# **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.

# 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.

#### 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 register of novel food authorisations.

#### 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 useby or a best-before date). You can find specific labelling requirements in our <u>Packaging and</u> labelling guidance.

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 nonacademic 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

#### 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 are permitted if the intention behind them is to conduct research to develop the novel food. The FSA recommends taste trials are guided by <u>advice</u> <u>published by the Advisory Committee on Novel Foods and Processes (ACNFP)</u>. 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.

The ACNFP guidance is still accurate, but the contact details on the page are now out of date. If you have any questions about this guidance, please contact <a href="mailto:novelfoods@food.gov.uk">novelfoods@food.gov.uk</a>

### **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: regulatedproducts@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.