

ANNEX E

Republic of the Philippines
Department of Agriculture
BUREAU OF PLANT INDUSTRY

PLANT QUARANTINE SERVICE
Manila

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BY: LYNNE

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

JUN 13 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) 807-9938	(+632) 807-9938	(+632) 807-9938
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 × TC1507 × MON 88017 × DAS-59122-7 and all progenies derived from	MON 87427: Common soil bacterium MON 89034: Common soil bacterium TC1507:	Corn	MON 87427 was produced by <i>Agrobacterium</i> -mediated transformation using vector PV-ZMAP1043.	Molecular characterization of each constituent event confirmed that: MON 87427 contains a

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	crosses of the product with any conventionally-bred corn, and corn-containing registered biotech events	Common soil bacterium MON 88017: Common soil bacterium DAS-59122-7: Common soil bacterium		MON 89034 was developed through <i>Agrobacterium</i> -mediated transformation using the binary vector, PV-ZMIR245. TC1507 was produced via microprojectile bombardment of corn cells, using a <i>PmeI</i> -linearized portion of plasmid PHP8999 containing two expression cassettes: <i>cry1F</i> and <i>pat</i> . MON 88017 was produced by <i>Agrobacterium</i> -mediated transformation of an inbred corn line with the plasmid vector PV-ZMIR39. DAS-59122-7 was generated by <i>Agrobacterium</i> -mediated transformation using plasmid PHP17662.	single intact <i>cp4 epsps</i> expression cassette integrated at a single locus within the corn genome. MON 89034 contains a single copy of the <i>cry1A.105</i> and <i>cry2Ab2</i> expression cassettes, stably integrated at a single locus within the corn genome. TC1507 contains a single copy of the <i>cry1F</i> and <i>pat</i> expression cassettes, stably integrated at a single locus within the corn genome. MON 88017 contains a single insertion with one copy of the <i>cry3Bbl</i> , <i>pvzmnir39</i> and the <i>cp4 epsps</i> cassettes, stably integrated within the corn genome. DAS-59122-7 contains a

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					single copy of the three gene cassettes <i>cry34Ab1</i> , <i>cry35Ab1</i> and <i>pat</i> gene cassettes, stably integrated at a single locus within the corn genome.
Scientific Name	<i>Zea mays</i> L.	<p>MON 87427: <i>cp4 epsps</i>: <i>Agrobacterium</i> sp. strain CP4</p> <p>MON 89034: <i>cry1A.105</i>: <i>B. thuringiensis</i> subsp. <i>kurstaki</i> <i>cry2Ab2</i>: <i>B. thuringiensis</i> subsp. <i>kurstaki</i></p> <p>TC1507: <i>Cry1F</i>: <i>B. thuringiensis</i> var. <i>aizawai</i> <i>pat</i>: <i>Streptomyces</i> <i>viridochromo</i> <i>genes</i></p> <p>MON 88017: <i>cp4 epsps</i>: <i>Agrobacterium</i> sp. strain CP4 <i>cry3Bb1</i>: <i>B. thuringiensis</i> subsp. <i>kumamotoensis</i></p> <p>DAS-59122-7: <i>cry34Ab1</i> & <i>cry35Ab1</i>: <i>Bacillus thuringi</i> <i>ensis</i> strain</p>	<i>Zea mays</i> L.	-	-

Designation	Regulated Article	Donor Organism	Host Organism	Vector or Vector Agent	Constituents of the Regulated Article
		PS149B1 <i>pat:</i> <i>Streptomyces viridochromogenes</i>			
Trade Name	RHS x SmartStax®	-	-	-	-
Other Designations	-	-	-	-	-

Country of Origin	MON 87427 × MON 89034 × TC1507 × MON 88017 × DAS-59122-7 was 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

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likewise warrants that the Regulated Article is to be imported solely and exclusively for direct use as food and feed or for processing.

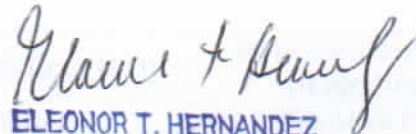

SHEMAINE O. CASTILLO

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

REPUBLIC OF THE PHILIPPINES)
MUNTINLUPA CITY)s.s

JUN 13 2018

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



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

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