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"Nuts & Bolts of US Regulatory Dossiers for Genetically Engineered Products"

Case Study

FEED THE FUTURE INSECT-RESISTANT EGGPLANT PARTNERSHIP

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FEED THE FUTURE INSECT-RESISTANT EGGPLANT PARTNERSHIP

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USAID FROM THE AMERICAN PEOPLE

Sathguru Catalysing Success Since 1985

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Bangladesh – Development of FSB resistant eggplant varieties

Problem

- **Brinjal/Eggplant** is severely damaged by **Fruit and Shoot Borer (BFSB)** causing 30 – 60% yield loss.
- Farmers spray chemical insecticides up to 100 times in the season

Technology

- ***cry1Ac* gene** from bacteria *Bt* has the potential to render eggplant resistant to BFSB
- **Mahyco** developed Bt eggplant, a genetically-modified eggplant by inserting a c*ry1Ac* gene (EE-1)

Development & Release

- **For Bangladesh, Bt Eggplant** was developed by backcrossing EE-1 into 9 popular eggplant varieties at BARI under the USAID-funded ABSP II project
- 4 varieties of BARI Bt eggplant were approved for limited scale release in October 2013

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Chronology of events to seek approval for deregulation and commercialization

USAID funded ABSP II facilitated the transfer of the Bt eggplant event ("EE-1") to BARI. This event was introgressed into nine locally developed, highly adapted, and commercially popular open-pollinated eggplant varieties.

April 2004
Letter of Intent to Mahyco for BARI

June 2004
ABSP II Letter of Intent to BARI for Bt Eggplant, July 2004: Acceptance by BARI and permission to send BARI varieties at Mahyco

June 2004
MoU – BARC, Cornell

February 2005
BARI – Mahyco Material transfer agreement

March 2005
Sub Licensing agreement Mahyco – Sathguru – BARI

29th May 2006
Mahyco transfer clearance letter to BARI (Providing EE-1 crossed BARI germplasm back to BARI as per DBT's Transfer Clearance Letter)

Contd…
Chronology of events to seek approval for deregulation and commercialization

2005
Backcrossing program initiated (BC1) at Mahyco

2006 – 2009
BC2 – BC4 at BARI and material evaluated under contained conditions

2009 – 2011
9 varieties underwent MLFTs in 7 locations

2011 – 2012
MLFT repeated in the same 7 locations with 9 varieties as requested by MoA

2013
Dossier submission and commercial release of 4 varieties

2014
Agriculture Minister Matia Chowdhury distributed saplings of approved Bt eggplant varieties among 20 farmers from 4 regions of Bangladesh

84 Multi location field trials conducted by Mahyco/BARI in 5 years (2008 – 2013)

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Regulatory approval in Bangladesh requires navigating through multiple inter-ministry committees and regulatory bodies

Ministry of Environment and Forest (MOEF)

- National authority and focal point to implement the Cartagena Protocol of Biosafety

National Committee on Biosafety (NCB)

- Ensures environmentally safe management of modern biotechnological development including R & D, introduction, use and trans-boundary movement of GMOs/LMOs

Biosafety Core Committee (BCC)

- Provide technical comments/recommendations to the NCB/govt. on policy, legal, and technical issues of biosafety
- Examine applications for any permit/license for the import of GMOs/LMOs/GE organisms for contained use, field trial, and field release and forward recommendations to the NCB for consideration.
- Arrange annual inspections and performance evaluations of all laboratories engaged in research, development, and demonstration (R&D) of GMOs/LMOs/GE

Institutional Biosafety Committee (IBC)

- Review activities conducted by the institutions and recommend research proposals for consideration by the NCB
- Undertake risk assessments in cooperation with research teams, if necessary, to determine appropriate containment and biosafety conditions.

Field Level Biosafety Committee (FBC)

- Monitor field trial of GMOs/LMOs/GE plants

National Technical Committee on Crop Biotechnology (NTCCB), MoA

- Formulate, review, update, or amend national policies, acts, rules, and guidelines on biosafety.
- Examine all applications submitted by any university/department/division of a research institute/private company within a specified timeframe and approve/reject the application on a case-by-case basis.

National Technical Committee on Crop Biotechnology (NTCCB), Core Committee, BARC

- Review technical aspects of the applications submitted to the NTCCB and make recommendations on specific biosafety approvals.

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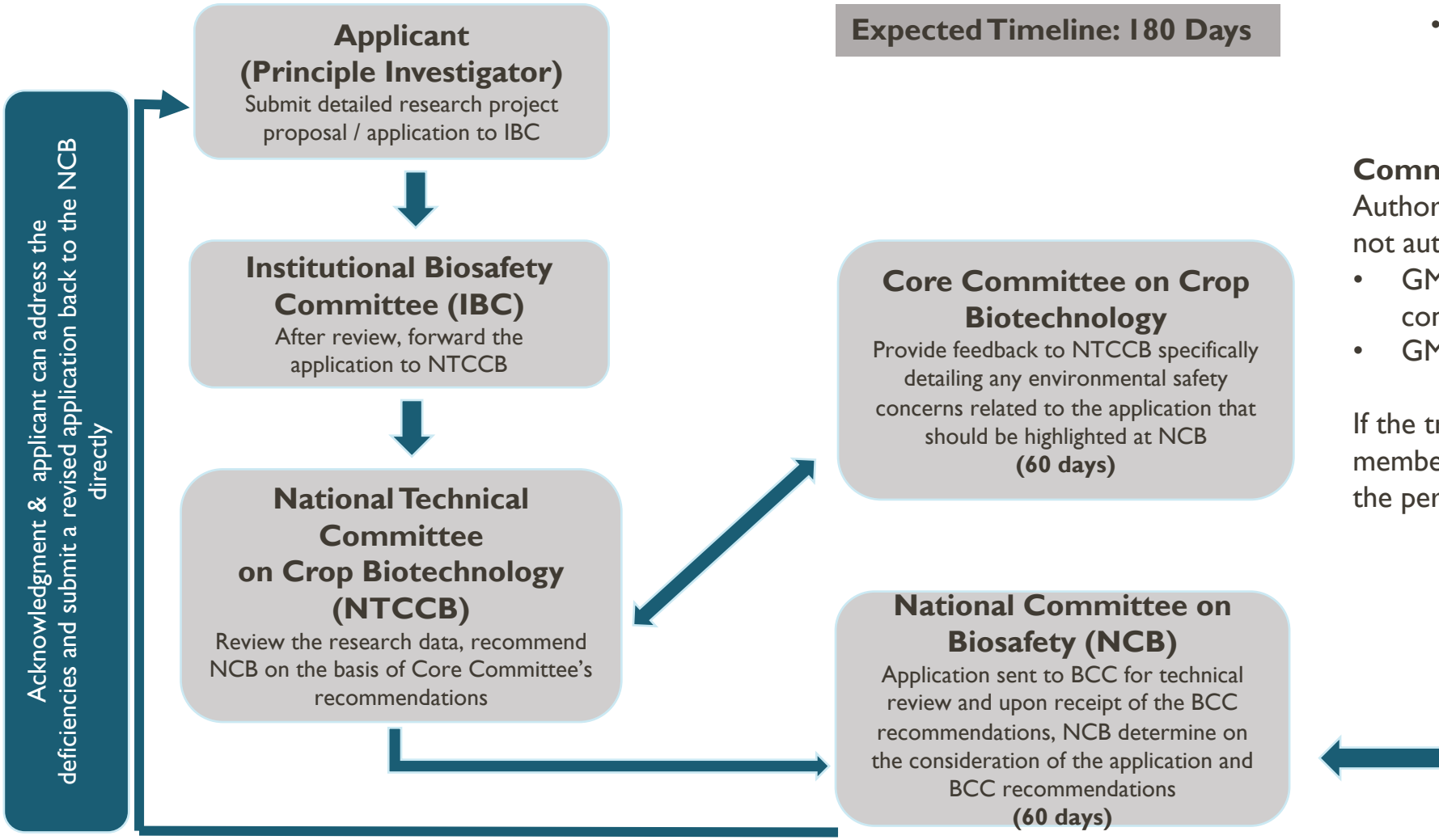
Approval process of GE plant cultivation for confined field trials & field release/cultivation



Expected Timeline: 180 Days

Confined Field Trial Applications:

- Approval with a 3-member Field Level Biosafety Committee to monitor the performance of the field trial, or not approved

Commercial Release Applications:

Authorized for release, with/without conditions, or not authorized

- GM plant is authorized for release with/without conditions.
- GM plant is not authorized for release

If the trial is approved, NCB identifies a three member Field Level Biosafety Committee to monitor the performance of the field trial.

Biosafety studies carried out for deregulation

Toxicity Tests

- Acute Oral Toxicity Tests (14 days) -
- Sub chronic Oral Toxicity (90 days) administered with transgenic seeds, produce, leaves

Skin Tests

- Primary skin Irritation Test
- Skin Sensitization Test
- Mucous membrane irritation test administered with transgenic seeds, produce

Pure Protein Studies

- Allergenicity Tests (60 days on pure protein)
- Protein Thermal Stability – (purified protein)
- Pepsin Digestibility Assay (transgenic produce)
- Subchronic (90 days) feeding studies (goats, white rabbits)

Feed Safety Studies

- Livestock Feeding Study (Ex: Chicken, Fish, Cow)
- Compositional Analysis of Key Components (Study Intended Nutritional Modifications & Unintended effects)
- Substantial Equivalence study
- Alkaloid composition report
- Detection in cooked food
- Nutritional analysis

Molecular studies

- Characterization and description of the inserted genetic material
- Characterization of the gene product
- Level and site of expression of the protein
- Studies on homology of the target protein to known protein toxins and allergens

Other Studies

- Pollen flow studies
- Soil microflora
- Gene equivalence
- Efficacy test at lab, greenhouse, Field level
- Protein expression profiles
- Baseline susceptibility
- Stability and inheritance of target gene
- Comparative studies on chemical composition (GM vs non-GM crop)

Agronomic and environmental safety studies carried out for deregulation

Agronomic Assessments

- Morphological characteristics
- Life cycle(s) of the plant (i.e. annual, biennial or perennial)
- Plant growth habit
- Reproductive biology and relevant modes of propagation
- Any changes to disease or pest susceptibility of the plant
- Fruit and shoot infestation
- Agronomic performance in terms of yield

Environmental Safety Assessment

- **BARI (From MLFT's)**
  - Effect of Bt Impact on Non-target organisms (Aphids, Jassids, Whitefly, Epilachna, Lady Bird Beetle)
  - Effect on soil microflora (Azotobacter, Rhizobium and populations of phosphate solubilising bacteria in the soil)
  - Germination, aggressiveness and weediness
  - **Baseline susceptibility of Bt eggplant:** Studies on the Relative Susceptibility of different strains of eggplant shoot and fruit borer against Bt Cry 1Ac and whole Plant assay
- **Third Party**
  - Analytical report on Nutritional Value (chemical composition) of 4 Bt eggplant varieties and their counterpart

Risk assessment

- Results of certain risk assessment tests (e.g., toxicological study) done at a qualified laboratory and accepted by the National Competent Authority of a developed country may be accepted without repeating the tests
- All agronomical trials (confined greenhouse/field trials) must be conducted/repeated in Bangladesh

Conditions associated with regulatory approval and commercial release of Bt eggplant varieties

- Bangladesh Agricultural Research Council and Ministry of Agriculture, BARI Bt eggplant-1,2,3 and 4 varieties could be released for limited cultivation in the field
- Concerned Ministry and Institute should prepare field production, planning for field biosafety management, emergency response, safety measures like isolation distance, management, border row management. Techniques for protection of local and indigenous variety and wild plants and inform the NCB and BCC.
- BARI will propose for field level Biosafety Committee formation to NCB for monitoring the biosafety measures to be taken in the area of limited Bt eggplant cultivation.
- Farmers needed to be trained on cultivation of Bt eggplant considering environment and biosafety measures.
- If there is any threat to environment and human health, proponent institute and concerned Ministry should take immediate action and to implement emergency plan so that the spread of threat and bad effects could be reduced.
- Proponent institute needs to take proper action so that marketing of Bt eggplant is done by labelling under the preview of biosafety rules.
- According to Cartagena Protocol on Biosafety to CBD, the details of biosafety measures taken in the area of release of Bt eggplant to be sent to NCB and BCC on monthly basis for publication in the biosafety clearing house.

Government Release Order Ref. No 22.00.0000.073.05.003.2012-271 | Dated: 30 October 2013

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Economic and health benefits derived by Bt eggplant growing farmers

Negligible fruit infestations in Bt eggplant compared to

45%

in the non-Bt eggplant[1]

61%

saving on pesticide cost to farmers as compared to non-Bt eggplant farmers[2].

6X

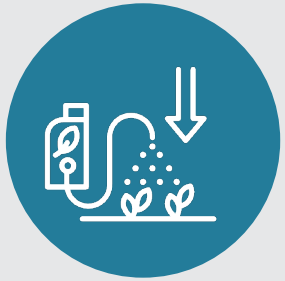
increase in farmers net returns to $2,151/ha for Bt eggplant/ha as compared to $357/ha for non-Bt eggplant[2]

21%

increase in gross revenue[3]

19.6%

higher fruit yield in Bt eggplant against non-Bt eggplant[3]



41%

reduction toxicity of pesticides applied, measured by Pesticide Use Toxicity Score (PUTS)[4]

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Bt Eggplant is the first publicly developed GM food crop in Bangladesh

- With the support from USAID and partnership with BARI, 4 BARI varieties were released with Bt technology in Bangladesh in 2013-14
- Adoption of Bt eggplant has gradually increased since its approval with over 65,00 farmers growing Bt eggplant varieties in the 2020-21 season and further growing
- The technology has contributed towards enhancing food and nutritional security in Bangladesh while protecting the health of farmers and the environment.


BARI Bt Begun 1(Uttara)


BARI Bt Begun-2 (Kazla)


BARI Bt Begun 3(Nayantara)


BARI Bt Begun-4 (ISD006)

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Complementary roles carried out by BARI, DAE and BADC to sustain the Bt eggplant supply chain

	Nucleus Seed Production	Breeder Seed (BS) Production	Foundation Seed (FS) Production	Quality Assessment	Seed Processing, packaging	Distribution	Post sales services
Actors	**BARI**	**BARI**	**BADC (BS from BARI)**	**BARI (Biotech and seed technology division)**	**BARI BADC**	**BARI BADC DAE**	**BARI DAE**
Functions	• Maintenance Breeding	• For all 4 commercial Bt varieties • Refuge seed production	• BARI Bt eggplant 2 and 4 • Refuge seed production	• BS testing genetic purity, germination and moisture • BADC FS testing for genetic purity at BARI	• Refuge packet inclusion in Bt eggplant seed packets • + 2 pager leaflet	• **BARI** to OFRD trials, DAE, farmers) • **BADC** to farmers via own dealers • **DAE** to farmer	• Trial (OFRD) management • Extension professionals trained by BARI • Farmer training by BARI and DAE • In- season field monitoring

Structured stewardship elements being introduced across supply chain
Data recording and maintenance at each stage to ensure end-to-end seed traceability

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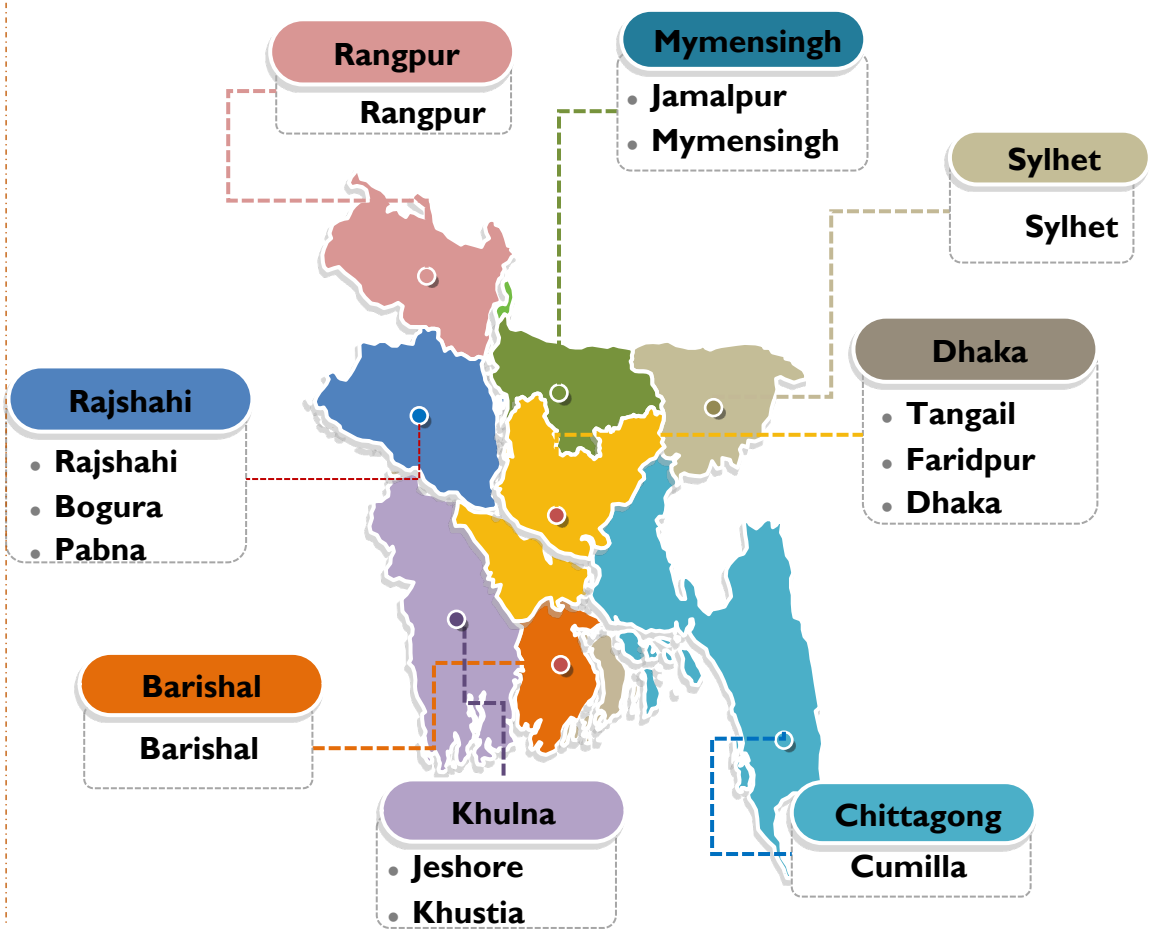
Bt brinjal seed sale/distribution channels

Seed Distribution Channels

BARI	DAE	BADC	Commercial Nursery
On Farm Research Division	Farmer groups	Dealers	• Commercial vegetable nurseries from 8 districts and Women-led nurseries

Target distribution in popular districts for *Bt* varieties

Preferred districts for growing Bt varieties



Pipeline: new products under development for Bangladesh

BARI is developing additional Bt eggplant varieties that are wilt tolerant and agronomically superior

- Backcrossing of BARI Begun 10 and BARI Begun 11 is in progress. Material expected to be ready by 2024

- ✓ Agronomically superior and wilt-resistant
- ✓ Can be grown year-round across Bangladesh (both Kharif and Rabi)
- ✓ Average yield potential of 45-50 tons/ha in winter and 30-35 tons/ha in summer
- ✓ BARI to seek for commercial release after meeting all the regulatory approvals

BARI Begun 10

BARI Begun 11

Improved versions of these newer varieties carrying the EE-1 event have the potential to increase the adoption and cover more eggplant-growing areas in Bangladesh, thereby increasing the impact of the technology

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BT EGGPLANT DEREGULATION AND REGULATORY STRATEGY

Philippines

Bt eggplant: First GM vegetable in the Philippines

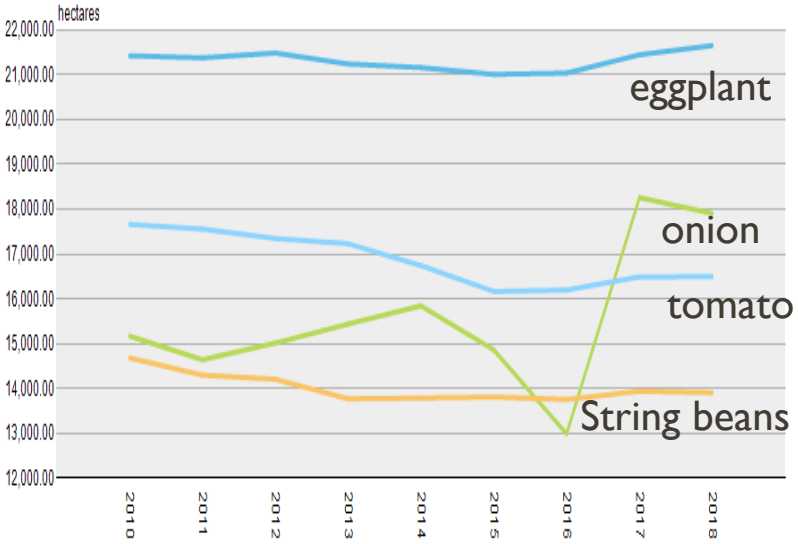
Eggplant (*Solanum melongena L.*)

- Also known as talong (Philippines)
- Wide range of variation in colors, shapes and sizes

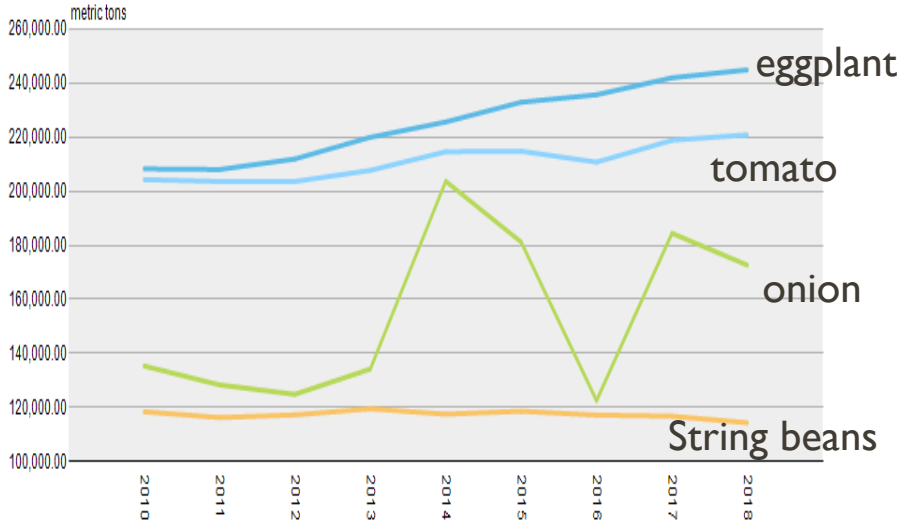
Production and consumption statistics in the Philippines

- #1 vegetable crop in area and volume
- #3 most consumed vegetable

Area planted (hectares)



Production volume (metric tons)



Bt eggplant: First GM vegetable in the Philippines

Eggplant fruit & shoot borer(EFSB), *Leucinodes orbonalis Guenee*

- Most destructive insect pest of eggplant and #1 constraint to eggplant production
- 42% yield loss from EFSB-damage shoot
- 93% yield loss from EFSB-damage fruit

60-80 spraying per cropping season to control EFSB

EFSB moth

female moth lay egg on leaves

larvae
(destructive stage)

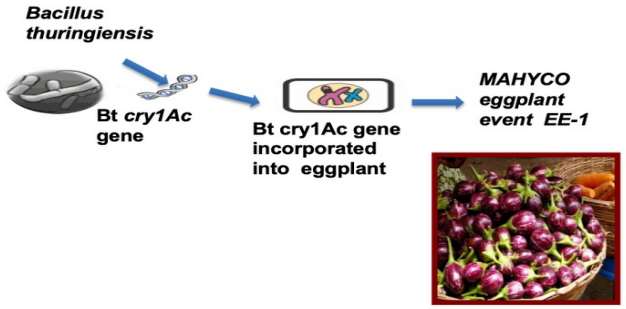
larvae feed on soft tissues

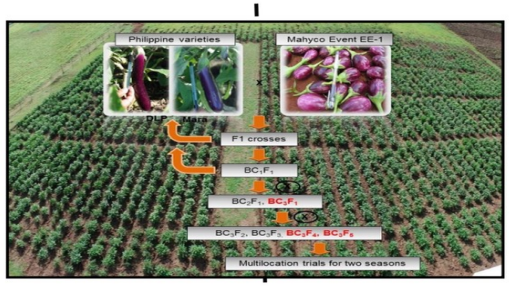
fruit damage

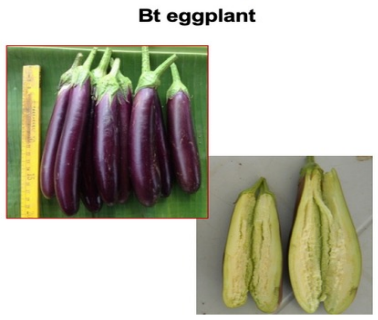
Bt Eggplant Product Development Pathway

Bt eggplant (Event EE-1) expresses **Cry1Ac** derived from *B. thuringiensis* providing protection against EFSB damage

Discovery/Event selection → Breeding / Field Trials → Variety Release







2000-2003 (India)

2004-2008 (India/Philippines)

2010-2012 (Philippines)

2021-present (Philippines)

Bt eggplant germplasm for comercialization
4 F1 hybrids,
3 OPVs

Up to 100 % protection against EFSB

R&D and Regulatory Timeline of Bt eggplant

Regulatory Stage	Regulatory Body/Regulation	Product Development/Regulatory Activities	Year and Location
Contained Trial	DOST-BC	First crossing Importation, backcrossing & selection	2003 (India) 2006-2007 (IPB, Phil.)
↓			
Confined Field Trial	DOST-BC	19 experimental lines, single location trial	2008-2009 (IPB Experimental Station)
↓			
Multi-location Field Trial	DA-BPI/ DA-AO 8 s. 2002	Multi-location field trials (MLT) of 3 OPVs and 4 hybrids	2010-2012 (4 sites across the Phil.)
↓			
Commercial Approval	DA-BPI/JDC 1 s. 2016 DA-BPI/JDC 1 s. 2021 FPA PIP	Approved for Direct use as FFP Approved for Propagation PIP registration	2021 2022 2022
↓			
Market Release	Variety Registration PVP Office NSIC NSQCS	Seed increase PVP Registration Pilot Planting	2022-2023 2023-2024 2023-2024

Eggplant regulatory landscape-Philippines

- The regulatory landscape in Philippines for Bt eggplant was unpredictable following the de facto moratorium which resulted from the Dec 8, 2015 Supreme Court decision to nullify DA AO 8 s 2002
  - Permanently stop Bt eggplant field trials
  - It ended until the issuance of the new multi-agencies Joint Department Circular 1 s 2016 (JDC 1 2016) on April 16, 2016 and the reversal of the 2015 SC decision on July 16, 2016
- A new complex and cumbersome system was being put in place
  - More agencies involved
  - More requirements than before (e.g. socio-economic assessment)
- Given previous court case, there was a need to build confidence in the data package to support the application for commercialization

Regulatory strategy

- **Objective:** to develop a dossier that was compliant with international practices (i.e. Codex) and at the same time complied with what the regulation requested in Philippines
  - While the new system in the Philippines was being established, the team decided to focus first on the preparation of a food and feed application (greater predictability).
  - An application for the approval of Event EE-1 eggplant for import and food and feed use was submitted on August 24, 2020.
    - Ensuring that international standards were met
    - Following any developments regarding data requirements specific to Philippines
    - Keeping an eye on the progress of applications made by other developers

Philippines regulatory strategy: USEPA consultation

- Given the high level of identity match (> 99%) of the Cry1Ac sequence in Event EE-1 eggplant with previous entries of Cry1Ac proteins in the NCBI database and its high similarity to other Cry1A-type proteins, the tolerance exemption previously granted for Cry1Ac was also applicable to Event EE-1 eggplant

Philippines regulatory strategy

- Approval for food and feed use was received on July 21, 2021
- Meanwhile, data requirements for cultivation applications became more clear
- The Philippines streamlined their regulatory process for GM crop cultivation on March 22, 2022, creating the right landscape for the submission of a cultivation application for Bt eggplant on March 30, 2022

Philippines regulatory strategy – Cultivation dossier preparation

- The cultivation package was developed using the same regulatory strategy as for the food and feed package: in line with international standards and tailored to the country requirements.
- Dossier Development:
  - Using existing relevant information previously generated (problem formulation and data transportability)
  - Conducting event independent studies
  - Updating bioinformatic searches
  - Performing an environmental risk assessment tailored to the Philippines
  - An IRM plan tailored to the Philippines
  - Socio-economic considerations
- Cultivation approval was received in October 18, 2022

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The Saga continues…

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April 19, 2023

The Supreme Court, during its *En Banc* deliberations on Tuesday, April 18, 2023, issued a writ of *kalikasan* in the case of G.R. No. 263565 *(Magsasaka at Siyentipiko Para sa Pag-Unlad ng Agrikultura, et al. v. Secretary of the Department of Agriculture, et. al.)* which sought to stop the commercial release of genetically modified rice and eggplant products.

The Court required the respondents Secretary of the Department of Agriculture, the Secretary of the Department of Environment and Natural Resources, the Secretary of the Department of Health, the Director of the Bureau of Plant Industry of the Department of Agriculture, the Philippine Rice Research Institute, and University of the Philippines – Los Baños (UPLB) to file a verified return within 10 days from service.

On October 12, 2022, petitioners, led by Magasasaka at Siyentipiko Para sa Pag-Unlad ng Agrikultura (MASIPAG), filed a *Petition for Writ of Kalikasan and Continuing Mandamus (With Prayer for Issuance of Temporary Environmental Protection Order)* before the Supreme Court seeking the issuance of a Temporary Environmental Protection Order (TEPO) directing respondents Department of Agriculture (DA) to (a) refrain from commercially propagating Golden Rice and issuing biosafety permits for commercial propagation of Bt Eggplant; (b) cease and desist from commercially propagating Golden Rice and Bt Eggplant until such time that proof of safety and compliance with legal requirements is shown; (c) declare all biosafety permits for Golden Rice and Bt Eggplant null and void; and (d) perform independent risks and impact assessments, obtain the prior and informed consent of farmers and indigenous peoples, and implement liability mechanisms in case of damage, as required by law.

Bt eggplant demonstrates that it is possible to publicly develop a GM crop and that its adoption can provide significant economic benefits to farmers while reducing the use of pesticides and impact on the environment

THANK YOU!