Novel foods

How to ensure the products you sell comply with the legislation for novel foods.

Novel foods are foods which have not been widely consumed by people in the EU before May 1997. This means that the foods don't have a 'history of consumption'. Examples of novel foods include:

- new foods, for example, phytosterols and phytostanols used in cholesterol reducing spreads
- traditional foods eaten elsewhere in the world, for example, chia seeds, baobab
- foods produced from new processes, for example, bread treated with ultraviolet light to increase the level of vitamin D present

We are responsible for ensuring that novel foods coming on to the market are safe for consumers.

Novel food legislation

Before the food can be legally marketed in the EU, novel foods are required to have a pre-market safety assessment and authorisation under the Novel Foods Regulation (Regulation (EU) No 2015/2283).

The regulation applies to any food and food ingredient that hadn't been used in the EU for human consumption to a significant degree before May 1997.

The food must also be either:

- food ingredients with a new or intentionally modified primary molecular structure
- micro-organisms, fungi, algae or cell culture
- plants or animals
- food produced by new production process that significantly changes the product nutritionally or in relation to the food safety risks
- minerals or engineered nano-materials

Food additives, flavourings, and extraction solvents used in the production of food are outside the scope of the novel foods legislation. These require pre-market safety assessment and authorisation under separate legislation.

FSA EXPLAINS

Recent changes affecting cannabidiol (CBD) products

There has been a recent change to the EU Novel Food Catalogue which affects some cannabidiol (CBD) products.

Food businesses have not been able to show there was a significant history of consumption of these products in food and food supplements prior to May 1997 in the EU.

Under the Novel Food Regulations, foods or food ingredients which do not have a history of consumption need to be evaluated and authorised before they are permitted to be placed on the market.

The FSA accepts the clarification from the EU that CBD extracts are considered novel foods. We are committed to finding a proportionate way forward by working with local authorities, businesses and consumers to clarify how to achieve compliance in the marketplace in a proportionate manner.

Union List and authorised novel foods

All novel foods that have EU authorisation are now included in a list in the EU legislation. Authorised novel foods must be:

- safe
- not misleading for the consumer
- not replace other foods in a way that would put consumers at a nutritional disadvantage

Unless the data protection measures are triggered, you can sell an authorised novel food in accordance with the conditions set out in the Union List. The Union list shows where data protection is in place.

You have to submit a novel food application if you want to sell a novel food in a way that is not in the Union List.

Where data protection is triggered, for a period of five years the authorisation can only be used by the applicant. This would not prevent other applicants seeking their own separate

authorisation.

Determining novel status

It is your responsibility to know if the novel foods regulation applies to a product you want to sell. While there is no single list of novel foods, or a list of foods that are not novel, you can check the following resources:

- the EU Novel food catalogue
- German novel food list
- Italian list of plants permissible for food supplement use
- Italian list of plants not permissible in food supplements list

The European Commission has further guidance on history of consumption.

Consultation process

A consultation process is available if you:

- are unsure of the status of your product
- have evidence that it has a history of consumption in the EU prior to May 1997

Commission implementing regulation (EU) 2018/456 details the information that is required by authorities to make a decision on whether the product is subject to the Novel Foods Regulation.

This consultation will need to be sent to the EU Member State that you wish to market the foods in first. It can only be sent to one Member State. If you intend to market your product in the UK first and wish to use the consultation process, send your consultation request to novelfoods@food.gov.uk. The outcome of this process will be made publicly available on the Commission's website.

If the consultation process decides your product is novel, then you will need to apply for authorisation to legally market the product in the EU.

Process for authorisation of a novel food

If you intend to market a novel food which has not been authorised, you will need to apply for authorisation. There are two authorisation routes under the EU Novel Food Regulation no. 2015/2283.

In both cases you must provide a dossier of information and submit it to the European Commission through an electronic portal.

Traditional foods from third countries

This is a simplified route to authorise products that have 25 years' continuous use by a significant

number of people in a country outside the EU.

This route has reduced data requirements reflecting their wide use in other parts of the world. The European Food Safety Authority (EFSA) has published guidance for traditional foods from third countries.

If no objections are received from Member States or EFSA within a four-month period, the product is authorised and placed on the Union List.

If objections are raised, there is an additional opportunity to address the areas highlighted through a traditional food application.

Full applications

For all other novel foods, a full set of information is required to be submitted to the Commission which will ask the advice of EFSA where appropriate. EFSA has published guidance on the scientific requirements of an application.

It can take up to nine months for a risk assessment to be completed when further information is not required. If there is a positive EFSA opinion, the Commission has a further seven months to authorise the food and add it to the Union List of novel foods.

Enforcement

Local authorities, including Trading Standards and Environmental Health Officers, are responsible for the enforcement of novel foods legislation.

If you have a concern about products being marketed which may be illegal or dangerous to health contact the relevant local authority.