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Report Highlights:

The Philippines is a biotechnology leader in Southeast Asia, highlighted by its co-sponsorship of the International Statement on Agricultural Applications of Precision Biotechnology at the World Trade Organization this year. With the many challenges of the COVID-19 pandemic, however, key milestones that were expected in 2020 have been delayed. The country approved Golden Rice for direct use in December of 2019, while the application for commercial propagation is expected soon. Likewise pending are positive regulatory developments that are now likely to be completed in 2021, including the review of current biotechnology regulations embodied in the Joint Departmental Circular of 2016. Meanwhile, next year should also see the debut of regulatory frameworks for genetically engineered animals and for new breeding techniques (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. The country again demonstrated its regional leadership on May 28, 2020 when it became the first in Asia to cosponsor the International Statement on Agricultural Applications of Precision Biotechnology at the World Trade Organization. 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) on 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 policy to govern products of new innovative biotechnologies (e.g., gene editing). Both faced delays due to the COVID-19 pandemic and are now expected in 2021.

Since its introduction, GE corn planted area has grown from 10,769 hectares in 2003 to 834,617 hectares during March 2019 to February 2020 (comprising the wet and dry seasons). This year, Philippine farmers planted approximately 26 percent more GE corn area than in 2018-2019, likely indicating increased acceptance and understanding of the benefits of biotechnology. According to contacts, if the use of counterfeit GE seeds were included, GE corn plantings would be higher. Meanwhile, the Golden Rice (GR2E) application for food, feed, and processing (FFP) was approved and found safe for consumption in December 2019. The application for commercial propagation is expected to be submitted soon. 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 2019, the Philippines was the tenth largest market for U.S. agricultural and related products with exports reaching \$3.0 billion, down 3 percent from a record 2018. It was the largest U.S. soybean meal market with \$787 million in sales. The Philippines was also the tenth largest market (and largest in Southeast Asia) for U.S. exports of consumer-oriented products, many of which contain GE-derived ingredients. Exports of high-value, consumer-oriented products reached \$1.1 billion in 2019, up 1 percent from 2018. Despite the challenges of COVID-19, 2020 year-to-date exports through August are 8 percent higher than 2019 levels. The usual peak consumption period during the holidays will likely be subdued this year, but exports are expected to surpass 2019 and possibly reach a record amount in 2020.

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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 in October 2019 and the DA's Bureau of Plant Industry (BPI) approved the corresponding biosafety permit the following month, finding that GR2E is as safe as conventional rice. The Application to Propagate is now expected by the end of 2020. Should regulators find no major concern, its approval may come in 2021. 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 at the University of the Philippines at Los Baños 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 BPI, GE corn planted area has grown from 10,769 HA in 2003 to over 830,000 in 2019/2020 (March-February). The growth in area over the past two decades likely indicates increased farmer acceptance and awareness of the safety and benefits of using GE corn. The following table is based on

data from BPI and shows the steady growth of biotech corn since its introduction, including a 26.7 percent increase in 2019/20 from the previous year's level. Currently, 98 percent of all GE crops planted are stacked varieties, according to BPI data. The current list of approved GE corn events for propagation can be viewed here.

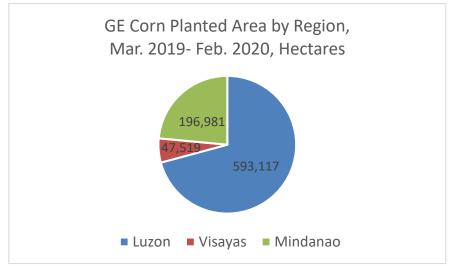
Philippine GE Corn Planted Area (Hectares)				
Year	Total			
2003	10,769			
2004	59,756			
2005	50,009			
2006	127,873			
2007	313,915			
2008	347,740			
2009	327,003			
2010	542,524			
2011	685,373			
2012	729,450			
2013	728,078			
Jan. 2014 – Mar. 2015	688,218			
Apr. 2015 – Mar. 2016	656,084			
Apr. 2016 – Mar. 2017	655,269			
Apr. 2017 – Feb. 2018	640,953			
Mar. 2018 – Feb. 2019	658,267			
Mar. 2019 – Feb. 2020	834,617			

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 has been detected across the region, was found last year in the Cagayan Valley region and has since spread throughout the country, according to local press reports. The DA notes that 11,000 hectares of corn farms have reported FAW, with economic losses estimated at 300 million pesos (\$6 million. Although this represents less than 1 percent of total Philippine corn area, the DA notes that 57 out of 81 provinces have had their corn harvest affected this year. To ensure the pest does not spread, the DA has established an interagency task force to coordinate measures to manage quarantine inspection, port disinfection, and distribution of informational material and crop protection products. Moreover, the DA has provided over 150 million pesos (\$3 million) of its quick response to help farmers with this concern, with

an additional 100 million pesos (\$2 million) to amplify pest control measures. According to a visiting GE expert, the country's adoption and cultivation of GE corn may delay the spread of the FAW.



Source: Bureau of Plant Industry

BPI's most recent data show that over 70 percent of GE corn in the Philippines is grown on Luzon island, with 24 percent in Mindanao, and 6 percent in the Visayas. This contrasts with Mindanao island representing about half of total – GE and conventional – corn production, per the Philippine Statistics Authority. Mindanao produces about 70 percent of Philippine white corn, which is primarily used for feed, whereas the area only represents 40 percent of yellow corn production, which goes to animal feed.

- c) EXPORTS: The Philippines exports no GE crops. Philippine corn is currently prohibited from being exported, although a local industry association has asked the government to lift the restriction when local corn prices are down.
- d) IMPORTS: The following table is a breakdown of U.S. exports of GE crops and by-products to the Philippines from 2017 to 2019. 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.

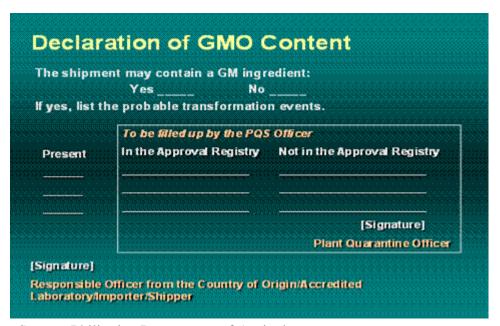
U.S. Exports to the Philippines, 2017-2019 (In Thousand Dollars)				
Commodity	2017	2018	2019	
Soybean Meal	747,264	883,779	787,800	
Ethanol (non-beverage)	101,231	125,258	94,038	
Distillers Grains	23,893	42,300	56,478	
Feeds & Fodders	47,676	63,456	53,372	

Soybeans	92,460	65,903	51,766
Coarse Grains (incl. corn)	13,100	31,459	16,718
Cotton	21,870	23,224	12,271
Sweeteners	11,093	14,207	9,498
Vegetable Oil (ex. soy)	7,362	7,336	7,527
Soybean Oil	381	239	231
TOTAL	1,066,330	1,257,161	1,089,699

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 \$1.1 billion in 2019, up 1 percent from 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:



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 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, Department of 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 specifies 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 products) 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 assessments, and feed safety is assigned to the Bureau of Animal Industry (BAI). The full text of the JDC may be viewed here.

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 into the country. The full SC decision issued on August 18, 2016 confirmed the JDC superseded the DA-AO 8. All approved transformation events 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 here. Application processing is expected to be completed in 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.

Following changes in key regulatory personnel, technology developers have noted that more consideration to timely approval is given to biosafety applications. Initiated by the National Committee on Biosafety of the Philippines (NCBP), the JDC is currently under review and the results are expected to be known in 2021.

b) APPROVALS: A list of approved applications for direct use, field trial, and propagation may be viewed here. As of October 8, 2020:

There are 52 "Transformation Events" or "TEs" approved for direct use (ANNEX I), and seven, all of which are corn, approved for propagation (ANNEX II).

The following approval registries are included as attachment to this report:

- ANNEX I Approval registry for the importation of regulated articles (single "TEs") for direct use as food and feed or for processing
- ANNEX III Approval registry of regulated articles (single "TEs") for propagation.
- c) STACKED OR PYRAMIDED EVENT APPROVALS: There were 23 combined trait products approved for direct use and six approved for propagation as of October 8, 2020.

Multi-trait or stacked event crops composed of approved individual "TEs" must reapply under the JDC. See the attached registry to learn more about:

- ANNEX II Approval registry for the importation of combined trait products for direct use as food, feed and for processing
- ANNEX IV 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 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 and its application was approved in December 2019. Applications for field trials may be found here.
- 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 was established and developed draft guidelines to regulate new breeding technologies. The National Committee on Biosafety of the Philippines' Resolution on New Breeding Techniques is expected in 2021.

- 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.

The most recent GE labeling bill filed under the 18th Philippine Congress is House Bill No. 6411. Introduced by Representative Allan Reyes on February 27, 2020, it is titled "An Act to be Known as 'The Philippine Genetically Modified Organism (GMO) Labeling Act, The Right-to-Know-Act' Requiring the Mandatory Labeling and Regulation of Food which are GMOs or Containing Substances Derived from GMOs and those Produced by Genetic Engineering Technologies, Providing Funds therefor and for other Purposes." It currently sits with the House Committee on Trade and Industry.

- 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.

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 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, with the Department of Agriculture establishing an interagency technical working group for genetically modified animals and animal products on July 27, 2020. The regulatory framework is expected to be finalized and submitted in 2021.
- 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 in 2021. Animal products are not expected to be covered, however, and will likely require separate regulations.
- d) LABELING AND TRACEABILITY: Not applicable.
- e) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable.
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): The Philippines currently does not have legislation to address intellectual property rights for animal biotechnologies.
- g) 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
- h) 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.

CHAPTER III: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

- a) COMMERCIAL PRODUCTION: No information is available regarding whether the Philippines produces food ingredients from microbial biotechnology.
- b) EXPORTS: Not applicable.
- c) IMPORTS: Not applicable.
- d) TRADE BARRIERS: Not applicable.

PART H: POLICY

a) REGULATORY FRAMEWORK: The Philippines currently does not have a regulatory process for the commercial production, use, and trade of biotech-derived microbes or microbial biotech-derived food ingredients. Post is not aware of any discussions pertaining to the drafting of regulation or trade policies on microbial biotech.

Executive Order No. 514, S. 2006 established the National Biosafety Framework and does not mention GE microbes or how they would be regulated. However, EO 514 does specify that all research and development applications, regardless of life form or intended use, shall be regulated by the Department of Science and Technology Biosafety Committee. There have been previous experiments using GE microorganisms, as noted here. For example, Roxas Holding, Inc. is conducting contained use/laboratory research on GE yeast in a pilot trial for boosting cellulosic ethanol production in the Philippines (i.e., bagasse from sugarcane).

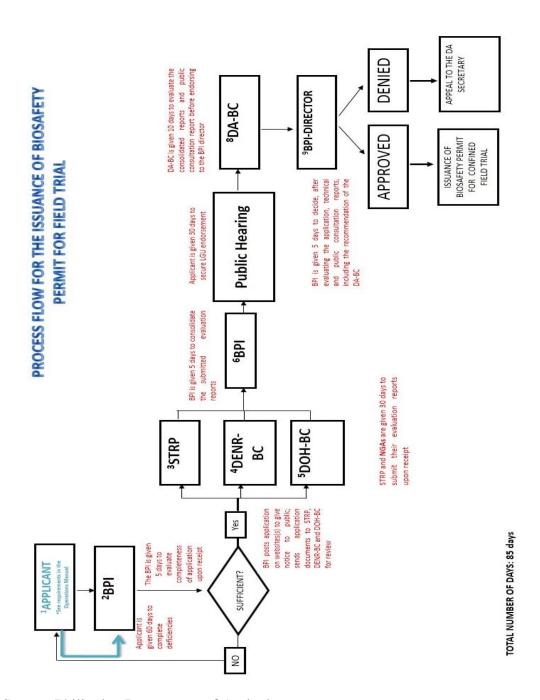
The Philippine Biosafety Guidelines for Contained Use of Genetically Modified Organisms (GMOs), Revised Edition, September 2014 stipulates that the guidelines will apply to all biotech applications under "contained use (i.e. laboratory, screenhouse, glasshouse, greenhouse) and confined test." The guidelines cover plants/crops, pharmaceutical plants, animals, forest trees, and microorganisms. The full guidelines can be found here. The policy and procedures to apply for contained use experiment of biotech microbes are listed on page 56 of the Biosafety Guidelines.

- b) APPROVALS: To date, no biotech microbes or derived food ingredients have been approved.
- c) LABELING AND TRACEABILITY: Not applicable.
- d) MONITORING AND TESTING: Not applicable.
- e) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable.
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): Not applicable.
- g) RELATED ISSUES: Not applicable.

PART I: MARKETING

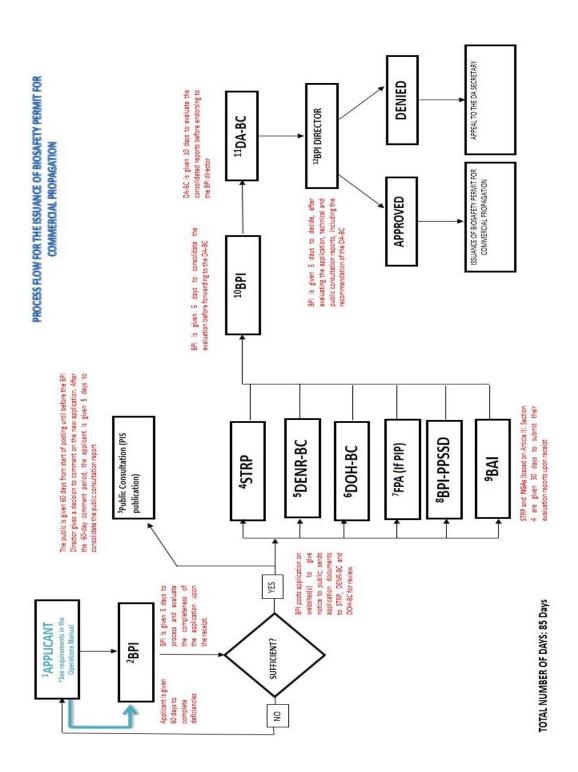
- c) PUBLIC/PRIVATE OPINIONS: Public awareness of microbial biotech is very low.
- d) MARKET ACCEPTANCE/STUDIES: Not applicable.

Annex I – Application for Field Trial



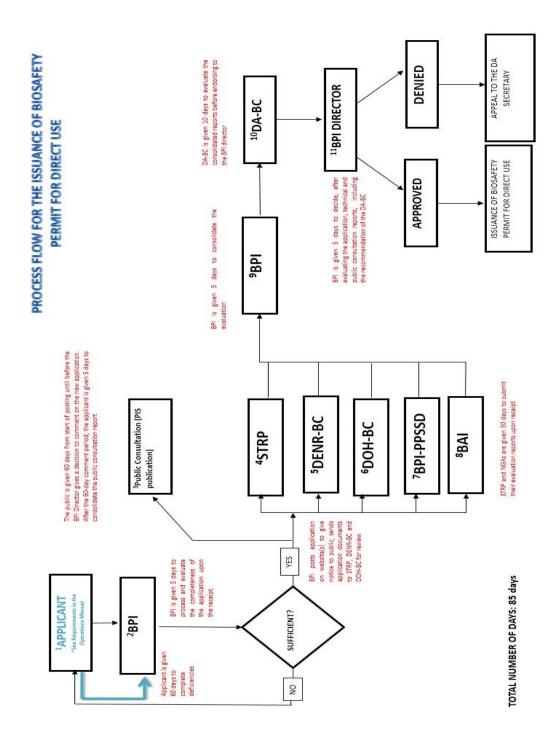
Source: Philippine Department of Agriculture

Annex II – Application for Commercial Propagation



Source: Philippine Department of Agriculture

Annex III – Application for Direct Use



Source: Philippine Department of Agriculture

Attachments: LIST OF REGULATED ARTICLES WITH VALID BIOSAFETY PERMIT oct 8 2020.pdf