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Report Highlights:

The Philippines has been a pioneer within Asia in adopting biotechnology crops. On April 17, 2024, the Court of Appeals (CA) ruling on the Writ of Kalikasan revoked the biosafety permit for commercial propagation of golden rice and directed the University of the Philippines Los Baños (UPLB) to cease and desist from commercially propagating and conducting activities relating to Bt eggplant. On October 17, 2024, the Philippine Government petitioned the Supreme Court (SC) to review the decision. Prior to the CA's decision, the Philippines has issued four biosafety permits for commercial propagation: cotton (2023), eggplant (2022), golden rice (2021), and corn (2002). The Philippines is the first country in Southeast Asia to issue regulatory frameworks on genetically engineered (GE) crops for cultivation and regulation for plants and plant products derived from the use of plant breeding innovations (PBIs). The country has also drafted the regulations on animal biotechnology but the policy has not been released.

EXECUTIVE SUMMARY

The Philippines continues to be a leader on biotechnology in Southeast Asia, having been the first in the region to have a regulatory framework on genetically engineered (GE) crops. A *Writ of Kalikasan* was issued on golden rice and Bt Eggplant on April 18, 2023. The Court Appeals (CA) ruling on the *Writ of Kalikasan* was issued on April 17, 2024, revoking the biosafety permit for commercial propagation of golden rice and directing the Bt eggplant developer UPLB to cease and desist from commercially propagating and conducting activities relating to Bt eggplant. The biosafety permit for commercial propagation was issued on cotton (2023), eggplant (2022), golden rice (2021), and corn (2002). GE corn area planted has increased from 10,700 hectares in 2003 to 709,000 hectares as of February 2024, estimated at around 85 percent of total corn area in the country.

The Philippines' biotechnology framework is comprised of three regulations: 1) revised Joint Department Circular (JDC1); 2) Department of Agriculture (DA) Memorandum Circular (MC) No. 8, which provides the regulatory policy for importation, handling and use, transboundary movement, release into the environment, and management of GE plants and plants products derived from the use of modern biotechnology; and 3) the National Committee on Biosafety of the Philippines NCBP Resolution No. 1, or, "the Regulation of Plant and Plant Products Derived from the Use of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs)." This regulation covers plants and plant products derived from PBI/NBTs and provides guidance for determining whether or not a specific plant should be regulated as a GE crop.

The revised JDC1 generally streamlined approvals by cutting the number of days for processing an application from 85 days to a maximum of 40 working days, while PBI/NBT regulation determination was shortened to 32 days, with both processes brought into compliance with the Ease of Doing Business law. An additional highlight is the formation of a Joint Assessment Group (JAG) to evaluate applications for field trials, commercial propagation, and direct use.

The Philippines has drafted a regulatory policy for GE animals, but it has not been released. The draft GE animals regulation is applicable to the following: 1) genetically engineered fish and other aquatic resources; 2) domesticated animals and biological products used for animal husbandry for veterinary purposes; and 3) biological agents used for biocontrol derived from the use of modern biotechnology and containing novel combinations of genetic materials. Products of gene editing that do not contain novel combinations of genetic materials are not covered.

The Philippines was the ninth largest market for U.S. agricultural and related products in 2023 with exports reaching \$3.6 billion. The country continues to be the largest U.S. soybean meal market, with \$1.3 billion in sales in 2023.

For more information, please see the following GAIN reports:

GAIN Agricultural Biotechnology Annual 2023
Philippines First in World to Approve Golden Rice for Propagation
Philippines Streamlines Biotechnology Regulations with Revised Joint Department Circular
Genome Edited Plant Regulations Published
FAIRS Annual Country Report

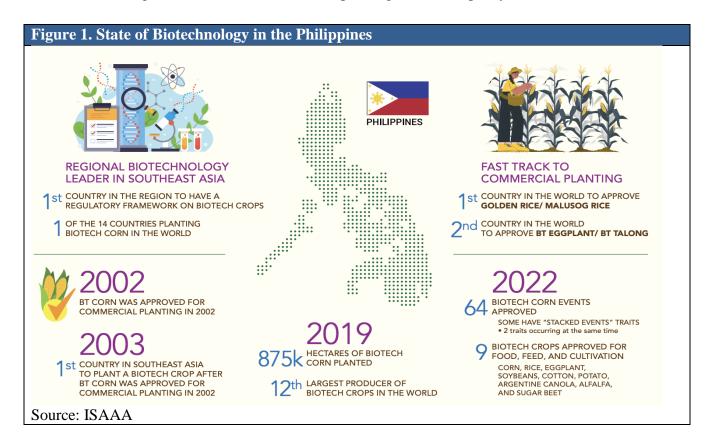
TABLE OF CONTENTS

CHAPTER 1: PLANT BIOTECHNOLOGY	
PART A: Production, and Trade	4
PART B: Policy	9
PART C: Marketing	20
CHAPTER 2: ANIMAL BIOTECHNOLOGY	
PART D: Production, and Trade	21
PART E: Policy	21
PART F: Marketing	22
CHAPTER 3: MICROBIAL BIOTECHNOLOGY	
PART G: Production, and Trade	23
PART H: Policy	23
PART I: Marketing	24
<i>C</i>	

CHAPTER 1: PLANT BIOTECHNOLOGY

The Philippines uses biotechnology as one tool to reach its food security goals, and to modernize its food systems to meet the United Nations <u>Sustainable Development Goal</u> number 2 of zero hunger by 2030. Agricultural biotechnology covers a range of tools, including traditional breeding techniques, to make or modify products, improve plants or animals, or develop microorganisms for specific agricultural uses. Modern biotechnology today includes the tools of genetic engineering.

The country remains a biotechnology leader in Asia, being the first to allow the planting of Bt corn and the first to set up a regulatory framework for genetically engineered (GE) crops. In 2019, the Philippines ranked 12th among the 29 countries in the world planting biotech crops, by area. (ISAAA, 2022).

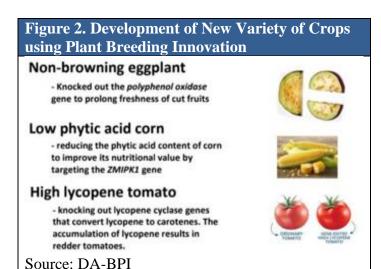


PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT: The University of the Philippines Los Baños-Institute of Plant Breeding (<u>UPLB-IPB</u>) is currently engaged in the development of new variety of crops using new breeding innovation (gene editing).

Ongoing research on rice, corn, banana, and eggplant under confined test and confined use are being undertaken by the International Rice Research Institute (IRRI), Philippines Rice Research Institute (PhilRice), Tropic Biosciences, Del Monte Fresh Produce, and UPLB.

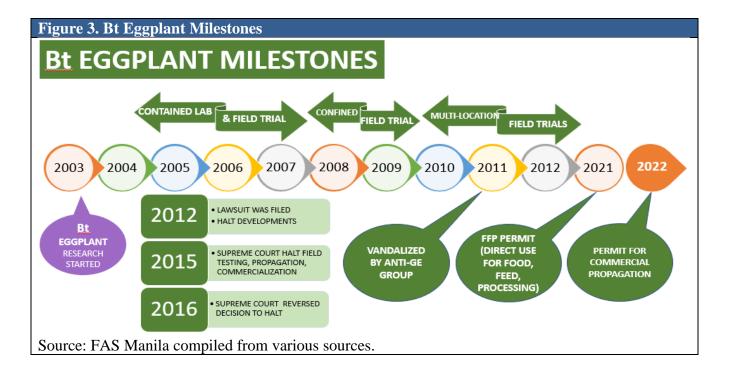
b) COMMERCIAL PRODUCTION: The Philippines has approved four GE crops for commercial propagation: corn (2002), rice (2021), eggplant (2022), and cotton (2023). Commercial propagation of rice and eggplant was stopped following the Court of Appeals (CA) decision on the *Writ of Kalikasan*.



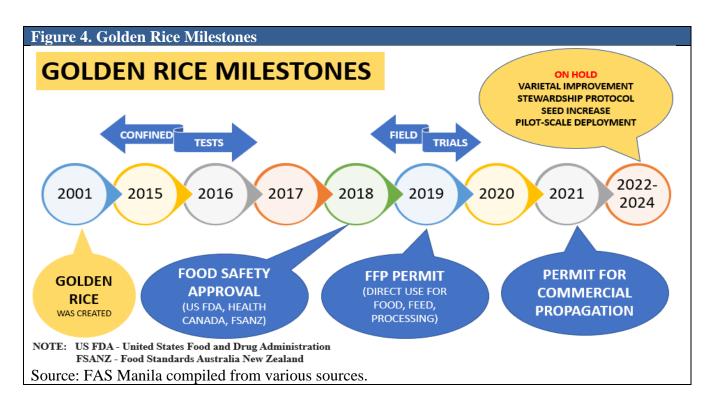
Cotton. On August 24, 2023, the Bureau of Plant Industry (BPI) issued a <u>Biosafety Permit</u> for the commercial propagation of Bt cotton developed by the Philippine Fiber Industry Development Authority (<u>PhilFIDA</u>). Bt cotton is resistant to bollworm (*Heliothis armigera*), as it contains the Bt fusion gene GFM Cry1A, synthesized based on the protein template of Cry 1Ab and Cry 1Ac protein. Bt cotton includes a gene taken from the soil bacterium *Bacillus thuringiensis* (Bt), which was also introduced in corn and eggplant in the Philippines.

PhilFIDA launched the Bt cotton Harvest Festival on May 7, 2024, marking the successful commercial harvest of Bt cotton. Based on PhilFIDA's multi-locational field trials, Bt cotton could yield 3 metric tons (MT) per hectare compared with 1-2 MT using present local varieties. PhilFIDA is collaborating with the Department of Trade and Industry (DTI) to revive the industry to supply the local weavers with locally produced cotton.

Eggplant. The CA ruling on the *Writ of Kalikasan* directed the Bt eggplant developer UPLB to cease and desist from commercially propagating and conducting activities relating to Bt eggplant under the Biosafety Permit issued on October 18, 2022. Bt eggplant contains a natural protein from the soil bacterium called *Bacillus thuringiensis*, which makes it resistant to eggplant fruit and shoot borer (EFSB). This Bt protein is targeted to EFSB and is safe for humans, animals, and other non-target insects. Various scientific studies also showed that Bt eggplant is safe for the environment when planted in open fields and can be an integral component of an Integrated Pest Management program. Reduction on the use of insecticides lowers production costs and provides more income to farmers. The Bureau of Plant Industry (BPI) issued a biosafety permit for direct use for food, feed, or processing for Bt Eggplant on July 21, 2021, determining it safe for consumption.



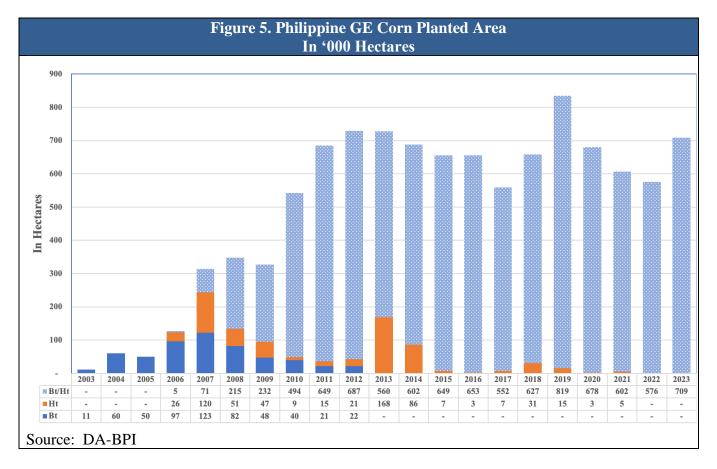
Rice. The CA ruling revoked the <u>biosafety permit</u> for commercial propagation of golden rice, ordering PhilRice to cease and desist from commercially propagating and conducting activities relating to golden rice under the biosafety permit issued on July 21, 2021. The ruling stopped all the activities including the Department of Agriculture's <u>Memorandum Order 19</u> Series of 2021 operationalizing the DA's full support for the deployment of Golden Rice.



On April 2022, Golden Rice was registered with the National Seed Industry Council (NSIC) as NSIC 2022 Rc 682GR2E or *Malusog* 1. Spearheaded by the PhilRice in partnership with the IRRI, the beta-carotene enriched rice aims to reduce vitamin A deficiency. The human body converts beta carotene into vitamin A, which is particularly relevant for impoverished populations who rely on rice for their daily meals. The Bill and Melinda Gates Foundation, the Rockefeller Foundation, United States Agency for International Development (USAID), and the Philippine Department of Agriculture - Biotechnology Program Office (DA-BPO) supported the golden rice project.

Corn. The development of GE corn started in 1996 under a collaborative study of UPLB-IPB and Pioneer Overseas Corporation. Since the approval of the first GE corn for propagation in 2002, more corn transformation events were developed by various companies. On July 27, 2023, the BPI issued the updated list of GE corn events approved for commercial propagation. This is to ensure that proper product stewardship of GM corn and other relevant policies are strictly complied with by all parties concerned. The BPI conducts regular monitoring, and any non-compliance with the existing rules and regulations is dealt with accordingly. There are two general traits developed for yellow corn: 1) insect resistance (Bt), which protects corn from pests, especially the Asiatic Corn Borer; and 2) herbicide tolerance, which allows the use of a single (instead of multiple) broad spectrum herbicide. Since the approval of Bt corn, and Roundup Ready (RR) or herbicide tolerant (HT) corn, companies also developed GE corn with stacked traits (Bt + HT), and the area planted with GE corn grew rapidly. GE corn area increased from 10,769 hectares in 2003 to 709,000 hectares as of February 2024. Currently, nearly all planted GE corn has stacked traits.

Fall armyworm or FAW (*Spodoptera frugiperda*) has been detected across the region. It was found three years ago in the Cagayan Valley region. FAW has severely impacted corn production by causing stunting and destruction of tassels and kernels, reducing grain quality and yield. The infestation has been reported in 12 regions in the country including key producing areas in Northern Mindanao. Seed companies are now doing research on biotech corn varieties resistant to FAW.



- a) EXPORTS: The Philippines prohibits corn exports, although a local industry association has asked the government to lift the restriction when local corn prices are down.
- b) IMPORTS: The Philippines imports a variety of GE crops <u>with approvals for direct use</u> including soybean, corn, cotton, canola, potato, rice, eggplant, and alfalfa. Refer here for the <u>status of applications</u> for direct use.

The Philippines was the ninth largest market for U.S. agricultural and related products in 2023 with exports reaching \$3.6 billion. The country continues to be the largest U.S. soybean meal market, with \$1.3 billion in sales in 2023. Philippine regulations require shipments of various imported plant and plant products to be accompanied by a "Declaration of "GMO" Content" signed by one of the following: the responsible officer from the originating country, an accredited laboratory, the shipper, or the importer.

In August 2021, BPI issued guidelines updating the list of commodities requiring the "GM" declaration, expanding to more products beyond bulk commodities. Importers remain authorized to sign the Declaration of "GMO" Content.

c) FOOD AID: The Philippines is a periodic food aid recipient through the USDA Food for Progress program. The importation of food aid commodities has been unimpeded by GE issues.

d) TRADE BARRIERS:
The recent CA ruling on the Wr
of Kalikasan, which issued the

	ation of GMO (
The shipm	ent may contain a GM ingr	edient:
	Yes No	
f yes, list t	he probable transformatio	n events.
	To be filled as by the pool	Am
	To be filled up by the PQS	
Present	In the Approval Registry	Not in the Approval Registry
-	er janeaussensensens er:	
	in Afr	[Signature]
		Plant Quarantine Officer

Source: DA

judgement to wit: *Item 8 - enjoining any application for contained use, field testing, direct use as food or feed, or processing, commercial propagation, and importation of genetically modified organisms until compliance with Item 7 is established.* The inclusion of all imported GE products created confusion especially among livestock and poultry producers as most feed ingredients are GE. Item 8 from the original CA ruling was removed following a Motion to Reconsider and importers report no issues accessing GE feed ingredients.

PART B: POLICY

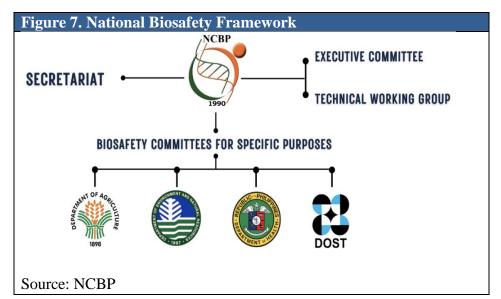
a) REGULATORY FRAMEWORK: The Philippines continues to be a leader in biotechnology in Southeast Asia. It was the first in the region to have a regulatory framework for GE crops, the first in Asia to approve cultivation of a GE crop for food and feed, and the first in the world to approve Golden Rice for cultivation.

Table 1: Biotechnology Policy and Regulation			
Legal Term	Legal Term	Laws and	Legal Definition
(in official	(in English)	Regulations where	(in English)
language)		the term is used	
"Genetically	"Genetically	Joint Department	"living modified organism" under
modified organism	modified	Circular (JDC) No.1,	the Cartagena Protocol on Biosafety
(GMO)"	organism	Series of 2021	and refers to any living organism
	(GMO)"		that possess a novel combination of
		Department of	genetic material obtained through
		Agriculture (DA)	the use modern biotechnology
		Memorandum	
		Circular (MC) No. 8,	

		Series of 2022	
		National Committee	
		on Biosafety of the	
		•	
		Philippines (NCBP)	
		Resolution No. 1,	
		Series of 2020	
Modern	Modern	JDC No.1, Series of	Refers to the application of: 1) in
biotechnology	Biotechnology	<u>2021</u>	vitro nucleic acid techniques,
			including recombinant
		DA MC No. 8	deoxyribonucleic acid (DNA) or
			direct injection of nucleic acid into
		NCBP Resolution	cells or organelles; or 2) fusion of
		No. 1, Series of 2020	cells beyond the taxonomy family,
			that overcome natural physiological
			reproductive or recombination
			barriers and that not techniques used
			in traditional breeding or selection
Plant Breeding	New Plant	JDC No.1, Series of	If contains a novel combination of
Innovations	Breeding	2021	genetic material obtained through
Illiovations	_		
	Techniques	DA MC No. 8	modern biotechnology
		NCBP Resolution	
27 1		No. 1, Series of 2020	
Novel	Novel	JDC No.1, Series of	A resultant genetic combination in a
Combination	combination	<u>2021</u>	living organism that is not possible
		DA MC No. 8	through conventional breeding.
		NCBP Resolution	
		No. 1, Series of 2020	
Plant-incorporated	Plant-	JDC No.1, Series of	Refers to pesticidal substance
protectant (PIP)	incorporated	<u>2021</u>	produced by plants and genetic
	protectant (PIP)		material necessary for the plant to
			produce the substance
Regulated article	Regulated	JDC No.1, Series of	Refers to genetically modified
	article	2021	plants and plant products under the
		DA MC No. 8	scope of the JDC
Responsible	Responsible	JDC No.1, Series of	Refers to an officer appointed by the
officer	officer	2021	applicant for the importation or
officer	omeer	2021	release into the environment of a
			regulate article who shall ensure that
			•
			all appropriate measures are taken to
			prevent significant risks to human
			health and the environment. The
			responsible officer shall be a
			resident of the Philippines and the
			highest-ranking officers of the
			applicant
"Stacked events"	"Stacked	JDC No.1, Series of	Refer to "genetically modified"

	events"	<u>2021</u>	plants and their products that have
			been developed using multiple
			transformation events encoding
			several proteins that confer specific
			traits
"Transformation	"Transformation	JDC No.1, Series of	Refers to the uptake and integration
event"	event"	<u>2021</u>	of specific sequences of DNA in the
			genome of the host organism in
			which the introduced DNA is
			intended to change the phenotype of
			the recipient organism in a
			predictable manner

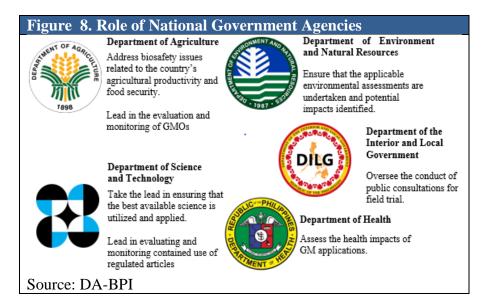
In 1990, Executive Order (EO) 430 created the National Committee on Biosafety of the Philippines (NCBP), tasked to formulate, review, and amend national policy on biosafety, and formulate guidelines on the conduct of activities on genetic engineering. EO 514 further strengthened the committee's work by establishing the National Biosafety Framework, prescribing guidelines for its implementation, and



strengthening the NCBP chaired by the Department of Science, and Technology (DOST) Secretary. It evolved with Administrative Order No. 1 (AO 1) in 2019, and after the Supreme Court ruled that AO 8 was null and void in 2015, was replaced by the Joint Department Circular No. 1 (JDC) in 2016.

In February 2022, the Philippines approved the revised <u>Joint Department</u>

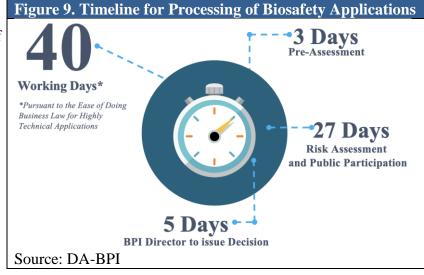
<u>Circular No. 1</u> (JDC1) signed by five departments. DOST, DA, Department of Environment, and Natural Resource (DENR), Department of Health (DOH), and Department of Interior, and Local Government (DILG). JDC1 provides the regulatory policy for importation, handling and use, transboundary movement, release into the environment, and management of GE plants, and plant products. The agencies involved reviewed and finalized the JDC to modernize and streamline the regulatory framework, taking note to comply with the Ease of Doing Business law.



The revised JDC generally streamlined the process by: 1) removing irrelevant requirements or redundant competent national authorities (CNA) roles; 2) reducing the required socio-economic considerations and making local government unit (LGU) endorsement optional; 3) improving text clarity (i.e. pertaining to Food, Feed, Processing applications; 4) introducing text relating to "transportability" of GE approvals from other countries;

5) deregulating GE crops after five years of record of safe use (commercial propagation, and FFP) and biosafety permits will remain valid unless revoked; 6) cutting the days to process an application from 85 days to a maximum of 40 working days in compliance with the Ease of Doing Business law or RA 11032, and any extensions of the time frame will have to be applied, and approved by the Anti-Red Tape Authority; 7) no longer requiring stacked GE plants and derived products to have a separate approval if

their single event components already have existing biosafety permits. An additional highlight is the formation of a Joint Assessment Group (JAG) to evaluate applications for field trial, commercial propagation, and direct use. This shortens the process, where before the different biosafety committees of the four Departments did their assessments independently. The above reforms shorten the approval timeline and are expected to reduce compliance costs and lower the barriers to commercializing biotech crops.



The CA ruling on the Writ of Kalikasan ordered concerned government agencies to perform their mandate under the applicable JDC, by submitting to this court the concrete mechanisms adopted to monitor all activities conducted under the JDC, and all measures taken to strengthen the risk assessment procedure set forth in JDC No1-2021, in accordance with the ruling in this case. The concerned government agencies, however, contend that the JDC1 is within international norms and submitted a Petition for Review to the Supreme Court (SC).

Table 2: Institutions in Crop Biotechnology Policy		
Regulations	Risk assessments, and registrations	
NCBP - mandated to formulate, review,	DENR - conducts risk assessment for impact of	
amend the biosafety guidelines.	biotech crops on the environment	
DOST-Biosafety Committee - processes	DOH - conducts risk assessment for the impact of	
applications for Contained use, and Confined	biotech crops as food on human health	
Test, and issues Certificates of Completion.		
DA-BPI, and DA-BC - consolidate and	DA-Bureau of Animal Industry (BAI) - conducts risk	
evaluate the risk assessment reports.	assessment for the impact of biotech crops as feed on	
The BPI Director issues Biosafety Permit for	animals	
applications for (Multi-location) Field Test,	DA-Fertilizer and Pesticides Authority (FPA) -	
Commercial Propagation, and Direct Use for	registration of plant incorporated protectants (PIP)	
food, feed, or processing		

Source: JDC1

Under the JDC1, the DOST and DA lead the implementation of biosafety guidelines. The other agencies involved are DOH, DENR, and DILG. For ease in compliance, the DOST-NCBP published these biosafety guidelines.

GE crops developed locally and intended to be commercially grown in the Philippines must undergo regulatory processes following the guidelines set forth under the JDC1. Only after a biosafety permit is issued with satisfactory completion and an approval of Commercial Propagation application is granted can the GE crop be registered with the National Seed Industry Council (NSIC). Under the Plant Variety Protection Act (PVPA), GE developers reserve the right to give exclusive contracts to seed companies for the multiplication and distribution of seeds to retailers and ultimately sale to the farmers.

Compliance with Other Regulations

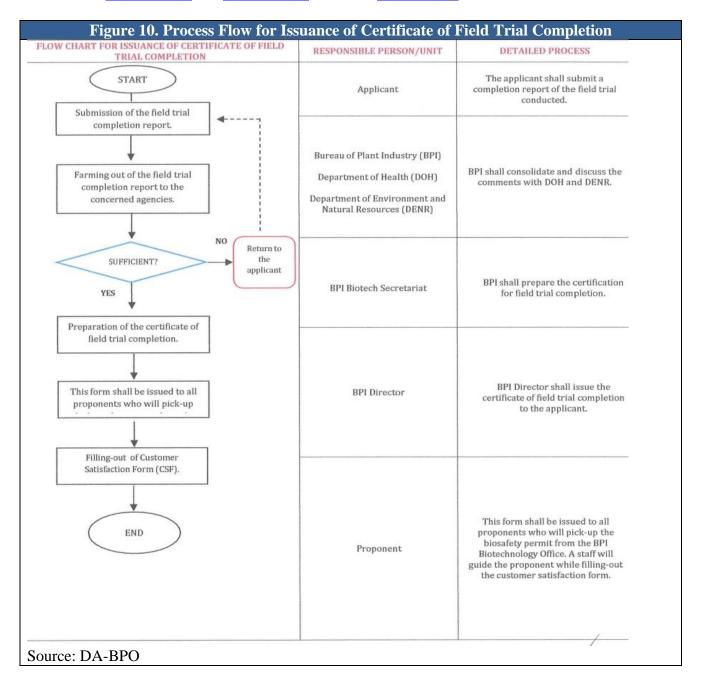
The Certificate of Non-Coverage from the JDC1 shall not excuse the product developer from complying with other relevant regulations of the DA, and other government agencies, such as those involving quarantine, pest risk analysis, varietal registration, and crop-specific standards and programs, where warranted.

b) APPROVALS/AUTHORIZATIONS: The status of applications for <u>direct use</u>, <u>field trial</u>, and <u>propagation</u> are listed on the <u>DA-BPI Biotechnology website</u>. In accordance with the JDC1, the Joint Assessment Group (JAG) shall review the application within ten working days upon acceptance of the application.

To date, there are two pending applications for direct use: herbicide tolerant <u>Soybean MON 94313</u> and HB4 Soybean and one for commercial propagation, Corn MON 87427.

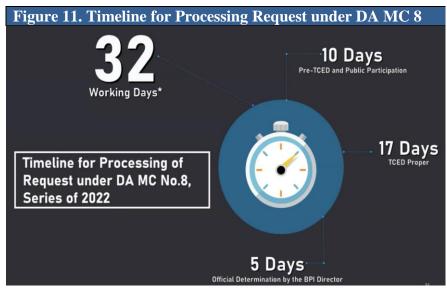
c) STACKED or PYRAMID EVENT APPROVALS/AUTHORIZATIONS: For GE Corn in the Philippines, recent varieties generally have stacked traits, a combination of Bt (insect resistance) and HT (herbicide tolerance). Stacked event crops composed of approved individual events no longer need to reapply under the revised JDC1. The guidelines for the listing of stacked events to the BPI Approval Registry can be accessed here.

d) FIELD TESTING: Below are the process and the regulatory institutions involved to conduct field trial. As of October 2024, there are three approved field trial applications under JDC 1: high iron and zinc rice IRS1030-031 and IRS1030-039, and corn MON 87427.



e) INNOVATIVE BIOTECHNOLOGIES: The DA issued Memorandum Circular No. 8 pursuant to the revised JDC1, which provides the regulatory policy for importation, handling and use, transboundary movement, release into the environment, and management of GE plants, and plants products derived from the use of modern biotechnology, and the NCBP Resolution No. 1, or the regulation of plant, and plant products derived from the use of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs). This regulation shall cover plants and plant products derived from NBTs/PBIs to

determine whether they should be regulated as GE crops. Defined under EO 514, products from PBIs can be classified as a "GMO" if they contain a novel combination of genetic material obtained through modern biotechnology. The NCBP defines a novel combination as a resultant genetic combination in a living organism that is not possible through conventional breeding. Otherwise, a product is "non-GMO" or conventional. The DA leads in evaluating and monitoring products of PBIs, and determining when products derived from PBIs are GE, and therefore regulated under the revised JDC1 following the set rules and procedures. The circular sets the procedural requirement for the conduct of a Technical



Consultation for Evaluation and Determinations (TCED), which determines if a PBI is genetically engineered or not. It will take 32 days to process the request submitted.

In a case when the PBI product is officially determined as not GE, a Certificate of Non-Coverage from the JDC1 shall be issued to the product developer. The certificate shall not excuse the product developer from complying with other relevant regulations such as those involving quarantine, pest risk analysis, varietal registration, and crop-specific standards and

Source: DOST-NCBP

programs.

Among PBI products issued with certificates of non-coverage registry are:

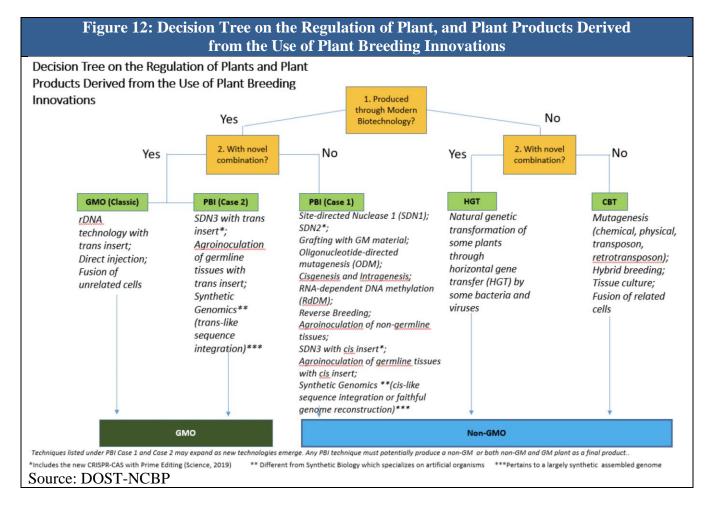
- Banana (*Musa acuminata*) with reduced browning
- High GABA sicilian rouge tomato
- Reduce browning banana (TRBOI 1001)
- Reduce browning banana (TRBOI 1002)

Technical Consultation for Evaluation and Determination

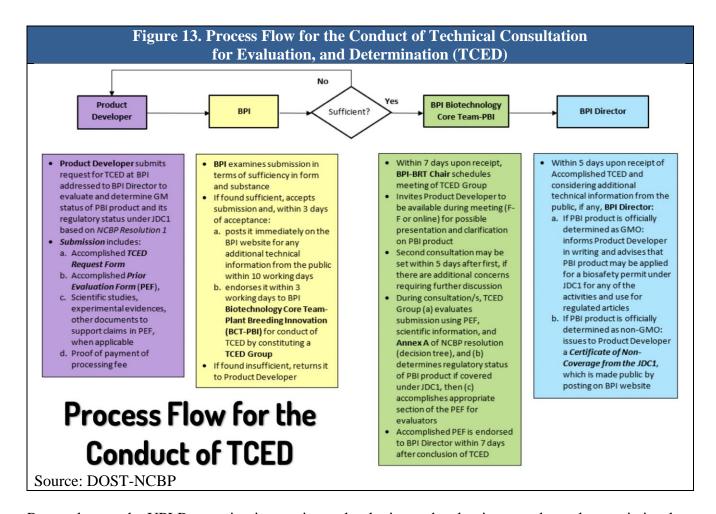
A product developer who intends to introduce a PBI product into the country shall submit to the Director of BPI a <u>TCED request</u>, which is a technical evaluation of the PBI product to determine whether the final product of the plant breeding process employed to produce the PBI product contains a novel combination of genetic material obtained through the use of modern biotechnology. For every officially accepted request, it shall form a TCED Group composed of three members responsible for the conduct of the technical evaluation, and determination on the regulatory status of the PBI product under the JDC1.

In the case of projects to develop or obtain PBI products that are still at the product concept or R&D phase, the product developer may, in anticipation that the expected target product falls under the scope

and coverage of the JDC1. In such a case, the TCED Group may perform a preliminary analysis, and provide an indicative answer that will be communicated by BPI to the product developer. Upon the request of the product developer, portions of the submission may be treated as confidential information.



An <u>Institutional Biosafety Committee</u> (IBC) is required in all institutions engaged in genetic engineering and/or genetic engineering work. IBC evaluates and monitors the biosafety aspects of their biological research. The committee shall be composed of five members with expertise in genetic engineering or pests, or who have the capability to assess the safety of research. At least two (2) members shall not be affiliated with the institution (apart from their membership with the IBC and shall represent the interest of the surrounding community with respect to health and protection of the environment.

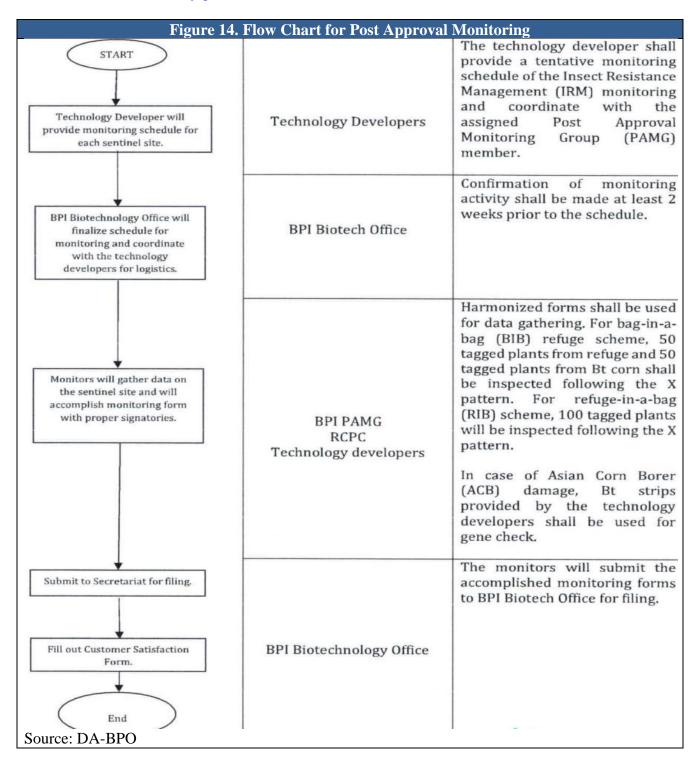


Researchers at the UPLB are using innovative technologies to develop improved eggplant varieties that are resistant to eggplant fruit and shoot borer (EFSB), and leafhopper (LH) using , IT-based phenotyping platforms, molecular marker technologies, and new breeding techniques to fast-track this development.

The <u>Philippine Genome Center</u> (PGC) was launched in 2011 under the University of the Philippines system. PGC is involved in a variety of genomics research, with <u>agriculture projects</u> including coconut, shrimp, coffee, abaca, banana (saba), sugarcane, pili, and dairy cattle. Other focus areas are development of diagnostic kits for identifying disease and genetic diversity of livestock, crops, forest trees, fish, and food. <u>UPLB research</u> also support studies on these crops.

- f) COEXISTENCE: There are no rules in place or proposed on coexistence. There are concerns raised such as gene flow across plantation that may reach organic crops.
- g) LABELING, and TRACEABILITY: Currently there are no labeling requirements for GE food products. The most recent GE labeling bill filed under the 18th Philippine Congress is <u>House Bill 6411</u> known as "The Philippine "GMO" Labeling, and Regulation Act, The Right-to-Know Act," which would require labeling and regulation of food containing GE ingredients or derived from GE. There has been little development on this Bill since 2020.

h) MONITORING, AND TESTING: The permit to propagate GE crops carries a stipulated provision that requires the technology developer to undertake insect resistance management practices (if the approved event is Bt), and/or weed resistance interventions if the event involved is glyphosate-tolerance. The monitoring and testing follow the process as presented in the field trials above, and the below process for post-approval monitoring. Details on testing, monitoring, and reporting requirements are included in the biosafety guidelines.



- i) LOW LEVEL PRESENCE (LLP) POLICY: In early 2009, the DA approved Administrative Order No. 1 (DA-AO No. 1) adopting Annex 3 of the Codex Plant Guideline i.e., "Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food" for the conduct of food safety assessment in situations of LLP of recombinant-DNA plant materials in food, and feed. DA-AO No. 1 directs the DA Policy and Regulatory Office to clarify issues, and formulate guidelines to implement the LLP policy. To date, no implementation guidelines have been issued, but DA-BPO commissioned a third party who conducted a study on LLP. The study results have yet to be released.
- j) ADDITIONAL REGULATORY REQUIREMENTS: After an application is approved, seed variety registration is required with the <u>National Seed Industry Council</u> (NSIC) under BPI. On June 29, 2021, NSIC issued <u>NSIC Resolution No. 5</u> or a resolution adopting a unified policy by NSIC on testing for variety registration of all "genetically modified" crops.
- k) INTELLECTUAL PROPERTY RIGHTS (IPR): There are no plant patents in the Philippines. The country achieved compliance with its obligations under the World Trade Organization Trade Related Aspects of Intellectual Property Rights Agreement on June 11, 2007 with the passage of Republic Act 9168, otherwise known as the Plant Variety Protection Act of 2002 (PVPA).

Under the PVPA, holders of Plant Variety Protection certificates have the right to authorize the production, reproduction, export, and import of the varieties they have developed. These rights extend to harvested material from the unauthorized use of their protected varieties – except if the use is by small farmers. Their rights also cover derived varieties (or those varieties predominantly derived from the initial variety under protection). Provisional protection is provided to breeders, entitling them to some remuneration from the time the application is published until the granting of the certificate of PVP.

- l) CARTAGENA PROTOCOL RATIFICATION: The Philippine Senate on August 14, 2006 adopted Senate Resolution No. 92 or the "Resolution Concurring in the Ratification of the Cartagena Protocol on Biosafety (CPB) to the UN Convention on Biological Diversity." The CPB ratification followed the March 2006 issuance of Executive Order No. 514, adopting the National Biosafety Framework (NBF), which was the interim implementing mechanism of the CPB. The NCPB oversees the implementation of the NBF and coordinates the implementation of decisions made under the Conference of Parties serving as Meeting of Parties (COP-MOP) in fulfilling the country's international obligations as a Party to the Cartagena Protocol on Biosafety.
- m) INTERNATIONAL TREATIES, and FORUMS: The Philippines actively participates in international forums, including Codex Alimentarius as well as related activities of the Asia Pacific Economic Cooperation (APEC).
- n) RELATED ISSUES: Additional information, and updates on related issues can be accessed on the DA-BPI's <u>biotechnology website</u>.

The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (NKLSP), which was finalized in 2010 and put into force in 2018, has not been ratified in the Philippines, despite the country being one of the negotiators. In 2016, the NCBP Technical Working Group (TWG) assessed the country's preparedness in implementing the NKLSP and tackled existing laws and policies that would

address the damage. Key findings indicated the lack of a unified operational definition of damage to biological diversity. Furthermore, the administrative nature of the NKLSP would require an agency authorized for its implementation.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: A study on <u>Public Perception on Agribiotechnology</u> was published by ISAAA on May 2023. Study findings revealed that Filipino stakeholders in general are supportive of biotechnology in crop production and consider it as beneficial to society in terms of food and medicines. Scientists are the most trusted sources of information but are ironically not that accessible and visible in the community. Social media, even if not highly trusted, is influential because it is the most accessible and omnipresent in many areas. Compared with the last perception study conducted in 2007, improvement of perception occurred in the following areas: (a) biotech information as being more useful, of better quality and better understood; (b) biotechnology regulations as protective of public safety and health, (c) higher motivation to join biotech-related activities that do not involve much of their time and money, and (d) more emphasis on end uses of biotechnology as food and medicines as primary consideration in making decisions about biotechnology.

Support for GE products remain strong among local corn farmers, hog and poultry raisers, feed millers, food processors, academics, and other end users. Although supportive, other large domestic food and agribusiness companies that are already using GE products prefer to remain silent on the issue. On the other hand, non-governmental organizations (NGOs), including environmental groups, organic agriculture advocates, and other civil society groups represent vocal opposition to agricultural biotechnology. There are also local government ordinances banning GE crops cultivation and products in specific localities. A majority of Filipinos, however, remain indifferent.

b) MARKET ACCEPTANCE/STUDIES: Despite the established safety of GE products, increased market acceptance is dampened by the misinformation campaign of anti-GE advocates. One indicator of market acceptance, however, is the growth in GE corn area from just 10.7 hectares planted in 2003 to 709,000 hectares in 2023.

In 2009, students from the Asian Institute of Management conducted market research on Golden Rice to identify attitudes and perceptions pertaining to diet and nutrition. Their <u>research</u> found that in general, despite the different color and being a GE crop, results showed high acceptability for Golden Rice, but also noted respondents had little knowledge on several key factors such as those pertaining to genetically engineered crops, vitamin A deficiency, and proper nutrition.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION, AND TRADE

a) RESEARCH, AND PRODUCT DEVELOPMENT: According to the Livestock Biotechnology Center (LBC), artificial insemination (AI) is the most widely applied animal biotechnology, particularly in combination with cryopreservation, allowing significant genetic improvement for productivity with other technologies such as monitoring reproductive hormones, estrus synchronization, and semen sexing for AI efficiency.

The Philippine Carabao Center adopts the somatic cell nuclear transfer technology, complementing other existing reproductive tools for buffaloes to develop/optimize a system for cloning through somatic cell nuclear transfer. Buffalo clone embryos have been successfully produced in-vitro.

There are no GE or genome-edited animals or clones under development. LBC notes that animal biotechnologies in the Philippines are in the development of rapid animal disease test kits, reproductive biotechnologies, and product development. Research on heat tolerant livestock is being studied.

- b) COMMERCIAL PRODUCTION: Not applicable.
- c) EXPORTS: Not applicable.
- d) IMPORTS: Not applicable.
- e) TRADE BARRIERS: There are no biotechnology-related trade barriers that negatively affect U.S. animal biotechnology exports.

PART E: POLICY

a) REGULATORY FRAMEWORK: The Philippines has drafted the regulatory framework for GE animals, including insects, but the policy has not been released pending request to conduct additional sessions of public consultation. The GE animal regulatory policy is applicable to the following: 1) genetically engineered fisheries, and other aquatic resources; 2) domesticated animals, and biological products used for animal husbandry for veterinary purposes; and 3) biological agents used for biocontrol derived from the use of modern biotechnology and containing novel combinations of genetic materials. Products of gene editing that do not contain novel combinations of genetic materials are not covered.

According to the draft regulation, the biosafety decision considers the following areas: 1) transparency, and public participation; 2) access to information; 3) socio-economic, ethical, and cultural considerations; 4) standard precaution; 5) risk assessment; and 6) environmental, and health risk assessment.

b) APPROVALS/AUTHORIZATIONS: Not applicable.

- c) INNOVATIVE BIOTECHNOLOGIES: Animal products are not covered in the development of regulations for plant products of genome editing (i.e., NCBP Resolution No. 1, Series of 2020). Animals made with innovative biotechnologies would likely need to be covered by a separate policy.
 - d) LABELING, and TRACEABILITY: Not applicable.
 - e) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable.
 - f) INTELLECTUAL PROPERTY RIGHTS (IPR): Not applicable.
- g) INTERNATIONAL TREATIES, and FORUMS: The Philippines is a member of the Codex Alimentarius, and the World Organization of Animal Health, and joins the discussions on agricultural biotechnology.
- h) RELATED ISSUES: The DA-LBC opened in 2014, and coordinates and monitors livestock biotechnology research and development in the Philippines.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Public awareness of GE animals is low. According to a report by a study group contracted by the DA, the regulatory issues associated with transgenic animals include food safety, environmental safety, ethical concerns, such as animal welfare, product efficacy, and effectiveness, and socioeconomics. Conducting webinars/seminars increases awareness, and it is expected to widen once the series of consultations are undertaken to finalize the regulatory framework for GE animals.

Based on the study on <u>Public Perception on Agribiotechnology</u> published by ISAAA on May 2023, Filipino stakeholders in general are supportive of biotechnology in crop production, but support is not as solid in terms of biotech in animal production. There was a perceived lack of knowledge about animal biotechnology. There was a certain level of reservation to support the technology. Study results revealed that stakeholders believed that some valid reservations remain depending on how the technology affects people and the environment over time. Grounds for having reservations about animal biotechnology were respect for animal rights and welfare, presence of unknown risks, interfering with nature, and religious grounds, among others.

b) MARKET ACCEPTANCE/STUDIES: Not applicable.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION, AND TRADE

- a) COMMERCIAL PRODUCTION: No information is available regarding whether the Philippines produces food or food ingredients derived from microbial biotechnology.
 - b) EXPORTS: Not applicable.
 - c) IMPORTS: Not applicable.
 - d) TRADE BARRIERS: Not applicable.

PART H: POLICY

a) REGULATORY FRAMEWORK: The Philippines currently does not have a regulatory process for the commercial production, use, and trade of biotech-derived microbes or microbial biotech-derived food and food ingredients. Post is not aware of any discussions pertaining to the drafting of regulation or trade policies on microbial biotech.

Executive Order No. 514, Series of 2006 established the National Biosafety Framework, and does not mention GE microbes or how they would be regulated. However, EO 514 does specify that all research, and development applications, regardless of life form or intended use, shall be regulated by the Department of Science and Technology Biosafety Committee. There have been previous experiments using GE microorganisms, as noted here.

The Philippine Biosafety Guidelines for Contained Use of Genetically Modified Organisms ("GMO"s), Revised Edition, September 2014, stipulates that the guidelines will apply to all biotech applications under "contained use (i.e. laboratory, screen house, glasshouse, greenhouse) and confined test." The guidelines cover plants/crops, pharmaceutical plants, animals, forest trees, and microorganisms. The full guidelines can be found here. The policy and procedures to apply for a contained use experiment of biotech microbes are listed on page 56 of the Biosafety Guidelines.

- b) APPROVALS/AUTHORIZATIONS: Not applicable.
- c) LABELING, and TRACEABILITY: Not applicable.
- d) MONITORING, AND TESTING: Not applicable.
- e) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable.
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): Not applicable.
- g) RELATED ISSUES: Not applicable.

PART I: MARKETING

- a) PUBLIC/PRIVATE OPINIONS: Public awareness of microbial biotech is very low.
- b) MARKET ACCEPTANCE/STUDIES: Not applicable

Attachments:

No Attachments