UK safety guidance on precision fermentation products

The Food Standards Agency, in partnership with Food Standards Scotland, has published the UK's first safety guidance for precision fermentation products.

Precision fermentation definition

Precision fermentation (PF) is a specialised form of fermentation that uses single-celled prokaryotic or eukaryotic microorganisms grown in a controlled environment. It uses biotechnological methods to cultivate selected or modified microorganisms (such as bacteria, yeast, or other microbes) to produce specific target molecules, including proteins, lipids, and vitamins.

Unlike traditional fermentation, which relies on natural microbial processes to generate broad metabolic products, precision fermentation is designed to produce high purity, well defined compounds. This is often achieved through the use of engineered microbial strains and advanced biotechnology.

After fermentation, the resulting ingredient is extracted and purified from the fermentation broth ensuring that no live production organisms remain in the final food product.

Precision fermentation product definition

Precision fermentation products are food or food ingredients containing components such as proteins, sugars, carbohydrates, vitamins and/or fats, produced by precision fermentation. Following fermentation, the desired product is separated from the fermentation broth and purified before being incorporated into food.

For the purposes of Regulation (EC) 853/2004 PF products where any animal-derived cells, tissue or material are introduced or involved at any stage of the process, are defined as products of animal origin (POAO). In such cases, businesses must apply existing food safety regulations during the production process.

This guidance has been developed using a robust, science-based framework and is one of the outputs of the Food Standard Agency (FSA) and Food Standard Scotland's (FSS) Innovation Research Programme, funded by the Department of Science and Technology (DSIT).

This new approach to regulation enables food regulators to support innovation by providing early clarity of regulatory expectations and on how business can demonstrate that their products are safe.

This approach is intended to **increase business confidence**, improve regulatory efficiency, and support the responsible growth of innovative food technologies, including precision fermentation.

Precision fermentation products: guidance on classification and HACCP principles

Introduction

This guidance has been developed to support businesses in understanding and correctly applying the requirements of the hygiene legislation when producing PF products.

It signposts the relevant legislation, explains how it applies in practice, and clarifies the responsibilities of food business operators.

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

Intended audience

This guidance is intended for all parties involved in the production of PF products for human consumption.

This guidance applies to businesses based in:

- England and Wales, where the FSA is the food safety authority
- Scotland, where FSS is the food safety authority

Legal status of guidance

This guidance is not law. It has been produced to provide guidance on the legal requirements of production of PF products and should be read together with the relevant legislation.

This guidance cannot cover every situation, and you will need to consider the relevant legislation itself to see how it applies in your circumstances.

While compliance with the law is mandatory, operators are not obliged to follow the advice in this guidance, as other ways of achieving compliance with the law may be equally valid.

Classification of precision fermentation products

It is the current position of both the FSA and FSS that PF 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 PF 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.

Information that can help determine POAO status for precision fermentation products

Information that can help determine whether a product would be considered to originate from animals for the purposes of Regulation (EC) 853/2004, are:

- Whether the genetic instructions used to engineer microorganisms are sourced from public genetic sequence databases, and are not obtained directly from animal tissue, cells or material; and
- Whether the DNA used in the production was synthesised, rather than extracted from an animal source.

This information can help indicate whether the genetic material used in the process originates from an animal source or not.

Examples of publicly available databases include:

- GenBank
- EMBL's European Bioinformatics Institute

Important note

This position reflects the current position of the FSA and FSS. It does not constitute statutory law. Given the rapid pace of technological development in this sector, this guidance may be reviewed and updated as further regulatory clarity or legislative change emerges.

We may use automated tools, including AI, to assist with drafting or processing information. All publications are reviewed by a human before publication or decision?making.