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

2. 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 to the applicant

3. 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

"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;

"Environmental Risk Assessment (ERA)"- refers to the evaluation of the likelihood that adverse effects on the conservation and sustainable use of biological diversity may occur as a result of exposure to a regulated article;

"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;

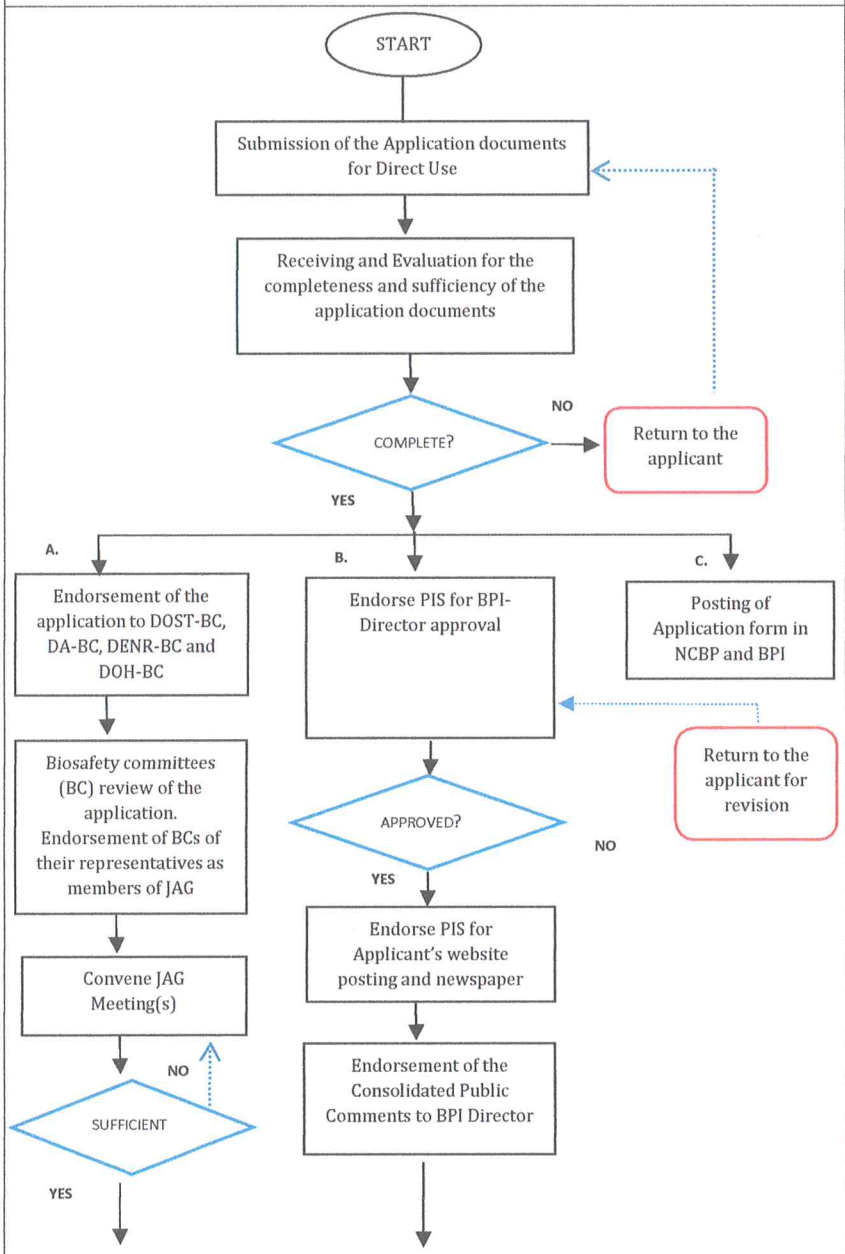
"Plant-incorporated protectant (PIP)" – refers to pesticidal substance produced by plants and the genetic material necessary for the plant to produce the substance;

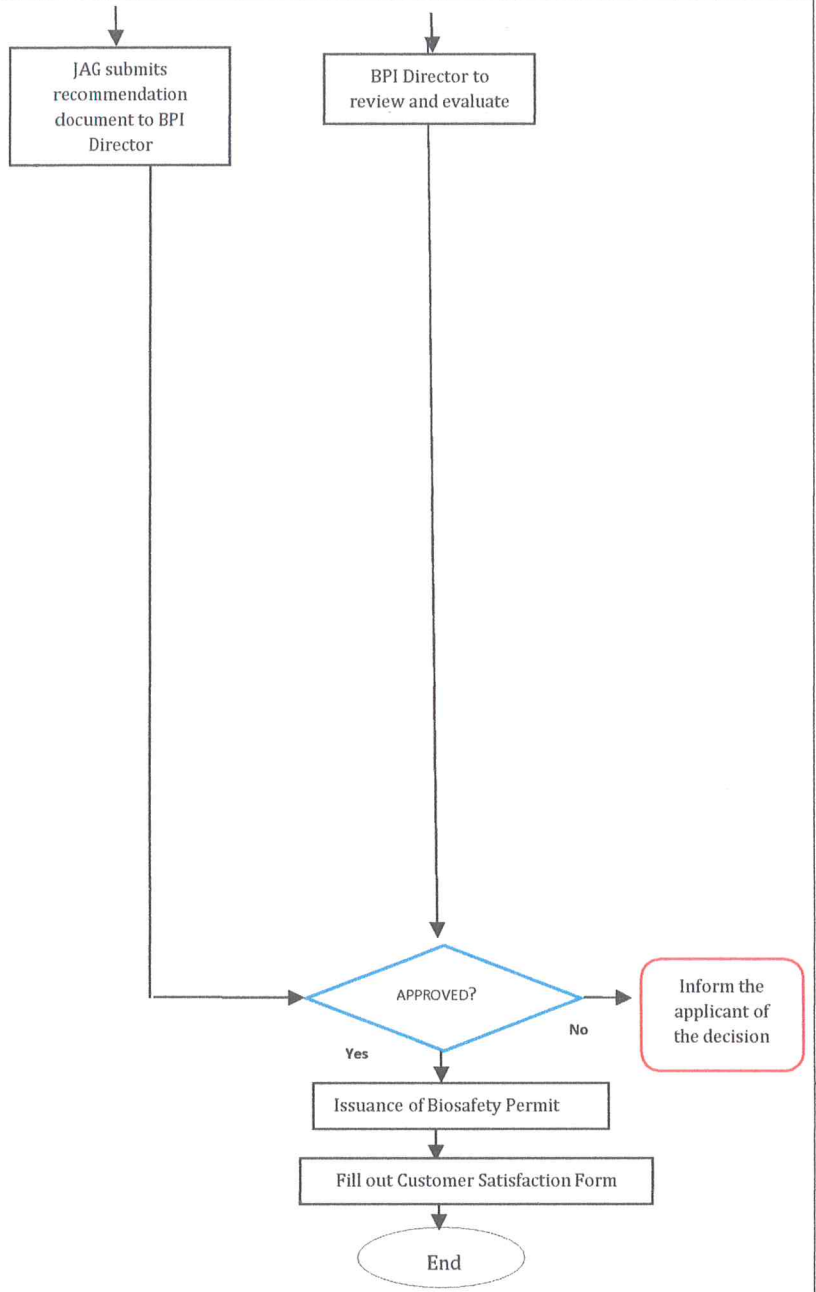
"*Public information sheet (PIS)"*- a document required by the BPI for the processing of application which aims to inform the public of the GM application, usually posted in a newspaper

"*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

4. Procedure

FLOW CHART FOR APPLICATION FOR COMMERCIAL PROPAGATION (SINGLE EVENT)	RESPONSIBLE PERSON/UNIT	DETAILED PROCESS
	Applicant	Submission of the following requirements to the Biotechnology Secretariat: 1. Application form 2. Technical dossiers 3. Risk Assessment Report 4. Proposed Public Information Sheet 5. Proof of payment
	Biotechnology Secretariat	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.
	Biotechnology Secretariat 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.Biotech Secretariat to upload the approved PIS on Biotech website. 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 Biotech Secretariat 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 Secretariat shall upload the application form on the Biotech website. C.2. The Biotech Secretariat shall inform and request posting of the application to the NCBP website.
BPI Director Biotech Secretariat Applicant	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, Biotech Secretariat will inform the applicant of the decision. Fill out the Customer Satisfactory Form

5. FORMS USED AND RECORDS GENERATED

APPLICATION FOR BIOSAFETY PERMIT FOR COMMERCIAL PROPAGATION

- Application Form
- Certification from BPI that the regulated article has undergone satisfactory field trial in Philippines
- 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
- Communication letters/correspondence*
- Query letters*
- PIS Proof of Publication
- Consolidated Report for Public Comments*
- Recommendation Document from JAG
- Biosafety permit
- Customer Satisfaction Form

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

Prepared by: BPI Biotechnology Secretariat

Approved by: OIC-Head