The Protein Made from Air Is Still a Whole Cell

Xanthobacter SoF1, Europe's November 2026 Novel-Food Opinion, and the Next Qualification Challenge for Gas-Fermented Biomass

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Abstract

On 9 November 2026, the European Food Safety Authority listed a new scientific opinion concerning powdered Xanthobacter sp. SoF1 biomass proposed as a novel food. The event is strategically important because gas-fed microbial production is moving from an attractive carbon-and-energy narrative toward ingredient-specific safety evaluation. This article distinguishes the nutritional promise of single-cell biomass from the identity, manufacturing, exposure and authorisation evidence needed to sell it. It examines why protein content alone cannot define product quality: nucleic acids, cell-envelope constituents, digestibility, residual minerals, batch variability, process gases and potential contaminants must be understood in the finished powder and in formulated foods. The discussion also compares the European Union, Spain, Great Britain and the United States, while recognising the limits of publicly accessible information on the new opinion. Finally, it proposes a testable research programme connecting biomass processing, matrix-dependent digestibility and analytical qualification. The central proposition is not that gas-fermented protein is new, but that whole-cell safety and functional performance require a joined-up industrial evidence system.

Keywords: Xanthobacter SoF1; single-cell protein; gas fermentation; novel foods; microbial biomass; digestibility; process validation; regulatory assessment.

1. A fresh regulatory signal, not a marketing authorisation

EFSA's novel-food topic page lists an opinion entitled "Safety of powdered Xanthobacter sp. SoF1 biomass as a novel food pursuant to Regulation (EU) 2015/2283", published on 9 November 2026 [1]. The reported subject is a bacterial biomass powder proposed for use in several food categories for the general population. Public indexing of the opinion indicates that information on production, composition, stability and specifications was considered sufficient and did not raise safety concerns [2]. The complete technical opinion was not reliably retrievable during preparation of this article; therefore, this article does not attribute numerical specifications, authorised use levels, protein digestibility scores or a final authorisation decision to that opinion.

This distinction is decisive. EFSA evaluates scientific safety; the European Commission and Member States manage authorisation and conditions of use. A favourable scientific opinion does not itself place a new ingredient on the Union list, and it does not authorise every manufacturer to market a different strain or differently produced biomass. Product identity, specifications, process and any data-protection conditions must be checked in the eventual implementing act [1,3].

The immediate industrial question is consequently not “Is air protein approved?” but “What precisely was assessed, what process produced it, and which conditions would make another product scientifically and legally comparable?” Those questions are more useful than a generic sustainability narrative.

2. What the process actually produces

2.1 Gas inputs, metabolism and biomass

The expression “protein from air” is useful shorthand but scientifically incomplete. Certain chemolithoautotrophic bacteria can obtain carbon from carbon dioxide and energy from oxidation of hydrogen, with oxygen serving as terminal electron acceptor under suitable conditions. Nitrogen and minerals must also be supplied in biologically accessible forms. The resulting product is microbial biomass: proteins coexist with lipids, carbohydrates, nucleic acids, cell-wall structures and residual inorganic constituents. The actual substrate, gas composition and nutrient balance depend on the organism and process. Patent disclosures concerning Xanthobacter SoF1 describe continuous cultivation with hydrogen, carbon dioxide and minerals, followed by biomass harvesting and possible drying or fractionation [4,5]. These disclosures demonstrate prior public technical work; they do not establish that every claimed industrial performance metric has been independently reproduced.

The production train typically involves inoculum qualification, sterile or hygienically controlled media preparation, gas delivery and transfer, controlled growth, cell separation, washing, stabilisation, drying and packaging. Each operation changes the final safety profile. For example, altered washing may affect soluble mineral carry-over; a change in drying severity may modify protein accessibility and sensory properties; and prolonged storage can affect oxidative stability or water activity. “Same organism” is therefore an inadequate substitute for “same qualified ingredient”.

2.2 The engineering problem hidden by the phrase “from air”

Gas–liquid mass transfer can constrain growth. Hydrogen and oxygen require careful process design, both for biological availability and for industrial safety. Agitation, gas recirculation, reactor pressure and bubble size affect transfer, but their energy requirements also influence environmental performance. A life-cycle claim must account for the electricity source, hydrogen production pathway, carbon dioxide capture and purification, nutrient manufacture, drying and logistics. Carbon fixation during cultivation is not equivalent to permanent carbon removal when the biomass is ultimately metabolised as food.

The relevant comparison is functional: kilograms of digestible, nutritionally usable protein delivered at the point of consumption, not merely kilograms of dry powder leaving a fermenter. This is an expert analytical interpretation, not a reported result for SoF1.

3. Whole-cell composition changes the safety question

3.1 Protein percentage is not protein quality

A dry-basis protein figure is influenced by analytical nitrogen conversion. Microbial nucleic acids and other nitrogenous components can cause total-nitrogen methods to overstate true protein if an inappropriate conversion factor is applied. Amino-acid composition, indispensable amino-acid

adequacy and digestibility should be evaluated separately. Digestibility can be influenced by cell-envelope integrity, particle size, drying, food matrix and processing history. A protein-rich powder may therefore require different nutritional interpretation from an isolated protein concentrate.

For food developers, the practical dossier should distinguish total nitrogen, amino-acid-derived protein, nucleic-acid content, amino-acid profile and validated digestibility measures. It should not convert in-vitro solubility into a claim of superior human absorption. Likewise, a microbiological reduction step cannot by itself prove that all potentially relevant cellular constituents have disappeared.

3.2 Nucleic acids, envelope constituents and residual activity

Whole-cell bacterial ingredients warrant assessment of nucleic acids and their contribution to purine exposure, particularly at substantial proposed daily intakes. Cell-envelope constituents, including lipopolysaccharide in relevant Gram-negative organisms, require organism-specific characterisation rather than a generic declaration that all bacterial biomass is harmless or harmful. Viable cells, antimicrobial-resistance determinants, toxigenic potential, adventitious contamination and unwanted metabolites should be addressed according to the strain and production route. Endotoxin concepts developed for parenteral products must not be transferred mechanically to oral foods: route, dose and toxicological context differ.

A robust assessment combines strain identity and genome-level information, production-organism safety, chemical and microbiological specifications, process controls and realistic consumption estimates. If process modifications change cell disruption, extraction or washing, they may alter exposure to constituents even when the amino-acid profile remains similar.

3.3 Minerals and the process-water boundary

Mineral inputs are not incidental. They support growth and can remain in biomass or associated process streams. A responsible dossier measures relevant elemental composition and contaminants, including any process-dependent carry-over. Water quality and cleaning chemistry must be managed as distinct control systems; one should not infer that a mineral-based water treatment is suitable for this process merely because both technologies use inorganic constituents. The hazard assessment must be specific to the manufacturing operation and its resulting material.

4. The industrial qualification problem: from fermenter to food

An ingredient is not sold as an abstract powder. It enters beverages, protein blends, bakery systems, meat alternatives, nutritional products or supplements, each with a different technological and exposure envelope. Thermal treatment can improve microbiological control but also change protein aggregation and flavour; acidification can affect dispersion; hydrolysis can increase solubility while changing bitterness, peptide profiles and residual enzyme considerations. Processing must therefore be evaluated as part of the final ingredient's identity and intended use.

Three hypothetical use cases illustrate the decision logic.

Case A - Acidic functional beverage

A developer seeks to incorporate gas-fermented biomass into a pH 3.8–4.2 drink. The first question is whether intact biomass disperses acceptably and remains physically stable. A sediment-free appearance is not equivalent to molecular dissolution; high-pressure homogenisation or enzymatic treatment may modify functionality but create a materially different ingredient. The test programme should include particle-size distribution, sedimentation kinetics, viscosity, flavour, heat stability,

microbiological validation and matrix-specific analytical recovery. Protein claims require legally appropriate nutritional measurement and labelling, not extrapolation from raw-material nitrogen.

Case B - High-protein savoury food

A retorted or cooked savoury formulation presents different constraints: thermal history, salt, lipid oxidation, Maillard chemistry and flavour development. Biomass composition and texture may be beneficial, but sensory acceptability cannot be assumed from amino-acid data. Studies should separate the contribution of the microbial ingredient from the base matrix and compare independent manufacturing lots. The appropriate endpoint is a stable, safe finished food with acceptable sensory properties and documented nutritional composition.

Case C - Supplement or protein concentrate

A concentrated serving creates a more direct exposure question than low-level inclusion in a complex food. Maximum daily intake, nucleic-acid burden, mineral contribution, allergenicity considerations and co-ingredients become central. A proposed health claim about absorption, metabolism or immune effects requires its own evidentiary and legal assessment; novel-food safety does not imply efficacy. If fractionation or hydrolysis changes the material materially, its coverage under any existing authorisation must be re-examined.

5. Comparative legal architecture

Territory	Primary route	Critical limitation
EU / Spain	Regulation (EU) 2015/2283; implementing Union list under Regulation (EU) 2017/2470	EFSA opinion ≠ marketing authorisation; identity, specifications and uses govern.
Great Britain	Retained/assimilated novel-food regime and UK competent-authority decisions	EU conclusions are informative but not automatically GB permissions.
Northern Ireland	Applicable EU-linked food rules under current arrangements	Assess separately from Great Britain.
United States	FD&C Act food-additive/GRAS framework, FDA oversight	Ingredient- and use-specific basis; EU approval is not US clearance.

Within the EU, the European Commission authorises novel foods under Regulation (EU) 2015/2283 and maintains the Union list through Regulation (EU) 2017/2470 [3,6]. EFSA's scientific evaluation is necessary in many cases but does not replace the final legal act. In Spain, directly applicable EU requirements coexist with national and regional enforcement. Labelling under Regulation (EU) 1169/2011 and claims under Regulation (EC) 1924/2006 require separate compliance analysis. Potential data protection under the novel-food regime may affect reliance on a particular applicant's proprietary evidence; this must be established from the specific authorisation text, not presumed.

Great Britain has its own authorisation pathway following EU exit. The UK Advisory Committee on Novel Foods and Processes published a discussion paper concerning Xanthobacter sp. SoF1 cells and application RP1326, describing dried non-genetically modified microbial cells [7]. That is an important independent regulatory record, but it should not be treated as proof of current GB authorisation. Northern Ireland requires separate analysis under applicable EU-linked arrangements. In the United States, manufacturers must establish an appropriate lawful basis under the FDA food-additive or generally recognised as safe framework, for the exact substance and

intended use [8]. A patent, safety opinion or overseas permission does not independently establish US market clearance.

The cross-jurisdictional lesson is that a common scientific core can support multiple submissions, but authorisation status, permitted uses, specifications, claims and labelling are market-specific. An “internationally compliant” blanket certificate is not an adequate substitute for this matrix.

6. What the patent record does, and does not establish

Public patent disclosures already describe Xanthobacter strains and gas-fed continuous production of single-cell protein, including references to the SoF1 deposit. US Patent 12,600,940 was issued on 14 April 2026; a related published application, US 2026/0193597 A1, appeared on 9 July 2026 [4,5]. Their presence is strong evidence that the general concept is neither unclaimed nor newly conceived in November 2026. Claims require jurisdiction-specific legal analysis, including ownership, priority, scope, status and freedom to operate. A patent grant is not scientific validation of nutritional superiority, nor is it permission to manufacture or sell a novel food.

The defensible white space is therefore not “inventing protein from air”. It may lie in independently validated downstream processing, improved compositional characterisation, lower-energy drying, matrix-specific functionality, or better risk-based release specifications. Each opportunity requires a structured prior-art search before any assertion of novelty or patentability.

7. Research & Innovation Opportunity

The unresolved problem

For gas-fermented whole-cell ingredients, the same operations that improve technological functionality, cell disruption, controlled hydrolysis, fractionation and drying, may alter digestibility, residual cellular-component exposure, flavour and regulatory identity. There is no basis in the sources reviewed to claim that a single integrated qualification protocol has never been proposed. The research opportunity is to test whether an explicit composition–process–matrix evidence model improves industrial decisions over conventional ingredient-specification testing.

A falsifiable hypothesis

Hypothesis: for a defined set of gas-fermented microbial biomasses, a protocol combining amino-acid-based protein quantification, nucleic-acid profiling, cell-envelope markers, validated digestibility testing and finished-matrix functionality will detect more consequential formulation and safety discrepancies than a workflow based primarily on crude protein, standard microbiological release and supplier declarations. This is a proposed research hypothesis, not an established result.

Study design and validation

Recruit several independently produced lots and, where lawful and available, more than one microbial biomass type. Apply a controlled processing matrix covering intact biomass, mechanically disrupted biomass and selected fractionated or hydrolysed preparations. Compare at least two food matrices, such as an acidic beverage and a thermally processed savoury product. Record dry-matter mass balance, true protein, amino-acid profile, nucleic acids, relevant cell-envelope constituents, mineral profile, microbial safety, process energy and stability. Use blinded laboratories for priority analyses and pre-register the endpoints and decision thresholds.

Digestibility should be assessed with appropriately validated methods and interpreted conservatively; in-vitro results are not direct human absorption data. Compare sensory outcomes, dispersibility, shelf-life performance and analytical reproducibility. A robust design would report both detection of meaningful discrepancies and false alarms, along with time, cost and interlaboratory variability. Any candidate processing step that materially changes identity or specifications must be assessed for novel-food regulatory implications before commercial use.

Industrial relevance and constraints

For INTABIOTECH, the most credible opportunity is a technical development and qualification platform for innovative proteins and functional beverages: compositional auditing, process optimisation, matrix compatibility, regulatory mapping and evidence-led product design. It would be premature to promise a proprietary ingredient, a new authorisation route or superior bioavailability without dedicated data. The research should proceed through feasibility, analytical validation, pilot processing and market-specific legal review.

8. Critical conclusions

The November 2026 SoF1 opinion is a meaningful regulatory signal for gas-fermented food ingredients, but it is not a licence to treat every hydrogen-grown bacterial powder as interchangeable or approved. The underlying fermentation concept is already documented in the patent record, and its environmental and nutritional merits depend on actual process and product data. What matters for industrial deployment is the identity of the whole-cell material, its production history, exposure profile and behaviour in the finished food.

A scientifically serious industry should move beyond two symmetrical errors: dismissing microbial biomass because it is unfamiliar, and endorsing it because its protein originates from gases and minerals. Both positions bypass the evidence. The more productive path is ingredient-specific safety, process-aware compositional analysis, transparent nutritional qualification and jurisdiction-specific authorisation. That is where credible innovation and useful regulatory thought leadership, can occur.

References and official sources

[1] EFSA. Novel food topic page; listing of Xanthobacter sp. SoF1 opinion, 9 November 2026. https://www.efsa.europa.eu/en/topics/topic/novel-food

[2] EFSA NDA Panel (2026). Safety of powdered Xanthobacter sp. SoF1 biomass as a novel food. EFSA Journal. DOI: 10.2903/j.efsa.2026.10327. https://doi.org/10.2903/j.efsa.2026.10327 (full text not accessible during this review).

[3] Regulation (EU) 2015/2283 on novel foods. https://eur-lex.europa.eu/eli/reg/2015/2283/oj

[4] US Patent 12,600,940 B2 (14 April 2026), Strains and processes for single cell protein or biomass production. https://patents.justia.com/patent/12600940

[5] US Patent Application 2026/0193597 A1 (9 July 2026), Strains and processes for single cell protein or biomass production. https://patents.justia.com/patent/20260193597

[6] Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods. https://eur-lex.europa.eu/eli/reg_impl/2017/2470/oj

[7] UK Advisory Committee on Novel Foods and Processes (2025). Xanthobacter sp. SoF1 Cells Discussion Paper, RP1326. https://acnfp.food.gov.uk/XanthobactersSoF1CellsDiscussionPaper

[8] US FDA. Generally Recognized as Safe (GRAS). https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras

[9] Regulation (EU) No 1169/2011 on food information to consumers. https://eur-lex.europa.eu/eli/reg/2011/1169/oj

[10] Regulation (EC) No 1924/2006 on nutrition and health claims. https://eur-lex.europa.eu/eli/reg/2006/1924/oj

[11] EFSA. Novel food application procedure, updated 6 May 2026. https://www.efsa.europa.eu/en/applications/novel-food

Related INTABIOTECH Knowledge Areas: Biotechnology; Innovative Proteins; Functional Ingredients; Food Safety; Nutrition; Regulatory Affairs; Processing Technologies; Emerging Research.

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