



Bureau of Plant Industry
PROCEDURES MANUAL

Document No.: BPI-QMS-BIOTECH-OPB

Effectivity Date: MAY 5, 2022

Revision No.: 2

Page 1 of 3

Operating Unit: BIOTECHNOLOGY OFFICE

Subject: OPERATIONALIZATION OF POST-APPROVAL MONITORING

- 1. Objective:** to conduct post-approval monitoring particularly insect resistance management
- 2. Scope:** approval for issuance of biosafety permits for commercial propagation. The post approval monitoring is a condition of commercial propagation.
- 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;

“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;

“Insect Resistance Management (IRM)”- a management in which resistance development of major pests is controlled;

“Post-approval monitoring”- refers to activities done after issuance of a biosafety permit for commercial propagation for the purpose of insect resistance and weed shift evolution monitoring;

“Post-approval monitoring group (PAMG)”- composed of BPI monitors designated for monitoring insect resistance and weed resistance in the field;

Prepared by: BPI Biotechnology Secretariat

Approved by: OIC-Head



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Page 2 of 3

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“Sentinel site”- a certain designated site where post-approval monitoring is done, representative of field conditions in the region.

4. Procedure

FLOW CHART FOR POST APPROVAL MONITORING	RESPONSIBLE PERSON/UNIT	DETAILED PROCESS
<pre> graph TD Start([START]) --> Step1[Technology Developer will provide schedule on each sentinel site.] Step1 --> Step2[PAMG Secretariat will finalize schedule for monitoring and coordinate with the techdevs and RCPCs for logistics.] Step2 --> Step3[On site: Monitors will gather data on the sentinel site. Monitors will accomplish monitoring form with proper signatories] Step3 --> Step4[Submit to Secretariat for filing.] Step4 --> End([End]) </pre>	Technology Developers	The technology developer shall provide a tentative schedule of the Insect Resistance Management (IRM) monitoring and coordinate with the assigned Post Approval Monitoring Group (PAMG) member.
	BPI Biotech Secretariat	Confirmation of monitoring activity shall be made at least 2 weeks prior to the schedule.
	BPI PAMG monitors RCPC monitors Techdev Monitors	Harmonized forms shall be used for data gathering. For bag-in-a-bag (BIB) refuge scheme, 50 tagged plants from refuge and 50 tagged plants from Bt corn shall be inspected following the X pattern. For refuge-in-a-bag (RIB) scheme, 100 tagged plants will be inspected following the X pattern. In case of Asian Corn Borer (ACB) damage, Bt strips provided by the technology developers shall be used for gene check.
	BPI Biotech Secretariat	The monitors will submit the accomplished monitoring forms and the secretariat will consolidate the data gathered.

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	Bureau of Plant Industry PROCEDURES MANUAL	Document No.: BPI-QMS-BIOTECH-018	
		Effectivity Date: May 5, 2022	
		Revision No.: 2	Page 3 of 3
Operating Unit: BIOTECHNOLOGY OFFICE			
Subject: OPERATIONALIZATION OF POST-APPROVAL MONITORING			

5. FORMS USED/RECORDS GENERATED

- Monitoring forms
- Consolidated monitoring report
- Tentative schedule of monitoring
- Communication letters/ correspondence

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