

Advancing Philippine Agriculture: Strategic Framework for the Commercialization of Biotech Innovations

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Policy Implications/Recommendations

- A well-defined vision, advocacy efforts, continuous financial support for research and development, significant investment in key capabilities for product commercialization, and collaboration with companies, research institutions, and government agencies can pave the way for sustained growth and success of biotech commercialization in the Philippines.
- The Philippines needs comprehensive legislation for biotechnology innovations and its products to strengthen the regulatory framework and provide robust legal protection against unjustified legal actions.

Introduction

The Philippines is uniquely positioned to lead in the development and commercialization of biotechnology products in Southeast Asia, having consistently supported the safe and responsible use of modern biotechnology for national development and pioneered the implementation of a regulatory framework for genetically modified (GM) crops in the region. This leadership position is reinforced by significant achievements in traditional biotechnology, genetic engineering, and gene editing, showcasing the country's robust capacity for innovation in agricultural science.

The regulatory landscape for biotech products in the Philippines is both comprehensive and adaptive, ensuring the safety and efficacy of modern biotech products through a well-structured framework. Adherence to international standards in assessing the food and environmental safety of biotech-derived products ensures that all products released into the market are safe for human and animal consumption and do not pose environmental risks. The country's science-based biosafety system is essential for ensuring that biotech innovations are developed and commercialized responsibly and safely.

Support for biotech research and development (R&D) is strong in the Philippines, with various government initiatives and collaborations with research institutions and the private sector. These efforts are crucial for fostering innovation and ensuring that biotech advancements contribute positively to agriculture and food security. Funding from the private and public sectors for biotech research and capacity-building programs are some of the measures implemented to support the growth of the biotech sector. To further strengthen the regulatory framework and provide legal protection for long-term strategic plans and programs, there is a recommendation to enact comprehensive legislation for genetically modified organisms (GMOs) and GM products.

This policy brief discusses the current policy landscape, regulatory framework, and status of local use and development, with key recommendations on biotech commercialization to guide policymakers in creating a supportive environment for biotech innovations in the country.

Consistent Support to Biotechnology in the Philippines

The Philippines has consistently demonstrated robust support for biotechnology, recognizing its potential to drive agricultural productivity, enhance food security, and promote sustainable development. This commitment dates back to the establishment of the National Institutes of Biotechnology and Applied Microbiology (BIOTECH) at the University of the Philippines Los Baños (UPLB) in 1979, under a presidential decree issued by former President Ferdinand Marcos, Sr. The creation of BIOTECH marked the institutionalization of biotechnology research and development (R&D) in the country, focusing on various biotechnological applications to support agriculture, health, and industry. This commitment continued under subsequent administrations. During President Corazon Aquino's term from 1986 to 1992, biotechnology was identified as a flagship program of the Department of Science and Technology (DOST). This era saw the establishment of the National Committee on Biosafety of the Philippines (NCBP) through Executive Order No. 430 in 1990, which laid the foundation for the country's biosafety regulatory framework. President Fidel V. Ramos further reinforced this commitment by making biotechnology a major component of the science and technology program from 1992 to 1998, leading to the establishment of a network of biotechnology institutes across the University of the Philippines (UP) campuses. President Joseph Estrada was also a strong supporter of biotechnology, being the primary author of the law that established the Philippine Carabao Center (PCC) when he was a Senator. When he became President, agricultural biotechnology was further promoted in government programs.

In 2001, President Gloria Macapagal-Arroyo issued a national policy statement emphasizing the government's support for the safe and responsible use of modern biotechnology to achieve food security, equitable health services, sustainable environmental management, and industrial development. This policy underscores the government's strategic vision of integrating biotechnology into national development goals and policies. Furthermore, her Presidential Proclamation No. 1414 signed in 2007 designates the last week of November each year as National Biotechnology Week. This initiative aims to raise public awareness and understanding of biotechnology, highlighting its contributions to

agriculture, health, and environmental sustainability through various activities organized by key government agencies. The administration of President Benigno Simeon Aquino III continued to support the adoption of biotech crops, with the country remaining one of the leading countries in the global adoption of these products, including the commercial planting of GM corn. His government also continued budgetary support for various biotechnology research programs and projects, including for the Philippine Rice Research Institute (PhilRice), which was co-developing Golden Rice with the International Rice Research Institute (IRRI), the Institute of Plant Breeding of the University of the Philippines Los Banos (UPLB-IPB), which was developing Bt eggplant, the then Cotton Development Authority (CODA, now integrated under the Philippine Fiber Industry Development Authority or PhilFIDA), which was developing Bt cotton, and the UP System, where the Philippine Genome Center (PGC) is housed.

The same strong budgetary support continued under President Rodrigo Duterte, in which the administration issued the current guidelines for GM plants and plant products and gene-edited plants, as well as the issuance of biosafety permits for the commercial propagation of Golden Rice and Bt eggplant. The biosafety permit for the commercial propagation of PhilFIDA's Bt cotton was issued under the current administration of President Ferdinand Marcos, Jr. as well as the certificates of non-coverage for three plant breeding innovations (PBIs) products: two banana products with reduced-browning traits and tomato variety exhibiting high levels of gamma-aminobutyric acid (GABA), an amino acid that aids in relaxation and helps lower blood pressure. These efforts illustrate the Philippines' holistic approach to fostering biotechnology, ensuring that regulatory frameworks, public awareness campaigns, and strategic policies collectively support the growth and integration of biotech innovations.

Science-Based, Robust, and Functioning Regulatory System

The Philippines' regulatory framework for modern biotechnology is designed to ensure the safe and effective development, commercialization, and use of biotech products. A cornerstone of this framework is Executive Order No. 514, which updated EO 430 and established the National Biosafety Framework (NBF) in 2006. The NBF mandates strengthening the NCBP, tasked with overseeing biosafety regulations and coordinating efforts among various government agencies involved in biotechnology regulation. This executive order emphasizes a science-based approach to risk assessment and management, ensuring that potential risks associated with GMOs are thoroughly evaluated to protect human health and the environment. Additionally, the NBF promotes public participation in biosafety decisions, enhancing transparency and accountability in the regulation of biotech products.

The Joint Department Circular (JDC) No. 1, Series of 2021, builds upon the foundation laid by EO 514 by providing updated guidelines for the research, development, handling, and use of GMOs in the Philippines. This interdepartmental circular is a collaborative effort of the DOST, Department of Agriculture (DA), Department of Environment and Natural Resources (DENR), Department of Health (DOH), and the Department of the Interior and Local Government (DILG). The JDC aims to streamline the regulatory process for GMOs, reducing bureaucratic delays and improving efficiency. It mandates comprehensive risk assessments to ensure that GMOs do not pose significant risks to human health and the environment, includes guidelines for conducting field trials, commercial release, and post-release monitoring, and emphasizes the importance of and provides mechanisms for public consultation and transparency in the regulatory process.

Complementing JDC no. 1, s2021 is the Department of Agriculture Memorandum Circular No. 8, Series of 2022, which provides guidelines for the regulation of products of gene-editing technologies applied in plants, or so-called products of PBIs. Through a well-defined technical evaluation and determination process, the circular establishes procedures to classify whether PBIs are considered GMOs under JDC no. 1, s2021, based on whether they contain novel combinations of genetic material obtained through modern biotechnology. Products identified as GMOs undergo the regulatory processes specified in the JDC, while products determined as non-GMOs are considered as conventional products, and then issued a certificate of non-coverage from the JDC. This approach ensures that the evaluation and regulation of PBIs are precise and science-based, maintaining the robustness and effectiveness of the Philippine biotech regulatory system.

Alignment with International Standards and Best Practices

The Philippines prioritizes adherence to international standards and best practices in assessing the food, feed, and environmental safety of biotech-derived products. These include standard-setting bodies, international treaties related to biotechnology, and international initiatives to promote safety in the use of biotech products. JDC no. 1, s2021 provides that the country adheres to the Codex Alimentarius Commission, specifically Guideline 44-2003: Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, and Guideline 45-2003: Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. These guidelines provide a rigorous framework for risk analysis and safety assessment of biotech foods. They emphasize the importance of evaluating the potential allergenicity, toxicity, and nutritional effects of foods derived from biotech.

The JDC, the PBIs guidelines, and the National Biosafety Framework are also compliant with the Cartagena Protocol on Biosafety, an international agreement under the Convention on Biological Diversity. This protocol aims to ensure the safe handling, transport, and use of living modified organisms (LMOs) resulting from modern biotechnology and establishes procedures for risk assessment and management, focusing on preventing adverse effects on biodiversity and human health. The Philippine regulatory system for biotech also benefited from the work of the Organisation for Economic Co-operation and Development (OECD) in developing biology consensus documents that offer guidance on the safety and regulatory aspects of biotech products. These documents cover various aspects of environmental safety and facilitate harmonized regulatory approaches across countries. The country's alignment with these international standards and best practices ensures that its biotech products are evaluated according to internationally recognized scientific principles and remain competitive in the global market, while the country also benefits from global collaboration in biotechnology R&D.

Approved and Commercialized Biotech Products in the Philippines

The Philippines has made significant advances in the commercialization of various biotech products, both traditional and modern, locally developed and adopted from abroad. These advancements have been driven by collaborative efforts among academia, public research institutions, government and international agencies, and the private sector.

The country has developed various homegrown biotech products, showcasing the country's capability to develop and commercialize biotechnology innovations tailored to local agricultural needs. Notable examples pioneered by local scientists include tissue culture technologies for the production of macapuno and the micropropagation of orchids and the induction of mango flowering using potassium nitrate. There are also biotech products that have been developed to enhance crop growth and yield, such as Bio N™, a charcoal-based inoculant containing nitrogen-fixing bacteria, and MycoGroe, a mycorrhizal inoculant. BioMeg is another microbial inoculant that significantly enhances crop yield and nutritional quality. This product supports sustainable farming practices by promoting healthier soil and increasing crop resilience.

Bt corn is the first and one of the most significant GM crops commercialized in the Philippines cultivated since 2003. High yielding corn varieties were genetically engineered to contain resistant genes from the bacteria *Bacillus thuringiensis* (Bt) against the Asiatic corn borer, a major corn pest in Asia. This biotech crop reduces the need for chemical pesticides, leading to higher yields and increased profits for farmers. Herbicide tolerant corn has also been allowed commercial planting in the country, which trait was later stacked with Bt corn to simultaneously address the two important problems of corn, the target insect pest and weeds. GM corn is widely adopted in the Philippines, significantly benefiting around 350,000 smallholder farmers and their communities by improving rural incomes and reducing the environmental impact of traditional farming practices. The area planted with GM corn has increased significantly during the past two decades, with the current area covering over 720,000 hectares.

Golden Rice, also known as Malusog Rice, is a genetically modified rice variety biofortified with beta-carotene, a precursor of vitamin A. Developed to address vitamin A deficiency, which is prevalent in many developing countries including the Philippines, this locally developed

"Pinoy biotech" product developed by PhilRice and IRRI has undergone extensive testing and regulatory review. In July 2021, Golden Rice received a biosafety permit for commercial propagation, making the Philippines the first country to approve for cultivation this nutritionally enhanced GM rice. Bt eggplant, another Pinoy biotech product, is genetically modified to resist the eggplant fruit and shoot borer, and received approval for commercial cultivation in 2022. This GM vegetable, developed by UPLB, significantly reduces the need for chemical pesticide sprayings, promoting more sustainable agricultural practices, and offering benefits to farmers by reducing crop losses and minimizing exposure to harmful pesticides. The third Pinoy biotech crop is Bt cotton, developed by CODA (now integrated under PhilFIDA) and recently obtained its biosafety permit for commercial planting. The government and its private sector partners hope to revive the cotton and textile industry in the Philippines that was thriving until the early 1980s, before the pink bollworm devastated the domestic cotton plantings.

The Philippines has also approved several biotech crops for direct use as food, feed, and processing (FFP). These include a variety of GM crops such as corn, soybean, canola, potato, sugar beet, alfalfa, and cotton. As of the latest data from the Bureau of Plant Industry Approval Registry, around 65 single GM events have been approved for FFP, which ensures that the country has access to a diverse range of biotech products, supporting food and nutritional security.

Strategic Recommendations

To ensure the sustained growth and success of biotechnology commercialization in the Philippines, it is essential to build on current achievements and address ongoing challenges. These strategic recommendations are designed to create a supportive and dynamic environment for biotech innovations, enhancing the country's leadership in agricultural biotechnology, improving food security and environmental sustainability, and driving economic growth.

Defining a Clear Vision and Objectives. Establishing a clear vision for the future of biotech in the Philippines is crucial. This vision should articulate how biotech innovations will address key challenges not only in agriculture but also in medicine, healthcare, green manufacturing, and industry toward a robust bioeconomy. A well-defined vision hopefully in the form of a national biotech industry roadmap can guide the development of commercial objectives and capabilities, ensuring that the country's biotech sector remains focused and aligned with its long-term goals.

IEC, Advocacy, and Engagement with Key Opinion Leaders. Effective information, education, and communication (IEC) strategies are essential for building public understanding and acceptance of biotech products. Advocacy efforts should continue to focus on educating the public about the benefits and safety of biotech innovations through various channels, including community outreach, educational programs, media campaigns, and stakeholder engagement. Transparent communication about the regulatory processes and safety assessments can help address public concerns and build trust. Advocacy initiatives with educational institutions, farmer organizations, industry associations, and non-governmental organizations amplify the message and reach a broader audience. Engaging with key opinion leaders (KOLs) early in the commercialization process can provide valuable insights and support. KOLs, with their credibility and expertise, can help generate awareness, drive adoption of biotech products, and provide credibility to new innovations. They should be continuously informed of interesting developments of laboratory, field trials and/or clinical studies, and their involvement in promotional activities can significantly impact the acceptance and adoption of biotech products.

Investing in Commercial Capabilities. Successful commercialization requires continuous financial support for research and development and significant investment in key capabilities for product commercialization, including compliance with a continuously-being-updated regulatory system, market research and product matching, and consumer engagement. Early and sustained investments in these areas can help biotech products achieve market readiness and ensure a smooth transition from R&D to commercial stages. This also involves developing a comprehensive marketing strategy for the successful commercialization of biotech products, which includes leveraging digital marketing, social media, industry conferences, and educational initiatives to raise awareness and promote the benefits of biotech products. Finally, efficient sales

and distribution networks are crucial to ensure product availability and market penetration. Agencies or companies engaged in biotech commercialization must consider various distribution channels, including partnerships with distributors, wholesalers, specialty pharmacies, and the likes to reach their target consumers effectively. Understanding customer segments and optimizing supply chain management is essential for maximizing sales and distribution efficiency.

Fostering Collaboration and Partnerships,; Protecting Intellectual Property, and; Creating a Supportive Ecosystem for Biotech Commercialization. Collaboration with other companies, research institutions, and government agencies can enhance the commercialization process. Partnerships can provide access to additional resources, expertise, and market opportunities, facilitating the successful launch of biotech products. Joint ventures, research collaborations, and public-private partnerships can help overcome commercialization challenges and accelerate the development of new biotech innovations. Likewise, intellectual property (IP) protection is vital for maintaining a competitive advantage in the biotech industry. Companies should secure patents, trademarks, and copyrights for their innovations. Additionally, international IP protection and licensing agreements are essential for safeguarding technologies in global markets. Regular IP audits can help monitor and enforce IP rights, minimizing the risk of infringement and protecting market position. Lastly, creating a supportive environment is crucial for the growth of the biotech industry. This involves fostering a collaborative environment and providing the necessary resources, such as biotech hubs, innovation centers, and funding opportunities. The Philippines can ensure continuous advancements in biotechnology by supporting the development of infrastructure, research capabilities, and public-private partnerships.

Enacting Comprehensive Legislation for GMOs and GM Products. Similar to other countries, the Philippines has unfortunately fallen victim to frivolous legal petitions by biotech critics that have reached the highest court of the land. These petitions question the evaluations and approvals of GM crops, notwithstanding the stringent science-based biotech regulations in the country. Such actions have created uncertainty and delayed the progress of biotech commercialization. To strengthen the regulatory framework and provide legal protection against future actions, it is recommended that the Philippines enact comprehensive legislation for GMOs, GM products, and other products developed through biotech innovations. This legislation should institutionalize, by an Act of Congress, the regulatory and approval processes that have been diligently laid down by the Executive Department and its instrumentalities through various administrative issuances. It should codify the roles and responsibilities of various regulatory bodies, sustain the existing mechanisms for public participation, establish timelines for the approval process, and uphold the criteria for safety evaluations based on internationally recognized scientific standards. By doing so, the legislation will ensure that the evaluation process is transparent, predictable, and resilient to legal challenges. It is important to note that the legislation should be designed with flexibility in mind, allowing for adaptive changes in response to the dynamic progress in biotechnology. This adaptive framework will enable the regulatory system to evolve in parallel with scientific advancements and emerging technologies, ensuring that it remains relevant and effective in the face of new developments. Such an approach will support continuous innovation and adaptation, fostering a resilient biotech sector capable of addressing future challenges and opportunities.

Additionally, the legislation should provide robust legal protection for biotech innovations, safeguarding them from unjustified legal actions. This includes establishing clear legal pathways for addressing disputes and ensuring that decisions made by scientific and regulatory authorities are respected and upheld. By creating a strong legal foundation, the Philippines can mitigate the consequences of lawsuits against the advancement of biotechnology and foster a stable environment for biotech research, development, and commercialization. Such a law will not only protect the biotech industry from legal uncertainties but also encourage investment and innovation by providing a secure regulatory environment. It will support the sustainable growth of the biotech sector, future-proofing the regulatory and policy environment, and ensuring that biotech innovations are developed and commercialized in a safe, efficient, and transparent manner. This comprehensive legislation will position the Philippines as a leader in modern biotechnology, driving economic growth and contributing to food security, improved health and wellness, industry development, and environmental sustainability.



Conclusion

The Philippines has made significant strides in biotech innovation, regulatory oversight, and commercialization. By continuing to support R&D, adhering to international safety standards, and maintaining a science-based regulatory framework, the country can enhance its leadership in modern biotechnology adoption and commercialization.

The strategic recommendations outlined in this brief, including defining a clear vision, continuously engaging in focused IEC and advocacy activities, investing in commercial capabilities, fostering collaboration and partnerships, protecting intellectual property, creating a supportive ecosystem, and enacting comprehensive legislation provide a comprehensive roadmap for advancing biotech commercialization in the country.

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