

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 6, 2016

(Date)

The Director
 Bureau of Plant Industry

Sir:

We –

RECEIVED
 MAY 10 2016

BY: LYNNE

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name	MONSANTO PHILIPPINES, INC.	Ms. Rachel P. Lomibao Commercial Lead	Dr. Gabriel Romero Regulatory Affairs Lead
Address	23 rd Floor Tower II, Insular Life Corporate Centre, Insular Life Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa City	23 rd Floor Tower II, Insular Life Corporate Centre, Insular Life Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa City	23 rd 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	Stacked Trait Product MON 15985 x MON 88913 and all progenies derived from crosses of the product with any conventionally-bred cotton, and cotton - containing registered biotech events.	MON 15895: Common soil bacterium MON 88913: Common soil bacterium	Cotton	MON 15985 was produced by particle bombardment method using DNA derived from the transformation plasmid PV-GHBK11. MON 88913 was produced by Agrobacterium method using DNA derived from the transformation plasmid PV-GHGT35.	Molecular studies demonstrated that cotton event MON 15985 contains one DNA insertion into the Bollgard cotton genome. The insert contains one copy of both the cry2Ab2 and the uidA (β -glucuronidase) cassettes. The cry2Ab2 and the uidA coding regions are each under the control of an enhanced CaMV 35S promoter and a NOS 3' polyadenylation sequence. Molecular characterization confirmed that MON 88913 contains one copy of the T-DNA (transferred DNA) at a single locus that contains two intact CR- ϕ <i>epsps</i> gene cassettes. No additional elements from the transformation vector PV-GHGT35, linked or unlinked to intact gene cassettes, were detected in the genome of MON 88913.
Scientific Name	<i>Gossypium hirsutum</i> L.	MON 15985 cry2Ab2: <i>Bacillus thuringiensis</i> var <i>kustaki</i> uidA: <i>Escherichia coli</i> strain K12 MON 88913: cp4epsps: <i>Agrobacterium</i> sp. strain CP4	<i>Gossypium hirsutum</i> L.	-	-
Trade Name	BollgardII x Roundup Ready® Flex Cotton	-	-	-	-
Other Designations	-	-	Scanned by CamScanner		

Country of Origin	Countries already commercializing MON 15985 x MON 88913. 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.



Dr. Gabriel O. Romero

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

Republic of the Philippines)
MANILA CITY

SUBSCRIBED AND SWORN TO before me this 06 day of MAY, 2016, affiant exhibiting to me his Passport No. EB9694613 issued on 29 Nov 2013 at DFA Manila.

Doc. No. 52 ;
Page No. 12 ;
Book No. XIX ;
Series of 2016.


NOTARY PUBLIC

MARIA ROWENA E. MOJICA-RODRIGUEZ
Notary Public for Munt. City (until 12/31/2017)
Appointment No. 16-002
B.P. Office Memorandum No. 47547
PTR No. 2064536/04 Jan 2016/Munt. City

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