

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**

SEP 25 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.bayer.com	erwin.vibal@bayer.com	shemaineocheda.castillo@bayer.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	Reduced lignin alfalfa KK179 and all progenies derived from crosses of the product with any conventionally-	Alfalfa	Alfalfa	KK179 was developed by <i>Agrobacterium tumefaciens</i> -mediated transformation of conventional alfalfa R2336 leaf tissue using	Molecular characterization of KK179 by Southern blot analyses confirmed that one copy of the <i>CCOMT</i> gene suppression

	bred alfalfa, and /or alfalfa containing registered-biotech events.			the plasmid vector PV-MSPQ12633	cassette (T-DNA I) was integrated into the alfalfa genome at a single locus. No T-DNA II or backbone DNA sequences from plasmid vector PV-MSPQ12633 were detected in KK179.
Scientific Name	<i>Medicago sativa</i> L.	<i>Medicago sativa</i> L.	<i>Medicago sativa</i> L.	-	-
Trade Name	HarvXtra®	-	-	-	-
Other Designations	-	-	-	-	-

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.


SHEMAINE O. CASTILLO

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

Republic of the Philippines)
CITY OF MUNTINLUPA)s.s

SEP 25 2018

SUBSCRIBED AND SWORN TO before me this ___ day of _____ with Affiant exhibiting to me his/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

BP Lifetime Member No. 05258, TIN 135478879

MCLE No. V-0004892, 12/16/2014, Philippines

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