

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**

**MAY 16 2016**

(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 Commercial Lead	Dr. Gabriel Romero 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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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 <sup>®</sup> alfalfa events J101 and J163 and all progenies derived from crosses of the product with any conventional ly-bred alfalfa, and /or alfalfa containing registered-biotech events.	<i>Agrobacterium</i> sp. strain CP4 for the <i>cp4 epsps</i> gene that encodes the glyphosate-tolerant CP4 EPSPS protein.	Alfalfa	J101 and J163 were developed through <i>Agrobacterium</i> -mediated transformation of alfalfa callus (from line R2336) using the double border, binary vector PV-MSHT4.	The molecular characterization shows that RR alfalfa J101 and 163 contain a single 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.

<sup>®</sup> Roundup Ready is a registered trademark of Monsanto Technology LLC.

Scientific Name			<i>Medicago sativa</i> L	-	-
Trade Name	RR <sup>®</sup> alfalfa J101 and J163	-	-	-	-
Other Designations	-	-	-	-	-

Country of Origin	Countries already commercializing RR <sup>®</sup> alfalfa J101 and 163. 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.



**Ms. Rachel P. Lomibao**

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

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Republic of the Philippines

**MUNTINLUPA CITY**

SUBSCRIBED AND SWORN TO before me this \_\_\_\_ day of 16 MAY 2016, 2016, affiant exhibiting to me her Driver's License D14-01-112430 issued on 22 Oct 2013 at DOTC LTO East Ave, Quezon City.

Doc. No. 64 ;  
Page No. 14 ;  
Book No. XIX ;  
Series of 2016.

  
NOTARY PUBLIC

**MARIA ROWENA E. MOJICA-ROBRES**  
Notary Public for Munt. City (until 12/31/2017)  
Appointment No. 16-002  
Roll of Attorney No. 47547  
IBP No. 1012162/24 Nov 2015/PPLM  
PTR No. 2064536/04 Jan 2016/Muntinlupa City