

2/22

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**

FEB 15 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 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
Tel. No.	(+632) 809-4848	(+632) 809-4848	(+632) 809-4848
Fax No.	(+632) 807-7581	(+632) 807-7581	(+632) 807-7581
Email Address	www.monsanto.com	erwin.g.vibal@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.

Designation	Regulated Article	Donor Organism	Host Organism	Vector or Vector Agent	Constituents of the Regulated Article
Common name	Stacked Trait Product MON 87427 × MON 89034 × MIR162 × NK603 and all progenies derived from crosses of the product with any conventionally-bred maize, and maize-containing registered biotech events.	MON 87427: Common soil bacterium MON 89034: Common soil bacterium MIR162: Common soil bacterium NK603: Common soil bacterium	Maize (corn)	MON 87427 was developed through <i>Agrobacterium</i> -mediated transformation of conventional maize LH198 x HiII using the vector PV-ZMAP1043. The vector contains one T-DNA consisting of the <i>cp4 epsps</i> coding sequence under a specific promoter and intron combination (<i>e35S-hsp70</i>). MON 89034 was developed through <i>Agrobacterium</i> -mediated transformation using the binary vector, PV-ZMIR245. MIR162 was produced by <i>Agrobacterium</i> -mediated method using transformation vector pNOV1300. NK603 was produced by particle acceleration using a linear DNA restriction fragment from the vector PV-ZMGT32.	Molecular characterization demonstrated that MON 87427 contains a single copy of the T-DNA at a single locus in the maize genome. There were no additional genetic elements, including backbone sequences from PV-ZMAP1043 detected, linked or unlinked to the intact T-DNA present in MON 87427. 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 studies demonstrated that MIR162 contains one copy of the <i>vip3Aa20</i> expression cassette integrated at a single locus within the maize genome, and the <i>pmi</i> gene as a plant selectable marker during development of MIR162. Molecular studies demonstrated that maize line NK603 contains a single copy of introduced DNA at a single locus. The insert contains two expression cassettes, each containing a single copy of the <i>cp4 epsps</i> gene.

Scientific Name	<i>Zea mays</i> L.	MON 87427: <i>cp4 epsps:</i> <i>Agrobacterium</i> <i>sp. strain CP4</i>	<i>Zea mays</i> L.	-	-
		MON 89034: <i>cry1A.105:</i> <i>Bacillus</i> <i>thuringiensis</i> <i>cry2Ab2: Bacillus</i> <i>thuringiensis</i> subsp. <i>kurstaki</i>			
		MIR162: <i>vip3Aa20:</i> <i>Bacillus</i> <i>thuringiensis</i> strain AB88 <i>pmi: Escherichia</i> <i>coli</i> strain K-12			
		NK603: <i>cp4 epsps:</i> <i>Agrobacterium</i> <i>sp. strain CP4</i>			
Trade Name	Trecepta™	-	-	-	-
Other Designations	-	-	-	-	-

Country of Origin	MON 87427 × MON 89034 × MIR162 × NK603 were originally developed and deregulated in U.S.* (* U.S. does not regulate a breeding stack of deregulated single events.)
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)

FEB 15 2018

SUBSCRIBED AND SWORN TO before me this ____ day of _____ with Affiant exhibiting to me his/her Community Tax Certificate no. EC2569267 dated OCTOBER 29, 2019 at DFA NCR SOUTH.


NOTARY PUBLIC

ELEONOR T. HERNANDEZ
Notary Public

Until December 31, 2019

Appt. No. 18-009, Attorney's Roll No. 38749

PTR No. 2800414, JAN. 3, 2018, Muntinlupa City

IBP Lifetime Member No. 05258, TIN 135478879

MCLE No. V-0004892, 12/16/2014, Philippines

ENAC27, L'Paseo, Jollibee Junction, Alabang,

1770 Muntinlupa City, Philippines

Doc. No. 158
Page No. 33
Book No. 113
Series of 2018