



Bureau of Plant Industry
PROCEDURES MANUAL

Document No.: BPI-QMS-BIOTECH-OP9

Preparation Date: August 9, 2022

Revision No.: 0

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Operating Unit: BIOTECHNOLOGY OFFICE

Subject: OPERATIONALIZATION OF THE LISTING OF STACKED EVENTS PRODUCED THROUGH CONVENTIONAL BREEDING IN THE BPI APPROVAL REGISTRY FOR COMMERCIAL PROPAGATION

1.0 Objective: This manual of procedure aims to provide guidance to the Bureau of Plant Industry for the listing of stacked events in the BPI Approval Registry for Commercial Propagation and Direct Use under the new DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, series of 2021 (JDC No. 1, s2021), with reference to the Memorandum signed on May 4, 2022 titled "Procedure for Listing of Stacked Traits in the Approval Registry for Propagation and Approval Registry for Direct Use."

2.0 Scope: This manual includes a step-by-step procedure for the listing of stacked events in the approval registry for commercial propagation and direct use starting from the receipt of the request submitted by the applicant to the listing of the stacked events in the approval registry.

3.0 Definition of Terms

"Applicant" – refers to the juridical person who, for the duration of the proposed activity, has control over the importation or release into the environment of a regulated article and shall ensure compliance with all the requirements in this Circular and the conditions specified in the relevant permit. An applicant may be: (1) any of the departments or agencies of the Philippine Government; (2) a university-based research institution in the Philippines; (3) an international research organization duly recognized by the Philippine Government and based in the Philippines, subject to terms and conditions agreed between the organization and the government of the Philippines; (4) a corporation registered with the Securities and Exchange Commission of the Philippines; or (5) a cooperative registered with the Cooperative Development Authority of the Philippines

"Biosafety" – refers to the condition in which the probability of harm, injury and damage resulting from the unintentional introduction and/or use of a regulated article is within acceptable and manageable levels.

"Genetically modified organism (GMO)" – also refers to "living modified organism" under the Cartagena Protocol on Biosafety and refers to any living organism that

Prepared by: BPI Biotechnology Secretariat

Approved by: OIC-Head

Date signed: 08-11-22

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possesses a novel combination of genetic material obtained through the use of modern biotechnology.

“Stacked events” – refer to genetically modified plants and their products that have been developed through conventional breeding using multiple transformation events encoding several proteins that confer specific traits.

4.0 Procedure

FLOW CHART	RESPONSIBLE PERSON/UNIT	DETAILED PROCESS
	Applicant	<p>The applicant shall submit a request letter to the Biotechnology Secretariat for the listing of stacked traits in the BPI Approval Registry for Commercial Propagation.</p> <p>*If in case one of the individual events contained in the stacked is owned by another technology developer, the applicant is required to present proof of authority to use the event*</p>
	Biotechnology Secretariat	<p>The Biotechnology Secretariat shall receive the applicant's request and verify the validity of individual stacked events of the Biosafety Permits for Commercial Propagation/ Direct Use of the individual events.</p>
	BPI Director and Biotechnology Secretariat	<p>The Director shall approve the request for listing in the BPI Approval Registry for Propagation only if each parental or component single event has a Biosafety Permit for Commercial Propagation.</p> <p>If approved, the Biotechnology Secretariat shall inform the applicant for the listing of the stacked events in the BPI Approval Registry through a formal communication letter signed by the BPI Director.</p>

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If disapproved, the Biotechnology Secretariat shall inform the applicant for the decision and any lacking documents for compliance.

5.0 Forms Used and Records Generated

- Request Form from the Applicant
- Proof of Authority to Use Event
- Biosafety Permits for Commercial Propagation/ Direct Use
- Decision Letter from BPI
- Updated BPI Approval Registry

6.0 Effectivity Date

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

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