

Prebiotic Probiotic Postbiotic Evolution in Food: Latin America Caribbean Trends Regulations

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Abstract: Prebiotic Probiotic Postbiotic Evolution in Food: Latin America Caribbean Trends Regulations.

Introduction. In recent years, Latin America and the Caribbean (LAC) has experienced growth in the demand for functional foods, particularly those with prebiotic, probiotic, and postbiotic (PPPs) properties, which are not subject to special regulation in the region. Prebiotics are defined as non-digestible ingredients or fibers. Probiotics are defined as harmless microorganisms incorporated into food with health benefits. Postbiotics are defined as substances derived from these microorganisms. **Objective.** The purpose of study is to identify products as PPPs that have been manufactured or marketed in LAC and to evaluate the health and content claims indicated on their labels according to available international scientific evidence.

Materials y methods. The article attempts to fill this gap by conducting a document content analysis (DCA) and a systematic literature review (SLR) of three main sources: the institutional national and international regulation platforms; the information on distribution channels of them in the World and LAC; finally, the literature reviews on formal databases Google Scholar and Scielo covering the period 2010–2025. This review will be applied with precision to three general food marketing regulations: Food safety declarations/regulations/government policies; inspections by product/market/raw materials and food manufacturing/marketing/labeling. **Results.** Findings indicate a lack of specific legislation for prebiotic, probiotic, and postbiotic foods in LAC. Opportunities for commercializing PPP products in the region are increasing, based on an exhaustive analysis of marketing strategies and the current regulatory framework. **Conclusions.** Better control of labeling information for these products aimed at consumers is needed, ensuring the clarity of their content globally.

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Keywords: functional foods, prebiotics, probiotics, postbiotics, food industry, regulation, claims.

Resumen: Prebiótico Probiótico Postbiótico Evolución en Alimentos: América Latina Caribe tendencias regulaciones. **Introducción.** En los últimos años, América Latina y el Caribe (ALC) ha mostrado un notable aumento en la demanda de alimentos funcionales especialmente con propiedades prebióticas, probióticas y postbióticas (PPPs), productos que actualmente no están sujetos a una regulación especial en la región. El estudio define a los prebióticos como fibras no digeribles; a los probióticos como microorganismos inocuos con beneficios para la salud; y a los postbióticos como sustancias derivadas de ellos. **Objetivo.** Identificar los productos PPPs fabricados o comercializados en ALC y evaluar las declaraciones de propiedades y contenido en sus etiquetas, contrastándolas con la evidencia científica internacional disponible.

Materiales y métodos. Para llenar el vacío regulatorio existente, el artículo emplea una metodología dual: un análisis de contenido documental (DCA) y una revisión sistemática de la literatura (SLR). Las fuentes analizadas son plataformas de regulación institucionales (nacionales e internacionales), canales de distribución en el mundo y ALC, y bases de datos académicas (Google Académico y Scielo) para el período 2010–2025, asegurando la validez del estudio. Esta revisión se centra en tres áreas regulatorias clave: inocuidad alimentaria (políticas), inspecciones (por producto, mercado y materias primas) y el etiquetado. **Resultados.** Indican una clara ausencia de legislación específica para los alimentos con PPPs en ALC. A pesar de esto, las oportunidades comerciales persisten actualmente y están creciendo, impulsadas por las estrategias de marketing y el marco regulatorio actual. **Conclusiones.** Es fundamental mejorar urgentemente la supervisión de la información en el etiquetado, garantizando su claridad para la protección global del consumidor. **Arch Latinoam Nutr 2025; 75(4): 299-309.**

Palabras clave: alimentos funcionales, prebióticos, probióticos, postbióticos, industria de alimentos, regulaciones, declaraciones.

Introduction

The functional food market is expanding due to rising demand for digestive and immune health

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products, particularly prebiotics, probiotics, and postbiotics (PPPs) (1).

The prebiotic health market (USD 2.99B in 2024) is driven by inulin use in dairy and infant formula, with a 5.15% Compound Annual Growth Rate (CAGR) (2024–2029) (2). Probiotic (USD 113.43B by 2029, CAGR: 7.53%) dominate Asia-Pacific, offering gut and immune benefits (3, 4) and is the fastest-growing region, with probiotic products available in 196 countries (2, 5). Postbiotics (e.g., microbial metabolites) gain traction for stability and clinical applications (6). This study analyzes regulatory gaps in LAC's PPP market using Asymmetric Information Theory (7,8,9), highlighting: misleading claims from producer-consumer information gaps, lagged standards vs. global frameworks (WHO, EFSA) and policy needs: transparent labeling, verified health claims, and safety protocols. Methods include a literature review (2010–2025, Google Scholar/Scielo) and internet market analysis of LAC distribution channels. In this analysis, information on prebiotics, probiotics, and postbiotics is analyzed for each continent and country only in the market where information on them was found.

Theoretical and Legal foundations review in the commercialization of the PPPs products in international markets PPPs regulation faces a “market for lemons” risk where low-quality products may substitute high-quality ones due to information asymmetry. Manufacturers exploit regulatory gaps by lowering standards post-market, while consumers struggle to verify label claims about strains and concentrations (10).

The functional food market addresses this through certifications, scientific studies and traceability technologies like blockchain. The Pan American Health Organization defines functional foods as containing bioactive components that offer health benefit beyond nutrition (10), supporting the shift from “adequate” to “optimal” nutrition (11). These foods must demonstrate safety and efficacy at normal consumption levels, though regulatory rigor varies globally.

Prebiotics (inulin, Fructooligosaccharides (FOS), Galactooligosaccharides (GOS) selectively nourish beneficial gut bacteria (12-13). While WHO/FAO (14) and EFSA provide guidelines, regulatory harmonization remains challenging.

Marketed in infant foods (improving stool quality and gut flora) (15), they now include innovative formats like pectin-derived oligosaccharides (POS) (16). However, high R&D costs and strict labeling requirements in developed countries hinder market growth.

Comparative international regulation PPPs food and distribution channels in the world Prebiotic food in the world and market and regulatory authority Prebiotic production has expanded significantly due to gut health awareness (17). Inulin, FOS, and GOS are widely used in functional foods, supported by evidence of microbiotabenefits (18-19). Market share leaders: Asia-Pacific (44%), North America (28%), Europe (19%) (20). EFSA/FDA approvals drive innovation (21), but cost and education challenges persist (22).

Asia Prebiotic Market

Asia Pacific's feed prebiotics market grows due to antibiotic restrictions, with India's FSSAI implementing new veterinary drug rules (2025) (23). Indonesia's National Agency of Food Control BPOM approved “prebiotic” for chicory-root inulin/oligofructose ($\geq 4.5\text{g/L}$, 30:70 ratio) in milk powder for ages 3+ (24), reflecting demand for digestive health solutions.

North America Prebiotic Market

United States: FDA regulates PPPs as food additives (21 CFR 172), GRAS substances (25), and dietary supplements (DSHEA) (26), requiring clinical studies for health claims (27). Canada classifies prebiotics as functional foods/NHPs under Food and Drug Regulations (28).

Europe Prebiotic Market- European Commission (EC)- Directorate General for Health and Consumers. Directive on Food Supplements (Directive 2002/46/EC)

The EU regulates prebiotics under multiple frameworks: food supplements must meet Safety standards (29), Regulation (EU) No. 432/2012 authorizes EFSA-backed health claims (31-32), and novel foods require safety assessments (34). Key points: “prebiotic” claims are unauthorized (30,35); approved ingredients like GOS and 3- Fucosyllactose (3-FL) undergo strict

evaluations (33-34). Regulation (EC) No 1924/2006 governs claims (33). Market leaders include Tereos Group and Royal Cosun (2). EFSA approves specific claims (e.g., gut health) but requires strong evidence (32,35). Recent approvals expand GOS uses (33-34).

Probiotic Food in the World and Market

Probiotics, live microorganisms providing health benefits when consumed adequately,

Have evolved from niche supplements to mainstream products. Growing awareness of the Gut microbiome's health role has driven scientific and commercial interest. Research Supports their benefits for gut health, immunity, and mental well-being (35,36).

FAO/WHO established probiotic evaluation guidelines in 2002 (37). Market leaders: Asia Pacific (36%), North America (25%), Europe (20%), LAC (15%), and MEA (5%). This growth reflects strong scientific validation and consumer demand for microbiome-supporting products.

North America Probiotic Market.

USA – FDA and Canada- HC. Food Directorate

It is possible to consider “functional foods” in any of the aforementioned food and supplement categories, based on their natural origin. From a legislative perspective, foods with probiotics could fit into several of the four food categories described by the FDA; however, in the United States, the health benefits of dairy products with added probiotics, prebiotics, or cultures are not explicitly recognized. The main probiotic strains in USA are: *L. acidophilus*. Source: Rhodia, Inc. (Madison, WI. USA.); *L. acidophilus* DDS-1. Source: Nebraska Cultures, Inc. (Lincoln, NE. USA); *L. crispatus* CTV05. Source: Gynelogix, (Boulder, CO, USA) and *S. boulardii*. Source: Biocodex Inc. (Seattle, WA. USA).

In Canada are: *L. fermentum* RC-14. Source: Urex Biotech Inc. (London, Ontario,

Canada); *L. acidophilus* R0011. Source: Institut Rosell (Montreal, Canada) (38).

European Union Probiotic Market

Global definitions of functional foods vary: Europe/U.S. classify them as GRAS, while LAC countries regulate them as supplements. Prebiotic/probiotic claims differ; postbiotics

Show promise for gut health (39). Key strains include *L. acidophilus* LA-1 (Chr. Hansen), *L. rhamnosus* GG (Valio Dairy), and others (38). Regulatory gaps persist, urging Standardized frameworks. Postbiotics gain traction for stability and clinical benefits.

Asia and Australian Prebiotic /Probiotic Market

China (MOH): Prebiotics/probiotics fall under multiple categories (40). GOS/FOS are fortifiers; inulin—novel food; lactulose—additive. “Prebiotic” claims restricted in infant foods. Approval: 1-2 years. Japan (MHLW/CAA): Regulates via FOSHU (41,42) & FFC (43). FFC updates mandate GMP by 2026 (43). Key strain: *L. casei* Shirota (Yakult) (38). Australian continent (FSANZ/TGA): Guides probiotics/postbiotics in medicines (44). Market strain: *B. lactis* HN019 (38).

Latin America and the Caribbean - (LAC) Prebiotic/ Probiotic Market

Latin America regulates prebiotics under varied frameworks, often overlapping with probiotics. Argentina (ANMAT): Functional ingredients/additives under Food Code Articles 1383 (approved prebiotics) & 1385 (claims) (45), plus Disposition 4980/2005 for Functional foods (46). Brazil (ANVISA): Classified as functional ingredients/additives under RDC16/1999 (48), RDC 18/2008 (scientific proof required) (49), and IN 60/2016 (Approved claims) (50). Chile: Prebiotics are additives (RSA Art. 120) (51,52) or supplements (Decree 309/2015) (52) but lack legal definition (53). Claims require evidence (54), facing classification challenges (55). Market includes products like NUP! Pylori OFF (56). Colombia (INVIMA): Functional ingredients under Res. 333/2011 (health benefits) (58) And 810/2021(labeling) (59). Mexico (COFEPRIS): Regulated as Functional ingredients/ additives under NOM-086 (functional foods) (60) and NOM-218 (supplements) (61), requiring premarket approval (62). Peru (DIGESA): Governed by Supreme Decree 007-98-SA (safety) (63) and Resolution 546-2013 (claims) (64), mandating scientific evidence. Regional challenges include inconsistent definitions despite growing demand.

Postbiotic Food in the World and Market

Postbiotics, derived from probiotic activity, enhance gut health (65) and immune function.

The global market is growing at 12-15% CAGR (2023-2030) due to gut health awareness and postbiotic stability (66)(67). North America (15-20% share): Largest market (U.S./Canada), led by ADM(USA)and Lallemand (Canada (2, 68).Europe(25-30%share):Strong in Germany/ France, with Nestlé (Switzerland) and Danone (France) leading (67) (69). Asia-Pacific (40-45% share): Fastest-growing (Japan/China/ India), driven by Morinaga Milk (Japan) (70). LAC (5%) & MEA (2%): Emerging markets (71). Applications: Supplements (40%), functional foods (30%), infant nutrition (15%), animal feed (10%) (72). Advantages: Shelf stability, proven efficacy (73, 74). Regulatory approvals (FDA/ EFSA/FSSAI) boost adoption (75).

Methodology in the normative economic analysis of food regulations

This study employs a sequential mixed-methods design, utilizing DCA to examine food regulatory frameworks (75,76) as the primary methodology and as a complementary analytical technique, the SLR was conducted following PRISMA guidelines, with a protocol registered in PROSPERO that defined PICOS/S inclusion/exclusion criteria. The search across key databases utilized controlled vocabulary and AI tools to prioritize relevant records and control for selection bias. The selection process was documented in a PRISMA flow diagram. Evidence quality was assessed using an adapted GRADE approach, integrating Asymmetric Information Theory with economic/social science concepts. The DCA analyzed the SLR corpus, employing a deductive-inductive coding matrix. Deductive categories integrated Asymmetric Information Theory to identify power structures and the FAIR (Findability, Accessibility, Interoperability, Reusability) and

DEIA (Diversity, Equity, Inclusion, and Accessibility) principles to examine discursive treatment. Inductive categories captured emergent themes. The resulting narrative synthesis intertwines the thematic findings from the SLR with the discursive analysis from the DCA. The FAIR/DEIA principles transversally guided methodological ethics, ensuring equity through the inclusion of grey literature and bias mitigation. Thus, this framework critically articulates "what is known" (SLR) with "how it is stated and what relations are configured" (DCA). The approach involves: (1) reviewing prior studies; (2) systematically analyzing regulatory documents; and (3) organizing data into three themes: food safety policies, product/market inspections, and manufacturing/labeling rules. Data sources include Google Scholar/Scielo (2010-2025), comparing Latin American (LAC) and international standards. DCA follows four phases: document selection, logical analysis, scientific abstraction, and multi-source synthesis (bibliographic/digital/institutional). Systematic Literature Review (SLR) principles enhance rigor (77), with an 8-step qualitative design. Step 5 includes: academic searches, snowballing, and gray literature collection. The protocol begins with: Stage 1 PICOS-guided research questions: "What regulatory advances exist in PPPs commercialization in LAC (2010-2025) vs. North America/Asia/Europe?". Implementation: Stage 2 applied the SLR protocol (78), analyzing LAC regulations via Scielo/Google Scholar and GEMINI AI (English/Spanish/Portuguese). Keywords: "pre/pro/postbiotics," "regulations," "LAC" (Table 1). Cultural contexts were addressed, focusing on three regulatory dimensions with narrative synthesis. Data Retrieval: Stage 3 extracted data from Google Scholar (global) and Scielo (LAC-specific), using: (1) database searches, (2) snowballing, and (3) gray literature. Screening followed FAIR/DEIA principles: abstract review → full- text analysis. No yield limits were set; gray literature supplemented peer-reviewed sources.

Test evaluation and analysis

Research was evaluated using: publication metrics (year/location); GRADE system (social science adaptation); 9-point relevance scale. Narrative synthesis compared evidence quality/quantity, employing three legislative-focused qualitative codes to streamline analysis. Methodological choices balanced rigor with resource optimization in regulatory literature examination.

Table 1. Search equations for PPP food in Human Health

| | |
|------------------------|---|
| SEARCH WORDS | (KEY ("prebiotic" OR "probiotic" OR "postbiotic") AND "safety regulations" "claims regulations") OR (KEY ("food security AND/OR ("government policies") (KEY "declarations and inspections by product/market") AND ("raw materials) AND/ OR (KEY "food manufacturing) AND/OR ("labeling") ("marketing") AND/OR/IN KEY ("LAC"). Spanish, English and Portuguese. |
| DIMENTIONS 1/ 2 / 3 | <p>1 Regulaciones de declaraciones de seguridad alimentaria y Políticas gubernamentales.</p> <p>1 Food Safety Claims Regulations and Government Policies.</p> <p>1 Regulamentos de Declarações de Segurança Alimentar e Políticas Governamentais.</p> <p>2 Regulaciones de declaraciones e inspecciones por producto/mercados vinculados como materias primas.</p> <p>2 Regulations of declarations and inspections by product/ market linked as raw materials.</p> <p>2 Regulamentos de declarações e inspeções por produto/ mercados vinculados como matérias-primas.</p> <p>3 Regulaciones de declaraciones que afectan a manufacturas de alimentos y etiquetado.</p> <p>3 Regulations of declarations that affect food manufactures and labeling.</p> <p>3 Regulamentos de declarações que afetam a fabricação e rotulagem de alimentos</p> |
| LITERATURE TYPE | Journal- All |
| PUBLICATION YEAR | 2010-2025 |
| TEMATIC AREA | Applied social sciences- Social sciences – Law- Multidisciplinary |

Source: Own elaboration, 2025

Results

The analysis of PPPs literature reveals a predominant focus on nutritional, medical, and biotechnological aspects rather than legal/regulatory frameworks. Despite using Scielo and Google Scholar - comprehensive databases for LAC publications in Spanish, English, and Portuguese - minimal documentation exists on PPPs regulations in the region. The study examined basic PPPs commercialization rules, tracking regulatory specifications and their evolution across countries. Methodological consistency was maintained through systematic citation management and comprehensive content analysis (beyond abstracts). Findings indicate ongoing global disagreement about defining functional foods/PPPs, with Economic organizations adopting varied conceptualizations.

While some nations update

Food regulations with technological advances, others resist adoption of PPPs, resulting in Scarce publications about regional regulatory progress.

LAC literature primarily addresses PPPs conceptualization, innovation, and applications rather than legislative aspects. Both databases show limitations: articles typically discuss general food characteristics or health/nutrition aspects without consistent legislative or public policy approaches. Google Scholar provided information across all three established search dimensions (food safety policies, product/market inspections, manufacturing/labeling), while Scielo mainly covered dimension 1 (food safety policies). This regulatory gap persists despite PPPs' growing commercial importance, highlighting the need for standardized definitions and region-specific legal frameworks that address both technological advancements and public health considerations. In both databases, bibliographic reviews reveal a paucity of peer-reviewed articles on the topic, as well as comparative studies between similar products in various Latin American topic,

as well as comparative studies between similar products in various LAC countries. The results indicate a lack of information on the legislative and marketing management of PPP food products. What they do share individually as a country and collectively is the use of the *Codex Alimentarius*. The initial results of the analysis in the Scielo database for the areas of social sciences, health, multidisciplinary and law, are shown in Table 2. Regulations on the types of foods addressed are more related to product quality controls and their production certifications for marketing—such as ISO 9000 or HACCP—

than to the identification of their content, nutrients, or special or differentiating characteristics. The Scielo database has indexed peer review; however, the Google Scholar database, although it finds a greater number of articles published in the three dimensions of the study indicated, the types of arbitration for their publication are different. Analysis reveals international PPPs regulations focus on certification, while LAC lacks value-based standards. Most cover only general food safety rules. Scielo yielded just one article (Dimension 1), versus Google Scholar's 14 (6-D1, 3-D2, 5-D3). See Table 2. Developed Nations (Japan/US/EU) have advanced PPPs frameworks, while LAC relies on *Codex Alimentarius* (WHO/FAO/WTO). Argentina,

Table 2. Scielo and Google Scholar Database Search of PPPs - LAC 2010-2025

| Search Criteria Dimension | No. of Items Found 2010-2025 | Number Database (Articles) Scielo Indexing Magazines | Main Area Research Study Objective in Human Health and country: |
|--|---------------------------------|---|---|
| 1.- Food safety declaration regulations/ government policies. | 2023 | 1 | -Applied social sciences -Social Sciences -Law- Brazil. -Multidisciplinary |
| 2.- Regulations of declarations and inspections by product/market linked as raw materials. | None found | There are no articles related to PPP food legislation in inspections product / raw materials in LAC. | -Applied social sciences -Social Sciences -Law -Multidisciplinary |
| 3.-Declaration regulations affecting food manufacturing/marketing/ labeling. | None found | There are no articles related to PPP food legislation affecting manufacturing labeling in LAC. | -Applied social sciences -Social Sciences -Law -Multidisciplinary |
| Search criteria | No. of items found 2010-2025 | Database Google Scholar Articles | Main Area Research Study objective: |
| | 2024 | 1 | Social Sciences and Law and Economics. Mexico. |
| 1.- Food safety declaration regulations/ government policies. | 2023 | 3 | |
| | 2022 | 1 | Multidisciplinary. México, |
| | 2015 | 1 | Argentina, Ecuador. |
| | 2022 | 1 | Social Sciences and Law and Economics |
| 2.- Regulations of declarations and inspections by product/market linked as raw materials. | 2021 | 1 | Argentina, Colombia. |
| | 2015 | 1 | Multidisciplinary. Argentina. |
| | 2023 | 1 | Social Sciences and Law and Economics |
| 3.-Declaration regulations affecting food manufacturing/ marketing and labeling | 2021 | 1 | Argentina, Colombia, México |
| | 2011 | 1 | |
| | | 1 | Multidisciplinary |
| Scielo: 1 Google Scholar: 14 Total: 15 articles | | | |

Source: Own elaboration, 2025

Brazil, Mexico, Chile, and Colombia dominate regional PPPs literature, but lack legislative proposals. Unlike US/Asia/Europe, no regulatory progress exists in LAC, with minimal research on policy changes for PPPs.

The study identified a small number of articles on regulatory aspects, partly due to the nature of the platforms consulted. Google Scholar and Scielo have a broad and universal scope, with a strong emphasis on scientific literature produced mainly in Latin America and the Caribbean, Spain, and Portugal, where regulatory debate is limited, and it was precisely for this reason that they were selected. The results indicate that there is global disagreement regarding the definition of functional foods/PPP, and that economic organizations adopt diverse conceptualizations.

Methodological consistency was maintained through systematic citation management and in-depth content analysis. This shows that developed countries update food regulations in line with technological advances, while developing countries only adopt PPPs, resulting in few publications on the evolution of regional regulations. The literature from Latin America and the Caribbean mainly addresses the conceptualization, innovation, and applications of PPPs, but not the legislative aspects of public policies.

Policy implications LAC and global markets show a legislative gap for PPPs regulation, with more research in nutrition/biotechnology than policy. Analysis focused on: (1) food safety policies, (2) product/market inspections, and (3) labeling rules. PPPs lack a universal definition but include health-enhancing foods. As a growing market segment, they require specific regulations and public health integration.

This study implemented a sequential mixed-methods framework to analyze regulatory frameworks for PPP products in LAC. The systematic review, conducted following PRISMA guidelines with a protocol registered in PROSPERO, identified and evaluated evidence on regulatory developments (2010-2025). The use of controlled vocabulary, AI tools (GEMINI AI), and an adapted GRADE approach integrating asymmetric information theory minimized selection biases. The inclusion of gray literature following FAIR/DEIA principles incorporated underrepresented perspectives. The DCA employed a deductive-inductive coding matrix. Deductive categories, based on asymmetric information theory and FAIR/DEIA principles, deconstructed regulatory discourse to

identify related structures. The inductive categories captured emerging themes. The narrative synthesis integrated the thematic findings of the SLR (food safety policies, inspections, and labeling regulations) with the discursive analysis of the DCA. This approach confirmed a critical regulatory gap in Latin America and the Caribbean, characterized by dependence on the Codex Alimentarius and the predominance of technoscientific approaches over normative ones. The study demonstrates that addressing this gap requires not only legislative proposals but also a discursive shift that prioritizes regulatory sovereignty, equity, and transparency.

Discussion

The obtained results confirm the existence of a critical gap in the regional scientific literature concerning the regulatory framework for PPPs. This discussion is structured around three main axes derived from the findings: First, the dominance of techno-scientific approaches over regulatory ones. The overwhelming preference for research on nutritional, medical, and biotechnological aspects reflects a global trend in PPP literature.

However, within the LAC context, this disparity is more acute, marginalizing legal and public policy research. This suggests that technological innovation and scientific research are advancing at a much faster pace than the regulatory capacity of countries in the region. The direct consequence is a legal vacuum that can hinder intra-regional commercialization, fail to protect consumers, and stifle R&D investment by creating an environment of legal uncertainty. Second, the dependence on the Codex Alimentarius and the lack of regulatory sovereignty. The finding that LAC countries share an almost exclusive use of the Codex Alimentarius as a normative reference is a double-edged sword. While it provides a harmonized and internationally recognized foundation, it also highlights a lack of endogenous regulatory development tailored to the region's specific

realities. The frameworks of Japan, the U.S., and the EU are proactive and integrated with their innovation and public health policies. In contrast, Latin America's reliance on general Codex standards, often focused on safety and quality certifications (ISO, HACCP), leaves crucial aspects of PPPs unaddressed, such as health claims, labeling veracity, and definition standardization. This lack of "regulatory sovereignty" places the region in a reactive position and makes it vulnerable to importing foreign regulations that may not be suitable. Third, the limitations of databases and the publication ecosystem. The methodological choice to use Scielo and Google Scholar was intentional to capture the intellectual production of LAC, but the results also expose the inherent limitations of this publication ecosystem. The scarcity of peer-reviewed articles on legislative aspects is not merely a search problem but a symptom of a larger research deficit. The predominance of grey literature and the lack of in-depth comparative studies indicate that regulatory knowledge may be dispersed in government reports, theses, or unindexed technical documents, making access and systematization difficult.

Furthermore, Google Scholar's superiority in retrieving information across all dimensions underscores its utility for comprehensive searches on emerging topics where formal literature is scarce, although it requires more rigorous screening. This translation maintains a formal American English academic tone, using precise terminology and complex sentence structures appropriate for scholarly discourse. It faithfully conveys the original Spanish meaning while adhering to conventions of English academic writing.

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Conflict of Interest

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