



Regulatory Status of Plant Breeding Innovations in the Philippines

November 8, 2023

Geronima P. Eusebio

OIC-Head

BPI Biotechnology Office

Background of the Policy

Department of Agriculture
(DA) commissioned a study

**“A Review of the New
Plant Breeding
Techniques (NBTs)
from the Viewpoint
of Regulation”**

**The study was
submitted to
National Committee
on Biosafety of the
Philippines (NCBP)**

The NCBP issued Resolution
No. 1, series of 2020

**“The Regulation of
Plant and Plant
Products Derived from
the Use of Plant
Breeding Innovations
(PBIs) or New Breeding
Techniques (NBTs)”**

RESOLVED: "that products from Plant Breeding Innovations **may be classified either as: (a) GMOs**, if – as defined under E.O. 514 s. 2006 - **they contain a novel combination of genetic material obtained through the use of modern biotechnology**, which "novel combination" the NCBP defines as a resultant genetic combination in a living organism that is not possible through conventional breeding; **or (b) non-GMOs or conventional products, if they do not contain a novel combination of genetic material**. A decision tree is attached to this resolution as Annex A"

RESOLVED: "that **only PBI-derived GM plants and plant products would be regulated under the JDC1**. Consequently, **PBI-derived non-GM plants and plant products would not be regulated under the said Circular**"

RESOLVED: "that the **DA shall issue guidelines** and take the lead **in evaluating and monitoring plant and plant products** derived from the use of modern biotechnology, including Plant Breeding Innovations"

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

Department of Science and Technology
Chair, National Committee on Biosafety of the Philippines


SECRETARY WILLIAM D. DAR

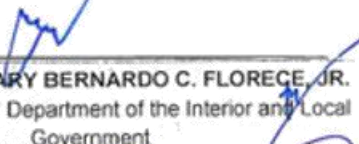
Department of Agriculture


SECRETARY ROY A. CIMATU

Department of Environment and Natural Resources

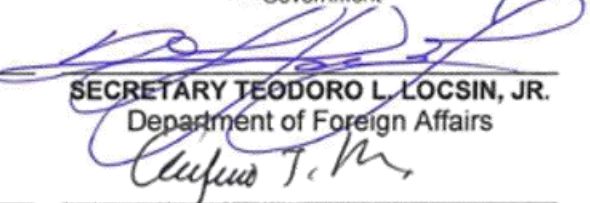

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Department of Health


UNDERSECRETARY BERNARDO C. FLORECE, JR.
Officer-In-Charge, Department of the Interior and Local Government

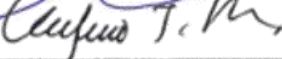

SECRETARY RAMON M. LOPEZ

Department of Trade and Industry

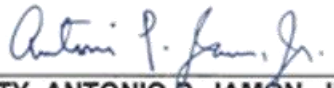

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Environmental Scientist Member


DR. EUFEMIO T. RASCO, JR.
Biological Scientist Member


DR. MA. CRISTINA D. PADOLINA
Physical Scientist Member


ATTY. ANTONIO P. JAMON, JR.
Consumer Representative


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Industry Representative

ON LEAVE
RET. GEN. MARCELO C. BLANDO
Community Representative



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MEMORANDUM CIRCULAR

No. 08

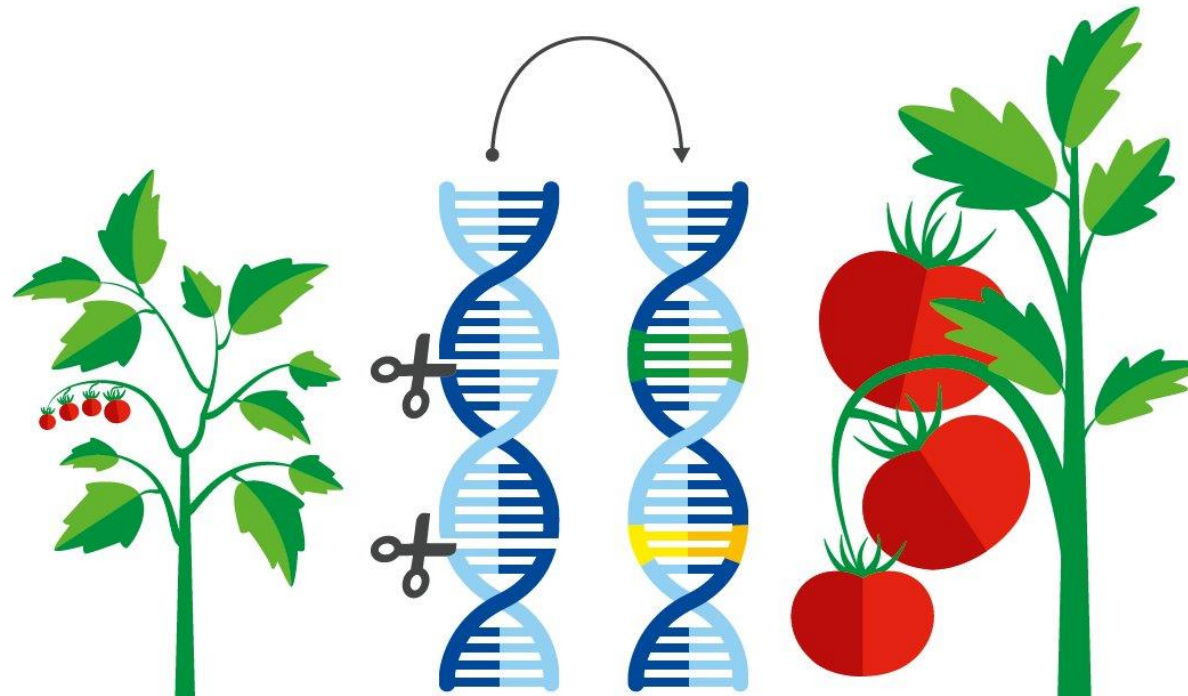
Series of 2022

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**

Issuance of DA MC No.08, Series of 2022

Plant Breeding Innovations (PBIs)

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



General Classification of Products of PBIs

Genetically Modified Organisms (GMOs)

- obtained through the use of modern biotechnology
- **contain novel combination** of genetic material

Defined by NCBP as a resultant genetic combination in living organism that is not possible through conventional breeding



Non-GMOs or Conventional Products

- obtained through the use of modern biotechnology
- **do not contain a novel combination** of genetic material in the final product

NCBP Resolution No.1, s2020 established that

- **only PBI-derived GM plants and plant products would be regulated under the JDC1**
- **PBI-derived GM plants and plant products would not be regulated under the said Circular**

Covered under JDC1, s2021?



Technical Consultation for Evaluation and Determination (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 a TCED?

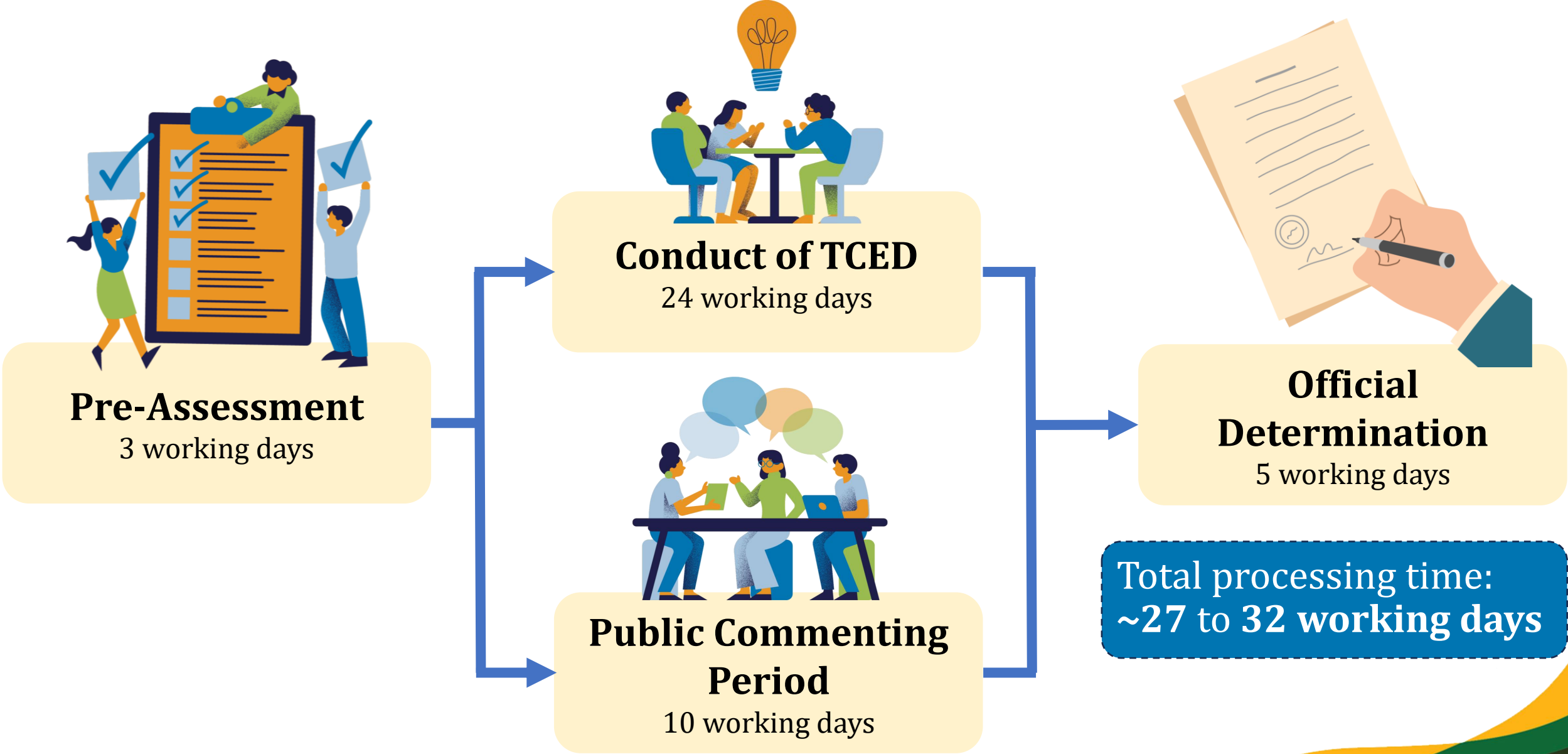
A **Product developer** refers to the natural or juridical person who developed the PBI product submitted for the determination of its regulatory status.

May include:

- 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



Submission of Request for TCED

Submission Requirements

- Printed and electronic copy of the TCED Request Form
- Accomplished Prior Evaluation Form (PEF)
- Scientific Studies, experimental evidence, and other documents to support the claims in the PEF



Acceptance of Submission

- The BPI Biotechnology Office reviews the sufficiency of the submission in form and substance
- If the submission **complies with the format and contains all the required information**, the **submission shall be officially accepted**
- The submission shall be forwarded to the BCT-PBI within 3 working days upon acceptance

**Technical Consultation for
Evaluation and Determination
(TCED) Request Form**

(Date)

The Director
Bureau of Plant Industry

Sir/Madame:

We –

Information	Product Developer	Agent (if applicable)	Representative of Agent (if applicable)
Name			
Address			
Tel. No.			
Fax No.			
Email Address			

hereby request for the conduct of a Technical Consultation for Evaluation and Determination (TCED) for the plant/product of Plant Breeding Innovation (PBI) described below:

Name of the PBI Product	
Identification of the PBI Product (organism)	Scientific Name:
	Common Name:
Phenotypic feature before and after genetic change (Explain in detail.)	

The following supporting documents are attached:

1. Accomplished Prior Evaluation Form (PEF)
2. Scientific studies, experimental evidences, and other documents to support claims in the PEF
3. Proof of payment of fees.

The undersigned certifies that based on his/her personal knowledge and/or authentic documents: (i) all the information in this request form and accompanying submission are true and correct; (ii) the submission contains all information and views on which to base a decision and includes relevant data and information known to the product developer which are unfavorable to the submission.

(Printed Name and Signature of Developer/Agent/Authorized Representative)

Republic of the Philippines)

SUBSCRIBED AND SWORN TO before me this ____ day of _____,
202__, affiant exhibiting to me his/her Community Tax Certificate No. _____
issued on _____ at _____.

Doc. No. ____;
Page No. ____;
NOTARY PUBLIC Book No. ____;
Series of 202__.

Prior Evaluation Form (PEF) for Products of Plant Breeding Innovation (PBI)

Part I. Background Information	
1. Name of Product Developer	
2. Office Address	
3. Telephone Number	
4. Email Address	
5. Website (if any)	
6. Name of Agent	
7. Position	
8. Mobile Number	
9. Email Address	

Part II. Description of the PBI Product	
1. Name of the PBI Product	
2. Identification of the PBI Product (organism)	Scientific Name:
	Common Name:
3. Phenotypic feature before and after genetic change (Explain in detail.)	

Part III. Description of the Plant Breeding Innovation (PBI) Procedure Used (To Be Used)		Reference/s (If Applicable)
1. Purpose of the PBI		
2. PBI procedure	<input type="checkbox"/> Oligonucleotide-directed mutagenesis (ODM) <input type="checkbox"/> Site-directed nuclease 1 (SDN1) <input type="checkbox"/> Site-directed nuclease 2 (SDN2) <input type="checkbox"/> Site-directed nuclease 3 (SDN3) cis insert <input type="checkbox"/> Site-directed nuclease 3 (SDN3) with trans insert <input type="checkbox"/> Cisgenesis <input type="checkbox"/> Intragenesis <input type="checkbox"/> RNA-dependent DNA methylation (RdDM)	

	<input type="checkbox"/> Reverse breeding <input type="checkbox"/> Agro-inoculation of non-germline tissues <input type="checkbox"/> Agro-inoculation of germline tissues with cis insert <input type="checkbox"/> Agro-inoculation of germline tissues with trans insert <input type="checkbox"/> Agro-infiltration <input type="checkbox"/> Grafting with GM material <input type="checkbox"/> Synthetic genomics with cis-like sequence integration or faithful genome reconstruction <input type="checkbox"/> Synthetic genomics with trans-like sequence integration <input type="checkbox"/> Others: _____	
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3. Genetic change in the organism		
a. Name of the molecular tools used		
b. Description and nucleotide sequence of the molecular tools used		
	i. Guide RNA ii. Nuclease iii. Nucleotide sequence to be introduced (if applicable) iv. Vectors (if applicable) v. Selection markers (if applicable) vi. Reporter gene (if applicable)	
c. Delivery system	<input type="checkbox"/> Agrobacterium-mediated <input type="checkbox"/> Particle bombardment/biolytic method <input type="checkbox"/> Floral-dip <input type="checkbox"/> PEG-mediated protoplast method <input type="checkbox"/> Others (specify) _____	
d. Nature of DNA changes	Original sequences (underline target bases): _____ Sequences after gene editing (underline new bases): _____	

Conduct of the TCED



Schedule of Meetings

- **1st TCED meeting:** within **7 working days upon receipt** of the officially accepted submission
- **2nd TCED meeting:** within **5 working days from the 1st TCED meeting**, if there are additional concerns that require further discussion

Maximum of two TCED meetings

Role of Product Developer

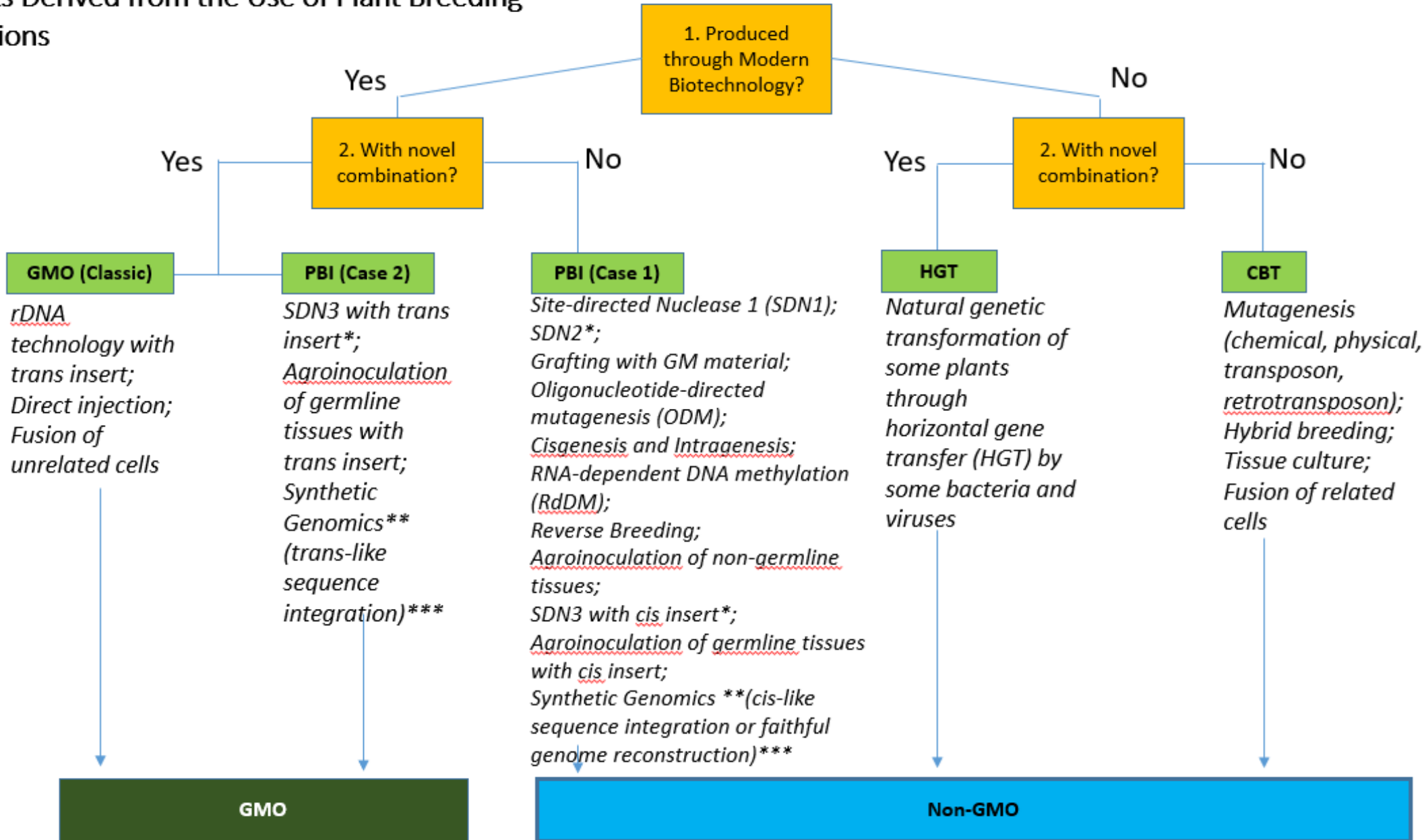
- The product developer or an authorized representative **should be available to join** the TCED meeting(s) **in-person or online**
- In case a **2nd TCED meeting** is arranged, the product developer shall **provide additional information and other studies within 5 working days** to complete the evaluation

Technical Determination

The TCED Group shall make its **technical determination** at the conclusion of the TCED.

The **BPI Biotechnology Office** shall **endorse the technical determination** to the Director of BPI within **7 working days** after the conduct of TCED.

Decision Tree on the Regulation of Plants and Plant Products Derived from the Use of Plant Breeding Innovations



Techniques listed under PBI Case 1 and Case 2 may expand as new technologies emerge. Any PBI technique must potentially produce a non-GM or both non-GM and GM plant as a final product..

*Includes the new CRISPR-CAS with Prime Editing (Science, 2019) ** Different from Synthetic Biology which specializes on artificial organisms ***Pertains to a largely synthetic assembled genome

Prior Evaluation Form (PEF) for Products of Plant Breeding Innovation (PBI)

For the Biotech Core Team-Plant Breeding Innovation (BCT-PBI) TCED Group:

Please check the appropriate box.

	Determined that the PBI Product is not a GMO and does not fall under the scope and coverage of the JDC1, s2021 based on the scientific evidence(s) presented by the Product Developer.
	Determined that the PBI Product is a GMO and falls under the scope and coverage of the JDC1, s2021 based on the scientific evidence(s) presented by the Product Developer.

<i>Printed Name</i>	<i>Signature</i>	<i>Date</i>



Public Commenting Period

An officially accepted submission shall be immediately **posted on the BPI website**



The public may submit to the Director of BPI any **technical information** on the submission within **10 working days** upon posting

Public submission is **limited to technical information only**

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 the PBI product is officially 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**

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 issued document which indicates 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

Appeal

An aggrieved party may **file an appeal** with the **DA Secretary** **within 15 days** from the receipt of the product developer of the decision or posting on the BPI website of the Certificate of Non-Coverage

Salient Points of the DA MC No.08, s2022

- It prescribes a product-based approach on the determination

The evaluation and determination focuses on the nature of genetic changes present in the product.

- It is not a regulation on product safety

JDC No.01, s2021 → evaluation of safety of GM plants for human and animal health, and the environment

DA MC No.08, s2022 → evaluation and determination if the PBI product is a GM plant/product

- There are two types of determination on the regulatory status of the PBI product

Technical determination → by TCED group (accomplished PEF and report to be submitted to BPI Director)

Official determination → by BPI Director (also considers technical information from public)



Department of Agriculture
Bureau of Plant Industry
Biotechnology Office

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Thank you!