1.0 Objective:

To issue biosafety permit for commercial propagation

2.0 Scope

This procedure starts from the receipt of the application submitted by the applicant, recording, risk assessment process, and ends with the issuance of biosafety permit for commercial propagation the applicant.

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
Biological diversity or Biodiversity	Refers to the variability among living organisms from all sources including, among others, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystem;
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;
Biosafety Permit	A document issued by BPI which signifies that the regulated article has been approved for Direct Use, Commercial Propagation, or Field Trial;

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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;
Joint Assessment Group	Refers to the qualified representatives from DOST-BC, DA-BC, DENR-BC and DOH-BC, who shall evaluate GM applications and determine whether a regulated article does not pose greater risk to human health and the environment compared to its conventional counterpart;
National Committee on Biosafety of the Philippines (NCBP)	Refers to the lead body tasked to coordinate and harmonize inter-agency and multisectoral efforts to develop biosafety policies and set scientific, technical and procedural standards on actions by agencies and other sectors to: (1) promote biosafety in the Philippines; (2) oversee the implementation of the National Biosafety Framework; (3)act as a clearing house for biosafety matters; and (4)coordinate and harmonize the efforts of all concerned agencies and departments in this regard;
Insect Resistance Management (IRM) Plan	Refers to the proposed management plan to delay and monitor the resistance of target organism of GM events with insect resistance trait(s);
Insect Resistance Management Advisory Team (IRMAT)	Serves as the scientific and technical advisory group on IRM matters to the Department of Agriculture (DA) and shall be tasked to provide technical advice to the DA and Bureau of Plant Industry (BPI);
Plant-incorporated protectant (PIP)	Refers to pesticidal substance produced by plants and the genetic material necessary for the plant to produce the substance;
Public information sheet (PIS)	A document required by the BPI for the processing of application which aims to inform the public of the GM application, usually posted in a newspaper;
Risk assessment	Refers to the procedure that identifies, evaluates and predicts the occurrence of possible hazards to human and animal health and the environment;
Single Event	A transformation event containing one or several proteins but is only considered as one transformation event.

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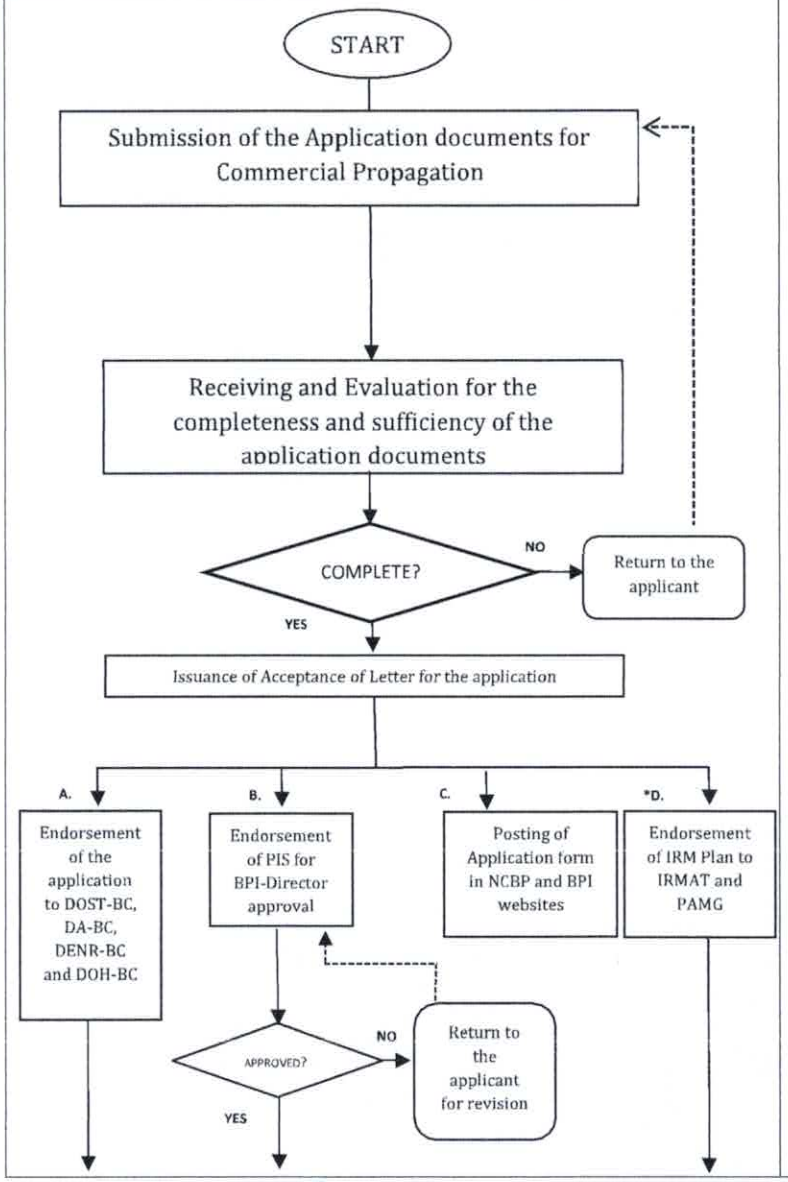
4.0 Procedure

FLOW CHART FOR APPLICATION FOR COMMERCIAL PROPAGATION (SINGLE EVENT)	RESPONSIBLE PERSON/UNIT	DETAILED PROCESS
	Applicant Biotechnology Office	Submission of the following requirements to the Biotechnology Office: 1. Application form 2. Technical dossiers 3. Risk Assessment Report 4. Proposed Public Information Sheet 5. Insect Resistance Management (IRM) Plan, if the applied GM event has insect resistance trait 6. Proof of payment Receiving and checking of completeness of required forms for the application. No application shall be formally accepted unless documentation is complete. The applicant will be advised if the application is accepted or if there are lacking documents.

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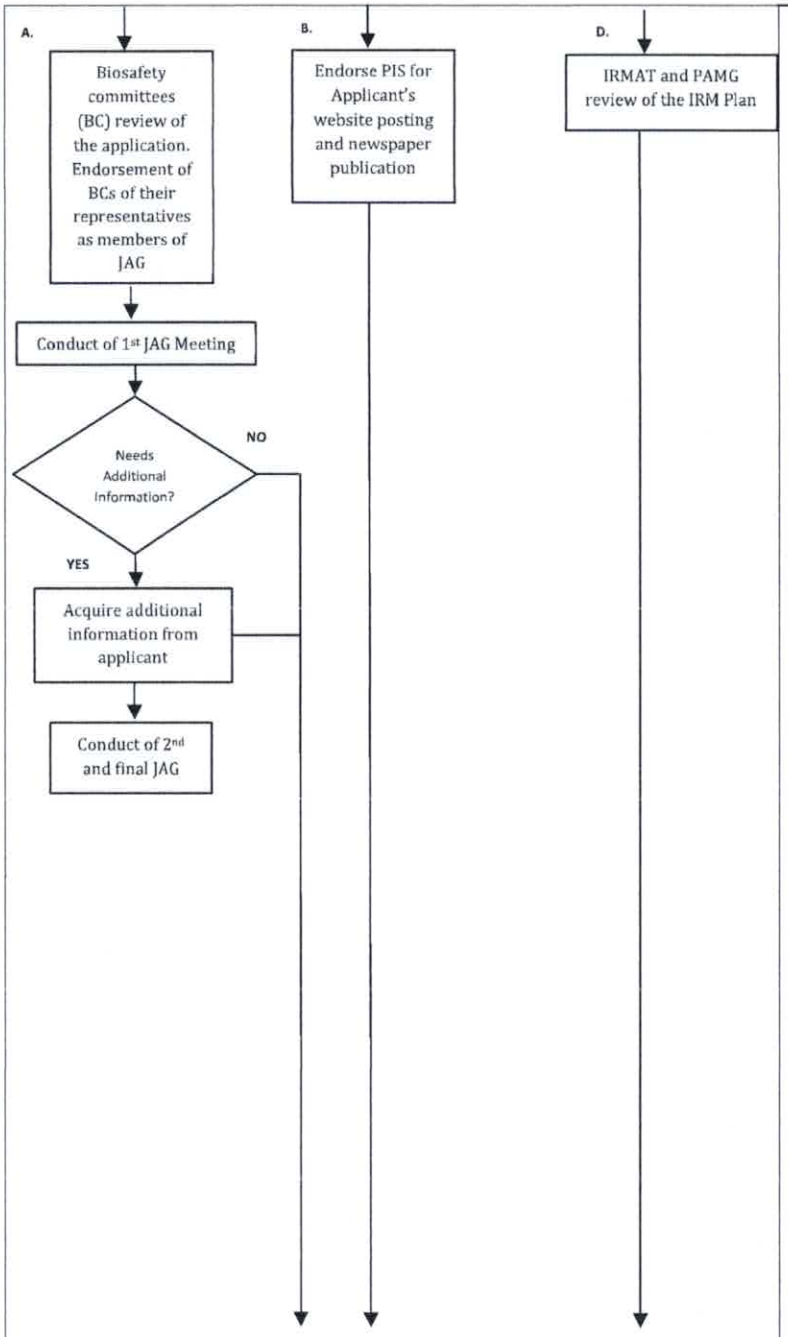

Biotechnology Office Applicant Biosafety Committees (DOST, DA, DENR, DOH)	If the application is sufficient, the BPI shall inform the applicant and: A. 1. Forward the application to the Biosafety Committees (BCs) of DOST, DA, DENR, and DOH for the initial biosafety assessment of the application. This shall be accomplished within 3 working days after acceptance of application. A. 2. The Joint Assessment Group composed of the elected representatives of the BCs shall convene within 10 working days upon receipt of the application documents. A second and final meeting may be conducted should be deemed necessary. A.3. The applicant shall ensure that an authorized representative is available during the JAG meeting. The need for any additional information will be immediately relayed to the applicant for their response within 5 working days upon receipt of the requested information. A.4. The final recommendation document shall be submitted to the BPI Director within 7 working days after the conclusion of the JAG meeting(s), resolving all requests for additional information and other outstanding issues. B.1.Endorsement of the PIS to the BPI Director for approval or disapproval (within 3 working days after acceptance of application). B.2.Biotechnology office to upload the approved PIS on Biotech website.

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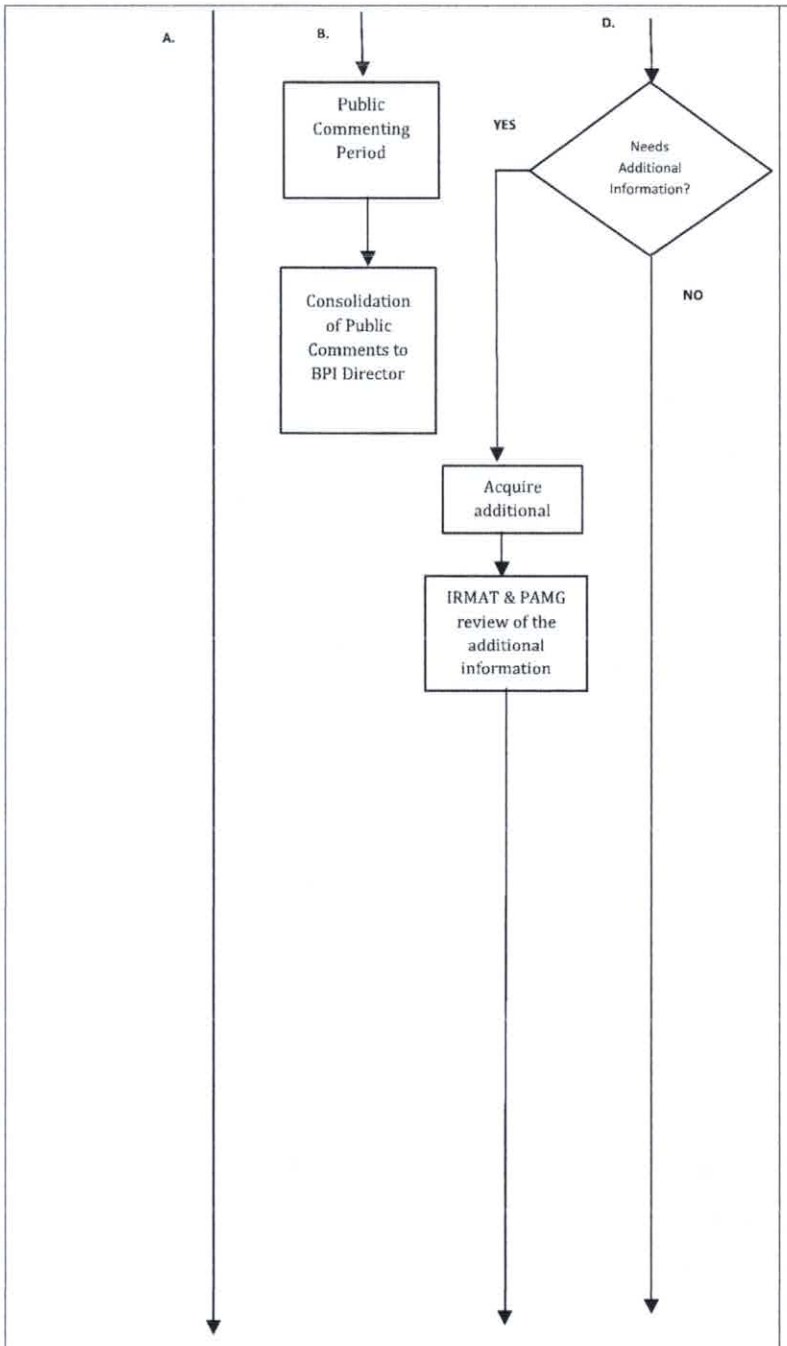

BPI Director

Biotechnology Office

Applicant

B.3. If approved, endorse the approved PIS to the applicant for website posting and newspaper publication. Otherwise, the PIS shall be returned to the applicant for revision.
B.4. The applicant shall post a copy of the approved PIS on their website and publish it in one newspaper of general circulation within 3 working days after receipt of approved PIS.
B.5. The Biotechnology office to consolidate and endorse public comments to the BPI Director within 2 working days after the termination of the commenting period (15 working days after newspaper publication of PIS).

C.1. Upon the receipt of the application, the Biotechnology office shall upload the application form on the Biotech website.
C.2. The Biotechnology office shall inform and request posting of the application to the NCBP website.

*For GM applications with Insect Resistance Trait only.

*D.1 IRMAT Members and the PAMG shall review and evaluate the proposed IRM plan in coordination with the Biotechnology Office
*D.2. Processing time for the IRM plan will be for 20 working days, this prescribed number of days may be extended once for the same number of days, if needed. A written communication will be given to the

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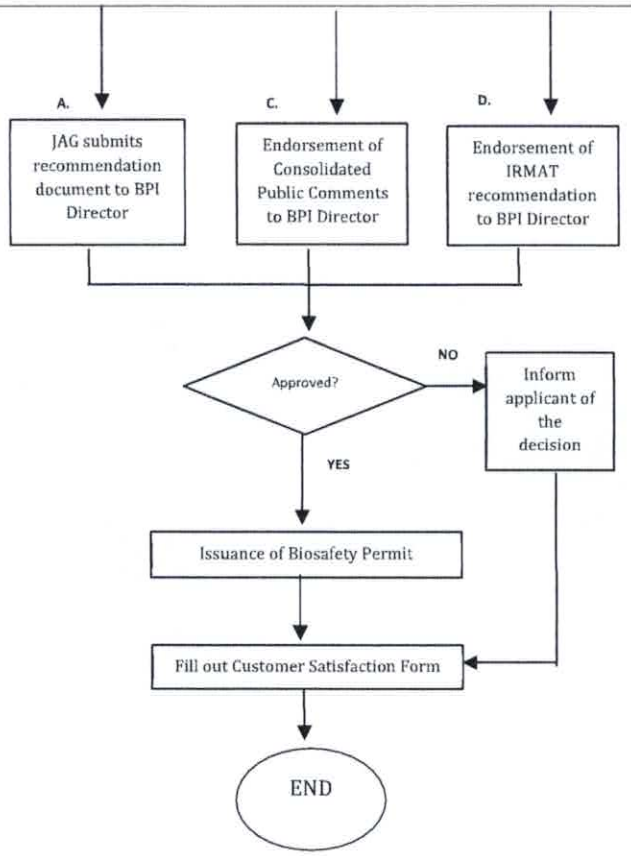

IRMAT, PAMG, and Biotechnology Office	applicant prior to the lapse of processing time. *D.2 The approved IRM plan shall be endorsed to the BPI Director as one of the bases for the issuance of the biosafety permit for commercial propagation
BPI Director	The BPI Director shall make a decision to approve or disapprove the application within five (5) working days upon receipt of the recommendation document from the JAG and consolidated public comments (if available). If approved, the BPI Director shall issue a Biosafety Permit. Otherwise, Biotechnology office will inform the applicant of the decision.
Biotechnology Office	
Applicant	Fill out the Customer Satisfactory Form

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5.0 FORMS USED AND RECORDS GENERATED

APPLICATION FOR BIOSAFETY PERMIT FOR COMMERCIAL PROPAGATION

Application Form
Technical dossiers
Risk Assessment Report Form
Public Information Sheet (PIS)
If PIP, certification from FPA that the applicant is duly licensed as pesticide handler in accordance with PD No. 1144
Proof of Payment for the Application
Electronic copy of submission
Checklist of application requirements
Acknowledgement letter
IRM Plan*
Communication letters/correspondence
Query letters*
PIS Publication
Consolidated Report of Public Comments*
Recommendation Document from JAG
Biosafety permit
Customer Satisfaction Form

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

6.0 References

DOST-DA-DENR-DOH-DILG Joint Department Circular No.1 Series of 2021

7.0 Effectivity

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

Bureau of Plant Industry
CONTROLLED COPY
DC Signature 03-24-23

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