



Bureau of Plant Industry
OPERATIONAL PROCEDURES

Document No.: BPI-QMS-BIOTECH-OP8

Preparation Date: February 22, 2023

Revision No.: 3

Page 1 of 3

Operating Unit: BIOTECHNOLOGY OFFICE

Subject: OPERATIONALIZATION OF POST-APPROVAL MONITORING

1.0 Objective

To conduct post-approval monitoring particularly on the implementation of Insect Resistance Management (IRM) Strategy.

2.0 Scope

This procedure manual only covers the operationalization of post-approval monitoring which is a part of the post-approval conditions as indicated in the Biosafety Permit for Commercial Propagation.

3.0 Definition of Terms

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.

Post-approval monitoring group (PAMG)

Composed of BPI monitors designated for monitoring insect resistance in the field.

Sentinel site

A certain designated site where post-approval monitoring is done, representative of field conditions in the region.

4.0 Procedure Details

FLOW	PERSON/UNIT RESPONSIBLE	DETAILS
------	-------------------------	---------

Prepared by:  TRACY MAE CEA

Science Research Specialist I, Biotechnology Office

Approved by:  GERONIMA P. EUSEBIO

OIC-Head, Biotechnology Office

Date Signed: MARCH 24, 2023



Bureau of Plant Industry
OPERATIONAL PROCEDURES

Document No.: BPI-QMS-BIOTECH-OP8

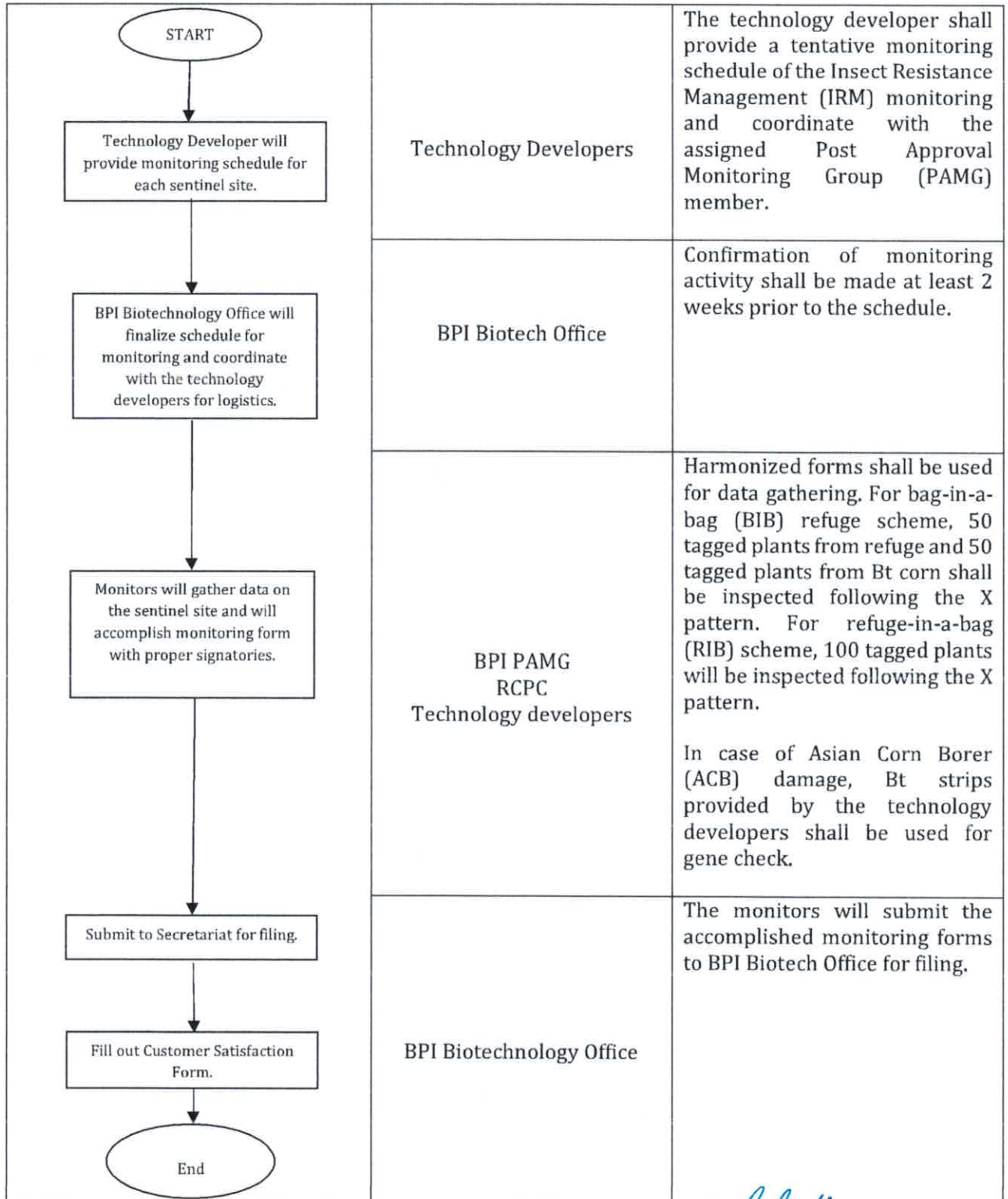
Preparation Date: February 22, 2023

Revision No.: 3

Page 2 of 3

Operating Unit: BIOTECHNOLOGY OFFICE

Subject: OPERATIONALIZATION OF POST-APPROVAL MONITORING



Prepared by: **TRACEY MAE CEA**
Science Research Specialist I, Biotechnology Office

Approved by: **GERONIMA P. EUSEBIO**
OIC-Head, Biotechnology Office
Date Signed: **MARCH 24, 2023**



Bureau of Plant Industry
OPERATIONAL PROCEDURES

Document No.: BPI-QMS-BIOTECH-OP8

Preparation Date: February 22, 2023

Revision No.: 3

Page 3 of 3

Operating Unit: BIOTECHNOLOGY OFFICE

Subject: OPERATIONALIZATION OF POST-APPROVAL MONITORING

5.0 Forms Used and Records Generated

Monitoring forms
Tentative schedule of monitoring
Communication letters/ correspondence

6.0 References

DA Memorandum Circular No. 2 s2014 - "Enhancing the Insect Resistance Management (IRM) Strategy for Bt Corn Targeting Asian Corn Borer (ACB)"

BPI Memorandum s2019 - "Guidelines in the Post-Approval Monitoring of Insect Resistance Management (IRM) for Corn Events Approved for Commercial Propagation"

7.0 Effectivity

The effectivity date of this document shall be five (5) working days after the approval by the authorized signatory.



Prepared by: TRACEY MAE CEA

Science Research Specialist I, Biotechnology Office

Approved by: GERONIMA P. EUSEBIO

OIC-Head, Biotechnology Office

Date Signed: MARCH 24, 2023