1.0 Objective

To issue biosafety permit applied for direct use as food and feed, or processing for single event.

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 direct use as food and feed, or for processing to 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.
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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Biosafety Permit	A document issued by BPI which signifies that the regulated article has been approved for Direct Use, Commercial Propagation, or Field Trial.
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.
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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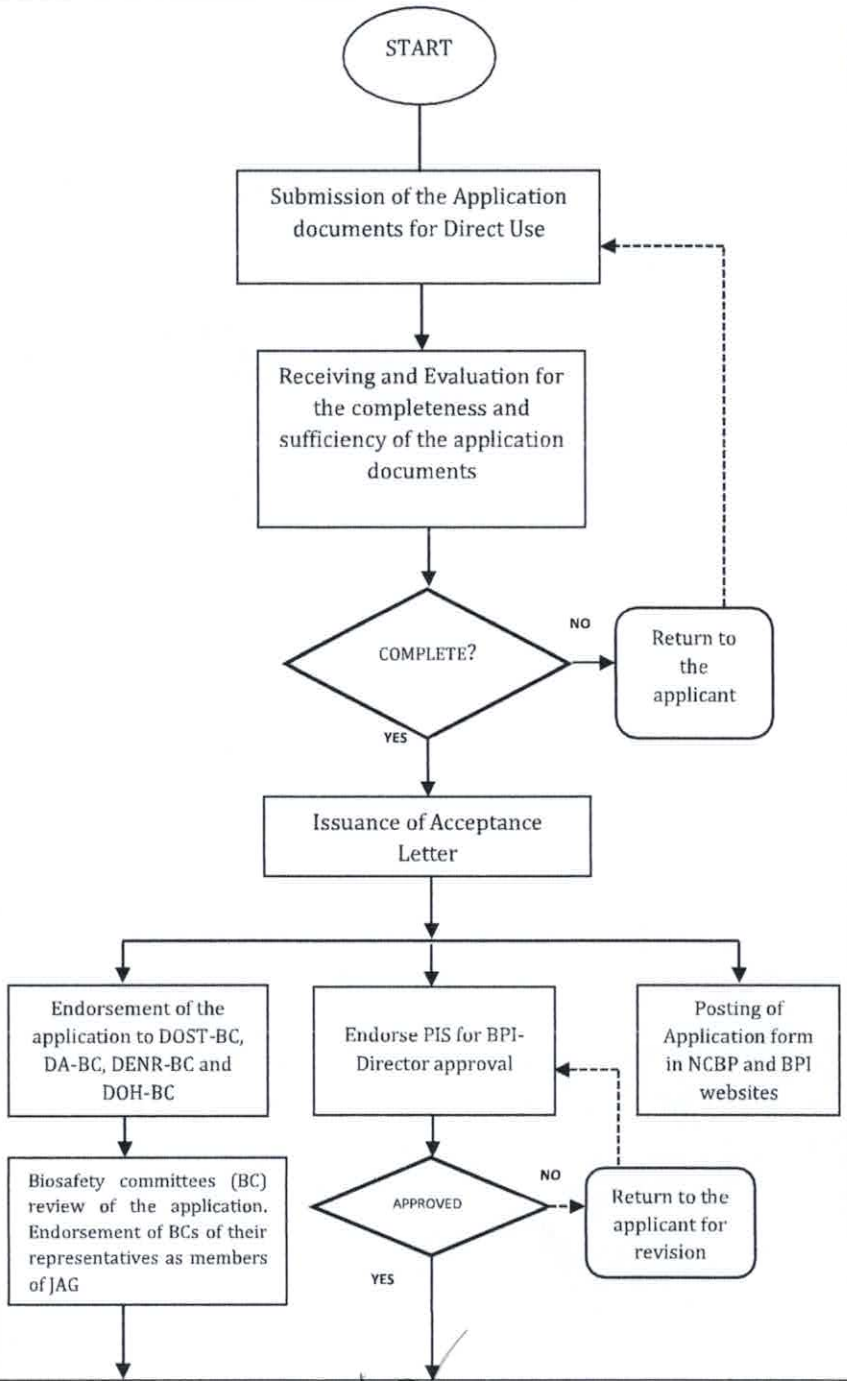
4.0 Procedure Details

FLOW	PERSON/ UNIT RESPON-SIBLE	DETAILS
	Applicant	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. Proof of payment of fees
	Biotech-nology Office	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. If the application is sufficient, the BPI shall inform the applicant and:
	Biosafety Commi-ttees (DOST, DA, DENR, DOH)	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.
	Applicant	

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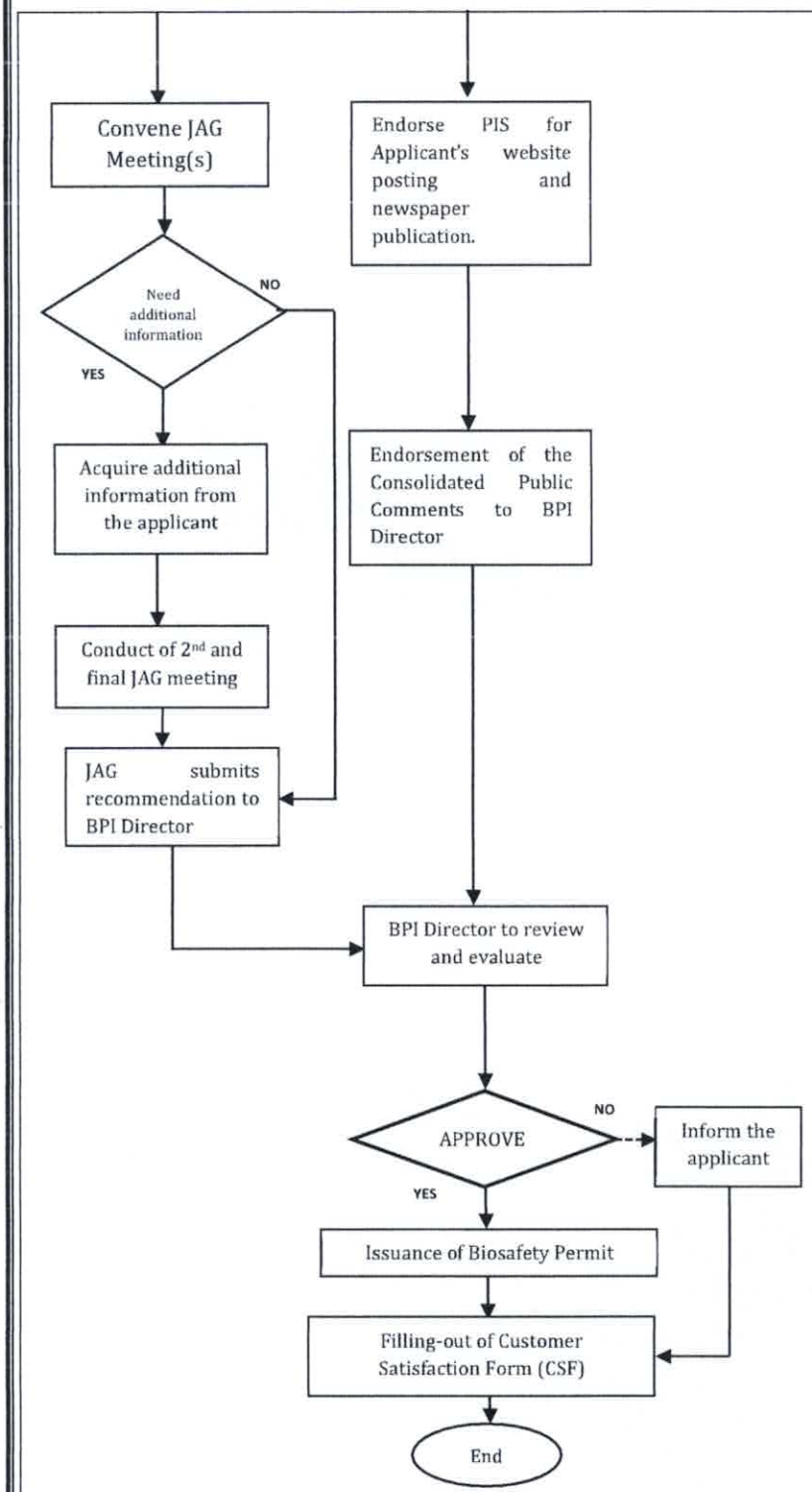

Joint Assess-ment Group	A.2. The Joint Assessment Group composed of the elected representatives of the BCs shall convene within 10 working days upon receipt of the application documents. A second and final meeting may be conducted should be deemed necessary. A.3. The applicant shall ensure that an authorized 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.
BPI Biotech-nology Office	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.Biotech Office to upload the approved PIS on Biotech website.

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	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.
	BPI Biotech-nology Office	B.5. The Biotech 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 Biotech Office shall upload the application form on the Biotech website. C.2. The Biotech Office shall inform and request posting of the application to the NCBP website.
	NCBP	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

	BPI Director	and consolidated public comments (if available). If approved, the BPI Director shall issue a Biosafety Permit. Otherwise, Biotech Office will inform the applicant of the decision.

5.0 Forms Used and Records Generated

Application Form
Technical dossiers
Risk Assessment Report Form
Public Information Sheet (PIS)
Proof of Payment for the Application
Electronic copy of submission
Acknowledgement letter
Checklist of application requirements
Communication letters/correspondence*
Query letters*
PIS Publication
Consolidated Report of Public Comments*
Recommendation Document from JAG
Biosafety permit
Customer Satisfaction Form

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

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.

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