

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**

DEC 03 2019  
(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	2/F Bayer House, Canlubang Industrial Estate, Calamba, Laguna 4028	2/F Bayer House, Canlubang Industrial Estate, Calamba, Laguna 4028	2/F Bayer House, Canlubang Industrial Estate, Calamba, Laguna 4028
Tel. No.	(+632) 3 226-4967	(+632) 3 226-4967	(+632) 3 226-4967
Fax No.	N/A	N/A	N/A
Email address	<a href="http://www.bayer.com">www.bayer.com</a>	<a href="mailto:erwin.vibal@bayer.com">erwin.vibal@bayer.com</a>	<a href="mailto:shemaineocheda.castillo@bayer.com">shemaineocheda.castillo@bayer.com</a>

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	Stacked Trait Product MON 531 × MON 1445 and all progenies derived from crosses of the product with any conventionally- bred cotton, and cotton- containing	MON 531: Common soil bacterium  MON 1445: Common soil bacterium	Cotton	MON 531 was produced by <i>Agrobacterium</i> - mediated transformation using the plasmid PV-GHBK04.  MON 1445 was produced by <i>Agrobacterium</i> - mediated transformation	Molecular characterization of each constituent event confirmed that:  MON 531 contains two copies of expression cassettes integrated within the cotton genome, but only has one intact

	registered biotech events.			using the plasmid PV-GHGT07.	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 in MON 531.  MON 1445 contains a single insert containing one copy of the cassettes coding for CP4 EPSPS protein and NPTII, a selectable marker protein. There is an <i>aad</i> gene inserted, however, it is under bacterial promoter and no AAD protein is expressed in MON 1445.
Scientific Name	<i>Gossypium hirsutum</i> L.	<u>MON 531:</u> <i>cry1Ac:</i> <i>Bacillus thuringiensis</i> <i>variety kurstaki</i>  <i>nptII:</i> <i>Escherichia coli</i>  <u>MON 1445:</u> <i>cp4 epsps:</i> <i>Agrobacterium</i> <i>sp. strain CP4</i>  <i>nptII:</i> <i>Escherichia coli</i>	<i>Gossypium hirsutum</i> L.	-	-
Trade Name	Bollgard® × Roundup Ready® Cotton	-	-	-	-
Other Designations	-	-	-	-	-




Country of Origin	Importers of commodities/grains 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 O. CASTILLO**

(Printed name and Signature of Responsible Officer/Authorized Representative)

Republic of the Philippines)  
MUNTINLUPA CITY )s.s

'10 3 DEC 2019'

SUBSCRIBED AND SWORN TO before me this \_\_\_ day of \_\_\_\_\_ with Affiant exhibiting to me her Passport with number P9866316A issued on December 7, 2018 at DFA NCR South.

**NOTARY PUBLIC**

**PATRICIO L. BONCAYAO, JR.**  
NOTARY PUBLIC  
2ND FLOOR, KFC (FORMERLY ANCESTRY) BLDG.,  
ROTONDA, ALABANG, MUNTINLUPA CITY  
MCLE COMPLIANCE NO. VI-0008152  
ISSUED ON 04-23-18  
UNTIL APRIL 14, 2022  
IBP LIFETIME MEMBER # 1010785-11-8828  
**PASAY CITY**  
PTR # 3252088-01-03-19  
NC-18-007, MUNTINLUPA CITY  
UNTIL 12-31-19  
TIN 137-734-581  
ROLL # 33796  
TEL NO. 800-70-18

Doc. No. 482  
Page No. 98  
Book No. 253  
Series of 2019.