Technical production methods of precision fermented foods: identification and characterisation of hazards

An overview of findings from a series of expert elicitation events on assessing novel food products made using precision fermentation of microorganisms.

Purpose and context

A series of four expert meetings was held to gather clear, practical advice for assessing novel food products made using precision fermentation of microorganisms. The aim of this advice is to make the approval process more consistent, faster, and easier to navigate, while protecting consumer safety and nutritional value. These events brought together specialist scientists and regulatory assessors to understand what “good evidence” looks like for areas that applicants often find challenging, and to identify recommendations.

Rationale for the events

Expert knowledge elicitation is an effective way to capture specialist judgement and ground decisions in expertise. The events focused on reaching consensus in three areas that most often create uncertainty:

- bioinformatics (computer-based checks of genetic information)
- digestibility assays (laboratory tests that mimic digestion to judge protein quality and allergy risk)
- a case study on a real application for beta-lactoglobulin (a milk protein made by precision fermentation)

Together, these topics cover key areas listed in the novel foods guidance, including:

- identity and purity
- potential hazards
- nutritional value
- how a product behaves during processing and storage

These issues determine whether a product is safe and fit for purpose.

Themes and discussion

For products where microbes are engineered to produce a purified ingredient, the focus should be on hazards that could survive manufacturing and purification, such as:

- traces that might trigger allergies
- bacteria-derived toxins

- genes linked to resistance to antibiotics

When the whole microbe (or most of it) is the product, correct identification of the species and proof that it has been made safe are critical.

In both cases, carefully reading the organism’s DNA, ideally through whole genome sequencing (WGS), was seen as the most reliable way to check identity and look for any warning signs. Computer predictions should be treated as a guide and must be backed by sensible laboratory evidence.

Digestion assay

This meeting focused on when and how to test proteins for how well the body can use them and how quickly they are broken down during digestion. Experts agreed that such tests are important where the product will meaningfully contribute to people’s protein intake, for example in dairy, egg or meat alternatives, or when a microbial biomass is marketed as a protein source.

For products used at very low levels purely for technical reasons, these tests are usually unnecessary.

Where tests are needed, a recognised laboratory method that simulates digestion should be used, with appropriate controls and careful documentation so results are trustworthy and repeatable.

Beta-lactoglobulin case study

The case study looked at a precision fermented version of beta-lactoglobulin, a major milk protein. This allowed the group to explore how to judge the following in a joined up way:

- allergenicity
- digestibility
- genetic and molecular safety
- composition and contaminants
- nutritional implications
- shelf life stability

The discussion stressed practical judgement over box-ticking, and the importance of backing up claims with scientifically validated data.

What we learned

Evidence should be proportionate

Not every product needs the same depth of evidence, but the evidence supplied must be the right kind and clearly explained.

For products made with engineered microbes to produce purified ingredients, the most important elements are:

- DNA-based identification of the production strain
- checks for genes or features that could indicate hazards
- evidence that manufacturing removes unwanted residues

For products where the microbe itself is consumed, correct naming, thorough safety processing, and checks for antibiotic resistance genes are essential, particularly if the processing is light and residues or DNA are more likely to remain.

Bioinformatics supports but does not replace laboratory work

Bioinformatics is a powerful tool, but not sufficient on its own. Reading and analysing the full genetic code helps find potential issues and confirm identity, but laboratory work is needed to confirm what is actually present in the final ingredient.

Digestion testing should reflect how the food will be used

If a protein is intended as a meaningful source of nutrition, then validated in-vitro digestion tests should be run on the ingredient as sold, with suitable reference proteins included in each run to ensure the numbers make sense.

Animal studies were rarely considered necessary, and only useful where in-vitro methods cannot address a specific, well-defined question.

Allergenicity assessment requires a realistic view of exposure

Risk depends on what people actually eat at a sitting and the level of the protein in that food, not on abstract dose calculations. Proteins that stay intact for longer in the stomach can raise concern, whereas those that are quickly broken down tend to be less problematic.

For the case study protein, understanding how processing affects its structure and digestibility was central to judging its allergy risk and whether further testing would be proportionate.

Inactivation and shelf life evidence often needs strengthening

Reliable kill-step validation should include:

- starting microbial counts
- clear time and temperature conditions
- measurable reductions
- checks across multiple batches

Shelf life claims should be supported by representative studies with repeated measurements, clear trends and appropriate statistics, particularly where safety, nutrition or key functional properties could change over time.

How this will improve the process

The events have mapped out a clearer, more predictable path for applicants and assessors. FSA and Food Standards Scotland (FSS) assessors will compile the lessons learned into an advice and recommendations document that will help inform applications.

For assessors, the discussions provided a consistent basis for judging sufficiency and proportionality.

The expected result is shorter review times, fewer rounds of questions, and decisions that are transparently grounded in science the public can understand.

Just as importantly, the agreed approach asks applicants to explain what they did, why it was suitable for the organism and product, and how the results support safety and nutritional

adequacy. This flexibility allows the system to keep pace with precision fermentation technological advances, based in scientific evidence, and advocating fairness and proportionality in the exercise of protecting consumers.

Read the technical production methods of precision fermented foods: identification and characterisation of hazards report in full for more information.