1.0 Objective:

To issue biosafety permit applied for field trial for single event.

2.0 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.

3.0 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.

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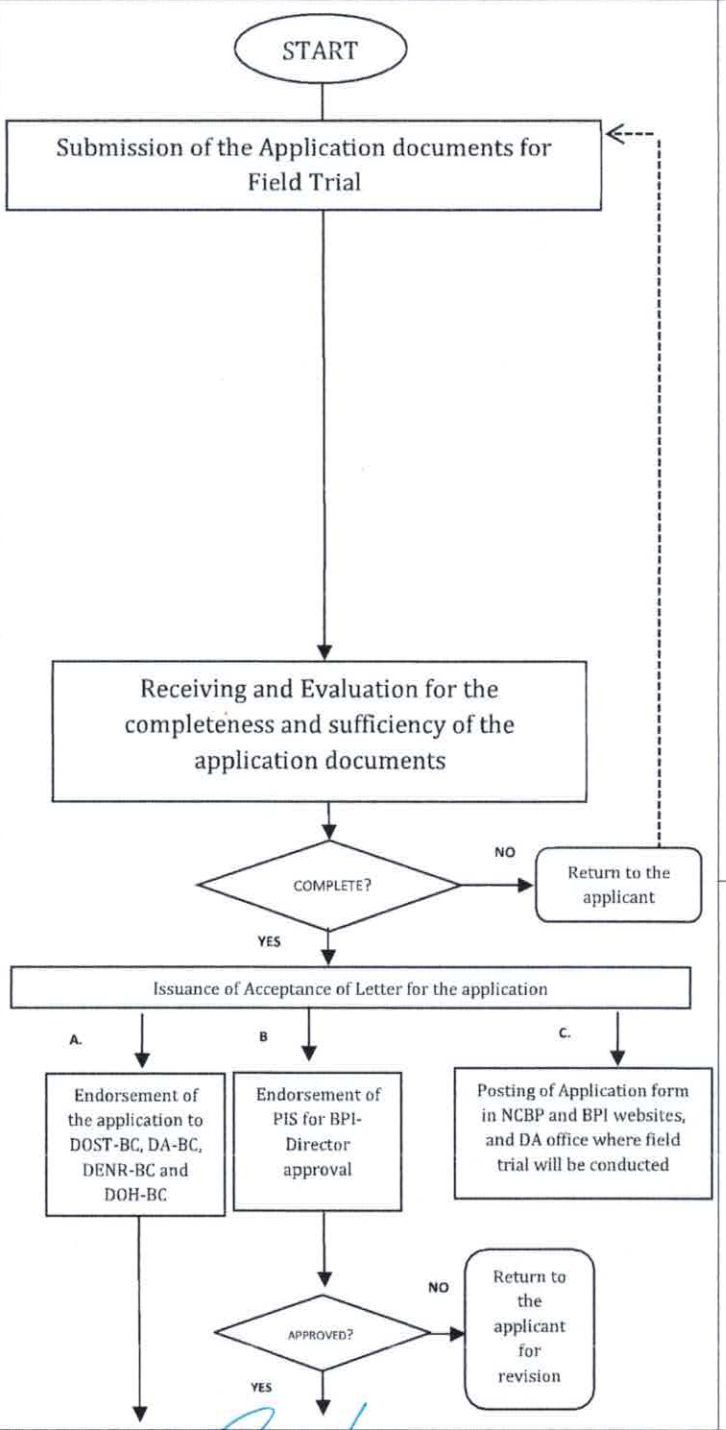
4.0 Procedure Details

FLOW	PERSON/UNIT RESPONSIBLE	DETAILS
	Applicant and Biotechnology Office	Submission of the application requirements to the Biotechnology Office: 1. Application form 2. DOST-BC certification for contained use (when applicable) 3. Initial risk assessment and proposed management procedures prepared by IBC 4. Contingency plan in case of *force majeure* 5. Public Information Sheet (PIS) 6. National Commission on Indigenous people (NCIP) Certification Precondition, if applicable 7. Free and Prior Informed Consent, (if site is within an ancestral domain or land) 8. Proof of payment Receiving and checking of completeness of required forms for the application. No application shall be formally accepted unless documentation is complete.
	Biotechnology Office DA-Regional Field Offices 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

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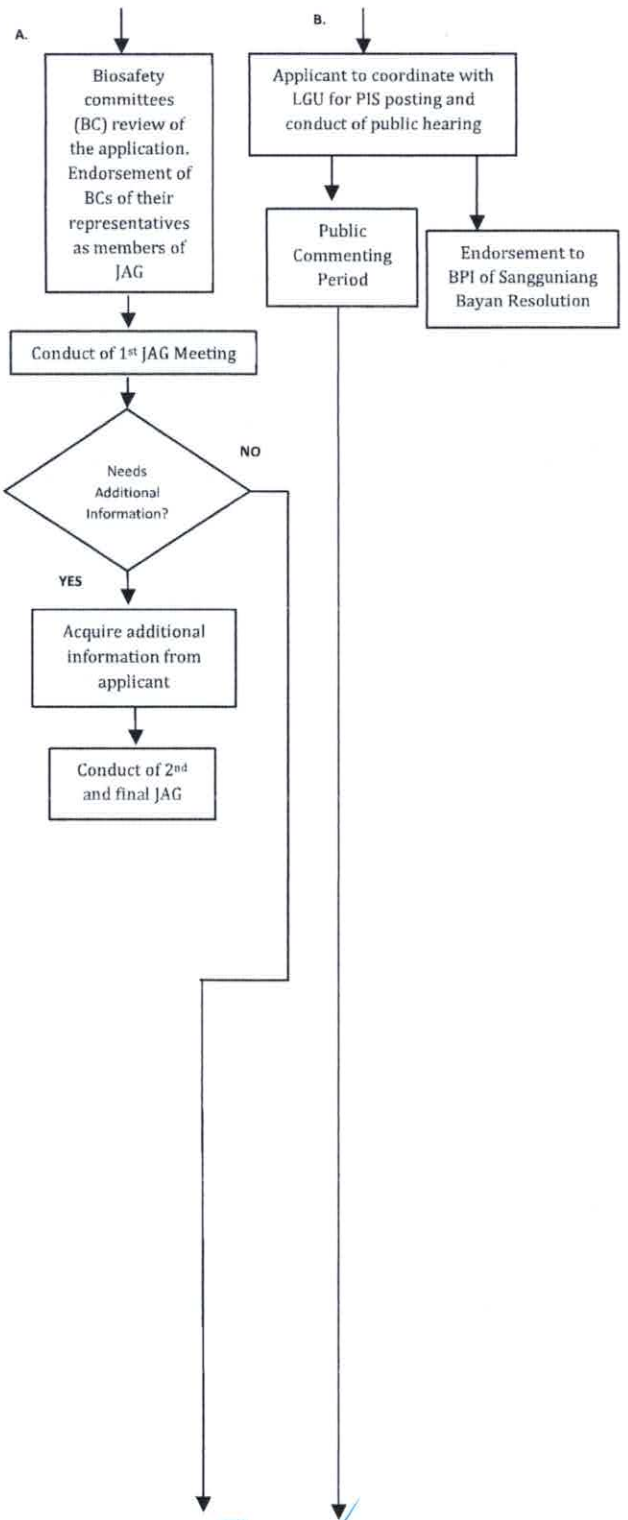

meeting can be conducted should be deemed necessary.

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 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).

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

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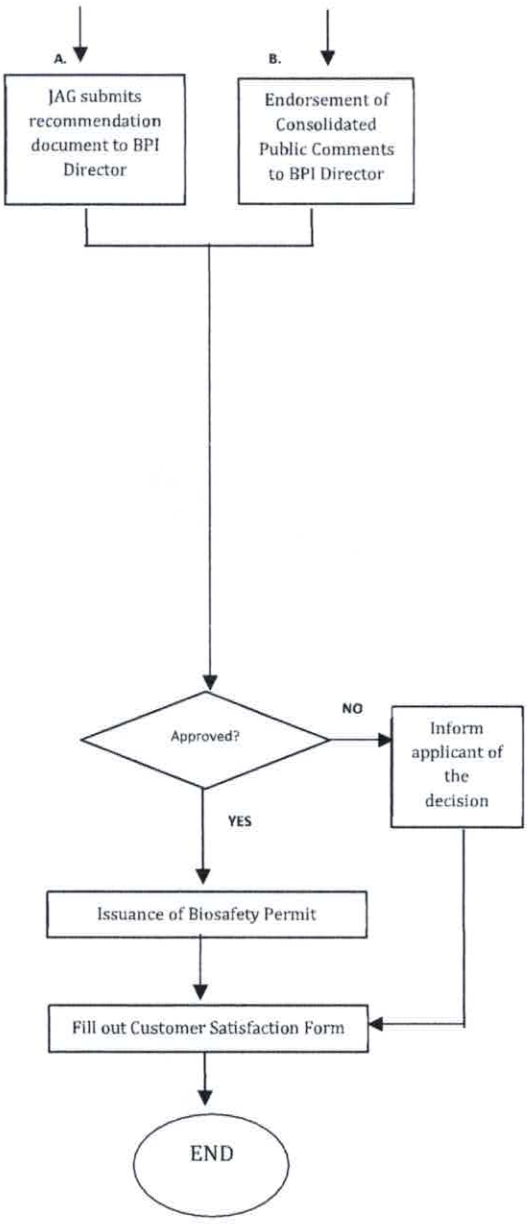		public hearing at least 5 working days after the posting of the PIS. B.3.3. The public hearing shall be conducted within 20 working days after receipt of the request, after which the City/Municipal Sanggunian shall issue its resolution. B.3. 4. Within two (2) working after the issuance of the Sanggunian resolution, the applicant shall submit to the BPI a written report on the public consultation C.1. Upon the receipt of the application, the Biotechnology office 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 Biotechnology Office 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, Biotechnology office will inform the applicant of the decision. Fill out the Customer Satisfactory Form

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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
Checklist of application requirements
Acknowledgement letter
Communication letters/correspondence
Query letters*
Proof of 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

8.0 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 Harpasmal 03-24-23

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