

# **Cell-cultivated products**

Guidance for businesses on cell-cultivated products and the authorisation process.

## What is a cell-cultivated product?

Cell-cultivated products cover a variety of foods that can be made using a production process without slaughter or traditional farming and agricultural practices. Cells isolated from animals or plants, including cells from meat, seafood, fat and offal, or eggs, are grown in a controlled environment, and then harvested to make a final food product.

**FSA Explains** 

#### Are cell-cultivated products the same as lab-grown meat?

Cell-cultivated products produced from animal cells are sometimes referred to as lab-grown meat (other names include cultured, cultivated, cell-cultured or cell-based). According to the <u>definition</u> of meat and products of animal origin included in Annex 1 of assimilated Regulation (EU) <u>853/2004</u>, however, cell-cultivated products are not defined as meat. Instead, they are considered to be products of animal origin.

# Cell-cultivated products status in Great Britain (GB)

Cell-cultivated products must be authorised before they can be placed on the market in GB. This is to ensure they have been through a rigorous and independent safety assessment. Because of the variety of products and complex production techniques involved, different regulations may apply to the process of their authorisation. They will also need to comply with all the regulations applicable to all food on the market, such as hygiene rules or general food law.

#### Northern Ireland

In Northern Ireland, novel foods and processes, including cell-cultivated products, must undergo a safety assessment and authorisation before being placed on the market. Businesses seeking to place their products on the NI market should follow EU rules and the European Commission's authorisation process. For guidance on starting this process, visit? Novel food applications: regulations and guidance page on?the EFSA?website.

Under Windsor Framework arrangements, regulated products (including cell cultivated products) authorised in GB may be placed on the Northern Ireland market if eligible for, and moved through, the Northern Ireland Retail Movement Scheme (NIRMS).

# Applying for authorisation

To place your cell-cultivated product on the GB market you must apply for authorisation using our <u>regulated product application service</u>. You must ensure that you choose the correct regulatory route for the assessment of your product.

Considering the methods that are used to create cell-cultivated products, we anticipate that most applications will be assessed under the <u>novel food regulations</u>. Novel food regulations apply to foods with no history of consumption in the United Kingdom (UK) or the European Union (EU) before 15 May 1997.

In some cases, applications may be assessed under the <u>Genetically Modified Organism (GMO)</u> <u>regulations</u>. If genetic modification has taken place during the process, please contact us to discuss your application. You can apply for both pre- and post-submission support through our cell-cultivated products <u>Business Support Service</u>.

#### Applying for authorisation under the novel food regulations

Applications for authorisation of cell-cultivated products are required for products considered a novel food under novel food regulations (assimilated Regulation (EU) 2015/2283).

Read our <u>Novel foods authorisation guidance</u> to find out how to apply for authorisation of your product as a novel food.

You can check the products already authorised for the use in Great Britain in our <u>register of novel</u> food authorisations.

## Cell-cultivated products supplementary guidance

Through the <u>cell-cultivated products sandbox programme (Feb 2025- Feb 2027)</u>, we are producing supplementary technical guidance on a range of topics relevant to these products. This supplementary guidance will help companies apply existing food regulations to these new products and assist them in completing their regulated product applications.

# Regulatory guidance: cell-cultivated products: classification and HACCP principles

This guidance will help businesses understand and correctly apply the requirements of hygiene regulations when producing cell-cultivated products. Further guidance expanding on additional hygiene-related topics will be developed and published through the course of the <a href="Sandbox">Sandbox</a> programme.

<u>This guidance</u> should be used by those developing cell-cultivated products produced using animal cells. These are products of animal origin, so businesses must apply existing food safety regulations during the production process. It contains references to relevant legislation that applies and what it means for food businesses.

Further guidance expanding on additional hygiene-related topics will be developed and published through the course of the programme.

# Technical guidance: supplementary guidance to applicants for assessment of Cell Cultivated Products (CCP) in food: Allergenicity and Nutrition

This guidance should be used to support the development of cell cultivated product dossiers supporting applications for novel food authorisation. This tailored guidance should be read in addition to the detailed guidance and application requirements are set out in <a href="mailto:assimilated?">assimilated?</a>
<a href="mailto:Regulation">Regulation (EC) 2017/2469</a>?and guidance previously developed by?EFSA. The?2016 EFSA? guidance?remains relevant as our approach to dossier assessment is based on EU processes. You should follow the parts that relate to the development of dossiers only and not the application process:?

• EFSA guidance on the preparation and presentation of an application for authorisation of a novel food?

These guidance documents should be used to support prospective cell-cultivated product companies in the development of novel food dossiers, identifying key safety hazards that should be considered in their risk assessment, and providing an overview of the data requirements to demonstrate that these have been effectively mitigated.

This guidance may be further developed as the techniques and technologies of cell-cultivated product production are further refined.

<u>This guidance</u> is the first piece of supplemental technical guidance for CCPs to have been published by the Sandbox programme. Future guidance on the topics of cell identity, production, microbiology, toxicology and growth media composition is underway and will be published through 2026.

# Applying for authorisation under the genetic modification regulations

GMO regulations specifically apply to the modification of an organism's genetic material (DNA) in a way that does not occur naturally by mating and/or natural recombination. These regulations are designed to ensure the food is safe for human consumption.

Read our <u>Genetically modified organisms authorisation guidance</u> to find out how to apply for authorisation of your product as a GM food.

You can check the list of GMOs authorised for import and use in food and feed in GB in our register of authorised GMOs.

#### Data protection

You may request that any confidential data supporting your application is not used without your permission by other businesses for five years from the date of authorisation.

## **Product safety**

All regulated products, no matter which regulations they fall under, undergo rigorous safety assessments.

All food businesses must comply with food safety law. With some exceptions, it applies to all stages of production, processing, and distribution of food and feed.

To place safe food on the market you must:

- · ensure traceability of food
- present food appropriately

- provide suitable food information
- withdraw or recall unsafe food
- ensure food and feed imported into, and exported from, GB comply with food law

You can find more information in our Managing food safety guide.

The main aim of <u>assimilated Regulation (EU) 178/2002</u>, also referred to as 'general food law', is to protect human health and consumers' interests in relation to food.

# Labelling

You must provide certain information with food products placed on the market to comply with the labelling rules. This includes products' ingredients, including allergens, and their durability (a use-by or a best-before date). You can find specific labelling requirements in our <u>Packaging and labelling guidance</u>.

We reserve the right under Article 9 of the novel food regulations to require additional specific labelling requirements if we consider it to be in the consumers' best interests.

If a product is assessed under the GMO regime, it will be labelled as 'genetically modified'.

The <u>assimilated Regulation (EU) 1169/2011</u> on the provision of food information to consumers brings together rules on general food labelling and nutrition labelling into one piece of legislation.

# Research on cell-cultivated products

We set high standards of food safety. Our research demonstrates our commitment to identifying how best to regulate new and innovative food production methods.

 Hazard identification: Identification of hazards in meat products manufactured from cultured animal cells

In March 2023, the FSA and FSS commissioned a report to identify the hazards associated with cell-cultivated products production processes. The purpose was to inform our risk assessment process for authorising these products.

Alternative proteins for human consumption

This report is a synthesis of desk research, based on thorough review of the academic and non-academic literature and of the alternative proteins start-up scene. It presents an analysis of the emerging market for alternative proteins, the potential implications and the potential policy responses that the FSA might need to consider.

• 3D printing technologies in the food system for food production and packaging

An evidence review was also undertaken in 2025 to examine consumer responses to cellcultivated products (meat, seafood, dairy and plants)

Rapid review on consumer responses to cell cultivated products

A 2025 report on best practice for cell banking techniques used in cell-cultivated products

Best Practice for Cell Banking Techniques Used in Cell-Cultivated Products

A 2025 report regarding microbial safety issues in meat and how these apply to cell-cultivated products

• How Do Microbial Safety Issues Associated With Meat Apply to Cell Cultivated Products?

#### **FAO and WHO report**

Food safety aspects of cell-based food

In April 2023, the Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organisation (WHO) released a report which compiles and evaluates all evidence to date on food safety in cell-cultivated products.

## **Novel food tasting trials**

Tasting trials of unauthorised novel foods may be permitted if the intention behind them is to conduct research to develop the novel food. The FSA recommends, as best practice, that taste trials are guided by advice published by the Advisory Committee on Novel Foods and Processes (ACNFP). Companies may communicate the fact they have conducted a taste trial through media activity where such publicity is ancillary to the main purpose of the trial as research and development.

If the intention of a tasting trial is to publicise a product or a company brand, then the tasting may amount to the unlawful placing on the market of an unauthorised novel food.

If you conduct a taste trial in the UK, you should refer to the recently updated <u>novel food taste trial guidance</u> to ensure the trial does not amount to an unlawful placing on the market of an unauthorised novel food.

## **Cell-Cultivated Products Sandbox Programme**

The Food Standards Agency (FSA), alongside FSS, have been awarded £1.6 million by the Department for Science, Innovation and Technology to better understand how cell-cultivated products are made and make an informed assessment of their safety. This research is part of a bigger programme sometimes referred to as a 'regulatory sandbox'. The sandbox is a dialogue programme where the FSA and FSS will work with industry, academic bodies, and other experts to gather knowledge about these products to inform our regulatory approach. This programme began in February 2025 and will run until February 2027.

We will explore the risks and hazards, how they can be managed, and what tests companies need to carry out to ensure their safety. We will also use this knowledge to decide how existing legislation applies to these innovative products. Insight from industry will be an important part of this process, helping us understand practical realities and technical approaches. Alongside this, we will draw on other sources of evidence such as scientific research, regulatory expertise and consumer perspectives. We will use the learning from all these sources to produce clear guidance for companies wishing to sell these new foods in Great Britain about how to produce safe food, what data to include in their applications to the FSA and FSS, and how existing food regulation will apply to these products.

Current sandbox participants are outlined below (please note, some changes have occurred to the participant lists since the sandbox was launched in March 2025 due to company changes):

Companies:

- BlueNalu
- Gourmey
- Hoxton Farms
- Mosa Meat
- Roslin Technologies
- Vital Meat
- Vow

#### Academic organisations:

- National Alternative Protein Innovation Centre (NAPIC)
- Cellular Agriculture Manufacturing Hub (CARMA)
- Bezos Centre for Sustainable Protein at Imperial

#### Industry bodies:

- Alternative Proteins Association (APA)
- Good Food Institute (GFI)

## Workshop summaries

As part of the Cell-Cultivated Products (CCP) Sandbox programme, we are running monthly workshops with industry participants, each one covering a certain area of production. Workshop summaries highlighting the key topics, challenges, and opportunities discussed during each session are published regularly. In conjunction with GFI Europe, we will be hosting regular webinars to share learnings from the programme with wider industry.

## **Business Support Service**

As part of the sandbox programme, we have launched a cell-cultivated products <u>Business</u> <u>Support Service</u> that is designed to support companies wishing to submit applications for cell-cultivated products to the GB market authorisation service. It supports the applicant throughout the life of the application, offering both pre- and post-submission support.

## **Getting help**

This advice is for guidance purposes and is not definitive.

If you have any questions on the application process, please contact the Regulated Products Team: <a href="mailto:regulatedproducts@food.gov.uk">regulatedproducts@food.gov.uk</a>

If you have any questions on CCPs more generally, please contact the CCP Sandbox team ccpsandbox@food.gov.uk

#### **Disclaimer**

This web page is intended for information purposes only. It does not guarantee your product will be assessed under a particular regulatory route. We reserve the right to make that decision. Please contact us for further advice.