



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

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# Outline of the presentation

1. Defining modern biotechnology
2. Objectives
3. International and domestic landscape
4. Policy, institutions, regulatory regimes
5. Economic surplus analysis
6. Challenges and recommendations



# Biotechnology

set of tools that uses living organisms to make or modify a product, improve plants, trees or animals, or develop microorganisms

## Modern Biotechnology

genetic engineering, gene technology, genetic modification, gene manipulation; genetic makeup of an organism altered through recombinant DNA technology; facilitates direct transfer of genes between organisms

## Genetically Modified Crop

resulting production after insertion with genetic material(s) obtained through modern biotechnology

# Modern biotechnology as a multifaceted solution?

- Proposes to solve sectoral problems on food security, agricultural productivity, pest and disease resistance, and micronutrient deficiency
- Role deemed as crucial in the growing demand for food and resources
- Introduction of biotech crops in the Philippines through *Bt* corn; not followed by other GM crops thereafter
- Review of regulatory application and structures pinpoints areas for optimization and check-and-balance

# 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 conducted the following:

- a. Review policy and related regulatory processes on modern biotechnology;
- b. Conduct case studies on technology development and commercialization; and
- c. Recommend ways forward for agriculture and modern biotechnology

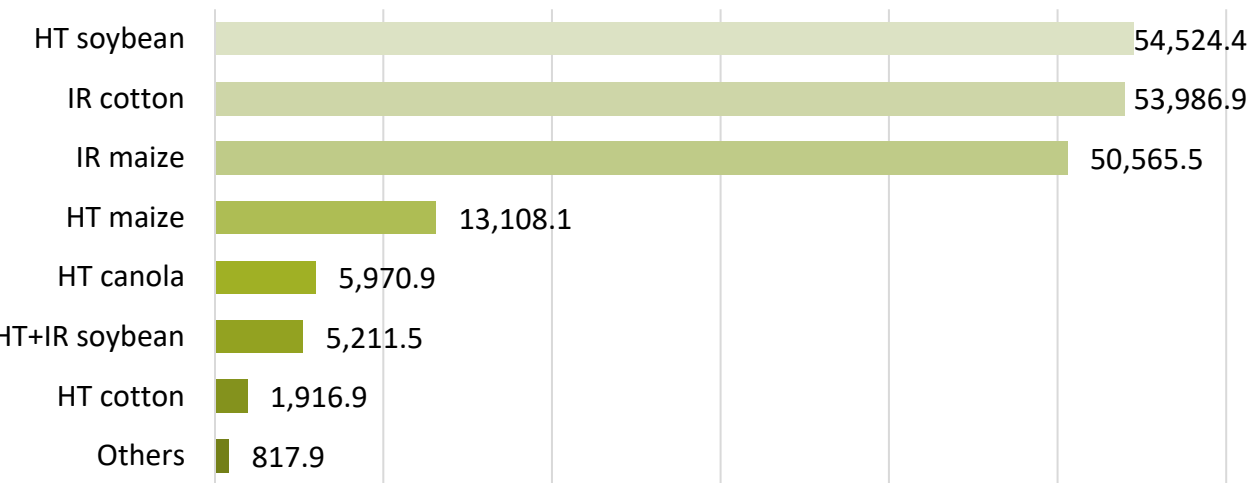
# Around 71 countries have adopted biotech; PH ranked 12<sup>th</sup> in 2019 data

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
9	Pakistan	2.5	Cotton
10	Bolivia	1.4	Soybeans
11	Uruguay	1.2	Soybeans, maize
<b>12</b>	<b>Philippines</b>	<b>0.9</b>	<b>Maize</b>
TOTAL		190.4	

Source: ISAAA 2019

- Global area of adoption accumulated to 190.4 mhas. Highest adoption is soybean, followed by maize, cotton, and canola
- Asia comprises 32% of corn production; PH contributes 0.9 mhas

# Farm income benefits around USD 186,102.1 million (1996-2016)



Note: Others include virus-resistant papaya and squash, and herbicide-tolerant sugar beet  
 Source: ISAAA 2016

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

- Herbicide-tolerant soybean highest gain followed by IR cotton, IR maize, and HT maize
- Income derived from biotech corn was around USD 92 million in 2013 alone and PHP 10,132/ha for farmer level (ISAAA 2019)
- Seasonal variability in income: PHP 7,482/ha during dry season, PHP 7,080 during wet season
- Net profitability is greater by 4-7% during wet season and 3-9% for dry season (ISAAA 2019)

# Technology reduced pesticide costs and increased environmental benefits

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
<b>Total</b>	<b>-671.2</b>	<b>-35,647.0</b>	<b>-8.2</b>	<b>-18.4</b>

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

- Pesticide expenditure decreased by 38%
- Added biodiversity gains valued at USD 150 billion (ISAAA 2019; Klumper & Qaim 2014)
- Biotech farms observed to have significantly higher populations of beneficial insects
- Transition to biotech accumulated an 18.4% change in environmental impact



# Hybrid corn in PH: higher farm inputs, higher returns

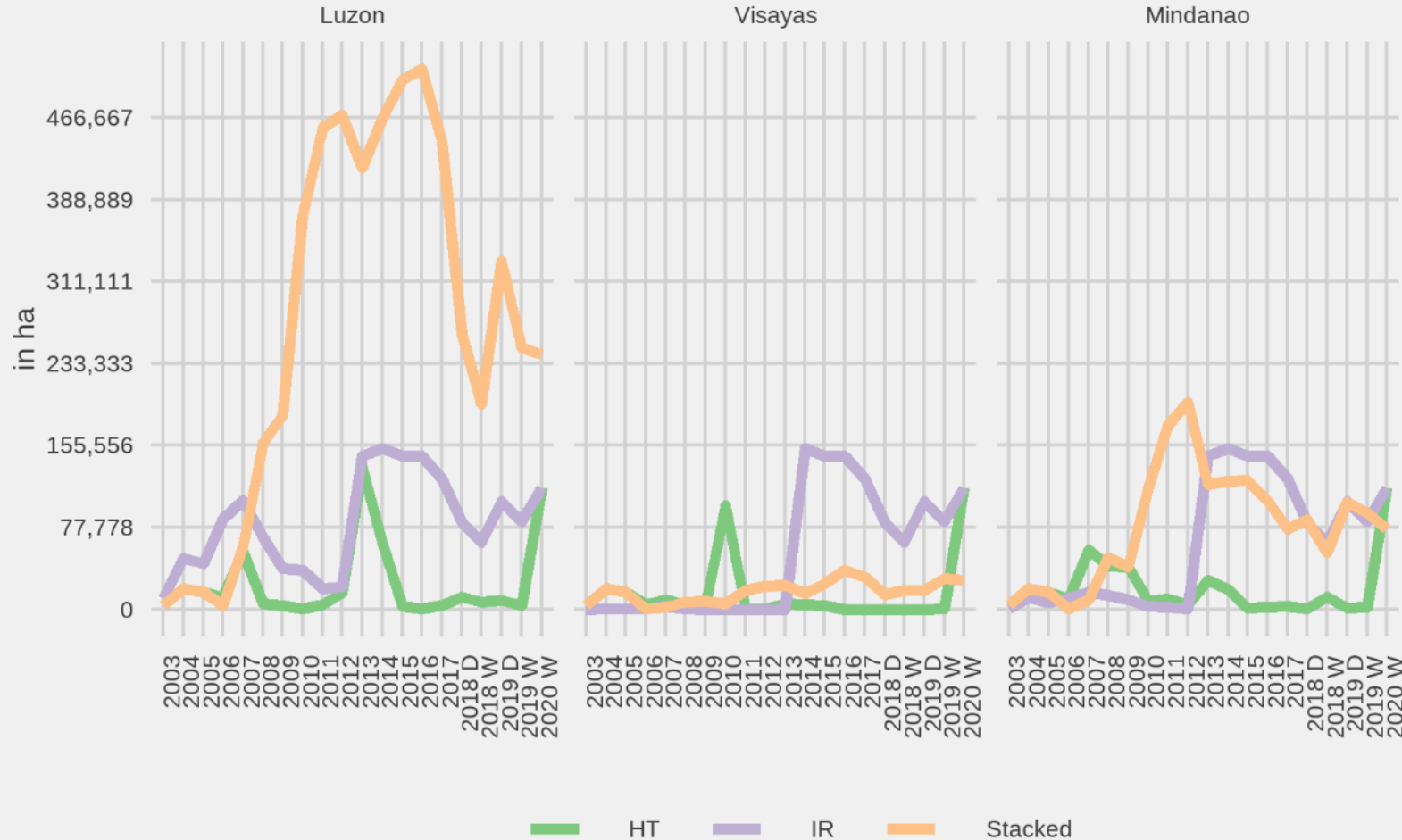
FARM INPUT	HYBRID	MODERN OPV	NATIVE OPV
seeds (kg/ha)	17.88	17.04	15.17
organic fertilizer (kg/ha)	9.65	7.21	7.8
solid inorganic fertilizer (kg/ha)	348	112.46	86.57
pesticides (li/ha)	3.58	1.03	0.39
labor requirement/ha (mandays)	46.60	45.45	45.19
hired labor (mandays)	36.15	13.81	13.81

CRS	HYBRID	MODERN OPV	NATIVE OPV
cost (php/ha)	39,979	15,518	14,208
cost (php/kg)	8.41	10.25	11.12
production (kg/ha)	4,754	1,514	1,278
price (php/crop)	11.8	11.12	12.64
gross earnings (php/ha)	56,118	19,142	16,988
avg returns (php/ha)	26,687	10,810	11,278
farmer net returns (php/ha)	16,139	3,624	2,780
net profit-cost ratio	0.40	0.23	0.20

Note: OPV = Open Pollinated Variant  
 Source: PSA 2013

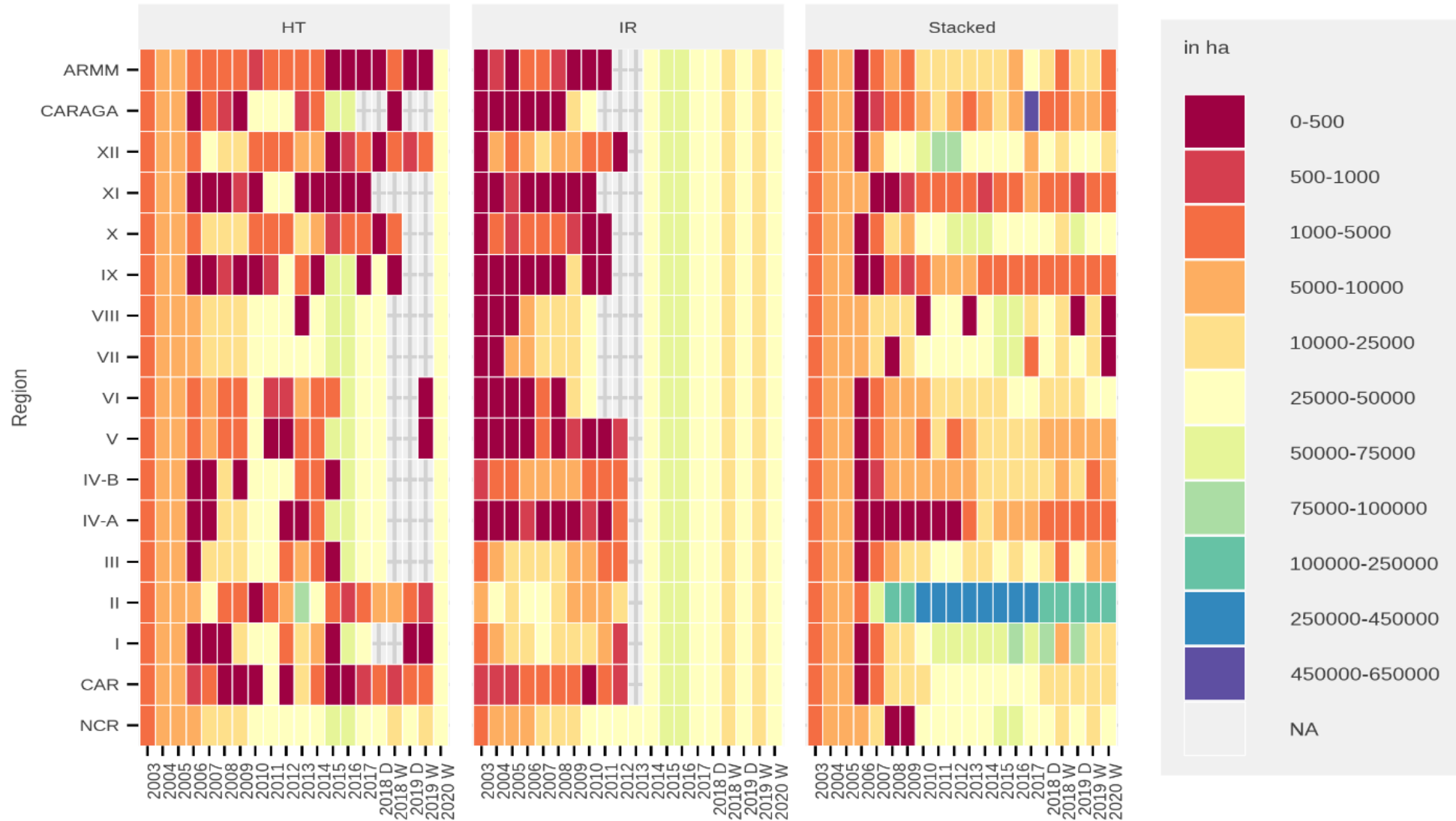
# Bt corn first commercially available GM crop in PH

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



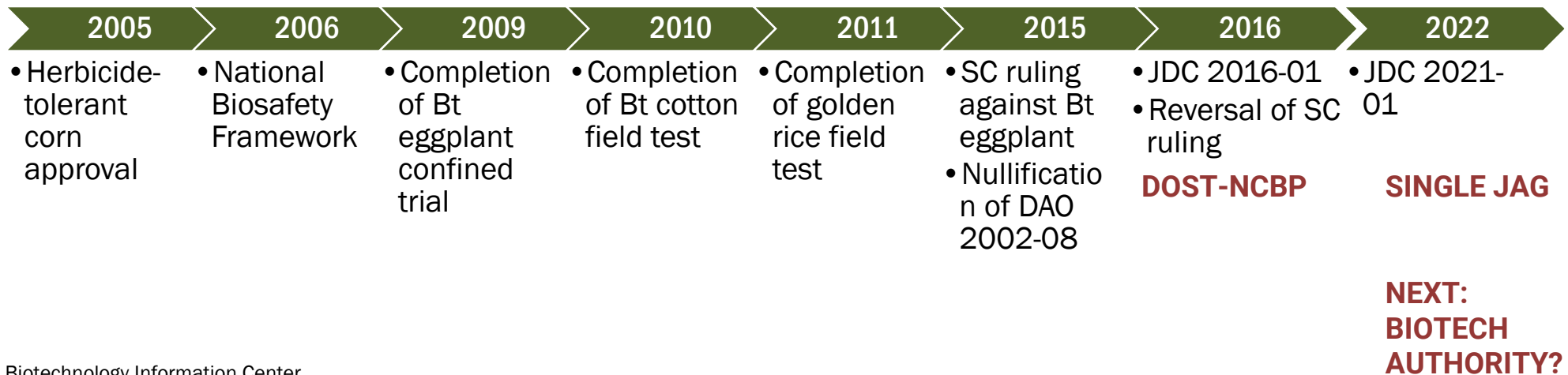
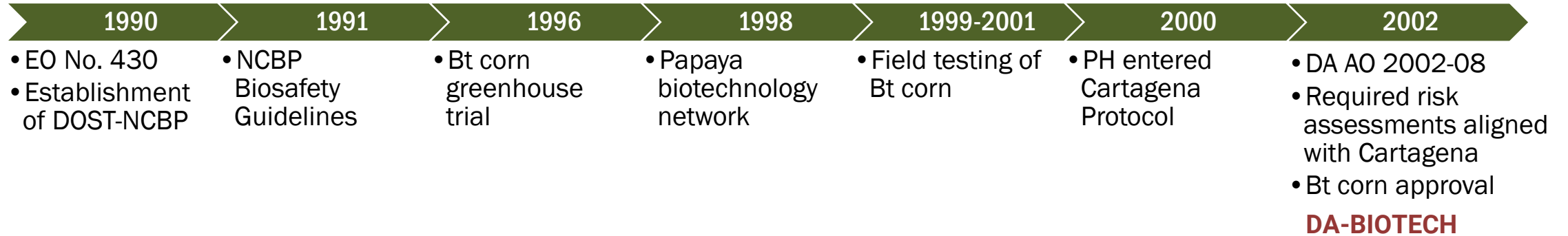
- Bt corn underwent regulatory process under DAO 2002-08
- Relatively fast due to mature technology
- Luzon has biggest adoption area

# Preference of stacked traits over insecticide resistant and herbicide tolerant varieties despite earlier adoption, Region 2 dominates



Source: BPI Biotech Office 2021

# Institutional oversight shift follows policy issuances



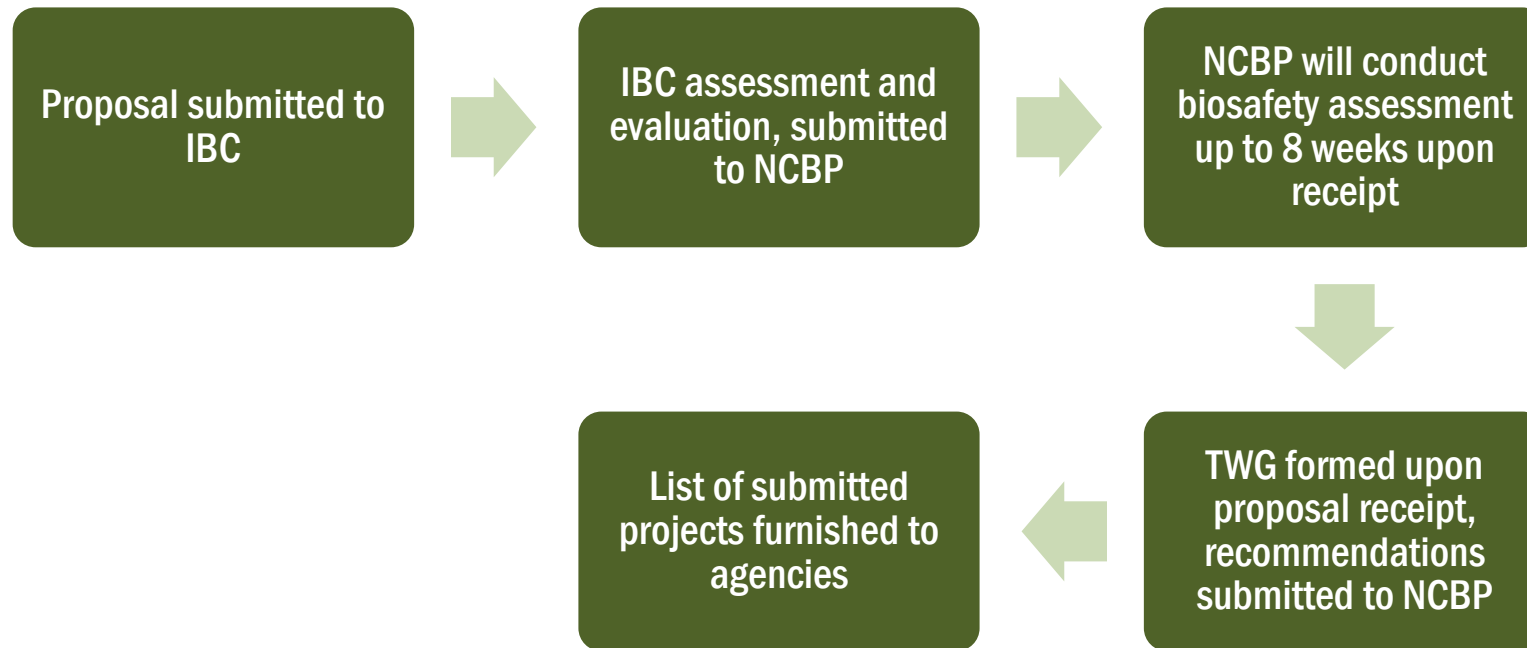
Source: SEARCA Biotechnology Information Center

# JDC creation a ‘terrible birthing’ or necessary precaution?

	<b>DA AO 2002-08</b>	<b>JDC 2016-01</b>
Institutions	DA, BPI, BAFPS, BAI	DOST-NCBP, DA, BPI, DENR, DILG, DOH, FPA, BAI Scientific and Technical Review Panel (STRP) Institutional Biosafety Committee (IBC)
Assessment	DA	DOST, DA, DENR, DOH
Permits	field test, release for propagation, importation for direct use	experimental use (laboratory research) , contained trial, open field trial, multi-location field trials, commercial propagation
Deregulation	Yes	Yes
Validity of permits	2 years (field trial), 5 years (propagation)	Same
Consultation	Barangay and City/Municipal LGUs	LGUs, local communities, IPs, Agri and Fisheries Council, and PAMB Requires an LGU ordinance
Public hearing	Optional, field testing	Confined and field trial phases
Consultation timeline	30 days	30 days
Process timeline	60 days	85 days

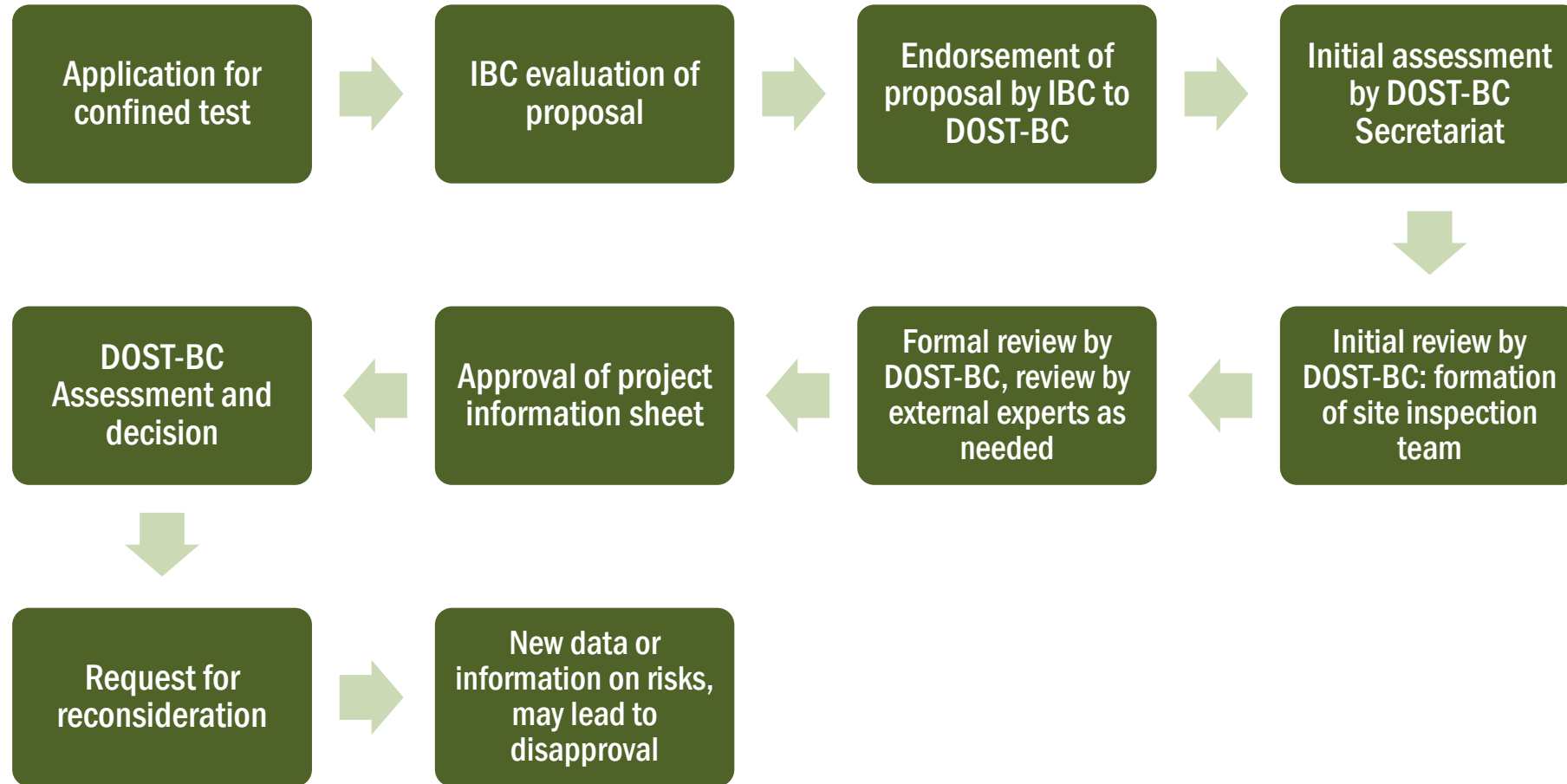
# Procedure for proposal

Research laboratory must be certified with NCBP/IBC biosafety standards



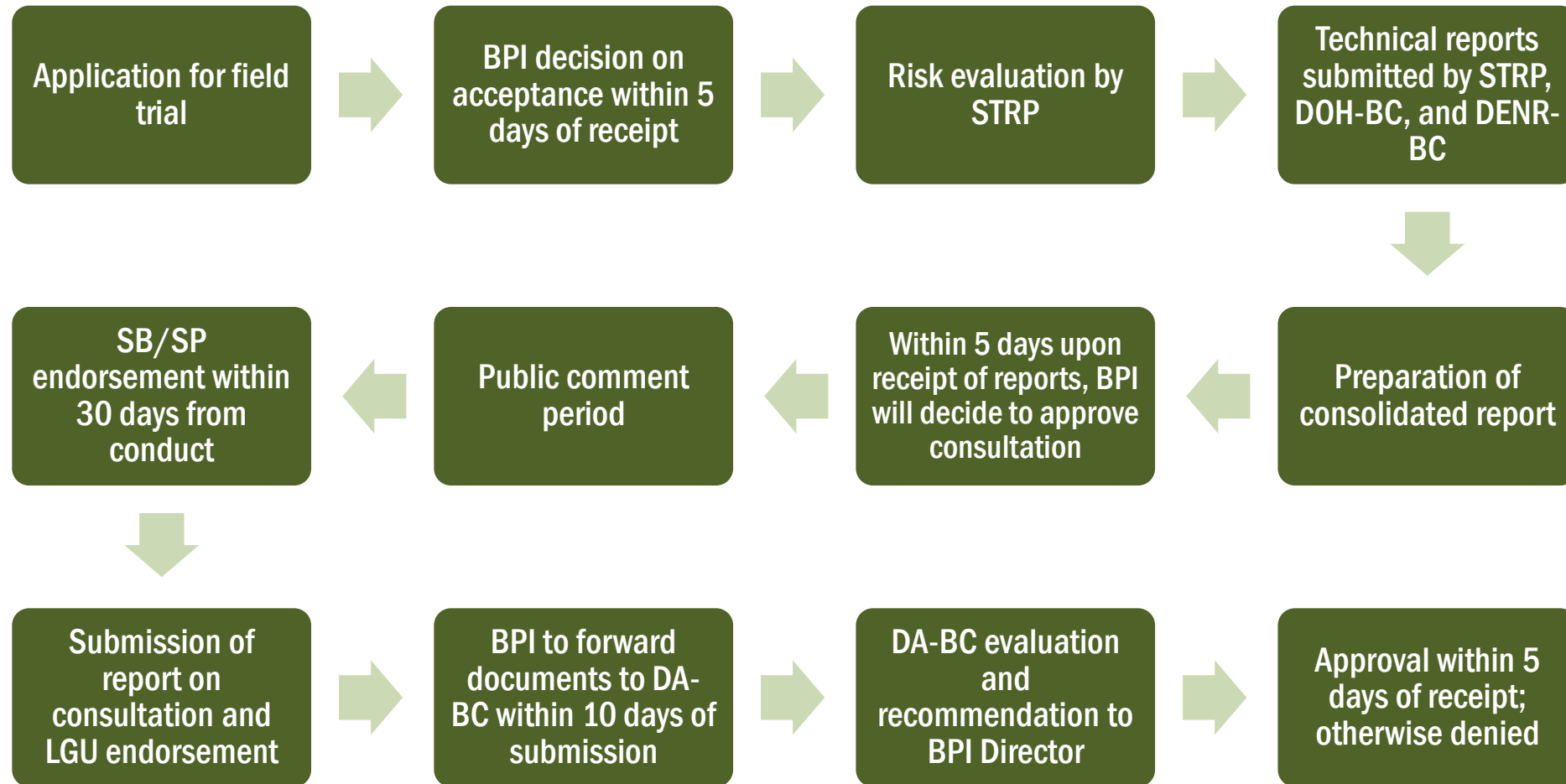
# Procedure for confined tests

Monitored closely by DA, DOH, DENR; public hearing part of process



# Procedure for field trials

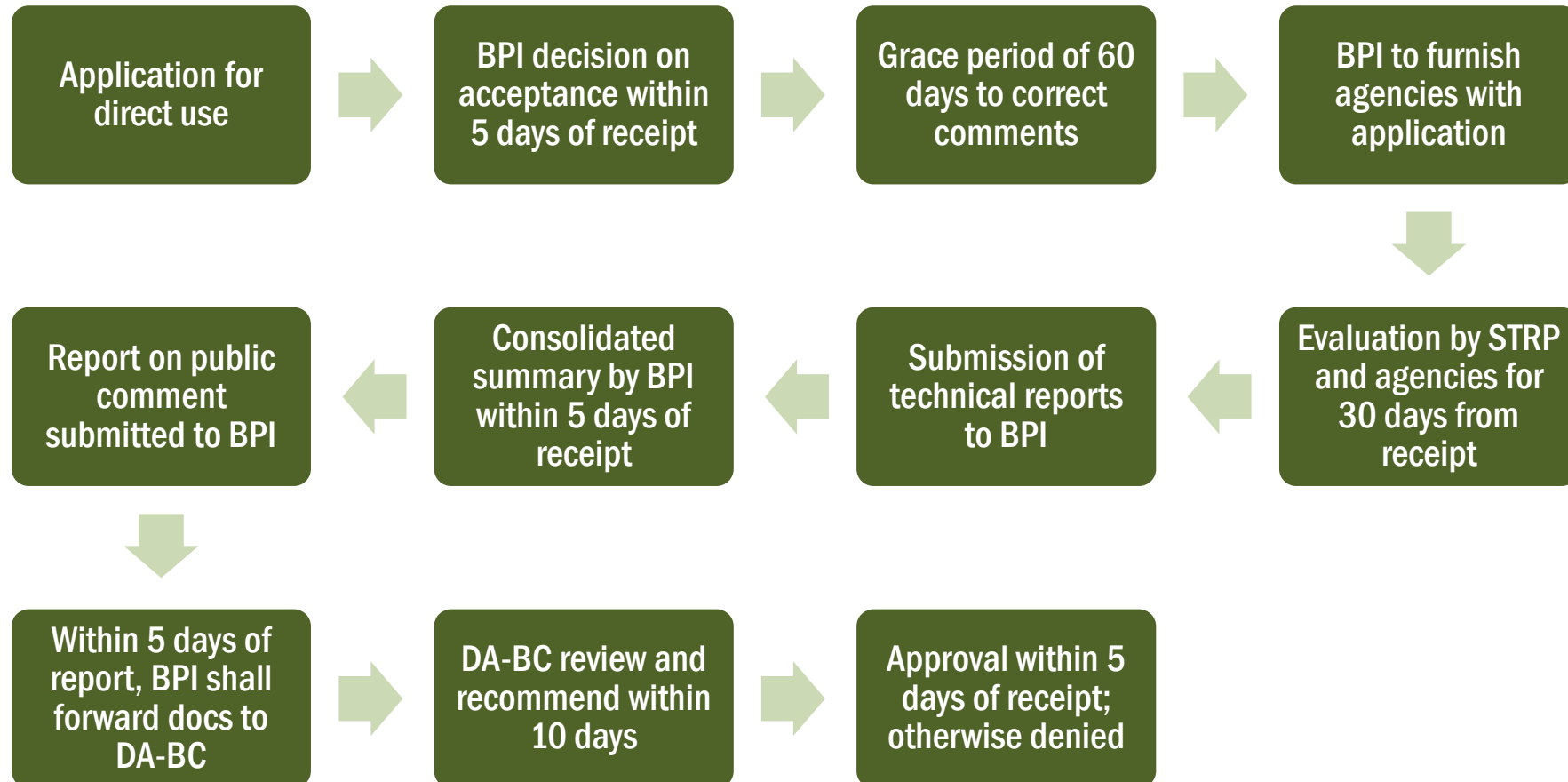
Trial sites evaluated separately, added permits required if within or near ancestral domain or NIPAS. Multistakeholder consultation and LGU ordinance needed.





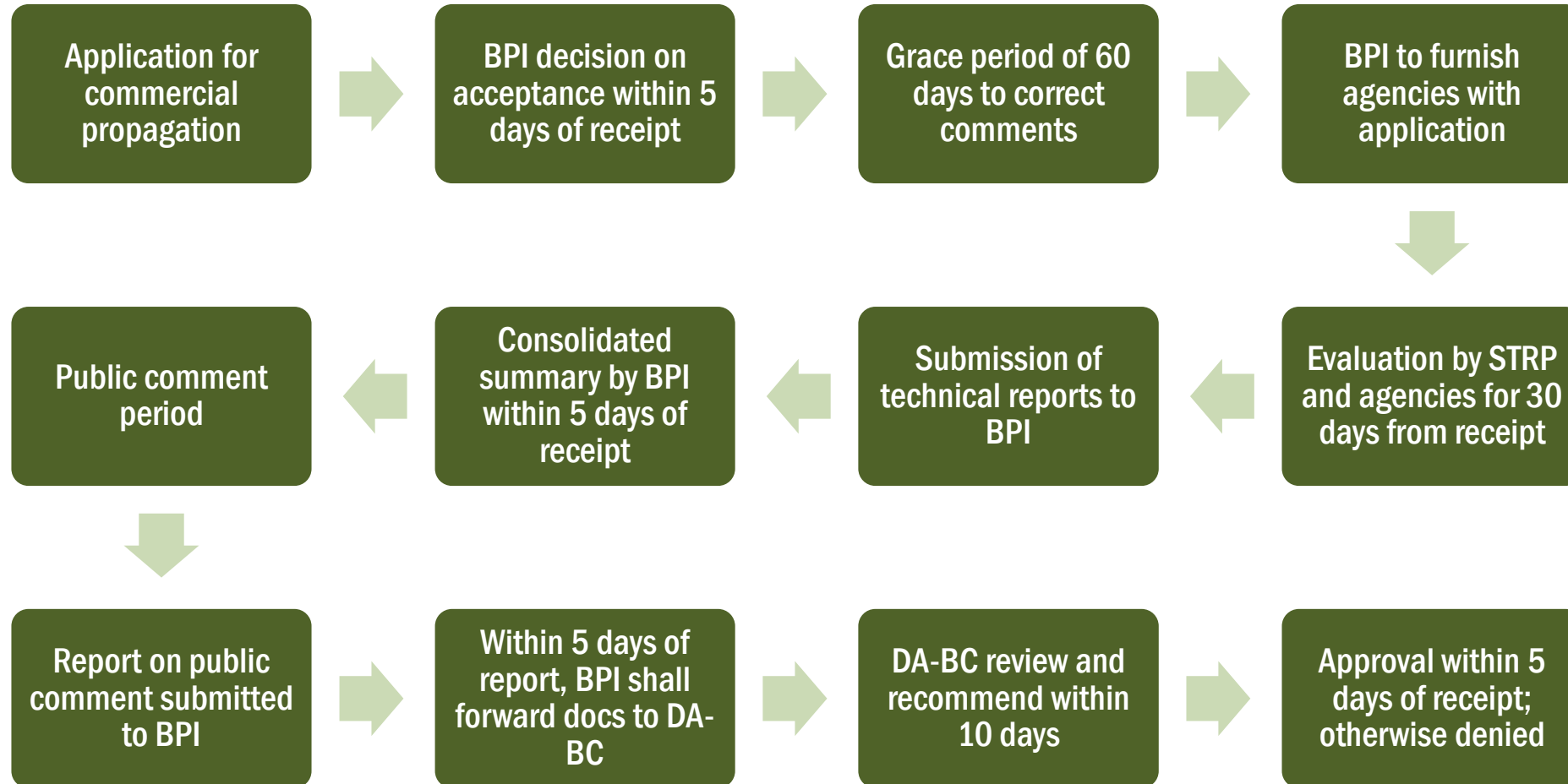
# Procedure for direct use for food, feed, & processing

## Added evaluation: Food safety standards, feed safety, and socio-economic considerations



# Procedure for commercial propagation

Parallel registration with FPA, seed distribution only for SEC-registered bodies



# 98 GM Applications under JDC 2016-01

## FIELD TRIAL (1)



*Golden Rice*

1 transformation event, approved  
Nueva Ecija, Isabela

## DIRECT USE (58)



*Corn*

20 approved, 12 on process



*Alfalfa*

2 approved, 1 on process, 1 pending



*Canola*

2 approved, 2 on process



*Cotton*

8 approved, 5 on process



*Oilseed rape*

2 approved, 1 on process, 1 pending



*Potato*

3 on process



*Corn*

12 approved, 1 on process (Monsanto)



*Golden Rice*

1 transformation event  
On process

## COMMERCIAL PROPAGATION (14)



*Golden Rice*

1 event, approved



*Soybean*

18 approved, 4 on process



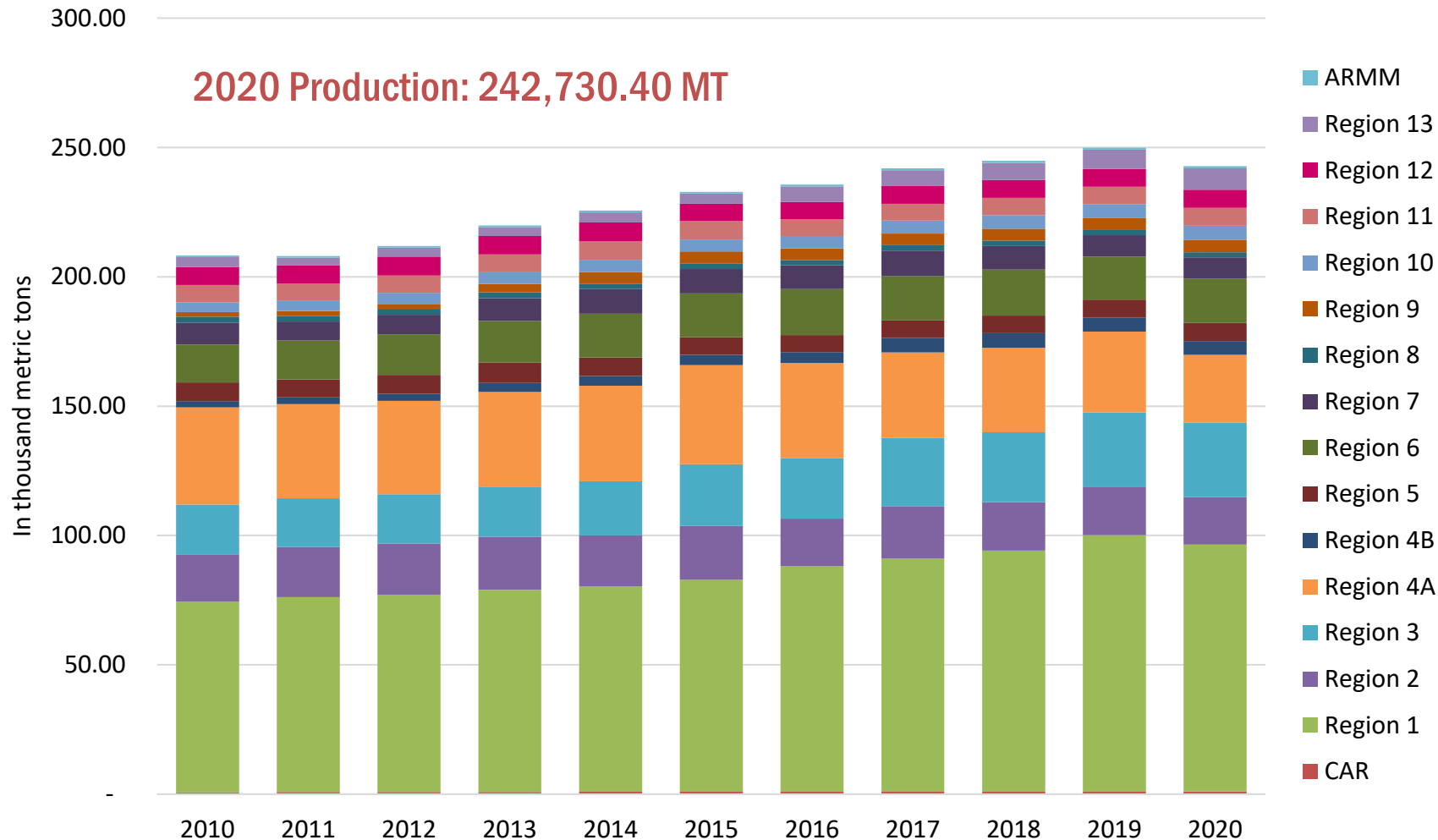
*Sugarbeet*

1 event, on process



# Economic Surplus Analysis of *Bt* eggplant

# Eggplant production in PH



- Comprises 1/3 of crop vegetables, production value highest among similar crops
- Self-sufficiency ratio is 100 percent vs the following:
  - a. Corn – 91.4
  - b. Rice – 85.0
  - c. Potato – 81.0
- Fruit and shoot borer infestation results to 80 percent yield loss (Hautea et al. 2016)

# Crop development of *Bt* eggplant

Local eggplant vulnerable to fruit and shoot borer



Photo credit: Rao 2010 through ISAAA

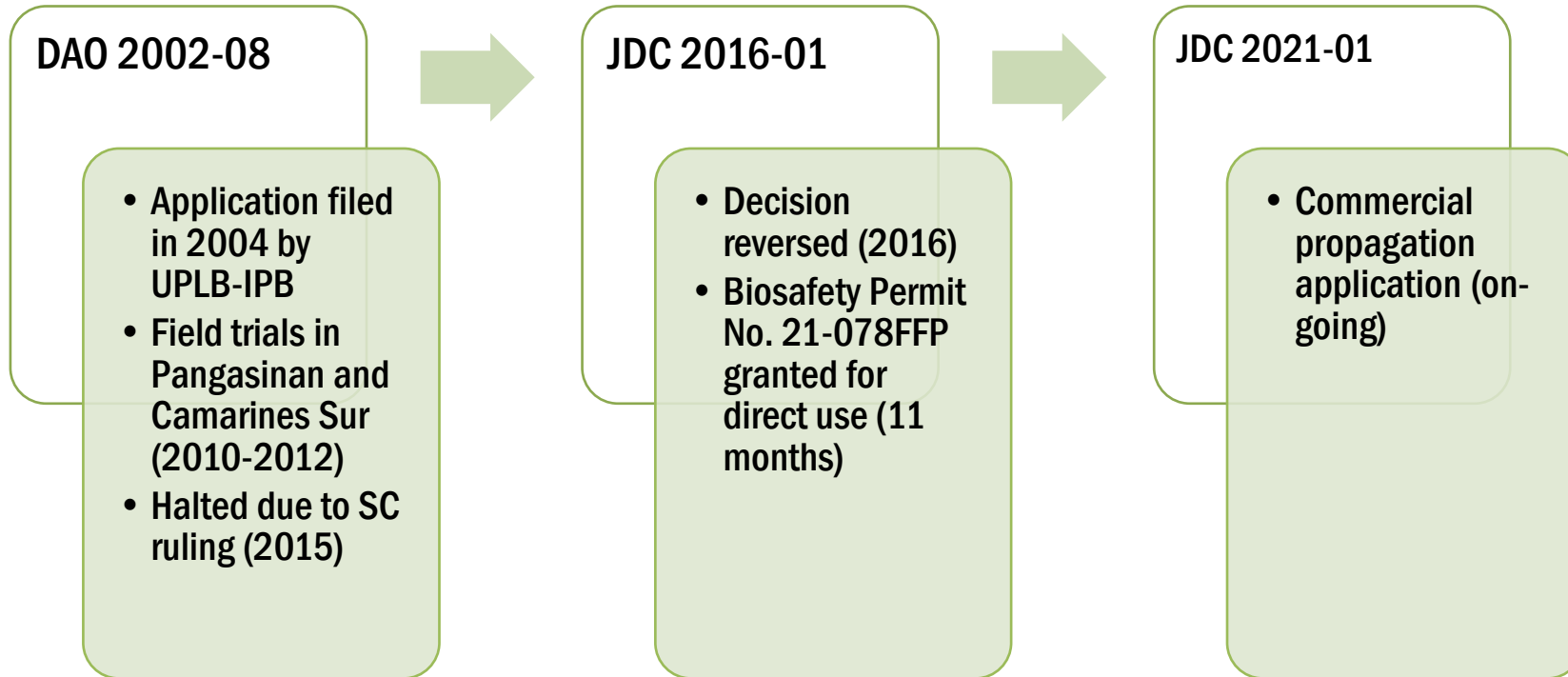


- Event comes from MAHYCO; applied in three countries – Bangladesh, Philippines, India
- Brinjal in Bangladesh but not preferred locally
- Two varieties: F1 hybrid and open pollinated. Farmer preference for the former



# Why *Bt* eggplant?

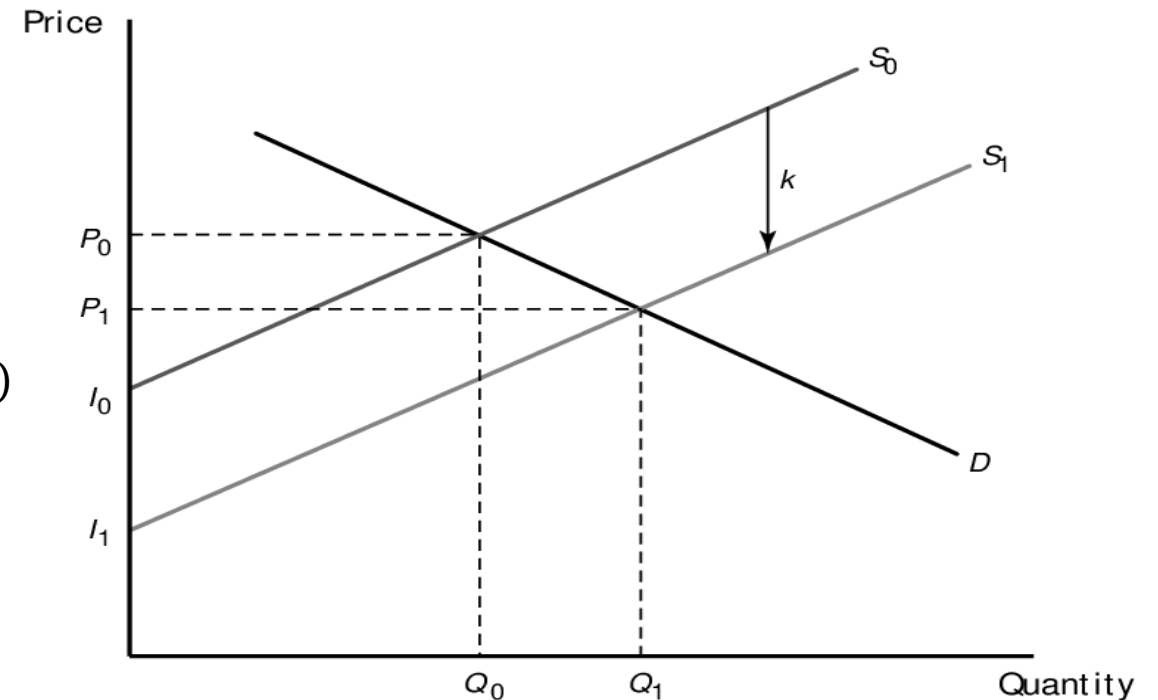
It is the only event to undergo three regulatory regimes.



# Methodology

- Use of economic surplus analysis as an ex-ante assessment of technology adoption under various market situations and assumptions within a closed economy model.
- Model drawn from the work of Alston, Norton, and Pardey (1995) and bt eggplant study of Francisco, Aragon-Chang, and Norton (2014).

Consumer surplus	$\Delta CS = P_t Q_t Z (1 + 0.5 Z \mu)$
Producer surplus	$\Delta PS = P_t Q_t (K - Z) (1 + 0.5 Z \mu)$
Total surplus	$\Delta TS = \Delta CS + \Delta PS = P_t Q_t K (1 + 0.5 Z \mu)$
Price change	$Z = K \frac{\varepsilon}{\varepsilon + \mu} = - (P_{(r+1)} - P_t) / P_t$



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 in  $\mu$  while elasticity of supply is  $\varepsilon$



# Assumptions in testing Bt eggplant viability

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	
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

# Sensitivity Analysis

Table 1. Supply elasticity scenarios (in PHP million)

$\epsilon$	0.50 (base)	0.40	0.25	0.75	1.00
$\Delta CS$	1,457.50	1,537.88	1,687.88	1,302.68	1,191.49
$\Delta PS$	2,331.99	3,075.76	5,401.20	1,389.52	953.19
$\Delta TS$	3,789.49	4,613.64	7,089.08	2,692.20	2,144.68
Res Cost	38.51	38.51	38.51	38.51	38.51
Reg Costs	31.53	31.53	31.53	31.53	31.53
Ext Costs	59.75	59.75	59.75	59.75	59.75
Total Costs	129.79	129.79	129.79	129.79	129.79
Net Benefit	3,659.70	4,483.85	6,959.29	2,562.41	2,014.89
NPV 5%	1,883.43	2,313.36	3,604.68	1,310.99	1,025.35
NPV 10%	997.75	1,229.95	1,927.37	688.58	534.30
<b>IRR</b>	<b>53.1%</b>	<b>56.5%</b>	<b>64.0%</b>	<b>47.4%</b>	<b>43.6%</b>

- IRR greater when supply is relatively inelastic. The more it reaches elasticity where quantity supplied changes at the same proportion with price, the lesser the IRR.
- Take into consideration inputs, production, seasonality, and marketing; cannot readily be produced or distributed

# Sensitivity Analysis

Table 2. Cost scenarios (in PHP million)    Table 3. Regulatory cost scenarios (in PHP million)

	75% of base	125% of base	Double	Quadruple
ΔCS	1,457.50	1,457.50	1,457.50	1,457.50
ΔPS	2,331.99	2,331.99	2,331.99	2,331.99
ΔTS	3,789.49	3,789.49	3,789.49	3,789.49
Res Cost	38.51	38.51	38.51	38.51
Reg Costs	23.65	39.42	63.07	126.14
Ext Costs	44.81	74.69	119.50	239.00
Total Costs	106.97	152.61	221.07	403.64
Net				
Benefit	3,682.52	3,636.88	3,568.42	3,385.85
NPV 5%	1,898.74	1,868.12	1,822.19	1,699.71
NPV 10%	1,008.35	987.16	955.38	870.63
<b>IRR</b>	<b>54.3%</b>	<b>52.0%</b>	<b>48.8%</b>	<b>41.6%</b>

regulatory procedure	Base	75% of base	125% of base	Double	Quadruple
containment	0.06	4.48	7.47	11.95	23.90
ltd field trial	0.07	4.98	8.30	13.28	26.56
multi-location ft	0.07	4.98	8.30	13.28	26.56
commercialization	0.06	4.73	7.88	12.61	25.23
Extension	0.07	4.98	8.30	13.28	26.56

- Base model IRR is 53.1 %. This simulation intuitively follows that the higher the costs, the lesser the IRR.
- The decrease in IRR is not as drastic, still exhibit positive rates even if costs are increased up to four times
- Regulatory costs highest during field trials and extension (travel costs, participatory processes). Also the longest and most expensive

# Sensitivity Analysis

Table 3. Adoption scenarios (in PHP million)

	Adoption at Year 5	Lag 1 year	Lag 2 year	Lag 3 year	Gain 1 year	Gain 2 year	Gain 3 year
DCS	2,712.22	804.66	488.40	247.11	1,504.27	1,887.38	2,291.01
DPS	4,339.55	1,287.46	781.45	395.38	2,406.82	3,019.81	3,665.62
DTS	7,051.77	2,092.12	1,269.85	642.50	3,911.09	4,907.20	5,956.63
Res Cost	38.51	38.51	38.51	38.51	38.51	38.51	38.51
Reg Costs	31.53	31.53	31.53	31.53	31.53	31.53	31.53
Ext Costs	59.75	59.75	59.75	59.75	59.75	59.75	59.75
Total Costs	129.79	129.79	129.79	129.79	129.79	129.79	129.79
Net Benefit	6,921.98	1,962.33	1,140.06	512.71	3,781.30	4,777.41	5,826.84
NPV 5%	4,007.74	976.26	544.61	225.04	2,004.10	2,608.62	3,276.69
NPV 10%	2,407.23	496.23	261.84	93.39	1,095.26	1,472.18	1,908.14
<b>IRR</b>	<b>112.3%</b>	<b>40.5%</b>	<b>31.4%</b>	<b>21.2%</b>	<b>59.6%</b>	<b>72.0%</b>	<b>88.5%</b>

- Adoption in base model starts at Year 9, reflecting delays in regulatory process. Adoption as early as Year 5 would result to more than 100% IRR while a further delay of as much as 3 years (Year 12) would decrease IRR to about 21.2%.
- Earlier adoption = higher IRR

# Comparison of regulatory process among GM crops; delays evident in the duration. Other crop development halted.

CROP	APPLICATION PROPOSAL	CONFINED TESTS	FIELD TRIALS	DIRECT USE FOR FFP	COMMERCIAL PROPAGATION
PRSV Papaya	1998	2012	2014 (1 <sup>st</sup> site)		
BT Cotton	2009	2010-2011	2018		
Golden rice	2017	2017-2018	2019	2019	Approved 2021
Bt eggplant	2005	2005-2007	2010-2012	2021	Ongoing

Per KII, PRSV Papaya was discontinued owing to its lower efficacy than sinta papaya and against PRSV itself.



# Key Insights and Recommendations

# Key insights in development and uptake of biotech products

## On Productivity:

- Hybrids 3-4X more profitable than OPV (corn); GM Corn cultivation lessens labor requirement damages and wastes
- GM Corn adoption is highest in Luzon, where Stacked varieties are preferred. IR and HT (Bt and round up ready) corn equally preferred in Visayas and Mindanao
- Bt Eggplant is economically viable in all scenarios with positive NPV and high IRR
- Golden Rice is micronutrient enriched in addition to similar productivity

## On Regulations: Stringent regulatory process, delays stem from bureaucratic inefficiencies

- JDC 2016-01 introduced added layers to ensure environment and health protection; but timelines extended
- There are massive opportunity costs due to delays;
- Highly technical vetting process requires the support of apt organic structure, competent staff and funding
- Weak mechanisms on revocation grounds, M&E augmentation required for necessary checks

## On Regulations: High costs on technology development, investment, and R&D

- More than 2 decades timeline from technology development to regulatory approval
- Approval period: 7-9 years GM Corn vs 10-13 years GM rice and eggplant; but GM rice 2019-2021 FT to CP
- Regulatory expense may be more than 30% of total investment

# Key insights in development and uptake of biotech products (cont'd)

## End-user Uptake: Market protection and intellectual property issues

- Intellectual property rights is outside of biosafety jurisdiction; patents are naturally skewed towards multinational tech developers.
- High seed costs may hinder farmers' technology uptake. This invites the proliferation of substandard and ukay seeds, which anecdotally captures 15-25% of the seed market.
- No provision lodged in current regulatory framework specifically for IP, but there is the Plant Variety Protection Office.
- Need to enhance link between technology development and industry stakeholders (seed production and distribution; acknowledgment of farmer seed systems)

## End-user Uptake: Economic Viability and Public welfare

- For Bt Eggplant: all scenarios viable with positive NPV and high IRR
- Public participation mechanisms need revisiting. Limiting exchanges during confined tests (optional) and field trials, may not be enough to appease interest groups (and possibly influence application termination).



# Recommendation: Balance Product Safety and Agricultural Sector Needs

## Short to medium term interventions

- Ensure clarity in policy interpretation and implementation, including stakeholder roles and public participation
- Enhance public consultation, and local stakeholder engagement. Intensify IEC to address acceptability of GM crops, and bridge knowledge and perception gaps
- Put up regulatory and enforcement mechanisms and standards on seed quality, price, distribution and IP
- Address organizational structure instability and non-retention of institutional memory due to staff movement for continuity and procedural integrity
- Increase Human capital investment / personnel development initiatives for both R&D and regulatory functions
- Augment interdepartmental policy (partially addressed thru JDC 2021) :
  1. Harmonize regulatory flow with coordinated time frame and simultaneous evaluation
  2. Conduct of risk assessments and clarify areas of inconsistencies, including delineation of roles among bodies
  3. Rationalize public hearing and community engagement/participation
  4. Streamline assessment periods; rationalize renewal for FFP, field trials, and commercial propagation

	<b>DA AO 2002-08</b>	<b>JDC 2016-01</b>	<b>JDC 2021-01</b>
Institutions	DA, BPI, BAFPS, BAI	DA, DOST, NCBP, DENR, DOH, DILG, BPI, FPA, BAI Scientific and Technical Review Panel (STRP) Institutional Biosafety Committee (IBC)	<b>DA, DOST, NCBP, DENR, DOH, DILG, BPI, IBC</b>
Assessment	DA	Biosafety Committees-DOST, DA, DENR, DOH	<b>Joint Assessment Group</b> <b>*exemption of stacked events</b> <b>*socioeconomic consideration removed</b>
Permits	field test, release for propagation, importation for direct use	experimental use (laboratory research) , contained trial, open field trial, multi-location field trials, direct use, commercial propagation	<b>field trial, commercial propagation, direct use</b>
Deregulation	Yes	Yes	<b>No</b>
Validity of permits	2 years (field trial), 5 years (propagation)	2 years (field trial), 5 years (propagation)	<b>In perpetuity</b>
Consultation	Barangay and City/Municipal LGUs	LGUs, local communities, IPs, Agri and Fisheries Council, and PAMB Requires LGU resolution	<b>LGUs, general public</b> <b>Requires LGU resolution</b>
Public hearing	Optional, field testing	Confined and field trial phases	<b>Field trial phase</b>
Consultation timeline	30 days	30 days	<b>20 days</b>
Timeline	60 days	85 days	<b>35-40 days (ARTA)</b>

# Salient points in JDC 2021-01

## Assessment

- Joint Assessment Group comprised of DA, DOST, DOH, DENR Biosafety Committees
- 10 days for individual review in each agency
- Exemption of stacked events if parental traits are approved
- Socioeconomic considerations removed at this phase

## Permits

- Field trial, direct use (FFP), commercial propagation
- Permit validity is in perpetuity, with grounds for revocation (has to be detailed in IRR)

## Consultation

- Only done for field trial phase
- Public hearing to be done in 20 days with general public in accordance with ARTA/EODB. Will require LGU resolution before recommendation.

# Recommendation: Balance Product Safety and Agricultural Sector Needs

## Medium to long term strategies

- Policy revision and institutional augmentation
  - Augment biosafety framework (EO 514)
  - Pass Modern Biotechnology legislation, establish possible central authority
  - Augment the organic structure and resource allocation of DA Biotechnology Centers to support agriculture and industrial development.
- Harmonize policy with other countries, regional bodies (e.g. ASEAN, APEC); Open Discussions on the Nagoya-Kuala Lumpur Protocol on Liability and Redress integral once GMOs are out in the market
  - International rules and procedures relating to living modified organisms, as applied to damage resulting from living modified organism and transboundary movement
- Capitalize on emerging opportunities and expand regulations to cover other organisms
  - New plant breeding techniques emerge to complement modern biotechnology
  - GM Animals
  - Forestry products
  - Microbial Biotechnology
  - Low level presence of GM and GM products
  - Labelling

# THANK YOU

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