



Ecuador's Fractured Biotech Laws: A Double-Edged Sword for Agricultural Innovation and Quality (2017-2025)

Fragmentación legislativa en biotecnología agropecuaria ecuatoriana: impactos divergentes en innovación y gestión de calidad (2017-2025)

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Abstract

This paper analyzes how fragmentation of the legal framework governing agricultural biotechnology shaped innovation and quality-management processes in Ecuador between 2017 and 2025. Based on qualitative documentary research, the study found that the Organic Law on Agrobiodiversity, Seeds, and Promotion of Sustainable Agriculture (LOADSFAS, 2017) does not constitute a coherent regulatory system. Instead, its own provisions establish two parallel regimes founded on opposing logics: a protectionist regime oriented toward Peasant Family Farming (AFC), organized around peasant seed and ancestral knowledge; and a technical-commercial regime aimed at Commercial Agriculture (AE), centered on certified seed. This regulatory coexistence has produced sharply different outcomes. In AFC, it has promoted agroecological innovation through 24 Seed Houses and the training of approximately 1,669 producers; in AE, it has generated legal uncertainty that hinders the adoption of modern biotechnologies. The cases of gene-edited rice and the regulation of non-psychoactive cannabis show how these contradictions become concrete barriers that weaken the competitiveness of Ecuador's agricultural export sector.

Keywords: agricultural innovation, quality management, commercial agriculture, agricultural legislation, food sovereignty.

Resumen

El presente trabajo analiza de qué manera la fragmentación del marco legal en la biotecnología agropecuaria ha condicionado, entre 2017 y 2025, los procesos de innovación y gestión de calidad en Ecuador. A partir de una investigación documental de carácter cualitativo, se determinó que la LOADSFAS (2017) no constituye un sistema normativo con coherencia, sino que contiene, dentro de sus artículos, dos regímenes paralelos con lógicas opuestas: uno de corte proteccionista, orientado a la Agricultura Familiar Campesina (AFC) y articulado en torno a la "semilla campesina" y los "saberes ancestrales"; y otro de naturaleza técnico-comercial, dirigido a la Agricultura Empresarial (AE), centrado en la "semilla certificada". Esta coexistencia normativa produce resultados muy distintos: mientras que en la AFC ha impulsado la innovación agroecológica con 24 Casas de Semillas y cerca de 1.669 productores capacitados, en la AE se ha generado incertidumbre legal que frena la adopción de biotecnologías modernas. Los casos del arroz con edición génica y la regulación del cannabis no psicoactivo muestran cómo estas contradicciones se traducen en barreras concretas que debilitan la competitividad del sector agroexportador ecuatoriano.

Palabras clave: innovación agrícola, gestión de calidad, agricultura empresarial, legislación agraria, soberanía alimentaria.



Introduction

Ecuador's agricultural sector is a strategic component of the national economy, contributing approximately 8% of gross domestic product in 2022 and ensuring food security for more than 17 million inhabitants (National Institute of Statistics and Censuses [INEC], 2023). Nevertheless, the development of agricultural biotechnology during 2017-2025 was conditioned by a legal framework characterized by overlapping rules whose objectives contradict one another.

This situation arises from the coexistence of two opposing regulatory approaches. On the one hand, the 2017 Organic Law on Agrobiodiversity, Seeds, and Promotion of Sustainable Agriculture establishes a protectionist framework focused on conserving genetic resources and safeguarding peasant farming systems. On the other hand, the Seeds Law and its implementing regulations promote a technical-commercial regime oriented toward certification and high-yield varieties, more closely aligned with the needs of export agriculture (Ministry of Agriculture and Livestock [MAG], 2021).

Ecuador's agricultural sector has a clearly differentiated dual structure. Commercial Agriculture (Agricultura Empresarial, AE), which accounts for 15% of Agricultural Production Units (UPAs), concentrates 80% of the land and 63% of irrigation water and focuses on technology-intensive agricultural exports. In contrast, Peasant Family Farming (Agricultura Familiar Campesina, AFC) represents 84.5% of UPAs but has access to only 20% of the land and 37% of irrigation water, while producing more than 60% of the country's food (Food and Agriculture Organization of the United Nations [FAO], 2024).

This duality is also reflected in legislation, where different legal instruments do not necessarily converge. The Agrobiodiversity Law, built around concepts such as peasant seed and ancestral knowledge, responds to AFC's need for protection. The Seeds Law, by contrast, targets a very different farmer: one who uses certified seed and operates under commercial quality standards consistent with the requirements of agricultural exports (Ministry of the Environment, Water, and Ecological Transition [MAATE], 2018).

The current regulatory framework does not operate as a neutral arbiter. In practice, it actively directs and conditions

the types of innovation to which efforts and resources are allocated. It has been relatively effective in ensuring constitutional protection of agrobiodiversity, yet this same approach has created areas of legal uncertainty that affect certain technological pathways and increase compliance costs, thereby undermining the competitiveness of Ecuador's agricultural exports (González et al., 2024).

Against this background, the available literature on agricultural biotechnology in Ecuador has addressed only parts of the problem. Some studies analyze seed regulations (Torres & Santos-Ordóñez, 2020), others examine agroecological innovation in AFC (Peñaherrera et al., 2021) or export competitiveness (González et al., 2024), but none has systematically integrated legislative fragmentation with its simultaneous effects on biotechnology innovation and quality management in both production models. This study therefore analyzed the contradictory effects that legislative fragmentation in agricultural biotechnology produced on innovation and quality management in Ecuador during 2017-2025. It examined the identified regulatory tensions, their concrete consequences for the two agricultural models, and their implications for the sustainability of Ecuador's agricultural export sector.

Materials and methods

Research approach and type

The study adopted a qualitative approach and a descriptive-analytical documentary design. Rather than quantifying how frequently legislative fragmentation occurs, it sought to understand the extent to which this regulatory structure conditions opportunities for innovation and mechanisms for quality management.

The study characterized Ecuador's regulatory framework for agricultural biotechnology by identifying the actors, objectives, and mechanisms of the parallel regulatory systems. It examined the relationship among the study variables-legislative fragmentation, innovation, and quality management-and interpreted how the legal structure generated divergent effects on AFC and AE. The design was nonexperimental and ex post facto because it analyzed existing events and regulations, including enacted laws and published management reports, without manipulating variables.

Scope of the study

The analysis covered 2017 through 2025. The starting year was selected because the enactment of LOADSFAS in 2017 consolidated the duality of the regulatory framework. The period extended to the most recent year covered by the study in order to include recent regulatory developments and impacts.

The study was limited to Ecuador and focused specifically on legislation governing agricultural biotechnology, including seed management, agricultural health, and control of genetically modified organisms (GMOs). It also drew on data and findings from neighboring countries and from other national cases in which discrepancies in biotechnology legislation had been documented.

Research phases

The research process was organized into three sequential phases to ensure a systematic approach. Phase 1 consisted of documentary review and the collection of relevant primary and secondary sources. Phase 2 involved systematizing and processing the information by organizing and classifying it for comparison and analysis. Phase 3 comprised critical analysis and interpretation of the systematized evidence in order to identify causal relationships and patterns and to formulate the study's findings, conclusions, and recommendations.

Information Sources

A source-triangulation strategy was used to validate the information and provide a comprehensive view of the phenomenon. The sources were classified as follows.

Primary Sources (Legal and Official Documents)

Primary sources included the Constitution of the Republic of Ecuador (2008), particularly the provisions declaring the country free of transgenic crops and seeds; LOADSFAS (2017) and its regulations; and the Organic Law on Agricultural Health. They also included technical regulations issued by MAG and the Agency for Phyto- and Zoosanitary Regulation and Control (AGROCALIDAD) concerning cultivar registration, seed imports, and specific crops such as non-psychoactive cannabis, together with MAG accountability reports, foreign-trade data from the Central Bank of Ecuador, and production statistics from INEC.

Secondary sources (academic literature and technical reports)

Secondary sources included indexed-journal publications on regulatory governance, agricultural innovation, and rural development in Ecuador and Latin America; documents from FAO (2006) and the Inter-American

Institute for Cooperation on Agriculture concerning family farming, agrobiodiversity, and Ecuadorian seed legislation; and reports by multilateral organizations such as the World Bank and FAO on non-tariff barriers and the competitiveness of agricultural exports.

Data processing and analysis techniques

The following qualitative techniques were applied to analyze the collected information:

The collected information was examined using two complementary qualitative techniques. First, a regulatory-comparison matrix systematically contrasted the objectives, actors, requirements, and mechanisms of the two seed systems contained in LOADSFAS, making the law's internal tensions visible. Second, the study analyzed selected cases - gene-edited rice and non-psychoactive cannabis - because they illustrate how regulatory ambiguity becomes a concrete obstacle for actors seeking to innovate within AE.

Results and discussion

Governance and legislative fragmentation

At the political and institutional levels, legislative fragmentation reflects a process of atomization that Garzón-Sherdek (2021) calls a 'chaos of reforms,' whose destabilizing effects extend to the agricultural regulatory system. When the legal environment is unstable, uncertainty is transferred to productive actors: companies avoid investing in biotechnology research and development because regulations may change, while small farmers face shifting rules that they are not always able to meet (Camino, 2021). In Ecuador, this dynamic is expressed through the coexistence of regulatory frameworks created at different political moments and based on logics that do not always converge (Méndez and Pino, 2025).

Biotechnology, innovation, and agricultural development

Biotechnology is an integrative discipline that uses biological systems, living organisms, or their derivatives to develop or transform products and processes for specific purposes (Ortega-Ante, 2020). Its scope extends from ancestral practices such as fermentation to advanced genetic-engineering techniques, making it one of the most versatile tools available to contemporary agricultural innovation (Franco, 2016; Ortega-Ante, 2020). Its best-known agricultural applications include developing drought-tolerant or disease-resistant varieties, improving the nutritional quality of food, and identifying more sustainable alternatives to conventional methods (Ortega-Ante, 2020). Biotechnology also contributes to the conservation of plant genetic resources through techniques



such as *in vitro* culture and cryopreservation, which are essential for safeguarding agrobiodiversity over the long term (Roura, 2023).

Biotechnology's innovative potential does not unfold in a vacuum; it depends substantially on the legal and economic environment in which it operates. Ecuador faces well-known obstacles, including inadequate investment, deficient infrastructure, and limited funding for research and development (Ortega-Ante, 2020), which are difficult to overcome without clear political commitment. Franco (2016) emphasized that sustainable technological development requires state policies that support training and expand access to knowledge. A well-constructed legal framework consistent with international commitments on the sustainable use of genetic resources could therefore serve as a genuine catalyst (Roura, 2023). Yet such coherence has been lacking: without effective coordination among research institutions, the state, and producers, scientific knowledge rarely becomes innovation accessible to those who need it most (Franco, 2016).

Quality management and access to international markets

In the agricultural export sector, quality management may be understood as the set of characteristics developed by a company or production system to meet customer expectations (Zavala-Choez and Vélez-Moreira, 2020). It is not merely an administrative procedure but a strategic decision: rigorous implementation builds confidence in products and processes and enables firms to position themselves in highly competitive markets (Almeida, 2019). In a globalized environment, quality is no longer an optional differentiator but a condition of entry, because consumers are increasingly demanding and exporters that fail to adapt are excluded from the market (Andrade et al., 2020; Zavala-Choez and Vélez-Moreira, 2020).

In foreign trade, certifications such as ISO 9001 and Fair Trade act as recognizable signals of trust. Although their adoption is formally voluntary, their absence may in practice become an insurmountable obstacle, since many buyers, particularly in the European Union and the United States, do not consider uncertified suppliers. These standards therefore function as *de facto* non-tariff barriers (Almeida, 2019). Ecuadorian exporters have consequently pursued certification to maintain access to those markets (Almeida, 2019; Espinoza et al., 2023). In

this setting, certified quality has ceased to be simply an internal-improvement strategy and has become a condition of competitive survival (Zavala-Choez and Vélez-Moreira, 2020).

Ecuador's dual agricultural model

Ecuador's agricultural sector is far from homogeneous: the divide between its two major production models reflects deep structural inequalities in access to land and resources. Commercial Agriculture (AE), also described as agribusiness or agrarian capitalism, follows an investor logic in which financial profitability is the primary objective (Rivera et al., 2019). Its most visible feature is concentration: only 6.4% of families control more than 60% of the country's cultivable land. Production is organized around large-scale export monocultures, oil palm, bananas, and flowers, with privileged access to irrigation and institutional credit (Houtart, 2017).

At the opposite end, AFC, which includes production by Indigenous communities, accounts for most of the country's production units but operates under clearly precarious conditions. More than 75% of peasant families farm fewer than 10 hectares, together representing only 11.8% of Ecuador's agricultural land (Guamán-Rivera, 2022). Despite this, or perhaps because of it, AFC sustains much of Ecuador's food sovereignty, producing 60% of the food consumed nationally while receiving only a minute share of the public agricultural budget (Houtart, 2017).

The 2017 Organic Law on Agrobiodiversity, Seeds, and Promotion of Sustainable Agriculture is the legal framework designed to protect AFC in Ecuador. Its principal objective is to protect, revitalize, and promote the country's plant genetic resources by ensuring free access to quality seed and encouraging sustainable agricultural models (LOADSFAS, 2017, Art. 1). The law explicitly recognizes peasant seed - native and traditional seed, and ancestral knowledge as cultural heritage and as pillars of food sovereignty, guaranteeing communities the right to conserve, use, and freely exchange their seeds (LOADSFAS, 2017, Arts. 1 and 8).

Comparison of the Organic Law on Agrobiodiversity (LOADSFAS)

The study's most revealing finding was that regulatory fragmentation is not confined to conflicts among separate legal instruments; it is embedded within LOADSFAS

(2017) itself. Rather than creating a unified seed-management system, the law establishes two parallel subsystems with distinct objectives, actors, rules, and operating logics, reproducing in law the structural duality that already characterizes Ecuadorian agriculture.

Table 1 compares these two regimes and highlights their conceptual and operational differences.

Table 1. Comparative matrix of seed regulatory systems in Ecuador (LOADSFAS, 2017).

Characteristic	Peasant seed system (nonconventional)	Certified seed system (conventional)
Legal basis	LOADSFAS, Chapter II, Arts. 27-32	LOADSFAS, Chapter III, Arts. 33-47
Principal objective	Protect agrobiodiversity, revitalize ancestral knowledge, and guarantee food sovereignty	Guarantee genetic and physiological quality, purity, and phytosanitary condition to maximize productivity and facilitate trade
Regulated actors	Farmers, communes, communities, peoples, and nationalities that conserve, use, and exchange native and traditional seed	Natural or legal persons registered as seed operators, including producers, importers, and distributors
Registration requirements	No formal registration is required for use, conservation, or free exchange. The state promotes use without imposing bureaucratic barriers	Cultivars must be entered in the National Cultivar Registry, and operators must be entered in the corresponding registry before seed may be marketed
Quality standards	Based on local knowledge and agroecological practices. Phytosanitary standards are required only for entry into the conventional market	Strict, uniform technical standards define purity, germination, health, and productivity and are verified through laboratory analysis and official control
Marketing	Free exchange and sale in local markets and fairs are encouraged. Appropriation of associated collective knowledge is expressly prohibited	Highly regulated. New, sealed packaging and labels with official tags are required to guarantee quality and traceability
Innovation approach	<i>In situ</i> conservation; participatory breeding led by farmers with technical support and without genetic engineering; revaluation of native varieties; and local adaptation	Conventional plant breeding, development of high-yield varieties, importation of advanced genetics, and protection of plant varieties

The table shows that LOADSFAS does not articulate a coherent regulatory system but two normative worlds that coexist without integration. The system designed for AFC is flexible and protectionist because it prioritizes seed diversity and community autonomy. The system designed for AE is rigid and technical because it privileges standardization, productivity, and compliance with market requirements. This duality is the most concrete expression of the legislative fragmentation examined in this study. The gap between regulatory design and productive reality is illustrated by rice, one of the country's most important crops: of more than 400,000 cultivated hectares, only 19% use certified seed, and approximately half of that share comes from INIAP itself (INEC, 2023). The technical-commercial certified-seed system created for AE therefore has very limited penetration even among the largest commercial crops.

Comparison of primary and secondary sources identified a systematic gap that is itself a central finding. The primary sources -LOADSFAS (2017), LOADSA, Ministerial Agreement No. 063 (MAG, 2023b), and MAG's official reports (2023) -describe a regulatory framework formally structured into two parallel subsystems. Secondary sources, including academic literature and technical reports from international organizations, consistently document that this regulatory design does not produce equivalent outcomes in practice. Three fractures between the legal text and empirical reality were identified. First, LOADSFAS (2017, Chapter II) formally guarantees free access to peasant seed without bureaucratic barriers, yet Suárez-Duque et al. (2020) and Mendoza et al. (2024) document that institutional disarticulation and poor coordination among levels of government limit these guarantees, particularly in areas with a weaker state presence. Second, the certified-seed system (LOADSFAS, Chapter III) establishes uniform technical standards intended to maximize productivity and facilitate trade, but INEC data (2023) show that only 19% of the rice-growing area uses certified seed, indicating that the technical-commercial design has not penetrated even the largest commercial crops effectively. Third, Ministerial Agreement No. 063 (MAG, 2023b) created a mechanism for new precision-breeding techniques intended to reduce legal uncertainty, but Torres and Santos-Ordóñez (2020) and the Cibus HT1/HT3 case (Cibus Inc., 2025) show that uncertainty persists in the absence of technical regulations specific to each type of new breeding technique (NBT). Companies investing in research and development thus lack full assurance regarding the regulatory treatment of future products. This divergence between law and practice confirms that fragmentation is not only a problem of formal design; it is reproduced during implementation and creates asymmetric effects on the two production models.

Divergent impacts on agricultural innovation

The fragmented legal framework is not neutral. It actively channels resources, incentives, and innovation efforts into two divergent trajectories aligned with the two agricultural subsectors. It promotes an agroecological innovation model for AFC while generating substantial legal uncertainty that obstructs AE's adoption of modern biotechnologies (Lechón and Chicaiza, 2019).

Ecuadorian agricultural exports face increasingly stringent phytosanitary and technical requirements in international markets (Albán et al., 2009). In floriculture, major non-tariff barriers include phytosanitary restrictions, royalties paid to breeders, and compliance with quality standards such as ISO (Albán et al., 2009). In the shrimp industry, regulations in the United States and the European Union impose complex food-safety systems-traceability, chemical-residue limits, turtle-excluder devices, and requirements under the Bioterrorism Act, that increase the cost and difficulty of exporting. Multilateral organizations such as the World Bank, FAO, and the Inter-American Development Bank agree that these technical and administrative requirements operate as invisible obstacles that reduce competitiveness (González et al., 2024). FAO therefore recommends strengthening the national phytosanitary authority, SESA-AGROCALIDAD, to overcome barriers to agricultural trade (FAO, 2006; Albán et al., 2009).

Promotion of agroecological innovation in peasant family farming (AFC)

With respect to AFC, both LOADSFAS and the policies implemented by MAG have performed relatively well in fulfilling the constitutional mandate to protect agrobiodiversity. An innovation-support ecosystem oriented toward conservation and resilience has gradually developed (Suárez-Duque et al., 2020). Unlike many statements of intent, it has produced programs with allocated resources and verifiable results (Peñaherrera et al., 2021).

MAG's 2023 management report documents concrete progress: 24 seed houses were established nationwide, providing physical infrastructure for in situ conservation and local exchange of genetic material. In addition, 1,669 producers received training in conservation techniques and ancestral practices associated with peasant seed, and 30 exchange fairs were organized to stimulate circulation

of these varieties (Ministry of Agriculture and Livestock, 2023a). These actions respond not only to LOADSFAS's protectionist provisions but also to participatory-innovation approaches promoted by international organizations (Andean Community, 2011; Food and Agriculture Organization of the United Nations, 2012). The legal framework can therefore be said to have acted as an effective catalyst for a specific model of innovation by strengthening AFC's genetic resources and restoring the value of knowledge that might otherwise have been lost.

In Ecuador, AFC is a central organizational model for conserving agrobiodiversity and reactivating local economies, generating more than 70% of rural employment and producing 60% of the food consumed nationally. Nevertheless, institutional disarticulation in the territory compromises the effectiveness of agroecological-innovation strategies such as the AFC Seal, Alternative Marketing Circuits (CIALCOs), and specialized credit for rural women. In areas such as Jipijapa canton, the lack of coordinated action among levels of government limits the impact of these policies. This underscores the urgent need for interinstitutional management that strengthens producer associations and enables transfer of innovative technologies to smallholders (Mendoza et al., 2024).

Legal uncertainty and barriers to biotechnology innovation in Commercial Agriculture (AE)

The situation is very different for AE. The regulatory framework creates ambiguity and risk that discourage serious investment in research and development involving advanced biotechnology. The most evident restriction is the constitutional prohibition on cultivating genetically modified organisms (Art. 401), which declares Ecuador free of transgenic crops and directly blocks one of the innovation pathways most widely used worldwide to improve crop productivity and resistance (Constituent National Assembly, 2008).

The analysis nevertheless shows that the situation is more complex than a simple prohibition. The legal framework creates gray areas that generate both obstacles and opportunities for innovation, as the following cases demonstrate.

Case study 1: Gene-edited rice

In May 2025, the Ministry of Agriculture evaluated the HT1 and HT3 herbicide-tolerance traits developed by

Cibus Inc. through its Rapid Trait Development System® (RTDS®) in rice (*Oryza sativa*). Because the traits do not incorporate recombinant DNA from an external organism, the Ministry concluded that they do not qualify as GMOs under Ecuadorian regulations and may therefore be marketed under the same rules as conventional seed (Cibus Inc., 2025). Commercialization in Ecuador will occur through Interoc, which is incorporating HT1 and HT3 into elite lines to provide weed-management solutions for rice growers. This decision was made possible by Ministerial Agreement No. 063 of September 13, 2023, which created the regulatory framework for precision-breeding techniques and established that products derived from those techniques may be treated as conventional varieties (MAG, 2023b). The decision is an important precedent because it opens a formal pathway for NBTs such as CRISPR-Cas9. However, the absence of rules specific to each type of NBT sustains uncertainty: companies investing in research and development still lack full assurance that future products will receive the same regulatory treatment, limiting the scale of investment.

Case study 2: Non-psychoactive *Cannabis* and industrial hemp

Regulation of non-psychoactive *Cannabis* or industrial hemp illustrates the tensions generated by the regulatory framework. MAG regulations establish minimum production areas for obtaining a license: 5 hectares in open fields or 2 hectares under greenhouse cultivation (Ministry of Agriculture and Livestock, 2020). An analysis by the Superintendency for the Control of Market Power determined that this threshold is an entry barrier that excludes most AFC producers and favors actors with greater investment capacity, namely AE (Superintendency for the Control of Market Power, 2022). The regulation also requires licensees to be legal entities, such as cooperatives or associations, thereby excluding natural persons (Art. 5), and defines the minimum area (Art. 9). The same article, however, allows the area requirement to be met progressively over as many as five years under a production plan, transforming the barrier into a scalability challenge. An alternative pathway is available through research or plant-breeding licenses, which require no minimum area and could be used to develop high-value niches without large tracts of land.

Case study 3: The constitutional ban on transgenic seeds and crops

The constitutional provision declaring Ecuador free of transgenic seeds and crops (Art. 401) has moved beyond the technical sphere into political and economic debate. Defenders of food sovereignty and agroecology consider it

a fundamental pillar. Advocates of modern biotechnology, by contrast, view it as an obstacle to adopting biotechnology solutions for concrete agronomic challenges, such as bananas' susceptibility to black sigatoka. The contradiction becomes more apparent when one considers that the 2013-2017 National Plan for Good Living simultaneously identified biotechnology as a priority development area (Bravo, 2017). Tension deepened in January 2022, when the Constitutional Court declared Article 56 of LOADSFAS unconstitutional. That provision had permitted the importation of transgenic seed for research; its invalidation reinforced the absolute character of the constitutional prohibition and closed one of the few existing avenues for scientific work in this field (Acción Ecológica, 2022). More troubling than the regulatory contradiction itself is the gap between formal legality and conditions in the field. Participatory monitoring in Los Ríos and Guayas provinces, cited as background predating the study period because it documents the structural baseline on which the post-2017 framework operated, detected glyphosate-resistant transgenic soybean. This finding reveals both the absence of systematic monitoring and the ineffectiveness of state controls. Regulatory ambiguity therefore not only slows formal innovation but also encourages an uncontrolled informal seed market, with consequent risks of genetic contamination of local varieties and greater dependence on agrochemicals in Ecuador's coastal areas (Intriago-Barreno and Bravo-Velásquez, 2016).

Organic Law on Agricultural Health (LOADSA)

The regulatory framework becomes still more complex with the Organic Law on Agricultural Health (LOADSA). Although the law seeks to modernize and harmonize phyto- and zoosanitary rules with international standards, it introduces another layer of control that directly affects quality management in primary production. It created the Agency for Phyto- and Zoosanitary Regulation and Control as the technical body responsible for regulating, controlling, and inspecting the entire production chain, from input use to slaughter facilities. For AE, this regulation is essential because compliance with good-practice, traceability, and phytosanitary-certification requirements is indispensable for access to export markets that demand strict pest and disease control. For AFC, however, these same requirements may operate as technical and economic barriers. Although the law exempts subsistence producers from certain registration duties, farmers seeking to enter formal or export markets must assume the cost and administrative burden of certifications and controls, exacerbating existing asymmetries and reducing competitiveness (National Assembly of Ecuador, 2017).



Complementary studies

Available studies reinforce this diagnosis. Biotechnology innovation in Ecuador has been constrained substantially by the absence of a national biosafety framework and by institutional weakness that prevents stated policies from becoming effective support for research (Torres and Santos-Ordóñez, 2020; Wendt and Izquierdo, 2003). Limited research and development funding and a historically superficial political understanding of the subject have also contributed to the absence of a clear sectoral policy for promoting biotechnology.

The paradox is that Ecuador occupies a significant position in green biotechnology within the Andean Community, having experienced 15 years of sustained growth in scientific output and international collaboration (Freire et al., 2022), yet this regional leadership has not produced comparable advances in modern biotechnology. Colombia and Brazil remain substantially ahead (Torres and Santos-Ordóñez, 2020). Adoption of new native varieties has reached 37%, with positive productivity effects, but remains limited nationally (Sánchez and Mendoza, 2019). The causes of this lag are multiple, an incomplete regulatory framework, lack of political commitment, inadequate infrastructure investment, and a negative public image, and together produce low regional competitiveness, limited economic effects because of weak industrial innovation, and environmental and social risks arising from regulations that do not cover all possible scenarios (Hastings, 2018).

Conclusion

The findings show that legislative fragmentation in Ecuadorian agricultural biotechnology is not an accidental consequence of imperfect planning but a structural condition embedded in LOADSFAS itself. The law has created two regulatory regimes operating according to opposing logics: a protectionist regime designed for AFC and a technical-commercial regime oriented toward AE.

In innovation, this duality has produced asymmetric effects. The legal framework has successfully promoted agroecological innovation and in situ conservation in AFC by recognizing the peasant-seed model as a tool of food sovereignty. At the same time, it creates legal uncertainty that stalls modern biotechnology innovation in AE. The absence of clear definitions for new breeding techniques, including gene editing, and bureaucratic obstacles affecting

new crops such as hemp discourage investment and reduce the competitiveness of agricultural exports relative to other countries.

Quality management presents an equally serious problem. LOADSA imposes international-level sanitary standards that are indispensable for exports, yet uniform application without regard to the actual capacities of each producer type excludes AFC from formal markets precisely when those producers attempt to enter them. This qualitative documentary study is limited to analysis of legal sources, institutional reports, and available academic literature; it did not include fieldwork or surveys of sector actors.

The concrete experiences of producers, companies, and public officials therefore remain outside its scope and constitute an agenda for future empirical research. The findings point to three priority regulatory needs. First, differentiated technical guidelines should be issued for each type of NBT so that Ministerial Agreement No. 063 is consolidated into specific regulations that provide legal certainty for research-and-development investment. Second, proportional phytosanitary-certification mechanisms should be designed for AFC to reduce administrative burdens without compromising market food-safety requirements. Third, formal interinstitutional coordination among MAG, AGROCALIDAD, and INIAP is needed so that regulatory policy, sanitary control, and scientific research operate coherently and do not generate new regulatory gray areas.

Conflict of interest

The authors declare that they had no conflicts of interest at any stage of this publication.

References

- Acción Ecológica. (2022). *La Corte Constitucional se pronuncia sobre el ingreso de semillas y cultivos transgénicos*. <https://www.accionecologica.org/la-corte-constitucional-se-pronuncia-sobre-el-ingreso-de-semillas-y-cultivos-transgenicos/>
- Albán, M. A., Espinosa, C., Albán, M., Muñoz, G., Gross, M. and Torres, M. (2009). *Evaluación rápida sobre comercio y ambiente (RTEA): Informe nacional de Ecuador*. Winnipeg, Canadá: International Institute for Sustainable Development.

- Almeida Guzmán, M. (2019). Implicaciones en la gestión estratégica de las empresas de la integración de los sistemas de gestión de la calidad, medio ambiente y seguridad y salud laboral, basados en estándares internacionales. El caso de Ecuador [Tesis Doctoral, 407 p., Universidad de Oviedo]. <http://hdl.handle.net/10651/51622>
- Andrade Arteaga, C., Sambonino Garcia, B., Franco Castañeda, Z., Ruiz Molina, K. del R. y Poveda Burgos, G. (2020). *Importancia del proceso de gestión de calidad total en las empresas exportadoras ecuatorianas para la sostenibilidad en los mercados internacionales*. En V Congreso Virtual Internacional Desarrollo Económico, Social y Empresarial en Iberoamérica.
- Asamblea Nacional Constituyente. (2008). *Constitución de la República del Ecuador*. Registro Oficial 449.
- Asamblea Nacional del Ecuador. (2017). *Ley Orgánica de Sanidad Agropecuaria*. Registro Oficial Suplemento 27.
- Bravo, E. (2017). Visiones y tensiones sobre el debate de los transgénicos en el Ecuador. *Perspectivas Rurales*. Nueva Época, 15(30). 11-29, DOI: <http://dx.doi.org/10.15359/prne.15-30.1>
- Camino, J. F. (2021). Elecciones Ecuador 2021 ¿Un retorno a la fragmentación e ingobernabilidad? *Ecuador Debate*, 112, 25-45.
- Cibus Inc. (2025). *Ecuador approves Cibus herbicide tolerance traits as equivalent to conventional breeding* [Comunicado de prensa]. Globe Newswire/ Investor Relations Cibus. <https://investor.cibus.com/news-releases/news-release-details/ecuador-approves-cibus-herbicide-tolerance-traits-equivalent>
- Comunidad Andina. (2011). *Agricultura Familiar Agroecológica Campesina*. https://www.comunidadandina.org/StaticFiles/2011610181827revista_agroecologia.pdf
- Espinoza Baque, H. A., Ruiz Álvarez, A. D. y Novillo Maldonado, E. F. (2023). Gestión de la calidad bajo la Certificación Fair Trade para las Empresas Exportadoras. *Polo del Conocimiento*, 8(3), 16-39.
- Franco, W. (2016). Propuestas para la innovación en los sistemas agroproductivos y el desarrollo sostenible del Valle Interandino en Carchi, Ecuador. *Tierra Infinita*, 2(1), 49-87.
- Freire, D., Fernández-Gómez, R., Reyes-Salinas, A., Castro, G., Dorca-Fornell, C. and Proaño, K. (2022). The colors of biotechnology in Ecuador: A general overview. *CABI Reviews*. <https://doi.org/10.1079/cabireviews202217027>
- Garzón-Sherdek, K. A. (2021). Elecciones Generales Ecuador 2021: reformas, fragmentación política y pendiente pandemia COVID-19. *Elecciones*, 20(21), 273-286.
- González Amador, C. Y., Velasco, J. y Miranda, J. J. (2024). Ecuador: Crecimiento resiliente para un futuro mejor (Cap. 5, pp. 120-143). Grupo Banco Mundial, Oficina Ecuador. <https://documents1.worldbank.org/curated/en/099050924131536292/pdf/P17797312cbabc01b189011ce0839cba821.pdf>
- Guamán-Rivera, S. A. (2022). Desarrollo de políticas agrarias y su influencia en los pequeños agricultores ecuatorianos. *Revista Científica Zambos*, 1(3), 15-28. <https://doi.org/10.69484/rcz/v1/n3/30>
- Hastings, D. P. (2018). Risky business: Agricultural development and environmental consequences in Indonesia and Ecuador. *Global Majority E-Journal*, 9(2), 71-83.
- Houtart, F. (2017). La agricultura campesina e indígena como una transición hacia el bien común de la humanidad: el caso de Ecuador. *Desacatos*, 56, 176-187.
- Instituto Nacional de Estadística y Censos (INEC). (2023). *Boletín técnico. Encuesta de Superficie y Producción Agropecuaria Continua 2023*. https://www.ecuadorencifras.gob.ec/documentos/web-inec/Estadisticas_agropecuarias/espac/2023/Boletin_tecnico_ESPAC_2023.pdf
- Intriago-Barreno, R. y Bravo-Velásquez, E. (2016). Primera detección de soya transgénica (*Glycine max*) cultivada en la costa ecuatoriana usando métodos de monitoreo participativo. *CienciAmérica*, 5(1), 75-82. <https://cienciamerica.edu.ec/index.php/uti/article/view/48>
- Lechón, W. y Chicaiza, J. (2019). De la agricultura familiar campesina a las microempresas de monocultivo. Reestructura socioterritorial en la sierra norte del Ecuador. *Eutopía: Revista de Desarrollo Económico Territorial*, 15, 192-210.
- Ley Orgánica de Agrobiodiversidad, Semillas y Fomento de la Agricultura Sustentable. (2017). *Registro Oficial Suplemento 10 de 08-jun.-2017*. Asamblea Nacional del Ecuador.



- Méndez Chaux, D. D. y Pino Uribe, J. F. (2025). Legislación consultiva vs legislación obligatoria: autonomía partidaria, inclusión y democracia interna en Colombia y Ecuador. *Reflexión Política*, 27(55), 89-109.
- Mendoza Marcillo, B., Pincay Menéndez, J., Merchán García, W., Narváez Campana, W., Bravo Zamora, R. y Daza Castaño, R. (2024). Estrategias de la agricultura familiar y campesina, en Jipijapa-Ecuador. *Conocimiento Global*, 9(2), 422-431. <https://doi.org/10.70165/cglobal.v9i2.434>
- Ministerio de Agricultura y Ganadería (MAG). (2020). *Reglamento para la Importación, Siembra, Cultivo, Cosecha, Post Cosecha, Almacenamiento, Transporte, Procesamiento, Comercialización y Exportación de Cannabis no Psicoactivo o Cáñamo y Cáñamo para Uso Industrial (Acuerdo Ministerial No. 109)*.
- Ministerio de Agricultura y Ganadería (MAG). (2021). *Política y Plan Nacional Agropecuario*. <https://www.rimisp.org/wp-content/uploads/2021/04/Plan-Nacional-Agropecuario-MAG-2021.pdf>
- Ministerio de Agricultura y Ganadería (MAG). (2023a). *Informe Rendición de Cuentas 2023*. <https://www.agricultura.gob.ec/wp-content/uploads/downloads/2024/03/MAG-Informe-Rendicion-de-Cuentas-2023.pdf>
- Ministerio de Agricultura y Ganadería (MAG). (2023b). *Acuerdo Ministerial No. 063: Marco regulatorio para el uso de las nuevas técnicas de mejoramiento de precisión*. MAG. <https://www.agricultura.gob.ec/acuerdos-ministeriales/>
- Ministerio del Ambiente, Agua y Transición Ecológica. (2018). *Ley Orgánica de Agrobiodiversidad, Semillas y Fomento de Agricultura Sustentable*. <https://www.ambiente.gob.ec/wp-content/uploads/downloads/2018/05/Ley-Organica-Agrobiodiversidad-Semillas-y-Fomento-de-Agricultura.pdf>
- Organización de las Naciones Unidas para la Agricultura y la Alimentación (FAO). (2006). *Ecuador: Nota de Análisis Sectorial: Agricultura y Desarrollo Rural*. Roma: FAO.
- Organización de las Naciones Unidas para la Alimentación y la Agricultura. (2012). *Estudios sobre innovación en la agricultura familiar*. Experiencias y enfoques de procesos participativos de innovación en agricultura. <https://www.fao.org/4/i3136s/i3136s.pdf>
- Organización de las Naciones Unidas para la Alimentación y la Agricultura. (2024). *Ecuador en una mirada*. <https://www.fao.org/ecuador/fao-en-ecuador/ecuador-en-una-mirada/es/>
- Ortega-Ante, D. A. (2020). Enfoque de la biotecnología industrial en Ecuador y la provincia de Esmeraldas. *Polo del Conocimiento*, 5(8), 1219-1227.
- Peñaherrera, D., Paucar, B., Narváez, G., Torres, C., Villavicencio, A., Panchi, N., Enríquez, A. y Escobar Manosalvas, J. D. (2021). *Insumos agroecológicos: estrategia de resiliencia al cambio climático en la Agricultura Familiar Campesina (AFC)*. <http://repositorio.iniap.gob.ec/handle/41000/5965>
- Rivera López, M. I., Estrada Hernández, J. A., Quiñonez, R. E. y Moreno García, R. R. (2019). Aproximación teórica y aplicada al modelo de diversificación integral de cultivos para el desarrollo agrícola y económico en el Cantón Quinindé, provincia de Esmeraldas, República del Ecuador. Mikarimin. *Revista Científica Multidisciplinaria*, 6(Edición Especial), 241-258.
- Roura Cadena, A. (2023). La biotecnología como herramienta para la conservación de los recursos fitogenéticos para la alimentación y la agricultura en Ecuador. *Catálisis*, 5(10), 1-4. https://www.catalisise.com/_files/ugd/780a0c_bbee984757ff4626b89186e4f52fbccb.pdf
- Sánchez, V. H. y Zambrano M., J. L. (2019). Adopción e impacto de las tecnologías agropecuarias generadas en el Ecuador. *La Granja: Revista de Ciencias de la Vida*, 30(2), 28-39. <http://doi.org/10.17163/lgr.n30.2019.03>.
- Suárez-Duque, D., Tapia, C., Vallejo, F., Estrada, S. y Delgado, H. (2020). *Conservación de agrobiodiversidad basada en agricultura familiar campesina (Publicación Miscelánea No. 457)*. INIAP/FAO/ Fundación Heifer Ecuador/MAG/GEF. <https://>

repositorio.iniap.gob.ec/bitstream/41000/5676/1/LIBRO%20AGROBIODIVERSIDAD-%20GEF-FAO-INIAP-2020.pdf

Superintendencia de Control del Poder de Mercado. (2022). *Informe de análisis de barreras normativas-Caso Cañaño*. <https://www.sce.gob.ec/sitio/wp-content/uploads/2022/04/VERSION-PUBLICA-DEL-INFORME-DE-ANALISIS-DE-BARRERAS-NORMATIVAS-%E2%80%93-CASO-CANAMO.pdf>

Torres, M., Santos-Ordóñez, E. (2020). Ecuador -Modern biotechnology in Ecuador-Development and legal framework. In: Chaurasia, A., Hawksworth, D.L.,

Pessoa de Miranda, M. (Eds.). *GMOs. Topics in Biodiversity and Conservation*, 19. Springer, Cham. https://doi.org/10.1007/978-3-030-53183-6_29

Wendt, J. and Izquierdo, J. (2003). Management of appropriate agricultural biotechnology for small producers: case study - Ecuador. *Electronic Journal of Biotechnology*, 6, 15-16. <https://doi.org/10.4067/S071734582003000100002>

Zavala-Choez, F. N. y Vélez-Moreira, E. M. (2020). La gestión de la calidad y el servicio al cliente como factor de competitividad en las empresas de servicios - Ecuador. *Dominio de las Ciencias*, 6(3), 264-281.

CRediT author contribution statement

Kristley Celi Sabando: Conceptualization, Methodology, Investigation, Formal analysis, Project administration, Writing - original draft, Writing - review & editing. **Diego Torres Avellán:** Investigation, Data curation, Validation, Writing - review & editing. **Joffre Paúl Añazco Chávez:** Resources, Supervision, Validation, Writing - review & editing.

