

Department of Agriculture BUREAU OF PLANT INDUSTRY

Biotechnology Office

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April 6, 2022

MEMORANDUM ORDER

No. <u>61</u> Series of 2022

Subject: DOCUMENT MANAGEMENT AND WEBSITE POSTING GUIDELINES OF THE BPI BIOTECHNOLOGY OFFICE

In the interest of service and pursuant to Sec 36 and 37of the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1 s2016, herein are the guidelines of the BPI Biotechnology Office pertaining to Document Management and Website Posting.

I. Application File

An application file shall be established for every application for Direct Use as Food and Feed or for Processing, Field Trial, Commercial Propagation and Deregulation and shall contain the application form, supporting documents, evaluation reports, written comments submitted by other government agencies and the public, and all other documents relating to the application. For the specific list of documents expected to the application file see Annexes below.

Each application file shall be assigned an identification number and the format shall be as follows:

For Direct Use

IDC-FFP-(01-N)

Field Trial

JDC-FT-(01-N)

Commercial Propagation

JDC-PROPA-(01-N)

Deregulation

JDC-DEREG-(01-N)

For Renewal applications each file shall be assigned and a unique identification number format shall be as follows:

For direct use

IDC-FFP-R-(01-N)

Field trial

JDC-FT-R-(01-N)

Commercial Propagation

IDC-PROPA-R-(01-N)

Deregulation

JDC-DEREG-R-(01-N)

For record keeping purposes, electronic copies of application file shall be kept by the BPI Biotech Office following the assigned identification number.

A summary of the application file or consolidated report shall be posted on the website of BPI Biotechnology Office (www.biotech.da.gov.ph).

EFFECTIVITY DATE: July 5, 2021 DOCUMENT NO.: BPI-QMS-KMT-I-F1 REVISION NO.: 2 A food-secure and resilient Philippines

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II. Posting of Notification to DA and DOST Regional Offices

The BPI shall make public all GM applications and Biosafety Permits for Direct Use, Field Trial and Commercial Propagation through posting on the NCBP and BPI Websites and in offices of the DA and DOST nationwide.

III. Updating and Publishing Approval Registry for Regulated Articles

The BPI shall keep and regularly update an Approval Registry for Regulated Articles of the following:

- A. Direct use as food and feed, or for processing;
- B. Commercial propagation;
- C. Field trial; and
- D. Deregulated articles.

This list is to be updated quarterly and uploaded to the BPI Biotech Website.

IV. Reporting of GM Crop Adoption per Season

In compliance with the DA Memorandum Circular No. 1 series of 2014, the BPI through the BPI Biotechnology Office shall prepare adoption rates per season based on the submission of technology developers. Adoption report shall be verified and signed by the Chair of the BPI Post-Approval Monitoring Group prior to website posting.

V. Biosafety Permit

Each Biosafety Permit shall be assigned an identification number and the format shall be as follows:

For Direct Use

YR-(001-N)FFP

Field Trial

YR-(001-N)FT

Commercial Propagation

YR-(001-N)Propa

The BPI Biotech Office shall keep an original copy of the Biosafety Permit that has been properly acknowledged, signed and dated by the technology developer.

A scanned copy of the permit shall be posted in the BPI Biotech Office website.

VI. Post-Approval Monitoring Reports



In compliance with the DA MC. No. 2 s 2014, the BPI PAMG Secretariat shall keep a copy of the Monitoring Schedule, duly accomplished monitoring forms, monitoring reports and other related documents for every monitoring activity yearly.

Each type of document shall be properly labeled and filed to respective folders, accordingly.

VII. Website posting

All documents will be screened for correctness and accuracy by the BPI Biotechnology Core Team prior to posting in the website (www.biotech.da.gov.ph). The types of documents and procedures to be posted shall be in accordance to the provisions of the JDC No.1 s2016.

VIII. Request for Public Records

For external parties requesting documents, the procedures stated in the DA FOI Manual shall be followed. The BPI Biotech Office shall only release a certified true copy of the record to the requesting party. Certification of these records shall be referred to the BPI Records Section and communications will be through the designated DA-BPI FOI Officer.

IX. Returning of Documents

Physical copies of the dossier shall be returned to the applicant once the application has been completed. A master copy of the application file shall be kept intact by the BPI Biotech Office. This protocol is to maintain confidentiality of the application file and other related documents.

X. Annexes

Annex A.1. Checklist for Application for Biosafety Permit for Direct use (Single/Stacked)

Annex A.2. Checklist for Application for Biosafety Permit for Field Trial (Single/Stacked)

Annex A.3. Checklist for Application for Biosafety Permit for Commercial Propagation (Single/Stacked)

The complete list of forms used and records generated by the Biotechnology Office are also reflected in the Procedures Manual per type of application.

XI.



XII. Effectivity

This order shall take effect immediately and supersedes all other orders inconsistent herewith.

GEORGE Y. CULASTE, PhD

Director

Annex A.1.

APPLICATION FOR BIOSAFETY PERMIT FOR COMMERCIAL PROPAGATION (___ SINGLE / __ STACKED) (__ INSECT RESISTANT / __ NON-INSECT RESISTANT)

Event:	
Date of Application:	
Date of Completion of Requirements:	
For checking of applications:	
REQUIREMENTS	✓ or X
1. Application Form (Annex E)	
2. Certification from BPI	
 New application: Certification that the regulated article has undergone satisfactory field trial in Philippines 	
 Renewal: Certified true copy of expired Biosafety Permit for Commercial Propagation 	
3. Technical dossiers (11)	
4. Duly accomplished SEC questionnaire	
5. Duly accomplished Risk Assessment Form (See Form 002)	
6. Public Information Sheet (PIS)	
English and Tagalog	
7. Field Trial Report	
8. Notarized Project Description Report (PDR)	
9. Environmental Risk Assessment (ERA)	
10. Notarized Environmental Health Risk Assessment (EHRA)	
 If PIP, certification from FPA that the applicant is duly licensed as pesticide handler in accordance with PD No. 1144 	
12. Proof of Payment (Application Fee)	
Php 1000.00	
13. Electronic copy of submission	
14. RAR Cost (c/o Executed MOA and WFP)	
Checked by:	
one	

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Masaganang Mataas na 🌡

Annex A.2.

APPLICATION FOR BIOSAFETY PERMIT FOR FIELD TRIAL (___ SINGLE / ___ STACKED) (__ INSECT RESISTANT / __ NON-INSECT RESISTANT)

Event:	
Date of Application:	
Date of Completion of Requirements:	
For checking of applications:	
REQUIREMENTS	✓ or X
1. 3 Copies of Application Form (Annex A)	
2. DOST-BC Certification of Experiment Completion	
3. Technical dossiers (8 copies)	
4. Information on Socio-economic, Cultural and Ethical (See SEC Form 01)	
5. Filled out Risk Assessment Report Form (RAR Form 001)	
6. PIS for Field Trial (Annex B)	
• In English and translated into a specific dialect where the field trial shall be	
conducted	
7. Project Description Report as prescribed by DENR-BC (See DENR PDR Form 001)	
8. NCIP Clearance (when applicable)	
9. FPIC (when applicable)	
10. Protected Areas Management Board endorsement (when applicable)	
11. Copy of Import Permit (when applicable)	
12. Oath of the Applicant (Please coordinate with the BPI BCT Secretariat)	
13. MOA and WFP	
14. Proof of Payment of Fees	
15. Electronic copy of submission	<u> </u>
Checked by:	
on:	

Annex A.3.

APPLICATION FOR BIOSAFETY PERMIT FOR COMMERCIAL PROPAGATION (___SINGLE / __ STACKED) (__ INSECT RESISTANT / __ NON-INSECT RESISTANT)

Event:	
Date of Application:	
Date of Completion of Requirements:	
For checking of applications:	
REQUIREMENTS	✓ or X
1. Application Form (Annex E)	
2. Certification from BPI	
 New application: Certification that the regulated article has undergone satisfactory field trial in Philippines 	
 Renewal: Certified true copy of expired Biosafety Permit for Commercial Propagation 	
3. Technical dossiers (11)	
4. Duly accomplished SEC questionnaire	
5. Duly accomplished Risk Assessment Form (See Form 002)	
6. Public Information Sheet (PIS)	
English and Tagalog	
7. Field Trial Report	
8. Notarized Project Description Report (PDR)	
9. Environmental Risk Assessment (ERA)	
10. Notarized Environmental Health Risk Assessment (EHRA)	
11. If PIP, certification from FPA that the applicant is duly licensed as pesticide handler in	
accordance with PD No. 1144	
12. Proof of Payment (Application Fee)	
Php 1000.00	
13. Electronic copy of submission	L
14. RAR Cost (c/o Executed MOA and WFP)	
Checked by:	
on:	