ORIGINAL RESEARCH & COMPARATIVE REGULATORY ANALYSIS

The Microbiome Ingredient Has Three Identities

Why taxonomy, product safety and functional efficacy cannot share one certificate in the 2026 regulatory landscape

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ABSTRACT

Three developments have sharpened the regulatory problem facing microbiome-derived ingredients: the US Food and Drug Administration's October 2026 final guidance on identity and safety information for new dietary ingredients; the European Union's 2026 amendment to the authorisation of pasteurised Akkermansia muciniphila; and EFSA's forthcoming scientific colloquium on microbiome regulatory science. Together they expose a persistent category error. Identifying a microbial species does not establish the safety of a particular strain or manufactured preparation, and demonstrating safety does not substantiate a claimed physiological benefit. This article distinguishes live organisms, inactivated microbial preparations, fermentation-derived molecules and complex consortia; examines the evidentiary limits of genomics, in-vitro assays and clinical biomarkers; and compares applicable food, supplement and feed regimes in the EU, Spain, Great Britain and the United States. It proposes a testable identity–safety–function evidence architecture, with explicit manufacturing change control, exposure assessment and prospective validation. The proposal is an industrial research framework, not an existing harmonised standard or a claim of invention.

KEYWORDS: *microbiome ingredients; Akkermansia muciniphila; postbiotics; novel foods; microbial safety; health claims; precision fermentation; regulatory science*

KNOWLEDGE CENTER CATEGORY: Biotechnology & Functional Ingredients / Regulatory Affairs

SEO SLUG: microbiome-ingredients-identity-safety-function-regulation-2026

META DESCRIPTION: Why microbiome ingredients need separate proof of identity, safety and function under 2026 EU, UK and US rules, with a practical research roadmap for industry.

INTERNAL TAGS: Microbiome; Novel Foods; Microbial Safety; Precision Fermentation; Regulatory Affairs; Animal Nutrition; Functional Ingredients; Emerging Research

01 | October 2026: three signals, not one new microbiome law

On 19 October 2026, the US Food and Drug Administration (FDA) announced final guidance addressing the identity and safety information expected in new dietary ingredient notifications. This was not a new general approval pathway for probiotics, nor did it convert supplements into pre-authorised products. It finalised specified sections of earlier draft guidance on identity, history of use or other evidence of safety, and the rationale for a safety conclusion. The statutory notification framework remains product- and use-dependent. [1,2]

In the European Union, Commission Implementing Regulation (EU) 2026/391 amended the conditions of use and specific labelling requirements for pasteurised Akkermansia muciniphila, a previously authorised novel food. In parallel, EFSA scheduled its 29th Scientific Colloquium, 'Decoding the Microbiome: From Knowledge Gaps to Actionable Regulatory Science', for 23–24 November 2026. The meeting will address both microbiome-mediated effects of chemicals and the assessment of biological or microbiome-based products. It is a future scientific event, not a completed assessment or new binding regulation. [3,8]

These developments converge on a fundamental industrial question: what, exactly, has been established when a supplier says that a microbial ingredient is identified, safe, beneficial or authorised? Each adjective belongs to a different evidentiary and legal proposition. Confusing them can lead to defective dossiers, misleading commercial claims and misplaced investment in analytical data that cannot answer the question being asked.

02 | The three identities of a microbiome ingredient

The first identity is biological: the taxon, strain, genetic lineage or microbial consortium actually used. Species-level identification may be insufficient where pathogenic traits, antimicrobial resistance, metabolic capabilities or production characteristics vary between strains. The second is product identity: what reaches the customer after cultivation, inactivation, extraction, purification, blending, drying and storage. The third is functional identity: the particular effect claimed at a specified dose, in a specified population or animal species, under defined conditions of use.

These identities can diverge sharply. A live strain with a given genome is not chemically identical to its heat-inactivated biomass. A purified fermentation-derived protein is not the production organism. A mixture of three strains is not necessarily equivalent to its components tested separately. A clinical effect observed for one preparation cannot be transferred to another by borrowing the species name. [4,12–14]

The analytical implication is to maintain three linked but distinct dossiers: an organism dossier, a manufactured-product safety dossier and a claim-specific efficacy dossier. Their separation does not multiply bureaucracy for its own sake; it prevents one favourable result from being used to answer a different question.

03 | A microbiome product is not necessarily a probiotic

The scientific vocabulary matters. A conventional probiotic is generally understood as a live microorganism that, when administered in adequate amounts, confers a health benefit on the host. A postbiotic, under the 2021 International Scientific Association of Probiotics and Prebiotics (ISAPP) consensus, is a preparation of inanimate microorganisms and/or their components that confers a health benefit on the host. The latter definition is scientific consensus terminology, not an automatic EU or US authorisation category. [12]

A fermentation-derived metabolite or purified protein should not be labelled a postbiotic merely because microbes produced it. The consensus definition does not make every purified metabolite a postbiotic. Likewise, 'precision fermentation' describes a manufacturing approach that can produce defined molecules; it does not tell us whether the final product contains viable organisms, qualifies as a novel food, or can support a health claim. [12–15]

This distinction is commercially material. Viable counts in colony-forming units (CFU) can be relevant for live microbial preparations but are inappropriate as a universal potency metric for inactivated cells. Conversely, total cell counts alone do not establish the potency of a postbiotic preparation. A purified ingredient may require compositional or activity-based specifications instead. The correct assay follows the product's actual mechanism and intended use, not a fashionable label.

04 | EFSA QPS: a safety shortcut with important limits

EFSA's Qualified Presumption of Safety (QPS) framework is a pre-assessment of taxonomic units, considering identity, accumulated knowledge and potential safety concerns. Qualifications can require strain-level demonstration, including the absence of acquired resistance genes to therapeutic antimicrobials. QPS may simplify parts of a sector-specific risk assessment; it is not itself a marketing authorisation, an efficacy opinion or a blanket guarantee for every strain and manufacturing process. [5,6]

The July 2026 BIOHAZ statement illustrates why the distinction matters. EFSA assessed notifications received through March 2026 and recommended certain taxonomic units for QPS while declining others because of safety concerns or insufficient knowledge. Among the organisms discussed, Listeria innocua was not recommended for QPS because of safety concerns; that is not equivalent to a universal prohibition of every possible use, but it demonstrates why a benign-sounding species name cannot substitute for a regulatory assessment. [5]

A particularly consequential qualification is 'for production purposes only'. It concerns situations in which experience with fermentation products does not justify direct exposure to viable production organisms. Evidence that viable cells are absent from the final product may therefore be decisive. The absence of viable cells, however, does not automatically prove that residual proteins, DNA, toxins or metabolites are irrelevant. [6]

05 | The 2025 EFSA guidance moves beyond the genome as a certificate

EFSA's November 2025 cross-cutting guidance on characterising microorganisms in the food chain specifies information on taxonomic identification, antimicrobial resistance, virulence and toxigenic potential, genetic modifications and the presence of viable cells, genetic material or substances of concern in products derived from microorganisms. It also recognises that potential impacts on the receiving microbiome may need case-by-case assessment. [4]

Whole-genome sequencing can identify candidate hazards and support strain identity, but it does not directly measure expression of a toxin, transfer of a resistance determinant under real conditions, survival after processing or the physiological effect of a final product. Conversely, a negative culture result does not necessarily establish absence of DNA or biologically active components. Genome, phenotype, process validation and exposure therefore occupy complementary positions in the safety case.

For industrial developers, this suggests a hierarchy: authenticate the strain and genetic stability; screen relevant hazard traits; demonstrate critical process controls; characterise the finished material; assess exposure and vulnerable populations; then validate any claimed function. Where the organism or process changes, the scope of the original evidence must be reconsidered rather than presumed transferable.

06 | Pasteurised Akkermansia: a concrete 2026 regulatory experiment

Pasteurised Akkermansia muciniphila is an unusually instructive case because the authorised product is not a conventional live probiotic. The EU originally authorised it as a novel food through Implementing Regulation (EU) 2022/168, with defined uses and protected proprietary data. Implementing Regulation (EU) 2026/391 subsequently extended specified uses to adolescents aged 12 to under 18, while retaining restrictions for pregnant and lactating women and age-dependent labelling conditions. The amendment does not authorise arbitrary use in all foods, nor does it authorise an unrestricted health claim. [8,9,26]

The 2026 amendment establishes age-specific daily use conditions in the Union list, including 2.1 × 10^10 cells for the 12-to-under-14 group, 3.0 × 10^10 for the 14-to-under-18 group and 3.4 × 10^10 for adults in the authorised product categories. These are conditions of use for the specified novel food, not generic safe doses for other Akkermansia preparations. Operators must consult the current Union-list entry, including specifications, labelling and any data-protection provisions. [8,9]

This case demonstrates a basic regulatory separation: authorisation establishes that a specified product can be marketed under defined conditions after a safety assessment. It does not establish that every proposed metabolic benefit is clinically proven or legally claimable. The identity of the authorised inactivated preparation must remain linked to its production and specifications.

07 | Two 2026 clinical trials show why endpoint discipline matters

The 2026 human literature on pasteurised A. muciniphila provides a useful contrast. In a randomised trial involving 90 adults who first lost weight through a low-energy diet, daily supplementation during a 24-week maintenance period was associated with less weight regain than placebo: approximately 1.2 versus 3.2 kg at the end of the maintenance phase, with a reported between-group P value of 0.012. This is evidence for a defined outcome in a defined study population, not proof of universal weight-management efficacy. [10]

A separate multicentre randomised trial in 142 adults with metabolic syndrome reported that its primary endpoint, whole-body insulin sensitivity assessed by the Matsuda index, did not differ after four months between the intervention and placebo groups. Exploratory and subgroup analyses suggested possible changes in other metabolic measures, including GLP-1 responses. These findings may generate hypotheses but do not convert a negative primary endpoint into a positive confirmatory trial. [11]

The two studies are not necessarily contradictory: they examined different populations, protocols and endpoints. They also cannot be pooled informally to manufacture a broad claim about obesity, diabetes or microbiome 'restoration'. At minimum, an evidence dossier must state the primary estimand, population, comparator, dose, treatment duration, multiplicity strategy and whether an effect was prespecified. Some investigators in the 2026 literature disclosed commercial or patent-related interests; such disclosures require transparent appraisal, not automatic dismissal. [10,11]

08 | A changed microbiome is not automatically a health benefit

Microbiome studies often report relative taxonomic abundance, alpha or beta diversity, predicted metabolic pathways and concentrations of short-chain fatty acids. These measurements can be scientifically useful, but none is a universal surrogate for improved human health or animal performance. Relative abundance is compositional: one organism can appear to increase because another decreases, even without an absolute rise in its cell count. Stool composition may also differ from microbial activity at mucosal sites or in the small intestine.

Causality requires attention to baseline heterogeneity, diet, medication, geography, batch effects, sequencing depth, absolute quantification, clinical endpoints and time. A biomarker associated with a favourable outcome is not necessarily a mediator of that outcome. Mechanistic plausibility can strengthen a causal case, but it cannot replace adequately designed human or target-animal studies. EFSA's planned November 2026 colloquium explicitly recognises that microbiome endpoints and regulatory methodologies are not yet sufficiently harmonised for consistent application. [3,22]

The commercially tempting shortcut is to demonstrate a shift in microbial composition and describe the ingredient as 'clinically proven to improve gut health'. That leap is not defensible without a validated link between the measured change and the specific claimed benefit, supported by the applicable claims regime.

09 | Manufacturing creates a second biological identity

A microbial ingredient's production history is part of its identity. The master cell bank, passage number, fermentation medium, oxygenation, pH, antifoam, harvesting, inactivation, drying and carrier selection can affect viable-cell recovery, residual metabolites, surface structures, immunologically active components and stability. A strain label on a specification sheet does not capture these changes. [4,13,14]

For inactivated preparations, a defensible release strategy may require validated absence of viable organisms, a quantitative cell or biomass assay, relevant structural or functional markers, impurity limits and a stability-indicating potency method. For live products, CFU at manufacture is not necessarily CFU at the end of shelf life or at the point of ingestion. For purified fermentation products, the critical hazards may be residual host-cell proteins, DNA, process chemicals, allergenic potential and contaminants rather than the viability of the original host. [13]

The UK Food Standards Agency's 2026 supplementary guidance on precision and biomass fermentation stresses product-specific narratives, bioinformatics, purification, kill-step validation, residual DNA and proteins, digestibility and allergenicity. These are guidance considerations, not universal numeric requirements applicable identically to every fermentation-derived ingredient. Their value is the insistence that evidence must follow the actual process and exposure. [13,14]

10 | Three regulatory questions before any product claim

Before discussing efficacy, a developer should answer three legal questions in order. First, what is the product under the relevant jurisdiction's classification: ordinary food ingredient, novel food, food additive, feed additive, dietary supplement ingredient or potentially a medicinal product? Second, is the ingredient permitted to be placed on the market in that category, at that dose and for that population? Third, what specific claims, if any, are authorised or otherwise lawful?

These are not interchangeable decisions. A food can be safe yet require pre-market novel-food authorisation. An authorised novel food may not support an unauthorised health claim. A product marketed with claims to treat disease can enter medicinal-product or drug territory even when its composition resembles a food supplement. Cross-border distributors must not assume that the answer in one market is portable to another. [6–9,16–20]

11 | European Union: novel-food status, safety and claims are separate

Regulation (EU) 2015/2283 requires operators to verify whether an ingredient is a novel food and, where relevant, to obtain authorisation before marketing it. Authorised novel foods appear in the Union list under Implementing Regulation (EU) 2017/2470, with specifications, conditions of use and labelling requirements. Some entries are subject to time-limited data protection. EFSA's updated 2024 scientific guidance addresses identity, production, composition, specifications, proposed uses, anticipated intake, nutrition, toxicology and allergenicity. [7,9,27]

Regulation (EC) No 1924/2006 separately governs nutrition and health claims made about foods. A product's novel-food authorisation does not imply approval of a claim such as 'reduces insulin resistance' or 'prevents obesity'. The operator must assess the wording, target population and applicable authorisation status. The distinction is particularly important where clinical studies report exploratory metabolic effects that have not been translated into an authorised EU claim. [16,17]

General food law, including Regulation (EC) No 178/2002, continues to apply. A product-specific authorisation does not excuse defective manufacture, contamination, incorrect labelling or failure to meet the authorisation's specifications. Where genetically modified production organisms are involved, the applicable GMO and sectoral rules require separate assessment; it is unsafe to infer an exemption merely because the final product contains no viable producer cells. [23]

12 | Spain: the word probiotic does not confer a health claim

Spain applies the directly applicable EU novel-food and claims rules, with national competent authorities involved in enforcement and novel-food status consultations. AESAN's published 2020 position acknowledged divergent Member State interpretations of the term 'probiotic' and indicated that its use on labels could be accepted under specified circumstances, while expressly maintaining that health claims require EU authorisation. This administrative position must be distinguished from a binding EU-wide authorisation of the term or of any physiological effect. [18]

For a Spanish manufacturer, the compliance file should therefore separate the ingredient's lawful status, the label's descriptive terminology and every explicit or implied health claim. The practical risk is not only a sentence such as 'improves immunity'. Product names, graphics, website narratives and sales presentations can also convey claims. The position of the relevant competent authority and the current EU register should be checked before a launch. [16–18]

An additional operational issue arises when a supplier provides a microbiological certificate expressed in CFU for a heat-treated preparation. Such a certificate may be scientifically meaningless as a potency measure for an inactivated ingredient; conversely, a cell-count certificate does not establish the absence of viable cells. Procurement and quality assurance must agree on the intended analyte and its acceptance criterion.

13 | Great Britain and Northern Ireland: fermentation guidance is not approval

Great Britain has its own regulated-products authorisation arrangements. In 2026, the Food Standards Agency and Food Standards Scotland published safety guidance and supplementary technical material for precision-fermentation products, identifying recurring dossier weaknesses in identity, bioinformatics, protein digestibility,

allergenicity, manufacturing controls and product composition. The guidance does not itself authorise a particular ingredient; ministerial decisions and the relevant legal framework remain decisive. [13–15]

Northern Ireland requires separate treatment because its applicable food rules retain important EU-linked elements. The UK cannot be described as a single, uniform microbiome ingredient authorisation territory. The FSA's September 2026 consultation on 16 regulated products further illustrates that regulatory decisions are product-specific and proceed through defined public processes rather than through a generic 'fermentation-approved' designation. [15,24]

A company exporting a postbiotic or fermentation-derived ingredient to several UK destinations should map the ingredient classification, authorisation status, conditions of use and claims requirements for each relevant jurisdiction, including Scotland and Northern Ireland. A dossier prepared for an EU novel-food assessment may provide useful science but is not automatically a Great Britain marketing authorisation.

14 | United States: the October NDI guidance has a precise scope

The FDA's 19 October 2026 announcement concerned final guidance on information for new dietary ingredient notifications (NDINs). Where the statutory NDIN requirement applies, the manufacturer or distributor generally submits a notification at least 75 days before interstate marketing, supported by a basis for concluding that the ingredient or supplement is reasonably expected to be safe under its intended conditions of use. The guidance finalises recommendations on identity, history of use or other safety evidence, and the safety rationale; it does not amend the statute or automatically apply to all microbial ingredients. [1,2]

A microorganism used in an ordinary food, a dietary supplement, a medical product and an animal feed may encounter different US regulatory routes. Depending on the intended use and legal status, conventional-food ingredients may require a food-additive authorisation or a valid generally recognised as safe (GRAS) basis; dietary supplements have their own statutory framework; disease-treatment claims can trigger drug regulation. On 10 August 2026, FDA also proposed a rule to strengthen oversight of GRAS claims; that proposal must not be described as a final rule. An NDIN is not equivalent to FDA pre-market approval of the product or an FDA endorsement of efficacy. [1,2,19,20]

For a cross-border supplier, this means that a European QPS assessment, an EU novel-food authorisation, a US GRAS conclusion and an NDIN address different legal questions. They can inform one another scientifically, but none should be presented as a substitute for the others.

15 | Animal nutrition: efficacy is part of the authorisation question

The animal-nutrition pathway introduces an additional distinction. Under Regulation (EC) No 1831/2003, a feed additive requires authorisation under the relevant category and conditions, with evidence that it is safe for the target animal, consumer, user and environment and that it delivers an authorised type of benefit. A microbial strain's QPS status may assist the safety assessment but cannot establish zootechnical efficacy or replace the feed-additive authorisation. [5,21]

For a proposed gut-microbiome-modulating additive in pigs, poultry or aquaculture, the dossier should identify the target species and production stage, the actual dose reaching the animal, feed processing survival or inactivation, relevant microbiological hazards, and the claimed outcome. Feed conversion ratio, mortality, growth, litter quality, pathogen shedding and faecal community composition are different endpoints. An observed microbial shift does not establish better performance or food safety.

The industrial opportunity lies in appropriately designed field trials with batch-controlled products, randomised pens or farms where feasible, prespecified outcomes and adequate statistical treatment of clustering. It is a methodological requirement, not an assumption that every microbial additive improves animal performance.

16 | An evidence specification that purchasing can actually use

A robust supplier qualification package should answer, in sequence: which exact strain or defined preparation is supplied; how its identity was verified; whether it is live, inactivated or purified; which safety hazards were assessed; how the manufacturing process is controlled; what potency assay is valid; which shelf-life conditions

preserve that potency; what exposure and population are covered; what authorisations apply; and what, if anything, the evidence supports as a claim.

For live products, request strain-resolved identity, viable count at end of shelf life, contaminant specifications, resistance-gene evaluation and handling stability. For inactivated products, request validated inactivation, appropriate biomass or structural markers and a product-specific potency strategy. For purified fermentation ingredients, request composition, impurity and residual host-component data. For consortia, request the identity and proportions of members, compatibility, stability and the evidence for the mixture itself. [4,13]

The acceptance decision should be scoped: approved for a defined food, feed or supplement use; conditionally approved pending specific data; or not approved. 'Probiotic grade', 'QPS strain', 'natural', 'clinically tested' and 'FDA compliant' are not adequate release specifications unless the supporting documents define exactly what they mean.

17 | Research & Innovation Opportunity

UNRESOLVED PROBLEM. Current development programmes often maintain organism genomics, manufacturing release testing, toxicology, clinical efficacy and market authorisation in separate databases. This makes it difficult to determine whether a changed fermentation lot, inactivation regime or carrier has invalidated an earlier safety inference or functional result. EFSA's forthcoming microbiome colloquium identifies a broader methodological readiness gap; it does not itself propose the specific industrial architecture developed here. [3,4]

WHY IT MATTERS. A product can pass species identification while failing to match the material used in a trial; an inactivated preparation can meet a cell-count specification while losing a relevant active structure; a clinical study can show a microbiome association without proving the marketed claim. Better linkage could prevent both unsafe approvals and the unnecessary rejection of scientifically defensible products.

WHAT IS ESTABLISHED. Strain identification, QPS screening, process validation, microbiome sequencing, targeted metabolomics, randomised trials and regulatory dossiers already exist. The literature also contains prior work on pasteurised Akkermansia and patent families with priority dates well before 2026, including EP3347030. None of those methods, nor the use of inactivated Akkermansia, is claimed here as new. [4,5,10–12,25]

WHAT REMAINS UNKNOWN. There is no demonstrated universal, prospectively validated method for linking all relevant microbial identity, process, safety, potency, clinical and jurisdictional evidence across diverse ingredient classes. It is also unclear which data layers improve decisions enough to justify their cost, and which are redundant for lower-risk applications.

PROPOSED HYPOTHESIS. A version-controlled identity–safety–function evidence passport, with predefined triggers for re-evaluation, will detect material product changes and prevent unsupported claim transfer more reliably than conventional document-by-document supplier qualification. This is a proposed research hypothesis, not an established standard, patented invention or demonstrated result.

DEVELOPMENT PATHWAY. Build matched pilot cases for (i) a live food strain, (ii) a pasteurised microbial preparation, (iii) a purified precision-fermented protein and (iv) a multi-strain animal-feed preparation. For each, define critical quality attributes, strain or producer identity, process variables, impurity profiles, validated potency measures, exposure, legal classification and claimed endpoints. Link batch-level records to trial material and authorisation specifications without disclosing unnecessary proprietary process details.

VALIDATION. Preregister decision rules and failure criteria; introduce blinded simulated changes in strain, heat treatment, drying and carrier; measure false acceptance and false rejection against expert adjudication; test across laboratories and manufacturers; compare performance with ordinary supplier files; quantify cost, decision time and auditability; and independently verify any predicted clinical or animal-performance effect in prospective studies.

REGULATORY CONSTRAINTS. The passport cannot replace EFSA assessment, EU authorisation, FDA statutory obligations, UK ministerial decisions, clinical substantiation or sector-specific feed requirements. A model prediction is not a marketing authorisation. Intellectual-property searches and freedom-to-operate analyses would be necessary before claiming a proprietary implementation or commercial exclusivity.

INDUSTRIAL RELEVANCE. If validated, the framework could improve sourcing of fermented proteins, microbial preservation ingredients, functional preparations and animal-nutrition products, while supporting change control, customer documentation and targeted R&D investment.

18 | AI and multi-omics: useful triage, not automated permission

Machine learning can integrate genome annotations, metabolomic fingerprints, process records and outcomes to prioritise tests or flag anomalous batches. Yet models trained on conventional lactic-acid bacteria may not extrapolate to uncommon anaerobes, complex consortia or inactivated preparations. Correlated multi-omics features are not automatically causal mechanisms. Data leakage, laboratory batch effects and selective outcome reporting can produce apparently impressive performance that disappears under external validation.

A defensible digital system should retain provenance: sequence assembly version, reference database, method, detection threshold, sample identity, process revision, study protocol and jurisdictional decision. It should record uncertainty and trigger human review when a change exceeds the validated domain. Regulatory classification and claim authorisation must remain explicit legal decisions, not outputs inferred from a similarity score. [4,22]

19 | Economics: test the decisive uncertainty first

The economic cost of a microbial ingredient is not just fermentation yield or cost per kilogram. It includes strain banking, contamination control, purification or inactivation, stability losses, analytical release, toxicology, clinical or animal trials, dossier preparation and market-specific restrictions. A cheaper ingredient with poor identity control can become expensive after a failed authorisation or a disputed claim. Conversely, not every product requires maximum-depth metagenomics and clinical testing when its use and risk profile do not justify them.

A rational development sequence starts with classification and feasibility: can the ingredient legally be marketed in the intended category, and what evidence will be needed? Next come manufacturing identity and hazards, then fit-for-purpose efficacy. Commercial pricing should be based on a realistic dose and validated function, not on an unsupported 'more CFU means more benefit' assumption. The value of an additional study should be judged by whether it resolves a decision-critical uncertainty.

20 | Evidence status: five propositions kept apart

ESTABLISHED EVIDENCE. EFSA has a cross-cutting microorganism characterisation framework and a QPS approach; the EU has specific novel-food authorisation and health-claim regimes; the FDA issued final NDIN identity/safety guidance in October 2026; and the UK has published fermentation dossier guidance. These frameworks differ in legal effect and scope. [1–9,13–21]

EMERGING EVIDENCE. Human trials with pasteurised Akkermansia have reported endpoint-specific metabolic findings, including a positive weight-maintenance result and a separate trial with a non-significant primary insulin-sensitivity endpoint. These results require product- and population-specific interpretation. [10,11]

EXPERT INTERPRETATION. Microbial taxonomy, manufactured-product safety and demonstrated function should be treated as three distinct but linked evidence identities. This is a synthesis of existing scientific and legal requirements, not a quotation from a single authority.

HYPOTHESIS. A version-controlled evidence passport could reduce unsupported extrapolation between strains, lots, processing conditions and claims. Its comparative benefit remains unproven.

RESEARCH AGENDA. Priorities include validated potency assays for inactivated preparations, causal mediation analysis, standardised clinical endpoints, cross-laboratory microbiome measurements, transferability criteria after manufacturing changes and prospective decision-system evaluation.

21 | Conclusions: identify the organism, qualify the product, prove the claim

The most important regulatory lesson of October 2026 is not that microbiome products need one more generic certificate. It is that they require the right evidence for three different questions. A species name is not a finished-product specification. A favourable safety assessment is not a health claim. A change in the microbiome is not

necessarily a clinically meaningful benefit. And an EU authorisation, UK assessment or US notification cannot be translated into another market's permission by analogy.

For food, supplement and feed manufacturers, the defensible sequence is to classify the product, verify its biological and manufactured identity, assess safety and exposure, substantiate the precise intended function, and apply the correct jurisdictional regime. The proposed identity–safety–function passport is a testable way to connect those tasks; it is not a substitute for any of them. A credible microbiome market will be built less by promising universal effects than by showing exactly what each preparation is, what it can safely do and where the evidence ends.

Related Knowledge Areas

Food Safety | Biotechnology | Nutrition | Regulatory Affairs | AI & Food | Functional Ingredients | Animal Nutrition | Processing Technologies | Emerging Research

Editorial Scope and Limitations

Independent academic–industrial analysis based on information available through 25 October 2026. The 23–24 November EFSA colloquium is forthcoming, not completed. Legal status is described for the cited instruments and must be checked against the consolidated law, current authorisation entries and the intended product before commercial action. This is not an EFSA, FDA, FSA, AESAN or European Commission opinion, a legal determination for a specific product, a health-claim authorisation, or a freedom-to-operate analysis. Proposed research hypotheses and development pathways are not validated performance claims. No INTABIOTECH product is represented as having demonstrated any of the effects discussed.

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