



Regulating Innovations: **NEW BREEDING TECHNIQUES in the PHILIPPINES**

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Head Secretariat, National Committee on Biosafety of the Philippines*

PRESENTATION OUTLINE

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Defining New Breeding
Techniques

2

The Philippines'
Regulatory System for
NBTs

3

Case in point: Tropic
Biosciences' reduced
browning banana/
Sanatech's GABA tomato

4

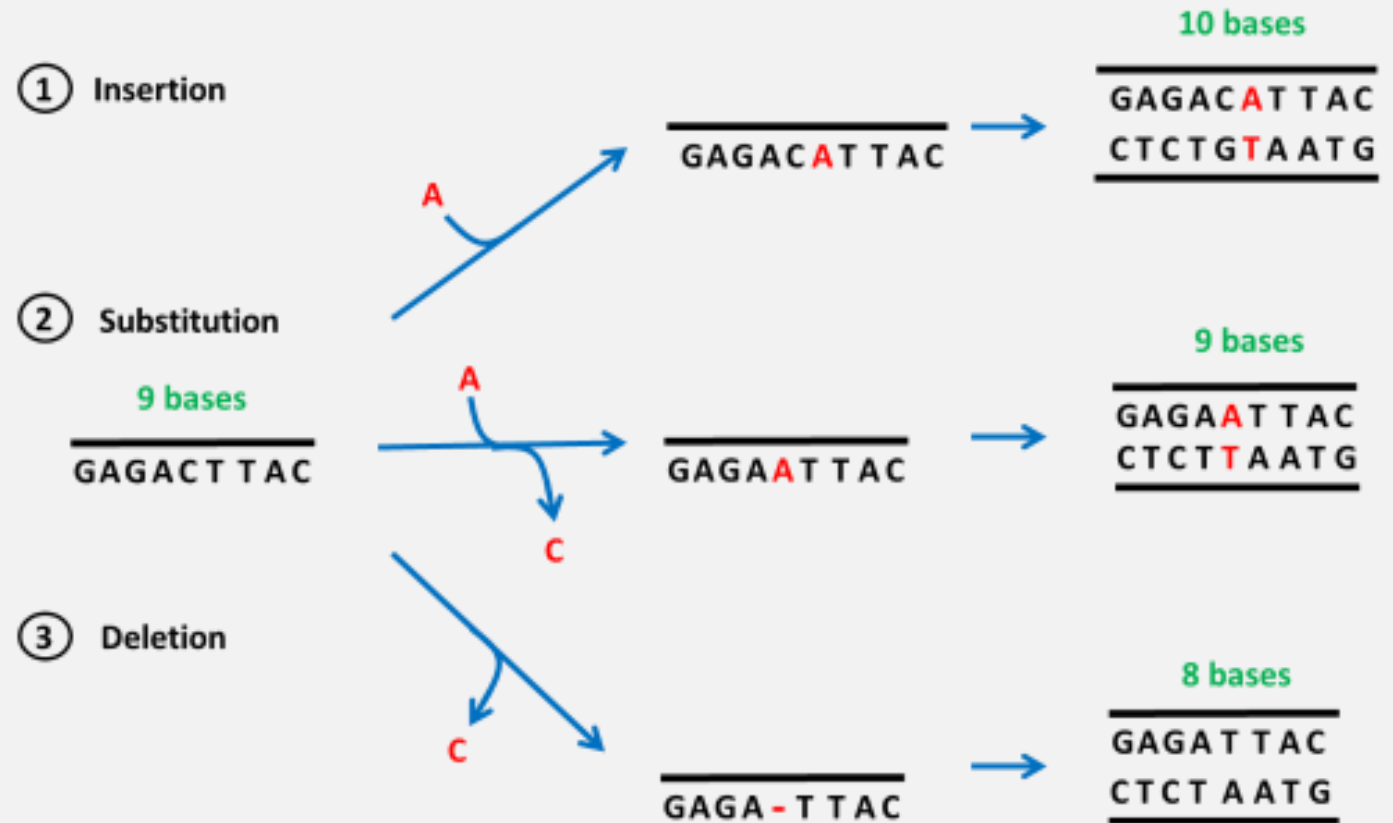
Policy directions for NBTs

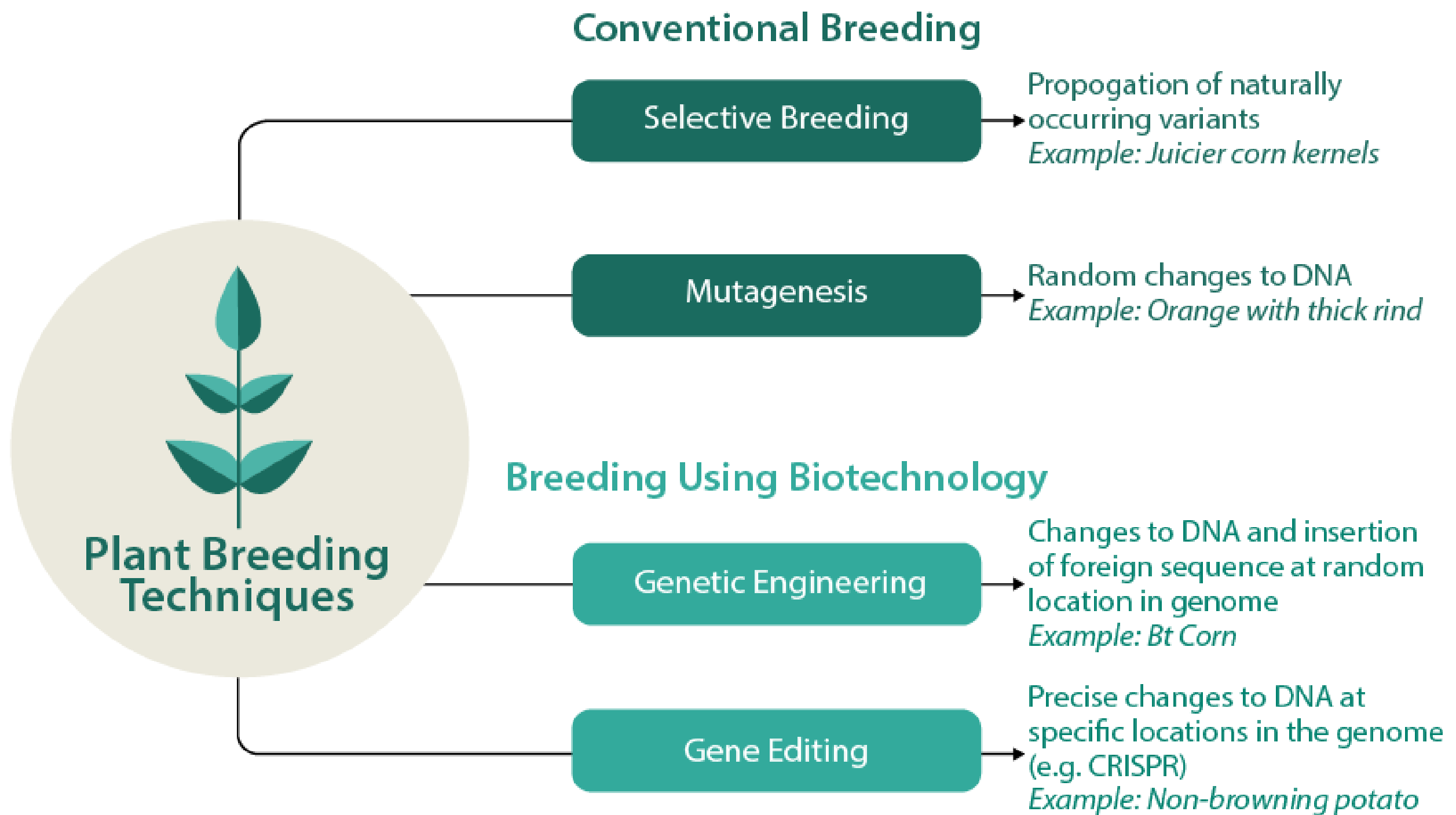
NEW BREEDING TECHNIQUES = PLANT BREEDING INNOVATIONS

a new set of molecular, genomics, and cellular tools that enable the **targeted** and **efficient** development of new varieties of crops with desired traits or characteristics in a way that is faster and more precise than conventional plant breeding techniques.

NEW BREEDING TECHNIQUES

Depending on the specific type of NBT, DNA can be modified by the introduction of base change, deletion, or insertion of a base or a few bases, resulting in a plant that could otherwise be produced through physical or chemical mutagenesis or by spontaneous mutation.





BACKGROUND ON NBT POLICY/REGULATION

2018

The Department of Agriculture Study Group recommended the NCBP to issue the country's policy on NBTs.

2020

NCBP Resolution No.1 was issued.

2022

DA Memo Circular No.8 was issued which provided the procedure in the determination of products of PBIs.

2023

The Philippines made its first PBI product determination: gene-edited banana with reduced browning as non-GMO.

NCBP RESOLUTION NO.1, s2020

PBI products may be classified either as GMO or non-GMO based on the presence of a novel combination of genetic material obtained using modern biotechnology.

Only PBI-derived GM plants would be regulated under the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, s2022

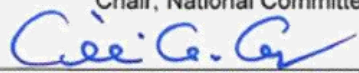
The Department of Agriculture shall issue guidelines in the evaluation and monitoring of PBIs.

RESOLUTION NO. 001
Series of 2020

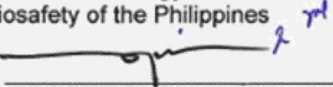
THE REGULATION OF PLANT AND PLANT PRODUCTS DERIVED
FROM THE USE OF PLANT BREEDING INNOVATIONS (PBIs) OR
NEW PLANT BREEDING TECHNIQUES (NBTs)


SECRETARY FORTUNATO T. DE LA PEÑA

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Chair, National Committee on Biosafety of the Philippines


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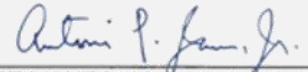
Environmental Scientist Member


DR. EUFEMIO T. RASCO, JR.

Biological Scientist Member


DR. MA. CRISTINA D. PADOLINA

Physical Scientist Member


ATTY. ANTONIO P. JAMON, JR.

Consumer Representative


MS. MA. LOURDES S. FLORENDO

Industry Representative

ON LEAVE

RET. GEN. MARCELO C. BLANDO

Community Representative

DEPARTMENT OF AGRICULTURE

MEMORANDUM CIRCULAR NO.8, S2022



Republic of the Philippines
OFFICE OF THE SECRETARY
Elliptical Road, Diliman,
Quezon City 1100, Philippines

MEMORANDUM CIRCULAR

No. 08

Series of 2022

Subject: **RULES AND PROCEDURE TO EVALUATE AND DETERMINE WHEN PRODUCTS OF PLANT BREEDING INNOVATIONS (PBIs) ARE COVERED UNDER THE DOST-DA-DENR-DOH-DILG JOINT DEPARTMENT CIRCULAR NO. 1, SERIES OF 2021 (JDC1, s2021) BASED ON THE NCBP RESOLUTION NO. 1, SERIES OF 2020**

TECHNICAL CONSULTATION FOR EVALUATION (TCED)

a technical evaluation of the PBI product to determine whether the final product of the PBI used contains a novel combination of genetic material.



Who conducts the TCED?

The BPI Biotechnology Core Team-Plant Breeding Innovation (BCT-PBI) shall form a **Technical Consultation for Evaluation and Determination (TCED) Group** composed of three (3) members, with at least two (2) members from the BCT-PBI and external expert, if necessary.

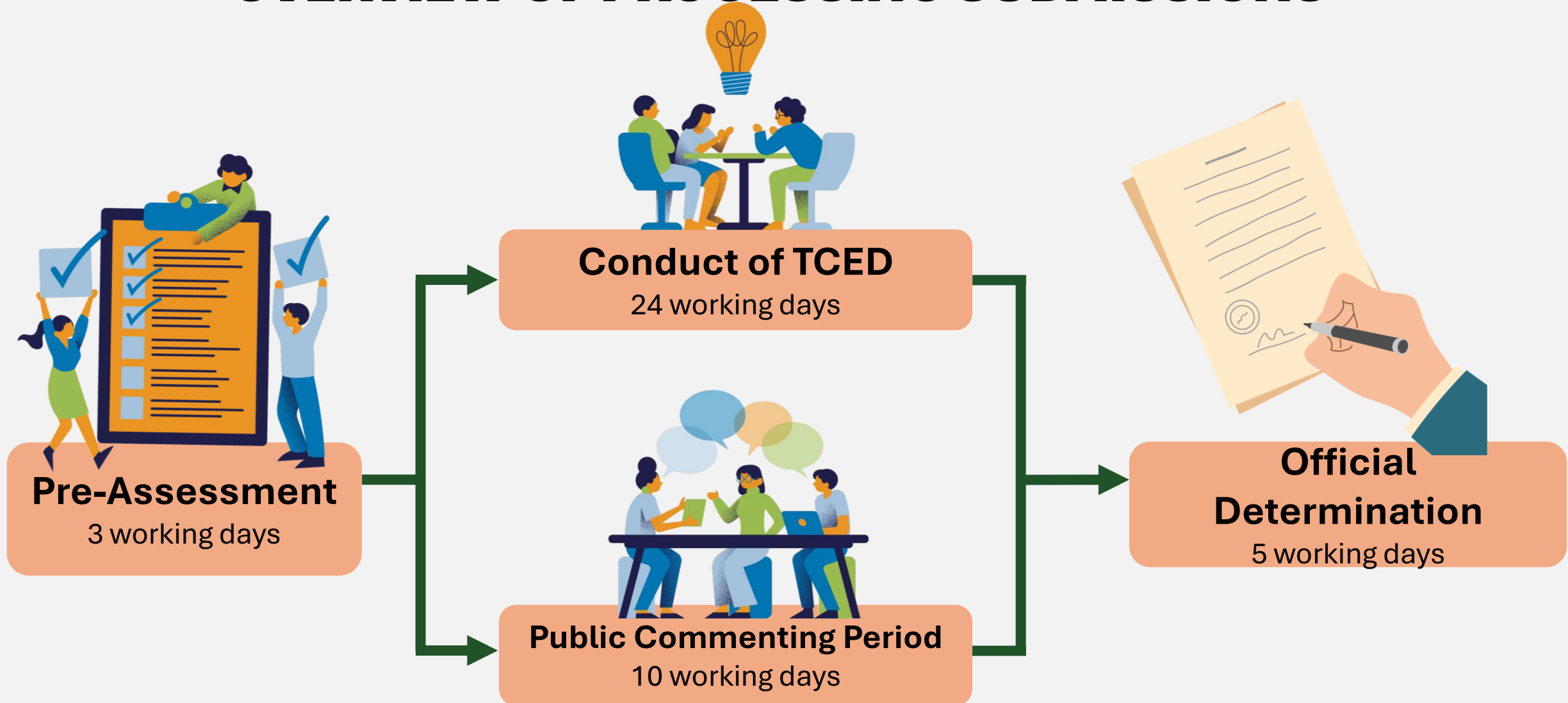
Who can submit a request for TCED?

A **Product developer*** refers to the natural or juridical person who developed the PBI product submitted for the determination of its regulatory status.

- Departments or agencies of the Phil gov't
- University with research institutions in the Phil
- Int'l research organization recognized by the Phil gov't
- Corporation registered with the Securities and Exchange Commission of the Philippines
- Cooperative registered with the Cooperative Development Authority of the Philippines

**A non-resident product developer shall appoint an agent who is a resident of the Philippines.*

OVERVIEW OF PROCESSING SUBMISSIONS



OFFICIAL DETERMINATION

*Considering the **accomplished PEF** from the **TCED Group** and the **technical information from the public**, the **Director of BPI** shall make the **official determination on the regulatory status of the PBI product** within 5 working days.*

if determined as GMO

- Inform the product developer in writing that the GM PBI product is under the scope of JDC No.1 s2021
- Advise the product developer to proceed with the application process of JDC No.1 s2021
- Monitor to ensure compliance to JDC No.1 s2021

if determined as non-GMO

- Issue to the product developer a Certificate of Non-Coverage from the JDC1, s2021 for the non-GM PBI product
- Post the Certificate of Non-Coverage on the BPI website

CERTIFICATE OF NON-COVERAGE FROM THE JDC1, S2021



Shall refer to the novel characteristics introduced in the current variety and the subsequent progenies.

Shall also apply to all germplasm or genetic backgrounds that will contain such characteristic produced by the product developer and/or its licensees in further breeding.

Shall not excuse the product developer from complying with other relevant regulations of the Department of Agriculture and other government agencies.

CASE IN POINT: TROPIC BIOSCIENCES' REDUCED BROWNING BANANA



Department of Agriculture
BUREAU OF PLANT INDUSTRY

692 San Andres Street, Malate, Manila, Philippines
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JAS-ANZ



CERTIFICATE OF NON-COVERAGE FROM JDC NO.1 S2021 BPI-PBI-CNC No. 23-001

This is to certify that the gene-edited banana plant (*Musa acuminata*) with reduced browning trait obtained through CRISPR/Cas9 and developed by TROPIC BIOSCIENCES with address at NORWICH RESEARCH PARK, INNOVATION CENTRE, NR4 7GJ is officially determined as NON-GENETICALLY MODIFIED ORGANISM and does not fall under the coverage of the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1 s2021 (JDC No.1 s2021) based on the scientific evidence(s) presented by the Product Developer.

This decision is based on the conducted Technical Consultation for Evaluation and Determination procedure described in DA Memorandum Circular No. 08 s2022 "Rules and Regulation to Evaluate and Determine when Products of Plant Breeding Innovations (PBIs) are Covered under the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1 s2021."

Information on the Product Developer and the PBI product

Official Determination on the regulatory status of the PBI product

CASE IN POINT: TROPIC BIOSCIENCES' REDUCED BROWNING BANANA

This certificate does not exempt the product developer's compliance with other relevant regulations of the Department of Agriculture and other government agencies such as, but not limited to, those involving plant quarantine, pest risk analysis, varietal registration, plant variety protection and crop-specific standards and programs, where warranted,

Statement of compliance with other regulations

This certification shall have no expiration and shall remain valid hereafter unless revoked through the process of appeal.

Validity of certificate

The product developer shall immediately notify the BPI in writing of any issues or new information that may affect this decision.

Issued on this 15th day of March year 2023 at the Bureau of Plant Industry, San Andres St., Malate, Manila.

Date of issuance


GERALD GLENN F. PANGANIBAN, Ph.D.
Director
Bureau of Plant Industry

CASE IN POINT: SANATECH SEED CO., LTD. HIGH GABA SICILIAN ROGUE TOMATO




Department of Agriculture
BUREAU OF PLANT INDUSTRY
 692 San Andres St., Malate, Manila, Philippines
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 ISO 9001:2015 Certified
 Quality Management System

CERTIFICATE OF NON-COVERAGE from JDC NO. 01 s. 2021
BPI-PBI-CNC No. 24-001

This is to certify that the gene-edited **HIGH GABA SICILIAN ROGUE TOMATO** (*Solanum lycopersicum*) obtained through CRISPR/Cas9 and developed by **SANATECH SEED CO., LTD.** with address at **LANDIC TORANOMON BLDG. 7F, 3-7-10 TORANOMON, MINATO-KU, TOKYO, JAPAN** is officially determined as **NON-GENETICALLY MODIFIED ORGANISM** and does not fall under the coverage of the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 01 s. 2021 (JDC No. 01 s. 2021) based on the scientific evidence(s) presented by the Product Developer.

This decision is based on the conducted Technical Consultation for Evaluation and Determination procedure described in DA Memorandum Circular No. 08 s. 2022 "Rules and Regulation to Evaluate and Determine when Products of Plant Breeding Innovations (PBIs) are Covered under the DOST-DA DENR-DOH-DILG Joint Department Circular No. 01 s. 2021".

This certificate does not exempt the product developer's compliance with other relevant regulations of the Department of Agriculture and other government agencies such as but not limited to those involving plant quarantine, pest risk analysis, varietal registration and crop-specific standards and programs, where warranted.

This certification shall have no expiration and shall remain valid hereafter unless revoked through the process of appeal.

The product developer shall immediately notify the BPI in writing of any issues or new information that may affect this decision.

Issued on this 2nd day of May year 2024 at the Bureau of Plant Industry, San Andres St., Malate, Manila.


GERALD GLENN F. PAGANIBAN, Ph.D.
 Director
 Bureau of Plant Industry

- ✓ Determined as non-GMO by Japan MAFF
- ✓ Determined as gene-edited food by Japan MHLW
- ✓ Deregulated by the US Department of Agriculture being not a pest nor containing pest sequences in its genome

GLOBAL REGULATORY LANDSCAPE FOR GENE-EDITED CROPS

Established regulatory criteria for new breeding innovations in different world regions in the past decade



NORTH AMERICA

 **US & CANADA AMONG FIRST COUNTRIES WITH CONCRETE REGULATORY DECISIONS ON NEW BREEDING INNOVATIONS**
SOYBEANS PRODUCING HIGH-OLEIC SOYBEAN OIL SOLD AS CALYNO
FIRST COMMERCIALIZED GENE-EDITED CROP IN THE US IN 2019 DEVELOPED USING TALENS



EUROPE

 **EU PROPOSAL ON NEW GENOMIC TECHNIQUES RELEASED IN JULY 2023**
UK'S PRECISION BREEDING BILL
INTRODUCED IN MAY 2022; BECAME A LAW IN MARCH 2023 AFTER RECEIVING ROYAL ASSENT
INTRODUCES SCIENCE-BASED AND STREAMLINED REGULATORY SYSTEM TO FACILITATE RESEARCH

AFRICA

 **4 COUNTRIES WITH ESTABLISHED GUIDELINES ON NEW BREEDING INNOVATIONS:**
NIGERIA (FEBRUARY 2022)
KENYA (MARCH 2022)
MALAWI (AUGUST 2022)
GHANA (OCTOBER 2023)

LATIN AMERICA

 **8 COUNTRIES WITH ESTABLISHED CRITERIA OF NEW BREEDING INNOVATIONS:**
BRAZIL • CHILE • COLOMBIA • ECUADOR GUATEMALA HONDURAS • PARAGUAY ARGENTINA

ARGENTINA PIONEER REGULATION ISSUED IN 2015

GENE-EDITED NON-BROWNING POTATO DEVELOPED USING CRISPR RELEASED IN 2018



ASIA AND THE PACIFIC

AUSTRALIA, JAPAN, PHILIPPINES, AND INDIA
ISSUED IMPLEMENTING REGULATIONS AND SOME APPROVED THEIR FIRST GENE-EDITED PRODUCTS

 **JAPAN**
STARTED SALE OF GENE-EDITED HIGH GABA TOMATO IN 2021

 **PHILIPPINES**
REDUCED BROWNING GENE-EDITED BANANA DETERMINED AS NON-GMO IN 2023
FIRST GENE-EDITED PRODUCT TO GO THROUGH THE PHILIPPINES' GENE EDITING REGULATORY PROCESS

International Comparisons

- ❖ The Philippines' approach aligns with regulatory trends in other regions:
- ❖ **Japan, Argentina, and Brazil:** NBTs are assessed based on the presence of foreign DNA. If absent, they are not regulated as GMOs.
- ❖ **European Union (EU):** NBTs are currently classified as GMOs, but there are ongoing discussions to update this stance.
- ❖ **United States:** NBTs are assessed based on the final product rather than the method used.



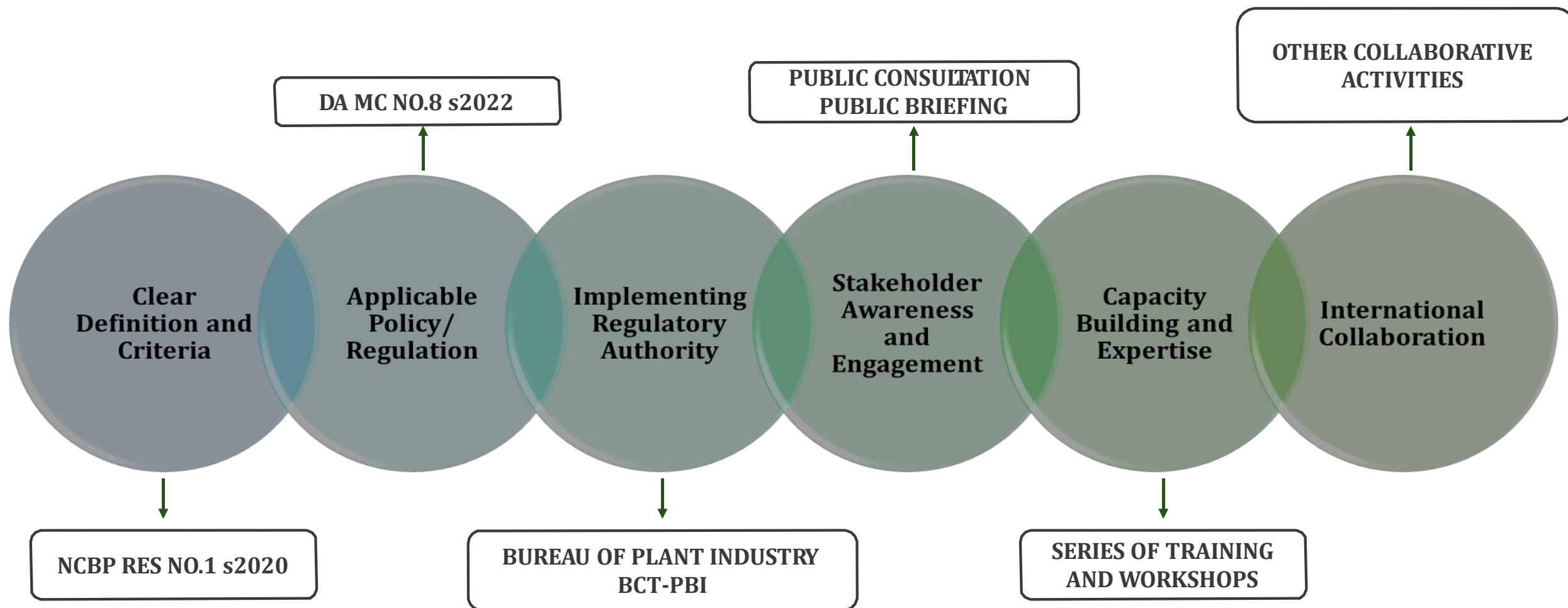
For more information, visit:
www.isaaa.org

Sources:
ISAAA. 2021. Breaking Barriers with Breeding: A Primer on New Breeding Innovations for Food Security. ISAAA Brief No. 56.
ISAAA Biotech Updates. <https://www.isaaa.org/kc/cropprotechupdate/>

Updated January 24, 2024

SDN1: site-directed nuclease
GMO: genetically modified organism
TALENs: transcription activator-like effector nucleases
CRISPR: clustered regularly interspaced short palindromic repeats
GABA: gamma-aminobutyric acid

 [isaaa.org](https://www.facebook.com/isaaa.org)  [isaaa.org](https://www.instagram.com/isaaa.org)  [isaaa_org](https://twitter.com/isaaa_org)  [isaaa](https://www.linkedin.com/company/isaaa)  [isaaaavideos](https://www.youtube.com/channel/UCisaaa)



Key Elements for a Science-based Determination



**Sicilian Rouge
High GABA**

Foods with
Function Claims

Notification · H617

**GABA's
Effect**

- 1 tomato**
Can lower
blood pressure
of people with
high blood
pressure
- 2 tomato**
can relieve
temporary stress
from work/studies
- 5-7 tomato**
can improve
quality (for
a deeper
refreshing
- 5-7 tomato**

4

Products issued with
certificate of non-
coverage registry

- Banana (*Musa acuminata*) with
reduced browning
- High GABA Sicilian Rouge Tomato
- Reduced Browning Banana
(TRB011001)
- Reduced Browning Banana
(TRB011002)



Philippines has cleared gene-edited reduced browning
bananas developed to reduce food waste

ARTICLE IN BIOTECH UPDATES: <https://tinyurl.com/tjxf2dn6>

www.isaaa.org



Development of New Variety of Crops using PBI

6TH INTERNATIONAL
RICE CONGRESS

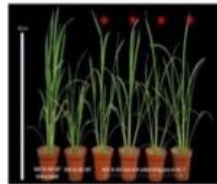
DISCUSSION

Genome Editing for Rice Sustainable Farming

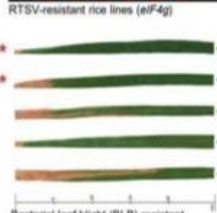
In this event, the Genetic Transformation Laboratory (GTL), IRRI will discuss plant gene or genome editing breakthroughs with experts from similar fields. The topic will address novel breeding technology research, genome-edited plant regulation, and outreach programs.

16-19 October 2023
Philippine International Convention Center (PICO)
METRO MANILA, PHILIPPINES



RTSV-resistant rice lines (eIF4g)



Bacterial leaf blight (BLB)-resistant lines (OsSweet14 and 13)



Non-browning eggplant

- Knocked out the *polyphenol oxidase* gene to prolong freshness of cut fruits



Low phytic acid corn

- reducing the phytic acid content of corn to improve its nutritional value by targeting the *ZMIPK1* gene



High lycopene tomato

- knocking out lycopene cyclase genes that convert lycopene to carotenes. The accumulation of lycopene results in redder tomatoes.

PhilRICE – DA Crop Biotech Center led project

UPLB – Institute of Plant Breeding led projects
(DOST PCAARRD funded projects)

Source: Dr. Reynante Ordonio Slide Deck

What's Next for New Breeding Techniques in the Philippines?

REGULATORY LANDSCAPE FOR GENE-EDITED CROPS IN ASIA AND OCEANIA

Established regulatory criteria for new breeding innovations in countries in Asia and Oceania in the past decade



Countries where products are likely to be regulated as conventional new varieties after recent regulatory policy updates.

Countries where there are noticeable policymaking discussions over proposals to treat SDN1 as conventional new varieties.

Countries where SDN1 products should be treated as GMO according to court interpretations based on old regulations.

AUSTRALIA, INDIA, JAPAN, PHILIPPINES, & THAILAND ISSUED IMPLEMENTING REGULATIONS AND SOME APPROVED THEIR FIRST GENE-EDITED PRODUCTS



JAPAN

STARTED SALE OF GENE-EDITED **HIGH GABA TOMATO** IN 2021
GENE-EDITED WAXY MAIZE APPROVED IN 2023; WAS NOT SUBJECT
TO JAPAN'S REGULATIONS FOR GENETICALLY ENGINEERED FOOD,
FEED, AND BIODIVERSITY



PHILIPPINES

REDUCED BROWNING GENE-EDITED BANANA DETERMINED
AS NON-GMO IN 2023; FIRST GENE-EDITED PRODUCT TO GO
THROUGH THE PHILIPPINES' GENE EDITING REGULATORY PROCESS
HIGH GABA TOMATO DETERMINED AS NON-GM IN MAY 2024

INDIA

IN MAY 2022, FINAL GUIDELINES FOR
SAFETY ASSESSMENT OF GENOME-
EDITED PLANTS WERE RELEASED

THAILAND

GROUNDBREAKING LEGISLATION FOR
GENOME-EDITED ORGANISMS SIGNED
ON JULY 11, 2024



For more information, visit:

www.isaaa.org

Sources:

ISAAA (2024). *Breaking Barriers with Precision: A Review of New Breeding*

SDN1: site-directed nuclease

GMO: genetically modified organism

GABA: gamma-aminobutyric acid

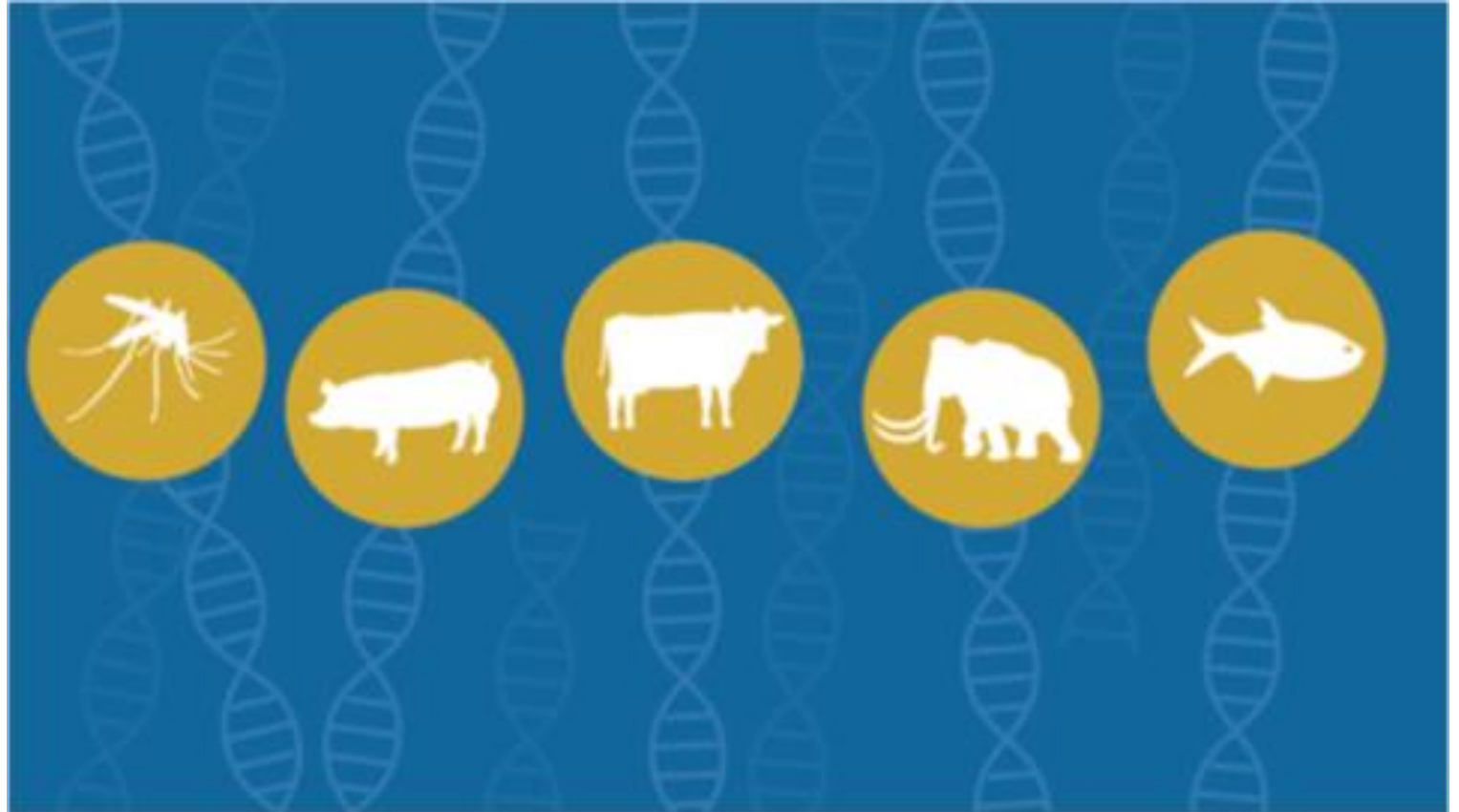
Our NBT regulation is aligned with most of the countries.

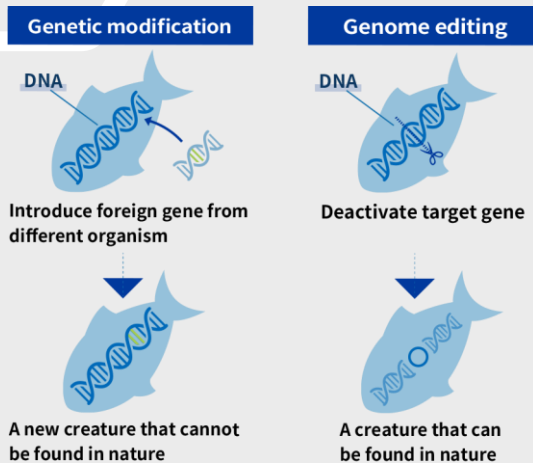
Research institutions such as **IRRI, PhilRice, UPLB, and PCAARRD** are exploring applications of NBTs for Philippine crops.

Capacity-building programs are needed to train regulators, scientists, and farmers on NBT adoption.

Educate stakeholders, farmers, and the public on NBTs

Are we
considering
developing a
policy on gene
edited
animals?





Drafted the guidance document
for GM/gene-edited fish



Preparing the groundwork for gene
editing in animals

**To Regulate, or Not to Regulate,
the Answer to the Question
The NCBP Policy on Plant Breeding
Innovations or New Breeding Techniques**

Ms. Ma. Lorelie U. Agbagala
DOST Assistant Scientist and NCBP Head Secretariat

Policy on Plant Breeding Innovations (PBIs) or New Breeding Techniques (NBTs) is based on the approach to the regulation of Genetically Modified Plant and Plant Products—the DOST-ILG Joint Department Circular No.1, Series of 2021.

Committee on Biosafety of the Philippines (NCBP) Resolution No.1, Series of 2020: The Committee recommends a product derived from the use of PBIs or NBTs as a product in determining whether a product will be exempted from the existing GM plant and product regulation.

Executive Order (EO) No. 514, Series of 2006, products from PBIs can be classified as a novel combination of genetic material obtained through modern biotechnology, as a novel combination as a resultant genetic combination in a living organism that is not conventional breeding. Otherwise, a product is a non-GMO or conventional.

Identified the Department of Agriculture (DA) as the primary agency for the evaluation

Use new specific traits also organisms. Techniques to combine DNA from two or more sources to achieve



POLICY BRIEF

To Regulate, or Not to Regulate, the Answer to the Question The NCBP Policy on Plant Breeding Innovations or New Breeding Techniques

Ms. Ma. Lorelie U. Agbagala
DOST Assistant Scientist and NCBP Head Secretariat

Key message:

**“Balancing innovation with responsibility,
the Philippines is building a science-based
and adaptive regulatory framework for new
breeding techniques to ensure safety,
sustainability, and public trust.”**



ACKNOWLEDGEMENT:

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- ❖ **Dr. Reynante Ordonio** of Philrice
- ❖ **Mr. Reimond Corona**
- ❖ **ISAAA for the infographics**

- ❖ https://www.linkedin.com/posts/international-rice-research-institute_converse-irc2023-irc2023-activity-7115930179335585792-E8S6/
- ❖ https://www.everycrsreport.com/files/2023-09-07_R47683_2f0ce7c030c6f4564721054c306ff6045e71321a.html

Thank you!



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