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Report Highlights:

The Philippines continues to be a regional biotechnology leader. Golden Rice (GR2E) field tests were harvested in October 2019 and the Application to Propagate is expected soon. The regulatory agencies of the United States, Australia, New Zealand, and Canada have already issued safety and nutrition approvals for GR2E. Parallel to this are positive regulatory developments that may come to fruition by early 2020, including the completion of an ongoing review of the current biotechnology regulations embodied in the Joint Departmental Circular (JDC) of 2016. Likewise, expected to be in place around the same time are regulatory frameworks for genetically engineered (GE) animals and another for new innovative biotechnologies (e.g. gene editing).

EXECUTIVE SUMMARY

The Philippines is 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 and products of innovative biotechnologies. 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, however, has slowed the processing of biosafety applications.

There have been no major trade disruptions and regulatory reforms are underway with a review of the current regulatory regime. Parallel to this are current efforts to have regulatory frameworks covering GE animals, as well as one that will govern products of new innovative biotechnologies (e.g. gene editing). Both are expected in early 2020.

Since its introduction in 2003, GE corn area planted has reached over 7.2 million hectares cumulatively. From March 2018 to February 2019, Philippine farmers planted GE corn on an estimated 660,000 hectares, relatively flat compared to the previous year's level. According to contacts, if the use of counterfeit GE seeds were included, GE corn plantings would be higher. Meanwhile, the Golden Rice (GR2E) field tests were harvested in October 2019. The permit to propagate may come as early as the end of 2019. The respective regulatory agencies of four countries, i.e., the United States, Australia, New Zealand, and Canada, have already issued the safety and nutrition approvals for GR2E.

In 2018, the Philippines was the 11th largest market for U.S. agricultural and related products by value with exports reaching \$3.1 billion, the highest ever. It was the largest U.S. soybean meal market with \$884 million in sales. The Philippines was also the 10th largest market by value for U.S. exports of consumer-oriented products, most of which contain GE-derived ingredients, at \$1.09 billion in 2018. For 2019, although year-to-date exports through August are below 2018 levels, Post expects a strong end to the year, with trade to surpass 2018 levels.

TABLE OF CONTENTS

CHAPTER I: PLANT BIOTECHNOLOGY	4
PART B: POLICY	
PART C: MARKETING	
CHAPTER II: ANIMAL BIOTECHNOLOGY	
PART E: POLICY	
PART F: MARKETING	

CHAPTER I: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: First, the Institute of Plant Breeding at the University of the Philippines at Los Baños (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. The dossier is currently being prepared for regulatory application.

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. The two GR2E field tests were harvested recently (October 4 & 9, 2019). The Application to Propagate is expected to follow soon. Should regulators find no major concern, the approval may come as early as early 2020. The respective regulatory agencies of four countries, namely, the United States, Australia, New Zealand, and Canada, have already issued the safety and nutrition approvals for GR2E.

Third, the screen house evaluation for Bt cotton and the confined trial were concluded 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 obtained the certificate of satisfactory completion of the multi-location test on November 11, 2018. The requirements for the Application for Propagation are being prepared. 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. The IPB, however, was not able to secure the necessary permits. Currently, the IPB is organizing a team that will pursue the project and undertake backcrossing and registration activities.

b) COMMERCIAL PRODUCTION: Based on data from the Bureau of Plant Industry (BPI), GE corn was planted in over 7.2 million hectares cumulatively since its introduction in 2003. The following table is based on preliminary data from BPI and shows area planted at 641,000 hectares during the March 2018 to February 2019 period, for a modest increase (3 percent) from the previous year's level. During the same period, over 95 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	
Jan. 2014 - March 2015	688,218	
April 2015 - March 2016	656,084	
April 2016 - March 2017	655,269	
April 2017 - Feb. 2018	640,953	
March 2018 - Feb. 2019	658,267	
Total	7,221,281	

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.

The fall armyworm or FAW (Spodoptera grugiperda), which had been detected in India and several Asia Pacific countries (Bangladesh, Nepal, Myanmar, Thailand, and China) has been found in the Cagayan Valley region, the country's top corn producing area, according to a local press report. The BPI, in a May 9, 2019 advisory, instructed its Regional Directors "to closely monitor the pest (i.e. FAW) by conducting detection surveys in your respected regions to determine its presence for immediate management". The FAW possible presence is forcing the Government of the Philippines (GPH) and agricultural chemical companies to coordinate and monitor the situation appropriately. According to a visiting GE expert, the country's adoption and cultivation of GE corn may delay the spread of the FAW if already present.

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 2016 to 2018. Soybean meal represents the majority of the exports and shows steady growth, followed by feeds and fodders and cotton. In 2018, Philippine imports of GE crops and by-products from the United States increased by 14 percent to over \$1 billion compared to the previous year.

CY US Exports to the Philippines (In Thousand \$)				
	2016	2017	2018	
Soybean Meal	729,100	747,400	884,400	
Feeds & Fodders	41,100	47,800	63,500	
Soybeans	104,100	92,900	66,000	
Sweeteners	24,600	11,100	14,200	
Coarse Grains	0	400	100	
Cotton	12,900	21,500	23,200	
Vegetable Oil*	7,100	7,400	7,300	
Soybean Oil	200	400	200	
TOTALS	919,100	928,900	1,058,900	

*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 over \$1.09 billion in 2018.

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. Following is a sample form of this declaration:

The shipm	ent may contain a GM ingr Yes No	edient: 	
f yes, list t	he probable transformatio		
	To be filled up by the PQS Officer		
Present	In the Approval Registry	Not in the Approval Registry	
		0. 000.000.000.000.000.000.000.000.000.	
		[Signature]	
		Plant Quarantine Officer	

- 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 have the most potential to disrupt U.S. exports of GE products, although there have been no trade disruptions reported 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 are 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.

The flow charts for applications for field tests, propagation, and direct use are at the end of this report. The charts 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 much longer. Stakeholders attribute the slow processing to confusing procedures, limited resources, and new and changing regulatory personnel. Local scientists, on the other hand, criticize local regulations as too restrictive in commercializing local GE research compared to foreign GE crops, citing the Bt eggplant project as a prime example.

After recent changes in key regulatory personnel, technology developers note that more consideration to timely approval is given to biosafety applications. Initiated by the NCBP, the JDC is currently under a review and the results are expected to be known sometime in early 2020.

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 May 9, 2019:

There have been 38 Transformation Events or TEs (Note: BPI data reported 37 only) approved for direct use (ANNEX I), and seven, all of which are corn, have been approved for propagation (ANNEX II).

The following approval registries are included at the end of this report:

- 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 21 combined trait products approved for direct use and three approved for propagation as of May 9, 2019.

Multi-trait or stacked event crops composed of approved individual TEs must reapply under the JDC. At the end of this report are:

- ANNEX IA Approval registry for the importation of combined trait products for direct use as food, feed and for processing and
- 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 (http://biotech.da.gov.ph/Decision_docs_jdc_field.php) has applied for field testing under the JDC. Public hearings were conducted for the GR2E field trial in July 2018.
- 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, although a Technical Working Group (TWG) has been formed to study and develop guidelines to regulate such products. A regulatory framework will likely be announced sometime in early 2020.
- 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 AND TRACABILITY: 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.

There has been at least one GE labeling bill filed under the 18th Philippine Congress. House Bill No. HB02780 (or "An Act Requiring the Mandatory Labeling of Food, Food Products and their Derivatives (processed or not) and Agricultural Products like Rice, Corn and Vegetables, Among Others, Containing Genetically Modified Organisms (GMOs) or Those

Produced by Genetic Engineering Technologies, Amending for the Purpose Republic Act No. 3720 Otherwise Known as 'The Food, Drugs and Cosmetics Act' and Republic Act No. 7394 Otherwise Known as 'The Consumers Act of the Philippines' and for Other Purposes") was filed on July 25, 2019 and referred to the Committee on Trade and Industry on July 31, 2019.

- 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.

1) 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 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 biosafety 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 (APEC).
- n) RELATED ISSUES: Further GE information and related issues are provided in the DA's biotechnology webpage: http://biotech.da.gov.ph/.

Information regarding for approved GE experiments may also be found at: http://dost-bc.dost.gov.ph/approvedexperiments

PART C: MARKETING

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.

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 the 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. Efforts along this line are underway, however, and a regulatory framework is expected to be approved sometime early 2020.
- 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. As mentioned in the Plant Section, efforts to develop regulations for products of genome editing are ongoing and a regulatory framework is expected at the turn of the year. It is unknown, however, if animal products will be covered.
- 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
- g) 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 in the Central Luzon state University (CLSU) compound.

National Freshwater Fishery Technology Center (BFAR-NFFTC)

CLSU Compound

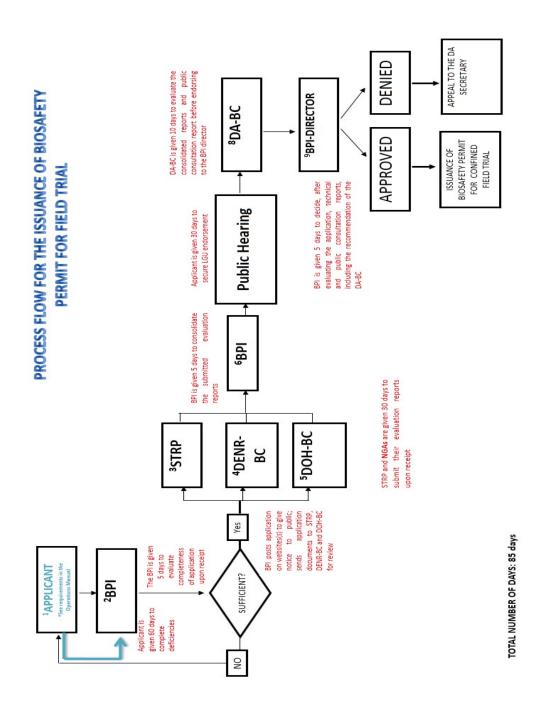
Tel no. +63 044 940 7157

Email: fisheries.biotech@gmail.com

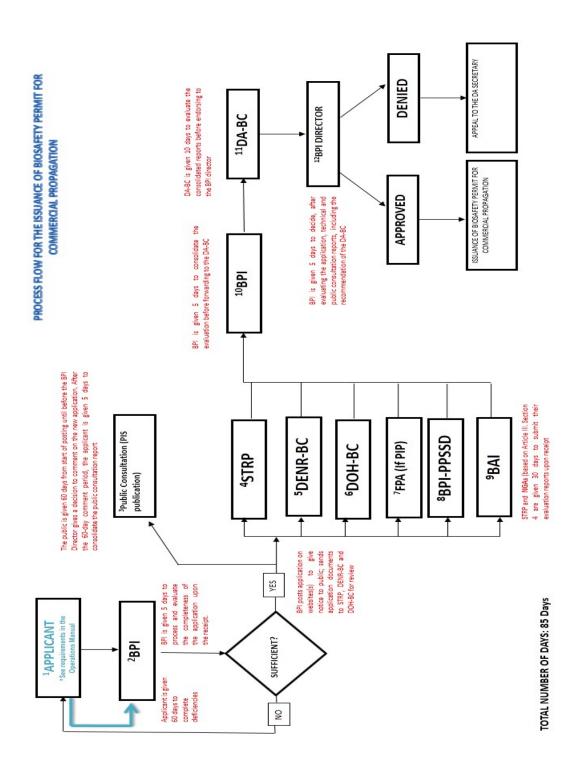
PART F: MARKETING

- 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.

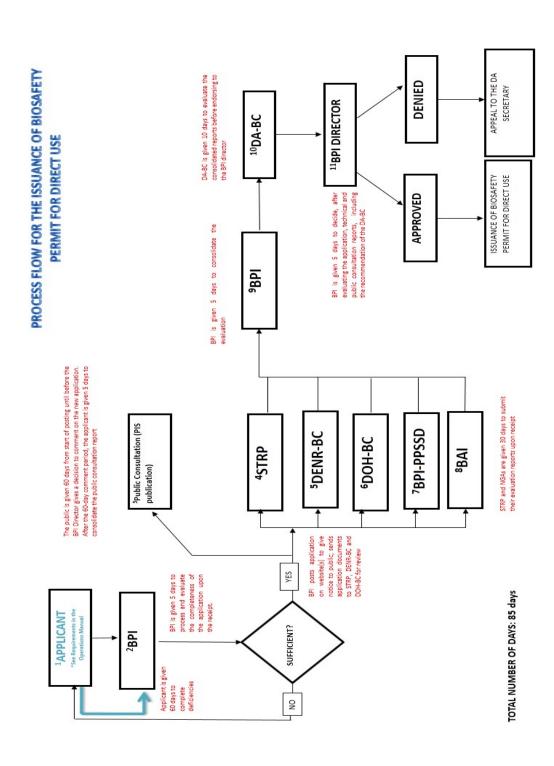
Annex I – Application for Field Trial



Annex II - Application for Commercial Propagation



Annex III – Application for Direct Use



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

http://biotech.da.gov.ph/upload/ANNEX-I-as-of-May-9-2019rev.pdf

• 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-IA-as-of-May-9-2019.pdf

- ANNEX II Approval registry of regulated articles for propagation http://biotech.da.gov.ph/upload/ANNEX-II-as-of-MAY-9-2019.pdf
- ANNEX IIA Approval registry for propagation of combined trait products http://biotech.da.gov.ph/upload/ANNEX-IIA-as-of-May-9-2019.pdf

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

Attachments:

No Attachments