

The Microbiome Is Not a Verdict

Why EFSA's 2026 Regulatory Agenda Demands Causal Endpoints, Strain-Level Identity and Function-Based Evidence for Food and Feed Biotechnology

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Abstract

The microbiome is becoming a regulatory question rather than merely a research descriptor. Ahead of its 23–24 November 2026 scientific colloquium, the European Food Safety Authority (EFSA) has identified unresolved questions about when microbiome changes constitute adverse effects, how microbial products should be characterised, and which evidence standards can support decisions. This article examines that agenda against EFSA's cross-sector microbial-characterisation guidance, applicable to feed dossiers from April 2026, its 2026 qualified-presumption-of-safety update, and two contrasting novel-food cases: pasteurised *Akkermansia muciniphila* and viable *Anaerobutyricum soehngenii* CH106. The central argument is that altered microbial composition is neither proof of harm nor proof of benefit. Regulatory inference requires a defined product, plausible exposure, functional and host endpoints, causal design, and context-specific assessment of uncertainty. A proposed Microbiome Evidence Ladder and an experimentally testable Function–Exposure–Host framework could help translate metagenomic signals into defensible food, feed and ingredient decisions without confusing scientific hypotheses, safety opinions, marketing authorisations and health claims.

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1 | A regulatory signal that deserves more than another probiotic headline

On 23–24 November 2026, EFSA and the French National Research Institute for Agriculture, Food and Environment (INRAE) will convene Scientific Colloquium 29, **“Decoding the Microbiome: From Knowledge Gaps to Actionable Regulatory Science.”** As of 12 October, the meeting is prospective and it has not yet issued conclusions. Its published agenda, however, is already an unusually precise statement of a regulatory-science problem. EFSA asks what constitutes an adverse microbiome effect, which data and reporting standards are fit for dossiers, and whether existing risk-assessment instruments can accommodate microbial-community endpoints. The programme explicitly covers chemical exposures and biological products in both human and animal health. Environmental microbiomes are outside this meeting’s scope and are reserved for a later initiative. [1]

The signal is not that regulators have suddenly discovered gut bacteria. It is that routine high-throughput sequencing has made microbial differences easy to describe while the meaning of those differences remains difficult to adjudicate. A **food additive, dietary intervention, pesticide residue or microbial feed** product can change measured community structure. Yet a changed profile alone cannot tell a risk assessor whether a host was harmed, benefited, adapted or merely varied within normal ecological limits.

The strategic question for ingredient developers is therefore not “Can we alter the microbiome?” but “What reproducible, host-relevant consequence follows from a defined exposure to a defined product?” That question connects microbiology, toxicology, nutrition, biostatistics, manufacturing science and food law.

2 | The conceptual error: treating composition as an outcome

A microbiome profile is an observation of an ecosystem under a particular sampling and analytical protocol. Relative abundances can change because one population expands, another contracts, total biomass changes, extraction efficiency differs, or sequencing depth and bioinformatic choices vary. A change in alpha diversity or the relative abundance of a named genus is not, by itself, a validated clinical endpoint.

This matters because terms such as **“balance”, “restoration” and “healthy microbiome”** can imply that a universal reference state exists. It does not. **Human and animal microbiomes vary with age, diet, medication, geography, disease, husbandry, feed formulation and sampling site.** Even a statistically significant shift can be biologically modest or transient. Conversely, a functional change in metabolite production may matter without a dramatic change in taxonomic composition.

The inference problem is directional since microbial composition may mediate an exposure’s effect on the host, may respond to a host change, or may be correlated with both through an unmeasured variable. Distinguishing these explanations is indispensable before using microbiome data as evidence of either efficacy or adversity.

3 | What EFSA is actually asking in 2026

The published colloquium programme identifies two separate regulatory domains. In chemical safety, the microbiome may be an exposure target and may also modify internal exposure through biotransformation. In biological-product safety, the product may itself consist of living organisms, inactivated microbial preparations or complex communities intended to alter the receiving ecosystem. [1]

EFSA intends to assess scientific readiness, prioritise adversity criteria and reporting standards, and develop a gap-closing action plan. Those are proposed outputs, not established requirements as of this article’s date. It would be inaccurate to describe the November meeting as having already adopted a new legal test.

This distinction matters commercially. Companies should prepare for increasingly explicit questions about microbiome effects, but should not present speculative future standards as binding law. The current legal obligations remain those of the applicable product category and authorisation route.

4 | A genuine regulatory change has already happened: microbial identity

The prospective colloquium sits on top of a concrete development. EFSA's Scientific Committee adopted cross-cutting guidance on characterising microorganisms in September 2025, and the guidance was published on 4 November 2025 as EFSA Journal e9705. It addresses **bacteria, yeasts, fungi, microalgae, protists and viruses** used in regulated food-chain products, whether genetically modified or not. It emphasises taxonomic identity, antimicrobial resistance, toxigenicity, virulence, antimicrobial substances, genetic modification and relevant residues of viable cells or DNA. [2]

EFSA's June 2026 applicant session states that feed-additive technical dossiers must fully comply with this characterisation guidance from 1 April 2026. That is an important implementation date, but it should not be generalised into a claim that every food product in every regulatory category became subject to an identical new deadline. The guidance's applicability depends on the sector and the dossier. [3]

The significance is methodological. A generic label such as "*Lactobacillus culture*" cannot substitute for a traceable strain identity and a characterisation of the actual commercial preparation. Genomic identification is not the entire safety assessment, but it establishes the identity of the biological entity being assessed.

5 | Qualified Presumption of Safety: useful, qualified and frequently misunderstood

EFSA's Qualified Presumption of Safety (QPS) system pre-assesses defined taxonomic units against identity, body of knowledge and safety concerns. Its 2026 update discusses qualifications and future microbial applications. A QPS recommendation is not a blanket authorisation of any product containing a microorganism, mainly because strain-specific qualifications, production conditions, intended use and other sectoral requirements remain relevant. [4,5]

QPS also cannot establish a claimed physiological benefit. A taxon may be suitable for a streamlined safety approach without evidence that a particular strain improves gut function, growth performance, immunity or metabolic health. The separation between safety and efficacy is fundamental to both feed-additive dossiers and consumer communications.

Complex microbial consortia add another challenge. Safety information on individual members does not automatically establish the safety of their combination, because ecological interactions, metabolites, resistance-gene exchange, persistence and exposure can change when organisms coexist. That is a hypothesis requiring product-specific investigation, not an argument that all consortia are hazardous.

6 | The *Akkermansia* case: an inactivated microbe is still a regulated ingredient

Pasteurised *Akkermansia muciniphila* offers a concrete example of how processing state changes regulatory identity. The EU authorised a defined pasteurised preparation as a novel food under Implementing Regulation (EU) 2022/168. EFSA later assessed an extension of use and, in September 2025, concluded that the specified preparation was safe for certain adolescent age groups at defined intakes while the safety of the proposed extension to pregnant and lactating women was not established. [6]

Commission Implementing Regulation (EU) 2026/391, effective from 16 March 2026, amended the authorised uses, maximum levels and specific labelling requirements in the Union list. The legal text -not a general description of the species- controls the populations, uses and quantities permitted. [7]

The example demonstrates three separations, to know: pasteurised cells are not interchangeable with live cells, safety for one population does not prove safety for another and novel-food authorisation is not an authorisation to make any particular health claim. This last distinction is often obscured in microbiome marketing.

7 | The *Anaerobutyricum* case: a favourable safety opinion is not market access

In July 2026, EFSA published a scientific opinion on freeze-dried viable *Anaerobutyricum soehngenii* CH106 as a proposed novel food. The Panel concluded that the preparation was safe at 2.0×10^9 active fluorescent units (AFU) per day for adults, excluding pregnant and lactating women. The assessment considered strain identity, manufacturing, genotoxicity, a 90-day toxicity study and human data. The animal-study margin of exposure reported by EFSA was 1,621. [8]

This is a materially different biological product from pasteurised *Akkermansia*. Its proposed viability, strain identity, enumeration metric and intended population are part of its safety proposition. The case also demonstrates why colony-forming units and other viable-cell metrics should not be treated as interchangeable without method validation.

A favourable EFSA opinion is a scientific assessment, not itself a Commission implementing authorisation. Before a product is marketed in the EU, its status and conditions must be checked against the current Union list. Nor does a favourable safety conclusion prove the claimed metabolic benefit of the strain. [8,9]

8 | Probiotic, postbiotic, fermentate and metabolite are not synonyms

Terminology determines which biological entity is being characterised. A probiotic, under the widely used scientific consensus, is a live microorganism administered in an adequate amount with a demonstrated host benefit. The ISAPP consensus defines a postbiotic as a preparation of inanimate microorganisms and/or their components that confers a health benefit. Purified metabolites alone are not postbiotics under that consensus definition. [10]

A fermentation-derived ingredient may contain cells, fragments, secreted metabolites, residual DNA, enzymes and process-derived impurities in proportions shaped by manufacturing. It should not be reclassified as a postbiotic merely because fermentation occurred, nor described as a probiotic if no viable microorganisms remain. In the EU, scientific terminology does not displace product-category law or health-claim rules.

For industrial development, the practical lesson is to define the test article precisely: strain or consortium, live or inactivated state, viable-cell count or validated alternative measure, biomass fraction, metabolite profile, carrier, stability and manufacturing history.

9 | From “dysbiosis” to a defensible adversity criterion

The term **dysbiosis**, and in some cases “**fermentative dysbiosis**”, is often used as if it were a diagnosis. It is better understood as a context-dependent description of an altered microbial ecosystem. The regulatory question is whether an alteration is causally connected to an adverse effect in the exposed host.

Candidate host-relevant outcomes include clinically meaningful gastrointestinal symptoms, compromised barrier function, pathogen overgrowth or shedding, infection risk, inflammatory injury, altered nutrient availability, and measurable effects on animal health or productivity. Each requires appropriate methods, pre-specified thresholds and interpretation within the target population.

A microbiome shift without host harm may be a biomarker, an adaptive response or a neutral fluctuation. A host adverse effect without a large detectable taxonomic shift may still be mediated by microbial functions or metabolites. Regulatory decision-making should therefore avoid requiring a simplistic diversity threshold or a universal “good bacteria” score.

10 | Chemical safety: the microbiome as both target and metabolic reactor

For food additives, pesticide residues, contaminants and other dietary chemicals, microbial communities may transform compounds before absorption or after biliary excretion. Microbial enzymes can activate, deactivate or

alter the persistence of chemical species. Conversely, a chemical may modify microbial metabolism without a clinically meaningful change in taxonomy.

A robust study must therefore consider at least three exposure layers: the administered compound, the transformed products and the internal exposure of the host. Where feasible, mass-balance approaches, targeted metabolomics, stable-isotope tracing and pharmacokinetic or toxicokinetic measurements can distinguish disappearance of a parent compound from actual risk reduction.

The relevant endpoint is not necessarily “more” or “less” of a microbial species. It may be the concentration and biological activity of a metabolite, coupled to an adverse host outcome. This argument is an expert synthesis of existing mechanistic principles; EFSA has not yet adopted a universal microbiome-specific toxicological decision rule. [1,2]

11 | Biological products: identity, persistence and interaction

For live microbial products, the exposure is itself biological. Viability, dose, gastrointestinal survival, transient passage, possible colonisation, metabolic output and host susceptibility all affect the risk profile. For complex consortia, interactions among strains can alter the behaviour of the preparation compared with single-strain experiments.

Whole-genome sequencing can support taxonomic identification and screening for genes of concern, but genotype does not always predict expressed phenotype under real process or gut conditions. Conversely, the absence of a known virulence marker is not a universal proof of safety. Phenotypic testing, manufacturing controls and use-specific evidence remain necessary.

Microbial products intended for immunocompromised patients, infants, pregnant women or other sensitive groups may require a different evidentiary approach from products intended for healthy adults or farm animals. This is a reason for targeted study, not for categorical assumptions about all live microorganisms.

12 | Why manufacturing is part of biological identity

For microbial ingredients, a strain name is necessary but insufficient. Growth medium, fermentation phase, oxygen exposure, downstream separation, concentration, drying, heat treatment, carriers and storage may alter viability, stress tolerance, cell-wall presentation and metabolite content. A laboratory batch and an industrial lot may therefore be genetically identical yet functionally different.

The dossier should specify critical quality attributes and acceptance criteria. Depending on the product, these may include strain authentication, purity, viability or inactivation, water activity, microbial contamination, toxin and antibiotic-resistance risk, residual processing substances, metabolite profile, stability and analytical method performance.

This is particularly relevant to direct-inoculation cultures and high-cell-density preparations. A stated count such as 10^{11} CFU/g is a potency specification only when its enumeration method, sampling scheme, uncertainty and end-of-shelf-life behaviour are defined. It does not establish performance in a specific food or feed matrix.

13 | The statistical trap in microbiome research

Microbiome sequencing generates high-dimensional, sparse and often compositional data. Standard relative-abundance analyses can create misleading correlations because increasing the relative share of one taxon necessarily changes the relative shares of others, even if their absolute numbers are unchanged.

Multiplicity, batch effects, extraction bias, sequencing platform, reference databases and bioinformatic pipelines can also create non-reproducible signatures. A large number of features does not compensate for weak randomisation, poor control of diet and medication, or an inadequate sample size for clinically meaningful endpoints.

A regulator-ready protocol should pre-register primary host outcomes, define the microbiome analyses as primary or supportive, justify sample size, report absolute microbial load where feasible, control false discovery, and use independent validation cohorts. Statistical significance must be distinguished from effect magnitude, reproducibility and clinical relevance.

14 | Causality is the missing bridge

The strongest causal designs depend on the question. Randomised controlled interventions can establish that an exposure changes a host outcome under specified conditions, but may not by themselves prove that a microbiome change mediates the effect. Mediation analysis, longitudinal sampling, mechanistic metabolite measurements, ex vivo systems and carefully justified animal models can strengthen that inference.

A useful causal sequence is identified as follows: ***defined intervention → confirmed exposure → measured microbial or metabolic change → temporally subsequent host effect → reproducible association under controlled conditions → mechanistic corroboration.***

Not every dossier requires the entire sequence. A novel-food safety assessment and a health-claim application answer different legal questions. The essential point is proportionality: the evidence demanded should match the decision being made, and a mechanistic hypothesis must not be substituted for a demonstrated human or animal benefit.

15 | The regulatory boundary between safety, efficacy and claims

Three regulatory decisions are frequently conflated. Safety asks whether a specified product is acceptably safe under defined conditions of use. Efficacy asks whether the product produces a claimed technological, zootechnical or physiological effect. Marketing authorisation asks whether the legal prerequisites for placing the product on the market have been met. Consumer health claims introduce a further, distinct requirement.

In the EU, Regulation (EU) 2015/2283 governs novel foods, Regulation (EC) No 1831/2003 governs feed additives and Regulation (EC) No 1924/2006 governs nutrition and health claims on foods. The product category and intended use determine the applicable route. [9,11,12]

A favourable safety opinion cannot be marketed as a validated health benefit. A scientific finding that a culture changes short-chain fatty acid concentrations does not automatically authorise a claim that it improves immunity, prevents disease or treats a metabolic disorder.

16 | European Union and Spain: one market, several distinct pathways

For EU food supplements containing a microorganism, novelty must be assessed against the applicable history-of-consumption and product criteria. If the preparation is a novel food, it must be authorised and listed under the conditions of Regulation (EU) 2015/2283 and the Union list. For microbial feed additives, an authorisation under Regulation (EC) No 1831/2003 is required where the product falls within its scope. A microorganism used as a processing culture may follow a different legal analysis from one deliberately marketed as a health-active ingredient.

In Spain, directly applicable EU regulations govern the substantive authorisation framework, while competent Spanish authorities carry out national enforcement and relevant controls. Spanish commercial labels and advertising must also comply with the EU health-claims framework and general prohibitions on misleading information. The term “probiotic” can itself raise claim-related interpretation issues; businesses should not assume that scientific usage confers unrestricted labelling permission.

For a company serving both human-food and feed customers, the same microbial strain may require different evidence and legal analysis in the two sectors. This is not duplication for its own sake: target species, exposure, efficacy and consumer risk can differ.

17 | Great Britain and Northern Ireland: do not treat the UK as one authorisation zone

Great Britain operates its own regulated-product authorisation system and public registers. The Food Standards Agency's register records authorised novel foods and feed additives for England, Scotland and Wales, while the UK government's novel-food guidance explains that Northern Ireland generally follows EU rules and the EU authorisation route, subject to specific movement arrangements. [13,14]

A microbial ingredient authorised in the EU should not automatically be assumed authorised in Great Britain, and the reverse is also unsafe. Conditions of use, specified strains, product forms and target populations must be checked against the relevant register and legal instruments.

For exporters, a single technical dossier can be a scientific core, but market-access conclusions require jurisdiction-specific annexes. The EU's March 2026 amendment concerning pasteurised *Akkermansia* should not be silently treated as an identical change to GB authorisation conditions.

18 | United States: food, supplement, animal feed and drug are separate decisions

The United States distinguishes conventional foods, dietary supplements, animal feed and products intended to treat or prevent disease. FDA explains that dietary-supplement manufacturers are responsible for safety and labelling, while a qualifying new dietary ingredient may require premarket notification under the statutory criteria. [15,16]

A microbial product promoted for disease treatment may be regulated as a drug or biological product rather than a food or supplement. FDA's guidance on early clinical trials of live biotherapeutic products addresses chemistry, manufacturing and control information for investigational products; it is not a general food-marketing authorisation. [17]

For live microbial dietary supplements, labelling questions such as CFU declaration have been the subject of FDA guidance, but a count does not establish a health benefit. For animal feed, intended claims and the status of direct-fed microbial preparations require separate analysis. [18]

The common scientific requirement across jurisdictions is precise identity and defensible evidence; the legal classifications and permissible claims are not interchangeable.

19 | Animal nutrition is the most immediate industrial test bed

Microbial feed additives are commercially attractive because measurable outcomes can include feed conversion, growth performance, digestibility, manure characteristics, silage quality and animal-health indicators. Yet these endpoints depend on species, age, basal diet, farm management and environmental conditions.

The same culture may behave differently in a feed premix, fermented feed, ensiling system or gastrointestinal tract. Evidence of acidification in a fermenter is not evidence of efficacy in an animal. Likewise, a strain that improves silage fermentation is not automatically authorised or effective as a gut microbiome modulator.

EFSA's existing assessments of *Lactiplantibacillus plantarum* silage additives illustrate the product-specific nature of efficacy evidence: additional studies were needed to support conclusions about reduced protein degradation in silage. [19]

A rigorous R&D programme should therefore separate technological performance in the feed matrix from zootechnical effects in the animal, and should assess both safety and efficacy under the intended legal category.

20 | Research & Innovation Opportunity: a Microbiome Evidence Ladder

Unresolved problem. The industry lacks a broadly harmonised, decision-oriented structure for ranking microbiome findings by how directly they support safety, efficacy or causal claims. EFSA's November 2026 programme explicitly identifies adversity criteria and evidence standards as unresolved issues. [1]

What is known. Sequencing, metagenomics and metabolomics can characterise communities and functions; strain-level genomic methods can identify microbial ingredients; intervention studies can test host outcomes; existing EU authorisation frameworks already demand product-specific safety and, where relevant, efficacy evidence.

What remains unknown. No universal taxonomic signature defines health across populations. The transferability of microbial biomarkers between species, diets, processing contexts and analytical platforms is uncertain. Causal links between many observed shifts and host outcomes remain weak.

Proposed framework (expert hypothesis, not an adopted EFSA standard):

Level 1 — Identity: verified organism(s), product form, dose and manufacturing process.

Level 2 — Exposure: viable/inactivated state, stability, delivery and relevant internal or luminal exposure.

Level 3 — Association: reproducible community or functional change, with controlled analytical bias.

Level 4 — Host relevance: pre-specified physiological, clinical or zootechnical outcome.

Level 5 — Causality: intervention evidence plus mechanistic or mediation support.

Level 6 — Regulatory translation: decision-specific safety, efficacy and claims evidence under the correct jurisdiction.

Validation pathway. Apply the ladder retrospectively to published EFSA microbial opinions and prospectively to multi-site studies; test inter-rater agreement, predictive validity, missing-data sensitivity and whether the ladder improves the quality of dossier decisions. **Regulatory constraint:** the ladder is a research tool and cannot replace existing legal data requirements or competent-authority decisions.

Industrial relevance. It could prevent expensive late-stage dossier failures by identifying whether a project has an identity problem, an exposure problem, an efficacy problem or a claims problem before investment in large trials.

21 | Research & Innovation Opportunity: Function–Exposure–Host (FEH) validation

A second research programme would test whether functional microbiome endpoints predict host-relevant effects more reliably than taxonomic abundance alone. The proposed Function–Exposure–Host (FEH) architecture would combine (i) a precisely characterised ingredient or chemical exposure, (ii) absolute and relative community measures, (iii) targeted metabolite and pathway readouts, and (iv) pre-specified host outcomes.

For a candidate microbial food ingredient, a plausible pilot could measure strain survival, short-chain fatty acid production, stool or luminal microbial profiles, gastrointestinal tolerance and a clinically meaningful endpoint in a randomised, blinded design. For feed applications, analogous endpoints might include feed conversion, digestibility and validated animal-health measures. All would require appropriate controls and statistical planning.

The hypothesis is not that one metabolite or pathway is universally beneficial. It is that a coherent causal chain may provide more transferable evidence than an isolated diversity index. Key risks include dietary confounding, cross-feeding, host-specific responses, sampling limitations and overinterpretation of surrogate endpoints.

The concept should be validated across independent cohorts, strains, manufacturing lots and matrices before any claim of predictive superiority is made. If it fails, the negative result would still clarify which measurements are not useful for regulatory translation.

22 | Implications for Industries and other operators' ingredient and fermentation portfolio

For Industry, the immediate opportunity lies in rigorous characterisation and application-specific validation rather than broad microbiome claims. Where the company evaluates fermentation cultures, enzyme preparations, functional ingredients or feed technologies, the first question should be what is being supplied, to define: a live strain, a mixed culture, a non-viable biomass, a fermentate, an isolated metabolite or a conventional ingredient manufactured using microorganisms.

A development dossier should connect strain identity and genome data, manufacturing route, viable-cell or inactivation status, residual DNA where relevant, metabolite and impurity profile, batch reproducibility, stability, intended matrix, dose and analytical uncertainty. Only then should claims of microbial modulation, improved shelf life, fermentation performance or animal benefit be tested under relevant conditions.

This does not imply that any existing commercialised product has a proven microbiome effect. It identifies a defensible R&D route for future microbial or fermentation-based projects. Proprietary formulations and process parameters can remain confidential while the external scientific argument focuses on evidence standards and validation principles.

23 | A practical decision matrix for developers

Before selecting an experiment, developers should identify the regulatory decision they need to support.

If the question is “**What is the product?**”, prioritise taxonomic identity, strain authentication, production process and compositional specifications.

If the question is “**Is it safe?**”, prioritise hazards, target population, exposure, stability, resistance and toxigenicity assessments, plus relevant toxicological and human or animal data.

If the question is “**Does it work?**”, define the claimed effect, comparator, relevant matrix or host, dose, endpoint and reproducibility criteria.

If the question is “**Can we sell it?**”, establish the correct food, feed, supplement or medicinal classification and verify the authorisation status in each jurisdiction.

If the question is “**Can we say it?**”, assess the proposed wording under the applicable health-claims, advertising and product-category rules.

This ordering is not bureaucratic. It is the shortest path to avoid generating expensive data that answer the wrong question.

24 | Evidence classification and limits of the present analysis

Established evidence: EFSA has published microbial-characterisation guidance; its 2026 QPS update is available. EU novel-food and feed-additive authorisation frameworks are in force, the EU has amended the conditions for pasteurised *Akkermansia* and EFSA has issued a favourable, population-limited safety opinion for viable *A. soehngenii* CH106. [2–9,11]

Emerging evidence: increasingly detailed microbiome and metabolomic studies may support more informative mechanistic assessments, but the general validity of many biomarkers and cross-population prediction remains unresolved.

Expert interpretation: a microbiome change should not be equated automatically with harm or benefit; the appropriate evidence depends on the regulatory question and target population.

Hypotheses and proposed research: the Microbiome Evidence Ladder and FEH architecture are original analytical proposals in this article. Their superiority has not been established and they are not official EFSA frameworks.

Temporal limitation: the EFSA November 2026 colloquium is forthcoming. No results, consensus recommendations or new binding microbiome endpoint rules are attributed to that future meeting.

25 | Conclusions: regulation needs consequences, not just microbial differences

Microbiome science has become analytically powerful before becoming uniformly decision-ready. Sequencing can reveal differences at unprecedented resolution, but regulatory decisions require more than the detection of difference.

The European developments of 2025–2026 show two complementary directions. **First**, microbial ingredients must be characterised with greater precision: identity, genomic traits, manufacturing and product state matter, and **second**, the interpretation of microbiome endpoints remains an open scientific problem, which EFSA is now addressing explicitly.

The two 2026 case studies make the distinction concrete. Pasteurised *Akkermansia* and viable *Anaerobutyricum* are not interchangeable biological entities, moreover, population-specific safety conclusions are not general health-benefit claims and a favourable EFSA scientific opinion is not automatically a market authorisation.

For food and feed biotechnology, the durable competitive advantage will not come from claiming that an ingredient “changes the microbiome.” It will come from demonstrating what changed, why it changed, whether the change matters to the host, and which legal decision the evidence can actually support.

The microbiome is evidence. It is not, by itself, a verdict.

Related Knowledge Areas

Biotechnology (microbial characterisation and fermentation); Food Safety (microbial hazards and host outcomes); Regulatory Affairs (EU, Spain, Great Britain, Northern Ireland and US); Nutrition (host-relevant efficacy); AI & Food (integrated multi-omics evidence); Functional Ingredients (live and inactivated microbial preparations); Emerging Research (causal microbiome endpoints).

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