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REVIEW ARTICLE

Law and innovation in food biotechnology: ethical implications for the production of functional foods

La ley y la innovación en la biotecnología alimentaria: implicaciones éticas en la producción de alimentos funcionales

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Abstract Functional foods have emerged as an innovative category within the food industry, promoted for their ability to offer additional benefits beyond essential nutrition. However, their commercialization poses significant legal and ethical challenges, particularly regarding regulating their health benefits, producer responsibility, and equity in access. This systematic review analyzes current legislation in various jurisdictions, including the European Union, the United States, and Latin America, comparing regulatory approaches and their impact on food safety and consumer protection. It also examines the main ethical dilemmas associated with promoting these products, such as labeling transparency, unequal access to functional foods, and using biotechnology in their development. The results show that while regulatory frameworks exist to regulate these issues, challenges persist in their practical implementation and the harmonization of standards internationally. It concludes that stricter and more consistent regulation, along with clear and accessible communication strategies for consumers, is essential to ensure safety and equity in the functional foods market.

Keywords functional foods, food legislation, ethics in biotechnology, labeling regulation, consumer safety.

Resumen Los alimentos funcionales han emergido como una categoría innovadora dentro de la industria alimentaria, promovidos por su capacidad para ofrecer beneficios adicionales más allá de la nutrición básica. Sin embargo, su comercialización plantea importantes desafíos legales y éticos, especialmente en lo que respecta a la regulación de sus propiedades saludables, la responsabilidad de los productores y la equidad en su acceso. Esta revisión sistemática analiza la legislación vigente en distintas jurisdicciones, incluyendo la Unión Europea, Estados Unidos y América Latina, comparando los enfoques regulatorios y su impacto en la seguridad alimentaria y la protección del consumidor. Se examinaron los principales dilemas éticos asociados a la promoción de estos productos, como la transparencia en el etiquetado, el acceso desigual a alimentos funcionales y el uso de biotecnología en su desarrollo. Los resultados muestran que, si bien existen marcos normativos que buscan regular estas cuestiones, persisten desafíos en su aplicación efectiva y en la armonización de estándares a nivel internacional. Se concluye que una regulación más estricta y homogénea, junto con estrategias de comunicación clara y accesible para los consumidores, es fundamental para garantizar la seguridad y equidad en el mercado de los alimentos funcionales.

Palabras clave alimentos funcionales, legislación alimentaria, ética en biotecnología, regulación del etiquetado, seguridad del consumidor.

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PUBLIS EDITORIAL

Introduction

In recent decades, the development of functional foods has gained significant relevance in the food industry and public health. These products, defined by their ability to provide additional benefits beyond essential nutrition, have been promoted as key tools in disease prevention and overall well-being improvement (Baker et al., 2022). However, their growing popularity has sparked debates about the legal and ethical implications of their production and commercialization, particularly regarding the regulation of their health properties, the accuracy of the information provided to consumers, and equity in access to these products (Intrasook et al., 2024).

From a legal perspective, the regulation of functional foods varies significantly across different jurisdictions. In the European Union (EU), legislation imposes strict requirements for the approval of health claims, demanding rigorous scientific backing before a product can claim health benefits (Regulation EC 1924/2006, 2006). In contrast, in the United States (U.S.), the Food and Drug Administration (FDA) allows manufacturers to use health claims without prior approval as long as they are based on scientific evidence and accompanied by a disclaimer (FDA, 2024). Regulation in many Latin American and Asia regions is even more lenient or inconsistent, raising concerns about consumer protection and market fairness (Ponte et al., 2024).

From an ethical perspective, the development of functional foods presents various dilemmas. One of the main challenges is ensuring transparency in the information provided to consumers and avoiding misleading marketing practices that may create false expectations about the real benefits of these products (Baker et al., 2022). The high cost of many functional foods limits access for lower-income populations, creating inequalities in the availability of products that could improve public health (Ohri-Vachaspati et al., 2019). Incorporating biotechnology in producing these foods, such as genetic modification or nanomaterials, has raised concerns about their long-term safety and impact on biodiversity (Ghimire et al., 2023).

In this context, it is essential to analyze the regulatory framework and ethical implications associated with innovation in functional foods to identify best practices for their regulation and commercialization. This review aimed to analyze current legislation in different countries regarding functional foods, evaluate the responsibility of producers, and identify the central ethical dilemmas associated with their development, commercialization, and promotion. This information will provide information for policy formulation that balances innovation in food biotechnology with consumer rights protection and equitable access to these products.

Methodology

This study used a systematic review approach, adhering to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. It focused on current legislation and ethical implications in producing functional foods through biotechnology. To achieve this, a structured search was conducted in scientific and legal databases to identify relevant studies and documents regulating functional foods and their ethical implications.

Various scientific, legal, and regulatory databases and institutional sources were selected for data collection. The scientific databases used included Scopus, Web of Science, PubMed, ScienceDirect, and SpringerLink, which provide access to relevant academic literature on food biotechnology and functional food regulation. Regarding legal and regulatory databases, EUR-Lex, the United States Food and Drug Administration (FDA), the European Food Safety Authority (EFSA), the Codex Alimentarius, LexisNexis, and the Official Journal of the European Union were consulted to obtain information on current legislation and international regulations. Reports from international organizations such as the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), and the Organization for Economic Co-operation and Development (OECD) were also included, as they address biotechnology and ethics in food production.

Key terms in English and Spanish were defined and combined using Boolean operators to search for information systematically. Expressions such as ("Functional foods" OR "biofortified foods") AND ("law" OR "legislation" OR "regulation") AND ("ethics" OR "moral responsibility" OR "consumer rights") and ("Biotechnology" AND "food production") AND ("legal framework" OR "policy") AND ("ethical considerations") were used. Filters were applied to restrict the results to publications from the last ten years (2015-2025) in English and Spanish, and priority was given to documents with full-text access.

The selection of studies was based on inclusion and exclusion criteria. Inclusion criteria considered publications from 2015 to 2025, research addressing the regulation of functional foods from a legal and ethical perspective, and documents in English and Spanish with full-text access. Conversely, studies that focused exclusively on nutritional benefits without reference to regulatory frameworks or ethical aspects, legislations not directly related to the production and commercialization of functional foods, and opinion articles without peer review were excluded.

The selection and data extraction were conducted in three stages. First, duplicate studies were removed using Zotero software. Then, titles and abstracts were reviewed to discard non-relevant studies. A full reading of the preselected

articles was conducted to assess their relevance to the study objectives.

The information was analyzed using a qualitative content analysis approach, employing NVivo software to identify patterns in regulation and ethical discussions. A legal analysis was performed by comparing regulations from different countries and international organizations, and an ethical analysis was conducted to identify dilemmas related to producer responsibility and consumer protection.

The methodological quality of the studies was assessed using the Joanna Briggs Institute (JBI) Critical Appraisal Tool, considering the clarity of objectives, methodological rigor, and relevance, excluding those that did not meet these standards. The results were organized into four main categories: current regulation of functional foods, focusing on regional legislation; producer responsibility, in terms of transparency in labeling and health claims; ethical implications, analyzing their impact on equity and consumer perception; and future trends and regulatory gaps, addressing challenges in the legislation and ethics of these products.

Results and discussion

The collected scientific and legal literature analysis identified key trends in regulating functional foods and the ethical implications of their production and commercialization. The results are presented in four main categories: (1) Current regulation of functional foods, (2) Producer responsibility, (3) Ethical implications, and (4) Future trends and regulatory gaps.

Current regulation of functional foods

The comparative analysis of regulatory frameworks reveals the heterogeneity in regulating functional foods (Table 1), highlighting the need for oversight to ensure consumer protection. The European Union (EU) has one of the most stringent systems globally, with Regulation (EC) 1924/2006 (2006), which requires that all nutritional and health claims be supported by robust scientific evidence and approved by the European Food Safety Authority (EFSA) before commercialization. This strict approach ensures that functional foods meet accuracy and safety standards, protecting consumers from misleading information. However, these regulations may also pose a barrier to innovation and the entry of new products into the market, as approval costs and timelines can be high for manufacturers.

In the United States (U.S.), the regulatory approach is more flexible, based on the Dietary Supplement Health and Education Act (DSHEA, 1994) and regulations from the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC). Unlike the EU, the U.S. does not require prior approval for health claims as long as they are supported by scientific evidence and accompanied by a disclaimer. This model promotes market growth and innovation, but also increases the risk of misleading advertising and products with insufficiently substantiated health claims. The FDA and FTC primarily focus on monitoring regulatory compliance and penalizing fraudulent practices after commercialization rather than preventing them. As a result, consumers are responsible for assessing the credibility of nutritional claims.

In Latin America, the regulation of functional foods is heterogeneous and varies by country. While countries like Brazil have developed more structured regulatory frameworks, in other parts of the region, oversight of these products is limited, allowing poorly substantiated claims to enter the market without rigorous evaluation. The lack of a unified standard complicates cross-border commercialization and creates uncertainty for producers and consumers. In many cases, advertising oversight and verifying health claims are insufficient, potentially leading to the proliferation of products with misleading information (Virgen & Mojica, 2024).

Meanwhile, in Asia, regulations vary significantly by country. In Japan, functional foods are subject to a well-defined regulatory system under the Foods for Specified Health Uses (FOSHU) category, which requires prior certification for products making health claims (Shimizu, 2003). The functional food market in China is expanding, but regulations are less stringent and depend on individual approvals for certain types of claims. A distinctive factor in this region is the influence of traditions and traditional medicine on the perception and regulation of these products, leading to regulatory approaches that differ from those in the West (Yang,

Table 1. Comparison of regulatory frameworks for functional foods

Region	Key legislation	Approval requirements	Claims oversight	Ethical considerations
EU	Regulation (EC) 1924/2006	Robust scientific evidence and prior approval	Strict control	Consumer protection, transparency
The U.S.	DSHEA (1994) FDA Food Labeling	Scientific evidence, but no prior approval	Moderate control	Commercial freedom vs. consumer rights
Latin America	Various national regulations	Varies by country	Limited oversight	Low control over advertising
Asia	Differentiated regulations (China, Japan)	Certification is required in some countries	Moderate control	Traditions and culture influence regulations

2008).

From an ethical perspective, stricter regulatory frameworks, such as the EU, prioritize consumer protection and transparency in commercializing functional foods, ensuring that nutritional claims are verifiable and scientifically supported (Coppens et al., 2006). In contrast, in regions with more flexible regulations, such as the U.S. and some countries in Latin America and Asia, there is a balance between commercial freedom and consumer rights, raising concerns about the accuracy of market information. The lack of a unified global standard creates inequalities in access to reliable products and complicates transnational oversight of functional foods (FAO/IFAD/UNICEF/WFP/WHO, 2023).

There is a clear need to move toward a more harmonized international regulatory framework that ensures both the safety and efficacy of functional foods and transparency in their commercialization. Cooperation between international organizations such as the FAO, WHO, and Codex Alimentarius could be key to establishing minimum standards that balance industry innovation with consumer protection. Implementing technologies such as artificial intelligence and blockchain for product traceability could enhance regulatory oversight and strengthen public trust in functional foods.

Producer responsibility

The responsibility of functional food producers is directly influenced by the regulatory framework of each country and the level of oversight imposed by health and consumer protection authorities (Pettoello-Mantovani & Olivieri, 2022). In the European Union (EU), companies must demonstrate the accuracy of nutritional claims before commercialization. In contrast, manufacturers can promote health benefits in the U.S. and some Latin American and Asia countries without prior scientific validation. This disparity creates a scenario where consumer protection varies significantly by jurisdiction, raising ethical and food safety challenges. The content analysis identified three key aspects of producer responsibility: transparency in labeling, advertising, health claims, and ingredient traceability.

Transparency in labeling

One key aspect of producer responsibility is transparency in labeling functional foods. In the EU, Regulation (EC) 1924/2006 (2006) establishes that any nutritional or health claim must be supported by verifiable scientific evidence and approved by the European Food Safety Authority (EFSA) before the product can be marketed. This ensures consumers receive precise and reliable information about the product's benefits.

In the U.S., although the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) oversee health claims, manufacturers can include claims without prior approval as long as they add a disclaimer stating that the FDA has not evaluated the claim and that the product is not intended to diagnose, treat, cure, or prevent diseases. This regulatory difference allows for greater flexibility in advertising but also increases the risk of consumers being exposed to potentially misleading information.

The labeling of functional foods varies widely in Latin America and Asia. While countries like Brazil and Japan have regulations that are more aligned with international standards, oversight is less rigorous in other nations, allowing the marketing of products with ambiguous or unverified claims. The lack of uniformity in labeling requirements makes it difficult to compare products and may lead to errors in consumer perception of their effectiveness (Gómez et al., 2023).

Advertising and health claims

In countries with less strict regulations, the advertising of functional foods may contain exaggerated or misleading claims about their health effects. For example, some products marketed in markets with lower oversight have been promoted with claims suggesting therapeutic benefits without sufficient scientific backing (Muela-Molina et al., 2021). This practice undermines the sector's credibility and can create false expectations among consumers, especially those seeking alternatives to improve their well-being or treat medical conditions.

From an ethical perspective, the lack of regulation in advertising these products raises dilemmas regarding producers' social responsibility. While some companies prioritize scientific evidence and transparency, others exploit legal gaps to maximize their sales without ensuring the accuracy of the information provided (García-Nieto et al., 2021). International organizations such as the World Health Organization (WHO) and the FAO have warned about strengthening regulations to prevent misinformation and protect consumers' right to make informed decisions.

Ingredient traceability

Another producer's responsibility is the traceability of the ingredients used in functional foods. In markets with strong regulations, companies must ensure that their products contain the declared bioactive compounds and that these come from safe and controlled sources. In regions with weaker regulations, the lack of clear traceability rules makes verifying the authenticity and quality of ingredients difficult, which could compromise consumer safety (Intrasook et al., 2024).

Some supplements and functional foods sold in unregulated markets contain lower concentrations of the declared active ingredients or even contaminants not specified on the label (Christoforou et al., 2021). This highlights the importance of implementing more rigorous traceability systems, such as using blockchain technologies to record and verify every stage of the supply chain.

Stricter oversight mechanisms must be established to ensure that consumers receive truthful and verifiable information about functional foods. Harmonizing regulatory standards at the international level could help reduce disparities in producer responsibility and improve transparency in labeling, advertising, and ingredient traceability.

Promoting consumer education by encouraging tools that allow for evaluating the credibility of health claims and more informed decision-making would be advisable. Collaboration between governments, international organizations, and the food industry is key to advancing toward more equitable and efficient regulation that protects consumer rights without stifling innovation in the functional food sector.

Ethical implications

The development and commercialization of functional foods raise important ethical dilemmas that require analysis from the perspective of equity, transparency in information, and the impact of biotechnology on food (Varzakas & Antoniadou, 2024). While these products represent an innovation with the potential to improve public health, their unequal access, lack of truthfulness in communicating their benefits, and the use of genetic manipulation technologies raise concerns that must be addressed through stricter regulations and greater industry accountability.

Equity and access to innovation

One of the main ethical challenges in commercializing functional foods is their accessibility to different socioeconomic groups. Most of these products have high prices due to their development, research, and marketing processes, which limit their availability to higher-income sectors (Baker et al., 2022). This creates a problem of food injustice, as the potential benefits of these products, such as the prevention of chronic diseases or the improvement of nutritional status, are limited to wealthier populations. At the same time, more vulnerable sectors remain exposed to less healthy diets.

From a public health perspective, inequity in access to functional foods limits their impact on reducing diet-related diseases such as obesity, diabetes, or cardiovascular diseases (Agurs-Collins et al., 2024). To mitigate this issue, policies such as subsidies or tax incentives would be necessary to expand access to these products in sectors with a higher risk of malnutrition and encourage the development of more affordable alternatives without compromising the quality and effectiveness of their benefits.

Truthfulness of information and consumer protection

Another critical aspect in the ethical debate surrounding functional foods is the transparency in communicating their health benefits (Schroeder, 2007). In markets with less stringent regulations, it has been identified that many nutritional and health claims are ambiguous, exaggerated, or lack solid scientific backing. This situation creates an information asymmetry between producers and consumers, affecting their decision-making about their diet.

In some countries, the lack of adequate regulation allows certain manufacturers to use misleading marketing strategies to promote their products, suggesting effects that have not been rigorously tested. This undermines the consumer's right to receive truthful information and can also create false expectations about the benefits of these foods, diverting attention from fundamental dietary habits like balanced eating and physical exercise (Gupta, 2023).

To address this issue, it is necessary to strengthen the oversight mechanisms on health claims in functional foods, requiring verifiable scientific evidence before marketing approval. In this regard, regulations like those in the European Union (Regulation EC 1924/2006, 2006) represent a model to follow, as they establish rigorous criteria for validating nutritional and health claims. However, in regions with more flexible regulations, such as the U.S., Latin America, and some Asian countries, there is still a need to improve oversight to prevent misinformation and protect consumer rights.

Genetic manipulation and bioethics

Biotechnology in the production of functional foods raises ethical questions about genetic manipulation, especially in products designed to alter metabolic functions or improve nutrient absorption. While advances in genetic engineering have enabled the development of foods with potential benefits, such as those enriched with essential fatty acids, modified probiotics, or crops fortified with vitamins and minerals, the introduction of genetically modified organisms (GMOs) into the food chain remains a controversial topic (Wikandari et al., 2021).

In the European Union, functional foods derived from GMOs are subject to strict regulation, requiring comprehensive safety studies before approval and mandatory labeling to ensure consumer transparency. In contrast, in the U.S. and other regions, the marketing of these products is more permissive, which has sparked debates about their potential long-term effects on human health and the environment (Hilbeck et al., 2020).

From a bioethical perspective, the genetic manipulation of food raises questions about intervention in natural biological processes and the possible impacts on biodiversity. The use of patents on certain biotechnological developments raises concerns about the concentration of control over food production in large corporations. This could limit the diversity of food supply and increase farmers' dependence on a small group of companies that dominate the GMO seed and crop market (Weale, 2010).

To ensure an ethical approach to the application of biotechnology in functional foods, it is crucial to promote regulations that balance innovation with safety and sustainability. Additionally, consumer education plays a key role in accepting these products, so it is necessary to provide clear, evidence-based information about the risks and benefits of genetically modified foods (Spackman, 2019).

The ethical implications of developing and commercializing functional foods highlight the need for stronger regulatory frameworks that ensure equity in access, truthfulness in information, and the responsible use of biotechnology. Regulatory bodies must adopt a consumer protection-based approach, ensuring that these products are accessible, safe, and backed by reliable scientific evidence (Holm, 2003).

The food industry must commit to ethical transparency and sustainability, avoiding deceptive marketing practices and promoting the responsible development of functional foods that benefit the entire population, not just privileged sectors (Varzakas & Antoniadou, 2024). Cooperation between governments, scientific institutions, and civil society will be key in designing policies that balance innovation with social justice, protecting public health and the integrity of the global food system.

Future trends and regulatory gaps

The regulatory framework for functional foods is undergoing a transformation driven by technological advancements, the globalization of trade, and the growing consumer demand for products with specific health benefits (Intrasook et al., 2024). However, the heterogeneity in current regulations and the speed of innovation in the sector present significant challenges. Three main trends in the evolution of functional food regulation have been identified: global regulatory harmonization, the integration of artificial intelligence in monitoring claims, and the development of regulations specific to biotechnology applied to these products.

Greater regulatory harmonization at the global level

One of the main challenges in regulating functional foods is the disparity of criteria between different regions. While the European Union (EU) has strict regulations, such as Regulation (EC) 1924/2006 (2006), which requires scientific validation of nutritional and health claims before commercialization, in other regions like Latin America and some Asian countries, supervision is less rigorous, allowing manufacturers to use ambiguous statements without sufficient scientific backing.

It is expected that in the future, there will be greater regulatory harmonization at the global level, driven by international organizations such as the European Food Safety Authority (EFSA), the U.S. Food and Drug Administration (FDA), and the Codex Alimentarius of the World Health Organization (WHO). Greater international cooperation would enable the creation of unified standards, reducing trade barriers and ensuring that consumers in different regions can access reliable and verifiable information.

However, harmonization faces significant obstacles, such as resistance from some industries to stricter regulations and differences in supervision systems between countries (Gómez et al., 2023). A viable approach would be the development of multilateral agreements that establish basic regulatory principles while leaving room for local adaptations based on each region's specific needs.

Integration of Artificial Intelligence (AI) in claim supervision

Verifying nutritional and health information in functional foods is a complex process that traditionally requires clinical studies and scientific reviews. However, the evolution of artificial intelligence (AI) is creating new opportunities to automate the supervision of claims and improve the detection of misleading statements (Sosa-Holwerda et al., 2024).

AI tools could analyze large volumes of scientific data and determine if a product's claims are supported by valid evidence. They could also facilitate market surveillance by monitoring labels, advertising campaigns, and digital content in real-time, identifying inconsistencies or unverified claims (Di Bitonto et al., 2024).

Some initiatives in this regard are already underway. For example, the FDA has explored AI algorithms to improve label reviews for dietary products, while EFSA has developed predictive models to assess the safety of new functional ingredients. However, the widespread implementation of these technologies requires specific regulatory frameworks to define the validity and reliability criteria for the algorithms used in claim supervision.

The use of AI in functional food regulation raises ethical and legal dilemmas related to the transparency of automated decision-making processes. It will be crucial to ensure that these systems are auditable and not subject to biases that favor certain companies or block legitimate innovations.

Specific regulation for biotechnology applied to functional foods

The development of functional foods has evolved beyond simple fortification with essential nutrients, advancing towards personalizing products based on genetic profiles and specific metabolic needs. Biotechnology enables the creation of optimized ingredients, probiotics designed to modulate the gut microbiota, and foods with bioactive compounds tailored to consumers' genetics (Damián et al., 2022).

While these innovations open new possibilities for disease prevention and wellness improvement, they pose ethical and regulatory challenges. In the European Union, legislation on genetically modified organisms (GMOs) is strict and requires thorough safety evaluations before commercialization. In contrast, regulations are more flexible in the U.S. and some regions of Asia, facilitating the introduction of genetically engineered functional foods without clear mandatory labeling.

As biotechnology moves toward personalized nutrition, regulations will need to address key issues such as:

Health risk assessment: Genetic modification of foods should undergo rigorous testing to rule out long-term adverse effects.

Transparency and labeling: Consumers have the right to know whether a functional food has been designed through biotechnology and how it may affect their health.

Protection of genetic data: Personalized nutrition requires analyzing individual genetic profiles, which raises concerns about privacy and the misuse of this information by companies or insurers.

To ensure the responsible development of these products, regulatory frameworks must evolve alongside biotechnological innovation, establish clear ethical boundaries, and promote honest communication with consumers. Figure 1 summarizes the main regulatory challenges in the future of functional foods.

The pursuit of global standards will shape the future of functional food regulation, adopting technologies such as AI in supervision and creating specific regulations for biotechnology applied to food. However, the evolution of these regulations will depend on the ability of international organizations to establish harmonized agreements and the willingness of the industry to adopt more transparent practices.

The current regulatory gaps pose risks to consumer protection and the credibility of the functional food sector. The lack of oversight in certain regions allows the proliferation of unsubstantiated claims, which could affect public trust and generate skepticism about the real benefits of these products.

In this context, strengthening regulatory frameworks with a science-based, ethical, and equitable approach is essential. Regulation must ensure that functional foods are accessible, safe, and supported by rigorous evidence. It must also prevent the spread of misleading marketing strategies and protect consumers' right to make informed decisions. Cooperation between governments, scientific bodies, and the private sector will be key to establishing regulations that foster responsible innovation without compromising public safety and well-being.

Conclusions

The development and commercialization of functional

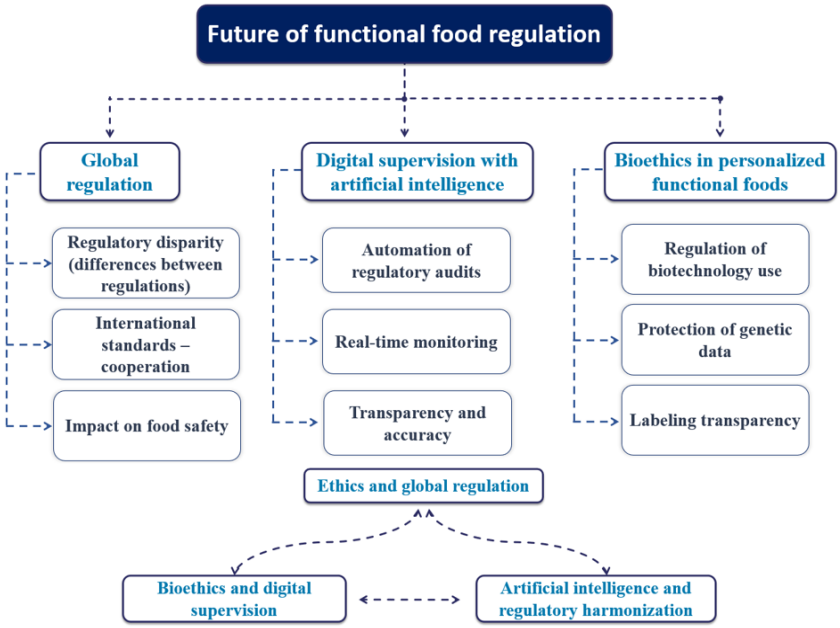

Figure 1. Main regulatory challenges in the future of functional foods.

foods represent an advancement in the food industry and the promotion of public health; however, their regulation and the associated ethical dilemmas remain critical challenges. A comparative analysis of legislation in different regions shows that while there are specific regulatory frameworks, such as Regulation (EC) 1924/2006 in the European Union and FDA regulations in the United States, discrepancies persist in the rigor of controls and the requirement for scientific evidence to support health claims. This lack of global harmonization may create inequities in access to safe and reliable products and confusion among consumers. From an ethical standpoint, transparency in labeling and the information provided to the public is essential to avoid deceptive practices that could lead to errors in decision-making regarding the consumption of these products. Biotechnology in the formulation of functional foods raises questions about its impact on health and the environment, highlighting the need for stricter regulatory oversight. In this context, it is crucial to move towards a more uniform and evidence-based regulatory model that balances innovation in biotechnology with consumer protection and equity in access to these foods. Greater international cooperation in formulating regulations and consumer education strategies is recommended to promote informed and responsible consumption of functional foods.

References

Agurs-Collins, T., Alvidrez, J., ElShourbagy, S., Evans, M., Gibbs, K., Kowtha, B., Pratt, C., Reedy, J., Shams-White, M., & Brown, A.G. (2024). Perspective: Nutrition Health Disparities Framework: A Model to Advance Health Equity. *Adv Nutr*, *15*(4), 100194. https://doi.org/10.1016/j.advnut.2024.100194

Baker, M.T., Lu, P., Parrella, J.A., & Leggette, H.R. (2022). Consumer Acceptance toward Functional Foods: A Scoping Review. *Int J Environ Res Public Health*, *19*(3), 1217. http://www.doi.org/10.3390/ijerph19031217

Christoforou, A., Norsen, S., Bernstein, J., & L'Abbe, M. (2021). Examining the Prevalence, Nutritional Quality and Marketing of Foods with Voluntary Nutrient Additions in the Canadian Food Supply. *Nutrients*, *13*(9), 3115. https://doi.org/10.3390/nu13093115

Coppens, P., da Silva, M.F., & Pettman, S. (2006). European regulations on nutraceuticals, dietary supplements and functional foods: a framework based on safety. *Toxicology*, *221*(1), 59-74. https://doi.org/10.1016/j.tox.2005.12.022

Damián, M.R., Cortes-Perez, N.G., Quintana, E.T., Ortiz-Moreno, A., Garfias, C., Cruceño-Casarrubias, C.E., Sánchez, M.E., & Bermúdez-Humarán, L.G. (2022). Functional Foods, Nutraceuticals and Probiotics: A Focus on Human Health. *Microorganisms*, *10*(5), 1065. https://doi.org/10.3390/microorganisms10051065

Di Bitonto, P., Magarelli, M., Novielli, P., Romano, D., Diacono, D., de Trizio, L., Mariano, A., Zoani, C., Ferrero, R., Manzin, A., De Angelis, M., Bellotti, R., & Tangaro, S. (2024). From data to nutrition: the impact of computing infrastructure and artificial intelligence. *Explor Foods Foodomics*, *2*, 810-29. https://doi.org/10.37349/eff.2024.00063

Dietary Supplement Health and Education Act (DSSHEA). (1994). *Public Law 103-417. Dietary Supplement Health and Education Act*. https://ods.od.nih.gov/About/DSHEA_Wording.aspx

FAO, IFAD, UNICEF, WFP & WHO. (2023). *The State of Food Security and Nutrition in the World 2023. Urbanization, agrifood systems transformation and healthy diets across the rural–urban continuum. Rome, FAO*. https://doi.org/10.4060/cc3017en

Food and Drug Administration (FDA). (2024). *Authorized Health Claims That Meet the Significant Scientific Agreement (SSA) Standard*. https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard

García-Nieto MT, Gonzálvez-Vallés JE, Viñarás-Abad M. (2021). Social Responsibility and Misleading Advertising of Health Products on the Radio. The Opinion of the Professionals. *Int J Environ Res Public Health*, *18*(13), 6912. https://doi.org/10.3390/ijerph18136912

Ghimire, B.K., Yu, C.Y., Kim, W.-R., Moon, H.-S., Lee, J., Kim, S. H., & Chung, I. M. (2023). Assessment of Benefits and Risk of Genetically Modified Plants and Products: Current Controversies and Perspective. *Sustainability*, *15*(2), 1722. https://doi.org/10.3390/su15021722

Gómez, C.V., Castillo, I.G., Martínez, I., & Ibañez, L. (2023). The Regulatory Status of Functional Foods in the Economic Integration Organizations of Latin America and the Caribbean. *Archivos Latinoamericanos de Nutrición*, *73*(4), 297-312. https://doi.org/10.37527/2023.73.4.005

Gupta, A. (2023). Deceptive advertising, regulation and naive consumers. *International Journal of Industrial Organization*, *91*, 103026. https://doi.org/10.1016/j.ijindorg.2023.103026

Hilbeck, A., Meyer, H., Wynne, B. & Millstone, E. (2020). GMO regulations and their interpretation: how EFSA's guidance on risk assessments of GMOs is bound to fail. *Environ Sci Eur*, *32*(54). https://doi.org/10.1186/s12302-020-00325-6

Holm, L. (2003). Food Health Policies and Ethics: Lay Perspectives on Functional Foods. *Journal of Agricultural and Environmental Ethics*, 531-544. https://doi.org/10.1023/B:JAGE.0000004966.67083.8a

Intrasook, J., Tsusaka, T.W., & Anal, A.K. (2024). Trends and current food safety regulations and policies for functional foods and beverages containing botanicals. *J Food Drug Anal*, *32*(2), 112-139. http://www.doi.

org/10.38212/2224-6614.3499
Muela-Molina, C., Perelló-Oliver, S., & García-Arranz, A. (2021). False and misleading health-related claims in food supplements on Spanish radio: an analysis from a European Regulatory Framework. *Public Health Nutr*, *24*(15), 5156-5165. doi: https://doi.org/10.1017/S1368980021002007
Ohri-Vachaspati, P., DeWeese, R.S., Acciai, F., DeLia, D., Tulloch, D., Tong, D., Lorts, C., & Yedidia, M. (2019). Healthy Food Access in Low-Income High-Minority Communities: A Longitudinal Assessment-2009-2017. *Int J Environ Res Public Health*, *16*(13), 2354. https://doi.org/10.3390/ijerph16132354
Pettoello-Mantovani, C., & Olivieri, B. (2022). Food safety and public health within the frame of the EU legislation. *Global Pediatrics*, *2*, 100020. https://doi.org/10.1016/j.gpeds.2022.100020
Ponte, L.G.S., Ribeiro, S.F., Antunes, A.E.C., Bezerra, R.M.N., & da Cunha, D.T. (2024). Beyond the Myths: Brazilian Consumer Perceptions of Functional Food. *Foods*, *13*(24), 4161. https://doi.org/10.3390/foods13244161
Reglamento CE No 1924/2006. (2006). *Reglamento del Parlamento Europeo y del Consejo relativo a las declaraciones nutricionales y de propiedades saludables en los alimentos*. https://www.boe.es/doue/2006/404/L00009-00025.pdf
Schroeder, D. (2007). Public Health, Ethics, and Functional Foods. *J Agric Environ Ethics*, *20*, 247-259. https://doi.org/10.1007/s10806-007-9033-1
Shimizu, T. (2003). Health claims on functional foods: the Japanese regulations and an international comparison. *Nutr Res Rev*, *16*(2), 241-52. https://doi.org/10.1079/NRR200363
Sosa-Holwerda, A., Park, O.H., Albracht-Schulte, K., Niraula, S., Thompson, L., & Oldewage-Theron, W. (2024). The Role of Artificial Intelligence in Nutrition Research: A Scoping Review. *Nutrients*, *16*(13), 2066. https://doi.org/10.3390/nu16132066
Spackman, C. (2019). Functional Foods. In: Kaplan, D.M. (eds) *Encyclopedia of Food and Agricultural Ethics*. Springer, Dordrecht. https://doi.org/10.1007/978-94-024-1179-9_94
Varzakas, T., & Antoniadou, M. (2024). A Holistic Approach for Ethics and Sustainability in the Food Chain: The Gateway to Oral and Systemic Health. *Foods*, *13*(8), 1224. https://doi.org/10.3390/foods13081224
Virgen, C.A., y Mojica, L. (2024). Revisión histórica y conceptual de los alimentos funcionales: antecedentes, perspectivas y desafíos. *Journal of Behavior and Feeding*, *4*(7), 11-20. https://doi.org/10.32870/jbf.v4i7.48
Weale A. (2010). Ethical arguments relevant to the use of GM crops. *N Biotechnol*, *27*(5), 582-7. https://doi.org/10.1016/j.nbt.2010.08.013
Wikandari, R., Manikharda, Baldermann, S., Ningrum, A., & Taherzadeh, M.J. (2021). Application of cell culture technology and genetic engineering for production of future foods and crop improvement to strengthen food security. *Bioengineered*, *12*(2), 11305-11330. https://doi.org/10.1080/21655979.2021.2003665
Yang, Y. (2008). Scientific substantiation of functional food health claims in China. *J Nutr*, *138*(6), 1199S-205S. https://doi.org/10.1093/jn/138.6.1199S

Conflicts of interest

The authors declare that they have no conflicts of interest.

Author contributions

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