

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**

SEP 05 2018

(Date)

The Director
Bureau of Plant Industry

Sir:

We -

Information	Applicant 1	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
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Information	Applicant 2	Responsible Officer (RO)	Representative of RO (if applicable)
Name	DOW AGROSCIENCES PHILIPPINES	MS. BELLA VICTORIA ERMITA Manager, Regulatory and Stewardship, Philippines	MS. BELLA VICTORIA ERMITA Manager, Regulatory and Stewardship, Philippines
Address	Dow AgroSciences B.V. Philippine Branch, 23 rd Floor, 6750 Bldg., Ayala Avenue, Makati City 1226, Philippines	Dow AgroSciences B.V. Philippine Branch, 23 rd Floor, 6750 Bldg., Ayala Avenue, Makati City 1226, Philippines	Dow AgroSciences B.V. Philippine Branch, 23 rd Floor, 6750 Bldg., Ayala Avenue, Makati City 1226, Philippines
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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 89034 × TC1507 × NK603 and all progenies derived from crosses of the product with any conventionally-bred maize, and maize-containing registered biotech events.	MON 89034: Common soil bacterium TC1507: Common soil bacterium NK603: Common soil bacterium	Maize (corn)	MON 89034 was developed through <i>Agrobacterium</i> -mediated transformation using the binary vector, PV-ZMIR245. TC1507 was produced via microprojectile bombardment of maize cells, using a PmeI-linearized portion of plasmid PHP8999. NK603 was produced by particle acceleration using a linear DNA restriction fragment from the vector PV-ZMGT32.	Molecular characterization confirmed that MON 89034 contains a single intact <i>cry1A.105</i> and <i>cry2Ab2</i> expression cassette integrated at a single locus within the maize genome. Molecular characterization confirmed the presence of single functional copies of the <i>cry1F</i> and <i>pat</i> gene expression cassettes, stably integrated at a single locus within the genome. Molecular studies demonstrated that maize line NK603 contains a single copy of introduced DNA at a single locus. The insert

Designation	Regulated Article	Donor Organism	Host Organism	Vector or Vector Agent	Constituents of the Regulated Article
					contains two expression cassettes, each containing a single copy of the <i>cp4 epsps</i> gene.
Scientific Name	<i>Zea mays</i> L.	MON 89034: <i>cry1A.105:</i> <i>Bacillus thuringiensis</i> <i>cry2Ab2:</i> <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> TC1507: <i>cry1F: Bacillus thuringiensis</i> var. <i>aizawai</i> pat: <i>Streptomyces viridochromogenes</i> NK603: <i>cp4 epsps:</i> <i>Agrobacterium</i> sp. strain CP4	<i>Zea mays</i> L.	-	-
Trade Name	Power Core™	-	-	-	-
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.

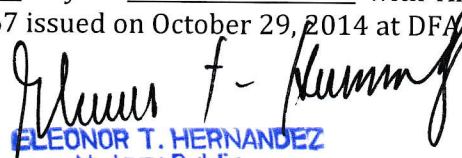

SHEMAINE O. CASTILLO

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

Republic of the Philippines)
 Muntinlupa City)S.S

SUBSCRIBED AND SWORN TO before me this SEP 05 2018 day of _____ with Affiant exhibiting to me his/her Passport with number EC2569267 issued on October 29, 2014 at DFA NCR South.

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 Book No. 138;
 Series of 2018.


ELEONOR T. HERNANDEZ
 Notary Public

Until December 31, 2019
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