

Animal-Free, Not Allergen-Free

Precision-Fermented Dairy Proteins Expose a Regulatory Blind Spot Between Molecular Identity, Allergen Labelling and Consumer Meaning

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October 2026

SEO Slug: *precision-fermentation-dairy-allergen-labelling-hidden-allergen*

Meta Description: *Precision-fermented dairy can be animal-free yet still allergenic. EU and UK rules expose a new gap between molecular identity, labels and consumer meaning.*

Internal Tags: *Precision Fermentation; Allergens; Beta-Lactoglobulin; Novel Foods; Food Labelling; Biotechnology; Regulatory Affairs; Food Safety*

Abstract

Precision fermentation can produce bovine milk proteins without a cow, but it cannot remove the biological allergenicity of the proteins themselves. That distinction is becoming a regulatory problem. In September 2026, Safe Food Advocacy Europe asked the European Commission to clarify how EU allergen-labelling rules should apply to precision-fermented dairy proteins when Regulation (EU) No 1169/2011 requires prominent communication of milk allergens while Regulation (EU) No 1308/2013 reserves dairy designations such as “milk” for products derived from mammary secretion. The United Kingdom has taken a more explicit position: existing allergen rules apply fully to precision-fermented foods, and regulators have warned that β -lactoglobulin may become a hidden allergen in categories where consumers do not expect milk protein. This article argues that the problem is deeper than wording. Precision fermentation separates biological identity from agricultural origin, forcing regulators to decide whether allergen communication should follow source, sequence, immunological cross-reactivity, manufacturing route or consumer expectation. A function-based allergen ontology may ultimately be needed.

Keywords: precision fermentation; beta-lactoglobulin; food allergy; allergen labelling; novel foods; recombinant proteins; food law; biotechnology

1. A New Food Can Carry an Old Allergen

Precision fermentation has created an unusual regulatory object: a protein that can be produced without the animal traditionally associated with it while remaining, at the molecular and immunological level, recognisable as that animal protein.

β -Lactoglobulin (BLG) is the clearest example. It is a major whey protein in bovine milk and an important milk allergen. Precision fermentation can instruct a genetically modified microorganism to produce BLG, after which the target protein is recovered and purified from the fermentation system.

The resulting ingredient may be lactose-free. It may be manufactured without cows. It may fit commercial narratives such as “animal-free”. None of those propositions means that it is safe for a person with clinically relevant cow’s-milk allergy.

This distinction is no longer theoretical. In June 2026, the UK Food Standards Agency explicitly warned that precision-fermented dairy alternatives can contain proteins such as BLG and that consumers may not expect an “animal-free” or dairy-alternative product to contain a potent milk allergen. In September, Safe Food Advocacy Europe asked the European Commission’s Directorate-General for Health and Food Safety to clarify how EU allergen rules should work for precision-fermented dairy proteins.

The emerging problem is therefore not whether precision fermentation can make dairy proteins. It can. The problem is whether food law, product naming, allergen communication and consumer mental models are ready for proteins whose biological identity and agricultural origin have been decoupled.

2. The Scientific Point Must Come First: Allergenicity Follows the Protein, Not the Cow

Food allergy is an immunological phenomenon, not a farming classification.

If a precision-fermented protein reproduces the relevant amino-acid sequence and conformational or linear IgE-binding epitopes of a known allergen, the absence of the original animal does not automatically eliminate allergenic potential. Indeed, FDA’s response to GRAS Notice 863 for fermentation-derived BLG records the notifier’s conclusion that the protein sequence is identical to bovine BLG and that the ingredient would produce milk-protein allergy in milk-allergic individuals.

This is scientifically unsurprising. IgE antibodies recognise molecular structures. They do not inspect the agricultural biography of the molecule. The regulatory implication is profound: “animal-free” describes a production route. “Milk-allergen-free” describes a biological safety property. They are not synonyms.

A product can therefore be simultaneously:

- manufactured without animals;
- free from lactose;
- compositionally different from conventional milk;
- unsuitable for people with milk allergy.

Any communication architecture that allows consumers to collapse those four propositions into one creates foreseeable risk.

3. Why This Has Become a 2026 Regulatory Issue

The timing matters because precision-fermented proteins are moving closer to mainstream regulatory assessment.

The **United States** has already accumulated multiple GRAS notices for fermentation-derived BLG and other recombinant animal proteins. FDA’s GRAS inventory, updated in September 2026, lists several BLG

preparations produced using *Trichoderma reesei*, *Komagataella phaffii*, *Aspergillus oryzae* and *Kluyveromyces lactis*.

Great Britain is actively assessing application RP1571 for precision-fermented BLG. The Advisory Committee on Novel Foods and Processes reviewed the application again in September 2026 after several earlier rounds of questions. The assessment has examined identity, production, composition, specification, contaminants and allergenicity.

Europe has not yet reached the same commercial stage for major precision-fermented dairy proteins, but the regulatory question must be solved before market entry rather than after an allergic incident. The September 2026 intervention by Safe Food Advocacy Europe is therefore important not because it creates law, but because it identifies a genuine legal-interface problem before the category reaches scale.

4. The EU Legal Tension: “Milk” as an Allergen Versus “Milk” as a Market Designation

Two EU legal regimes approach the word “milk” for different purposes.

Regulation (EU) No 1169/2011 on food information to consumers lists “milk and products thereof (including lactose)” in Annex II among substances or products causing allergies or intolerances. Article 21 requires Annex II allergens used in the manufacture or preparation of a food and still present in the finished product to be indicated with clear emphasis in the ingredients list, subject to the Regulation’s detailed rules.

Regulation (EU) No 1308/2013, by contrast, protects dairy designations in the common organisation of agricultural markets. Its milk-and-milk-products provisions define “milk” as the normal mammary secretion obtained from milkings and reserve terms including whey, cream, butter, buttermilk, caseins, cheese and yogurt for qualifying milk products, subject to specified exceptions.

These regimes were designed for different policy objectives.

The FIC Regulation is concerned with safe and non-misleading consumer information, including allergen protection. The CMO Regulation protects agricultural product designations and prevents non-dairy products from presenting themselves as dairy products. Precision fermentation now places the same word at the intersection of those objectives.

A recombinant BLG may be immunologically a milk allergen while not being “milk” in the agricultural-origin sense used to reserve dairy designations. This does not necessarily mean that the two Regulations are legally irreconcilable. It means that their interaction was not drafted with this technological configuration clearly in view. The Commission may be able to resolve the issue through interpretation, implementing practice, novel-food conditions of use or future legislative amendment. But the need for explicit regulatory clarity is real.

5. A Critical Legal Nuance: The EU Answer Is Not Yet as Simple as “Write MILK”

It would be premature to state that current EU law has already produced a definitive, universally accepted labelling formula for precision-fermented BLG.

Annex II of Regulation 1169/2011 refers to “milk and products thereof”. A precision-fermented BLG molecule is biologically equivalent or highly comparable to a milk protein, but its production substrate is not mammary secretion. That creates an interpretive question: does the allergen category attach to the molecular allergen itself, to derivation from the listed source, or to both?

The public intervention by SAFE specifically asks the Commission to clarify this point. Until competent authorities establish a definitive interpretation, companies should not treat the absence of explicit wording for precision fermentation as permission to minimise allergen communication.

The opposite precaution is more defensible: assume that a known allergenic protein must be communicated in a manner that protects allergic consumers, while obtaining jurisdiction-specific advice on the legally correct terminology.

This is a case where food-safety logic is clearer than labelling syntax.

6. Great Britain Has Been More Explicit

The UK Food Standards Agency published specific business guidance on 16 June 2026. Its position is direct: existing allergen-labelling rules apply fully to precision-fermented foods.

The FSA used dairy-alternative products containing precision-fermented BLG as its example. It warned that “animal-free” can be conflated by consumers with “plant-based” or “dairy-free”, potentially exposing milk-allergic consumers to risk. That guidance is especially important because it treats marketing architecture as part of allergen risk.

A technically correct ingredients list may not be enough if the front-of-pack presentation creates a strong contrary expectation. This is a crucial regulatory principle for emerging foods: compliance cannot be assessed only at the level of isolated words. The total presentation matters. A product described prominently as “animal-free dairy alternative” can create a different consumer expectation from a conventional protein supplement, even if both contain the same BLG.

The more surprising the allergen is in the product category, the stronger the case for conspicuous risk communication.

7. The UK BLG Assessment Reveals the Hidden-Allergen Problem in Practice

The April 2026 ACNFP minutes for RP1571 are unusually informative.

The Committee noted that the novel food consisted predominantly of BLG but also contained fungal proteins derived from the genetically modified production organism. It requested that identity and specification information accurately reflect that composition. The Committee also considered inorganic arsenic contamination traced to a filtration aid, demonstrating that precision-fermentation safety assessment extends beyond the target protein to the manufacturing system.

Most importantly for this article, ACNFP concluded that the applicant had not fully resolved concerns regarding milk-allergic consumers. The Committee noted a potentially elevated risk of serious reactions because acute BLG exposure from the novel food could exceed exposure from the same amount of milk powder in some proposed food categories. It also identified the possibility of a “hidden food allergen” when BLG is used in categories where milk is not normally expected.

This is a decisive conceptual point. The safety problem is not only whether BLG is allergenic. That is established. The risk is the interaction between allergen potency, dose, food category and consumer expectation.

8. Dose Matters: Molecular Identity Is Not the Whole Risk Assessment

Two products can contain the same allergenic protein and present different practical risks. Risk depends on exposure.

Precision fermentation may permit manufacturers to formulate highly concentrated protein systems. A food containing purified BLG can deliver a different acute dose from conventional milk, milk powder or whey-containing foods.

For an allergic consumer, that difference can matter clinically.

Consequently, allergen assessment for precision-fermented proteins should not stop at sequence identity or IgE-binding potential. It should consider:

- concentration of the allergenic protein;
- serving size;
- foreseeable consumption pattern;
- food categories in which the protein will appear;
- whether consumers normally expect the allergen in those categories;
- possible cross-contact and manufacturing controls;
- the clarity and prominence of allergen communication.

This suggests that future authorisations may need to treat allergen risk partly as a condition-of-use question rather than solely as an intrinsic property of the ingredient.

9. The Production Organism Creates a Second Allergen Layer

Precision fermentation can create two conceptually different allergen questions.

The first concerns the target protein: for example, recombinant bovine BLG.

The second concerns residual proteins from the production microorganism. The UK ACNFP identified fungal proteins in the BLG preparation and considered the risk to consumers with clinically relevant fungal allergy to be low, but the finding is important. A highly purified recombinant protein is still produced within a biological manufacturing system, and residual host-cell proteins can form part of the final compositional profile.

The FSA's 2026 technical review of precision-fermentation production methods identifies host-cell remnants, contaminants, genetically modified microorganism-related hazards, allergenicity and unintended biological activity among the relevant risk clusters. This means that “the target molecule is known” does not complete the safety assessment. Manufacturing identity matters.

10. The United States: Commercial Precedent, but Not a Universal Template

The United States offers the most developed commercial precedent.

FDA has issued “no questions” letters for multiple GRAS notices involving fermentation-derived BLG. GRN 863, closed in March 2020, is especially instructive. FDA's response records that the notifier considered the fermentation-derived protein identical in sequence to bovine BLG and recognised that milk-allergic individuals would be expected to react. FDA also highlighted allergen labelling obligations under the Federal Food, Drug, and Cosmetic Act.

More broadly, FDA's current allergen guidance treats milk as a major food allergen and requires appropriate declaration in FDA-regulated foods. The US framework should not, however, be mechanically exported to Europe or Great Britain. GRAS status addresses safety under intended conditions of use; it does not create an EU novel-food authorisation, nor does a US labelling solution automatically satisfy European rules.

The important comparative lesson is narrower: regulators can accept fermentation-derived proteins as food ingredients while still treating their allergenic identity as biologically continuous with the conventional protein.

11. “Animal-Free” Is a Production Claim, Not a Safety Claim

The phrase “animal-free” is commercially attractive because it communicates a production distinction in two words.

It is also semantically dangerous. Consumers can interpret “animal-free” as:

- no animal was used in production;
- no animal-derived molecule is present;
- equivalent to plant-based;
- dairy-free;
- suitable for vegans;
- safe for milk-allergic consumers.

Those interpretations are not equivalent. FSA consumer research has found that awareness of precision fermentation remains low. In February 2026, only 20% of surveyed UK respondents had heard of precision fermentation and 15% had heard of precision-fermented dairy. FSA’s evidence review also found that consumers without prior knowledge can associate “animal-free” or “non-animal” terminology with plant-based products. This is precisely the environment in which technically true marketing can become practically misleading.

A statement can be factually correct in isolation and still produce a dangerous overall impression.

12. Vegan, Dairy-Free, Lactose-Free and Milk-Allergen-Free Must Be Separated

Precision-fermented dairy proteins force the food industry to disentangle four labels that consumers often treat as overlapping.

Lactose-free concerns the carbohydrate lactose.

Milk-allergen-free concerns allergenic milk proteins.

Dairy-free is a market-facing term whose legal meaning and consumer interpretation can vary by jurisdiction and context.

Vegan concerns avoidance of animal-derived products and, depending on the standard or certifier, may involve production-process considerations.

A precision-fermented BLG ingredient can be lactose-free while still being allergenic to a milk-allergic consumer. Whether it can legitimately be called vegan or dairy-free is not answered merely by toxicology. It depends on legal, certification, compositional and consumer-information frameworks. The operational rule for product developers should be simple: never infer one claim from another.

13. The Regulatory White Space Is Bigger Than Dairy

The same problem will recur with other recombinant food proteins. Precision-fermented ovalbumin can reproduce an egg allergen without a chicken egg. Recombinant lactoferrin (for instance) can reproduce a bovine protein without conventional dairy production.

Future technologies could produce seafood proteins, collagen-related proteins, enzymes or other molecules whose allergenic identity is historically associated with a biological source that is absent from the manufacturing chain. The regulatory system therefore needs a principle that scales. Source-based allergen lists were rational when the source and the allergenic molecule travelled together.

Precision fermentation separates them. The future question is whether allergen regulation should remain primarily source-based or evolve toward a hybrid model that recognises molecular identity and clinically demonstrated cross-reactivity.

14. Research & Innovation Opportunity

A Molecular Allergen Ontology for Precision-Fermented Foods

Unresolved problem. Existing allergen-labelling systems are largely organised around source foods: milk, egg, fish, crustaceans, peanuts, soy and others. Precision fermentation can reproduce individual allergenic proteins without the source food being physically present.

Why it matters. Source-only classification can become ambiguous when production origin and immunological identity diverge. At the same time, replacing familiar source words with molecular protein names could reduce consumer comprehension.

What is already known. Protein sequence, structure, IgE-binding data, clinical allergy history and food-source relationships are already used in allergenicity assessment. Bioinformatics is increasingly integrated into novel-food and biotechnology assessment.

What remains unknown. There is no broadly implemented regulatory ontology that links a precision-fermented target protein to the clinically relevant source allergen, expected cross-reactivity, concentration, food category and consumer-facing declaration.

Proposed hypothesis. A machine-readable allergen ontology could preserve the simplicity of source-based consumer warnings while allowing regulators and manufacturers to reason at molecular level.

A conceptual chain could be: **target protein → sequence/structure → known allergen family → clinical source category → cross-reactivity evidence → exposure level → required consumer warning.**

Validation pathway.

1. Build a curated reference set of major regulated food allergens and their clinically relevant proteins.
2. Map recombinant proteins to source allergens using sequence and structural evidence.
3. integrate serum IgE and clinical challenge evidence where available.
4. incorporate concentration and serving-size exposure.
5. test whether the ontology correctly classifies known conventional and precision-fermented ingredients.
6. validate consumer-facing terminology through comprehension studies in allergic and non-allergic populations.
7. establish governance for database updates, versioning and expert review.

Regulatory constraint. Such a system would support, not replace, statutory allergen lists. Any change in mandatory declarations would require action by competent legislators or authorities.

Industrial relevance. The ontology could support novel-food dossiers, formulation screening, supplier qualification, automated label checking and cross-jurisdictional compliance.

This is a proposed research architecture, not an established regulatory method.

15. A Second Opportunity: Allergen Exposure-by-Design

The next innovation step should go beyond identifying whether a protein is allergenic.

Product developers could model allergen exposure during formulation.

A digital tool could combine:

- allergen concentration in the ingredient;
- inclusion rate;
- serving size;
- target population;
- food category;

- likely co-consumption;
- processing effects;
- analytical verification;
- jurisdiction-specific labelling rules.

The output would not be a medical prediction of reaction severity. That would be scientifically unjustified without clinical data. Instead, it could flag formulations in which a known allergen appears at unusually high acute exposure or in an unexpected category. This is particularly relevant to purified recombinant proteins, because technological success can increase protein concentration far beyond the level consumers associate with the traditional source food.

16. Implications for Product Naming and Marketing

The marketing challenge should not be solved by banning useful descriptors reflexively. Consumers need to understand how the product was made. Terms such as “precision-fermented” or “animal-free” can convey meaningful information. But those terms should be subordinated to safety-critical communication.

A defensible label architecture for a future precision-fermented BLG product would need to achieve at least three goals:

1. explain the production concept without implying plant origin;
2. communicate clearly that the product contains a milk-allergenic protein;
3. avoid protected dairy designations where the law does not permit them.

This may require layered communication rather than one perfect term. Front-of-pack descriptors, ingredient names, allergen emphasis, explanatory statements and digital information can each perform different functions. The policy objective should be comprehension, not semantic purity.

17. Implications for Analytical Control

Allergen management also creates an analytical question.

Conventional milk-allergen methods were developed around conventional milk proteins in familiar matrices. Precision-fermented ingredients may contain a narrower protein profile: for example, abundant BLG without casein. An assay targeting casein would therefore be a poor proxy for a BLG-only precision-fermented ingredient.

The UK has already commissioned work examining methods for detecting allergens in novel alternative proteins. This area will become increasingly important as commercial products diversify. Analytical control should be matched to the actual recombinant protein, not merely to a generic “milk” test.

This is another example of the broader principle: molecular precision in manufacturing requires molecular precision in verification.

18. Practical Implications for Food and Biotechnology Companies

Companies developing or buying precision-fermented proteins should incorporate allergen strategy before formulation lock.

The minimum programme should include:

- exact molecular identity of the target protein;
- relationship to regulated and clinically relevant allergens;
- residual host-cell protein profile;
- validated allergen-detection methods;

- concentration and acute-exposure modelling;
- intended food-category analysis;
- consumer-expectation assessment;
- jurisdiction-specific labelling review;
- front-of-pack claim review;
- cross-contact controls;
- post-market complaint and adverse-event surveillance.

Supplier documentation should state explicitly whether an “animal-free” ingredient contains proteins that are known allergens from animal-derived foods. The absence of an animal raw material is not sufficient supplier information.

19. Implications for producers and other operators

For producers and the industry at large, the opportunity is not to attach itself prematurely to a fashionable protein category. It is to build competence at the interface between ingredient identity, biotechnology, allergen safety and regulatory communication. A useful internal framework would classify innovative proteins through five independent questions:

Molecular identity: What protein or protein family is actually present?

Manufacturing identity: Which organism, construct and downstream process produced it?

Immunological identity: Is the protein a known allergen or meaningfully cross-reactive with one?

Regulatory identity: How is it classified and authorised in each target jurisdiction?

Consumer identity: What will a reasonable consumer think the product is, based on the total presentation?

These five identities can diverge. Recognising that divergence early can prevent formulation, labelling and market-access failures later.

20. The Deeper Regulatory Lesson: Origin Is Losing Its Monopoly on Identity

Food law has historically classified many products through origin.

Milk came from mammals. Egg proteins came from eggs. Animal proteins came from animals.

Biotechnology is breaking that alignment.

A molecule can now have:

- one biological identity;
- another manufacturing origin;
- a third regulatory category;
- and a fourth consumer meaning.

This is not merely a precision-fermentation problem. Similar questions will arise with cell cultivation, molecular farming, engineered enzymes and increasingly sophisticated bioconversion. Regulatory systems will need to decide which identity matters for which purpose. For allergen safety, biological and immunological identity should carry substantial weight. For protected food names, agricultural origin may remain decisive. For novel-food authorisation, manufacturing process and compositional identity matter. For marketing, consumer understanding matters.

Trying to force all four questions into a single label word is unlikely to succeed.

21. Conclusions

Precision fermentation has created an apparently paradoxical food: a dairy protein that can be made without dairy farming and yet remain unsafe for a person with milk allergy. The paradox disappears once production origin and biological identity are separated.

The scientific principle is straightforward. Allergenicity follows molecular recognition and exposure, not the presence of a cow in the supply chain.

The regulatory problem is more difficult. EU allergen rules and protected dairy designations were developed for a food system in which source and molecule usually travelled together. Precision fermentation breaks that assumption. The United Kingdom has responded more explicitly by warning that existing allergen rules apply and that BLG may become a hidden allergen in unexpected food categories. In the EU, the September 2026 request for clarification shows that the interaction between allergen terminology and dairy-name protection deserves authoritative resolution.

The industry should not wait for perfect terminology before adopting good safety practice.

“Animal-free” must never be allowed to imply “allergen-free”. The more important long-term opportunity is to redesign allergen governance around a hybrid architecture: simple source-based warnings for consumers, supported underneath by molecular identity, exposure data, bioinformatics and clinically relevant cross-reactivity. Precision fermentation does not make allergen regulation obsolete. It makes it necessary to become more precise.

Related Knowledge Areas

- Food Safety — allergen exposure, analytical verification and hidden-allergen risk.
- Biotechnology — precision fermentation, recombinant proteins and host-cell residuals.
- Regulatory Affairs — novel foods, allergen labelling and protected dairy designations.
- AI & Food — molecular allergen ontologies, automated label checking and exposure modelling.
- Functional Ingredients — high-purity protein ingredients and formulation risk.
- Emerging Research — molecular identity as a future layer of allergen governance.

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