Managing Environmental and Health Risks: the Philippine Biosafety System (focus on the safety and nutritional benefits (Golden Rice and Bt talong)

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NCBP & DOST- Biosafety Committee

Outline

01 Philippines Biosafety Regulatory Framework

02 Activities that need regulatory approvals

03 Current Guidance on Risk Assessment

04 Case Studies: Golden Rice
Bt talong

BT Talo

PI) has
for
Golden
e Rice
July 2021.

BT Talong is nov
approved for Direct
Use as Food, Feed, or
for Processing (FF

The Department of Agriculture - Bureau
Industry (DA-BPI) has granted th
permit for direct use as food
processing (FFP) of BT Talong to th
the Philippines Los Baños

Golden Rice


SURPRISE!


SWEET'N LOW
SKIPPY
Welch's
Grape Jelly
IGH FRUCTOSE
CORN SYRUP
HEINZ
TOMATO KETCHUP
CHEEZ-IT


DIAPERS
MOTRIN
MEAT


ARE GMO FOODS SAFE?
NON GMO
VIRUS FREE PAPAYA 4395
BORER FREE
GMO
MADE WITH GMO SOYBEAN OIL
NOW WITH BETA CAROTENE
SUNFLOWER OIL
VIRUS-FREE PAPAYA
VITAMIN A ADDED
NOW WITH VITAMIN A
HERBICIDE TOLERANT

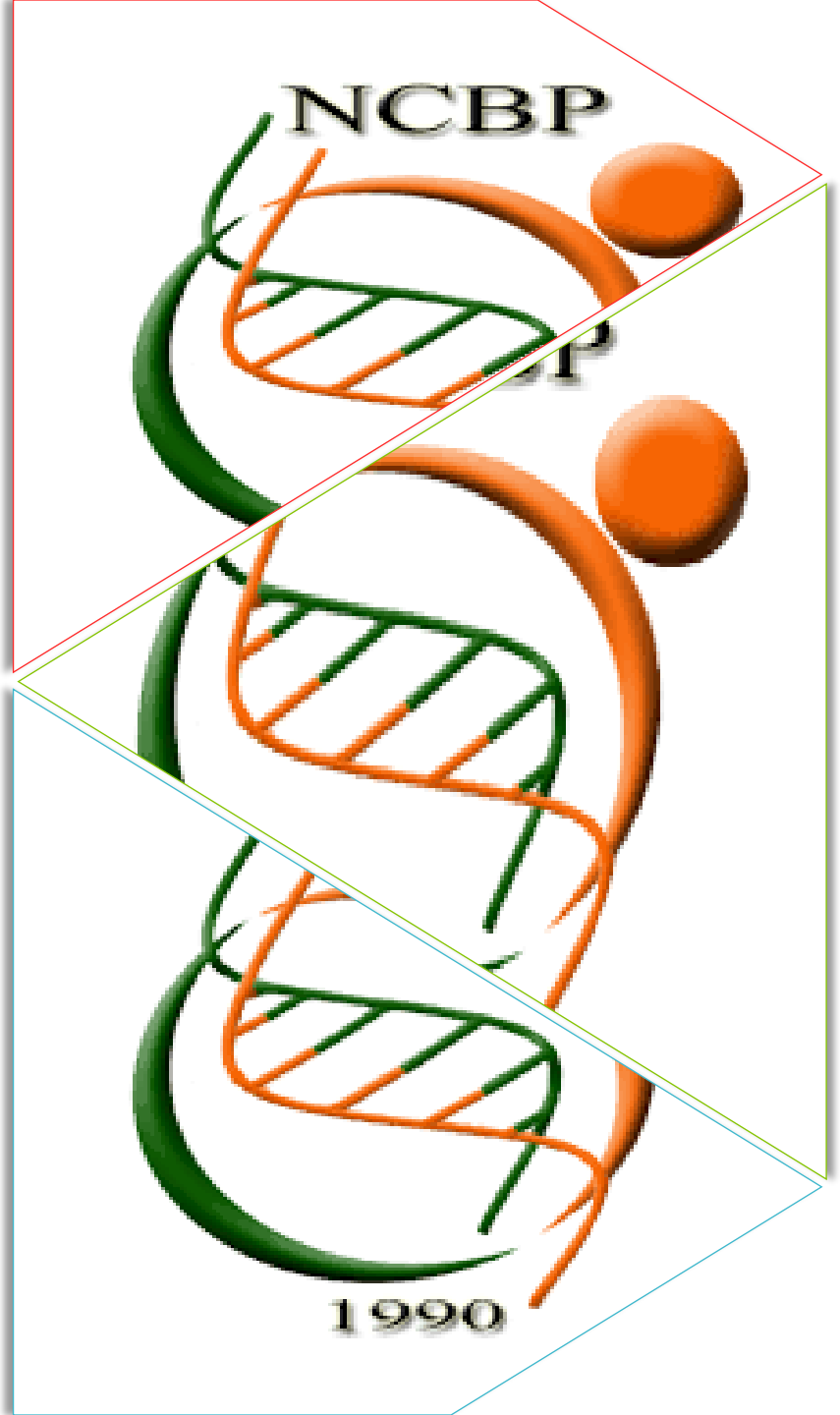
How do we ensure that GMOs are safe for use and consumption and safe in the environment?

- GMO crops are studied extensively to make sure they are safe for people, animals and the environment
- The Philippine regulatory agencies have rigorously evaluated the food and feed and environmental safety of GMO
- The safety of GMOs has been affirmed by agricultural and food safety regulatory agencies around the world
- Various scientific bodies around the world and a panel of scientists, researchers, agricultural and industry experts reviewed over 20 years of data since GMOs were introduced including around 900 studies and tests and concluded that GMOs are safe to eat

For 31 years, the Philippine Biosafety Regulatory System has been in place to ensure that products of modern biotechnology are used safely and responsibly…

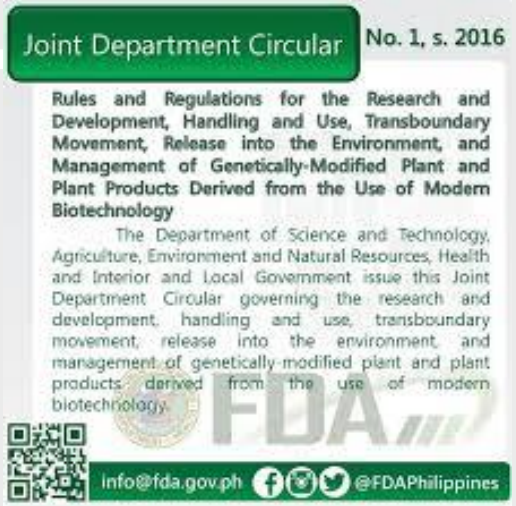
EXECUTIVE ORDER NO. 514

Establishing the **National Biosafety Framework,** Prescribing Guidelines for its Implementation, **Strengthening the National Committee on Biosafety of the Philippines,** and for Other Purposes



NATIONAL COMMITTEE ON BIOSAFETY OF THE PHILIPPINES

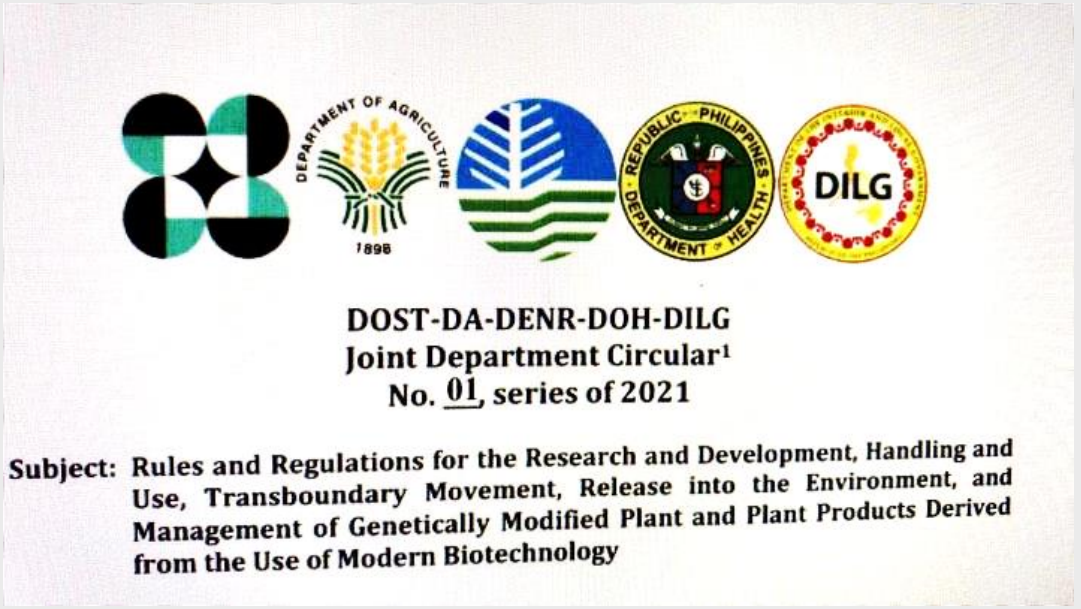
"The NCBP shall be the lead body to coordinate and harmonize inter-agency and multi-sector efforts to develop biosafety policies in the country (where such are not already stipulated by law) and set scientific, technical, and procedural standards on actions by agencies and other sectors to promote biosafety in the Philippines; oversee the implementation of the NBF; act as a clearing house for biosafety matters; and coordinate and harmonize the efforts of all concerned agencies and departments in this regard. (Section 4.1)"



Joint Department Circular No. 1, s. 2016

Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Plant and Plant Products Derived from the Use of Modern Biotechnology

The Department of Science and Technology, Agriculture, Environment and Natural Resources, Health and Interior and Local Government issue this Joint Department Circular governing the research and development, handling and use, transboundary movement, release into the environment, and management of genetically-modified plant and plant products derived from the use of modern biotechnology.



DOST-DA-DENR-DOH-DILG
Joint Department Circular[1]
No. 01, series of 2021

Subject: **Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically Modified Plant and Plant Products Derived from the Use of Modern Biotechnology**

Role of National Government Agencies in the Safety Assessment of GM Crops

Department of Agriculture

Lead in addressing biosafety issues related to the country's agricultural productivity and food security.

Lead in the evaluation and monitoring of regulated articles.

Department of Environment and Natural Resources

Ensure that the applicable environmental assessments are undertaken and potential impacts identified.

Lead in evaluating and monitoring bioremediation, improvement of genetic resources, and wildlife genetic resources.

Department of the Interior and Local Government

Oversee implementation of the activities undertaken in specific
LGUs in relation to the conduct of public consultations as required by the Local Government Code.

Department of Science and Technology

Lead in ensuring that the best science is utilized and applied in adopting biosafety policies and in making biosafety decisions

Lead in evaluating and monitoring contained use of regulated articles

Department of Health

Formulate guidelines and review results of assessing the health impacts posed by modern biotechnology.

Lead in evaluating and monitoring processed food derived from or containing GMOs.

Step by step introduction of GM plant into the environment

Contained/Confined Test

Laboratory, screenhouse/greenhouse

Field Trial

Multi-location field trial

Commercial propagation

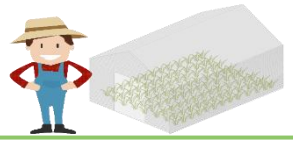
Large-scale planting

Direct use for FFP

For consumption and other purposes

Activities that need regulatory approvals

Department of Agriculture – Bureau of Plant Industry



Contained Use

Confined Test

Field Trial

Commercialization

Direct Use for food, feed and processing

DOST –Biosafety Committee

Contained Use/ Confined Test

Section 8. Policy on Contained Use and Confined Test of Regulated Articles. The contained use, including experiments inside laboratory, screenhouse, greenhouse, and glasshouse, and confined test of regulated articles, including risk assessment shall be governed by the DOST-BC in accordance with the Biosafety Guidelines for Contained Use of Genetically Modified Organisms.

Laboratory and Greenhouse Tests

Why perform laboratory and greenhouse trials?

What are the issues/concerns?

Field Trial

SECTION 10. Policy on Field Trial of Regulated Articles.

No regulated article shall be released into the environment for field trial unless a Biosafety Permit for Field Trial has been secured in accordance with this Circular.

Only regulated articles that satisfactorily passed the process on contained use or confined test supervised and officially endorsed by DOST-BC may be subject of application for a Biosafety Permit for Field Trial.

Field Trials

- What are the objectives of conducting field trials?
- What are the safety concerns?
- Basis of approval?

Field Trials

- **Risk assessment are focus on:**
- Measures to prevent unintended dispersal of seeds/plants
- Measures to prevent unintended pollen flow
- Measures to prevent the crop from persisting or re-seeding after the trial is completed
- Effect to environment/NTOs

Field Trials

3 Pillars of Confinement:

1. prevent the new genes (contained in pollen, seeds or any other part of the plant) from escaping the trial site

2. prevent the GM plant material from being consumed by humans or livestock

3. prevent the GM plant materials from escaping, establishing and persisting in the environment

Commercial Propagation

SECTION 15. Policy on Commercial Propagation of Regulated Articles. No regulated article shall be released for commercial propagation unless:

- a Biosafety Permit for Commercial Propagation has been secured;
- based on field trial, the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart;
- food and feed safety studies show that the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart; and
- if the regulated article is a pest-protected plant, its transformation event that serves as plant-incorporated protectant (PIP) has been duly registered with the Fertilizer and Pesticide Authority (FPA).

Environmental issues:

- Gene Flow
- Changes in Levels of Weediness or Invasiveness
- Horizontal Transfer of Engineered Traits to Other Species
- Biodiversity
- Impact on Non-Target Organisms

Direct Use for Food, Feed or for Processing

SECTION 20. Policy for the Direct Use of Regulated Articles for Food and Feed, or for Processing.

No regulated article, whether imported or developed domestically, shall be permitted for direct use as food and feed, or for processing, unless:

- **a Biosafety Permit for Direct Use has been issued by the BPI;**
- **in the case of imported regulated article, the regulated article has been authorized for commercial distribution as food and feed in the country of origin; and**
- **regardless of the intended use, the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart.**

??? to answer in the assessment process…

- Do the donor and recipient organisms have a history of safe use?
- Are the new substances produced e.g. proteins safe to consume?
- Have potential allergens been introduced into or increased in the food?
- Are there changes in the content of other important substances e.g. toxicants, anti-nutrients?
- Has the composition and nutritional value changed?
- In what forms will the food or food products derived from it be consumed?
- Do the newly introduced substances survive processing, shipment, storage, and other preparation?
- What is the expected human dietary exposure?
- If an antibiotic resistance or other selectable marker is present, is it safe?

CURRENT GUIDANCE ON RISK ASSESSMENT

Safety Assessment

Basic Concepts

COMPARATIVE SAFETY ASSESSMENT

Regulatory Data & Information for Comparative Assessment

Gene/protein safety → **Environment Food/Feed Safety** ← **Crop Safety**

Gene(s) & Introduced Genetic Material
- Source(s)
- Molecular characterization of insert sequence/ copy #/ integrity / no backbone/generational stability

Agronomic Equivalence
- Growth, Morphology
- Yield , Fitness
- Susceptibility to pests,
- pathogens
- Cultivation practices

Protein(s)
- History of safe use and consumption
- Function / specificity / mode of action
- Amino acid sequence
- Levels
- Potential toxicity or allergenicity

Food / Feed Composition
- Proximate analysis
- Key nutrients
- Key anti-nutrients
- Key metabolites

ENVIRONMENTAL RISK ASSESSMENT

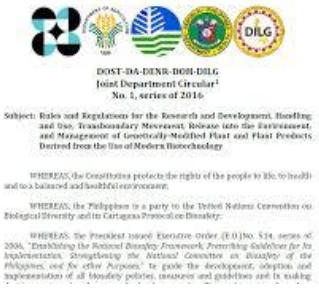
- *Establishing an Environmental Impact Statement System (P.D. 1586)*
  - *Project Description Report*
    - *Location and Description of Receiving Environment*
    - *Risk exposure*
    - *Environmental Management Plan (potential impact and mitigating measures)*
- *Environmental Risk Assessment*
  - *Persistence and invasiveness*
  - *Gene flow*
  - *Impact on biodiversity*
  - *Effects on non-targets*

The Cartagena Protocol on Biosafety

OECD

BETTER POLICIES FOR BETTER LIVES

Convention on Biological Diversity



DOST-DA-DENR-DOH-DILG
Joint Department Circular[1]
No. 1, series of 2016

Subject: Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Plant and Plant Products Derived from the Use of Modern Biotechnology

WHEREAS, the Constitution protects the rights of the people to life, to health and to a balanced and healthful environment;

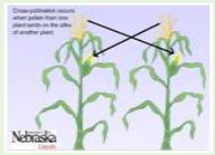
WHEREAS, the Philippines is a party to the United Nations Convention on Biological Diversity and its Cartagena Protocol on Biosafety;

WHEREAS, the President issued Executive Order (E.O.) No. 514, series of 2006, "*Establishing the National Biosafety Framework, Prescribing Guidelines for its Implementation, Strengthening the National Committee on Biosafety of the Philippines, and for other Purposes,*" to guide the development, adoption and implementation of all biosafety policies, measures and guidelines and in making

ENVIRONMENTAL RISK ASSESSMENT

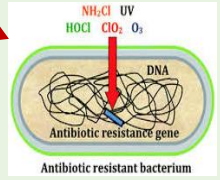
Gene flow

❖**Transfer of inserted genes**



Cross-pollination with other varieties

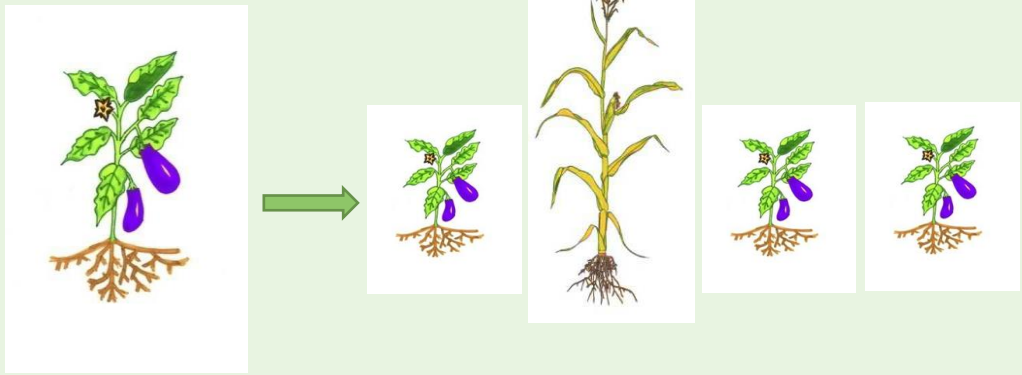
Cross-pollination with wild relatives



Horizontal gene transfer

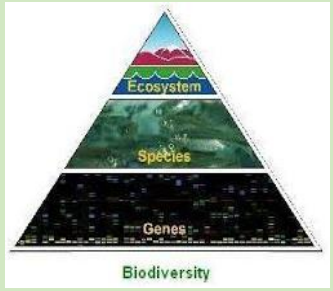
Weediness (invasive)

- What are the key concerns?
  - Increased weediness
  - The GM plant could be more invasive in natural habitats
  - Volunteers of the GM plant may be more difficult to control in the production field in subsequent years



ENVIRONMENTAL RISK ASSESSMENT

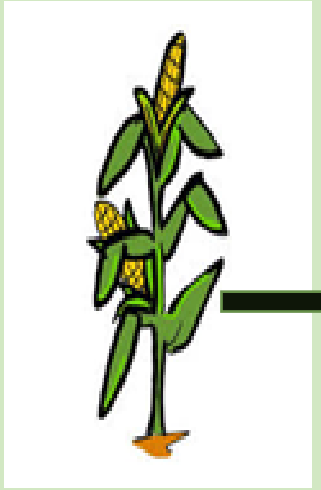
Biodiversity



- **Consider:**
  - The receiving environment
  - Native flora and fauna
  - Agricultural crops
  - Farm animals

Effects on NTOs

- **What are the key concerns?**



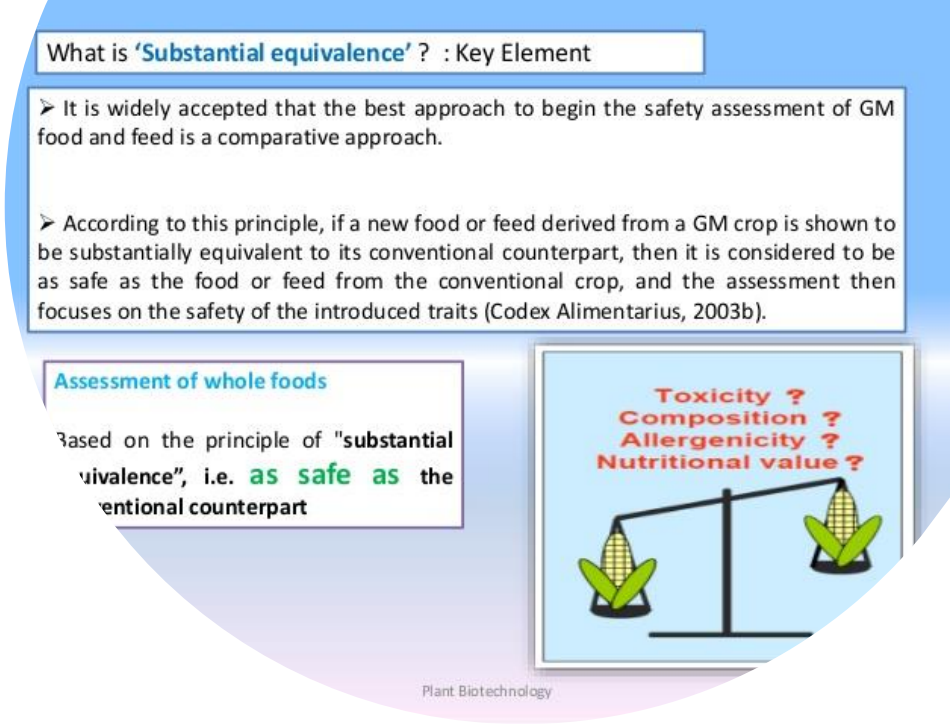
Toxic to non-target organisms (NTOs) that provide valuable ecosystem functions (pest control, pollination, decomposition, etc)

The GM plant could be toxic to valued NTOs outside the agricultural field

PIP tested against family/group representative or sentinel or indicator species

FOOD AND FEED SAFETY ASSESSMENT

- CODEX Alimentarius Guidelines
- Organization of Economic Cooperation and Development (OECD)
- FAO-WHO Food Safety Risk Analysis Guide
- DOH-Health Impact Assessment



Comparative Assessment = Substantial Equivalence

A) Description of the recombinant-DNA plant;

B) Description of the host plant and its use as food;

C) Description of the donor organism(s);

D) Description of the genetic modification(s);

E) Characterization of the genetic modification(s);

F) Safety assessment:

a) expressed substances (non- nucleic acid substances);

b) compositional analyses of key components;

c) evaluation of metabolites;

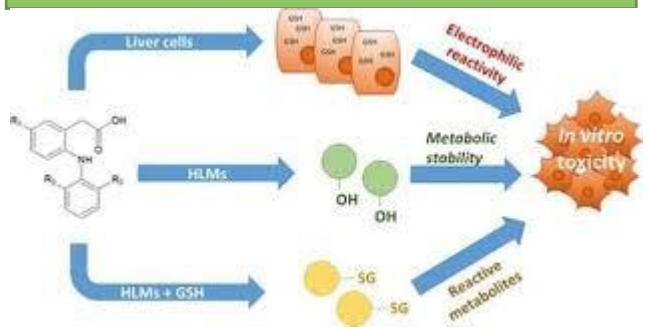
d) food processing;

e) nutritional modification; and

G) Other considerations.

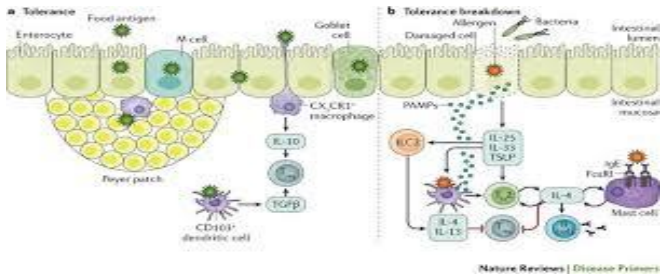
Toxicity

- History of safe use
- Amino acid sequence similarity between the new protein and known protein toxins and anti-nutrients
- Resistance to digestion of the new protein



Allergenicity

- Source of the newly expressed protein
- Amino acid sequence similarity
- Physico-chemical properties of the newly expressed protein
- Specific serum screening



Compositional Analysis/Nutritional Considerations

- Unintended changes in food composition:
  - Key nutrients
  - Natural toxicants
  - Anti-nutrients
- Dietary exposure assessment

SOCIO-ECONOMIC, ETHICAL & CULTURAL CONSIDERATIONS

- Productivity (yield)
- Cost efficiency
- Net farm income (profitability)
- Trade (import substitution)
- Global competitiveness

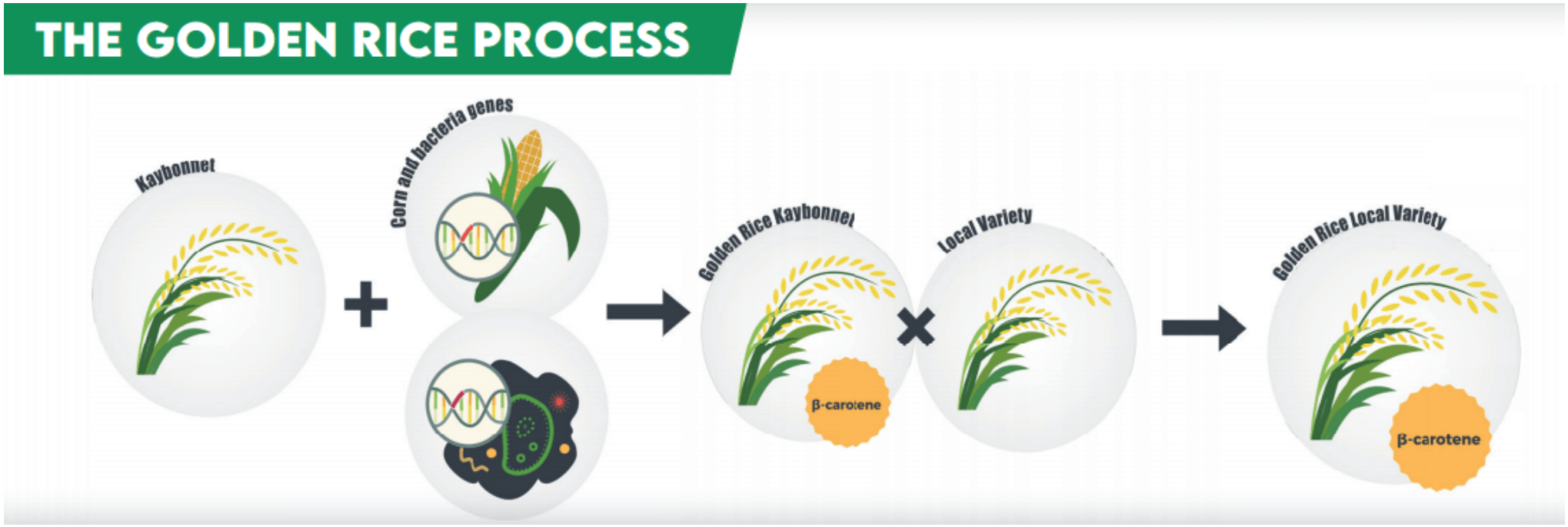
nple Countries Legislation Socio-nomic Considerations

Country	Party CBD	Party CPB	Conduct Confined Field Trials	Approvals for Comm.	Language of relevant text considering socio economic considerations	Relevant Regulatio
Argentina	Y	N	Y	Y	Decision on the convenience of the commercialization the genetically modified material over its impact on markets, in charge of the National Market Directorate, so as to avoid potential negative impacts on Argentinean exports.	*Resolution of SAGyP Resolutions and n°57/0 SAGPyA*
razil	Y	Y	Y	Y	Article 48, Paragraph 1. The National Biosafety Council – CNBS shall: II- analyze, upon request by CTNBio, in the context of convenience, socioeconomic opportunity and national interest, requests to grant license on the commercial use of GMO and GMO derivatives; Article 50. CNBS shall decide, upon request by CTNBio, on matters of socioeconomic convenience and opportunity and national interest on the granting of a license for GMO and GMO derivatives commercial license.	*Decree NO. OF Novemb 2005*
	Y	N	Y	Y	Socio-economic considerations will be conducted through partial studies that should include different social and economic impacts	*Honduras d*
		Y	Y	N	"in reaching a final decision, the Authority shall take into account ... (e) socio-economic consideration arising from the impact of the GMO on the environment."	*Kenya draft*
		Y	Y	N	"no approval shall be given unless the GMO will not have adverse socio-economic impacts."	*Uganda dra regulations*
		Y	N	N	The decision-making procedures shall take into consideration risk assessment, which involves scientific, socio-economic, cultural and ethical considerations.	*Nigeria Nat Biosafety Fi 2005.*
			Y	Y	"The Council may in performing its function in terms of sub regulation (8), consider the socio-economic impact that the introduction of a genetically modified organism may have on a community living in the vicinity of such introduction"	*GMO Act 1 No. 15 of 1*
				Y	"Socio-economic, cultural and ethical considerations. Impacts on small farmers, indigenous people, women, small and medium enterprises, and the domestic scientific community to be taken in to account."	*Executive O (EO514)*

Case study: Golden Rice Beta-carotene enriched

Table 6. Potential Contribution of Rice Containing Event GR2E to Meeting Vitamin A Needs in Bangladesh and the Philippines

	mean daily rice consumption (g, raw)[a]	EAR[b] (μg/day RAE[c])	RDI[d] (μg/day RAE)	β-carotene equiv[e] from GR2E Rice (μg/day)	% of EAR[f]	% of RDI
		Bangladesh				
preschool-aged children	157	210	300	561	89	62
school-aged children (6−14 years)	261	275	400	932	113	78
nonpregnant, nonlactating women (15−49 years)	360	500	700	1285	64	46
		Philippines				
preschool-aged children (6 months−	100	210	300	357	57	40


THE GOLDEN RICE PROCESS
Kaybonnet
Corn and bacteria genes
Golden Rice Kaybonnet
β-carotene
Local Variety
Golden Rice Local Variety
β-carotene

Contained experiment

- DOST-BC Ref No. 2005-0193: Development of elite indica golden rice cultivars with levels of provitamin A carotenoids

- Date Applied: 4 April 2005
- Date Approved: 24 May 2005

- Biosafety consideration: transgenic plants will have no adverse effect on the environment for the period of experiments

- Biosafety measures to be taken:
  - The tested plants will be kept in isolation in the CL4 transgenic greenhouse to prevent access of unauthorized personnel;
  - The plant materials for disposal will be placed in sealed plastic bags;
  - The plants grown in CL4 will be destroyed and the pots and soil will be autoclaved at high temperatures and high pressure;
  - The plant material from screenhouse (CS07) will be disposed through burning of straw;
  - CS07 would be kept under lock;
  - CS07 facility is adequate to prevent rats, birds, etc.;
  - Transgenic seeds harvested from CL4 and CS07 will be kept in hermetically sealed aluminum foil packages and stores in locked refrigerators designated for storage of transgenic seeds in TCGE Laboratory of IRRI. Movement of all materials will be dome in compliance with all relevant biosafety and phytosanitary requirements of the Philippines

Confined tests

"Production of plant materials for compositional analysis and for other biosafety tests of Golden rice event GR2E under confined test conditions in the Philippines"

PhilRice-Batac Brgy. Tabug, City of Batac (DOST-BC Ref. No. 2015-0290)

Date Applied: 1 April 2015
Date Approved: 15 May 2015

PhilRice-CES Brgy. Maligaya, Muñoz, Nueva Ecija (DOST-BC Ref. No. 2015-0291)

Date Applied: 7 April 2015
Date Approved: 8 May 2015

PhilRice-Isabela Brgy. Malasin, San Matreo, Isabela (DOST-BC Ref. No. 2015-0292)

Date Applied: 1 April 2015
Date Approved: 14 May 2015

Conditions for approval:

- ✓ At least 150 meters physical or temporal reproductive isolation of the GMO shall be observed at all times;
- ✓ All confinement measures should be in place before the actual transplanting of rice seedlings;
- ✓ The proponent shall ensure that only authorized personnel are allowed inside the test site;
- ✓ The proponent shall ensure that rodent control measures are in place and that stray animals are excluded from the test site while trials are being conducted;
- ✓ The proponent shall ensure the security of the trial, the field workers and the monitors;
- ✓ In case of undue destruction of the experimental materials, the proponent should implement measure to prevent inadvertent escape of f any viable materials;
- ✓ The rice grains or any plant part shall not be eaten or fed to humans, wildlife and livestock;
- ✓ A disposal pit shall be provided within the test site;
- ✓ The harvested grains shall be properly labeled and stored at the designated seed storage facility, while plant materials and other plant debris should be buried in a pit or plowed under;
- ✓ The proponent shall leave the test site fallow for at least 30 days. Emergence of volunteer plants shall be monitored and shall be uprooted and disposed

TABLE 4 | Agronomic performance of BRRI dhan29 GR2E NILs

Parameter	SHT 2009 (n = 11)				
	BC_3F_4 NILs (avg ± SD)	BRRI dhan29	Mean difference		
Days to maturity	126.4 ± 2.1	125.5	0.9		
Plant height	102.5 ± 6.8	104.1	−1.6		
Panicles/hill	10.4 ± 0.8	9.7	1.0*		
Panicle length	26.6 ± 1.0	27.5	−0.9	2	
Flag leaf length	40.9 ± 3.5	43.2	−2.3		
Flag leaf breadth	2.2 ± 0.1	2.2	−0.0		
Spikelets/panicle	269.6 ± 60.5	257.7	11.9	173.9 ±	
% spikelet sterility	39.1 ± 13.6	31.2	7.9	58.3 ± 8.	
1000-grain weight	19.1 ± 0.7	19.9	−0.8	–	
Grain yield/plant (g)	20.0 ± 5.4	23.6	−3.6	11.9 ± 4.3	
Grain yield (t/ha)	–	–		–	
Grain length (mm)	8.3 ± 0.1	8.5	−0.2	–	
Grain breadth (mm)	2.4 ± 0.1	2.5	−0.1	–	
LB ratio	3.4 ± 0.1	3.6	−0.2	–	
Milling yield (%)	77.5 ± 10.2	66.1	11.4	–	
Head rice yield (%)	54.9 ± 16.9	58.2	−3.3	–	–
Amylose (%)	21.3 ± 0.4	30.3	−9.0**	24.0 ± 2.4	27.9
Total carotenoids (μg/g)	6.42 ± 0.56	–	–	10.16 ± 0.23	–
Range of TC (μg/g)	5.8–7.6	–	–	5.25–19.38	–

SHT, Screen house trial; CFT, confined field trial.
*;**Significant at 5 and 1% level of probability, respectiv

TABLE 5 | Yield and grain quality attributes of selected BC_5F_4 NILs of GR2-E BRRI dhan29.

Designation	DM	PH	GL	GW	TGW	YLD
12062 GR 2-E:14-40-7-8	147	112	8.4	1.8	21.8	7.2
2062 GR 2-E:14-40-7-16	151	105	8.5	1.7	21.1	7.1
60 GR 2-E:2-9-89-16	144	108	8.4	1.8	20.4	7.5
0 GR 2-E:2-17-36-10	146	105	8.3	1.8	20.9	7.0
GR 2-E:14-40-7-21	145	112	8.4	1.8	20.2	7.8
R 2-E:2-7-63-1	147	108	8.6	1.8	20.9	7.3
2-E:14-40-7-23	143	103	8.5	1.8	20.8	7.4
-E:2-7-63-2	145	105	8.4	1.8	21.3	7.8
	148	108	8.8	1.8	21.4	7.0
	3.1	2.8	0.24	0.24	1.44	0.7

PH, Plant height (cm); GL, Grain length (mm); GB, Grain width (mm); TWG, Thousand grain weight (g); YLD,
content at 2 months after harvest; Tr, Translucent; Ck, Check; LSD, Least significant difference.

Multi-location field trial

Biosafety Permit for Field Trial Number 19-001: "Field Trial to Generate Data for Environmental Biosafety Risk Assessment of Beta-Carotene Enriched "Golden Rice" Event GR2E in the Philippines"

Date Applied: February 28, 2017
Date Approved: May 20, 2019

Field Trial Risk Assessment

- ***History of Safe Use:***
  - *Rice has a long history of safe use as food and has not been found to be allergenic nor a source of toxicants*
- ***Characteristics of the Host Plant:***
  - *Rice is grown throughout the Philippines and worldwide and how it is cultivated by populations dependent on rice has defined the habitat and ecology of the plant and other agronomic characteristics. Cultivated rice varieties do not have weediness characteristics*
- ***Characterization and safety assessment of the GM product:***
  - *The genetic change in the accumulation of provitamin A in the GR2E rice endosperm is not expected to affect or alter the reproductive biology of the crop*
- ***Proposed field Trial Site:***
  - *The sites were representatives of the receiving environment for GR2E for collecting relevant agronomic and phenotypic data. The sites are under the care and control of PhilRice which will facilitate compliant management of the proposed activities*
- ***Environmental Risk Assessment (DENR):***
  - *Field trial of GR2E is safe to the environment and biodiversity, no known allergens nor potential toxicity; low chance of interbreeding or genetic exchange (0.08-0.92%) with conventional counterpart or with other species*
- ***Environmental Health Risk (DOH)***
  - *Field trial is acceptable subject to monitoring based on compliance with (EHIA)*
- ***Socio-economic, ethical and cultural concerns (SEC Expert)***
  - *GR2E is being developed to address serious health problem posed by vitamin A deficiency in the Philippines. No changes required to farm management practices relative to the non-GM variety*

GR2E for Direct Use as Food, Feed or for Processing

Date Applied: February 28, 2017
Date Approved: December 10, 2019

...nit for Direct Use as Food and Feed,
or for Processing
Number 19-060FFP

...nd licensed by Philippine Rice Research Institute (PHILRICE) and ...esearch Institute (IRRI), with office addresses at PHILRICE Central ..., Maligaya, Science City of Munoz, Nueva Ecija and Pili Drive, University ... Los Banos, Los Banos, Laguna, respectively, has undergone satisfactory ...ment for the issuance of biosafety permit for direct use as food and feed, or ... pursuant to the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, ...o and found to be as safe as conventional rice.

...ttee shall take appropriate measures to prevent accidental and unintentiona... ...reproduction and its recurrence and thereby protect human and animal health ...e environment. A Plant Quarantine Officer and his/her duly authorize... ...sentatives shall be allowed access during regular business hours to the facility wher... ...regulated article is located and to any records relating to the importation of th... ...gulated article, if applicable.

Issued on **December 10, 2019** at the Bureau of Plant Industry, San Andres St., Malat... Manila subject to conditions stated at the back of this permit, and shall expire ... **December 9, 2024**.

Provitamin A Biofortified Rice Event GR2E

upporting Information for the Risk Analysis Report for a Genetically Mod
Plant for Direct use as Food, Feed, or Processing

SUBMITTED TO

Bureau of Plant Industry, Ministry of Agriculture
Department of Agriculture
692 San Andres St., Malate
Manila 1004 Philippines

SUBMITTING ORGANIZATIONS

Philippines Rice Research Institute (PhilRice)
PhilRice Central Experimental Station
Maligaya, Science City of Munoz, 3119 Nueva Ecija
Philippines
– and –
International Rice Research Institute (IRRI)
Pili Drive, UPLB, Los Baños, 4031, Laguna
Philippines

2. History of Use of the Host and Donor Organisms

2.1. Host Organism

Rice is the common name for the plant *Oryza sativa* L., which has a long history of use as food dating back at least 4000 years. Rice is used in various forms including whole and milled grain, flour and bran. The husks may be used for fertilizers and animal feed as well as for fibre production. Numerous varieties of rice have been developed from subspecies indica, japonica, and javanica. Over 90 percent of rice production and consumption is in Asia, with around five percent from the Americas, three percent from Africa and another one percent from Europe and Oceania. The crop is well adapted to diverse growing conditions from cool climates to deserts (with irrigation) and is able to perform well in areas with saline, alkaline, or acid-sulphate soils.

2.1.3. Key Nutrients and Anti-Nutrients

**Brown, milled, polished, and parboiled ric
humans in the form of grain after being c
also used in food manufacturing including in**

4. Molecular Genetic Characterization of GR2E Rice

Southern blot analyses (Southern, 1975) were performed to investigate the number of sites of insertion of the pSYN12424 T-DNA, the integrity of introduced genetic elements, the absence of plasmid backbone sequences, and the multi-generational stability of the inserted DNA (Cueto et al., 2016). A complete description of the methods used, including locations and identities of various hybridization probes, is presented in Appendix A, beginning on page 99.

MOLECULAR CHARACTERIZATION

4.1. Insert Copy Number within the GR2E Rice Genome

3. The Genetic Modification

3.1. Transformation Method

The *Agrobacterium*-mediated transformation of the japonica rice cultivar Kaybonnet using plasmid pSYN12424 was previously described by Paine et al. (2005). Briefly, embryogenic cultures were established from mature embryos on Murashige and Skoog basal salt mixture (MS)-callus induction medium (CIM) (4.3 g/l MS salts, 5 ml/l B5 vitamins, 30 g/l sucrose, 500 mg/l proline, 500 mg/l glutamine, 300 mg/l casein hydrolysate, 2 mg/l 2,4-D, 3 g/l Phytagel, pH 5.8). Embryogenic calli (3-4 mm) were inoculated with *Agrobacterium tumefaciens* harbouring plasmid pSYN12424 and incubated at 22°C for two days, followed by transfer onto MS-CIM media containing ticarcillin (400 mg/l), and then onto mannose selection media (MS-CIM containing 17.5 g/l mannose, 5 g/l sucrose, and 300 mg/l ticarcillin) for five weeks in the dark. Proliferating colonies were transferred to regeneration medium (MS-CIM with 0.5 mg/l indole acetic acid, 1 mg/l zeatin, 200 mg/l ticarcillin, 20 g/l mannose, 30 g/l sorbitol, no sucrose), grown in the dark for 14 days and then moved to light at 30°C for 14 days. Shoots were transferred to MS medium containing 20 g/l sorbitol for two weeks and then to soil.

3.2. Description of the Potentially Introduced Genetic Material

Agrobacterium-mediated transformation was performed using plasmid pSYN12424 (Figure 3), which contains three gene expression cassettes within the T-DNA (Figure 4). These gene expression cassettes are briefly described below, and summarized in Table 4.

The first cassette contains a copy of the *crtI* gene from *Pantoea ananatis* (Misawa et al., 1990) that is fused in-frame at the 5' terminus with the pea (*Pisum sativum*) RUBISCO SSU transit peptide encoding sequence (Coruzzi et al., 1984). Transcription of the *crtI* gene is controlled by the rice *GluA-2* promoter (Takaiwa et al., 1987) for targeted expression

6. Protein Safety

As a macronutrient, protein is an essential component of the human diet and, although individual proteins mediate a diverse range of biological functions, consumption of proteins as a class of dietary substances is not inherently associated with adverse effects (FAO/WHO, 1996). Only a small number of dietary proteins have the potential to exert anti-nutritional or toxic effects, or elicit allergic reaction in previously sensitized individua

Assessing the safety of newly-expressed proteins produced in the edib genetically engineered food crop is an integral component of the overall sa As there is currently no single criterion that is sufficiently predictive of pot allergenicity, a "weight-of-evidence" approach is recommended for hazar that considers the history of use, amino acid sequence similarity to k allergens, function or mode of action, digestibility under standardized *in* stability to heat or processing, and expression levels and potential dietary e 2003; Delaney et al., 2008). Conventional toxicology studies are not consi where the newly-expressed protein, or a closely related one, has been c in food at equivalent intakes or where the new substance is not prese (Codex, 2003; HC, 2006). Only when a potential for hazard has beer when the previous assessment does not permit a determination of safety, is characterization warranted (Delaney et al., 2008; Hammond et al., 201 characterization may include appropriate oral toxicity studies or other h toxicology studies when the protein's biochemical function suggests it may toxic to non-target organisms.

A tiered "weight-of-evidence" approach was followed in assessing the safety CRTI, and PMI proteins expressed in GR2E rice, and is described in the follo

2.1.5. Allergy

Rice is not considered by allergists to be a common allergenic food. Although nearly one-half of the world population consumes cooked rice on a daily basis, published evidence indicates that food allergy to rice is rare. However, rice allergy has been reported in countries of Asia including Japan, Malaysia, Thailand, and Indonesia and in some European countries including Finland, France, Spain, Sweden, Denmark, Estonia,

7. Compositional Analysis

For new varieties without purposefully altered nutritional properties, which includes the vast majority of currently authorized genetically modified crops, the compositional assessment is part of the weight-of-evidence approach for evaluating whether there were any unanticipated consequences of the genetic modification. The experience with genetically modified crop plants with introduced traits conferring insect-resistance and/or herbicide-tolerance has indicated that the incorporation of these traits has little biologically meaningful impact on the composition of key nutrients and anti-nutrients (Harrigan et al., 2010). As with products of conventional plant breeding, most compositional variation is due to environmental and agronomic factors, and the base genetics of the plant variety (Harrigan et al., 2007; Ricroch, 2013).

The compositional evaluation of crops intentionally modified to express altered nutritional properties is intended to determine whether the composition differs significantly from its traditional counterpart aside from the intended change in nutrient composition and to assess the safety of the intended change and any unintended changes. Nutritionally improved varieties may be expected to contribute significant new sources of dietary nutrients or other bioactive phytochemicals. To assess the safety and nutritional impact of these products, it is important to have knowledge of how much of these products will be consumed in the overall human diet or in animal feeds. The safety and nutritional quality of these products can only be assessed in the context of their proposed uses and consequent intake.

Table 4. Fatty Acid Composition of Grain Samples Derived from GR2E and Control Rice

component	GR2E mean[a]	GR2E range	control PSBRc82 mean	control PSBRc82 range	p value[b]	lit. range[c]
Saturated Fatty Acids (% Total Fatty Acids)						
myristic (C14:0)	0.44	(0.35–0.52)	0.39	(0.25–0.49)	0.198	0.25–1.10
palmitic (C16:0)	19.50	(18.80–20.40)	18.5	(15.8–19.1)	0.222	14.90–31.20
stearic (C18:0)	2.25	(1.95–2.78)	2.11	(1.71–2.68)	0.049	1.50–2.80
arachidic (C20:0)	0.86	(0.74–0.99)	0.89	(0.74–1.02)	0.197	0.40–1.02
behenic (C22:0)	0.51	(0.41–0.59)	0.54	(0.[illegible]		
lignoceric (C24:0)	0.93	(0.69–1.25)	1.00	(0.[illegible]		
Unsaturated Fatty Acids (% Total Fatty Acids						
palmitoleic (C16:1)	0.19	(0.16–0.22)	0.19	(0.[illegible]		
oleic (C18:1)	39.70	(38.40–41.30)	40.20	(38[illegible]		
linoleic (C18:2)	33.5	(32.40–34.40)	34.00	(30[illegible]		
α-linolenic (C18:3)	1.63	(1.34–2.31)	1.64	(1.[illegible]		
eicosenoic (C20:1)	0.48	(0.41–0.54)	0.52	(0.[illegible]		

[a]Values represent the least-squares mean of three replicate samples collected over two gr
Philippines (n = 24 for each entry). For each analyte, the lowest and highest individual values
The concentrations of the following fatty acids were below the lower limit of quantification an
lauric (C12:0); pentadecanoic (C15:0); heptadecanoic (C17:0); eicosadienoic (C20:2); e
(C22:1); nervonic (C24:1). [b]Statistical significance was assigned at $p < 0.05$. [c]The combine

Amino Acid Composition of Grain Samples Derived from GR2E and Control Rice

component	GR2E mean[a]	GR2E range	control PSBRc82 mean	control PSBRc82 range	p value[b]	lit. range
Essential Amino Acids (mg/100 g DB)						
line	212	(162–276)	215	(157–281)	0.659	140–281
cine	329	(241–446)	332	(237–464)	0.787	240–460
ne	644	(464–886)	651	(462–921)	0.743	460–920
	299	(216–443)	294	(211–434)	0.711	210–430
ionine	169	(124–228)	166	(127–215)	0.602	130–310
ylalanine	440	(324–593)	444	(317–622)	0.799	280–620
nine	309	(235–400)	308	(217–409)	0.942	220–410
ophan	73.4	(44.2–107)	74.9	(50.9–101)	0.795	50–180
	468	(341–627)	474	(338–653)	0.699	340–650
Nonessential Amino Acids (mg/100 g DB)						
ne	455	(329–625)	460	(331–628)	0.74	330–630
ine	564	(409–737)	564	(408–782)	0.988	410–850
ic acid	708	(493–1010)	710	(497–994)	0.960	500–990
ne	156	(117–214)	155	(113–198)	0.767	100–260
nic acid	1354	(942–1980)	1360	(890–1990)	0.898	890–199
ne	389	(293–495)	393	(292–511)	0.716	290–510
ne	376	(276–510)	381	(278–521)	0.678	280–540
	401	(296–540)	401	(231–556)	0.998	230–560
ine	214	(158–282)	207	(133–291)	0.531	130–480

epresent the least-squares mean of three replicate samples collected over two growing seasons from each of four locations
s (n = 24 for each entry). For each analyte, the lowest and highest individual values across years and locations are shown in parent
are expressed on a dry basis (DB). [b]Statistical significance was assigned at $p < 0.05$. [c]The combined literature range was derived fro
and ILSI crop composition database.[45]

Table 5. Concentrations of Vitamins, Carotenoids, and Antinutrients in Grain Samples Derived from GR2E and Cont

component	GR2E mean[a]	GR2E range	control mean	control range	p value[b]	lit.
Vitamins (mg/kg DB)						
thiamine (B1)	3.13	(2.33–3.77)	3.08	(2.35–3.81)	0.634	2.35
niacin (B3)	36.9	(23.4–58.3)	32.6	(20.2–48.8)	0.417	20.2
pantothenic acid (B5)	9.15	(7.31–11.9)	9.13	(7.22–11.4)	0.929	7.22
pyridoxine (B6)	2.72	(2.22–3.3)	2.75	(2.1–5.42)	0.919	2.1–
folic acid (B9)	0.91	(0.56–2.56)	0.88	(0.39–1.54)	0.881	0.39
α-tocopherol	2.98	(2.47–3.87)	2.75	(2.1–3.5)	0.336	2.1–
Carotenoids (mg/kg DB)						
β-cryptoxanthin	0.31	(0.23–0.46)	<LOQ[d]			
		(0.35–1.32)	<LOQ			
		(1.96–7.31)	<LOQ			
		(0.5–1.32)	<LOQ			
		(3.5–10.9)	<LOQ			
Antinutrients						
		(0.58–1.1)	0.88	(0.61–1.23)	0.622	0.6–
		(0.28–1.71)	1.0	(0.03–4.17)	0.828	0.03

three replicate samples collected over two growing seasons from each of four locatio
analyte, the lowest and highest individual values across years and locations are shown in pa
the LOQ of 0.9 mg/kg dry weight for all samples tested and are not included in this table. [b]
ombined literature range and ILSI crop composition database.[45] [d]LOQ = limit of quantif

d Mineral Composition of Grain, Straw, and Bran Samples Derived from GR2E and Control

	GR2E mean[a]	GR2E range	control PSBRc82 mean	control PSBRc82 range	p value[b]	lit. range
Grain Samples						
	5.89	(4.95–7.17)	6.02	(5.00–7.06)	0.374	3.61–8.6
	1.42	(0.84–2.16)	1.34	(0.56–1.98)	0.711	0.56–3.4
	8.1	(6.07–11.2)	8.26	(6.03–11.40)	0.545	5.9–11.8
	84.6	(81.0–86.9)	84.4	(81.1–86.40)	0.560	80.0–86.
	12.3	(11.1–13.8)	12.3	(10.9–13.60)	0.802	7.6–28.4
	18.5	(15.7–21.7)	17.7	(15.6–18.80)	0.352	10.8–18.
	22.1	(17.5–35.5)	20.6	(16.2–32.80)	0.477	15–32.8
	12.0	(10.1–14.6)	11.1	(10.1–12.30)	0.213	8.6–18.1
TDF (%DB)	17.0	(12.8–20.3)	16.9	(11.4–21.40)	0.955	11.4–23.
amylose (%DB)	12.9	(7.31–18.6)	12.8	(6.76–18.60)	0.955	6.76–18.
starch (%DB)	59.5	(32.8–71.5)	61.1	(28.1–73.90)	0.689	28.1–73.
Ca (mg/100 g DB)	22.5	(14.2–35.0)	21.4	(15.3–29.8)	0.554	10–150
Cu (mg/100 g DB)	0.39	(0.18–0.68)	0.37	(0.22–0.51)	0.544	0.2–1.3
Fe (mg/100 g DB)	3.96	(2.37–10.6)	4.57	(2.58–9.08)	0.514	1.6–9.08
Mg (mg/100 g DB)	131	(87.5–185)	133	(102–157)	0.631	30–170
Mn (mg/100 g DB)	6.61	(4.33–8.39)	6.47	(4.85–7.78)	0.674	2–11.7
P (mg/100 g DB)	327	(211–461)	329	(241–383)	0.870	190–470
K (mg/100 g DB)	346	(236–597)	339	(222–472)	0.666	170–472
Na (mg/100 g DB)	1.5	(0.56–3.81)	1.3	(0.54–3.07)	0.467	0–100
Zn (mg/100 g DB)	2.31	(1.63–3.21)	2.19	(1.73–2.78)	0.569	0.2–3.6
Straw Samples						
ash (%DB)	25.7	(21.1–30.4)	25.3	(20.6–30.2)	0.463	10.8–24
crude fat (%DB)	2.58	(1.31–4.8)	2.72	(1.0–6.15)	0.767	0.9–6.15
crude protein (%DB)	6.13	(3.16–11.3)	6.12	(2.85–10.2)	0.974	2.4–10.2

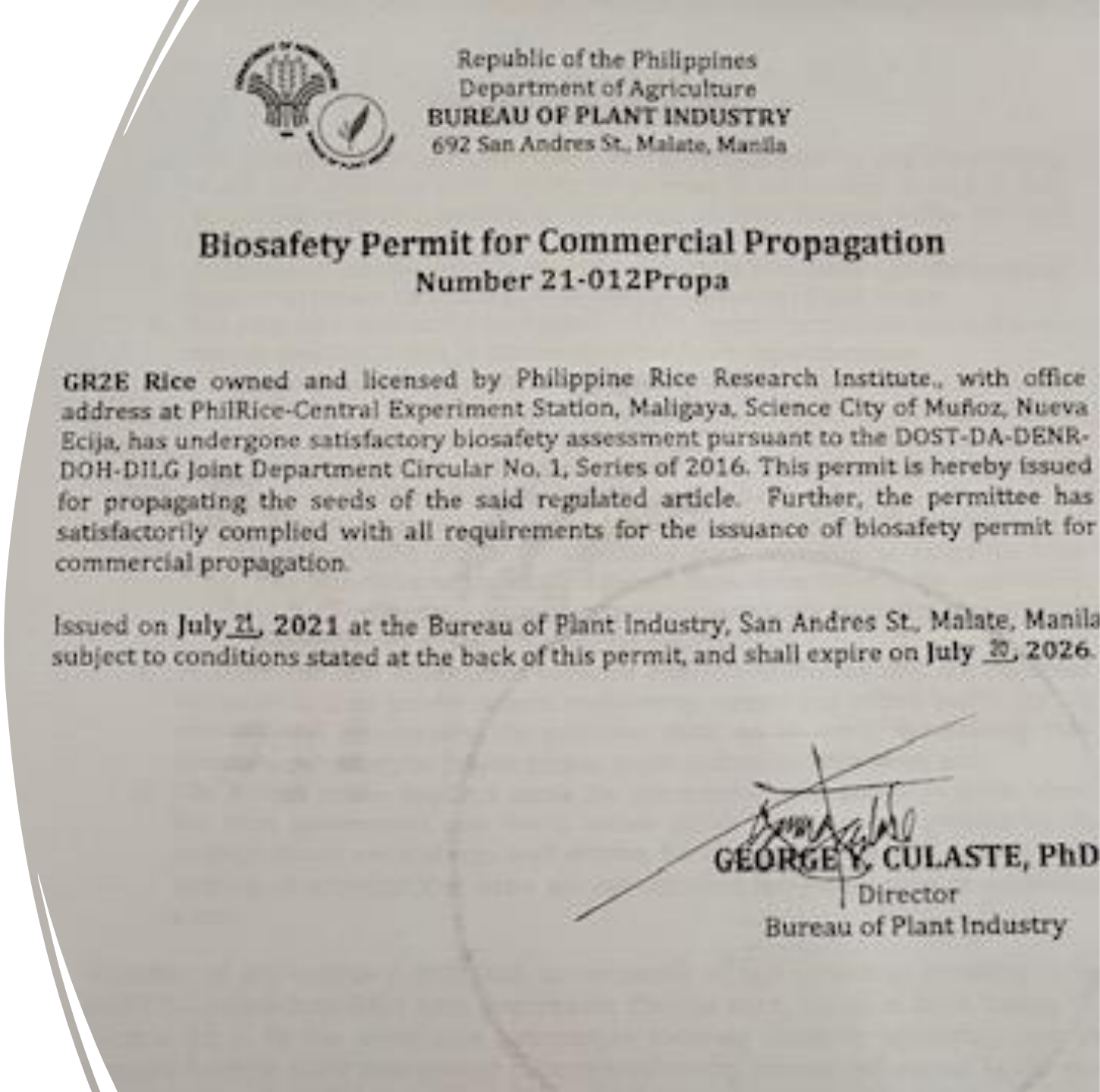
Table 1. Compositional Parameters Analyzed in the Paddy Rice, Rice Stra

compound	paddy rice
proximates and fiber	moisture, crude protein, crude fat, ash, acid detergent fiber (ADF), neutral det and carbohydrate.
minerals	calcium, phosphorus, magnesium, potassium, zinc, manganese, copper, iron,
vitamins	thiamine (B1), riboflavin (B2), niacin (B3), pantothenic acid (B5), pyridoxi
polysaccharides	total starch and amylose
fatty acids	caprylic (C8:0), capric (C10:0), lauric (C12:0), myristic (C14:0), pentadecanoic (C15:0), palmitic (C16:0), palmitoleic (C16:1 Δ heptadecanoic (C17:0), stearic (C18:0), oleic (C18:1 Δ9), linoleic (C18:2 Δ9,12), α-linolenic (C18:3 Δ9,12,15), arachidic (C2 eicosenoic (C20:1), eicosadienoic (C20:2Δ11,14), eicosatrienoic (C20:3 Δ11,14,17), arachidonic (C20:4 Δ5,8,11,14), behenic (erucic (C22:1 Δ13), lignoceric (C24:0), and nervonic (C24:1 Δ15)
amino acids	lysine, arginine, glycine, histidine, isoleucine, leucine, phenylalanine, threonine, valine, alanine, aspartic acid, glutamic acid, proline, tyrosine, cysteine, methionine, and tryptophan
carotenoids	β-cryptoxanthin, *all-trans*-α-carotene, *all-trans*-β-carotene, 9′-*cis*-β-carotene, and total carotenoids
bioactive compounds	phytic acid and trypsin inhibitor

compound	rice straw and bran
proximates and fiber	moisture, crude protein, crude fat, ash, ADF, NDF, crude fiber, and carbohydrate
minerals	calcium and phosphorus

Commercial Propagation

- *Date Applied: October 24, 2021*
- *Date Approved: July 2021*
- *Biosafety Permit Number: 21-012 Propa*



Republic of the Philippines
Department of Agriculture
BUREAU OF PLANT INDUSTRY
692 San Andres St., Malate, Manila

Biosafety Permit for Commercial Propagation
Number 21-012Propa

GR2E Rice owned and licensed by Philippine Rice Research Institute., with office address at PhilRice-Central Experiment Station, Maligaya, Science City of Muñoz, Nueva Ecija, has undergone satisfactory biosafety assessment pursuant to the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, Series of 2016. This permit is hereby issued for propagating the seeds of the said regulated article. Further, the permittee has satisfactorily complied with all requirements for the issuance of biosafety permit for commercial propagation.

Issued on **July 21, 2021** at the Bureau of Plant Industry, San Andres St., Malate, Manila subject to conditions stated at the back of this permit, and shall expire on **July 20, 2026**.

GEORGE Y. CULASTE, PhD
Director
Bureau of Plant Industry

Risk Assessment

Safety considerations:

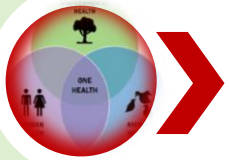
- ✓ General Description including taxonomy and morphology
- ✓ Centers of origin, geographical distribution and agronomic practices
- ✓ Reproductive biology
- ✓ Genetics
- ✓ Hybridization and introgression
- ✓ Various interactions with other organisms (ecology)

Biosafety Permit Conditions

Inform the public by publishing in any of the top three leading newspapers

Limitation of planting and/or commercial propagation within agricultural lands, classified as Alienable and Disposable (A&D lands)

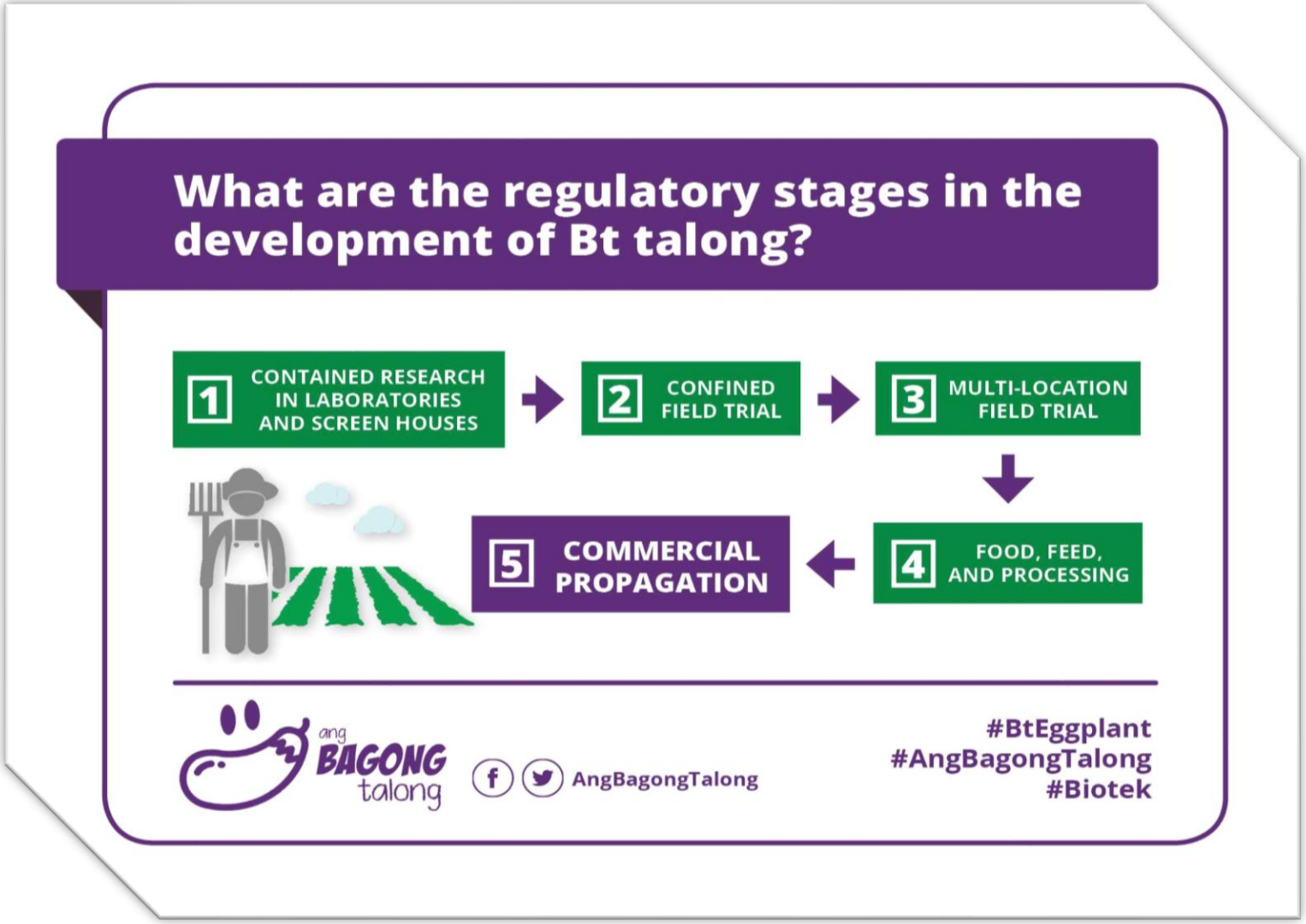
In the event new information becomes available indicating that GR could pose greater risks to biodiversity, human and animal health, necessary measures to protect human health and the environment should be undertaken



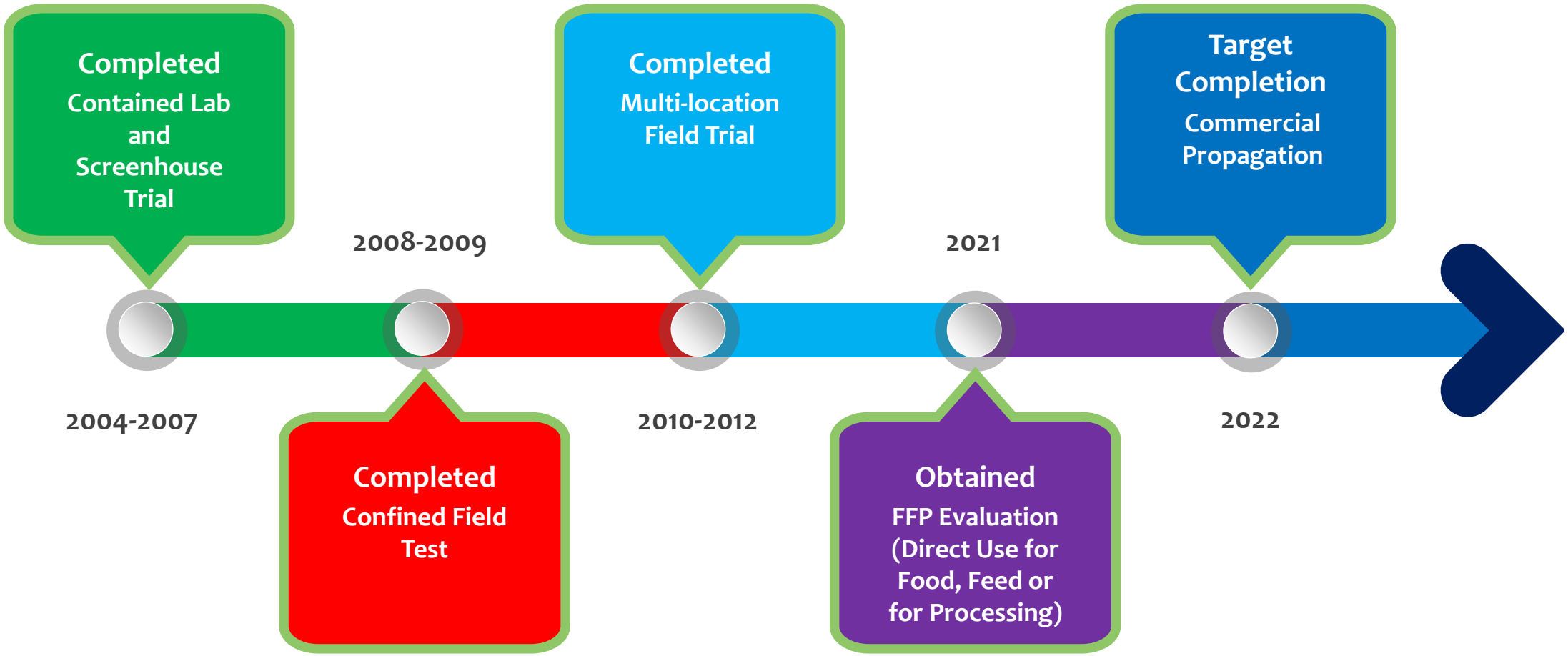
Should not be planted in areas where the local government unit has a known policy or ordinance prohibiting entry or propagation of any GMO. Should be labeled “not intended for propagation in prohibited areas”

Case study: *Bt* eggplant

(resistant to eggplant fruit and shoot borer)



Timeline of *Bt* eggplant Development



Contained Use

- Development and Commercialization of Fruit and Shoot Bt Gene into – BL2 Greenhouse Philippine Eggplant Varieties; contained experiment at IPB
- Completed March 2007

- Development and Commercialization of Fruit and Shoot -Resistant Bt Eggplant: Generation Advancement of Backcross Selections with Mahyco Transformation Event EE -1 and Development of Experimental Hybrids; contained experiment IPB BL2 Greenhouse
- Completed 2009

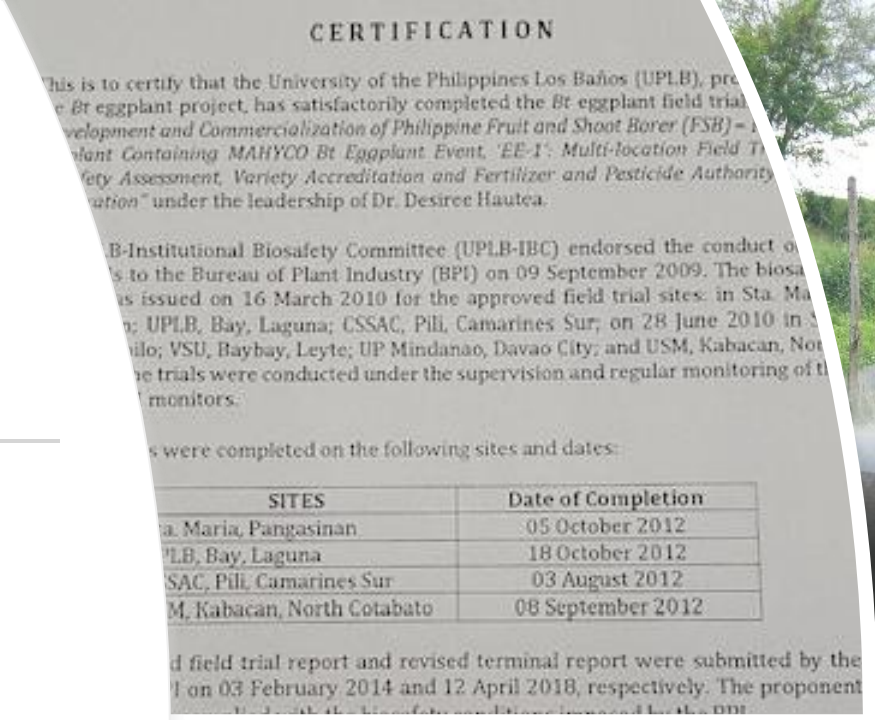
Confined Field Test

Limited Confined Field Trial (CFT) (2008-2009)

- Development and Commercialization of Fruit and Shoot Borer-Resistant Eggplant: Confined Trial of BC3F1 Line Selections with Mahyco Transformation Event EE -1 for – test IPB Experiment Station Evaluation of: horticultural and nutritional; confined field Further Generation Advance and Line Selection
- Completed May 28, 2008

Multi-location Field Trial

- Aug. 3, 2009 – IPB, UPLB applied for multi - location field trial to BPI
- Mar. 15, 2010 – BPI approved the MLT in 7 sites
- Safety assessment studies conducted:
  - Bioefficacy study and horticultural performance
  - Environmental safety studies:
    - Effect on non -target organisms
    - Comparative responses of Bt eggplant and its non -Bt counterpart to common pests and diseases
    - Genetic stability of the Bt trait
    - Survey of wild relatives of eggplant and their capacity to hybridize with eggplant



CERTIFICATION

This is to certify that the University of the Philippines Los Baños (UPLB), pr
e Bt eggplant project, has satisfactorily completed the Bt eggplant field trial
velopment and Commercialization of Philippine Fruit and Shoot Borer (FSB) –
lant Containing MAHYCO Bt Eggplant Event, 'EE-1': Multi-location Field T
fety Assessment, Variety Accreditation and Fertilizer and Pesticide Authority
ation" under the leadership of Dr. Desiree Hautea.

B-Institutional Biosafety Committee (UPLB-IBC) endorsed the conduct o
s to the Bureau of Plant Industry (BPI) on 09 September 2009. The biosa
s issued on 16 March 2010 for the approved field trial sites: in Sta. Ma
; UPLB, Bay, Laguna; CSSAC, Pili, Camarines Sur; on 28 June 2010 in
ilo; VSU, Baybay, Leyte; UP Mindanao, Davao City; and USM, Kabacan, No
e trials were conducted under the supervision and regular monitoring of t
monitors.

s were completed on the following sites and dates:

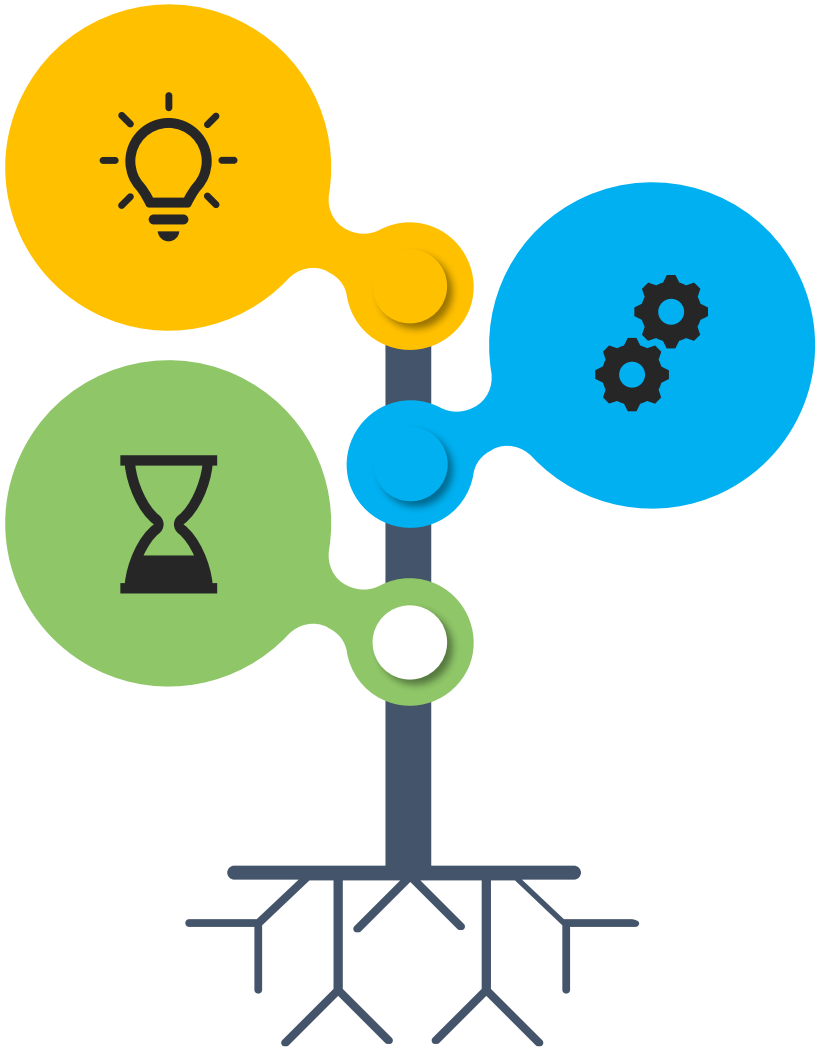
SITES	Date of Completion
a. Maria, Pangasinan	05 October 2012
LB, Bay, Laguna	18 October 2012
SAC, Pili, Camarines Sur	03 August 2012
M, Kabacan, North Cotabato	08 September 2012

d field trial report and revised terminal report were submitted by the
I on 03 February 2014 and 12 April 2018, respectively. The proponent

Conditions to prevent pollen flow/seed dissemination

Observe the 200m physical isolation fromall eggplant field outside the enclosed experimental area at all times

Strictly implement monitoring/inspection of the surrounding 200m radius isolation to ensure that no wild relatives are present within the isolation distance



Ensure that the whole field trial area be provided with pollen trap plants (4 rows of non-Bt eggplant

Conditions to prevent persistence in the environment

Remove fruits before they ripen, fruits that retained for seeds shall be bagged

All viable plant materials shall be destroyed

All Bt and non-Bt eggplant shall be collected, chopped and buried within the site

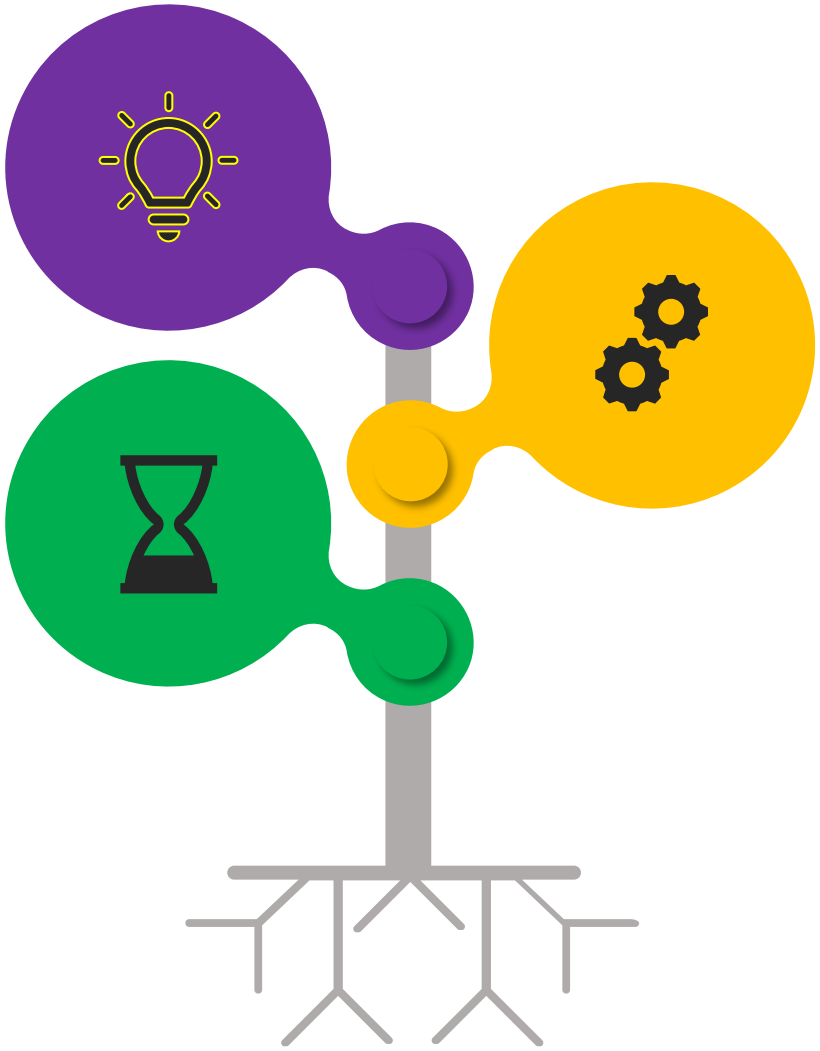
The site will not be used for a minimum of 60 days after completion of the field trial

The site must be left undisturbed and volunteer plants monitored

Conditions to prevent introduction into the food/feed pathways

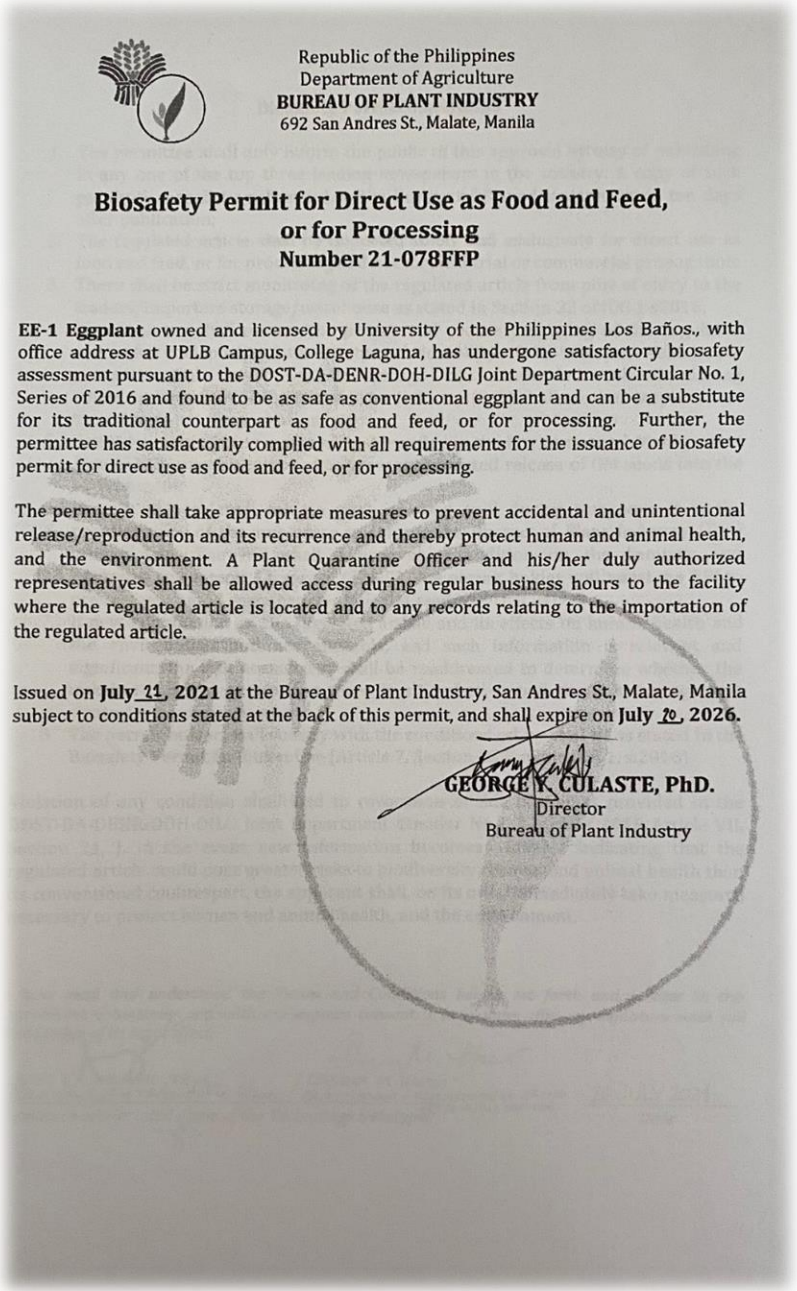
Movement and storage of Bt eggplant seeds and viable plant materials are controlled

Ensure that stray animals are excluded from the trial site



Ensure that only authorized persons are allowed inside the trial sites

Direct Use Food, Feed or Processing



Republic of the Philippines
Department of Agriculture
BUREAU OF PLANT INDUSTRY
692 San Andres St., Malate, Manila

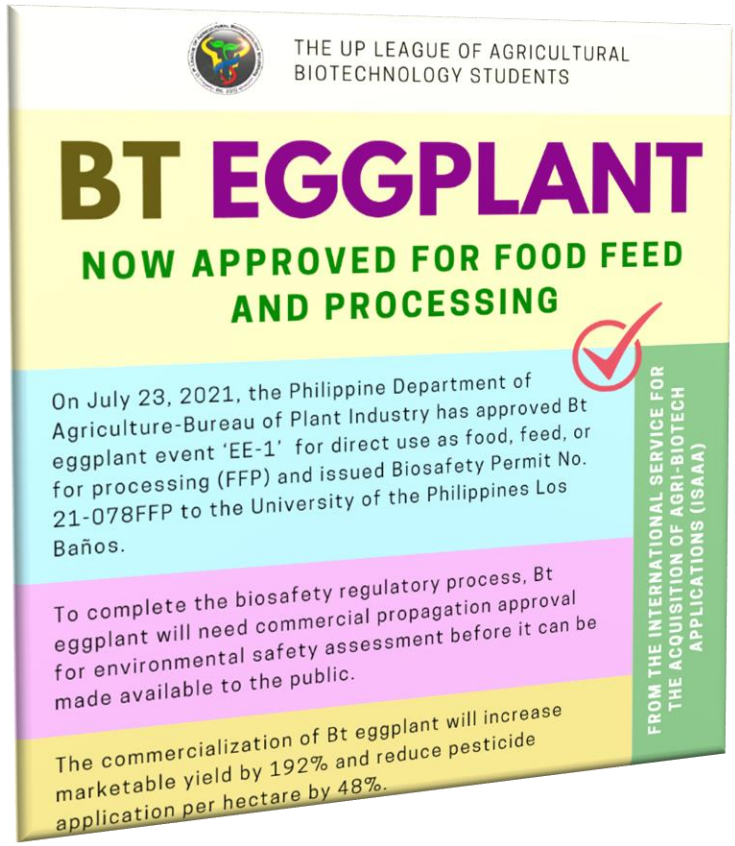
Biosafety Permit for Direct Use as Food and Feed, or for Processing
Number 21-078FFP

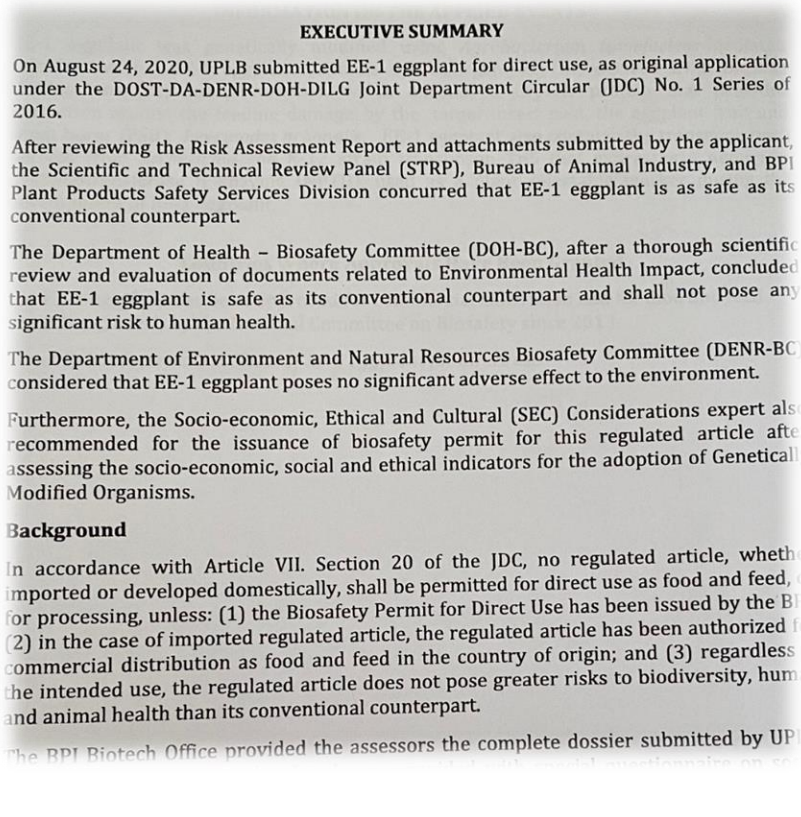
EE-1 Eggplant owned and licensed by University of the Philippines Los Baños., with office address at UPLB Campus, College Laguna, has undergone satisfactory biosafety assessment pursuant to the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, Series of 2016 and found to be as safe as conventional eggplant and can be a substitute for its traditional counterpart as food and feed, or for processing. Further, the permittee has satisfactorily complied with all requirements for the issuance of biosafety permit for direct use as food and feed, or for processing.

The permittee shall take appropriate measures to prevent accidental and unintentional release/reproduction and its recurrence and thereby protect human and animal health, and the environment. A Plant Quarantine Officer and his/her duly authorized representatives shall be allowed access during regular business hours to the facility where the regulated article is located and to any records relating to the importation of the regulated article.

Issued on **July 21, 2021** at the Bureau of Plant Industry, San Andres St., Malate, Manila subject to conditions stated at the back of this permit, and shall expire on **July 20, 2026.**

GEORGE Y. CULASTE, PhD.
Director
Bureau of Plant Industry





EXECUTIVE SUMMARY

On August 24, 2020, UPLB submitted EE-1 eggplant for direct use, as original application under the DOST-DA-DENR-DOH-DILG Joint Department Circular (JDC) No. 1 Series of 2016.

After reviewing the Risk Assessment Report and attachments submitted by the applicant, the Scientific and Technical Review Panel (STRP), Bureau of Animal Industry, and BPI Plant Products Safety Services Division concurred that EE-1 eggplant is as safe as its conventional counterpart.

The Department of Health – Biosafety Committee (DOH-BC), after a thorough scientific review and evaluation of documents related to Environmental Health Impact, concluded that EE-1 eggplant is safe as its conventional counterpart and shall not pose any significant risk to human health.

The Department of Environment and Natural Resources Biosafety Committee (DENR-BC considered that EE-1 eggplant poses no significant adverse effect to the environment.

Furthermore, the Socio-economic, Ethical and Cultural (SEC) Considerations expert als recommended for the issuance of biosafety permit for this regulated article afte assessing the socio-economic, social and ethical indicators for the adoption of Genetical Modified Organisms.

Background

In accordance with Article VII. Section 20 of the JDC, no regulated article, wheth imported or developed domestically, shall be permitted for direct use as food and feed, for processing, unless: (1) the Biosafety Permit for Direct Use has been issued by the B (2) in the case of imported regulated article, the regulated article has been authorized commercial distribution as food and feed in the country of origin; and (3) regardless the intended use, the regulated article does not pose greater risks to biodiversity, hum and animal health than its conventional counterpart.

The BPI Biotech Office provided the assessors the complete dossier submitted by UP

Commercial propagation

Application for Commercial Propagation & Registration of Bt Eggplant 'Event EE-1' as Plant-Incorporated Protectant (PIP) to the Fertilizer and Pesticide Authority (FPA)

Parting words…

"Scientific and regulatory agencies around the world have repeatedly and consistently found crops and foods improved through biotechnology to be as safe as, if not safer than, those derived from any other method of production. … Opposition based on emotion and dogma contradicted by data must be stopped"

Laureates Letter Supporting Precision Agriculture (GMOs)

Thank You!


BT Tala
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ment of Agriculture -
of Plant Industry (DA-BPI) has
ted the biosafety permit for
commercial propagation of Golden
Rice to the DA - Philippine Rice
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