

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

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Philippines

AGRICULTURAL BIOTECHNOLOGY ANNUAL

Philippine Agricultural Biotechnology Situation and Outlook

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Report Highlights:

In December 2015, the Philippines Supreme Court (SC) enjoined Bt eggplant trials and struck down existing genetic engineering (GE) regulations so that a new set of rules could be promulgated. An inter-departmental working group drafted new GE regulations in a Joint Departmental Circular (JDC) that was approved on March 2016. In a July 26, 2016 press briefing, and subsequently in its August 18, 2016 final decision issuance, the SC reversed course and lifted restrictions to commercialize Bt eggplant, but upheld that the JDC supersedes existing GE rules. The shift in biotechnology regulations has resulted in delays in the processing of biosafety permits, although there have been no reported trade disruptions to date.

SECTION I. EXECUTIVE SUMMARY

The Philippines is the 12th largest market for U.S. agricultural and related products by value in 2015 with exports reaching \$2.5 billion. It was the second largest U.S. soybean meal market valued at \$635 million. The Philippines is also the 13th largest market by value for U.S. exports of consumer oriented products at \$900 million in 2015.

The Philippines is a regional biotechnology leader with widespread acceptance of agricultural biotechnology and science-based regulations in place. The country is looked upon by its neighbors for policy guidance and as a regulatory model for GE products. The Philippines was the first Asian country to allow the planting of a GE crop (Bt corn). In 2015, GE corn area planted was close to 660,000 hectares, with the entire crop being stacked-trait.

Philippine national elections were held in May 2016 which resulted in a change of administration and changes to GE-pertinent department and bureau heads. Although there have been public statements from some high-level officials offering lukewarm support for GE, these have yet to be made official policy.

The JDC provides more consideration to socio-economic issues and environmental impacts in risk assessment procedures. Additionally, all expiring biosafety permits and new applications are required to apply under the new regulations. No phasing-in period was provided, so there have been delays in the processing of applications. However, there are no reported trade disruptions to date. Biosafety permits are valid for five years.

SECTION II: 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 (US AID-ABSP 2). All relevant field tests had been completed. Bt eggplant remains poised to be the first locally-developed GE crop to be commercialized after restrictions were lifted by the SC (refer to Regulatory Framework, POLICY). The application to commercialize may happen by 2017.

For the beta-carotene-enriched rice or Golden Rice (GR) project, three seasons of multi-location field trials at four to five locations have been completed. Results reported include consistently high beta-carotene in mature grains stored under ambient temperature, although grain yield was lower than expected. New confined field trials (using a new event) were executed in several sites with the last confined field test conducted late last year. The initial results are promising, although the next steps are unknown. The 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.

Bt cotton screen house evaluation was completed in 2010, and the confined trial in 2011. Evaluation results from the screen house, the confined field experiment, and the first year of the multi-location field test showed the efficacy of Bt cotton hybrids against the cotton bollworm. The Bt cotton technology is being evaluated by the Philippine Fiber Industry Development Administration. The current status of the project is unknown.

The IPB-UPLB project on the delayed ripening papaya with ring spot virus-resistance completed its first field test. Preparations for the second field test and its eventual varietal registration are still underway.

b) Commercial Production:

Based on data from the Bureau of Plant Industry (BPI), GE corn was planted to over 5.2 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 656,000 hectares during the April 2015 to February 2016 period. During the same period, all GE crops were stacked varieties, according to BPI.

GE 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
Jan. 2014-Mar. 2015	688,218
Apr. 2015 – Feb. 2016	656,079
Total	5,266,787

Source: Bureau of Plant Industry

The following table shows overall GE corn areas and how they relate to overall corn production and area harvested. Overall corn production and area harvested in 2015 (April 2015-February 2016) declined 2.8 percent and 1.7 percent, respectively, compared to their 2014 levels. GE corn area slightly declined (4.7 percent) from 688,000 hectares in 2014 to 656,000 hectares in 2015, according to preliminary BPI data. In 2015, GE corn accounted for 26 percent of all Philippine corn area (estimated at over 2.6 million hectares). Industry contacts claim that GE corn area would be higher if the data took into account the use of counterfeit GE seeds.

Average yields in 2015 (2.94 MT/hectare) were lower than the previous year's average of 2.98 MT/hectare). GE corn area, however, declined 5.5 percent in 2014 from the previous year's level, according to preliminary data from the BPI. In general terms, the decline in corn production and area planted in 2015 is attributed to the adverse effects of the El Nino weather disturbance, as well as damages by several typhoons, according to the Philippine Statistics Authority. No significant increase in GE corn output and area harvested is expected in 2016 mainly due to weather-related calamities that affected Northern Luzon, a major grain producing region.

Corn: Philippine Production, Area Harvested & Yield 2003-2015			
	2013	2014	2015
National Production (K MT)	7,377	7,771	7,553
Total Area (K Has.)	2,564	2,611	2,566
Yield (MT/Has.)	2.88	2.98	2.94
% Production Growth	-0.41	5.34	-2.81
% Growth in Total Area	-1.16	1.83	-1.72
GE Corn Area (K Has.)	728.08	688.22*	656.08**
% GE/Total Area	28.40	26.36	25.57
Growth in GE Area (K Has.)	-1.37	-39.86	-32.14
% Growth in GE Area	-0.19	-5.47	-4.67

*January 2014-March 2015

**April 2015-February 2016

Source: Philippine Statistics Authority and 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 2013 to 2015. Philippine imports of GE crops and by-products from the U.S. slightly declined in 2015 compared to the previous year's level. U.S. exports of GE products were valued \$770 million in 2015, down by \$14 million from 2014.

CY US Exports to the Philippines (In Thousand \$)			
	2013	2014	2015
Soybean Meal	605,500	590,000	635,000
Feeds & Fodders	39,200	39,400	35,400
Soybeans	24,600	56,000	47,400
Sweeteners	53,300	73,500	28,200
Coarse Grains	24,000	700	0
Cotton	13,500	16,500	17,500
Vegetable Oil*	6,600	7,700	6,700
Soybean Oil	200	300	200
TOTALS	766,900	784,100	770,400

*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 or GE-derived ingredients. Sales of U.S. consumer oriented products were \$900 million in 2015, the 13th largest market by value for the United States.

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:

The delays in the processing of biosafety permits under the JDC have the most potential to negatively affect U.S. exports of GE products. So far, there have been no reported trade disruptions.

Part B: POLICY

a) Regulatory Framework:

As a regional leader in biotechnology, the Philippines draws attention from domestic and international anti-biotechnology groups. 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 response, 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.

In general terms, the JDC indicates the responsibilities of DA, DENR, and the DOH in the conduct of risk assessment. Environmental risk assessment will be conducted by DENR while the DOH is responsible for environmental health impact and food safety assessment. The DILG's role is mainly coordinating with the other departments in overseeing public consultations. The DOST remains as the lead agency for evaluation and monitoring regulated articles (i.e., approved GE events) intended for contained use, while the DA continues to take the lead in the evaluation and monitoring of regulated articles.

The full text of the JDC may be viewed at:

<http://www.ncbp.dost.gov.ph/21-joint-department-circular/32-jdc-final>

In a July 26, 2016 press briefing, the SC reversed its December 2015 decision which effectively halted the field testing, propagation, commercialization, and importation of GE products in the country. The full SC decision was issued on August 18, 2016, and confirmed that the JDC superseded the DA-AO 8.

While many local GE advocates hailed the SC reversal, some industry stakeholders are concerned that the JDC did not provide an extension or grace period for the renewal of expiring biosafety permits approved under DA-AO 8. All approved transformation events (TEs) under DA-AO 8 have to reapply under the JDC.

Attached is the DA Operations Manual which outlines the procedural requirements in securing biosafety permits for field trials, commercial propagation, and for direct use as food, feed, or processing. Note the flow charts on the procedure for applications on pages 10, 13, and 16 have been revised, and are provided at the end of this report. The total number of processing days for applications is 85 days. Industry, however, has reported delays beyond the 85 day period. The affected commodities include corn and soybeans, which are insufficiently produced and critical for the expanding livestock and poultry industries. The other JDC-pertinent departments have yet to finalize their procedures and issue corresponding guidelines.

According to local contacts, the delays in application processing times were expected, citing the change in regulations and a new administration. Philippine national elections were held in May 2016, and the Rodrigo Duterte administration assumed office in July 2016. Biosafety assessments are relatively new to some of the departments, and personnel changes are unavoidable. Some personnel occupying key positions in GE regulatory offices are still holding office in an “acting” capacity.

b) Approvals:

The links to the relevant approval registries are provided below:

APPROVAL REGISTRIES

Some of the official government links are unavailable but should be back once technical glitches are resolved.

Name	Subject	Dated
ANNEX I	Approval registry for the importation of regulated articles for direct use as food and feed or for processing <u>Please see Attached Annex 1</u>	8-Dec-15
ANNEX IA	Approval registry for the importation of combined trait products for direct use as food, feed and for processing http://biotech.da.gov.ph/upload/ANNEX_IAasofsep102015.pdf	10-Sep-15
ANNEX II	Approval registry of regulated articles for propagation http://biotech.da.gov.ph/upload/ANNEX_IIsasofsep102015.pdf	10-Sep-15
ANNEX IIA	Approval registry for propagation of combined trait products http://biotech.da.gov.ph/upload/ANNEX_IIAasofsep102015.pdf	10-Sep-15
ANNEX III	List of Regulated Articles for Importation for Direct Use Requiring a Declaration of "GMO" Content http://biotech.da.gov.ph/upload/Annex_III_as_of_Dec_15_2011.pdf	15-Dec-11
ANNEX IV	Approval Registry of Regulated Articles for Field Trial http://biotech.da.gov.ph/upload/annexIV.pdf	6-Nov-15
ANNEX V	Registry of un-renewed regulated articles <u>Please see Attached Annex V</u>	10-Sep-15

Source: Bureau of Plant Industry

c) Stacked or Pyramided Event Approvals:

Refer to Annex IA and Annex IIA in the APPROVAL REGISTRIES Table. Multi-trait or stacked event crops composed of approved individual TEs have to reapply under the JDC.

d) Field Testing:

Refer to Annex IV in the APPROVAL REGISTRIES Table. GE field trials fall under the responsibility of DA-BPI. Field testing applications are required to undergo public hearings in coordination with the concerned local government unit (LGU) prior to its endorsement. There are currently no ongoing field tests.

e) Innovative Biotechnologies:

There are currently no regulations covering innovative biotechnologies in plants and plant products in the Philippines.

f) Coexistence:

There is no Philippine policy on cultivation coexistence of conventional crops with non-GE 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 at the Philippine House of Representatives (PHOR) of the 17th Congress. House Bill 3686 or *“The Philippine Genetically Modified Organism (GMO) Labeling Act, The Right-to-Know-Act”*, and House Bill 3810 both require the mandatory labeling of GE food and food products which are at least 0.9 percent genetically engineered. Both bills are currently with the Committee on Health, but are likely to be transferred to the Committee for Trade and Industry of the PHOR.

For imported bulk commodities, Philippine regulations require shipments 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:

Declaration of GMO Content

The shipment may contain a GM ingredient:
 Yes _____ No _____

If yes, list the probable transformation events.

	To be filled up by the PQS Officer	
Present	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: 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 Philippine DA approved Administrative Order No. 1 (DA-AO No. 1) adopting Annex 3 to 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 the TE has been assessed and approved by BPI, seed registration is still required with the National Seed Industry Council 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 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 (PVP) 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 (CPB) to the UN Convention on Biological Diversity*”. The CPB ratification follows 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 National Committee on Biosafety of the Philippines (NCBP) issues guidelines and standards on risk assessment, environmental impact assessment, socio-economic, ethical and cultural assessments. The NCBP oversees the implementation of the NBF, as well as coordinate and harmonize efforts and activities of the various concerned agencies and departments. The Philippines will be sending a delegation to the Meeting of the Parties to the CPB in Mexico in December 2016.

m) International Treaties/Fora:

The Philippines actively participates in international biotechnology events including Codex Alimentarius meetings as well as the Asia Pacific Economic Cooperation’s High Level Policy Dialogue on Agricultural Biotechnology (APEC-HLPDAB). The 2016 APEC-HLPDAB was held in Piura, Peru on September 19-20, 2016.

The Philippines participated in the 2016 APEC-HLPDAB Workshop “*Strengthening Innovation and Cooperation among APEC Economies to Advance Science and Facilitate Trade*”, as well as in the APEC Food Security Ministerial Meeting.

n) Related Issues:

The following is a link to the DA’s biotechnology webpage which provide pertinent GE information and related issues: <http://biotech.da.gov.ph/>

The webpage of the NCBP (<http://ncbp.dost.gov.ph/>) provides information regarding regulatory requirements for experiments on modern biotechnology.

Part C: PLANT BIOTECHNOLOGY MARKETING ISSUES:

a) Public/Private Opinions:

While in the process of drafting new GE regulations according to the JDC, the Philippine Government conducted public consultations in the Luzon, Visayas, and Mindanao regions. The consultations revealed strong GE support from local corn farmers, hog and poultry raisers, feedmillers, food processors, academe, and other end users. Large domestic food and agribusiness companies already using GE products, however, preferred to be silent on the issue. GE opposition was represented by non-governmental organizations (NGOs), including environmental groups, organic agriculture advocates, and other civil society groups. The broad representation of pro-GE groups indicated how critical GE feedgrain was in the supply chain.

Local GE corn farmers appeared to be the most vocal and passionate among GE supporters. Attempts by anti-GE groups to counter the arguments by GE corn farmers and GE end-users were few and ineffective. A poultry industry leader challenged regulators and anti-GE groups to explain why the EU prohibited GE feedgrain production, but at the same time allowed GE feedgrain imports. The same leader advocated for pragmatism in GE decision making when no satisfactory explanation was provided.

b) Market Acceptance/Studies:

Despite the phenomenal adoption of GE corn technology in the Philippines, there remain a few provinces, municipalities, and cities that maintain anti-GE ordinances. Similarly, while most knowledgeable Filipinos are generally supportive of biotechnology, 'noisy' anti-GE groups give the impression they represent a considerable percentage of consumers. In reality, a significant number of Filipinos are either unaware of the benefits of GE technology, or are indifferent as to whether a product is GE or not.

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:

As a follow up to the 1st International Workshop on *the "Food and Environmental Safety Assessment of Genetically Modified Animals"*, held in Buenos Aires, Argentina in 2011, Post facilitated the travel of a local participant to the 2nd International Workshop for Regulation of Animal Biotechnology in Brasilia, Brazil from August 18-21, 2014.

f) Related Issues:

The Livestock Biotechnology Center in Munoz, 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
National Headquarters and Gene Pool
Science City of Munoz, 3120 Nueva Ecija
PHILIPPINES
Tel. no. +63 044 456 0729
Fax no. +63 044 456 0730
Email: livestock.biotech@gmail.com

Part F: MARKETING

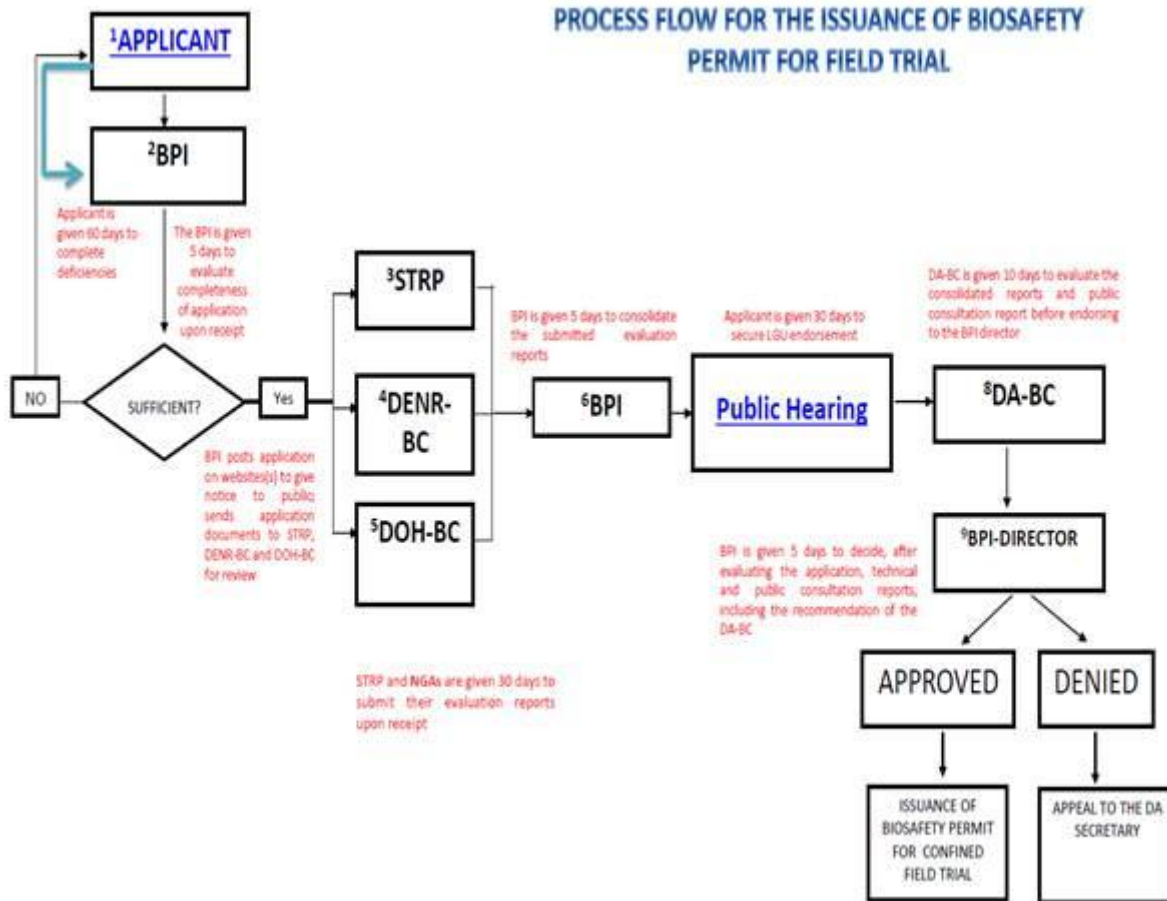
a) Public/Private Opinions:

Public awareness on GE animals is low.

b) Market Acceptance/Studies:

Not applicable.

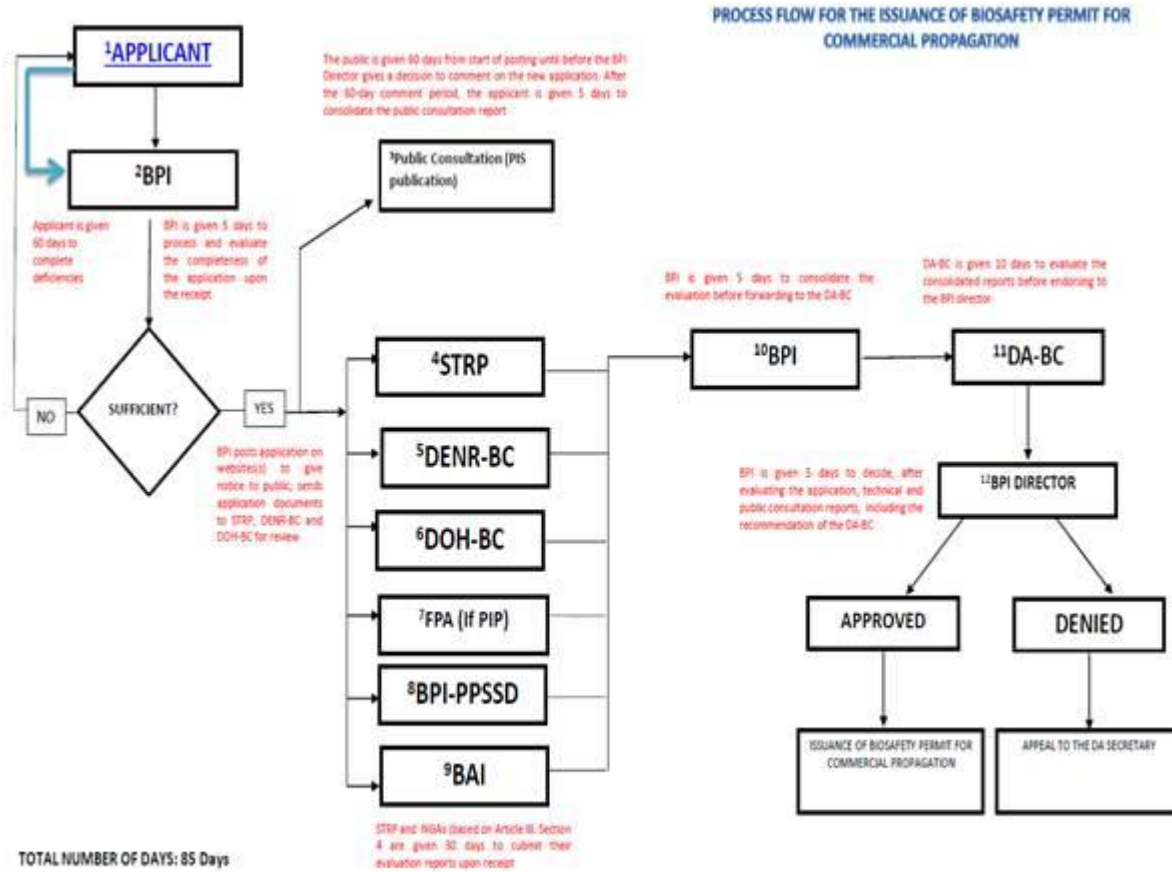
Annex I – Application for Field Trial



TOTAL NUMBER OF DAYS: 85

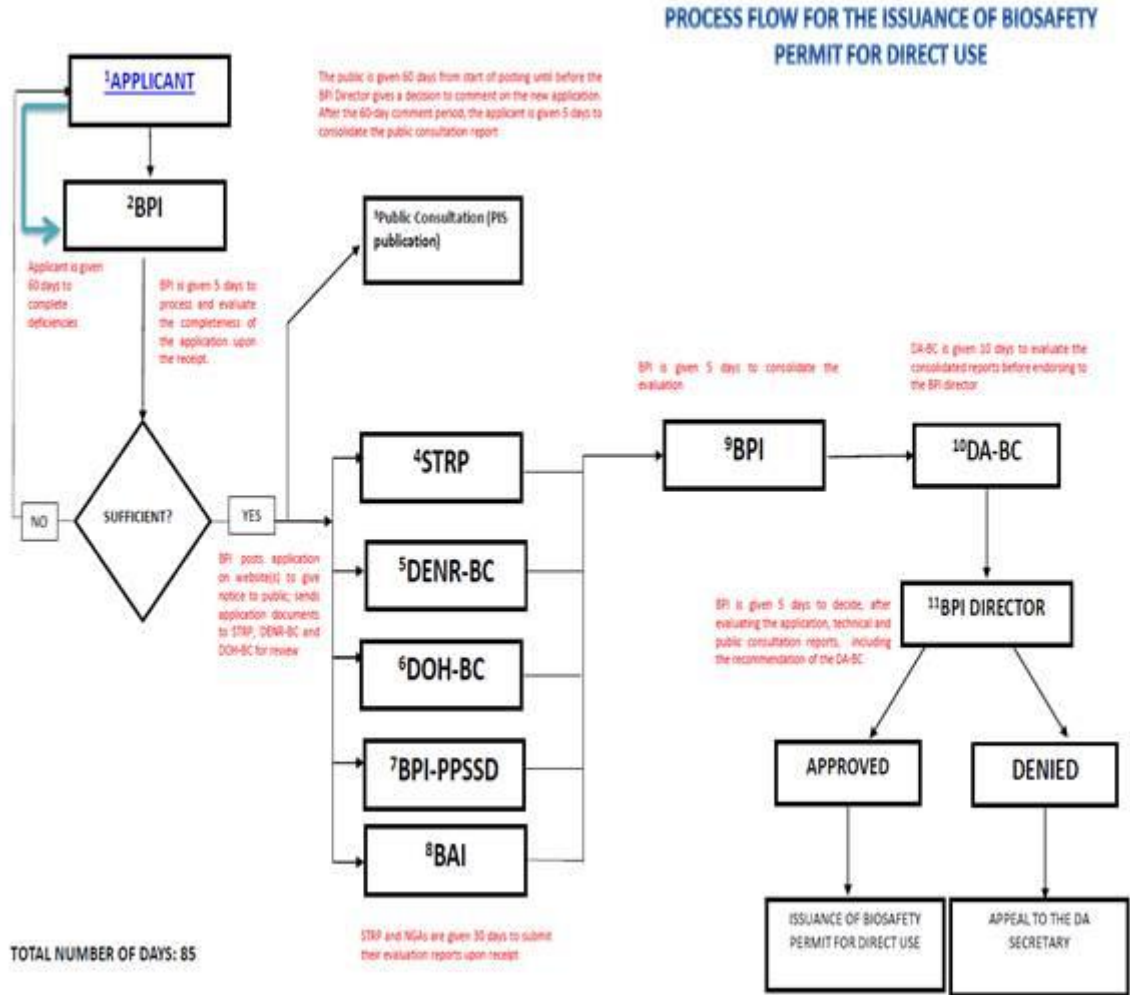
Source: Philippine Department of Agriculture

Annex II – Application for Commercial Propagation



Source: Philippine Department of Agriculture

Annex III – Application for Direct Use



Source: Philippine Department of Agriculture

