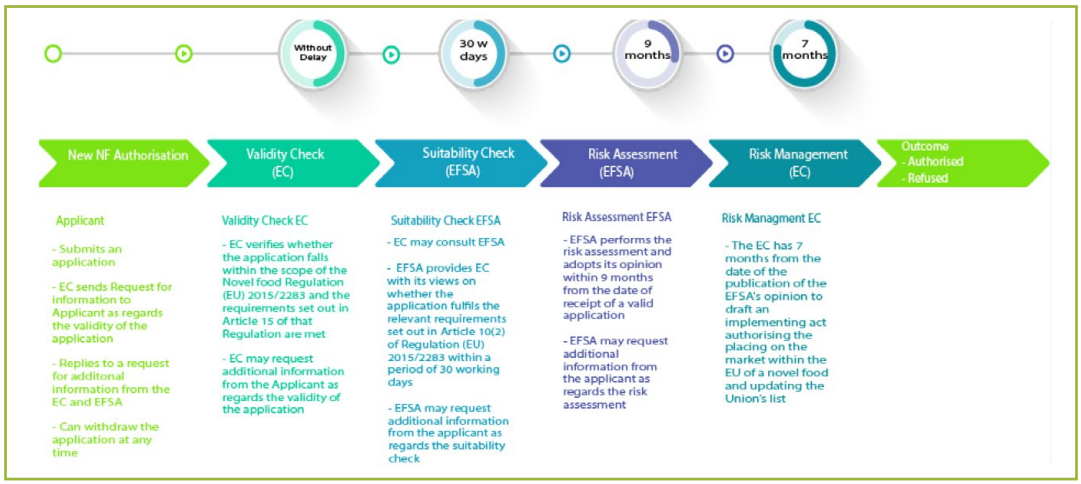
- Safe for consumers
- Properly labelled, so as not to mislead consumers
- Consumption would not be nutritionally disadvantageous for the consumer in any way

For placing Novel Food in EU markets, pre-market authorisation on the basis of an evaluation is necessary.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R2283. The date of 15th may 1997 refers to the date, when the first Regulation on novel food came into force.

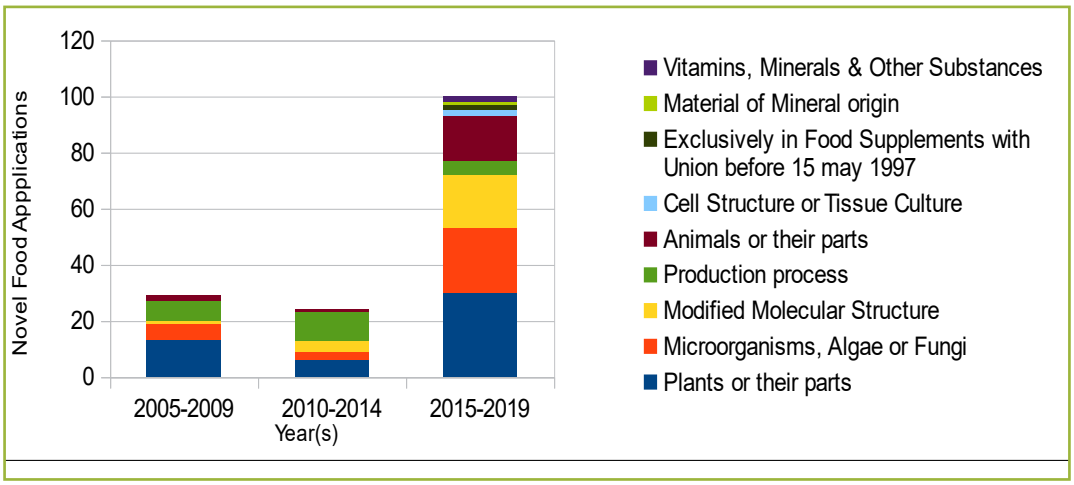
Authorization Workflow[2]

For Novel Foods



For Traditional Foods

Diverse Novel Food Applications that entered EFSA's assessments[3]



[2] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_novel-food_e-submission-system_user-guide_en.pdf

[3] Data Source: https://www.researchgate.net/publication/342780239_Novel_Foods_in_the_European_Union_scientific_requirements_and_challenges_of_the_risk_assessment_process_by_the_European_Food_Safety_Authority

Novel Food authorisations granted in EU in 2020

Nicotinamide Riboside Chloride — Applicant : ChromaDex Inc, USA

The novel food is a synthetic form of nicotinamide riboside. It has been authorized to be used as a source of niacin in food supplements intended for the general adult population at the maximum use levels of 300 mg/day, excluding pregnant and lactating women 230 mg/day for pregnant and lactating women.[4]

Spermidine-rich wheat germ extract — Applicant : TLL The Longevity Labs GmbH, Austria

It is obtained from non-fermented, non-sprouting wheat germs (*Triticum aestivum*) by the process of solid-liquid extraction targeting specifically, but not exclusively polyamines. Though it was authorized as a novel food in 2017, it has been re-authorized with changed specifications to increase the level of cadaverine from the current < 0.1 µg/g to ≤ 16.0 µg/g.[5]

Lacto-N-Tetraose — Applicant : Glycom A/S, Denmark

Lacto-N-tetraose is an oligosacharide naturally present in human breast milk. The new food, lacto-N-tetraose (LNT), is obtained by microbial fermentation with the genetically modified strain of Escherichia coli K12 DH1. Microbial source LMT is authorized in a large number of food categories, viz. unflavoured pasteurised and unflavoured sterilised milk products, flavoured and unflavoured fermented milk based products including heat-treated products, cereal bars, flavoured drinks, infant formula and follow-on formula, processed cereal-based food, baby food for infants and young children, milk-based drinks and similar products intended for young children, foods for special medical purposes, and total diet replacement foods for weight control, as well as in food intended for the general population excluding infants.[6]

Partially defatted Chia seed (*Salvia hispanica*) powder — Applicant : Access Business Group International LLC, USA

It is authorized to be used in a number of food categories like, unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk, flavoured fermented milk products including heat-treated products, confectionery, fruit and vegetable juices, fruit and vegetable nectars and similar products, flavoured drinks; food supplements, excluding the ones for infants and young children, pasta.[7]

Protein extract from pig kidneys — Applicant : Sciotec Diagnostic Technologies, GmbH, Austria

It was authorized as novel food ingredient in 2013 and in 2020 Commission authorized the request to include enteric coated tablets as an allowed form of protein extract from pig kidneys to be used in foods for special medical purposes and in food supplements, in addition to the currently authorised enteric coated encapsulated pellets. It is authorized to be used for special medical purposes, and in food supplements, is 3 capsules/day, corresponding to 12.6 mg pig kidney extract a day.[8]

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[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R0016
[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R0443
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R0484
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R0500
[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R0973

Vitamin D_2 mushroom powder — Applicant : Oakshire Naturals, LP., USA

A granular powder made from homogenised *Agaricus bisporus* mushrooms that have been exposed to UV light is authorized to be used in a variety of foods and beverages as well as fortified foods and food supplements.[9]

Dried *Euglena gracilis* — Applicant : Kemin Foods L.C., USA

It is dried whole cell Euglena, which is the dried biomass of the microalga *Euglena gracilis*. The novel food is produced by fermentation followed by filtration and a heat-killing step of the microalga to ensure the absence of viable *Euglena gracilis* cells in the novel food. Authorised to be used as a novel food in a number of food categories like: breakfast, granola and protein bars; yoghurt; yoghurt beverages; fruit juices, smoothies and nectars, vegetable juices; fruit-flavoured drinks; meal replacement beverages. It may also be used in food supplements, excluding food supplements for infants, and in total diet replacement for weight control, excluding total diet replacement for weight control for infants.[10]

Extract from *Panax notoginseng* and *Astragalus membranaceus* — Applicant : NuLiv Science, USA

The novel food contains two extracts. One is an ethanol extract of the roots of *Astragalus membranaceus* (Fisch.) Bunge. The other is a hot water extract of the roots of *Panax notoginseng* (Burkill) F.H. Chen that is further concentrated using absorption on a resin and subsequent elution with 60% ethanol. At the end of the manufacturing process both extracts are mixed (45–47.5% of each extract) with maltodextrin (5–10%).[11]

Chromium containing yeast (*Yarrowia lipolytica*) biomass — Applicant : Skotan S.A., Poland

The novel food, authorized to be used a food supplement is the dried and heat-killed chromium-containing biomass of the yeast Yarrowia lipolytica, which is produced by fermentation in the presence of chromium chloride followed by a number of purification steps and a heat-killing step of the yeast to ensure the absence of viable Yarrowia lipolytica cells in the novel food[12].

Selenium containing yeast (*Yarrowia lipolytica*) biomass — Applicant : Skotan S.A., Poland

The novel food, authorized to be used as food supplement is the dried and heat-killed selenium-containing biomass of the yeast *Yarrowia lipolytica*. produced by fermentation in the presence of sodium selenite followed by a number of purification steps including a heat-killing step of the yeast to ensure the absence of viable *Yarrowia lipolytica* cells in the novel food[13].

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R1163
[10] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R1820
[11] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R1821
[12] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020R1822&from=EN
[13] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R1993

Traditional Foods authorized to enter EU market in 2020

Theobroma cacao L. — Applicant : Nestec York Ltd. and Cabosse Naturals NV., USA

The traditional food is the fruit pulp from the cocoa (*Theobroma cacao L*) plant, which is the "aqueous, mucilaginous and acidic substance in which the seeds are embedded". Cocoa fruit pulp is obtained by splitting cocoa pods followed by separation from husks and beans; the pulp is then subject to pasteurisation and freezing. Cocoa pulp juice and/or cocoa concentrated pulp juice are produced following processing (enzymatic treatment, pasteurization, filtration, and concentration).

It was demonstrated that fruit pulp, pulp juice, concentrated pulp juice from *Theobroma cacao* L. have a history of safe food use in Brazil.[14]

Infusion of Coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* — Applicant : AM Breweries, India

The traditional food consists of an infusion of leaves from *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A.Froehner (family: Rubiaceae). The traditional food is prepared by mixing a maximum of 20 g of dried leaves from *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A.Froehner with 1 L of hot water. Leaves are removed and the infusion is then subjected to pasteurization (at least 71 °C for 15 seconds).

Coffea arabica *Coffea canephora*

The infusions are authorized to be used as such or as an ingredient in other beverages by the general population. EFSA noted that the leaves of Coffea arabica contain Epigallocatechin gallate (EGCG) and therefore, the presence of EGCG in the infusion from coffee leaves of Coffea arabica L. and/or Coffea canephora cannot be excluded. On that basis, the Authority established a maximum level of 700 mg of EGCG per litre of the infusion.

This traditional food has a history of safe food use in Africa, Asia and North America.[15]

Sugars obtained from cocoa (Theobroma cacao L.) pulp — Applicant : Cabosse Naturals NV, USA

Sugars are obtained from the concentrated cocoa pulp (*Theobroma cacao* L.) juice either via a drying process or via a purification process to produce high purity glucose or fructose.[16]

Important Links:

Novel Food catalogue: https://ec.europa.eu/food/safety/novel_food/catalogue_en

Detailed e-submission Process: https://ec.europa.eu/food/sites/food/files/safety/docs/fs_novel-food_e-submission-system_user-guide_en.pdf

Role of EFSA : https://www.efsa.europa.eu/en/topics/topic/novel-food

[14] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R0206
[15] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R0917
[16] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R1634

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