

# Placing innovative foods on the market in Great Britain

An overview of innovative food regulations, guidance and key compliance considerations for Great Britain.

## Overview

This information note provides key regulations relevant to the authorisation of, and the post-market requirements for, innovative food and feed products.

It is primarily aimed at businesses developing innovative foods, but may also be useful for manufacturers and retailers.

It covers:?

- which products need authorisation before you can sell them?
- how to check if your product is already authorised?
- how to apply for authorisation?
- what you need to do after authorisation?
- how to access further support?

This information note is for general information only and is not legal advice. It is not an exhaustive overview of relevant regulations. It is designed to help readers understand the regulatory landscape of innovative new foods and to clarify, at a high level, some boundaries between regimes.

Responsibility for compliance with regulations sits with the relevant food business operator (FBO).

Where the regulatory status of a product is unclear, businesses should refer to the relevant legislation and seek appropriate advice and/or use formal determination routes (for example, the [novel foods 'Article 4' consultation process in Great Britain](#) should be used to determine if a product is a novel food).

## General Food Law requirements

[General Food Law](#) applies to all food marketed in Great Britain (GB). The principal aim of General Food Law is to protect human health and consumers' interest in relation to food. It covers all stages of production, processing and distribution of food and feed.

All food businesses must follow food and feed safety law.

Some food products need additional regulation. This includes certain food products that might pose higher safety risks, such as those that are new and haven't been widely consumed before.

# Regulated products

## What are regulated products?

Certain food and feed products ('regulated products') require authorisation before they can be placed on the market in GB. This is because they might present specific risks, uncertainties or novel characteristics that require additional oversight to ensure their safety.

The Food Standards Agency (FSA) maintains a [register of authorised regulated products authorised for use in GB](#). The FSA also publishes a [register of applications received](#) (for information only), which is separate from the register of authorised products.

A business with an innovative food product should familiarise themselves with the [types of products which require regulated products authorisation](#).

If the product might sit within a regime, it is important to check if the product is already authorised, and if so, whether the intended use falls within the terms of authorisation. This is to help determine if the product can already be marketed in GB, or if a regulated product application must be made.

To place a regulated product on the market in Northern Ireland (NI), different arrangements apply (including EU processes, with limited provision for eligible pre-packed retail goods moved via the Northern Ireland Retail Movement Scheme).

## Checking the register and terms of authorisation

Products on the [authorised regulated products register](#) can already be used in all GB nations, as long as they meet the terms of their authorisation as listed, alongside [General Food Law](#).

If a business intends to use an authorised product beyond its original terms of authorisation, then a modification to the authorisation will need to be applied for.

Contact the FSA at [regulatedproducts@food.gov.uk](mailto:regulatedproducts@food.gov.uk) if it's unclear whether a modification to the existing authorisation is required.

## When an application is needed

If an innovative product is not listed on the relevant GB register, an application is likely to be required before it can be placed on the GB market.

Read our [regulated products application guidance](#).

## Authorisation process

To apply for authorisation, submit a dossier through the [regulated products authorisation portal](#). The authorisation process involves a rigorous scientific safety assessment, followed by risk management considerations and a public consultation.

To help with understanding the authorisation process, the FSA and FSS have produced:

- a [process flow chart for regulated product applications](#)
- a [process flow chart for novel food applications](#), which contains information on the steps that applicants should take before applying for novel food authorisation

## Authorisation regimes for innovative foods

Regulated products are authorised under different regimes. Each regime covers a type of product that is set in legislation. A full list of regimes and the relevant guidance can be found in the [regulated products application guidance](#).

The main regimes relevant to innovative foods are listed below.

### **Genetically modified organisms (GMOs) as food and feed**

[Genetically modified organisms](#) are plants and animals with a genetic make-up that has been modified using techniques of biotechnology. Genetic modification allows scientists to produce plants, animals and micro-organisms with specific qualities.

Genetically modified food and feed contains or consists of GMOs, or is produced from GMOs.

### **Precision bred organisms (PBOs)**

[Precision bred organisms](#) are plants or animals where the genetic makeup of the organism has been altered using techniques of modern biotechnology (such as gene editing) in a precise way.

To qualify as a PBO, the changes to the organism must be those that could have also been achieved through traditional breeding methods.

This legislation applies in England only. Elsewhere in GB, products falling under this definition would be regarded as GMOs.

### **Flavourings**

[Flavourings](#) are used to add a new taste or odour to a food or improve the existing taste or odour of a food.

#### **Smoke flavourings**

[Smoke flavourings](#) are added to foods, such as meat or cheese, to give them a 'smoked' flavour as an alternative to traditional smoking.

### **Extraction solvents**

[Extraction solvents](#) are used in food processing to help dissolve and separate parts of a food.

The extraction solvent is removed before the resulting food or ingredient is used, but technically unavoidable residues or derivatives may remain.

### **Food additives**

[Food additives](#) are substances added to food to perform a specific technological function. This includes:

- making food look or taste better
- extending the storage and shelf-life of food
- maintaining the nutritional composition of food
- helping the food production process

### **Food enzymes**

[Food enzymes](#) are present in microorganisms, plants and animals and act as catalysts in various chemical reactions. This means that they increase the rate of the reactions.

Because of this they can be useful in the production of food or certain food ingredients (like flavourings), achieving increased yields or more efficient production processes.

### **Novel foods**

[Novel foods](#) are any food that was not used for human consumption to a significant degree within the United Kingdom (UK) or the European Union (EU) before 15 May 1997.

### **Food contact materials**

[Food contact materials](#) (FCMs) are materials and articles that come into contact with food during its production, processing, storage, preparation or serving.

## **Choosing the right regime**

The regime that a product should be authorised under can depend on several factors, including how it is produced and its intended use(s).

The requirements for an application dossier, and any terms of authorisation may vary depending on the regime the product is applied under.

It is important for applicants to consider all the possible intended use cases of a product because changes to use could affect the scope of the safety assessment.

A regulated product application cannot be made for novel foods alongside any of the regimes listed in [Regulation \(EU\) 2015/2283](#). The regulation explicitly excludes:

- a genetically modified (GM) food
- a food produced from precision bred plants
- a food enzyme
- a food additive
- a food flavouring
- an extraction solvent

Therefore, if a product that is thought to be a novel food is found to have additional technical uses (for example, as a colouring or a flavouring), another regime may apply instead of novel foods (for example, food additives or flavourings).

Some products may be used as both a technical and non-technical ingredient. In this case, two separate regulated product applications can be made (for example, a novel food application and a separate food additive application).

The production method can change which regime applies.

### **Precision fermentation**

For example, the microorganisms used in precision fermentation may be genetically modified. If these are completely removed from the final product then it's likely that the product would be classed as a novel food.

However, if genetically modified microorganisms remain in the final product, then the application may instead fall into the scope of the GMO legislation.

In this case, other regimes may additionally apply, such as food additives or flavourings, depending on the intended use of the product and its function in food.

## **Cell-cultivated products**

Similarly, cell-cultivated products are commonly considered within scope of the novel foods regime in Great Britain.

However, depending on the production process and the characteristics of the final product, other regimes may be relevant instead.

For example, if genetic modification has taken place in the process of production and genetically modified organisms remain in the final product, then applications may need to be assessed under the GMO regulations.

## **Novel food status: Article 4 consultation**

In GB, there is a formal consultation process (an Article 4 consultation request), for businesses that are unsure whether a product falls within the [Novel Foods legislation](#) and/or can provide evidence of significant consumption in the UK or EU before 15 May 1997.

A Food Business Operator (FBO) should first consult the resources on the [novel foods authorisation guidance](#). If the FBO remains unclear on the status of a product as a novel food, the FBO should submit the Article 4 request by following the [regulated products application guidance](#).

It is the responsibility of the FBO to provide the necessary evidence that a product is not novel. In Great Britain, the FSA and FSS can determine the novel status of a product via the Article 4 consultation process.

In Northern Ireland, novel foods must undergo a safety assessment and authorisation before being placed on the market. Businesses seeking to place their products on the Northern Ireland market should follow EU rules and the [European Commission's authorisation process](#).

## **Taste trials before authorisation**

If a product is (or may be) a novel food, businesses may want to conduct taste trials before acquiring market authorisation. Taste trials before a product is placed on the market may be permissible where the main purpose is to conduct research and development, and not to publicise a product or a company brand. [\(footnote 1\)](#)

The FSA and FSS have published [taste trials guidance](#) to help businesses ensure that they are complying with the law and to support safe and ethical trials. This includes additional information on taste trials for GMOs.

## **Post-authorisation regulations**

[Each regime](#) has its own set of legislation. It is important to know the full set of regulations related to the specific legislation for the regime, and how this needs to be applied to ensure compliance with the law.

Between regimes, there may be different regulations to follow post-authorisation. Authorisations may include conditions of use and other requirements set out in the relevant regime and/or the terms of authorisation.

Alongside [General Food Law](#), things to consider post-authorisation can include:

- specific labelling requirements
- aspects related to the safety assessment such as Acceptable Daily Intakes (ADIs) or restrictions for vulnerable groups (for example, under 18s)

This is not an exhaustive list, and the relevant legislation sets out which regulations apply to the regime a product falls within.

## Food safety requirements

All food, including regulated products, must follow [General Food Law](#), which includes regulated products. This includes [managing food safety](#), [food traceability](#) and [food hygiene](#).

We also recommend applying [Hazard Analysis and Critical Control Point \(HACCP\)](#) principles to production and distribution.

Additionally, FBOs must comply with [allergen labelling](#) requirements, including [precautionary allergen labelling](#). The FSA and FSS provide guidance for food businesses on correctly providing allergen information to consumers:

- [FSA allergen information guidance](#)
- [FSS allergen information guidance](#)

Businesses should also consider rules on the claims made about foods (for example, nutrition and health claims) and wider [advertising and marketing requirements](#). These can affect how innovative products are presented to consumers.

Products of Animal Origin (POAO) that are [imported](#) or [domestically produced](#) are subject to further regulation due to the higher toxicological and microbiological risks they pose.?

[Cell-cultivated products](#) and precision fermented products that use animal cells, tissues, or other material in the production process are classed as POAO. Depending on the production method used, other innovative food products may be classed as POAO.

## Regulations across government

Depending on the nature of a product and how it is developed and manufactured, additional requirements may apply that sit outside FSA and FSS' remit.

Businesses should consider whether they need to engage with other regulators, other government departments or competent authorities to fulfil their obligations. Businesses considering bringing a new product to market should fully investigate their regulatory obligations associated with their product type.

Some products or development activities have requirements beyond food or feed market authorisation. For example, deliberate release of GMOs into the environment (including certain research activities) is controlled by the competent authorities in each UK nation:

- England: The Department for Environment, Food and Rural Affairs
- Northern Ireland: The Department of Agriculture, Environment and Rural Affairs
- Scotland: The Scottish Government
- Wales: The Welsh Government

This authorisation is separate from the regulated product market authorisation under the GMO food and feed regulated products regime. Guidance on [developing genetically modified](#)

[organisms](#) is available.

## Borderline products

Some foods, such as certain food supplements, may require regulation and authorisation as medicines. Whether or not a product is classified as a medicine depends on its ingredients, intended purpose and any health claims made by the manufacturer or seller.

The FSA and FSS do not decide whether a product is a medicine. The Medicines and Healthcare products Regulatory Agency (MHRA) decides whether a product meets the definition of a medicinal product.

Where the regulatory status of a product is uncertain, MHRA decides whether it might be a medicine rather than a food.

Find out [how to tell if your product is a medicine](#).

## Devolved nations

### Four nation roles and decision-making

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The FSA provides information on [four-country working](#) and this outlines the responsibilities for ensuring food safety across the four nations.

The FSA and FSS make independent evidence-based recommendations to respective ministers in England, Wales, and Scotland on the authorisation of regulated products.

In Northern Ireland, the minister is kept informed. Ministers in England, Wales and Scotland then make independent authorisation decisions.

### Northern Ireland and the Windsor Framework

[The Windsor Framework](#) is an agreement between the UK and EU. It outlines the process for trade and is a unique set of arrangements to support the flow of foodstuffs including food contact materials from GB to Northern Ireland.

This allows GB standards in public health, marketing (including labelling) and organics to apply for pre-packed retail goods moved via the NI Retail Movement Scheme (NIRMS) to Northern Ireland.

Further information on the [Windsor Framework](#) is available on GOV.UK.

### Market access considerations

There are some differences in food policy between the four nations. The [United Kingdom Internal Market Act 2020](#) introduces access principles (mutual recognition and non-discrimination) that can affect whether certain 'relevant requirements' apply when that goods are sold across the UK (subject to exclusions and specific arrangements).

The mutual recognition principle is the principle that goods which have been lawfully produced in, or imported into, one part of the UK can be sold in another part of the UK without the need to comply with local rules.

For the purposes of applying the mutual recognition principle, a good is deemed to have been 'produced in' a part of the UK (if not wholly produced there) if the most recent significant production step which is a regulated step has occurred there.

For further guidance on market access principles, see [guidance for traders on complying with the UK Internal Market Act 2020](#).

## Business support and guidance

The FSA's [Innovative Food Guidance Hub](#) provides tailored guidance, up-to-date information and practical support on a range of innovative food categories, including providing business support.

If you need more information or support with your application, contact us at [regulatedproducts@food.gov.uk](mailto:regulatedproducts@food.gov.uk) or visit the [Innovative Food Guidance Hub](#).

## Checklists for businesses, manufacturers and retailers

The points listed are for general information only and are not exhaustive. FBOs, manufacturers and retailers are responsible for following the law.

### For businesses

Before applying for market authorisation, consider:

- which regulatory regime(s) might apply to my product (based on what it is, how it is produced, and how it will be used)?
- are there any other potential uses of my product (now or in future) that could change which regime applies?
- have I checked whether a similar product (or substance) is already authorised, and whether my intended use falls within the existing terms of authorisation?
- how might my production method, sourcing, or intended uses affect which regulatory regime(s) apply?
- have I considered my obligations under General Food Law, including food safety management, hygiene, traceability, and allergen information?
- do I have appropriate evidence and documentation to support the safety of my product for its intended consumer groups and conditions of use?
- have I considered any requirements outside FSA or FSS remit that may apply (for example, environmental, medicines, or other sector-specific requirements)?
- do I need to engage with any other government departments or regulators? For example, where other notification or approval routes apply?

### For manufacturers

If you're producing an authorised innovative food, consider:

- does the food carry any allergen risks (including cross-contact), and are controls in place?
- are there any specific terms of authorisation that affect manufacturing (for example, specifications, purity criteria, maximum use levels, or permitted food categories)?
- are there any additional labelling requirements or mandatory statements linked to the authorisation, ingredients, or intended consumers I need to consider?

- are traceability and record-keeping arrangements in place to support verification, incident management, and (where needed) withdrawal/recall?
- have I applied appropriate food safety management (for example HACCP-based controls) for the process and product type?
- do I need to engage with any other government departments, regulators or competent authorities? For example, if other approval or notification routes apply?
- if I supply across the UK (including movements involving NI), have I considered whether any nation-specific requirements or arrangements may affect placement on the market, labelling or movement of goods?

### **For retailers**

If you're introducing an innovative food product, consider:

- have I obtained sufficient assurance from my supplier or manufacturer that the product is authorised where required and is within the relevant terms and conditions of authorisation?
- are there any additional labelling requirements for this product (including allergen information and any terms of authorisation-related information)?
- are storage, handling and shelf-life controls appropriate for the product type (for example cold chain requirements where relevant)?
- if selling across the UK (including NI), have I considered whether any specific arrangements may affect movement or sale?

1. The definition of "placing on the market" is broad and can include free-of-charge transfers such as trade samples. [Taste Trials Guidance](#).