

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**

APR 27 2021

(Date)

The Director
Bureau of Plant Industry

Sir:

We -

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name	MONSANTO PHILIPPINES, INC.	MR. IJINAS IVAN LAO Country Commercial Lead	MS. MARIA LUISA C. PAHUYO Regulatory Science 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	Stacked trait product MON 87427 × MON 89034 × MON 810 × MIR162 × MON 87411 × MON 87419 and all progenies	<u>MON 87427:</u> Common soil bacterium <u>MON 89034:</u> Common soil bacterium <u>MON 810:</u> Common soil	Maize	MON 87427 was produced by <i>Agrobacterium</i> - mediated transformation using vector PV-ZMAP1043. MON 89034	Molecular characterization of each constituent event confirmed that: MON 87427 contains a single intact <i>cp4 epsps</i> expression

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	derived from crosses of the product with any conventionally bred maize, and maize-containing registered biotech events.	<p>bacterium</p> <p><u>MIR162:</u> Common soil bacterium</p> <p><u>MON 87411:</u> Common soil bacterium</p> <p><u>MON 87419:</u> Common soil bacterium</p>		<p>was developed through <i>Agrobacterium</i>-mediated transformation using the binary vector PV-ZMIR245.</p> <p>MON 810 was produced by particle acceleration method using DNA solution containing two plasmids, PV-ZMBK07 and PV-ZMGT10. Only PV-ZMBK07 with the <i>cry1Ab</i> gene was integrated into the plant genome.</p> <p>MIR162 was produced by <i>Agrobacterium</i>-mediated method using transformation vector pNOV1300.</p> <p>MON 87411 was produced by <i>Agrobacterium</i>-mediated transformation using plasmid vector PV-ZMIR10871.</p> <p>MON 87419 was produced</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>MON 810 contains a single intact <i>cry1Ab</i> expression cassette integrated at a single locus within the maize genome.</p> <p>MIR162 contains one copy of the <i>vip3Aa20</i> expression cassette integrated at single locus within the maize genome, and the <i>pmi</i> gene as a plant selectable marker during the development of MIR162.</p> <p>MON 87411 contains one copy of the intended T-DNA containing the DvSnf7 suppression</p>

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				by <i>Agrobacterium</i> -mediated method using transformation vector PV-ZMHT507801.	cassette and the <i>cry3Bb1</i> and <i>cp4 epsps</i> expression cassettes that is stably integrated at a single locus. MON 87419 contains a single copy of introduced DNA at a single locus. The insert contains one intact copy of the <i>dmo</i> and <i>pat</i> expression cassettes.
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> and subsp. <i>aizawai</i> <i>cry2Ab2:</i> <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i></p> <p><u>MON 810:</u> <i>cry1Ab:</i> <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i></p> <p><u>MIR162:</u> <i>vip3Aa20:</i> <i>Bacillus thuringiensis</i> strain AB88 <i>pmi:</i> <i>Escherichia coli</i> strain K-12</p> <p><u>MON 87411:</u> <i>cp4 epsps:</i> <i>Agrobacterium</i> sp.</p>	<i>Zea mays</i> L.		

Designation	Regulated Article	Donor Organism	Host Organism	Vector or Vector Agent	Constituents of the Regulated Article
		strain CP4 <i>cry3Bb1</i> : <i>Bacillus thuringiensis</i> subsp. <i>kumamotoensis</i> <u>MON 87419</u> : <i>dmo</i> : <i>Stenotrophomonas maltophilia</i> <i>pat</i> : <i>Streptomyces viridochromogenes</i>			
Trade Name	-	-	-	-	-
Other Designation	-	-	-	-	-

Country of Origin	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.

***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.


MARIA LUISA C. PAHUYO
(Printed name and Signature of Responsible Officer/Authorized Representative)

Republic of the Philippines)
IMBA, CAVITE)s.s

SUBSCRIBED AND SWORN TO before me this ___ day of 27 APR 2021 with Affiant exhibiting to me his/her Passport with number P7303932A issued on May 24, 2018 at DFA NCR South.

Doc. No. 441;
Page No. 89;
Book No. 5;
Series of 20 21.


NOTARY CESAR ANTHONY S. SOLIS
NOTARY PUBLIC-UNTIL JUNE 30, 2021 BY BM NO. 375
PTR NO. 4166290 CAVITE, JAN. 4, 2021
IBP LIFE TIME NO. 031212 CAVITE
MCLE COMPLIANCE NO. VI-0011888
PASIG CITY, VALID UNTIL APRIL 14, 2022
ROLL NO. 55902