

2. 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

Office:	Biotechnology Office			
Classification:	Highly Technical			
Type of Transaction:	G2B – Government to Business, G2G – Government to Government			
Who may avail:	<ol style="list-style-type: none"> 1. Departments or agencies of the Philippine Government 2. University-based research institution in the Philippines 3. 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. Corporation registered with the Securities and Exchange Commission of the Philippines 5. Cooperative registered with the Cooperative Development Authority of the Philippines 			
CHECKLIST OF REQUIREMENTS			WHERE TO SECURE	
<ol style="list-style-type: none"> 1. Application Form 2. Technical Dossiers 3. Risk Assessment Report 4. Proposed Public Information Sheet 5. Insect Resistance Management, if application 6. Proof of Payment 			BPI Central Office- Biotechnology Office	
CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submit pertinent documents	Check application and supporting documents for sufficiency	None	15 minutes	Biotechnology Office

2. Secure a copy of the Order of Payment and pay the Application Fee	2.1 Prepare acknowledgment receipt			Biotechnology Office
	2.2. Issue Order of Payment	Php 1,000.00	30 minutes	Accounting Section
	2.3 Issue Official Receipt			Cashier Section
3. Receive official acceptance letter for the application	3.1 Review completeness and sufficiency of technical documents	None		Biotechnology Office
	3.2 Issue acceptance letter and posting of application on BPI or Biotechnology website			
	3.3 Inform and request National Committee on Biosafety of the Philippines (NCBP) to post the application on the NCBP website	None		Biotechnology Office NCBP
	3.4 Farm out and endorse the application documents to concerned agencies and assessors	None	3 working days upon acceptance of application	Biotechnology Office

4. Conduct of Public Participation through posting and publication of PIS*	4.1 Issue approved PIS for website posting and newspaper publication	None	3 working days upon acceptance of application	BPI Director Biotechnology Office
	4.2 Confirm the publication and posting of the approved PIS	None	Within 3 working days after receipt of the approved PIS from the BPI	Biotechnology Office Applicant
	4.3 Post the approved PIS on the BPI or Biotechnology Office website	None	3 working days upon acceptance of application	Biotechnology Office
	4.4 Conduct the public comment period	None	15 working days after the posting and publication of PIS	BPI Director Biotechnology Office Applicant
	4.5 Compile the received comments and endorse to the applicant	None	2 working days after the termination of the public comment period	Biotechnology Office
	4.6 Collect the applicant's response to the received comments during the public comment period	None	5 working days after the endorsement of compiled comments to the applicant	Biotechnology Office Applicant

	4.7 Endorse the consolidated report, reflecting the public comments the applicant's response, to the BPI Director	None	2 working days after the receipt of the compiled comments	Biotechnology Office BPI Director
5. Pay Risk Assessment Review Cost	5.1 Prepare Acknowledgment Receipt	180, 000**	30 minutes	Biotechnology Office
	5.2. Issue Order of Payment			Accounting Section
	5.3 Issue Official Receipt			Cashier Section
6. Attendance to the Joint Assessment Group (JAG) meeting(s)*	6.1 Evaluate and conduct the safety risk assessment of the application during the 1 st or final JAG Meeting	Included in the Risk Assessment Review Cost	Within 10 working days after the receipt of the application from the BPI	JAG Biotechnology Office Applicant
	6.2 Request additional information from the applicant, if necessary	None		JAG Biotechnology Office Applicant
	6.3 Collect the requested additional information from the applicant	None		Biotechnology Office Applicant

			the request for additional information	
	6.4 Conduct of the second or final JAG meeting, if deemed necessary	None	Within 5 working days upon receipt of the requested additional information	JAG Biotechnology Office Applicant
	6.5 Request additional information from the applicant, if necessary	None		JAG Biotechnology Office Applicant
	6.6 Collect the requested additional information from the applicant	None	Within 5 working days upon the endorsement of the request for additional information	Biotechnology Office Applicant
	6.7 Submit the JAG's final recommendation document to the BPI Director	None	Within 7 working days after the conclusion meeting(s) of the JAG and resolving all requests for additional information	JAG Biotechnology Office BPI Director

			and other outstanding issues.	
7. Receive decision on the proposed IRM plan for events with Insect Resistant (IR) trait*	7.1 Endorse the proposed IRM plan to the Insect Resistance Management Advisory Team (IRMAT) and Post Approval Monitoring Group (PAMG)	None	3 working days upon the acceptance of the application	Biotechnology Office IRMAT PAMG
	7.2 Evaluate and assess the proposed IRM plan	Included in the Risk Assessment Review Cost	20 working days but may be extended once for the same number of days if needed	Biotechnology Office IRMAT PAMG
	7.3 Endorsement of the IRMAT recommendation to the BPI Director	None		Biotechnology Office IRMAT BPI Director
8. Receive the decision on the application	8.1 Review the recommendations and decide whether to approve or disapprove the application	None	5 working days to approve or deny upon receipt of recommendation document	BPI Director
	8.2 Approve the application through the signing of the Biosafety Permit for Commercial Propagation, or issue a letter informing the disapproval of the application	None		BPI Director Biotechnology Office

	8.3 Release the original copy of the signed Permit for Commercial Propagation to the applicant	None	5 minutes	Biotechnology Office
	8.4 Endorse the certified true copies of the Biosafety Permit to the Biosafety Committees	None		<p>Department of Science Technology - Biosafety Committee (DOST-BC)</p> <p>Department of Agriculture-Biosafety Committee (DA-BC)</p> <p>Department of Environment and Natural Resources-Biosafety Committee (DENR-BC)</p> <p>Department of Health-Biosafety Committee (DOH-BC)</p> <p>Biotechnology Office</p>

	8.5 Post the Biosafety Permit on the Biotechnology or BPI website	None	24 hrs within the receipt of the applicant	Biotechnology Office
8. Fill out the Customer Satisfaction Form (CSF)	Issue and collect the accomplished CSF	None	2 Minutes	Biotechnology Office Applicant
TOTAL			40 working days***	

**Simultaneous process*

****The total processing time only includes the process from the official acceptance of the application to its approval/disapproval. Moreover, the duration may be affected by the evaluation of the IRMAT.*

Commercial Propagation

**Computation of Fees

Activity	Estimated Cost	
	Logistic and other Support Services	Unit Amount (Php)
Issuance of acknowledgment letter and posting of application on Biotechnology website	Communication/ Documentations	10,000.00
	Supplies and materials	10,000.00
Farming out and endorsement of Application documents to concerned agencies	Travel expenses	10,000.00
IRMAT Risk Assessment Review	Payment for risk assessment review (10,000.00 x 6 IRMAT expert)	6,000.00
Pre-Evaluation of DA-BC	Payment for risk assessment review (meetings)	5,000.00
Evaluation and Safety Risk Assessment of the application and 1st JAG Meeting. A second and final meeting may be conducted if deemed necessary.	Meeting, communication, documentation, & others	5,000.00

	Payment for risk assessment review (15,000.00 x 3 DA-BC expert)	45,000.00
2 nd and final JAG Meeting and Risk Assessment	Meeting expenses, documentation, and others	5,000
Sub-Total		150,000
Incidental Expenses/ logistic support/ purchase of supplies and equipment (20 percent of Sub-Total)		30,000
Grand Total		180,000