Lay summary of the expert elicitation events assessing novel foods using precision fermentation

A summary of meeting discussions 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 safeguarding consumer safety and nutritional value.

We brought together specialist scientists and regulatory assessors to understand what 'good evidence' looks like for areas that applicants find recurrently challenging, and to identify proportionate recommendations.

Rationale for the events

Expert knowledge elicitation is an effective methodology for capturing the best available judgement, ensuring decisions are grounded in specialist understanding. These expert elicitation events were designed to draw out consensus on 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 are issues that determine whether a product is both safe and fit for purpose.

Themes and discussion

In the bioinformatics discussions, experts agreed that expectations should match the type of product. When microbes are engineered to produce a purified ingredient, the focus should be on

any hazards that could survive the manufacturing and purification steps, 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, reading the organism's DNA in depth, ideally through whole genome sequencing (WGS), was seen as the most reliable way to check identity and look for any warning signs. This was with the understanding that computer predictions are a guide and must be backed by sensible laboratory evidence.

The digestion assay 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.

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 allergenicity, digestibility, genetic and molecular safety, composition and contaminants, nutritional implications, and shelf life stability in a joined up way.

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

What was learned

Proportionality should guide both applicants and assessors.

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 greatest value comes from solid DNA based identification of the production strain, sensible checks for genes and features that could point to hazards, and proof 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. This is particularly true if the processing is light and residues or DNA are more likely to remain.

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 be clearly linked to 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.

Assessing allergenicity demands 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 alone.

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.

Other parts of dossiers, such as proof that microbes are inactivated and that products remain stable over shelf life, often need strengthening. Reliable 'kill step' validation includes:

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

Shelf life claims should be backed 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 FSS assessors will create an advice and recommendations document using the lessons learned. This document will help inform applications. For assessors, the discussions provide a consistent basis for judging sufficiency and proportionality. The expected result is:

- shorter review times
- fewer rounds of questions
- decisions that are transparently grounded in science the public can understand

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 up with precision fermentation technological advances, based in scientific evidence and advocating fairness and proportionality at the same time as protecting consumers.