FAQ: precision fermentation market authorisation in Great Britain

Advice about applying for market authorisation of precision fermentation products in Great Britain.

This resource should be read together with our regulated products application guidance.

Precision fermentation

What is precision fermentation?

Precision fermentation is a?modern?form of the traditional fermentation process.

In precision fermentation, scientists program microbes (tiny living organisms like yeast or bacteria) to make new, specific food ingredients. These include proteins, sugars and fats. These foods are created without using animals or plants.?

Precision fermentation works by instructing the microbes?to make a particular molecule – like whey protein (found in milk and protein shakes) or egg white protein. The microbes are grown in fermentation tanks and fed sugars, which start producing the target ingredient.?

Learn more about precision fermentation.

Registering as a food business

Do I need to register as a food business?

Not necessarily. If you're submitting regulated product applications, you only need to register as a food business if you are involved in preparing, handling, distributing or selling food. This includes online and distance selling.

Eligible businesses should register at least 28 days before beginning operations to make sure they're compliant with food safety and hygiene requirements.

Find out how to get ready to start your food business.

General Food Law

What is General Food Law?

Regulation (EC) No 178/2002 (the General Food Law regulation) sets out the core principles and responsibilities of food law.

The principal aim of General Food Law is to protect human health and consumers' interest in relation to food. It applies to all stages of production, processing and distribution of food and feed,

with some exceptions. Food businesses must comply with food and feed safety law.

Find out more about General Food Law.

What are the key definitions of General Food Law?

Article 3 of the General Food Law regulation sets out essential definitions?that apply in general food law.

These definitions?establish?the broad reach of food law, making clear that regulatory obligations apply throughout the food supply chain and rest with the operator exercising control over food business activities.

Find out more about General Food Law and Regulation (EC) No 178/2002.

Key definitions:?

Food law

The laws, regulations and administrative provisions governing food in general, and food safety in particular. It covers all stages of production, processing, and distribution of food, and also feed produced for, or fed to, food-producing animals.

Food business

Any undertaking, whether for profit or not, and whether public or private, carrying out activities related to any stage of production, processing or distribution of food.

Food business operator (FBO)

The natural or legal person responsible for ensuring food law requirements are met within the food business under their control.

Stages of production, processing and distribution

Any stage, including import, from and including primary production of a food up to and including its storage, transport, sale or supply to the final consumer; and, where relevant, similar stages for feed.

Applying for regulated product authorisation

What are regulated products?

Certain food and feed products, called regulated products, must go through a risk analysis process. They require market authorisation before they can be sold.

Explore our regulated products guidance hub.

Who assesses regulated product applications in Great Britain?

In Great Britain, the Food Standards Agency and Food Standards Scotland are responsible for assessing the safety of food and animal feed in England and Wales, and Scotland respectively. They provide independent, evidence-based advice to their respective government ministers, who make the final authorisation decisions within

their jurisdictions,

Northern Ireland continues to follow EU food and feed law. Under the Windsor Framework, eligible pre-packed retail goods that are authorised for sale in GB can be moved into Northern Ireland through the Northern Ireland Retail Movement Scheme (NIRMS).

Explore our regulated products guidance hub.

What information do I need to submit when applying for a regulated product authorisation?

When applying for a regulated product authorisation you must submit a complete dossier containing administrative, technical and safety information.?

What you need to put in the dossier depends on which regulated product regime the product falls under (for example, novel foods or food additives).

A complete dossier must include the following:

- administrative information
- technical information
- safety information

The Food Standards Agency?and?Food Standards Scotland regime-specific guidance explains how to prepare an?application dossier.

Where applicable, follow European Food Safety Authority (EFSA) dossier development guidance (content and data expectations). Do not use EFSA's EU application process.

In Great Britain, you don't currently need to pre-notify us of studies intended to support your novel food application.

?Read our regulated products application guidance.

What if my product falls under more than one regulatory regime?

Some products, particularly those involving genetic modification or other advanced technologies, may require authorisation under more than one regime.

If this is the case for your product, contact regulatedproducts@food.gov.uk before applying.?

?Read our regulated products application guidance.

Should I include a Hazard Analysis and Critical Control Point (HACCP) plan in my application?

Where applicable, we recommend including a Hazard Analysis and Critical Control Point (HACCP) plan.

Please check Article 5 of Regulation (EC) 852/2004 on the hygiene of foodstuffs, which sets out requirements to implement procedures based on HACCP principles, to find out which HACCP procedures you should follow.

Applying for novel food authorisation

What is the novel food regime?

The novel food regime is intended to regulate foods that require oversight but cannot be appropriately categorised under any other existing regulatory regime.

The regime does not apply to:

- genetically modified foods within the scope of Regulation (EC) No 1829/2003?
- food additives, flavourings, enzymes and extraction solvents regulated under their respective legislation

Novel foods must be authorised before they can be placed on the market in Great Britain (GB). They must comply with Regulation (EU) 2015/2283 as it applies in GB.

Before applying for novel food authorisation, applicants must check all relevant regulated product regimes and make sure their product does not fall within one of these alternative frameworks.

What is a novel food?

Under Regulation (EU) 2015/2283, a product is a novel food if it meets both of these requirements:

- was not consumed to a significant degree before 15 May 1997
- meets at least one category in Article 3 of Regulation (EU) 2015/2283, such as:??
    - new molecular structures?
    - foods from microorganisms, fungi, algae?
    - cell-cultured?foods?
    - foods produced using new processes?
    - nanomaterials?
    - new sources of vitamins/minerals?
    - foods previously used only in supplements (if now intended for wider use)?

Read our novel foods authorisation guidance.

Can a novel food contain other regulated products like additives or flavourings?

Yes. A novel food product?may?contain?or use?other?authorised regulated products, such as food additives or flavourings, as components of the final product.

However, if the product has not been authorised for the specific food categories requested, you may need:

- a modification to the existing authorisation
- a new application

Read our novel foods authorisation guidance.

When would I need a new application or modification for those components?

If a component (such as an additive, flavouring or enzyme) has not been authorised for the specific food categories for which approval is sought, you may need:

- a modification of the existing authorisation
- a new application

Read our novel foods authorisation guidance.

Are there additional requirements for vitamins, minerals or supplements?

Yes, in some cases. It may need to be included in supplements and fortified food lists if the novel food is:

- a new source of a vitamin or mineral
- intended for use in food supplements as a concentrated source of certain substances

Supplements and fortified food lists are managed by the Department of Health and Social Care in England and Wales and Food Standards Scotland in Scotland. Northern Ireland are kept informed through the UK-wide nutrition framework.

Read our novel foods authorisation guidance.

Who is responsible for deciding whether a product is a novel food?

Article 4 of Regulation (EU) 2015/2283 places responsibility on food business operators to determine whether a product falls within scope of the novel foods regime.

If, after consulting available guidance, you are unsure if your product is a novel food, you should consult the Food Standards Agency and Food Standards Scotland. Make sure you give us enough information to allow us to decide. We encourage you to engage with us early, to avoid unnecessary or incorrect applications.

Where are the requirements for novel food applications set out?

Administrative and scientific requirements are contained in Regulation (EU) 2017/2469 on laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 on novel foods.

European Food Safety Authority (EFSA) guidance remains relevant because the Great Britain approach is based on established EU processes.

Which parts of European Food Safety Authority (EFSA) guidance should I follow?

Follow only the parts relating to development and content of dossiers. Do not follow sections relating to the EU application process itself.

Read our novel foods authorisation guidance.

Modifying existing authorisations

When would I need to?modify?an existing authorisation??

It depends on the product's existing authorisation. Regulation (EC) 1331/2008 on the procedure for food additives, food enzymes and food flavourings modifications sets out more detail.

A modification may be?required?if:?

- a precision fermentation production process uses an?already authorised? additive, enzyme or flavouring in a new way?
- the technical function or food category changes?

- specifications or?safety relevant?characteristics change?

Examples:

- a change to the taxonomic designation of a microorganism with no impact on composition, characteristics, or safety profile - likely no new assessment required
- an extension of use, a change to the final product, or any modification likely to affect consumer exposure or safety - likely full assessment required

If you aren't sure whether you need to modify an existing authorisation, get in touch with us before you apply. Email regulatedproducts@food.gov.uk for early advice.

Does changing the production method change the regulatory regime??

Generally, no. Where a product is already authorised under another regulatory regime, it will? generally remain regulated under that regime even if the method of production changes (for example, where production shifts to a precision fermentation process).

This is because food law focuses on the function and nature of the final product, rather than just the manufacturing method. This approach is consistent across regulated product frameworks.

Changes affecting composition or safety may require authorisation updates.?

Read our novel foods authorisation guidance.

Could a production change still require regulatory action?

Yes. While the regime may not change, a new method may require a modification if it affects the product's characteristics, specifications or conditions of use.

Read our novel foods authorisation guidance.

Do modifications to an authorised novel food require an application?

Yes. Any modification to an authorised novel food requires an application under Article 10 of Regulation (EU) 2015/2283.

Do I always need to submit a full dataset for a novel food modification?

No. The scope and data needs depend on the nature and significance of the change.

You must provide a clear and verifiable justification showing that the proposed changes do not affect the conclusions of the original safety assessment.

However, under Article 3(4) of Regulation (EU) 2017/2469, you may not need to submit the full dataset normally required where modifying:

- conditions of use
- product specifications
- specific labelling requirements
- post-market monitoring requirements

Products of animal origin

What are products of animal origin (POAO)?

Regulation (EC) 853/2004 sets out specific hygiene rules for food of animal origin. Annex I (8.1) states:

"'Products of animal origin' means:

- food of animal origin, including honey and blood; live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption; and other animals destined to be prepared with a view to being supplied live to the final consumer."

If a product is classified a product of animal origin (POAO), it must?comply with POAO regulations. This includes the Products of Animal Origin Regulations 2008 and related importing and exporting guidance.

Is my precision fermentation product classed as a product of animal origin (POAO)?

Precision fermentation products where any animal-derived cells, tissue or material are introduced or involved at any stage of the process, fall within the definition of products of animal origin (POAO), as set out in Annex 1 to Regulation (EC) 853/2004 which establishes specific hygiene rules for food of animal origin.

For example, where the starting material includes animal-derived cells (such as bovine-derived cells), the resulting precision fermentation product is considered to derive from animal cells. This is because the production process uses ingredients that originate from a cell, or cells, taken from animals.

This classification applies solely for the purposes of Regulation (EC) 853/2004 and the associated hygiene requirements. It does not predetermine how the product is classified under other areas of food law.

If the genetic instructions used to program the microorganisms are obtained digitally, rather than directly from animal tissue or cells, and the DNA used in the production was synthesised rather than extracted from an animal source, the microorganisms are not considered to originate from animals. In such cases, the process falls outside the scope of POAO for the purposes of Regulation (EC) No 853/2004.

How can I demonstrate that my precision fermentation product is not a product of animal origin (POAO)?

You must provide evidence that the genetic instructions used to program the microorganisms come from recognised public genetic sequence databases rather than from direct animal tissue.

When instructions are sourced digitally, the microbes are not considered to originate from animals, and the process falls outside products of animal origin scope.

Read UK safety guidance on precision fermentation products to find out more about determining POAO status.

Genetically modified (GM) food authorisation

What governs genetically modified food and feed authorisations in Great Britain?

Before any genetically modified (GM) food or feed can be placed on the market in Great Britain, it must be authorised in accordance with Regulation (EC) No 1829/2003 on genetically modified food and feed.

Key provisions include:

- Article 4 – general requirements for GM food and feed
- Article 5 – applications for authorisation
- Article 6 – scientific assessment and opinion
- Article 7 – granting of authorisation

When is a precision fermentation product classified as genetically modified food?

If the final food product contains recombinant DNA or viable micro-organisms, it is classified as a genetically modified (GM) food and must be authorised under the GM regulatory framework.

GM products are separated into four categories for risk assessment purposes. Each category has specific requirements on what the end product will contain and how this should be approached by risk assessors.

More information on these categories can be found in the European Food Safety Authority (EFSA) technical guidance on genetically modified microorganisms products.

Can a product be authorised as both a novel food and a genetically modified food?

No. A product cannot be authorised as both a novel food and a genetically modified food.

Can a product be both genetically modified and another regulated product type?

Yes. A product may fall into another category (such as food additive, flavouring or enzyme) and also be genetically modified (GM). In such cases, it may require authorisation under both:

- the relevant sectoral regime
- the GM framework

When might a modification be required for an already-authorised genetically modified ingredient?

If a product contains or is produced from an already-authorised genetically modified (GM) ingredient but the proposed use differs (for example, new food category or altered conditions of use), a modification may be required. Article 10 covers modification, suspension or revocation of authorisations.

See Regulation (EC) No 1829/2003 on GM food and feed.

What guidance applies to genetically modified application dossiers in Great Britain?

The European Food Safety Authority (EFSA) has developed technical guidance describing data and information required for genetically modified organism dossiers. This remains relevant for Great Britain (GB) submissions because GB scientific assessment standards are based on established EU approaches.

Follow the sections of the EFSA's guidance about dossier development and content. Do not follow sections describing the EU application procedure.

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