



REGULATORY FRAMEWORKS AND GOVERNANCE OF NEW BREEDING TECHNIQUES: A GLOBAL ANALYSIS OF POLICY IMPACTS ON BIO-INNOVATION

**Marcos regulatorios y gobernanza de las nuevas técnicas de mejoramiento
genético: un análisis global del impacto de las políticas en la bioinnovación**

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Aceptado: 18/11/2025; Publicado: 19/11/2025

ABSTRACT

Bio-innovation, encompassing developments in new breeding techniques (NBTs), presents substantial opportunities for addressing global challenges, though its progress is fundamentally shaped by surrounding regulatory frameworks. Three primary categories of regulations emerge as particularly influential: innovation-promoting frameworks centered on intellectual property rights, regulations targeting societal objectives that indirectly drive innovation, and structural frameworks affecting corporate strategies. Successful bio-innovation systems demonstrate the importance of interdisciplinary collaboration, stakeholder integration, and professional expertise in bridging academic research and industrial applications. Larger companies generally show greater adaptability to regulatory compliance compared to smaller enterprises, while emerging technologies require continuous evolution of governance structures to balance innovation promotion with safety and ethical considerations. Diverse governance models, ranging from permissive to precautionary approaches, influence bio-innovation development and deployment. The effectiveness of these frameworks depends on their implementation flexibility and ability to foster sustainable bio-innovation systems addressing global challenges while promoting economic growth and environmental sustainability. Regulatory harmonization plays a crucial role in fostering cross-border collaboration and mitigating risks associated with emerging biotechnologies. Through strategic alignment of public policies and regulatory frameworks, countries can develop conducive environments for bio-innovation, though challenges persist in regions with limited research funding and infrastructure development. The future trajectory of bio-innovation will increasingly depend on international standards harmonization while maintaining regional specificity in regulatory approaches, requiring ongoing dialogue between policymakers, researchers, and industry stakeholders to ensure balanced oversight supporting scientific advancement without stifling innovation to achieve tangible societal benefits.

Keywords: biosafety, gene editing, genetic engineering, genomics, GMO, intellectual property

RESUMEN

La bio-innovación, que abarca el desarrollo de nuevas técnicas de mejoramiento genético (NBTs), ofrece importantes oportunidades para abordar los desafíos globales, si bien su progreso está fundamentalmente condicionado por los marcos regulatorios existentes. Tres categorías principales de regulaciones destacan por su gran influencia: los marcos

que promueven la innovación centrados en los derechos de propiedad intelectual, las regulaciones que persiguen objetivos sociales que impulsan indirectamente la innovación y los marcos estructurales que afectan las estrategias corporativas. Los sistemas de bio-innovación exitosos demuestran la importancia de la colaboración interdisciplinaria, la integración de las partes interesadas y la experiencia profesional para conectar la investigación académica con las aplicaciones industriales. Las empresas de mayor tamaño suelen mostrar una mayor adaptabilidad al cumplimiento normativo en comparación con las empresas más pequeñas, mientras que las tecnologías emergentes requieren una evolución continua de las estructuras de gobernanza para equilibrar el fomento de la innovación con la seguridad y las consideraciones éticas. Diversos modelos de gobernanza, que van desde enfoques permisivos hasta precautorios, influyen en el desarrollo y la implementación de la bio-innovación. La eficacia de estos marcos depende de su flexibilidad de implementación y de su capacidad para fomentar sistemas de bio-innovación sostenibles que aborden los desafíos globales, a la vez que promueven el crecimiento económico y la sostenibilidad ambiental. La armonización regulatoria desempeña un papel crucial en el fomento de la colaboración transfronteriza y la mitigación de los riesgos asociados a las biotecnologías emergentes. Mediante la alineación estratégica de las políticas públicas y los marcos regulatorios, los países pueden desarrollar entornos propicios para la bio-innovación, si bien persisten desafíos en las regiones con financiación limitada para la investigación y un desarrollo de infraestructura deficiente. La trayectoria futura de la bio-innovación dependerá cada vez más de la armonización de las normas internacionales, manteniendo al mismo tiempo la especificidad regional en los enfoques regulatorios. Esto requiere un diálogo continuo entre los responsables políticos, los investigadores y los actores de la industria para garantizar una supervisión equilibrada que apoye el avance científico sin frenar la innovación y permita alcanzar beneficios sociales tangibles.

Palabras clave: bioseguridad, edición genética, ingeniería genética, genómica, OMG, propiedad intelectual

Forma de citar el artículo (Formato APA):

Ortiz, Rodomiro. (2025). Marcos regulatorios y gobernanza de las nuevas técnicas de mejoramiento genético: un análisis global del impacto de las políticas en la bioinnovación. *Anales Científicos*. 85(2), 67-74. <https://doi.org/10.21704/ac.v86i2.2333>

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1. INTRODUCTION

The emergence of New Breeding Techniques (NBTs) represents a transformative shift in agricultural innovation, offering unprecedented precision in genetic modification while challenging existing regulatory frameworks worldwide. These technologies (Table 1), encompassing gene editing and other genetic engineering related methods, hold significant promise for enhancing crop productivity, improving food security, and advancing sustainable agriculture.

Table 1. A few promising new breeding techniques (NBTs) falling under the regulatory frameworks

Technique category	Examples	Description	Regulatory considerations
Gene editing	CRISPR, Base editing	Precise modifications to DNA sequence	Varies by country; some exempt from GMO regulation
Epigenetic modification	Gene expression regulation	Alters gene activity without changing DNA sequence	Often regulated based on final product characteristics
Cisgenesis	Genetic modification using species-compatible genes	Uses genes from sexually compatible species	Regulation varies; some countries treat similarly to conventional breeding
RNA interference	Gene silencing techniques	Controls specific gene expression	Regulated based on mechanism and application
Reverse breeding	Double haploid technology	Creates homozygous lines quickly	Generally considered a crossbreeding technique

The global governance landscape surrounding NBTs is characterized by substantial heterogeneity, reflecting diverse approaches to regulation and oversight. While Argentina pioneered regulatory guidelines in 2015 (Whelan & Lema 2015), establishing itself as a reference center for biosafety under the United Nations' Food and Agriculture Organization (FAO), other nations have adopted varying frameworks (Fernández Ríos et al. 2024). This regulatory diversity brings complex challenges for international coordination and trade, particularly as countries grapple with whether NBT-derived products should be regulated similarly to genetically modified organisms (GMOs).

Recent developments have seen increasing regional cooperation, exemplified by the Southern Agricultural Council (CAS), which brings together agricultural ministries across Argentina, Bolivia, Brazil, Chile, Paraguay, and Uruguay. Through Technical Group 5 (GT5-CAS), these nations have committed to promoting science-based decision-making and avoiding unscientific

barriers to trade in gene-edited agricultural products (Fernández Ríos et al. 2024).

The regulatory status of NBTs remains dynamic, with frameworks evolving rapidly. Multiple countries now conduct analyses on a case-by-case basis, focusing on novel combinations of genetic material as a threshold for regulation (Seyran & Craig 2018). This approach ensures consistency with conventional breeding regulations when products are indistinguishable, prioritizing trait assessment over technology-based oversight.

Despite these advances, significant challenges persist. Regulatory uncertainty affects development costs and innovation pathways, particularly impacting small enterprises and academic institutions. The lack of international harmonization creates complexities for researchers, breeders, and policymakers, underscoring the need for clear, science-based regulatory approaches that balance innovation with risk assessment.

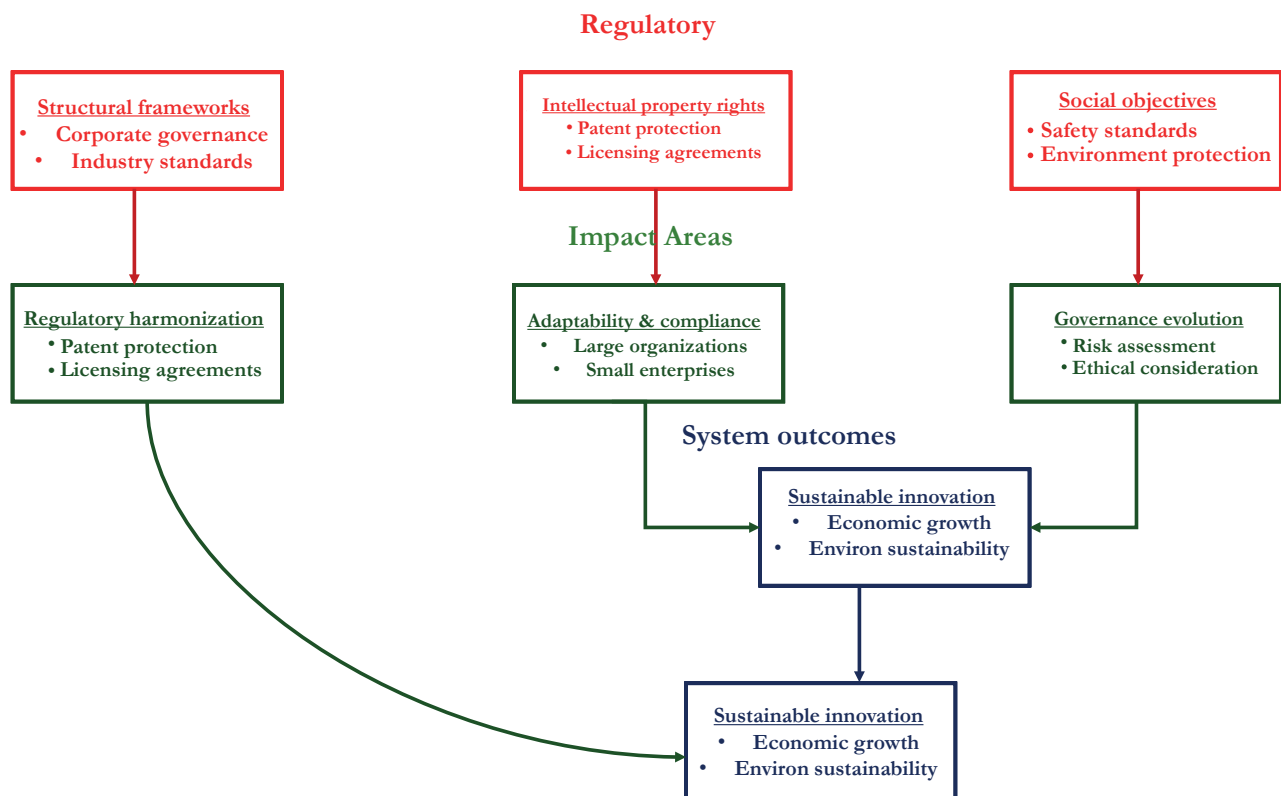


Figure 1. Regulatory aspects, potential impacts and system outcomes shaping the bio-innovation landscape

Growing international consensus recognizes the importance of coordinated oversight systems for NBT crops, particularly in addressing food security challenges and sustainable agricultural development (Figure 1), such as global population growth, climate change impacts, land degradation and persistent human malnutrition. Effective governance requires careful consideration of ethical, social, and economic implications, fostering public dialogue and ensuring transparency to build trust and facilitate responsible deployment of these technologies.

2. A BIO-INNOVATION REALITY: AGROBIOTECHNOLOGY

Agrobiotechnology represents the integration of biological tools into agricultural practices, fundamentally transforming how we approach farming and crop development. This field encompasses several interconnected aspects that collectively enhance agricultural productivity and sustainability.

At its core, agrobiotechnology manifests through various sophisticated techniques (Ortiz 2014), including tissue culture methods that generate clean planting materials, particularly vital for vegetatively propagated crops. Genetic engineering stands as another cornerstone application, enabling the development of Bt insect-resistant cultivars of cotton and maize, alongside herbicide-tolerant germplasm of cotton, maize, oilseed rape, and soybean. Furthermore, genetic modification has yielded drought-tolerant maize cultivars and nutritionally enhanced variants, exemplified by Golden rice.

Modern crossbreeding practices have undergone significant advancement through DNA marker-assisted methodologies, which accelerate genetic progress through precise marker-aided backcrossing techniques and efficient breeding line conversion processes. These advances are complemented by genomic estimated breeding values (Desta and Ortiz 2014), facilitating enhanced selection protocols through speed breeding and phenomics applications (Admas *et al.* 2024).

The biological dimension of agrobiotechnology extends into crop protection and resilience enhancement, where biological control agents and biopesticides serve as sustainable alternatives to traditional chemical pesticides. Moreover, microbiome research has emerged as a crucial component (Dwivedi *et al.* 2025), contributing substantially to improved crop resilience through sophisticated microbial interactions that strengthen plant defenses and enhance overall agricultural sustainability.

3. WHAT ARE NEW BREEDING TECHNIQUES?

They are advanced plant breeding methods combining crossbreeding knowledge with modern agrobiotechnology tools (Ortiz 2014). These techniques have emerged as powerful tools for genetic improvement of crops, thus offering more precise and efficient ways to develop desirable traits viz. a viz. crossbreeding method. The development and application of NBTs involve several interconnected processes and considerations. Figure 2 shows a comprehensive overview of how these NBTs work and their significance for agrifood systems. NBTs are a significant advancement over crossbreeding methods, which rely on cross pollination and selection (after testing) over multiple generation. NBTs enable direct trait introduction through precise genetic modification. The key characteristics of NBTs relate to precision and speed by direct manipulation of target genes, thus reducing breeding cycle viz. a viz. crossbreeding and having more predictable outcomes. The most popular NBTs are gene editing, RNA dependent DNA-directed RNA interferences (RNAi),

oligonucleotide directed mutagenesis and site directed nucleases. They are useful for addressing global food security under a changing climate (Pixley *et al.* 2022). Despite its advantage, NBTs require a careful consideration of regulatory frameworks, public acceptance, and equitable access to ensure their benefits reach all stakeholders in the agricultural sector. Regulatory approval is essential for commercializing gene edited crops to ensure their biosafety and of their products.

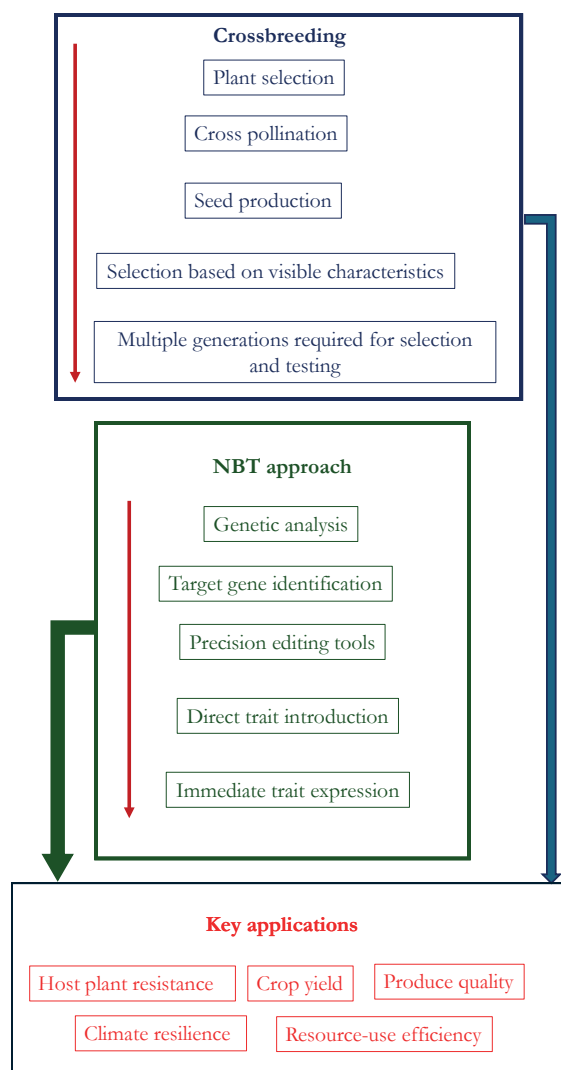


Figure 2. Crossbreeding, new breeding techniques (NBTs) and key applications in agrifood systems

4. GOVERNANCE, POLICY AND REGULATIONS

Governance functions as a comprehensive system encompassing rules, institutions, and practices that guide decision-making processes (Kraak *et al.* 2024). While traditionally associated with governmental bodies, modern governance extends far beyond traditional boundaries to incorporate civil society organizations, private sector entities, and international organizations, creating a complex interplay of stakeholders and interests.

Policy development emerges as a strategic planning mechanism, manifesting as high-level plans or courses of action designed to achieve specific objectives. Within the agricultural domain, these take various forms, including national agricultural policies, biosafety protocols, and intellectual property rights frameworks. Regulations, serving as the operational backbone of these policies, materialize as legally binding rules and procedures that facilitate practical implementation. Examples include mandatory labeling requirements, environmental risk assessment protocols, and structured approval processes for novel cultivar development.

Frameworks assume a pivotal role in modern agricultural governance, primarily functioning as risk mitigation instruments. Their effectiveness stems from their comprehensive approach to addressing multifaceted challenges, including health-related concerns, environmental impacts, and socioeconomic considerations. Beyond risk management, frameworks contribute significantly to establishing public trust through enhanced transparency and accountability mechanisms. They foster innovation by building predictable and supportive environments for research and development initiatives. Furthermore, frameworks promote equity by ensuring that emerging breeding technologies benefit smallholder farmers and vulnerable populations, thereby addressing historical disparities in agricultural development.

According to Dwivedi *et al.* (2017), the alignment of governance structures, policy frameworks, and regulatory mechanisms is essential for realizing an ideal food system. Such a system must simultaneously deliver multiple critical outcomes: adequate human nutrition and health benefits, preservation of biodiversity, avoidance of negative ecological impacts, and assurance of farmer livelihoods. Additionally, it must maintain diverse landscapes while ensuring equitable access to fundamental resources such as land, water, seeds, and other essential inputs. Through this integrated approach (Burgaz *et al.* 2024), it becomes feasible to realize the fundamental aspirations of global agrifood systems, specifically in terms of equity, inclusivity, nutritional value, health promotion, and sustainability.

5. REGULATORY FRAMEWORKS

Three distinct yet interconnected regulatory frameworks shape the landscape of bio-innovation ecosystems. Innovation-promoting frameworks center on intellectual property rights and patent protection systems, creating mechanisms for enterprises to safeguard their innovations and recover investments. Through licensing agreements, these frameworks facilitate technology transfer while generating financial incentives that fuel ongoing research and development initiatives. For instance, patent protection for novel agrobiotechnology processes enables enterprises to profit from their discoveries while maintaining competitive advantages in the market.

Regulations targeting societal objectives focus on broader societal goals rather than direct innovation support. These

regulations establish safety standards for biological products and processes, implement environmental protection measures, and define ethical boundaries for research and development. Biosafety protocols serve as prime examples of such regulations, ensuring genetically modified organisms do not harm agroecosystems. Structural frameworks, meanwhile, influence organizational operations and business strategies by defining corporate governance requirements, establishing industry-wide standards and practices, and guiding resource allocation and operational procedures. Laboratory accreditation and quality control systems exemplify these structural frameworks in action.

These frameworks demonstrate dynamic interaction, as illustrated in **Figure 1**, showing how they operate together within the bio-innovation ecosystem. The red boxes represent the three core frameworks, while green indicates their immediate impacts and blue shows the ultimate outcomes. Their convergence demonstrates their interconnected nature, as evidenced by how patent protection works alongside safety standards and corporate governance to enable technology development, market access, and sustainable business operations.

Each framework plays a crucial role in the system, with innovation-promoting frameworks providing the foundation for investment and development, while societal objective regulations ensure responsible innovation. Structural frameworks bring the operational environment necessary for implementation. Together, they construct a balanced system that supports technological advancement while protecting society and ensuring sustainable development. This integrated approach proves particularly vital in bio-innovation, where rapid technological progress must be carefully managed to ensure public safety and environmental protection while fostering continued innovation.

6. REGULATORY CHALLENGES FOR NBTS: THE CASE OF GENE EDITING

As noted above, gene editing may transform agricultural innovation by enabling precise modifications to crop genetics, enhancing productivity, produce quality, host plant resistance, and resilience to changing environmental conditions. However, the implementation of gene editing faces substantial regulatory hurdles due to marked variations in oversight approaches across different regions. The European Union maintains a stringent regulatory stance, classifying genome-edited organisms as GMOs, subjecting them to comprehensive pre-market requirements and ongoing monitoring protocols (Purhagen *et al.* 2023). In contrast, some nations in Africa, Asia, and Latin America have adopted more flexible frameworks that distinguish between conventional breeding methods and genetic modifications, particularly for products without foreign DNA (Fernández Ríos *et al.* 2025). These regulatory disparities create complex challenges for global agricultural innovation. The varying requirements across regions significantly impact commercialization timelines and costs, as developers must navigate multiple regulatory

pathways and conduct redundant testing procedures. Small enterprises face difficulties, as they often lack the resources necessary to comply with diverse regulatory requirements, potentially limiting their participation in technological advancement.

The differences in regulatory approaches affect not only development costs but also product traceability and international trade. When regulatory frameworks vary significantly between regions, it becomes increasingly difficult to ensure consistent monitoring and safety assurance across borders. This situation often leads to delays in bringing innovative products to market, ultimately affecting research and development decisions as companies must carefully consider regional regulatory requirements when selecting crops for improvement. The varying levels of oversight create distinct environments for innovation across different regions. More flexible regulatory approaches, particularly in Latin America, have demonstrated success in encouraging local technological development and participation by smaller enterprises (Genetic Engineering and Society Center 2023). For instance, Argentina's prior consultation system has proven effective in facilitating agricultural innovation while maintaining safety standards (Lewi *et al.* 2025). Similarly, China has implemented streamlined approval processes lasting one to two years, focusing primarily on food safety and environmental impact assessments (Yang and Zhou 2024).

These regulatory variations significantly influence global trade patterns and technological adoption rates. While strict regulations in regions like Europe may provide high levels of consumer protection, they also increase development costs and reduce returns on investment, potentially discouraging innovation. In contrast, more flexible frameworks tend to accelerate commercialization timelines and encourage broader participation in agricultural biotechnology development, particularly among small and medium-sized enterprises.

The current regulatory landscape presents both opportunities and challenges for the future of gene editing technologies. As these technologies continue to evolve and play increasingly important roles in addressing global challenges such as food security and climate change, finding balance between safety oversight and innovation becomes crucial. The success of regional harmonization initiatives, such as the ABRE-Bio agreement between Latin American countries (Zarate *et al.* 2023), demonstrates potential pathways toward more coordinated international approaches while maintaining appropriate safety standards.

7. FACILITATING ACCEPTANCE OF NBTs IN THE GLOBAL SOUTH

Limited regulator capacity, insufficient funding, public acceptance issues, technical expertise gaps, and coordination difficulty are the main hurdles for adopting NBTs in most of the developing world. Often, the debate in the Global South around agrobiotechnology is influenced by the concerns from the members of the

Organization for Economic Co-operation and Development (OECD), which may not align with their urgent food security needs.

The developing world faces several interconnected challenges in implementing NBTs, with scientific capacity limitations forming a critical bottleneck. The persistent brain drain phenomenon continues to erode local expertise, as scientists migrate to better-equipped facilities in developed nations, while insufficient funding for research and development further compounds these difficulties. Compounding these issues, many developing countries lack adequate research infrastructure, creating significant barriers to independent technology development and adaptation.

Regulatory challenges present another major obstacle to NBT implementation. Many developing nations struggle with inadequate regulatory frameworks due to insufficient technical expertise and limited institutional capacity. This often leads to what experts' term "regulatory paralysis," where approvals for NBTs are significantly delayed or denied entirely due to inadequate risk assessment capabilities. The lack of robust regulatory agencies with sufficient technical expertise hampers the ability to conduct proper safety evaluations and monitoring, effectively blocking access to potentially beneficial technologies.

Public perception challenges significantly impact NBT adoption in developing regions. Anti-GMO campaigns, often originating from northern countries and receiving foreign funding, contribute to widespread misinformation and biased public perception. Despite scientific evidence supporting the benefits of NBTs, political opposition frequently aligns with public skepticism, creating additional barriers to technology adoption. This resistance persists even when technologies demonstrate clear potential benefits for local agriculture and food security.

Intellectual property rights present a particularly challenging barrier for smallholder farmers in developing nations. Strong patent protection by multinational corporations also limits access to NBT seeds, making these potentially beneficial technologies unaffordable for many small-scale agricultural producers. This concentration of ownership in the hands of a few companies creates significant market access barriers, potentially excluding the very farmers who could benefit most from improved cultivars ensuing from the use of NBTs.

The interplay between these challenges leads to complex implementation barriers. For instance, inadequate regulatory frameworks often stem directly from insufficient scientific capacity, while public opposition can further reduce political support for strengthening regulatory agencies. Similarly, intellectual property constraints are exacerbated by limited local research infrastructure, making it difficult for developing nations to develop their own adapted versions of NBTs. Understanding these interconnected challenges is crucial for developing effective strategies to enhance NBT adoption in developing regions.

Recent developments suggest potential pathways forward. Some African countries, such as Kenya and Nigeria, have made progress by establishing guidelines that distinguish between conventional, intermediate, and transgenic products, applying different levels of regulation based on the nature of genetic modification (Adegbañu et al. 2024, Akinbo et al. 2025). These adaptive approaches demonstrate that developing nations can create balanced regulatory frameworks that address both safety concerns and innovation needs. Additionally, regional cooperation initiatives, such as the New Partnership for Africa's Development (NEPAD) program, show promise in strengthening national regulatory capacities and promoting harmonized biosafety policies across member states.

The success of these emerging solutions depends heavily on international cooperation and knowledge transfer. Developed nations can play a crucial role by supporting capacity building programs and sharing expertise in regulatory development. Furthermore, flexible licensing arrangements and technology transfer agreements could help make NBTs more accessible to smallholder farmers while maintaining necessary safety standards. Addressing these challenges comprehensively requires a coordinated approach that considers the unique circumstances and needs of developing nations while ensuring appropriate safeguards for environmental and human health.

8. OUTLOOK

An approach focusing on developing crops that address specific local challenges such as abiotic stress adaptation, host plant resistance, and enhanced nutrition represents a crucial strategy for fostering the utilization of NBTs in crop genetic improvement throughout the Global South. This needs-based approach aligns directly with regional priorities and demonstrates immediate practical value for local agricultural communities.

Regional cooperation stands as a vital component in establishing effective frameworks for NBT implementation. By harmonizing country-level policy structures, sharing specialized expertise, and streamlining regulatory processes, nations can collectively reduce their individual administrative burdens while maintaining rigorous standards. This collaborative approach enables more efficient resource allocation and accelerates the development timeline for beneficial agricultural technologies.

Public-private partnerships (PPPs) emerge as powerful instruments for channeling investment into NBT development, particularly when focused on accelerating pro-poor agricultural innovations. Their effectiveness is significantly enhanced when they actively support local innovation ecosystems through targeted funding of indigenous research initiatives and startup ventures. This strategic approach helps establish sustainable, self-reliant bio-innovation environments that respond directly to regional needs rather than external imperatives.

The establishment of robust regulatory frameworks requires careful consideration of multiple critical

elements. Risk assessments must be grounded firmly in scientific evidence rather than emotional or political considerations, ensuring decisions reflect objective reality rather than subjective influences. Approval processes should operate within predetermined timelines and follow well-defined procedural steps, eliminating unnecessary delays that could impede technological progress. Open channels of communication with farmers, consumers, and civil society organizations serve as essential mechanisms for addressing concerns and cultivating public trust and confidence in NBT applications.

Any policy on intellectual property rights requires a thoughtful calibration to balance competing interests effectively. While providing adequate incentives for innovation is crucial, these policies must simultaneously ensure accessibility of NBT's benefits for smallholder farmers. This delicate balance can be achieved through carefully crafted compulsory licensing provisions or public-private benefit-sharing agreements that recognize both the need for innovation incentives and equitable access to beneficial NBTs.

Creating an enabling environment for NBT utilization necessitates comprehensive investment in both local research and development infrastructure and human capacity enhancement. Science-based regulatory systems must be strengthened while maintaining efficiency, and regional collaboration frameworks should be reinforced to facilitate policy harmonization. Transparent and inclusive public engagement processes help maintain momentum for NBT adoption by addressing stakeholder concerns proactively.

Ultimately, policymakers face the imperative of prioritizing food security objectives over ideological divisions, leading to the development of context-specific, pro-poor policies that enable effective NBT deployment in crop improvement programs. The success of this endeavor relies heavily on close collaboration between scientists, innovators, and farmers to develop practical, user-friendly technological solutions. Clear communication of scientific benefits and risks remains essential throughout the implementation process. Through effective governance mechanisms, policy and regulatory frameworks can transform from potential barriers to innovation into foundational elements supporting sustainable, equitable food security outcomes throughout the Global South.

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