

## 24. Application for Issuance of Biosafety Permit for Commercial Propagation

The Biotechnology Office of the Bureau of Plant Industry (BPI) issues Biosafety Permit for Commercial Propagation

<b>Office:</b>	Biotechnology Office	
<b>Classification:</b>	Highly Technical	
<b>Type of Transaction:</b>	G2B – Government to Business, G2G – Government to Government	
<b>Who may avail:</b>	<ol style="list-style-type: none"> <li>1. any of the departments or agencies of the Philippine Government;</li> <li>2 a university-based research institution in the Philippines;</li> <li>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;</li> <li>4. a corporation registered with the Securities and Exchange Commission of the Philippines; or</li> <li>5. a cooperative registered with the Cooperative Development Authority of the Philippines;</li> </ol>	
<b>CHECKLIST OF REQUIREMENTS</b>		<b>WHERE TO SECURE</b>
<ol style="list-style-type: none"> <li>1. Application Form (Annex E) <i>(1 original, 2 photocopy)</i></li> <li>2. Certification from BPI <i>(1 photocopy)</i>  <ul style="list-style-type: none"> <li>-New application: Certification that the regulated article has undergone satisfactory field trial in the Philippines</li> <li>-Renewal: Certified true copy of expired Biosafety Permit for Commercial Propagation</li> </ul> </li> <li>3. Technical dossiers <i>[with FFP approval, IR- 13 copies, Non-IR- 5, with no FFP approval- IR- 15 copies, Non-IR- 7 copies]</i></li> <li>4. Duly accomplished SEC questionnaire <i>(1 original, 2 photocopy)</i></li> <li>5. Duly accomplished Risk Assessment Form (See Form 002) <i>[with FFP approval, IR- 13 copies, Non-IR- 5, with no FFP approval-IR- 15 copies, Non-IR- 7 copies]</i></li> <li>6. Public Information Sheet (PIS)</li> <li>7. Field Trial Report <i>[with FFP approval, IR- 13 copies, Non-IR- 5, with no FFP approval- IR- 15 copies, Non-IR- 7 copies]</i></li> <li>8. Notarized Project Description Report (PDR) <i>(1 original, 2 photocopy)</i></li> <li>9. Environmental Risk Assessment (ERA) <i>(1 original, 2 photocopy)</i></li> <li>10. Notarized Environmental Health Risk Assessment (EHRA) <i>(1 original, 2 photocopy)</i></li> <li>11. If PIP, certification from FPA that the applicant is duly licensed as pesticide handler in accordance with PD No. 1144 <i>(1 photocopy)</i></li> <li>12. Proof of Payment (Application Fee)</li> </ol>		<p>BPI Central Office-Biotech Applicant Applicant</p> <p>Applicant</p> <p>BPI Central Office-Biotech BPI Central Office Biotech</p> <p>BPI Central Office-Biotech BPI Central Office-Biotech</p> <p>BPI Central Office-Biotech BPI Central Office-Biotech</p> <p>Applicant</p>

13. Electronic copy of submission				
CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submit pertinent documents	1.1 Receive and check the application	None	15 minutes	BPI Biotech Secretariat
2. Pay Application Fees	2.1 Biotech Secretariat prepares acknowledgement receipt	Php 1,000.00	15 minutes	BPI Biotech Secretariat
	2.2. Accounting Section Issues Order of Payment			BPI Accounting Section
	2.3 Cashier Section issues Official receipt			BPI Cashier Section
3. Review of Application	3.1. Review completeness and sufficiency of technical documents	None	5 Days	Biotech
	3.2. Farm out the application to the assessors and concerned agencies			
4. Pay Risk Assessment Review Cost	4.1 Secretariat prepares acknowledgement receipt	**see computation of fees	15 minutes	BPI Biotech Secretariat
	4.2. Accounting Section Issues Order of Payment			BPI Accounting Section
	4.3 Cashier Section issues Official receipt			BPI Cashier Section
5. Risk Assessment and SEC Impact Assessment Proper	5.1 Safety risk assessment of application of DA and other regulatory agencies: a. Safety Risk Assessment	None	30 days	

	<ul style="list-style-type: none"> <li>b. Feed Safety</li> <li>c. Food Safety</li> <li>d. Environmental Risk Assessment</li> <li>e. Environmental Health Impact Assessment</li> <li>f. Insect Resistance Management Plan Review</li> <li>g. Review of PIP registration</li> <li>h. Socio-economic, ethnical &amp; cultural impact review</li> </ul>			<p>STRP BAI BCT BPI-PPSSD DENR-BC</p> <p>DOH-BC</p> <p>IRMAT</p> <p>FPA-BCT</p> <p>SEC Expert</p>
	5.2. Gather individual technical reports from the assessors	None	2 Days	BPI Biotech Secretariat
	5.3 Preparation of the consolidated summary of the technical reports	None	5 Days	BPI Biotech Secretariat
6. Conduct public consultation and submit report thereof	6.1 Receive the applicant's report on public comment	None	60 days from the conduct of public consultation (simultaneous with application evaluation)	BPI Biotech Secretariat
	6.2 Forward the report on public comment, application and all related documents to the DA-BC	None	5 days	BPI Biotech Secretariat
	6.3 Review and evaluate the individual technical reports of STRP and concerned agencies and the applicant's written report on public consultation	None	10 days	DA-BC/ Biotech Core Team
	6.4. Denies or approves the application	None	5 Days	BPI Director

7. Receiving of the Biosafety Permit for Direct Use	7.1 Issuance of Biosafety Permit for Direct Use	None	5 minutes	BPI Biotech Secretariat
8. Fill up customer feedback form.	8.1 Issue and collect feedback form	None	5 Minutes	BPI Biotech Secretariat
<b>TOTAL</b>			<b>85 Days &amp; 55 Minutes</b>	

### Commercial Propagation

#### \*\*Computation of Fees

<b>A. Application Review Cost</b>	Php 20,000.00
<b>B. Risk Assessment Review Cost</b>	
<sup>2</sup> Feed Safety Scientific document	5000.00 400.00/ scientific document
STRP (x3 single, x1 stacked)	30,000.00/ STRP
<sup>2</sup> Food Safety	3000.00
Socio-economic, Ethical and Cultural Impact Review	20,000.00
<sup>1</sup> Insect Resistance Management Plan Review (x6 members)	10,000.00/IRMAT member
<sup>1</sup> Review of PIP registration Scientific document	400.00/scientific document
DA and BPI Biosafety Assessment	57,0000.00
<b>C. Administration Fees &amp; Incidental Cost</b>	20% of A+B

\*If the application has an insect resistance trait, these reviews will be added

\*If the application is for commercial propagation and already has prior approval for direct use, there is no need to include Food and Feed Safety Assessments