

A Systems-Level Review of Economics, Business Strategy, and Food Science in the Development and Policy Governance of Functional Health Foods

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Abstract

Functional health foods have emerged as a major interdisciplinary domain integrating food science, nutrition, economics, business strategy, and regulatory policy. This review synthesizes evidence from studies published between 1998 and 2026 to examine the scientific foundations, market dynamics, regulatory frameworks, and systemic interactions shaping the functional food sector. The analysis reveals that bioactive compounds such as probiotics, polyphenols, omega-3 fatty acids, dietary fibers, and phytochemicals exert physiological benefits through multiple mechanisms including gut microbiome modulation, anti-inflammatory activity, cardiometabolic regulation, and antioxidant defense. Despite strong experimental and clinical evidence supporting certain health benefits, translation into consistent public health outcomes is constrained by variability in bioavailability, food matrix interactions, and individual biological differences. Economic analysis demonstrates rapid global market expansion, particularly in the United States and China, though high product prices and regulatory complexities limit widespread accessibility. Regulatory governance varies significantly across jurisdictions, ranging from Japan's Food for Specified Health Use (FOSHU) system to the European Union's stringent health-claim authorization framework. These differences strongly influence innovation strategies and commercialization pathways. A systems-level perspective reveals that successful functional food ecosystems require sequential alignment between scientific validation, regulatory frameworks, and business innovation. Emerging technologies—including personalized nutrition, artificial intelligence-driven product design, microbiome-targeted foods, and nano-delivery systems—offer opportunities to overcome current limitations, but also necessitate regulatory evolution and greater interdisciplinary coordination. Overall, the functional food sector represents a rapidly expanding yet complex innovation ecosystem where scientific evidence, economic incentives, regulatory policy, and consumer perception interact to shape the development and global governance of health-promoting foods.

Keywords

Functional foods, Food science innovation, Bioactive compounds, Nutrition policy, Health claims regulation, Food economics, Business strategy, Personalized nutrition, Nutrigenomics, Regulatory governance.

Introduction

Functional foods have emerged as a significant area of research and commercial innovation at the intersection of nutrition science, food technology, and preventive healthcare. Unlike conventional foods that primarily provide basic nutrition, functional foods contain biologically active compounds capable of exerting beneficial physiological effects beyond their fundamental nutritional value. These foods are increasingly recognized as potential tools for addressing major public health challenges such as cardiovascular disease, metabolic disorders, obesity, and chronic inflammation (Fekete et al., 2025; Mittal et al., 2023).

The scientific foundation of functional foods is based on the identification and incorporation of bioactive compounds—including probiotics, polyphenols, omega-3 fatty acids, dietary fibers, and various phytochemicals—that interact with biological systems through mechanisms such as gut microbiome modulation, anti-inflammatory activity, cardiometabolic regulation, and antioxidant defense (Fekete et al., 2025; Xinyun Zhang et al., 2025). Advances in nutritional biochemistry, microbiome research, and nutrigenomics have strengthened the mechanistic understanding of how these compounds influence human health, while clinical trials and epidemiological studies increasingly provide evidence supporting their role in disease prevention and metabolic health improvement (Fekete et al., 2025; Ma et al., 2026).

Parallel to scientific developments, the global functional food industry has expanded rapidly over the past two decades. Market analyses indicate significant economic growth in regions such as the United States, Europe, and Asia, driven by rising consumer awareness of diet-related health risks and increasing demand for health-promoting foods (Daliri & Lee, 2015; Shan et al., 2025). Despite this growth, the commercialization of functional foods remains complex, requiring alignment between scientific validation, regulatory approval, and business strategy. High development costs, limited regulatory clarity, and challenges in communicating scientifically substantiated health claims often hinder successful product development and market adoption (Jones et al., 2008; Morrison, 2015).

Regulatory governance represents another critical dimension shaping the functional food sector. Different jurisdictions employ diverse regulatory frameworks to evaluate and authorize health claims associated with functional foods. For example, Japan pioneered the regulatory recognition of functional foods through the establishment of the Food for Specified Health Use (FOSHU) system in 1991, allowing limited health claims following scientific evaluation (Verschuren, 2002). In contrast, the European Union introduced a stricter regulatory structure under Regulation No. 1924/2006, requiring extensive scientific substantiation, including randomized controlled trials and systematic reviews, before approving health claims (Lawrence & Rayner, 1998; Jones et al., 2008). These variations illustrate the broader tension between promoting innovation in food science and ensuring consumer protection through rigorous evidence standards.

Given the multidisciplinary nature of the functional food sector, understanding its development requires a systems-level perspective that integrates scientific discovery, regulatory policy, economic incentives, and consumer behavior. Previous studies have emphasized that innovation in functional foods is shaped by complex feedback loops between research institutions, regulatory agencies, industry stakeholders, and consumers (Fekete et al., 2025; Shan et al., 2025). Consequently, the success of functional food ecosystems depends on coordinated interactions among these domains.

This review therefore synthesizes evidence from studies published between 1998 and 2026 to examine the functional food sector through an integrated framework encompassing food science, economics, business strategy, and policy governance. By analyzing how these domains interact, the study aims to provide a comprehensive understanding of the factors influencing the development, commercialization, and regulatory management of functional health foods.

Functional Food Sector Analysis: Scientific, Economic, and Regulatory Heterogeneity

The functional food sector exhibits substantial heterogeneity across scientific, economic, and regulatory domains, reflecting context-dependent rather than contradictory findings. Ten studies spanning 1998-2026 reveal that bioactive compounds including probiotics, polyphenols, omega-3 fatty acids, and dietary fiber operate through multiple biological pathways (gut microbiome modulation, anti-inflammatory processes, cardiometabolic regulation) (Fekete et al., 2025), with evidence from randomized controlled trials demonstrating reductions in LDL cholesterol, improved insulin sensitivity, and mitigation of oxidative stress (Fekete et al., 2025). However, translation to consistent health benefits faces challenges from variability in bioavailability, food matrix effects, and interindividual differences in genetics and gut microbiota (Ma et al., 2026). Economic dynamics show rapid market growth (US market reaching \$8.62 billion by 2015 [Daliri & Lee, 2015], Chinese market growing at 13% annually [Shan et al., 2025]), yet functional foods priced 3-5 times higher than conventional products create socioeconomic barriers limiting accessibility to affluent consumers (Fekete et al., 2025).

Regulatory frameworks remain highly fragmented: Japan's FOSHU system enables health claims through biomarker evidence (Verschuren, 2002), while Europe's EU Regulation 1924/2006 requires randomized controlled trials, yielding limited approved claims despite substantial research investment (Lawrence & Rayner, 1998; Jones et al., 2008). Business strategies succeeding commercially leverage familiar delivery vehicles and existing consumer understanding through "natural match" approaches (Daliri & Lee, 2015), while novel bioactives requiring consumer education face adoption barriers. Systems-level integration analysis reveals that successful functional food ecosystems require sequential stakeholder alignment: scientific validation preceding regulatory framework development, which enables business model innovation (Xinyun Zhang et al., 2025).

Feedback loops between domains shape development trajectories, with regulation influencing innovation through exemptions and prohibitions, and market incentives driving scientific research priorities (Lawrence & Rayner, 1998; Jones et al., 2008). The "mechanism-to-evidence-to-regulation" framework proposed by Xinyun Zhang et al. (2025) links molecular insights with clinical validation and regulatory implications, though implementation faces coordination challenges from public understanding deficits, regulatory inconsistencies, and cross-border harmonization difficulties. Emerging opportunities in personalized nutrition, artificial intelligence-driven product design, microbiome-targeted foods, and nano-encapsulation delivery systems may address current limitations (Ma et al., 2026; Fekete et al., 2025), but require substantial R&D investment and evolution of regulatory frameworks designed for standardized products rather than individualized nutrition approaches. For functional foods with established mechanisms, clear health indications, and familiar delivery formats, market success is achievable in jurisdictions with science-based regulatory pathways, though outcomes remain concentrated in affluent consumer segments rather than achieving broad public health impact (Daliri & Lee, 2015; Shan et al., 2025). The nutshell is depicted in figure-1.

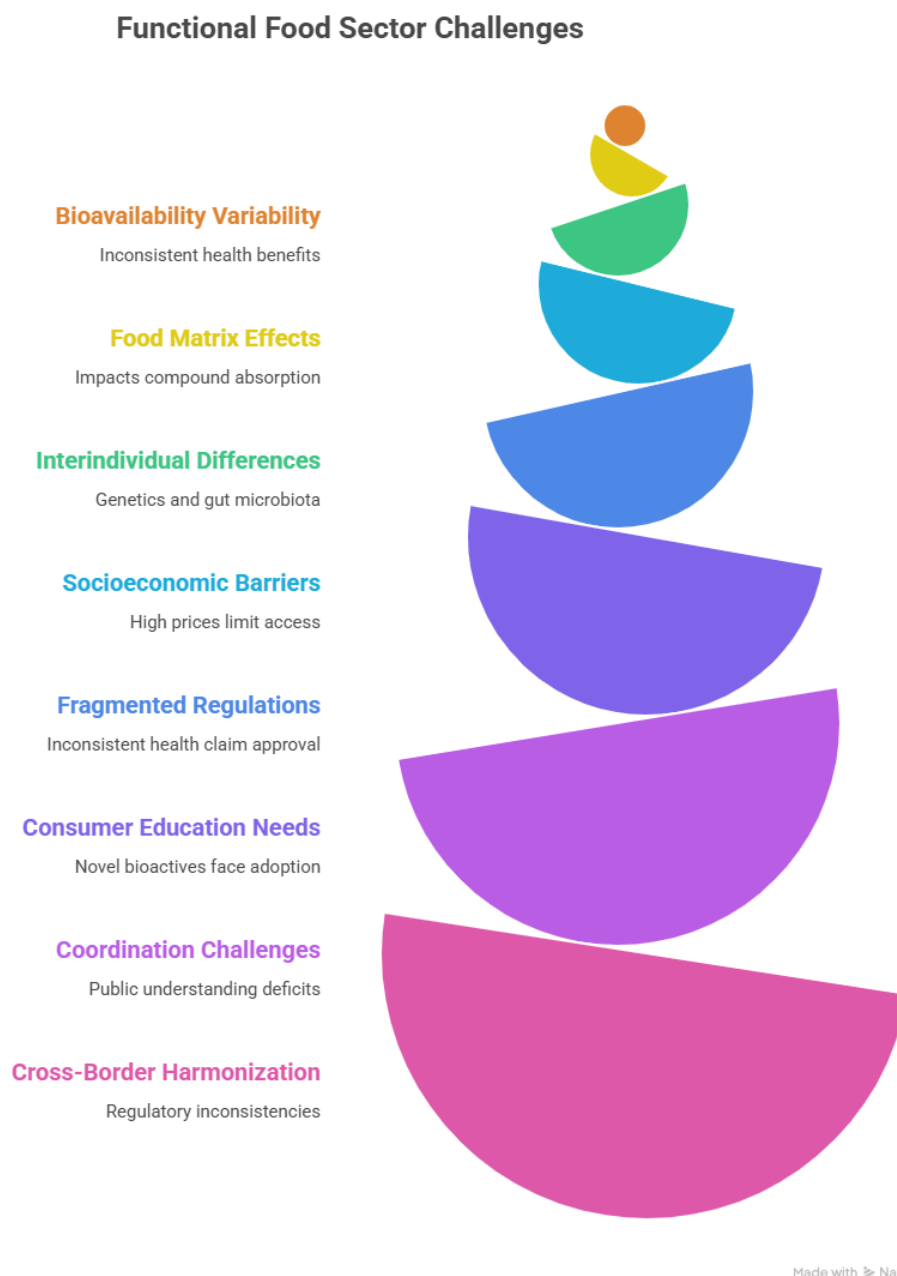


Figure-1. Challenges of the functional food development sector

Thematic Analysis

Scientific and Technical Foundations

The bioactive compounds most frequently examined across studies include probiotics and prebiotics, polyphenols, omega-3 fatty acids, dietary fiber, and various phytochemicals including catechins, flavonoids, and carotenoids (Mittal et al., 2023). These compounds operate through multiple biological pathways: gut microbiome modulation, anti-inflammatory processes, cardiometabolic regulation, immune support, and antioxidant mechanisms (Fekete et al., 2025). Xinyun Zhang et al. (2025) provide the most comprehensive mechanistic framework, describing how beta-glucan, omega-3 PUFAs, dietary fiber, and catechins orchestrate synergistic effects at molecular, cellular, and systemic levels to counteract oxidative stress, chronic inflammation, metabolic dysregulation, and gut microbiota imbalance.

Food processing technologies and delivery methods receive limited detailed attention in most studies, though several innovations are noted. Fekete et al. (2025) mention microencapsulation and biofortification as key processing approaches, while Xinyun Zhang et al. (2025) highlight nano-encapsulation and liposomes as delivery systems to enhance bioavailability. Daliri & Lee (2015) discuss fermentation technologies and the use of milk as a carrier for added nutrients in functional dairy products. However, processing conditions are consistently identified as a challenge affecting bioavailability and consistency (Ma et al., 2026).

Evidence standards and validation requirements vary across regulatory jurisdictions. Fekete et al. (2025) emphasize that randomized controlled trials and systematic reviews are the primary evidence base supporting health claims, with specific mention of clinical trials and epidemiological studies demonstrating reductions in LDL cholesterol, improved insulin sensitivity, and mitigation of oxidative stress. Lawrence & Rayner (1998) highlight the importance of systematic reviews as a method for evaluating the validity of scientific evidence and establishing criteria for data quality. Verschuren (2002) notes that the EU PASSCLAIM project was developed to provide means for evaluating the scientific basis for health claims, emphasizing experimental studies, epidemiological studies, and the use of biomarkers. Xinyun Zhang et al. (2025) call for high-level evidence-based frameworks and large-scale cohort studies to validate interaction mechanisms. The emphasis on clinical substantiation reflects a shift toward evidence-based validation, though the cost and complexity of conducting adequate trials remain significant barriers (Morrison, 2015; Jones et al., 2008).

Economic Dynamics and Market Structure

Market size data show substantial economic impact across regions. The United States represents the world's largest functional food market, with expected growth of 21% to reach \$8.62 billion by 2015, driven primarily by demand for energy drinks and fortified dairy products (Daliri & Lee, 2015). More recent data from Feibiao Shan et al. (2025) indicate the US dietary supplement market alone reached \$55.7 billion in 2020, while the EU food supplement retail market was valued at \$22.69 billion in 2020. The Chinese health and functional food market demonstrates particularly rapid expansion, growing from 222.7 billion Yuan in 2019 to 298.9 billion Yuan in 2022, representing a compound annual growth rate exceeding 13% (Shan et al., 2025).

Economic barriers to adoption include high product costs relative to conventional foods. Fekete et al. (2025) report that functional foods are 3-5 times more expensive than conventional products, limiting accessibility to lower-income populations and creating health inequalities. Consumer spending patterns are influenced by multiple factors including product format, socio-demographic characteristics, information sources, health motivation, and price sensitivity (Ma et al., 2026). Verschuren (2002) notes that European consumers show increasing demand for healthier products, yet few functional food products have successfully reached the market due to the high cost of developing scientific support for health claims and challenges in communicating diet-related information.

Investment patterns reflect the high-stakes nature of functional food development. Xinyun Zhang et al. (2025) describe substantial investment by the food industry, research institutions, and government departments in developing scientifically substantiated products. The integration of advanced technologies such as genomics, microbiomics, and artificial intelligence implies significant ongoing R&D investment (Fekete et al., 2025). Feibiao Shan et al. (2025) highlight how positive ingredient lists encourage scientific research and innovation by providing clear regulatory pathways. However, Morrison (2015) raises sobering questions about the costs of delivering quality clinical data versus the prospective rewards currently available through product commercialization, suggesting potential misalignment between investment requirements and market returns.

Table-1. Economic Landscape of the Global Functional Food and Supplement Market

Category	Key Findings & Market Data	Primary Drivers / Barriers	Source(s)
Regional Market Size	USA: \$8.62B (2015); \$55.7B (Supplements, 2020)		
	EU: \$22.69B (Supplements, 2020)	Energy drinks, fortified dairy, and rapid 13% CAGR in China.	Daliri & Lee (2015); Shan et al. (2025)
	China: 298.9B Yuan (2022)		
Consumer Accessibility	Price premium is 3–5x higher than conventional foods.	Socio-demographics, health motivation, and price sensitivity.	Fekete et al. (2025); Ma et al. (2026)
Investment & Innovation	High investment in Genomics, AI, and Microbiomics for product R&D.	Industry, institutional, and government backing for scientific substantiation.	Zhang et al. (2025); Fekete et al. (2025)
Market Entry Barriers	High costs of clinical data and scientific support for health claims.	Rigorous regulatory pathways vs. uncertain commercial rewards.	Verschuren (2002); Morrison (2015)
Regulatory Impact	"Positive ingredient lists" streamline innovation.	Clearer pathways encourage research and development.	Shan et al. (2025)

Business Strategy and Competitive Positioning

Innovation strategies span a continuum from science-driven to market-driven approaches. Fekete et al. (2025) describe a science-driven model emphasizing interdisciplinary research and collaboration, with integration of technologies like nutrigenomics, artificial intelligence, and biofortification. Xinyun Zhang et al. (2025) detail how advancement of functional foods is guided by precision, efficacy, and scientific rigor, with integration of multi-omics analyses and real-time physiological monitoring for personalized nutrition. In contrast, Lawrence & Rayner (1998) identify marketing-driven product development strategies where manufacturers promote health claims as a way to differentiate products. Verschuren (2002) notes the tension between developing products consistent with consumer culture versus the expense and time required for scientific validation.

Competitive positioning strategies emphasize differentiation through scientifically validated health claims (Fekete et al., 2025). Xinyun Zhang et al. (2025) highlight innovations in delivery systems like nano-encapsulation and liposomes as competitive approaches to enhance bioavailability. Daliri & Lee (2015) emphasize the importance of consumer familiarity with functional compounds and natural matches between carriers and functional compounds in driving acceptance. The probiotic space exemplifies these dynamics, with widespread perceived health benefits yet limited regulatory success creating both opportunities and challenges (Jones et al., 2008).

Partnership models emphasize cross-sector collaboration. Fekete et al. (2025) advocate for coordination among healthcare professionals, nutrition scientists, policymakers, and the food industry to maximize impact. Morrison (2015) calls for greater harmonization of regulatory guidelines across sectors, while Feibiao Shan et al. (2025) recommend cross-border cooperation and international harmonization of regulations to facilitate global trade. Daliri & Lee (2015) emphasize the need for collaboration between food producers and scientists to advance functional food technology.

Branding and marketing strategies focus heavily on consumer perceptions and transparent communication. Fekete et al. (2025) highlight the critical role of consumer perceptions and expectations in product success, emphasizing the need for transparent communication about health benefits and limitations. Xinyun Zhang et al. (2025) note how sustainability and clean label demands influence production processes, reflecting market pressures for ethical marketing and consumer trust. Several studies identify digital tools and personalized nutrition platforms as emerging approaches for consumer engagement (Ma et al., 2026).

Policy Governance and Regulatory Frameworks

Regulatory bodies and definitions vary substantially across jurisdictions. In Asia, Japan pioneered specific frameworks with the introduction of Foods for Specified Health Use (FOSHU) in 1991, allowing limited health claims after approval from the Ministry of Health (Verschuren, 2002). The European Union adopted a working definition in 1999 stating that “a food can be regarded as functional if it is satisfactorily demonstrated to beneficially affect one or more target functions in the body, beyond adequate nutritional effects”, later implementing EU Regulation No. 1924/2006 governing nutrition and health claims (Lawrence & Rayner, 1998; Jones et al., 2008). In the United States, the FDA regulates dietary supplements under distinct frameworks from conventional foods. Feibiao Shan et al. (2025) provide detailed comparisons across multiple countries: China’s State Administration for Market Regulation (SAMR) and National Health Commission (NHC), South Korea’s Korea Food and Drug Administration (KFDA), Australia’s Therapeutic Goods Administration (TGA), India’s Food Safety and Standards Authority of India (FSSAI), and Russia’s Rospotrebnadzor all maintain different definitional and classification schemes.

Health claim substantiation requirements reflect the tension between innovation promotion and consumer protection. Lawrence & Rayner (1998) propose maintaining a general prohibition on health claims while accommodating specific exemptions supported by scientific substantiation. The Codex Alimentarius Commission provides international guidelines for health claims, though implementation varies considerably (Shan et al., 2025). The EU PASSCLAIM project was developed to evaluate the scientific basis for health claims through experimental and epidemiological studies with biomarkers as key elements (Verschuren, 2002). Fekete et al. (2025) emphasize that health claim substantiation should be supported by randomized controlled trials and systematic reviews, while Xinyun Zhang et al. (2025) note strict evidence standards for approval by bodies like the European Food Safety Authority (EFSA).

Labeling requirements and consumer protection measures vary by jurisdiction but increasingly emphasize transparency. Fekete et al. (2025) call for clear communication of scientific evidence

on labels, proposing a potential “functionality scale” to help consumers understand the strength of evidence. Lawrence & Rayner (1998) emphasize that labels should accurately convey scientific findings. Feibiao Shan et al. (2025) note emphasis on transparency and traceability across multiple regulatory systems. However, the risk of misleading claims remains a consistent concern across all governance frameworks examined.

International harmonization efforts face substantial challenges. Feibiao Shan et al. (2025) describe fragmented regulatory frameworks with inconsistent definitions and divergent safety evaluation systems hindering global trade and consumer trust. The paper advocates for internationally standardized positive and negative ingredient lists to promote trade. Morrison (2015) calls for greater harmonization of regulatory guidelines to facilitate market access. However, fundamental differences in regulatory philosophy persist: Asian approaches often embrace traditional “food as medicine” concepts, while Western frameworks maintain sharper distinctions between foods and pharmaceuticals (Shan et al., 2025; Verschuren, 2002).

Table-2. Comparative Regulatory Frameworks for Functional Foods and Supplements

Regulatory Component	Regional Approaches & Governance Bodies	Key Definitions & Standards	Source(s)
Asia-Pacific	Japan: MHLW (FOSHU framework since 1991).		
	China: SAMR & NHC.	Pioneers of "food as medicine"; allows specific health claims (FOSHU).	Verschuren (2002); Shan et al. (2025)
	S. Korea: KFDA; India: FSSAI; Australia: TGA.		
Western Markets	EU: EFSA (Regulation 1924/2006).	Focus on "target functions" beyond nutrition; strict distinction between food and medicine.	Lawrence & Rayner (1998); Jones et al. (2008)
	USA: FDA (Dietary Supplement Health and Education Act).		
Substantiation Standards	EU PASSCLAIM: Uses biomarkers, RCTs, and systematic reviews.	Requires high-level scientific evidence (gold standard) to avoid misleading consumers.	Verschuren (2002); Fekete et al. (2025); Zhang et al. (2025)

	Codex Alimentarius: International guidelines for claims.		
Labeling & Transparency	Proposed "Functionality Scales" to indicate evidence strength.	Focus on traceability and accurate communication of scientific findings.	Fekete et al. (2025); Lawrence & Rayner (1998)
Harmonization Barriers	Fragmentation of safety evaluations and divergent regulatory philosophies.	Fragmented definitions hinder global trade and consumer trust.	Shan et al. (2025); Morrison (2015)

Systems Integration and Interdependencies

Feedback loops between domains shape functional food development in multiple ways. Fekete et al. (2025) identify consumer perceptions and expectations as influencing product development, while regulatory frameworks affect innovation trajectories. Lawrence & Rayner (1998) describe how regulation influences innovation through exemptions and prohibitions on health claims, with public health and consumer associations influencing policy through critiques and suggestions. Verschuren (2002) notes how the introduction of FOSHU in Japan created a feedback loop allowing limited health claims after regulatory approval, while expensive and time-consuming scientific validation in Europe affects business strategies. Jones et al. (2008) highlight how regulation influences innovation through systematic approaches for reviewing scientific data, with market incentives (improved market share and higher commodity prices) driving the development of products with health claims.

Stakeholder interactions demonstrate complex coordination requirements. Fekete et al. (2025) emphasize the need for collaboration among healthcare professionals, nutrition scientists, policymakers, and the food industry to maximize functional food impact. Verschuren (2002) describes the EU PASSCLAIM project as involving industry, academia, consumer groups, and regulators in evaluating scientific evidence. Daliri & Lee (2015) note that consumer acceptance and preferences influence product development decisions. However, integration challenges persist: Fekete et al. (2025) identify public understanding deficits, regulatory inconsistencies, and socioeconomic barriers as key obstacles, while Lawrence & Rayner (1998) point to lack of empirical evidence and outdated policies hindering effective integration.

Systems-level frameworks proposed or implemented vary in comprehensiveness. Xinyun Zhang et al. (2025) present the most explicit systems approach with their "mechanism-to-evidence-to-regulation" framework linking molecular insights with clinical validation and regulatory implications. This framework emphasizes integration of multi-omics analyses and real-time physiological monitoring for individualized formulations, leveraging innovations in delivery systems to enhance bioavailability, and establishing high-level evidence-based frameworks for interaction mechanisms. Feibiao Shan et al. (2025) emphasize integrating traditional knowledge with scientific validation to ensure market accessibility and consumer safety, calling for

internationally standardized positive and negative ingredient lists and harmonized global standards for food safety management.

Policy changes affect scientific research priorities and business strategies in multiple ways. Verschuren (2002) notes how expensive scientific validation requirements in Europe limit market access, while EU Framework Programmes for research on food and nutrition provide coordination mechanisms across science and policy domains. Mittal et al. (2023) suggest that harmonizing regulations can promote international trade and development, influencing business strategies. Lawrence & Rayner (1998) describe how regulatory frameworks provide secure environments for product development and marketing when properly structured.

Key Challenges and Barriers

Scientific and technical challenges center on evidence generation and translation. Ma et al. (2026) identify variability in bioavailability, food matrix effects, processing conditions, and interindividual differences in genetics and gut microbiota as limiting consistent translation of functional foods into health benefits. Fekete et al. (2025) call for advances in nutrigenomics, artificial intelligence, next-generation probiotics, and biofortification to address current scientific limitations. Lawrence & Rayner (1998) note difficulty in translating clinical trial results to real-world scenarios and the need for systematic reviews to validate health claims. Xinyun Zhang et al. (2025) highlight challenges in ensuring stability and bioavailability of functional ingredients and the need for long-term, costly scientific investment to establish evidence-based health claims. Regulatory and policy challenges dominate discussions across studies. Ma et al. (2026) identify heterogeneity in definitions and health claim substantiation requirements across the United States, European Union, Japan, and China as a fundamental barrier. Fekete et al. (2025) point to inconsistencies in health claim regulations and lack of standardized definitions and criteria for efficacy. Shan et al. (2025) describe fragmented regulatory frameworks with inconsistent definitions and divergent safety evaluation systems hindering global trade and consumer trust, noting that while Asia and the West maintain robust regulations, African countries struggle to align traditional practices with modern safety standards. Morrison (2015) highlights limited success in gaining approved health claims in Europe and the need for regulatory harmonization. Lawrence & Rayner (1998) identify lack of empirical evidence, outdated policies, and unclear guidelines on health claims as persistent challenges.

Economic and business challenges include market access barriers and cost structures. Fekete et al. (2025) note that high functional food costs make them inaccessible to lower-income populations, exacerbating health inequalities. Morrison (2015) raises concerns about costs of delivering quality clinical data versus potential rewards. Verschuren (2002) observes that developing scientific support for health claims is expensive and time-consuming, limiting market reach. Xinyun Zhang et al. (2025) emphasize the high cost of scientific investment required for health claims.

Consumer-related challenges span multiple dimensions. Ma et al. (2026) identify influences of product format, socio-demographic characteristics, information sources, health motivation, and price sensitivity on perception and purchasing behavior. Fekete et al. (2025) point to insufficient public understanding of scientific evidence, consumer perceptions and expectations, and misleading marketing strategies as barriers. Xinyun Zhang et al. (2025) note knowledge gaps and information overload affecting consumer acceptance and education. Lawrence & Rayner (1998) highlight lack of understanding and trust in health claims and the potential for misleading claims to undermine consumer confidence. Mittal et al. (2023) identify the challenge of dealing with skeptical consumers.

Cross-sector coordination challenges emerge as a consistent theme. Lawrence & Rayner (1998) call for integrated policies that balance innovation with consumer protection. Xinyun Zhang et al. (2025) emphasize the need for societal acceptance and real-world application of scientific

evidence. Shan et al. (2025) describe disparities in management methods and the challenge of integrating traditional knowledge with scientific validation. Morrison (2015) highlights difficulty in presenting the totality of scientific evidence required for regulatory approval.

Table-3. Multidimensional Challenges in the Functional Food Sector

Challenge Category	Key Technical & Systemic Barriers	Impact on Industry/Society	Source(s)
Scientific & Technical	Bioavailability & Matrix Effects: Interaction between ingredients and food structure.	Inconsistent health outcomes; difficulty translating clinical trials to the real world.	Ma et al. (2026); Fekete et al. (2025); Zhang et al. (2025)
	Interindividual Variability: Genetic and microbiota differences.		
Regulatory & Policy	Global Heterogeneity: Divergent definitions and safety standards (US vs. EU vs. Asia vs. Africa).	Hindered global trade; lack of consumer trust; "Outdated" policy frameworks.	Shan et al. (2025); Morrison (2015); Lawrence & Rayner (1998)
Economic & Business	High R&D Costs: Massive investment required for clinical data.		
	Price Premiums: Functional foods cost significantly more than conventional alternatives.	Misalignment between investment and market returns; creation of health inequalities.	Fekete et al. (2025); Morrison (2015); Verschuren (2002)
Consumer & Social	Information Overload: Skepticism toward claims and misleading marketing.		
	Demographic Sensitivity: Influence of	Reduced consumer confidence; knowledge gaps regarding actual scientific evidence.	Ma et al. (2026); Zhang et al. (2025); Mittal et al. (2023)

	education and price on purchase.		
Coordination & Integration	Traditional vs. Modern: Difficulty integrating traditional knowledge with scientific validation.	Fragmented management methods; struggle to present "totality of evidence."	Shan et al. (2025); Zhang et al. (2025); Lawrence & Rayner (1998)

Synthesis

The functional food sector exhibits substantial heterogeneity in findings across regulatory frameworks, scientific approaches, economic models, and outcomes. Rather than representing contradictions, this heterogeneity reflects context-dependent validity where different approaches succeed within specific margins.

Regulatory Context Shapes Innovation Trajectories

Studies finding successful functional food development cluster in jurisdictions with clear, science-based regulatory pathways. Japan's FOSHU system, introduced in 1991, created a feedback loop allowing manufacturers to obtain limited health claims after regulatory approval, which facilitated market growth while maintaining safety standards (Verschuren, 2002). In contrast, Europe's more restrictive framework under EU Regulation 1924/2006 has yielded limited success in approved health claims despite substantial clinical research investment (Jones et al., 2008). The divergence stems not from one approach being "correct" but from different regulatory philosophies: Japan's system accepts traditional food-medicine concepts and biomarkers as evidence, while Europe requires randomized controlled trials and systematic reviews for substantiation. Both may be valid within their respective contexts - Asian markets with long traditions of functional foods versus European markets prioritizing pharmaceutical-level evidence standards (Shan et al., 2025; Lawrence & Rayner, 1998).

Economic Viability Depends on Market Maturity and Consumer Sophistication

Markets showing robust growth (US reaching \$8.62 billion by 2015, China growing at 13% annually) differ systematically from markets with limited uptake (European products struggling to reach consumers) (Daliri & Lee, 2015; Shan et al., 2025). The successful markets share characteristics: established consumer familiarity with functional food concepts, relatively permissive regulatory environments allowing health communication, and pricing structures that segment premium functional foods from conventional alternatives. In contrast, markets with accessibility challenges typically feature functional foods priced 3-5 times higher than conventional products, creating socioeconomic barriers (Fekete et al., 2025). The apparent contradiction - simultaneous market growth and accessibility challenges - resolves when recognizing that growth concentrates in affluent consumer segments while lower-income populations remain excluded, suggesting that current business models succeed commercially but fail from a public health equity perspective.

Scientific Validation Requirements Create Non-Linear Cost-Benefit Relationships

Studies emphasizing high evidentiary standards (randomized controlled trials, systematic reviews) report challenges in market commercialization, while studies accepting broader evidence bases (biomarkers, traditional use) report easier regulatory pathways (Verschuren, 2002; Shan et al., 2025). This pattern reflects diminishing returns to evidence investment: the first level of scientific substantiation (basic safety data, mechanistic plausibility) enables market entry in permissive jurisdictions at modest cost; the second level (human intervention trials, dose-response

data) allows health claims in moderately strict jurisdictions at substantial cost; the third level (large-scale RCTs, long-term safety data) meets the highest regulatory standards but at costs that may exceed potential market returns. Morrison (2015)'s observation about "sobering" cost-benefit ratios thus applies specifically to high-evidence-threshold markets, not universally. Companies can succeed by matching evidence investment to target market requirements rather than pursuing maximum substantiation across all contexts.

Consumer Acceptance Varies by Product Category and Delivery Context

Studies reporting high consumer acceptance focus on familiar delivery vehicles (dairy products with added probiotics) or products addressing widely recognized health concerns (omega-3 for heart health, fiber for digestive health) (Daliri & Lee, 2015). Studies reporting consumer skepticism or trust deficits typically address novel bioactives, processed delivery systems (microencapsulation), or products making broad health claims (Fekete et al., 2025). This divergence reflects consumer mental models: functional foods succeeding commercially leverage existing category understanding (milk is healthy, probiotics improve digestion) through "natural match" strategies, while products requiring consumer education about novel mechanisms face adoption barriers. The insight for strategy is that science-driven innovation (novel bioactives, advanced delivery systems) requires substantially greater investment in consumer education and trust-building than market-driven innovation that extends familiar functional food categories.

Policy-Science-Market Integration Succeeds Through Sequential Stakeholder Alignment

The most successful functional food ecosystems described across studies share a temporal sequence: scientific validation precedes regulatory framework development, which enables business model innovation (Xinyun Zhang et al., 2025). Japan's trajectory exemplifies this: decades of research on functional ingredients in traditional foods enabled creation of FOSHU regulatory framework, which then stimulated commercial innovation (Verschuren, 2002). Attempts to reverse this sequence - developing products ahead of regulatory clarity or regulatory frameworks ahead of scientific consensus - consistently encounter barriers. Europe's challenges with functional food approvals reflect premature regulatory standardization before achieving scientific consensus on appropriate evidence standards, while Latin America's case-by-case approval process reflects regulatory framework development outpacing scientific infrastructure. The mechanistic explanation is that each stakeholder group (scientists, regulators, industry) requires stable inputs from prior stages: regulators need scientific evidence standards, industry needs regulatory predictability, consumers need trusted institutions. Disrupting this sequence creates coordination failures (Lawrence & Rayner, 1998).

Bioavailability and Individual Variability Create Context-Dependent Efficacy

The translation challenge identified by Ma et al. (2026) - variability in bioavailability, food matrix effects, and interindividual differences in genetics and gut microbiota limiting consistent health benefits - explains why clinical trials showing efficacy at the population level (meta-analyses reporting LDL reductions, improved insulin sensitivity) can coexist with real-world inconsistent outcomes. The reconciliation lies in understanding functional foods as precision nutrition tools rather than pharmaceutical interventions: effects manifest reliably only when matched to individual biological contexts. Studies conducted in populations with specific deficiencies, genetic profiles, or microbiome compositions show robust effects, while studies in heterogeneous populations show modest average effects with high variance. This suggests future success requires moving from population-level functional food marketing to personalized nutrition approaches using biomarkers, genomics, and microbiome profiling - a shift already underway but not yet reflected in regulatory frameworks designed for standardized products (Fekete et al., 2025; Xinyun Zhang et al., 2025).

For functional foods with established bioactive mechanisms (probiotics, omega-3, specific polyphenols), targeting populations with clear health needs (gut dysbiosis, cardiovascular risk,

inflammatory conditions), delivered through familiar food matrices (dairy, oils), and supported by randomized controlled trial evidence, market success is achievable in jurisdictions with science-based regulatory frameworks (Japan, moderate-threshold US claims, emerging Asian markets) (Daliri & Lee, 2015; Shan et al., 2025). Expected outcomes include premium pricing, affluent consumer adoption, and measurable but modest health impacts at population scale.

For novel bioactives, complex delivery systems, or broad health claims, the evidence-to-market pathway requires substantially greater investment in scientific validation, regulatory engagement, and consumer education. Success likelihood remains context-dependent on achieving sequential stakeholder alignment and avoiding mismatches between evidence level, regulatory requirements, and market expectations (Morrison, 2015; Fekete et al., 2025).

Table-4. Precision Nutrition and the Evidence-to-Market Pathway

Strategy Component	Key Mechanisms & Findings	Requirements for Success	Source(s)
The Translation Gap	Disconnect between population-level efficacy (e.g., LDL reduction) and inconsistent real-world outcomes.	Understanding variability in bioavailability, food matrix effects, and genetics.	Ma et al. (2026)
Precision Nutrition Shift	Moving from standardized marketing to personalized approaches using biomarkers and genomics.	Matching functional ingredients to specific biological contexts/deficiencies.	Fekete et al. (2025); Zhang et al. (2025)
Established Bioactives	Focus on probiotics, omega-3s, and polyphenols in familiar matrices (dairy, oils).	Targeting specific health needs (e.g., gut dysbiosis) via RCT-backed evidence.	Daliri & Lee (2015); Shan et al. (2025)
Market Outcomes	Premium pricing and adoption by affluent, health-motivated consumers.	Operating within science-based regulatory frameworks (e.g., Japan, USA).	Daliri & Lee (2015); Shan et al. (2025)
Novel & Complex Systems	Broad health claims and complex delivery systems face high failure risks.	Substantial investment in scientific validation and stakeholder alignment.	Morrison (2015); Fekete et al. (2025)

Conclusion

The functional food sector represents one of the most dynamic intersections between food science innovation, health promotion, and economic enterprise. This review demonstrates that the development and governance of functional health foods cannot be understood through a single disciplinary lens. Instead, the sector operates as a complex system in which scientific research, regulatory policy, economic incentives, and consumer behavior interact continuously to shape innovation trajectories and market outcomes. Scientific research has provided compelling evidence that bioactive compounds such as probiotics, omega-3 fatty acids, polyphenols, and dietary fibers can exert measurable physiological effects through mechanisms including gut microbiome modulation, anti-inflammatory responses, and cardiometabolic regulation. Nevertheless, translating these mechanisms into consistent health outcomes remains challenging due to variability in bioavailability, food matrix interactions, and interindividual biological differences. These scientific limitations highlight the importance of advancing technologies such as nutrigenomics, microbiome research, and precision nutrition to better align functional food design with individual biological contexts. From an economic perspective, the global functional food market has expanded rapidly, reflecting strong consumer demand for health-oriented products. However, high research and development costs, expensive clinical validation requirements, and premium pricing structures limit accessibility for many populations. Consequently, while functional foods have achieved significant commercial success, their broader public health impact remains constrained by socioeconomic inequalities in product availability and affordability. Regulatory governance continues to play a critical role in shaping innovation pathways and market dynamics. Differences in regulatory frameworks—such as Japan’s FOSHU system, the European Union’s stringent health claim approval process, and the United States’ distinct treatment of dietary supplements—create diverse environments for product development and commercialization. These variations demonstrate how regulatory philosophy influences both scientific evidence requirements and industry investment strategies. Greater international harmonization of regulatory standards may help facilitate global trade, improve consumer trust, and promote more consistent health claim validation. A systems-level perspective reveals that successful functional food ecosystems depend on sequential alignment among key stakeholders. Scientific validation establishes the biological basis for functional ingredients, regulatory frameworks provide structured pathways for health claim authorization, and business innovation translates these findings into marketable products. When these elements evolve in coordination, functional food sectors can develop efficiently; when they diverge, barriers to innovation and market adoption emerge. Looking forward, emerging technologies—including artificial intelligence-driven product formulation, personalized nutrition platforms, microbiome-targeted interventions, and advanced delivery systems such as nano-encapsulation—are likely to reshape the functional food landscape. However, these advancements will require substantial research investment, updated regulatory approaches, and improved consumer education to ensure safe and effective implementation. In conclusion, functional foods represent a promising yet complex strategy for promoting health through diet. Their future development will depend on interdisciplinary collaboration among scientists, policymakers, industry stakeholders, and healthcare professionals to ensure that scientific innovation translates into accessible, evidence-based products capable of delivering meaningful public health benefits.

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