

European Commission



Novel Food

> Health and Food Safety

Introduction

A novel food is a food or food ingredient that was rarely or never consumed in the European Union (EU) before May 1997. That year the first provisions on novel food in the EU came into force, in the form of Regulation (EC) No 258/97.

Definition

The term 'novel food' refers to food not consumed to any significant degree by humans in the EU prior to 15 May 1997.

Novel food refers to new food sources or newly developed and innovative food, food produced using new technologies and production processes, and food traditionally eaten outside of, but not within the EU.



Examples of different types of novel foods:

- agriculture products from third countries — e.g. chia seeds
- extracts from plants rapeseed protein
- a new food-producing process — bread, mushroom or milk treated with UV light for increasing vitamin D content
- new nutrient sources docosahexaenoic acid (DHA) oil from micro-algae.

New regulation

The 1997 novel food legislation needed to be reviewed taking into account recent scientific and technological developments.

The new novel food regulation (Regulation (EU) 2015/2283) was adopted on 25 November 2015 by the European Parliament and the Council. These new rules will fully apply from 1 January 2018.

The new novel food legislation will improve of foods available to them.

The general criteria for the definition of novel foods remain unchanged: novel foods are foods and food ingredients not consumed in the EU to a significant degree before 15 May 1997 (i.e. before the entry into force of the current novel food regulation).

Durian Flesh



The **main improvements** of the new regulation

- The **authorisation procedure** has 1. been streamlined and centralised. and includes generic authorisation. The European Commission processes all applications and grants authorisations. As a result, all food business operators may place their authorised novel food on the market, as long as the conditions for use and the labelling requirements are respected.
- 2. **Safety evaluations** are to be carried out by the European Food Safety Authority (EFSA). The European Commission consults EFSA on applications. and bases authorisation decisions on the outcome of FFSA's evaluations
- The European Union Novel Food 3. **list** is where all authorised novel foods will be listed







Applications in the pipeline

Any applications not finalised under the current rules by 1 January 2018 (when the new regulation comes into effect) will be decided under the new regulation.

More information on novel food

- 4. Efficiency and transparency will be improved by establishing deadlines for the safety evaluation and authorisation procedure, thus reducing the overall time spent in the authorisation process.
- To facilitate trade there will be faster and more proportionate safety assessment for traditional foods from third countries having a history

of safe food use. The new regulation introduces a simplified assessment procedure for traditional foods from third countries that are new to the EU. If the traditional food in question can historically be demonstrated to be safe, and no safety concerns are raised by EU Member States or EFSA, that traditional food may be placed on the market on the basis of a notification from the applicant.



Omega 3 krill oil

European Novel Food Catalogue

The Novel Food Catalogue is an informal IT tool listing products of animal and plant origin and other substances that are subject to the novel food regulation. This is

based on information regarding history of consumption of these products in the EU Member States.

New technologies and innova-6. **tions** have the potential to reduce the environmental impact of food production, enhance food security and bring benefits to consumers. Such innovative foods can benefit from data protection provisions allowing

an applicant to get an individual authorisation to place a novel food on the market. Data protection is based on newly developed scientific evidence and proprietary data, and is limited in time to 5 years.



List of authorised novel foods to be placed on the EU market

A complete list of authorised novel foods is available on the European Commission's website, including:

- authorisations of novel foods by individual Member States
- authorisations of novel foods through Commission decisions

authorisations of novel foods granted by simplified 'notification' procedures.

In addition, alongside the list of authorised novel foods there is also a list of novel foods where, by Commission decision, authorisation has been refused.



Labelling

Novel food is covered by the general labelling requirements set out in Regulation (EU) No 1169/2011.

In particular, the label must mention the name of the food

In some cases, labelling for novel foods may have additional requirements to help consumers use the product safely, e.g. a warning that the novel food is not recommended for vulnerable groups. Moreover, any nutritional and health claim must be compatible with the Health and Nutrition Claims Regulation (EC) No 1924/2006.



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