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## **Report Name:** Agricultural Biotechnology Annual

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### **Report Highlights:**

The Philippines has been a pioneer within Asia in adopting biotechnology crops, and recently approved Bt cotton as the 4th genetically engineered (GE) crop cleared for commercial propagation after corn (2002), rice (2021), and eggplant (2022). The Philippines ranked 12th among the 29 countries in the world that planted biotech crops in 2019. In 2022, area planted with biotech corn reached 576,000 hectares. The Philippines is the first country in the world to approve Golden Rice for commercial propagation. Moreover, it is first in Southeast Asia to issue regulatory frameworks on genetically engineered (GE) crops for cultivation and passed a regulation for plants and plant products derived from the use of plant breeding innovations (PBIs), also referred to as New Plant Breeding Techniques (NBTs). The draft policy and regulations on animal biotechnology are under review and targeted for release before the end of 2023 or early in 2024.

## ***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. Corn, rice, eggplant, and cotton are GE crops currently allowed for commercial propagation. The biosafety permit for commercial propagation of Bt cotton was issued on August 24, 2023, making it the 4<sup>th</sup> GE crop approved for commercial propagation after corn (2002), rice ([2021](#)), and eggplant ([2022](#)). Planting of Bt eggplant and golden rice continues while the GE corn area planted has increased from 10,700 hectares in 2003 to 576,000 hectares as of February 2023.

The country is moving forward with the implementation 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 JDC 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, which 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 eighth-largest market for U.S. agricultural and related products in 2022 with exports reaching \$4.1 billion, up 17 percent from 2021. The country continues to be the largest U.S. soybean meal market, with \$1.15 billion in sales in 2022.

For more information, please see the following GAIN reports:

[GAIN Agricultural Biotechnology Annual 2022](#)

[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](#)

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## 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 [Sustainable Development Goal](#) 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 as the biotechnology leader in Asia, being the first to allow the planting of Bt corn and being 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 (ISAAA, 2022). It is also the first in the world to approve Golden Rice. Research and development (R&D) continue on other potential GE crops, and the country is moving towards developing GE animals.

### PART A: PRODUCTION AND TRADE

#### a) RESEARCH AND PRODUCT DEVELOPMENT:

GE products being developed include Papaya Ringspot Virus-Resistant (PRSV-R) papaya, and Multiple Virus Resistant (MVR) tomato.

**Papaya.** The University of the Philippines Los Baños – Institute of Plant Breeding (UPLB-IPB) developed PRSV-R Papaya with funding from the Department of Science, and Technology – Philippine Council for Agriculture, Aquatic, and Natural Resources Research, and Development ([DOST-PCAARRD](#)), and support from USAID. It completed its first field trial in 2014, and a second field trial in 2017. Preparations for further trials are underway.

**Tomato.** The MVR tomato is still being studied. UPLB has started on cutting-edge CRISPR research, and screening for viral disease resistance under the Fulbright Scholarship Program of the United States. The tomato research will be continued in the Philippines with support from USDA’s Agricultural Research Service and Foreign Agricultural Service.

Discussion on research on GE sugarcane is underway and is being considered for future research.

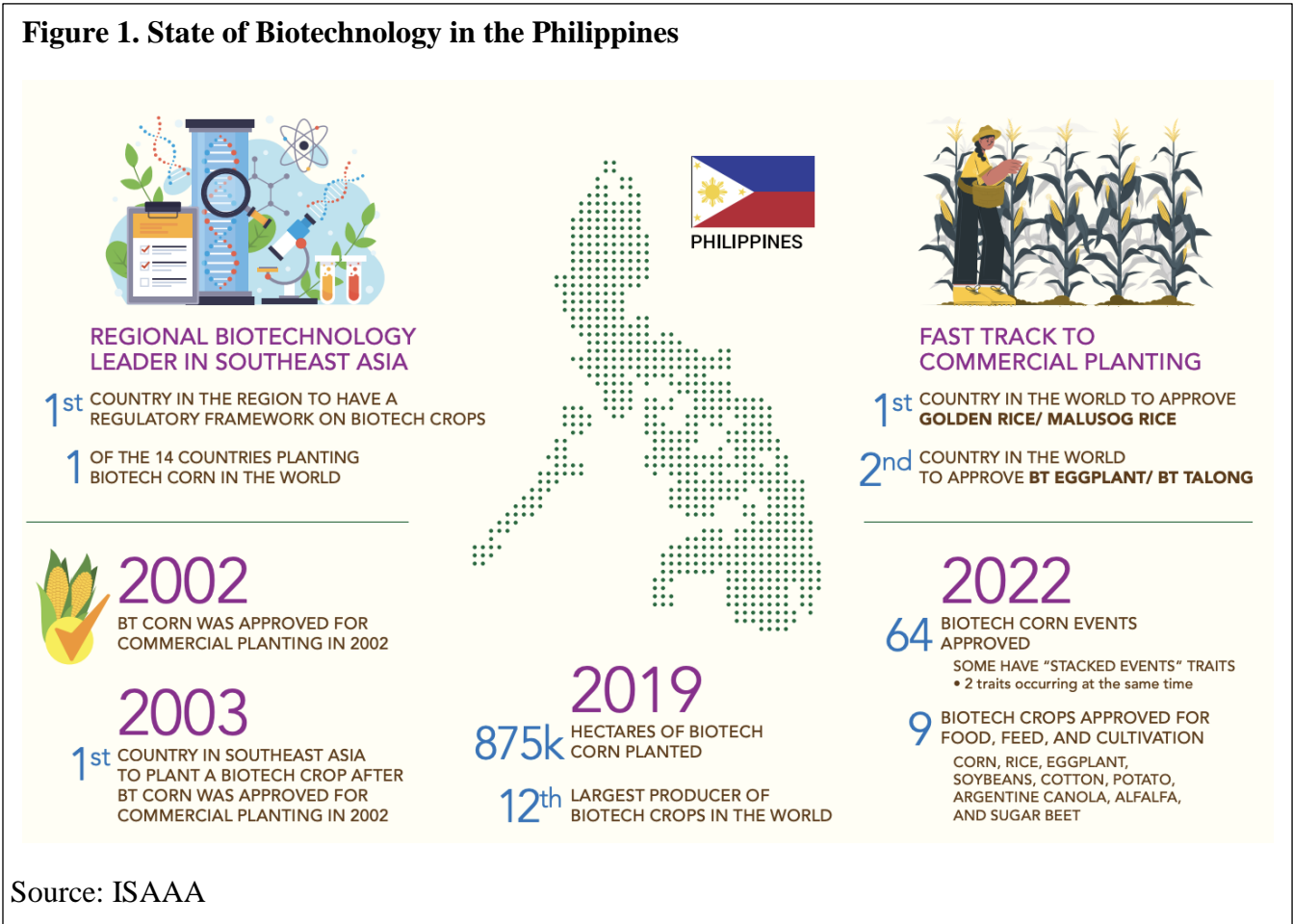
b) COMMERCIAL PRODUCTION: The Philippines recently approved its fourth GE crop, Bt cotton, making it the 4<sup>th</sup> GE crop approved for commercial propagation after corn (2002), rice ([2021](#)), and eggplant ([2022](#)). Bt eggplant has just launched while the rollout of Golden Rice commenced following its approval in 2021. GE corn was approved for commercial propagation in 2002.

**Cotton.** On August 24, 2023, the Bureau of Plant Industry (BPI) issued a [Biosafety Permit](#) for the commercial propagation of Bt cotton developed by the Philippine Fiber Industry Development Authority ([PhilFIDA](#)). Bt cotton replaces the need to control the bollworm through the application of synthetic chemical pesticides harmful to human health and the environment.

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. Field trials have shown more harvestable bolls and reduction in pesticides application.

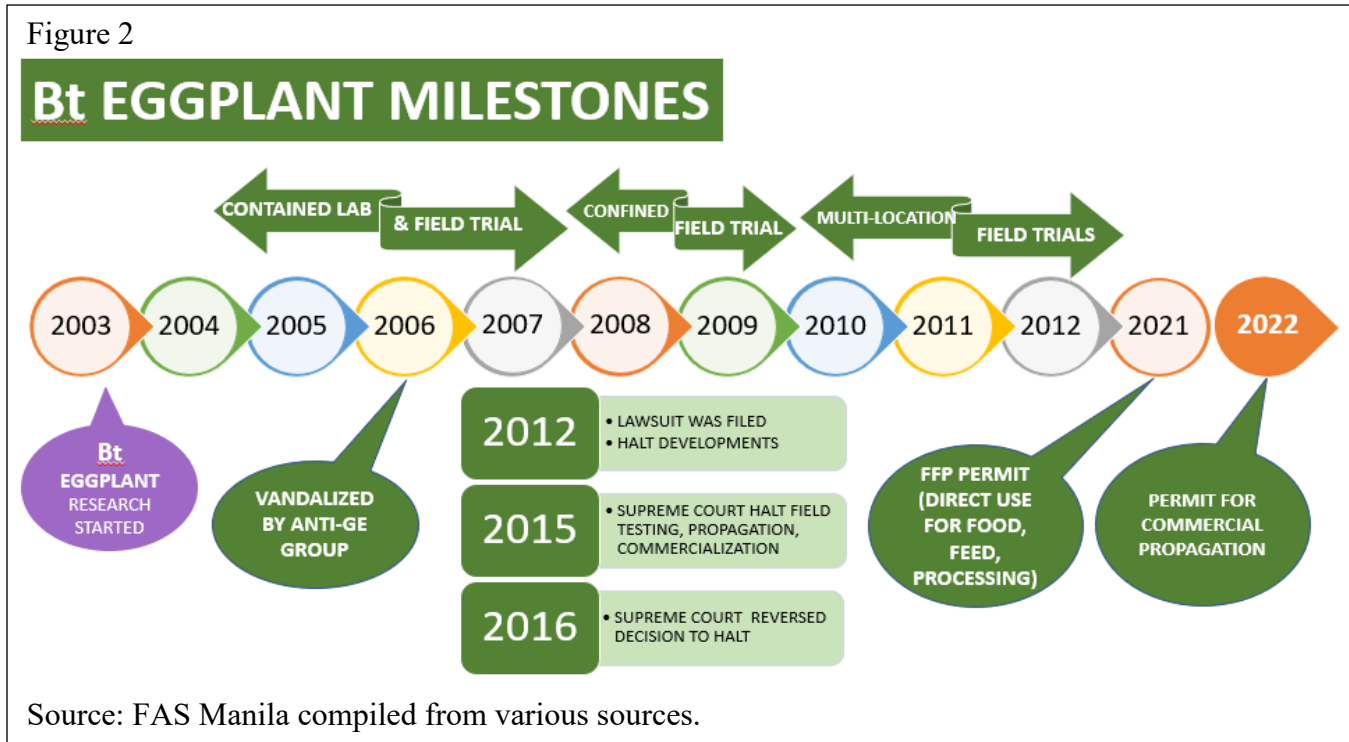
The PhilFIDA has conducted multi-locational field trials in Luzon and Mindanao with promising results. Bt cotton could yield 3 tons per hectare compared with 1-2 tons using present local varieties. Bt cotton can address the issue of pests, increase yields, and deliver higher profits for farmers. Paired with the development of Bt cotton will be the promotion of heirloom and organic cotton production technology. PhilFIDA collaborates with the Department of Trade and Industry to revive the industry to supply the local weavers with locally produced cotton.



**Eggplant.** On October 18, 2022, the Philippines cleared Bt eggplant as its third GE [approved for commercial propagation](#) following Bt corn and Golden Rice. 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. The University of the Philippines Los Banos - Institute of Plant Breeding ([UPLB-IPB](#)) conducted the research on Bt Eggplant to address the major pest known as eggplant fruit and shoot borer.

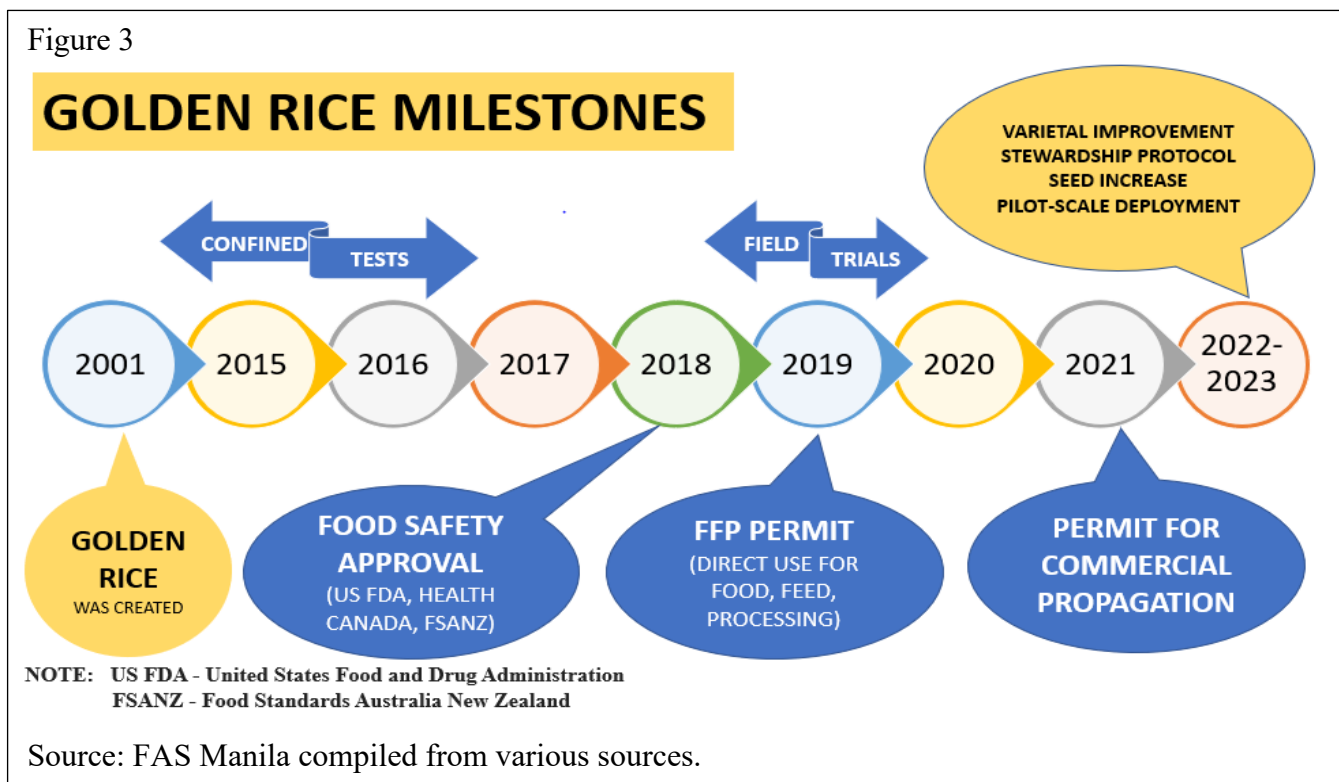
Figure 2



**Rice.** On July 21, 2021, the [Philippines approved Golden Rice](#) for commercial propagation. On March 18, 2021 DA issued [Memorandum Order 19](#) Series of 2021 operationalizing the Department’s full support for the deployment of Golden Rice. The Department, through its attached agencies, bureaus, and regional operations extends technical and logistical support to the DA-PhilRice in facilitating seed production, distribution, training, and communication.

On April 2022, Golden Rice with PSB Rc 82 background was registered with the National Seed Industry Council (NSIC) as NSIC 2022 Rc 682GR2E or *Malusog 1*. The Bureau of Plant Industry – National Seed Quality Control Services (BPI-NSQCS) finalizes the seed certification guidelines for genetically modified rice such as Golden Rice. Spearheaded by the Philippine Rice Research Institute (PhilRice) in partnership with the International Rice Research Institute (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.

Figure 3



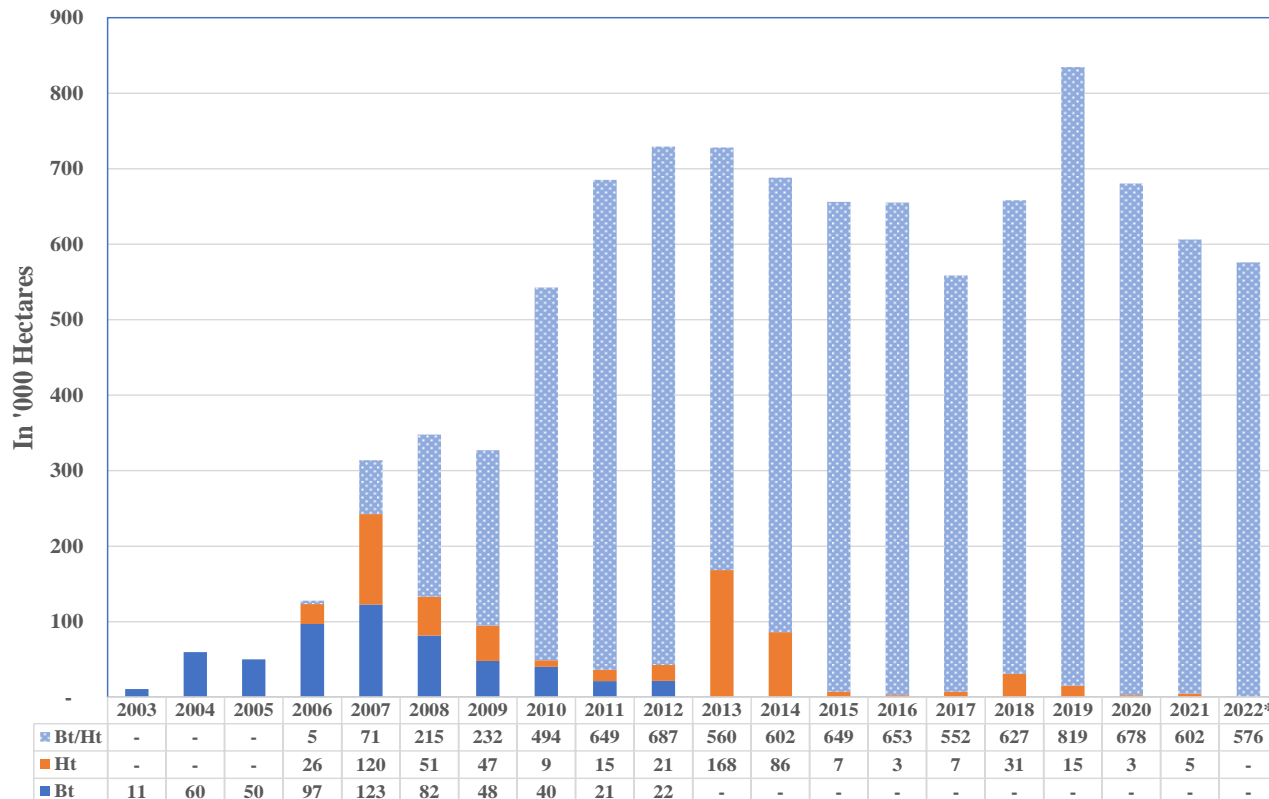
**Corn.** The development of GE corn started in 1996 under a collaborative study of UPLB-IPB and Pioneer Overseas Corporation. Since the approval of the first GE corn for propagation in 2002, more corn transformation events were developed by various companies and given biosafety permits. On July 27, 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. The BPI released the only approved GM corn seeds with the corresponding permit holder and licensees to corn dealers. 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 576,000 hectares as of February 2023. The growth is an indication of increasing acceptance of using GE corn. The 2021 acreage dropped from 2019's high and may be explained by logistical challenges during the Covid-19 pandemic. Currently, nearly all planted GE corn has stacked traits.

Fall armyworm or FAW (*Spodoptera grugiperda*) has been detected across the region. It was found three years ago in the Cagayan Valley region, and has since spread throughout the country, according to DA.

On March 31, 2021, the DA issued [Memorandum Order 26](#), establishing the Fall Armyworm Management Project. It entails the conduct of pest monitoring and surveillance and the distribution of interventions in managing FAW incidences in corn production areas. The direct interventions include

the distribution of pheromone lures, pesticides, power sprayers, ICT equipment, and pest awareness materials.

**Figure 4: Philippine GE Corn Planted Area  
In '000 Hectares**



Note: \*As of February 2023 only.

Source: DA-BPO

a) EXPORTS: The Philippines exports no GE crops. 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 with approvals for direct use including soybean, corn, cotton, canola, potato, rice, eggplant, and alfalfa. Refer here for the [status of applications for direct use](#).

The Philippines was the eighth largest market for U.S. agricultural and related products with exports reaching \$4.1 billion in 2022, up 16 percent from 2021. The country continues to be the largest U.S. soybean meal market (all of which is GE), with \$1.15 million in sales in 2022. 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 of 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 consistent food aid recipient through the USDA Food for Progress program (e.g., GE soybean meal). The importation of food aid commodities has been unimpeded by GE issues.

d) **TRADE BARRIERS:** Delays in the processing of biosafety permits have the most potential to disrupt U.S. exports of GE product, although there have been no trade disruptions so far on food and related products. One notable issue has been on cotton imports. It was only recently when BPI approved the removal of baled cotton in the list of commodities that require GMO declaration. Prior, Philippine cotton importers claimed that it is difficult to provide the Declaration of “GMO” Content due to the multiple sources of cotton in a single bale.

**Figure 5: Sample Form – Declaration of “GMO” Content**

**Declaration of GMO Content**

The shipment may contain a GM ingredient:  
 Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, list the probable transformation events.

Present	To be filled up by the PQS Officer	
	In the Approval Registry	Not in the Approval Registry
_____	_____	_____
_____	_____	_____
_____	_____	_____

[Signature]  
 Plant Quarantine Officer

[Signature]  
 Responsible Officer from the Country of Origin/Accredited Laboratory/Importer/Shipper

Source: DA

**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.

<b>Table 1: Biotechnology Policy and Regulation</b>			
Legal Term (in official language)	Legal Term (in English)	Laws and Regulations where the term is used	Legal Definition (in English)
“Genetically modified organism (GMO)”	“Genetically modified organism (GMO)”	<a href="#">Joint Department Circular (JDC) No.1, Series of 2021</a>  <a href="#">Department of Agriculture (DA) Memorandum Circular (MC) No. 8, Series of 2022</a>	“living modified organism” under the Cartagena Protocol on Biosafety and refers to any living organism that possess a novel combination of genetic material obtained through the use modern biotechnology

		<a href="#">National Committee on Biosafety of the Philippines (NCBP) Resolution No. 1, Series of 2020</a>	
Modern biotechnology	Modern Biotechnology	<a href="#">JDC No.1, Series of 2021</a> <a href="#">DA MC No. 8</a> <a href="#">NCBP Resolution No. 1, Series of 2020</a>	Refers to the application of: 1) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) or direct injection of nucleic acid into cells or organelles; or 2) fusion of 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 Innovations	New Plant Breeding Techniques	<a href="#">JDC No.1, Series of 2021</a> <a href="#">DA MC No. 8</a> <a href="#">NCBP Resolution No. 1, Series of 2020</a>	If contains a novel combination of genetic material obtained through modern biotechnology
Novel Combination	Novel combination	<a href="#">JDC No.1, Series of 2021</a> <a href="#">DA MC No. 8</a> <a href="#">NCBP Resolution No. 1, Series of 2020</a>	A resultant genetic combination in a living organism that is not possible through conventional breeding.
Plant-incorporated protectant (PIP)	Plant-incorporated protectant (PIP)	<a href="#">JDC No.1, Series of 2021</a>	Refers to pesticidal substance produced by plants and genetic material necessary for the plant to produce the substance
Regulated article	Regulated article	<a href="#">JDC No.1, Series of 2021</a> <a href="#">DA MC No. 8</a>	Refers to genetically modified plants and plant products under the scope of the JDC
Responsible officer	Responsible officer	<a href="#">JDC No.1, Series of 2021</a>	Refers to an officer appointed by the applicant for the importation or 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

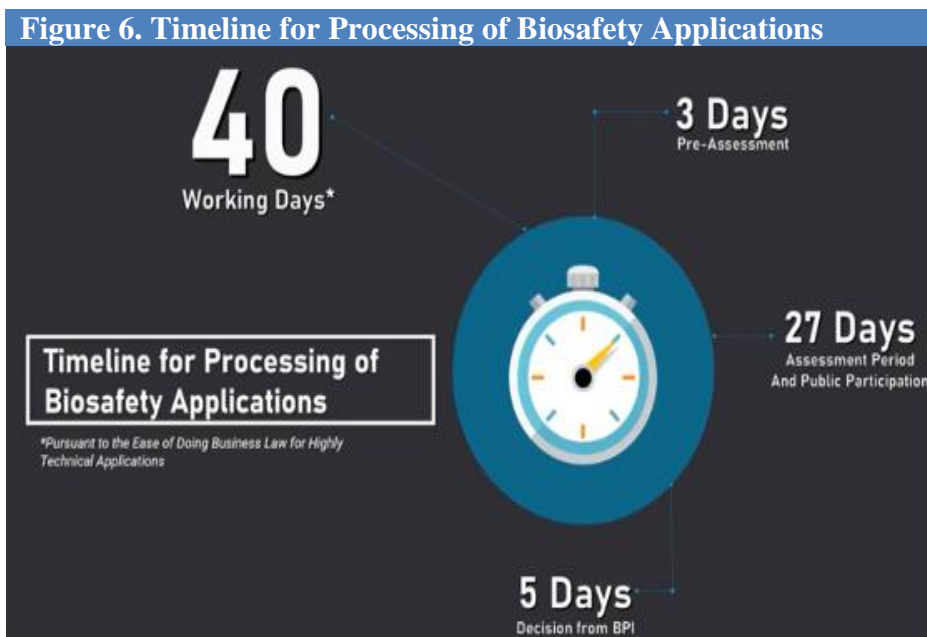
“Stacked events”	“Stacked events”	<a href="#">JDC No.1, Series of 2021</a>	Refer to “genetically modified” plants and their products that have been developed using multiple transformation events encoding several proteins that confer specific traits
“Transformation event”	“Transformation event”	<a href="#">JDC No.1, Series of 2021</a>	Refers to the uptake and integration 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 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 [Joint Department Circular No. 1](#) (JDC1) signed by Department of Science, and Technology (DOST), Department Agriculture (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 wait for approvals and processes drastically and are expected to greatly reduce compliance costs and lower the barriers to commercializing biotech crops.



Source: DOST-NCBP

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

Source: JDC1

**Table 3: Role of National Government Agencies in the Safety Assessment of GE Crops**

Department of Agriculture (DA)	Lead in addressing biosafety issues related to the country’s agricultural productivity and food security. Lead in the evaluation, and monitoring of regulated articles.
Department of Science and Technology (DOST)	Lead in ensuring that the best science is utilized and applied in adopting biosafety policies, and in making biosafety decisions. Lead in evaluating and monitoring contained use of regulated articles.
Department of Environment and Natural Resource (DENR)	Ensure that the applicable environmental assessments are undertaken, and potential impacts identified. Lead in evaluating and monitoring bioremediation, improvement of genetic resources, and wildlife genetic resources.
Department of Health (DOH)	Formulate guidelines and review results of assessing the health impacts posed by modern biotechnology. Lead in evaluating and monitoring processed food derived from or containing “GMOs.”
Department of Interior and Local Government (DILG)	Oversee implementation of the activities undertaken in specific LGUs in relation to the conduct of public consultations as required by the Local Government Code.

Source: JDC1

On September 24, 2021, the Philippine government created a [Review Team](#) on the implementation of the JDC1 on the regulation of GE plant and plant products.

Under the JDC1, the DOST and DA lead the implementation of biosafety guidelines. The other agencies involved are DOH, DENR, and DILG. Every stage of the research and development of GE crops is regulated until reaching the commercialization phase. For ease in compliance, the DOST 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. The process flow is presented [here](#). 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 sell 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.

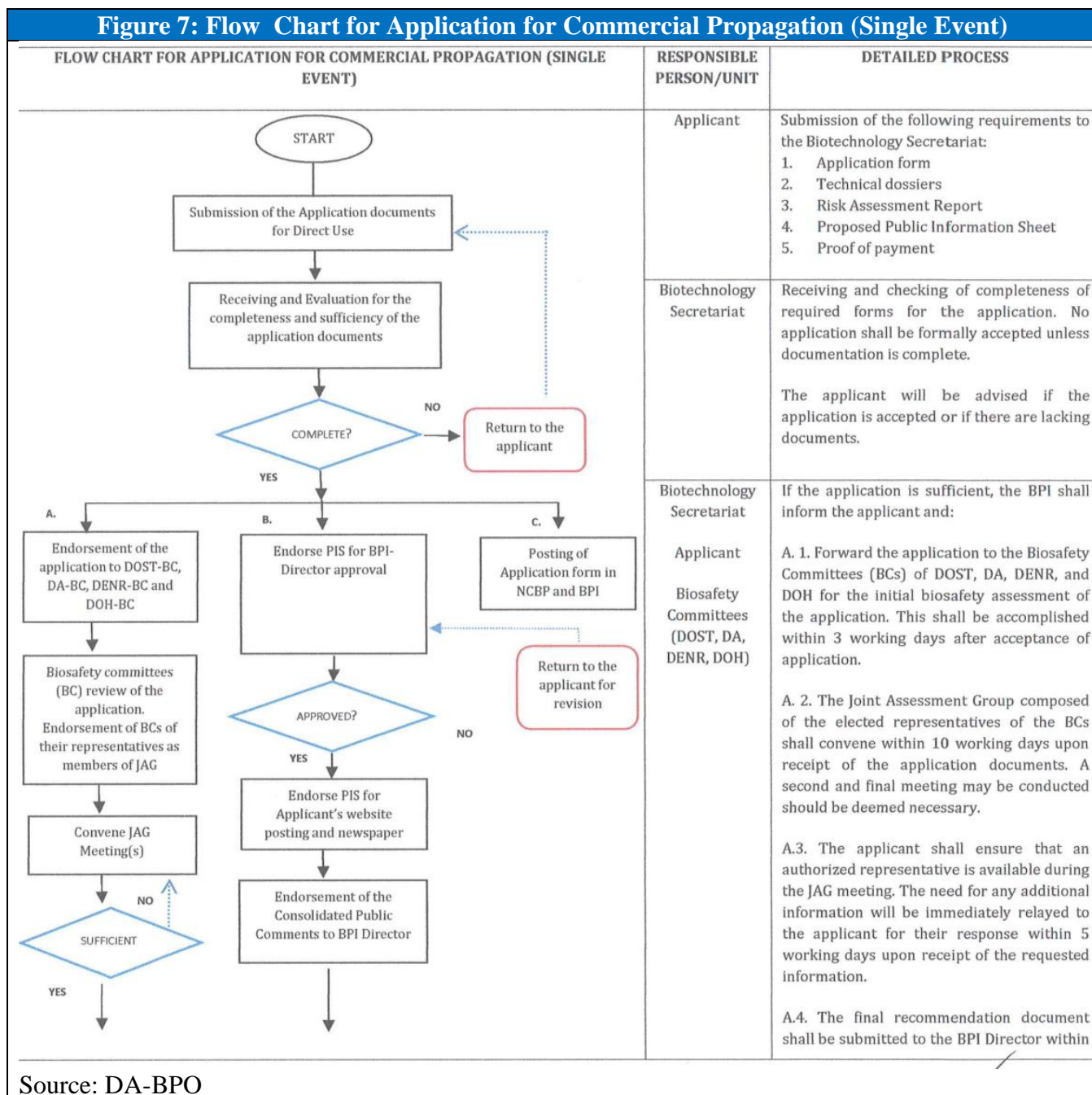
b) APPROVALS/AUTHORIZATIONS: The status of applications for [direct use](#), [field trial](#), and [propagation](#) are listed on the [DA Biotechnology website](#). On March 17, 2023, the Philippine Fiber Industry Development Authority (PhilFIDA) submitted its [application for biosafety permit](#) for commercial propagation of Bt cotton (GFM cry1A) under the Joint Department Circular No. 1 Series of

2021 ([JDC1](#)) to the Bureau of Plant Industry (BPI). On March 20, 2023, BPI sent the [acceptance](#) to PhilFIDA having completed the required documents. On April 20, 2023, BPI reviewed PhilFIDA's [Public Information Sheet](#) (PIS) and found it sufficient. In accordance with the JDC1, the Joint Assessment Group (JAG) shall review the application within ten working days upon acceptance of the application. The JAG, however, required additional information for appropriate action by PhilFIDA, which delayed the process. The JAG, composed of representatives from Department of Science and Technology, Department of Agriculture, Department of Environment and Natural Resources and Department of Health, and Department of Agriculture-Biosafety Committee, required additional information and needed more time.

In April 2023, the Philippines approved gene-edited reduced browning bananas. BPI has technically evaluated and determined gene-edited banana to be non-GE, and the first gene-edited product to go through the Philippines' gene editing regulatory process.

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. This development continues the Philippines' recent achievements in biotech, having [streamlined the overall regulatory framework](#) for genetically engineered plant products in January 2022 through the revised JDC1.

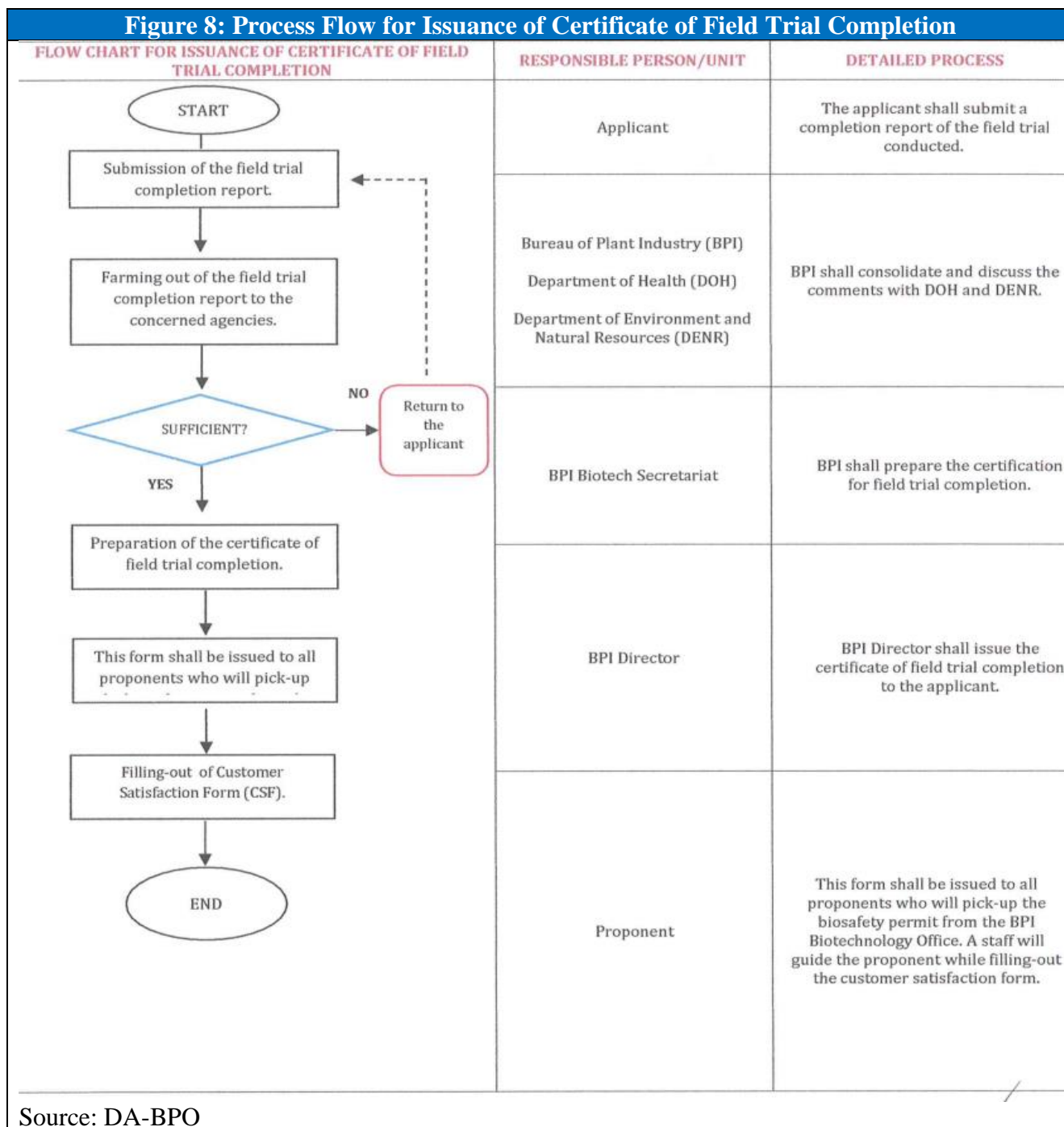
**Figure 7: Flow Chart for Application for Commercial Propagation (Single Event)**



Source: DA-BPO

d) **FIELD TESTING:** Below are the process and the regulatory institutions involved to conduct field trial. A field trial to generate data for environmental biosafety risk assessment of Golden Rice was conducted, and [approved on May 20, 2019](#), the only field trial application so far under JDC 1.

**Figure 8: Process Flow for Issuance of Certificate of Field Trial Completion**

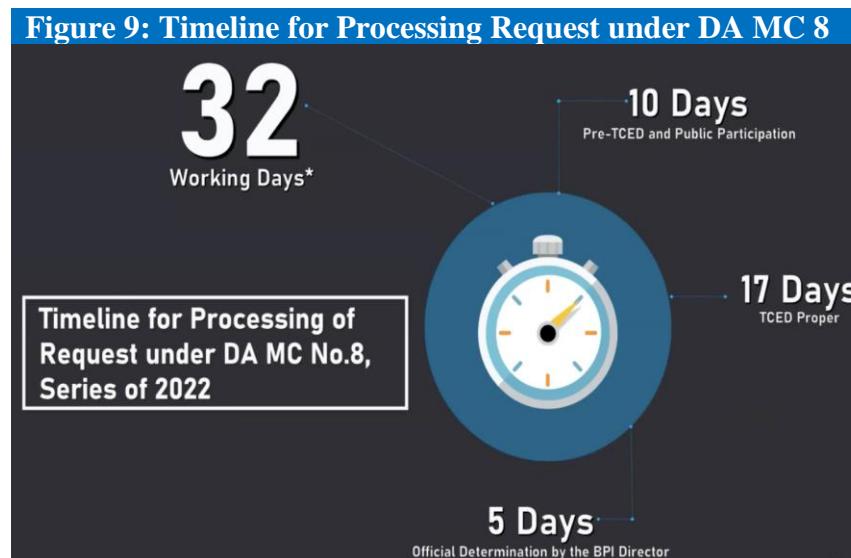


Source: DA-BPO

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 contains 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 a “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. 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 programs.

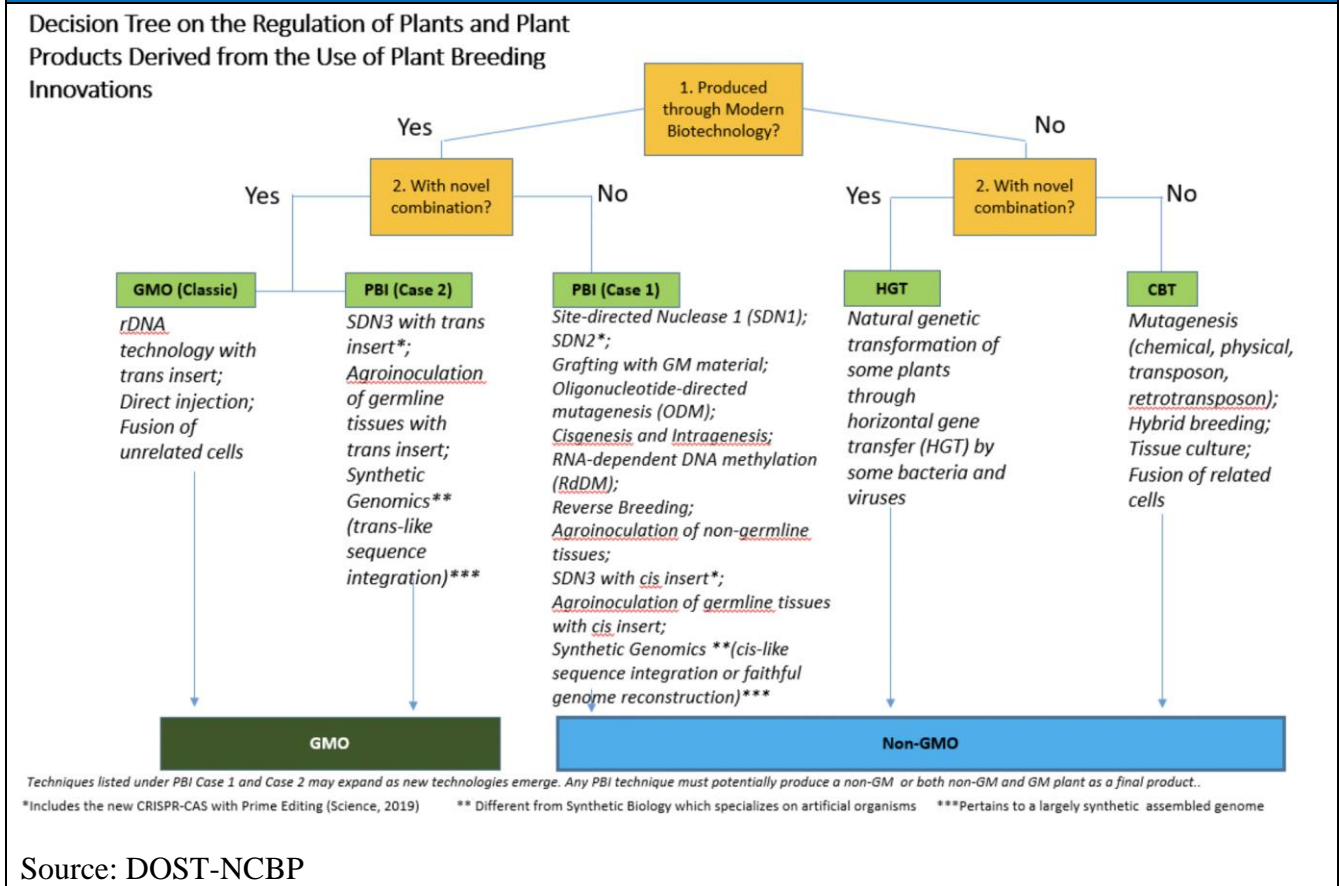
Source: DOST-NCBP

### Technical Consultation for Evaluation and Determination

A product developer who intends to introduce a PBI product into the country shall submit a request to the Director of BPI for Technical Consultation for Evaluation, and Determination (TCED), 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.

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 file a request for TCED, in anticipation that the expected target product falls under the scope and coverage of the JDC1 s2021. 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.

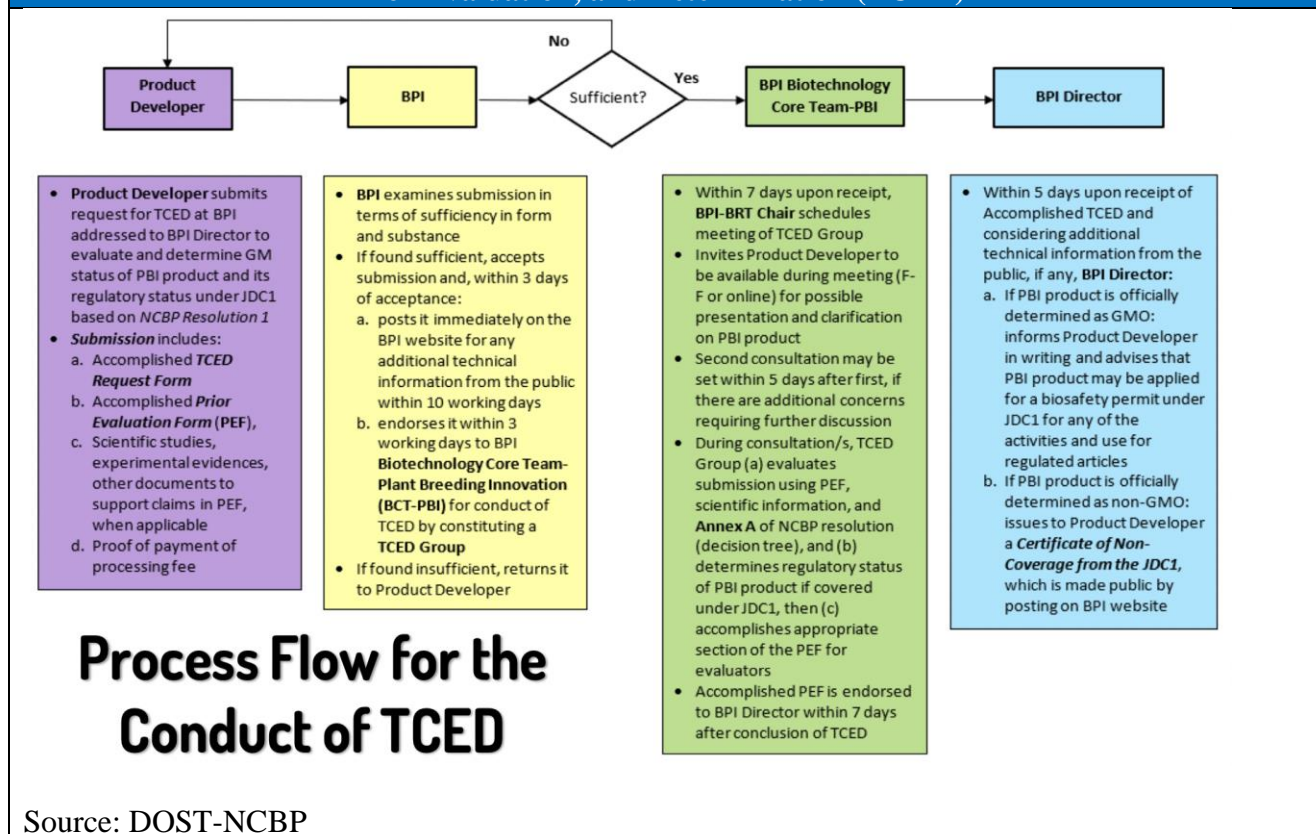
**Figure 10: Decision Tree on the Regulation of Plant, and Plant Products Derived from the Use of Plant Breeding Innovations**



**BPI Biotechnology Core Team (BPI-BCT) – Plant Breeding Innovation.** Composed of qualified technical staff from BPI and shall be chaired by the BPI Assistant Director for Regulatory Services.

- For every officially accepted request, it shall form a Technical Consultation for Evaluation and Determination (TCED) Group composed of three (3) members, with at least two (2) members from the BCT-PBI selected based on availability, and the other member appointed by the Chair of the BCT-PBI as an external expert, if deemed necessary.
- TCED Group shall be responsible for the conduct of the technical evaluation, and determination on the regulatory status of the PBI product under the JDC1, s2021.
- The BPI Director shall issue succeeding policy on the BCT-PBI on its composition, specific duties, and responsibilities in the implementation of this Circular.

**Figure 11: Process Flow for the Conduct of Technical Consultation for Evaluation, and Determination (TCED)**



On April 4, 2023, the DA created the Department of Agriculture Biosafety Committee ([DA-BC](#)), chaired by the Director of the Bureau of Agriculture and Fisheries Standards (BAFS) and a representative from UP-Diliman as Vice-Chair. Committee members are BAI, PhilFIDA, PhilRice, UPLB, BPI, Fertilizer and Pesticide Authority (FPA), Food Development Center (FDC).

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

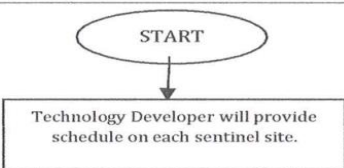
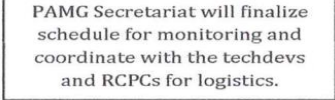
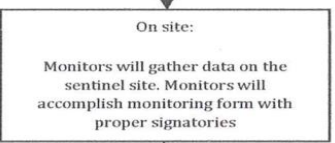
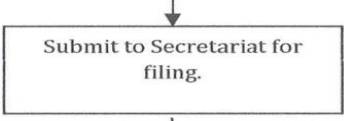
The [Philippine Genome Center](#) was launched in 2011 under the University of the Philippines system. PGC is involved in a variety of genomics research, with [agriculture projects](#) including coconut, shrimp, coffee, abaca, banana (saba), sugarcane, pili, and dairy cattle. Other focus areas are development of diagnostic kits for identifying disease and genetic diversity of livestock, crops, forest trees, fish, and food. [UPLB research](#) 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 causing contamination, which can lose status as organic products.

g) LABELING, and TRACEABILITY: Currently there are no labeling requirements for GE food products. The most recent GE labeling bill filed under the 18<sup>th</sup> Philippine Congress is [House Bill 6411](#) 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 since the 2020 report.

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 process follows 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](#).

**Figure 12: Flow Chart for Post Approval Monitoring**

FLOW CHART FOR POST APPROVAL MONITORING	RESPONSIBLE PERSON/UNIT	DETAILED PROCESS
 <pre> graph TD     Start([START]) --&gt; Step1[Technology Developer will provide schedule on each sentinel site.]     Step1 --&gt; Step2[PAMG Secretariat will finalize schedule for monitoring and coordinate with the techdevs and RCPCs for logistics.]     Step2 --&gt; Step3[On site: Monitors will gather data on the sentinel site. Monitors will accomplish monitoring form with proper signatories]     Step3 --&gt; Step4[Submit to Secretariat for filing.]     Step4 --&gt; End([End])           </pre>	Technology Developers	The technology developer shall provide a tentative schedule of the Insect Resistance Management (IRM) monitoring and coordinate with the assigned Post Approval Monitoring Group (PAMG) member.
	BPI Biotech Secretariat	Confirmation of monitoring activity shall be made at least 2 weeks prior to the schedule.
	BPI PAMG monitors RCPC monitors Techdev Monitors	Harmonized forms shall be used for data gathering. For bag-in-a-bag (BIB) refuge scheme, 50 tagged plants from refuge and 50 tagged plants from Bt corn shall be inspected following the X pattern. For refuge-in-a-bag (RIB) scheme, 100 tagged plants will be inspected following the X pattern.  In case of Asian Corn Borer (ACB) damage, Bt strips provided by the technology developers shall be used for gene check.
	BPI Biotech Secretariat	The monitors will submit the accomplished monitoring forms and the secretariat will consolidate the data gathered.

Source: DA-BPO

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 are yet to be released.

j) **ADDITIONAL REGULATORY REQUIREMENTS:** In October 2020, all technology developers filing GE applications were required to submit [two studies](#) to hasten the biosafety approval process, and information on any changes in the product.

After an application is approved, seed registration is still required with the [National Seed Industry Council](#) under BPI. On June 29, 2021, NSIC issued [NSIC Resolution No. 5](#) 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.

In cases of infringement, the holder of the PVP certificate may petition the regional trial court for relief. As with other intellectual property rights laws, the local courts are relied on for enforcement. Under the PVPA, farmers are accorded the traditional right to save, use, exchange, share, or sell their farm produce of a protected variety, except when the sale is for the purpose of reproduction under a commercial marketing agreement. The exchange and sale of seeds among farmers is allowed on the condition that these are reproduced and replanted on their own lands.

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 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's [biotech website](#).

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 [Public Perception on Agribiotechnology](#) 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. After almost 16 years from the previous perception study, 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.

A comparison of biotech perception between “GMO” and “Non-GMO” provinces was also conducted. “Non-GMO” areas covered three provinces where GMOs are not allowed entry by virtue of a provincial resolution. They are Oriental Mindoro, Negros Occidental, and North Cotabato. Study results revealed that there were overwhelming similarities among respondents in “GMO” and “non-GMO” areas. In fact, being in an area where “GMO” was banned had no effect at all on the public’s perception and attitude towards biotech. Ironically, those from “non-GMO” areas showed better knowledge on biotech in food production than those from “GMO” areas. More stakeholders in the “non-GMO” areas were also more optimistic and interested in biotech and fewer stakeholders regarded biotech as being hazardous.

On April 18, 2023, the [Supreme Court issued a writ of kalikasan](#) on Golden Rice and Bt Eggplant. The petition filed on October 12, 2022, sought to stop the commercial release of the recently approved Bt Eggplant and stop the progress of Golden Rice. This is a repeat of the much-publicized Supreme Court ruling in December 2015, as well as the JDC public consultations in 2016, brought the GE debate into the public realm. Many policy makers, including Philippine legislators and members of the judiciary, have expressed increased interest in obtaining current information on GE crops and products.

Support for GE products remains strong among local corn farmers, hog and poultry raisers, feed millers, food processors, academics, and other end users. Although supportive, 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 and products. The 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 by 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 576,000 hectares in 2023.

One Singapore-based research group in 2021 found that many Filipino consumers are unaware of what GE products are in the market and unsure if they are consuming them. The study noted a plurality of consumers (33 percent) were undecided as to whether they would consider GE foods in the future, compared to 21 percent very likely/likely, and 41 percent who responded they were very unlikely/unlikely.

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 research [presentation](#) 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, oestrus 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.

The Philippines is still at the stage of [DNA barcoding](#) for livestock and poultry. The UPLB College of Agriculture and Food Science did a study on [genotyping dairy cattle](#) but stopped at Phase 1.

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.

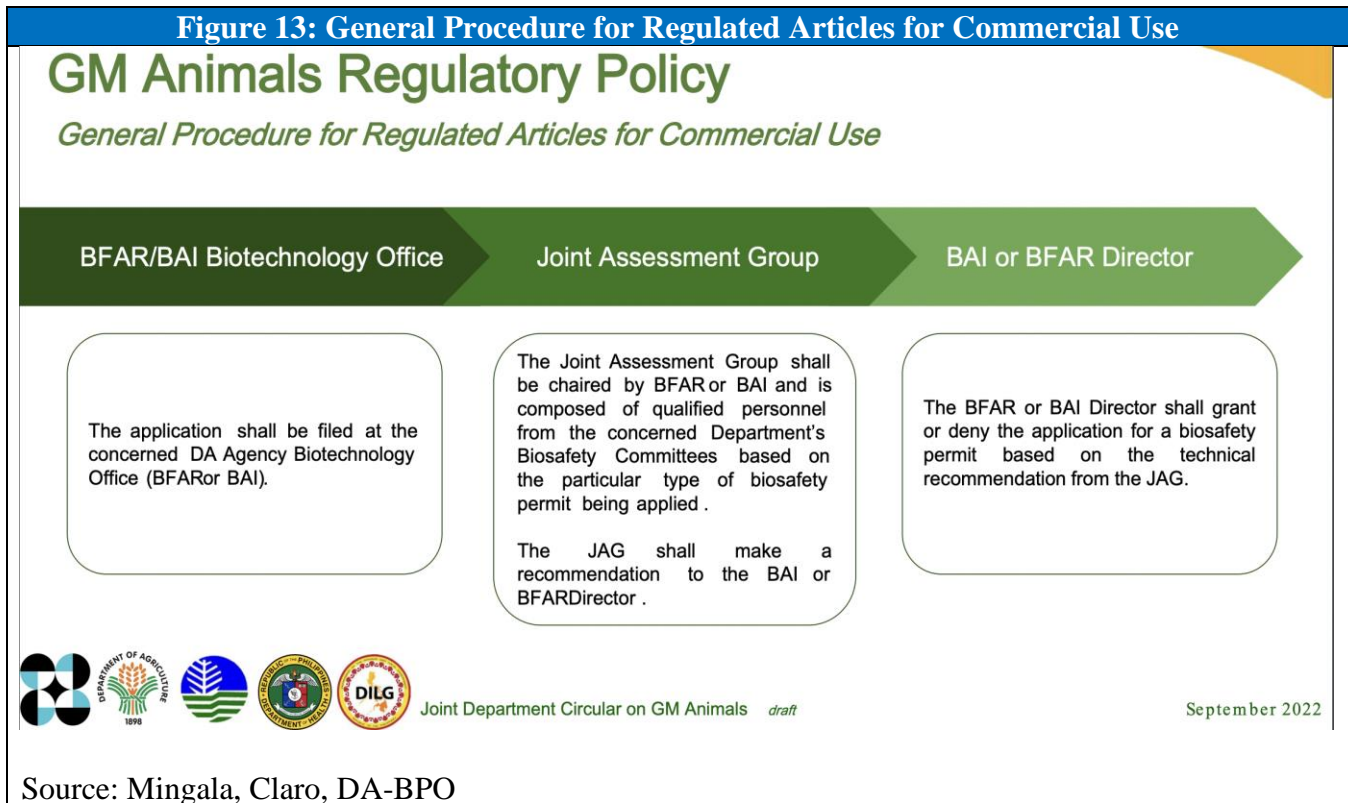
### ***PART E: POLICY***

a) **REGULATORY FRAMEWORK:** The Philippines has drafted the regulatory framework for GE animals, including insects. The finalization of the policy regulations has been stalled on issues over the responsible agency that should cover mosquitos. The DA cannot cover mosquitoes, as they are neither food nor feed. The responsible agency could either be the Department of Environment and Natural Resources or the Department of Health. Mosquitoes have therefore been excluded and the regulatory framework is focused on agricultural animals. 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.



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.

The draft JDC on “GM” Animals follows the below general procedure:



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's Livestock Biotechnology Center 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 [Public Perception on Agribiotechnology](#) 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.

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.

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.

- a) **REGULATORY FRAMEWORK:** Not applicable
- 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