Required Report - public distribution

**Date:** 10/24/2018
**GAIN Report Number:** RP 1835

# Philippines

# Agricultural Biotechnology Annual

# Philippine Agricultural Biotechnology Situation and Outlook

**Approved By:**
Ryan Bedford
**Prepared By:**
Perfecto Corpuz

**Report Highlights:**
The Philippines continues to be a regional biotechnology leader. However, the biosafety application process is taking an extended amount of time under current regulations, embodied in the Joint Departmental Circular (JDC) of 2016. There have been no reported trade disruptions so far, but the resulting delays in application processing may gradually erode this leadership status.

## SECTION I: EXECUTIVE SUMMARY

The Philippines remains a regional biotechnology leader, having been the first Asian country to allow the planting of a genetically engineered (GE) crop (Bt corn in 2003), and is moving forward on a regulatory framework for GE animals. A change in GE plant regulations as embodied in Department of Agriculture (DA) Administrative Order No. 8 (DA-AO 8) to the Joint Department Circular (JDC) in April 15, 2016 has resulted in the slow processing of biosafety applications. There have been no major trade disruptions, but the delay in approvals has the potential to disrupt U.S trade. It likewise may gradually erode the country's GE leadership status in the region.

The Philippines was the 12th largest market for U.S. agricultural and related products by value in 2017 with exports reaching $2.7 billion. It was the largest U.S. soybean meal market with nearly $750 million in sales. The Philippines was also the 12th largest market by value for U.S. exports of consumer-oriented products, most of which contain GE-derived ingredients, at $964 million in 2017. For 2018, exports are on track to surpass 2017 levels, with soybean meal sales reaching record levels.

Since its introduction in 2003, GE corn area planted has reached over 5.9 million hectares. From April 2016 to March 2017, GE corn was planted on an estimated 655,000 hectares, relatively flat compared to the previous year's level. According to contacts, GE corn plantings would be higher if the use of counterfeit GE seeds were calculated.

**TABLE OF CONTENTS**

## CHAPTER I: PLANT BIOTECHNOLOGY

### PART A: PRODUCTION AND TRADE

a) Product Development:

First, the Institute of Plant Breeding of the University of the Philippines at Los Banos (IPB-UPLB) is responsible for the development of the fruit and shoot borer-resistant eggplant (Bt eggplant). The Maharashtra Hybrid Seed Company donated the Bt eggplant technology 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 or USAID-ABSP 2. All relevant field tests have been completed and Bt eggplant remains poised to be the first locally developed GE crop to be commercialized.

Second, the beta-carotene-enriched rice or Golden Rice (GR2E) project of the Philippine Rice Research Institute (PhilRice) 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. On February 28, 2017, PhilRice applied for field trials to generate data for environmental biosafety risk assessment. Public consultations on its field test application were held on July 18 and 20, 2018. The project has concluded confined field tests.

Third, the screen house evaluation for Bt cotton and the confined trial were completed in 2010 and 2011, respectively. 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. The project is still waiting for the certificate of satisfactory completion of the multi-location test prior to applying for commercial propagation. The Philippine Fiber Industry Development Administration is promoting the cotton technology.

Fourth, the Institute of Plant Breeding (IPB) at the University of the Philippines at Los Baños (UPLB) is the proponent of the delayed ripening papaya with ring spot virus-resistance project. It completed its first field test in 2014. Instead of preparing a second field trial in 2017, backcrossing of the F1 hybrid to the transgenic line will be conducted. Preparation of permits for the above-mentioned contained trial and its eventual varietal registration are underway

b) Commercial Production:

Based on data from the Bureau of Plant Industry (BPI), GE corn was planted on over 5.9 million hectares 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, fairly flat compared to the previous year's level. During the same period, roughly 99 percent of all GE crops planted were stacked varieties, according to BPI data.

| GM Corn Adoption by Event (ha) | |
|---|---|
| **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

GE corn area would be higher if the use of counterfeit GE seeds were included. Sold as conventional seeds, counterfeit GE seeds are produced with Bt and Roundup Ready (RR) traits. Although cheaper, they are inferior in quality and sold without proper stewardship measures. The same source estimates counterfeit GE seeds at around 10 percent of overall Bt corn seeds.

c) Exports:
The Philippines exports no GE crops.

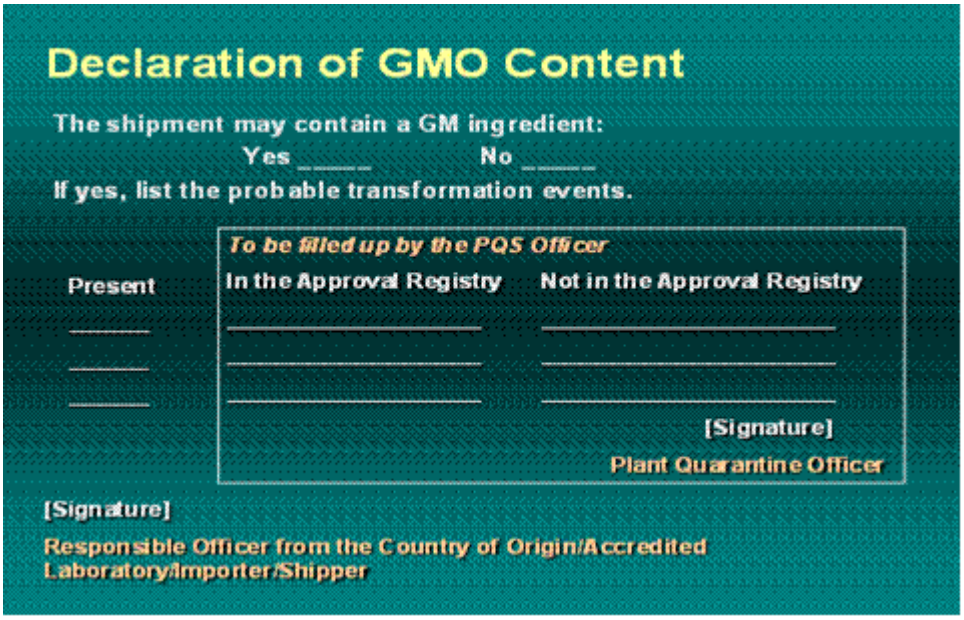
d) Imports:
The following table is a breakdown of U.S. exports of GE crops and by-products to the Philippines from 2015 to 2017. Soybean meal represents the majority of the exports and shows steady growth, followed by soybeans and feed and fodders. In 2017 Philippine imports of GE crops and by-products from the United States increased by one percent to $929 million, compared to the previous year.

| CY US Exports to the Philippines (In Thousand $) | | | |
|---|---|---|---|
| | 2015 | 2016 | 2017 |
| Soybean Meal | 635,000 | 729,100 | 747,400 |
| Feeds & Fodders | 35,400 | 41,100 | 47,800 |
| Soybeans | 47,400 | 104,100 | 92,900 |
| Sweeteners | 28,200 | 24,600 | 11,100 |
| Coarse Grains | 0 | 0 | 400 |
| Cotton | 17,500 | 12,900 | 21,500 |
| Vegetable Oil* | 6,700 | 7,100 | 7,400 |
| Soybean Oil | 200 | 200 | 400 |
| | | | |
| TOTALS | 770,400 | 919,100 | 928,900 |

*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 $964 million in 2017.

Philippine regulations require shipments of imported bulk commodities 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. A sample form of this declaration is given below.




**Source: Philippine Department of Agriculture**

e) Food Aid:
The Philippines is a consistent food aid recipient (i.e., GE soybean meal through the Food for Progress program), and the importation of food aid commodities have been unimpeded by GE issues. The Philippines does not provide food aid.

f) Trade Barriers:
Delays in the processing of biosafety permits under the Joint Departmental Circular (JDC) have the most potential to disrupt U.S. exports of GE products, although there have been no reported trade disruptions so far.

**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 Supreme Court (SC) which ruled on December 8, 2015 that existing GE regulations i.e., 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 trials of Bt eggplant (which had already been completed) and declared DA-AO 8 null and void. Hence, it halted the processing of applications for contained use, field trials, 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. The Joint Department Circular (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 assessments will be conducted by DENR, and 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, and DA, through BPI, evaluates and issues all permits such as field trials, propagation, and direct use for food or feed. BPI-Plant Product Safety Services Division Food handles safety assessment, and feed safety is assigned to the Bureau of Animal Industry (BAI).

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 issued on August 18, 2016 confirmed the JDC superseded the DA-AO 8. All approved transformation events (TEs) under DA-AO 8 had to reapply under the JDC.

On July 18, 2017, the Fertilizer and Pesticide Authority (FPA) approved and issued Memorandum Circular No. 10 (MC 10) or *"Guidelines for the Registration of Plant-Incorporated Protectants (PIPs) in Pest-Protected Plants (PPP) and other Agricultural Pesticidal Substances Derived from Modern Biotechnology"*. PIP registration is a major sticking point under the DA's biosafety application system, and the issuance of MC 10 was considered a major relief for applicants. Prior to MC 10, all PIPs were under conditional approval only.

The flow charts for applications for field tests, propagation and direct use are 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, limited resources, and new and changing regulatory personnel. Local scientists, on the other hand, criticized local regulations as too restrictive in commercializing local GE research compared to foreign GE crops currently being commercialized, citing the Bt eggplant project. Issuance of the inter-agency procedural manual cited in the previous annual report has not happened to date. However, there are ongoing discussions among the concerned agencies, which have resulted in some recent approvals.

b) Approvals:

A list of approved applications for direct use, field trial, and propagation may be viewed at: http://biotech.da.gov.ph/Approval_Registry.php. As of August 28, 2018:

There have been 30 Transformation Events (TEs) approved for direct use (ANNEX I), and six have been approved for propagation (ANNEX II).

The following approval registries are attached:

- ANNEX I - Approval registry for the importation of regulated articles for direct use as food and feed or for processing and
- ANNEX II - Approval registry of regulated articles for propagation.

c) Stacked or Pyramided Event Approvals:

There were 15 combined trait products approved for direct use and three approved for propagation as of August 28, 2018.

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

- ANNEX IA - Approval registry for the importation of combined trait products for direct use as food, feed and for processing or
- ANNEX IIA - Approval registry for propagation of combined trait products.

d) Field Testing:
Field testing applications are required to undergo public hearings in coordination with the concerned local government unit (LGU) prior to its endorsement. To date, only the Golden Rice (GR2E) project has applied for field testing under the JDC. Public hearings were conducted for the GR2E field trial in July 2018. The concerned local government units have yet to issue the required resolution for the trial to proceed.

e) Innovative Biotechnologies:
The Philippines does not use innovative technologies in any product development. 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 would not require labeling for GE packaged foods. The PFDA position is 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." In late 2013, the PFDA issued a statement attesting to the safety of GE and GE-derived foods, adding that GE foods were substantially equivalent to their conventional counterparts.

At least three GE food labeling bills have been filed at the Philippine House of Representatives (PHOR) of the 17th Congress. House Bill 3686, 3810, and 5311 all call for the mandatory labeling of GE food products. The Committee on Trade and Industry held its first hearing on August 28, 2018. No date has been set for the second hearing. Advocates for mandatory GE labelling claim the "consumers' right to know" amidst doubts of its alleged safety, while groups supportive of GE cite the unnecessary and increased cost of labeling. Another consumer group called for a delayed decision pending an extensive educational campaign on GE food.

h) Monitoring and Testing:
Monitoring 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 (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 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 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.

m) International Treaties and Forums:
The Philippines actively participates in international biotechnology events including Codex Alimentarius and International Plant Protection Convention meetings, as well as related activities of the Asia Pacific Economic Cooperation. Two Philippine delegates participated in APEC's High Level Policy Dialogue on Agricultural Biotechnology workshop (HLPDAB) in Brisbane, Australia on August 1-3, 2018.

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

Information regarding regulatory requirements for GE experiments may be found at the webpage of the NCBP (http://www.ncbp.dost.gov.ph/).

**Part C: PLANT BIOTECHNOLOGY MARKETING ISSUES:**

a) Public/Private Opinions:
Support for GE products remains strong among local corn farmers, hog and poultry raisers, feed millers, food processors, academe, 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. The overwhelming majority of Filipinos remain 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. It has 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.

The Philippine National Biotechnology Week (NBW), created by Presidential Proclamation No. 1414 series of 2007, is the biggest biotech event in the country. Held during the last week of November, the NBW features seminars, exhibits, field trips, and other GE promotional activities. The Department of Agriculture (DA), Department of Science and Technology (DOST), Department of Health (DOH), Department of Environment and Natural Resources (DENR), Department of Trade and Industry (DTI), Department of Interior and Local Government (DILG), and Department of Education (DepEd) implement the NBW.

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 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 73 percent believe they would benefit from food biotechnology in the next five years through improved quality and more affordable prices.

## CHAPTER II: ANIMAL BIOTECHNOLOGY:

### Part D: PRODUCTION AND TRADE

a) Product Development:
There are no Philippine GE or genome-edited animals or clones under development currently or expected to be on 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 biotechnology-related trade barriers that negatively affect U.S. animal biotechnology 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) Approvals:
To date, no GE animal event or product has been approved.

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

d) Labeling and Traceability:
Not applicable.

e) Intellectual Property Rights (IPR):
The Philippines currently does not have legislation to address intellectual property rights for animal biotechnologies.

f) International Treaties and Forums:
The Philippines is a member of Codex Alimentarius and the World Organization of Animal Health, and joins the discussions on agricultural biotechnology

f) Related Issues:
The DA's Livestock Biotechnology Center in Muñoz City, 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

Also located in Muñoz City is the DA's Fisheries Biotechnology Center stationed at the National Freshwater Fishery Technology Center, Bureau of Fisheries and Aquatic Resources (BFAR-NFFTC) in the Central Luzon state University (CLSU) compound.

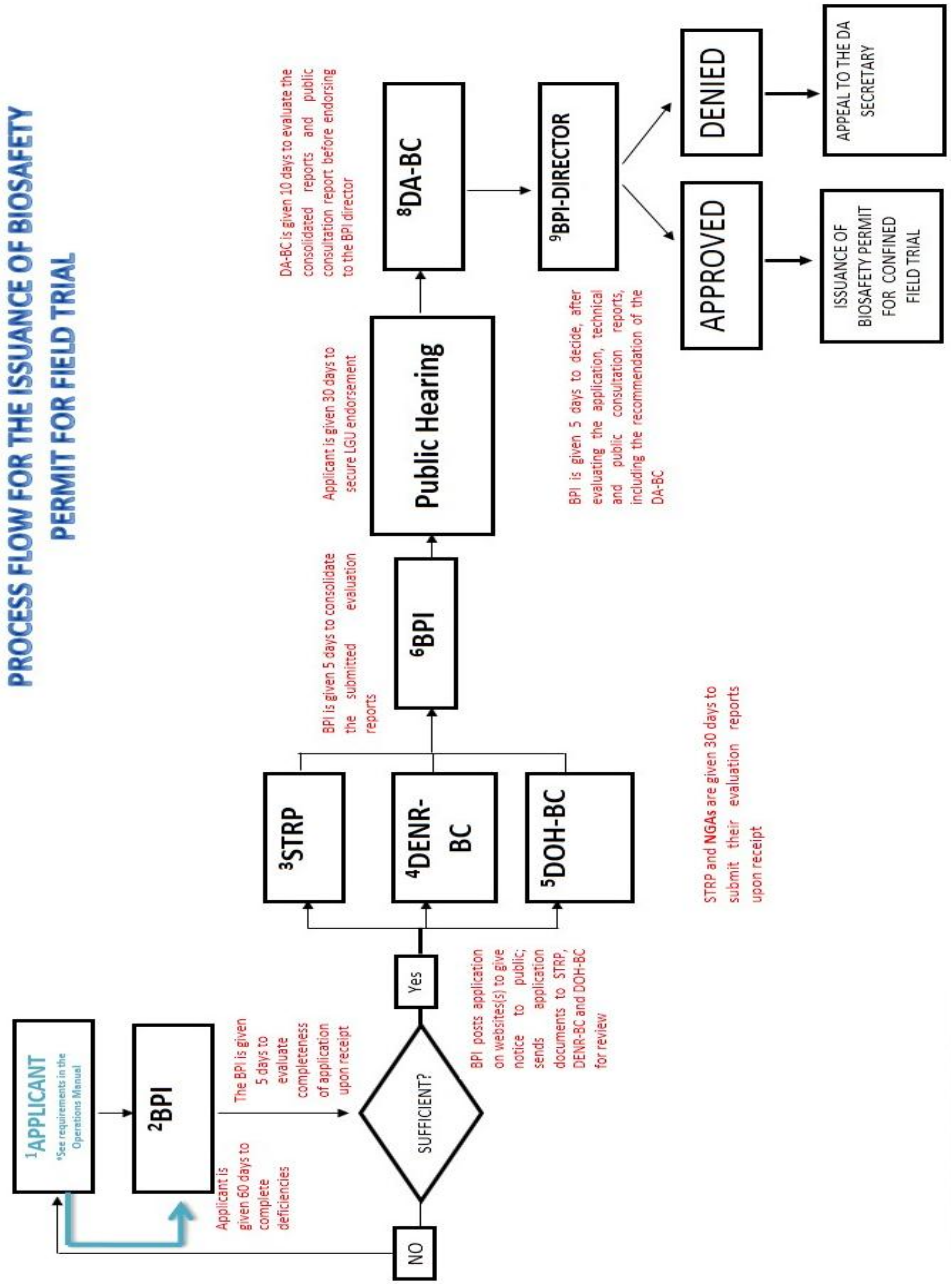
National Freshwater Fishery Technology Center (BFAR-NFFTC)
CLSU Compound
Tel no. +63 044 940 7157
Email: fisheries.biotech@gmail.com

**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 socio-economics.

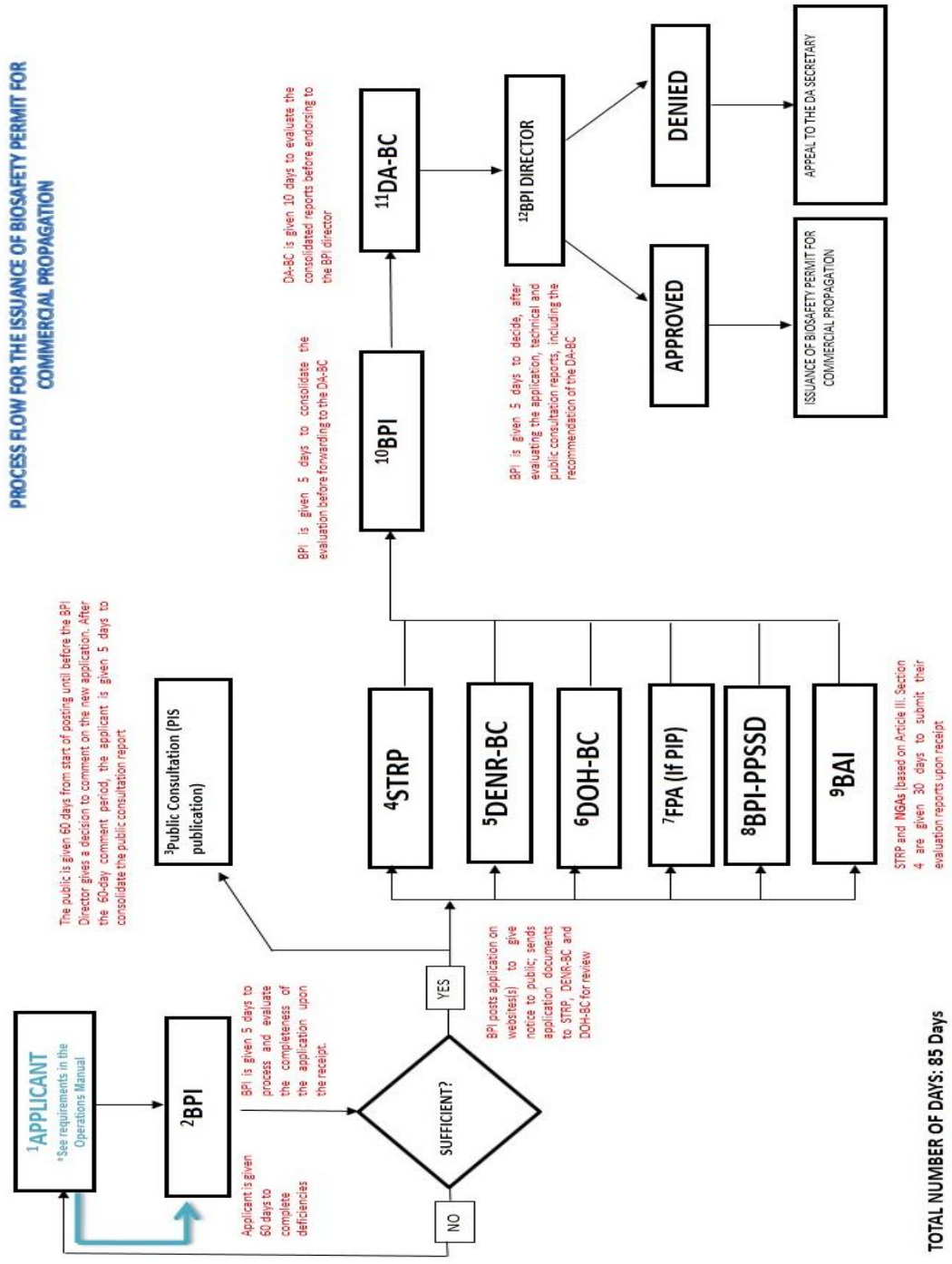
b) Market Acceptance/Studies:
Not applicable.

**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

- ANNEX I - Approval registry for the importation of regulated articles for direct use as food and feed or for processing

- ANNEX IA - Approval registry for the importation of combined trait products for direct use as food, feed and for processing

- ANNEX II - Approval registry of regulated articles for propagation

- ANNEX IIA - Approval registry for propagation of combined trait products

Note: these attachments are distinct from the flow charts listed above as Annexes I through III.