

ANNEX E

Republic of the Philippines
 Department of Agriculture
 BUREAU OF PLANT INDUSTRY
 PLANT QUARANTINE SERVICE
 Manila

MAR 31 2017

(Date)

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

The Director
 Bureau of Plant Industry

Sir:

We –

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name	MONSANTO PHILIPPINES, INC.	Ms. Rachel P. Lomibao Country lead	Ms. Shemaine O. Castillo 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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Email Address	www.monsanto.com	rachel.pascua.lomibao@monsanto.com	shemaine.ocheda.castillo@monsanto.com

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

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 APR 03 2017

BY: LYNNE

Designation	Regulated Article	Donor Organism	Host Organism	Vector or Vector Agent	Constituents of the Regulated Article
Common Name	MON 87411 and all progenies derived from crosses of the product with any conventionally-bred corn, and corn -containing registered biotech events.	Common soil bacterium <i>cry3Bb1: Bacillus thuringiensis subsp.kumamotoensis</i> <i>cp4 epsps: Agrobacterium sp. strain CP4</i> Partial DNA fragment that is designed to partially match the gene present in western corn rootworm encoding the SNF7 subunit of the ESCRT-III complex (DvSnf7)	Corn	MON 87411 was produced by Agrobacterium-mediated method using transformation vector PV-ZMIR10871.	Molecular characterization of MON 87411 was assessed by Next Generation Sequencing and Junction Sequence Analysis (NGS/JSA) using a combination of sequencing, polymerase chain reaction (PCR), and bioinformatics. It confirmed that one copy of the intended T-DNA containing the DvSnf7 suppression cassette and the <i>cry3Bb1</i> and <i>cp4 epsps</i> expression cassettes that is stably integrated at a single locus. No backbone DNA sequences from plasmid vector PV-ZMIR10871 were detected in MON 87411.
Scientific Name	<i>Zea mays</i> L.	<i>Bacillus thuringiensis subsp.kumamotoensis</i> <i>Agrobacterium sp. strain CP4</i>	<i>Zea mays</i> L.	-	-
Trade Name	Corn Rootworm3	-	-	-	-
Other Designations	-	-	-	-	-

Country of Origin	Countries already commercializing MON 87411 corn. 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.
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* 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

MAR 31 2017

SUBSCRIBED AND SWORN TO before me this ____ day of _____, 20____, affiant exhibiting to me her Passport No. **EC2569267** issued on **October 29, 2014** at **DFA NCR South**.

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Book No. 266
Series of 20 17

PATRICIO L. BONGAYAO, JR.
Notary Public **NOTARY PUBLIC**
2nd Floor, V.L.C. (formerly Ancestry), Bldg.
Rotonda, Alabang, Muntinlupa City
MCLE Compliance No. V-0021121
Issued on 01-03-2017
BP Lifetime Member # 1010785-11-06-15
Pasay City
PTR # 2420114-01-03-2017
Until December 31, 2017
NC-16-014, Muntinlupa City
TIN 137-734-581
ROLL # 33796
P.O. No. 800-70-10