Republic of the Philippines Department of Agriculture BUREAU OF PLANT INDUSTRY

PLANT QUARANTINE SERVICE Manila

	Application for Biosafety Permit for Field Trial	
		(Date)
	The Director Bureau of Plant Industry	
	Sir/Madame:	
	We –	

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name			
Address			
Tel. No.			
Fax No.			
Email Address			

based upon the endorsement of the following members of the Institutional Biosafety Committee (IBC) -

Information	Member No. 1	Member No. 2	Member No. 3	Member No. 4	Member No. 5
Name					
Designation					
Address					
Tel. No.					
Fax No.					
Email Address					
Vote					
Signature					
If no signature, reason for such					
			1		

hereby request for issuance of Biosafety Permit for Field Trial for the genetically modified (GM) plant/plant product described below:

Designation	Regulated Article	Donor Organism	Host Organism	Vector or Vector Agent	Constituents of the Regulated Article
Common Name					
Scientific Name					
Trade					
Name					
Other Designations					

Means of Movement	
By Whom	
-	

Entity(ies) Who Developed/ Supplied Regulated Article	Entity # 1	Entity # 2	Entity # 3 (Use another sheet as necessary)
Name			
Address			
Tel. No.			
Fax No.			
Email Address			

- * The following supporting documents are attached:
 - 1. DOST-BC certification, if the Regulated Article to be used for field trial was developed in the Philippines.
 - 2. Proposed Public Information Sheet for Field Trial (Annex "B")
 - 3. Technical dossier, which must include the following:
 - a. Molecular biology of systems used/to be used to produce Regulated Article
 - b. Anticipated/actual expression of altered genetic material in the Regulated Article, and how this expression differs from that of non-GM parental organisms
 - c. Data/other information on genetic stability of the introduced gene material
 - d. Biological materials accompanying the Regulated Article during movement (where appropriate)
 - e. Proposed experimental or production design
 - f. Description of field testing site/s
 - g. Proposed procedures, processes & safeguards to prevent escape & dissemination of Regulated Article from intended field testing site/s
 - h. Proposed method of final disposition
 - Any information known to applicant that Regulated Article may pose greater risk to human health and environment than unmodified host organism
 - 4. Information on socio-economic, cultural and ethical consideration
 - 5. Project Description as prescribed by DENR-BC;
 - 6. Project Description as prescribed by DOH-BC:
 - 7. NCIP Clearance (when applicable)
 - 8. Import permit (when applicable);
 - 9. IBC Endorsement andthe Risk Assessment Report; and
 - 10. Proof of payment of fees.

the information in this application are true and correct; and (ii) this views on which to base a decision and includes relevant data and unfavorable to the application. The undersigned likewise warrants solely and exclusively for use in field testing.	information known to	o the applicant which are
(Printed Name and Signature of Respo	nsible Officer/Autho	rized Representative)
Republic of the Philippines)		
SUBSCRIBED AND SWORN TO before me this affiant exhibiting to me his/her Community Tax Certificate at		, 200 issued or
Doc. No; Page No; Book No; Series of 200	NOT	ARY PUBLIC

The undersigned certifies that based on his/her personal knowledge and/or authentic documents: (i) all

PUBLIC INFORMATION SHEET FOR FIELD TRIAL

(To be accomplished by the Applicant in a language/dialect known to the community where the field trial is to be conducted and notarized)

PROPOSAL FOR THE FIELD TRIAL OF (Insert name of the Regulated Article).

- 1. Name of the Applicant
- 2. Address of the Applicant
- 3. Telephone Number/ Facsimile Number and E-Mail Address of the Applicant
- 4. Name of Project Leader
- 5. Name of Responsible Officer/Authorized Representative
- 6. Description of the Regulated Article for Field Trial (mention the crop, transformation event, new trait conferred, name of the gene transferred, method of transformation, and advantages of the trait conferred)
- 7. Purpose (s) of the Field Trial (state the objectives of the proposed project)
- 8. Potential Benefits and Risks of the Regulated Article Relative to the Non-Modified Host Organism
 - a) Potential Benefits (describe how the new trait will benefit farming, the farmer, the environment, and society as a whole)
 - b) Potential Risks (summarize human and animal health, and environmental assessments done and studies implemented indicating potential effects on human and animal health, and the environment)
- 9. Brief Summary of the Effects of the Regulated Article on the Target Organism, If It is a Pest Protected Plant (add any information known on its effects on non-target organism)
- 10. Location (with GPS coordinates) and Size of the Proposed Field Trial Site
- 11. Duration of the Field Trial
- 12. Method of Disposal of Regulated Article after Field Trial
- 13. Government Agencies Consulted Before Field Trial

For Additional Information on the proposed field trial, please contact:

(Name of Responsible Officer/Authorized Representative)

(Address)

(Telephone/FascimileNos& E-mail Address)

The public is hereby invited to submit their comments on the proposed field trial from the date of posting until the public hearing, to:

Director
Bureau of Plant Industry
San Andres, Malate, Manila
Telephone Number 521-1080
Fax Number 521-1080
E-Mail bpibiotechsecretariat@vahoo.com

Approved for Posting:

Director				
Bureau	of Plant	Industry		
Date:				

Republic of the Philippines Department of Agriculture BUREAU OF PLANT INDUSTRY

PLANT QUARANTINE SERVICE Manila

Application for Biosafety Permit for Commercial Propagation

(Date)	

The Director Bureau of Plant Industry

Sir:

We-

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name			
Address			
Tel. No.			
Fax No.			
Email Address			

hereby request for issuance of Biosafety Permit for Commercial Propagation for the genetically modified (GM) plant/plant products describe below

Designation	Regulated Article	Donor Organism	Host Organism	Vector or Vector Agent	Constituents of the Regulated Article
Common					
Name					
Scientific					
Name					
Trade					
Name					
Other					
Designations					

Identification No. of the Field	
Testing Application File	

- 1. Certification from the BPI 1) for new application, that the regulated article has undergone satisfactory field trial in the Philippines, 2) in cases of renewal, a certified true copy of the expired Biosafety Permit for Commercial Propagation
- 2. A technical dossier consisting of scientific literature, unpublished studies or data from tests performed, or such other scientific materials relied upon by the applicant to show that the release for commercial propagation of the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart;
- 3. Copy of the proposed Public Information Sheet for Commercial Propagation (Annex "D") including information required for evaluation of environmental and health impacts;
- 4. Information on socio-economic, cultural and ethical considerations:

^{*} The following supporting documents are attached:

- 5. Field trial report:
- Project Description as prescribed by DENR-BC;
 Project Description as prescribed by DOH-BC;
 Applicant's Risk Assessment Report;
 Import Permit (when applicable); and
 Proof of payment of fees.

The undersigned certifies that based on his/her personal knowled information in this application are true and correct; (ii) this application which to base a decision and includes relevant data and informatio unfavorable to the application. The undersigned like wise warrants solely and exclusively for commercial propagation.	tion contains all information and views on n known to the applicant which are
(Printed Name and Signature of Respon	sible Officer/Authorized Representative)
Republic of the Philippines)	
SUBSCRIBED AND SWORN TO before me this affiant exhibiting to me his/her Community Tax Certificate at	No issued or
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PUBLIC INFORMATION SHEET FOR COMMERCIAL PROPAGATION

(to be accomplished by the Applicant and notarized)

PROPOSAL FOR THE COMMERCIAL PROPAGATION OF (Insert Name of the Regulated Article)

- 1. Applicant's Name
- 2. Applicant's Address
- 3. Telephone Number/ Facsimile Number, E-Mail Address of the Applicant
- 4. Name of Responsible Officer/Authorized Representative
- 5. Description of the Regulated Article for Commercial Propagation (mention the crop, transformation event, new trait conferred, name of the gene transferred, method of transformation, and advantages of the trait conferred)
- 6. If to be imported, Country (ies) of Origin of the Regulated Article
- Brief Summary of Potential Effects on Human and Animal Health and the Environment (summarize human and animal health and environmental assessments done and studies implemented indicating potential effects on human and animal health and the environment)
- 8. Brief Summary of Potential Benefits (Describe how the new trait will benefit farming, the farmer, the environment, and society as a whole)
- 9. Countries Where Approvals Have Been Granted (for FFP; for Commercial Propagation)

The public is hereby invited to submit their comments to the BPI Director (within 60 days from the date of publication) on the Proposed Commercial Propagation of Name Transformation Event.

Bureau of Plant Industry
San Andres, Malate, Manila
Telephone Number 521-1080
Fax Number 521-1080
E-Mail bpibiotechsecretariat@yahoo.com

Approved for Publication:	
	Director
	Bureau of Plant Industry
	Date:

Republic of the Philippines Department of Agriculture BUREAU OF PLANT INDUSTRY

PLANT QUARANTINE SERVICE Manila

Application for Biosafety Permit for Direct Use as Food and Feed, or for Processing

 (Date)	

The Dir	ector	
Bureau	of Plant	Industry

Sir:

We-

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name			
Address			
Tel. No.			
Fax No.			
Email Address			

hereby request for issuance of Biosafety Permit for Direct Use for the genetically modified (GM) plant/plant product described below.

Designation	Regulated Article	Donor Organism	Host Organism	Vector or Vector Agent	Constituents of the Regulated Article
Common					
Name					
Scientific					
Name					
Trade					
Name					
Other					
Designations					

Country of Origin	
Quantity	
Flight/Voyage No	
Port of Entry	
Proposed Schedule	

*The following supporting documents are attached

- 1. In the case of imported regulated article, notification from the exporter or country of origin in accordance with existing international agreements on the transboundary movement of genetically modified organisms:
- 2. Information on socio-economic, cultural and ethical considerations:
- 3. Copy of the proposed PIS for Direct Use, (Annex "F") including information required for evaluation of environmental and health impacts:
- 4. In cases of renewal, certified true copy of expired Biosafety Permit for Direct Use issued by BPI; and
- 5. Proof of payment of fees
- 6. To facilitate review of the application, the applicant may submit documents to show that the regulated article is allowed for commercial distribution as food and feed by the regulatory authorities in the country of origin; and poses no greater risks to biodiversity, and human and animal health than its conventional counterpart. If the regulated article is intended for use as feed or for processing into feeds, the applicant may submit documents to show that the regulatory authorities in the country of origin have likewise determined that the regulated article poses no greater risks to biodiversity, and human and animal health than its conventional counterpart.

The undersigned certifies that based on his/her personal knowledge and/or authentic documents: (i) all the information in this application are true and correct; and (ii) this application contains all information and views on which to base a decision and includes relevant data and information known to the applicant which are unfavorable to the application. The undersigned likewise warrants that the Regulated Article is to be imported solely and exclusively for direct use as food and feed or for processing.

	(Printed name and Signature of Responsible Of	ficer/Authorized Represent	ative)
Republic of the Philippin	es) _)		
SUBSCRIBED affiant exhibiting to m	AND SWORN TO before me this day of the his/her Community Tax Certificate No at		, 200 issued o
Doc. No; Page No; Book No; Series of 200 .		NOTARY PUBLIC	

PUBLIC INFORMATION SHEET FOR DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING

(to be accomplished by the Applicant and notarized)

PROPOSAL FOR DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING [Insert Name of the Regulated Article]

- 1. Applicant's Name
- 2. Applicant's Address
- 3. Telephone Number/ Facsimile Number, E-Mail Address of the Applicant
- 4. Name of Responsible Officer/Authorized Representative
- 5. Description of the Regulated Article for Direct Use (mention the crop, transformation event, new trait conferred, name of the gene transferred, method of transformation, and advantages of the trait conferred)
- 6. If to be imported, Country (ies) of Origin of the Regulated Article
- 7. Brief Summary of Potential Effects on Human and Animal Health and the Environment (summarize human and animal health and environmental assessments done and studies implemented indicating potential effects on human and animal health and the environment)
- 8. Brief Summary of Potential Benefits (Describe how the new trait will benefit farming, the farmer, the environment, and society as a whole)
- 9. Countries Where Approvals Have Been Granted (for FFP; for Commercial Propagation)

The public is hereby invited to submit their comments to the BPI Director (within 60 days from date of publication) on the Proposal for the Importation of <u>Name Transformation Event</u> for direct use as food and feed, or for processing

Director
Bureau of Plant Industry
San Andres, Malate, Manila
Telephone Number 521-1080
Fax Number 521-1080
E-Mail bpibiotechsecretariat@yahoo.com

Approved for Publication:	
	Director
	Bureau of Plant Industry
	Date:

ANNEX G

LIST OF REGULATED ARTICLES WITH VALID BIOSAFETY PERMIT UNTIL THEIR EXPIRATION DATE

I. Regulated Articles (single transformation event) for Direct Use

Regulated Article	Date of Expiration
Corn MON88017	March 20, 2016
Soybean A5547-127	June 22, 2016
Alfalfa J101 and J163	August8, 2016
Corn 59122	August8. 2016
Liberty Link (LL) 62 Rice	May 15, 2017
Soybean MON87701	May 15, 2017
Corn MIR604	October 4, 2017
Corn MON87460	November 14, 2017
Soybean MON89788	November 15, 2017
Corn MON810	December 2, 2017
Corn 3272	February 6, 2018
Corn BT11	July 18, 2018
Soybean 40-3-2	July 18, 2018
Soybean 305423	September 8, 2018
Corn NK603	September 9, 2018
Corn TC1507	October 6, 2018
Canola RT73	October 21, 2018
Corn BT176	October 23, 2018
Corn GA21	November 19, 2018
Corn T25	December4, 2018
Cotton 1445	December4, 2018
Cotton 15985	December 4, 2018
Soybean A2704-12	January 22, 2019
Cotton 531	February 4, 2019
Corn MON89034	April 28, 2019
Soybean MON 87708	May 4, 2019
Soybean MON87705	November 27, 2019
Corn MON87427	November 27, 2019
Corn MIR162	February 10, 2020
Canola MON88302	April 23, 2020
Soybean MON87769	April 23, 2020
Corn 5307	June 10, 2020
Sugarbeet H7-1	July 27, 2020
Cotton COT102	September 8, 2020
Soybean FG72	September 8, 2020
Soybean CV127	October 28, 2020
Cotton MON88913	November 25, 2020

II. Regulated Articles (stacked transformation events) for Direct Use

Regulated Article	Date of Expiration
Cotton 15985 x RR Flex Cotton (MON88913)	April 19, 2016
Corn MON88017 x Corn MON810	June 30, 2016
Corn Bt11 x Corn DAS59122 x Corn MIR604 x	August 2, 2016
Corn TC1507 x Corn GA21	
Corn Bt11 x Corn GA21	January 22, 2017
Corn 59122 x Corn NK603	February6, 2017
Corn TC1507 x Corn 59122	February 6, 2017
Corn 59122 x Corn TC1507 x Corn NK 603	February 6, 2017

Corn TC1507 X Corn MON810 x Corn NK603	May 15, 2017
Corn Btl x Corn MIR604	December 12, 2017
Corn MIR604 x Corn GA21	December 12, 2017
Corn Btl1 x Corn MIR604 x Corn GA21	February 28, 2018
Corn Btl1 x Corn MIR162	October 28, 2018
Corn Btl1 x Corn TC1507 x Corn GA21	January 22, 2019
Soybean 305423 x Soybean 40-3-2	April 29, 2019
Corn 87460 x Corn MON89034 x Corn NK603	July 9, 2019
Corn MON89034 x Corn NK603	July 21, 2019
Soybean MON87701 x Soybean MON89788	September 25, 2019
Corn MON87460 x Corn MON89034 x Corn MON88017	September 25, 2019
Corn MON89034 x Corn MON88017	Oct. 18, 2019
Corn TC1507 x Corn DAS59122 x Corn	October 27, 2019
MON810 x Corn MIR604 x Corn NK603	
Corn GA21 x Corn T25	December 8, 2019
Corn TC1507 x Corn MON810 x Corn MIR162 x	Jan. 7, 2020
Corn NK603	
Corn MON810 x Corn NK603	Jan. 7, 2020
Cotton 531 x Cotton 1445	Jan. 7, 2020
Cotton 15985 x Cotton 1445	Jan. 7, 2020
Corn MON89034 x Corn 1507 x Corn 88017 x	Feb. 8, 2020
Corn 59122	
Corn Btl1 x MIR162 x GA21	February 11, 2020
Corn Bt11 x MIR162	February 11, 2020
Corn NK603 x Corn T25	April 21, 2020
Corn Bt11 x Corn MIR162 x Corn GA21	July 27, 2020
Corn 3272 x Corn Bt11 x Corn MIR604 x Corn	July 27, 2020
GA21	
Corn BT11 x Corn MIR162 x Corn MIR604 x	July 27, 2020
Corn GA21	
Corn MON89034 x Corn 1507 x Corn NK603	Jul 27, 2020
Corn BT11 x Corn MIR162 x Corn TC1507 x	
Corn GA21	Jul 27, 2020
Corn Bt11 x Corn MIR162	December 6, 2020
Corn Bt11 x Corn MIR162 x Corn GA21	December 6, 2020
Corn Bt11 x Corn TC1507 x Corn GA21	December 6, 2020

III. Regulated Articles (single transformation events) for Propagation

Regulated Article	Date of Expiration
Corn MON810	Nov. 18, 2016
Corn TC1507	Dec. 2, 2017
Corn GA21	December 8, 2018
Corn NK603	Nov. 23, 2019
Corn Btl1	Mar. 15, 2020
Corn MON89034	Apr. 22, 2020

IV. Regulated Articles (stacked transformation events) for Propagation

Regulated Article	Date of Expiration
Corn MON89034 x Corn NK603	March 3, 2016
Corn TC1507 x Corn MON810 x Corn NK603	March 30, 2019
Corn TC1507 x Corn MON810	August 6, 2019

Corn TC1507 x Corn NK603	August 6, 2019
Corm MON810 x Corn NK603	July 15, 2020
Corn Btll x Corn GA21	Sept. 5, 2020
Corn Bt11 x Corn TC1507 x Corn GA21	October 25, 2020