



Bureau of Plant Industry
OPERATIONAL PROCEDURES

Document No.: BPI-QMS-BIOTECH-OP9

Preparation Date: February 22, 2023

Revision No.: 1

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Operating Unit: BIOTECHNOLOGY

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

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 intentional and unintentional introduction and/or use of a regulated article is within acceptable and manageable levels;

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MARCH 24, 2023



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Commercial propagation

Refers to the introduction or delivery for introduction into commerce of a regulated article for regeneration into plants or plant products for consumption by humans or animals;

Genetically Modified Organism (GMO)

Also refers to "living modified organism" under the Cartagena Protocol on Biosafety and refers to any living organism that 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 Detail

FLOW	PERSON/UNIT RESPONSIBLE	DETAILS
<pre> graph TD Start([START]) --> Step1[Submission of the request for listing of stacked events in the BPI Approval Registry for Commercial Propagation or for Direct Use] Step1 --> Step2[Receiving of request and verification of the validity of Biosafety Permits for Commercial Propagation/ Direct Use of the individual events] </pre>	Applicant	<p>The applicant shall submit a request letter to the Biotechnology for the listing of stacked traits in the BPI Approval Registry for Commercial Propagation and for direct use.</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> <p>* Proposed IRM Plan subject to the approval of IRMAT and BPI, if applicable</p>
	Biotechnology Office	<p>The Biotechnology Office 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>

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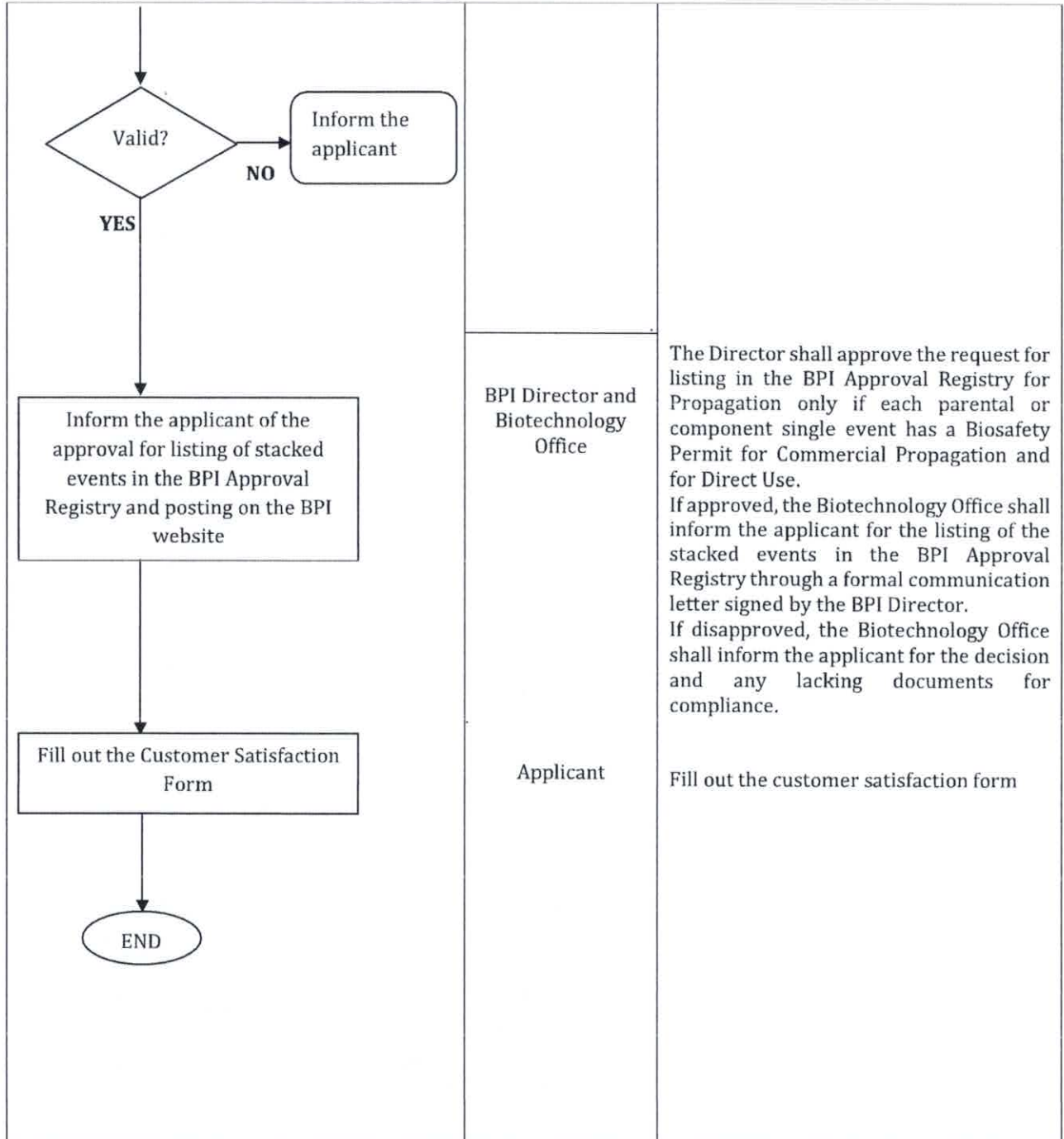
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5.0 Forms Used and Records Generated

Request Form from the Applicant
Proof of Authority to Use Event (e.g. Letter of Authorization (LOA))
Biosafety Permits for Commercial Propagation/ Direct Use
Insect Resistance Management Plan (if applicable)
Decision Letter from BPI
Updated BPI Approval Registry

6.0 References

None

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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