

Required Report: Required - Public Distribution **Date:** November 14, 2022

Report Number: RP2022-0058

Report Name: Agricultural Biotechnology Annual

Country: Philippines

Post: Manila

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

The Philippines is a regional biotechnology leader and the first country in the world to approve Golden Rice for commercial propagation. The Bt Eggplant biosafety permit was signed on October 17, 2022, allowing commercial propagation. Planting of Golden Rice has started since its approval in 2021, while Bt corn acceptance has grown with more than 600,000 hectares planted in 2021. The Philippines recently passed a revised regulatory policy for importation, handling and use, transboundary movement, release into the environment, and management of genetically engineered (GE) plants and plant products derived from the use of modern biotechnology, and also 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 is under review for the target release before the end of 2022 or early 2023.

EXECUTIVE SUMMARY

The Philippines continues to be a leader on biotechnology in Southeast Asia, having been the first in the region to have regulatory framework on GE crops. Corn, Golden Rice, and Bt Eggplant are GE crops currently allowed for commercial propagation. The biosafety permit for commercial propagation of Bt Eggplant was signed on October 18, 2022. Planting of Golden Rice just started since its approval in 2021, while GE corn planted area has grown from 10,700 hectares in 2003 to 600,000 hectares in 2021.

The country is moving forward with the implementation of three regulations: revised Joint Department Circular (JDC1); Department of Agriculture (DA) Memorandum Circular (MC) 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 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 with exports reaching \$3.5 billion in 2021, up nine percent from 2020. The country continues to be the largest U.S. soybean meal market, with \$960 million in sales in 2021.

The passing of the three regulations is proof of the Philippines' commitment to science and improvements in biotechnology, which was further highlighted by the recent approval of Bt Eggplant (October 2022) and Golden Rice (July 2021) for commercial propagation.

For more information, please see the following GAIN reports:

GAIN Agricultural Biotechnology Annual 2021

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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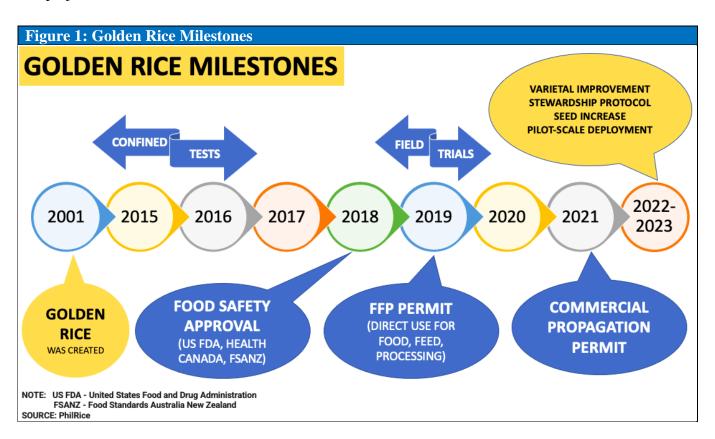
CHAPTER 1: PLANT BIOTECHNOLOGY

The Philippines uses biotechnology as one tool to reach its food security goals, and to modernize its food systems to meet the United Nations <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.

PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT: 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.



The Philippines has several genetically engineered (GE) crops in the research and regulatory approval pipeline:

Bt Eggplant - The University of the Philippines - Institute of Plant Breeding (<u>UPLB-IPB</u>) conducted the research on Bt Eggplant to address the major pest known as eggplant fruit and shoot borer (EFSB). The biosafety permit for commercial propagation was signed on October 18, 2022, seven months from submission of <u>application for commercial propagation</u> on March 30, 2022. The Bureau of Plant Industry (BPI) issued a <u>biosafety permit</u> for direct use for food, feed, or processing for Bt Eggplant on July 21, 2021, determining it safe for consumption.

Bt Cotton - The Philippine Fiber Industry Development Authority (PhilipIA) promotes Bt Cotton as a solution to the challenges of cotton bollworm, although an application for commercial propagation remains forthcoming. Paired with the development of Bt cotton will be the promotion of heirloom and organic cotton production technology to revive the Philippine cotton industry. The Philipia collaborates with the Department of Trade and Industry (DTI) to revive the industry to supply weavers with locally produced cotton.

Other products being developed include Papaya Ringspot Virus-Resistant (PRSV-R), and Multiple Virus Resistant (MVR) tomato. 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. Meanwhile, MVR tomato is still being studied. Dr. Hayde Galvez of 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 United States Department of Agriculture - Agricultural Research Service (USDA-ARS) and Foreign Agricultural Service (FAS). PhilRice and IRRI have ongoing gene editing researches on rice. Meanwhile, discussions to conduct research on GE sugarcane are underway.

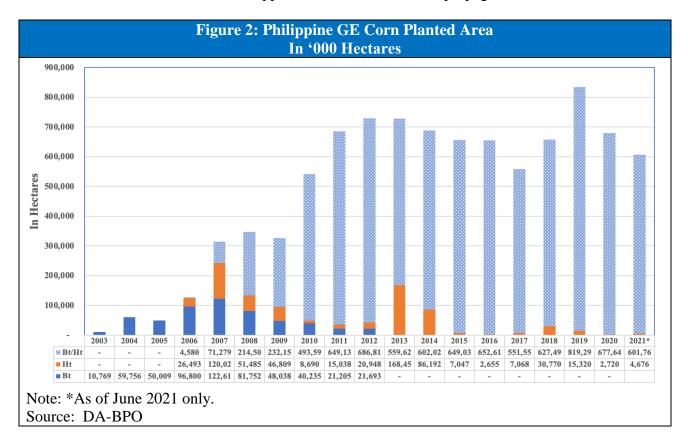
b) COMMERCIAL PRODUCTION: Corn, Golden Rice, and Bt Eggplant are GE crops currently allowed for commercial propagation in the Philippines. Bt Eggplant was recently approved with its biosafety permit signed on October 18, 2022.

Rice. On July 21, 2021, the <u>Philippines approved Golden Rice</u> for commercial propagation. On March 18, 2021 DA issued <u>Memorandum Order 19</u> Series of 2021 operationalizing the Department's full support to 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.

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.

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

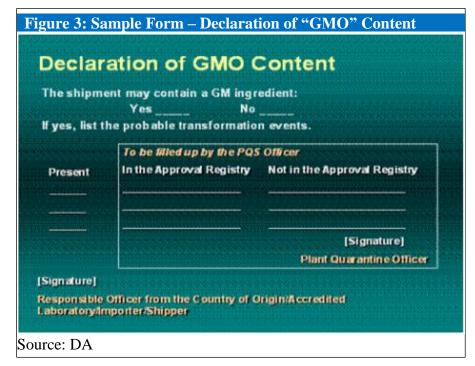
single (instead of multiple) broad spectrum herbicide. Since the approval of Bt corn in 2002, and Roundup Ready (RR) or herbicide tolerant (HT) corn, companies also developed GE corn with stacked traits (Bt + HT), and the area planted with GE corn grew rapidly. GE corn area increased from 10,769 hectares in 2003 to 601,764 hectares as of June 2021. The growth is an indication of increasing acceptance of using GE corn. The 2021 acreage is actually a drop 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. The current list of approved GE corn events for propagation is available here.



Fall armyworm or FAW (*Spodoptera grugiperda*) has been detected across the region. It was found two 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.

c) 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.



d) 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 \$3.5 billion in 2021, up nine percent from 2020. The country continues to be the largest U.S. soybean meal market (all of which is GE), with \$960 million in sales in 2021.

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 <u>guidelines</u> updating the list of commodities requiring the "GM" declaration, <u>expanding to more products beyond bulk commodities</u>. Importers remain authorized to sign the Declaration of "GMO" Content.

- e) FOOD AID: The Philippines is a consistent food aid recipient though the USDA Food for Progress program (e.g., GE soybean meal). The importation of food aid commodities has been unimpeded by GE issues.
- f) 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 is on cotton imports. Cotton importer claimed that it is difficult to provide the Declaration of "GMO" Content due to the various sources of cotton in a bale. The BPI requires a laboratory test to identify the transformation events that maybe present in the cotton shipment.

PART B: POLICY

a) REGULATORY FRAMEWORK: The Philippines continues to be a leader on biotechnology in Southeast Asia. It was the first in the region to have a regulatory framework on 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 language)	(in English)	Regulations where	(in English)
		the term is used	
"Genetically modified	"Genetically	Joint Department	"living modified organism" under
organism (GMO"	modified	Circular (JDC) No.1,	the Cartagena Protocol on
	organism (GMO"	Series of 2021	Biosafety and refers to any living
			organism that possess a novel
		Department of	combination of genetic material
		Agriculture (DA)	obtained through the use modern
		Memorandum Giral (MG) Na 9	biotechnology
		Circular (MC) No. 8,	
		Series of 2022	
		National Committee	
		on Biosafety of the	
		Philippines (NCBP)	
		Resolution No. 1,	
		Series of 2020	
Modern biotechnology	Modern	JDC No.1, Series of	Refers to the application of: 1) in
	Biotechnology	<u>2021</u>	vitro nucleic acid techniques,
			including recombinant
		DA MC No. 8	deoxyribonucleic acid (DNA) or
			direct injection of nucleic acid
		NCBP Resolution	into cells or organelles; or 2)
		No. 1, Series of 2020	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	New Plant	JDC No.1, Series of	If contains a novel combination of
Innovations	Breeding	2021	genetic material obtained through
	Techniques	DA MC No. 8	modern biotechnology
	1	NCBP Resolution	
		No. 1, Series of 2020	
Novel Combination	Novel	JDC No.1, Series of	A resultant genetic combination in
	combination	<u>2021</u>	a living organism that is not
		DA MC No. 8	possible through conventional
		NCBP Resolution	breeding.
DI	DI .	No. 1, Series of 2020	D.C
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

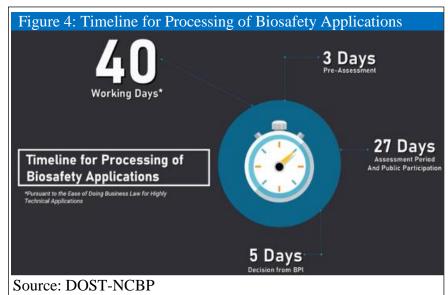
Regulated article	Regulated article	JDC No.1, Series of 2021 DA MC No. 8	Refers to genetically modified plants and plant products under the scope of the JDC
Responsible officer	Responsible officer	JDC No.1, Series of 2021	Refers to an officer appointed by the applicant for the importation or release 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"	JDC No.1, Series of 2021	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"	JDC No.1, Series of 2021	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. Further strengthened by EO 514 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. 8 (AO 8) in 2009, 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 Circular No. 1</u> (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). The 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, making 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 <u>Anti-Red Tape Authority</u>; 7) Stacked GE plants and derived products will not require 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.

The passing of the revised JDC1 is proof of the Philippines' commitment to science and improvements in biotechnology, and their status as a regional biotechnology leader, which was further highlighted by its passage in 2021 of Golden Rice and in 2022 of Bt Eggplant for commercial propagation.

Table 2: Institutions in Crop Biotechnology Policy		
Regulations	Risk assessments, and registrations	
NCBP - mandated to formulate, review,	DENR - conducts risk assessment for impact of biotech	
amend the biosafety guidelines.	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

Table 3: Role of N	Vation Government Agencies in the Safety Assessment of GE Crops
Department of	Lead in addressing biosafety issues related to the country's agricultural
Agriculture	productivity and food security. Lead in the evaluation, and monitoring of
(DA)	regulated articles.
Department of Science	Lead in ensuring that the best science is utilized and applied in adopting
and Technology	biosafety policies, and in making biosafety decisions. Lead in evaluating
(DOST)	and monitoring contained use of regulated articles.
Department of	Ensure that the applicable environmental assessments are undertaken, and
Environment and	potential impacts identified. Lead in evaluating and monitoring
Natural Resource	bioremediation, improvement of genetic resources, and wildlife genetic
(DENR)	resources.\
Department of Health	Formulate guidelines and review results of assessing the health impacts
(DOH)	posed by modern biotechnology. Lead in evaluating and monitoring
	processed food derived from or containing "GMOs."
Department of Interior	Oversee implementation of the activities undertaken in specific LGUs in
and Local Government	relation to the conduct of public consultations as required by the Local
(DILG)	Government Code.

Source: JDC1

The Philippine government created the <u>BPI Biotech Core Team</u> (BPI-BCT) in 2017 to assist in the implementation of biotechnology activities. A new <u>composition</u> (MO 135) of the BPI-BCT was implemented in June 2021.

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.

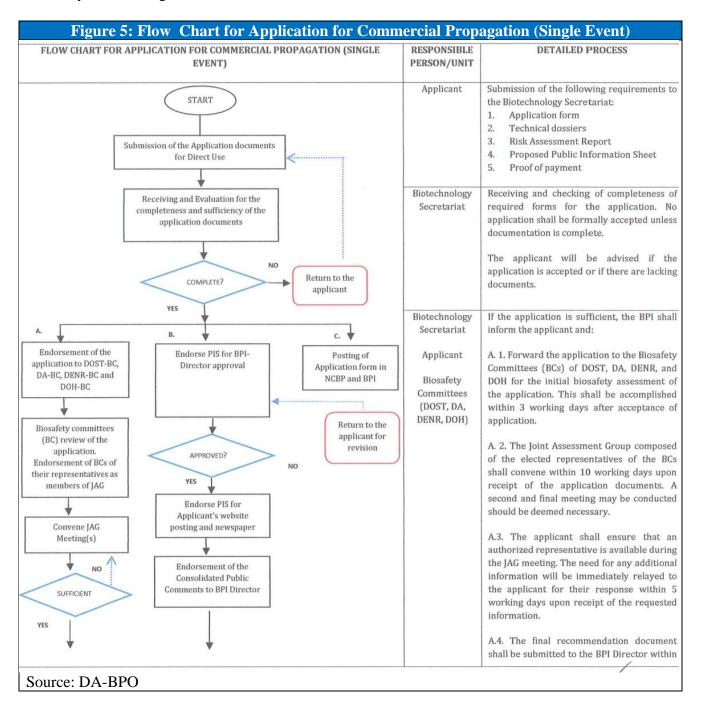
GE crops developed locally and intended to be commercially grown in the Philippines must undergo regulatory processes following the guidelines set forth under the JDC1. The process flow is presented here. Only after a biosafety permit is issued with the satisfactory completion, and an approval of Commercial 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 <u>direct use</u>, <u>field trial</u>, and <u>propagation</u> are listed on the <u>DA biotech website</u>. The BPI recently approved the Bt eggplant's application for commercial propagation, which was <u>submitted on March 30, 2022</u>, and signed on October 17, 2022.

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 <u>streamlined the overall regulatory framework</u> for genetically engineered plant products in January 2022 through the revised JDC1.



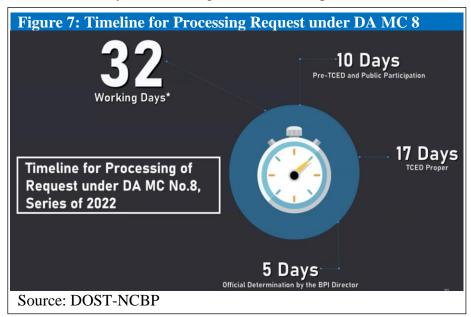
d) FIELD TESTING: Below is the process, and the regulatory institutions involved. A field trial to generate data for environmental biosafety risk assessment of Golden Rice was conducted, and <u>approved on May 20, 2019</u>, the only field trial application so far under the JDC 1.

Figure 6: Process Flow for Issuar	nce of Certificate of Field T	rial Completion
CHART FOR ISSUANCE OF CERTIFICATE OF FIELD TRIAL COMPLETION	RESPONSIBLE PERSON/UNIT	DETAILED PROCESS
START Submission of the field trial	Applicant	The applicant shall submit a completion report of the field trial conducted.
Farming out of the field trial completion report to the concerned agencies.	Bureau of Plant Industry (BPI) Department of Health (DOH) Department of Environment and Natural Resources (DENR)	BPI shall consolidate and discuss the comments with DOH and DENR.
SUFFICIENT? NO Return to the applicant	BPI Biotech Secretariat	BPI shall prepare the certification for field trial completion.
Preparation of the certificate of field trial completion. This form shall be issued to all proponents who will pick-up	BPI Director	BPI Director shall issue the certificate of field trial completio to the applicant.
Filling-out of Customer Satisfaction Form (CSF).	Proponent	This form shall be issued to all proponents who will pick-up the biosafety permit from the BPI Biotechnology Office. A staff will guide the proponent while filling-ou the customer satisfaction form.

e) INNOVATIVE BIOTECHNOLOGIES: The DA issued <u>Memorandum Circular No. 8</u> 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 <u>NCBP Resolution No. 1</u>, 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 or not they should be regulated as GE crops. Defined under EO

514, products from PBIs can be classified as a "GMO" if it 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,



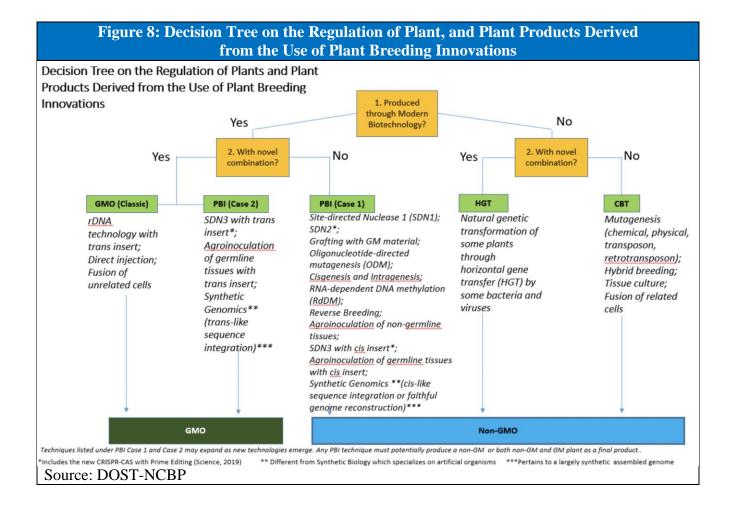
and therefore regulated under the revised JDC1. The circular sets the procedural requirement for the conduct of a Technical Consultation for Evaluation and Determinations (TCED), which determines if a PBI is genetically engineered or not. It will take 32 days to process the request submitted.

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.

Technical Consultation for Evaluation and Determination

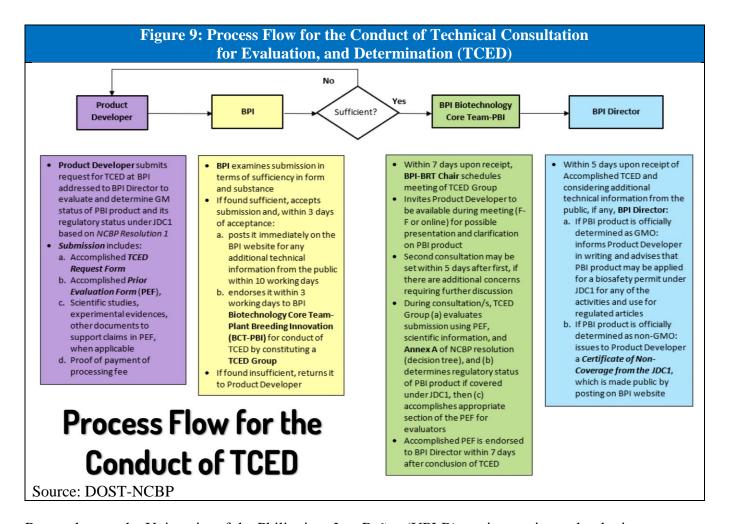
A product developer who intends to introduce a PBI product into the country shall submit a request to the Director of BPI for Technical Consultation for Evaluation, and Determination (TCED), which is a technical evaluation of the PBI product to determine whether or not the final product of the plant breeding process employed to produce the PBI product contain 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.



BPI Biotechnology Core Team – Plant Breeding Innovation (BCT-PBI). 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.



Researchers at the University of the Philippines Los Baños (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. It was reported that the project is almost complete in its target to discover the natural defense mechanisms of wild eggplant accessions against EFSB and LH.

The <u>Philippine Genome Center</u> 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 researches</u> also support studies on these crops.

- f) COEXISTENCE: There are no rules in place or proposed on coexistence.
- 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 House Bill 6411 known as "The Philippine "GMO" Labeling, and Regulation Act, The Right-to-Know Act," which

would require the mandatory 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 10: Flow (Chart for Post Approval M	Monitoring
FLOW CHART FOR POST APPROVAL MONITORING	RESPONSIBLE PERSON/UNIT	DETAILED PROCESS
Technology Developer will provide schedule on each sentinel site.	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.
PAMG Secretariat will finalize schedule for monitoring and coordinate with the techdevs and RCPCs for logistics.	BPI Biotech Secretariat	Confirmation of monitoring activity shall be made at least 2 weeks prior to the schedule.
On site: Monitors will gather data on the sentinel site. Monitors will accomplish monitoring form with proper signatories	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.
Submit to Secretariat for filing.	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 (<u>DA-AO No. 1</u>) 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 implementing guidelines have been issued but DA-BPO commissioned a third party to undertake a study to be finished before the end of 2022.

j) ADDITIONAL REGULATORY REQUIREMENTS: In October 2020, all technology developers filing GE applications were required to submit <u>two studies</u> to hasten the biosafety approval process, and information on the changes on the product.

After an application is approved, seed registration is still required with the <u>National Seed Industry</u> <u>Council</u> under BPI.

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 that 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 <u>biotech website</u>.

On September 30, 2021, the Philippine Department of Agriculture inaugurated the Crop Biotechnology Center housed in the Philippine Rice Research Institute (PhilRice) in the Science City of Munoz, Nueva Ecija. The Center was funded with PhP277 million (\$5.4 million) from the U.S. Public Law 480 program and is poised to be the country's hub for innovative research for a variety of crops.

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 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: The recent petition filed on October 17, 2022 in the Supreme Court to stop commercial propagation of the recently approved Bt Eggplant and Golden Rice will again raise issues. The much-publicized Supreme Court ruling in December 2015, as well as the JDC public consultations in 2016, brought the GE debate into the limelight. It raised public curiosity, and interest in GE. 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, academia, 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 issued 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 10,700 hectares planted in 2003 to nearly 602,000 hectares in the first half of 2021, increasing further in 2022.

Preliminary findings from 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 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 <u>presentation</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, 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 has 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 <u>DNA barcoding</u> for livestock and poultry. The UPLB College of Agriculture and Food Science did a study on <u>genotyping dairy cattle</u> but stopped at Phase 1.

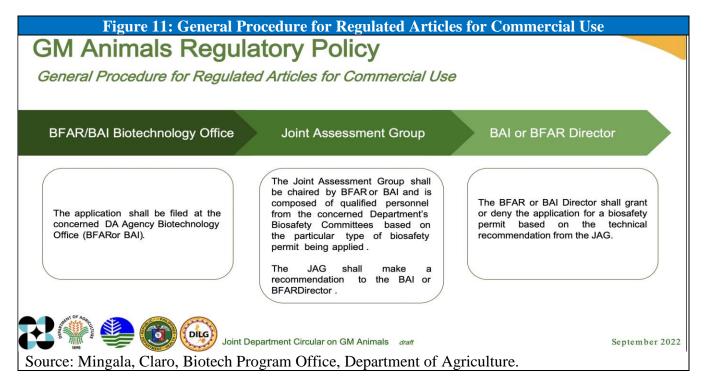
- b) COMMERCIAL PRODUCTION: Not applicable.
- c) EXPORTS: Not applicable.
- d) IMPORTS: Not applicable.
- e) TRADE BARRIERS: There are no biotechnology-related trade barriers that negatively affect U.S. animal biotechnology exports.

PART E: POLICY

a) REGULATORY FRAMEWORK: The Philippines has drafted the regulatory framework for GE animals, including insects. The finalization of the policy regulations got stalled on issues over the responsible agency that should cover mosquitos. The DA cannot cover as mosquitos are not food or feed. The responsible agency could either be the Department of Environment and Natural Resources or the Department of Health. 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.
 - 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 with 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) REEMTED ISSUES. Not applicable	g)	RELATED ISSUES:	Not applicable.
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PART I: MARKETING

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

Attachments:

No Attachments