

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 19 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	Roundup Ready® alfalfa event J163 and all progenies derived from	Common soil bacterium	Alfalfa	J163 was developed through <i>Agrobacterium</i> -mediated	The molecular characterization shows that RR alfalfa J163 contains a single

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	crosses of the product with any conventionally-bred alfalfa, and /or alfalfa containing registered-biotech events.			transformation of alfalfa callus (from line R2336) using the double border, binary vector PV-MSHT4.	copy of the T-DNA at a single locus of integration from plasmid PV-MSHT4, and all genetic elements of the <i>cp4 epsps</i> expression cassette from this plasmid are present in the insert and are intact.
Scientific Name	<i>Medicago sativa</i> L.	<i>Agrobacterium</i> sp. strain CP4	<i>Medicago sativa</i> L.	-	-
Trade Name	RR® alfalfa J163	-	-	-	-
Other Designations	-	-	-	-	-

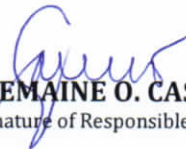
Country of Origin	Countries already commercializing RR® alfalfa J163. Importers of commodities will have to provide their own sources.
Quantity	Importers of commodities/grains will have to provide the quantities they need to import.
Flight/Voyage No	Importers of commodities/grains will have to provide 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**

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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)

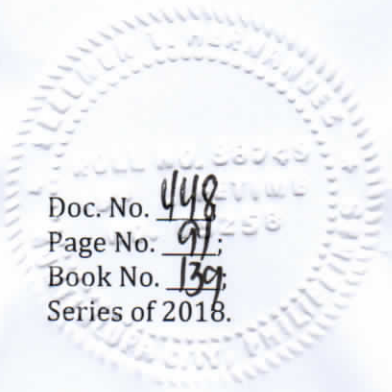
Republic of the Philippines)
MUNTINLUPA CITY)s.s

SUBSCRIBED AND SWORN TO before me this ___ day of SEP 19 2018 with Affiant exhibiting to me 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, 2013, Muntinlupa City
IBP Lifetime Member No. 05258, TIN 135478879
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