Policy Brief

pISSN: 2345-5357
eISSN: 2423-4214

OPEN ACCESS

APPLIED FOOD BIOTECHNOLOGY, 2026, 13 (1): e35 (1-10)
Journal homepage: www.journals.sbmu.ac.ir/afb

From Scientific Criteria to Policy Action: An Evidence-Informed Governance Framework for Probiotic Dairy Products

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Article Information

Article history:

Received	04 Sep 2026
Revised	06 Nov 2026
Accepted	10 Nov 2026
Published	17 Nov 20261

Keywords:
Dairy products, Food gover-nance, Food regulation, Iran, Probiotic, Quality assurance, Traceability

How to cite:
Fadavi MM, Hosseini S, Fadavi G, Mohammadi-Nasrabadi F, Tajabadi Ebrahimi M, Esfarjani F. from scientific criteria to policy action: an evidence-informed governance framework for probiotic dairy products. Appl Food Biotechnol. 2026; 13 (1): e35 (1-10).
http://doi.org/10.22037/afb.v13i1.53889

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Abstract

Background and Objective: The public-health value of probiotic dairy products depends on delivering characterized strains at efficacious levels through shelf life. Translating international scientific criteria into continuous regulatory oversight remains a challenge. This study aimed to develop an evidence-informed governance framework to strengthen quality assurance and regulation of probiotic dairy products in Iran.

Materials and Methods: This study synthesized international scientific literature and regulatory guidelines, incorporating insights from Iranian exploratory assessments and policy dialogues. Core scientific requirements specifically strain characterization, safety, health benefits, and viability were operationalized into regulatory functions, institutional responsibilities, and performance indicators.

Results: The proposed six-stage governance cycle DEFINE, IDENTIFY, VERIFY, MONITOR, INFORM, and EVALUATE integrates national standards, strain traceability, safety and efficacy validation, end-of-shelf-life viability verification, risk-based surveillance, transparent labeling, and digital traceability. It also includes a three-year implementation roadmap and measurable performance indicators, identifying commercial compliance at expiry as a core metric.

Conclusion: Effective probiotic governance requires a transition from static pre-market approval to continuous, life-cycle regulation. The proposed framework establishes a practical pathway linking scientific evidence, laboratory verification, industry accountability, and market surveillance to ensure consumer protection in Iran.

Conflict of interest: The authors declare no conflict of interest.

What is "already known" on this topic:	• Dairy matrices may enhance probiotic viability and survival through the gastrointestinal tract. • Probiotic functionality depends on strain, intended use, dosage, and empirically demonstrated health outcomes. • Scientific criteria for probiotic quality should be translated into an operational governance system that continuously protects consumers and enhances regulatory accountability.
What this article adds:	• Proposes a six-stage governance framework for probiotic dairy products in Iran. • Translates scientific criteria into practical regulatory functions and responsibilities. • Prioritizes end-of-shelf-life probiotic viability and risk-based market surveillance. • Introduces a three-year roadmap with measurable indicators for continuous regulatory

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1. INTRODUCTION

Probiotics have become a cornerstone of the functional food sector, particularly within dairy products such as yogurt, fermented milks, and specialized beverages [1].While dairy matrices offer favorable environments for probiotic delivery, factors such as acidity, post-acidification, and oxygen are known to reduce the viability of these microorganisms in such products; furthermore, the mere presence of a microorganism in a food matrix does not substantiate a claim that it is a probiotic [2]. True probiotic functionality is strictly dependent on strain identity, intended use, dosage, and empirically demonstrated health outcomes [3]. International scientific consensus defines probiotics as live microorganisms that, when administered in adequate amounts, confer a health benefit on the host [4]. Translating this definition into regulatory practice requires robust criteria, including precise strain characterization, documented safety, human clinical evidence, and sustained cellular viability at an efficacious dose throughout the product shelf life [5].

Globally, regulatory frameworks governing probiotics exhibit substantial heterogeneity. Within the European Union, the European Food Safety Authority (EFSA) classifies the term "probiotic" intrinsically as a health claim, thereby imposing stringent restrictions on its commercial labeling [6]. Conversely, jurisdictions such as Italy and Canada have implemented specific national guidelines permitting the designation, contingent upon the rigorous guarantee of a minimum viable cell count (e.g., 10^6 CFU per daily dose) [7]. In contrast, the United States Food and Drug Administration (FDA) regulates these products primarily through structure/function claims. Despite these international disparities, a critical public policy challenge remains universal: traditional regulatory paradigms reliant exclusively on static, manufacturing-stage approvals are inadequate for consumer protection. Because bacterial viability fluctuates dynamically in response to environmental stressors during commercial distribution and extended storage, pre-market authorization alone cannot guarantee point-of-consumption efficacy [8]. While previous Iranian literature identified foundational market gaps, technological barriers, and stakeholder perspectives, a critical operational question remained unaddressed: How can scientific criteria for probiotic quality be translated into an operational governance system that continuously protects consumers and enhances regulatory accountability? This study bridges that gap by establishing a comprehensive, risk-based governance architecture tailored for Iran.

2. MATERIALS AND METHODS

To develop the life-cycle governance framework, this study employed a multi-method approach consisting of two main phases: rapid literature and regulatory document review and structured policy dialogues.

2.1. Literature Review and Document Analysis

This study synthesized international scientific literature and regulatory guidelines. A comprehensive search was conducted using academic databases including PubMed, Scopus, and Web of Science for publications published between 2016 and 2026. The primary search terms included probiotic regulation, food governance, probiotic dairy products, and "quality assurance" [9]. Furthermore, official regulatory documents and guidelines from key international and national authorities were systematically reviewed [10]. These included standards and monographs from the Food and Agriculture Organization, the World Health Organization, the Codex Alimentarius Commission, EFSA, the United States FDA, Health Canada, Food Standards Australia New Zealand, and Japan's Foods for Specified Health Uses (FOSHU) regulatory framework. Inclusion criteria focused on English and Persian peer-reviewed studies and official reports related to probiotic oversight, while studies lacking regulatory or public health implications were excluded.

2.2. Structured Stakeholder Policy Dialogues

To ensure the proposed framework is applicable to the national context, the study incorporated insights from Iranian exploratory assessments and structured stakeholder dialogues. These qualitative policy dialogues involved key experts and policymakers purposively sampled from relevant sectors, including the National Nutrition and Food Technology Research Institute, the Standard Research Institute, academic institutions, and dairy industry representatives. The discussions aimed to identify technological barriers, contextualize international regulatory standards, and translate core scientific requirements specifically strain

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characterization, safety, health benefits, and viabilityinto practical regulatory functions for Iran [9].

3. RESULTS AND DISCUSSION

3.1. Conceptual Basis and Policy-Oriented Governance Architecture

In Iran, probiotics are regulated under the supervision of the Iran FDA (attached to the Ministry of Health and Medical Education). Depending on their intended purpose, delivery form, and claim level, probiotic products fall under distinct administrative frameworks: pharmaceuticals / therapeutic probiotics: formulated as capsules, powders, or solutions meant for clinical conditions, requiring rigorous drug registration, dossier evaluation, and Good Manufacturing Practice (GMP) compliance; dietary supplements: products sold in measured doses (tablets, sachets) for general health promotion, regulated under supplement and natural health product guidelines; Functional Foods & Dairy: Probiotics added to conventional foods (e.g., probiotic yogurt, kefir, fortified beverages), governed by food safety standards, national standard protocols, and labeling rules.

A functional regulatory system for probiotic dairy products must bridge the critical chasm between complex scientific evidence and enforceable, practical requirements[9]. Figure 1 shows the governance framework for probiotic dairy products. This six-stage regulatory cycle shifts the governance paradigm from static pre-market authorization to continuous accountability. The framework systematically links pre-market assurance with post-market oversight by integrating foundational standard-setting (DEFINE) and precise strain-level molecular authentication (IDENTIFY) with comprehensive safety, efficacy, and shelf-life validation (VERIFY). Real-world product integrity is subsequently maintained through proactive, risk-based surveillance across supply chains (MONITOR) and transparent consumer communication (INFORM). Finally, the overarching architecture undergoes periodic appraisal using objective indicators (EVALUATE) to ensure sustained public health protection and regulatory adaptation.

To ensure the sustained impact of this architecture, the overall success and efficacy of the proposed governance model must be measured using rigorous, objective indicators. Among these metrics, a particularly vital core performance indicator is the percentage of commercially sampled probiotic dairy products that successfully meet the specified viable-count requirement at the exact end of their shelf life. This specific indicator directly connects regulatory enforcement to actual consumer exposure and protection (Table 1). However, an increase in reported total volume or frequency of confirmed regulatory deviations and product defects could reflect better monitoring, so this indicator needs careful interpretation.

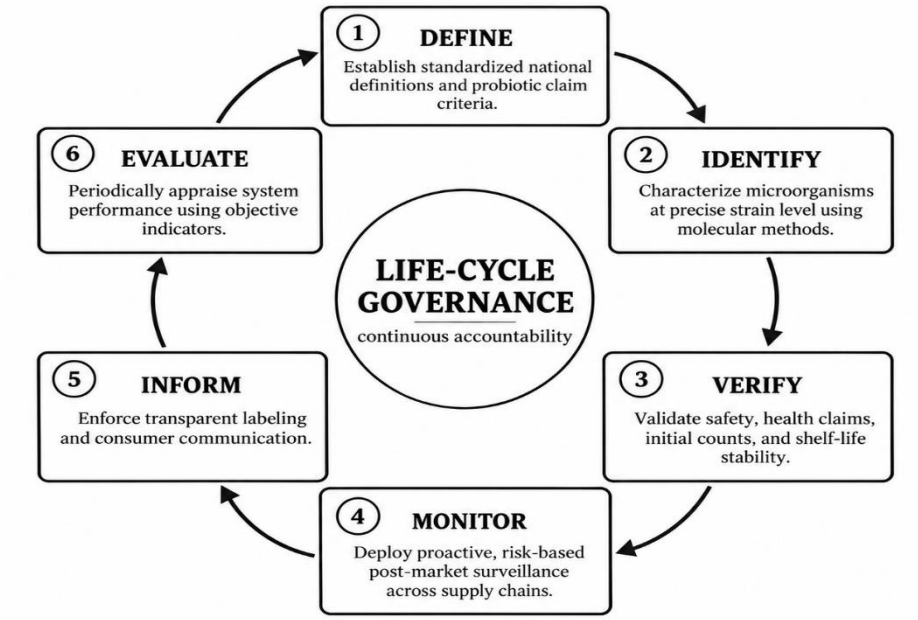


Figure 1. The Continuous Life-Cycle Governance Framework for Probiotic Dairy Products

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Table 1. Proposed Monitoring Indicators and Target Directions for Probiotic Governance†

Domain	Indicator	Target Direction
Regulatory clarity	Proportion of probiotic dairy products covered by harmonized national standards	Increase
Strain identity	Percentage of commercial products verified for authentic strain-level identity	Increase
Viability	Percentage of samples meeting minimum viable count requirements at the end of shelf life	Increase
Label accuracy	Proportion of products whose commercial label claims match independent laboratory findings	Increase
Surveillance	Total number of commercial probiotic products tested annually	Increase
Non-compliance	Total volume or frequency of confirmed regulatory deviations and product defects	Decrease
Traceability	Percentage of commercial batches fully integrated into digital traceability platforms	Increase
Consumer knowledge	Proportion of consumers correctly identifying and interpreting probiotic label information	Increase
Corrective action	Average operational time elapsed from detection of non-compliance to regulatory enforcement	Decrease
Transparency	Number of annual governance and market surveillance reports publicly published	Increase

† Indicators are designed for continuous tracking by the multistakeholder regulatory committee, serving as empirical benchmarks for periodic framework evaluation and regulatory refinement.

3.2. Comparative Analysis with Global Regulatory Frameworks

While the proposed six-stage life-cycle governance framework is explicitly tailored to Iran's domestic context and infrastructural capacities, its core architecture structurally aligns with and strategically adapts the regulatory paradigms of leading global authorities. In the European Union, EFSA enforces a highly stringent regime where precise strain-level identification and safety profiling are absolute prerequisites for any health claim authorization [6]. Similarly, Japan FOSHU system mandates exhaustive scientific substantiation of both safety and functional efficacy prior to market entry [11]. The DEFINE, IDENTIFY, and VERIFY stages of the proposed Iranian framework closely mirror these rigorous international pre-market demands. However, whereas EFSA and FOSHU systems operate within highly mature technological ecosystems, the Iranian framework incorporates a phased, three-year implementtation roadmap to gradually build domestic laboratory and institutional capacity without halting market operations. A critical regulatory differentiator addressed in this framework is the approach to post-market viability and shelf-life verification. Under Japan FOSHU system, maintaining the declared viable probiotic cell count until the exact end of the product's shelf life is a mandatory statutory requirement, rigorously enforced through market surveillance [12]. Conversely, in the United States, while the FDA requires that labels remain truthful and not misleading at the time of consumption, the specific enforcement of end-of-shelf-life Colony-Forming Units (CFUs) often relies heavily on voluntary industry best practices (e.g., guidelines by the International Probiotics Association) rather than systematically mandated government testing of dairy matrices [13]. By institutionalizing End-of-Shelf-Life Verification as a mandatory regulatory checkpoint within the VERIFY, and subsequently during the MONITOR and EVALUATE stages, the proposed Iranian model proactively can address a regulatory gap that allows manufacturing-stage compliance to substitute for point-of-consumption efficacy. This positions the Iranian framework closer to the stringent Japanese FOSHU model, ensuring that consumer protection is legally anchored to real-world product performance rather than mere initial formulation.

3.3. Proposed regulatory requirements

A foundational tenet of modern food governance is that every regulatory, industrial, or commercial claim must be linked to a corresponding, scientifically validated verification mechanism. To ensure institutional accountability and prevent unsubstantiated functional claims, regulatory authorities must establish clear, enforceable parameters across all dimensions of product formulation, labeling, and market performance. Traditional systems that rely solely on premarket dossier approvals often fail because they cannot capture dynamic changes in bacterial survival, formulation shifts, or storage stresses occurring post-manufacture [14]. So, the proposed regulatory architecture explicitly aligns each mandatory requirement with its specific verif-ication instrument. This linkage bridges gap between theoretical standard and empirical compliance, ensuring that safety and efficacy are continuously demonstrated throughout product life cycle. Table 2 shows requirements span microbial characterization, safety substantiation, clinical claim validation, viability thresholds, post-market surveillance, consumer transparency, and digital traceability.

Table 2. Alignment of Mandatory Regulatory Requirements with Corresponding Verification Instruments†

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Mandatory Regulatory Requirement	Core Focus / Operational Parameter	Corresponding Verification Instrument
Strain-Level Identity	Confirmation of specific taxonomic identity using molecular methods.	Genomic sequencing reports, deposition certificates in recognized culture collections, and national strain registries.
Documented Safety	Verification of absence of transferable antibiotic resistance genes and pathogenic traits.	Toxicological assessments, in vitro safety profiling, and genomic safety dossiers.
Scientific Health Claims	Substantiation of physiological or clinical benefits linked to the specific microorganism and dosage.	Peer-reviewed clinical trials, human intervention studies, and scientific dossier evaluations.
Viability Thresholds	Maintenance of minimum effective cell counts (typically ≥106 CFU/g or mL) through shelf life.	Enumeration assays and quantitative microbiological testing under simulated storage conditions.
End-of-Shelf-Life Verification	Assessing cellular survival at the exact point of commercial expiry.	Proactive retail sampling, laboratory re-testing protocols, and expiry-date compliance audits.
Risk-Based Market Surveillance	Stratified oversight prioritizing high-risk formulations, novel strains, or historical non-compliance.	Periodic randomized market sampling, tier-based inspection frequencies, and targeted audits.
Transparent Labeling	Mandatory disclosure of precise strain designations, viable counts, and proper storage guidelines.	Pre-market label approvals, regulatory label audits, and marketplace compliance checks.
Digital Traceability	End-to-end electronic tracking connecting raw ingredients, batches, laboratories, and distribution.	Cloud-based blockchain or relational database logs linking batch numbers to test results.

†CFU: Colony-Forming Units. Verification instruments must be administered or certified by accredited national reference laboratories and authorized regulatory bodies to ensure legal enforceability and scientific validity across the commercial life cycle.

Blockchain is employed as a novel tool for digital tracking, aiming to provide verifiable information regarding the supply chain and ensure that all relevant stakeholders have access to this data. Its application within food supply chains offers numerous benefits, including enhanced transparency, real-time access to product information, the prevention of fraudulent activities, resistance to tampering, reduced operational costs, improved traceability, superior product quality, guaranteed safety and authenticity, and a more organized certification process. However, whether these anticipated benefits justify the associated technical complexity, implementation costs, and data management requirements remains a subject that warrants further examination [15].

3.4. Transparency and Digital Traceability

Digitalization should not be viewed solely as an industrial efficiency tool, but rather as a powerful instrument for enhancing regulatory accountability. An integrated digital system could seamlessly connect products, batches, probiotic strains, laboratory results, shelf-life data, distribution channels, and market surveillance. Moreover, a comprehensive digital traceability system would support targeted product recalls, effectively avoiding the necessity of broad, disruptive market withdrawals [16]. Product labeling must function primarily as a consumer-protection mechanism rather than a mere marketing instrument [17]. At a minimum, labels on probiotic dairy items must transparently communicate the specific probiotic microorganism, the strain designation wherever scientifically appropriate, the viable quantity, relevant serving information, designated storage conditions, the expiry date, and evidence-based health information consistent with regulatory requirements [18]. Furthermore, any health claims must be rigorously linked to empirical evidence corresponding directly to the specific microorganism, dosage, and health outcome, rather than relying on generalized statements regarding probiotics as a collective category [19].

3.5. Institutional architecture

Effective food governance necessitates clearly defined and meticulously delineated institutional responsibilities. This precise allocation of duties is paramount, as fragmented accountability can inadvertently generate regulatory voids wherein individual stakeholders erroneously assume that a separate institution bears the burden of verification. To eliminate ambiguity, institutional roles must be systematically structured to ensure an unbroken chain of oversight from standard formulation to market surveillance. As detailed in Table 3, the proposed architecture clearly distributes core responsibilities and measurable performance indicators across all relevant stakeholders, including food regulatory authorities, national standards organizations, accredited testing laboratories, dairy manufacturers, academic research centers, scientific associations, consumer advocacy bodies, digital traceability platforms, public health agencies, and a centralized multistakeholder regulatory committee. While existing

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literature often focuses solely on laboratory quality criteria or isolated regulatory guidelines, this framework provides an integrated, end-to-end governance mechanism specifically adapted to the institutional and market realities of the Iranian food sector. The principal contribution lies in the synergistic integration of scientific evaluation with practical implementation tools (monitoring, stakeholder engagement, and structured evaluation).

Table 3. Proposed Institutional Responsibilities and Performance Indicators

Stakeholder	Core Responsibility	Proposed Indicator
Food Regulatory Authority	Licensing, market surveillance, and legal enforcement	Percentage of sampled products compliant with regulatory standards
National Standards Organization	Development, harmonization, and periodic revision of national standards	Number of probiotic standards updated or established
Accredited Laboratories	Independent analytical testing and microbiological verification	Number of commercial products tested annually
Dairy Manufacturers	Implementation of GMP/HACCP protocols and probiotic stability assurance	Percentage of products meeting end-of-shelf-life viability criteria
Universities & Research Institutes	Generation of scientific evidence and independent strain validation	Number of scientifically validated strains registered
Scientific Associations	Provision of technical guidance, clinical insight, and professional consensus	Number of technical guidelines developed
Consumer Organizations	Consumer advocacy, education, and market transparency promotion	Consumer awareness and market literacy score
Digital Platform	End-to-end product, batch, and laboratory result traceability	Percentage of commercial batches digitally traceable
Public-Health Authorities	Integration of food governance with broader preventive health policies	Number of national programs incorporating evidence-based probiotic guidance
Multistakeholder Regulatory Committee	Periodic framework evaluation, multi-sector coordination, and policy revision	Publication of the annual governance performance report

Note: GMP: Good Manufacturing Practices; HACCP: Hazard Analysis Critical Control Point. Performance indicators are designed to be monitored annually by the multistakeholder regulatory committee to ensure continuous institutional accountability.

3.6. Policy action

Regarding recommended policy pathways, regulatory implementation must proceed progressively rather than simultaneously, as national authorities do not need to establish every complex component at the exact same time. Attempting immediate, wholesale enforcement across all domain's risks overwhelming institutional capacities and generating administrative bottlenecks. Instead, the national regulatory system should adopt a staged trajectory, initially focusing on establishing standardized definitions, robust laboratory testing methods, and baseline surveillance, and subsequently expanding toward formal certification and full digital traceability (Table 4). This phased strategy ensures that regulatory maturation parallels the technical and infrastructural growth of the domestic dairy sector.

Table 4. Strategic Policy Options and Implementation Progression†

Implementation Phase	Strategic Policy Focus	Operational Objectives	Expected Outcome
Phase 1 (Foundation Building)	Standardization and baseline harmonization	Establishing legal definitions, standardizing laboratory assay methods, and initiating baseline market surveillance.	Creation of a clear regulatory baseline and alignment with international scientific criteria.
Phase 2 (Operational Expansion)	Verification and compliance strengthening	Implementing mandatory strain identification, enforcing end-of-shelf-life viability thresholds, and deploying risk-based market sampling.	Broad enforcement of product authenticity and systematic identification of non-compliant items.
Phase 3 (Institutional Maturation)	Certification and digital integration	Launching formal product certification schemes, deploying full digital batch traceability, and institutionalizing periodic performance reviews.	A fully transparent regulatory system ensuring long-term consumer protection and industry trust.

†Progression across phases is managed by the multistakeholder regulatory committee, ensuring that transition milestones are met before advancing to subsequent regulatory tiers.

3.7. Three-year implementation roadmap

To ensure a structured, systematic, and manageable transition, implementation is organized across a phased three-year roadmap. Year 1 focuses primarily on estab-

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lishing the regulatory foundation, emphasizing regulatory clarity and analytical capacity by harmonizing national definitions with internationally accepted scientific principles, establishing a probiotic strain registry, and standardizing laboratory methods. Year 2 transitions the system from rule development toward empirical verification, implementing representative market sampling with a particular focus on shelf-life validation, independent surveillance, and pilot digital traceability. Finally, Year 3 institutionalizes long-term accountability by introducing routine performance evaluation, public reporting, comprehensive regulatory revision, and formal national certification schemes (Figure 2).

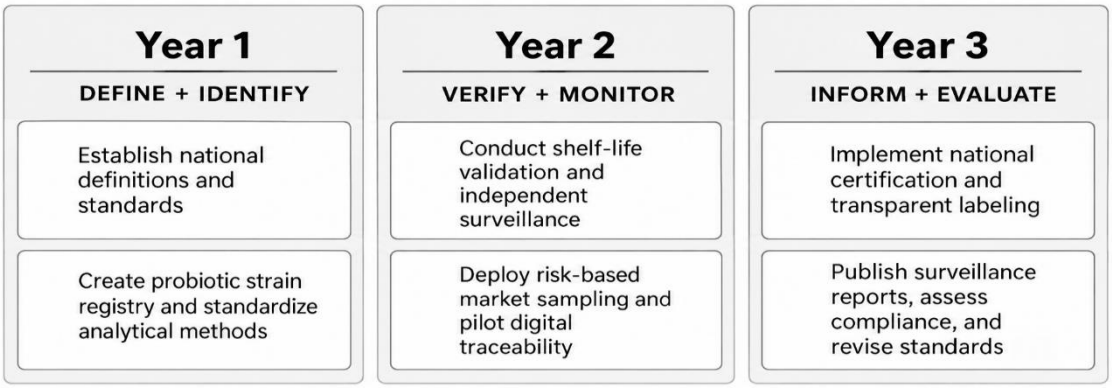


Figure 2. Three-Year Phased Implementation Roadmap for Probiotic Dairy Governance

3.8. Strengths and limitations

While existing literature often focuses solely on laboratory quality criteria or isolated regulatory guidelines, this framework provides an integrated, end-to-end governance mechanism specifically adapted to the institutional and market realities of the Iranian food sector. The principal contribution lies in the synergistic integration of scientific evaluation with practical implementation tools (monitoring, stakeholder engagement, and structured evaluation). However, the framework was not validated by an expert panel or a Delphi process. Cost estimate, measurement uncertainty, analysis of laboratory capacity, and regulatory impact were not discussed, too. Future validation through a proposed pilot study involving selected dairy products and regulatory stakeholders before any broader national rollout is recommended.

4. CONCLUSION

Establishing a robust regulatory framework for probiotic dairy products requires a decisive shift from static, incremental approval to continuous verification throughout the product life cycle and prior to market launch. The future trajectory of the probiotic sector in Iran depends on the capacity of national regulatory systems to ensure that scientific claims remain linked to real-world product quality. Moving away from fragmented controls toward an integrated governance model anchored by the sequential functions of defining standards, identifying microbial strains, verifying scientific claims, monitoring market compliance, informing consumers, and evaluating system performance establishes an unbroken chain of accountability. Although the framework has not yet been tested in practice, it is expected that within this holistic model, strain-level identity, documented safety, empirical evidence of benefit, sustained viability through the end of shelf life, transparent labeling, risk-based post-market surveillance, and digital traceability can function as interdependent pillars of consumer protection. While exploratory market findings in Iran underscore an urgent need for strengthened oversight, they serve as a vital signal for systematic and representative monitoring rather than a definitive national non-compliance prevalence estimate. Ultimately, adopting this integrated governance pathway by harmonizing scientific evidence, rigorous laboratory verification, industry accountability, and consumer transparency can empower Iran to move beyond basic regulatory compliance, fostering measurable public health value, enduring consumer trust, and sustainable functional-food innovation.

5. DECLARATION STATEMENTS

5.1. Acknowledgments

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The authors acknowledge the support of the Research Council of the National Nutrition and Food Technology Research Institute, Faculty of Nutrition Sciences and Food Technology, Shahid Beheshti University of Medical Sciences, and thank all participants who contributed to the policy dialogue.

5.2. Conflicts of Interest

The authors declare no conflicts of interest.

5.3. Author contributions

All authors contributed substantially to the concept-tualization and design of the study, data collection, analysis and interpretation, manuscript preparation or critical revision, and final approval of the manuscript.

5.4. Funding

The National Nutrition and Food Technology Research Institute, Faculty of Nutrition Sciences and Food Technology, Shahid Beheshti University of Medical Sciences, Tehran, Iran (Grant No. 43016375) supported this study.

5.5. Data Availability Statement

No new publicly available dataset was generated for this study. The evidence base consisted primarily of published literature and qualitative policy-dialogue information.

5.6. Ethics.

Ethical approval was obtained from Shahid Beheshti University of Medical Sciences (IR.SBMU.nnftri.Rec. 1404.034).

5.7. Using Artificial Intelligent Chatbots

During manuscript preparation, artificial intelligence-assisted tools were used for language and grammatical editing as well as for creating figures. The authors reviewed and edited the generated text and take full responsibility for the scientific content, interpretation, and final manuscript.

6. REFERENCES

1. Abdul Manan M. Progress in probiotic science: prospects of functional probiotic-based foods and beverages. Int J Food Science. 2025; 2025(1): 5567567. https://doi.org/10.1155/ijfo/5567567.

2. Habiba MU, Rahman MM, Augustin MA, Varela C, Morris H, Bozkurt H. Traditional Fermented Dairy Products as Reservoirs of Bifidobacterium With Probiotic Potential: From Microbial Diversity to Functional Characterization. Compr Rev Food Sci Food Safety. 2026; 25(4): e70540.https://doi.org/10.1111/15414337.70540.

3. Churin AA, Sokolyanskaya LO, Lukina AP, Karnachuk OV. Current concepts in probiotic safety and efficacy. Nutrients. 2026; 18(4): 696. https://doi.org/10.3390/nu18040696.

4. Hill C, Guarner F, Reid G, Gibson GR, Merenstein DJ, Pot B, et al. The International Scientific Association for Probiotics and Prebiotics consensus statement on the scope and appropriate use of the term probiotic. Nature Rev Gastroenter & Hepatol. 2014;11(8):506-14. https://doi.org/10.1038/nrgastro.2014.66.

5. Cordaillat-Simmons M, Rouanet A, Pot B. Live biotherapeutic products: the importance of a defined regulatory framework. Experim Mol Med. 2020; 52(9): 1397-406. https://doi.org/10.1038/s12276-020-0437-6.

6. Ziegler D, Stark J, Meier S, Brodmann P. Microbiological Safety of Probiotic Food Supplements. Food Risk Assess Europe. 2026;4:0088E. https://doi.org/10.2903/fr.efsa.2026.FR-0088.

7. Binda S, Hill C, Johansen E, Obis D, Pot B, Sanders ME, et al. Criteria to Qualify Microorganisms as "Probiotic" in Foods and Dietary Supplements. Front Microbiol. 2020; 11: 1662. https://doi.org/10.3389/fmicb.2020.01662.

8. Spacova I, Binda S, Ter Haar JA, Henoud S, Legrain-Raspaud S, Dekker J, et al. Comparing technology and regulatory landscape of probiotics as food, dietary supplements and live biotherapeutics. Front Microbiol. 2023; 14: 1272754. https://doi.org/10.3389/fmicb.2023.1272754.

9. Maddah G, Roustaee R, Mohammadi-Nasrabadi F, Ebrahimi MT, Esfarjani F. Probiotic Dairy Products: An overview and Health Policy: Health Policy of probiotic dairy product. Appl Food Biotechnol. 13(1): e16 (1-21). https://doi.org/10.22037/afb.v13i1.52656.

10. Fusco V, Fanelli F, Chieffi D. Authenticity of probiotic foods and dietary supplements: A pivotal issue to address. Crit Rev Food Sci Nutr. 2022;62(25):6854-71. https://doi.org/10.1080/10408398.2021.1907300.

11. Sato K, Kodama K, Sengoku S. The Co-Evolution of markets and regulation in the Japanese functional food industry: balancing risk and benefit. Foods. 2025; 14(9): 1581. https://doi.org/10.3390/foods14091581.

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12. Nwakoby I, Iheukwumere I, Iheukwumere C, Nwakoby N, Idigo M, Ike V. Afr J Nutr Appl Res. 2025;1(1):1-8. https://doi.org/10.54117/an7vv661

13. FDA. Policy regarding quantitative labeling of dietary supplements containing live microbials: draft guidance for industry. Rome Italy: U.S. department of health and human services, food and drug administration, center for food safety and applied nutrition, 2018.

14. Li LY, Ramachandran R, Ross JS, Wallach JD. Pre-market and postmarket real-world evidence studies supporting U.S. Food and Drug Administration regulatory decision-making, 2016-2024. Clinic Trial. 2026; 23(4): 363-74. https://doi.org/10.1177/17407745251415190.

15. Vasileiou M, Kyrgiakos LS, Kleisiari C, Lappas PZ, Tsinopoulos C, Kleftodimos G, et al. Digital transformation of food supply chain management using block-chain: A systematic literature review towards food safety and traceability. Bus Inf Syst Eng. 2026;68(4):919-46. https://doi.org/10.1007/s12599-025-00948-0.

16. Siddique A, Gupta A, Sawyer JT, Huang TS, Morey A. Big data analytics in food industry: a state-of-the-art literature review. NPJ Sci Food. 2025; 9(1): 36. https://doi.org/10.1038/s41538-025-00394-y.

17. Sibanda T, Marole TA, Thomashoff UL, Thantsha MS, Buys EM. Bifidobacterium species viability in dairy-based probiotic foods: Challenges and innovative approaches for accurate viability determination and monitoring of probiotic functionality. Front Microbiol. 2024; 15: 1327010. https://doi.org/10.3389/fmicb.2024.1327010.

18. Merenstein D, Guzzi J, Sanders ME. More Information Needed on Probiotic Supplement Product Labels. J Gen Int Medic. 2019; 34(12): 2735-7. https://doi.org/10.1007/s11606-019-05077-5.

19. Fredua-Agyeman M, Larbi EA. Inaccurate labelling practices in probiotic products: A regulatory shortfall in Accra, Ghana. PloS one. 2025; 20(5): e0322194. https://doi.org/10.1371/journal.pone.0322194.

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Policy Brief

pISSN: 2345-5357
eISSN: 2423-4214

APPLIED FOOD BIOTECHNOLOGY, 2026, 13 (1): 35 (1-10)
Journal homepage: www.journals.sbmu.ac.ir/afb

از معیارهای علمی تا اقدام سیاستی: چارچوب حکمرانی مبتنی بر شواهد برای محصولات لبنی پروبیوتیک

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چکیده

سابقه و هدف: ارزش سلامت عمومی محصولات لبنی پروبیوتیک به باقی ماندن سویه‌های مشخص در سطوح مؤثر در طول عمر مفید بستگی دارد. تبدیل معیارهای علمی بین‌المللی به نظارت نظارتی مستمر همچنان یک چالش است. این مطالعه با هدف توسعه یک چارچوب حاکمیتی مبتنی بر شواهد برای تقویت تضمین کیفیت و تنظیم مقررات محصولات لبنی پروبیوتیک در ایران انجام شد.

مواد و روش ها: این مطالعه، متون علمی بین‌المللی و دستورالعمل‌های نظارتی را با در نظر گرفتن نظرات حاصل از ارزیابی‌های اکتشافی و گفتگوهای سیاسی ایران، ترکیب کرد. الزامات علمی اصلی، به‌ویژه توصیف سویه، ایمنی، مزایای سلامتی و قابلیت حیات، در عملکردهای نظارتی، مسئولیت‌های نهادی و شاخص‌های عملکرد عملیاتی شدند.

یافته‌ها: چرخه مدیریتی شش مرحله‌ای پیشنهادی، تعریف، شناسایی، تأیید، نظارت، اطلاع‌رسانی و ارزیابی، استانداردهای ملی، قابلیت ردیابی سویه، اعتبارسنجی ایمنی و اثربخشی، تأیید قابلیت حیات در پایان عمر مفید، نظارت مبتنی بر ریسک، برچسب‌گذاری شفاف و قابلیت ردیابی دیجیتال را ادغام می‌کند. همچنین شامل یک نقشه راه اجرایی سه ساله و شاخص‌های عملکرد قابل اندازه‌گیری است که انطباق تجاری را در زمان انقضا به عنوان یک معیار اصلی شناسایی می‌کند.

نتیجه‌گیری: مدیریت مؤثر پروبیوتیک‌ها نیازمند گذار از تأیید ایستا قبل از ورود به بازار به تنظیم مداوم چرخه عمر است. چارچوب پیشنهادی، مسیری عملی را ایجاد می‌کند که شواهد علمی، تأیید آزمایشگاهی، پاسخگویی صنعت و نظارت بر بازار را به هم پیوند می‌دهد تا از حمایت از مصرف‌کننده در ایران اطمینان حاصل شود.

واژگان کلیدی: فرآورده‌های لبنی، حکمرانی غذا، مقررات غذایی، ایران، پروبیوتیک، تضمین کیفیت، قابلیت ردیابی

تاریخچه مقاله
دریافت: ۴ سپتامبر ۲۰۲۶
داوری: ۶ نوامبر ۲۰۲۶
پذیرش: ۱۰ نوامبر ۲۰۲۶
چاپ: ۱۷ نوامبر ۲۰۲۶

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