

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**

AUG 19 2019

(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
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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	Stack trait product MON 87427 × MON 89034 × TC1507 × MON 87411 × DAS-59122-7 and all progenies derived from crosses of the product with any	MON 87427: Common soil bacterium MON 89034: Common soil bacterium TC1507: Common soil bacterium MON 87411:	Maize	MON 87427 was produced by <i>Agrobacterium</i> -mediated transformation using vector PV-ZMAP1043. MON 89034 was	Molecular characterization of each constituent event confirmed that: MON 87427 contains a single intact <i>cp4 epsps</i> expression

<p>conventionally-bred maize, and maize-containing registered biotech events.</p>	<p>Common soil bacterium. DAS-59122-7: Common soil bacterium</p>		<p>developed through <i>Agrobacterium</i>-mediated transformation using the binary vector, PV-ZMIR245.</p> <p>TC1507 was produced via microprojectile bombardment of corn cells, using a <i>Pmel</i>-linearized portion of plasmid PHP8999 containing two expression cassettes: <i>cry1F</i> and <i>pat</i>.</p> <p>MON 87411 was produced by <i>Agrobacterium</i>-mediated transformation using plasmid vector PV-ZMIR10871.</p> <p>DAS-59122-7 was generated by <i>Agrobacterium</i>-mediated transformation using plasmid PHP17662.</p>	<p>cassette integrated at a single locus within the maize genome.</p> <p>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 maize genome.</p> <p>TC1507 contains a single copy of the <i>cry1F</i> and <i>pat</i> expression cassettes, stably integrated at a single locus within the maize genome.</p> <p>MON 87411 contains one copy of the intended T-DNA containing the <i>DvSnf7</i> suppression cassette and the <i>cry3Bb1</i> and <i>cp4 epsps</i> expression cassettes that is stably integrated at a single locus.</p> <p>DAS-59122-7 contains a single copy of the three gene cassettes</p>
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					<i>cry34Ab1</i> , <i>cry35Ab1</i> and <i>pat</i> gene cassettes, stably integrated at a single locus within the maize genome.
Scientific Name	<i>Zea mays</i> L.	<p><u>MON 87427:</u> <i>cp4 epsps:</i> <i>Agrobacterium</i> sp. strain CP4</p> <p><u>MON 89034:</u> <i>cry1A.105:</i> <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> <i>cry2Ab2:</i> <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i></p> <p><u>TC1507:</u> <i>cry1F:</i> <i>Bacillus thuringiensis</i> var. <i>aizawai</i> <i>pat:</i> <i>Streptomyces</i> <i>viridochromogenes</i></p> <p><u>MON 87411:</u> <i>cp4 epsps:</i> <i>Agrobacterium</i> sp. strain CP4 <i>cry3Bb1:</i> <i>Bacillus thuringiensis</i> subsp. <i>kumamotoensis</i></p> <p><u>DAS-59122-7:</u> <i>cry34Ab1</i> & <i>cry35Ab1:</i> <i>Bacillus thuringiensis</i> strain PS149B1 <i>pat:</i> <i>Streptomyces</i> <i>viridochromogenes</i></p>	<i>Zea mays</i> L.	-	-
Trade Name	SmartStax® PRO	-	-	-	-
Other Designations	-	-	-	-	-

Country of Origin	Importers of commodities/grains will have to provide their own sources.
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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

19 AUG 2019

SUBSCRIBED AND SWORN TO before me this ___ day of _____ with Affiant exhibiting to me his/her Passport with number P9866316A issued on December 7, 2018 at DFA NCR South.

DOC. NO. 427
PAGE NO. 87
BOOK NO. 248
SERIES 2019

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FORMERLY ANCESTRY,
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ISSUED ON 4-23-18
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Doc. No. ____;
Page No. ____;
Book No. ____;
Series of 2019.