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The Regulatory Paradigm of Probiotics in the EU and the US

Economic Impact, Scientific-Technological Consequences, and Prospects for Evolution Toward an Evidence-Based Model

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Executive Summary

Probiotics constitute one of the most studied and commercially developed categories of functional ingredients worldwide. However, their development has followed radically divergent trajectories depending on the regulatory framework of each jurisdiction.

The central problem

The European Union has adopted a significantly more restrictive position since Regulation (EC) 1924/2006. EFSA's interpretation has led, in practice, to the impossibility of using the term "probiotic" itself in commercial labeling.

Scope of analysis

- Historical evolution of regulation in the EU and the U.S.
- Economic consequences of both models
- Scientific implications in light of the microbiome
- Regulatory pathways to harmonize protection and innovation

Introduction: Gut Microbiota and Human Health

The interaction between gut microbiota and human health is one of the fastest-growing scientific fields of the last two decades. Technologies such as NGS, metagenomics, metabolomics, and transcriptomics have revealed that intestinal microorganisms actively participate in metabolic, immunological, endocrine, and neurological processes.

> "Live microorganisms that, when administered in adequate amounts, confer a health benefit on the host."
>
> — *WHO/FAO Definition of Probiotic*

This seemingly simple definition contains the central regulatory challenge: the need to unequivocally demonstrate which specific microorganisms produce which specific benefits and under what consumption conditions. The controversy arises precisely in the interpretation of the expression **"health benefit"**, the conceptual core upon which radically different regulatory frameworks have been built between Europe and the United States.

Historical Evolution of the Global Probiotics Market

SECTION 2.1

Although the consumption of fermented foods has accompanied humanity for millennia, the modern commercial development of probiotics can be traced back to the 1980s and 1990s. Companies such as Yakult, Danone, Nestlé, and Valio led the way with specific strains, and from the early 2000s growth was extraordinary.

Lactobacillus casei and *L. rhamnosus*

Pioneer strains in commercial fermented products, linked to digestive well-being.

Bifidobacterium lactis

Key strain in supplements and functional dairy products with high commercial prevalence in Europe.

Lactobacillus acidophilus

One of the most widely distributed strains worldwide, present in yogurts with annual growth of 15–20%.

The European Boom Before EFSA (2002–2008)

SECTION 2.2

Between 2002 and 2008, Europe led the global market for functional yogurts. Brands such as **Activia®, Actimel®, Yakult®, LC1®** and **Vifit®** built their positioning around messages that European consumers clearly recognized as distinctive health-related attributes tied to digestive wellness.

Digestive balance

The primary communication axis toward consumers throughout this period of growth.

Intestinal transit

A widely used concept with strong acceptance in Northern and Central European markets.

Immune support

An emerging claim that drove new product lines and investment in clinical research.

Gastrointestinal well-being

An umbrella concept under which much of the functional marketing strategy was structured.

Investments in clinical research grew in parallel with the market: numerous companies developed proprietary programs to characterize specific strains and study their physiological mechanisms of action.

The European Regulatory Turning Point

SECTION 3.1 — REGULATION (EC) 1924/2006

The adoption of Regulation (EC) No. 1924/2006 on nutrition and health claims represented a radical shift in the European regulatory approach, whose fundamental objective was to protect consumers from misleading or insufficiently science-backed claims.

Mandatory Scientific Evaluation

Every health claim had to be scientifically evaluated before commercial use, eliminating the sector's previous self-regulation.

Reversed Burden of Proof

The responsibility for demonstrating the scientific soundness of each claim fell exclusively on the applicant, not on the regulatory authority.

Positive List of Claims

Only claims expressly authorized after passing EFSA's evaluation could be used in commercial communications.

EFSA's Evaluation: Grounds for Rejection

SECTION 3.2

Starting in 2008, EFSA evaluated thousands of health claim applications related to probiotics. The vast majority were rejected for three recurring reasons of particular technical and scientific relevance.

1

Insufficient Strain Characterization

EFSA required precise taxonomic identification at the strain level: genus, species, specific strain, and demonstrated genetic stability. It was not sufficient to indicate *Lactobacillus spp.* or *Bifidobacterium spp.* in a generic manner.

2

Lack of Physiological Effect Definition

Expressions such as "improvement of intestinal flora" or "digestive balance" were deemed insufficient because they did not describe a concrete, measurable, and clinically verifiable physiological benefit.

3

Insufficient Clinical Causality

Controlled clinical trials were required — double-blind, randomized, and reproducible — with demonstrable effects in a **healthy population**. This last requirement made the approval of health claims extraordinarily difficult.

The Practical Ban on the Term "Probiotic"

SECTION 4

One of the most controversial legal-technical consequences was the interpretation that the term **"probiotic"** itself automatically implies a health claim. Several Member States adopted this position, with direct effects on the market.

- Numerous products stopped using the word "probiotic" on their labeling and commercial communications.
- It was replaced by expressions such as **"live ferments"** or "active cultures," terms with less communicative impact.
- Direct and transparent communication with consumers about physiological benefits was drastically reduced.

⚠ **Regulatory Paradox**

An ingredient whose internationally recognized scientific definition explicitly includes a health benefit cannot be identified as such in a large portion of the European market. The claim, implicit in the scientific definition itself, paradoxically became the cause of its commercial ban.

Economic Consequences for the European Industry

SECTION 5

>1,500M€

Accumulated Losses

Estimated by Euromonitor International across six key European markets, likely underestimating the real impact.

100,000M$

Projected Global Market

Potential of the global microbiome sector over the next decade, from which Europe could be excluded as a leader.

Lower R&D Investment

Companies have fewer incentives to fund costly clinical trials when the chances of obtaining an authorized claim are extremely slim.

Loss of Global Leadership

Europe is ceding ground to the US, Japan, South Korea, and China in the development of new strains and microbiological innovation ecosystems.

Reduced Investment Attraction

Venture capital funds prefer more predictable regulatory environments, with safer and more viable returns on investment.

Technological Opportunity Cost

Europe runs the real risk of becoming an importer of microbiological innovation developed in other regions of the world.

The American Model: DSHEA and Its Consequences

SECTION 6

The *Dietary Supplement Health and Education Act* (DSHEA, 1994) established an approach radically different from the European one, allowing the so-called **Structure/Function Claims** without prior FDA authorization.

Examples of Permitted Claims

- Supports digestive balance
- Helps maintain gut health
- Promotes normal immune function

Without the need for prior regulatory authorization.

Corporate Responsibility and Consequences

The company must have reasonable scientific evidence and avoid therapeutic claims, including the corresponding legal disclaimer. The FDA and FTC intervene after the fact if claims are misleading, with **extremely severe penalties**.

The result: the U.S. has become the world's leading market for probiotic supplements, the primary destination for microbiome investment, and the largest generator of biotech startups associated with functional microorganisms.

The Asian Rise: A Competitor That Won't Wait

SECTION 7

While Europe debates the use of the word "probiotic," Asia leads global sector growth. The combination of more flexible regulation, greater state investment, and rapid technological adoption has fostered the creation of highly competitive innovation ecosystems.

China

Currently one of the largest global markets for functional microbiological products, with strategic state investment and unprecedented industrial scale.

Japan

Historical pioneer of the "functional foods" concept with the FOSHU system, an international regulatory benchmark since the 1990s.

South Korea

A regulatory framework that allows communicating specific benefits of probiotic strains, driving a highly export-oriented biotechnology industry.

Vietnam

A fast-growing emerging market, benefiting from more accessible functional regulation and rising local demand for gut health products.

The current scientific problem: EFSA was right, but perhaps arrived too soon

SECTION 8

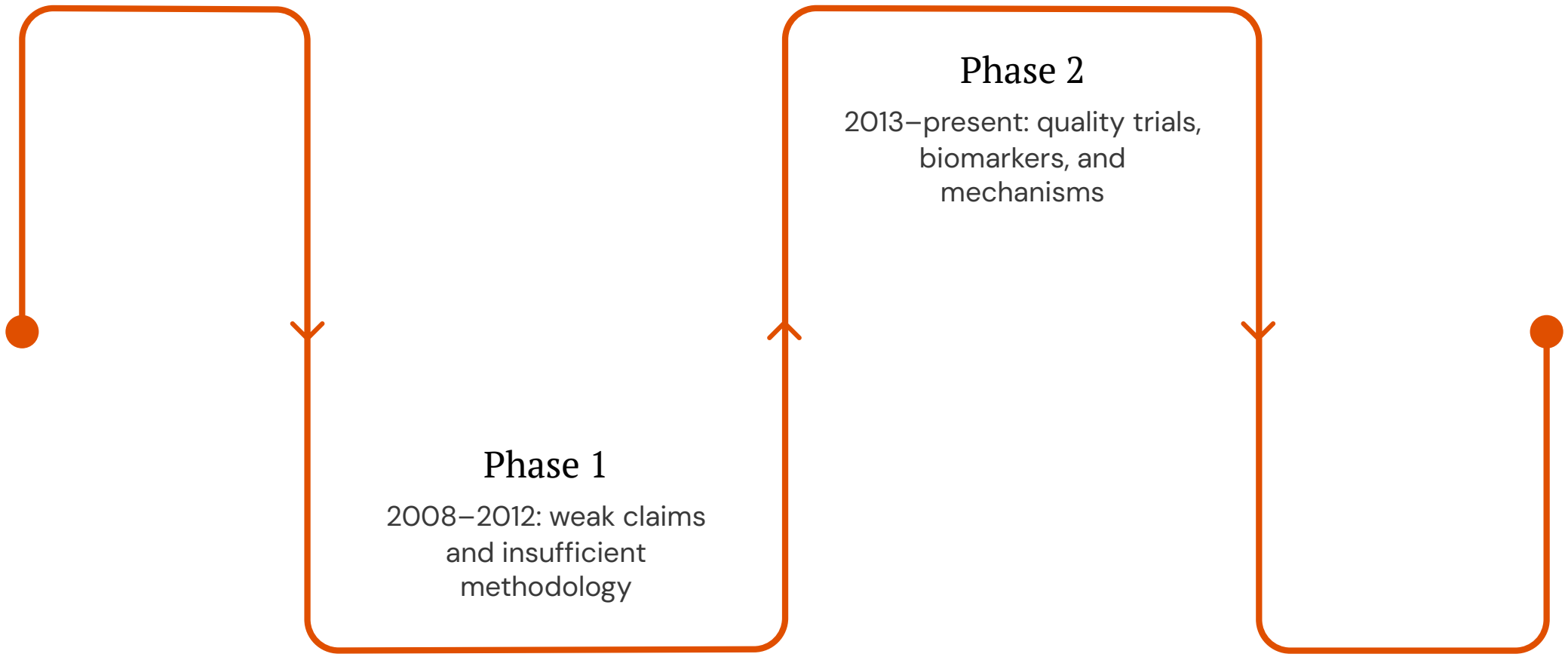
From a standpoint of scientific rigor, many claims submitted between 2008 and 2012 were indeed weak. However, the current scientific landscape is radically different.

Today there are hundreds of high-quality clinical trials on well-characterized strains, and the development of microbiological biomarkers allows for establishing causal mechanisms far more robust than those available fifteen years ago.

Strains with current solid clinical evidence

- *Lacticaseibacillus rhamnosus* GG
- *Bifidobacterium animalis* subsp. *lactis* BB-12
- *Lactiplantibacillus plantarum* 299v
- *Saccharomyces boulardii* CNCM I-745

Among many other strains with robust and reproducible evidence profiles.



The science of the microbiome has advanced exponentially. The European regulatory framework should be updated to reflect this new state of scientific knowledge.

New concepts and pathways for regulatory reform

SECTION 9

Postbiotics

Metabolites or cellular components capable of exerting biological effects without the need for live microorganisms.

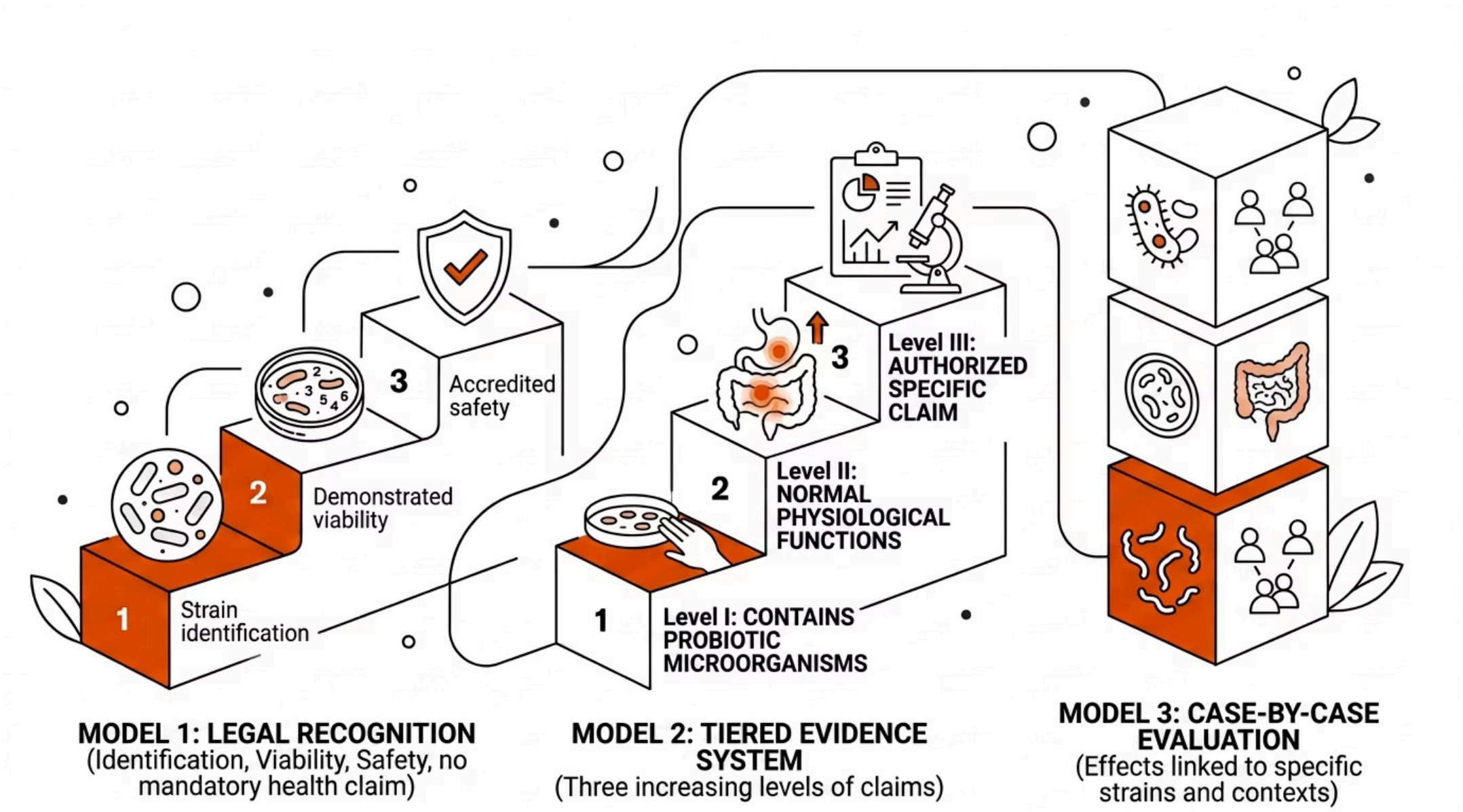
Paraprobiotics

Inactivated microorganisms with demonstrated physiological activity, which could overcome regulatory limitations on viability.

Synbiotics

Rational combinations of probiotics and prebiotics with clinically documented synergistic effects.

Proposed regulatory reform models



Future perspectives: the microbiome race

SECTION 10

The global microbiome market could well exceed $100 billion over the next decade. Its reach extends far beyond traditional sectors and is moving into fields that are still undeveloped today.

Functional foods and personalized nutrition

Formulations tailored to the individual microbiological profile of the consumer.

Microbiological therapies and precision medicine

The microbiome as a therapeutic target in oncology, autoimmune diseases, and mental health.

Smart microbiological preservation and control

New frontiers in food safety, reduction of processing-related damage, and metabolic fermentation control.

Metabolomics and food genomics

Study of the health impact of recurring consumption of processed foods from a genomic and metabolic perspective.

The European regulatory question will be **decisive** in determining whether Europe participates as a technology leader or merely as a consumer of innovation generated in other regions of the world.

Conclusions

SECTION 11

European regulation of probiotics is one of the most relevant examples of tension between consumer protection and technological innovation. The advances of the last fifteen years in microbiology, genomics, and microbiome sciences justify a deep reconsideration of the current regulatory framework.

1 Maintain European scientific rigor

EFSA's high level of scrutiny has raised global standards of evidence. This asset must not be sacrificed but integrated into a new, more agile model.

2 Incorporate flexible evaluation mechanisms

Tiered systems, strain-specific authorizations, and recognition of the term "probiotic" represent balanced solutions between safety and evidence.

3 Preserve European leadership in biotechnology

Without regulatory reform, Europe faces the real risk of losing prominence in one of the most promising sectors of nutrition and biotechnology in the 21st century.

The evolution toward tiered evaluation systems and strain-specific authorizations could represent the balanced solution that Europe needs to reclaim its position of leadership in global microbiological innovation.

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