

Prebiotic Research and Development

Key Considerations for Prebiotic Validation and Health Claim Substantiation

Prebiotics form a high-potential category in the health and nutrition space, with expanding evidence linking their intake to not only digestive health, but also metabolic, immune and cognitive health. However, substantiating prebiotic status and health benefits remains challenging — especially for regulatory approval of health claims. Additionally, the ‘prebiotic’ term is not recognised by all regulatory authorities, as is the case for the European Union.

Recent publications from the International Scientific Association for Probiotics and Prebiotics (ISAPP) and from the International Life Sciences Institute (ILSI Europe) provide science-based, complementary guidance to help researchers and industry professionals navigate these challenges. Together, these resources outline essential considerations to assist scientific validation of prebiotics and bridge the gap between scientific and regulatory recognition of prebiotic health effects.

How are prebiotics defined?

Prebiotic

Consensus definition A substrate that is selectively utilized by host microorganisms conferring a health benefit on the host (Gibson et al., 2017)

Simple way to conceptualise Food for beneficial microbes residing on or within the host.

Demonstrated health benefit required? Yes

A non-exhaustive list of prebiotic examples include: Galactooligosaccharides, fructooligosaccharides, inulin, lactulose, certain types of resistant starch and human milk oligosaccharides.

Keep in mind Look for appropriate characterisation and research to confirm the prebiotic status and health benefits of an ingredient.




Prebiotic research areas (examples):

Digestive health

- Bowel movement;
- Gastrointestinal discomfort (Irritable Bowel Syndrome);
- Nutrient digestion and absorption.

Metabolic health

- Overweight & obesity;
- Glycemia and insulin sensitivity;
- Cardiometabolic risk factors.

Immune health

- Defense against pathogens;
- Vaccination response;
- Allergen hypersensitivity.

Cognitive health

- Mood, anxiety or psychological stress;
- Cognitive function.

Can my product be classified as a prebiotic?

While the consensus definition of prebiotics is well established, specific guidance on pathways and requirements to demonstrate prebiotic status can assist researchers in planning and conducting prebiotic research and development work. In a 2024 Expert Recommendation, ISAPP proposed clear scientific criteria to support the classification of compounds as prebiotics. The guidance includes adequate substance characterisation, compositional and functional measures of microbiome modulation, defining and demonstrating selective utilisation, minimum criteria for demonstrating health benefits and linking these to microbiome mediation, and further guidance on approaches for demonstrating causality and addressing confounders.

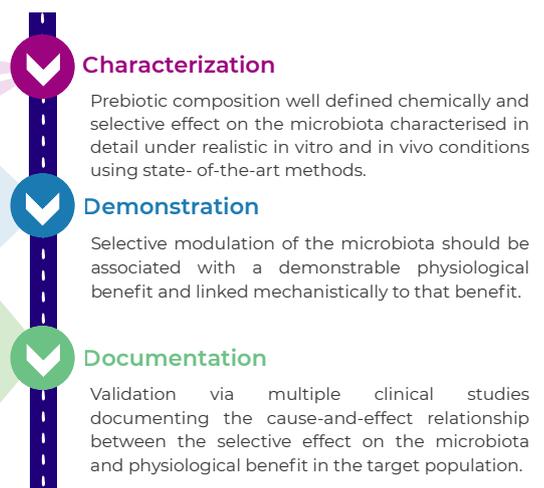
The ISAPP **Checklist of Cumulative Required Evidence for a Prebiotic** (extract below) summarises recommendations to follow in order to classify a substance as a prebiotic.

Criterion	Check
Defined structure, purity and stability	<input checked="" type="checkbox"/>
Proposed mechanism linking microbiome changes to health benefit	<input checked="" type="checkbox"/>
Selective utilization in target host	<input checked="" type="checkbox"/>
Health benefit in target host	<input checked="" type="checkbox"/>
Selective utilisation and health benefit demonstrated concurrently in target host	<input checked="" type="checkbox"/>
Safe for intended use	<input checked="" type="checkbox"/>
Dose and formulation	<input checked="" type="checkbox"/>
Confirmatory evidence (optional for classification, but needed for health claim)	<input checked="" type="checkbox"/>

Can I associate a health claim to my product? A focus on Europe.

Guidance to assist the effective translation of research into substantiated product claims varies between countries. In the European case, there is currently no guidance from regulatory authorities on making a "prebiotic" health claim in the EU. Following a collaborative effort from academic, industry and regulatory experts, ILSI Europe published in 2024 a **strategic roadmap** to overcome current scientific and regulatory hurdles in order to achieve this ambition (below).

In addition, ILSI proposes that standardized methodologies, validated biomarkers, and a stronger demonstration of causal correlation links between prebiotics, microbiota modulation, and health outcomes, supported by a plausible and substantiated mechanism of action as causality, will support this roadmap.



ISAPP's guidance and checklist aim to harmonize research approaches, support dialogue between researchers and regulators, and encourage innovation in the prebiotic field.

ILSI Europe's guidance aims to support the development of robust scientific dossiers that can lead to the recognition of "prebiotic" in EU-approved health claims.

References:

- Hutkins, R., Walter, J., Gibson, G.R. et al. *Classifying compounds as prebiotics — scientific perspectives and recommendations.* Nat Rev Gastroenterol Hepatol 22, 54–70 (2025). <https://doi.org/10.1038/s41575-024-00981-6>
- ISAPP's Checklist of Cumulative Required Evidence for a Prebiotic: <https://isappscience.org/resource/checklist-of-cumulative-required-evidence-for-a-prebiotic>

References:

- Tuohy, K., Vaughan, E. E., Harthoorn, L. F., Blaak, E. E., Burnet, P. W. J., Busetti, A., ... Calder, P. C. (2024). *Prebiotics in food and dietary supplements: a roadmap to EU health claims.* Gut Microbes, 16(1). <https://doi.org/10.1080/19490976.2024.2428848>