

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 22 2017**

(Date)

The Director  
 Bureau of Plant Industry

Sir:

We –

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name	MONSANTO PHILIPPINES, INC.	Ms. Rachel P. Lomibao Country Lead	Ms. Shemaine O. Castillo Regulatory Affairs lead
Address	23 <sup>rd</sup> Floor Tower II, Insular Life Corporate Centre, Insular Life Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa City	23 <sup>rd</sup> Floor Tower II, Insular Life Corporate Centre, Insular Life Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa City	23 <sup>rd</sup> Floor Tower II, Insular Life Corporate Centre, Insular Life Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa City
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Email Address	<a href="http://www.monsanto.com">www.monsanto.com</a>	<a href="mailto:rachel.pascua.lomibao@monsanto.com">rachel.pascua.lomibao@monsanto.com</a>	<a href="mailto:shemaine.ocheda.castillo@monsanto.com">shemaine.ocheda.castillo@monsanto.com</a>

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 87708 × MON 89788 × A5547-127 and all progenies derived from crosses of the product with any conventionally-bred soybean, and soybean - containing registered biotech events.	MON 87708: A gram negative bacterium commonly present in aquatic environments, soil, and plants  MON 89788: Common soil bacterium  A5547-127: Common soil bacterium	Soybean	MON 87708 was produced by <i>Agrobacterium</i> -mediated method using transformation vector PV-GMHT4355.  MON 89788 was developed through <i>Agrobacterium</i> -mediated transformation using the binary vector, PV-GMG0X20  A5547-127 was generated through direct gene transfer using vector pB2/35SΔcK.	Molecular studies demonstrated that MON 87708 contains a single copy of the <i>dmo</i> expression cassette that is stably integrated at a single locus within the soybean genome.  Molecular characterization confirmed that MON 89788 contains a single intact <i>cp4 epsps</i> expression cassette integrated at a single locus within the soybean genome.  Molecular studies demonstrated that A5547-127 contains one copy of the <i>pat</i> gene cassette and truncated parts of the <i>bla</i> gene (which are not expressed) at the 5' and 3' ends of the insert in a single genetic locus in the soybean nuclear genome.
Scientific Name	<i>Glycine max</i> (L.) Merr.	MON 87708 :  <i>dmo: S. maltophilia strain DI-6</i>  MON 89788:  <i>cp4 epsps: Agrobacterium sp. strain CP4</i>  A5547-127:  <i>pat: Streptomyces viridochromogenes</i>	<i>Glycine max</i> (L.) Merr.	-	-

Trade Name	HT3 Soybean	-	-	-	-
Other Designations	-	-	-	-	-

Country of Origin	MON 87708 × MON 89788 × A5547-127 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.

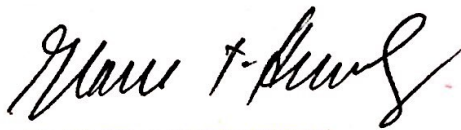
The undersigned certifies that based on his/her personal knowledge and/or authentic documents: (i) all the information in this application are true and correct; and (ii) this application contains all information and views on which to base a decision and includes relevant data and information known to 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)  
CITY OF MUNTINLUPA)

AUG 22 2017

SUBSCRIBED AND SWORN TO before me this \_\_\_\_\_ day of \_\_\_\_\_ with Affiant exhibiting to me his/her Community Tax Certificate no. EC2569267 dated October 29, 2014 at DFA NCR SOUTH



**SECONOR I. HERNANDEZ**  
Notary Public

Until December 31, 2017

Appt. No. 16-027, ANCO, T. 16/49  
PTR No. 2389716, Jan. 3, 2017, Muntinlupa City  
BPL Life time Member No. 05258, TIN: 13547887  
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