

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**

RECEIVED
OCT 10 2019

BY:

SEP 30 2019

(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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Email address		erwin.vibal@bayer.com	shemaineocheda.castillo@bayer.com

Information	Applicant 2	Responsible Officer (RO)	Representative of RO (if applicable)
Name	DOW AGROSCIENCES B.V. PHILIPPINES Member of Corteva Agriscience Group of Companies	MR. ARUN MITTAL Country Manager	MS. BELLA VICTORIA ERMITA Regulatory and Stewardship Manager
Address	8/F iSquare Building, 15 Meralco Avenue, Ortigas Center, Pasig City 1605, Philippines	8/F iSquare Building, 15 Meralco Avenue, Ortigas Center, Pasig City 1605, Philippines	8/F iSquare Building, 15 Meralco Avenue, Ortigas Center, Pasig City 1605, Philippines
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Fax No.	(+632) 687-5114	(+632) 687-5114	(+632) 687-5114
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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 × MON 88017 × DAS-59122-7 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 MON 88017: Common soil bacterium. DAS-59122-7: Common soil bacterium	Maize	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 <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 maize line with the plasmid vector PV-ZMIR39. DAS-59122-7 was generated by <i>Agrobacterium</i> -mediated transformation using plasmid	Molecular characterization of each constituent event confirmed that: 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. 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. MON 88017 contains a single insertion with one copy of the <i>cry3Bbl.pvzmnir 39</i> and the <i>cp4 epsps</i> cassettes, stably integrated within the maize genome. DAS-59122-7

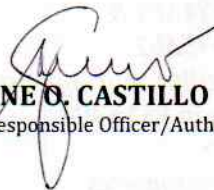
				PHP17662.	contains a single copy of the <i>cry34Ab1</i> , <i>cry35Ab1</i> , and <i>pat</i> gene cassettes, stably integrated at a single locus within the maize genome.
Scientific Name	<i>Zea mays</i> L.	<p><u>MON 89034:</u> <i>cry1A.105:</i> <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> and subsp. <i>aizawai</i> <i>cry2Ab2:</i> <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i></p> <p><u>TC1507:</u> <i>cry1F:</i> <i>Bacillus thuringiensis</i> var. <i>aizawai</i> <i>pat:</i> <i>Streptomyces viridochromogenes</i></p> <p><u>MON 88017:</u> <i>cry3Bb1:</i> <i>Bacillus thuringiensis</i> subsp. <i>kumamotoensis</i> <i>cp4 epsps:</i> <i>Agrobacterium</i> sp. strain CP4</p> <p><u>DAS-59122-7:</u> <i>cry34Ab1</i> & <i>cry35Ab1:</i> <i>Bacillus thuringiensis</i> strain PS149B1 <i>pat:</i> <i>Streptomyces viridochromogenes</i></p>	<i>Zea mays</i> L.	-	-
Trade Name	SmartStax®	-	-	-	-
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)



)s.s

SUBSCRIBED AND SWORN TO before me this 13th day of SEP 2019 with Affiant exhibiting to me his/her Passport with number P9866316A issued on December 7, 2018 at DFA NCR South.

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PATRICIO L. BUNCAYAO, JR.
NOTARY PUBLIC
2ND FLOOR, KLC (FORMERLY ANCESTRY)
BLDG., ROTONDA, ALABANG, MUNTINLUPA CITY
MCLE COMPLIANCE NO. VI-0008192
ISSUED ON 04-23-18
VALID UNTIL 4-14-22
IBP LIFETIME MEMEBR NO. 1010785-11-06-15
PASAY CITY
PTR # 3252088-01-03-19
NC-18-007, MUNTINLUPA CITY
UNTIL 12-31-19
TIN 137-734-581
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