



Bureau of Plant Industry
OPERATIONAL PROCEDURES

Document No.: BPI-QMS-BIOTECH-OP11

Preparation Date: June 14, 2024

Revision No.: 0

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Operating Unit: Biotechnology Office

Subject: **OPERATIONALIZATION OF TECHNICAL CONSULTATION FOR EVALUATION AND DETERMINATION FOR PRODUCTS OF PLANT BREEDING INNOVATIONS (PBI) COVERED UNDER THE DOST-DA-DENR-DOH-DILG JOINT DEPARTMENT CIRCULAR NO.01, S2021 BASED ON THE NCBP RESOLUTION NO. 01, S2020**

1.0 Objective

To conduct a Technical Consultation for Evaluation and Determination (TCED) when products of plant breeding innovations are covered under the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 01, s2021, and make an official determination on the regulatory status of the product.

2.0 Scope

This procedure starts from the receipt of the request for TCED with supporting documents submitted by the product developer, acceptance of the submission, conduct of TCED, and ends with the document or issuance indicating the official determination on the regulatory status of the product.


3.0 Definition of Terms

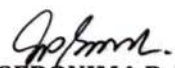
BPI Biotechnology Core Team - Breeding Innovation (BCT-PBI)

Composed of qualified technical staff of BPI and chaired by the Assistant Director for Regulatory Services. BCT-PBI shall be responsible for the conduct of the TCED and supervise all activities related to DA Memorandum Circular No. 08, s2022

Certificate of Non-Coverage from the JDC No. 01, s2021

A document granted to a PBI product when it is officially determined as non-GMO after the conduct of TCED. It covers the novel characteristic introduced in the current variety and its subsequent progenies and extends to all germplasm or genetic backgrounds that will contain such characteristic produced by the product developer and/or its licensees in further breeding

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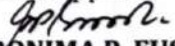
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External expert	Refers to an individual with expertise on genetics, molecular biology, molecular breeding, bioinformatics, and related disciplines that is appointed by the Chair of the BCT-PBI. He/she must not be an official staff or employee of the Department of Agriculture or any of its attached agencies. Further, he/she must not be directly or indirectly employed by or engaged with a company or institution with pending submissions of request for determination covered by DA MC No. 08, s2022
Genetically modified organisms (GMOs)	Refers to organisms that contain a novel combination of genetic material obtained through the use of modern biotechnology but unattainable through conventional breeding
Non-GMOs or conventional products	Refers to plants and/or plant products that do not contain a novel combination of genetic material in the final product
Plant Breeding Innovations (PBIs)	Refers to novel techniques that employ molecular, genomic, 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
Product Developer (PD)	Refers to a natural or juridical person who developed the PBI product submitted for the evaluation and determination of its regulatory status under the JDC1, s2021 and may include: a) any of the departments or agencies of the Philippine Government; b) a university with research institutions in the Philippines; c) an international research organization duly recognized by the Philippine government; d) a corporation registered with the Securities and Exchange Commission of the Philippines; or e) a cooperative registered with the Cooperative Development Authority of the Philippines

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Technical Consultation for Evaluation and Determination (TCED) Group

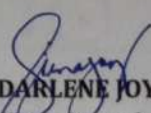
Composed of three (3) members, with at least two (2) members from the BCT-PBI selected based on availability and the other member appointed by the Chair of the BCT-PBI as an external expert. They shall be responsible for the conduct of the technical evaluation and determination on the regulatory status of the PBI product under the JDC No. 01, s2021.

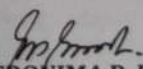
Technical Consultation for Evaluation and Determination

Refers to the technical evaluation of the PBI product to determine whether or not the final product of the plant breeding process employed to produce the PBI product contains a novel combination of genetic material obtained through the use of modern biotechnology

Official Determination

Refers to the final authoritative decision on the regulatory status of the PBI product under the JDC No. 01, s2021 as determined by the BPI Director

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4.0 Procedure

FLOW	PERSON/UNIT RESPONSIBLE	DETAILS
<pre> graph TD START([START]) --> A[Submission of Request for TCED with supporting documents] A --> B[Receiving and Evaluation of the completeness of submitted documents] B --> C{COMPLETE?} C -- NO --> D[Return to product developer] D -.-> A C -- YES --> E[Issuance of Acceptance Letter for the submission] E --> F[Endorsement of submission to BCT-PBI] E --> G[Posting of accepted submission on BPI website] F --> H[Selection of TCED group members] H --> A((A)) G --> B((B)) </pre>	<p>Product Developer</p>	<p>Submission of the application requirements to the Biotechnology Office:</p> <ol style="list-style-type: none"> 1. Printed and electronic copy of the accomplished TCED Request Form 2. Accomplished Prior Evaluation Form (PEF) 3. Scientific studies, experimental evidence, and other documents to support claims in the PEF 4. Proof of payment of processing fee
	<p>Biotechnology Office</p>	<p>Receiving and checking of the sufficiency in form and substance of requirements. No application shall be formally accepted unless documentation is complete.</p> <p>The applicant will be advised if the application is accepted or if there are lacking documents.</p>
<p>Issuance of Acceptance Letter for the submission</p> <p>Endorsement of submission to BCT-PBI</p> <p>Posting of accepted submission on BPI website</p> <p>Selection of TCED group members</p> <p>(A)</p> <p>(B)</p>	<p>Biotechnology Office</p> <p>TCED Group</p> <p>Product Developer</p>	<p>If the submission is sufficient, BPI shall issue an acceptance letter to the product developer and:</p> <p>A. 1. Forward the submission to the BCT-PBI within 3 working days upon acceptance for the constitution of the TCED Group.</p> <p>A. 2. The TCED Group, composed of 2 members from the BCT-PBI and 1 member as an external expert, shall convene within 7 working days upon official</p>

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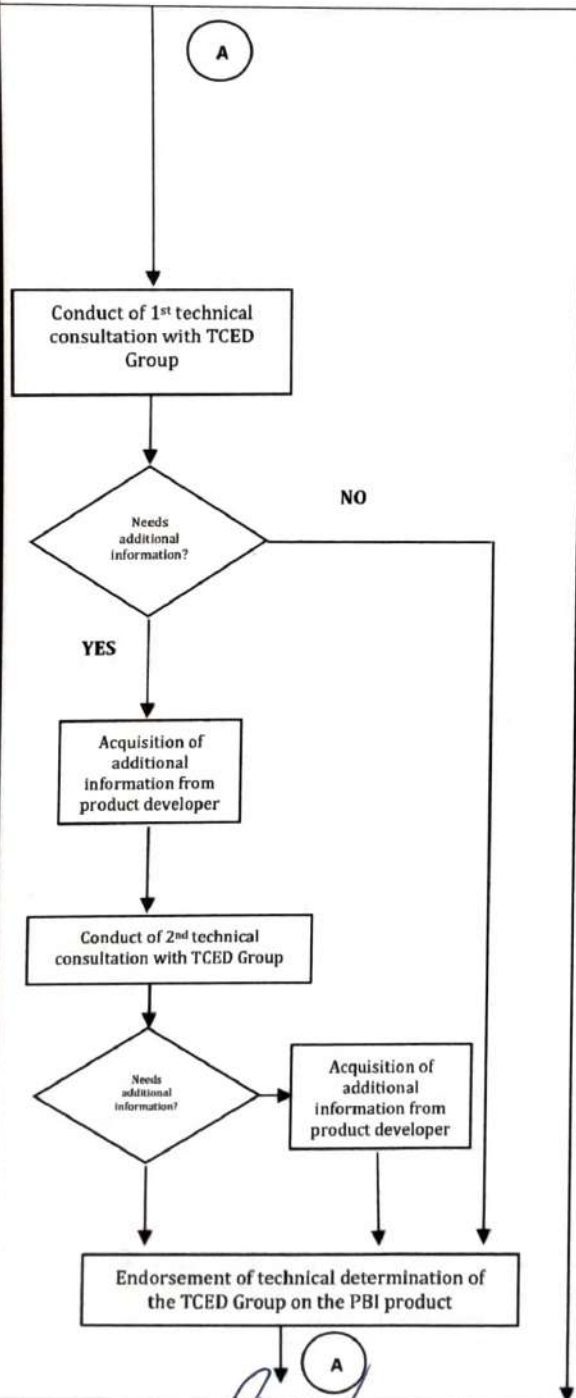
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Chair of BCT-PBI
Product Developer
Biotechnology Office

acceptance of documents. The Chair of the BCT-PBI shall invite the product developer to be available for presentation and clarification on the submission during the scheduled technical consultation.

A. 3. The TCED Group shall discuss and review the submission, particularly the PEF and supporting documents, for the evaluation of the PBI product. Where appropriate, the TCED Group shall verify if there is sufficient scientific evidence on the absence of event(s) transiently used in the breeding process.

A. 4. Within 5 working days from the first technical consultation, the TCED Group may set a second consultation if there are additional concerns that require further discussion. In such a case, the Chair of the BCT-PBI shall immediately communicate to the product developer the need to provide additional information and other studies to complete the evaluation. This information must be provided by the developer within 5 working days.

A. 5. The TCED Group shall make a technical determination on the regulatory status of the PBI product under the JDC No. 01, s2021. This shall be indicated in the appropriate section of the PEF for evaluators.

A. 6. The BPI shall document the discussions of the TCED Group during the conduct of the TCED.

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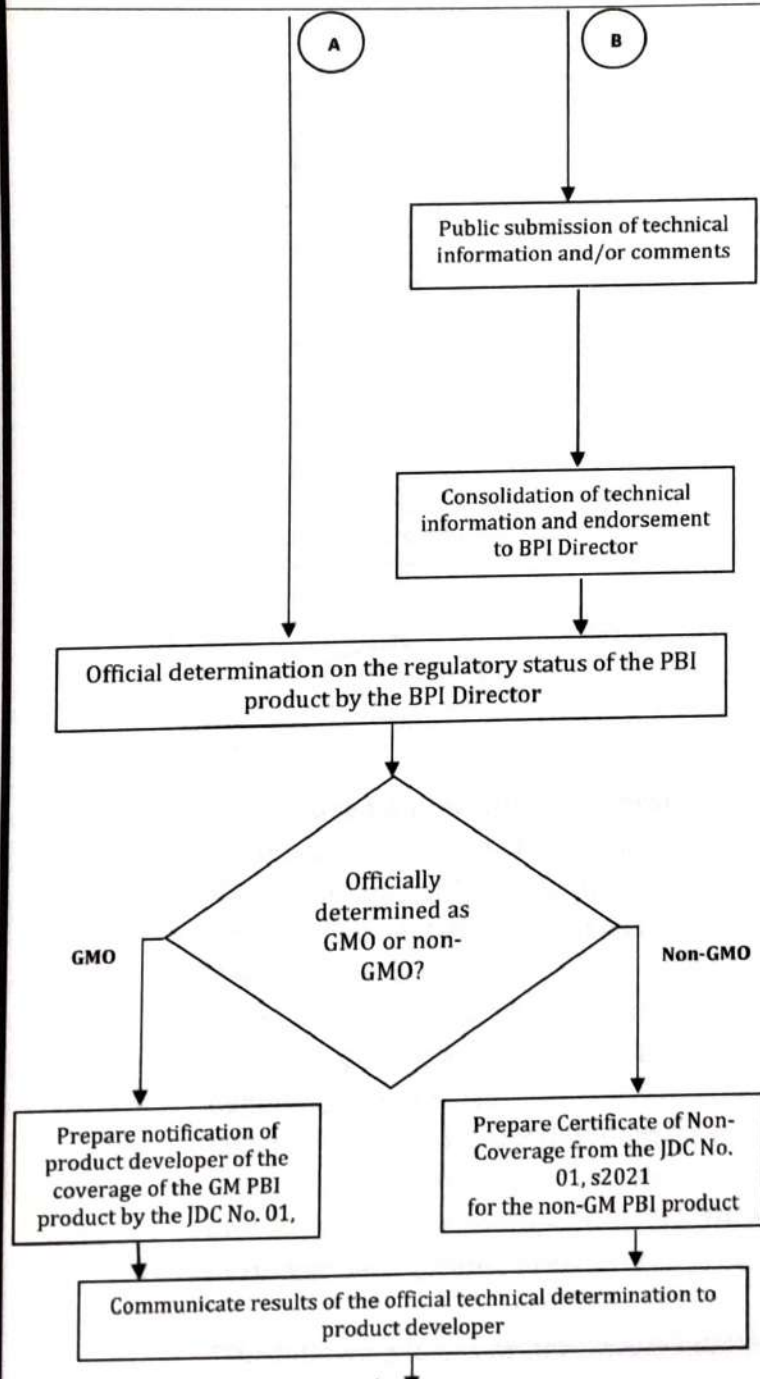
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Biotechnology Office

The accomplished PEF indicating the technical determination of the TCED Group on the PBI product shall be endorsed to the Director of BPI within 7 working days after the conclusion of the TCED.

B. 1. Immediately post the accepted submission on the BPI website. The public may submit any technical information on the submission to the BPI Director within 10 days upon posting.

B. 2. The BPI shall consolidate and endorse the technical information sent by the public to the BPI Director.

Director of BPI

The Director of BPI shall make the official determination on the regulatory status of the PBI product under the JDC No.01, s2021, considering any additional technical information from the public, within 5 working days from the receipt of the accomplished PEF from the TCED Group.

Biotechnology Office

If the PBI product is officially determined as a GMO, BPI shall inform the product developer in writing that the GM PBI product is under the scope and coverage of the JDC No. 01, s2021. BPI shall also advise the product developer to proceed with the application process under the JDC No. 01, s2021 should the developer desire to secure a biosafety permit for any of the activities and use for regulated articles. The official determination on the regulatory status of the GM PBI product shall

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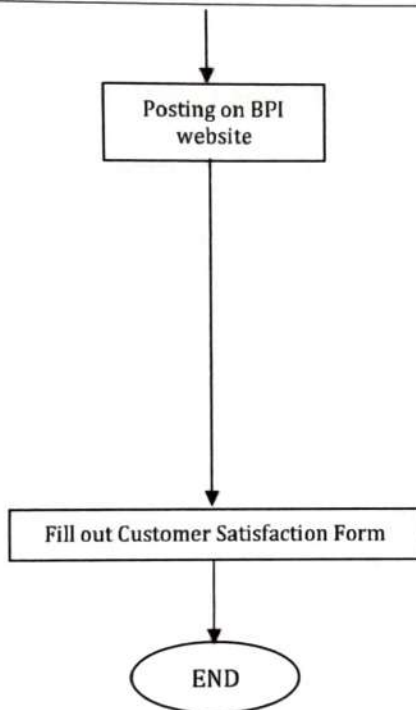
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be made public by posting on the BPI website.

If the PBI product is officially determined as a non-GMO, BPI shall issue to the product developer a Certificate of Non-Coverage from the JDC1, s2021 for the non-GM PBI product, which shall also be made public by posting on the BPI website.

Product developer


Product developer shall fill out the customer satisfactory form

5.0 Forms Used and Records Generated

- Technical Consultation for Evaluation and Determination (TCED) Request Form
- Electronic copy of TCED Request Form
- Proof of Payment of Processing Fee
- Acknowledgement letter
- Communication letters/correspondence*
- Technical Consultation for Evaluation and Determination (TCED) Group External Expert Selection Form*
- Consolidated Report of Public Comments*
- Prior Evaluation Form (PEF) for Products of Plant Breeding Innovation (PBI)
- Certificate of Non-Coverage from the JDC No. 01, s2021*
- Customer Satisfaction Form

*The following forms or documents may be generated as needed.

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6.0 References

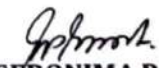
Department of Agriculture Memorandum Circular No. 08, Series of 2022

7.0 Effectivity

The effectivity date of this document shall be five (5) working days after the approval by the authorized signatory.



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