

ANNEX E

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

MAY 16 2018

(Date)

The Director  
 Bureau of Plant Industry

Sir:

We –

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name	MONSANTO PHILIPPINES, INC.	Mr. Erwin G. Vibal Country Lead	Ms. Shemaine O. Castillo Regulatory Affairs Lead
Address	23 <sup>rd</sup> Floor Tower II, Insular Life Corporate Centre, Insular Life Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa City	23 <sup>rd</sup> Floor Tower II, Insular Life Corporate Centre, Insular Life Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa City	23 <sup>rd</sup> Floor Tower II, Insular Life Corporate Centre, Insular Life Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa City
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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	Cotton event MON 531 and all progenies derived from crosses of the product with any conventionally-bred cotton, and cotton-containing registered biotech events.	Common soil bacterium	Cotton	Cotton line MON 531 was produced by <i>Agrobacterium</i> -mediated transformation method using DNA derived from the transformation plasmid PV-GHBK04.	Two copies of expression cassettes are integrated within the cotton genome, which consist of E35S promoter, <i>cry1Ac</i> gene, 7S 3' terminator, <i>aad</i> gene, 35S promoter, <i>nptII</i> gene, and NOS 3' terminator. MON 531 only has one intact functional insert of full length <i>cry1Ac</i> , <i>aad</i> , and <i>nptII</i> genes. The <i>aad</i> gene is under bacterial promoter and no AAD protein is expressed.
Scientific Name	<i>Gossypium hirsutum</i> (L.)	<i>cry1Ac</i> : <i>Bacillus thuringiensis</i> variety <i>kurstaki</i>  <i>nptII</i> : <i>Escherichia coli</i>	<i>Gossypium hirsutum</i> (L.)	-	-
Trade Name	Bollgard® Cotton	-	-	-	-
Other Designations	Bollgard, Insect-Protected Cotton	-	-	-	-

Country of Origin	United States. Importers of commodities will have to provide their own sources.
Quantity	Importers of commodities/grains will have to provide the quantities they need to import.
Flight/Voyage No	Importers of commodities/grains will have to provide the flight/voyage no.
Port of Entry	Importers of commodities/grains will have to provide the port of entry.
Proposed Schedule	Importers of commodities/grains will have to provide the schedule of importation.

\* 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.

  
SHEMAINE OCHEDA CASTILLO

Name and Signature

Republic of the Philippines)

Muntinlupa City

**CITY OF MUNTINLUPA**

SUBSCRIBED AND SWORN TO before me this 16 day of MAY 2018 with Affiant exhibiting to me her passport ID with no. EC2569267 dated October 29, 2014 at DFA NCR South.

NOTARY PUBLIC

  
ELEONOR T. HERNANDEZ  
Notary Public

Until December 31, 2018

Appt. No. 18-009, A.P. Roll No. 38749

PTR No. 2800414, Muntinlupa City

IBP Lifetime Member No. 3258, TIN 135478879

MCLE No. V-0004892, 12/15/2014/Philippines

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