1. **Objective:** to issue biosafety permit for field trial

2. **Scope:** this procedure starts from the receipt of the application submitted by the technology developer, recording, risk assessment process, and ends with the issuance of biosafety permit for field trial to the applicant

3. **Definition of Terms**

"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 ecosystems;

"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

"Field Trial " – refers to any intentional introduction of a regulated article into the environment, as authorized by the Bureau of Plant Industry, wherein specific isolation and mitigating measures are imposed to restrict movement outside an approved site;

"Institutional Biosafety Committee"- The IBC shall be composed of at least five (5) members, three (3) of whom shall be designated as scientist-members and the other two (2) shall be community representatives. All scientist-members must possess scientific or technological knowledge and expertise sufficient to enable them to properly evaluate and monitor any work involving regulated articles conducted by the applicant. The community 11 representatives must not be affiliated with the applicant and must be actively engaged in community affairs in the locality where the activities are to be conducted.

"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.

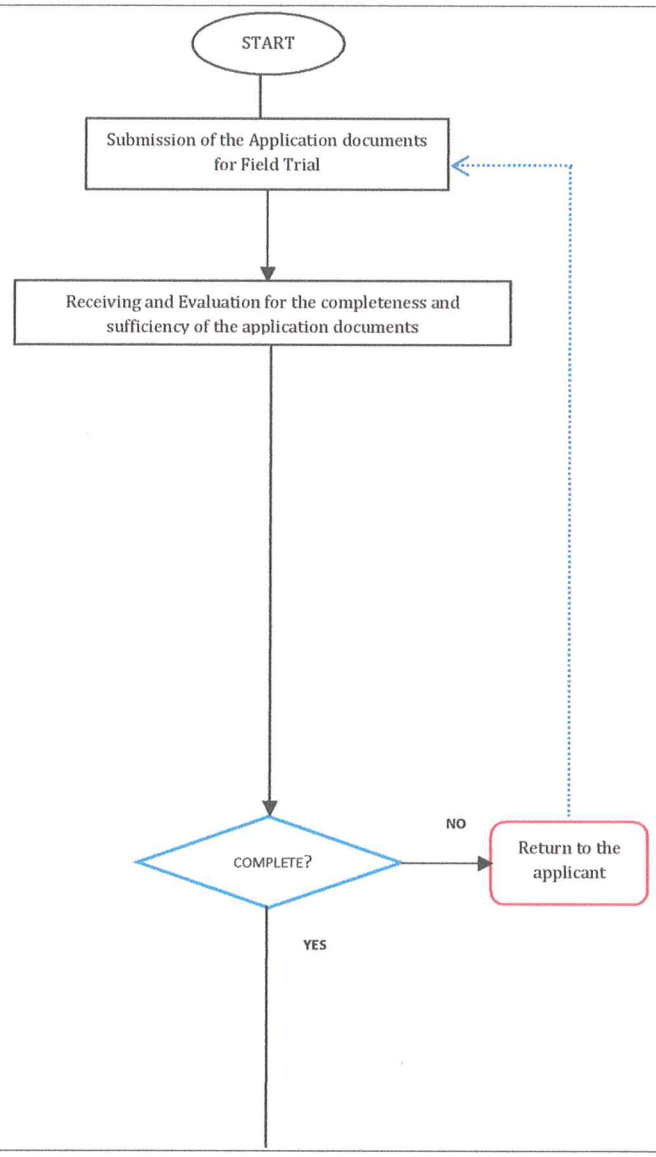
"Public hearing" – refers to the face-to-face or virtual meeting with stakeholders to provide information and opportunity for them to submit comments on any application for field trial of a regulated article;

"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;

"Risk assessment" – refers to the procedure that identifies, evaluates and predicts the occurrence of possible hazards to human and animal health and the environment;

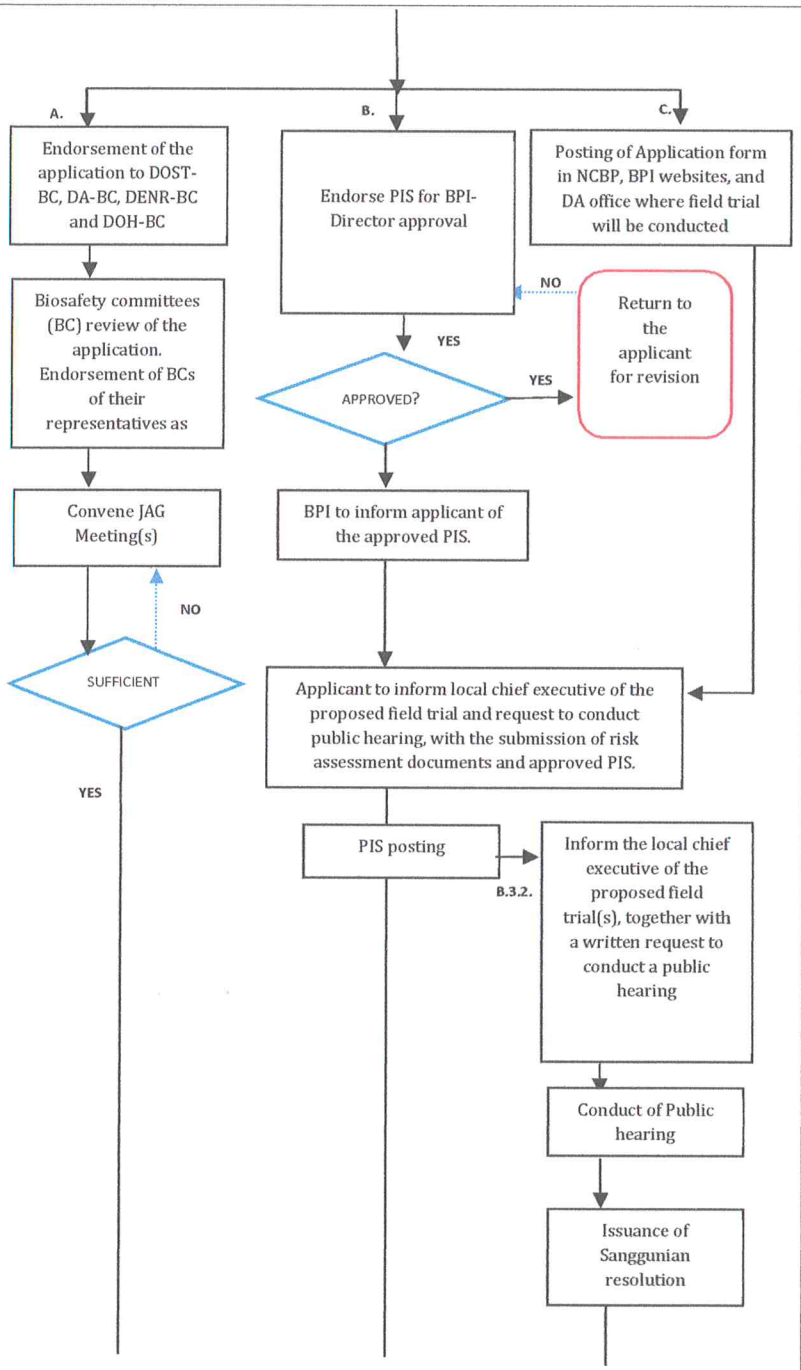
"Risk management" – refers to the appropriate mechanisms, measures and strategies to regulate, mitigate, and control risks identified in the risk assessment;

4. Procedure

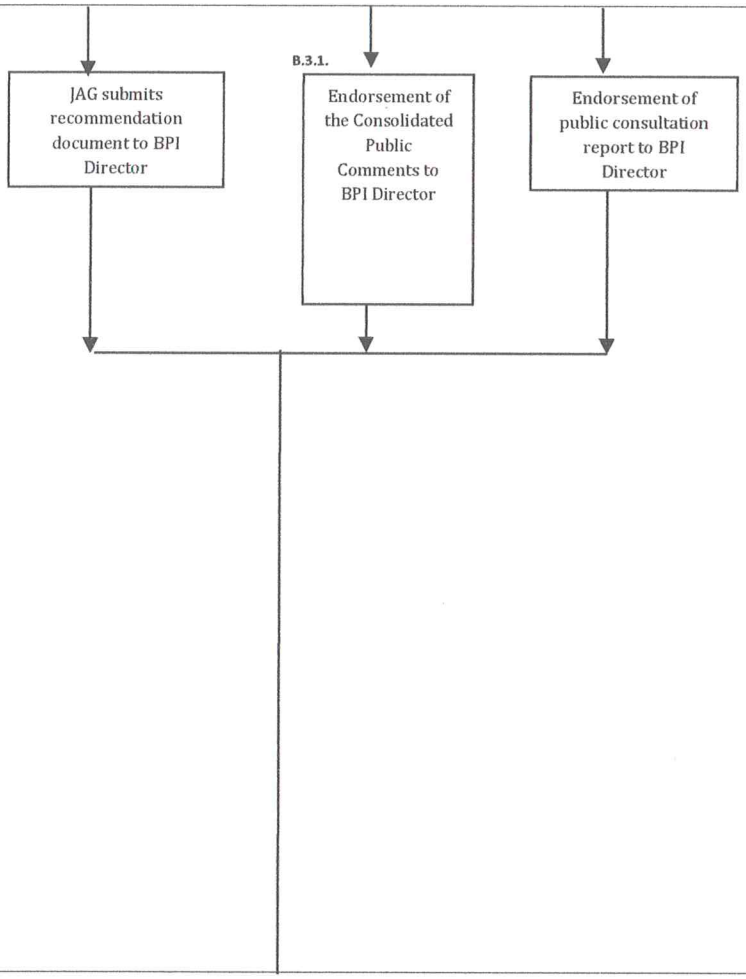
FLOW CHART FOR APPLICATION FOR FIELD TRIAL (SINGLE EVENT)	RESPONSIBLE PERSON/UNIT	DETAILED PROCESS
	Applicant	Submission of the application requirements to the Biotechnology Secretariat: • Application form • DOST-BC certification for contained use (when applicable) • Initial risk assessment and proposed management procedures prepared by IBC • Contingency plan in case of *force majeure* • Public Information Sheet (PIS) • National Commission on Indigenous people (NCIP) Certification Precondition, if applicable • Free and Prior Informed Consent, *(if site is within an ancestral domain or land)* • Proof of payment Applications for permits for regulated articles developed in other countries may be filed directly for a Biosafety Permit for Field Trial if the BPI determines that the data set generated in other countries is applicable to the local setting.
	Biotechnology Secretariat National Committee on Biosafety of the Philippines	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.

Prepared by: BPI Biotechnology Secretariat

Approved by: OIC-Head



Applicant Biosafety Committees (DOST, DA, DENR, DOH) Local Government Unit	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 can 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. If approved, inform the applicant of the approved PIS for the endorsement of proposed field trial, public hearing, and PIS to the local chief executive of the LGU where the field trial will be conducted. If disapproved, advise disapproval reason to the applicant. B.3. The applicant shall post a copy of the approved PIS to (2) conspicuous place within the vicinity of municipality and (2) in the barangay within 5 working days prior to public hearing.



B.3.1 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).

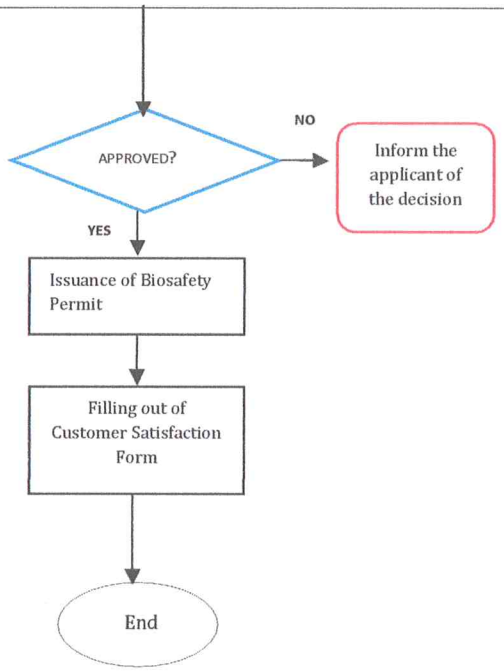
B.3.2. The applicant shall inform the local chief executive of the proposed field trial(s) to be conducted in the LGU, together with a written request to conduct a public hearing at least 5 working days after the posting of the PIS.

B.3.3. The public hearing shall be conducted within 20 working days after receipt of the request, after which the City/Municipal Sanggunian shall issue its resolution.

B.3.4. Within two (2) working after the issuance of the Sanggunian resolution, the applicant shall submit to the BPI a written report on the public consultation

C.1. Upon the receipt of the application, the Biotech secretariat shall upload the application form on the Biotech website and endorse the application forms to the DA offices where the field trial shall be conducted and to NCBP for their website posting.

C.2. The process shall proceed and follow the process of bullet B.2. as stated above.

	BPI Director Biotech Secretariat Applicant	BPI Director to approve or disapprove the application and inform the decision to the Biotech Secretariat. If approved, Biotech secretariat will issue the Biosafety permit for the applied event. The applicant shall sign and pick up the Biosafety permit. If disapproved, Biotech secretariat will inform the applicant of the decision.

5. FORMS USED AND RECORDS GENERATED

APPLICATION FOR BIOSAFETY PERMIT FOR COMMERCIAL PROPAGATION

- Application Form for Field Trial
- Electronic copy of submission
- DOST-BC Certification of Experiment Completion for contained use*
- Initial risk assessment and proposed management procedures prepared by Institutional Biosafety Committee (IBC)
- Contingency plan in case of *force majeure*
- National Commission on Indigenous people (NCIP) Certification Precondition*
- Free and Prior Informed Consent, *if site is within an ancestral domain or land*
- Technical dossiers

- Public Information Sheet (PIS) for Field Trial
- Proof of Payment for the Application
- Acknowledgement letter
- Communication letters/correspondence*
- Query letters*
- PIS Publication
- Consolidated Report for Public Comments*
- Recommendation Document from JAG
- Biosafety permit
- Customer Satisfaction Form

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