A Review of Policies on Crop Biotechnology: Impacts on Food Security and Agriculture Development in the Climate Change Era

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A REVIEW OF POLICIES ON CROP BIOTECHNOLOGY: IMPACTS ON FOOD SECURITY AND AGRICULTURE DEVELOPMENT IN THE CLIMATE CHANGE ERA

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Executive Summary

This study was commissioned by the Philippine Council for Agriculture and Fisheries of the Department of Agriculture to review the policies governing the crop biotechnology development in the country in relation to the national goals of agriculture development and food security in an era of climate change characterized by periods of drought, prolonged rainfall and extreme weather events.

An extensive review of literature was conducted to gain a historical perspective of the development and regulation of biotechnology crops through the process of genetic engineering which started from recombinant DNA (r-DNA) techniques in which the resulting products are called genetically modified organisms (GMOs) or living modified organisms (LMOs). The science has evolved at a relatively fast rate in the last five years or so to what is now called genome or genetic editing that employs new breeding techniques or NBTs such as Site Directed Nucleases or SDNs. While the scientists of yesteryears who were engaged in r-DNA sought process-based regulation of GMOs, the scientists of today who are engaged in SDNs are seeking for product-based regulation which is still consistent with a science-based regulation of biotechnology. In the course of reviewing the literature on the regulatory policies governing crop biotechnology, this study finds three major reforms in the regulatory system that are being proposed, looks at their merits in the context of what current and future needs and attempts to unify them into a policy advocacy that shall promote the responsible use of science in the development and deployment of biotech crops geared towards the achievement of development goals—food security and agriculture development in the climate change era.

Studies on the economics of GM crop adoption and regulation are reviewed next which reveal the benefits from GM crops but the high cost of regulation owing to the inefficiencies in the regulatory processes and the strong influence of anti-GMO on the developmental and regulatory activities appeared to have stalled the development and commercialization of biotech crops beyond GM corn. Ultimately, this has also limited if not stalled the growth in crop production. A great potential lies in gene edited products that do not contain foreign genes and are therefore non-GM. For one, such non-GM products if regarded as conventional varieties and therefore not regulated can benefit the public quickly and also may no longer be strongly opposed by the anti-GM groups. Although scientists say that at the moment, there are varietal improvements that would still require the insertions of a foreign gene. Thus, a review literature and a DA-commissioned study on NBT and key informant interviews (KII) altogether support a change from process-based to product-based regulatory approach.

The study proceeded with an ex-post farm level impact validation of GM corn in two leading GM corn areas in the country through virtual Focus Group Discussions (vFGD's) to gather insights as to the farmers' experience with the GM technology and validate the results of the studies by Yorobe and Quicoy (2006) using 2004 survey data and Afidchao et al. (2014) using 2010 survey data. In both of these reviewed studies, GM corn showed remarkable yield superiority and income advantage over non-GM corn. Results of the vFGD's showed the general conclusion of these studies still hold—GM corn is superior over hybrid varieties in Isabela and Bukidnon and is superior over counterfeit (Sige-Sige) variety in Bukidnon. On the overall, the yield advantage ranges from 1 to 3 MT per ha whereas the returns-above-cash-cost advantage ranges from 3,000 to 20,000 pesos/ha. Thus, GM corn continues to be an economically viable option for farmers despite the high cost of GM seeds of about 10,000 pesos/ha. Especially for financially-challenged farmers the seed cost per ha provides enough incentive to switch from authentic to counterfeit GM corn such as in the case of Sige-Sige in the province of Bukidnon. Sige-sige is an open pollinated variety with GM materials.

Counterfeit seeds is bad for business from the viewpoint of the developer or the seed industry sector but for farmers they are a better alternative especially in drought prone, hilly areas of Bukidnon where the risk of crop loss is high and difficulty of recovering the cost of seeds alone is

great. There is a possibility that with Bt-containing counterfeit corn, a breakdown in the insect resistance may occur and this can be a public concern. An empirical study is suggested to investigate the existence of insect resistance breakdown.

To bring down the cost of GM corn seeds and to disincentivize the use of counterfeit GM seeds, the experts in the Roundtable Discussion (RTD) suggested to persuade the private companies that develop GM corn to donate one or two GM events within a humanitarian arrangement with public research similar to the experience with Golden Rice and Bt eggplant. Or perhaps private developers can donate old GM varieties to local companies engaged in seed production to expand the breadth of farmers' access to GM technology.

Another GM technology awaiting approval (for an extended period) for commercial release is Bt eggplant. An ex-ante farm level impact validation was similarly conducted through vFGD in three leading eggplant areas in the country—Pangasinan, Nueva Ecija and Isabela. Results of the ex-ante assessment for Bt eggplant done by Francisco (2014) recommended that Bt be introgressed onto hybrid variety. Eggplant varietal adoption at the municipal/city level favors Hybrid (77-100%); OPV eggplant adoption is estimated at no more than 23%. The high adoption rates for Hybrids are because of yields and incomes being generally higher when compared to OPV, the vFGD data supports the recommendation of Francisco (2014) to introgress Bt onto recently released elite Hybrid varieties and also to recently released elite OPVs. Incomes are at risk to crop loss due to eggplant fruit and shoot borer (EFSB) and farmers mitigate such risk through intensive erstwhile calendar applications of a cocktail of insecticides, some of which were smuggled with unknown active ingredients. Farmers are aware about the extent of overuse and reported discomforts felt by the applicators although they have no idea as to the degree of health hazards imposed by certain types of insecticides including the smuggled products. The study recommends that the Fertilizer and Pesticide Authority (FPA), as part of its pesticide monitoring activity, to work together with the local agriculture offices and local health offices in educating farmers regarding the health hazards of pesticides, especially those considered highly hazardous and those that are smuggled with unknown active ingredients.

The infamous decision of the Court of Appeals to halt the regulatory and developmental activities pertaining to GM under the DA's Administrative Order No. 2 (s.2002) or AO-8 in 2015 and the hailed reversal of such decision by the Supreme Court in 2016 giving credit to the Joint Circular No.1 (s.2016) or JDD-1 motivated the Congress to heed the call of the Supreme Court during the reversal decision to legislate a regulatory body. The decision of the Court of Appeals in 2015 to halt the development activities pertaining to GM under DA's Administrative Order No. 8, s. 2002, which was consequently affirmed by the Supreme Court, led to the formulation and issuance of DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1 (JDC-1) in 2016. Upon the issuance of JDC-1, the Supreme Court reversed its decision and further called on Congress to create a regulatory body in relation to products of modern biotechnology. Thus, Representative Sharon Garin authored the "Modern Biotechnology Act of 2008", otherwise known as House Bill No. 3372. The Bill proposes the creation of a Biotechnology Authority of the Philippines with dual functions—developmental and regulatory. Although BioAP considers all products of biotechnology, this study looked at its crop component only.

An ex-ante assessment of the BioAP was done using a two-round Policy Delphi Survey (PDS) participated by 26 experts engaged in various fields of biotechnology — scientists/researchers, regulators, and advocates — from public, international and non-government agencies. The PDS questionnaire was designed using an input-to-impact framework. With the copy of House Bill 3372 (2019 version) and other relevant information provided along with the PDS questionnaire, the expert-respondents pointed out provisions in the bill that they assessed to be crucial in invigorating the research in and development of biotech crops and in streamlining or improving the efficiency of the regulatory system. It was found that, under the assumption that the provisions are supported by clear and explicit implementing rules and regulations (IRR), then BioAP may indeed be instrumental in the development and rolling out of biotech crops. . Further, if BioAP will function

primarily as a research and development institution then a roadmap can be drawn that is consistent with national development goals.

Two important reservations were raised by the PDS participants: 1) BioAP cannot assume the dual roles of both promoting and regulating biotech crops, and 2) the anti-GMO influence on public perception and court decisions continues to be a threat to any development efforts. The first issue was brought to a roundtable discussion (RTD) of 11 experts led by national scientists and academician from NAST and economists; the recommendations were: 1) BioAP to take on the promotional role or a research and development institution (RDI) for agricultural biotechnology and provide a supportive role to the regulatory body and 2) reinstate the regulatory leadership role of the National Biosafety Committee of the Philippines (NCBP) as it was prior to 2002 and strengthen the NCBP with funding and plantilla support.

Currently, national and international scientists are rallying for product-based regulation. At the moment, the country's regulation is process-based which was short-sighted as it implicitly assumes that genetic engineering of crops will always involve an insertion of transgene or foreign gene in the gene of crops. As new breeding techniques evolved surprisingly fast, genetic engineers developed biotech crops with no foreign gene inserted in the final product or in the biotech crop variety. Scientists argue that regulation should be based on the product and not on the process and if this will be adopted then rapid growth in the biotech crop development activities and the accompanying releases of biotech crop varieties are expected to ensue. A switch in the composition of R&D investments from one that is dominated by multinational companies to one that is actively participated by the public agencies and small biotech enterprises are also likely as Argentina experiences in recent years.

While this project was ongoing, the NCBP was finalizing the recommendations from two technical working groups (TWGs) that were both created in 2019. The first TWG recommended reforms to improve the effectiveness and efficiency of regulation under the JDC-1 while the second TWG crafted the "NCBP Resolution on Plant Breeding Innovation," based on the results of the DA-commissioned study on NBTs.

To address the issues related to the current crop biotech policies, the study recommends the following — a) reinstate the leadership role on the regulatory function of NCBP through an Executive Order and b) expedite the adoption of the TWGs' recommendations on "Reforms to the JDC-1" and "NCBP Resolution on the PBI." The second recommendation is to make major changes in the BioAP Bill in consideration of the following: 1) BioAP should focus on a developmental role and mandate for agriculture biotechnology, basically as Research and Development Institute, 2) improve the provision statements in the Bill for clarity and explicitness, and 3) write a separate Bill (may be a Senate Bill) to legislate a crop or agricultural biotechnology regulatory body, assigning such to NCBP and strengthening the same with support in developing human resource for regulatory functions. The mandate of NCBP shall be in formulating, revising, and implementing the regulatory process/framework.

I INTRODUCTION

I.1 Background and Significance of the Study

Agricultural development is propelled primarily by technologies provided by advances in science. Specifically, for crop production, these technologies are embodied in the seed. A wide array of literature documents the impacts of the first Green Revolution of the 1960's that apparently ended in the late 1990's, centering on the benefits from modern varietal adoption. Studies suggest that conventional breeding has lost its relevance in boosting productivity while our country continues to deal with challenges in poverty alleviation and food security in an era of climate change. A spring of hope comes with modern biotechnology to push the full take off of a second Green Revolution. Crops can now be genetically engineered to provide them with abilities to self-protect from pests and diseases, tolerate abiotic stresses or be biofortified with vitamins and minerals. Further, with the increasing occurrences of extreme weather events and the changing patterns of rainfall that further worsen our food security problem, there is a compelling need to develop varieties resilient to climate change through genetic engineering and gene editing.

The discovery of a method to shear a gene from one bacterium to insert in another (Cohen et al., 1973) marked the beginning of the Modern Biotechnology era in 1973. Not too long after this discovery, President Marcos issued the Letter of Instruction No. 1005 S.1980, releasing PHP10M to fund the creation of the Institute of Biotechnology at the University of the Philippines in Los Baños (UPLB-BIOTECH). The mandate of UPLB-BIOTECH is to take leadership in the science of biotechnology. However, in recognition of the risks involved in modern biotechnology research during its early years, the national and international scientists in Los Baños formed an Ad Hoc committee in 1987 with the intent to regulate themselves by proposing biosafety[1] guidelines. These guidelines are science-based assessment of risks of modern biotechnology research on human health and the environment (Mendoza et al., 2009). This initiative culminated into the issuance of Executive Order No.430 (EO 430) by President Aquino in 1990 that installed the National Committee on Biosafety of the Philippines NCBP . EO 430 supports research and development (R&D) in modern biotechnology and addresses the associated risks. The country's biosafety guidelines are based on those enforced in the developed countries and, over time, they were adjusted to domestic needs/conditions and to comply with the terms of the Cartagena Protocol on Biosafety

[1] The current biosafety regulatory guidelines define "biosafety" as the condition in which the probability of harm, injury and damage resulting from the intentional and unintentional introduction and/or use of a "regulated article" is within acceptable and manageable levels. Further, "regulated article" refers to a genetically-modified organisms and its products, but limited to genetically-modified plants and plant products under the scope of the Joint Departmental Circular No. 1, Series of 2016.

Currently, the country leads in Southeast Asia in terms of GE research and development, commercialization and operating a science-based biosafety regulatory system. However, the USDA warns that delays in the processing of biosafety applications endanger our leadership status (Bedford and Corpus, 2018). The Philippines may take pride in the fact that science takes precedence over passion in the formulation of biosafety regulatory policy, but, how effective and efficient are these policies? How are the policies impacting our agriculture development and food security?

I.2 Objectives of the Study

General Objective: To understand the prevailing and emerging crop biotechnology policy environment in the country and draw insight into its implications on the food industry and agriculture development in a climate change era.

Specific objectives:

1. Synthesize data/information on domestic and international policies related to crop biotechnology from literature review:
    a. Challenges in achieving food security and agriculture development: the 2nd Green Revolution,
    b. Working definition of modern crop biotechnology,
    c. Role of modern biotechnology policy;

2. Assess the competitiveness (effectiveness and efficiency) of the country's biotechnology policy in contributing to food security and agriculture development;
3. Identify innovative policy approaches and other effective policy initiatives; and
4. Formulate policy recommendations for action and advocacy.

II REVIEW OF LITERATURE

II.1 Challenges of Agriculture Development and Food Security in the Context of Climate Change Era

II.1.1 Climate Change and Food Security: Philippines Experience

The Philippines, a member of Southeast Asia, has high climate change susceptibility and vulnerability that extremely affect the livelihood of rural people dependent on farming (IPCC, 2014). According to the World Risk Index (2019), the Philippines ranks as the third most at-risk country in terms of potential impacts of climate change in the water supply. As reported by International Food Policy Research Institute (2016), the Philippines will experience a probable reduction of 6.1% on cereals yield and 24% increase on its prices in 2050 due to climate change. The International Panel on Climate Change (2014) reported that Asia has an increasing risk of crop failure and lower crop production that could lead to food insecurity from the present to 2080. The National Nutrition Survey (NNS) in 2018 reported that 53.9% of households are food insecure.

Food and Agricultural Organization (2014) reported that food insecure families tend to live in rural areas, have less access to agricultural assets, and are more dependent on crop farming. A study by Lansigan, De los Santos and Coladilla (2000) revealed that climate variability influences the growth and yield of crops, noting that losses from this surge annually. The International Food Policy Research Institute (2016) similarly showed that climate change in the Philippines will decrease crop yields and in turn will raise the price of food that will make people transform production and consumption patterns. Israel & Briones (2005) observed that the Philippines is highly vulnerable to food insecurity due to stressors such as drought, extreme weather and climate, and pest infestations.

From the prior statements, it is clear that climate change imposes a high risk on food security and agriculture development in the Philippines, from crop production to food distribution and consumption. Despite the “green revolution”, which was supposed to be the answer to food security, malnutrition and poverty, the less developed countries still suffer a decline in aggregate food supply leading to hunger and insufficiency.

II.1.2 The First Green Revolution

The philanthropic organizations such as Rockefeller Foundation and Ford Foundation invested in the founding of the International Rice Research Institute in the 1960. The grand concept was to aid countries in Asia feed its population with domestically grown rice and solve hunger altogether. Borrowing the new breeding techniques employed in wheat, IRRI developed and released the first dwarf variety that was also dubbed as the miracle rice, IR-8. IRRI breeders relentlessly continued

phenotyping and crossing for higher yield, pest resistance, and grain quality while also doing its own socio-economic research to study constraints to yield and adoption. The Philippines as a host country was the first to benefit from IRRI's newly bred varieties as these varieties were first field tested in the country and foundation seeds were distributed to a limited number of farmers. President Marcos zeroed in on the opportunity and launched a national rice program called Masagana 99 Rice Production Program in the year 1973. Under this program, modern seed varieties and agronomic practices were sourced from IRRI and UPLB. The rest is history. By the late 1970s and for a short period of time, the country turned from a rice importer to an exporter. Science and technology came first and the government quickly grabbed the opportunity and thus the first green revolution in the Philippines.

The introduction of the first modern variety translated into an improvement in the crop performance for rice. As the main staple food of Filipinos, rice is the most important agricultural crop in the Philippines. From 1971 to 1972, there was a decrease of 8.67% in the yield of rice. With the adoption of modern rice varieties, marking the onset of the first green revolution, the percent growth rate became positive and increased by 15.33% between 1972-73 (Table 1). Consequently, it improved the food security situation, nutrition status, and income. Hayami and Kikuchi (1999) in a study of a Laguna village during the green revolution showed a noticeable increase in yield growth rate of rice at 4.3% per year. It reduced poverty by benefiting the rural areas that were usually comprised of low-income and rice-dependent households. But like any technology, conventional tools in breeding during the green revolution finally approached its limit so that productivity gains at the margin declined (Figure 1). What used to be modern and innovative became conventional and irrelevant, marking the end of the first green revolution. A potential increase in productivity can only be done by exploring more innovative ways of improving crop agronomic traits.

Although the green revolution technologies are exhausted, the problems before the 1970s are still true to this day. There is still a need and, consequently, pressure to scientists to improve crop performance and meet food demand in a period when agricultural lands are getting scarcer with land conversion. Agriculture has reached its land frontier. Figure 1 shows that arable land has apparently reached its peak in 2012.

Further, crop production is pressed on the other side by climate change, deterioration of natural resources, water and land scarcity, growing population and urbanization. Climate change affects the average temperature resulting in differences in crop productivity across regions. Variations in rainfall and rainfall patterns can lead to soil erosion and soil moisture reduction. Upsurge in the atmospheric concentration of carbon dioxide may be beneficial to crops but such benefits can be cancelled out by the effects (of higher carbon dioxide emission) on the ozone layer that eventually leads to a rise in global temperature and extreme weather events. Harvey et al. (2018) in a study

of small farmers in Latin America reported detrimental impacts of extreme weather events on crop yields, pest and disease incidence, household income, and, in some cases household food security.

Table 1. Growth in the yield of rice during the Green Revolution era, Philippines, 1970-1980.

Year	Rice Yield (MT/ha)	Annual Growth Rate (%)
1970	1.64	-2.38
1971	1.50	-8.54
1972	1.37	-8.67
1973	1.58	15.33
1974	1.67	5.70
1975	1.81	8.38
1976	1.93	6.63
1977	2.10	8.81
1978	2.11	0.48
1979	2.15	1.90
1980	2.23	3.72

Source of Data: International Rice Research Institute

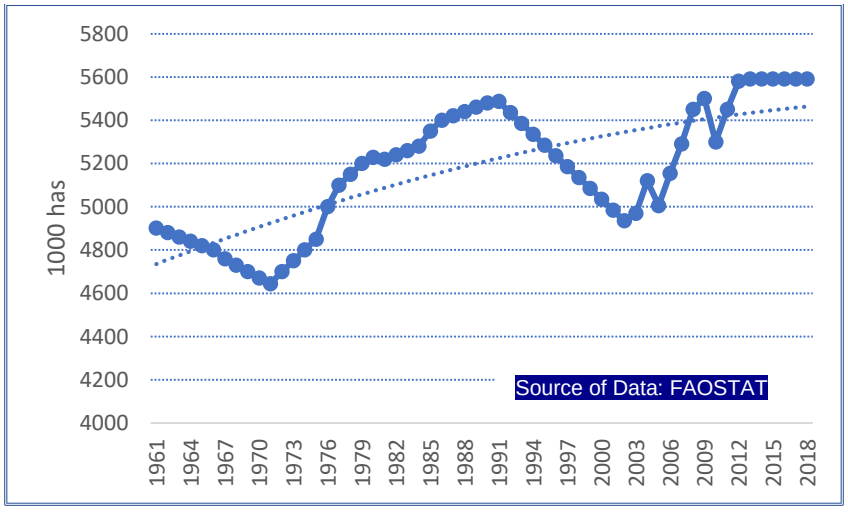

Figure 1. Arable land, Philippines, 1961-2018.

Lobell, Burke, Tebaldi, Mastrandrea, Falcon, & Naylor (2008) states that to increase food production and to ensure food security, the yield per hectare or the area under cultivation must increase. Food shortages can occur if the yield per hectare increases at a slower rate of population (Masipa, 2017). Increasing the area under cultivation is out of the option considering an increasing demand for non-agricultural uses of land for housing, commercial, and industrial purposes. Also, increasing the area under cultivation would require investments in irrigation which is costly and expensive. In addition, the use of marginal lands for farming is not recommended due to its

limitation for agricultural use and being generally fragile and at high environmental risk (Wiegmann, Hennenberg & Fritsche, 2008). Lastly, the cultivation frontier has come to a close. Bordey et. al. (2017) also found out that increasing other farm inputs to increase the yield does not translate to higher income, since most farmers in provinces in the country operate using near profit maximizing levels of input. Hence, there is no incentive for farmers to increase input use to increase yield. The only solution, then, is to improve productivity, profitability, and sustainability of limited agricultural land areas .

FAO and DFWI (2015) also state that higher crop intensification and greater annual productivity, with variation in environment, input and practices, are requirements to reach a production mark without mass transformation of land to agriculture. The yield gap between potential (experimental) yield and actual yield represents an opportunity for emerging technologies. The yield gap is usually attributed to the occurrences of pests and diseases and extreme weather events.

In Figure 2, trend lines for the yield of new rice varieties released between 1960 through 2018 from NSIC and the national rice yield from USDA during the same period were plotted. As shown in the figure, both the potential and actual yields of rice are generally increasing. However, the slope for actual yield is negative which means the marginal increase decreases with time but the rate of increase for potential yield is positive.

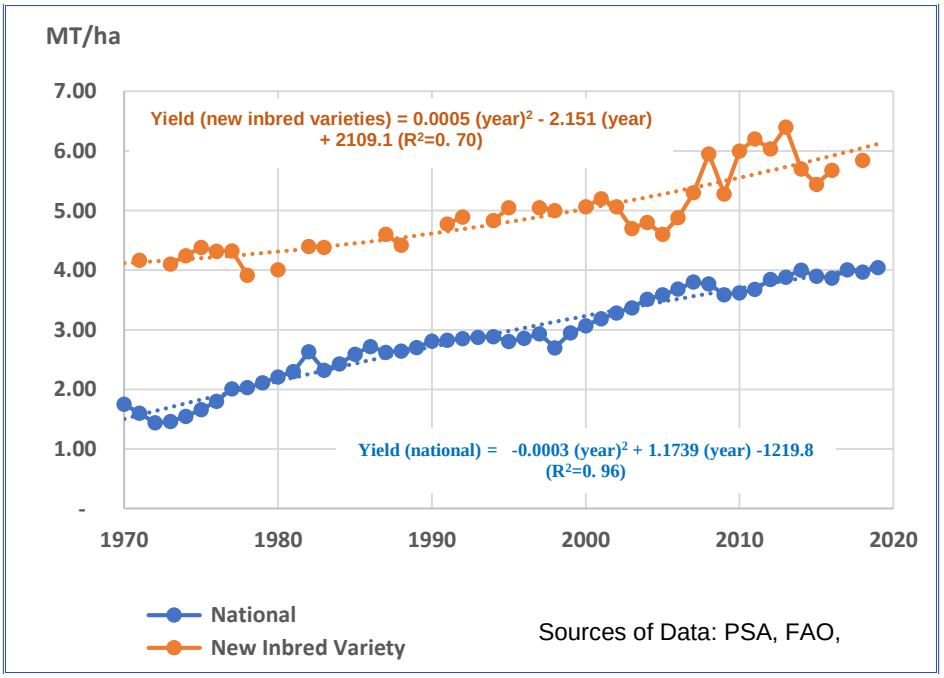

Figure 2. Yield of new varieties vs national average, Philippines, 1960-2018.

The difference between the two lines is the yield gap which is usually attributed to attacks of pests and diseases and extreme weather events. Filling this gap presents a challenge to crop developers, specifically, conferring traits to crops for pest and disease resistance and tolerance to water and temperature stresses through genetic transformation and gene editing.

II.1.3 The Second Green Revolution

Modern biotechnology is the solution to the problem of global food insecurity. Modern biotechnology, specifically, genetic engineering opens new opportunities to overcome the limitations of crops to adapt to climate change, defend itself from pests, and even improve its nutritional value. It can increase yields while diminishing the use of fertilizer, herbicides and insecticide; generate dry season or salt resilience on crop plants; expand shelf life; decrease postharvest losses; and improve the nutrient content of crop produce. Creating such products through biotechnology can play an important role in securing the food supply, addressing the health problems of the developing countries, and dealing with climate change. The National Research Council (2009) argues that the creation of a “bioeconomy” from an extensive application and practice of biotechnology can lead to a sustainable use of limited resources.

Thus, modern biotechnology can lead to a second green revolution. These modern biotechnology tools can overcome the limits of the first green revolution. Conventional plant breeding took about ten years to develop a variety. Marker assisted techniques of modern biotechnology shortened the breeding period to about six years. Further, other techniques of modern biotechnology such as genetic transformation, gene editing, embryo transfer and others allowed what was impossible in conventional breeding possible such as conferring traits that are not naturally found in the crops.

II.1.4 Food Security and Biotechnology

Modern biotechnology can aid in food security by improving the agronomic and quality attributes of the crop.

Agronomic Traits

Modern biotechnology tools can enhance agronomic traits and quality traits which affect production performance and the commodity characteristic itself. Agronomic traits refer to qualities that increase or stabilize the yield of crops. Qaim and Virchow (2000) explained that these agronomic traits usually modify input mixes that ultimately affect the level of production so they can also be called input traits. Examples are crops with resistance for pests and diseases. Here, modern biotechnology can aid to decrease the pest associated with losses and the deployment of chemical control measures.

Insect/Pest Resistance

Rao, Pray & Herring (2015) reported that commercialized application of biotechnological products targets the less usage of agrochemicals. These pests or insect resistance crops can eliminate the specific pest or insect in a certain commodity by producing their own Bt. It's a built-in mechanism of protection against the targeted insect or pest to make them resistant. Inserting Bt to exactly where the target insects are feeding results in lower use of agro-chemicals and exposure of farmers to these kinds of chemicals. Bt corn is a prime example of an insect- or pest-resistant crop that is commercialized in the Philippines. Yorobe and Quicoy (2006) found that preliminary Bt corn adoption in the Philippines provides a significant increase in farm yields and profits among the Bt farmers. Mutuc, Rejesus, Pan & Yorobe (2012) also showed that there is a decrease in yield from pests associated with losses.

Disease Resistance

The introduction of modern biotechnology tools can enhance crop productivity by transferring virus qualities to the variety that makes it resistant to diseases. For instance, papaya varieties were developed for resistance to papaya ringspot virus by molecular biologists from Cornell University, the University of Hawaii, and the Upjoin Company.

Improved Resistance to Pesticide/Herbicide

Heavy usage of chemical inputs is sometimes necessary to optimize yield. Chemical control of insect pests, pathogens and weeds can damage and harm the environment. Monsanto developed the Roundup-Ready technology, which was first introduced in 1996 as GM soybeans. Roundup-Ready (RR) plants are not affected by herbicide glyphosate. The decreased requirement of herbicides on herbicide tolerant varieties results in better control of weeds, improved yields, no-carryover of herbicide residues, better soil, water and air quality. This allows savings compared to conservative tillage to reduce weeds or multiple applications of different types of herbicides to selectively eliminate weeds. According to ISAAA (2013), the adoption of RR lowers the loss of soil carbon and carbon emission and decreases the use of fuel that lessens soil erosion. Thus, these crops can contribute to the mitigation of climate change.

Abiotic Tolerance

With the use of modern biotechnology tools, growing crops in areas of problematic soil and water conditions can be made possible. Tolerance for saline soils, drought and flood, heat and cold stresses can now be conferred on crops through genetic transformation and gene editing. These tolerance traits when conferred can reduce the risk of crop losses due to abiotic stresses. Examples are GM Barley and GM Wheat with saline tolerance and, in Africa, water efficient maize.

Output Traits

On the other hand, the chemical structure, appearance and composition of the crop product are called quality traits or output traits. It was elaborated that modifying these traits can be beneficial

to low income households. Ideally, the trait is to be conferred on the popular varieties of principal food crops.

Potential Improvements in the Nutritive Value of Plants
Modern biotechnology can be used to introduce or concentrate certain nutrients such as vitamin A, Zinc, Iron, and Iodine into common dietary staple food plants as a way of delivering ideal levels of key nutrients or fighting nutritional deficit (Uzogara, 2000).

Enhancement of macronutrients in crops can increase the protein content, remove allergenic flavor, increase level of unsaturated fatty acids and decrease the level of saturated fatty acid that all have health beneficial effects to human diet (Liu & Brown, 1996). One of the recent developments in modern biotechnology is Golden Rice wherein the precursor of vitamin A called beta-carotene is made present in the endosperm, the edible part of rice and planned to use for areas lacking in dietary vitamin A (Cano, Diaz and Moragado, 2017).

Improved Texture or Appearance of Food and Better Flavor
For the creation of longer shelf life and low risk of decay, crops can be modified to ripen longer than usual. Tomato, modified to delay its ripening, was the first genetically modified food product. Also, enhancing the activity of plant enzymes improves the flavor by transforming aroma precursor into flavoring compounds.

II.1.5 Climate change, Food Security and Biotechnology

Table 2 shows that biotechnology can provide a solution to impact food security in a climate change era. The techniques and tools of modern biotechnology can therefore aid to lessen the effects of climate change on crop production, food supply, and household food security.

Table 2. Impact of Climate Change in Food Security and Biotechnology as a Solution.

Climate Change	Impacts	Biotechnology as a Solution
Increase in average temperature	Reduced quantity and reliability of agricultural yield Destruction of crops or lowering crop productivity	Heat stress tolerant crops
Changes in amount of rainfall	Reduced Water Availability Heavy reliance on irrigation Poor quality of crops due to deteriorating water quality	Water efficient crops
Increased severity of drought	Decreased crop yield Increased probability of fire	Drought tolerant crops
Increased intensity of extreme events	Soil erosion Increased land degradation and desertification Inability to cultivate land Damage to crops and food stores	Tolerance to abiotic stress crops

Source: Masipa (2017) & Study Notes

II.1.6 Application of Biotechnology in Philippine Agriculture

The only commercialized biotechnological product in the Philippines so far is GM corn that has insect resistance and herbicide tolerance traits. GM corn is the only crop approved for the commercial production of modern biotechnology which can be used as human food or feed for livestock. It also made the Philippines the first Southeast Asian country propagating a product of modern biotechnology. In the pipeline of product development are Bt eggplant, Golden Rice, Bt cotton and Papaya with ringspot virus-resistance project. This may take time to be commercialized due to stifling regulations and measures needed to comply with biosafety requirements. No crops are being exported to other countries. The Philippines imports GE crops from the United States such as soybean and GE-derived products for processing. Science-based safety regulations are continuously enhanced in adherence to emerging issues and an internationally acceptable set of biosafety standards. Compliance with these regulations may be cumbersome and time consuming albeit necessary. However, there are reported delays in the approval process and these may be due to some bottlenecks in the implementation of these regulations. Smyth et al. (2016) showed how delays reduce the rate of return on biotechnology R&D by the private sector and that the same applies to public R&D.

II.2 Current State of Crop Biotechnology

II.2.1 Definition of Terms

Biotechnology. The term Biotechnology was coined by a Hungarian engineer named Karl Ereky in 1919 (Bhatia, 2018). He defined biotechnology from its root words “Bio” which is biological processes and “Technology” which is the application of knowledge for practical purposes. In combination, biotechnology can be defined as the use of biological processes to solve problems or make useful products. This broad meaning was used by many scientists until a more accurate definition was decided by the United Nations in the Convention on Biological Diversity(CBD) held in Rio de Janeiro, Brazil in 1992. According to the Article 2 of the CBD, biotechnology is “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use” (UN, 1992). A more updated definition was released by the International Service for the Acquisition of Agri-biotech Applications (ISAAA) which defined biotech as “a set of tools that uses living organisms or parts of organisms to make or modify a product, improve plants, trees or animals, or develop microorganisms for specific uses” (Navarro et al., 2010).

Agricultural Biotechnology. Today, biotechnology is widely used as a tool to enhance crop production and performance, shorten crop varietal development, improve livestock production, and make biofertilizers and biofuels from agricultural waste. All these require an understanding of the DNA and the application of modern techniques such as recombinant DNA technology. Agricultural

biotechnology is defined as a range of tools, including traditional breeding techniques, that alter living organisms, or parts of organisms, to make or modify products; improve plants or animals; or develop microorganisms for specific agricultural uses. Modern biotechnology today includes the tools of genetic engineering (USDA Agricultural Biotechnology Glossary, n.d.).

From Ancient to Modern Biotechnology. Biotechnology covers a large part of history and can be divided or categorized into three phases of development. The beginning of biotechnology can be traced back as early as the ancient period when man transitions from hunter to gatherer. This phase is called Ancient Biotechnology. The collection of wild plants, cultivating them, and selecting the best yielding varieties for the growing season are the earliest biotechnological techniques (Verma, Agrahari and Singh, 2011). The domestication of plants (and animals) became the foundation of breeding techniques for the selection of desired traits over generations.

After centuries, people discovered how to apply the natural biological processes of living cells to their domestic lives, which is the start of Classical Biotechnology. The discovery of the fermentation process and the course of development thereon can be used to describe the classical phase (Khan, Qurashi, Hussain, Hayee and Ali, 2003). This stage also includes biotechnological applications such as the brewing of beer from barley, wine making, fermentation of milk into yoghurt and cheese, and the use of vaccines for the livestock (Visser, 2001).

The groundwork for the transition of Classical to Modern Biotechnology was laid upon the discovery of genes by Gregor Mendel and the discovery of the structure of deoxyribonucleic acid (DNA) by James Watson. The knowledge of the mechanism of how traits are passed from generation to generations paved the way to producing desired changes in an organism through direct manipulation of the DNA. Currently, modern biotechnology, as defined in the Cartagena Protocol on Biosafety, means the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles, or the fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection (Secretariat of the Convention on Biological Diversity, 2000).

Modern Biotechnology is largely based on DNA technology. The key components of modern biotechnology are as follows: Genomics, Bioinformatics, Genetic Engineering, Molecular Breeding, Diagnostics, and Vaccine Technology (Persley and Siedow, 1999). From these aspects of modern biotechnology, genetic engineering will be the focus of this study.

Genetic Engineering is a method of introducing or eliminating specific genes in an organism that changes the genetic constitution of cells apart from selective breeding. This technology is based on the use of a vector for transferring useful genetic information from a donor organism into a cell

or organism that does not possess it (Food and Agriculture Organization, n.d.). The products of such technique are termed as Genetically Modified Organisms (GMOs). They can be defined as organisms (i.e., plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination (World Health Organization, 2017). Instead of GMO, the term Living Modified Organism (LMO) was used by the Cartagena Protocol on Biosafety and some other international agreements. It was defined as the means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (Secretariat of the Convention on Biological Diversity, 2000). The term LMO is functionally the same as GMO and thus can be used interchangeably.

Other Relevant Terms. The international legal basis of the Philippine biotechnology policies is largely concerned with the biosafety of GMOs. According to the Joint Department Circular 1 of 2016 , Biosafety refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology.

Another principle adopted by the Philippine policies is *Risk Assessment*. It is used to make informed decisions regarding LMOs. As defined by the JDC, Risk refers to the combination of the likelihoods that an adverse consequence of a biohazardous activity or trait will occur and the magnitude of such a consequence. Risk Assessment refers to the procedure that identifies, evaluates and predicts the occurrence of possible hazards to human and animal health and the environment while Risk Management refers to appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment including those conditions imposed by concerned departments or agencies.

II.2.2 Scope of the Study

This study mainly focuses on modern biotechnology, not on the ancient and classical biotechnology, and its application on agricultural biotechnology, particularly on crops. Developments and advances in modern biotechnological tools like gene editing, marker-assisted breeding, genomic sequencing, and bioinformatics will be tackled, with emphasis on GMOs.

II.2.3 The Philippine Biosafety Regulatory Policy[2]

II.2.4 The Philippine Biotechnology Policy Statement

Recall that the country continues to recognize the role of biotechnology for crop production, agriculture modernization, and a sustainable environment and that where there are risks to humans and the environment, the country is to promote its safe and responsible use. As President Arroyo stated in 1991, “We shall ensure that all technologies that we promote, including modern

[2] Unless otherwise stated, this section is heavily lifted from several DOST Biosafety documents.

biotechnology, will provide farmers and fisherfolks the opportunity to increase their overall productivity and income; enhance the welfare of consumers; promote efficiency, competitiveness, and improved quality standards of local industries – all within the paramount objective of attaining safely and sustainable development, including its human, social and environmental aspects."

The national government agencies such as the DA and the DOST have harmonized their crop research agenda. The "crop biotechnology program" of the DA is thus woven into the agenda of other agencies.

II.2.5 The Philippine Biosafety Policy

All genetically modified or engineered organisms fall under regulated articles[3]. Biosafety measures employ science-based risk assessments of the possible adverse effects of the use of regulated articles on the health and the environment. Various national government agencies play specific roles in the implementation. The NCBP is mandated to formulate the policies in consultation with the science and public communities. Implementation is carried out by the DOST, DA, DENR, and the DILG. The Philippine Biosafety Organizational Structure in Figure 3 was established in 2014 just before the JDC-1 (2016).

Risk Assessments are performed for all regulated articles to identify and evaluate the potential adverse effects on the receiving environment as well as risks to human health. The assessments under the JDC are carried out in a scientifically sound manner and adopts the "Precautionary Approach" in compliance with the Cartagena Protocol on Biosafety. The risk assessment also adopts Principle 15 of the 1992 Rio Declaration on Environment and Development which states that, "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Further, the risks of a GE crop, for example, shall be compared in the context of the risks posed by the traditionally bred crop. As stated in the Cartagena Protocol, the steps involved are as follow:

a) Identification of the novel genotypic and phenotypic characteristics associated with the GMO, evaluation in terms of the perceived hazard qualitatively and identification of measurable properties in order to more accurately assess the risk;

b) Evaluation of the likelihood of the adverse effect taking into account the level and kind of exposure the GMO will be subjected to upon introduction to the environment;

[3] As of this writing, while the JDC-1 is under review, the proposal put forth by the DOST-Biosafety Committee that outlines the "regulatory decision path" for the products of genome editing is up for signature by the departmental secretaries.

c) Evaluation of the consequences of the adverse effect if it occurs;

d) Estimation of the overall risk based on the estimated likelihood and consequences of the adverse effect;

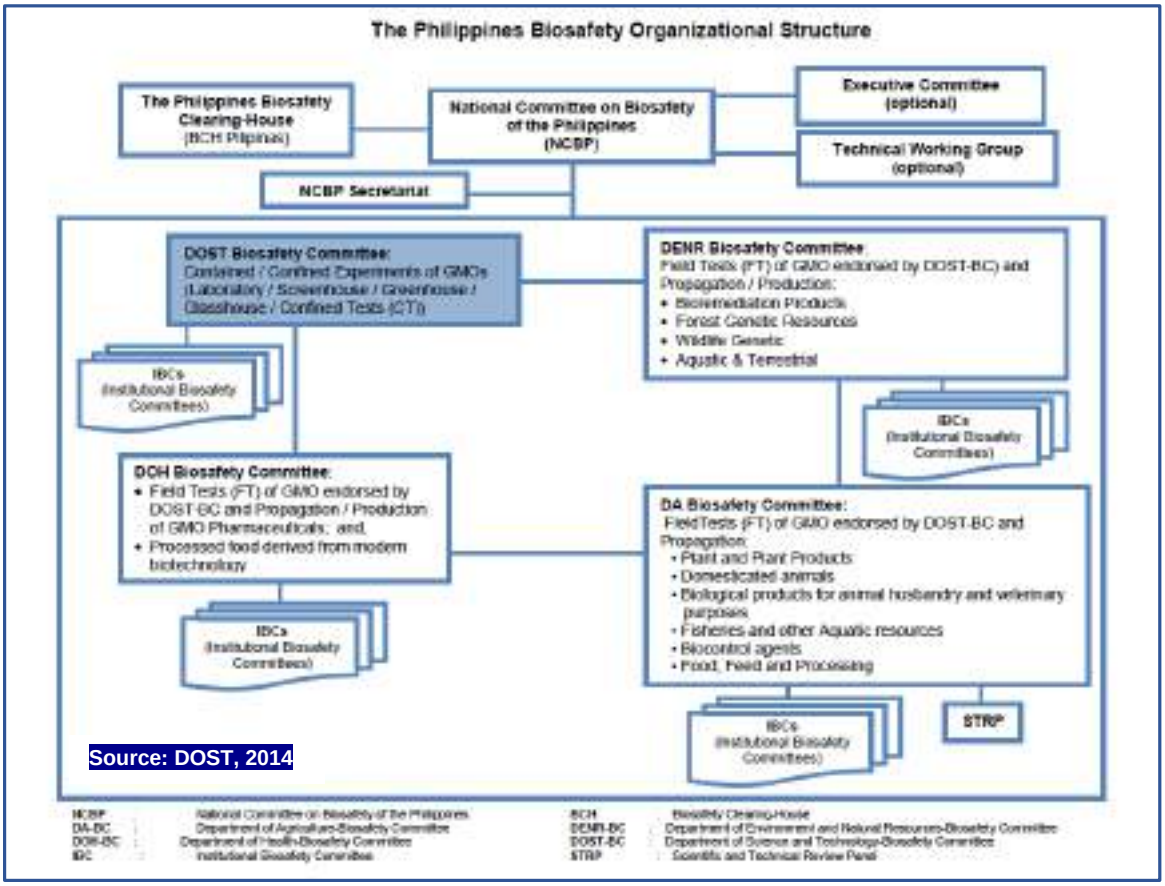

Figure 3. The Philippine Biosafety Organizational Structure.

e) Recommendation whether the risks identified are manageable or acceptable and the identification of the strategies for risk management if necessary; and

f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

The Biosafety Framework/Regulations. Genetically engineered (GE) or genetically modified (GM) crops developed locally and intended to be commercially grown in the Philippines must undergo four distinct and sequential regulatory processes according to the guidelines set forth under the Joint Departmental Circular No. 1 series of 2016 or JDC-1. This basically says that every stage of

the research and development of GE crops is regulated until the commercialization phase. The biosafety guidelines are provided and published online by the DOST for ease in compliance.

The process begins with securing a permit for Contained Use[4] and/or Confined Test[5], then moves to Confined Field Trial[6] and subsequently to Commercial Propagation[7]. Only after a biosafety permit is issued with the satisfactory completion and approval of Commercial Propagation application can the GE crop be optionally registered with the National Seed Industry Council. Under the Plant Variety Protection Act (PVPA), GE developers reserve the right to give exclusive contracts to seed companies for the multiplication and distribution of seeds to retailers and ultimately sell to the farmers. Figures 6 through 8 illustrate the process flow from Contained Use until Commercial Propagation. Exportation[8] to the country of GE crops to be used as food, feed, or processing will need to apply for biosafety permit for Direct Use (Figure 9). Each of these processes is estimated to take 85 days to complete. The estimated processing time can be used to measure the efficiency of our regulatory system; we can assess its performance comparing data on actual versus the 85-day processing time, identify the delimiting factors or bottlenecks, and recommend improvements.

Contained Use. Regulatory measures are installed from the very beginning of research and product development, for example, the contained use of GE materials in laboratories during transformation events. The process starts with the technology developer or researcher submitting a proposal packet and the required application forms that seek an endorsement from its Institutional Biosafety Committee (IBC). The IBC is composed of three in-house experts not involved in the research and two members representing the community. Finding that the proposal-application is satisfactory and complete, it is then endorsed to the DOST Biosafety Committee. The full process flow in (Figure 4) indicates processing time to be at least 67-70 days from the time it is received by DOST-BC. The researcher has to satisfy the BC of only one department—the DOST—who sends

[4] *Contained Use* refers to any operation, undertaken within a facility, installation or other physical structures, which involves genetically modified organisms (GMOs) that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment. It includes experiments inside the laboratory, screenhouse, greenhouse, or glasshouse.

[5] *Confined Test* refers to a field test of genetically modified plants not approved for general release, in which measures for approved isolation and materials confinement are enforced in order to confine the experimented plant material and genes to the test site.

[6] *Confined Field Trial* refers to any intentional introduction into the environment of a regulated article that passed the contained use and confined test, for purposes of research and development, and for which specific confinement and mitigating measures may be imposed. Field trials may be conducted in a single site or in multiple sites.

[7] *Commercial Propagation* refers to the introduction or delivery for introduction into commerce of a regulated article for regeneration into plants or plant products for consumption by humans or animals.

[8] The burden of DS permits application rests on the exporter and not on the importing country. See the 2018 USDA FAS report.

the “letter of action” to the head of the institution of the researcher and copies to the BPI and other national government departments as necessary.

During the transformation phase, the genetic engineer extracts the gene of interest from the donor organism, clones and designs it before finally inserting the clone or copy of the foreign gene into the cells of the recipient crop—the transformed plant cells are then regenerated into transgenic plants. The plant breeder assumes the succeeding tasks of crossing the transgenic plant with elite lines.

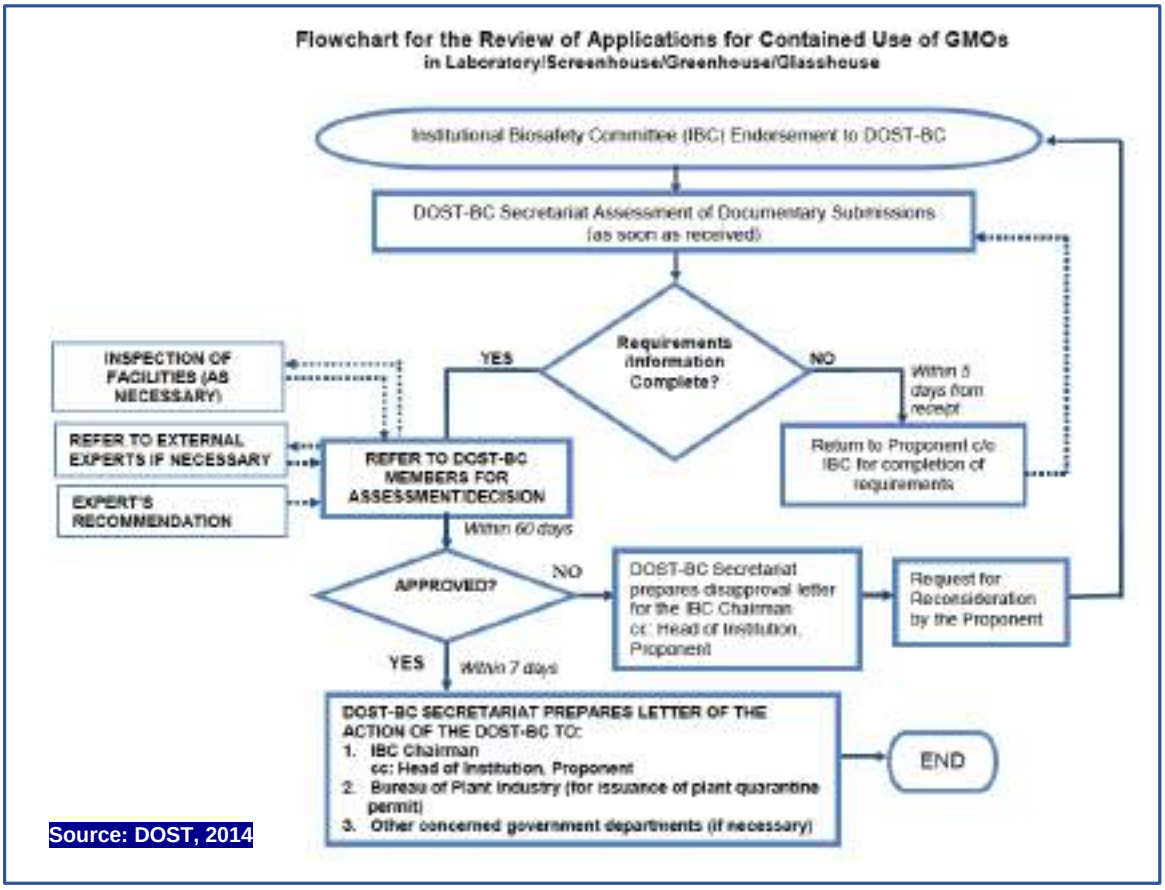

Figure 4. Process flow for Contained Use application.

Confined Test. After successfully completing the transformation during the contained use phase, the next step is for the putative transgenic event(s) to be evaluated within a small confined test site. The researcher then prepares a proposal-application for this drawing from the results of the completed contained use. The process flow (Figure 5) is very similar with that for contained use except that before final approval, the DOST-BC approved Project Information Sheet is posted for comments; the comments, if any, are provided to the IBC of the researcher for appropriate action.

During this phase, the plant breeder performs backcross breeding[9] wherein transgenic plants are crossed with elite breeding lines using traditional plant breeding methods to combine the desired traits of elite parents and the transgene into a single line. The offspring are repeatedly crossed back to the elite line to obtain a high yielding transgenic line. The result will be a plant with a yield potential close to current hybrids that expresses the trait encoded by the new transgene.

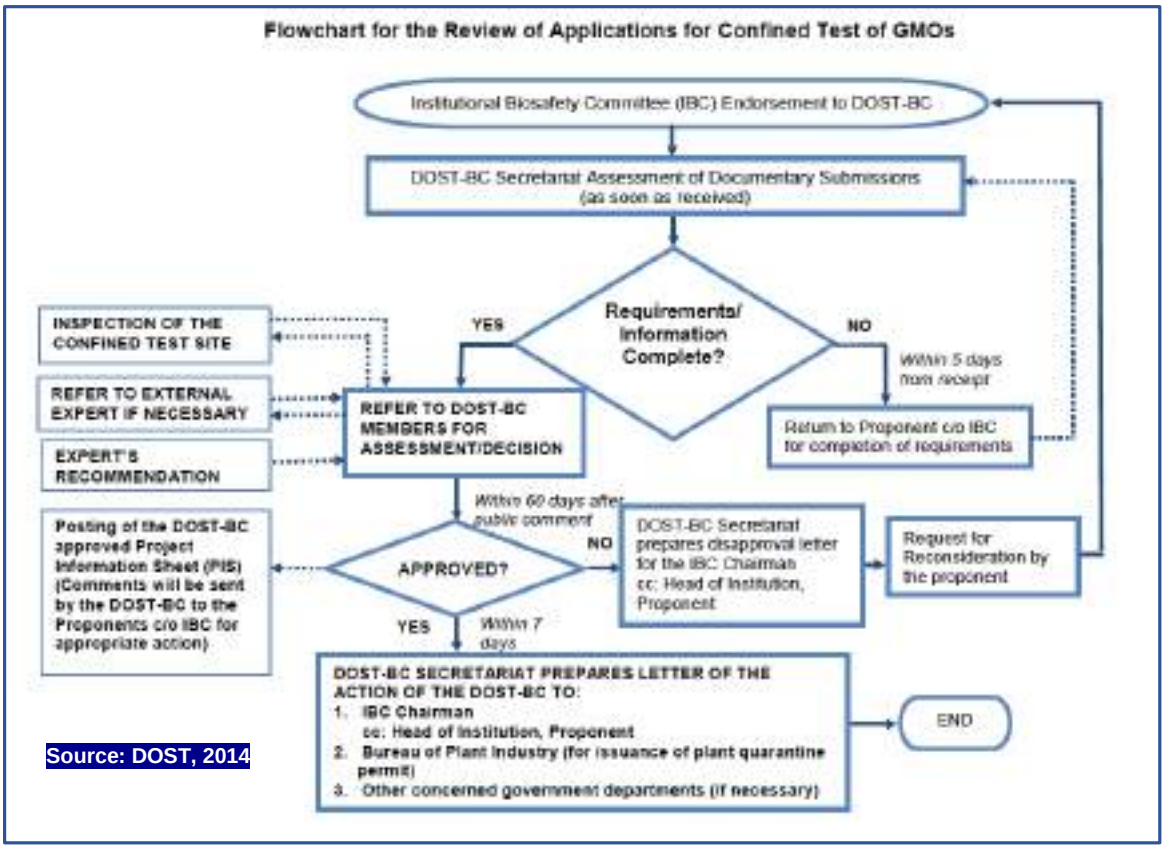

Figure 5. Process flow for Confined Test application.

Confined Field Trial. The data from Contained Use/Confined Trial are used in the application proposal for Confined Field Trial. These applications are submitted to the DA Bureau of Plant Industry for review. The process flow in Figure 6 shows the five competent national authorities (NCAs) that are enjoined to review/evaluate the application before the DA-BPI finally makes a decision to approve or deny. The total number of days to complete the process (85 days) and its distribution in the process is also specified. The biosafety permit issued finally allows the technology developer to proceed with the confined field trial (or multilocation trial).

[9] http://agbiosafety.unl.edu/education/summary.htm.

This phase is similar to the multilocation trial done for conventionally bred varieties wherein the agronomic performance is evaluated in various locations of the country.

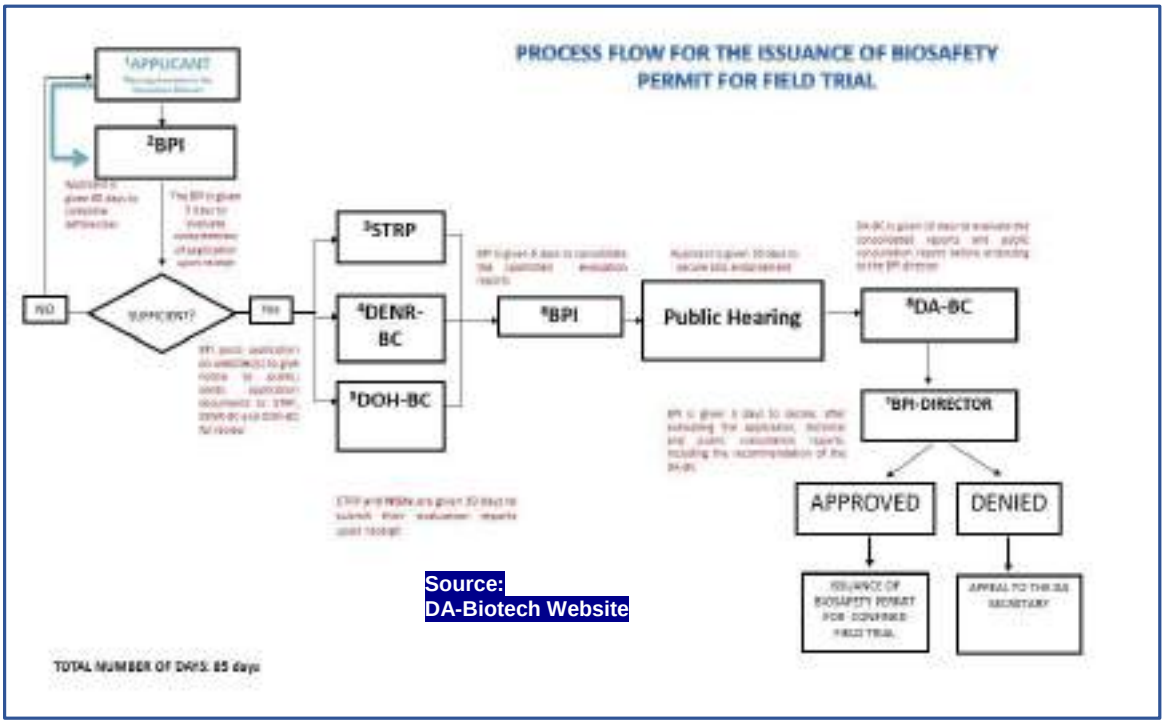

Figure 6. Process flow for Field Trial Application under JDC-1 (2016).

Commercial Propagation. After the field trial is successfully completed, a biosafety permit to commercially grow the GE crop may now be applied for. The process flow is shown in Figure 7. The BPI receives and reviews applications, posts the application in its website for public comments, and forwards the application for review by the Scientific and Technical Review Panel (STRP[10]) composed of non-DA scientist-experts, DENR-Biosafety Committee (DENR-BC), DOH-Biosafety Committee (DOH-BC), Fertilizer and Pesticide Authority (FPA) (if Pesticide-in-Plant or PIP), BPI-Plant Product Safety Services Division (BPI-PPSSD) and Bureau of Animal Industry (BAI). The GE developer summarizes public comments received while the BPI consolidates the evaluations done by the STRP, DENR-BC and DOH-BC. Consolidated evaluations are sent to the DA-BC for further review and if satisfactory, is endorsed to the BPI Director for approval. Once final approval is given,

[10] STRP is composed of a pool of non-DA scientists with expertise in the evaluation of the potential risks of regulated articles to the environment and human health. The number of experts and fields of expertise needed for the STRP review of the application shall be determined by the BPI based on the nature of the regulated article, the details and scope of the field trial, the availability of expertise in the pool and whether or not the regulated article is intended for commercial propagation or direct use. Each member shall submit an independent report to the BPI. (Section 7, JDC 1, s. 2016)

a biosafety permit for commercial propagation is issued to the GE developer. The whole process is estimated to take 85 days if there were no deficiencies in the applications and no setbacks. The next ***optional*** steps after successfully passing the regulatory requirements are varietal registration with NSIC and seed multiplication/certification with BPI.

Direct Use. In compliance to the Cartagena Protocol on Biosafety and the Codex Alimentarius, the NCBP requires all GE crops to be exported to the country for food, feed and processing uses to apply for Direct Use. The process as illustrated in Figure 8 appears exactly the same as the application for commercial propagation except for the FPA as part of the NGAs if the GE crop is PIP (Plant Incorporated Protection). In addition, FFP application does not require documentation of the multi-location field trial results.

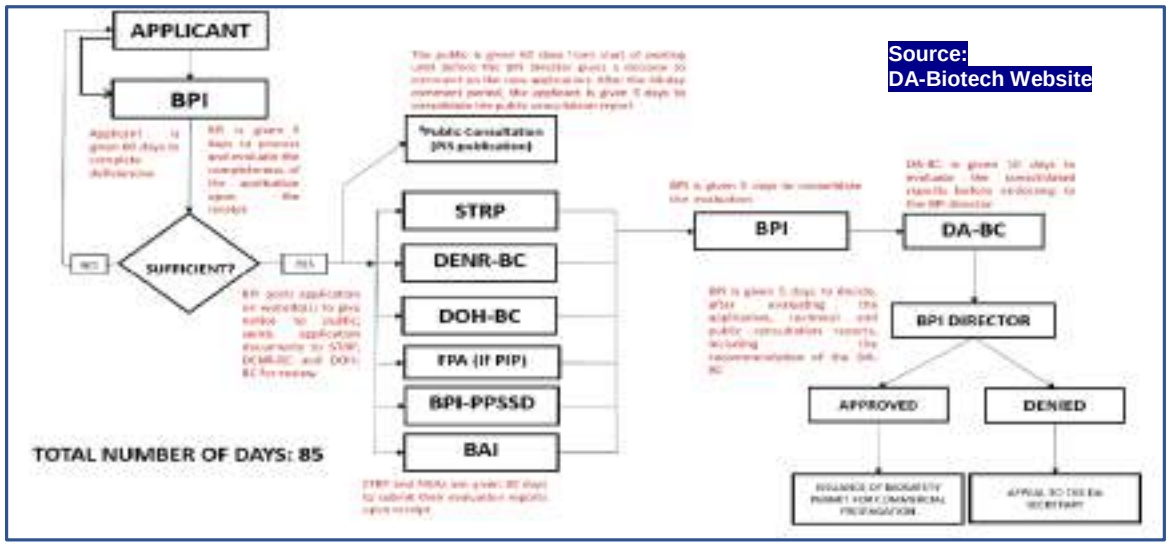

Figure 7. Process flow for Commercial Propagation application under the JDC-1 (2016).

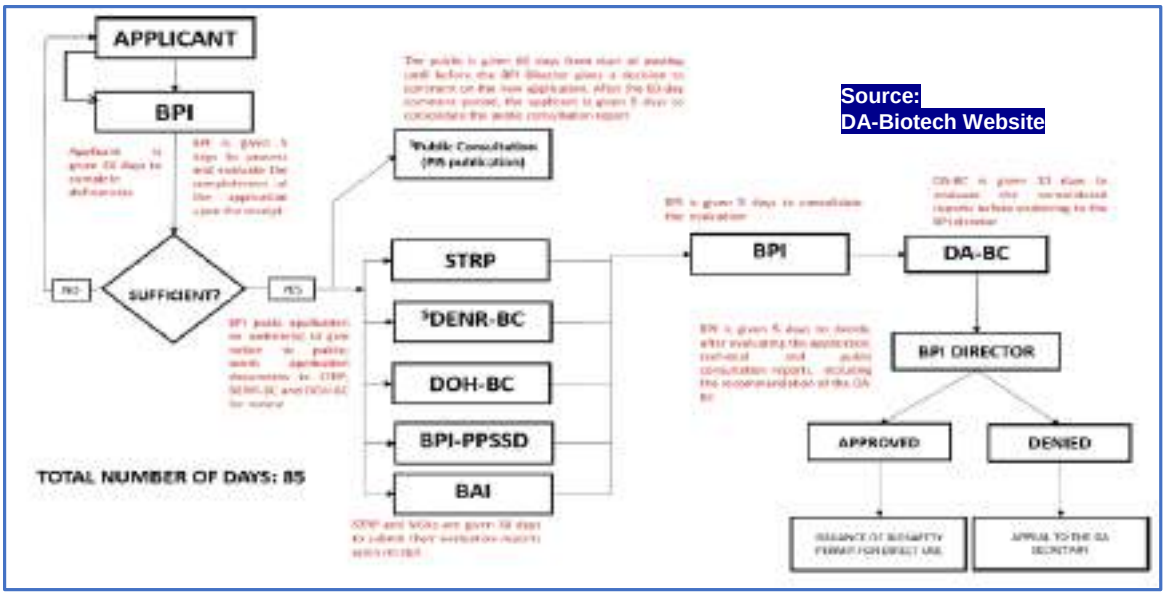

Figure 8. Process flow for Direct Use (FFP) application under JDC-1 (2016).

II.3 Role of Policy

The 2009 National Policy Statement on Modern Biotechnology President states that, "<the government> shall promote the safe and responsible use of modern biotechnology and its products as one of the several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment, and industry development." We find that the government has always been pro-science and considers modern biotechnology as one of its priority research areas and an agricultural development strategy. The Department of Science and Technology (DOST), in drawing a roadmap for a Harmonized National Research and Development Agenda for the years 2017-2018, declares that "the AANR sector supports the use of advanced and emerging technologies such as biotechnology, genomics, bioinformatics … as R&D tools to find S&T solutions to AANR problems or develop new products with significant potential impact to the sector." Indeed, advances in crop biotechnology, such as marker-assisted breeding, genomics, genetic engineering and genetic editing, can overcome the limitations of conventional methods to breed crops with the desired traits in a short period of time. Crop biotechnology can provide tremendous benefits to farmers, consumers and the country at large. It can address the challenges of productivity (close in the yield gaps and tolerate unfavorable environments)[11], health, food security, and poverty in an era of heightened concerns over environmental protection and climate change resiliencies.

[11] It is conceivable to think of a crop variety that possesses most if not all the following desired traits: pest resistance, abiotic tolerance (climate-change resilient), high yielding, biofortified with vitamins or minerals lacking in a poor people's diet, and less-fertilizer requiring.

Innovations in modern biotechnology was promoted in a “business as usual” mode in the early years of biotech research with the scientists taking upon itself the (public, ethical and social) responsibility of ensuring safety to humans and the environment. At the turn of the decade, public concerns that are grounded on fears compelled our policy makers to expand the decision making process to include public consultations in the formulation and implementation of regulations. These regulations are, nevertheless, still science-based and in compliance with the Cartagena Protocol on Biosafety of the Convention of Biological Diversity. It is still through science that our policies intend to erase public fears and resistance to modern biotechnology.

The basic roles of biotechnology policy are (1) to encourage innovation through research and development, (2) to ensure the safety of human health and the environment, and (3) to facilitate the commercialization of biotech products. Currently, biosafety regulations under the Joint Departmental Circular No.1 S.2016 are implemented by several departments; these departments conduct the risk assessments in the aspects of regulation that fall under their mandates[12].

II.3.1 History

It can be noted that over time, being a small and developing country, the national biotechnology program and regulatory policies can be affected by global events, directly or indirectly, particularly by the science, issues, and regulatory measures of the rest of the world, specifically, those of the big countries in Asia, Europe and North America. This suggests that the national innovation system is influenced by the global system. Below is presented a chronological account of the evolution of the country’s biotechnology-related policies along with relevant experiences and events in other countries as well. Those of other countries are presented in italics.

1973
In California-USA, Cohen et al. (1973) developed a method to shear a gene from one organism and to insert it into another. The method enabled them to genetically engineer the first organism, i.e., transfer of gene that encodes antibiotic resistance from one strain of E. coli to another. This begins the era of Modern Biotechnology.

1974-75
The media, government officials, and scientists began to worry about the risks genetically engineered organisms may impose to humans and the environment. A moratorium on GE projects was observed in 1974 while awaiting for a multi-stakeholder meeting to discuss such risks. In the Asilomar Conference of 1975 held in California-USA, various stakeholders deliberated on ways to address the said risks. The very first biosafety guidelines were put forward that allowed GE projects to continue. Three resolutions came out of the conference, namely: (1) safety containment

[12] The foregoing is heavily lifted from the homepage of the DA Biotechnology website http://biotech.da.gov.ph/.

regulations; (2) safety responsibility rests on the principal investigator; and (3) fluidity of the guidelines with the further advances in science (Rangel, 2015)

1980

As advances in biotechnology especially in genetic engineering along with safety guidelines are achieved in the USA, the Philippines quickly jumped in the bandwagon (so to speak). At the very outset, the government has demonstrated support for the science of biotechnology. President FE Marcos issued the Letter of Instruction No.1005 s.1980 granting PHP10 Million to the University of the Philippines at Los Baños (UPLB) that created and mandated the Institute of Biotechnology (UPLB-BIOTECH) to take on the leadership in agricultural, forestry, industrial, and environmental biotechnology. Given the chronology of policies and global events governing modern biotechnology below, we see that the promotion of innovation came first before there were regulations.

1987

Recognizing the potential harm of the introduction of exotic species and genetic engineering, the joint Ad-hoc committee on biosafety from UPLB, the International Rice Research Institute (IRRI) and Department of Agriculture (DA) used as reference the biosafety guidelines of Australia, United States, and Japan to formulate one that's applicable to the scientists' research and development work in genetic manipulation (GM) and the ultimate use or cultivation in the case of GM crops. A draft of a Philippine biosafety policy was submitted to the Office of the President. Several rounds of consultations with the private and public sectors, scrutinizing the guidelines, followed. (DOST, 1991).

Meanwhile, the first GMO crop in the US underwent a 5-year long health and environment field testing: Flavr Savr tomato variety developed by private company, Calgene, Inc. It contains a DNA sequence that increases the firmness and extends the shelf life of tomatoes (Rangel, 2015). Approval by the USDA for Flavr Savr was granted in 1992.

1990

On October 15, 1990, cognizant of the potential of modern biotechnology to improve the lives of the people and to create hazards if not handled properly, President Corazon C. Aquino signed Executive Order (EO) 430 that created the National Committee on Biosafety of the Philippines (NCBP). The mandates of NCBP are to formulate, review and amend national policy on biosafety and formulate guidelines on the conduct of activities on genetic engineering. The NCBP is comprised of representative of the Departments of Agriculture (DA); Environment and Natural Resources (DENR); Health (DOH); and Science and Technology (DOST); 4 scientists in the fields of biology, environmental science, social science and physical science; and 2 respected members of the community (Mendoza et al., 2009).

The Philippines was the first member of the Association of Southeast Asian Nations (ASEAN) to initiate a biotechnology regulatory system with the issuance of EO 430. The country's biosafety regulatory system follows strict scientific standards and has become a model for member-countries of the ASEAN seeking to become producers of agricultural biotechnology crops (Gonzales, 2018).

1991

In 1991, NCBP formulated the Philippine Biosafety Guidelines to regulate the introduction, importation, movement, field release of potentially hazardous genetic materials. It specifies the required physical and biological containment and safety procedures. The PBG applies to all institutions engaged in genetic engineering work whether public, private, or international. The guidelines contain the national policies on biosafety, organizational structure of biosafety committees, procedures for evaluation of proposals with biosafety concerns, procedures and Guidelines on the introduction, movement and field release of regulated materials, and physico-chemical and biological containment and procedures.

1993

The Philippines signed a multilateral treaty under the Convention of Biological Diversity (CBD) in 1993. This internationally-binding treaty was finalized in Nairobi in May 1992 and opened for signature at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, Brazil on June 5, 1992. There are 193 parties that signed the agreement, including the Philippines. The treaty entered into force on December 29, 1993. The Conference of the Parties was formed to be the governing body of the convention.

The CBD is considered as a main international instrument for sustainable development regarding biodiversity using its three main goals: (1) conservation of biodiversity, (2) sustainable use of biodiversity, and (3) equitable sharing of the benefits arising from the use of genetic resources.

The convention recognizes the potential of modern biotechnology in meeting the global needs for agriculture and health care, facilitating the access to and transfer of technologies (including biotechnology) relevant to the attainment of the goals of the convention, while distributing the benefits derived from biotechnologies on a fair and equitable basis. On the other hand, the convention also emphasizes the need to protect the environment and human health from the possible threats of biotechnology and its products, which can be referred to as biosafety. Specifically, Article 8(g) seeks to regulate, manage or control the risks from biotechnology at a national level, while Article 19 paragraph 3 points out the need of a protocol for the safe transfer, handling and use of LMOs.

1995

On 2 February 1995, president Fidel Ramos issued Presidential Proclamation No. 526 constituting the various biotechnology institutes within the University of the Philippines System as the network

of the national institutes of biotechnology, and designating the said network as a National Center of Excellence in Molecular Biology and Biotechnology.

Three additional biotechnology institutes were established within the University of the Philippines (UP) System—UP Diliman, UP Manila and UP Visayas—that focus on industrial biotechnology, health biotechnology, and marine biotechnology respectively. In UPLB, more research institutes, other than BIOTECH, also engage in biotechnology research; these are the Institute of Plant Breeding, Institute of Biological Sciences, Institute of Animal Sciences, Institute of Food Science and Technology, and the College of Forestry and Natural Resources.

Beyond the UP system, the Department of Agriculture institutionalized agri-biotech centers, namely, the Philippine Rice Institute(PhilRice), Philippine Coconut Authority (PCA), Bureau of Plant Industry (BPI), the Bureau of Animal Industry (BAI), and the Industrial Technology and Development Institute (ITDI).

1995-1998

The United States Food and Drug Administration approved the first GE Corn—Bt Corn—in 1995. This was followed by a herbicide tolerant GE Corn in 1996. By 2019, GE Corn adoption is at 92% by area in the US. According to Hutchison et al. (2010), due to the introduction of Bt maize there has been an areawide suppression of European corn borer populations spilling over the benefits to non-Bt corn growers.

Bt Corn was also quickly adopted for commercial production in Canada and Argentina in the same period. The biotechnology policies in these two countries were as permissive as that in the US. (Paarlberg, 2000)

France (and essentially the EU) approved the commercialization of three Bt Corn varieties from the US in 1996 (Louet, 2000). However, the “green” parties are strong and where a “mad cow disease” crisis in 1996 sensitized the media to food safety issues, the GM crop revolution encountered strong social resistance (Paarlberg, 2000).

EU began imposing separate labeling requirements on GM foods in 1997. Further, EU blocked the registration of any new varieties of GM crops as a precautionary measure rather than based on scientific evidence that GM foods are no less safe than conventional foods. This had the effect of halting the import of GM-containing food products. (Paarlberg, 2000)

At the second meeting of the Conference of the Parties in 1995, an Ad Hoc Working Group was formed by the UN to draft a protocol specifically taking on transboundary movement of LMOs that may have adverse effects on biological diversity.

1997

The Agriculture Fisheries Modernization Act (AFMA) was signed into a law in December of 1997. The main objective of AFMA is to modernize agriculture, including infrastructure, facilities, and R&D. AFMA recognized biotechnology as a major strategy to increase agricultural productivity.

1998

The NCBP formulated the Guidelines on the Planned Release of Genetically Manipulated Organisms (GMOs) and Potentially Harmful Exotic Species (PHES) that establishes criteria for deliberate release of GMOs and PHES into the Philippine environment. It excludes from its coverage work performed under contained conditions; work done in the laboratories and greenhouses; product uses that are already being regulated by other departments; and other activities as the National Committee on Biosafety of the Philippines may in the future declare to be excluded.

The US Environmental Protection Agency (EPA) imposed structured refuge requirements on a piecemeal basis beginning with Cry9C field corn (Matten et al., 2012). The strategy was drawn from a collection of refuge strategies submitted by registrants as part of an agreement for voluntary refuge requirements between the years 1995 through 1998 and also based on a white paper (EPA, 1998) that endorsed a science-based “high dose/refuge strategy.” This means that GE corn possessing a high dose of Bt toxin was planted with a refuge of non Bt corn either in an adjacent block or around it. The purpose of refuge is to provide moths feeding on Bt maize to mate with moths feeding on non Bt and thereby slow the buildup of resistance. The U.S. government has imposed this strategy as part of its regulatory approval process where policing was left largely in the hands of biotech companies; the resulting compliance appeared to be very low (Just et al., 2006).

2000

Supplemental to CBD, the Philippines agreed (in principle) to adhere to the terms of the Cartagena Protocol on Biosafety. The Protocol was finalized and adopted in Montreal, Canada on January 29, 2000. It aims to "contribute to ensuring an adequate level of the safe transfer, handling and use of living modified organisms resulting from modem biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on transboundary movements."

2001

The Philippine government recognized the potential of modern biotechnology for crop production, agriculture modernization, and a sustainable environment. On July 16, 2001, President Gloria Macapagal-Arroyo issued the Policy Statement on Modern Biotechnology, reiterating the government policy on promoting the safe and responsible use of modern biotechnology.

2002

On April 3, 2002, Department of Agriculture Administrative Order No. 8, Series of 2002 was issued implementing the guidelines for the importation and release into the environment of Plants and Plant Products Derived from the Use of Modern Biotechnology.

The first Bt Corn DK 878 developed by Monsanto was approved for release and commercial production in 2002. Bt provides Corn the ability to self-protect from lepidopteran pests. Transformations for herbicide tolerance (HT) and stacked Bt and HT ensued. National adoption rate for GE corn is estimated at 46% in 2017 (ISAAA, 2018).

2003

Senate Resolution 92 ratifies the adoption of Cartagena Protocol on Biosafety (CBP) to the UN CBD. The Protocol provides an international regulatory framework regarding the safe transfer, handling and use of LMOs with potential adverse effects to the environment and human health, excluding pharmaceuticals for humans. This makes way for the environmentally sound application of biotechnology, maximizing its benefit while minimizing the risk.

To avoid the build-up of insect resistance for Bt Corn, the DA Memorandum Circular No.17 S.2003 was signed on 23 December 2003. Under this MC, science-based Structured Refuge strategy required seed companies to package seeds in the combination of 80% Bt and 20% Bt non-Bt, bag-in-a-bag when one or both of the conditions are breached: (1) adoption rate of 80% Bt corn in a cluster/production/area/system of contiguous 200 has or more or (2) a period of two years after the implementation of this strategy. The burden of compliance monitoring falls on the DA Integrated Resistance Management (IRM) team. DA shall collaborate with private companies in educating all stakeholders regarding the mechanics of the strategy (DA, 2003).

2004

Perhaps to address more effectively the public fears and resistance to GMO, there must be a platform for scientists to reach out to the public and promote the understanding of modern biotechnology, its uses and its contributions to agriculture, medicine, industry, and the environment. Thus, by virtue of Proclamation 1414 the Philippines celebrates the National Biotechnology Week every third week of November. The week-long event done annually is participated by different national government agencies, Non-Government Organizations (NGOs), State Colleges and Universities (SUCs), and private academic institutions.

2006

On March 17, 2006, President Gloria Macapagal-Arroyo issued Executive Order No.514 establishing the National Biosafety Framework (NBF), prescribing guidelines for its implementation, reorganizing the National Committee on Biosafety of the Philippines, and for other purposes. The NBF prescribes a more transparent, meaningful and participatory public consultation on the

conduct of field trials beyond the posting and publication of notices and information sheets, consultations with some residents and government officials, and submission of written comments. The objectives of the Framework are to strengthen the existing science-based determination of biosafety to ensure safe and responsible use of modern biotechnology for the benefit of the Philippines and its citizens; enhance the decision-making system on the application of products of modern biotechnology to make it more efficient, predictable, effective, balanced, culturally appropriate, ethical, transparent and participatory, and serve as Guidelines for implementing international obligations on biosafety.

2011

The Philippine Genome Center (PGC) under the UP Systems was launched in 2011. The center is heavily involved in genomics and bioinformatics research. Its mission is to provide a deeper understanding and promote the judicious application of advanced knowledge and emerging technologies in genomics and bioinformatics in health and medicine, agriculture, biodiversity, forensics and ethnicity, industry and the environment for the benefit of Filipinos and the rest of humanity. Its mandates are (1)implement and promote research program-driven agenda on identified priority areas of national need and of competitive advantage in order to achieve a leading position in the country, region, and in the world; (2)train future scientists, researchers and experts in genomics and bioinformatics of the country; (3)promote a link between academic research, government and private industries for the development of genome-based applications; and (4)provide access to state-of-the-art tools for genomic research and bioinformatics in order to strengthen the academic and research infrastructure of the country. (PGC homepage)

2013

On 17 May 2013, the Court of Appeals (CA) in the case of field testing of Bt Talong, ruled in favor of Greenpeace et al. and declared a "cease and desist" order to Bt Talong field trials and to restore and rehabilitate (the field trial sites).

2014

Upon the recommendation of the Insect Resistance Management Advisory Team (IRMAT) to the Bureau of Plant Industry (BPI), refuge requirement for ‘refuges’ in fields planted to Bt Corn was revised through DA Memorandum Circular (MC) No.2 S. 2014 entitled “Enhancing the Insect Resistance Management (IRM) Strategy for Bt Corn Targeting the Asian Corn Borer (ACB).” It also recognizes new knowledge and developments in crop biotechnology and biosafety, including new Bt products and modes of action with their pyramided or stacked traits, seed blends, and a better understanding of pest biology. The new directive requires the Bt corn technology developers and marketers to sell to farmers Bt corn seed and those of non-Bt hybrids for the refuge crop mixed together in one bag at a percentage ratio of 5:95 to 10:90, bag in a bag. (Rodriguez, 2014). This means a seed blend mixture of one kg of non-GM and 9 kg of GM corn.

2015

Following the Bt Talong Saga, ISAAA et al. lost in its appeal for the SC to reverse the CA 2013 decision. Further it nullified and voided the DA AO No.8 S.2002 and temporarily halted applications for contained use, field testing, propagation and commercialization, and importation of GMO until AO No. 8 is replaced with a new one and in accordance with the law. Private and public R&D suffered a setback as a result of the CA decision.

2016

In response to the nullification of DA AO8, the Technical Working Group composed of representatives from the Departments of Agriculture (DA), Science and Technology (DOST), Environment and Natural Resources (DENR), Health (DOH), and Interior and Local Government (DILG) drafted the Joint Department Circular No.1, Series of 2016 (JDC 2016) 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'. An arduous series of meetings and five public consultations were conducted until the JDC 2016 was finally approved and signed by the Secretaries of the abovementioned agencies on March 7, 2016; the same took effect on April 15, 2016. Under this Circular, the direct involvement of government agencies are as follow: the DOST to regulate applications for contained use and confined test of regulated articles; the DA to evaluate applications for field trial, commercial propagation and transboundary movement of regulated articles; the DENR to evaluate environmental risks and impacts of regulated articles; the DOH to evaluate of environmental health impacts of regulated articles; and the DILG to supervise public consultation during field trial.

Motion for Reconsideration by ISAAA vs Greenpeace regarding Bt Talong was finally granted on July 26, 2016. The original judgment is reversed.

President Obama made a strong commitment to address international food securities head on through its Global Hunger and Food Security Initiative. Supported by a house bill, the Global Food Security Act of 2009 under S.384, H.R. 3077, a salient feature of this act different from previous laws is the support of the United States to biotechnology research programs in developing countries (Hanrahan and Ho, 2009). This was ratified in 2016.

2018

PCAARRD undertook a project on developing a harmonization framework for the biosafety guidelines and research protocols for biosafety for the member-countries of the Association of Southeast Asian Nations (ASEAN). Harmonization is going to be an integral component in the operationalization of ASEAN Economic Community (AEC) Blueprint 2025. By this, member countries may realize lower regulatory cost, faster adoption of GM technologies, expanded ASEAN intra and rest-of-the-world trade in agricultural products, enhanced productivity of the feed grain-

livestock sectors, and cross-cultural integration of capacity building activities. However, a comprehensive review of the biosafety policies governing modern biotechnology reveals that member-countries differ with respect to the existence of a biosafety regulatory framework and assessment protocols and, thus, there are gaps. The study recommends several things to consider to further harmonization efforts (Gonzales et al., 2018).

A study team composed of researchers and lawyers was commissioned by the DA Biotechnology Program Office (DA BPO) to review the research and regulatory landscape for NBTs in the Philippines and in other countries. Recommendations as regards product-based regulation of NBTs were proposed.

2019

The first GE rice, Golden Rice 2E was approved for direct use in the Philippine in December 2019. This gives the country an edge to maintain the leadership in the region.

JDC-1 (2016) review. An Ad Hoc Technical Working Group (AH-TWG) was assembled at the behest of the competent national authorities to consider the feedback supplied by the developers and the regulators themselves as regards the performance of JDC-1. The TWG formed by the NCBP in May 2019 is composed of representatives from the national agencies, academe, national research system, and other stakeholders. The recommended reforms are to be finalized by late 2020 or early 2021.

2020

A bill proposing the "Modern Biotechnology Act" has been in the works at the House of Representatives since 2018 (17th Congress) under HB-7906 and HB-7705 under the sponsorship of Reps. S.S. Garin and G.M. Arroyo, respectively. Finally, filed under HB 3372 (18th Congress) in August 2019, it was reviewed and passed by the House Committee on Science and Technology in January 2020. As of this writing, the bill is being reviewed by the House Committees on Appropriations and Ways and Means after which it will be passed for the 2nd plenary reading.

As an offshoot of the DA-commissioned NBT study, the NCBP considered the recommendations and formed another TWG which crafted a 2020 NCBP Resolution on a product-based regulation of the Plant Breeding Innovation (PBI).

II.3.2 Biosafety policy changes

Four distinct periods of policy changes occurred from 1990 to date. Period I is from 1990-2002 under EO 430 (1990), Period II is from 2003-2015 under DA-AO8 (2002) and the Cartagena Protocol on Biosafety that focused on the international regulations for the transboundary movement of GMOs. The year of 2016 was a dark period where processing of applications for

contained/confined test, field trial, and commercialization were put on a stand-still because of the "cease and desist" order on DA-AO8 by the Supreme Court. Period III is from 2017 to date under JDC-1 (2016). The country is now at the threshold of a policy change, Period IV, with House Bill 3372 otherwise called the "Modern Biotechnology Act of 2018." Table 3 outlines the changes that occurred/occurring during these four periods.

Policy Periods I and II

The DOST Undersecretary for Research and Development was the NCBP Chair for the first period, while the DOST Secretary assumed the position in the second period. The NCBP assumed a regulatory role for both periods. It also led the implementation for the first period and covered the processing of applications for Contained Use (CU) and Confined Test (CT). The transition to the second period saw a change in the implementation of biosafety regulations: the formalization of DA-BPI functions, the DA to be the leading agency, and the DOST to process the applications for CU and CT (that used to be with NCBP). As a result, the DA-BPI approved applications for Field Trial (FT), Commercial Propagation (CP), and Direct Use for Food or Feed, or for Processing (DU-FFP). This institutionalization of activities to DA and DOST distributed the burden of funding the administrative expenses from the NCBP alone to the said departments.

Table 3. Four policy periods governing biosafety regulation in the Philippines.

Point of Difference	**Period I 1990-2002**	**Period II 2003-2015**	**Period III 2016-to date**	**Period IV Emerging Policy Change**
Legal	EO 430, National Committee on Biosafety of the Philippines (NCBP)	DA AO8 (2002); Cartagena Protocol; EO 514 (2006), National Biosafety Framework	JDC No.1 s.2016	HB 3372: BioAP (Biotechnology Authority of the Philippines)
Leadership	DOST Undersecretary for R&D	DOST Secretary	DOST Secretary	Executive Director appointed by the President
Regulatory Role	NCBP	NCBP	NCBP	BioAP
Source of Funds	DOST	Departmental Funds	Departmental Funds	Gen. Appropriation
Implementation	NCBP leads NCBP approves CU and CT	DA leads; DOST approves CU and CT; DA-BPI approves FT, CP, DU-FFP	DOST leads; DOST approves CU and CT; DA-BPI approves FT, CP, DU-FFP	BioAP
Reference Guidelines	Biosafety Guidelines for Small-Scale Lab. Work (NCBP S.1), Large-Scale Contained Work & Glasshouse Trials (NCBP S.2); and Planned Release of GMOs and PHEs (NCBP S.3).	National Biosafety Framework (2004)	Biosafety Guidelines for Contained Use Revised Edition (2014) DA-Biotech Flowchart (Manual of Operations?)	To be revised and updated by BioAP
Scope of regulation	Contained Use Confined Use Limited Field Test GMO and Potentially harmful exotic species (PHES)	Contained Use Confined Test Field Test Commercial Propagation Direct Use	Contained Use | (Cert. of Confined Test | Completion) Field Test | (Bio- Comm. Prop. | Safety Direct Use | Permit)	
Permit Issued	Import GMOs Limited Release into the environment	Import GMOs Limited & General Release into the environment	Import GMOs Certificate of Completion Biosafety Permit	
Other Provisions				"Centralized" biotechnology program; Support development of scientific human resource, facilities; Sustained funding for Biotech prog for Agric and regulation; Render illegal vandalism of field experiments and field trials; Exemptions from gov. procurement system and donors funds' tax.

The NCBP authored the first three guidelines for biosafety regulation: 1) NCBP Series No.1—The 1991 Biosafety Guidelines for Small-scale Laboratory Work, 2) NCBP Series No. 2—Biosafety Guidelines for Large-Scale Contained Work and Glasshouse Trials, and 3) NCBP Series No. 3—The 1998 Biosafety Guidelines for Planned Release of GMOs and PHEs. After the implementation of the DA AO8 in 2002, the National Biosafety Framework replaced the NCBP reference guidelines.

The Biosafety Guidelines for Planned Release by the NCBP required the applicant to submit a project proposal containing information on the article to be regulated with supporting data and relevant scientific literature appended in the proposal. A rational risk-benefit analysis is also submitted, where the potential risks are identified along with the corresponding mitigation measures implemented. In addition, a Public Information Sheet (PIS) for public notification is posted in the location of the test site or in the affected areas of the proposed release. If the proposed release has potential significant risks as judged by the IBC, a public hearing is conducted after the last day of the publication of PIS.

Upon the implementation of the Cartagena Protocol and the shift to AO8, changes in the application processes were made. The literature supporting the application is now separated from the project proposal, referred to as a technical dossier. The risk-benefit analysis is replaced by the Risk Assessment procedure stated in the Cartagena Protocol. A sequential order of contained use, followed by field trials then commercial propagation is followed, and certificates of completion of the previous phase is required for the next phase application.

In the first period, the application processes consisted of Contained Use, Confined Use, Limited Field Test, and Planned Release to Environment of GMOs and PHES. Upon the implementation of AO8, application processes were modified to Contained Use, Confined Test, Field Test, Commercial Propagation, and Direct Use for Food, Feed, & Processing. Only two types of permits were released in the first period—(1) the Importation of GMOs and (2) the Limited release into the environment. The implementation of the AO8 added a new type of permit, which is the General Release to the Environment (equivalent to commercial propagation).

Policy Period III

In a way, there were only a few technical changes made from AO8 to JDC but the big change is in the process flow in that the developers now have to deal *individually* with five national agencies. The NCBP Chair, the leading regulatory agency and the source of funds were retained. DOST replaced DA as the lead implementing agency. With the JDC still following the NBF, the NCBP released a Biosafety Guidelines for Contained Use while some revisions for the process application occurred. Separate permits for each application are now issued which are used for compliance to the next phase.

After the SC ruling in 2015, AO8 is now replaced by JDC-1 (2016). A Risk Assessment Report as a requirement in the filing of application is now explicitly stated in the new legislation. The public hearing, which was required only when a potential risk was identified under the IBC, is now mandatory for field trial application. The applicant is also to provide potential socio-economic, ethical and cultural impact of the activity, as well as proof of payment of fees.

Policy Period IV

JDC-1 (2016) offered a quick fix to replace the defunct AO8 as the aftermath of the Bt Eggplant saga. The new regulatory system can be said to be effective in ensuring safety to human health and the environment as evidenced by historical data, however, it did not fare well with respect to efficiency. The processing target of 85 days for direct use as food, feed or for processing turned out to be a number of months and not days—taking up to 65 months to complete the regulatory process in extreme cases.

There are three concurrent initiatives being undertaken to expedite the processing of biosafety applications and the development of biotech crops. Two technical working groups (TWGs) were created by the NCBP—one was to review and recommend reforms to the JDC-1 and another to recommend science-based regulation of the products of plant breeding innovations (PBI). The third initiative is House Bill 3372 that proposes to create the Biotechnology Authority of the Philippines. These will all be taken up in greater detail in the succeeding sections.

III METHODOLOGY

To answer the four objectives and the project being a review, the study relied first and heavily on an extensive and intensive review of related literature. The information collected from the literature were validated, assessed or evaluated using four data collection methods (Table 4). Adjustments and protocols were crafted to execute the data collection activities electronically and virtually since the activities fell during the time that the country was basically on a lockdown or quarantine period in light of the COVID 19 pandemic. Each of these methods is discussed in detail in the succeeding subsections.

Table 4. Data collection methods for each of the study objectives.

Objectives	Literature Review	Virtual Focus Group Discussion	Key Informant Interview	Policy Delphi Survey	Roundtable Discussion cum Workshop
1.Synthesize data/information on domestic and international policies related to crop biotechnology					
2. Assess the competitiveness (effectiveness and efficiency) of the country's biotechnology policy in contributing to food security and agriculture development					

3. Identify innovative policy approaches and other effective policy initiatives	□	□	□	□
4.Formulate policy recommendations for action and advocacy	□	□	□	□

III.1 Policy to Impact Framework

A national crop biotechnology policy has two seemingly independent parts to make it whole: a policy that promotes the development and utilization of crop biotechnology and another that regulates the same. Without one or the other, no biotech crop can be developed, commercialized, and consumed and no farmer or consumer can benefit from the technology. Thus, a policy intervention can be regulatory, developmental/promotional or both?

This study considers the eventual impacts of changes in biotechnology policy on food security and agriculture development to come in three stages. The general framework to be used is illustrated in Figure 9. This study examines (1) the proposed changes in the biosafety regulations and biotech R&D promotion; (2) ascertain the ex-ante consequences of those changes in the Biotechnology Innovation System or BIS; (3) assess the ex-ante outcomes of the products of innovation (i.e., transgenic and genome edited crops) on agricultural performance; and finally, evaluate the ex-ante impact on food security, climate change resiliency, and global competitiveness.

In the first stage, the changes in policy can have positive or negative consequences in the innovation system. For example, changes in the biosafety regulations, implementation procedures, and the dynamics of institutions involved can have an enabling or deterring effects on the innovation processes. A policy that promotes, on the other hand, would almost always stimulate or invigorate research and development activities or the innovation processes.

In the second stage, the products of innovation such as GM (transgenic) and genome edited crops are extended to reach farmer end users. With a strong support system for technology dissemination and IEC program for public awareness, these GE crops are eventually adopted and result in easily verifiable outcomes at the farm household level. These verifiable outcomes or indicators are improved productivity, lower costs/higher incomes, improved nutrition/health and thus, making farm households resilient to climate change.

In the third stage, extensive and sustained diffusion of GE technology may significantly contribute to long term macro impacts such as food security, agriculture development, and global competitiveness. There are many other programs at play in the national innovation system for which modern biotechnology is just but one. The degree of contribution shall depend on a stronger national crop biotechnology program that prioritize in developing products important to food security and climate change resiliency and an efficient and cost effective biosafety regulatory mechanism.

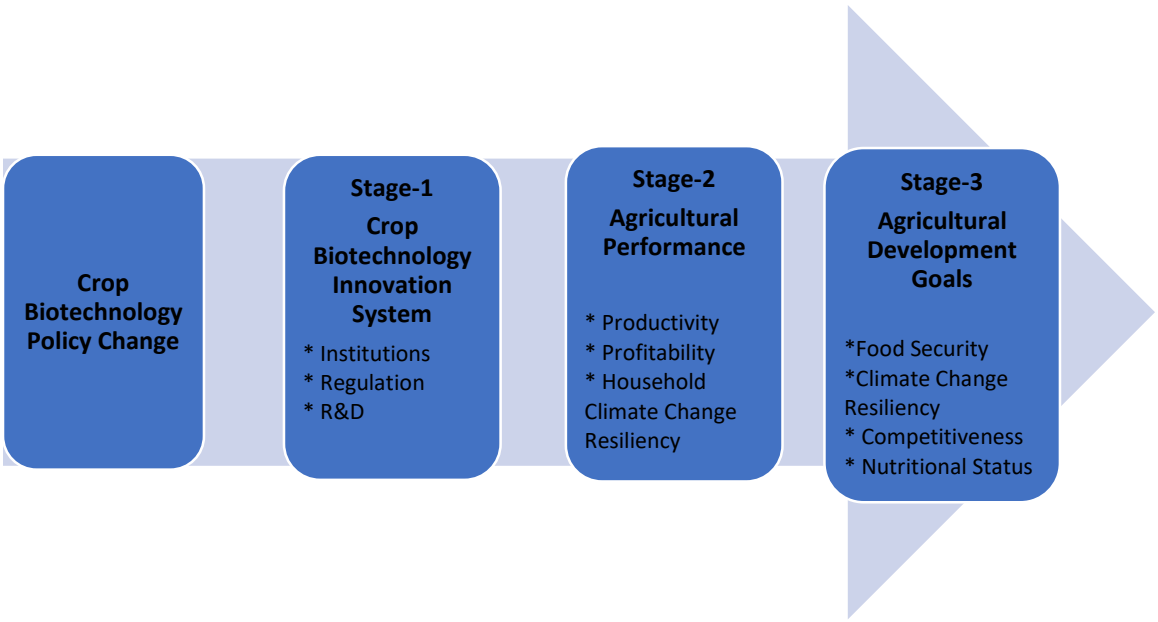

Figure 9. Three-stage Policy to Impact framework.

III.2 Measuring Impact on the Innovation System

This section looks at the first two stages in the above framework in order to answer study objective 2—competitiveness of the crop biotechnology policy. Policy competitiveness is defined as the relative ability or capability of a given policy proposition to achieve a given policy intent. The policy intents in this case are regulatory — referring to the safe handling and use of GMOs)— and developmental or promotional — promote the development and utilization of biotechnology crops.

An ex-ante assessment of the ability or capability of an emerging policy that has either or both intents can be undertaken within an input-to-impact evaluation framework. This implies that the desired policy is impact driven where the final outcomes of the policy intervention are farm level yield and income gains in the short-run and climate change resiliency, agriculture development and food security in the long-run.

For an economic unit to be competitive, it has to be able to sell at a much lower cost relative to its competitors. Lowering the costs of crop production can be achieved through a technological change that would either increase yield (higher production at the same input level) or reduce input use and unit cost at the same yield. Another way is through pecuniary gains associated with superior quality attributes of the crop or crop products. Through advances in biotechnology breeding methods and techniques it is possible to confer traits on crops that would result in higher yield, less input-requiring or add value to the crop through enhanced quality traits. It is ironic to find that the biosafety regulation that allowed big companies to develop and commercialize GM corn appeared to have

constrained the public research institutes to develop or commercialize their own biotech crops such as what happened to Bt eggplant, PRSV-resistant papaya, MVR tomato, and Bt rice.

As will be shown in the succeeding discussion, inefficiencies in the regulatory system and the lack of capital among developers to cover compliance costs and delays may have contributed significantly to the failure of publicly developed biotech crops to be commercialized. This must be a frustrating experience for the breeders in public biotech institutes/agencies including those in the international research centers that perhaps might have made them wish that their works did not have to be regulated. An otherwise strong motivation to find and discover genome editing tools that will enable breeding without involving or leaving a transgene in the crop. Scientists then and now are conscious about safety but, where regulation is not necessary, scientists will say so.

Innovation is a complex phenomenon involving the production, diffusion, and translation of technological knowledge into new products and processes (Samara et al., 2012). An innovation system is composed of science and technology institutions that individually, in partnerships or collectively contribute to the creation and diffusion of new technologies as influenced by economic and social factors and "within which governments form and implement policies to influence the innovation process" (Metcalfe, 1995). The influence of policies could either deter or enable discoveries and innovations.

Policies have direct impacts on the innovation system. For example, a national policy that aims to enhance industry competitiveness and food security can increase public expenditures in plant breeding research so that new plant varieties (technological products) can be developed and also invest in extension and development of seed systems, or subsidize seeds and fertilizers to hasten the technological uptake or diffusion. Regulation may and can have a curtailing effect on the research activities.

In this study, an *ex-ante* assessment of an emerging policy —the House Bill 3372 or "Modern Biotechnology Act" that creates the Biotechnology Authority of the Philippines— was elicited from experts in the field of crop biotech research and regulations using a Policy Delphi Survey. Details are discussed further below.

III.2.1 Crop Biotechnology Innovation System

This study adopts an innovation system (IS) approach as described by Dantas (2005) to analyze the impacts of a biotechnology and biosafety regulatory policy on the development and utilization of biotech crops. An innovation system is defined as a network of organizations within an economic system that are directly involved in the creation, diffusion and use of scientific and technological knowledge, as well as the organizations responsible for the coordination and support of these

processes. The interactions and relationships among the institutions are non-linear as there are loops, intersections and feedback. A caveat of this study is that it does not consider such nonlinearity and applies the IS approach as a multi-stage, linear biotechnology innovation system.

The organizations in the crop biotechnology innovation system illustrated in Figure 10 are: (1) the innovators or R&D organizations; (2) R&D funding institutions; (3) Policy Makers; (4) Policy Implementers; (5) Support Institutions; and (6) Technology Users and Impact Beneficiaries. The direction of consequences and impacts goes from Biosafety Policy having either a stimulating or deterring consequence on Innovation in crop biotechnology (first stage) and then the Innovation in crop biotechnology having a direct impact on production, cost savings, incomes, and eventually on food security and agriculture development. It should be noted that although the Innovators are the source of technology, there are other contributors for diffusion of GE technology to take place and once the full benefits are accounted for, only a fraction of it is attributable to the sources of Innovation.

Innovation: R&D Organizations and Funding. The systems consider science, technology and innovation as the main driver of agricultural or economic growth. The institutions engaged in crop biotechnology innovations are the private companies[13] which are normally motivated by profits, the government which is motivated by domestic market failure, and the international organizations which are motivated by global market failure and humanitarian goals. The DOST and the DA consider modern biotechnology, i.e. biotechnology, as one of the tools for breeding new seeds with traits not possible to achieve by conventional means. For crop biotechnology, the R&D organizations are UPLB-BIOTECH, UPLB-IPB, PhilRice, IRRI, Central Luzon State University (CLSU), Visayas State University (VSU), University of Southern Mindanao (USM), UP-Diliman, Philippine Coconut Authority (PCA), Philippine Sugar Research Institute (PHILSURIN), Sugar Regulatory Agency (SRA) and private (multinational) companies such as Monsanto and Syngenta among others. R&D funding sources are national appropriations, department budget, international donors, and various financial instruments.

Innovations aiming for inclusive growth would mean developing crop-trait combinations that are most important and most valuable to the poor farmers and poor consumers. The difference between the green revolution of the past and gene revolution of today is that international and public R&D spearheaded the green revolution whereas it is the private companies that are leading the gene revolution. Past R&D concentrated in the breeding of rice, wheat, and other crops that mattered most to the poor. And since the government crafted policies that were supportive of technology diffusion, the green revolution swiftly took off. Meanwhile, in the last 25 years or so of the

[13] The research and development of innovative biotech products is an expensive and uncertain process and private companies need substantial resources if they are to translate basic science into products (Bio, n.d.).

gene revolution, it has been the private multinational companies that have the capital, facilities, and expertise to develop GE crops. These GE crops, after successfully hitting the US market can be said to have spilled over to the developing countries such as the Philippines. In lieu of patents, these companies are given exclusive rights to sell seeds under the Philippine Plant Variety Protection Act of 2002 (RA 9168)[14]. Farmers who did not pay royalties for the green revolution seeds end up paying the developers a premium for the GE seeds. Studies proved the economic benefits of adopting GE crops (to be covered in later sections) in the early years of its diffusion but there is danger of losing such gains to the high cost of seeds. Diffusion of this technology was swift in the US but quite slow in the Philippines. But, at least, the country embraced gene revolution when other countries hesitated.

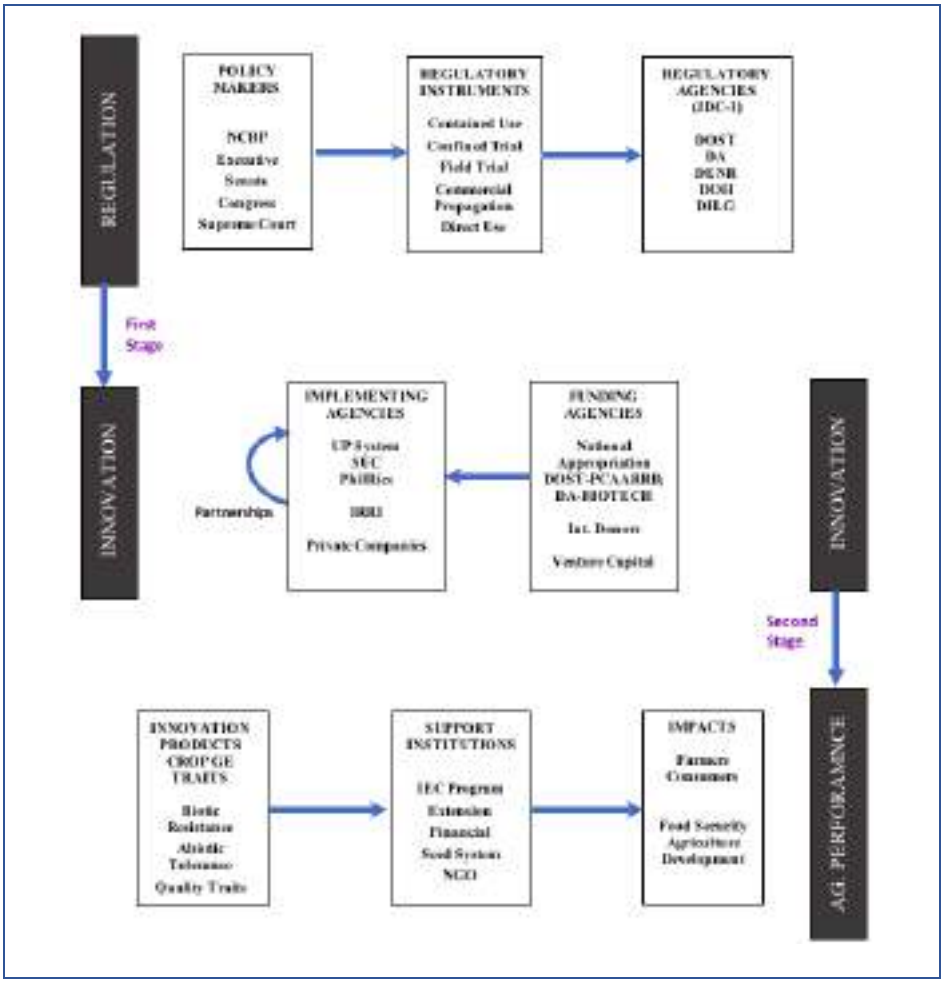

Figure 10. Biotechnology Innovation System and the two-stage

[14] The holders of a Certificate of Plant Variety Protection shall have the right to authorize any of the following acts: a) Production or reproduction; b) Conditioning for the purpose of propagation; c) Offering for sale; d) Selling or other marketing; e) Exporting; f) Importing; and g) Stocking.

However, the crops that matter most to the poor are not likely sufficiently profitable to attract private investments; another market failure. Thus, if GE crops have to be pro-poor then there should be increased funding and capacity for public R&D. As it was during the green revolution, once the traits are conferred on the crops (that mattered most to the poor) through public R&D and distributed through the national extension network then the technology embodied in the seed becomes a non-exclusive, non-rival public good. Non-exclusive means no one can be excluded to use the technology and non-rival means the use of one does not prohibit the use of another. And so the farmers would not have to pay a premium for the access to biotech crops.

Private and public R&D have distinct research priorities but they may also engage in partnerships. An example of partnerships is Syngenta (a private company) donating commercial rights on the Golden Rice to IRRI so the latter can confer the trait on old varieties preferred or popular in a country. In the Philippines, IRRI partnered with PhilRice. As a partner, PhilRice was to apply for biosafety permits and conduct field trials.

Meanwhile, the role of UP aside from engaging in R&D is in providing undergraduate and graduate education in biotechnology sciences, thus, building human capital and supplying scientists or experts to R&D centers.

Biosafety Policy: Policy makers, implementers and the regulatory instruments. From an economic perspective, the very root of this whole policy inquiry is the failure of the market to incorporate the risks (or uncertainties) associated with the use of genetically modified organisms in the pricing system. This boils down to an existence of a supply for GMO risks on the one hand and the non-existence of demand for the same on the other hand. Economists refer to the risks resulting from an otherwise legitimate activity (genetic engineering as a breeding tool) that affect the utility or satisfaction of others as externalities. In the case of GMO, such externalities (or the costs of risks) are internalized by way of government-instituted biosafety regulations where the cost of compliance is borne by the breeder or technology developer. To illustrate, when Bt Corn was first introduced in the once permissive US, non-target butterflies were adversely affected and one of these was an already endangered species—the Monarch butterflies. The cultivation of Bt Corn then, regarded as a legitimate activity, caused a disutility to the butterfly enthusiasts and environmental protection advocates by further endangering the existence of Monarch butterflies. Because there was no market for such an externality, the government intervened and regulation was the instrument of choice.

As discussed previously, all stages of R&D activities have to go through and satisfy the requirements of each regulatory instrument. The policy makers that determine the biosafety regulatory framework are the NCBP (created through EO 430, further strengthened by EO 514 and

chaired by the DOST Secretary), the executive office of the President (EO's), the legislative houses of Representatives and the Senate, and the Supreme Court in its adjudication capacity.

The NCBP, after decades of painstaking consultations with scientists and other stakeholders, have formulated the biosafety guidelines published in 1991, 1998, 2004 and 2014. As discussed in the previous section, there are five regulatory instruments under the current JDC-1 (s. 2016).

The first president to give recognition to modern biotechnology was President Marcos through Letter of Instruction 1005 in 1980 granting PHP 10 million to UPLB-BIOTECH. The executive branch of the government was targeted by the scientists in 1987 as the quickest way to have a committee on biosafety established. Eventually, EO 430 was signed by President Aquino in 1990; it created the NCBP with the principal mandate of formulating the biosafety guidelines and providing compliance oversight. About ten years later, President Arroyo issued a Policy Statement on Modern Biotechnology 2001 and then signed EO 514 in 2006.

The legislative branch—Senate and Congress—have the ability to write and amend the law pertaining to GMO. House Representative Sharon S. Garin has sponsored House Bill 3372 known as "Modern Biotechnology Act of 2018." The bill calls for the abolition of NCBP and be replaced by the to-be-created Biotechnology Authority of the Philippines (BioAP) as an agency under the DOST to promote safe and responsible use of biotechnology in the country. BioAP is to revise the current regulatory regime believing that that it is still "based on outdated knowledge and assumptions" that cause delays.

The judicial branch had a history of influence when the Court of Appeals nullified and voided DA AO8 in 2015. This was reversed by the Supreme Court in 2016.

Under the JDC-1, the DOST and DA spearhead the implementation of the biosafety guidelines. The other departmental agencies involved are the DOH, DENR, and the DILG. The roles of these agencies are already discussed in the previous section.

Support Institutions. For the diffusion of GE crops to occur, a reliable seed system should be in place to ensure a seed supply at the right quality and at affordable prices to farmers. In addition, the farmers would need technical, financial support, and may be a type of risk sharing at the early stage of diffusion. Farmers should be informed about the uniqueness of the crop—its nature, traits, and differing planting or crop care practices. Picking up a new genetically engineered variety, given all the publicized anti-GMO activities of the well-funded interest groups, is likely to be perceived as risky by the farmers. Subsidies and contract growing are one of the ways to share monetary risks. The support institutions for the diffusion of GE crops are the mass media, national extension system

network, seed system, NGOs, and financial support mechanism. Mass media can play the significant role of promoting the GM crops as safe for feeds and human consumption.

Finally, the ultimate recipients and beneficiaries of biotechnology innovations—the farmers and consumers. The widely diffused productivity-increasing, cost-reducing, nutrition-enhancing, and income-increasing GE crops will eventually contribute to food security and agriculture development.

III.2.2 The Policy Change Delphi Inquiry

Policy changes in the last decade

Biosafety regulations have changed and adjusted according to advances in science and changing circumstances over the years since it was first put in place 30 years ago. There were many defining moments such as the first GM and first anti-GMO experience—when the field trials for Bt corn was vandalized and scientists were compelled to explain the science of GM in laymen's terms to the public. But, the five-year battle between the developer of Bt Talong and various anti-biotech or anti-GMO groups was more defined than all others. Strong oppositions prematurely halted the field trial in UP Mindanao in December 2010, uprooted the plants in the field trial in UPLB and filed a "writ of kalikasan" with the Supreme Court (SC) which was turned over to the Court of Appeals (CA).[15] Expert witnesses provided testimonies and arguments during the seven-month hearing that ensued. What followed were a May 2013 decision by the CA in favor of the anti-GMO groups a December 2015 SC decision that supported the CA decision and even went further by nullifying the AO8 (the regulatory framework at the time) and suspending all regulatory applications until a new administrative order is crafted in accordance with the law. Thus, five national departments finalized a new regulatory framework, the Joint Departmental Circular No.1, series of 2016 (JDC-1) that took effect in April 2016 and replaced AO8. Bt Talong proponents filed a motion for consideration and finally the SC overturned its decision in July 2016.

The JDC-1 probably satisfied the Supreme Court's concept of a more transparent, participatory, comprehensive, and with strict adherence to high standards of risk assessment but for the applicants/developers, although JDC-1 allowed the resumption of applications, it is nevertheless inefficient and costly. Hence, an Ad Hoc Technical Working Group was created to review and reform the JDC-1. Further, just like any other regulatory system for crop biotechnology across the globe, amendments have to be made to adapt to the rapid advances in plant breeding science and biotechnology methods and tools.

[15] http://isaaablog.blogspot.com/2016/12/the-trial-of-bt-talong-field-trials.html

Almost concurrently, House Bill 3372 dubbed as the “Modern Biotechnology Act of 2018” was proposed and passed the first reading in January 2020. Under this Bill as discussed earlier, drastic changes are proposed and foremost is the abolition of NCBP and the creation of the Biotechnology Agency of the Philippines (BioAP). While the JDC-1 review and HB 3372 revision are proceeding almost simultaneously, a Policy Delphi survey was conducted to assess ex-ante the consequences of HB 3372 on innovations (inputs and processes) and agricultural performance (outcomes and impacts).

The Policy Delphi Survey (PDS)

Delphi is a method for structuring an effective non-face-to-face communication process to allow a group of individuals who are anonymous to one another to deal with a complex of problem using a multi-round survey where the individuals are first provided information on the problem and then asked to respond to a series of Likert-type of questions or statements. As a data collection method, it normally consists of three rounds of consultations to a heterogenous group of individuals. As a communication method, the researcher provides a mechanism for the participants to give their individualized opinions freely, share those opinions with everyone while maintaining anonymity and later on provide feedback . The feedback process is repeated in the succeeding rounds. It is possible to achieve or goal for a consensus in the final round. Individual consultations can be done through face-to-face interviews but recently, these are done conveniently carried out virtually or electronically.

Over time, the Delphi technique continues to evolve also. It comes in two types —Traditional and Policy Delphi. Traditional Delphi is a technique used to get a consensus about a technical topic from a panel of experts; an example are varietal adoption studies in rice (Tsusaka et al., 2015). Policy Delphi, according to Manley (2013) and Turoff (2002) does not aim for consensus (if ever, the consensus reached is rather unintended) but to generate the strongest possible opposing views and opinions on the consequences and impacts of a policy. Thus, it is important to invite experts from a wide variety of backgrounds with respect to current and previous engagements in crop biotechnology to participate in the study to acquire the strongest opposing views. Identifying those experts is the first crucial step. The second important step is preparing the PDS instrument which is composed of a well thought set of issues, questions and documents supporting the issues being addressed in the questionnaire. Thirdly, summarizing the varied opinions and views into clustered categories. Fourth, designing the questionnaire making sure that it is user-friendly. Finally, diligently following through with the experts to respond within the requested time.

Participants to the PDS

The aim of this study in the use of PDS is to generate the strongest possible opposing views in regards the strengths and weaknesses of the provisions in HB 3372 in order to achieve its functions and objectives through the agency it proposes to create—the Biotechnology Authority of the

Philippines or BioAP. The anticipated consequences of BioAP on the regulatory processes and on the promotion of R&D or development of biotech crops and the anticipated eventual impacts on the adoption of new genetically engineered varieties, incomes, food security, household climate change resiliency and the like were evaluated *ex-ante* by eliciting the comments and opinions from experts engaged or had previous engagements in crop biotechnology research, biosafety committee, regulation, or activities aimed at creating public awareness regarding the safety and benefits of biotech crops. To get the strongest possible opposing views, anti-GM or anti-biotech leaders were invited to participate but such invites were turned down. Representatives from the five regulatory departments—DOST, DA, DENR, DILG, and DOH—were sought and the study succeeded except for representation from DOH. The profile of the 26 experts who participated in the Policy Delphi Survey are shown in Table 5. Overall , the study was able to acquire a good representation from various groups of stakeholders.

Table 5. Affiliations and involvements of the 26 expert-respondents in crop biotechnology, Policy Delphi Survey, 2020.

Most recent affiliation		**Organization type**		**Biosafety regulation involvement***	
National Agency	42%	Private	58%	DOST-NCBP-BC	31%
Academic	23%	Public	8%	DA	27%
Int. Ag. Res. Center	15%	International	8%	DENR	15%
NGO	15%	Any combination	27%	IBC	8%
Private	4%			DILG	4%
				DOH	0%
				None	38%
GMO-orientation		**NGO involvement**			
Pro-GMO	81%	National	15%		
Anti-GMO	0%	International	15%		
Neutral	19%	Both	5%		
		None	65%		

*23% of the experts had more than one biosafety regulation involvement in their career.

PDS Instruments

The experts received a questionnaire, a set of documents that provide background information on the issues pertained in the questionnaire and a cover letter explaining the purpose and mechanics of the survey and requested return date for completed questionnaire.

Issues Addressed and background materials provided

1. *Ex-ante* evaluation or assessment of BioAP. The experts were requested to first examine the provisions under HB 3372 which describe the features and functions of BioAP before providing qualified answers to a Likert-scaled series of questions:

Relative to the current regulatory system (under JDC-1) can BioAP lead or contribute, directly or indirectly, to a list of positive results under four sections

a) Direct consequences of BioAP on the promotion of R&D across sectors and on the efficient processing of biosafety regulatory applications,
b) Generation of a variety of biotech crop-trait outputs,
c) Reduction in the input cost and increased farm income outcomes, and
d) Eventual impacts on food security, climate-change resiliency, environmental, and nutrition.

Two documents were provided in support of BioAP *ex-ante* assessment—the published version of the HB 3372 (dated August 10, 2019) and the Cartagena protocol on biosafety.

2. Prevalence of counterfeit GM corn seeds. A literature search on GM corn returned reports of counterfeiting in the two major GM corn regions—II and X. Two old and apparently obsolete seed laws were described that could have provided legal remedies. Respondents were asked to comment on the problem and suggest solutions.

3. Downward trend in the GM corn area between years 2013-2018. This appeared in a report by APAARI (2019) and was presented to the experts so they can comment on the possible causes for the trend and suggest solutions to reverse it. A brief on the corn industry profile was provided in support of these last two issues.

4. Food security. As part of the national goal and to which technological solutions are usually the first option a country explores, respondents were presented the trend in cereal area and production vis a vis the growth in population and then asked to assess how crop biotechnology may contribute to food security.

5. *Ex-ante* estimation of Bt eggplant adoption. This is obviously not an issue but was added to the questionnaire—a direct elicitation of the adoption rates to compliment the costs and income data collected via virtual Focus Group Discussion (vFGD) which will be discussed in the next section. A brief on the eggplant industry profile was provided in support of this adoption estimation.

6. *Probing questions on Liability and Redress.* Realizing the need to assess the country's position with respect to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (NKLSP), questions regarding the merits and a possible argument for ratifying the protocol or otherwise were added to the questionnaire for the second round.

PDS Questionnaire.

Two sets of questionnaires were prepared, one each for the two rounds. A *common* questionnaire is deployed in the 1st round and *customized* questionnaires in the 2nd round. The issues being

addressed are the same, the only difference is that in the second round, summarized responses and the respondent's response from the first round are presented feedback and an opportunity to revise 1st round answers in the 2nd round. In this study, the 1st round questionnaire was in digital format—Google Forms—and MS Word while the 2nd round questionnaire was in Excel format. These PDS instruments are in Appendix A and B.

Two Delphi Rounds
In the interest of time only two rounds instead of three were done.

Round-1:
The questionnaire was prepared in digital format as Google Forms (a free online survey tool)—and the supporting documents in PDF[16]. The link to the google form was emailed to 36 expert-invitees. Response to the survey was monitored and in the event that the participants had trouble with unstable internet connection or difficulty responding online, the Word version of the questionnaire to input their answers with the supporting documents were emailed. Of the 36 expert-invitees, 14 successfully completed the survey online, 12 completed the survey in Word, and ten dropped out. Round 1 ran through the entire month of May 2020.

Round-2:
Data from Round-1 were immediately encoded and summarized. Customized questionnaires for Round-2 included the summarized results, Round-1 response and probing questions that are unique to the respondents. Making twenty-six unique questionnaires was made possible by using formulas and links in Excel. The Excel-formatted questionnaire was emailed to the 26 respondents three weeks after the completion of the 1st round. Round-2 ran from June 23 through July 8, 2020.

Analysis:
The responses were sorted, grouped and summarized. Simple summary statistics such as averages and percentages based on frequency counts were employed to support the narrative.

III.2.3 Key Informant Interviews

Key Informant Interviews were conducted with UPLB researchers involved in NBTs to elicit comments and suggestions on the relevant issues and initiatives surrounding the regulation of NBTs in the Philippines. Two sets of interviews were done. The first one was done through email, where the document file of the discussion material and the set of questions (Appendix C) was sent to the key informant for answering. The second one was held in a virtual platform through Zoom, where the project team leaders and members were also in attendance.

[16] https://docs.google.com/forms/d/e/1FAIpQLSfhx7kXL-bM6veXaQwwGvENyXyUueOadSp-uVWL67FAmW473g/viewform?usp=sf_link

III.2.4 Crop Biotechnology Policy Round Table Discussion and Workshop

Drawing from the results of the two-round PDS and KIIs, three major policy issues besetting the crop biotechnology R&D and regulation were identified and background materials were prepared for an RTD cum workshop. The objective of the discussion was to elicit feedback and opinions regarding the problems and issues and recommendations for policy reforms from the top experts in the field of biotechnology. These experts are recognized for their scientific achievements, historical knowledge and direct involvements in the science and regulation of biotech crops in the country. Eleven experts participated in the RTD and three of them were selected to steer the discussion on three issues: 1) Counterfeiting of GM corn seeds, 2) Regulation of NBT products, and 3) The BioAP under HB 3372 (Appendix D).

III.2.5 Impact on the Agricultural Performance

The duration of this study precludes a thorough impact evaluation, randomized control trials, or farm survey data collection. But just to provide an approximation and rapid assessment, quantitative and qualitative data were collected through focus group discussions (FGD). The study considers FGD as the best method given the time and budget constraints. In an FGD, farmers are selectively chosen for their knowledge about the resources, practices and problems in their respective villages. These farmers are then gathered together to discuss specific topics of interest using guide questions by the moderator or facilitator. FGD is most ideal for qualitative data but in this study, quantitative data on production, farm area, input use and prices, and varietal adoption were likewise collected.

With the COVID-19 pandemic and the “new normal”, however, another adjustment to FGD needed to be made. Under the new normal, aside from wearing masks and social distancing, crossing municipal, provincial, and regional boundaries are restricted. Farmer assemblies for the purposes of agricultural training, educational activities or other related events are limited to 10 or 15 people. To overcome travel bans, the FGDs turned virtual which involved modifying some of the FGD protocols which underscored the role of the local agriculture offices in the gathering together of farmers and serving as co-facilitator.

Virtual FGD Protocols:

1. Establish contacts with the municipal/city agriculture offices, create contact databases, provide a brief about the project and FGD objectives, and logistic requirements. As necessary, send out a formal letter of requests to conduct the vFGD to the Governor, Provincial Agriculturist, and Municipal/City Agriculturist.
2. Logistic support from the agriculture office—spacious and quiet room that can accommodate the six farmers, the agriculture and office coordinator(s) while remaining compliant with social

distancing; stable and strong internet connection; and a laptop or desktop with at least one of the following communication apps installed—Zoom, Google Meet, or FB Messenger.

3. Logistic support from PCAARRD—transportation allowance to ferry the farmers from their residences and return, meals allowance, courier allowance, and small token for the participants and the co-facilitator.
4. Three virtual meetings. The 1st meeting is a pre-vFGD activity with the corn or eggplant coordinator wherein the terms-of-reference, logistics, farmer selection, and mechanics of the FGD are discussed. The 2nd meeting is the actual vFGD. The 3rd meeting is verification of results and addressing data gaps.
5. Technical support from PCAARRD—copy of FGD guidelines, visual aids and props (manila papers, meta cards, and markers) to be used during the FGD, and a short training on the conduct of FGD. Filled out visuals are shipped back to PCAARRD.

III.2.6 Field validation of farm benefits from GM corn adoption

Two old surveys were done in 2004 and 2010 to measure the farm benefit advantage of GM corn adoption by Yorobe and Quicoy (2006) and Afidchao (2014), respectively. Another survey that touched on counterfeit GM corn in Bukidnon was done in 2018. This study purports to validate if the benefits reported in the early years of GM corn still hold to this day and also investigate the farm benefits from counterfeit seeds.

In terms of GM corn area, the top ranking province in the two top regions were selected for the FGD and these are Isabela in Region II and Bukidnon in Region X. The Provincial Agriculturists were consulted to decide on the three municipalities/cities that could comply with the vFGD protocols and where there are yellow corn areas planted to GM, Hybrid, OPV, or counterfeit seeds. At the municipal/city level, the Municipal/City Agriculturists were consulted to decide on three villages in their domain that could satisfy the same criteria. Formal letters of requests were sent as requested. For the corn vFGD, one out of the six villages was dropped due to peace and order situation (Cabanglasan, Bukidnon).

The guidelines used in the actual virtual FGD is in Appendix E. The technical inquiry has three parts—varietal adoption, management and cultural practices, production and disposal, and production problems. The discussion was facilitated by the project team with the assistance of the staff at the local agriculture office. The meetings in each of the study sites lasted for no less than four hours with a 30-minute break but often taking longer because of intermittent internet connection. There were at least a couple of cases wherein cellphone calls were used while waiting for internet connection to return.

III.2.7 Ex-ante estimates of farm level benefits from Bt eggplant

A review of literature revealed the popularity of hybrid eggplant in the country. Because the Bt eggplant developed in 2010 was an inbred or open pollinated variety, its potential yield was not as high as the regular (non-Bt) hybrid eggplants. Introducing Bt eggplant will be challenged by the yield and income superiority of hybrid eggplant varieties although the insecticide costs may be high. Compared to the regular (non-GM) inbred varieties, Bt eggplant is expected to have a higher percentage of marketable yield and lower cost of insecticides. If Bt is going to be deployed, what would be the strategic places where it can be initially introduced for maximum adoption and greatest impact? This is the motivation behind this section.

The regions and then the provinces with the largest area planted to eggplant were selected for this study and these are: Pangasinan (Reg. I), Nueva Ecija (Reg. III), and Isabela (Reg. II). Data from the Philippine Statistics Authority (PSA) show that in 2018, the three provinces comprised 18.05% (3,907 ha), 7.84% (1696.50 ha), and 4.68% (1,014 ha) of the national area planted to eggplant, respectively. This was then narrowed down to eight sites based on the agricultural offices' capability to provide the logistic requirements for a virtual FGD: Cabanatuan City and the Municipalities of Aliaga and Talavera for Nueva Ecija, the cities of Ilagan and Santiago, as well as the Municipality of Roxas in Isabela, and the municipalities of Asingan and Villasis in Pangasinan. Similar to the process for GM corn, the study sought the help of Provincial Agriculturists in choosing three municipalities/cities with eggplant production. Unfortunately, in Pangasinan, one chosen municipality requested to opt out of the study due to limited internet connection in the area (Manaoag, Pangasinan).

The guidelines used in the conduct of virtual FGD is in Appendix F. Similar to the corn experience, the meetings took at least four hours to complete with a 30-minute break. Connectivity problems were experienced in all of the study sites.

IV RESULTS AND DISCUSSION

IV.1 Field Validation of the Farm Level Impacts of GM Technologies

To measure agricultural performance, this study collected and analyzed data to measure the farm benefits from GM crops. Varietal adoption is, generally, a decision farmers make based on at least two indicators—productivity gain and increased net incomes. GM crops are special because unlike conventional crops, there is a chance that the public may perceive GM to be unsafe despite the overwhelming evidence saying otherwise. That is why, a strong information, education, and communication program is crucial for GM crops to reach the farm and the dining table. Once such

public fears are overcome, farmers will adopt the new varieties according to the benefits from such decisions.

In the Philippines, keeping farm records is rather rare but farmers have their own way of determining which varieties, inputs or production practices make economic sense. Although they can be swayed to remember the volume of harvest, prices received, prices paid, seed rates, insecticides applications, and other farm expense items they do not seem to be mindful enough to record such let alone compute for rates of return. However, in order to make an argument for the economic rationale behind switching from an old to a new technology, from an old to a new variety, from non-GM to GM, such data should be collected, recorded, and processed into per hectare or per kg costs, returns or their ratios.

Two GM crops considered in this study are the first and only GM crop commercialized in the Philippines—GM corn—and the first GM crop for human consumption—Bt Eggplant. Since GM corn has been in the farmers' fields for more than 15 years now, this study did a field validation of farm benefits by comparing the current performance of GM corn fields versus the literature estimates computed 16 and 10 years ago. Furthermore, in the light of the proliferation of fake GM corn, the farm performances of GM versus counterfeit GM seeds are compared. For Bt eggplant that is hoped to be introduced sometime soon, comparisons are made between the current farmers' varieties and practices and the Bt eggplant to evaluate the gains from switching to Bt eggplant.

IV.1.1 Ex-post Validation of the Farm Benefits from GM Corn

The impact of yellow corn to food security is indirect since the demand for it is derived from the feed demand for poultry and hogs or swine. And as income increases, human diet becomes more diversified where the consumption of eggs, meat, and milk becomes greater. As the demand for meat, egg, and dairy products increase so does the demand for yellow corn. In fact, corn production responds positively to increases in the prices of chicken and pork (Nasol et al., 1982).

Corn grains and grits are fed to hogs and chickens while the corn stalks, leaves, and immature ears can be fed to ruminants such as cows. Cereal constitutes 50% of poultry diets in the US (Dei, 2017). The same is true in the Philippines in the case of commercial feeds: it constitutes 50% of commercial poultry feeds and 40% of commercial feeds for hogs (Castillo, 2015). Corn silage production was reported to have gained grounds in Central Luzon (Flora, 2019). This is a mixture of fermented high-moisture feed. Corn silage is good forage for ruminant animals because it is high in energy and digestibility. Corn silage from the Philippines was particularly noted for its quality. Former DA secretary Piñol estimated the domestic requirement for yellow corn in 2017 to be around

5.6 million tons[17] which would roughly be 6 million tons by 2020 given the trend in poultry and hog production. Figure 11 illustrates how the feed demand for poultry, eggs, and hog production were met by domestic production and importation of yellow corn. The country had years of self-sufficiency after the introduction of Bt corn in 2003. However, the government permits importation during the years of low supplies due to extreme weather events, climate change phenomena (El Niño and La Niña) and possibly also because of yield penalties with farmers shifting from GM to counterfeit GM that was formally reported in 2008 and is still being practiced to date.

Figure 11. Yellow corn production and imports vis-à-vis poultry, eggs, and hog production, 2000-2019, Philippines.

GM corn varietal adoption

The first and only biotech crop commercialized in the Philippines is GM yellow corn. There are two general traits developed for yellow corn thus far and these are Bt which protects corn from the attack of lepidopterous pests especially the Asiatic Corn Borer or ACB, a major pest of corn, and herbicide tolerance trait which allows the use of a single (instead of multiple) broad spectrum herbicides. Since the approval of Bt corn (MON 810) in 2002 and Roundup Ready (RR) or herbicide tolerant GM corn three years later the private companies also developed GM corn with stacked traits (Bt + HT). Over the years the corn planted to GM grew at 1.5% annually so that by 2019, it accounted for 59% of the total yellow corn area (Figure 12).

Region-wise, the regions with the largest GM corn area in 2019 are Regions II and X and for this reason they were chosen as study sites. Top ranking GM corn provinces were chosen in the regions—Isabela for Reg. II and Bukidnon for Reg. X. In each of the provinces, two to three municipalities were chosen as study sites but no longer based on GM corn area but based on the abilities of the local agricultural offices to provide the logistics required for virtual FGD. Six farmers knowledgeable about the corn production practices in their villages or barangays were invited to participate in each site.

[17] https://www.gmanetwork.com/news/money/economy/596386/phl-ready-to-export-corn-to-asian-neighbors-pi-ntilde-ol/story/

The first activity in the vFGD was assessing varietal adoption in their respective domains. The farmers identified the corn varieties planted in their villages according to three different types as applicable—GM, Hybrid, and Counterfeit GM. The study did not find OPV yellow corn in any of the sites. For Bukidnon, the corn coordinator and six farmers from the municipalities San Fernando and Don Carlos provided estimates for the wet season 2019. For Isabela, the municipalities in the study were Sta. Maria, Ilagan, and Cauayan and the data elicited was for dry season 2019. Results show that the yellow corn areas in these study sites are predominantly GM (Figure 13) where adoption rates ranged from 75% to 100%. There is still a large percentage of areas that are non-GM in Bukidnon. In fact, based on PSA and BPI data, the adoption rates in Regions II and X are 90% and 52%, respectively. Moreover, the remaining 48% of the yellow corn area in Region X can be surmised to be planted to counterfeit GM-OPV locally known as sige-sige and hybrids. Counterfeit GM-hybrid were also reported in Region II which are locally known as "Vietnam", "Tanduyong", and "Labus" but these fake GMs allegedly did not really gain popularity and eventually disappeared in the area because they performed poorly (low yields). The list of varieties named by farmers and corn coordinators during the vFGD are Appendix G.

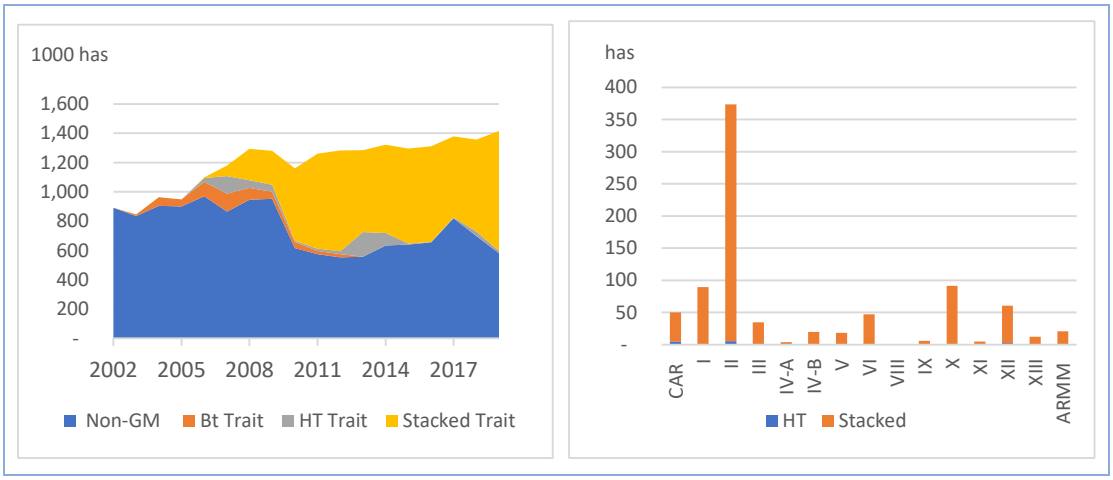

Figure 12. GM corn adoption (2002-2019) in the Philippines and GM area by region (2019).

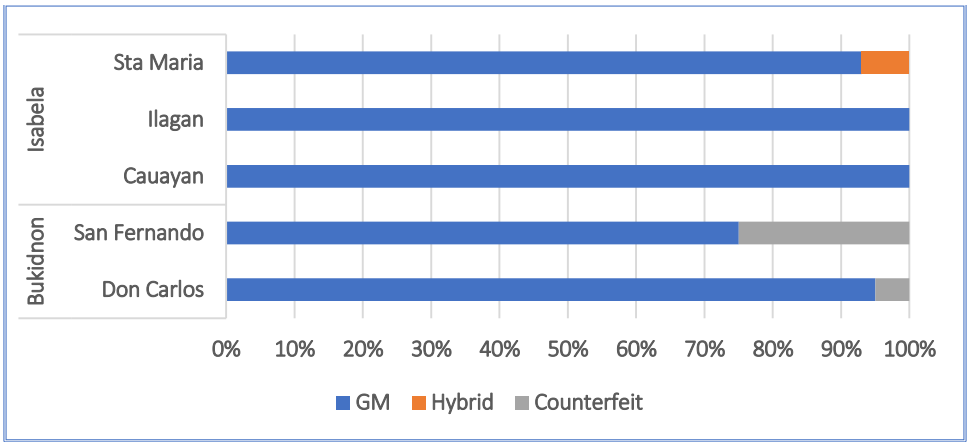

Figure 13. Varietal adoption for yellow corn elicited from farmers (Reg. II) and Bukidnon (Reg. X), virtual FGDs in Isabela 2020.

It has been 18 years since the first GM corn was introduced in the market. Yorobe et al. (2005) and Afidchao et al. (2010) used survey data to study the farm level impacts of GM corn and showed the economic gains for farmers who switched from non-GM to GM varieties. Over the years, there were reports complaining the high cost of GM seeds that even the DA Secretary (Piñol) ordered a probe on the high prices of GM seeds in 2019[18]. Another issue is the proliferation of fake GM seeds that are either hybrid or OPV. The incentives for farmers to plant fake or counterfeit seeds is the high price of the authentic seeds and its adaptability to local conditions as will be discussed below.

The purpose of the vFGDs is to validate the benefits reported in the literature using field data. Cognizant of the gold standard for assessing farm benefits or impacts are random control trials and surveys, it is with caution that the results are going to be interpreted. No claim of cause and effect shall be made from the results but merely an indication. Given the resource and time constraints in the project which was further exacerbated by the COVID-19 pandemic, a virtual FGD was the best if not the only option available.

Comparative cost structure

There are seven cash cost input items for corn production. Inputs such as for land preparation, seed rates, and crop establishment are dependent on land size and land topography so that when per hectare analysis is done, they are more or less fixed and would hardly vary with yield or yield targets. Fertilizer directly affects yield and pest control inputs affect production in terms of the mitigated yield loss. Harvest and post-harvest inputs are directly related or dependent on yield and are also affected by the weather conditions during harvest and topography. Hilly or rolling lands are harder and more laborious to work on than flat lands.

The per hectare cash costs for GM corn varied from 36,437 to 52,115 pesos. These basically represent the operating cash requirements for corn production that would either come from the

[18] https://www.pna.gov.ph/articles/1064505

farmers' own pockets or from lenders. The three major expenditure items are harvest-post harvest (27%), fertilizer (25%) and seeds (23%). Insecticide costs are quite low, in Bukidnon, insecticides use (only for seed treatment) is very minimal. It is possible that insect pressures were low or that all the varieties have expressed resistance to ACB and other lepidopterous pests. Harvesting operation is done manually in Bukidnon while mechanical harvester is an option in Isabela although the costs are very close to manual labor. Shelling is done mechanically. The cost structure for GM corn in all the sites in Figure 14 show a big proportion of the expenditure on GM seeds (20% to 30%). Price of GM seeds range from 3,400 to 5,700 pesos/9-kg bag and the seed cost would simply be twice as much at a seed rate of 18kg/ha. The DA includes in its program the distribution of free GM corn seeds and fertilizers. If not for the subsidies, the GM adoption rate in Bukidnon would have been lower where the planting of Sige-Sige variety (OPV variant of the GM corn with RR or HT trait) is quite popular owing to its adaptability to the local conditions and the 20% savings in seed cost.

The alternative to GM corn in the study sites are Hybrid and Sige-Sige varieties. Yellow corn OPV varieties were hard to come by in Isabela because of the discontinuity in its cultivation — only on occasions that the farmers would want to plant OPV corn that the agriculture office would request for seeds from the DA regional field offices or research centers. Probably because the prices of hybrid seeds are very close to GM, farmers decide to choose GM over non-GM hybrid. The comparative cost structures of cultivating GM, Sige-Sige and Hybrid are illustrated in Figure 15. The biggest difference is obviously in the cost of seeds. Since Sige-Sige can be recycled, it is basically "free" and not considered a cash cost. When asked to value Sige-Sige seeds from the previous harvest, farmers quote the prevailing price for it as seed material which runs between 20 to 70 pesos per ha. In peso terms, the cash expenditures were 44,289/ha, 30,366/ha and 30,311/ha for GM, Sige-Sige, and Hybrid corn, respectively. Between GM and Sige-Sige, the difference seems to be accounted for by the cost of seeds whereas between GM and Hybrid, the difference seems to be accounted for by the lower fertilizer application in the latter. Again it is noteworthy that insecticide costs were quite low not just for GM but also for Sige-Sige and Hybrid corn.

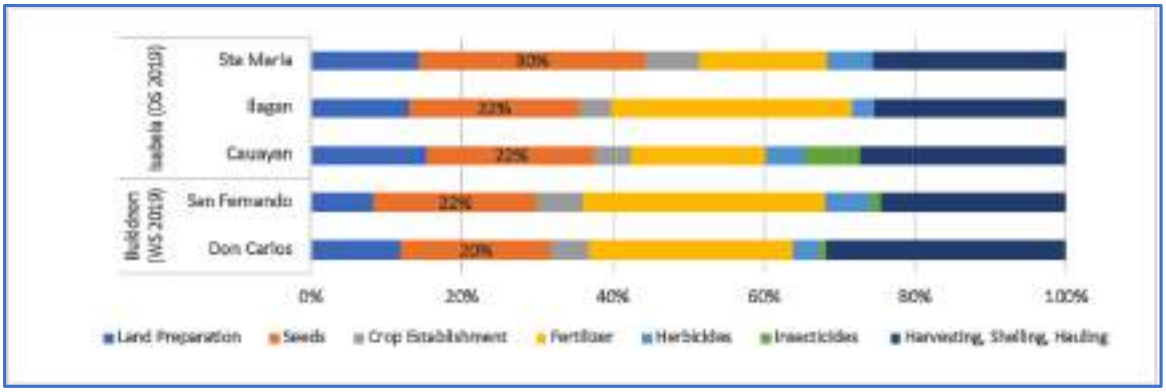

Figure 14. The cost structure of GM corn in Isabela and Bukidnon, vFGD 2020.

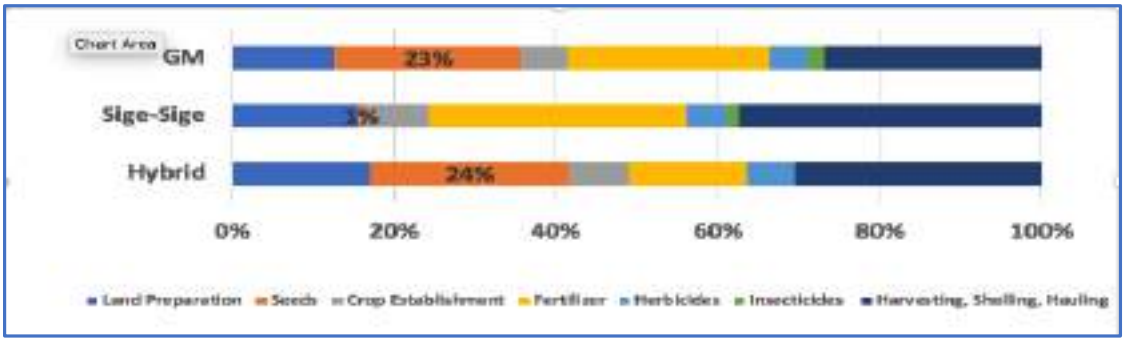

Figure 15. The cost structure of GM, Sige-Sige and Hybrid Corn in Isabela and Bukidnon, vFGD 2020.

Fall armyworm infestation

Reports of corn fields infestation by fall armyworm or FAW[19] in Cagayan Valley and Mindanao made the news during the time of the FGD. The DA Secretary Dr. William Dar created a DA-interagency national fall armyworm task force to contain the disease. The agricultural officers in the study sites during the FGD period checked infestations and damages in their respective areas and found that, fortunately, infestations occurred only in small pockets of corn fields and were thus pretty much contained. FAW studies are currently being done at UPLB. A Syngenta Bt corn variety with resistance breakdown to FAW was reported in Brazil after three years of release (Fatoretto et al., 2016). But so far, no GM variety claiming resistance to FAW is released or commercialized in the Philippines. With the recent extensive floods in Region II, it is possible that FAW may not be a concern in the corn area in the near future. Likewise, no significant FAW infestation was reported in Bukidnon during the conduct of the FGD.

Refuge system practices

The principle behind a refuge system for Bt seed technology is discussed in Sec. II.3 (2014) . The burden of stewardship involves the DA-IRMAT and the seed developers. It used to be that the seed refuges are packed and planted separately. Seed developers train farmers regarding the practice through the agricultural offices. While some of the farmers reported they have followed the recommended planting of refuges, some did not. Seed mixing of GM and refuges was preferred early on.

Absence of refuges in Sige-Sige seeds and the danger of low Bt dose can be a cause of concern. The DA-IRMAT requires the dose to produce a 99% kill and refuge seeds of 1 kg per 9 kg of GM

[19] Fall Armyworm is commonly found in the US, a prominent pest in Brazil, and was first spotted in West Africa in 2016. It is a migratory pest and can be very destructive. https://croplife.org/news/bt-technology-helps-protect-crops-from-fall-armyworm/

seeds to avoid or slow down the build-up of insect resistance to Bt. This regimen is non-existent in Sige-Sige or any generic counterfeit GM corn for that matter. The experts in the RTD pointed out that a breakdown of resistance-to-insects in Bt corn is a public concern and recommend that the stewardship aspect of counterfeit GM corn be studied.

Comparative performance of seed technologies

It is said that the technology is embodied in the seed so the three seed variety types can be regarded as three seed technologies. A corn farmer faces the options to cultivate any of the seed technologies available to him. So in the case of Isabela, the choice is between GM and Hybrid whereas in Bukidnon, the choice is between GM and Sige-Sige. Choices are made based on two parameters of performance—Yield and Profitability. The input demands and cash outlays are also important factors to consider. If the farmer does not have enough operating capital then he will opt to change the input rates or combinations. In the case of the seed technologies, some farmers in Bukidnon opted to choose Sige-Sige over GM and Figure 16 would explain the reasons why. From this figure, the shape of the net income above cash cost (IACC) follows the shape of yield—the higher the yield, the greater the IACC. Two anomalies are observable. First, GM corn yield is higher but IACC is lower in Isabela than in Bukidnon. Second is that Sige-Sige outperformed Hybrid corn. Since these are just FGD data then no statistical analyses can be made to say anything with confidence. However, the results provide interesting insights that explain the high GM corn regional adoption rates in Region II-Cagayan Valley of 90% (Isabela) and the lower adoption rates in Region X-Northern Mindanao of 52% (Bukidnon).

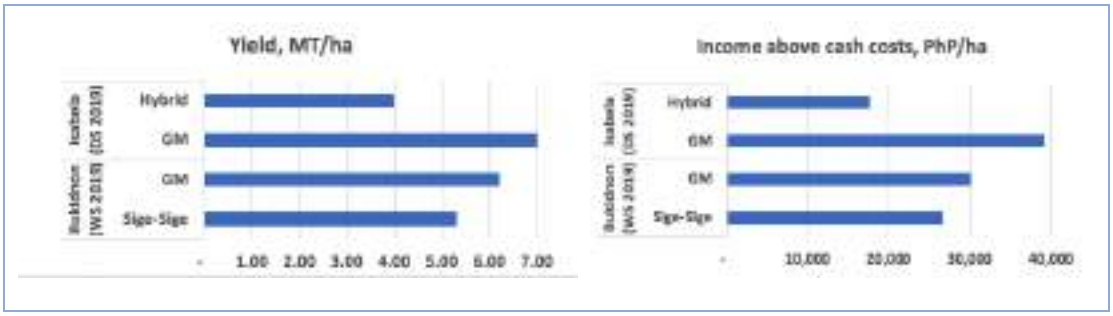

Figure 16. Comparative performance of three corn seed technologies, Isabela and Bukidnon, virtual FGD, 2020.

Comparative viability

The main purpose of this section is the field validation of positive impacts of GM corn on farm yield and returns from two old studies published in 2006 and 2010. Over time, the GM varieties commercialized improved in terms of multi-resistance, multi-tolerance and yield. However, the prices of inputs, especially seeds have also risen over time and unfortunately the farm gate price of GM corn has not kept pace. Yet, the hypothesis being tested here is that GM corn has remained viable. The results from the two studies and the results from the virtual FGDs are presented in

Table 6. The two parameters are yield (MT/ha) and IACC-CC ratio. Since the ratio is unit less then no adjustments for inflation is necessary.

Isabela: Results of the virtual FGD conducted in Isabela show that GM corn continues to be a viable technology as evidenced by the high yields and by the positive IACC-Cash Cost ratio. Yields from the v-FGD sites (5.35—7.00 MT/ha) were comparable if not higher than those reported in the two old studies (4.90—5.30 MT/ha). The IACC-CC ratio ranges from 0.46 to 1.07 while the estimates of the same from the 2006 and 2014 studies reviewed are both 1.09. The ratio for Sta. Maria is comparable with the old studies; however, those for Ilagan and Cauayan are lower despite the comparable yields. Noting that yield increased but viability declined then input prices could have risen faster than output prices between the time periods.

Table 6. Field validation of the farm benefits from GM corn.

	Yield (MT/ha)	Income Above Cash Cost (IACC) (P/kg)	Cash Cost (CC) (P/kg)	IACC-CC Ratio
		Isabela		
Yorobe & Quicoy, 2006 (Bt)	5.30	4.66	4.27	1.09
Afidchao et al., 2014 (Stacked)	4.90	5.96	5.49	1.09
Current Study, GM Corn				
Cauayan	5.57	3.79	8.21	0.46
Ilagan	5.35	4.51	8.49	0.53
Sta Maria	7.00	5.59	5.21	1.07
Current Study, Hybrid				
Sta Maria	4.00	4.42	7.58	0.58
		Bukidnon		
Yorobe & Quicoy, 2006 (Bt)	4.22	0.87	5.99	0.15
Current Study, GM Corn				
Don Carlos	6.20	4.84	8.41	0.58
San Fernando	4.04	1.20	10.33	0.12
Current Study, Sige-Sige				
Don Carlos	5.30	5.03	6.47	0.78
San Fernando	5.03	7.15	7.55	0.95

Bukidnon. Viability of GM corn cultivation is likewise evident in Bukidnon with yields and IACC-CC ratio in the current study (4.04—6.20 MT/ha and 0.12—0.58, respectively) being larger on the average than the 2006 studies (4.22 MT/ha and 0.15, respectively). Data shows that when GM corn is compared to Sige-Sige corn, the former outperforms the latter in terms of yield of almost a ton difference and IACC (about 3,000 pesos/ha) but the other way around if in terms of IACC-CC ratio because of the big difference in seed cost (9,645 pesos/ha). Sige-sige seeds are often sourced from the farmers' harvest the previous season.

The above discussion points out the high costs of GM seeds. In fact, it is for this reason that Sige-Sige has gained popularity in Bukidnon so that when the yield and IACC-CC ratio are compared to GM, the decision of farmers to choose it over GM seeds.

Key findings—GM Corn field validation

GM corn has a yield advantage of about 1-3 MT/ha over the alternatives – Sige-Sige and Hybrid. This was validated by the virtual FGDs conducted in Bukidnon and Isabela. Income advantages of GM corn based on returns above cash cost were estimated at 3,000 pesos/ha over Sige-Sige in Bukidnon and around 20,000 pesos/ha over Hybrid in Isabela. Further proving that GM technology generates positive farm level impact that is indicative of its potential contribution to agriculture development and food security. However, the income gains from GM corn can be easily offset by the high price of seeds that account for about 20% of the total cash costs. Moreover, Sige-Sige is a counterfeit GM OPV and is popular in Bukidnon because of its comparable yield with GM corn and alleged effectiveness as a mitigating strategy to the risks of yield loss due to drought especially in hilly areas.

The sustainability of GM corn production is challenged by the high cost of GM seeds and the proliferation of an otherwise counterfeit OPV-variant of GM corn. The DA regional offices subsidize GM corn production by distributing free GM corn seeds and fertilizers to farmers. This provides a short term fix but in the long run, it is not sustainable just considering the large amount of money subsidies entail especially if done annually.

In this regard, the RTD panel of experts recommended (1) establishing arrangements with the developers of GM corn so they can donate old GM varieties to local seed producers and improve farmers' access to cheaper GM seeds and (2) investigating the possibility of the breakdown of insect resistance to Bt in areas where counterfeit GM seeds are popularly grown.

The durability of Bt technology to Asiatic corn borer (ACB) for example has not been challenged in the country probably because the Philippine landscape is mostly fragmented and quite diverse especially in Mindanao. The threat could be present in Cagayan Valley (Region II) where GM corn is cultivated in contiguous areas. Maintaining a refuge system can be critical to the durability and sustainability of the technology. Fall armyworm (FAW) were reported to be more damaging than ACB in Brazil and West Africa. There were reports of FAW migration in the Philippines at the start of year (2020) but the Department of Agriculture is keeping a watchful eye on this pest.

IV.1.2 Ex-ante Validation of the Farm Benefits from Bt Eggplant

Area planted for eggplant in the Philippines is estimated at 21,819 hectares in 2019, a 0.8% increase from the previous year, while production was 249,890 metric tons or an annual yield of 11.5 tons/ha (Philippine Statistics Authority, 2019a). At the reported average farmgate price of 22.80 pesos/kg (Philippine Statistics Authority, 2020), production is valued at approximately 262,200 pesos/ha. Eggplant farmers are vegetable farmers engaged in the cultivation of several other crops either sequentially or concurrently—pepper corn, squash, okra, pole sitao, rice, tomato, bitter gourd, bottle gourd, jute, mungbean, onion, cabbage, papaya, sponge gourd, and turnip.

Eggplant is considered a good cash crop especially around November through December when the prices are high. Incomes from eggplant can be higher than rice and other vegetables. It is also a long duration crop, which means that the farmer can choose to continue harvesting until the eighth or tenth month. Even in months when prices are low, sales from eggplant provide funds for the farmers' daily expenses.

Eggplant Fruit and Shoot Borer (EFSB) is the most damaging of all pests. Farmers spend large amounts on various types of insecticides in order to control eggplant fruit and shoot borer (EFSB) and despite such efforts there are still significant yield losses. According to Dr. Cesar Quicoy, "up to about 80 percent of eggplant can be lost" when using traditional eggplant varieties (Simeon, 2018). The risks imposed by high pest pressure, the perceived risks of loss and the farmers attitudes towards those risks influence farmers pest control decisions — in terms frequency, choice of insecticide brands, and the combination of insecticides. Farmers in the FGD know from experience that spraying will save their day from yield losses and for as long as the marginal benefits in terms of the value of production loss averted exceeds the costs of pest control then farmers will continue with their chosen EFSB control practice regime.

A non-chemical approach to control EFSB is by developing a variety with an antagonistic trait against EFSB — Bt eggplant. The UPLB-IPB collaborated with Cornell University and the Maharashtra Hybrid Seeds Company (Mahyco) under the project Agricultural Biotechnology Support Program II (ABSPII). Mahyco developed and donated a Bt event called EE-1 to the project. This Bt event has an insecticidal protein called Cry1Ac from Bacillus thuringiensis (Bt). The UPLB-IPB used the Bt material in order to develop Bt eggplant varieties with targeted resistance against EFSB (Francisco, 2009).

To date, Bt eggplant has completed three out of the four regulatory stages/requirements and these are: confined trials conducted from 2005 to 2007, single-location, limited confined field trial from 2008 to 2009, and multi-location trials in four sites from 2010 until 2012 (Carillo, 2018). In a study by (Hautea, et al., 2016), confined field trials in Pangasinan showed that all Bt eggplant lines in the experiment exhibited high field efficacy. During the 2nd trial where pest pressure was most severe, Bt lines provided control of EFSB shoot damage and fruit damage as well as a reduction in larvae infestation.

Unfortunately, the biosafety application for commercial propagation for Bt eggplant was temporarily halted in December 2015 after the Supreme Court decided in favor of the civil society groups who petitioned against the field testing of the GM crop using the Writ of Kalikasan argument. The ISAAA, Environmental Management Bureau, CropLife Philippines, the University of the Philippines (UP), and the UP Los Baños (UPLB) Foundation filed motions for reconsideration and in 2016, the Supreme Court reversed its 2015 ruling (Carillo, 2018). Developers of Bt eggplant resumed efforts

to apply for biosafety application following the strategy for Golden Rice. In September 2020, UPLB-IPB submitted a proposal for Direct Use for food, feed or processing. A biosafety permit application for commercial propagation is to follow soon.

Francisco (2014) assessed the ex-ante farm benefits for Bt eggplant in Pangasinan and Camarines Sur using the multi-location field trial data for Bt eggplant and non-Bt eggplant (open pollinated varieties or OPVs) in crop year 2010-2011 and farm survey in the same sites for the same period. The study showed the yield and income advantages of Bt eggplant over non-Bt eggplant which lends support to the commercialization of the former. However, the survey showed a popular farmers' practice in the area — the planting of Hybrid eggplant varieties — which resulted in yields higher than the Bt OPV eggplant variety. Thus, introgression of Bt on Hybrid eggplant was suggested.

To validate the results of Francisco (2014), data on the farmers' choice of eggplant varieties, input use, farm practices, and production problems were collected using FGD. The basic question is whether there are enough potential farm benefits from Bt eggplant that would incentivize the farmers to adopt the technology. Analysis of FGD data presented henceforth provides an approximation of the costs and returns to eggplant production and estimates the potential benefits of switching to Bt eggplant. The cost and returns analysis for each site was computed on a per hectare and per farm bases to determine the net farm income and net cash income for the planted varieties in 2019—hybrid and open-pollinated varieties (OPV) or inbred. Partial budget analyses were likewise done to assess the benefits of switching from hybrid or OPV to Bt eggplant.

Eggplant varietal adoption

There are two types of eggplant varieties that farmers can choose from: open-pollinated or inbred varieties and hybrids. The seeds of OPV or inbred can be obtained from previous harvest and are thus recyclable. Farmers acquire new seeds when a marked decline in the productivity or quality of the fruits happen. It is recommended to replace recycled seeds with new ones every three or four seasons (Vizcayno, Hugo, & Alvarez, 2014). Hybrids have more vigor and higher yield than their inbred counterparts (Arncken & Dierauer, 2005). However, seed-saving or recycling cannot be done with hybrid as it would result in significant loss in vigor and inferior performance (Vizcayno, Hugo, & Alvarez, 2014).

In each of the eight FGD sites (cities/municipalities), six farmers were invited from three villages or barangays. They were asked to enumerate the OPV and hybrid eggplant varieties that are observed to have been planted in their respective barangays during the 2019 crop year. Given the data provided by the agriculture office on the eggplant area for the three villages and the rest of the villages in the municipal/city, the farmers estimated the proportion of area planted to each variety type. Results of the elicited varietal adoption in Figure 17 show the overwhelming

popularity of hybrid varieties (77% to 100% adoption rates by area) because of its higher yield compared to OPV. Farmers in the cities of Cabanatuan and Ilagan explained that OPV seeds can no longer be found in their respective areas. At the provincial level, Nueva Ecija has the highest adoption rate for hybrid varieties at 92%, followed by Pangasinan (87.5%) and Isabela (86.7%). These findings validate the results of the 2011 survey by Francisco (2014) where majority of the farmers planted hybrid varieties.

A significant proportion of eggplant, i.e., 21% to 23% by area, is still planted to OPV or inbred varieties — in Asingan (Pangasinan), Santiago and Roxas (Isabela) and in Aliaga (Nueva Ecija).

The most popular hybrid varieties were Prolifica and Fortuner F1 as these were reported in seven out of the eight study sites. These were followed by Calixto F1 and Morena F1 as reported in six and four of the eight sites, respectively. There is an expressed preference for East-West Seeds which accounts for 60% of the varieties (Table 7). Some of these hybrid varieties were released after 2011 (Bt eggplant trial was for CY 2010-2011); in fact, three most popular varieties—Prolifica, Fortuner F1, and Calixto F1—were released in 2016, 2013, and 2019, respectively. As regards the open-pollinated varieties, farmers listed the following that were either sparsely planted in 2019 or in the years prior: Aurora Round Green, Baguinay, Balbalosa, Ilocos Round Green, Japayuki, Liwet, Mistisa, Native, and Tatlong Puti Parat.

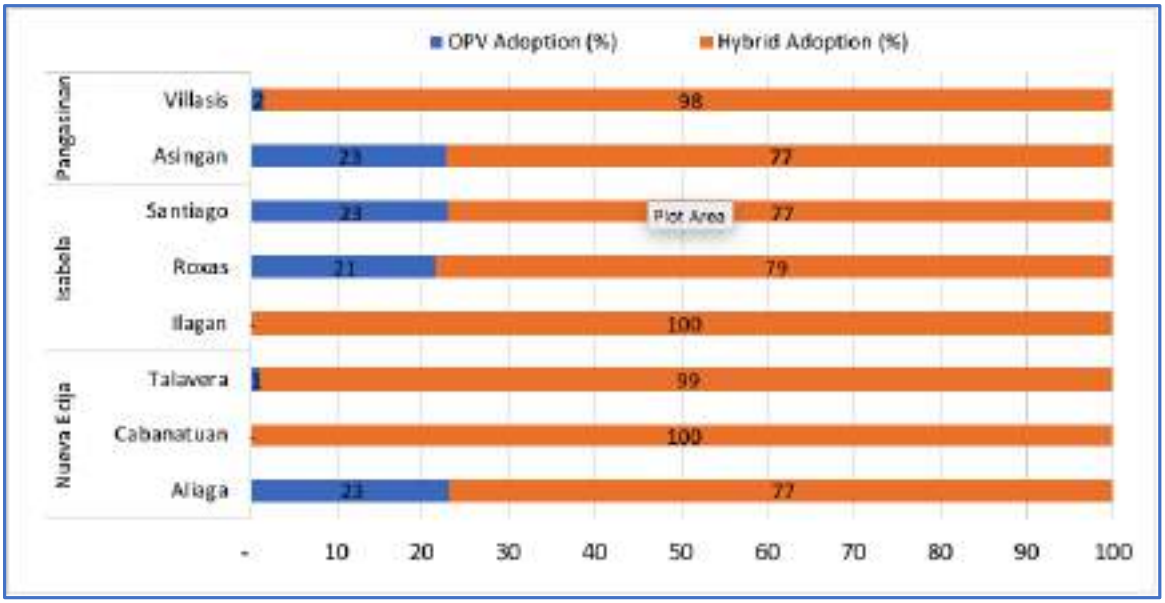

Figure 17. Eggplant varietal adoption by municipality/city in the provinces of Pangasinan, Isabela and Nueva Ecija, virtual Focus Group Discussion, 2020.

Table 7. Hybrid eggplant varieties reported in Pangasinan, Isabela, and Nueva Ecija, virtual FGD 2020.

Varieties	Seed Company	Number of cities/	Percentage (%)

		municipalities	
Prolifica	SeedWorks	7	88
Fortuner F1	East-West Seeds	7	88
Calixto F1	East-West Seeds	6	75
Morena F1	East-West Seeds	4	50
Gwapito F1	East-West Seeds	2	25
Casino F1	East-West Seeds	2	25
Warhawk F1	Condor/Allied Botanical Corporation	1	13
Banate King	East-West Seeds	1	13
Maharlika Sikat F1	Ramgo	1	13
Thunderbolt F1	Condor/Allied Botanical Corporation	1	13

Cost of Eggplant production

The actual length of production cycle varied across sites, from three to nine months. To have comparable estimates of costs and incomes, the following assumptions were used:

1. Seven-month cropping period:
   a. Land preparation: 1 month
   b. Transplanting to flowering period: 2 months
   c. Harvesting period: 4 months
2. Farmgate price of eggplant: 22.80 pesos/kg, average for 2019 (PSA, 2019)

There are four eggplant production choices identified in the study sites — Hybrid, OPV, and "pesticide-safe" eggplant which could either be Hybrid or OPV — and although in a lot of ways they are very similar still they significantly differ in terms of cultural practices, product type, farm gate prices, input uses/costs, and possibly income. Hybrid eggplants are known for their purple color and elongated shape. OPVs are usually round or elongated but shorter than hybrid and usually green but can also be purplish. "Pesticide-safe" eggplant is part of the pesticide-free vegetables and fruits advocacy[20] and the Food Safety Program in DA Region II[21] adopted in Santiago City, Isabela in 2019. To be labeled and sold as pesticide-free, these eggplants need to pass the pesticide residue test.

[20] https://www.manilastandard.net/lgu/luzon/301215/santiago-city-advocates-pesticide-free-vegetables-and-fruits.html
[21] https://www.facebook.com/DACagayanValley/posts/2177559085892472

Photo credits: Lazada.com, Shopee.com, DA-RFO2

Figure 18. Eggplant production choices (OPV, Hybrid, and Pesticide-safe), Northern Luzon, Philippines, virtual FGD 2020.

Planting materials. There are two distinct practices with regards the planting of hybrid eggplant—farmers either buy ready-to-plant seedlings in trays or prepare their own seedlings where the former appeared to be more popular than the latter. Seedlings-in-trays are especially popular in five study sites— Aliaga, Cabanatuan, Talavera, Ilagan, and Villasis. The sources of ready-to-plant seeds are seedling farms and East West seedling dealers which normally require pre-ordering with a lead time of one month. There are 128 seedlings per tray and the price ranged from 150 to 250 pesos/tray. Farmers pay a higher price for seedlings obtained directly from East West. Depending on the distance between hills (which differed among farms), the number of seedling trays per hectare varied widely from 50 to 100; closer hills require more seedlings. Thus, seedling costs per ha ranged from 9,000 to 20,667 pesos (Table 8). Farmers explained that ready-to-plant seedlings spare them of the labor required in putting up a seedbed. More importantly, eggplants grow uniformly because of the less "transplanting shock" compared to seedlings reared in seedbeds. Growing seedlings in seedbeds were popular in Roxas, Santiago, and Asingan. This practice cuts the seedling costs by at least a third —3,300 to 4,600 pesos/ha.

Meanwhile, farmers who planted OPVs do not buy seeds because either the seeds are recycled or acquired for free from nearby DA research field offices, however, they had to raise their own seedlings. The labor costs of raising seedlings in seedbeds range between 400/ha to 640 pesos/ha (Table 9).

Land Preparation. Lands for eggplants should be well prepared usually with two passes each of plows and harrows. Private service providers charge a contract price of 1,500—2,500 pesos/ha/pass for plowing and 1,800 to 4,000 pesos/ha/pass for harrowing. Under the DA farm mechanization project, the agricultural offices distribute four-wheel tractors to farmer cooperatives

or barangays which then provide land preparation service at subsidized rates just enough to cover the costs of fuel and wages for the operator.

Table 8. Per hectare cost and income, Hybrid eggplant by municipality/city and by province, virtual FGD, 2020.

	ISABELA			NUEVA ECIJA		PANGASINAN			
ITEM	**Santiago***	**Ilagan**	**Roxas**	**Aliaga**	**Cabanatuan**	**Talavera**	**Asingan**	**Villasis**	**Pooled****
					MT per ha				
Total harvest (MT/ha)	15.83	29.81	37.33	20.98	43.20	29.93	35.14	40.86	33.89
Production Sold	12.63	29.62	29.87	16.78	25.92	22.07	33.39	28.19	26.55
Home Cons-HC	0.06	0.04	0.37	0.10	0.22	0.30	0.35	0.20	0.23
Given Away-GA	0.06	0.05	3.36	0.10	0.22	2.83	0.35	0.20	1.02
Rejects	3.08	0.10	3.73	3.99	16.85	4.73	1.05	12.26	6.10
					Pesos per ha				
Cash Returns									
Production Sold	288,040	675,317	680,960	382,635	590,976	503,242	761,194	642,789	605,302
Non-Cash Returns									
HC & GA	2,660	2,109	85,120	4,783	9,850	71,344	16,025	9,316	28,364
TOTAL RETURNS	290,700	677,426	766,080	387,418	600,826	574,586	777,219	652,104	633,666
Cash Cost									
Seed Preparation	4,240	20,000	3,300	11,050	20,667	9,000	4,600	12,908	11,646
Seed/Seedling Inputs	3,600	20,000	3,000	11,050	20,667	9,000	4,200	12,908	11,546
Labor	640	-	300	-	-	-	400	-	350
Land Preparation	2,000	4,360	8,700	5,400	9,950	6,700	7,440	9,600	7,450
Transplanting	3,200	2,700	2,600	4,500	4,500	2,750	7,140	4,400	4,084
Fertilizer	12,314	38,868	34,950	37,486	48,403	43,410	24,632	34,440	37,456
Fertilizer Inputs	12,314	33,430	34,950	22,186	32,403	29,310	18,032	23,240	27,650
Labor	-	5,438	-	15,300	16,000	14,100	6,600	11,200	11,440
Herbicide	670	1,000	-	2,967	2,140	2,120	-	5,320	1,935
Herbicide Inputs	370	1,000	-	1,467	1,590	2,120	-	4,440	2,123
Labor	300	-	-	1,500	550	-	-	880	977
Manual Weeding	3,600	4,700	7,500	2,300	8,100	3,400	5,880	6,640	5,503
Insecticides	4,400	10,450	33,333	30,367	57,033	19,683	128,996	128,965	58,404
Insecticide Inputs	3,200	8,000	33,333	20,767	37,833	19,683	101,936	98,165	45,674
Labor	1,200	2,450	-	9,600	19,200	-	27,060	30,800	17,822
Irrigation	2,100	6,720	6,999	7,560	11,200	5,400	19,200	8,941	9,431
Harvest & Postharvest	54,756	80,000	70,400	80,000	153,600	64,800	89,760	98,560	91,017
Transportation	12,633	29,619	29,867	16,782	25,920	22,072	33,386	28,192	26,548
Total Cash Cost	99,913	198,417	197,649	198,412	341,513	179,335	321,034	337,966	253,475
Non-Cash Cost									
Imputed Labor	4,250	500	27,900	-	-	17,500	-	-	6,556
Total Non-Cash	4,250	500	27,900	-	-	17,500	-	-	6,557
TOTAL COSTS *(B)*	141,157	198,917	225,549	198,412	341,513	196,835	321,034	337,966	260,032
Net Income *(A)*	**186,537**	**478,509**	**540,531**	**189,006**	**259,312**	**377,751**	**456,185**	**314,138**	**373,633**
Income-Cost Ratio (A)/(B)	**1.79**	**2.41**	**2.40**	**0.95**	**0.76**	**1.92**	**1.42**	**0.93**	**1.44**

* Pesticide-safe Hybrid eggplant in Santiago, Isabela only; all other study sites are regular Hybrid eggplant.
** Average for regular Hybrid eggplant; excludes Santiago, Isabela.

Transplanting. After the land has been thoroughly prepared, furrows are marked in the morning and the seedlings are manually transplanted in the afternoon. The number of hired labor ranged from 17-20 persons per ha, predominantly women. Costs of transplanting were invariant among farmers within a site but varied widely across sites (2,600 to 7,140 pesos/ha) owing to the differing wage rates (200 to 400 pesos/day).

Fertilizer. All farmers apply fertilizers that contain the three macronutrients—Nitrogen, Phosphorus and Potassium. The quantity applied varied widely within and between study sites but, the frequency and timing of application were more or less the same. There was also wide variation in the wage rates for fertilizer application (side dressing) across sites — 150 to 400 pesos/day. It was a common practice to provide snacks and/or lunches to hired laborers. Some of the farmers mixed foliar fertilizer with insecticides. The average per ha fertilizer cost for Hybrid, OPV, and PS-Hybrid and PS-OPV eggplants were 37,456, 10,490, 37,486 and 12,314 pesos, respectively.

Table 9. Per hectare cost and income, OPV eggplant, virtual FGD, 2020.

	PS-OPV Santiago (Isabela)	OPV Asingan (Pangasinan)
	MT per ha	
TOTAL HARVEST	33.33	25.00
Production Sold	26.67	24.25
Home Cons-HC	0.03	0.03
Given Away-GA	0.03	0.03
Rejects	6.60	0.70
	Pesos per ha	
Cash Returns		
Production Sold	608,000	552,900
Non-Cash Returns		
HC & GA	1,505	1,140
TOTAL RETURNS	609,505	554,040
Cash Cost		
Seed Preparation	640	400
Seed/Seedling Inputs	-	-
Labor	640	400
Land Preparation	2,000	7,440
Transplanting	3,200	7,140
Fertilizer	12,314	10,420
Fertilizer Inputs	12,314	6,900
Labor	-	3,520
Herbicide Costs	670	-
Herbicide Inputs	370	-
Labor	300	-
Manual Weeding	3,600	5,880
Insecticide	4,400	97,000
Insecticide Inputs	3,200	75,000
Labor	1,200	22,000
Irrigation	2,100	19,200
Harvest and Postharvest	115,288	89,760
Transportation	26,667	24,250
Total Cash Cost	*170,879*	*261,490*
Non-Cash Cost		
Imputed Labor	4,250	-
Total Non-Cash Cost	*4,250*	-
TOTAL COSTS	175,129	261,490
NET INCOME	**434,376**	**292,550**
Net Income-Cost Ratio	**2.48**	**1.12**

Insecticide. Eggplant production, just like any other vegetables, is insecticide-intensive. The common practice for both hybrid and OPV was that the moment harvesting commences then insecticides or cocktails of different kinds were sprayed a day after and then a day before harvest or twice in between harvests that is why the cost can be as high as 129,000 pesos/ha. The list of insecticide brands reported by the farmers is rather long and some of them are even unlabeled or bear unrecognizable foreign labels. In other words, some of these insecticides were not approved by the FPA and were sold in the black market as simply insecticides recommended for eggplant. One of the farmers explained that smuggled insecticides are more potent than what can be bought in the market and if not for these then crop loss would have been unbearable.

For pesticide-safe eggplant production in Santiago City (Isabela), the farmers were encouraged by the agriculture office to limit their application of insecticides to just once a month. Thus, insecticide expenses amounted to only 4,400 pesos/ha.

Weed control. Farmers control weeds either chemically, mechanically or manually. Those that opt for herbicides do not need to mechanically remove weeds using animal-drawn plow (off-barring and hilling-up) or manually remove weeds with human labor. The choice between manual and chemical appeared to be influenced by preference with the latter being stronger than the former. Average weed control was 7,042 pesos/ha.

Pest Monitoring. All farmers monitor the plots for pest infestation either daily or every other day, spending one to two hours per day for a one-hectare field. With insecticide spraying following a calendar schedule, the only decision farmers make is the choice of insecticides to mix together based on their field observations.

Irrigation. Eggplant requires constant irrigation. The farmers own shallow tube wells. The estimates provided by farmers for irrigation varied widely — from 2,100 to 19,200 pesos/ha.

Harvest and post-harvest. These are labor-intensive activities consisting of manual picking of the fruits, hauling, sorting, and bagging. The number of hired labor depends on the farm size or volume of harvest. To some extent it is also dependent on the farmgate price because when farmgate prices fall below 10 pesos/kg the farmers would hold off selling until they go back up and in the meantime will allow people to pick fruits for their own use or for animal feed. But when prices are high (above 40 pesos/kg), hired laborers demand higher wages and the farmers oblige. Normal harvestings are in a four-day interval which comes to about seven times in a month.

Cost structure across production choices. As mentioned above, there were four production options in the study sites and their management differed not just in terms of chemical input use but also planting density. The costs of Hybrid and OPV are comparable at 269,549 pesos/ha and 261,490 pesos/ha, respectively. Pesticide-safe (PS) eggplant production has lower planting density and lower chemical use; thus, the total cost of inputs are much lower because of the lower costs of seedings, fertilizers and insecticides. Between PS-OPV and PS-Hybrid, the average per ha production costs are much higher for the former (175,129 pesos) than the latter (104,163 pesos) where the difference is attributable to the higher yield and therefore larger harvest-postharvest costs for the PS-OPV.

Figure 19 compares these four production options with the 2010 survey done by Francisco (2014) with respect to costs of production at 2019 constant prices. It appears that under a “normal”

production regime, eggplants are now costlier to produce than 10 years ago—by about 25,000 pesos per hectare.

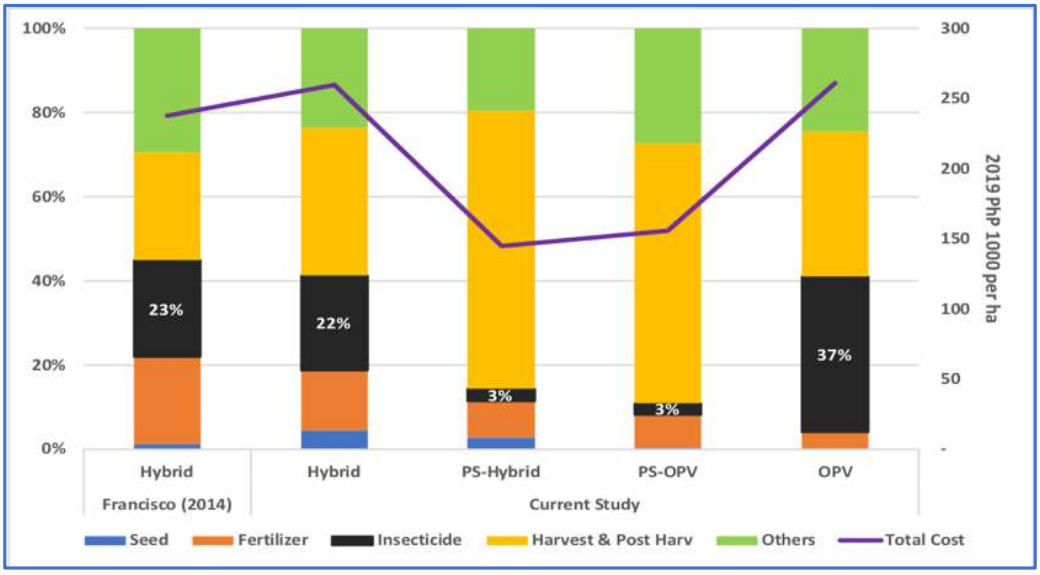

Figure 19. Per hectare average production cost (2019 prices), four eggplant production choices—Hybrid, OPV, Pesticide-safe—and Francisco (2010) study.

Across sites, the estimated per hectare production cost varied widely — from 141,157 to 261,490 pesos — presumably because of the variation in the volume of harvest and consequently variation in the harvest and postharvest costs. Farmers in Asingan, and Villasis (Pangasinan) are intensive users of insecticides, spraying about twice in between harvest and spending for the 6-month cropping season a total of 128,996 and 128,965 pesos/ha, respectively. Cabanatuan (Central Luzon) farmers sprayed less at about half the costs (57,033 pesos/ha) of the intensive insecticide users but they incurred higher labor costs for land preparation, fertilizer, weeding and for harvest and postharvest activities alone – they paid the highest at 153,600 pesos/ha.

The composition of the eggplant production costs in Figure 19 goes to show that harvest and postharvest activities comprise a sizable part of the farmers' total expenses with 34% (Hybrid) and 66% (PS-OPV) of the average expenses. This was followed by insecticide expenses which comprised 37% (OPV) and 3-4% (PS-OPV or PS-Hybrid) of the total costs. Recall that for the pesticide-safe eggplants, farmers were supposed to spray only once every month compared to the normal frequency of once or twice in between harvests or 8-16 times a month. Fertilizer accounted for 14% (Hybrid) and 7% (PS-OPV) of the total costs.

Compared to Francisco's 2010 survey in Pangasinan, the costs of production (converted to 2019 prices) are comparable for the Hybrid and OPV from the current study. The proportion spent on the three major inputs are also comparable.

Eggplant Production and Disposal

The farmer respondents were asked about their average production for the past cropping season (2019-2020), how much was rejected from their produce, and how much was given away and consumed by their household.

Gross yield for hybrid ranged from 29.93 MT/ha to 43.20 MT/ha. While the gross yield of PS-Hybrid was very low at 15.83 MT/ha, the yield of PS-OPV was comparable to Hybrid (with intensive insecticide use) at 33.33 MT/ha. The volume of eggplants that are damaged by EFSB and rejected ranged from 1% to 39% of the gross production Figure 20. Two locations stood out to have reported very low rejects of 1% to 3% and they are Ilagan, Isabela and Asingan, Pangasinan. Pest pressure was reported to be quite low in Ilagan so that insecticide costs amounted to only 10,400 pesos/ha or 5% of total costs. Farmers in Asingan, on the other hand, spent between 97,000 (OPV) to 128,999 pesos/ha (Hybrid) or 37% to 40% of total costs. After the rejects (0.3% to 39%), everything else was sold (60% to 99%) with nil quantities consumed at home (no more than 1%) or given away (0.1% to 9.5%).

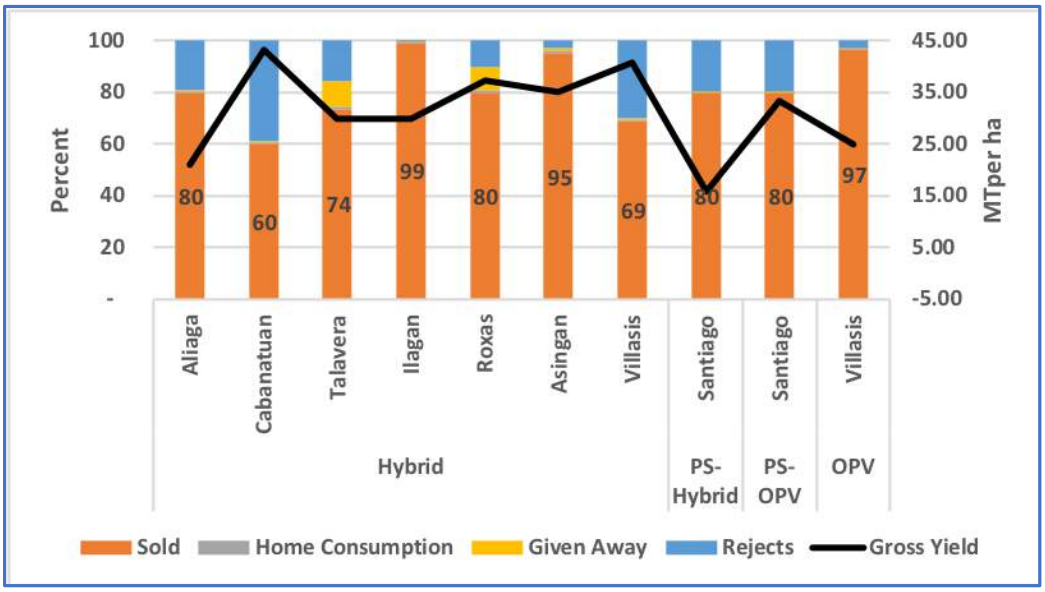

Figure 20. Production and disposal, Hybrid and OPV eggplant in the provinces of Pangasinan, Isabela and Nueva Ecija, virtual FGD, 2020.

Silvosa, et al. in 2012 studied the yield and response of eggplants to fruit and shoot borer under an integrated pest management system. The hybrid variety used was Banate King F1 and the open-pollinated variety used was Dumaguete Long Purple. Results showed that average eggplant yield per hectare was 40 tons with no significant difference between gross yields of Banate King and Dumaguete Long Purple. This yield was obtained from a total of 22 harvests (3 months of

harvesting). If it is equalized with the number of harvests in this study (32 harvests; 4 months of harvesting), the resulting yield for eggplant would be approximately 58 MT/hectare. This goes to show that potential yield for eggplant could exceed 55 MT/ha in four harvesting months under favorable conditions.

When the rejection figures from the FGD are averaged and compared to the study done by Francisco (2014), the Bt eggplant from the dry season field trial in Pangasinan has the highest proportion of rejects at 27% with a marketable yield of 21.46 MT/ha. It should be noted that there were no insecticides applied to Bt eggplant. The results of Francisco's survey during the same period reveal that farmers prefer Hybrid varieties because of their superiority over OPV in terms of yield. While the field trial proved the superiority of Bt over the non-Bt-OPV, the surveyed Hybrid farms based on the Francisco study showed the superiority of Hybrid by 9.5 MT/ha in terms of marketable yield. In Figure 21, the 2010 hybrid yield from Francisco (2014) is consistently higher than the hybrid and OPV either because of its lower proportion of rejects or high yield potential.

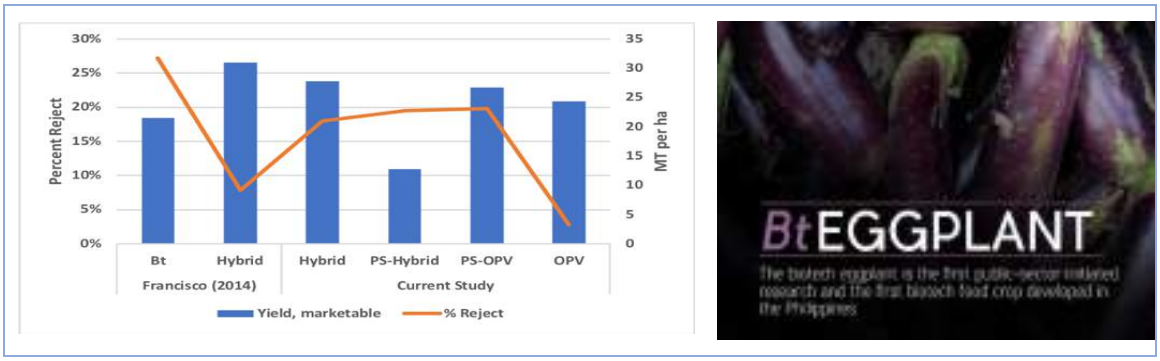

Figure 21. Marketable yield and rejects, various eggplant varieties, Francisco (2014) study versus vFGD results.

Farm Benefits Validation

Marketable Yield. Revisiting Figure 21, Bt eggplant's marketable yield is lower than all others except for PS-Hybrid (pesticide safe production) which is reasonable since in the presence of pest pressure, production can really be lost to EFSB unless insecticides are used as control. The marketable yield of Hybrid from the 2010 survey by Francisco (2014) is higher than all others in the current study; under similar EFSB control regime, it is higher by 4.5 MT/ha than the Hybrid in the current study owing to the greater proportion of rejects since their gross yields are the same. There are two possibilities—either the Hybrid varieties now are more susceptible to EFSB or the insecticides the present farmers use are less potent. These could be further studied.

Per hectare costs and returns. The cost and returns analysis per site was computed on a per hectare basis to allow comparison of values across sites. On the average, the net cash income of

eggplant farmers across sites were 434,376, 373,633, 292,550 and 186,537 pesos/ha for PS-OPV, Hybrid, OPV, and PS-Hybrid respectively.

The net incomes from the current study — Hybrid, OPV or PS-Hybrid and PS-OPV — are all higher than the net income for Bt variety in 2019 prices (Figure 22). In fact, even the farm income of Hybrid from the 2010 survey (Francisco, 2014) is higher. Again there are two possible reasons. First is that hybrid is obviously more high yielding than OPV (Bt was introgressed on OPV). Second is that the yield of the more recently released varieties have improved over time. It has been 10 years since the field trial. The elite OPVs of today have superior yields than those released 10 years ago into which the Bt was introgressed. Compared to the net income of Hybrid in 2010 (Francisco's study), the net incomes from Hybrid and PS-OPV are comparable. Eggplant is a very profitable farm enterprise.

However, in terms of the rates-of-return measured as the ratio of net income to total cost, Pesticide-safe (PS) production regime of OPV and Hybrid gave remarkably good results, and if the production options are evaluated in terms of ROR, PS production outranked all others. This surely is an interesting finding. This pesticide-safe production system can be further studied. The current study proves that challenge for Bt eggplant.

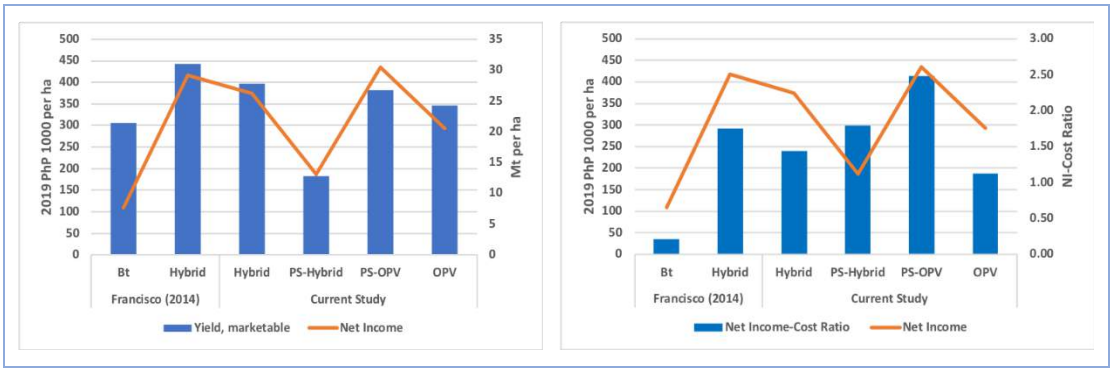

Figure 22. Comparative performance of eggplant production, Francisco (2014) study versus current study (vFGD 2020 results).

Per farm costs and returns. The estimated income per hectare is large and creates an impression that eggplant production had made the farmers rich but it is rather seldom to find farms as large as a hectare or more. In fact, according to the HVC coordinators in the study sites, most of the eggplant farms are small with areas of 1,000 to 3,000 square meters (0.1 to 0.3 ha). A usual practice in Pangasinan is to divide farm lots into the planting of different vegetables—eggplant, okra, bitter melon, string beans and chili, among others. Figure 23 shows the estimated average per farm incomes in the FGD sites. The OPV eggplant farms were usually small. Large farms prefer Hybrid varieties. Those practicing pesticide-safe eggplant production were also small. Large farms (1.24 ha) that planted Hybrid eggplants earned an estimated net income of 463,305 pesos/farm for a 7-month cropping period or 66,186 pesos/farm/month. Small Hybrid farms (0.49 ha) earned 183,080

pesos/farm for the crop period or 26,154 pesos/farm/mo. Moderate sized OPV farms (0.80 ha) made 33,434 pesos/ha/month. Farms that adopted pesticide safe regime were small but the winner is PS-OPV (0.30 ha) with an estimated income of 18,616 pesos/farm/month whereas the PS-Hybrid (0.25 ha) made the lowest net income of 6,662 pesos/farm/month and this is not bad!

Farmers plant eggplants all year round. Once they observe a decline in the volume of weekly harvest, the old plants are pulled out, the land is prepared and the new crop cycle begins.

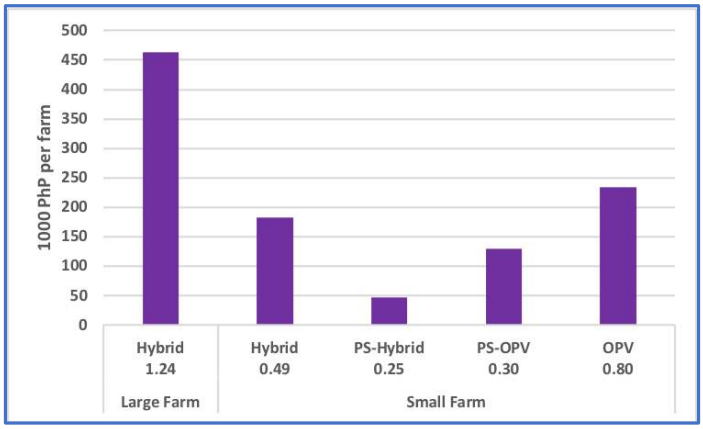

Figure 23. Per farm income from eggplant production, vFGD, 2020.

Production Problems and Constraints. The single greatest concern of eggplant farmers is the fruit and shoot borer or EFSB. Thus far the only effective means of control at the farmers' disposal is through the use of insecticides or an interplay of insecticides and fertilizers where the latter provides a boost for eggplant to recover from pest damage. It is common to mix two to three kinds of insecticides in one spray. And in some of the sites, farmers subscribe to unregistered insecticides—some with no labels and others with Chinese characters void of English translations. Sold in the black market, these unregistered insecticides were allegedly more potent. Other pest problems although of minor importance were aphids, bacterial wilt, damping off, and verticillium wilt.

Although the cost of seedlings is miniscule when compared to other inputs, farmers in Roxas, Santiago, and Villasis thought that Hybrid seeds were expensive. Indeed they are when compared to OPV seeds that the regional DA offices distribute for free through the local agriculture offices. Farmers in Roxas reported several problems: 1) lack of eggplant varieties to choose from; 2) difficulty in selling when prices are too low (below 15 pesos/kg); and 3) shortage of hired labor or the high cost of labor. Farmers attribute the pseudo shortage of labor to the 4Ps program of the government[22]. Ilagan farmers also had difficulty selling eggplant when prices were too low to recoup the costs of harvesting, sorting, packaging and transport. As the farmers wait for prices to rise,

[22] https://lawphil.net/statutes/repacts/ra2019/ra_11310_2019.html

they allow neighbors to pick fruits for free. Other problems reported were the lack of capital and inadequate extension support.

Health Impacts of Insecticide Use

Eggplant farms, just like any other vegetable farm, are like battlefields for insecticides against insect pests. As a valuable cash crop, eggplants are fed with fertilizers quite intensively, however, greener leaves and plumper fruits attract insects to lay eggs and feed on the crop. Farmers seek comfort from insecticides as a risk mitigating action as they secure harvests and incomes from risks of damage or yield loss. The decision to spray is highly influenced also by the spray decisions of adjacent eggplant farms as the moths could easily fly over to lay eggs in unsprayed plots.

Two distinct FGD sites — Santiago and Asingan — provide some interesting comparison as regards the apparent effect of insecticide use on the marketable yield of Hybrid and OP varieties (Table 10). Santiago eggplant farms were sprayed only once-a-month in compliance with the city-wide low insecticide use program whereas Asingan farms were sprayed up to eight times a month. Under low insecticide use (Santiago), OPV outperformed Hybrid by 14.04 MT/ha (marketable yield). Under high insecticide use (Asingan), Hybrid outperformed OPV by 9.14 MT/ha (marketable yield). It appears that OPV outperforms Hybrid at low insecticide use whereas Hybrid outperforms OPV at high insecticide use.

Between sites, the marketable yield of OPV in Isabela is higher than in Asingan by 2.42 MT/ha despite the significantly higher insecticide expenditures in the latter. Such variation in yield performance may be attributed to the site-specific yield potential of the varieties used.

Table 10. Production and insecticide use in eggplant production, Hybrid versus OPV, Santiago (Isabela) and Asingan (Pangasinan), virtual FGD, 2020.

	Low Insecticide Use (Isabela)			High Insecticide Use (Asingan)		
ITEM	**Hybrid**	**OPV**	**Difference**	**Hybrid**	**OPV**	**Difference**
			Production (MT/ha)			
Gross Yield	15.83	33.33	-17.50	35.14	25.00	10.14
Marketable Yield	12.63	26.67	-14.04	33.39	24.25	9.14
			Insecticide Costs (pesos/ha)			
Total	4,400	4,400	0.00	128,996	97,000	31,996
Insecticide Inputs	3,200	3,200	0.00	101,936	75,000	26,936
Labor	1,200	1,200	0.00	27,060	22,000	5,060

Heavy application of insecticides can affect the health of the farmer and farm workers, especially since it is a common practice in their area to spray insecticides every other day once harvesting commences. Especially when farmers count “too many” moths in the field, insecticides are applied daily to mitigate the risk of ruit damages from EFSB. Farmers are aware of some health hazards to the persons hired to spray toxic farm chemicals and to the eggplant consumers too. In fact, those

who use unregistered insecticides plant pesticide-free eggplants in a separate plot for home consumption.

Table 11 lists the 34 brands of insecticides used in eggplant production as reported by participating farmers in the vFGDs. Prevathon SC is the most popular, reported in seven out of the eight study sites, followed by Lannate 40 SP, Ace Malathion 57 EC, Brodan 31.5 EC, Kill, and Longdeth. Of these six, the last two are not registered with the FPA and so the active ingredients are unknown.

Table 11. Toxicity of insecticides used for eggplant in the eight virtual FGD study sites, 2020.

Brand	Number	Percent	Active Ingedient	WHO Hazard Classification
Prevathon SC	7	87.5	Chlorantraniliprole	U
Lannate 40 SP	6	75	Methomyl	Ib
Brodan 31.5 EC	5	62.5	BPMC (Fenobucarb) + Chlorpyrifos	II + II
Ace Malathion 57 EC	5	62.5	Malathion	III
Kill	5	62.5	*Not FPA Registered*	N/A
Longdeath	5	62.5	*Not FPA Registered*	N/A
Solomon 300 OD	3	37.5	Imidacloprid + Beta-Cyfluthrin	II + Ib
Sevin 50 WP	2	25	Carbaryl	II
Super Cartap 50 SP	2	25	Cartap Hydrocloride	II
Kotetsu 10 SC	2	25	Chlorfenapyr	II
Alika	2	25	Thiamethoxam (12.6%) + Lambda-cyhalothrin (9.5%)	II + II
Pegasus 500 SC	2	25	Diafenthiuron	III
Parker Neem	2	25	Organic Pesticide	N/A
Supernet	2	25	Methy Eugenol (biopesticide)	N/A
Taiwanese Insecticide	2	25	*Not FPA Registered*	N/A
Exalt 60 SC	2	25	Spinetoram	U
Bulldock 025 EC	1	12.5	Beta-cyfluthrin	Ib
Furadan 3 G	1	12.5	Carbofuran	Ib
Scorpio 40 SP	1	12.5	Methomyl	Ib
Megatonic	1	12.5	Methomyl + Fertilizer	Ib
Orthene 75 SP	1	12.5	Acephate	II
Chix 2.5 EC	1	12.5	Beta-cypermethrin	II
Eja Cypermethrin 5 EC	1	12.5	Cypermethrin	II
Knock Out 5 EC	1	12.5	Cypermethrin	II
Perfekthion 40 EC	1	12.5	Dimethoate	II
Ascend 50 SC	1	12.5	Fipronil	II
Pennant 500 EC	1	12.5	Phenthoate	II
Selecron 500 EC	1	12.5	Profenofos	II
Actara 25 WG	1	12.5	Thiamethoxam	II
Guardmax 247 ZC	1	12.5	Lambda-cyhalothrin + thiamethoxam	II + II
Judo 60 EC	1	12.5	Butachlor	III
Fenos 480 SC	1	12.5	Flubendiamide	III
Benevia	1	12.5	Cyantraniliprole	U
Virtako 40 WG	1	12.5	Chlorantraniliprole+Thiamethoxam	U + II

The World Health Organization (WHO, 2019) provides guidelines for the classification of pesticides by hazard. The criteria used in the classification below was developed by a joint Food and Agriculture Organization (FAO) and WHO meeting on pesticide management; the main criteria being the oral and dermal toxicity to rats. Based on these, the 34 reported insecticides were categorized accordingly (Table 12). According to the WHO hazard classification, 17.6% of the insecticide brands eggplant farmers reported in the vFGD falls under category Ib, indicating high level of acute or chronic hazards to human health, which means that the insecticide applicators

(with no application safety protocol followed such as wearing protective suit, mask, gloves, and boots) and all other people with direct exposure to these highly hazardous insecticides (e.g., those preparing and mixing of insecticides, by-standers during application, people entering freshly treated fields, and consumers eating "freshly sprayed" eggplants) were putting themselves at high health risk. Hi gh levels of acute toxicity could lead to immediate health effects such as headache, nausea or vomiting, while c hronic or repeated exposure can cause developmental disorders and even cancer. During the FGD, farmers expressed that they were aware of their excessive insecticides use. It manifests in the form of headaches and a burning sensation in the skin. They also indicated concern for the health of their laborers, family members, and themselves, but claim that it is difficult to reduce usage because of the high likelihood of production losses due to EFSB.

Of the five insecticides not falling in any of the WHO categories, two are organic (Parker Neem and Supernet) and three are described by the farmers as "Smuggled" (Kill, Longdeath, and Taiwanese insecticides). Since farmers subscribed to these smuggled insecticides for their relatively more powerful control effects on EFSB it is possible that they belong to the highly (or even extremely) hazardous category. It may be worthwhile to call these to the attention of the LGU and the FPA; monitoring of pesticides in the local markets is suggested. For eggplants and vegetables in general, the agriculture office may provide a list of extremely and highly hazardous pesticides that farmers should be wary about.

Table 12. Percentage of insecticides reported belonging to 2019 WHO hazard classification.

2019 WHO Hazard Classification*	Description	Number	Percent
Class Ib	Highly hazardous	6	17.6
Class II	Moderately hazardous	16	47.1
Class III	Slightly hazardous	4	11.8
Class U	Unlikely to pose hazard	3	8.8
N/A	*"Smuggled" or Organic*	5	14.7
Total		34	100.0

* The 2019 WHO Hazard Classification includes Classes Ib through III above and Ia for 'Extremely hazardous', FM for 'Fumigant, not classified' and O for 'Obsolete as pesticide, not classified.'

Lu (2014) studied the health of eggplant farmers in relation to pesticide use and reported mild pesticide poisoning that concerned farmer-respondents such as skin itchiness or burning sensation, redness of the eyes, muscle pains and headaches (acute health hazards per WHO's description). All the respondents felt sick immediately after the pesticide application. Exposure to pesticide health hazards were also suspected to affect households with close proximity to the eggplant farms. Consumers of eggplant with significant pesticide residue could also be at health risks. The study suggested monitoring of such residues in the eggplant and the environment. Also

suggested is an education or awareness campaign regarding the environmental and human health impacts of pesticide use.

A very important edge of Bt eggplant over the regular Hybrid or OPV is the reduced need for insecticide application. This was achieved in GM corn as discussed above. The positive effect of reduced pesticide usage on farmers' and consumers' health may be enough motivation to adopt Bt eggplant. Quicoy (2014) estimated a 60% reduction in insecticide use with Bt eggplant.

Ex ante farm benefits of switching to Bt eggplant:
The yield data of Bt eggplant in Pangasinan obtained from the Francisco (2014) study was adjusted into a six-month season (first harvest at 60 days after transplanting and four months of harvestings thereafter) to render the data comparable to the pre-adjusted data from the virtual FGD. In addition, the following assumptions were made in order to estimate the net incremental benefits from switching to Bt eggplant. Assumptions 2.a and 3.a are borrowed from Quicoy (2014):

1. Added/Reduced Returns
    a. Difference in the value of marketable yield between Bt and current practice
    b. Farmgate price: 22.80 pesos/kg
2. Reduced Costs
    a. Sixty percent of insecticide costs (inclusive of labor) is saved with the adoption of Bt eggplant
3. Added Costs
    a. The market price of Bt eggplant seeds are twice the price of hybrid seeds.
    b. Transportation cost changes in proportion to the changes in marketable yield.

The net incremental benefits (NIB) of switching from the current practice to Bt eggplant are shown in Table 13. Low yield and high pesticide costs provide financial motivation for adoption. With that, Bt eggplant adoption is likely among hybrid farmers in Santiago (where pesticide-safe eggplant production is practiced), Aliaga, Talavera, Villasis, and Cabanatuan in decreasing order of NIB. Among the OPV farmers, Bt adoption is likely in Asingan.

The results would have been more favorable to Bt eggplant if Bt was introgressed in the more recently released elite OPV or Hybrid varieties noting that the field trials were done in 2010-2011 which means that Bt was introgressed on an elite OPV that is already at least ten years old this year. The Bt yield from the field trial data is generally lower than those of Hybrid and OPV in the current study (see Figure 22) because it is an OPV and because it is old. It is therefore recommended that the developers go back to the breeding stage and introgress Bt to the current elite OPV and if possible also Hybrid varieties.

The health benefits from low insecticide that can result from Bt eggplant can provide an additional incentive to adoption.

Table 13. Partial Budget: Incremental net benefits from switching to Bt eggplant by municipality, vFGD 2020.

Particulars	NUEVA ECIJA			PANGASINAN			ISABELA	
	Aliaga	Cabanatuan	Talavera,	Villasis	Asingan	Santiago	Ilagan	Roxas
				HYBRID (pesos/ha)				
Added Returns	150,581	-	29,974	-	-	245,176	-	-
Reduced Costs	30,367	59,567	19,683	133,771	138,995	4,400	16,683	39,813
Total Added Benefits	180,948	59,567	49,657	133,771	138,995	249,576	16,683	39,813
Added Costs	6,604	-	1,315	-	-	10,753	-	-
Reduced returns	-	57,760	-	109,573	227,978	-	142,101	147,744
Total Added Costs	6,604	57,760	1,315	109,573	227,978	10,753	142,101	147,744
Incremental Net Benefits	**174,344**	**1,807**	**48,342**	**24,198**	**(88,983)**	**238,823**	**(125,419)**	**(107,931)**
				OPV (pesos/ha)				
Added Returns					-	-		
Reduced Costs					97,863	7,680		
Total Added Benefits					97,863	7,680		
Added Costs					-	-		
Reduced returns					19,684	74,784		
Total Added Costs					19,684	74,784		
Incremental Net Benefits					**78,179**	**(67,104)**		

Support Institutions

Awareness, knowledge, and attitude towards Bt Eggplant. Awareness is a starting point and somewhat fleeting but knowledge is more durable and can better influence people's attitudes toward trying new things. During the virtual FGD, the farmers were asked regarding their awareness and knowledge about Bt eggplant and if the answer was affirmative, they were also asked if they were willing to plant and eat it. Farmers in four areas (Ilagan, Roxas, Asingan, and Villasis) were aware of Bt eggplant's built-in resistance to EFSB. All participants were interested in knowing more about Bt eggplant; their curiosity arose from hearing the purpose of the FGD. Those who were not aware at the beginning were not willing to plant and consume but once they were given an explanation about the Bt technology and the biosafety risk assessments had to go through before it can be released for planting or consumption, their decisions changed. Providing end-users with a simplified scientific explanation (in layman's language) of the development and biosafety risk assessment benefits GM crops is necessary in order for farmers and consumers to overcome the "fears" and "wrong notions" about them.

A study by Pangilinan and Bagunu (2015) that determined the perception of farmers towards GM crops in general found that farmers agreed that GM crops can be a cost-effective alternative to non-GM as it has greater yield, result in reduced soil pollution, and reduce pest control cost (with pest resistance trait conferred on GM varieties). Moreover, farmers thought that GM crops are safe to use (or as safe as the non-GM alternative) and that they are willing to cultivate and promote GM

crops. While the farmers kept an open mind to adopt and consume Bt eggplant, the same could not be said of the consumers.

The participants in the virtual FGD eagerly await for the commercialization of Bt eggplant. They even enquired how the seeds will be produced and distributed. Some of the farmers suggested for the Bt eggplant developer to work with local farmers in the production of seeds. Further, aware that their sites were chosen because they were considered the major suppliers of eggplant in the region, they hoped that it gives them an edge for the technology to be rolled out first in their localities.

Escaño (2013) pointed out that the science community relayed the information regarding Bt eggplant as a technological breakthrough emphasizing the health and income benefits to farmers, "the next gold mine", "salvation of the poor", "an achievement that could throw open the gates to a new green revolution of super crops" and "solution to food production problems." The excitement in the community fell apart when the anti-GMO moved to stop the Bt eggplant field trial in 2012. This anti group was (and still is) critical of anything GMO arguing about the potential risks it impose on human health and the environment. They cited studies published in refereed journals that apparently prove the adverse effects of GMOs to human health. Moreover, GMOs may induce the emergence of different pests and that not enough tests have been done to establish with certainty that Bt eggplant has no detrimental effects on friendly insects.

The scientists then realized the need to engage in public dialogues and speak in plain language to be understood. The information gap between the public and the scientific community cannot be made more apparent. Scientists need to adopt an effective communication strategy where the goal is not just to inform, but also to identify, connect, and engage with the public and other stakeholders (Escano, 2013).

Current Initiatives to Improve Eggplant. In the meantime that the biosafety application to commercialize Bt eggplant is held up by some regulatory hurdles, the DOST-PCAARRD is funding a five-year project called "Development of Improved Eggplant Varieties with New Plant Defense Genes for Multiple Insect Resistance Using Innovative Technologies." The project, now on its second year, is being implemented by the Institute of Plant Breeding of the University of the Philippines Los Baños (IPB-UPLB) in collaboration with the National Institute of Molecular Biology and Biotechnology of the University of the Philippines Diliman (NIMBB-UPD), Japan's University of Tsukuba, and the Southeast Asian Regional Center for Graduate Study and Research in Agriculture (SEARCA). The project is developing improved eggplant varieties using genomics, IT-based phenotyping platforms, molecular marker technologies, and new breeding techniques. It will be testing the effects of selected traits to eggplant, and one of its objectives is to develop eggplant resistance to the fruit and shoot borer (Peralta, 2018).

Key Findings—Bt eggplant benefits validation

This study has shown that eggplant farming can be a very profitable endeavor but heavy use of insecticides appeared to be necessary in order to keep production losses to EFSB in check. However, insecticide exposure, especially to highly hazardous types according to WHO classification, poses the risks of acute and chronic health problems not just to the farmers but also to consumers considering the practice to spray pesticides just before harvest and the short shelf life of eggplants so that consumer-households prefer to cook freshly harvested produce.

Results of incremental net benefits calculations favoring the ten-year old Bt eggplant over the current hybrid and OPV varieties are promising as they are but could be much better if Bt is introgressed to more recently released varieties that are definitely better performing than the elite varieties from ten years ago. This is likely already in the consideration of the developers.

The current study found that it is clear to the farmers' minds that there are risks related to the overuse and apparent prophylactic applications of insecticides to control EFSB and other pests in eggplant, however, the long-term health impacts of prolonged insecticide use are not clear to them. The study echoes suggestions of previous studies (Lu, 2014) to include in farmer training the deleterious consequences or effects of insecticide use, especially those falling in WHO category I and smuggled types sold in the market, to human health and the environment. These activities could be included in the training programs of the local agricultural offices and local health centers in partnership with the private sector.

IV.2 Current Status of Crop Biotechnology Policies

In this section, the status of policies relating to the development and regulation of biotechnology crops is discussed for the Philippines and then relative to other advanced countries including Argentina and then relative to the SEA countries.

IV.2.1 Status in the Philippines

The 2009 National Policy Statement[23] is clear — the country encourages the development of products using modern biotechnology methods and tools but not without regulation to ensure the safe and responsible use of the technology and its products. Development and regulation are like the bride and the groom in a marriage, without one or the other there can be no marriage or the existence of one is predicated on the other. The following provides an account of the status of crop biotechnology development and regulation in the country.

Public Institutions with Biotechnology Research Mandates

UPLB-BIOTECH is mandated to take the leadership in biotechnology research and development by virtue of LOI 1005 (1980) in addition to its original mandates of developing cost-effective and environment-friendly technologies to produce goods and services that are comparable or better alternatives to conventional products for use in the following sectors: agriculture, environment, energy and industry the year prior.

UPLB-IPB is mandated to lead crop biotechnology research by virtue of RA 7308 (1992) in addition to its original mandates when it was created in 1975.

UPLB-IPB entered into a USAID-funded project called Agricultural Biotechnology Project II with Cornell University in 2003. Three biotech crops were targeted for development — fruit and shoot borer resistant Bt eggplant, ringspot virus resistant PRSV-R papaya, and multiple virus resistant MVR tomato. The multi-location trial for Bt eggplant was completed in 2012 but it experienced a setback in 2012 due to oppositions from various local and international anti-GMO groups. Development of PRSV-R papaya between 2014-2017 also experienced a setback. These will be further elaborated below.

PhilRice. The PhilRice in partnership with IRRI has recently developed beta-carotene biofortified rice called Golden Rice GR2. It passed the application for field trial and application food, feed or processing in 2019.

[23] Promote the safe and responsible use of modern biotechnology and its products to achieve food security, equitable access to health services, sustainable and safe environment, and industry development.

PhilFIDA. As of March 2020, the Philippine Fiber Industry Development Authority awaits the approval of Bt Cotton for commercial propagation.

DOST-PCAARRD & DA-BIOTECH. As the frontiers of science are explored, these agencies invest in basic crop biotech R&D in genome editing that employ site-directed nuclease technology — SDN-1, SDN-2 and SDN-3. DOST follows the genomics-biotechnology roadmap for years 2017-2022 and DOST-PCAARRD's research portfolio includes about PhP77.22 billion in genome editing projects that are currently being undertaken in various universities. DA-Biotech funded just this year the first gene editing project for rice at PhilRice.

Private Institutions involved in Crop Biotech Research

Also in 1997, the first GM corn developed by Monsanto was approved for multi-location trial and by December 2002, this first GM crop, Bt Corn was released for commercial cultivation. From then on, other private companies joined the bandwagon. To date, there are at least 57 GM corn varieties registered to Monsanto, Pioneer, and Syngenta among others (Appendix H).

Status of GM Crops Under Development

Genetic engineering is a type of genetic modification that involves the purposeful addition of a foreign gene or genes that contain the targeted trait to the genome of an organism. It is the process of removing a gene fragment from one organism and transferring it to another. Thus the development of GM (or transgenic) crops start with the extraction of the full DNA from the donor organism. Cloning or separating the gene fragment of interest from the DNA and making thousands of copies of it follows. Then the genetic engineer designs a modified gene so that it would be able to do its job once inside the recipient organism. This is done in a test tube by cutting and replacing genes with enzymes. Tissue culture is used to propagate masses of undifferentiated plant cells called callus. The modified gene is inserted into some cells of the callus by various means. The transformed plant cells are regenerated to transgenic plants, these plants are grown to maturity and allowed to produce seeds. The genetic engineer has completed the job and turns over the transgenic seeds to a plant breeder who then performs a series of backcross breeding to confer the transgenic traits to popular or elite crop varieties . The resulting plant will yield potential very close to the elite variety that expresses the trait encoded by the transferred gene.

Regulation of GM begins with the extraction or importation of the foreign DNA or cloned DNA fragment to cloning, gene design and transformation through an application for contained use (laboratory, screenhouse, glasshouse or greenhouse). The proposal to import and safety protocols to be implemented during the research are provided by the developer to the NCBP or the DOST-BC.

It is encouraging to note the volume and diversity of applications towards the development of GM transgenic) crops that were approved by DOST from 1991 through 2020 (Table 14).

Table 14. Approved applications for contained use and confined test by the DOST, Philippines, 1991—2020.

	Under NCBP 1991-Mar 2002 (EO 430)	Under NCBP Apr 2002-2008 (AO-8)	Under DOST-BC 2009-2015 (AO-8)	Under DOST-BC 2016-2020 (JDC-1)
		Contained Use*		
Number approved	88	55	35	17
Num. approved/yr	9	7		4
Crops	Banana, Coconut, Corn, Mushroom, Papaya, Mango, Rice, Tomato	Abaca, Banana, Corn, Eggplant, Papaya, Rice, Sweet Potato, Tomato	Rice, Corn, Papaya, Tomato, Sweet potato, Squash	Rice, Eggplant, Coconut
Institutions	UPLB, DA-CODA, DA-PhilRice, DA-PCA, IRRI, Dole Philippines, Sudaco, Pioneer Hi-Bred	UPLB, MMSU, UP-Mindanao, DA-CODA, DA-PhilRice, IRRI, CIMMYT, Monsanto, Pioneer, Syngenta	UPLB, UP-Mindanao, VSU, DA-PhilRice, IRRI, Syngenta, Pioneer Hi-Bred	UPLB, DA-PhilRice, IRRI
		Confined Test		
Number approved		4	16	7
Crops		Eggplant, Papaya, Rice, Corn	Rice, Corn, Cotton, Papaya	Rice, Coconut
Institutions		UPLB, IRRI, Pioneer Hi-Bred	DA-PhilRice, UPLB, DA-CODA, IRRI, Pioneer Hi-Bred	DA-PhilRice, UPLB, IRRI

* Laboratory, Glasshouse, Screenhouse or Greenhouse
Source: http://dost-bc.dost.gov.ph/approvedexperiments

Bt Eggplant. A major pest of eggplant is the Eggplant Fruit and Shoot Borer (EFSB), an insect that feeds exclusively on eggplant and may account for about 80% of yield loss. The larva of the insect bores inside the fruit, making tunnels which renders the eggplant fruit unacceptable for marketing and consumption. The use of chemical insecticide to control EFSB can be employed, but the method imposes environmental and health risks as it also jacks up the production costs.

A biotechnology solution is the development of Bt Eggplant or Bt Talong. The development of Bt Talong in the Philippines was initiated by a private-public partnership. The Maharashtra Hybrid Seed Company (Mahyco) partnering with public research agencies in the Philippines, India, and Bangladesh was made possible by the Agricultural Biotechnology Support Project II (ABSP II) of Cornell University and USAID (Shelton, 2017). This partnership aims to create a “pro-poor” channel for the distribution of open-pollinated lines for the farmers while also establishing a commercial channel where the hybrid varieties can be sold at a higher price. It is a synergistic

collaboration aimed to facilitate the development and delivery of a research product, i.e., Bt Talong to the poor. The transition of biotechnology product development to commercialization and entry in the Southeast Asian market is facilitated by the IPB as the Southeast Asian Regional Coordination Center.

Bt Talong contains a gene from *Bacillus thuringiensis* that confers resistance to lepidopterous pests such as EFSB. Research started in 2003, confined trials completed in 2009, and multi-location trials approved and completed in 2012. During the field trial in UPLB, it was vandalized by an anti-GMO group in 2011. The conflict reached the Supreme Court which decided in favor of the anti-GMO in 2015. Although such a decision was overturned in 2016, it deterred the developer from applying for commercial propagation. Following the strategy of Golden Rice (to be discussed below), Bt Talong applied for direct use as food, feed and processing (FFP) in September 2020.

Bt Cotton. The Bt Cotton research is spearheaded by the Philippine Fiber Industry Development Authority (PhilFIDA) to answer the industry's problem on bollworm infestation (*Heliothis armigera*). Currently, all cotton needed by the local textile industry is imported (Asis, 2017). Our dependency on the importation of cotton is expected to turn around once the Bt Cotton is approved for commercial propagation in the country. The greenhouse evaluation was already completed in 2010, the confined field trial tests in 2011 and the multi-location field trials in 2015. As of 2018, the plan was to source the Bt Cotton seeds from India as part of the application for commercial propagation in the country (Arcalas, 2018).

PRSV-R Papaya. A major limiting factor in the papaya industry is its susceptibility to Papaya Ring Spot Virus (PRSV). A variety of papaya totally resistant to the virus was developed by IPB. The project received domestic funding from the DOST-PCAARRD and international support from the USAID through the Agricultural Biotechnology Support Project II (ABSP II) and EMERGE (Yorobe, n.d.). It completed its first field test in 2014 and onto the second trial in 2017 but it stopped because of a setback. Instead the F1 hybrid is backcrossed to the transgenic line. Preparations for the confined trial and varietal registration are underway.

Golden Rice. Golden Rice is a transgenic crop infused with genes from maize and a soil bacterium, allowing the grains to produce beta carotene. The development of Golden Rice was spearheaded by the International Rice Research Institute in partnership with the Philippine Rice Research Institute (PhilRICE). The project was supported by Bill and Melinda Gates Foundation, the Rockefeller Foundation, USAID, and the DA Biotechnology Program. In February 2017, PhilRICE applied for confined field trials for environmental biosafety risk assessment. Public consultation for the field trials were held in July 2018. The multi location field trials were conducted in Munoz, Nueva Ecija and San Mateo, Isabela in September and October 2019, respectively. Golden Rice was approved for direct use as FFP in December 2019 as the crop proved to be as safe as

conventional rice. The approval for commercialization of the crop is next. Golden Rice is deemed as a dietary solution for the people suffering from micronutrient malnutrition caused by Vitamin A deficiency.

GM Corn. Currently, only GM Corn is commercially propagated in the Philippines, with 658,267 cultivated from March 2018 to February 2019. The development of the GM Corn started in 1996 under a collaborative study of UPLB-IPB and Pioneer Overseas Corporation (APAARI, 2019). At the time, the event MON810 was already proven effective against European Corn Borer (*Ostrinia nubilalis*) so its efficacy was to be tested on the Asiatic Corn Borer (*Ostrinia furnacalis*). A contained efficacy trial in August 1996 confirmed the effective protection of MON810 against ACB. However, the material used in the trial was for a temperate climate. Another successful efficacy trial, this time using a tropical material, by Cargill Philippines, Monsanto's subsidiary, gave rise to MON819. The confined testing of MON819 by Agroseed (formerly Cargill) in General Santos and South Cotabato followed. After a two-season multilocation field testing in 2001, the first GM crop was approved for commercial propagation in 2002. Since then, more transformation events in corn were accomplished by the private companies and given biosafety permits. Most of the recent varieties have stacked traits, a combination of Bt (insect resistance) and HT (herbicide tolerance).

Status of Gene-edited Crops Under Development

The list of gene editing projects of PCAARRD is listed in Table 15. There are only two projects on gene editing, both started in 2018 and are still ongoing. The project entitled "Targeted Genome Editing using CRISPR-Cas9 Technology: Capacity Building and Proof-of-Concept in Rice, Corn, and Tomato" applies the latest genome editing technology, CRISPR-Cas9, on rice, corn and tomato.

Table 15. List of gene-editing projects funded by PCAARRD.

Project Title	Source of Funds	Implementing Agency	Total Project Cost, PhP	Start Date	End Date
Targeted Genome Editing using CRISPR-Cas9 Technology: Capacity Building and Proof-of-Concept in Rice, Corn, and Tomato (Old Title: Application of CRISPR-Cas9 Genome Editing Technology Towards Improvement of Economically Important Philippine Crops)	PCAARRD GIA	UPLB	40,550,717	01-Jul-2018	30-Jun-2021
Development of Improved Eggplant Varieties with New Plant Defense Genes for Multiple Insect Resistance using Innovative Technologies	PCAARRD GIA	UPLB, UPD	36,668,412	01-Jul-2018	30-Jun-2023

PhilRice with funding from DA-Biotech initiated a project in 2020 to improve rice through gene editing. Using CRISPR/Cas9 tools it targets to edit the genes in selected popularly grown rice varieties for resistance to tungro and bacterial leaf blight and also for grain amylose content[24].

Institutions Involved in Crop Biotechnology Regulatory Policy

Lending from Sec. 3.3.12 of the NBF, the JDC-1 defines regulated articles to pertain to genetically modified organisms and its products. Currently, these are institutions involved in the regulation of biotech crops under the JDC-1.

NCBP to date is mandated to formulate, review, amend the biosafety guidelines.

DOST-Biosafety Committee processes applications for Contained use and Confined Test and issues Certificate of Completion.

DA-BPI and DA-BC: consolidate and evaluate the risk assessment reports. The BPI Director finally issues Biosafety Permit for applications for (Multi-location) Field Test, Commercial Propagation, and Direct Use for food, feed or processing

Risk assessments and registration are done by the following national departmental agencies.

1) DENR: conducts risk assessment for impact of biotech crops on the environment
2) DOH: conducts risk assessment for the impact on of biotech crops as food on human health
3) DA-BAI: conducts risk assessment for the impact of biotech crops as feed on animals
4) DA-FPA: Registration of PIP

Challenges under the current system: The JDC-1

High regulatory compliance costs. Regulating the development and release of transgenic GE crops is costly to the developer, to the government regulators and possibly to the society (Table 16). For one, it imposes a direct and real cost to the developer, i.e., the costs of acquiring regulatory knowledge and operating laboratory, greenhouse, field confinement structures, and equipment that would have not been necessary otherwise. For plant-incorporated-protection (PIP) GE traits, imposing refuges cost both the farmers (in terms of forgone income) and developers (cost of training farmers, monitoring efficacy, and reporting to the IRM committee). Secondly, the government institutions that design the guidelines through the issuance of EOs, AOs, and JAOs, provide local or international technical training to staff, administer, certify, legislate , enforce, and even litigate—bear the costs of such. Finally, the regulatory delays and long-term disincentivizing effect of regulation on investment in GE crop research and development impose a cost to the society in terms of the gains or benefits that could have accrued to farmers and consumers had the safe, supply-increasing and price-reducing GE crop technology been made

[24] According to Dr. RT Ordonio in his presentation given at the Webinar on Gene Editing, 24 November 2020 in celebration of the 16th National Biotechnology Week.

available to them without delay. The snail pacing Gene Revolution being unable to swiftly address food security in comparable speed with its predecessor may have been caused by overregulation.

Biosafety regulation is governed by liability rules which means that transgenic crops are regarded as risky to human health and the environment until the developers are able to prove otherwise. No transformation or importation of genetically modified organisms can be done without first applying for “biosafety permits” to do so. Step-by-step, from the transformation events done in laboratories to greenhouse tests to multi location field trials and onto the release of transgenic crop varieties, the burden of proof that such processes and the eventual end products are safe rest on the shoulders of the developers—private firms and public research institutions alike. The government, on the other hand, bears the burden of putting up a reliable science-empowered regulatory body and an efficient, effective, and trained personnel in each of the agencies involved in enforcing the regulations, making sure that rigorous yet necessary risks assessments are done to the mark.

Table 16. Cost of biosafety regulations in the Philippines.

Cost borne by	**Details**
Compliance cost by technology developers private firms and public research institutions	Cost of acquiring regulatory knowledge or generating data to fulfill risk assessment requirements
	Construction, operation, and maintenance of: laboratory facility, greenhouse, field confinements and equipment not done otherwise
	Income loss to farmers and enforcement costs to PIP GE crop developers from placing a refuge system in compliance with IRM
Regulatory costs by government institutions involved in regulation	Penning EO, AO, JAO or legislating bills
	Writing guidelines, monitoring, and reporting
	Providing local or international technical training to staff
	Administering
	Issuing biosafety permits
	Enforcing
	Litigating
Welfare loss borne by the society	Benefits that could have accrued to farmers and consumers had transgenic GE crops been made available.
	Delays and disenchanted investments hinder achieving food security and agricultural development goals.

Source of basic idea: US Environmental Protection Agency as presented in Pray et al., 2006

Majority, if not all, of these developers experienced difficulties in complying with the requirements under the strict biosafety guidelines and the lengthiness of the process (Mendoza et al., 2009). There are also too many agencies involved in the risk assessments and a lack of dedicated, regular and trained staff in these agencies. These could explain why it is almost impossible to achieve the 85-day biosafety permit processing period for multi-location field trials, commercial propagation, and direct use. Processing times can easily turn from 85 days to years. Compliance in itself is already burdensome and any inefficiency adds to the burden. These costs can be debilitating to small private firms and public research institutes and discourage innovations altogether.

Bayer et al. (2010) estimated the costs of compliance with biosafety regulations for four transgenic crops that were under development in the Philippines during the time of the study. These are Bt eggplant, multiple virus resistant or MVR tomato, Bt rice and papaya ringspot virus or PRSV-resistant papaya. It has been 10 years since the publication of this study yet none of these transgenic events had been commercialized although one of the four, Bt eggplant, may be released in 2021. Another transgenic crop also expected for release soon is Golden Rice GR2 which was not covered in the Bayer study. The main findings of this study are:

1. Processing of regulatory applications is long, 5-8 years;
2. The costs of compliance are almost as much as if not higher than R&D costs. The estimated ratios of R&D costs to regulatory costs are: 47-53 for Bt eggplant, 48-52 for multiple virus resistant (MVR) tomato, 56-44 for Bt rice, and 37-63 for papaya ring spot virus PRSV) resistant papaya. The R&D costs for these crops at 2010 prices are $420,000 for Bt eggplant, $434,000 for MVR tomato, $889,000 for Bt rice, and $148,000 for PRSV papaya;
3. When long term valuations are done over a "varietal development and useful life" of 20 years at 5% discount rate, the net present value was found to significantly decline with delays in the approval and not affected by the increase in the compliance costs. However, when funds are sparse and dependent upon the "generosity" of donors, the magnitude of costs could be enough to kill the project.

Long Delays—Causes. During the first meeting of the TWG for JDC-1 review in June 2019, Mr. Abe Manalo presented the results of his investigation involving the biosafety permit applications for food, feed or processing. Under the JDC-1, processing of such applications should take 85 days only (see Figure 7). A total of 56 approved applications from years 2016-2018 were traced back for delays by looking at the number of days each of the applications spent at each layer of regulation. Under JDC-1, each regulator (STRP, PPSSD, DOH, DENR, SEC expert, and BAI)[25] is concurrently given 30 days to complete the risk assessment or evaluation but actual durations were 2.4 times to 9.3 times much longer. After completing these evaluations, the BPI writes a recommendation to the DA Biosafety Committee. DA-BC makes a final review and sends its approval advise to the BPI Director who then issues/denies a biosafety permit. The DA BC is given 10 days but the average actual number of days was 155 so it was basically 15.5 times longer. The study collated the following recommendations for the developers (basically private companies):

1. Strict adherence to the specified lead times;

[25] STRP-Scientific Technical Review Panel, PPSSD-Plant Product Safety and Services Department, DOH-Department of Health, DENR-Department of Environment and Natural Resources, SEC-Socio Economic Consideration, BAI-Bureau of Animal Industry.

2. Further capacitate the DA-BAI on modern biotechnology principles and techniques and GM feed safety evaluation;
3. Review the role of DA-BC in the process flow and avoid redundancy in the technical evaluations of CNAs and STRP;
4. Streamline the review process—for example, work by ad referendum;
5. Registration of breeding stacks for FFP once single events have been individually approved, similar to to US, Canada, Japan and others;
6. Deregulation of single events for FFP with (10 years?) history of safe use; and
7. Finalize and issue the Manual of Operations.

Two root causes of the problems above are the lack of dedicated full-time and trained personnel and sustained budget to finance the regulatory operations so the assessments can become the primary job and not something being just squeezed in.

GMO oppositions. The actions of anti-GMO groups strongly influenced the biosafety regulations of the Philippines. Their acts of vandalism against Bt corn field trials in 1997 shocked the scientists but this was minor compared to the legal pursuit against Bt talong in 2012 that eventually led to a frozen period for GM research activities and GM trade. and the crafting of a more stringent regulatory system (JDC-1) to replace the one (DA-AO8) the Supreme Court ordered to cease and desist. The Supreme Court suggested a legislated regulatory body to overcome the vulnerability to legal challenges.

GM seed counterfeiting. Another issue to the developers of GM corn is the prevalence of fake GM corn seeds. Counterfeit GM hybrid and GM OPV were reported in Regions II and X, respectively. The developers have sought the BPI regarding this problem. What laws cover GM seed counterfeiting? The Intellectual Property Rights law excludes seeds. The two seed laws—SIDA and PVPA—are old and do not cover GM let alone hybrid seeds. The private companies also argue that farmers' purchase of counterfeit GM is bad not just for their business but also for the corn farmers' income, corn supply, and insect management resistance.

Innovations in breeding science. This is more of an opportunity than a challenge. There are plant genome projects being undertaken under PCAARRD funding that can potentially release biotech but non-transgenic varieties in the next 3-5 years provided that reforms in the regulation are made to delineate or distinguish non-transgenic products of genome editing from the transgenic products developed through rDNA methods. There is a great opportunity to boost crop production with the varieties developed using the new tools or plant breeding innovation. The challenge is fast tracking the reforms so that regulations are based on the products and not the process of genetic modification.

IV.2.2 Status Among Advanced Countries

This section presents the regulatory policies and approaches for the countries of Argentina, Australia, Canada, European Union (EU), Japan, and the United States. They were chosen because of the extensive available literature about their regulatory policies and approaches. A brief description of their GM regulatory system and treatment of the products of NBTs are presented. These same countries were studied by Dederer and Hamburger (2019) for a comparative analysis of regulatory frameworks since the countries cover a wide range of attitudes towards GM plants. Argentina, Canada, and USA are supportive of GMOs, Australia and Europe are reluctant, while Japan is an absolute abstainer of GM cultivation.

In the review of the regulations, the following aspects are discussed: a) the key policies that established the regulatory systems of each country, b) the relevant departments or agencies implementing the regulations, c) the sources of technical expertise in the regulation, and d) the responses or efforts in the regulation relevant to NBTs. Furthermore, the regulatory trigger used by the countries is extracted from their corresponding policies and was determined whether it would fall as a product-based or product-based trigger.

Regulatory systems utilize triggers in order to sort the products that are risky and, consequently, should be captured by the regulation. The trigger is essentially the point of entry into regulation. Triggers may be in the form of a definition (e.g., GMO definition), a list where it would enumerate the techniques that would automatically be subject to regulation, or an exempting criterion (e.g., SECURE Rule of the USDA-APHIS), depending on how the policy of the country was designed. The more important aspect to consider is whether the trigger is product-based or process-based. A product-based trigger investigates the characteristics of the final product in determining its regulatory status, while a process-based trigger considers the technique or process used to create the product.

European Union (EU)

The Regulatory Framework of EU was established through multiple directives. Directive 90/219/EEC and Directive 90/220/EEC pioneered the regulation of genetic engineering activities, dealing with the contained use of genetically modified microorganisms, and environmental release of genetically modified organisms (Schauzu, 2013). In 2001, Directive 2001/18/EC replaced Directive 90/220/EC, setting forth the procedure for approval of GMO release into the environment or market, in which the EU Member States are required to comply. Meanwhile, Regulation (EC) No. 1829/2003 governs the authorization for food and feed (Schauzu, 2013). GMO authorization applies a “one door, one key” approach, where only one application is required to be submitted in order to obtain authorization for cultivation, food and feed. In 2003, the EU signed and approved the Cartagena Protocol to be incorporated in their regulation. The Regulation 1946/2003/EC was

established to address the transboundary movements of GMOs, aligning with the provisions in the Cartagena Protocol.

The responsibility for authorizing field trials is given to member states alone, whereas the authorizations for cultivation, for food and feed uses, and for import are done both at the member states and EU levels (Eckerstorfer et al., 2019). Technical expertise comes from the European Food Safety Authority (EFSA) where a Scientific Committee and Scientific Panel is appointed. External Experts are also sought on an ad hoc basis for contributions on the EFSA work (EFSA, 2017).

The GMO definition is used in the regulation for both cultivation and food uses. Directive 2001/18 defines GMOs as “organisms in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination” (Papademetriou, 2014). The trigger for regulation is the characteristics of the method used to induce the genetic alteration; thus, regulation is process-based.

As regards the regulation of NBTs, the ruling of the Court of Justice to the European Union (CJEU) in July 2018 determines that site-specific, directed mutagenesis techniques such as Zinc-Finger Nucleases (ZFN), Transcription activator-like effector nucleases (TALENS), and Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) are covered by the existing legislation (Voigt and Münichsdorfer, 2019). The exemption of mutagenesis methods does not apply to directed mutagenesis since their accompanying risks might prove to be similar to GMOs from transgenesis and will not be aligned with the precautionary principle applied in the EU legislation (Eckerstorfer et al., 2019). Exemptions will only be applied if the technique has a long history of safe use in a conventional manner (Wasmer, 2019). The ruling of the Court of Justice of the European Union (CJEU) in 2018 implies that the direction of NBT regulation in EU will take the process-based approach and will likely influence the decisions for emerging techniques as well (Eckerstorfer et al., 2019). Currently, all NBTs will be regulated in the EU.

United States (US)

The Coordinated Framework of the Regulation of Biotechnology published in 1986 by the White House Office of Science and Technology Policy governs the regulation of biotechnology products in the United States (Lassoued et al., 2020). Responsibilities for regulatory assessments are divided into three agencies: the USDA-APHIS for ensuring the safety of crops for environmental release (including field trials), interstate movement, and import, the EPA for ensuring safety to the environment of crops with plant-incorporated protectants, and the FDA for ensuring safety of consumption of food and pharmaceuticals (Lassoued et al., 2020; Eckerstorfer et al., 2019; Grossman, 2019).

The United States does not use a formal definition of GMOs as a regulatory trigger, but instead base the regulatory jurisdiction on the intended use of the product and the product-specific risks. The USDA's Animal and Plant Health Inspection Service (APHIS) regulates GM plants through the "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests" of the Code of Federal Regulations, which will be referred to as the "USDA-APHIS regulations" for simplification. By virtue of the USDA-APHIS regulation, organisms which have been "altered and produced through genetic engineering" and if the recipient or source organism, or the vector used in the genetic alteration, is found to be a plant pest (Grossman, 2019). Plants resulting from conventional breeding methods are only regulated if they exhibit the qualities of a plant pest.

On the other hand, the US Food and Drug Administration (FDA) regulates food that are adulterated, which is indicated by the presence of "poisonous or deleterious" added substance, or an unsafe additive (Grossman, 2019). This means that the food regulation just focuses on the safety of the food product, irrespective of the method used to create the food.

The response to NBTs came in the form of amendments to the existing USDA-APHIS regulations. The update was prompted by the Executive Office of the President (EOP) in 2015, who directed the responsible federal agencies for regulation - the USDA, EPA, and FDA- to update the Coordinated Framework in preparation for the future biotechnology products (Lassoued et al., 2020; Eckerstorfer et al., 2019; Grossman, 2019). On May 18, 2020, the USDA published the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule that revises the APHIS' regulation of genetically engineered plants, which was the first significant revision of the regulation since 1987. The rule entered into force last August 17, 2020.

The regulation for gene editing is set forth by the USDA's SECURE Rule, which establishes the exemptions in regulation for plants, as well as rules for regulatory status review and permitting. In the previous regulation, regulatory oversight depends on the use of plant pest in the development, in which removing regulatory oversight for genetic engineering products unlikely to pose a plant pest risk is time-consuming. The new rule speeds up the regulations by focusing on the properties of the product rather than the use of plant pests .

The SECURE rule exempts plants with single modifications harboring the following changes: (a) a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or (b) a targeted single base pair substitution; or (c) introduction of a gene known to occur in the plant's gene pool, or a change in a targeted sequence to correspond to a known variation of such a gene. These exemptions were formulated considering that the plants are "unlikely to pose an increased plant pest risk compared to conventionally bred plants" (Congressional Research Service, 2020). Based on the exemptions, SDN-1 will not be regulated, and SDN-3 will be regulated if the insert is foreign.

Canada

The policies governing the regulation are based on the specific product, namely the Seeds Act for plant varieties and the Food and Drugs Act for products for human consumption.

In Canada, all seeds to be used in unconfined cultivation and not cultivated before December 1996 will automatically need a notification and authorization. Additional requirements will be imposed if the product is a plant with novel trait (PNT) (Smyth, 2019). The Seeds Act, administered by the Plant Health and Biosafety Directorate of the Canadian Food Inspection Agency (CFIA), specifies the criteria to be used for determining novelty. Under Part V of the Seeds Act, a plant has a novel trait if the trait intentionally introduced is new to the stable cultivated populations of the same species in Canada and has the potential to affect the specific use and safety of the plant with respect to the environment and human health (Shearer, 2014). Such criteria include the weediness potential, gene flow, plant pest potential, and potential adverse effects on non-target organisms and biodiversity (Smyth, 2019; Eckerstorfer, 2019). The technology or process used to create the product is irrelevant in determining the regulatory status.

For food regulation, the novel food definition is used. Food coming from a genetically modified plant, animal, or microorganism that: a) exhibits characteristics it didn't before, b) no longer exhibits characteristics that are previously present, and c) one or more characteristics of the organism no longer falls within the anticipated range for that organism (Canadian Food Inspection Agency, 2020). Additionally, novel foods also cover food that have no history of safe use as a food. In contrast with the PNT criteria, there is a GMO component in the novel food definition.

Once novelty is determined, a pre-market assessment for the products will be required by the regulators (Friedrichs et al., 2019). The product developers are responsible to determine if their product qualifies as novel, but the final decision on the novelty rests on the regulators. Developers can undergo pre-submission consultations to discuss with regulators about the submission content and the regulatory requirements (Shearer, 2014).

Technical expertise can be found across the different regulatory departments for product assessment (Ellens et al., 2019; Flint et al., 2000). Government researchers may also be tapped for conducting safety assessments.

There were some policy challenges arising from genome editing. Canada is currently conducting consultation and feedback procedures to address the identified challenges (Friedrichs et al., 2019). The PNT trigger will still apply

Australia

The 2001 Gene Technology Act (GTA) of the gene technology regulatory framework enforces the GM regulation in Australia. Each state then provides for a legislation mirroring the Act (Ludlow, 2019). The GTA also establishes the Gene Technology Regulator (GTR), which holds power over the regulatory legislations of each state, contributing for a consistent gene technology regulation in

Australia (Duensing et al., 2018). Its office, the Office of the Gene Technology Regulator (OGTR), is responsible for field trials and commercialization of GM plants (Heinemann, 2014). Risk assessments are done by the Gene Technology Technical Advisory Committee, where 20 scientific experts are appointed part-time. External advisers are also appointed for scientific advice, whether on a continuing or ad hoc basis.

Australia uses two separate criteria for regulating different product uses: the GMO definition for cultivation and the Gene Technology definition for food use. In the GTA, GMO is defined as (a) an organism modified by gene technology, (b) an organism that has inherited particular traits from an organism in which the traits are from gene technology, or (c) anything declared by the regulations to be GMO (Ludlow, 2019). The Act also provided exceptions from the GMO classification, pertaining to an organism that has undergone mutation where no foreign nucleic acid was introduced. Gene Technology is also defined as any technique for gene modification, excluding sexual reproduction, homologous recombination, or any other techniques specified in the regulations, such as natural mutagenesis, and mutagenesis induced by electromagnetic radiation, particle radiation, and chemical radiation (Ludlow, 2019). For food regulation, the Gene Technology definition is also used. Based on how Gene Technology was defined, it is essentially similar to the definition of GMO for cultivation except that there is no reference specifying for the progenies (Ludlow, 2019). In general, the regulation follows a process-based approach based on the use of gene technology.

The 2019 amendment of the GTA gave clarification to the classification of genome-edited products but still retained the process-based approach leveraging on the use of templates in the process. Genome modification without templates (or SDN-1) would not be regulated as GMOs, while SDN-2, SDN-3, and ODM would be regulated (Friedrichs et al., 2019). If intermediate GMO products occur during the process, the final product would be classified as non-GMOs if no guide template was involved in inducing the genome repair, and if there are no modifications left in the resulting organism as a result of the gene technology (El-Mounadi, 2020). Organisms modified using RNA interference (RNAi) techniques are not regulated if the genome cannot be changed by the technique, and if the introduced RNA cannot be translated to proteins or infectious agents.

This update to the regulatory oversight relies on the equivalence of risks imposed by these techniques with respect to natural mutations, while also considering that the detection of the products will be difficult since they are almost indistinguishable from naturally-occurring mutants (Office of the Gene Technology Regulator, 2018). The regulation of SDN-2 and ODM is based on the possible occurrence of substantial changes from successive rounds of modification, which could be addressed through exclusions based upon product features, but that would oppose the process-based definition of GMO in the GTA. Therefore, amendments opted to regulate the whole techniques themselves.

Japan

Japan acceded the Cartagena Protocol in 2004, which led to the enactment of the Cartagena Law: The Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Tsuda et al., 2019). The Cartagena Law defines Living Modified Organisms (LMOs) as “an organism that possesses nucleic acid, or a replicated product thereof, obtained through use of Modern Biotechnology.” The presence of an inserted nucleic acid in the final product triggers the regulation for both cultivation and food use, indicating a product-based approach.

Organisms to be subject to controlled field tests will have to undergo application under the Ministry of Education, Sports, Science, and Technology (MEXT), the Ministry of Agriculture, Forestry, and Fisheries (MAFF), and the Ministry of the Environment (MOE). The MAFF and MOE conduct consultation with scientists for safety approvals (Ebata et al., 2013). LMOs to be assessed are first categorized into either Type 1 or Type 2 groups. Type 2 involves the contained use of LMOs with the prevention of their dispersal to the environment, while Type 1 involves the open use of LMOs which can be for field trials, commercial cultivation, import, and distribution (Ebata et al., 2013).

An Expert Committee was created to discuss the regulatory status of genome edited products. The outcome of the meetings, which materialized into a report, was provided feedback by the public and government advisory bodies. The Japanese Ministry of Environment decided that organisms made using gene editing without an inserted foreign DNA will not be considered as GMO, indicating a product-based approach. Cases where the integrated DNA was crossed out and absent from the final product will not be subject to regulation (Tyagi et al., 2019). The final products of SDN-1 methods will not create a GMO, while products of SDN-2 and SDN-3 are classified as GMOs (Tyagi et al., 2019).

Argentina

The Argentinian regulatory system is governed by Resolution 701/11, which is aligned with the definitions provided in the Cartagena Protocol (Whelan and Lema, 2015). The definition of GMOs and biotechnology in the resolution is identical with the definitions in the CPB. GMOs were stated as: “any vegetable organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.”

Each application is assessed on a case-by-case basis, where each transformation event is treated individually. The regulation defines transformation events as “the insertion in the plant genome in a stable and joint arrangement, of one or more genes or DNA sequences that are part of a defined gene construct.” Applications involving stacked events, where two or more events are inserted in the same genome, must undergo a separate assessment and authorization procedure. Technical assessment and advise for approval of GMOs is provided by the CONABIA, where representatives from the academia, public-, and private sectors comprise the committee (Flint et

al., 2000). The CONABIA has already reviewed more than 1500 applications and is continuously developing capacities as necessary (USDA-FAS, 2016).

Argentina issued the Resolution 173 of 2015, which makes the country the first to enact a regulation for products of NBTs. The resolution does not modify but clarifies instead the fate of NBT products in the regulation (Lassoued, 2020). It states that regulation depends on the presence of novel combinations, which can be described as the permanent introduction of a genetic construct into the genome (Friedrichs, 2019; Whelan and Lema, 2019). Developers can also consult about the projected regulation of the hypothetical product during the design stage, which the decision for the assessment can be obtained within 60 days. Upon completion of the product and submission of molecular biology studies on the actual modification, the decision will be retained if the product remains the same as with the preliminary inquiry (Whelan and Lema, 2019). As of June 2018, most applications out of the 12 requests for regulatory status of NBT applications, were ruled out of the Argentinian regulation.

Whelan et al. (2020) explored the effects of the above product-based NBT regulatory criteria on the pattern of R&D in biotech, specifically on what can be regarded as the economic profile of innovations. The study reports a change from what used to be dominated by multinational companies to a more diverse group of developers led mostly by small and medium enterprises (SMEs) and public research institutions. Moreover, the product profiles are more diversified in terms of traits and organisms.

Thematic analysis

The regulations adopted across the countries reviewed are quite diverse in terms of regulatory approaches, however, there were some regulatory tools or practices found to be common among them . The aim of this section is to compare the Philippines with countries that have advanced regulatory system and draw some insights for regulatory reform. Table 17 summarizes these similarities and differences.

Regulatory Trigger. The first comparison is on the type of entry point or trigger in the regulation. A product-based regulation seems to be the common theme among the countries embracing GMO cultivation such as Canada, Argentina, and United States. Based on the accumulated scientific evidence and experience with GMOs, the risk potential is dictated by the characteristics of the product and not the process used (Sprink et al., 2016; Duensing et al., 2018). Furthermore, similar products can now be created using different techniques, and it would be inconsistent these products are subject to varying regulatory scrutiny (Marchant and Stevens, 2015). Thus, a product-based trigger is more appropriate for a scientifically-sound, risk-based, and consistent regulation.

Plant-trait-mechanism of action combination. A product-based approach allows the consideration of the plant-trait-mechanism of action combination in determining regulation, which is being

practiced by US and Argentina, and in part by Canada. The established knowledge and experience from the previously done successful assessment or approved applications can be applied to new applications with a similar combination, reducing the data requirements for the new application which consequently lowers the cost for the applicant (Beker et al., 2016). There can be two possible scenarios in which the similarity of the combination can be considered: a) both the approved and the new application that have a similar combination are single, independent events ($x^{approved} = x^{new}$), and b) the approved application is a stack of events (for example, an xyz stack, with each letter representing one event) and the new application is an intermediate stack of the approved application (combinations of either xy, xz, yz, or xyz) or single, independent event (x or y or z). If a scenario occurs that the new application is a stack of previously approved independent events (for example, stack xy from the approved x and y events), the new application will still undergo the full regulation because the possible effects of the interaction of the events will have to be assessed.

Regulated Article. Each country differs in how a regulated article is defined in the regulation. Most countries, including the Philippines, depend on the GMO definition. On the other hand, Canada and United States are unique among the countries compared because their regulations are not specifically tailored for GMOs. In particular, Canada's definition for food regulation (Novel Food) and US' definition for cultivation regulation (plants that are genetically engineered and meets the definition of a plant pest) only have a GMO component. On the other hand, Canada's Novel Trait definition and US' Adulterated Food definition does not distinguish between GMO and non-GMO. This means that no stricter rules are applied on GMOs than the conventional products, which may be more advantageous for developers. However, this alone may be inconclusive because the other factors in play such as the social and political factors should be considered first.

Table 17. Crop biotechnology regulatory approaches in selected countries.

	Philippines	Canada	Argentina	United States	Australia	European Union	Japan
Attitude towards GM cultivation	Supportive	Supportive	Supportive	Supportive	Reluctant	Reluctant	Abstainer
	Process-based	Product-based	Product-based	Product-based	Process-based	Process-based	Product-based
Regulatory Trigger (Process-based or Product-based)	Development involves Modern Biotechnology	Plant-traits new to the Canadian environment and may impose safety risks.	Stable integration of DNA in final product	Potential risk of intended product use (plant-pest risk in the context of plants)	Use of gene technology	Alteration not occurring naturally	Stable integration of DNA or RNA in final product
Considers plant/crop-trait-mechanism of action or crop-trait combination	✗	In part through Directive 98-08	Through Resolution 318/2013	Through SECURE Rule	✗	✗	✗
Regulated Article	GMO	Novel Trait; Novel Food	GMO	Genetically engineered with plant pest traits (PPT); Adulterated food	GMO; Gene Technology	GMO	LMO
Regulation required for Cultivation	GMO	Novel Trait for environmental release	GMO	GE with PPT	GMO	GMO	LMO
Regulation required for Food	GMO for food, feed or processing	Novel Food	GMO for Food	Adulterated food	Gene Technology	GMO for Food and Feed	LMO for Food
One-Door-One-Key	✗	✗	✗	✗	✗	Regulation 1829/2003 allows single application for both food/feed and cultivation	✗
Technical Expertise: Organic	✗	Plant Biosafety Office (PBO) Plant and Biotechnology Risk Assessment (PBRA)	✗	USDA-APHIS EPA FDA[26]	✗	Scientific Panel on GMOs	✗

[26] https://www.epa.gov/sites/production/files/2017-01/documents/2017_coordinated_framework_update.pdf

Technical Expertise: Non-Organic	Biosafety Committees	Expert Consultation	Technical advisor (CONABIA) composed of representatives from the private and public sector	✗	a) Gene Technology Technical Advisory Committee on part-time basis b) Expert advisers that may be continuing or ad-hoc	External Experts	Consultation with experts
Regulation of NBTs	Draft NCBP Resolution	Ongoing review of policy	Resolution 173 (2015) supplementary to the Resolution 701/11	Amendment of USDA-APHIS regulations through the SECURE Rule (2020)	Amendment of Gene Technology Act (2019)	Released legal interpretation through the CJEU ruling (2018)	Decision of the MOE (2019)
SDN-1 regulated	✗	If PNT	✗	✗	✗	✓	✗
SDN-2 regulated	✗	If PNT	Case-by-case	Case-by-case	✓	✓	Case-by-case
SDN-3 regulated	Case-by-case	If PNT	✓	✓	✓	✓	✓

One-Door-One-Key Principle. The “one-door-one-key” principle allows the approval for multiple uses using only a single application, which could potentially lead to a faster process. However, in practice, the principle is not commonly used since the EU is reluctant to GM crop cultivation, so applicants mostly apply for food and feed use only. Knowing that the application for cultivation is expected to be rejected, filing a separate application is more attractive for developers. Furthermore, the principle is leaning towards an “all-or-nothing” approach where the approval for one use will depend on the favorable outcome in the assessment of the other use (Yusuf, 2014). This becomes problematic when applied in the national context that is similar to the EU where the attitude towards the two uses differ significantly. Therefore, the applicability of the “one-door-one-key” principle largely depends on the context of the country.

Technical Expertise. Lastly, the presence of an organic source of technical expertise in the regulation may also prove to be helpful. For the purpose of this study, an organic source of technical expertise will be characterized as the presence of in-house and full-time experts who are mandated to perform the assessments. On the other hand, a non-organic source will be characterized by outsourced experts, or ad-hoc committees. Across the countries compared, a non-organic source of expertise is more common. It is notable that Canada and United States, the countries that have the highest number of cultivation approvals from 1992-2014, both have an organic source of technical expertise (Aldemita et al., 2015). Japan is quite notable because it ranks just below Canada and the US for the number of approvals for cultivation despite having no organic source of experts. In relation, it is similar to Argentina but CONABIA, the technical advisory body, differs from the non-organic sources that it is already established in relation to the regulatory body while still having part-time experts, who are representatives from institutions and the academe. Having an organic source of technical expertise allows the regulatory body to take more responsibilities and evolve alongside the increasing demand for regulations in terms of the number of applications. Furthermore, having non-organic technical experts has drawbacks such as the limited efficiency due to their ad-hoc and part-time nature (Mackenzie, 2000).

Literature accounts regarding the technical expertise of regulations are limited , and thus what is presented may only describe the in-house capacity of countries to a certain extent. Nevertheless, it can be observed that countries most commonly appoint experts for assessments that are independent of the regulatory body. While there is involvement of technical expertise in the regulation of Japan and EU, the reluctance of GMO use still remains, which may be more affected by the political environment of the country.

Recommendations

In the Philippines, a process-based approach is still employed with the existing JDC-1 regulation. However, the initiatives for policy reform through the Draft NCBP Resolution indicate that the Philippines is leaning towards the direction of a product-based regulation. There is also an

opportunity for the Philippines to follow the lead of Argentina and US in considering the crop-trait-mechanism of action combination in the regulation. The stringent process of regulating each event independently can be loosened up for events having similar combinations with the already finished applications. This change can be incorporated within the ongoing JDC-1 review. Additionally, while the Philippine regulation will still continue to be tailored for GMOs, the experience of Canada and the United States demonstrate that implementing a regulation that does not distinguish between GMOs and non-GMOs is possible.

The One-Door-One-Key principle from the EU can be advocated by the Philippines to be pursued through the ASEAN. The mutual recognition of the principle across the EU Member States can be mirrored in the ASEAN level in the future, given that the challenges encountered by the EU will be considered in designing the procedures implementing the principle. This will be only possible if the countries in the Southeast Asian region pursue a similar organization with the EU. The other ASEAN countries with no approved GM crops yet can significantly gain from this principle, and it will also be a step forward for inclusivity in the biosafety frameworks in the ASEAN.

Lastly, for the source of technical expertise, the Philippines only has the biosafety committees for the conduct of risk assessment. Considering the drawbacks of not having in-house experts, the Philippines invest more in its regulators.

IV.2.3 Status Among Southeast Asian Countries

Countries with GM crops cultivation

Aside from the Philippines, Myanmar (Burma), Vietnam, and Indonesia have also areas planted to GM crops. The Philippines has an estimated 834,617 hectares of GM corn under cultivation as of 2019. Myanmar has an estimated 490,000 hectares of GM corn for the years 2017-2018 and Bt Cotton (Ngwe Chi 6) was approved under a previous version of the Seed Law and accounted for 380,000 MT of total production during the 2017-18 cropping period. Vietnam has 28,500 hectares of GM corn in 2017. Indonesia has approved GM sugarcane for commercialization but the crop is only grown in the private lands of PT Perkebunan Nusantara XI, the developer company. The SEA countries that have not engaged in GM cultivation are Singapore, Malaysia, and Thailand.

GM crops in the pipeline

The following discussion is heavily lifted from the 2019 USDA-FAS' Agricultural Biotechnology Annuals for the Philippines, Myanmar, Vietnam, Indonesia, Singapore, Malaysia, and Thailand.

Philippines. The Philippines has several GM crops in the research pipeline; among them are Golden Rice, Bt Eggplant, and Bt Cotton. They are in the mature phases of development and are up for application for commercial propagation.

Myanmar. Although considered a “biotech mega-countries” by ISAAA (Larsson, n.d.), Myanmar engages very little in GM crop research development because of the absence of a biosafety guidelines or regulations for GMOs despite having many scientists working on biotechnology from the public and private sectors. It does not have any biotech crop in the pipeline.

Vietnam. Vietnam, also lags behind in research; the country has approved the field trials for corn, cotton, and soybeans but has only conducted multi-location field trials for Bt corn that has resistance to an emerging problem pest — fall armyworm (FAW). This pest was said to have infested 15,000 ha in August 2019. Eight applications for new biotech hybrid corn varieties were submitted to the Ministry of Agriculture and Rural Development (MARD) between December 2016 and December 2017 and await approvals. Four out of the eight pending corn varieties have resistance against FAW. As of October 2018, approvals for 30 out of the 51 dossiers registering for GE events for food and feed use were still pending including events for corn, soybean, canola, cotton, alfalfa, and sugar beets. From October 2018 to September 2019, MARD has approved three events for corn, five for soybean and two for alfalfa. The delay may have been due a policy shift wherein agricultural commodities with competitive advantage to satisfy both demands of the local and exports were prioritized. Another reason is the government’s priority on organic crops, under Decree 109, to address the overuse of chemicals in agricultural production. MARD also repealed Circular 69/2009 that regulated the field trials for environmental risk assessment which put on hold the review of the multi location field trial for corn. Eighteen GM Corn with stacked traits were commercialized in Vietnam. As of 2018, the area allotted to GM corn has reached 40,000 hectares.

Indonesia. Indonesia is a wild card—it has more GM crops in the pipeline than the Philippines. Several government agencies and universities are involved in GM crop research. First is the Indonesian Institute of Science (LIPI) that is developing tungro virus resistance, drought tolerance, salinity tolerance and blast resistance in rice, and extending the shelf life of cassava. Second is the Indonesia Center for Agricultural Biotechnology and Genetic Resources (ICABIOGRAD); it is conducting research on late blight resistant potato, nitrogen-use efficient rice, Bt Rice, and genome editing for gemini virus resistant chili, greening disease resistant citrus, and cadmium absorbent rice. There is also a plan to conduct confined field trials on nitrogen-efficient rice. Third, the University of Jember is developing high glucose content sugarcane and Golden Rice (IR36 and IR64 to be included). Late blight resistant potato is also being developed with partners JR Simplot Company, Michigan University, University of Minnesota, and the University of Idaho. Fourth, the Arcadia Biosciences Inc. has also completed their research on nitrogen-efficient rice. Fifth, PT Perkebunan Nusantara XI have completed the confined field trials for stem borer resistant rice and virus resistant tomato, and the field trials for mosaic virus resistant sugarcane. In 2018, drought tolerant sugarcane was approved for commercialization. However, PTPN XI is not registered to sell or distribute seeds to farmers; its production is limited only to the company’s private lands. It is also

unlikely for the company to apply for registration because the demand for the seeds would only come from specific areas suffering from drought. Applications for the commercialization of herbicide tolerant corn (NK603 and GA21) are pending for processing while waiting for the monitoring guidelines.

Malaysia. Malaysia has yet to commercialize GM crops, but confined field trials are already underway on papaya and could be ready for commercialization in the next few years. The focus of research on biotechnology is on tissue culture, molecular markers, bio-pesticides, IPM (Integrated Pest Management), and natural fertilizers. There was an attempt to develop GE papaya with delayed ripening but the project stopped at its initial field trial phase.

Thailand is evidently quite skeptical and a laggard in regard to biotechnology. In 2003, the Thai government issued a blanket ban on field trials due to public opposition . However, it granted permissions for field trials in 2007 under certain restrictions. The country also has a de facto ban on commercial propagation. Research projects were therefore discontinued by company developers and other research institutions. There is one attempt by Monsanto to conduct field trials on NK603 herbicide-resistant corn in 2013 but the supposed partner, the Naresuan University, backed out. Syngenta and Pioneer also discontinued their projects. Commercial production is also banned in Thailand. Due to the current situation of the policy, GM crop research is severely affected although there are some in development. Bt Cotton prototype is in progress while herbicide tolerant pineapple, vein-banding mottle virus resistant chili and yellow leaf curl virus resistant tomato are awaiting biosafety test (Biosafety Clearing House of Thailand, 2009).

Singapore. The country is not into the development of biotech crops and not into GM cultivation. The only approval in 2015 was granted to JOil (S) Pte Ltd to conduct small-scale field trials on GE Jatropha kernels with high oleic acid to be used in the biofuel industry. As of October 2019, 41 GE products have been approved for food and feed ingredients.

The status of research and development on GM crops in Southeast Asian countries is shown in Figure 24. Of the 29 crop-traits currently under development, majority (21) are still in the experimental and confined trial stages and only eight are at the field trial/commercial propagation proposal stages. The Philippines is leading in the race to completion but if everything goes well for Indonesia, it may steal the lead in the future.

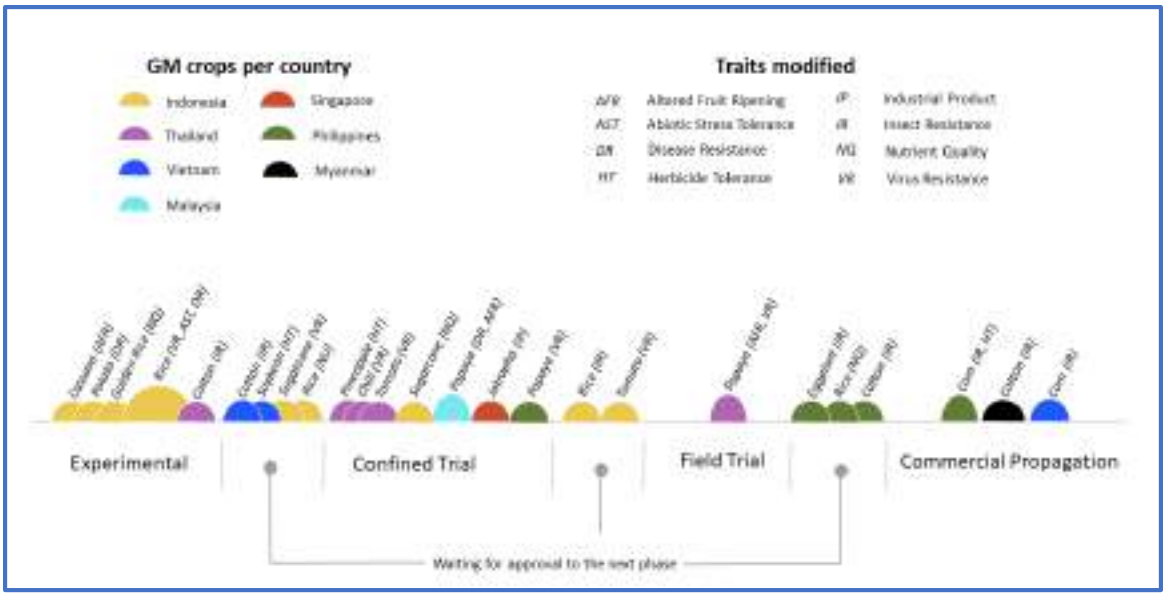

Figure 24. Status of GM crop development in Southeast Asia, 2019.

Gene Edited Crops Research

A newly emerged tool to gene editing is becoming popularly used in most of the countries in Southeast Asia — the CRISPR-Cas9 (Clustered Regularly Interspaced Palindromic Repeats). CRISPR technology is used in Myanmar, Philippines, Indonesia and Singapore but only Myanmar and the Philippines use it in crop varietal improvement research. Myanmar applies the technology in tomatoes to improve its flavor and quality while the Philippines use it to develop resistance to rice blast. Several countries have the capacity for genome editing of crops (Table 18), and to conduct experimental studies. There is also capacity for marker-assisted selection (MAS) in crop research for SEA countries (Table 19). MAS is less controversial than other genomics technologies and is thus more widespread. MAS is used in developing varieties of staple crops that are of importance to the country.

Table 18. Utilization of genome editing tools for crops in Southeast Asia.

Country	Marker	Crop	Purpose
Indonesia	CRISPR-Cas9	N/A	N/A
Malaysia	CRISPR-Cas is being employed for genome editing in research, however there is no clear indication of its employment in particular crops	N/A	N/A
Myanmar	CRISPR	Tomato	Improve flavor and quality
Philippines	CRISPR-Cas	Rice	Enhanced rice blast resistance
Singapore	TALEN/CRISPR	N/A	N/A
Thailand	N/A	N/A	N/A
Vietnam	N/A	N/A	N/A

Source: FAO, 2019

Table 19. Use of marker-assisted selection in the crop sector in the Asia-Pacific region.

Country	Marker	Crop	Purpose
Indonesia	TS4	Rice	Broad spectrum resistant Xoo strains.
Malaysia	SSR markers	Rice	Resistance to brown plant hopper.
Myanmar	SSR or SNP	Rice	Adequate genotyping and phenotyping
Philippines	DNA fingerprinting for sugar cane; SSRs and SNPs for rice	Sugar cane and rice	To eliminate susceptibility of sugar cane to downy mildew and smut. Increased root length and biomass in rice.
Singapore	SSR markers	N/A	N/A
Thailand	N/A	Cassava; sugar cane	Aroma maker, enhance sweetness.
Vietnam	SSR markers	Rice Q5DB variety	Saline tolerance.

Source: FAO, 2019

Table 20 shows the crops being studied or developed under genome research in Southeast Asia. The Philippines and Indonesia have the most crops researched. In the Philippines, most of the genomic research is performed by the Philippine Genome Center (PGC). Figure 25 shows the allocation of budget on genomics and biotech projects by commodity of the Crop Research Division and Forestry and Environment Research Division of PCAARRD. Since 2002, there are already 32 genomics projects including the ongoing ones. Coconut is the most studied crop, with 14 projects out of the 32, followed by mango with 6 projects. Abaca and sugarcane both have two projects each, while papaya, potato, maize, tomato, coffee, cacao, rubber, and rice have one project each. Of the PhP 453 million budget for all genomics projects, 62.1% is allotted to coconut, 10.4% to mango, and 27.5% to all other crops.

Table 20. Sequenced crop genomes in Southeast Asian countries.

Country	Crop
Philippines	Coconut, Coffee, Abaca, Saba Banana, Sugarcane, Pili
Indonesia	Sorghum, Cocoa, Tobacco, Rice, Papaya, Robusta coffee
Myanmar	Mungbean, chickpea
Vietnam	Rice, Robusta Coffee
Thailand	Rice

Source: Thottathil, Jayasekaran and Othman, 2016

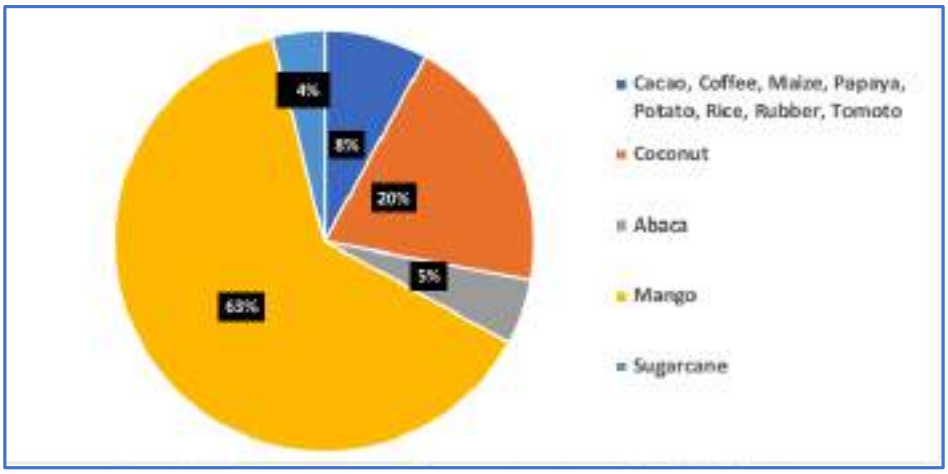

Figure 25. Budget allocation of genomics-related PCAARRD-funded projects per commodity, 2002-2018.

Biotech Crop Regulation

Gonzales et al. (2018) categorized the ten ASEAN member states into three groups based on the level of involvement in biosafety management and biotechnology development. Group 1 consists of Indonesia, Malaysia, Philippines, Vietnam, and Thailand, all having an existing regulatory framework and assessment protocols. Group 2 consists of Cambodia, Lao PDR, and Myanmar, the countries only having a draft framework, while Group 3 includes Brunei and Singapore which do not have an existing framework.

Group 1. USDA (2018) pointed the regional biotechnology leadership to the Philippines as it was the first country to have a regulatory framework for GE crops and also the first to allow their cultivation through the creation of the NCBP in 1990. The country is also moving forward with several initiatives to reform the current regulatory system under JDC-1. Indonesia also has a regulatory framework but it was not complete until 2016. Though it has completed its Risk Assessment Framework and Environmental Food Safety Guidelines, approvals of GE applications could not proceed until the monitoring and control system is in place. Malaysia's biotechnology policy takes the form of the National Biosafety Board regulations but the lack of manpower caused the approval process to exceed the targeted 180 days processing time. Vietnam is growing GM crops and follows the Biosafety Decree 9 of 2010 as its legal framework. On the other side of the spectrum, Thailand's regulations are currently restricted to research and the commercialization of GE crops are banned. A draft of the National Biosafety Law has been created but this has yet to take effect.

Group 2. Myanmar, despite being considered as a "biotech mega-country," has no clear regulatory policy for biotechnology. A draft National Biosafety Framework was last updated in 2009, and the regulators continue to update the draft guidelines. Laos established its National Biosafety Framework in 2004 and ten years later this framework was enforced under the Biotechnology

Safety Law; however, the protocol for contained use is only “partially placed” while the protocols for field trials and FFP are still under review (Gonzales et al., 2018). Cambodia adopted the National Biosafety Framework (NBF) in 2004 similar to the Philippines. Four years later (2008), the National Biosafety Law established the protocols for regulating GMOs imported for contained use, intentional release to the environment, and direct use as food or feed or for processing were developed. It took a couple of years later (2010) and a sub-decree to establish the implementing procedure. So Cambodia is able to regulate GMO for field trials and direct use only.

Group 3. Singapore does not have a framework but has guidelines for GMOs for food and feed. Singapore is not really an agricultural country and has not signed as a party to the Cartagena Protocol. Singapore follows the Guidelines on the Release of Agriculture-Related GMOs by the Genetic Modification Advisory Committee (GMAC).

IV.3 Emerging Innovative Policy Approaches and Initiatives

> *Innovative policy provides an interface between research and technological development policy; it aims to create a conducive framework for bringing ideas to market.*

Mackenzi (2015) recognizes that regulatory systems should be risk-based and focused on meeting societal protection goals. However, since the time transformations were used in crops, there has been no evidence that unique hazards exist either in the use of the technique or in the movement of genes between unrelated organisms. He then argued for changes in biotechnology policy to consider the following “principles”:

(1) The assessment of risks should be based on the nature of the organism engineered onto another and the environment into which it was introduced and not on the method by which it is produced.

(2) Risk assessment needs to be commensurate with the level of risk. More data at higher cost does not mean a higher level of safety and more cost-effective approach can be pursued without compromising environmental protection.

(3) Familiarity with certain trait-crop combination should enable streamlined approaches (e.g., notification versus full application).

(4) Harmonize/standardize data requirements to facilitate simultaneous submission in multiple geographies <countries>. Pursue inter-agency technical collaboration, e.g., mutual recognition of safety assessments.

(5) Consider data transportability, i.e., equivalent agro-ecosystems exist across countries and this knowledge can rationalize requirements for trial locations.

(6) Consider risk and benefit of assessment where the benefits accrue to the public sector and small-medium enterprises.

IV.3.1 The BioAP: Ex-ante assessment

The BioAP proposal

To expedite the regulatory decision-making process, House Bill 3372[27], otherwise called *Modern Biotechnology Act,* proposes to create the Biotechnology Authority of the Philippines or BioAP as an agency of the DOST with its own Presidential-appointed executive director. The NCBP that has assumed a diminishing regulatory role since its creation in 1990 and will be totally abolished as BioAP takes a central role in biosafety regulation. In addition, it will also take on promotional functions such as taking the lead in modern biotechnology programs by providing support to the development of the scientific human resources, modernize facilities and also sustained funding. It will be in the annual General Appropriations Allocation with an initial funding of PhP5 million. Unauthorized destruction of biotech crops during experiments will not be punishable by law. The production and sale of fake GMO seeds will also be prohibited. Financial aid given to BioAP or other agencies involved in modern biotechnology will be exempted from donor's tax. The following highlights the rationale, the provisions and policy goals of BioAP under House Bill 3372 otherwise called the "Modern Biotechnology Act of 2018."

Rationale. The inefficiencies in the regulatory system, lack of legal personality, lack of funds, obsolete rules on regulated articles, the stalling of biotech crop development and the pursuit of national goals challenged by climate change individually and together are the rationale behind the proposed BioAP. Thus, the aim is to expedite the regulatory decision-making process in biotechnology to help ensure the health and well-being of Filipinos, promote competitiveness, help reduce hunger and poverty, and help mitigate the effects of climate change.

Provisions. The bill proposes BioAP to have the dual role of regulating and promoting biotechnology and specifically the following:

1. Revise the biosafety guidelines such that they are simplified, product-based, and still science-based built through a consensus among scientists;

2. Abolish the NCBP and replace with the Biotechnology Authority of the Philippines (BioAP) as an agency of DOST. The Executive Director of the BioAP will be appointed by the President upon recommendation of the DOST Secretary;

[27] Representative Sharon S. Garin sponsored this Bill. It underwent the first reading on 6 August 2019 and was referred to the Committee on Science and Technology chaired by Rep. Erico A. Aumentado. On 21 January 2020, the Bill was approved with minor amendments. Currently, the Bill is with the Committee on Appropriations chaired by Rep. Isidro Ungab and the Committee on Ways and Means chaired by Rep. Joey Salceda. After these committees pass the bill then it will be reported out at the plenary for a second reading and approval. The text for HB 3372 before the January 2020 revisions is available online at http://congress.gov.ph/legisdocs/basic_18/HB03372.pdf.

3. BioAP will have its own funds (P500 million as initial funds) under the General Appropriations which would enable the agency to: a) support capacity building and long-term modern biotechnology programs of government universities and research institutions, b) establish state-of-the-art facilities, c) provide sustained funding for modern biotechnology programs including agriculture, d) lead in educating the public regarding modern biotechnology, and e) serve as arbiter of all issues particularly in matters of biosafety of GMOs;

4. BioAP shall make it illegal and punishable by law: a) unauthorized destruction of biotech crops during experiments, and b) production and sale/distribution of fake GMO seeds; and

5. Financial aid given to BioAP or other agencies involved in modern biotechnology will be exempted from donor's tax and constitute a deductible to donor's tax. Also exemptions from the Government Procurement System.

Policy Goals. Implicit in the above are the following policy goals or expected policy outcomes

1. Promote or guard the safety of human health and consumers
2. Promote high level of biotech research and development of biotech crops
3. Assure availability of scientific human resources in biotechnology
4. Support biotechnology course programs in public academic institutions

Ex-ante assessment of BioAP relative to status quo

This study adopts the definition of competitiveness in addressing the second objective as the relative ability or capability of a given policy proposition to achieve a given policy intent. In the case of BioAP the two policy intents as far as crop biotechnology is concerned are regulatory (i.e., the safe handling and responsible use) and promotional or development (i.e., develop biotech crops and contribute to food security and agriculture development in a climate change era). Thus, ex-ante assessment was done in an input—impact framework. This suggests a biotechnology policy that is forward-looking and impact-driven wherein such policy in the short-run invigorates the R&D in crop biotechnology, in the medium-run renders the end users of biotech crops competitive and in the long run, contributes to meeting the national goals on food security and agriculture development.

Results of a Policy Delphi Survey participated 26 expert-respondents are presented below. These assessments are subject to the experts' knowledge and experience in biotechnology (in the fields of research, promotion, or regulation), understanding of the provisions for BioAP under HB 3372, and appreciation of the Policy Delphi and the input-thru-impact framework.

Impact-driven Biotechnology Policy. A forward-looking policy envisions the impacts it targets to create. Biotechnology policies targeted towards food security and agriculture development in a climate change era means working backwards, that is, finding technological solutions, best route to deliver those technologies and devising policies that would drive a technological breakthrough

to happen in order to meet those goals. There may be technical, economic, or social barriers to overcome in the process. Drawing from previous discussions, this involves identifying crops and traits that need to be prioritized in working towards the national goals, discovering and applying new breeding methods/tools, providing a reliable seed system, extension services, perhaps input subsidies at the initial phase, public awareness of the benefits of biotech crops, incentives for private and international investments, and increased government spending in research infrastructure and activities. Crops that are of food security significance, traits that are climate change tolerant, and other crop-trait combinations of high market value may render the farmers or the industry competitive and the technology sustainable. Competitiveness at the farm and at the national level is an important key to agriculture development. As mentioned before, the experiences with anti-GMO or anti-biotech groups that drove the regulatory system to pose hardships on the biotech crop developers prevented crop biotechnology to boom and to this day, the Gene Revolution being hoped for continue to shy away. Such are the motivations behind the House Bill 3372 and the proposed BioAP and also for this section of the study. The research problem is: Will BioAP be able to reform the regulatory system, render it efficient and the compliance costs bearable for developers, stimulate investments in crop biotechnology, contribute to development of important crop-trait combinations , improve the bottom line, and eventually in the attainment of national development goals?

To address the research problem above, an ex-ante assessment framework was used (Figure 26). The experts were provided with a primer on BioAP and a copy of the Bill for reference and then asked to evaluate a series of BioAP “target effect” statements using a 5-point Likert scale: Agree, Somewhat Agree, Not Sure, Somewhat Disagree, and Disagree. After ticking a response, the experts explained their choices and in the process, they pointed out the problems with the current situation (R&D, regulation, commercialization, etc.), the strengths and weaknesses of the BioAP in addressing those problems and suggested ways to achieve the desired input (stimulated crop biotechnology academic and research activities), output (biotech crops), outcome (farm level yield and income gains) and impact (scaled out adoption leading to the attainment of national development goals).

On the overall, the assessments were promising (Figure 27). The degrees of confidence measured in terms of the proportion of experts who agreed that BioAP will have positive direct or indirect consequences and impacts on the INPUT (54%), OUTPUT (47%), OUTCOME (38%), and IMPACT (33%) are very affirmative although decreasing the more distant or indirect the consequences are which is expected considering the many other actors, agencies or organizations involved in achieving them. Details of these results are as follow.

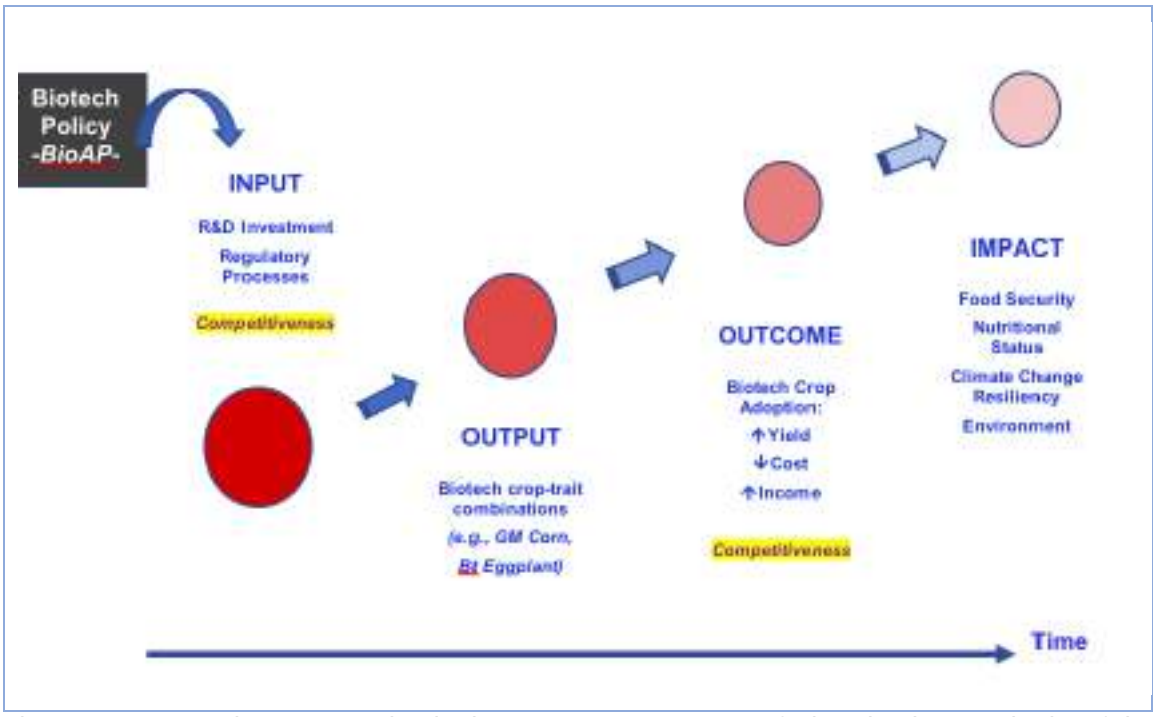

Figure 26. Input-to-impact mapping in the ex-ante assessment of Biotechnology Authority of the Philippines (BioAP) under HB 3372 (2019), Survey, May-July 2020.

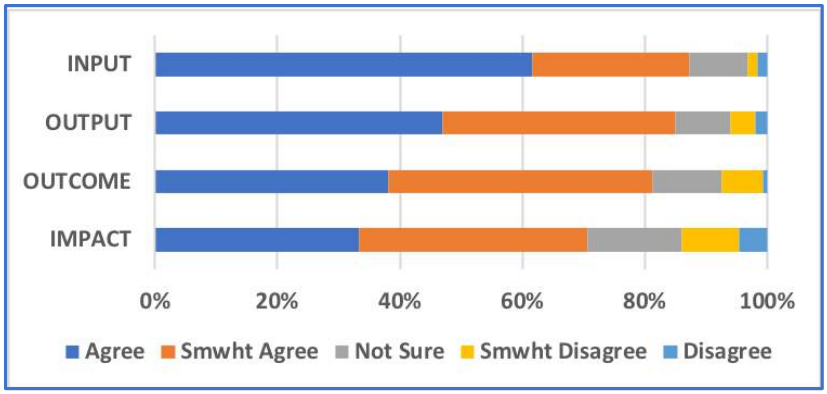

Figure 27. Ex-ante assessment of the direct input effects and indirect output-outcome-impact of BioAP, 26 expert-participants, Policy Delphi Survey, May-July 2020.

The national R&D program for crop biotechnology falls under the DOST Harmonized National Research and Development Agenda, specifically under the Agriculture, Aquatic and Natural Resources (AANR) Research and Development Agenda it is stated, *"The AANR sector supports the use of advanced and emerging technologies such as biotechnology, genomics, bioinformatics, … as R&D tools to find Science and Technology (S&T) solutions to AANR problems or develop new products with significant potential impact to the sector."* A DOST genomics-biotechnology roadmap for years 2017-2022 is in Appendix J. The projects handled by DOST-PCAARRD in relation to crop biotechnology is in Table 15. Thus, crop biotechnology researches in the SUCs and UP System are funded by PCAARRD and valued at about PhP78 million for projects spanning from

2018—2023. UPLB-IPB had crop biotech projects on eggplant, tomato, and papaya in collaboration with Cornell University and with funding from USAID. PhilRice has a project on Golden Rice in collaboration with IRRI and with funding from the Bill & Melinda Gates Foundation.

Under the House Bill, the proposed BioAP will have a promotional functions or roles for public R&D, academic institutions and for public awareness/acceptance of biotech products (Table 21). These functions and roles can have far reaching implications to research activities and may finally bring about the Gene Revolution. This will be further discussed later.

Drivers of R&D investments. Experts assessed eight input statements that pertain to establishing biotechnology facilities, laboratories and equipment; building up of technical manpower in public biotech R&D, increasing the budget and human capacity for regulators, more scholarships for undergraduate and graduate biotech degrees, and greater investments in biotech R&D. The results of assessments in Figure 28 show that experts anticipate BioAP to deliver the infrastructure and human resources needed for a vibrant R&D enjoined by not just the government research agencies but also by the international research centers and private companies and all these to be made possible by the provisions specified in Table 21. Those who fully agreed ranged between 24% to 68% but when those who somewhat agreed are added in, 68% to 92% of the experts believe that BioAP will be able to accomplish its promotional and developmental functions.

Public R&D will benefit most from BioAP's leadership in biotechnology development especially in developing long term programs for sustained (GAA) funding. If BioAP is to "formulate strategies, policies and guidelines for modern biotech programs" then the public R&D institutions should more or less align its program with BioAP. Similarly, given the high cost of developing biotech crops, the national program may be aligned with those of the international research centers or of the private companies to promote partnerships and exploit external sources of research funds. One of the experts commented that PhP500 million is unlikely to fund all the provisions let alone cover the cost of developing just one biotech crop. Instilling new technical knowledge in talented human resources through education and capacity building are the foundation and the driving force of any academic and research institution. Further equipping such talents with updated facilities, laboratories and equipment will propel research activities and result in more outputs such as biotech crops in a shorter period of time.

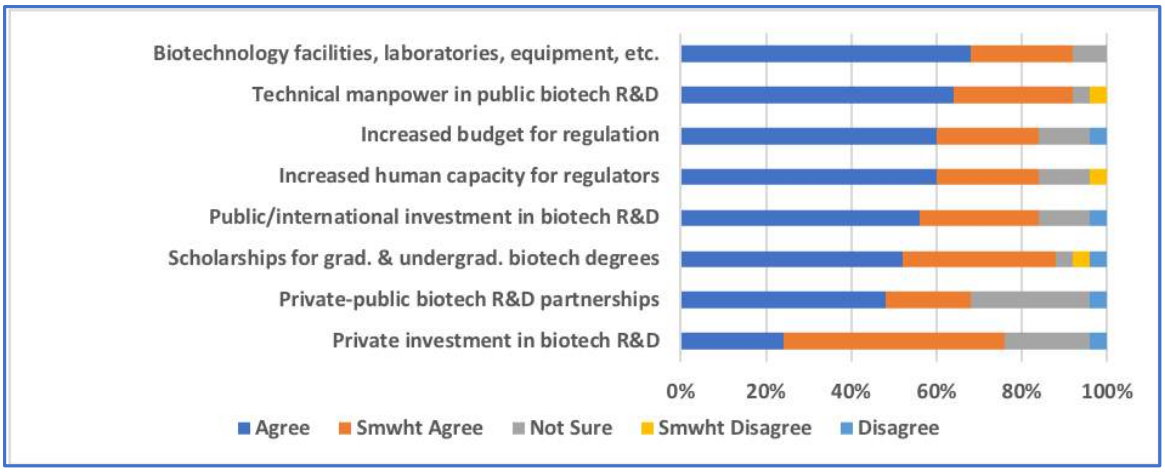

Figure 28. Ex-ante assessment of the BioAP: direct consequence on public R&D and indirect consequence on the international and private investment.

Table 21. Promotional functions of BioAP in public R&D, academe and public awareness as specified in House Bill 3372.

HB 3372 provisions	Public R&D	SUCs/UP System	Public Awareness
Sec. 3.a Leadership in biotechnology development	▯		
Sec. 3.b Development of scientific human resource	▯	▯	
Sec. 3.e Establish state-of-the-art facilities	▯		
Sec. 3.d Sustained funding for modern biotechnology programs	▯		
Sec. 6.a Formulate strategies, policies and guidelines for modern biotechnology programs	▯		
Sec. 6.c Capacity building at par with developed countries	▯		
Sec. 6.d Develop long-term programs as basis for sustained funding	▯	▯	
Sec. 6.e Promote public information on the benefits from modern biotechnology	▯	▯	▯
Sec. 15 Exemptions from donors' taxes and the Government Procurement System	▯	▯	▯
Sec. 17 Initial GAA funding of Php500 million. Annual GAA funding to fully implement the provisions	▯	▯	▯

Source: http://www.congress.gov.ph/legisdocs/basic_18/HB03372.pdf

Another bottleneck in the conduct of research is the delays in acquiring materials and equipment for use in research because of the bureaucracy of the Government Procurement System (GPS). The experts appreciate utmost concern to fight corruption but argue for a more efficient system especially for items that will be used for research purposes.

Scientists—plant breeders and crop genetic engineers alike—are sincerely concerned about the safety of people and the environment from the plant varieties that they develop. In the old days, public trust was a given and farmers were generally excited to try new "modern" crop varieties. But, now scientists have to gain public trust. Promoting public education and not just perception has turned crucial after bad campaigns, acts of vandalism against biotech field experiments and winning a civil lawsuit at the Supreme Court by anti-GM or anti-biotech groups. The responsibility to promote public awareness regarding the safety record and benefits from biotech crops to this day has been assumed by the UPLB and non-government entities such as the ISAAA and SEARCA. Developers learned the hard way how important it is to reach out to the public including the justices of the country and speak plainly what genetic engineering (and now they have to explain crop genomes and genome editing) and its products are all about.

An interesting dynamics exist in the research activities cutting across sectors. National and international research used to dominate crop development R&D. A time when donor funds overflowed to international research centers to develop modern cultivars and train local breeders and students. International Agricultural Research Centers (IARCs) and National Agricultural Research Systems (NARS) have a long standing relationship although this became less and less intensive in recent years as the private seed companies took part in the research network. In the last couple of decades, there has been increasing partnership between private companies and IARCs and between IARCs and NARS—a good example is the Golden Rice Humanitarian Project where partnerships were forged between Syngenta and IRRI and between IRRI and PhilRice.

Non-positive feedbacks were also received from 8% to 32% of the experts for any of the eight input statements. The skepticism came from the lack of clarity in the provisions with respect to how the GAA will be allocated and details regarding the plantilla positions for regulators.

Threshing from the long list of narratives fed back by the 26 experts regarding the INPUT statements, the common driver of investment in all the sectors is a streamlined and efficient regulatory system (Table 22) with significantly fewer application documents to submit, shorter processing period, and reduced compliance cost. At the current system, only the big companies are able to afford the costs of regulatory compliance. Public and international researchers will hopefully have a chance for see their biotech crops through commercialization. Another driver for international R&D investment in the country (in partnership with the NARS) is a policy that aligns the national research priorities with those of the IARCs. As for the private R&D, by its personality, the main drivers are markets and profits and intellectual protection of their trade. Being profit-oriented (which is but rational and not intrinsically bad), private companies will put their coins in commercial crops where they will be able to have the highest rate of return. Crops orphaned by

these private companies that are of prime importance to nutrition, poverty goals, climate change resiliency and food security are best taken up by the NARS and possibly by the IARCs.

Table 22. Drivers of investments in crop biotechnology R&D, Policy Delphi Survey, 2020.

Public R&D Investment	International R&D investment	Private R&D investment
1. Streamlining and efficient implementation of biosafety regulatory processes, thus, lower cost of regulatory compliance	1. Streamlined and efficient implementation of biosafety regulatory processes	1. Streamlined and efficient implementation of biosafety regulatory processes
2. BioAP's allocation of direct funding to R&D, capacity building in research and academic personnel	2. National research priorities aligning with those of the international research centers	2. Intellectual property protection
3. Roadmap for a national biotechnology program		3. Markets and profits

Ex-ante assessment of the effectiveness and efficiency of the regulatory system under BioAP. The provisions under the Bill that would enable BioAP to implement an effective and efficient regulatory system are outlined in Table 23. The experts assessed the expected performance of BioAP based on the provisions.

Table 23. Regulatory functions of BioAP as specified in HB 3372.

Section	Provision
Sec. 5	Rationalize regulatory process.
Sec. 6g	Abolish the NCBP and other modern biotech regulatory bodies and BioAP absorbs their functions
Sec. 6b	Ensure regulations are science-based & simplified, product-based & not process-based
Sec. 10	2 stages in Biosafety regulations: 1) biosafety assessment and (2) commercial competitiveness and related criteria. Have the position of IFPRI and LAG on SE Criteria.
Sec. 11	Public and private R&D organization to have a product safety committee to perform biosafety assessment, certify and submit for BioAP's approval in accordance with its guidelines.
Sec. 12	In case of conflict between international commitments and the science-based, product-oriented approach, the latter shall prevail.
Sec. 6f	Arbiter of all issues relating to biotechnology, particularly those involving biosafety of GMOs
Sec. 13	Criminal acts: a) destruction of biotech crops; b)sale and distribution of fake GM seeds;
Sec. 14	c) other acts violative of the regulations. Penalties for criminal acts: PhP 0.5-10 million
Sec. 10	2 stages in Biosafety regulations: 1) biosafety assessment and (2) commercial competitiveness and related criteria. Have the position of IFPRI and LAG on SE Criteria.

Source: http://www.congress.gov.ph/legisdocs/basic_18/HB03372.pdf

Since the commercialization of Bt Corn (MON 810) in 2003 there has been no incidence of anything less than the safe cultivation and use of GM corn for feeds. Thus, the past and current biosafety regulation with its science-based risk assessment protocols proved effective and consistent with the national policy statement, "promote the safe and responsible use of modern biotechnology and

its products…". Despite the problems cited by Manalo (2019) such as the absence of the Manual of Operations, and lack of expertise among regulators, the regulatory system evidently proved effective in ensuring safety. "But at what cost?", one may ask. Is it possible that the long safety record rather suggest overregulation that could have harmed the developers? Even harmed the society in measures of the forgone benefits from the biotech crops that did not survive the regulation.

Almost 60% agreed (92% if the 'somewhat agree' is included) that the lead time in processing of applications for biosafety permits will be made short in compliance with RA 11032. (See Figure 29). According to this the EODB law, the prescribed lead time for highly technical applications is 20 days and for multi-stage system the lead time is increased by its multiple. In a personal communication with NCBP staff, upon consultation with the Anti-Red Tape Authority, the prescribed lead times for field trials, commercial propagation, and direct use for FFP applications should be reduced from 85 to 40 days as the processing is considered highly technical and a multi-stage system. If this come through then it shall be hailed by one of the respondents who said, "A lengthy regulatory process that does not add to scientific rigor is a disservice to public R&D."

"Biotech products have been muddled with misinformation and fearmongering campaigns by the anti-GMO groups for decades," according to one of the experts, "so it is about time a government agency such as BioAP promote public awareness. An effective information, education and communication (IEC) program would benefit from reputable personalities preferably in science to talk about scientific facts and evidences of safety in understandable language. Fifty-five percent (84% if the 'somewhat agree' is included) of the experts agreed that BioAP will be able to deliver such by partnering with groups that are already into IEC such as ISAAA, SEARCA and UPLB.

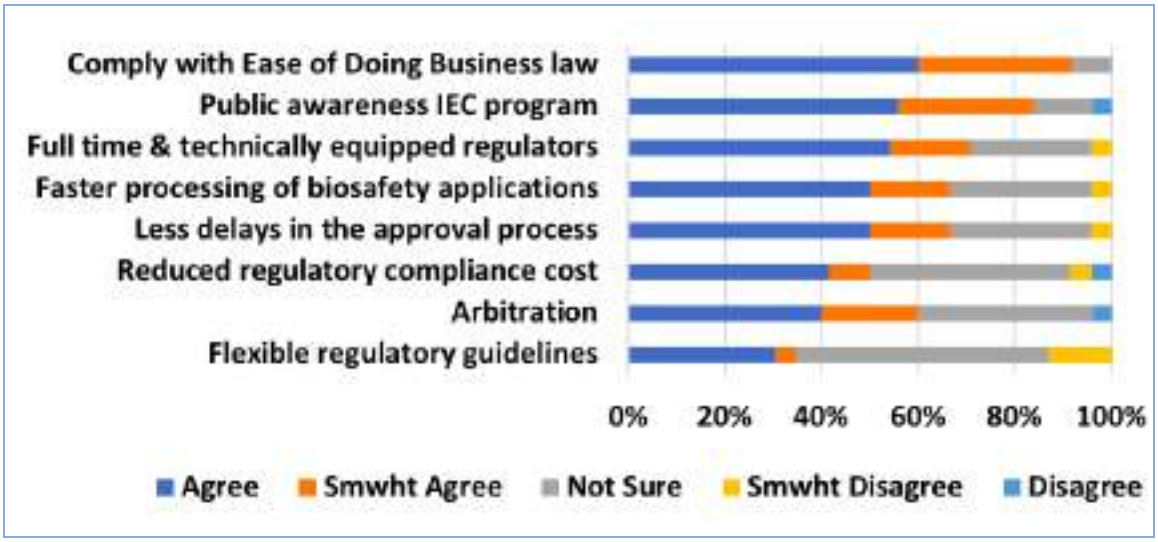

Figure 29. Effectiveness and efficiency assessment of the regulatory system under BioAP, 26-expert-respondents, Policy Delphi Survey 2020.

In the PDS, experts evaluated eight statements using the same 5-point Likert scale and remarked on the statements or qualified their choice. The respondents assessed if BioAP as described in the Bill will lead to a more effective and more efficient regulatory system.

Biosafety risk assessments are technical tasks that require specialized skills. To regulate effectively, there should be full time and technically trained staff. The NCBP holds trainings to equip regulators however if these staff are on a contractual appointment then naturally they will leave for a better job and off goes the investment in training. As an agency with GAA funding, the respondents suggest adding a text in the Bill for plantilla positions specifically for the hiring of qualified staff in order to create a pool of in-house experts.

Consequential to compliance with EODB and plantilla positions, about 50% of the respondents agreed that processing of applications shall be faster or with less delays. A centralized regulation or having to deal with a single agency is obviously much more efficient versus making 25 copies of the application documents and dealing separately with the STRP, DA, DENR, and DOH which some respondents refer to as “layers of bureaucracy”. However, a lesser proportion of respondents see the increase in efficiencies to translate into reduced compliance cost, only about 40% agreed.

As regards arbitration, 40% of the respondents agreed that BioAP can provide an effective arbitration as “small” conflict arises surrounding scientific issues assuming there will be competent (skilled and cool-headed) arbiters. “Conflicts should be first taken up with BioAP for initial arbitration and all efforts should be made to resolve the issue otherwise the case would have to be referred to the court which should be avoided as this is counterproductive to the industry.” However, half of the respondents criticized this role as being inappropriate, impractical, and ineffective especially when the conflict is initiated by the anti-GMO groups where no arbitration is expected to work. A respondent remarked that unless these anti-GMO personalities are converted like Mark Lynas or BioAP is bestowed with police powers then even a legislated BioAP will be unable to prevent a court case nor will it ensure winning.

Finally, on the issue of flexing regulatory guidelines to keep regulation relevant with a fast evolving science, only 30% agreed that this could happen with a legislated BioAP hoping that science-based and product-based principles shall prevail. Majority (65%) expressed reservations as to the ease by which amendments in a legislated regulatory system could be made. There seems to be an apparent trade-off: benefit from the improvements (budget, etc.) for the difficulty and time it will take to amend the law. Those who provided negative assessments disapproved the legislative approach and insisted on non-legislative means such as AO,EO or JAO.

Conflicting BioAP Roles. In the course of assessing the strengths and limitations of BioAP in being able to bring about an effective and efficient regulatory function and stimulating the development of the biotechnology industry, the respondents appreciated each individually. While others believed that BioAP should take on both roles others realize that assuming both roles by the same agency can be quite conflicting. A respondent forewarned that the government agencies that assume both roles "eventually succumb to political machinations and fail to deliver." With that, some thought it best for BioAP to take on the regulatory role while others a development/promotional role.

The motivation behind legislating a regulatory agency was drawn from the decision of the Supreme Court to reverse the unfavorable 2015 decision regarding the Bt Talong case where of the Court of Appeals noted that "there is no single law that governs the study, introduction and use of GMO in the country[28]" and therefore "recommend to Congress curative legislations[29]." The response of House Representatives to write House Bill 3372 and propose BioAP is well appreciated by the experts who believed in this "solution" to the vulnerability of EOs and AOs to legal challenges. However, majority of the experts oppose legislating a regulatory body for reasons such as 1)a regulatory law is difficult to amend while administrative issuance is easier to revise; and 2)the volume of applications per year that ranges between 30-40 does not justify an investment in a separate regulatory agency. Thus, the alternative role for BioAP is the promotion of research and development of biotech crops with a minor reservation that while the agency can be a catalyst for R&D funding the success of research and development is not assured or as long as there are strong anti-GM groups. To this, some respondents suggested strengthening the IEC program with scientific facts and evidence to counter the fears the anti- groups sow in the public's mind.

On the overall, the respondents find the comprehensive functions of BioAP well-intentioned but too ambitious that in the end might prove ineffective as one being jack-of-all-trades and master-of-none. The PDS did not aim specifically for this issue to be resolved so this was brought to the roundtable which will be discussed later in the report.

Output-Outcome-Impact Linkages. Given the assessments on the direct consequence of BioAP on R&D investments and on improving the effectiveness and efficiency of the biosafety regulatory system, the respondents proceeded in assessing the anticipated outputs (after 3 years or more) of such and the resulting outcomes (3-6 years after the release of the first biotech crop variety) and

[28] https://elaw.org/system/files/ph.greenpeacese.pdf

[29] https://elaw.org/system/files/ph.eggplantsept2014_0.pdf and https://www.informea.org/sites/default/files/court-decisions/International%20Service%20for%20the%20Acquisition%20of%20Agri-Biotech%20Applications%2C%20Inc.%20v.%20Greenpeace%20Southeast%20Asia.pdf

impacts (when the biotech crop has reached an adoption rate of at about 50%[30] and has significantly increased market supply and affected market prices). This part of the survey is best administered to respondents who have a cognitive appreciation of or prior exposure to the input to impact framework. Despite the lack of it, the results are quite optimistic as the proceeding discussion will show.

Output. The outputs of biotech innovation backed with an effective and efficient regulation are biotech crop-trait combinations that contribute most to competitiveness (including the wellbeing or welfare of farmers and consumers) and the national development agenda. Among the important provisions under the Bill and suggested enhancements to develop these biotech crops are:

1) Construction of state-of-the-art facilities and laboratories and "harmless hassles" in the purchase of equipment—the GAA exemption is appreciated.
2) Clear, long-term R&D roadmap with guaranteed and sustained funding.
3) Guarantee and sustain high levels of investments in the public academic and research institutions that are engaged in crop biotechnology.
4) Mandate DBM to assist the BioAP in formulating a multi-year budget accord, including staff build-up to required levels.
5) Stimulate private investments via specific and definitive fiscal incentives that can further be spelled out in the IRR.
6) Give priority to frontier applied science in genetic engineering such as innovative biotechnology methods and tools.
7) A streamlined regulatory system manned by "true experts"; this will incentivize biotech R&D in general.
8) Adopt a product-based regulation that keeps pace with plant breeding innovations. The first generation biotech crops have foreign inserts. The 2nd generation biotech crops may or may not have foreign inserts. If risks are associated with foreign inserts then those with none should be considered the same as conventionally bred crops.

The European Innovation Scoreboard (EIS, 2009) presents empirical evidence proving strong positive correlations between R&D expenditure and output measures of innovative actions. Thus, with the expected increase in R&D investment with BioAP the 26 respondents provided *ex-ante* assessments on the resulting Biotechnology Innovation System (BIS). Figure 30 illustrates the proportion of the respondents who agreed that the BIS will be able to deliver the following outputs:

[30] Adoption rate is arbitrary.

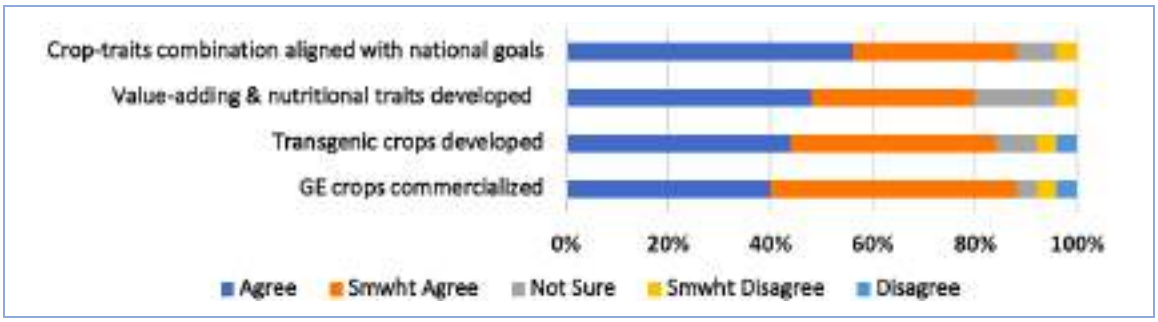

Figure 30. Ex-ante assessment of BioAP's contribution to Output of BIS, PDS 2020.

Crop-trait combinations aligned with national goals such as food security and reduction in poverty (56%). Any government agricultural endeavor has to align with the national development goals. "This requires proper programming and sustained funding support. BioAP and public R&D agencies must craft a harmonized long-term research agenda and roadmap that are aligned with national goals on food and nutrition, the environment and other economic and social goals," said a respondent who used to work with a national department.

Value-adding and nutrition-enhancing traits conferred on crops (48%). One strategy to achieve competitiveness is to develop crops where there is high demand or develop traits that the market puts a premium. A respondent cited papaya as an example in which domestic and international demands are high and in which the market puts a premium for delayed ripening. For the nutrition-enhancing traits it is not only biofortification but also low glycemic index rice or low phytate corn.

Increased number of transgenic crops developed (44%) and commercialized (40%). Respondents unanimously emphasized that a streamlined or efficient regulatory process in itself can already incentivize researchers to develop more biotech crops knowing that these crops can be commercialized in no time.

Outcome. Outcomes are the result of technology adoption but for adoption to occur there are some requisites and the most important are an effective IEC program, a supportive extension system and a reliable seed system. The IEC will promote the GM crop and its products to the farmers so they will understand the technology and adopt the new variety and to the consumers so they will know that rigorous risk assessments were done and it is safe to consume the GM products. Private companies have their own way of or reaching out to the minds of the farmers but usually the company sales representatives work through and with the commodity coordinators (corn coordinator or high value crop coordinator for example) in setting up and conducting meeting with the farmers. For publicly developed biotech crops, the DA's extension system is the best bet to reach out to farmers. Finally, a reliable seed system should be in place and this too can be done through the DA's regional field units to multiply the seeds or to collaborate with local seed producers within the network of the secondary or tertiary agricultural offices. With these support system, the

farmers will now be able to realize the outcomes of a biotechnology innovation system (BIS). The PDS respondents assessed the farm benefits to adoption of biotech crops positively and the proportion who agreed are as follow: an improvement in crop yields (44%), increase in farm incomes (44%), reduced health hazard associated with pesticide use (44%), and reduced production costs (40%) (Figure 31). However, the proportions who agreed to the success of the BIS in the wider adoption (29%) and consumer acceptability (28%) of transgenic crops are much lower citing the need to overcome the disinformation and fears the anti-GMO groups had spread.

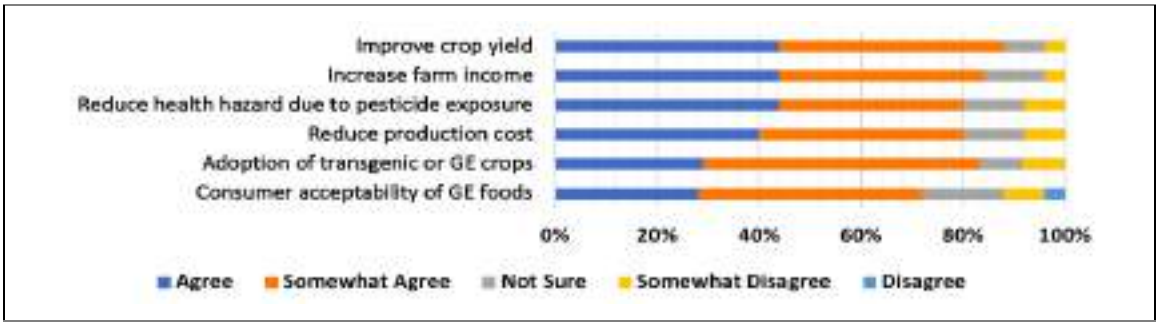

Figure 31. Ex-ante assessment of BioAP's contribution to Outcomes of BIS, 26 expert-respondents, Policy Delphi Survey, 2020.

There are words of caution from the respondents. As regards farm income gains and in the case of GM corn, the reported gains may be offset by the high cost of GM seeds and the emergence of pests other than ACB and to which the Bt technology has not addressed. The price of seeds is also a significant determinant of adoption and this is backed by the popularity of Sige-Sige seeds in Bukidnon as will be covered later.

Impact. The national goals are even harder to imagine for a few respondents but majority appreciates the impact statements and explained that although indirectly and quite a long-shot, the BIS with BioAP will contribute positively to the attainment of the national goals, other strategies may contribute more but BioAP will have a share or "additive effect" as a respondent remarked no matter how small. If the "Somewhat Agree" response is interpreted as "Agree" although with reservations then it is interesting to count them among those who agree on the long-term impacts because the proportions of the positive responses for all the impact statements are 60% and beyond. Although, those who agree 'without reservation' are between 24% to 40% of the 26 respondents only (Figure 32). But, still very optimistic. It can be said that these experts are visionaries and able to project the impacts of an emerging set-up for the BIS with the enabling effects of BioAP. In fact, some of the respondents use words such as "great possibility," "should be the goal," "can be instrumental," and "can contribute." One of the respondents suggests the necessity of deliberate strategies such as a promotional policy and efficient regulation to generate the impacts including impact targeting by ensuring that the poorest and the most vulnerable population groups are given access to biotech crops.

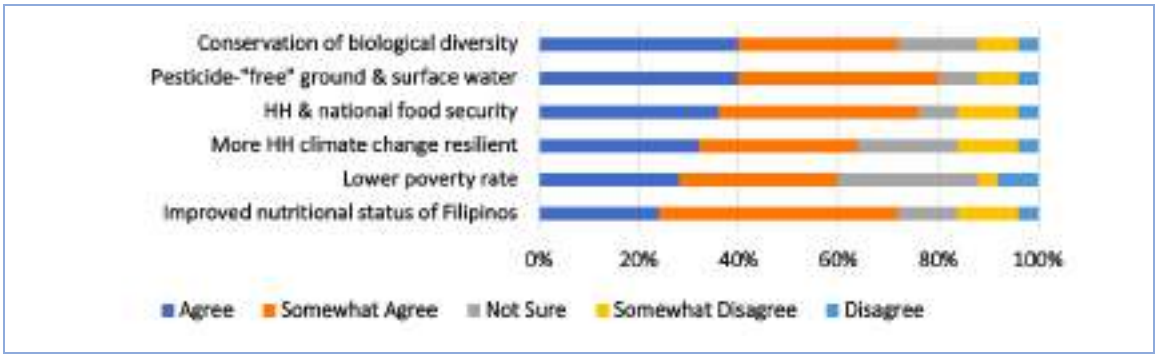

Figure 32. Ex-ante assessment of BioAP's contribution to Impacts of BIS, 26 expert-respondents, Policy Delphi Survey, 2020.

As regards the conservation of biological diversity, the premise is that if biotech crops can increase yield and aggregate supply then there will be less pressure to expand agriculture to forested areas. Also, biotech crops that can effectually reduce pesticides and fertilizer usage can result in the diversity of flora and fauna.

PIP technology can not only save the health of pesticide applicators but also lower the risks of water contamination. Measuring such impacts requires baseline data and may be quite expensive especially when it involves people. But, logically, lowering the use of agricultural chemicals will lower the risk of health impairment or water contamination.

Developing biotech crops with tolerance to abiotic stresses may be a long shot for now but it should receive priority in the R&D if the goal is to expand the frontier of increased productivity. Considering that most of the poorest of the poor reside in climate change vulnerable areas, biotech crops resilient to flooding and drought can be an effective instrument to alleviate poverty and promote household food security and health.

Improving the nutritional status can be achieved in two ways—through the increase in income and through the increase in the nutritional content of crops. There are of course other instruments or strategies towards this goal but profitable and competitive farming is quite a sustainable solution.

IV.3.2 Review of the JDC-1

Per recommendation of the five competent national authorities (CNAs) involved in the regulation, the NCBP formed an Ad Hoc technical working group (AHTWG) on 20 May 2019 to review the JDC-1 (2016) after three years of operation[31]. The AHTWG is composed of representatives from the CNAs (DOST, DA, DOH, DENR, DILG, DTI and DFA), public academic and research institutions and other stakeholders. The objectives of the TWG are to review the challenges experienced by the CNAs that led to delays in approvals of regulated articles, review the JDC-1

[31] Personal communication with Ms Lorelie U. Agbagala of the NCBP.

provisions, recommend amendments to the provisions, and clarify the roles and responsibilities of the CNAs in the regulation of GM plant and plant products for field trial, commercial propagation, and direct use as food, feed or processing. So far, at least six meetings were held and the matrix of proposed reforms is in Appendix I.

As mentioned previously, the JDC-1 (2016) was drafted almost in haste to replace AO8 after the Supreme Court issued a cease and desist order against AO8 in 2015. The anti-GMO pressure for regulation to consider the *writ of kalikasan* argument added DENR and DOH among the regulators and DILG to oversee public consultations. Recalling Figure 6 thru Figure 8 and the discussion in Section II.3.2, JDC-1 is indeed fraught with problems relating to lack of full time well trained regulators, bureaucracy, redundancy and inefficiencies.

The 12-point reforms to the JDC-1 summarized in Table 24 basically remove irrelevant requirements or redundant CNA roles, reduce the required socio-economic considerations and LGU endorsement to optional, improve the clarity of text (i.e. pertaining to FFP application), introduce text relating to “transportability” of GM approvals from other countries, deregulate GM crops after five years of record safe use (CP and FFP), and cutting the days to process application from 85 days to a maximum of 40 days in compliance with the “Ease of Doing Business” law or RA 11032. In terms of implementation, the DOST-BC will take care of contained/confined use applications while the DA shall take care of applications for (multi-location) field trials, commercial propagation and direct use for food, feed, or processing. By these reforms, approval delays of months and years can be completely avoided and compliance cost greatly reduced. From the viewpoints of public and international research centers, the reforms if implemented as stated shall essentially break the barrier to commercializing their crop varieties. Donors would also be encouraged to fund research activities in crop biotechnology knowing that the regulatory inefficiencies are removed. These reforms are to be finalized by the Ad Hoc TWG in a meeting by late 2020 to early 2021 and hopefully not later. It is still unclear, however, how the new regulatory system shall take form—perhaps another Joint Administrative Order?

The recommended reforms did not include (maybe because they were not considered within the purview of the TWG’s objectives) concerns about dedicated funding for the operations of NCBP, the need for plantilla positions to hire qualified and technical staff to serve as in-house experts, and how to imbue a sense of commitment among the department secretaries to attend meetings where non-confrontational discussions and consultations regarding certain technical, regulatory, guidelines/processes, and other issues can be carried out.

Further, the recommended reforms did not consider the “temporal limitation” of the definition for “regulated articles” under JDC-1 to refer to genetically-modified plants and plant products which was based on the state of genetic engineering 30 years ago. In the last five years or so, crop

biotechnology evolved at an accelerated pace with the increased utilization of genomics information and genome editing tools (also called new breeding tools or NBT) in plant breeding. Scientists clamor to spare products of genome editing that do not involve the insertion of foreign genes and therefore do not fall under GM category as it was known 30 years ago which was the reason for biosafety regulation. Perhaps an additional text referring to the presence of foreign genes in the final product will provide clarity to the definition of “regulated articles.”

Table 24. Twelve recommended reforms to the JDC-1, 6th meeting of the AHTWG in December 2019.

Issue with JDC-1	Proposed Reform	Reform Promotes—
(1) Validity of biosafety permits for FFP and Commercial Propagation for five (5) years requires constant renewals.	Remove expiration of biosafety permits for FFP and Commercial Propagation. (Delist after 5 years of safe use.)	Effectiveness
(2) Interpretation by a former DA-DC official that the current regulation does not allow locally developed GM products to be applied for Direct Use as FFP prior to or simultaneous with an application for Field Trial, unlike imported GM products	There is no ambivalence in the language of the JDC1—an application for FFP is not required to follow the sequential process of undergoing first Field Trial then Commercial Propagation.	Efficiency
(3) The JDC1 has strictly prescribed a sequential approval process for regulated articles to be applied for Commercial Propagation: Contained Use → Confined Test → Field Trial → Commercial Propagation.	For GM plants that were fully developed in the country of origin prior to introduction in the Philippines, allow these products to skip the Contained Use phase and/or the Confined Test phase, on a case-to-case basis, upon the evaluation and decision of the DOST-BC.	Effectiveness
Note: Items (4), (5) and (6) are related with each other: (4) Non-applicability of Environment Impact Assessment (EIA) System to GMO biosafety evaluation (per DENR) (5) Non-applicability of the Environment Health Impact Assessment (EHIA) System to GMO biosafety evaluation (per DOH) (6) Relative to items (4) and (5) above, the requirement for technology developers to submit a Project Description Report for applications for Field Trial and Commercial Propagation is not applicable for GMO biosafety evaluation.	Remove the applications of EIA and EHIA from the revised guidelines, including the requirement to submit a Project Description Report.	Efficiency
(7) The DENR should not be involved in the evaluation of products for Direct Use as FFP (per DENR).	Remove the DENR's role in the evaluation of products for FFP.	Efficiency
(8) The DOH should not be involved in the evaluation of products for Direct Use as FFP (per DOH)	Remove the DOH's role in the evaluation of products for FFP.	Efficiency
Note: Items (9), (10) and (11) are related with each other: (9) Core function of DENR on the biosafety evaluation of GM plants and products (10) Core function of DOH on the biosafety evaluation of GM plants and products (11) Efficiency and effectiveness of current bodies in the DA, DENR and DOH undertaking biosafety evaluation of GM plants and products.	The DENR should focus its evaluation on environmental risk assessment of GM plants applied for Field Trial and Commercial Propagation. The DOH should focus its evaluation in assisting the DA on food safety assessment of GM plants and plant products applied for FFP and Commercial Propagation. Instead of department-based Biosafety Committees (BCs) conducting separate evaluations of GM plants and products, the DA, DENR and DOH should form with other relevant agencies two (2) technical working groups – one for environmental safety and the other for food and feed safety.	Effectiveness & Efficiency

(12) Socio-economic, ethical and cultural considerations (SEECC) are integral to biotech decision making, but are not part of GMO risk assessment.	SEECC should be removed from the biosafety evaluation of GM plants and plant products applied for FFP, Field Trial, or Commercial Propagation. Rather, discussions on SEECC can be part of the public consultation process where government, in its decision to adopt or not a GM plant or plant product, may take into account "socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities".	Efficiency
(13) The mandatory requirement from an applicant for Field Trial to secure an LGU endorsement or favorable resolution prior to the conduct of the Field Trial is overly onerous and burdensome.	Make optional the securing of an LGU endorsement or resolution for the conduct of the Field Trial.	Efficiency
(14) The JDC1 is silent on how stacks are regulated. However, the current practice is to still require breeding stacks (i.e., stacked events in one GM product combined thru conventional breeding) to undergo biosafety evaluation, even if the component single events have been previously granted individual biosafety permits. This has led to problems of non-synchronicity of valid biosafety permits.	Breeding stacks – with component individual single events that have undergone full safety assessment and been granted individual biosafety permits – should be deemed as safe as their authorized component single events and not be required to undergo a separate safety evaluation process.	Effectiveness & Efficiency
(15) The JDC1 is being interpreted as having a zero-tolerance policy for unapproved GM events in the Philippines but already approved in the country of origin – even if found as trace elements in commodity shipments at low-level proportion. This has caused trade disruption in the past.	Introduce a text on Low-Level Presence (LLP) policy in the revised guidelines that would allow the country to assess the safety of unapproved GM materials at low levels in terms of allergenicity and toxicity using the FAO principles of food safety assessment in LLP situations.	Effectiveness & Efficiency
(16) RA 11032 (or the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018") shall also apply to this new guidelines being drafted.	Incorporate the relevant provisions of RA 11032 in the new guidelines, particularly in the preamble, definition of terms, covered activities, and timelines. *<New timeline for the processing of applications for Field Trial, Commercial Propagation, and Direct Use for FFP: from 85 days to 40 days.>*	Efficiency

Source: AHTWG to JDC-1 Reforms, 2019. JDC-TWG 6th Meeting. http://www.ncbp.dost.gov.ph/images/6th_JDC/Item_4.1-Matrix_of_JDC_Proposals-for_TWG_Final_Decision.pdf

IV.3.3 NCBP Resolution on Plant Breeding Innovation (PBI)

Utilization of genomic information and genetic editing tools has been trending in peer reviewed journals worldwide in the last four years (Menz et al., 2020). The Philippines may not be as visible as other countries in international journals but nevertheless has been engaged in utilizing CRISPR-Cas-System for various crops as discussed earlier. The frontiers of science in this field is indeed expanding rapidly. In contrast to the genetic engineering scientists of the late 1980s who sought for process-based regulation, the gene editing scientists of late are seeking for product-based regulation.

DA-Commissioned Study

Not losing sight of the value of gene editing to agriculture and cognizant of the speed of its progress, the Department of Agriculture Biotechnology Program Office (DA-BPO) commissioned a group of scientists and lawyers to study the state-of-the-art in new breeding techniques or NBTs and how regulation has to keep pace. The study team was composed of Dr. Reynante L. Ordonio, Atty. Paz J. Benavidez II, Atty. Edmund Jason G. Baranda, and Dr. Ruben L. Villareal. The specific study objective were to review the NBT R&D, the regulatory landscape, survey NBT regulations in other countries, and evaluate what would work for the Philippines. The final report was completed in November 2018.

Definition of GMO. The study first dealt with the definition of GMO as 'novel combinations' which was not elaborated much in the EO 514. The term was proposed to be defined as "those not likely formed in nature or not possible through conventional breeding." Using this trigger, the GMO products of NBTs including SDN3, agro-infiltration of germline tissues, and cell fusion can distinguished from the non-GMO products. Some NBTs can also produce GMOs through the introduction of short DNA fragments, or remnant border sequences from the gene construct. A 20-base pair threshold was proposed as a trigger for regulatory review. It was argued that fragments equal to or less than 19 bp have a high probability of being found in the genome, and could therefore not result in a novel combination. If the fragment is at least 20 bp, the similarity to the target organism's genome is assessed. If the sequence matches with a sequence in the organism's genome, it will not be considered as a novel combination. On the other hand, if the sequence is unique to a foreign organism, it is considered as a novel combination and the product is classified as GMO and provide a working and clear definition for a product-based regulation. In the end the study defined novel combination of genetic materials to refer to those not likely to be formed in nature and not possible through conventional breeding.

Regulatory treatment of NBT products. The study suggests that plants that are produced using NBTs, but do not possess novel combination of genetic materials and are not GMOs as defined

under applicable laws should be regulated under laws applicable to non-GMOs, unless a new law provides otherwise. Products or organisms that are non-GMOs shall be outside the ambit of EO 514, NBF, JDC-1, and other guidelines on GMOs.

KII/RTD Consultation

The above 20-bp rule which aims to provide clarity on what "novel combinations of genetic materials" that defines a GMO was brought to the experts for discussion in two separate activities — Key Informant Interview (KII) and Roundtable Discussion (RTD). Properly distinguishing GMO and non-GMO products of NBTs can provide a working and clear guide for a product-based regulation. The experts explained that determining the novelty should be crop-specific, and should require the developer to provide baseline information on the crop. However, it runs the danger that this term would suggest that all novel combinations are risky, when in fact, scientists carefully select only the combinations that are good. It was also recommended that instead of the legal term "novel combinations," the scientific term should be used. However, the term "novel combinations" is the internationally accepted definition of GMO from the Cartagena Protocol; it should be retained. It is recommended that the regulation remain to be consistent with the language of the Cartagena Protocol since it will be the "harmonizing factor" among the 173 countries currently ratified to the Protocol (Duensing et al., 2018).

Hence, the proposed 20-bp rule was suggested to be dropped because it is problematic especially considering that the threshold can be easily met naturally through mutations, hybridization, and viral infections. Furthermore, the rule may become obsolete in the near future with the rapid developments in science. It should be pointed out that the 20-bp rule was already discarded in Argentina because it does not have a sound basis, and while there were reasons arguing to retain the rule, they do not relate to regulatory definitions and thus, were not accepted (Whelan and Lema, 2015). No other country included or mentioned the 20-bp rule, so far. Nevertheless, it was pointed out that the Philippines should remain engaged and open to the outcomes of the international discussions about the rule.

The possibility of having a preliminary assessment (consultation) on the regulatory status of a hypothetical product (similar to that of Argentina) was also discussed. Although the benefits of this early guidance to developers are recognized it is deemed not applicable to the Philippines since the country lacks the in-house capacity to do assessments, unlike in other countries like Canada, and United States (Ellens et al., 2019). Considering this shortcoming, pursuing preliminary assessments in the Philippines cannot be supported as of yet.

Some points were also raised relating to the implications of a heterogeneous NBT regulations among trading countries. If the entering product of NBT is unregulated in the country-of-origin, the details regarding the deregulation should be probed. A possible loophole is the possibility of genetic

modification in the traded product being undetectable. On the other hand, if the product is regulated in the source country, the product's information can be found in the source country's GMO registry and it will primarily depend on the country's regulations on how to decide on the product's fate. In light of the perceived challenges to trade, the importance of standardization or harmonization among countries was emphasized.

NCBP Resolution on PBI

The DA-BPO forwarded the final copy of the study by Ordonio et al. (2018) to the NCBP for consideration. NCBP then formed a technical working group TWG composed of the CNAs, three consumer representatives, and one from the NAST. On 7 April 2020, the TWG proposed an NCBP Resolution on PBI which basically provides a regulatory decision tree for the products of PBI or NBT. Only the classic GMO with transgene insert and SDN-3 with transgene insert in the final product are proposed to be regulated. As of this writing, the resolution is being circulated around for signatures of the TWG members. NCBP is hoping to get all the signatures by end of 2020 after which the DA will formulate the implementing rules and regulations (IRR). The IRR will specify the department or entity that will screen PBI products and determine which would require regulation. These developments were briefly presented by Dr. Cariño in the One CGIAR Global Webinar Series on Genome Editing[32] in October 2020. Details of this development are provided below.

Further elaborated by Cariño (2020), the discussions on the new breeding technology started with the DOST Biosafety Committee as early as 2011 when IRRI submitted its first proposal on the use of precise gene targeting methods for improving rice. This initial submission triggered interest in the newly evolving breeding technologies that target specific sequences in the genome, and resulted in alterations of a few nucleotides or specific gene segments. As products of this new technology are developed, and started to enter the market, the DA commissioned the study described above. The DA forwarded the report to NCBP and with enforcing comments from the National Competent Authorities in the Symposium and Workshop on Risk Assessment and Regulation of Genome-Edited Plants held in October 2019 the NCBP formed the TWG which drafted the resolution. The resolution refers to PBIs as "a new set of molecular, genomics, and cellular tools that enable the targeted and efficient development of new varieties of crops with desired traits in a way that is faster and more precise than conventional plant breeding techniques."

In the new regulation, the use of Modern Biotechnology and the possession of novel combinations of genetic materials are the criteria used to determine regulatory status of products. Similar with the proposal in the DA-commissioned study, the term "novel combinations of genetic materials" will be defined under the resolution as "a resultant genetic combination in a living organism that is not

[32] https://www.icrisat.org/wp-content/uploads/2020/10/Regulation-and-Genome-Edited-Plants_Webinar-4.pdf

possible through conventional breeding." Furthermore, a decision tree in determining the regulation of PBIs was also presented (Figure 33). Products that did not involve Modern Biotechnology in the method of development such as the products of mutagenesis, hybridization, tissue culture, and fusion of related cells will fall under the regulation of non-GM or conventional products. The resolution also considered the possible formation of products that involved Modern Biotechnology but harbored a novel combination, such as those resulting from the horizontal gene transfer (HGT) by some bacteria and viruses. This suggests that novel combinations may also arise naturally which results to a naturally transformed plant. However, despite the presence of novel combinations, the HGT products are classified as non-GM since they were not produced through Modern Biotechnology.

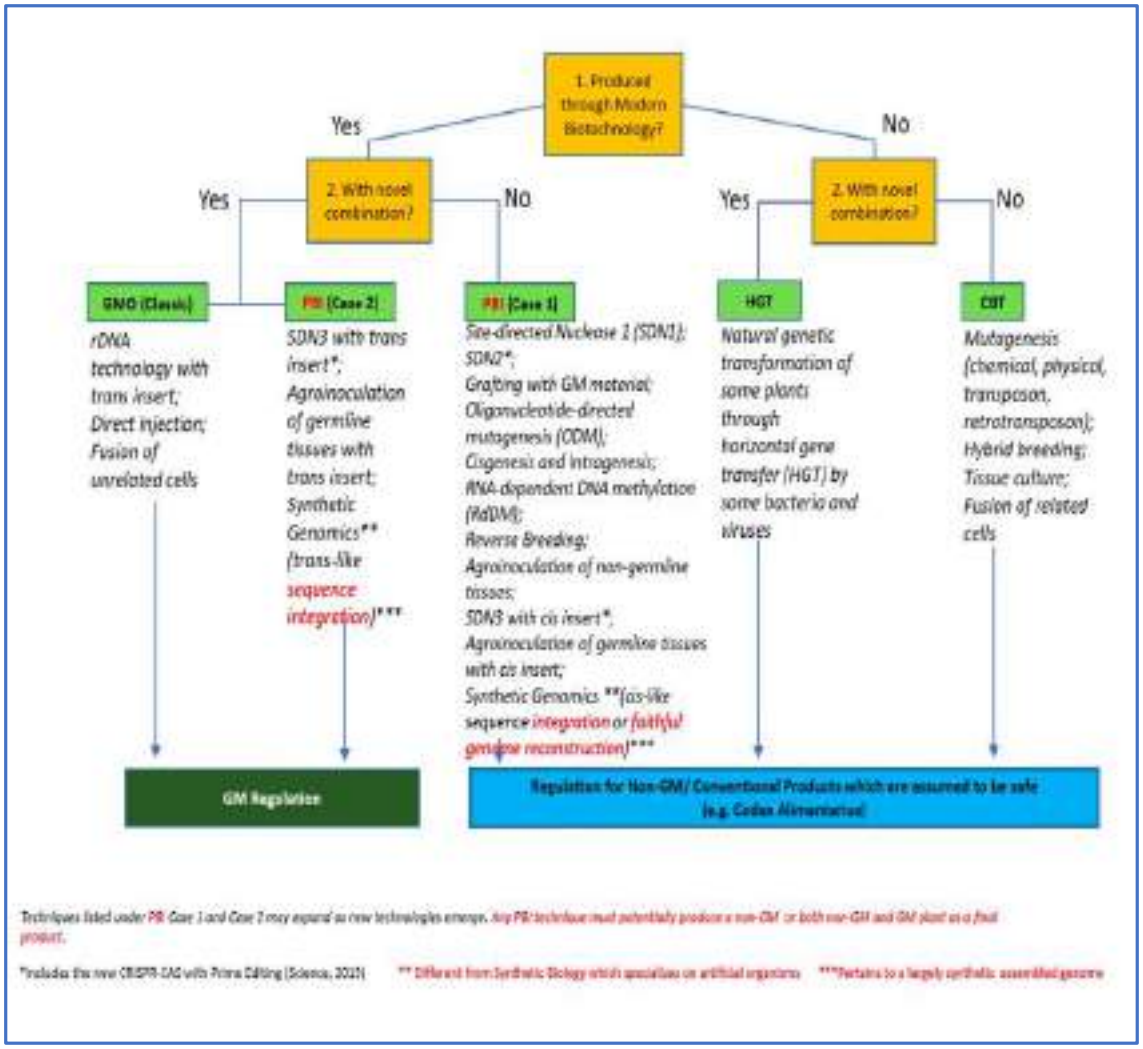

Figure 33. The regulation of plant and plant products derived from the use of Plant Breeding Innovations, Draft Resolution (NCBP, April 2020).

For products produced through Modern Biotechnology, the absence of novel combinations distinguishes the PBIs with products similar to conventional products (under the PBI Case 1), classifying them as non-GM. This potentially exempts a long list of PBIs from the regulation, as seen in the decision tree. Other PBIs that can incorporate novel combinations such as SDN3, Agro-inoculation of germline tissues with trans insert, and Synthetic Genomics with trans-like sequence integration would trigger regulation, similar to the "Classic" GMOs regulated in the current framework. The characteristic of the products that indicated the presence of novel combinations is the insertion of a gene or a smaller fragment of genetic material from a non-sexually compatible species, which is indicated as a "trans insert" in the decision tree. Accordingly, the counterpart PBIs with cis insert, which introduces genes from the same or a closely-related species, are considered as non-GM.

In terms of the implementation of the proposed regulation for SDN1 and SDN2 where insertions of a foreign gene are involved but only in the initial phase, the organism will continue to be regulated in the contained phase by the DOST-BC until such time that the insert is bred out. A certificate declaring that no novel combination remains in the organism will be given to the developers. The DA will then takeover in the oversight of the organism according to its rules for non-GM plants.

IV.3.4 On Liability and Redress: The Nagoya-Kuala Lumpur Protocol

As regards the risks involved in the transboundary or intercountry movement of GMOs, the rules and procedures to address liability and redress in the event of accidental damage were openly discussed during the first meeting of the parties to the CPB. Several years of negotiations resulted in an elaborated damage mechanism—the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (NKLSP)—which was finalized in 2010 and put into force in 2018. However, the Philippines has not ratified and signed to signify commitment to the NKLSP despite being one of the negotiators.

However, there has been initiatives undertaken in the country towards the implementation of the NKLSP. In 2016, a Technical Working Group was constituted by the NCBP to "assess the country's preparedness in implementing the Protocol and to identify existing laws and policies in the country that would address the damage." Key findings of the TWG indicate the lack of a unified operational definition of damage to biological diversity arising from the use of LMOs to date. Furthermore, the administrative nature of the NKLSP would require an agency authorized for its implementation.

Meanwhile, the UP Law Center carried out a project on developing a framework to implement the NKLSP in the country should the country decide to accede to the Protocol. A TWG was also created for the project composed of representatives from different competent national authorities: Dr. Vermando Aquino from UP Diliman NIMBB, Prof. Edgardo Carlo Vistan from the UP College of

Law, Atty. Jacqueline Espenilla and Atty. Celeste Ruth Cembrano Mallari from the UP Law Center, Ms. Amparo Ampil from the DA, and Atty. J. Anthony Pena formerly from the DENR. The TWG identified the DENR as befitting to implement the NKLSP since it has the responsibility over the conservation and sustainable use of Biodiversity under the Admin Code of 1987. The TWG also identified key technical issues that need to be considered in the implementation. Firstly, to determine the value or extent of damage to biodiversity, a baseline of the ecosystem must be established first. The baselining must then apply a good risk assessment procedure in order to prevent overestimating or underestimating the hazards and risks. Secondly, proving the causation of the GMO to damage will be difficult because of the complex interaction of GMOs with the environment. Lastly, to reasonably attribute a damage to a GMO, the concerned authority must then be able to trace the cause of damage within an appropriate time period, but the TWG found difficulties to determine this time period.

The NCBP conducted an in-depth review of the NKLSP provisions and then proposed a legislation to the Congress. The DENR-BC stated that they recognize the need to establish a law addressing redress for GMO damage, but they decided not to support the draft bill for now considering the "stringent requirements" imposed on the DENR. Although the DENR recognizes the need for a baseline in determining damage it currently lacks the technical capacity and budget to conduct the baselining. Instead, DENR endorsed the following regulations to be sufficient in addressing potential damage resulting from transboundary movement of GMOs: Wildlife Resources Conservation and Protection Act (RA 9147), Expanded National Integrated Protected Areas System Act of 2018 (RA 11038), and the Civil Code of the Philippines on Damages, among others. In the drafted 4th National Report to the Cartagena Protocol, rules in relation to damages can be found in the Philippine Biosafety Guidelines where product proponents are required to submit contingency plans and response measures. In the event of incidents, the proponents are also obliged to inform the regulatory agencies and undertake measure to mitigate the risks.

Thus, the issue the country faces in so far as the NKLSP is concerned is not about the need for a liability regime but rather the political will to implement the applicable domestic laws. If the Philippines is really committed to support the liability mechanism then future efforts from concerned agencies, particularly the DENR, should be directed towards fulfilling the requirements of the NKLSP where the domestic laws on GMO damage can be applied. It would greatly help if the developers, the end users of GMO technology, the public, and other stakeholders can be given clarity on how accidental damages from transboundary movements can be addressed in the even they happen. This may create a sense of assurance of protection so GMO utilization may further expand in the country.

V CONCLUSION

Objective 1: Synthesize data/information on domestic and international policies related to crop biotechnology from literature review:

The study reviewed the regulatory policies and approaches in Argentina, Australia, Canada, Japan, United States, and the European Union. Seven aspects were discussed: a) regulatory trigger; b) plant/crop trait-mechanism of action, c) regulated articles, d) regulation required for cultivation, e) regulation required for food, f) technical expertise, and g) regulation of new breeding techniques or plant breeding innovations.

Countries that embrace GM crop cultivation has a product-based regulation

The attitude towards GM cultivation among the selected countries are generally supportive except for Australia, which is reluctant, and Japan, an abstainer. In the countries where GM products cultivation is supported, the biotechnology regulation is triggered by the risks posed by the product (i.e. product-based regulation) and not by the process used (or process-based regulation). On the other hand, the Philippines remains to have a processed-based regulatory trigger. A study by Whelan et al. (2020) explored the effects of the above product-based regulatory trigger, particularly on new breeding techniques, on the pattern of R&D in biotech in terms of the economic profile of innovations. The study reports a change from what used to be dominated by multinational companies to a more diverse group of developers led mostly by small and medium enterprises (SMEs) and public research institutions. Moreover, the product profiles are more diversified in terms of traits and organisms.

Biotechnology supportive countries adopt a plant/crop trait-mechanism of action

A product-based approach also allows the consideration of the plant-trait-mechanism of action combination in determining regulation, which is being practiced by US and Argentina, and in part by Canada. This permits the established knowledge and experience from the previously done successful assessment or approved applications to be applied to new applications with a similar combination, reducing the data requirements for the new application which consequently lowers the cost for the applicant (Beker et al., 2016). As a result, new applications with similar plant-trait-mechanism of action with an approved application can undergo a streamlined process. At present, the Philippines has not yet adopted such streamlined mechanism.

Defining regulated article in each country differs

Most countries, including the Philippines, depend on the GMO definition. On the other hand, Canada and United States are unique among the countries compared because their regulation are not specifically tailored for GMOs. In particular, Canada's definition for food regulation (Novel Food) and US' definition for cultivation regulation (plants that are genetically engineered and meets the definition of a plant pest) only have a GMO component. On the other hand, Canada's Novel Trait definition and US' Adulterated Food definition does not distinguish between GMO and non-GMO. This means that no stricter rules are applied on GMOs than the conventional products, which may be more advantageous for developers.

The Philippines has very limited expertise organic to its regulatory body, unlike Argentina (regular provider established), Canada (both organic and non-organic expertise), and the US (organic expertise)

Human resource or technical expertise in the regulation was also assessed in the study. Technical expertise that is organic to the regulatory body will be referred to as organic technical expertise and characterized as the in-house and full-time experts who are mandated to perform the assessments. On the other hand, a non-organic technical expertise will be characterized by outsourced experts, or ad-hoc committees. Across the countries compared, organic technical expertise is more common. It is notable that Canada and United States, the countries that have the highest number of cultivation approvals from 1992-2014, both have an organic technical expertise (Aldemita et al., 2015). Japan is quite notable because it ranks just below Canada and US for the number of approvals for cultivation despite having no organic source of experts.

Argentina has the National Commission on Biotechnology (Conabia), the technical advisory body, is an established regulatory body with part-time experts, who are representatives from institutions and the academe. This also allowed Argentina to perform preliminary assessment (consultation) on the regulatory status of a hypothetical product. Although the benefits of this early guidance to developers are recognized, it is deemed not applicable to the Philippines since the country lacks the in-house capacity to do assessments, unlike in other countries like Canada, and United States (Ellens et al., 2019). Considering this inadequacy, pursuing preliminary assessments in the Philippines cannot be supported as of yet.

Having technical expertise that is organic to the regulatory body allows to take more responsibilities and evolve alongside the increasing demand for regulations in terms of the number of applications. Furthermore, having non-organic technical experts has drawbacks such as the limited efficiency due to their ad-hoc and part-time nature (Mackenzie, 2000). In the Philippines, there remains to be inadequacies in the human resources organic to the regulatory bodies or in technical manpower and expertise dedicated to the regulatory functions (Manalo, 2019).

The Philippines became the first Southeast Asian country to have a regulatory framework

While the Philippines needs to keep up with the advance countries in adopting effective and facilitating biotechnology policies and institutional support, the USDA (2018) pointed biotechnology leadership to the Philippines among its Asian neighbors. The Philippines is the first country in Southeast Asia to have a regulatory framework for GE crops and also the first to allow their commercial propagation through the creation of the NCBP in 1990. From the first established regulatory policy through EO 430, to its transformation as an Administrative Order (AO-8), to its revival through the Joint Department Circular-1 (JDC-1), the Philippines still continues to move forward with several reforms that targets to make the current regulatory system more efficient and effective.

It was only in 2016 when Indonesia established a regulatory framework for GM/GE crops. Though it has completed its Risk Assessment Framework and Environmental Food Safety Guidelines, approvals of GE applications could still not proceed until the monitoring and control system is in place. Malaysia's biotechnology policy takes the form of the National Biosafety Board regulations but the lack of manpower caused the approval process to exceed the targeted 180 days processing time. Vietnam is growing GM crops and follows the Biosafety Decree 9 of 2010 as its legal framework. On the other side of the spectrum, Thailand's regulations are currently restricted to research and the commercialization of GE crops are banned. A draft of Thailand's National Biosafety Law is yet to take effect.

Myanmar, despite being considered a "biotech mega-country," having an estimated 490,000 hectares of land for GM corn cultivation, has no clear regulatory policy for biotechnology. A draft National Biosafety Framework was last updated in 2009, and the regulators continue to update the draft guidelines. Laos established its National Biosafety Framework in 2004 and ten years later this framework was enforced under the Biotechnology Safety Law; however, the protocol for contained use is only "partially placed" while the protocols for field trials and FFP are still under review (Gonzales et al., 2018). Cambodia adopted the National Biosafety Framework (NBF) in 2004 similar to the Philippines. Four years later (2008), the National Biosafety Law established the protocols for regulating GMOs imported for contained use, intentional release to the environment, and direct use as food or feed or for processing were developed. It took a couple of years later (2010) and a sub-decree to establish the implementing procedure. So Cambodia is able to regulate GMO for field trials and direct use only.

Singapore does not have a framework but has guidelines for GMOs for food and feed. Singapore is not an agricultural country and has not signed as a party to the Cartagena Protocol. Singapore

follows the Guidelines on the Release of Agriculture-Related GMOs by the Genetic Modification Advisory Committee (GMAC).

Among the Southeast Asian Countries, the Philippines has the most crop biotechnology products under the (in ongoing? That has undergone?) field trial like eggplant, rice, and cotton. While the golden rice has been recently approved for direct use, application for its commercial propagation is still in process. The Philippines is also the first country to approve GM corn for food or feed in 2002. Upon the initial approval for the commercial propagation of Bacillus thuringiensis (Bt) Bt MON 810 in 2002, a total of 10,000 hectares were planted with the Asian corn borer-resistant corn in 2003 (Panopio and Navarro, 2011). Since 2003-2015, Filipino farmers who planted Bt corn earned an estimated $642 million (ISAAA, 2017).

The Philippines takes a supportive stance on biotechnology; regulatory policies in place

Zooming in on the biotechnology-related policies in the Philippines, the national policy statement promotes “the safe and responsible use of modern biotechnology and its products to achieve food security, equitable access to health services, sustainable and safe environment, and industry development.” This national pronouncement directs the concerned national government agencies like the Departments of Science and Technology, Agriculture, Environment and Natural Resources, and Health to support biotechnology initiatives. The DOST and DA have been investing in crop biotechnology R&D, particularly in genome editing that employ site-directed nuclease technology — SDN-1, SDN-2 and SDN-3. DOST follows the genomics-biotechnology roadmap for years 2017-2022 and DOST-PCAARRD’s research portfolio is worth PhP77.22 billion and includes genome editing projects that are currently being undertaken in various universities. The DA-Biotech funded just recently the first gene editing project for rice. The RDIs engaged in biotechnology R&D are UPLB-BIOTECH, UPLB-IPB, PhilFIDA, PhilRice from the government side and form the private sector, Monsanto and Syngenta, among others.

On the regulatory side, the Joint Department Circular of DOST, DA, DENR, DOH, and DILG (referred to as the JDC-1) serves as the current regulatory policy and was established to replace the DA AO8, the implementing guidelines for importation and release of PPP derived from modern biotechnology. JDC-1 contains the rules and regulations for 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. Currently, the institutions involved in the regulation of biotechnology crops under the JDC-1 are as follows:

1. NCBP to date is mandated to formulate, review, amend the biosafety guidelines.
2. DOST-Biosafety Committee processes applications for Contained use and Confined Test and issues Certificate of Completion.
3. DA-BPI and DA-BC: consolidate and evaluate the risk assessment reports. The BPI Director finally issues Biosafety Permit for applications for (Multi-location) Field Test, Commercial Propagation, and Direct Use for food, feed or processing

On the other hand, the risk assessments and registration are done by the following national departmental agencies:

1. DENR: conducts risk assessment for impact of biotech crops on the environment
2. DOH: conducts risk assessment for the impact on of biotech crops as food on human health
3. DA-BAI: conducts risk assessment for the impact of biotech crops as feed on animals
4. DA-FPA: Registration of plant incorporated protectants (PIP)

Risk assessments are performed for all regulated articles to identify and evaluate the potential adverse effects on the receiving environment as well as risks to human health. Based on Sec. 3.3.12 of the National Biosafety Framework, regulated articles pertain to genetically modified organisms and its products. The assessments under the JDC are carried out in a scientifically sound manner and adopts the “Precautionary Approach” in compliance with the Cartagena Protocol on Biosafety. The risk assessment also adopts Principle 15 of the 1992 Rio Declaration on Environment and Development which states that, “where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” Further, the risks of a GE crop, for example, shall be compared in the context of the risks posed by the traditionally bred crop. As stated in the Cartagena Protocol, the steps involved are as follow:

1. Identification of the novel genotypic and phenotypic characteristics associated with the GMO, evaluation in terms of the perceived hazard qualitatively and identification of measurable properties in order to more accurately assess the risk;
2. Evaluation of the likelihood of the adverse effect taking into account the level and kind of exposure the GMO will be subjected to upon introduction to the environment;
3. Evaluation of the consequences of the adverse effect if it occurs;
4. Estimation of the overall risk based on the estimated likelihood and consequences of the adverse effect;

Objective 2: Assess the competitiveness of the country's biotechnology policy in contributing to food security and agriculture development

Efficiency in completing biosafety applications and effectiveness in ensuring safe use of biotechnology used as parameters in assessing biotechnology policies

The country's policy and institutional framework for crop biotechnology seek to regulate crop biotechnology research, development, and production or commercialization to ensure that none of the associated biosafety risks transform into serious and irreversible hazards to public health and the environment. On the one hand, these policies must be examined to ensure that it does not arrest technological developments and preclude the public from benefiting from the promises of biotechnology. Assessing the competitiveness of these policies therefore needed a two-pronged analysis such that two important aspects are examined—effectiveness and efficiency of policies in facilitating biotechnology products development and indicative contribution of biotechnology to agricultural development and food security. Put simply, if the policies can facilitate development of products that contribute to agricultural development and food security while at the same ensure that any biotechnology initiatives shall adhere to safe handling and responsible use, it is deemed to be competitive.

Decreasing trend of permits issued and delayed processing observed in the regulatory process across differing policy regime

In terms of efficiency, the ultimate measure is the number of completely processed biotechnology applications (approved or disapproved) per year. Approved applications for contained use and confined test in the country seemed to follow a decreasing trend across different policy periods. For contained used, there were a total of 88 approved applications issued under EO 430 period and 55 and 35 approved applications under the AO-8 and JDC-1 periods, respectively. For the applications for confined testing, a total of 20 applications were approved under the AO-8 regime and seven under the current policy, JDC-1. The applications came from different research institutions like UPLB, UP Mindanao, VSU, DA-PhilRice, DA-PCA, IRRI and private institutions such as Monsanto, Syngenta, and Pioneers.

In operational terms, efficiency can also be gauged by comparing the prescribed number of days of approval process with the actual number of days of approval process. In comparing the actual number of days to the prescribed number of days of application processing, significant delays have been noted. For example, under JDC-1, each regulator (STRP, PPSSD, DOH, DENR, SEC expert, and BAI) is concurrently given 30 days to complete the risk assessment or evaluation but actual durations were 2.4 times to 9.3 times much longer. After completing these evaluations, the BPI writes a recommendation to the DA Biosafety Committee. The DA-BC makes a final review and

sends its approval advise to the BPI Director who then issues/denies a biosafety permit. The DA BC is given 10 days but the average actual number of days it took to complete the final review was 155, or 15.5 times longer than what is prescribed. Manalo (2019) also cited the absence of the Manual of Operations that would have served as a guiding document and facilitated the processing of biosafety applications.

There is also a need to review the process flow and role of DA-BC in processing biosafety applications for (Multi-location) Field Test, Commercial Propagation, and Direct Use for food, feed or processing to avoid the “observed” redundancy in the technical evaluations of the CNAs and the STRP.

No adverse effects on the environment and human health have been recorded or empirically established

Under effectiveness, the regulatory policy is deemed successful if it prevents or continue to prevent any incidence of biosafety hazards originating from biotechnology initiatives and the use of biotechnology products. What has also been confirmed by the study is that, given almost a hundred of approved applications, no adverse effects on the environment and human health have been recorded or empirically established. As in the case of GM corn for feeds, which has been commercialized since 2003, there has been no incidence of anything less than the safe when it comes to its cultivation. This is a testament to the effective and scientifically sound manner the risk assessments have been performed to identify and evaluate the potential adverse damages. The assessments under the JDC-1 adopts the “Precautionary Approach” in compliance with the Cartagena Protocol on Biosafety and the Principle 15 of the 1992 Rio Declaration on Environment and Development which states that, “where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”

Indicative positive impacts of crop biotechnology products noted as GM corn remains to be financially viable and highly productive

The indicative contribution of biotechnology products can be measured by analyzing its impacts at the farm level and suggestive self-sufficiency effects. The study conducted an ex-post impact analysis of the adoption of GM Corn, which is the only commercialized biotechnology product in the country and widely planted in CAR and Regions 1, 2, and 10. What this study has first validated is that GM corn could offer a yield advantage of about 1—3 mt per ha over other seed technologies

like Sige-sige and Hybrid. Such findings are consistent with the findings of Yorobe and Quicoy (2006) and Afidchao et al. (2014), indicating that GM corn remains to be a viable technology for the farmers. Income advantages of GM corn based on returns above cash cost were estimated at 3,000 pesos per ha over Sige-Sige, a counterfeit in GM OPV in Bukidnon and around 20,000 pesos per ha over Hybrid in Isabela. Further proving that GM technology generates positive farm level impact that is indicative of its potential contribution to agriculture development and food security.

At the industry level, GM corn's impacts on food security has been observed using the demand for corn derived from the feed demand for poultry and swine. As the demand for meat, egg, and dairy products increases so does the demand for yellow corn. In fact, corn production responds positively to increases in the prices of chicken and pork (Nasol et al., 1982). Data suggests that feed demand for poultry, eggs, and hog production were met by domestic production and importation of yellow corn (Figure 11). However, extreme weather events and climate change phenomena resulted in years of low supplies that required the government to permit importation.

The sustainability of GM corn as a technology is however challenged by the high cost of GM seeds and the proliferation of an otherwise counterfeit OPV-variant of GM corn

The income gains from GM corn can be easily offset by the high price of seeds that comprise 20% of the total cash costs. The DA has programs distributing free GM seeds and if not for these subsidies, the GM adoption rate in Bukidnon would have been lower where planting of Sige-Sige variety (OPV variant of GM corn with RR or HT trait) is quite popular owing to its adaptability to the local conditions and the 20% savings in seed cost. Moreover, Sige-Sige is allegedly effective in mitigating the risks of yield loss due to drought especially in hilly areas. Sige-sige is also reported to be recycled, treating it as basically "free" and may not be considered a cash cost. While the farmers valued Sige-sige at cheaper prices of 20 to 70 pesos per ha, risks of genetic erosion would be present in its continuous recycling. There is also reported absence of refuges in Sige-sige seeds and the danger of low Bt does can a major source of genetic erosion. The DA-IRMAT requires the dose to produce a 99% kill and refuge seeds of 1 kg per 9 kg of GM seeds to avoid or slow down the build-up of insect resistance to Bt. This regimen is non-existent in Sige-sige or any genetic counterfeit GM corn. Experts in the RTD pointed out that a breakdown of resistance-to-insects in Bt corn is a public concern and recommend that the stewardship aspect of counterfeit GM corn be studied.

Ex-ante estimates for Bt eggplant shows areas for improvement

An ex-ante estimates of farm level benefits from Bt talong was also derived in the study. To date, Bt talong has completed three out of the four regulatory stages: confined trials (2005 to 2007), single-location, limited confined field trial (2008 to 2009), and multi-location trials in four sites (2010 to 2012). The confined trials in Pangasinan showed that all Bt eggplant lines exhibited high field efficacy and provided control of EFSB shoot and fruit damage as well as larvae infestation reduction. However, the current ex-ante analysis estimates that hybrid varieties show a higher yield compared to Bt eggplant. Revisiting Figure 21, Bt eggplant's marketable yield is lower than all others except for PS-Hybrid (pesticide safe production) which is reasonable since in the presence of pest pressure, production can really be lost to EFSB unless insecticides are used as control. The marketable yield of Hybrid from the 2010 survey by Francisco (2014) is higher than all others in the current study; under similar EFSB control regime, it is higher by 4.5 MT/ha than the Hybrid estimates in the current study owing to the greater proportion of rejects since their gross yields are the same.

Crop biotechnology products have a huge potential to positively impact on food security; However, institutional and regulatory policies reforms are needed to facilitate, accelerate, and continue innovations

Both the ex-post and ex-ante assessments reveal two important points. First is that GM technologies indeed has the potential to positively impact on food security. It is productivity improving—as shown by the yield advantages over other seed technologies, profitable, and has the potential to stabilize farm performance as a results of its biotic resistance traits. Nevertheless, there are threats to crop biotechnology products such as risks of genetic erosion or depleted durability and risks of obsolescence.

This brings the second point that, similar to other technologies, biotechnology products require continuous improvement and innovations as the dynamic environment presents new and emerging concerns. The Philippines, having a diverse landscape, may also require various biotechnology products suited to the various physical context. As what has been observed in GM corn, Sige-sige seeds are more preferred by farmers in Bukidnon because of its adaptability to local conditions and its observed ability to withstand drought, which is not yet present in the current GM corn strains referred to in this study. In the case of Bt talong, where there is high preference among farmers for hybrid varieties, there is a point to the suggestion of Franciso (2014) to introgress Bt on hybrid varieties. Bt introgressed on hybrid varieties would have high potential rate of adoption due to the farmers' preference for hybrid and insecticide cost-reducing potential.

As noted earlier, while the regulatory policies are deemed to be effective, processing of biosafety permits are noted to be inefficient. If reforms are not made in the status quo, continuous

improvement and innovations in crop biotechnology would not be possible. And so the country may not get the best out of the biotechnology's potential to contribute to food security.

Objective 3: Identify innovative policy approaches and other effective policy initiatives

In the first two objectives, the study examined the existing biotechnology-related policies abroad and in the country and presented the assessment of policies in terms of effectiveness and efficiency. Three major issues figured prominently in the assessment, the first one being the limited institutional support as shown by inadequate in-house or regular technical experts and absence of manual operations. The second issue is the observed redundancy in functions and inclusion of requirements that are deemed unnecessary. The last one is the adherence to a process-based regulatory trigger. The first two issues are intertwined as both contribute to the significant delays in processing the biosafety applications. Continuous implementation of a process-based approach, on the other hand, presents the possibility of subjecting all new breeding techniques or plant breeding innovations to the regulations for GM, even if the resulting product is non-GM, instead of putting them through the traditional regulation meant for the non-GM crop products. The process-based approach also requires that such novelty be crop-specific, and therefore requires baseline information of the crop's genomic sequence, which is not currently available.

The study then proceeded with the examination of emerging policy options such as the proposed Modern Biotechnology Act (or BioAP), JDC-1 reforms, product-based regulation adoption, and Nagoya-Kuala Lumpur Supplementary Protocol ratification. This provided the study ex-ante insights that are useful in identifying innovative policy approaches. Results of the policy review were validated with the experts and consensus of the science community on the said policy areas were obtained through a two-round Policy Delphi Survey, roundtable discussions, and key informant interviews. The validated points are as follows:

BioAP Bill must focus on the promotional and developmental roles

BioAP or House Bill 3372 proposes to create Biotechnology Authority of the Philippines as an agency of the DOST with its own Presidential-appointed executive director. The NCBP, which has assumed a diminishing regulatory role since its creation in 1990, will be totally abolished as BioAP takes a central role in biosafety regulation. BioAP will also take on promotional functions such as taking the lead in modern biotechnology programs by providing support to the development of the scientific human resources, modernize facilities and also sustained funding. Unauthorized destruction of biotech crops during experiments will not be punishable by law while the production and sale of fake GMO seeds will also be prohibited.

What the BioAP attempts to address are the inefficiencies in the regulatory system, lack of legal personality, lack of funds, obsolete rules on regulated articles, the stalling of biotech crop development and the pursuit of national goals challenged by climate change individually. The proposed bill therefore aims to provide rightful institutional support and expedite the regulatory decision-making process to accelerate biotechnology innovations. Implicit in these motivations are the following policy goals: safety of human health and consumers, accelerated crop biotechnology research and development, availability of scientific human resources in biotechnology, and continuous capacity development. The salient provisions in the bill are summarized as follows:

1. Revise the biosafety guidelines such that they are simplified, product-based, and still science-based built through a consensus among scientists;
2. Abolish the NCBP and replace with the Biotechnology Authority of the Philippines (BioAP) as an agency of DOST. The Executive Director of the BioAP will be appointed by the President upon recommendation of the DOST Secretary;
3. BioAP will have its own funds (P500 million as initial funds) under the General Appropriations which would enable the agency to: a) support capacity building and long-term modern biotechnology programs of government universities and research institutions, b) establish state-of-the-art facilities, c) provide sustained funding for modern biotechnology programs including agriculture, d) lead in educating the public regarding modern biotechnology, and e) serve as arbiter of all issues particularly in matters of biosafety of GMOs;
4. BioAP shall make it illegal and punishable by law: a) unauthorized destruction of biotech crops during experiments, and b) production and sale/distribution of fake GMO seeds; and
5. Financial aid given to BioAP or other agencies involved in modern biotechnology will be exempted from donor's tax and constitute a deductible to donor's tax. Also exemptions from the Government Procurement System.

However, based on the scientists and experts, the BioAP taking the dual role of both regulating and promoting biotechnology R&D may be quite conflicting. An expert who participated in the Policy Delphi Survey also forewarned that the government agencies that assume both roles "eventually succumb to political machinations and fail to deliver."

The results of the consultations and validation meetings support the proposition for BioAP to concentrate on the promotion of research and development (R&D) in biotechnology. Further, it has to be an agency solely for agriculture. The name does not have to be BioAP or the bill dubbed as "Modern Biotechnology Act" but something for Agriculture as recommended in the round-table

discussions. Whatever the name of the agency will finally be, it should be committed to support the acceleration of biotechnology innovations. The BioAP must also focus on improving infrastructure, human resource capacity, partnerships, and investments in R&D.

NCBP may be reinstated with the leadership role on the regulatory functions

The motivation behind legislating a regulatory agency was drawn from the decision of the Supreme Court to reverse the unfavorable 2015 decision. This is regarding the Bt Talong case where of the Court of Appeals noted that "there is no single law that governs the study, introduction and use of GMO in the country" and recommended to Congress to establish a regulatory agency through a legislation. The response of House Representatives to write House Bill 3372 and propose BioAP is well appreciated by the experts who believed in this "solution" to the vulnerability of EOs and AOs to legal challenges.

On the other hand, the experts in the roundtable discussion recalled how efficient NCBP was in the processing of applications during the early years. It was therefore recommended not just to keep NCBP but for NCBP to be given adequate institutional support. Doing so may be in the form of a legislation, thereby instituting the NCBP as a Commission with adequate appropriations for institutional and capacity development. Under this institutional reform, NCBP as a Commission would be empowered with sustained funds dedicated for its regulatory operations and plantilla positions so it can hire, develop, and retain qualified technical staff, in so doing a pool of regulatory experts shall be established. This would address the observed lack of commitment among the CNAs to attend meetings and comply with the specified lead times to process applications and the lack of dedicated technical staff to do the risk assessments.

Integral to the reform is bestowing the NCBP with powers to formulate and amend regulatory policies. In this manner, the regulatory policies will remain flexible, as it can be changed to fit the dynamic context of biotechnology, public health, and environment, and in general to keep up with the developments in science. A legislation can be used to empower the NCBP and transform it into a regulatory body that formulates policies. The regulatory policies need not be legislated.

Facilitate regulatory reforms and transition through a JAO or EO

The JDC-1 review that the NCBP, DOST-BC and the DA are pursuing if done swiftly to reform the regulatory system may add vigor to the research activities and speed up the development and release of biotech crops not just from the private sector but more importantly from the public and international research centers.

As mentioned previously, the JDC-1 (2016) was drafted almost in haste to replace AO8 after the Supreme Court issued a cease and desist order against AO8 in 2015. The anti-GMO pressure for regulation to consider the *writ of kalikasan* argument added DENR and DOH among the regulators and DILG to oversee public consultations. Recalling Figure 6 thru Figure 8 and the discussion in Section II.3.2, JDC-1 is indeed fraught with problems relating to lack of full time well trained regulators, bureaucracy, redundancy and inefficiencies.

The 12-point reforms to the JDC-1 summarized in Table 24 basically remove irrelevant requirements or redundant CNA roles, reduce the required socio-economic considerations and LGU endorsement to optional, improve the clarity of text (i.e. pertaining to FFP application), introduce text relating to "transportability" of GM approvals from other countries, deregulate GM crops after five years of record safe use (CP and FFP), and cutting the days to process application from 85 days to a maximum of 40 days in compliance with the "Ease of Doing Business" law or RA 11032.

In terms of implementation, the DOST-BC will take care of contained/confined use applications while the DA shall take care of applications for (multi-location) field trials, commercial propagation and direct use for food, feed, or processing. By these reforms, approval delays of months and years can be completely avoided and compliance cost greatly reduced. From the viewpoints of public and international research centers, the reforms shall essentially break the barrier to commercializing their crop varieties. Donors would also be encouraged to fund research activities in crop biotechnology knowing that the regulatory inefficiencies are removed. These reforms are to be finalized by the Ad Hoc TWG in a meeting by late 2020 to early 2021.

Further, the recommended reforms did not consider the "temporal limitation" of the definition for "regulated articles" under JDC-1 to refer to genetically-modified plants and plant products which was based on the state of genetic engineering 30 years ago. In the last five years or so, crop biotechnology evolved at an accelerated pace with the increased utilization of genomics information and genome editing tools (also called new breeding tools or NBT) in plant breeding. Scientists clamor to spare products of genome editing that do not involve the insertion of foreign genes and therefore do not fall under GM category as it was known 30 years ago which was the reason for biosafety regulation. Perhaps an additional text referring to the presence of foreign genes in the final product will provide clarity to the definition of "regulated articles."

NCBP to adopt the TWG proposed resolution on PBI

The TWG proposed an NCBP Resolution on PBI which basically provides a regulatory decision tree for the products of PBI or NBT. Only the classic GMO with transgene insert and SDN-3 with

transgene insert in the final product are proposed to be regulated. As of this writing, the resolution is being circulated around for signatures of the TWG members. NCBP is hoping to get all the signatures by early 2021 after which the DA will formulate the implementing rules and regulations (IRR). The IRR will specify the department or entity that will screen PBI products and determine which would require regulation. These developments were briefly presented by Dr. Cariño in the One CGIAR Global Webinar Series on Genome Editing in October 2020. Details of this development are provided below.

Further elaborated by Cariño (2020), the discussions on the new breeding technology started with the DOST Biosafety Committee as early as 2011, when IRRI submitted its first proposal on the use of precise gene targeting methods for improving rice. This initial submission triggered interest in the evolving breeding technologies that target specific sequences in the genome, and resulted in alterations of a few nucleotides or specific gene segments. As products of this new technology are developed, and started to enter the market, the DA commissioned the study described above. The DA forwarded the report to NCBP and with enforcing comments from the National Competent Authorities in the Symposium and Workshop on Risk Assessment and Regulation of Genome-Edited Plants held in October 2019 the NCBP formed the TWG which drafted the resolution. The resolution refers to PBIs as “a new set of molecular, genomics, and cellular tools that enable the targeted and efficient development of new varieties of crops with desired traits in a way that is faster and more precise than conventional plant breeding techniques.”

In the new regulation, the use of Modern Biotechnology and the possession of novel combinations of genetic materials are the criteria used to determine regulatory status of products. Similar with the proposal in the DA-commissioned study, the term “novel combinations of genetic materials” will be defined under the resolution as “a resultant genetic combination in a living organism that is not possible through conventional breeding.” Furthermore, a decision tree in determining the regulation of PBIs was also presented (Figure 33). Products that did not involve Modern Biotechnology in the method of development such as the products of mutagenesis, hybridization, tissue culture, and fusion of related cells will fall under the regulation of non-GM or conventional products. The resolution also considered the possible formation of products that involved Modern Biotechnology but harbored a novel combination, such as those resulting from the horizontal gene transfer (HGT) by some bacteria and viruses. This suggests that novel combinations may also arise naturally which results to a naturally transformed plant. However, despite the presence of novel combinations, the HGT products are classified as non-GM since they were not produced through Modern Biotechnology.

For products produced through Modern Biotechnology, the absence of novel combinations distinguishes the PBIs with products similar to conventional products (under the PBI Case 1),

classifying them as non-GM. This potentially exempts a long list of PBIs from the regulation, as seen in the decision tree. Other PBIs that can incorporate novel combinations such as SDN3, Agro-inoculation of germline tissues with trans insert, and Synthetic Genomics with trans-like sequence integration would trigger regulation, similar to the "Classic" GMOs regulated in the current framework. The characteristic of the products that indicated the presence of novel combinations is the insertion of a gene or a smaller fragment of genetic material from a non-sexually compatible species, which is indicated as a "trans insert" in the decision tree. Accordingly, the counterpart PBIs with cis insert, which introduces genes from the same or a closely-related species, are considered as non-GM.

In terms of the implementation of the proposed regulation for SDN1 and SDN2 where insertions of a foreign gene are involved but only in the initial phase, the organism will continue to be regulated in the contained phase by the DOST-BC until such time that the insert is bred out. A certificate declaring that no novel combination remains in the organism will be given to the developers. The DA will then takeover in the oversight of the organism according to its rules for non-GM plants.

Ratifying the Nagoya-Kuala Lumpur Supplementary Protocol requires strengthened capacity and commitment of NGAs

There have been initiatives undertaken in the country towards the implementation of the NKLSP. In 2016, a Technical Working Group was constituted by the NCBP to "assess the country's preparedness in implementing the Protocol and to identify existing laws and policies in the country that would address the damage." Key findings of the TWG indicate the lack of a unified operational definition of damage to biological diversity arising from the use of LMOs to date. Furthermore, the administrative nature of the NKLSP would require an agency authorized for its implementation.

Meanwhile, the UP Law Center carried out a project on developing a framework to implement the NKLSP in the country should the country decide to accede to the Protocol. A TWG was also created for the project composed of representatives from different competent national authorities: Dr. Vermando Aquino from UP Diliman NIMBB, Prof. Edgardo Carlo Vistan from the UP College of Law, Atty. Jacqueline Espenilla and Atty. Celeste Ruth Cembrano Mallari from the UP Law Center, Ms. Amparo Ampil from the DA, and Atty. J. Anthony Pena formerly from the DENR. The TWG identified the DENR as befitting to implement the NKLSP since it has the responsibility over the conservation and sustainable use of Biodiversity under the Admin Code of 1987. The TWG also identified key technical issues that need to be considered in the implementation.

Firstly, to determine the value or extent of damage to biodiversity, a baseline of the ecosystem must be established first. The baselining must then apply a good risk assessment procedure in

order to prevent overestimating or underestimating the hazards and risks. Secondly, proving the causation of the GMO to damage will be difficult because of the complex interaction of GMOs with the environment. Lastly, to reasonably attribute a damage to a GMO, the concerned authority must then be able to trace the cause of damage within an appropriate time period, but the TWG found difficulties to determine this time period.

The NCBP conducted an in-depth review of the NKLSP provisions and then proposed a legislation to the Congress. The DENR-BC stated that they recognize the need to establish a law addressing redress for GMO damage, but they decided not to support the draft bill for now considering the "stringent requirements" imposed on the DENR. Although the DENR recognizes the need for a baseline in determining damage it currently lacks the technical capacity and budget to conduct the baselining. Instead, DENR endorsed the following regulations to be sufficient in addressing potential damage resulting from transboundary movement of GMOs: Wildlife Resources Conservation and Protection Act (RA 9147), Expanded National Integrated Protected Areas System Act of 2018 (RA 11038), and the Civil Code of the Philippines on Damages, among others. In the drafted 4th National Report to the Cartagena Protocol, rules in relation to damages can be found in the Philippine Biosafety Guidelines where product proponents are required to submit contingency plans and response measures. In the event of incidents, the proponents are also obliged to inform the regulatory agencies and undertake measure to mitigate the risks.

Moving forward, ratifying to the NKL Supplementary Protocol is not an issue of recognizing the need for a liability regime but an issue of implementation. Establishing a liability regime would require resources that the Philippines is not prepared to give. If the Philippines is really committed to support the liability mechanism then future efforts from concerned agencies, particularly the DENR, should be directed towards fulfilling the requirements of the NKL Supplementary Protocol. In the meantime, the domestic laws on GMO damage can be applied. It would greatly help if the developers, end users of GMO technology, the public, and other stakeholders can be given clarity on how accidental damages from transboundary movements can be addressed in the even they happen. This may create a sense of assurance of protection so GMO utilization may continue to expand in the country.

Objective 4: Formulate policy recommendations for action and advocacy

The study has established the significant role biotechnology plays in helping to achieve food security. The study also identified sustainability of biotechnology and regulation as the two major areas that influence biotechnology's ability to contribute to food security.

1. ***Pursue further biotechnology product development and strengthen the value proposition for GM technologies***

The sustainability of biotechnology is dictated by its value proposition, which is dependent on the technologies' specific or unique benefits, relevance, and accessibility. As shown in the findings from the field, sustainability of GM corn is confronted by the high cost of GM seeds and the proliferation of an otherwise counterfeit OPV-variant of GM corn, which is observed to be more effective in adapting to droughts. There is then a need to intensify the development of GM crops, particularly those including traits that are more relevant in major production areas. Traits to be developed consist of abiotic stress-tolerance that will help adapt to climate change (i.e. as in the case of Bukidnon where sige-sige seeds have been found to be more preferred by locals or relevant to the place because of their ability to adapt to drought), agronomic and quality traits (i.e. the need to continuously improve or stabilize productivity and improve nutritive value), and diseases/insect/pest resistance. Experts also suggested to focus the development of key commodities with key traits. There is also a need to address the high cost of existing GM corn seeds, one possibility is through a humanitarian licensing agreement similar to Golden Rice.

2. ***Disseminate science-based information on safety of GM products and health benefits***

Continuous biotechnology development should be coupled with intensified dissemination of science-based information on the safety of GM products. As mentioned earlier, in the past decades where GM products, specifically GM Corn, has been cultivated, no incidence of biosafety hazards has been noted and this is a testament to the scientific grounding—biased towards ensuring biosafety—of the regulatory process. On the other hand, for crop production with threats of pest infestation, there are cases where biological controls would not be enough and the only effective means of control is the use of insecticides. It is in those cases where health impacts of insecticide use and the ability of crop biotechnology products, with pest/diseases/infestation resistance, to mitigate the negative health impacts must be underscored. It is therefore important for such science-based information to be disseminated to gather public support and help achieve an environment that is facilitative in biotechnology development.

3. ***Lobby for executive issuances to amend the regulatory process in a "transitory period"***

A transitory period to amend the regulatory process may be prioritized, pending the legislative action that will institutionalize a regulatory body. As mentioned in the earlier parts of the report, there is already a JDC-1 review and the PBI/NBT regulation proposal from the NCBP, DOST-BC

and the DA that may be pushed for implementation through an executive issuance. This will already put in place regulatory policies that are meant to better facilitate biosafety permit applications.

4. ***Develop the capacity of NCBP as a Commission bestowed with leadership in regulation through legislation***

What became apparent in the policy review is the need to amend the regulatory process such that it will keep pace with the developments in science yet still be effective in ensuring biosafety. Consequently, proposed amendments to the existing regulatory framework/process were presented. However, effectiveness and efficiency of the amendments will be dictated by the capacity of the actors (institutions or individuals/experts) to implement and comply. Amending the regulatory process should then be well supported by building the capacity of the entities or institutions involved in the formulation and implementation of the regulatory policies (e.g. Biosafety committees in the NGAs). Then again, while NCBP shall be institutionalized through a legislation, formulation and amendment of the regulatory policies must not be legislated and instead, be included as part of NCBP's authority.

5. **Establish the Biotechnology Authority of the Philippines as a lead biotechnology development and promotion institute**

Developments in biotechnology is happening in high-speed. Having a dedicated development and promotion institute will provide clear leadership in biotechnology development in the country. The NCBP will remain as the regulatory body on biotechnology, but the institute will lead all development and promotion initiatives and ensure adequate resources are provided to support research, technology promotion and commercialization activities being pursued by the existing biotechnology research institutes in the country. It shall also support NCBP in addressing the need to have dedicated experts performing biotechnology regulatory functions.

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