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Modern Biotechnology Application and Regulation in the Philippines: Issues and Prospects

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Modern Biotechnology Application and Regulation in the Philippines: Issues and Prospects

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Abstract

Modern crop biotechnology is being considered as a novel solution to the long-standing problems of food insecurity, low crop productivity, pest and disease prevalence, and micronutrient deficiency, particularly in developing and climate-vulnerable economies. Empirical evidence of its benefits encouraged the development and adoption of genetically modified organisms (GMOs) and related products, fostering global market dynamism. The Philippines' early adoption of technology and its inclusion among countries with highest GMO corn hectarage in early 2000s motivated the creation of regulatory guidelines and biosafety policies which informed development and commercialization timelines. The study reviewed the enabling regulatory structures to determine entry points for augmentation while an economic surplus analysis of GMO eggplant was carried out as case study to estimate welfare benefits and potential opportunity costs for both consumers and local growers. Results showed that across simulations, even with the most conservative adoption delays due to regulatory lags, viable figures were still obtained with the lowest IRR at 20 percent. Notwithstanding contrary sentiments from interest groups, the government's priority must be to make available the modern biotechnology option, in both farm and household table, in the most prudent but expedient way possible. The huge opportunity losses attached to suboptimal bureaucratic regulatory functioning have to be stemmed.

Keywords: biotechnology, modified crops, GMOs, regulatory process

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Modern Biotechnology Application and Regulation in the Philippines: Issues and Prospects

Sonny N. Domingo and Arvie Joy A. Manejar[1]

1. Introduction

1.1. Background of the study

Biotechnology is defined as a modification and improvement of living organisms from living genetic materials. Under this umbrella is modern biotechnology which employs genetic engineering, gene technology, genetic modification, and gene manipulation among others to produce genetically modified crops in the agricultural sector for instance (ISAAA nd).

While arguably contentious and open to cultural sensitivities, modern crop biotechnology options have the potential to address sectoral problems on food security, agricultural productivity, pest and disease infestation, and micronutrient deficiency. It is considered as a multifaceted solution to the growing demand for food and resources as populations and economies continue to grow. Increased yields and pest resistance, and improved farm incomes are some of the more evident claims supporting the adoption of modern biotechnology crops.

The introduction of genetically modified (GM) crops in the Philippines started with the regulatory approval for commercial propagation of Bt corn in the early 2000's. Technology adoption took off like wildfire, quickly achieving almost one million hectares of plantation in various regions of the country.

The initial set of regulatory guidelines and policy through the Department of Agriculture (DA) Administrative Order (AO) No. 08 series of 2002 were facilitative in directing the process of assessment, approval and commercialization of GM crops. However, ensuing challenges and resistance, mostly from anti-modern biotechnology groups necessitated a change in policy. Executive Order 514 or the National Biosafety Framework of the Philippines was passed in 2006, enhancing regulations and risk assessment processes, including the clarification of institutional roles and expanding the NCBP. EO 514 also considered compliance with the provisions of the Cartagena Protocol and Codex Alimentarius.

The Supreme Court voided DA AO No. 08 in 2015 and was eventually replaced by Joint Department Circular (JDC) No. 01 series of 2016. The Supreme Court also stopped the field trials of Bt Eggplant and other GM crops in the pipeline, although the ruling was eventually overturned a year later. The issuance of JDC No 01 instituted stricter biosecurity provisions including the conduct of environmental impact assessments and public consultations.

Reviewing two decades of regulatory dynamism and policy application would help pinpoint areas for improvement and possible augmentations toward the common goal of harnessing benefits from modern biotechnology.

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1.2. Objectives

Generally, the study determined the issues and prospects in the application and regulation of modern biotechnology in the Philippines' agricultural sector.

Specifically, the study reviewed policy and related regulatory processes on modern biotechnology; conduct case studies on technology development and commercialization; and, looked at ways for modern biotechnology and agriculture to move forward.

1.3. Policy questions

Biotechnology has been introduced in the country as early as the 1970s, and the Philippines was one of the first nations to adopt biotech crops. In comparison however to its earlier counterparts, the local agricultural sector exhibited heavy dependence on maize crops but lags in other commodities' adoption rates and approval events. This situation prompted a discussion on policy and regulatory weaknesses related to development and commercialization of modern biotechnology in the country's landscape.

The presence of modified improved crops in international markets also gave rise to welfare and environmental policy debates. While modern biotechnology ensured benefits, risk mitigation in other aspects remained much of a gray area. Trade regulations like Cartagena Protocol and National Biosafety Framework were good avenues of regulations, but the extent of their guidelines left much to be qualified. This circled back to the last policy question of what necessary augmentations should be undertaken to facilitate ideal outcomes of modern biotechnology-related regulatory processes.

2. National landscape

2.1. Background on biotechnology

Growing industrialization and structural transformation characterized most of developed economies while developing countries' agricultural income lagged vis-à-vis non-farm economies in a situation called Schultz stage. These gaps led to disparities between rural and urban locations and depleted the resource base which exacerbate lagged productivity and food insecurity (Barrett et al. 2010). Agriculture expansion was the immediate option but may not always be the case when resource inputs like land and water remained finite (Anthony & Ferroni, 2012), thus the consideration for biotechnology.

Biotech crops were the fastest adopted technology in modern agriculture. Global trade figures in 2010 showed 90 percent of the 15.4 million farmers planted insect or herbicide resistant biotech crops. With their increased yield from developing countries, it was set to outpace the production of industrialized nations (Anthony & Ferroni, 2012). The ease of adaptability across small and large farms, and the upgrading of attributions (seed care and coating, resilience against climate stresses, and pest resistance) also contributed to the uptake (Asia News Monitor 2014; Anthony & Ferroni 2012).

The introduction of biotechnology to world markets caused three economic responses: (a) supply shifts in emerging economies, leading to global price decline; (b) import regulations; and (c) emergence of niche markets for organic and conventional substitutes (Gruère et al., 2011). It also enabled cross-country multilateral trades under the trade liberalization strategy of the World Trade Organization (WTO). Their strategies to ease market barriers and standardize regulations reportedly affected developing countries the most as they may not have

the capacity to comply with international standards, lack mechanisms to protect domestic production, or find it costly to meet regulations (Dibden, Higgins, & Cocklin, 2011).

In the context of the Philippines, the agricultural sector contributed 10.2 percent share to its gross domestic product[2] in 2020, but it reported the least contraction from the COVID-19 pandemic at only 0.2 percent negative change[3], highlighting its significance in ensuring food security amidst disruptions. Harnessing biotechnology and its promise of increased productivity yields can be instrumental in sustaining and improving agricultural outputs.

2.2. Crop development

Around 71 countries adopted biotech crops and were observed to reach saturation levels. Adoption and commercialization between 1996 and 2019 have reached cumulative figures of 190.4 mhas (million hectares) and USD 2.7 billion revenue, respectively.

Corn, soybeans, cotton, and canola were the first four crops developed and adopted in biotechnology, but the list eventually covered alfalfa, sugar, beets, papaya, squash, eggplant, tomatoes, mustard, sweet potato, and cassava. Table 1 showed area and adoption rates of top biotech crops while Table 2 listed the distribution by country.

Philippines was ranked 12th with 0.9 million hectares of corn among mega-biotech countries. It placed second after India in the Southeast Asian region in terms of adoption area. Asia, in total, comprised 32.2 percent of the global production of 184 million hectares of corn (ISAAA, 2019).

Table 1. Area and adoption of biotech crops, 2019

Commodity	Area (in mhas)	Adoption rate
Soybeans	91.9	48.2
Maize	60.9	32.0
Cotton	25.7	13.5
Canola	10.1	5.3
Other	1.8	1.0

Note: Other includes sugar beets, potatoes, apples, squash, papaya, and brinjal/eggplant

Source: ISAAA 2019

Table 2. Area and adopted crops by country, 2019

Rank	Country	Area (mhas)	Biotech crops
1	USA	71.5	Maize, soybeans, cotton, alfalfa, canola, sugar beets, potatoes, papaya, squash, apples
2	Brazil	52.8	Soybeans, maize, cotton, sugarcane
3	Argentina	24	Soybeans, maize, cotton, alfalfa
4	Canada	12.5	Canola, soybeans, maize, sugar beets, alfalfa, potatoes
5	India	11.9	Cotton
6	Paraguay	4.1	Soybeans, maize, cotton
7	China	3.2	Cotton, papaya
8	South Africa	2.7	Maize, soybeans, cotton

[2] Agriculture contributed 9.2 percent in 2019 GDP.

[3] Industry contracted by 13.1 percent while services by 9.1 percent (PSA 2021).

Rank	Country	Area (mhas)	Biotech crops
9	Pakistan	2.5	Cotton
10	Bolivia	1.4	Soybeans
11	Uruguay	1.2	Soybeans, maize
12	Philippines	0.9	Maize
13	Australia	0.6	Cotton, canola, safflower
14	Myanmar	0.3	Cotton
15	Sudan	0.2	Cotton
16	Mexico	0.2	Cotton
17	Spain	0.1	Maize
18	Colombia	0.1	Maize, cotton
19	Vietnam	0.1	Maize
20	Honduras	<0.1	Maize
21	Chile	<0.1	Maize, canola
22	Malawi	<0.1	Cotton
23	Portugal	<0.1	Maize
24	Indonesia	<0.1	Sugarcane
25	Bangladesh	<0.1	Brinjal/Eggplant
26	Nigeria	<0.1	Cotton
27	Eswatini	<0.1	Cotton
28	Ethiopia	<0.1	Cotton
29	Costa Rica	<0.1	Cotton, pineapple
	Total	190.4	

Note: Figures are rounded off to the nearest hundred thousand. Those who grow more than 50,000 ha or more are identified as the top 19 biotech mega-countries.
Source: ISAAA 2019

Bt corn was the first commercially available GM crop in the Philippines after eight years of application process. Since it was developed outside, Bt corn only underwent field trials under DAO 2008-02 with DA as the sole assessor for multi-location field trials, commercial propagation, and importation for direct use. Table 3 showed the history of corn application and approval events from its introduction in 2002 to 2014.

Table 3. Approval of biotech corn events in the Philippines, 2002-2014

Event	Trait	Year of Approval/Renewal
MON810	IR	2002/2007
MON863 X MON810	IR	2004
NK603	HT	2005/2010
Bt11	IR	2005/2010
MON810 X NK603	IR/HT	2005/2010
GA21	HT	2009
Bt11/GA21	IR/HT	2010
MON89034	IR/HT	2010
MON89034 X NK603	IR/HT	2011
TC1507	HT	2013
TC1507 X MON810	HT/IR	2014

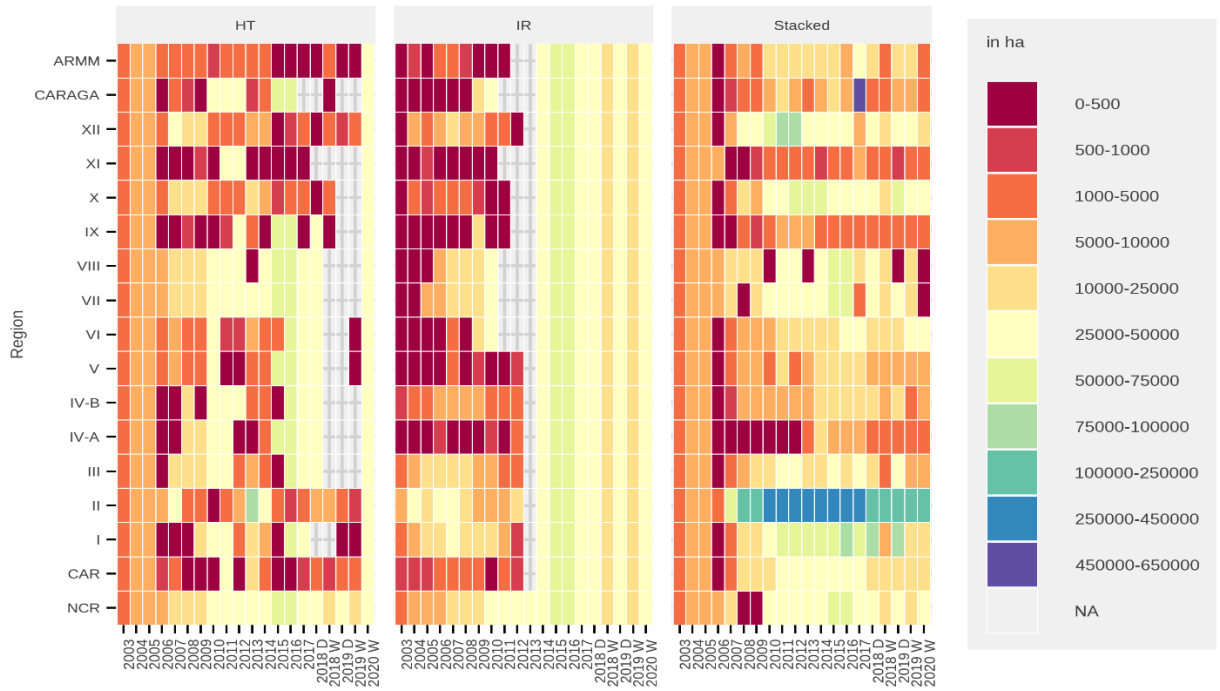
TC1507 X MON810 X NK603	HT/IR	2014
TC1507 X NK603	HT	2014

Source: ISAAA 2018

Figure 1 showed the adoption trend of GM corn varieties across the years. Insect resistant (IR) corn was present from 2003 to 2012, reaching its peak in 2007 with 120,000 hectares. These were comprised largely by Regions I, II, and III. Herbicide tolerant (HT) varieties entered in 2006 and reached its highest adoption in 2013 with over 160,000 hectares. It was likewise dominated by Region II, followed by Regions XII and X. HT varieties eventually dwindled after 2013.

Stacked traits, a combination of HT and IR, came in by 2007 and easily surpassed the adoption area of the individual traits. Caraga farmers, apart from the usual Region II figures, adopted the trait only in 2017 and pushed the area beyond one million hectares.

Figure 1. GM corn adoption data of regions per trait, 2003-2020

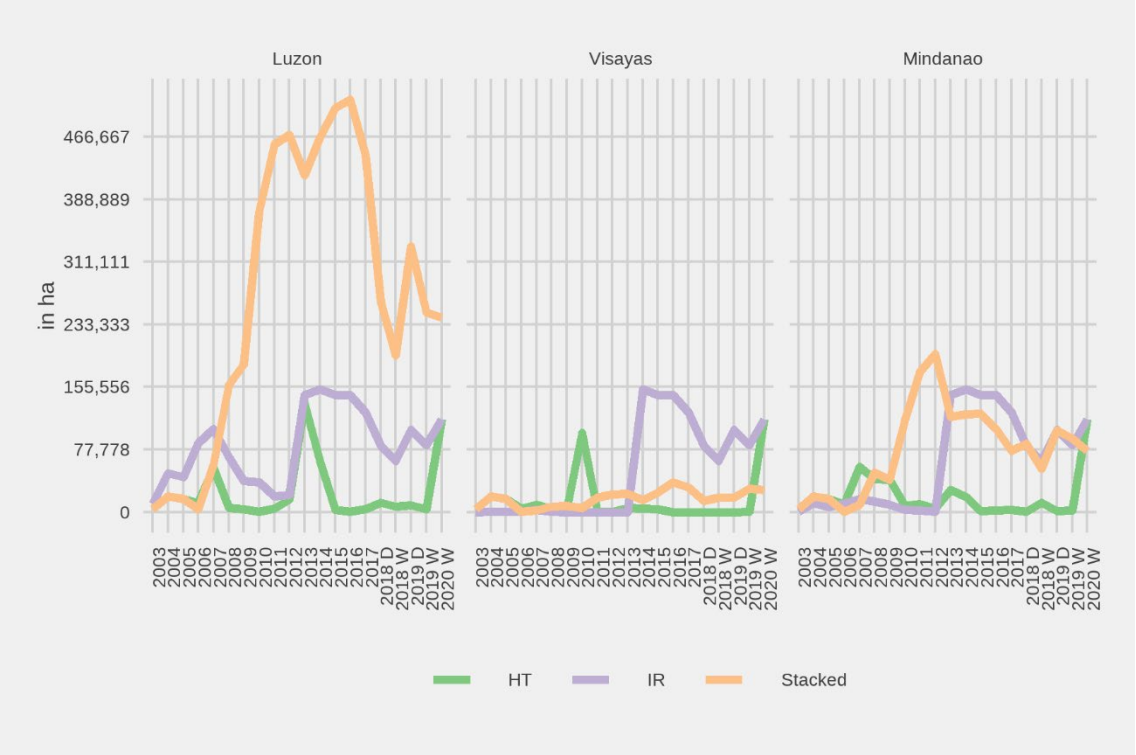


Notes: Stacked = HT and IR; 2014 covers January 2014 to March 2015; 2015 covers April 2015 to March 2016; 2016 covers April 2016 to March 2017; 2017 covers April 2017 to March 2018; 2018 W (Wet Season) covers April to July 2018; 2018 D (Dry Season) covers August 2018 to February 2019. 2019 W covers March to July 2019; 2019 D covers August 2019 to February 2020; 2020 W covers March to July 2020

Source: BPI Biotech Office 2021

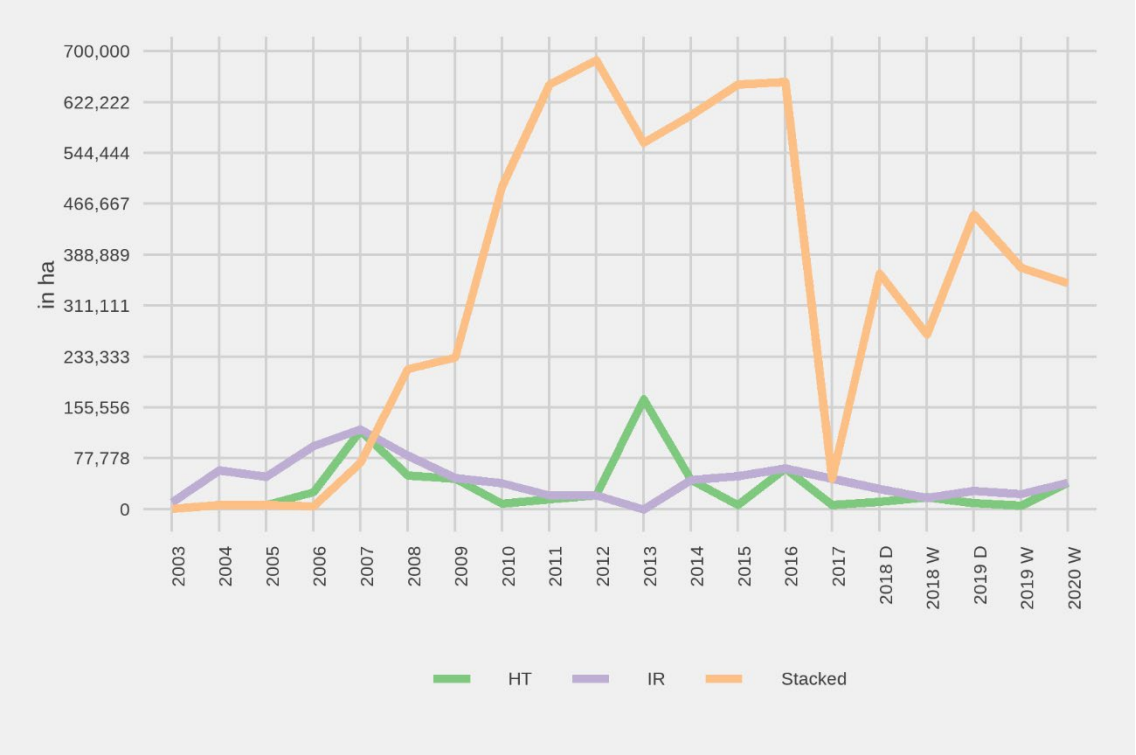
Luzon dominated all three traits due to Region II's large adoption figures. Visayas' adoption areas were dwarfed in comparison to its counterparts (Figure 2). The generally high values of stacked traits indicated stronger preference of farmers towards the superior benefits of stacked since its introduction in 2006 (ISAAA, 2019). IR GM corn was phased out in 2012, and HT traits in 2020 wet season (Figure 3).

Figure 2. Cumulative GM corn adoption data by island group, 2003-2020



Source: BPI Biotech Office

Figure 3. Total GM corn adoption data by trait, 2003-2020

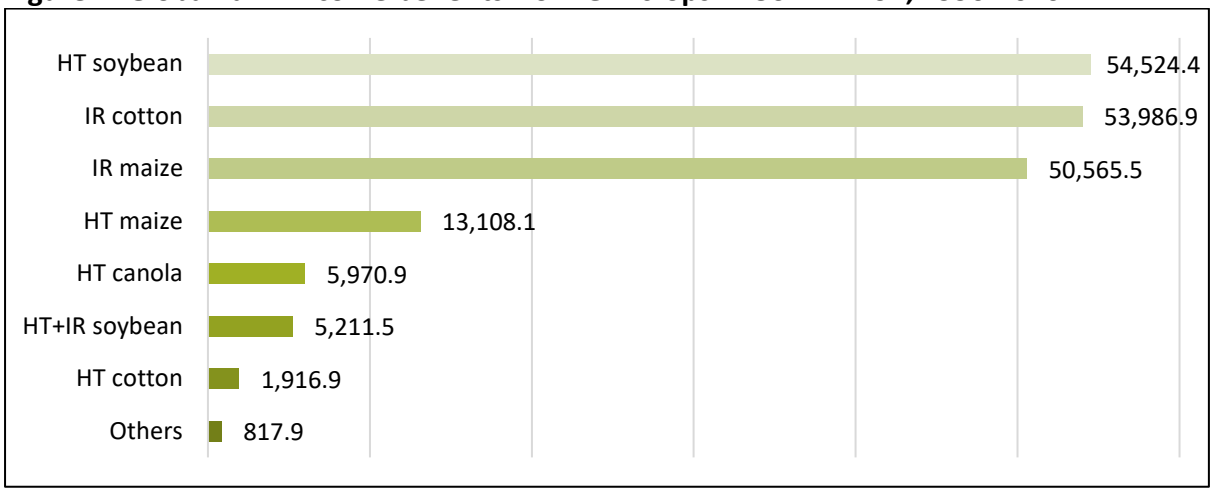


Source: BPI Biotech Office

2.3. *Welfare benefits*

Empirical evidence backed the benefits espoused by biotechnology. In a showcase of farm income benefits since biotech introduction in 1996 to two decades later, GM crops have been able to generate USD 186,102.1 million farm income. Herbicide tolerant soybean provided the highest gain with USD 54,524.4 million, then IR cotton, IR maize, and HT maize. These were also the top crops adopted across countries.

Figure 4. Global farm income benefits from GM crops in USD million, 1996-2016



Note: Others include virus-resistant papaya and squash, and herbicide-tolerant sugar beet

Source: ISAAA 2016

The yield productivity and mitigated loss from extreme weather events increased income of corn farmers by 200 USD million per year. Those who have adopted biotech corn saw an eight percent income advantage, 42 percent return of investment, and 19 percent increment in income improvement. For the Philippines, income derived from biotech corn was around USD 92 million in 2013 alone and PHP 10,132 per hectare for farmer level (ISAAA, 2019).

There was also seasonal variability in income; Php 7,482 per hectare during dry season and Php 7,080 during wet season. Net profitability was greater by four to seven percent during wet season and three to nine percent for dry season (ISAAA, 2019). Much of the potential benefits of biotechnology rested on its ability to resist extreme climate changes. For a typhoon-stricken country, the estimated benefits would greatly help increase the quality of life of farmers and sustain food security thresholds. Table 4 consolidated the benefits of Bt corn adoption based on the SIKAP/STRIVE, Inc. Study as provided by DA Biotech Office.

Table 4. Farm benefits of GM corn

Benefits (in PHP)	Bt corn	HT trait	Stacked trait
Net income	85 million	438 million	6.422 billion
Value of labor saved	12 million	117 million	645 million
Profit over mixed seeds		8-85% higher	38-87% higher
ROI over mixed seeds		12-156%	73-160%
ROI over ordinary hybrid corn		6-9%	9-30%

Source: SIKAP/STRIVE Inc. Study through DA-Biotech

In a separate study by Klumper & Qaim (2014), a 22 percent yield increase was associated with 68 percent profit gain and 38 percent reduction in pesticide expenditure. The mitigated losses created additional gains for biodiversity contribution at USD 150 billion, a very different angle on contrary claims. Biotech farms were also observed to have significantly higher populations of beneficial insects (ISAAA, 2019).

Biotech crops reportedly will not wipe out indigenous Philippine plants but will harness their natural health traits to develop biopesticides. There were also no established environmental and human health issues that would coexistence of organic farming and agriculture biotechnology thus these options remain free for choosing among farmers (Asia News Monitor 2015a).

Examining active ingredient usage was one way of capturing environmental gains. For instance, the shift to IR cotton reduced active ingredient usage by 288 million kg, and HT maize by 239.3 kg. These transitions from herbicide and insecticide use averaged an 18.4 percent change from status quo of pesticide usage (Table 5).

Table 5. Measuring impacts of transitions from herbicides and insecticides to GM technology, 1996-2016

GM trait	Change in volume of AI used (million kg)	Change in field EIQ impact (million field EIQ/ha units)	% change in AI use on GM crop	% change in environmental impact associated with herbicide and insecticide use on GM crops
HT soybean	13.0	- 8,526.0	0.4	- 13.4
HT+IR soybean	- 7.4	- 678.0	- 6.1	- 6.3
HT maize	- 239.3	- 7,859.0	- 8.1	- 12.5
HT canola	- 27.3	- 931.0	- 18.2	- 29.7
HT cotton	- 29.1	- 706.0	- 8.2	- 10.7
IR maize	- 92.1	- 4,142.0	- 56.1	- 58.6
IR cotton	- 288.0	- 12,762.0	- 29.9	- 32.3
HT sugar beet	1.0	- 43.0	9.9	- 19.4
Totals	- 671.2	- 35,647.0	- 8.2	- 18.4

Note: AI = active ingredient, EIQ = environmental impact quotient (a universal indicator where various envi impacts of individual pesticides are integrated into a single field value per hectare. EIQ is multiplied by amount of pesticide ai used per hectare to produce a field EIQ value)
Source: ISAAA 2016

Adoption of technology to smallholder farms depended on a number of factors, the first of which was investment and funding levels. In the current landscape, this was shouldered by private technology developers who can meet the high capital costs needed for the initial distribution and adoption. The second factor was the strength of regulatory frameworks, but the high development, long approval period, and regulatory costs could later develop as barriers to entry too (Anthony & Ferroni 2012). Market sensitivity, international trade risks, and fear of export losses further added to low confidence in trading and investment (Gruère et al., 2011).

Instances of patent challenges have stonewalled distributors and market providers. Heller & Eisenberg (1998) referred to this term as tragedy of the anti-commons, leading to non-utilization of seeds and related products which could have been beneficial for the public. Anthony & Ferroni (2012) believed this could be overcome when local universities and

institutions would conduct their own research and development to reinforce country ownership on the knowledge development.

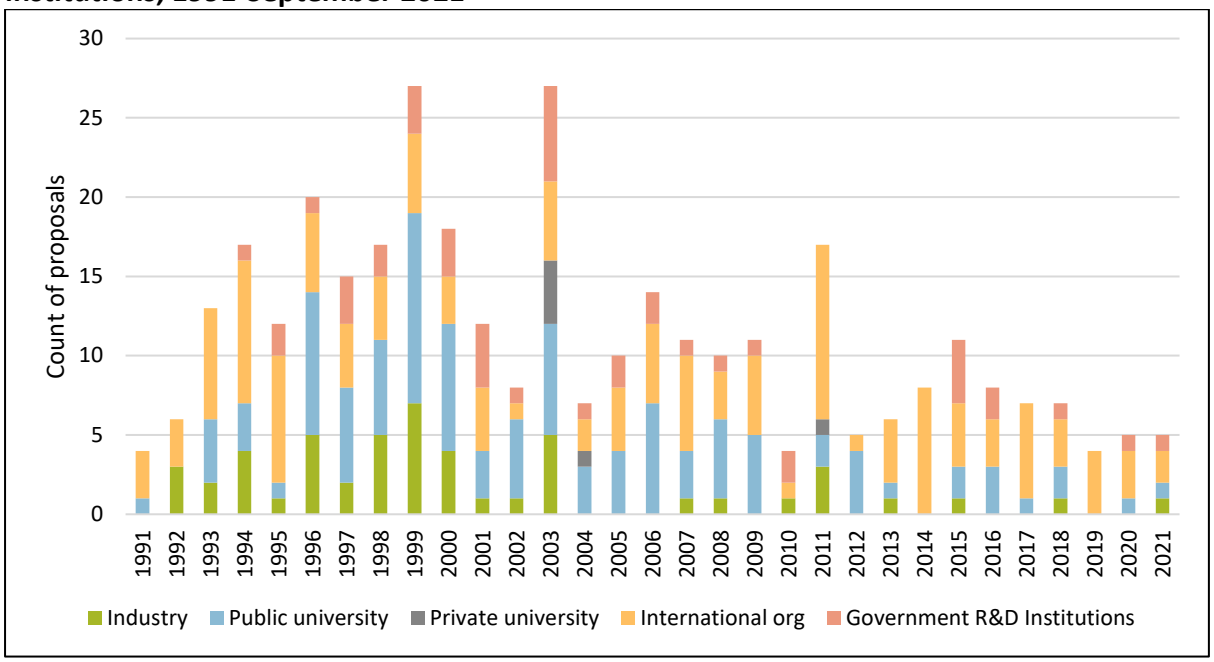
There was robust response on that front with around 346 proposals submitted to National Committee on Biosafety of the Philippines (NCBP) and DOST-Biosafety Committee for eventual funding between 1991 and 2021, bulk of which were proposed by international research institutions and public universities. Out of the total, 308 were approved, five were rejected, and the remaining 33 were withdrawn or incomplete. However, the country was deemed incapacitated to transition from development to commercialization per DA's insights. The problem was rooted in the limited technical human resource (traditional breeders and modern biotechnology researchers), and low retention rate of country experts. Knowledge and technical transfer from trainings also suffered continuity gaps due to lacking facilities and technology transfer offices.

Table 6. Research proposals submitted to NCBP and DOST-BC, 1991-September 2021

	Industry	Private university	Public university	Government research institution	International research institution	Total
Contained facility tests						
Involving GMOs	20	6	97	29	117	269
Involving PHES	20		9	5	0	34
Not within purview of NCBP/DOST-BC				1		1
Total	40	6	106	35	117	304
Field Tests						
Involving GMOs	8			1		9
Involving PHES				1		1
Total	8			2		10
Confined Tests						
Involving GMOs	2		3	8	18	31
Beyond purview of DOST-BC				1	1	1
Total	2	0	3	9	19	32
Approved	37	5	97	36	133	308
Not approved		1		3	1	5
Withdrawn or incomplete	13		12	6	2	33
Grand total	50	6	109	45	136	346

Source: DOST-NCBP Secretariat 2021

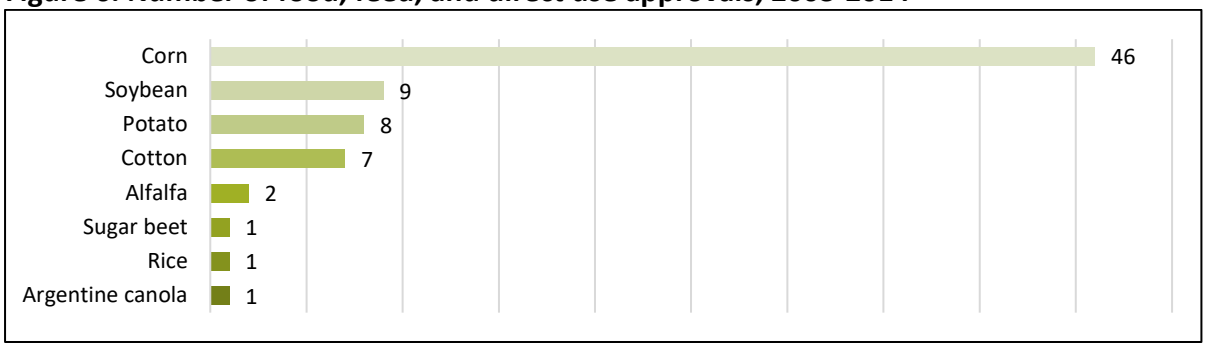
Figure 5. Number of research proposals submitted to NCBP and DOST-BC by various institutions, 1991-September 2021



Note: 1991-2008 cover proposals submitted to NCBP; 2009-Sept 2021 cover proposals submitted to DOST-BC
Source: DOST-NCBP Secretariat 2021

United States granted the highest cumulative number of approvals with a total of 539 events. Meanwhile, the Philippines had 75 approvals in 2014 and ended with 244 in 2019. Food approvals took up 116 events, 114 for feed, and 14 for cultivation. The low figure for cultivation implied the country's hesitancy to grow biotech crops and mirrored the sector's environmental risk aversion.

Figure 6. Number of food, feed, and direct use approvals, 2003-2014



Source: DA Biotech 2014

2.4. Policy and institutions

2.4.1. DA Biotech Program

USDA funded the DA-Biotech Program as a foreign-assisted project from 2000 to 2013; it was established to develop regulatory policy for modern biotechnology and create a policy environment for technologies and biotechnology applications. AFMA's provision (RA 8435) on appropriation continued the funding after the program completion. Since then, its

bureaucratic structure was divided into Biotech Research for Development[4]; Institutional Capacity Enhancement[5]; Information and Education Campaign[6]; Policy Research and Advocacy[7]. These components have respective technical advisory groups and committees of experts from academe and government institutions.

A steering committee filled with Department of Science and Technology-Philippine Council for Agriculture, Aquatic and Natural Resources Research and Development (DOST-PCAARD), University of the Philippines (UP) System, Department of Trade and Industry (DTI), Department of Environment and Natural Resources (DENR), Philippine Chamber of Commerce and Industry (PCCI), Biotech Coalition of the Philippines (BCP), and industry and farmer representatives and chaired by the DA Undersecretary of Policy and Planning served as supplemental support to DA's structure.

2.4.2. National Committee on Biosafety of the Philippines (NCBP)

On the other hand, the issuance of Executive Order No. 430 in 1990 established the NCBP, a policy-making body operating in ex-officio[8] composed of representative from Department of Health (DOH), DENR, DA, DTI, and DOST as the secretariat. The National Biosafety Framework (NBF), formulated in 2006 through EO 514 under NCBP, provided the foundation for the entire regulatory structure.

NCBP's institutional arrangement apparently hampered bureaucratic changes (e.g. streamlining deadlines), a common problem among institutionalized ad hoc committees where responsibilities are added on without sufficient support. Further, the regulatory direction was between the process or the product safety remained a gray matter.

2.4.3. BPI Biotech

Bureau of Plant Industry (BPI) – Biotechnology Office acted as an entry point to applications and permit issuances and overall was a key player in the regulatory process. Average annual application of genetically modified (GM) crops would usually reach eight to ten, including original and for renewal, those developed domestically, and those from outside institutions, but the count dampened since the onset of the pandemic.

The aforementioned institutions were mandated to carry out certain provisions of pertinent policies. Over time, the scope and extent of their power and bureaucratic influence changed as the landscape for biotechnology in the country evolved.

Table 7. Lists of related policies and events on the evolution of Philippine agriculture biotechnology

Year	Policy/Activity
1990	Executive Order No. 430 Establishment of NCBP
1991	NCBP Biosafety Guidelines
1996	Bt corn greenhouse trial

[4] Previously named as Biotech Research and Development. Supports research activities of public institutions and provides laboratory protocols on biotechnology tools.

[5] Main thrust divided into trainings, partnerships, and facility upgrades for regulatory and research agencies.

[6] Fosters partnership with public, private, and non-government organizations to communicate benefits and science behind biotechnology to improve acceptability rates

[7] Commissions policy studies to inform eventual decisions and investments.

[8] No mandated fund allocation or permanent personnel resource, but a separate technical working group was formed within the committee to serve as its core manpower.

Year	Policy/Activity
1998	Papaya biotechnology network
1999-2001	Field testing of Bt corn
2000	Philippines entered Cartagena Protocol
2002	DA AO 2002-08
	Required risk assessments aligned with CPB
	Bt corn approval
2005	Herbicide-tolerant corn approved
2006	Formulation of NBF
2009	Completion of Bt eggplant confined trial
2010	Completion of Bt cotton field test
2011	Completion of golden rice field test
2015	SC ruling against Bt eggplant
	Nullification of DA 2002-08
2016	Issuance of JDC 2016-01
	Reversal of SC ruling

Source: SEARCA Biotechnology Information Center

2.5. Regulatory processes

2.5.1. Domestic regulatory processes

The DA's Administrative Order 2002-08 initially guided the country's regulatory process and required science-based risk assessments in compliance with Cartagena Protocol. As an offshoot, four permits were identified for each biotech crop application: application to field test, application to release for propagation, application for importation for direct use, and petition for delisting. DA served as the sole assessor throughout the whole process.

On December 8, 2015, the Supreme Court passed the ruling on ISAAA versus Greenpeace, halting the regulatory and approval process of Bt talong and nullifying the DAO, citing the lack of environmental and health precautionary measures (ISAAA, 2018).

The AO was soon replaced by Joint Department Circular (JDC) 2016-01. DA was joined by DOST, DENR, DOH, Department of Interior and Local Government (DILG), DA-Scientific and Technical Review Panel[9], and Institutional Biosafety Committees[10]. The court decision was eventually reversed in July 26, 2016 and granted nine motions for reconsideration to petitioners (ISAAA, 2016).

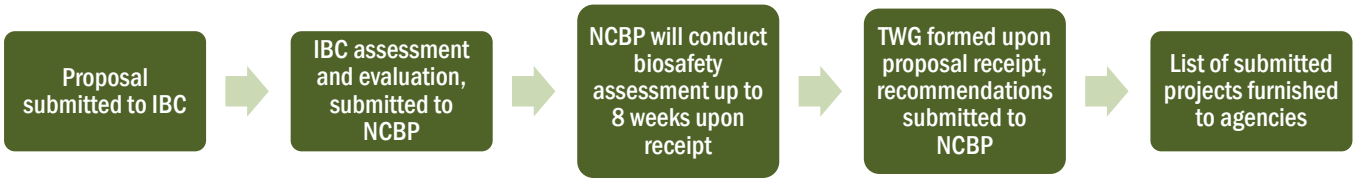
Under the direction of JDC, the process was broken down into the following permit applications, (1) confined tests, (2) single and multi-location field trials, (3) direct use for food, feed, and processing (FFP), and (4) commercial propagation. Safety assessments from the JDC members were conducted for each phase. Each agency was governed by their respective processes and assessment guidelines based on corresponding aspects (e.g. DENR for environmental safety, DOH for human health consumption) to avoid duplication. However, overlaps may still occur between DA and Food and Drug Administration (via a third party) for the FFP phase.

[9] Pool of non-DA scientists to evaluate risk assessments, analyze issues raised by public, and evaluate petitions for deregulation.

[10] Company or institution applying for and granted permits shall constitute an IBC prior to the test. Should have three scientist-members and two community representatives.

Proposals were evaluated initially by the proponent's Institutional Biosafety Committees and submitted to NCBP. Genetic manipulation was allowed only for public welfare and natural environment, and if there were no other existing or foreseeable alternative approaches to deliver the same outcome. NCBP's own assessment will take at most eight weeks upon receipt, and they may revert it back to IBC for revisions. Copies will also be furnished to agencies.

Figure 7. Proposal procedure



Source: Author's illustration based on DOST-NCBP's Philippine Biosafety Guidelines

If approved, the next step will be confined test, but it must meet any one of the following classifications: (1) GM crops commercially available in the country where they are developed, and there is adequate information available for domestic assessment; (2) GM crops developed locally in approved laboratories and screenhouse but data is sufficient for risk assessment; (3) GM crops whose size and growth habits require areas not afforded by standard screenhouses e.g. papaya; (4) other crops and events that warrant limited release under confined conditions.

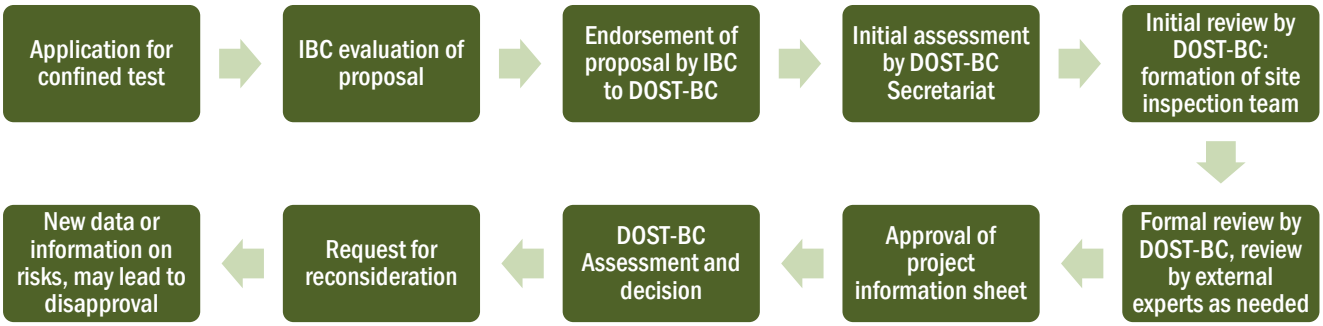
The application will be initially evaluated by IBC and endorsed to DOST-Biosafety Committee for site inspection and expert assessments from STRP and/or external panel. Their recommendations shall not be submitted later than 30 days from receipt of inspection findings of DOST-BC.

Public consultation in this phase would be conducted through posting of project information sheet (PIS). The guidelines emphasized posting of simpler and laymanized PIS versions in English and vernacular language for easier understanding of the community. The duration will take three weeks, and proof of posting should be submitted to DOST-BC within 10 days from last day of posting. If deemed necessary, the public hearing will be carried out. Further, a comment period will commence for 30 days, and the proponent should respond to all queries not later than 15 days upon receipt.

In the case where no comment was received, the proposal for confined tests will be assessed within 60 days, and will be evaluated based on the contents of proposal, IBC's findings, site suitability, STRP and external reports review, public comments, and other relevant documents.

During the two-year validity of the permit, reconsideration requests can still be filed and approvals revoked under these reasons: non-compliance with biosafety guidelines, reliable data reporting threats to human health and environment, and other grounds as deemed reasonable by DOST-BC. DA, DENR (environment), and DOH (human health) shall monitor effects for confined trial.

Figure 8. Biosafety guidelines for confined tests



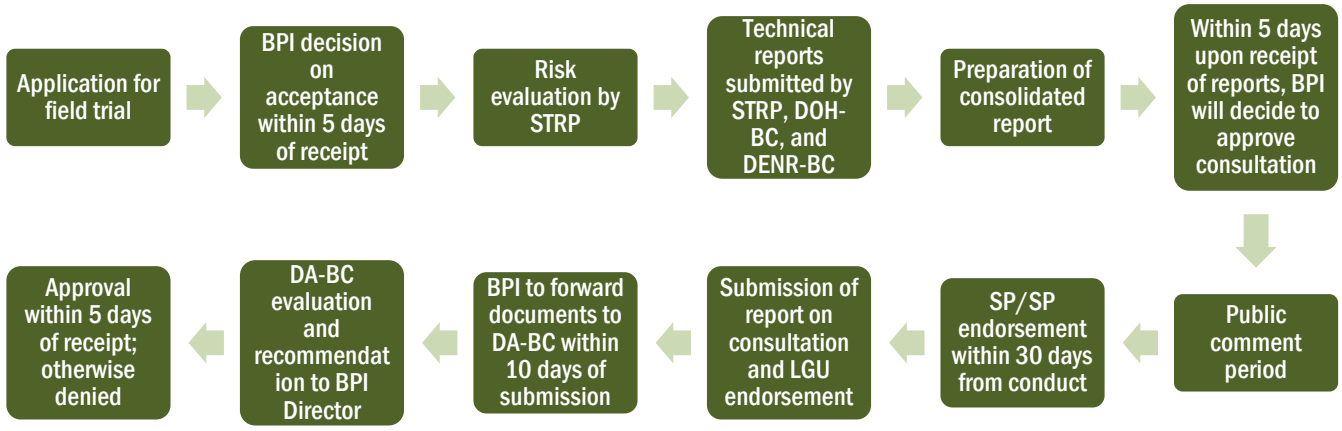
Source: Author's illustration based on DOST-NCBP's Philippine Biosafety Guidelines

Field trials will follow, and each site shall be evaluated separately. If the area would fall within an ancestral domain or protected area, the proponent must secure an FPIC[11] and PAMB[12] endorsement prior the biosafety process. The IBC-endorsed application will now go through to BPI instead of DOST-BC, and will be evaluated and assessed by STRP, DOH-BC, and DENR-BC.

The public hearing was explicitly required to invite representatives from LGUs, local communities, IPs, agriculture and fisheries council, and PAMB. After which, Sangguniang Bayan or Panlalawigan will provide endorsement. BPI will consolidate reports of consultation and endorsement and forward these to DA-Biosafety Committee for evaluation and recommendation and to BPI director for the approval.

Permit issuance will be granted for each field trial site, valid for two years and subject to extension. The aforementioned revocation grounds are also applied in this process.

Figure 9. Biosafety guidelines for field trials

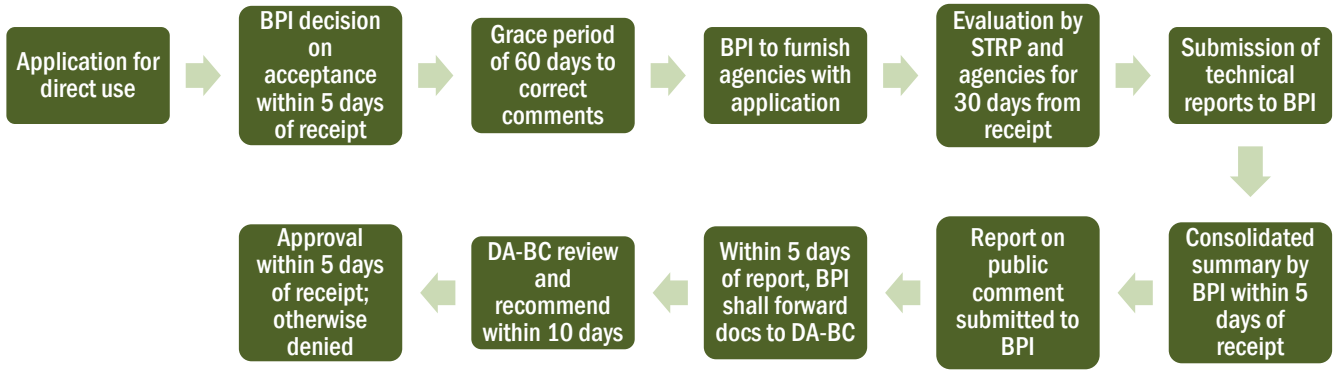


Source: Author's illustration based on DOST-NCBP's Philippine Biosafety Guidelines

[11] free, prior, and informed consent
[12] Protected Areas Management Board

Direct use for food, feed, or processing followed field trials. While this process also stuck to the same general process, layers were added, particularly on the assessment stage – BPI-Plant Product Safety Services Division (PPSSD) for food safety standards, Bureau of Animal Industry (BAI) for feed safety, and external experts for socio-economic considerations. The public comment period now involved PIS' circulation in two newspapers within 60 days. The permit, once awarded, will be valid for five years.

Figure 10. Biosafety guidelines for direct use for food, feed, or processing (FFP)

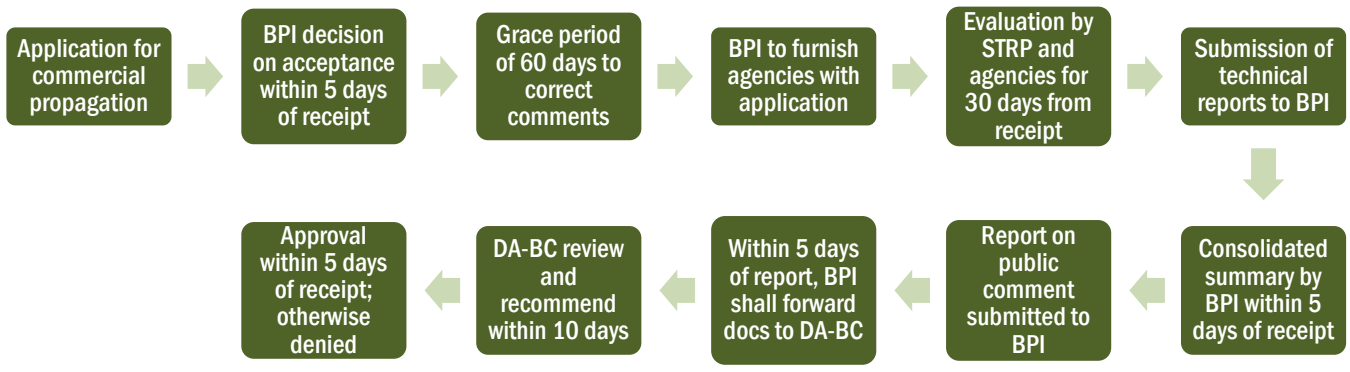


Source: Author's illustration based on DOST-NCBP's Philippine Biosafety Guidelines

The final stage in the regulatory process would be commercial propagation which should first fulfill the following conditions: (1) biosafety permit is secured; (2) field trial conducted does not pose risks; (3) food, feed, and safety studies do not show risks; (4) pest-resistance article is registered with Fertilizer and Pesticide Authority (FPA). The evaluators for risk assessment expanded to include FPA, BPI-PPSSD, and BAI. Public comment period followed that of FFP permit and its validity.

Should an LGU prohibit commercial propagation in their jurisdiction, labelling of seeds and GM crop products should explicitly state that propagation is not intended in those areas. This also meant that guidelines for planting should comply with regulations of other agencies, particularly that of DENR for environmental health. The approval would be still subjected to revocation grounds in light of reliable information and aforementioned reasons.

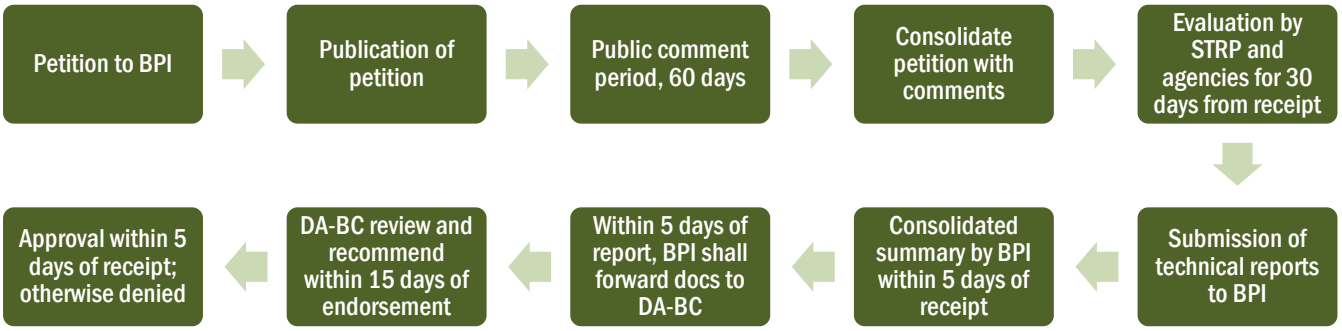
Figure 11. Biosafety guidelines for commercial propagation



Source: Author's illustration based on DOST-NCBP's Philippine Biosafety Guidelines

A technology developer can apply for deregulation when they want a biotech crop to be taken off regulations. Like any other permit, the petition will undergo 30 days of assessment before the DA-BC convenes. Only one event application so far has been filed with BPI since the passage of JDC but was not acted due to absent grounding provisions in the IRR.

Figure 12. Guidelines for deregulation



Source: Author's illustration based on DOST-NCBP's Philippine Biosafety Guidelines

2.5.2. Amendments

The joint circular was supposed to address the lapses of the earlier regulatory framework however, issues continued to emerge, the most prominent of which were bottlenecks during assessments and public consultations. In light of these comments, the JDC underwent assessment in 2021, and several key changes were proposed.

Renewals on permit validities were removed and replaced by one-time approvals. Routine review will still be conducted upon receipt of new and reliable information against the biotech crop. All independent assessments were also merged into one Joint Assessment Group. A stakeholder remarked that this was noncompliant with the framework, but the agencies reasoned out that biosafety committees will have at least 10 working days to independently review the application prior to convening.

Moreover, public comment periods were shortened and would only need an LGU resolution for endorsement. The NCBP secretariat stated that the period actually increased to 15 working days due to ARTA mandate, but given that consultation timeline would be arbitrary, an exemption from the policy has been submitted and pending feedback.

Deregulation will also be phased out, but greater emphasis will be directed to revocation grounds so permits can be invalidated at any time. These shifts aimed to address the major points of delay in the process, but they may arguably loosen the stringency in regulation.

Figure 13. Key comments on JDC 2016-01 Amendments

COMMENT	DOST-DA-DENR-DOH-DILG RESPONSE
BPI's Joint Assessment Group which will come from different agencies	Representatives from DA, DOST, DENR, and DOH. Shall be determined by BCs in these agencies (same composition for previous JDC)
Pending applications prior to effectivity of revised JDC subject to which circular?	Transitory provision: shall be processed under JDC 2016-01 within 85 days of application

COMMENT	DOST-DA-DENR-DOH-DILG RESPONSE
Upon issuance of biosafety permit for direct use, technology is deregulated.	No deregulation under proposed JDC. BPI will monitor compliance to permit conditions, can be subjected to revocation instead
Realistic estimated timelines	Reckoning of days stopped whenever more info or clarification is needed.
Addressing delays	Creation of JAG will reduce time required for risk assessment process to be carried out. New mechanism for application processing delineates the risk assessment from public participation process.
Several applications evaluated at the same time	Multiple applications = multiple JAGs. Each JAG shall be responsible for risk assessment of each application
On renewal of permit	No more renewal, one-time approval. Upon new information containing risks to human health and environment, review will be conducted
Several sacrifices for revised JDC: dissolved public consultation mechanisms; law not covering matters to biosafety to health and environment; removed possibility of independent assessment because of JAG; significant reduction of opportunity and spaces for stakeholder dialogue	Public comment period increased from proposed 10 to 15 working days. NCBP Secretariat will request from ARTA an omnibus exemption for processing of all applications.
Absence of liability and redress mechanism	Section 36 of JDC has remedies of JDC, applied in cases of violations
Nonconformity of JDC to National Biosafety Framework	Under draft JDC, all applications shall be transmitted to DOST, DA, DOH, DENR-BC within 3 working days of application receipt. BCs shall designate two reps to JAG for a meeting within 13 working days. BCs should have at least 10 working days to independently review the application.
Several sacrifices for revised JDC: dissolved public consultation mechanisms; law not covering matters to biosafety to health and environment; removed possibility of independent assessment because of JAG; significant reduction of opportunity and spaces for stakeholder dialogue	Public comment period increased from proposed 10 to 15 working days. NCBP Secretariat will request from ARTA an omnibus exemption for processing of all applications.
Absence of liability and redress mechanism	Section 36 of JDC has remedies of JDC, applied in cases of violations

Source: Authors' compilation

2.5.3. International interface

Optimizing the potential of biotechnology would ultimately depend on a country's mechanisms and structures on biosafety, labeling, and transboundary movement. Countries were expected to provide traceability systems on the sources of biotech products, and guidelines allowing for

the coexistence of traditional and organic. However, developing countries fell short of such expectations (Rao 2017).

Cartagena Protocol on Biosafety, which the Philippines was signatory of, was a non-mandatory agreement that provided model policies and regulations on modified organisms. The extent of this agreement only covered global market, and national standards were up to country governments. The protocol also did not cover non-biosafety indicators such as socio-economic acceptability and ethical considerations (Godfrey, 2013).

DA posited that the inclusion of socioeconomic considerations should be placed at the initial stage before the conduct of simultaneous assessments; if there were no benefits to gain from its development, investment could be better funneled to another technology.

The global biotechnology sector was generally pushing for harmonization of regulations under one unified standard, however this may not be feasible as each country have their own risk factors and regulatory processes retrofitted to their nuances.

3. The case of Bt eggplant

3.1. Crop development

Eggplant comprised one third of crop vegetables in the Philippines and while its production value was estimated highest among similar crops, fruit and shoot borer would target the crop during early vegetative and fruiting stages, resulting to lower marketable yields over time. Farmers resorted to heavy use of pesticides to mitigate losses. One emerging alternative in the future would be to adopt Bt eggplant which has lower EIQ than ordinary varieties (Francisco, Health and environmental impacts of Bt eggplant, 2014).

Bt eggplant with resistance against the fruit and shoot borer was developed by Maharashta Hybrid Seed Company (MAHYCO)[13] and first planted in Bangladesh in 2014. The crop had now been adopted by 91,270 smallholder farmers. The Philippines followed suit in its introduction in 2004, and the application progressed up to multi-location field trials in Pangasinan and Camarines Sur from 2010 to 2012. However, the Court of Appeals ruled against its field trials due to lacking scientific basis and under the basis of Writ of Kalikasan. Table 8 compiled the comments carried over from the case that were deemed unresolved by stakeholders in the recent amendment discussion of JDC 2016.

After its reversal in 2016, the application has been granted Biosafety Permit No. 21-078FFP for food, feed, and processing event and was reported to almost complete its commercial propagation approval (ISAAA 2021).

[13] https://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=351

Table 8. Compiled comments during the SC Ruling on Bt talong

COMMENT	DOST-DA-DENR-DOH-DILG RESPONSE
Applicant chooses IBC Members (no dissenting opinion)	Community representatives should meet JDC qualifications[14], thoroughly screened by DA-BC
NCBP not sufficient oversight for people's participation	NCBP mandate provided for by EO 514
Posting in Public Information Sheet in two places near field testing site not enough to raise awareness. Info too complex for public posting.	Field trial expected not to bring irreparable damage to human health and environment
Scientific and Technical Review Panel does not have a community representative. Supposed to evaluate risks.	Revised JDC does not include the participation of JDC. Assessments to be done by Joint Assessment Group (JAG)
Non-documentation of public consultation	Proof of conduct is LGU resolution from Sanggunian
No appeal procedure	Section 35 of revised JDC provides for filing of request for decision reconsideration

3.2. Methodology

3.2.1. Conceptual framework

Economic surplus analysis model was used to conduct an ex-assessment of technology adoption of bt eggplant as a case study under various market situations and assumptions within a closed economy. This was adapted from the work of Alston, Norton, and Pardey (1995), Francisco (2006), Bayer et al. (2008), and Francisco, Aragon-Chang, and Norton (2014).

Both supply and demand curves were assumed linear and other commodity prices constant in a closed economy model with partial equilibrium. The formulas for parameters were expressed as followed:

Equation 1. Parameters for economic surplus model

Consumer surplus $\Delta CS = P_t Q_t Z(1 + 0.5Z_\mu)$

Producer surplus $\Delta PS = P_t Q_t (K - Z)(1 + 0.5Z_\mu)$

Total surplus $\Delta TS = \Delta CS + \Delta PS = P_t Q_t K(1 + 0.5Z_\mu)$

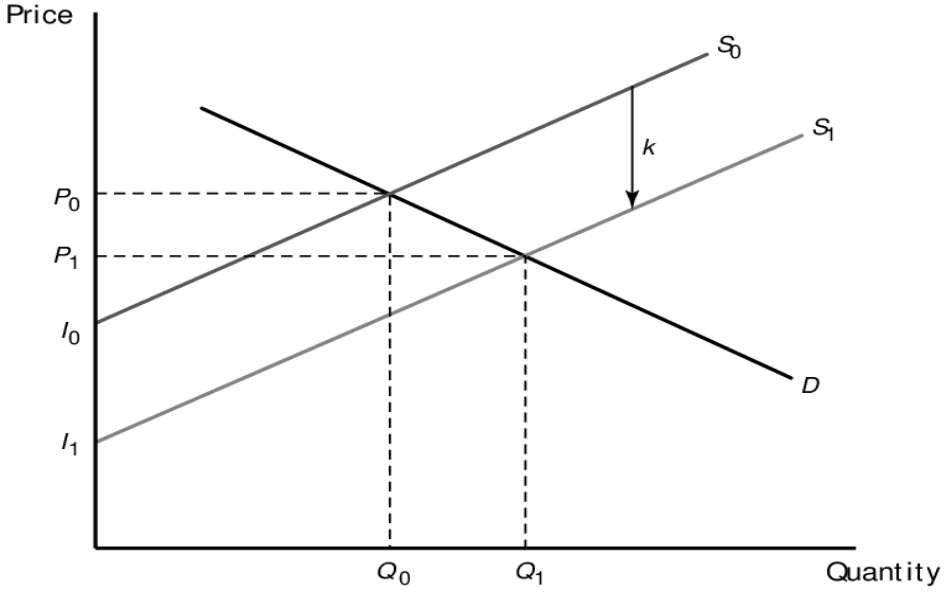
Price change $Z = K\frac{\varepsilon}{\varepsilon+\mu} = -(P_{(r+1)} - P_t)/P_t$

Source: Bayer et al. (2008)

[14] On IBC membership: Representative must not be affiliated with applicant, may include elected LGU officials, residents and CSOs represented in Local Poverty Reduction Action Team pursuant to DILG MC 2015-45. For multi-location, representative shall be designated per site. If it will affect cover AD or protected areas, representative should either be IPs or PAMB.

Where P_t and Q_t are price and quantities at time t. K is vertical shift of supply curve, and Z is change in price due to supply shift. Absolute value of price elasticity of demand is expressed as μ while elasticity of supply is ε.

Figure 14. Graph of closed economy model



Adoption rate was based on expert's opinion while majority of the variables were lifted as proxy in existing datasets. The assumed production area for the whole Philippines was the eggplant production in 2020 while average yield was generated from PSA's cost and return simulations. All costs were referenced from Francisco (2006) and Bayer et al. (2008), but these were updated to 2020 prices using World Bank's GDP deflator. All assumptions were listed in the table below, following the parameters needed for the model.

Table 9. List of assumptions for economic surplus model

VARIABLE	DEFINITION	VALUE	SOURCE/BASIS
PHP/ton	Price per ton in PHP	14,860.00	OpenStat 2020
PHP/kg	Mean price received by farmers	14.86	Cost and returns of eggplant production, PSA 2020
Yield (t/ha)	Average yield	11.14	OpenStat 2020
Total Philippines area	Assumed production area for the whole Philippines	21,780	OpenStat 2020
Extension cost	Assumed extension cost (e.g. public consultations)	59,749,821.80	Francisco 2014
Research cost	As released or invested	38,505,092.71	Bayer et al. 2008, adjusted to 2020 prices
Regulatory cost	As paid/invested	31,534,343.17	Bayer et al. 2008, adjusted to 2020 prices
Success probability	Probability that yield increase will be achieved	0.65	
Supply elasticity		0.50	Francisco 2006
Demand elasticity		0.80	Francisco 2006
Annual depreciation of technology	Assumed 0 technology depreciation for the first 15 years	0.00	

VARIABLE	DEFINITION	VALUE	SOURCE/BASIS
Proportional change in input cost		(0.18)	Computed from Francisco 2014 data
Base quantity	Average yield x production area	242,629.20	Computed from OpenStat 2020 data

Source: Authors' compilation

3.2.2. Data collection and analysis

Primary data gathering was conducted through key informant interviews (KII) and focus group discussions (FGD) involving national and local agencies and research institutions. Secondary sources were generated through ISAAA, PSA, DA, BPI, and DOST.

3.3. Economic surplus analysis of Bt eggplant

Using above parameters, simulations were carried out for bt eggplant's adoption. The first of these was supply elasticity under five scenarios: 0.50 for base model, 0.40, 0.25. 0.75, and 1.00. The closer the price elasticity is to zero (0), the more inelastic[15] the supply curve is.

The internal rate of return (IRR) was highest at price elasticity of 0.25 and lowest at the elasticity of 1. The more it reached elasticity where quantity supplied changed at the same proportion with price, the lesser the IRR. Considering the lead time for input procurement, production, seasonality, and marketing, bt eggplant cannot be easily produced or distributed thus the values returned.

Table 10. Sensitivity analysis for supply elasticity

e	0.50 (base)	0.40	0.25	0.75	1.00
ΔCS	1,457,496,139	1,537,879,619	1,687,875,280	1,302,677,651	1,191,489,579
ΔPS	2,331,993,823	3,075,759,239	5,401,200,898	1,389,522,827	953,191,663
ΔTS	3,789,489,962	4,613,638,858	7,089,076,178	2,692,200,478	2,144,681,242
Res Cost	38,505,093	38,505,093	38,505,093	38,505,093	38,505,093
Reg Costs	31,534,343	31,534,343	31,534,343	31,534,343	31,534,343
Ext Costs	59,749,281.80	59,749,281.80	59,749,281.80	59,749,281.80	59,749,281.80
Total Costs	129,788,718	129,788,718	129,788,718	129,788,718	129,788,718
Net Benefit	3,659,701,245	4,483,850,140	6,959,287,460	2,562,411,760	2,014,892,525
NPV 5%	1,883,425,445	2,313,357,250	3,604,682,698	1,310,989,185	1,025,346,875
NPV 10%	997,753,085	1,229,954,157	1,927,367,127	688,578,300	534,295,653
IRR	53.1%	56.5%	64.0%	47.4%	43.6%

Source: Authors' calculations

The second simulation was for different cost scenarios. This aimed to capture the increasing costs that may be demanded at any particular stage of the adoption process. Containment would usually take two years of testing, field trials (limited and multi-location) two years,

[15] Changes in price will not change the quantity supplied. Relatively inelastic supply (1>n>0) means the percentage change in quantity supplied changes by a lower percentage than the change in price. A unit elastic supply with a price elasticity value of 1 means the change in price will be followed with a proportional change in quantity supplied.

commercialization stage for one year, and extension through public consultations and farmer dialogue which can occur throughout all nine years of the regulatory process.

Table 11. Cost scenario breakdown

regulatory procedure	Base		75% of base		125% of base		Double		Quadruple	
	Cost (PHP)	Time (years)	Cost (PHP)	Time (years)	Cost (PHP)	Time (years)	Cost (PHP)	Time (years)	Cost (PHP)	Time (years)
containment	5,974,928.18	2	4,481,196	2	7,468,660	2	11,949,856	2	23,899,713	2
ltd field trial	6,638,809.09	1	4,979,107	1	8,298,511	1	13,277,618	1	26,555,236	1
multi-location ft	6,638,809.09	1	4,979,107	1	8,298,511	1	13,277,618	1	26,555,236	1
commercialization	6,306,868.63	1	4,730,151	1	7,883,586	1	12,613,737	1	25,227,475	1
Extension	6,638,809.09	9	4,979,107	9	8,298,511	9	13,277,618	9	26,555,236	9

Source: Adapted from Bayer et al. (2008)

The IRR from the base model was estimated at 53.1 percent. The simulation below intuitively followed that the higher the costs, the lesser the rate of return. However, the decrease in IRR was not as drastic; and the quadruple increase in costs still resulted to a 41.6 percent IRR, relatively higher in comparison to the base value.

Table 12. Sensitivity analysis of under various cost scenarios

	75% of base	125% of base	Double	Quadruple
ΔCS	1,457,496,139	1,457,496,139	1,457,496,139	1,457,496,139
ΔPS	2,331,993,823	2,331,993,823	2,331,993,823	2,331,993,823
ΔTS	3,789,489,962	3,789,489,962	3,789,489,962	3,789,489,962
Res Cost	38,505,093	38,505,093	38,505,093	38,505,093
Reg Costs	23,650,757	39,417,929	63,068,686	126,137,373
Ext Costs	44,811,961.35	74,686,602.25	119,498,563.59	238,997,127.19
Total Costs	106,967,811	152,609,624	221,072,343	403,639,593
Net Benefit	3,682,522,151	3,636,880,338	3,568,417,620	3,385,850,370
NPV 5%	1,898,735,018	1,868,115,871	1,822,187,151	1,699,710,563
NPV 10%	1,008,346,806	987,159,363	955,378,199	870,628,427
IRR	54.3%	52.0%	48.8%	41.6%

Source: Authors' calculations

The next simulation tackled the timeline of adoption. It hoped to capture the consequences of delays (lags) and efficiencies (gains) in the regulatory process. The base model started the adoption at Year 9, but uptake among farmers as early as Year 5 would result to a 112.3 percent IRR while delays into Year 12 would decrease IRR to about 21.2 percent. Comparatively, the postponement of adoption has far greater foregone losses than an increase in regulatory costs.

Table 13. Sensitivity analysis of adoption timelines

	Adoption at Year 5	Adoption (2)	Lag 1 year	Lag 2 year	Lag 3 year	Gain 1 year	Gain 2 year	Gain 3 year
ΔCS	2,712,217,489	1,143,250,764	804,662,742	488,403,915	247,114,306	1,504,265,133	1,887,383,709	2,291,010,516
ΔPS	4,339,547,983	1,829,201,223	1,287,460,386	781,446,264	395,382,889	2,406,824,213	3,019,813,934	3,665,616,826
ΔTS	7,051,765,472	2,972,451,987	2,092,123,128	1,269,850,178	642,497,194	3,911,089,346	4,907,197,644	5,956,627,342
Res Cost	38,505,093	38,505,093	38,505,093	38,505,093	38,505,093	38,505,093	38,505,093	38,505,093
Reg Costs	31,534,343	31,534,343	31,534,343	31,534,343	31,534,343	31,534,343	31,534,343	31,534,343
Ext Costs	59,749,281.80	59,749,281.80	59,749,281.80	59,749,281.80	59,749,281.80	59,749,281.80	59,749,281.80	59,749,281.80
Total Costs	129,788,718	129,788,718	129,788,718	129,788,718	129,788,718	129,788,718	129,788,718	129,788,718
Net Benefit	6,921,976,754	2,842,663,270	1,962,334,410	1,140,061,461	512,708,477	3,781,300,628	4,777,408,926	5,826,838,624
NPV 5%	4,007,740,485	1,461,292,150	976,261,643	544,608,105	225,041,201	2,004,098,693	2,608,619,081	3,276,694,074
NPV 10%	2,407,228,443	772,030,120	496,227,722	261,837,084	93,388,272	1,095,263,197	1,472,184,164	1,908,136,649
IRR	112.3%	49.5%	40.5%	31.4%	21.2%	59.6%	72.0%	88.5%

Source: Authors' calculations

3.4. Comparisons

In terms of investment, DA funneled most of its assistance to Bt eggplant with a PHP 22.8 million counterpart, followed by GM corn, and Bt cotton.

Table 14. Investment comparison among GM crops

GM Crops	Total investment	Agency counterpart
Bt eggplant	21,993,661.66	22,836,885.90
GM corn	29,387,384.92	6,586,477.70
Bt cotton	16,276,358.29	4,279,172.00
GM abaca	551,954.09	-
GM cotton and GM abaca (combination)	2,700,000.00	-
Transgenic papaya	13,390,800.78	-
Golden rice	15,400,000.00	3,690,468.00

Source: DA-Biotech Office 2021

The next table compared the regulatory process among various biotech crops in the country. The delays were evident given the duration in years, three of which passed through two regulations and undergoing a third without final approval for commercial propagation. While regulatory security was fulfilled, this stringency also foregone additional productivity and welfare for farmers.

Table 15. Regulatory process comparison among GM crops in the Philippines

Crop	Application proposal	Confined tests	Field trials	Direct use for FFP	Commercial propagation
PRSV Papaya	1998	2012	2014 (1st site)		
BT Cotton	2009	2010-2011	2018		
Golden rice	2017	2017-2018	2019	2019	2021
Bt eggplant	2005	2005-2007	2010-2012	2021	

4. Synthesis of challenges

Although the need for technological novelty in agriculture is palpable, barriers in the development and uptake of modern biotechnology products remain evident. Low productivity, pest and disease infestation, and compromised quality of produce can all be addressed through modern biotechnology products, but lengthy and stringent regulatory processes and high technology development costs have kept most of local agriculture from fully benefitting from such advancement. Aside from GMO corn varieties, which passed vetting during the early 2000's, the Philippine agriculture has yet to fully harness the potential this technological novelty offers.

Concerns range from obstructive regulatory framework and processes, bureaucratic inefficiencies and institutional limitations, high investment cost for R&D, market protection and intellectual property issues, and resistance from interest groups. Action can be from different fronts: regulations and processes need to be streamlined and harmonized, involved institutions need to be capacitated with permanent dedicated structure and staff for biosafety assessment, and community and stakeholder education and participation need to be enhanced.

Evidences abound with GMO corn already benefitting local growers for almost two decades since hurdling early regulatory requirements. Ex ante projections on Bt eggplant development and eventual commercial adoption also points to high returns from modern biotechnology. The newly approved golden rice for commercial propagation further promises huge welfare returns. Such validate positive claims on modern biotechnology from available literature, and provide the impetus in prudently streamlining and possibly fast-tracking vetting processes.

5. Recommendations and ways forward

5.1. Regulatory framework and process

While policy amendments are necessary to ease regulatory lags, the current set of biosafety framework and relevant guidelines is an attempt to balance product safety concerns and agricultural sector needs. Albeit stringency is necessary, current regulatory inefficiencies inevitably lead to massive opportunity costs due to associated delays and bottlenecks as seen in the economic surplus runs, and actual encountered issues in processing Modern Biotechnology product applications. There must be a way to shorten the laboratory-to-market route and timeline without compromising environment and consumer safety.

Short to medium term interventions to minimize foregone welfare for both technology developers and product consumers must focus on ensuring clarity in policy interpretation and implementation; including institutional and stakeholder roles and participation. The Inclusion of public review, consultation, and local stakeholder engagement are critical in addressing technology transfer apprehensions, and in ensuring the appropriateness of developed modern biotechnology products to local requirements. Medium to long term strategies must include policy revision and institutional augmentation.

5.2. Institutional concerns

Implementation issues are sometimes rooted in institutional inefficiencies and procedural bottlenecks. The agencies' approach should be able to address these bureaucratic limitations that hamper the process covering an essentially two-stage vetting process in the Philippines: environmental safety approval and food-feed-processing approval. The ideal would be to come close to a lean centralized process as espoused by other countries (i.e. Bangladesh), with

prudent institutional involvement from relevant government bodies, while being true to biosafety principles and standards. Process redundancies must be minimized to rationalize approval timelines.

Addressing organizational structure instability and non-retention of institutional memory due to staff movement are key in promoting continuity and procedural integrity. Human capital investment must also help reverse high personnel turnover, and the prevalent practice of non-permanent designation of staff to biosafety regulatory functions. Personnel development initiatives must also answer bureaucratic weaknesses, particularly on the lack of capacity building and professional progression within the service, amid the rapid pace of biotechnology advancement.

5.3. Production and marketing

Notwithstanding the positive claims by supporters and proponents of modern biotechnology, certain interest groups and a part of the general public still need convincing regarding the safety and acceptability of GMO crops and their products. An apt information and education (IEC) campaign is key in bridging the knowledge and perception gap. Value chain stakeholders must also be capacitated not only on the technical merits of modern biotechnology products, but also on how to handle cultural sensitivities amid disinformation and valid scientific challenges.

Except for GMO corn growers who have been planting enhanced crop varieties for almost two decades now, most Filipino farmers need proper appreciation and training on the novelty, and cultural and handling requirements of modern biotechnology crops and their products. This will be apparent once the commercial propagation and distribution of golden rice (and soon Bt eggplant) takes traction in the country. Although the input requirements may not significantly differ in the cultivation of GMO crops, their presence in the field together with traditional varieties may be a cause for alarm. Organic crop and heirloom variety producers will particularly not be welcoming when it comes to proximity concerns in the field.

Appropriate GMO product labeling is also necessary to address consumption hesitancy, promote transparency under a sensitive and competitive environment. GM crops and traditional and organic products must be able to coexist in both the field and market without displacing or compromising the production integrity of one or the other.

Farmers and intermediaries will be especially interested on seed distribution, and input cost and cultural management differences. Those in the academe and agricultural research must be vigilant in looking at pest resistance to GM varieties.

ISAAA (2019) encouraged provision of material inputs, stronger technical assistance, enabling policy environment on modern biotechnology adoption and uptake. Given the experience with GM corn where there is the proliferation of expired seeds and black market, the DA is recommended to put up regulatory and enforcement mechanisms and standards on seed quality, price and distribution. Alternative markets should not be monopolized by financiers or traders to further ease market barriers.

A complementary move is to provide incentives for local researchers delving further into modern biotechnology. A short term move for now is to augment funding for process screening, monitoring and evaluation, and research and development. Inadequate funding or appropriations for institutions looking into the application of modern biotechnology, like the

Bureau of Plant Industry, compromises monitoring and evaluation activities and service delivery[16], including conduct of biotechnology proposal and program/project assessment.

Intellectual property protection issues need to be addressed, as not doing so will disincentivize technology development proponents and cause instability and possibly market failure within the value chains. There is no policy provision lodged in current regulatory frameworks on proprietary rights, but there is a Plant Variety Protection Office under the BPI that serves to protect local plant breeders. Emerging threats and problems include IP infringements (i.e. use of proprietary genetic materials from GM crops without the consent of technology developers) and entry of substandard or lower quality seeds through informal channels or black market.

5.4. Policy, legislation

Recommendations in the longer term point to augmentations in the biosafety framework, revision of EO 514, and passage of the Modern Biotechnology Act or a legislative form thereof[17]. An applicable legislation should establish a central authority on modern Biotechnology in the Philippines may it be under the current stewardship of DOST or another institutional arrangement. The regulatory processes among involved national government agencies need to be streamlined to minimize decision-making lags and attached regulatory costs.

The amendment of the implementing rules and regulations of JDC 2016-01 is considered the most feasible entry point in the short term. It is expected to include the following:

1. Harmonization of processes in one regulatory flow, common time frames, and simultaneous evaluations;

2. Conduct of risk assessments for relevant agencies;

3. Clarification of areas of inconsistencies, delineation of roles and sequences among involved institutional bodies;

4. Rationalization of public hearing and community engagements to a manageable frequency and number;

5. Reduction of the length of joint assessment periods;

6. Removal of renewal for commercial propagation and field trials and creation of one-time approval and lifetime permit[18]

More comprehensive regulatory provisions may be required with the rapid advancement in modern biotechnology and related fields, as well as the growing list of genetically modified commodities and their products entering both global and domestic markets. Focus may be given to stringent GM food labeling, low level presence detection and appraisal, GM animals regulation, and new plant breeding techniques to complement modern biotechnology. The same policy augmentations must serve to protect the consuming public and the integrity of the

[16] Ongoing monitoring on weed resistance of ongoing field trials in preparation for future claims. This project is not programmed with funds as it does not have legal basis.
[17] House Bill No. 3372 filed by Representative Sharon Garin for the Eighteenth Congress.
[18] For context, permit for field trial expires after two years; commercial propagation, and FFP after five years. BPI Biotech Office requested to have continuous oversight monitoring function over approved commodities in the new JDC.

environment, while not stifling the advancement of technology and its adoption by farmers and local value chain stakeholders.

The huge opportunity losses attached to suboptimal bureaucratic regulatory functioning have to be stemmed. Notwithstanding contrary sentiments, Fully vetted modern biotechnology crops and products have their place in improving the productivity of the agriculture sector, with great potential welfare benefits for both local producers and consumers. The government's priority must be to make available the modern biotechnology option, in both farm and household table, in the most prudent but expedient way possible.

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