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"International Perspectives on the Safety Regulation of Genetically Modified Foods (GMOs): A Comparative Analysis of Effectiveness and Transparency — Case Studies: United States, Canada, European Union, Brazil, China, Japan, India, Iran"

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ABSTRACT

This research paper compares with a comparative analysis of the effectiveness of international and national regulatory bodies related to transgenic products (GMOs) in ensuring the safety and transparency of bioengineered food in nine selected countries including Iran, India, China, Japan, Russia, the United States, Canada, the European Union, and Brazil. This research has been conducted using a qualitative method and a comparative-documentary analysis approach. Data is collected through library and documentary methods including national laws and regulations, guidelines from regulatory agencies Such as the U.S. FDA and the EFSA of the European Union and the corresponding institutions in China, Japan, Brazil, India, Russia and Iran, scientific articles, policy reports, and documents of the Cartagena Protocol on Biosafety and documents of international organizations WHO, FAO, CODEX, WTO have been collected and analyzed. Based on the findings, three divergent regulatory models were identified: product-based model (United States, Canada, Brazil), process-based model (European Union), strategic and limiting model (Russia, and to some extent China, India, Iran, Japan). It is worth mentioning that the emergence of new genomic techniques (NGTs) has created a new complexity in the international regulation of this field. The results of this research can help policymakers, regulators, and key stakeholders to balance safety concerns with the benefits of technology by moving from unresolved disputes to convergence, and to design a more sustainable future for agricultural biotechnology through efficient regulatory systems, Strategic investments (such as more sophisticated applications such as plant vaccines; the use of artificial intelligence in international platforms) to design a more sustainable future for agricultural biotechnology.

1-Introduction

The regulation and oversight of genetically engineered foods (GMOs) and GM foods are among the most controversial issues in contemporary food safety and agricultural policy.Countries, influenced by various factors such as concerns over potential impacts on human health; genetic and environmental contamination; and economic and commercial interests, have adopted different regulatory models and approaches to ensure consumer safety and protect the environment. These decisions are based on scientific viewpoints, religious concerns, domestic and cultural policies, international commitments, and external pressures [1-2-3].

Given the importance of terminology in this field, two main definitions include:According to Article 3 of the United Nations Cartagena Protocol on Biosafety, a 'Living Modified Organism' (LMO) is defined as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology' [4]. This definition has served as the primary basis for many international biosafety regulations [5]. According to the World Health Organization (WHO), GMOs, i.e., genetically modified organisms *can be defined as organisms (i.e. plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination.* This technology is often referred to as "modern biotechnology" or "genetic engineering".

The history of genetically modified crops dates back to the 1980s, when scientists first managed to transfer foreign genes to plants using disarmed strains of *Agrobacterium tumefaciens*. This breakthrough laid the foundation for transgenic crops as a new branch of biological science. [7–8]. One of the most well-known examples this technology was the transfer of genes from the bacterium *Bacillus thuringiensis* (Bt) into corn and cotton, which significantly improved their resistance to pests.[9]. In 1994 FLAVR SAVR Tomatoes became the first GE food crop approved by US Food and Drug Administration [10]. Since the mid-1990s, large-scale cultivation of (Bt)corn, resistant soybeans to pests and herbicides began in countries like the United States, Brazil and Argentina, this rapid expansion prompted the development of complex regulatory frameworks [11].

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Recently, the emergence of new gene editing technologies, New Genomic Techniques (NGTs), particularly the CRISPR-Cas9 system, has transformed the landscape of biotechnology. These "molecular scissors" allow for precise and targeted changes in the genome without the need to insert foreign DNA [12–13]. New genomic techniques (NGTs) have prompted many governments to revise their legal frameworks, such as the CHIPS and (Science) Act, Executive Order No. 14,081 of 2022 in the U.S., the European Commission's proposal in July 2023 to regulate products produced using new genomic techniques (NGT), and the European Parliament's report (EPRS No. 754549) to distinguish between traditional GMOs and gene-edited species [14-15-16].

The main pillar of the international regulatory frameworks for GMO products is regulated by three bodies for monitoring and evaluating the trade and biosafety of these products, including: the Cartagena Protocol on Biosafety, the Codex Alimentarius Commission, and the World Trade Organization (WTO) agreements (SPS/TBT) [17]. The Cartagena Protocol, adopted in 2000 and entered into force in

2003, is based on the Advanced Informed Agreement (AIA) on the safe transboundary movement of modified living organisms and operates on the basis of the Precautionary Principle (which is rooted in Article 15 of the Rio Declaration, Articles 10,6 and 11,8 of the Protocol) [4-5].

The Codex Commission, established by FAO and WHO, develops science-based standards for the safety aspects of GM crops and their food-derived products. and has become the dispute resolution authority in the WTO [18]. FAO and WHO have also provided tools, training program, and information platforms to help countries in safety assessment and risk management [19]. However, the major focus of these frameworks is on human food safety, and animal feed safety, which represents 70 to 90 percent of GMOs product consumption, has received less consideration [20]. The World Trade Organization (WTO), through its SPS, TBT and TRIPS agreements, provides a framework to prevent trade barriers and ensures that national regulations are based on scientific principles. The conflict between the principle of environmental precaution in the Cartagena Protocol and the requirements of evidence-based free trade in the WTO forms the main backdrop of regulatory tensions. On the other hand, the WTO faces new regulatory tensions regarding gene-edited products [21-22-23].

According to previous research, the national legal and regulatory frameworks for GMOs in selected countries reveal a diverse range of approaches and fundamental divergence. Underlying this divergence are two different models of biotechnology regulation These two philosophies are: The process-based approach focuses on the process of production and genetic engineering of organisms and is based on the precautionary principle. This view is led by the European Union [24-25], and the product-based view, which criters the final characteristics of the product and relies on the principle of substantial equivalence, is dominant in the United States and Canada [26-27].

In the United States, with a product-based approach, the three primary agencies with responsibilities for regulation of biotechnology products are the U.S. Environmental Protection Agency (EPA), U.S. Food and Drug Administration (FDA), and U.S. Department of Agriculture (USDA), and regulated crops such as corn, soybeans, cotton, sugar beets, and canola [28]. Mandatory labeling is enforced through the National Bioengineering Food Disclosure Standard (NBFDS). The legal framework includes the assessment of the safety of the final product and environmental risk, and gene editing products are largely outside the GMO framework. Canada, China, Japan, India, the European Union, Brazil, Russia, and Iran also each have their own national frameworks with specific approaches, different labeling requirements, and diverse cultivation levels, which collectively represent the challenges of international coordination and operational complexities [31, 32, 33, 34, 35, 36, 37, 38, 39, 40].

In 2024, about 209.8 million hectares of genetically modified (GM) crops were cultivated in worldwide. The United States had the largest area of genetically modified crops worldwide, at 75.4 million hectares, Brazil with 67.9 million hectares, and Argentina with 23.8 million hectares in second and third place. In terms of acreage [worldwide], the most commonly genetically modified crops are soybeans, corn, cotton, and canola.[41]

Numerous research and studies have shown that foods derived from bioengineered (GE) products that are currently commercially available are safe

and do not differ significantly from non-GM products, despite the scientific convergence on safety, the importance of data transparency, post-market monitoring, and evaluation of each product on a case-by-case basis is emphasized and recommended [42]. For example, Nicolia et al. (2014) in a ten-year review of scientific papers found no significant evidence of direct negative effects on human health, emphasizing the importance of long-term monitoring studies [43]. As reported by the U.S. National Academies of Sciences, Engineering, and Medicine (NASEM) in 2016, "There is no documented evidence of a difference in human health risks between current commercialized GE products and conventionally modified products. This is based on a meta-analysis of more than 3,000 studies involving decades of research, including long-term nutrition studies on zinc. Combined analyses and epidemiological data from populations that have used these products extensively [9].

A report by the Pew Research Center found that while 88% of scientists from the American Association for the Advancement of Science (AAAS) believed GM foods were safe, only 37% of the general public agreed. This 51% gap underscores profound challenges in scientific communication and public trust [44]. The center's report also found in 2020 that many people around the world are skeptical about the safety of genetically modified foods, based on a survey of 20 countries surveyed On average, 48% of people believe GM foods are unsafe to eat. Only 13% of people consider them safe. In countries such as Russia (70%), Italy (62%), and India (58%), the majority of people consider GM food to be unsafe. In the U.S.: Only 27% of Americans in the survey said GM foods are safe to eat. Thirty-eight percent said they were unsafe. 33% were unsure [45].

It is worth mentioning that with the rapid technological and scientific advances in biotechnology, especially new gene editing technologies such as CRISPR/Cas, since these technologies do not necessarily insert foreign DNA into the genome, it has led to new regulatory and policy challenges. Many countries disagree on whether products derived from them should be subject to strict GMO regulations. This "regulatory gap" has fueled uncertainty in international trade and investment in innovation. On the other hand, issues such as labeling and public acceptance and the management of unwanted transboundary pollution continues to be a major controversy globally [46].

The international and national legal and regulatory frameworks for GMOs are an attempt to strike a balance between important areas such as scientific innovation, food security, public health, environmental protection, and, of course, international trade. The main challenge in regulating GMOs is, on the one hand, exploiting the potential benefits of biotechnology such as increasing agricultural productivity, improving nutritional value, and reducing pesticide consumption, and managing long-term safety concerns (allergenization, toxicity, gene transfer), environmental impacts, and corporate dominance of the food chain on the other hand.

The aim of this study was to identify and comparatively analyze the efficiency and effectiveness of regulatory frameworks for transgenic crops It is carried out in ensuring safety and transparency, and assessing the compliance of these regulations with international standards and institutions. The fundamental principle in this regard is adherence to the slogan "Food safety is non-negotiable" and responsibility for any contamination in the supply chain is also strongly considered. This research seeks to answer questions such as: what are the similarities and differences between GMOs biosafety policies and regulations in selected countries, how effective have existing regulatory frameworks been in

ensuring food safety and responding to public concerns, and combining up-to-date original and supplementary data (by 2024) The first comprehensive review of the current status of GMOs regulations in nine major countries (USA, Canada, EU, etc.) Brazil, China, Japan, India, Iran, Russia) offers. Key innovations of this research include: a comprehensive comparative analysis containing a systematic review of the differences and similarities of regulatory frameworks at the global level, the exploitation of new technologies such as artificial intelligence to strengthen safety measures, and the effectiveness assessment of the development of new criteria to measure the effectiveness of regulatory systems in ensuring transparency and safety.

This study also analyzes the situation of Iran along with selected countries, and provides practical policy suggestions to improve the national regulatory framework and align it with optimal international experiences. Webster provides further convergence of biotechnology safety laws, strengthening sustainability measures, and providing policy proposals to improve regulatory systems in Iran and other countries.

2-Research Materials and Methods

2-1-Research Design

The aim of this study was to compare and analyze and evaluate the effectiveness of regulatory frameworks related to genetically engineered foods (GMOs) in selected countries (United States, Canada, European Union, Iran, China, India, Japan, Brazil, and Russia) using mixed-methods research method with an explanatory sequential design approach. [48] .Based on the document analysis, each country was considered separately and the legal texts and their regulatory framework were analyzed in depth, which provided the possibility of a deep understanding of qualitative analysis of the regulatory systems and then compare, rank and quantitatively evaluate them through an index-based matrix. [49-50-51].

2.2- Data collection from primary and secondary sources

This research includes the collection and detailed review of a wide range of documents in order to clarify the existing contexts, frameworks and monitoring mechanisms in the selected countries. Data were collected by library and documentary methods, a combination of valid primary and secondary sources. Primary Sources include national laws, executive regulations, regulations, and official guidelines published by the regulatory bodies of each country such as the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the U.S. Department of Agriculture (USDA). Secondary sources also include a range of international documents to specialized databases, including the full text of the Cartagena Protocol and the guidance documents of global organizations such as the WHO, FAO and the Codex Alimentarius Commission, as well as the ISAAA database and the FAO Biosafety Platform. In addition, technical and government reports such as USDA FAS analytical reports and related economic reports such as PG Economics, And scientific research articles published in reputable international journals (peer-reviewed journals) that analyzed policymaking, risk assessment, and public opinions in the target countries, and analyses published by reputable NGOs (both for and against), such as the Pew Research Center (also simply known as Pew), were used to obtain data-based analysis perspectives and information.

2.3- Establishing a country profile to identify the main and operational indicators

In this study, first, a detailed plan and conceptual map were created to be compatible with the criteria of comparative research and evidence-based policy-making, we created a "country profile" for each of the nine countries. Therefor to create a standard and comparable comparative analytical basis, the main research tool is the index-based evaluation matrix, nineteen key indicators related to food safety regulations of bioengineering GMOs were identified and defined operationally, these indicators cover various aspects of a regulatory system from the legal structure to its practical consequences and formed the basis for subsequent scoring and analysis. The 19 indicators of analysis are:

Legal Framework - Monitoring & Enforcement System - Role & Responsibility of Regulatory Bodies - Regulatory Stringency - Product Approval Process - Transparency & Public Participation - Innovation & Market - Risk Assessment Method - Licensing Process - Containment Process – Cartagena Protocol Membership - Labeling Requirements - Economic Benefits & Impacts - Stakeholder Views - Approved GMO Events - Consumer Acceptance Percentage - Safety Concerns - Cultivation Area - Post-Market Monitoring.

2.4- Implementation of index-based matrix (qualitative and quantitative scoring) and determination of purposeful sampling and valgostatistical method and analysis Based on these indicators, a Quantitative Comparative

Implementation of the index-based matrix (qualitative and quantitative scoring) and determining purposeful sampling and the method of valgostatistical and analysis

Based on these indicators, a Quantitative Comparative Assessment Matrix Designed which countries were placed in columns and indicators in rows, this matrix was completed in the qualitative phase with descriptive data and in the quantitative phase with numerical data, providing the possibility of structural comparison. In it, each index was assigned a numerical score from 1 to 5, For example, the risk assessment index of the scoring scale from 1 to 5 is very clear and scientific; the indicators cover different dimensions of the effectiveness of regulatory systems and have a specific criterion and scoring scale. For each country, based on the collected data, each of the sub-indicators was assigned a specific score. Then, descriptive statistical methods (such as calculating the weighted mean for each major indicator) and multi-criteria decision-making techniques, especially the Analytic Hierarchy Process (AHP), were used to assign each country a final score in the field of "regulatory effectiveness"

The selection of the studied countries (United States, Canada, European Union, Brazil, China, Japan, India, Iran and Russia) based on the following indicators (Table 1) to represent a wide range of regulatory approaches and their position in the global production and trade in the field of bioengineering products (GMOs) provides a comprehensive and multifaceted analysis of the global landscape.

Table 1- Criteria for Selecting the Countries under study with Legal and Regulatory approach in the Field of GM Products

categorization	Countries	Key Features
Role in Production, Export & Import	United States, Canada, Brazil (Major Producers) and European Union, Japan (Main Importers)	Largest producers and exporters of GMOs, over 85% of global crops; science-based regulatory systems and trade facilitation; focus on final product assessment.
Diversity in Regulatory & supervisory Approaches	Countries representing different approaches	Product-based (Canada), coordinated inter-agency structure (USA), precautionary/strong regulatory (EU, Japan), developmental/rapid adoption (Brazil), in transition/extensive with state control (China, India), limited or banned (Russia), and a case with a national biosafety law but imbalanced implementation (Iran).
Emerging Powers & Large Markets	China, India	Huge population and high need for food security; heavy investment in agricultural biotechnology; evolving regulatory systems balancing food self-sufficiency, environmental protection, and public concerns.
Unique & Strategic Approaches	Emerging economies (e.g., Brazil, India, China); Strategic considerations (Japan, Russia, Iran)	Japan: Dual approach; strict on traditional GMOs but open to gene editing. Russia: Complete ban on GMO cultivation motivated by national security and support for domestic production. Iran: Legal framework based on the Cartagena Protocol; accompanied by implementation challenges and internal debates. In BRICS countries, GMO policy is symbolic of larger national challenges including: food security (China), economic development vs. national sovereignty (India, Brazil), and national identity/geopolitical positioning (Russia)

Source: Research Finding

3- Results and Discussion

In this section, qualitative and quantitative content analysis, international and national perspectives on bioengineered food regulations (GMOs) and its safety and transparency assessment are discussed. The results provide new insights into the legal and regulatory landscape of GMOs. Systems of Regulation and Supervision, Observance of Review Procedures, now become an element of regulation in the research, development, and deployment strategies of GMOs crops by technology developers in the public and private sectors. International agreements and harmonized standards can provide guidance and facilitate regulatory review by national authorities.

3.1- Drawing the Profile Structure of Selected Countries in the Regulation of Bioengineered Food Materials (GMOs)

Table 2 provides an overview and comparison of the key findings of the research and a comparative matrix of bioengineered food regulatory frameworks of GMOs in selected countries, which shows the divergence and convergence of policies and regulatory frameworks and key similarities and differences in how to ensure the safety and transparency of bioengineered food (GMOs) in the study countries of the United States, Canada, Iran, Japan, China, Russia, India, Brazil ,European Union.

Table 2- Comparative Matrix of Bioengineered Food Regulatory Frameworks (GMOs) in Selected Countries

Country	Main regulatory bodies	Main inputs (cultivation or major imports)	Regulatory Approach	Labeling Requirements (Requirement & Threshold)	Legal Framework & Key Technical Process	Cultivation status	Compliance with the Cartagena Protocol	Stance on Gene Editing (e.g., CRISPR)
USA	USDA, EPA, FDA	Corn, Soy, Cotton, Sugar Beet	Product-based	Mandatory (NBFDS), but with many exemptions (5% threshold)	Law: Coordinated Framework (1986). Process: Safety assessment of final product and environmental risk	Widespread	Not a Member	Mostly outside GMO regulatory framework
Canada	Health Canada, CFIA	Canola, Corn, Soy, Sugar Beet	Product-based (Novel Foods	Voluntary, no threshold	Law: Food and Drugs Act. Process: Safety assessment of "novel food"	Widespread	Not a Member	Developing (product-based approach)
China	؛MARA,NBC GAC؛SAMR	Cotton (cultivation), Soy and Corn (imports)	Process-based (cautious); Strategic	Mandatory, no threshold (any detectable presence)	Law: Regulation on Safety Administration of Agricultural GMOs (2001). Process: Multi-stage safety assessment and field trials	Limited (expanding)	Member	Under review (cautious approach)
Japan	FSC, MHLW, MAFF,MOE	Imports: Corn, Soy, Canola	Process-based; Product-based for SDN-1	Mandatory, 5% threshold	Law: Food Sanitation Act, Cartagena Act. Process: Safety assessment of food, feed, and biodiversity impacts	Very limited	Member	Outside GMO regulatory framework
India	GEAC, FSSAI	Cotton (Bt Cotton)	Process-based (very cautious)	Mandatory, 1% threshold	Law: Environment Protection Act (1986), Rules (1989). Process: Environmental and food risk assessment, confined trials	Limited (Cotton only)	Member	Exempt from GMO laws
European Union	European Commission, EFSA کشورهای عضو	Corn (limited cultivation), Imports: Soy	Process-based; Precautionary principle	Mandatory, 0.9% threshold	Law: Directive 2001/18/EC, Regulation (EC) 1829/2003. Process: Centralized scientific risk assessment (by EFSA), traceability, post-market monitoring	Very limited	Member	Under GMO laws

Brazil	CTNBio, CNBS, MAPA, ANVISA, IBAMA	Soy, Corn, Cotton	Hybrid; Science-based for NGTs	Mandatory, 1% threshold	Law: Law No. 11,105/2005. Process: Case-by-case scientific risk assessment	Widespread	Member	Outside GMO regulatory framework
Russia	Rospotrebnadzor, Rosselkhoznadzor	Imports: Soy and Corn (animal feed)	Cautious approach (full ban)	Mandatory, 0.9% threshold	Law: Federal Law 358-FZ (2016). Process: State registration and monitoring of imported products	Banned	Member	Developing regulations
Iran	Ministry of Health, Ministry of Agriculture Jihad, Department of Environment; National Biosafety Council	Imports: Corn, Soy, Rapeseed	Process-based (based on Cartagna Protocol)	Mandatory,	Law: National Biosafety Law (2009). Process: Risk assessment based on application and licensing	No widespread commercial cultivation	Member	No clear legal stance

Source: Research Finding

Based on the findings, three regulatory divergence patterns were identified in this study: 1) The "Product-based" model (United States, Canada, Brazil) focuses on the characteristics of the final product. If a genetically modified product is "Substantially Equivalent" in terms of safety and composition to its non-GMO counterpart, similar regulations are applied [52-53]. 2) The "Process-based" model (European Union) views genetic engineering as a factor requiring strict oversight. This model is based on the "Precautionary Principle," thus requiring all GMO products to undergo risk assessment and obtain approval before entering the market [54-55-56]. 3) The "Policy Duality" model is strategic and restrictive. The main feature of this model is the representation of a policy duality between prohibition and internal restrictions and the import of genetically modified products to meet domestic needs (Russia, and to some extent China, India, Iran, Japan). These countries are closer to the process-based approach and use regulations to achieve strategic goals. Some of these goals include food security and sovereignty (such as Russia's ban on domestic cultivation), domestic technology development (such as China's efforts), trade support, and public opinion management [34-35-36-37-54-57-58-59-60-61-62].

In the world, the emergence of "novel genomic techniques" (NGTs) has brought about significant convergence in the biotechnology regulatory sector, prompted a global revision of the definition of "transgenic," and opened up a new and more complex regulatory landscape. This has led to a global revision of the regulatory definition of biotechnology. Many countries, despite their different stances on traditional GM crops, are developing distinct and often more lenient regulatory paths for gene editing products [63].

3.2- Identifying the main and conceptual regulatory pattern of transgenic crops (GMOs) in selected countries based on the scope of concentration of regulatory responsibility

In this study, the selected countries can be considered in the field of regulating the powers of the regulatory bodies of transgenic crops (GMOs) in two areas: 1) concentrating the competencies in a single

and strong body, or 2) coordination between several existing organizations, thus overseeing the main issues including: public safety and environmental protection: ensuring that there is no harm to human health and the environment, transparency and traceability: Establishing Appropriate Labeling and Tracking Systems - Scientific Evaluation: Using the Highest Scientific Standards in Evaluation - International Coordination: In compliance with the Cartagena Protocol and other international treaties, five main regulatory patterns of transgenic crops (GMOs) were identified.:

1.The De-centralized/Coordinated Model (USA) clearly refers to three agencies: the Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).

2. Centralized Super-Agency Model: India, Brazil This model centralizes the final authority to evaluate and make decisions in one or more hierarchical institutions with full authority. In Brazil, CTNBio is an independent scientific-technical body whose decisions are binding on the government and plays a pivotal role in the approval of products. India's GEAC (Genetic Engineering Evaluation Committee) is the highest decision-making authority. In a six-stage structure of RCGM, RDAC, GEAC at the national level, IBSC, SBCC, DLC at the local level.

3.Supra-national/National Hybrid Model: The European Union (EU) developed and highlighted a hybrid model through interaction between the European Food Safety Authority (EFSA) which conducts scientific risk assessments and the European Commission, along with Member States responsible for risk management and final licensing decisions.

4. Ministry-Based Models: China, Japan, Russia, Iran China: Ministry of Agriculture and Rural Affairs (MARA) and National Agricultural Biosafety Committee (NBC) play a pivotal role in overseeing all assessments Japan: Cooperation is taking place between the Ministry of Health, Labor and Welfare (MHLW), the Ministry of Agriculture, Forestry and Fisheries (MAFF), and the Ministry of Environment (MOE) to manage the two-stage approval process. Russia: Registration responsibilities among several federal services, including the Rospotrebnadzor Food/Agriculture Ministry, and the Ministry of Health. Iran: Responsibilities are shared between the Ministry of Agricultural Jihad, the Ministry of Health and Medical Education, and the Environmental Protection Agency and is coordinated by the National Biosafety Committee at a high level.

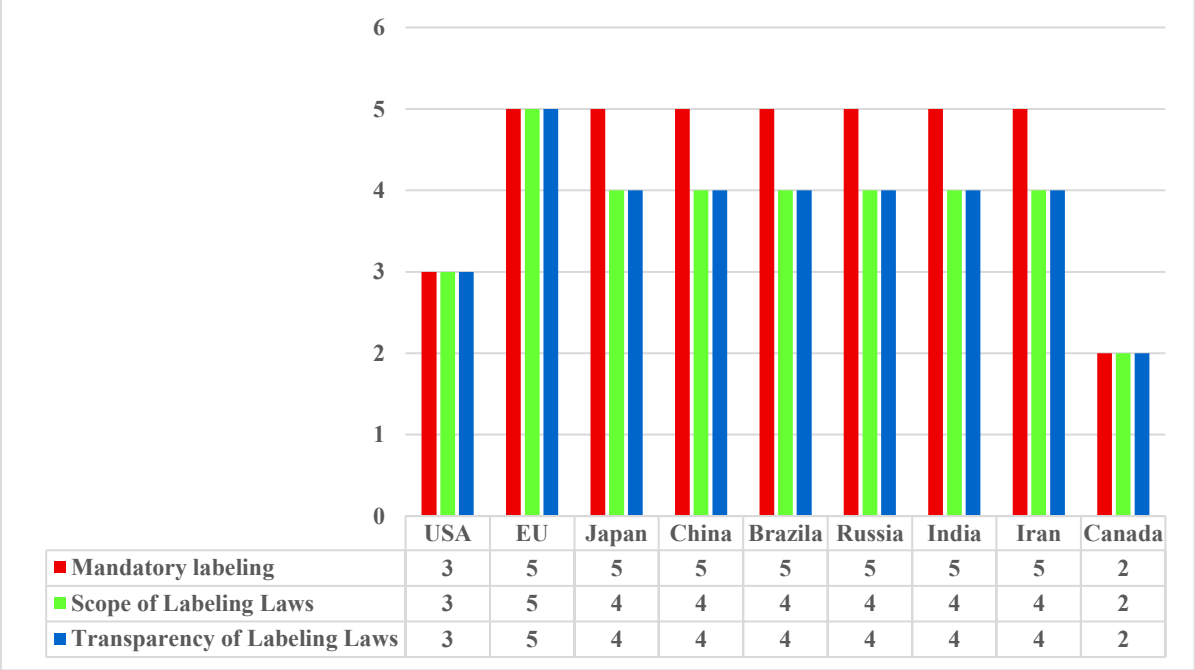
5. Two-Agency Model: Canada Responsibilities are shared jointly between Health Canada, the new food safety officer, and the Canadian Food Inspection Agency (CFIA). These entities are responsible for evaluating new plant traits, ensuring feed safety, and monitoring labeling implementation.

3.3. Evaluation of the effectiveness of transparency in the management of public trust in GMO crops in the study countries

According to the criteria of Table 2, transparency is essential as a tool to manage public trust and political risk, especially through clear and effective labeling, to build consumer trust and empower individuals to make informed decisions in accordance with their values. Mandatory labeling requirements (requirements and thresholds) for transgenic foods exist in the European Union, China, India, Brazil, Russia, Iran and Japan, while in Canada

labeling is voluntary. This shows the importance of the consumer's right to be informed. In the past, the United States had a voluntary approach. With its implementation, the National Bioengineered Food Disclosure Standard (NBFDS) (as of 2022) introduced a mandatory disclosure requirement for "bioengineered" food. The threshold determines what percentage of GMO content in a product requires mandatory labeling.The strictest: EU and Russia (0.9%), India (1%), and Brazil1%Iran: Unspecified threshold;United States and Japan (5%).China, has the toughest approach. (Any discernible presence) has practically no threshold. . However, in the latest draft, they proposed a threshold of 3%, which represents a potentially major policy shift towards coordination with other countries. Overall, the European Union has the most stringent and Canada has the leniest requirements for labeling GM crops (according to Chart 1) among selected countries. This diversity reflects various economic, political, and social factors influencing each country's approach to this technology.

Notably, the emergence of new gene-editing techniques, countries' different approaches to technologies such as CRISPR (NGTs/SDNs) has created a new policy challenge regarding labeling given their regulatory philosophy.



	USA	EU	Japan	China	Brazila	Russia	India	Iran	Canada
Mandatory labeling	3	5	5	5	5	5	5	5	2
Scope of Labeling Laws	3	5	4	4	4	4	4	4	2
Transparency of Labeling Laws	3	5	4	4	4	4	4	4	2

Source: Research Finding

Fig 1-Chart of GMO Labeling Requirements in Selected Countries

3.4. Drawing up the international regulation of bioengineered food GMO/LMO and aligning 9 selected countries with international standards.

Table 3 of the implementation matrix of the International Food Frameworks for GMO/LMO Bioengineering in the nine selected countries shows that most countries have tried to bring domestic mechanisms in line with the Cartagena Protocol on Biosafety and the Codex Alimentarius Guidelines for Food Safety, but the interpretation and level of rigor vary.

Table 3 - Implementation Matrix of International Food Frameworks for Bioengineering GMO/LMO in 9 Selected Countries

Country	National Laws and Specialized institutions	Key Technical Processes	Implemented International Frameworks
USA	Coordinated Framework for Regulation of Biotechnology (1986) - Plant Protection Act ،FD&C Act ،TSCA نهادها: USDA-APHIS ،FDA-CFSAN/OVR ،EPA	FDA licensing APHIS for field testing and environmental release - Voluntary Bioengineered (BE) Disclosure Rule	Cartagena Protocol Codex Alimentarius WTO SPS/TBT
Canada	Novel Foods Regulations (1999)- CFIA ،Health Canada نهاد ها	- Pre-market safety assessment - CFIA authorization for cultivation and import - Voluntary labeling and mandatory for allergens	Cartagena Protocol Codex Alimentarius WTO SPS/TBT
European Union	Directive 2001/18/EC - Regulation (EC) No 1829/2003 & 1830/2003 **Bodies:** EFSA, DG SANTE, National Authorities	- Step-wise risk assessment - Supply chain traceability and labeling from 0.9% GMO - Frequent inspection of imported shipments	Cartagena Protocol Nagoya Protocol Codex Alimentarius WTO SPS/TBT
Brazil	Biosafety Law No 11.105/2005 - Decree 4680/2003 **Bodies:** CTNBio, MAPA, ANVISA	- CTNBio risk assessment for release and commercial cultivation - OECD-based feeding and environmental studies - MAPA labeling from 1% GMO	Cartagena Protocol Codex Alimentarius WTO SPS/TBT
Iran	National Biosafety Law (approved 2009) **Bodies:** National Biosafety Council, Ministry of Jihad-e-Agriculture, Ministry of Health	- National Council technical permit for lab and field - Step-wise risk assessment guidelines - Drafting labeling regulations	Cartagena Protocol Codex Alimentarius WTO SPS/TBT
India	Rules 1989 on Hazardous Organisms & GMO - FSSAI Regulations (2018) نهادها: GEAC (MoEFCC) ،FSSAI	- GEAC approval for testing and cultivation - FSSAI food safety assessment - Mandatory labeling above 5% GMO	Cartagena Protocol Codex Alimentarius WTO SPS/TBT
China	Regulations on Safety Administration of Agricultural GMOs (2001/2002) **Bodies:** MOA, AQSIQ (Import control)	- MOA agricultural safety certificate issuance - Field tests according to national standard - Mandatory labeling above 5% GMO	Cartagena Protocol Codex Alimentarius WTO SPS/TBT
Japan	Cartagena Act (2003) - Food Safety Basic Act (2003) **Bodies:** MAFF, MHLW, NITE	- NITE environmental risk assessment - MAFF/MHLW approval for cultivation and import - Voluntary food labeling	Cartagena Protocol Codex Alimentarius WTO SPS/TBT
Russia	Federal Law No 86-FZ on GMOs (1996) & subsequent amendments **Bodies:** Rosselkhoznadzor, Rospotrebnadzor	- State registration of GMOs before production - Permit for environmental testing and periodic monitoring - Mandatory labeling of all GMOs	Cartagena Protocol Codex Alimentarius WTO SPS/TBT

Source: Research Finding

The Cartagena Biosafety Protocol, adopted by 173 countries until 2024, reflects a broad international commitment to ensure the safe use of GMOs. Its provisions, emphasizing the principle of precaution and mechanisms such as the Prior Informed Agreement (AIA) for cross-border movement, and key aspects including the establishment of a Biosafety Clearing Centre (BCH); regulations on movement, transportation, packaging and identification; risk assessment and management; supporting capacity building; awareness and public

participation serve as a global "standardizer" for biosafety regulations;

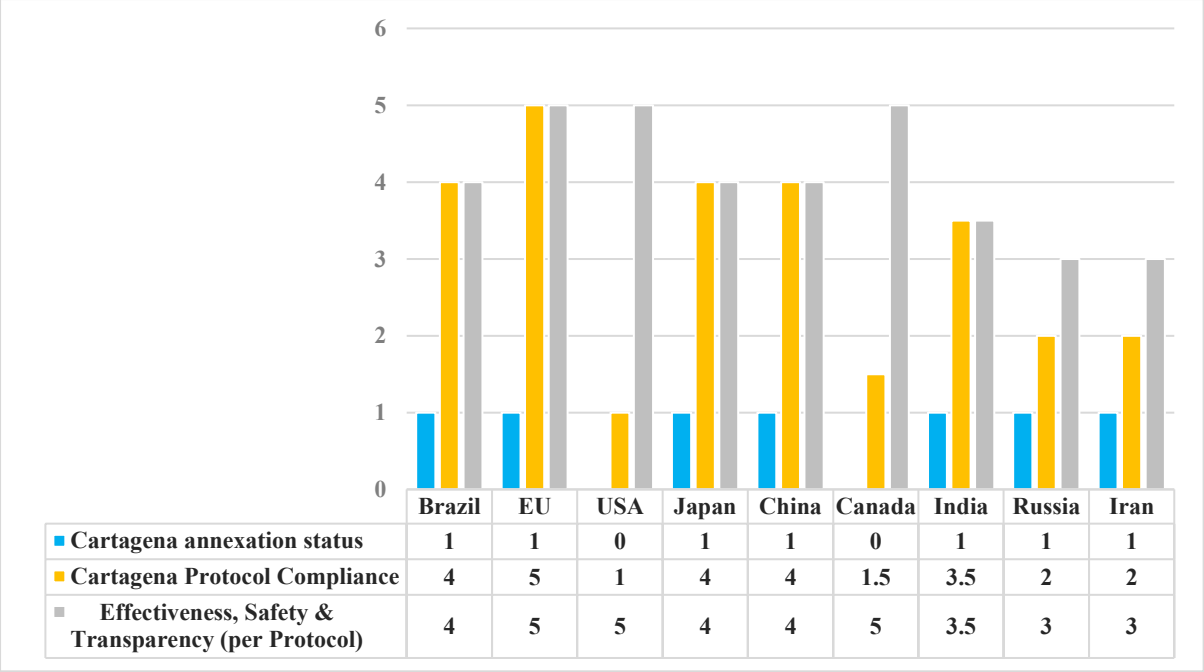
Among the countries studied, the European Union, Brazil, China, India, Iran, Japan, and Russia are all members of the protocol. In contrast, the United States and Canada, as the two largest producers and exporters of genetically modified products, retained more flexibility in their systems by not adhering to the protocol. In the chart (2), the status of accession to the Cartagena Protocol (blue column) in the graph of the majority of accedation with (value 1) and the non-acceding countries (value 0) shows that this is a strategic choice, not a monitoring. This gap in membership has created two parallel governance systems:

One for protocol members and the other for major non-member exporters, leading to constant friction in international forums and trade. The criterion of alignment with protocol values (indicated by the orange column) indicates the extent to which national laws and regulations comply with the requirements and standards of the Cartagena Protocol. Highest alignment (5): The European Union shows the highest level of alignment (5), indicating full and strict compliance with the provisions of the Protocol. High alignment (4): Brazil, Japan, and China have a high alignment with protocol values. Moderate upward alignment: India (3.5) performs well in this regard.Moderate downward alignment: Russia and Iran have a moderate downward alignment with a score of 2. Low alignment: The U.S. (1) shows the lowest alignment, which is consistent with the country's lack of formal accession to the Protocol. Canada is also in a low alignment with 1.5.

The Effectiveness Measure on Safety and Transparency (indicated by the grey column) which shows the effectiveness of national frameworks for assessing safety and ensuring transparency on GM crops based on the principles of the Protocol. Highest Effectiveness (5): The European Union, the United States, and Canada have the highest score (5) in this area. This shows that although the United States and Canada have not acceded to the Protocol, they do have strong and effective national systems for assessing the safety and transparency of GM crops. High effectiveness (4): Brazil, Japan, and China have high effectiveness (4) in their safety and transparency systems. Moderate to high effectiveness: India and Russia show relatively good effectiveness with a score of 3.5. Moderate effectiveness (3): Iran is at a moderate level with a score of 3.

The chart clearly shows that formal accession to the protocol (indicated by the blue column) does not necessarily mean the highest level of alignment (indicated by the orange column) or effectiveness (indicated by the gray column). For example, the U.S. and Canada have the highest levels of effectiveness (5) in assessing safety and transparency, despite not being annexed.

The EU ranks highest on all three criteria (accession, alignment and effectiveness), reflecting a comprehensive and rigorous approach to biosafety. Iran has acceded to the Protocol, but the level of alignment with the Protocol's values and the effectiveness of its safety and transparency estimation is lower than that of leading countries and needs to be strengthened. China and Japan are in a balanced position, ranking high or very well on all three criteria.



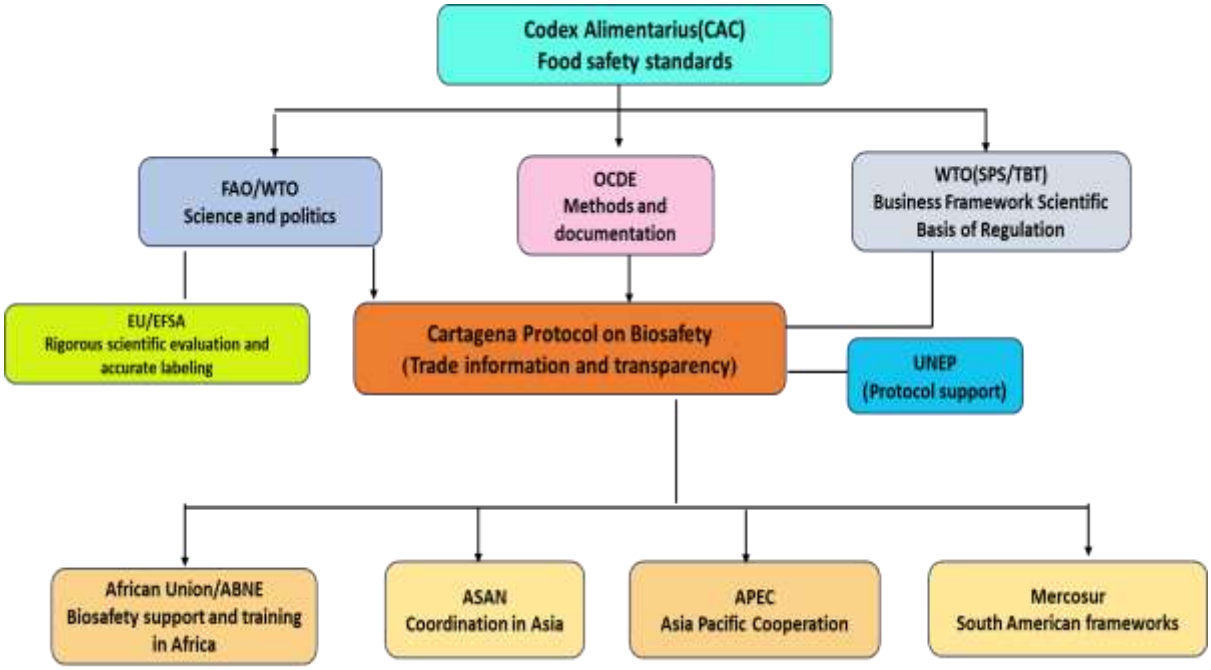
	Brazil	EU	USA	Japan	China	Canada	India	Russia	Iran
Cartagena annexation status	1	1	0	1	1	0	1	1	1
Cartagena Protocol Compliance	4	5	1	4	4	1.5	3.5	2	2
Effectiveness, Safety & Transparency (per Protocol)	4	5	5	4	4	5	3.5	3	3

Source: Research Finding

Fig 2- Chart of the status of accession and alignment of selected countries with the Cartagena Protocol on Biosafety and Effectiveness on the Safety and Transparency of these Products

Acceptance of the guidelines and guidelines of the Codex Alimentarius Commission, which establishes international food safety standards for the evaluation of transgenic foods, is one of the important criteria for international scientific regulation and coordination. The European Union, Japan, India, and Iran have specifically invoked and used these principles. This makes Codex a globally recognized standard for assessing risks. However, regarding mandatory labeling, they have not yet reached a global consensus, and this issue is left to the decision of each country. The lack of a unified global standard is one of the main reasons for regulatory divergence globally. The World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) provide basic frameworks and definitions for assessing food safety. These organizations emphasize that transgenic foods that enter the global market have passed the necessary safety assessments and are unlikely to be dangerous to human health. They also emphasize the importance of a case-by-case assessment approach.

In Figure 1, a flowchart related to international institutions and organizations that are active in the field of standardization and safety monitoring of GM crops is displayed. This chart depicts the global regulatory landscape for food safety and transboundary movement of LMO organisms and shows that Codex Elementarius sets general food safety standards. While the Cartagena Protocol on Biosafety manages specific aspects of transgenic organisms with the support of organizations such as UNEP and regional coordination/implementation by various bodies such as the EU/EFSA, African Union, ASEAN, APEC and Mercosur. And the World Trade Organization (WTO) provides a trade regulatory framework for agreements under the supervision of SPS and TBT.



Source: Research Finding

Fig 3- Flowchart of international institutions and organizations in the field of standardization and monitoring of GMO safety

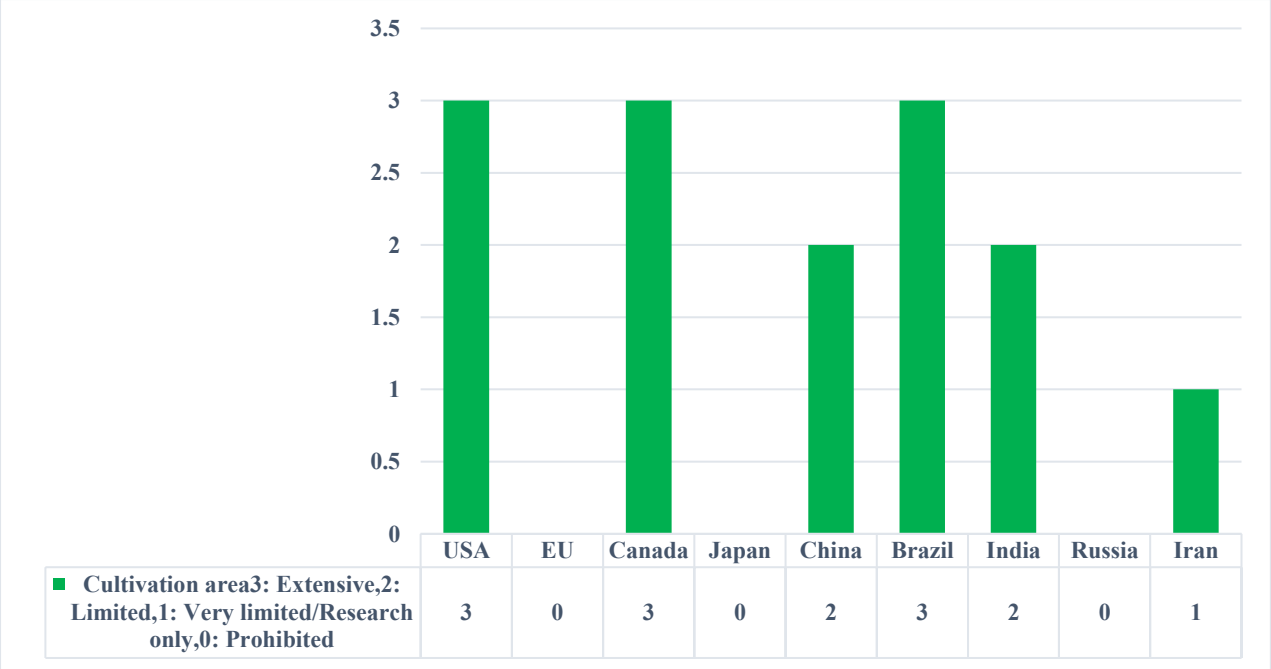
The findings of the comparative matrix table show that regulatory frameworks for bioengineered (transgenic) foods in selected countries, especially in relation to New Genomic Techniques (NGTs) such as CRISPR, have created new challenges for regulatory regulation. Outside of the U.S., Japan, and Brazil, gene editing has fallen out of strict frameworks, because this technology usually does not import foreign genetic material, and the result is similar to natural mutations**.**

In the European Union, a strict stance is taken and gene editing is subject to GMO rules, except in special cases. China, Canada, and Russia are still reviewing and formulating their approaches in this regard.

3.5. Analysis and ranking of GMO crop cultivation status in 9 selected countries

The status of GM crop cultivation in the studied countries according to the findings of Table 2 and Fig 4 is divided into four groups:

Extensive: The United States, Canada, and Brazil have extensive commercial cultivation (USA: 75.4 million hectares (35.9% global share); Brazil: 67.9 million hectares (32.4% global share); Canada: 11.7 million hectares (5.6% global share). Prohibited: The European Union, Japan, and Russia have very limited cultivation or have virtually banned it. Limited: China has commercial cotton cultivation and is expanding; India only cultivates Bt cotton (11.2 million hectares (5.3% global share).Very limited cultivation: Iran has only limited research on the cultivation of GM crops.The EU's restrictive environment has hindered commercial production and research. Russia's complete ban completely eliminates the domestic cultivation market. India's complex process has created a significant bottleneck, with only one GM product commercialized in more than two decades. Globally, the most important GM crops include: soybean: 105.1 million hectares (nearly half of the total), corn: 68.4 million hectares, cotton: 24.8 million hectares, rapeseed: 10.4 million hectares



Source: Research Finding

Fig4- Comparison of cultivation status GMO in selected countries

3.6. Weighting and ranking of selected countries in the field of GMO crops (using 6 main indicators and 19 sub-criteria) and Analytic Hierarchy Process (AHP)

In this research, to rank the selected countries (USA, Canada, European Union, Brazil, China, Japan, India, Russia and Iran) With the aim of ranking the effectiveness of GM crop laws in ensuring safety and transparency (using 6 main indicators and 19 sub-criteria). Analytic Hierarchy Process (AHP) is a multi-criteria decision-making technique used to rank options based on different criteria. were used. The advantages of this method are: Scientific weighting based on the actual importance of the criteria; logical consistency: CR < 0.1 guarantees; complete transparency of all traceable steps; flexibility of changing weights for different scenarios. The methodological core of this research is a scoring and weighting matrix designed to convert qualitative and quantitative evaluations into a composite index.

The comprehensive analysis and evaluation of regulatory frameworks was designed based on 6 main criteria and 19 sub-criteria. These indicators cover various aspects of a regulatory system, from its legal structure to its practical implications.

1. Legal & Institutional Framework (16.1%)
Sub-criterion: legal framework; role and responsibility of regulatory bodies; membership of the Cartajena Protocol
2. Safety & Risk Management (25.9%)
Sub-criterion: risk assessment method; safety concerns; confinement process; Supervision after entering the market
3. Approval & Licensing Process (30.7%)
Sub-criterion: product approval process; license process; The level of regulatory strictness
4. Transparency & Participation (10.5%)
Transparency & Participation
Sub-criterion: Transparency and public participation; Labeling requirements; Stakeholder perspectives
5. Market & Implementation (10.5%)
Sub-criterion: Innovation and market; Confirmed GMO events; Area under cultivation; Economic benefits and impacts
6. Consumer & Social Factors (6.2%)

Sub-criterion: Consumer acceptance rate; Monitoring and enforcement system

Creating a pairwise comparison matrix:(Saaty scale)

1 = Same, 3 = Moderate importance, 5 = Strong importance, 7 = Very strong importance, 9 = Extraordinary importance

Table 4 - Matrix 6×6 for the main criteria

Criterion	legal	safety	confirmation	transparency	market	consumer
legal	1.000	0.500	0.333	0/2	0/2	0/3
safety	2.000	1.000	0.500	0/3	0/3	0/4
confirmation	3.000	2.00	1.000	0/2	0/2	0/3
transparency	0.500	0.333	. 0.500	0/1	0/1	0/2
market	0.500	0.333	0.500	0/1	0/1	0/2
consumer	0.333	0.025	0.333	0/5	0/5	0/1

Source: Research Finding

Calculated weights:

Legal and Institutional Framework 0.1626 (16.1%); Safety and Risk Management 0.2592 (25.9%); Approval and Licensing Process 0.2998 (30.7%); Transparency and Participation 0.1076 (10.5%); Market and Implementation 0.1076 (10.5%); Social and Consumer Factors 0.0632 (6.2%); Total Weights 1.000000

Compatibility Ratio Calculation:

Calculating λ max:

A × w = [1.0121, 1.6326, 1.9261, 0.6592, 0.6592, 0.3897] λ max = Average (Aw/w) = 6.2279

Consistency Index (CI)

CI = (λmax - n)/ (n - 1) = (6.2279 - 6)/ (6 - 1) = 0.0456

Consistency Ratio (CR)

RI = 1.25 برای) n=6(

CR = CI/RI = 0.0456/1.25 = 0.0365

Result CR = 0.0365 < 0.1 Acceptable Compatibility

The consistency ratio shows the level of structural validity of these comparisons, and its low (less than 0.1) indicates high validity.

Calculating the weights of the sub criteria

Equal distribution method in each category, top sub-criteria: product approval process: 0.0999 (99.9%), licensing process: 0.0999 (99.9%), regulatory strictness: 0.0999 (99.9%), risk assessment method: 0.0648 (48.6%)

Countries Scoring Matrix Scoring Scale (1-5)

5 = Excellent 4 = Good 3 = Medium 2 = Poor 1= Very Poor 0= No Membership

Scoring Example:

EU: Highest scores on safety and approval 5.5; US: strong in the market and innovation 5.5; Iran: weaker on most metrics (average 2.5)

Table5- Index-Based Evaluation Matrix of Selected Countries

Country/ Index	America	Canada	European Union	Iran	China	India	Japan	Brazil	Russia
Legal Framework	4	4	5	3	4	3	4	4	3
Monitoring & Enforcement System	4	4	5	3	4	3	4	4	3
Role & Responsibility of Regulatory Bodies	5	4	5	3	4	3	4	4	3
Regulatory Stringency	3	3	5	4	4	4	4	3	4
Product Approval Process	4	4	5	3	4	3	4	4	3
Transparency & Public Participation	3	3	4	2	2	2	3	3	2
Innovation & Market	5	4	2	2	4	3	3	4	2
Risk Assessment Method	4	4	5	3	4	3	4	4	3
Licensing Process	4	4	5	3	4	3	4	4	3
Containment Process	3	3	4	3	4	3	3	3	3
Cartagena Protocol Membership	0	0	1	1	1	1	1	1	1
Labeling Requirements	2	2	5	4	5	3	5	5	4
Economic Benefits & Impacts	5	4	2	2	4	3	3	4	2
Stakeholder Views	3	3	2	2	2	3	3	3	2
Approved GMO Events	5	4	2	1	3	2	2	4	2
Consumer Acceptance Percentage	3	3	2	2	2	3	2	3	2
Safety Concerns	3	3	5	4	3	4	4	3	4
Cultivation Area	5	4	1	1	4	2	1	4	1
Post-Market Monitoring	3	3	5	2	3	2	3	3	3

Source: Research Finding

Table 6 - Results of Analytic Hierarchy Process (AHP) for Evaluation of Key Indicators of Selected Countries

Country/Main Index	Legal and institutional framework	Safety and risk management	Approval and licensing process	Transparency and participation	Market and implementation	Social and consumer factors
America	0/60	0/65	3/73	3/53	0/100	0/70
Canada	0/60	0/65	3/73	3/53	0/80	0/70
European Union	3/73	0/95	0/100	3/73	0/35	0/70
Iran	7/46	0/60	7/66	3/53	0/30	0/35
China	0/60	0/70	0/80	0/60	0/75	0/60

India	7/46	0/60	7/66	3/53	0/50	0/60
Japan	0/60	0/70	0/80	3/73	0/45	0/60
Brazil	0/60	0/65	3/73	3/73	0/80	0/70
Russia	7/46	0/65	7/66	3/53	0/40	0/50

Source: Research Finding

Calculating Weighted Points; Final Formula:

Final score = (benchmark score × benchmark weight) Σ

Example calculation for the European Union:

Legal framework: 5 × 0.0542 = 0.2711;
Safety and risk: 5 × 0.0648 = 0.3240;
Verification process: 5 × 0.0999 = 0.4995;
Total: 4.0214

The results of the AHP analysis show

Table 7- Ranking of Selected Countries in the Field of GM Products (Using 6 Main Indicators and 19 Sub-Criteria) Using AHP Method

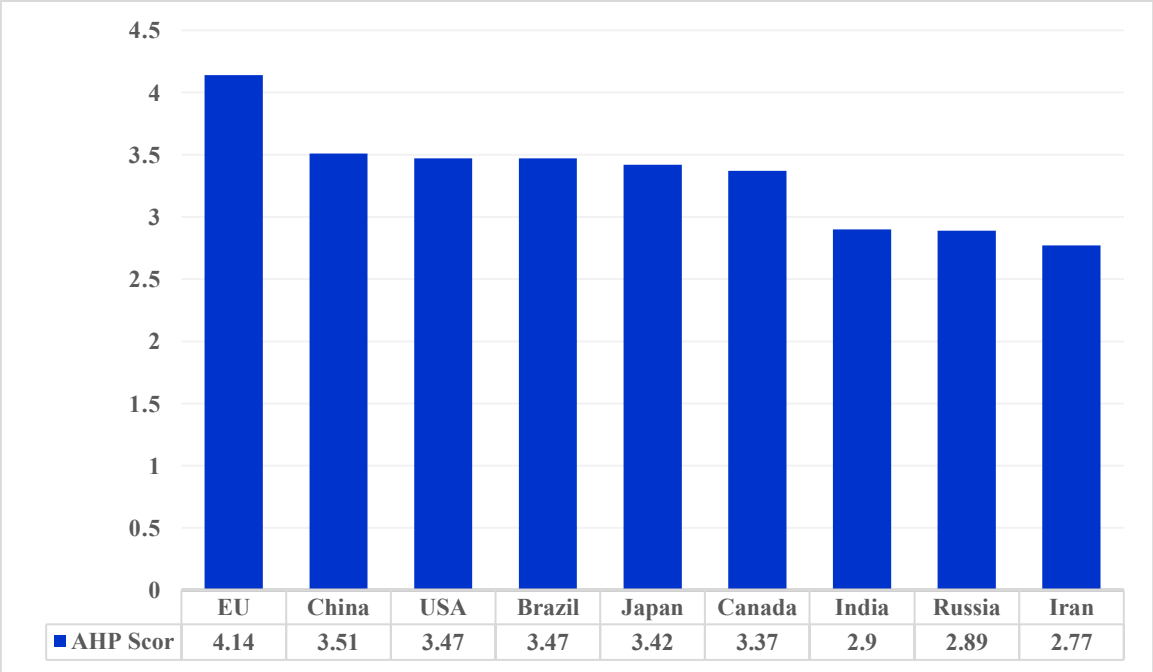
Country/index	AHP score	percentage	rank
European Union	4/14133	**82/82%**	1
China	3/51224	70/24%	2
America	3/47241	69/44%	3
Brazil	3/47241	69/44%	4
Japan	3/43474	68/49%	5
Canada	3/36741	67/34%	6
India	2/9045	58/08%	7
Russia	2/88575	57/71%	8
Iran	2/7685	55/37%	9

Source: Research Finding

Table 7 and Figure 4 show the weighting and ranking of selected countries in the field of GM crops using 6 main indicators and 9 sub-criteria and using the scientific and multiple hierarchical method of AHP. The final score of each country indicates the combined weight of that country in the set of defined indicators, and the higher score indicates the higher rank of that country. The European Union has obtained the highest ranking with a score of 4.14, which indicates the strength, quality, and high performance of the indicators examined. China, the United States, Brazil, Japan, and Canada all rank in a mid-range near score between 3.37 and 3.51, indicating that countries are performing relatively well across the overall indicators.

The U.S. and Brazil, the largest producers of GM crops, are in close competition with a score of 3.47 and are in the middle because they are not members of the Cartagena Protocol. India (2.90) and Russia (2.89) are also in the lower ranks, indicating the lack of development of defined

indicators and national policies of these countries. Iran with a score of 2.77 is ranked at the lowest and indicates the need to strengthen indicators and sub-criteria and planning and development in this field of documented GM crops.



Source: Research Finding

Fig5- Ranking Chart of Selected Countries in the Field of Transgenic Products (Using 6 Main Indicators and 19 Sub-Criteria) Using AHP Method

7.3. Evaluation of the Effectiveness of the Regulatory Regulation of GMO Products on Safety and Transparency Requirements Based on Key Indicators

In this research, the effectiveness of regulatory systems on the safety and transparency requirements of GMO products was evaluated and identified based on four main criteria, which are: **Safety and Risk Reduction:** Its indicators include the accuracy and rigor of scientific evaluation, the existence of post-market monitoring programs, and the ability to react to new risks, **Transparency and public trust:** Its indicators include clarity of laws, public access to assessment data, and the practical effectiveness of the labeling system in providing consumers with choice. **Economic Empowerment and Innovation:** Its indicators include product approval rates and times, trade volumes, and internal R&D activities.**Predictability and regulatory efficiency:** Its indicators include the clarity of the legal framework, the consistency of decisions, and the length and complexity of the approval process.

The analysis of the findings of Table 8 of the comparative evaluation matrix of the effectiveness of the regulatory system based on the above four criteria shows the different models of the effectiveness of the regulatory systems in the selected countries.

Table 8 - A Comparative Evaluation Matrix for the Effectiveness of Regulatory Systems Based on 4 Main Criteria in Selected Countries

Country/Criterion	Safety and Risk Mitigation	Transparency and Public Trust	Economic Empowerment and Innovation	Regulatory Predictability and Efficiency
USA	**High:** Robust scientific assessments by three specialized bodies.	**Medium:** Mandatory disclosure exists, but flexible formats (QR codes) reduce immediate on-package visibility	**High:** Efficient process, encourages innovation, and leads in cultivation and development	**High:** Clear framework and relatively fast, predictable processes.
Canada	**High:** Rigorous, science-based safety assessments by Health Canada.	**Medium:** Labeling is voluntary, leaving consumer choice to the market.	**High:** Scientific and efficient process, supporting innovation and agricultural trade.	**High:** Transparent, science-based process with predictable outcomes.
European Union	**Very High:** Extremely strict assessments and post-market monitoring.	**High:** Mandatory labeling, traceability, and public participation aim for trust.	**Low:** Long and political process, limits approvals, and suppresses cultivation.	**Low:** Political impasses and uncertainty make the process unpredictable and inefficient.
China	**High:** Centralized, state control over safety.	**Low:** Processes are opaque, and decisions are often made without public justification.	**High (Strategic):** Facilitates imports for industry and targets domestic R&D.	**Variable:** The process for imports can be unpredictable and influenced by politics.
Brazil	**High:** Rigorous scientific assessments by the specialized body CTNBio.	**Medium:** Labeling laws are evolving, and public debates continue.	**Very High:** Efficient process has made Brazil a GMO production and export giant.	**High:** Scientific and fast process leads to predictable outcomes.
Japan	**Very High:** Multi-layered and rigorous assessments by several ministries.	**Low:** Complex bureaucratic processes and political	**Low (Domestic):** Domestic cultivation is practically halted, limiting domestic innovation.	**Medium:** The process is scientific, but bureaucratic complexity can slow it down.
India	**High:** Dual framework of GEAC and FSSAI ensures rigorous assessments.	**Medium:** Proposed labeling rules are strong, but implementation is a challenge.	**Low (Domestic):** A practical ban on cultivation has halted innovation in	**Low:** Complex bureaucratic processes and political
Russia	**High (State Control):** The government has full control over safety.	**Low:** Decisions are made by decree with little transparency.	**Low:** A ban on cultivation eliminates any domestic innovation and development.	**High (in certainty):** The rules are clear (cultivation ban), but state power to ban imports creates trade uncertainty.
Iran	**Medium:** Laws exist, but reports indicate gaps in implementation and monitoring.	**Low:** Legal ambiguities and weak enforcement of labeling undermine transparency.	**Low:** Regulatory uncertainty and trade limitations hinder innovation and development.	**Low:** Contradictions in laws and irregular enforcement create an unpredictable environment.

Source: Research Finding

The U.S.A., Canada model prioritizes economic empowerment and regulatory predictability, which leads to reduced transparency for some stakeholders.

The EU model by prioritizing transparency and public trust by applying the principle of prudence, creates a significant cost to economic empowerment and regulatory efficiency.

The China, Brazil model prioritizes economic empowerment as a national and state strategic goal with varying levels of transparency and predictability.

The Russia, Iran Model This model puts state control and national security above anything else.

4- Conclusions and suggestions

4-1- Result

A comparative analysis of the regulation of bioengineered food (GMOs) reveals that the effectiveness of the existing regulatory system in ensuring their safety and transparency in selected countries. This effectiveness depends on several factors including: the legal approach (whether it focuses on the process or the product), the capacity and efficient of regulatory institutions to implement scientific evaluation and keep pace with the advancement of technology and innovation, the ability of the government and interested organizations to manage transparency and public trust, and the balance between innovation and solving cross-border challenges. GMOs are not solely a scientific issue, but are a complex confluence of science, politics, economics, and social and religious values.

Significant results regarding the effectiveness of the existing regulatory system in ensuring safety and transparency in this field in the studied countries detected as follows: The United States and Canada have facilitated innovation and widespread adoption with a scientific, product-oriented approach and trade, and have been successful in ensuring safety, but due to flexibility in labeling and less public participation, they have had weaknesses in transparency and have faced criticisms in the field of transparency for consumers.

The European Union ensures the highest level of safety and transparency through a process-based model, featuring a strict legal framework, a prudential approach, comprehensive risk assessment requirements, and mandatory labels. Although, the system complex and time consuming, has gained the trust of consumers due to public participation and post market monitoring. However, this has come at the cost of almost completely halting domestic innovation and commercial cultivation.

Brazil, India, and China, as agricultural giants, are simultaneously pursuing innovation and safety due to government support and developing regulatory frameworks, and have adopted a more pragmatic approach, while having rigorous regulatory systems, embracing the economic and strategic benefits of this technology, and becoming major players in global production.

However, in China, transparency and public participation still require improvement. Japan follows a cautious model in which massive imports are accompanied by a reluctance to cultivate domestically, reflecting an attempt to balance industrial needs with public concerns. With a very restrictive approach and a ban on cultivation, Russia has adopted an ideological stance based on national food security, but this has come at the cost of limiting innovation and economic benefits.

Despite having an advanced legal framework, Iran is in the transition phase, and its main challenge are the transformation of laws and approvals into commercial reality and the lack of adequate laboratory, and regulatory infrastructure for import control and post-market monitoring.

The effectiveness of regulations and regulatory systems for genetically modified products was assessed in this study based

on two main criteria: safety and transparency. The results showed that, despite fundamental differences in regulatory approaches, none of the systems studied (even the more liberal ones) resulted in a documented food safety crisis related to GMOs. This shows that

This shows that the scientific risk assessment processes carried out in all of these countries, regardless of the underlying philosophy, have been successful in preventing unsafe products from entering the market. The record of more than two decades of widespread consumption of these products without credible evidence of harm confirms the efficacy of scientific principles of risk assessment that have been shared globally (such as the Codex).

In the field of transparency assessment, significant results were observed in three aspects of effectiveness: High effectiveness: The European Union, Russia, and Iran score the highest in transparency for consumers due to their compulsory, comprehensive, and low-threshold labeling requirements. In the context of transparency assessment, significant results were observed in three aspects of effectiveness: **High effectiveness:** The systems of the European Union, Russia, and Iran achieved score the highest in transparency for the consumer due to mandatory, comprehensive, and low-threshold labeling requirements. These systems prioritize the right to make informed choices. **Moderate effectiveness:** In Brazil, India, and China, are at a moderate level of transparency. This is due to their mandatory labeling combined with higher thresholds or operational complexities. **Low Effectiveness:** The Canadian system provides the lowest level of direct transparency to the consumer due to its voluntary labeling Similarly, the U.S. system offers due to the use of unconventional terminology, high thresholds, and multiple exemptions.

The Cartagena Protocol has played an important role in regulatory convergence as a balanced approach to policymaking, but there are still significant differences in implementation. Economic analysis shows that trade barriers to GMOs impose significant costs, while public concerns remain a major challenge to the wider adoption of the technology.

The future challenge for all countries is to create dynamic regulatory frameworks that can keep pace with the pace of scientific advances such as new gene editing techniques (NGTs) and strike a logical balance between science, economics, and social and religious values. To date, however, there has been no concrete policy coordination effort on how genome edited organisms should be regulated in international organizations such as the Cartagena Biosafety Protocol (CPB), the Food Codex Commission (Codex), and the Organization for Economic Co-operation and Development (OECD). Policy formation has taken place in the absence of clear rules, and each country has made its own internal considerations and data collection.

The EU is exploring a new, more flexible regulatory pathway for some plants derived from NGTs, which could lead to the creation of a two-tiered system and a closer approach to a product-based approach. Countries such as Japan, Brazil have developed much lighter regulatory pathways for these new technologies.Russia’s approach similarly suggests that gene-edited organisms need not be subject to the same strict regulations as transgenic These changes show that regulatory boundaries are evolving. The dynamics could lead to greater international convergence in the future or, conversely,

lead to an even more complex legal paradigm by creating new and more complex categories.

4-2- Suggestions

-In order to enable effective regulation of the safe use of transgenic crops in the future along with enforcing strict controls on their imports and releases, the establishment of the International Compensation Fund for Genetic Contamination, modeled on the European Union, provides an efficient pathway for the approval and commercialization of new technologies.

-Creating open-access platforms for risk assessment information, meaningful public consultation, and clear text-based, standardized, and understandable labeling requirements will be useful to build trust and increase meaningful transparency rather than symbolic transparency, to empower consumers, build public participation, and develop a global labeling protocol in partnership with the WTO.

-Regulatory organizations should participate in the development cycle of GM crops in accordance with new technologies by supporting independent projects and research to reduce conflicts of interest in assessments.

-Strengthening the role of international bodies such as the OECD, Codex Alimentarius, WTO, and EFSA in periodically reviewing laws and formulating global guidelines for risk assessment tailored to a focus on product characteristics and actual risks, rather than just production technology, can reduce unnecessary rigor, Prevent regulatory divergence in the field (without compromising safety) and foster innovation to adapt to scientific advances (gene editing, NBTs) and new experiences and maintain their effectiveness.

-International and national strategic investments (more sophisticated applications such as plant vaccines; the use of artificial intelligence in international platforms) will accelerate a more sustainable future for agricultural biotechnology.

-Regional and international coordination (especially at the regional level such as Asia, Latin America, the Persian Gulf) in risk assessment methods and standards Countries should consciously seek to design systems to best balance the objectives of safety, transparency and support for responsible innovation, which can reduce the regulatory burden and facilitate trade and create relative balance.

4.3- Policy recommendations for the countries studied

-In the European Union, it is proposed, to increase the labeling threshold in order to reduce supply chain costs without compromising the principle of consumer choice and to further develop the NGT framework to provide clear and science-based pathways for innovation.

-In the United States, it is proposed to strengthen the executive capacity of the Department of Agriculture to reduce reliance on private litigation, to increase consumer confidence, to move towards standardized disclosure on packaging, and to evaluate the effectiveness of the QR code option under NBFDS.

-In China, India, and Russia, it is proposed, to continue the policy of building public trust by increasing the transparency of internal safety assessment processes, in order to realize the return on significant investment in research and development in this field, creating efficient platforms for the path of commercialization.

-In Canada, Japan, Brazil, it is proposed to accelerate the balance between maintaining safety and supporting innovation by exploiting their position as large agricultural traders to lead international regulatory dialogue and cooperation in order to coordinate regulatory and mutual identification.

-In Iran, it is proposed, to implement and disseminate institutional integration and ensure full cooperation and coordination between the Ministries of Health, Agricultural Jihad, and the Department of Environmental Protection and Foreign Affairs through a common information platform and integrated guidelines, a review of the "implicit ban on cultivation" and a distinction between classical engineering and gene editing that can be used reduce the import dependence on oil and oilseeds. Public education should be done using the media to improve the understanding of GM technology. Reference laboratory infrastructure for accurate and rapid detection of GMOs at customs and at home should be updated and efficient. Facilitating domestic innovation in order to develop local GM products with the local traits required by the country, in order to reduce economic dependence on foreign companies.

It is worth mentioning that this research presented a comprehensive, structured, and multifaceted method for the comparative analysis of the complex regulation of GMOs at the global level. The "index-based matrix" method was introduced as a powerful analytical tool that is able to analyze the complexities of different regulatory systems into measurable and comparable components. This approach allows policymakers, the grassroots community, and stakeholders to move beyond a purely descriptive review to an in-depth, evidence-based assessment of policy effectiveness.

This research is presented as an optimal approach for three main reasons:

1) By defining 19 diverse indicators that encompass all key dimensions from the legal framework and technical processes to the economic and social consequences, it provides a multifaceted and complete picture of each country's regulatory system (country profile). This comprehensiveness avoids one-dimensional analyses that focus on only one aspect (such as labeling).

2) Using a standardized and transparent scoring system, this method provides qualitative and quantitative comparability between countries. It helps to identify patterns, ranking countries based on specific criteria of policy models.

3) The main strength of this method is its unique ability to integrate data (data integration), quantitative analysis (matrix scores) with qualitative analysis (contextual interpretation). This integration demonstrates not only the "what" of differences, but also the "why" of these differences in different political, economic, and cultural contexts, leading to deeper, more meaningful, and more practical inferences for policymaking.

Finally, this analytical research can be used as a dynamic and repeatable model to monitor and evaluate future developments in the field of agricultural biotechnology and its regulations at the global level, and help to form a more harmonized, transparent, and science-based international and national regulation.

Conflict of Interest

There are none to declare.

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Author Contributions

All authors have contributed to the design, analysis, writing, and approval of the final manuscript in this manner

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مقاله علمی_پژوهشی

دیدگاه بین المللی به مقررات ایمنی مواد غذایی مهندسی زیستی (GMO) تحلیل تطبیقی؛ ارزیابی اثربخشی انها در تضمین ایمنی وشفافیت (مورد مطالعه : امریکا کانادا اتحادیه اروپا برزیل چین ژاپن هند ایران روسیه).

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چکیده

این مقاله پژوهشی به تحلیل تطبیقی اثربخشی تنظیم گری نهادهای بین‌المللی، ملی مرتبط با محصولات تراریخته (GMOs) در تضمین ایمنی و شفافیت مواد غذایی مهندسی زیستی در نه کشور منتخب شامل ایران، هند، چین، ژاپن، روسیه، ایالات متحده، کانادا، اتحادیه اروپا و برزیل میپردازد. این پژوهش با روش کیفی و رویکرد تحلیل تطبیقی-اسنادی (*Comparative-Documentary Analysis*) انجام شده است..داده‌ها از طریق روش کتابخانه‌ای و اسنادی شامل قوانین ومقررات ملی کشورها، دستورالعمل‌های آژانس‌های نظارتی مانند FDA آمریکا و EFSA اتحادیه اروپا و نهادهای متناظر در چین، ژاپن، برزیل، هند، روسیه و ایران، مقالات علمی، گزارش‌های سیاست گذاری و اسناد پروتکل کارتاهنا درباره ایمنی زیستی و اسناد سازمان‌های بین‌المللی WHO، FAO، CODEX؛ WTO گردآوری وتحلیل شده اند .کشورهای منتخب به صورت هدفمند (*Purposeful Sampling*)انتخاب شده‌اند تا طیف متنوعی ازنظام های نظارتی باشند.برای مقایسه بین کشورها از ماتریس شاخص محور استفاده شد .براساس یافته هادراین تحقیق سه مدل نظارتی واگرا؛ مدل مبتنی بر محصول(ایالات متحده، کانادا، برزیل) ، مدل مبتنی بر فرآیند(اتحادیه اروپا)؛ مدل راهبردومحدود کننده (روسیه، و تا حدی چین، هند، ایران، ژاپن) شناسایی شد. شایان ذکراست ظهورتکنیک‌های ژنومی جدید (NGTs) پیچیده گی جدید در تنظیم گری بین‌المللی این حوزه ایجاد کرده است.نتایج این پژوهش میتواند به سیاست‌گذاران، نهادهای نظارتی و ذی‌نفعان کلیدی کمک کند تا با حرکت از مناقشات حل نشده به سمت همگرایی، نگرانی‌های ایمنی را با منافع فناوری متعادل سازند و نظام‌های نظارتی کارامد، سرمایه‌گذاری‌های راهبردی (کاربردهای پیچیده ترمانند واکسن گیاهان؛ بکارگیری هوش مصنوعی در پلتقرمهای بین المللی) آینده‌ای پایدارتر برای بیوتکنولوژی کشاورزی طراحی کنند.