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Philippines

Agricultural Biotechnology Annual

Philippine Agricultural Biotechnology Situation and Outlook

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Report Highlights:
The Philippines continues to be a regional biotechnology leader. Bt eggplant remains poised as the first locally-developed, genetically-engineered (GE) crop to be commercialized while field trials of Golden Rice (GR) are expected in the near-term future, the exact timeline of which is unknown. Although there have been delays in the processing of biosafety applications under the regulatory process known as Joint Departmental Circular (JDC) there have been no reported trade disruptions. Improvements in the implementation of the JDC regulations are expected starting late 2017 with the issuance of harmonized inter-agency procedures.

Section I. Executive Summary:

The Philippines was the 12th largest market for U.S. agricultural and related products by value in 2016 with exports reaching $2.7 billion. It was the largest U.S. soybean meal market with sales reaching $730 million. The Philippines was also the 11th largest market by value for U.S. exports of consumer oriented products at $923 million in 2016.

The Philippines remains a regional biotechnology leader having been the first Asian country to allow the planting of a GE crop (Bt corn in 2003). A December 2015 Supreme Court (SC) ruling halted the field testing of Bt eggplant (which had already been completed) and declared null and void existing biotechnology regulations. Although the ruling was later overturned, new regulations to permit use of biotechnology were rushed into effect under the JDC. The new GE regulations as embodied in the JDC provide more consideration to socio-economic issues and environmental impacts. Biosafety approvals have been slow and according to stakeholders the new regulations are cumbersome and complicated. Although there have been no trade disruptions, the delays in permit approvals have the most potential to disrupt U.S trade.

Improvements are expected starting in late 2017 with the anticipated issuance of an inter-agency manual of procedures. Further regulatory refinements are likely in 2018 as well. Many policy makers including legislators and members of the judiciary will likely enhance GE policy because of a growing interest in GE's potential role in rural development. After close to 15 years of commercial production of GE corn, studies have shown GE corn farmers have increased their incomes and Philippine corn production has improved. There have been no scientifically proven environmental or health issues attributed to its widespread cultivation.

Currently, there are no labeling requirements for GE food products. At least two GE food product labeling bills have been filed in the Philippine House of Representatives (PHOR) of the 17th Congress. A hearing on the bills was scheduled for August 23, 2017 but was postponed. The new hearing date has yet to be set.

Section II. Author Defined:

PLANT AND ANIMAL BIOTECHNOLOGY

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CHAPTER I: PLANT BIOTECHNOLOGY

Part A: PRODUCTION AND TRADE

a) Product Development:

Development of the fruit and shoot borer-resistant eggplant (Bt eggplant) is led by the Institute of Plant Breeding of the University of the Philippines at Los Banos (IPB-UPLB). The Bt eggplant technology was donated by the Maharashtra Hybrid Seed Company to UPLB through a royalty-free sublicense agreement facilitated by Sathguru Management Consultants and Cornell University through the U.S. Agency for International Development-Agricultural Biotechnology Support Project II (USAID-ABSP 2). All relevant field tests have been completed. Bt eggplant remains poised to be the first locally-developed GE crop to be commercialized.

The beta-carotene-enriched rice or GR project is being developed by the Philippine Rice Research Institute (PhilRice), and is supported by the Bill and Melinda Gates Foundation through a grant to the International Rice Research Institute (IRRI). There is also support from the Rockefeller Foundation, USAID, and the Philippine Department of Agriculture's (DA) Biotechnology Program. The project has concluded confined field tests. On February 28, 2017, PhilRice applied for field trials to generate data for environmental biosafety risk assessment.

The screen house evaluation for Bt cotton was completed in 2010, and the confined trial in 2011. The last evaluation year of the multi-location test was completed in 2015, and the related lab experiments in 2017. The evaluation further confirmed the bioefficacy of the Bt cotton hybrids against the cotton bollworm. Currently, the project is waiting for the certificate of satisfactory completion of the multi-location test prior to applying for commercial propagation. The Bt cotton technology is being evaluated by the Philippine Fiber Industry Development Administration.

The IPB-UPLB project on the delayed ripening papaya with ring spot virus-resistance completed its first field test in 2014. As recommended by experts, backcrossing of the F1 hybrid to the transgenic line will be conducted instead of preparing a second field trial in 2017. Preparation of permits for the above-mentioned contained trial and its eventual varietal registration are underway

The Philippines does not use innovative technologies in any product development.

b) Commercial Production:

Based on data from the Bureau of Plant Industry (BPI), GE corn was planted on over 5.9 million hectares in the Philippines since its introduction in 2003. The following table is based on preliminary data from BPI and shows area planted at 655,000 hectares during the April 2016 to March 2017 period. During the same period, roughly 99 percent of all GE crops planted were stacked varieties, according to BPI data.

GM Corn Adoption by Event (Has.)	
Year	**Total**
2003	10,769
2004	59,756
2005	50,009
2006	127,873
2007	313,915
2008	347,740
2009	327,003
2010	542,524
2011	685,373
2012	729,450
2013	728,078
January 2014 - March 2015	688,218
April 2015 - March 2016	656,084
April 2016 - March 2017	655,269
Total	5,922,061

Source: Bureau of Plant Industry

c) Exports:

No GE crops are exported by the Philippines.

d) Imports:

The following table is a breakdown of U.S. exports of GE crops and by-products to the Philippines from 2014 to 2016. Philippine imports of GE crops and by-products from the U.S. increased 20 percent in 2016 compared to the previous year's level. U.S. exports of GE products were valued at $922 in 2016, up from $770 million in 2016.

CY US Exports to the Philippines (In Thousand $)			
	2014	**2015**	**2016**
Soybean Meal	590,000	635,000	729,100
Feeds & Fodders	39,400	35,400	41,100
Soybeans	56,000	47,400	107,400
Sweeteners	73,500	28,200	24,600
Coarse Grains	700	0	0
Cotton	16,500	17,500	12,900
Vegetable Oil*	7,700	6,700	7,100
Soybean Oil	300	200	200
TOTALS	784,100	770,400	922,400

*excluding Soybean oil group

Source: U.S. Bureau of Census Trade Data

The table excludes exports of U.S. consumer oriented products, most of which contain GE-derived ingredients. Sales of U.S. consumer oriented products to the Philippines reached $923 million in 2016, making it the 11th largest market by value.

e) Food Aid:
The Philippines is a consistent food aid recipient (i.e., Food for Progress) and there have been no biotechnology issues that impede the importation of food aid commodities. The Philippines does not provide food aid.

f) Trade Barriers:
Prolonged delays in the processing of biosafety permits under the JDC have the most potential to negatively affect U.S. exports of GE products.

Part B: POLICY

a) Regulatory Framework:
In 2012, a lawsuit was filed to halt the commercialization of Bt eggplant. The case was elevated to the SC which ruled on December 8, 2015 that existing GE regulations as embodied in DA Administrative Order No. 8 (DA-AO 8) did not sufficiently cover the minimum requirements of the principles of risk assessment embodied in the National Biosafety Framework (NBF). The SC permanently enjoined the field testing of Bt eggplant (which had already been completed) and declared null and void DA-AO 8. Hence, it halted the processing of applications for contained use, field testing, propagation and commercialization, as well as the importation of GE products. Specifically, the SC pointed to shortcomings in DA-AO 8 pertaining to the following: (1) Public consultation; (2) Department of Environment and Natural Resources (DENR) involvement; and (3) Risk assessment standards and practices.

In 2016, experts from the DA, Science and Technology (DOST), DENR, Health (DOH), and Interior and Local Government (DILG), crafted a Joint Department Circular entitled *Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Plant and Plant Products Derived from the Use of Modern Biotechnology*. On March 8, 2016, after a series of consultations and several revisions, the DOST-DA-DENR-DOH-DILG JDC No. 1, Series of 2016 was approved, and took effect April 15, 2016. According to local experts, the JDC provides more consideration to socio-economic issues and environmental impacts in risk assessment procedures compared to DA-AO 8.

The JDC indicates the responsibilities of DA, DENR, and DOH in the conduct of risk assessment. Environmental risk assessment will be conducted by DENR while DOH is responsible for environmental health and food safety impact assessments. The DILG's role is mainly coordinating with the other departments in overseeing public consultations. DOST remains as the lead agency for evaluation and monitoring regulated articles (i.e., approved GE events) intended for contained use, while DA continues to take the lead in the evaluation and monitoring of regulated articles. DA, through BPI, is still tasked to evaluate and issue all permits such as field trials, propagation, and direct use for food or feed. Food safety assessment is given to BPI-Plant Product Safety Services Division while feed safety assessment was assigned to Bureau of Animal Industry (BAI) in accordance with Food Safety Act of 2013.

The full text of the JDC may be viewed at:

http://biotech.da.gov.ph/upload/Signed_DOST-DA-DENR-DOH-DILG_JDCs2016.pdf

In a July 26, 2016 press briefing, after reviewing the impact of its ruling, the SC reversed its December 2015 decision to halt the field testing, propagation, commercialization, and importation of GE products in the country. The full SC decision was issued on August 18, 2016, but confirmed that the new JDC still superseded the old DA-AO 8. All approved transformation events (TEs) under DA-AO 8 had to reapply under the JDC.

The flow charts for applications for field tests, propagation and direct use are provided at the end of this report. They may also be viewed at http://biotech.da.gov.ph/Process_flow.php. The indicated number of application processing is 85 days. Approvals, however, generally take over a year. Stakeholders attribute the slow processing to confusing procedures and to new and changing personnel. A harmonized inter-agency manual of procedures is currently being developed and should speed up the process. DA contacts expect the issuance of this manual by the end of 2017.

As of October 17, 2017, there have been 39 applications for direct use, 2 for propagation, and one for field testing for processing under the JDC (Attached APPLICATIONS UNDER PROCESS).

On a longer-term basis, a science-based advocacy group, the Coalition for Agriculture Modernization in the Philippines (CAMP), hopes to work with legislators to refine complicated and cumbersome GE regulations, as well as provide general support for biotechnology and promote food security.

b) Approvals:

All approved transformation events (TEs) under DA-AO 8 have to reapply under the JDC.

Under DA-AO8, there were 37 regulated articles approved for direct use as food and feed and for processing (Attached ANNEX I) through December 8, 2015. In addition, there were 6 regulated articles approved for propagation (Attached ANNEX II) during the same period. TEs approved for propagation are also approved for direct use for food and feed and for processing.

On February 1, 2017, Bayer's soybean A5547-127 was approved for direct use under the JDC.

c) Stacked or Pyramided Event Approvals:

Multi-trait or stacked event crops composed of approved individual TEs have to reapply under the JDC.

Under DA-AO8, there were 35 combined-trait products approved for direct use as food and feed and for processing (Attached ANNEX IA) through December 8, 2015. There were also 6 stacked-trait crops approved for propagation (Attached ANNEX IIA) during the same period. Combined-trait products approved for propagation are also approved for direct use as food and feed and for processing.

Two stacked-trait products have been approved under the JDC, namely, Monsanto's corn MON89034 x NK603 for commercial propagation (approved on September 30, 2016) and Monsanto's soybean MON87708 x MON89788 for direct use (approved on February 1, 2017).

d) Field Testing:
All approved TEs under DA-AO 8 have to reapply under the JDC. Field testing applications are required to undergo public hearings in coordination with the concerned local government unit (LGU) prior to its endorsement.

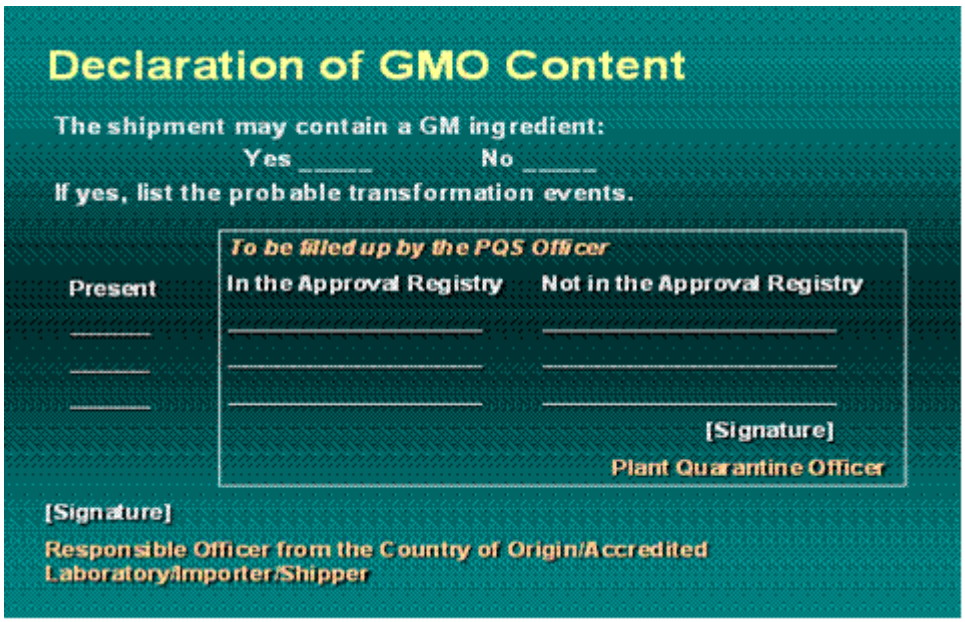
e) Innovative Biotechnologies:
There are currently no regulations covering innovative biotechnologies in plants and plant products in the Philippines. Local regulators, however, have indicated their inclination towards a 'product' rather than a 'process' approach to regulating products of innovative technologies.

f) Coexistence:
There is no Philippine policy on cultivation coexistence of GE crops with conventional crops (including organic agriculture), and there are no rules in place or proposed on coexistence.

g) Labeling:
Currently, there are no labeling requirements for GE food products. In its *"Draft Guidelines on Labeling of Prepackaged Foods Derived from or Containing Ingredients from Modern Biotechnology,"* the Philippine Food and Drug Administration (PFDA) indicated that it will not require labeling for GE packaged foods. The PFDA position is largely based on the Codex Alimentarius standards on labeling as described in the "Compilation of Codex Texts Relevant to Labeling of Foods Derived from Modern Biotechnology." The PFDA in late 2013 issued a statement attesting to the safety of GE and GE-derived foods, adding that GE foods were substantially equivalent to conventional counterparts.

At least two GE food product labeling bills have been filed in the PHOR of the 17th Congress. House Bill 3686 and House Bill 3810 both require the mandatory labeling of GE food. Both bills were filed with the Committee on Health, but are likely to be transferred to the Committee for Trade and Industry of the PHOR. HB 3686 seeks to direct the DOH to implement mandatory labeling of food, food products, and agricultural products that are GE or contain GE ingredients. A hearing on HB 3686 on August 23, 2017 was scheduled but postponed. The new hearing date has yet to be set. HB 3810 and any other similar bills will likely be coalesced into HB 3686.

Philippine regulations require shipments of imported bulk commodities 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. DA maintains that the declaration is part of its food and environment safety regulations, and that it brings the Philippines into compliance with Article 18.2 of the Cartagena Protocol on Biosafety (CPB) i.e., Handling, Transport, Packaging and Identification Requirements for Living Modified Organisms for Contained Use and Environmental Release. Since implementation, Post is not aware of any trade-related disruption as a result of this requirement. A sample form of this declaration follows:



Source: Philippine Department of Agriculture

h) Monitoring and Testing:
Monitoring by BPI of GE crop propagation is handled by BPI's Post Approval Monitoring group. 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.

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 implementing guidelines have been issued.

j) Additional Regulatory Requirements:
After an application is approved, seed registration is still required with the National Seed Industry Council under BPI.

k) Intellectual Property Rights :
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 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 being protected). Provisional protection may be 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 upon 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 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 to the UN Convention on Biological Diversity."* The CPB ratification followed the March 2006 issuance of Executive Order No. 514 adopting the NBF, which was the interim implementing mechanism of the CPB.

The National Committee on Biosafety of the Philippines (NCBP) issues guidelines and standards on risk assessment, environmental impacts, and socio-economic, ethical and cultural assessments. The NCBP oversees the implementation of the NBF, as well as coordinates and harmonizes efforts and activities of the various concerned agencies and departments. It sets the scientific standards for guidance by other Departments, serves as the bio-safety clearing house, and coordinates the implementation of decisions made under the Conference of Parties serving as Meeting of Parties (COP-MOP) to fulfill the country's international obligations as Party to the Cartagena Protocol on Biosafety.

From December 4-17, 2016, Philippine delegates participated in the COP-MOP 8 in Cancun, Mexico. The team included representatives from the DOST, DENR and DOH. The group's active participation resulted in the Philippines' growing influence in COP-MOP discussions. On the sideline of COP-MOP 8, the delegation took the lead as the chief organizer of the Asia Biosafety Clearing House Family's side event entitled "*For a Successful Asia BCH Family*". The activity highlighted milestones achieved by the Asian Region in relation to the regional Biosafety Clearing House.

m) International Treaties/Fora:

The Philippines actively participates in international biotechnology events including Codex Alimentarius meetings as well as related events of the Asia Pacific Economic Cooperation (APEC). The APEC 2017 Food Security Week and APEC High-Level Dialogue on Enhancing Food Security and Sustainable Agriculture in Response to Climate Change were held from August 18-25, 2017 in Can Tho City, Viet Nam.

The Philippines actively participated in the APEC High Level Policy Dialogue on Agricultural Biotechnology (APEC-HLPDAB) Workshop *"Driving from 1G to 5G"* held August 18-19, 2017 as well as during the HLPDAB Meeting on August 20, 2017. Both events featured several Filipino experts/speakers.

n) Related Issues:
Pertinent GE information and related issues are provided in the DA's biotechnology webpage: http://biotech.da.gov.ph/.

The webpage of the NCBP (http://ncbp.dost.gov.ph/) provides information regarding regulatory requirements for GE experiments.

Part C: PLANT BIOTECHNOLOGY MARKETING ISSUES:

a) Public/Private Opinions:
GE support from local corn farmers, hog and poultry raisers, feedmillers, food processors, academe, and other end users remains strong. Large domestic food and agribusiness companies already using GE products prefer to be 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. However, the overwhelming majority of Filipinos are indifferent.

The much publicized SC ruling in December 2015, as well as the ensuing JDC public consultations in 2016, brought the GE debate into the limelight. The experience not only galvanized like-minded GE stakeholders, it also raised public GE curiosity and interest. It created the demand for more information. Relative to this, many policy makers including Philippine legislators and members of the judiciary have expressed interest in obtaining current information regarding the status of U.S. research, regulation, and commercial production of GE crops and products.

b) Market Acceptance/Studies:
Despite the established safety of GE products, increased market acceptance is dampened by the misinformation campaign by anti-GE advocates.

The last known Philippine GE consumer survey was done in 2008 by the Singapore-based Asian Food Information Center. The survey indicated that 59 percent of Filipino consumers had a positive perception of biotechnology, and that 73 percent believe they would benefit from food biotechnology in the next five years through improved quality and more affordable prices.

CHAPTER 2. ANIMAL BIOTECHNOLOGY:

Part D: PRODUCTION AND TRADE

a) Product Development:
There are no Philippine GE or genome-edited animals or clones under development that are expected to be in the market within the next five years.

The Philippines uses conventional techniques to improve livestock, including artificial insemination, embryo transfer, in-vitro embryo production, and ovum-pick. DNA-based techniques are confined to development of diagnostic kits for major animal diseases and markers.

b) Commercial Production:
Not applicable.

c) Exports:
Not applicable.

d) Imports:
Not applicable.

e) Trade Barriers:
There are no known biotechnology-related trade barriers that negatively affect U.S. exports.

Part E: POLICY

a) Regulatory Framework:
There is currently no legislation or regulations in place covering the development, use, import, or disposal of livestock clones, GE animals, or products derived from these animals or their offspring in the Philippines.

b) Innovative Biotechnologies:
There are currently no regulations covering innovative biotechnologies (such as genome editing) in animals in the Philippines.

c) Labeling and Traceability:
Not applicable.

d) Intellectual Property Rights (IPR):
The Philippines currently does not have, nor is it considering, legislation to address intellectual property rights for animal biotechnologies.

e) International Treaties/Fora:
See section on International Treaties/Fora in the Plant Section as animal biotechnology is also incorporated.

f) Related Issues:
The Livestock Biotechnology Center in Muñoz, Nueva Ecija was opened in August 2014, and coordinates and monitors livestock biotechnology research and development in the Philippines. Contact details are as follows:

Livestock Biotechnology Center
Philippine Carabao Center (PCC)
National Headquarters and Gene Pool
Science City of Muñoz, 3120 Nueva Ecija
PHILIPPINES
Tel. no. +63 044 456 0729
Fax no. +63 044 456 0730
Email: livestock.biotech@gmail.com

Part F: MARKETING

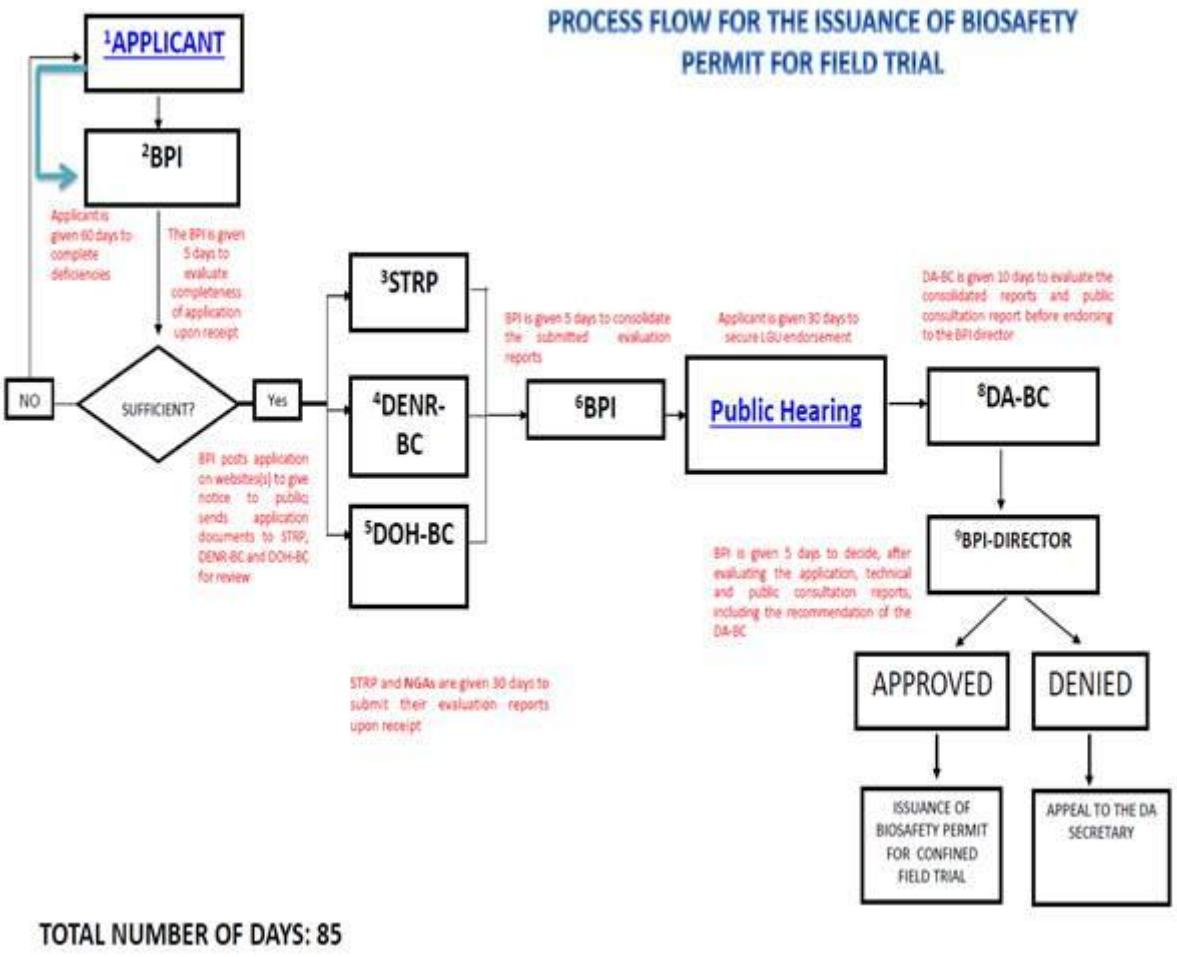
a) Public/Private Opinions:
Public awareness on GE animals is low.

b) Market Acceptance/Studies:
Not applicable.

LIST OF ACRONYMS

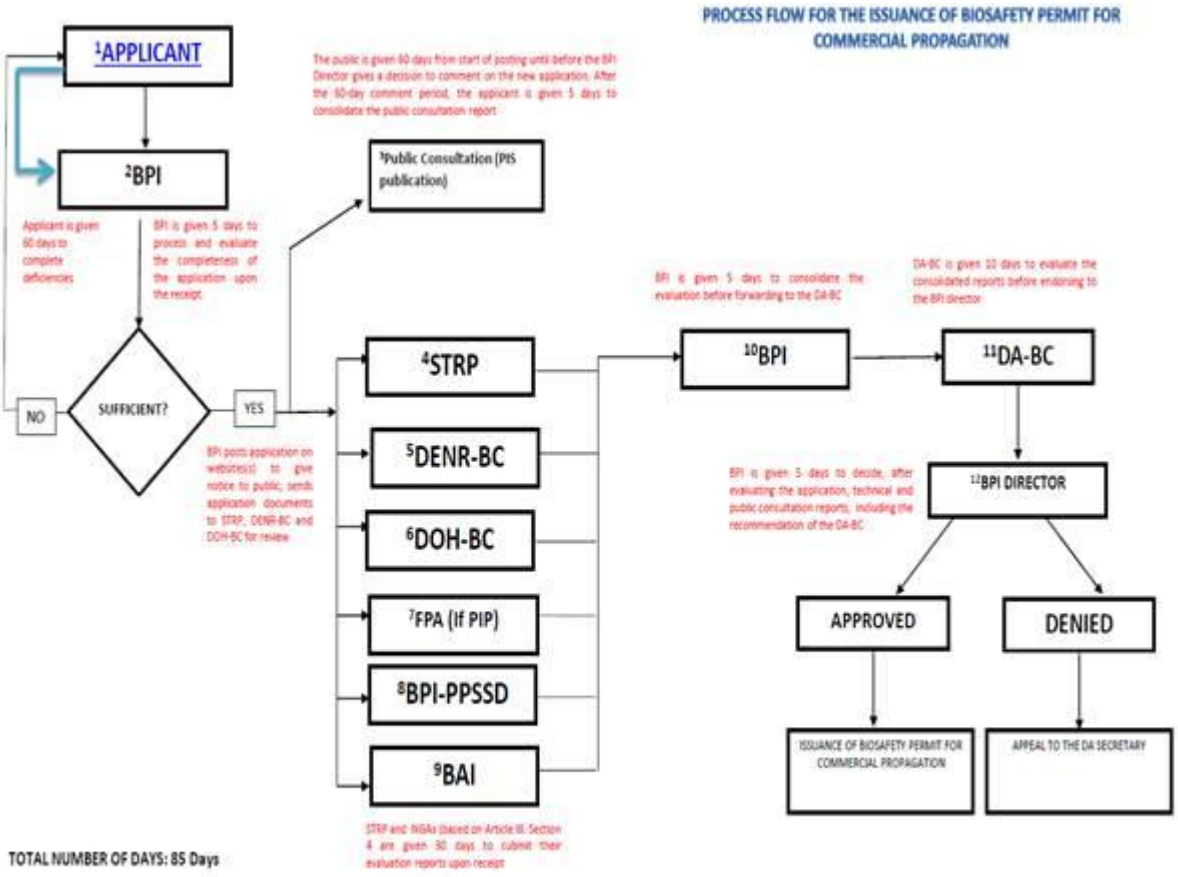
Administrative Order No. 8	AO 8
Asia Biosafety Clearing House Family's	ABF
Asia Pacific Economic Cooperation	APEC
Biosafety Committee	BC
Bureau of Plant Industry	BPI
Cartagena Protocol on Biosafety	CPB
DA Administrative Order No. 1	DA-AO No. 1
Golden Rice	GR
High Level Policy Dialogue on Agricultural Biotechnology	HLPDAB
International Rice Research Institute	IRRI
Joint Departmental Circular	JDC
Low Level Presence	LLP
National Biosafety Framework	NBF
National Committee on Biosafety of the Philippines	NCBP
Non-governmental organizations	NGOs
Philippine Carabao Center	PCC
Philippine Food and Drug Administration	PFDA
Philippine Rice Research Institute	PhilRice
Philippine Department of Agriculture	DA
Philippine House of Representatives	HOR
Philippine Department of Interior and Local Government	DILG
Philippine Department of Science and Technology	DOST
Philippine Department of Environment and Natural Resources	DENR
Philippine Department of Health	DOH
Plant Variety Protection Act	PVPA
Supreme Court	SC
transformation events	TE
U.P. Los Baños	UPLB
U.S. Agency for International Development	USAID

Annex I – Application for Field Trial



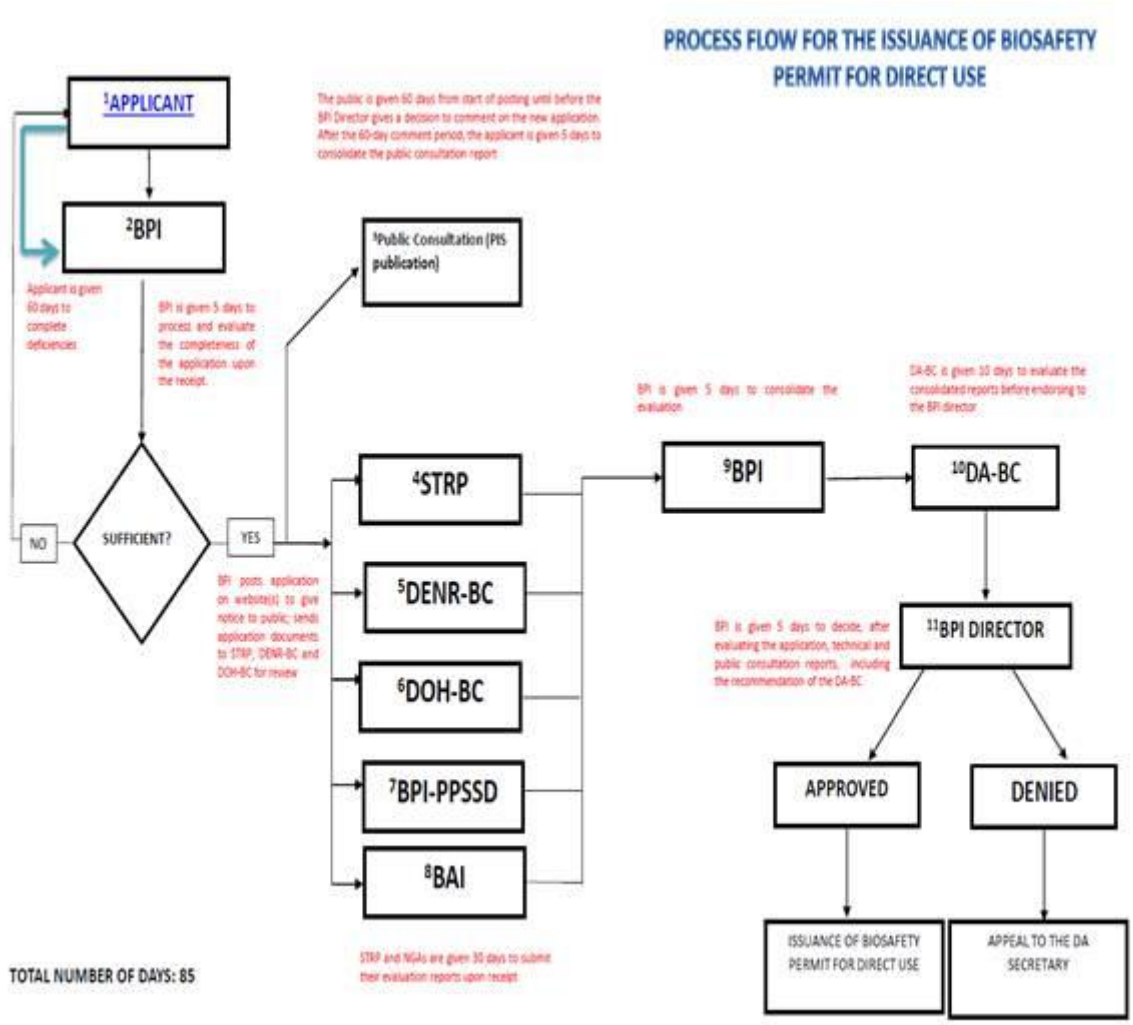
Source: Philippine Department of Agriculture

Annex II – Application for Commercial Propagation



Source: Philippine Department of Agriculture

Annex III – Application for Direct Use



Source: Philippine Department of Agriculture