

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**

21 JUN 2020

(Date)

The Director
Bureau of Plant Industry

Sir:

We -

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name	MONSANTO PHILIPPINES, INC.	MR. IINAS IVAN LAO Country Commercial Lead	MS. MARIA LUISA C. PAHUYO Regulatory Science Lead
Address	2/F Bayer House, Canlubang Industrial Estate, Calamba, Laguna 4028	2/F Bayer House, Canlubang Industrial Estate, Calamba, Laguna 4028	2/F Bayer House, Canlubang Industrial Estate, Calamba, Laguna 4028
Tel. No.	(+632) 3 226-4967	(+632) 3 226-4967	(+632) 3 226-4967
Fax No.	N/A	N/A	N/A
Email address	www.bayer.com	iinas.lao@bayer.com	louise.pahuyo@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	Combined-trait product J101 x J163 and all progenies derived from crosses of the product with any conventionally -bred alfalfa,	Common soil bacterium	Alfalfa	J101 and J163 were respectively developed through <i>Agrobacterium</i> -mediated transformation using the double border,	Molecular characterization of each constituent event confirmed that J101 and J163 respectively contain a single copy of the T-DNA at a single

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	and alfalfa-containing registered biotech events.			binary vector PV-MSHT4.	locus of integration from plasmid PV-MSHT4, and all genetic elements of the <i>cp4 epsps</i> expression cassette from this plasmid are present and intact.
Scientific Name	<i>Medicago sativa</i> L.	<i>Agrobacterium</i> sp. strain CP4	<i>Medicago sativa</i> L.	-	-
Trade Name	Roundup Ready® Alfalfa	-	-	-	-
Other Designation	-	-	-	-	-


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.



MARIA LUISA C. PAHUYO

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

Republic of the Philippines)
BIRAN CITY)s.s

SUBSCRIBED AND SWORN TO before me this JUN 21 2020 day of _____ with Affiant exhibiting to me his/her Passport with number P7303932A issued on May 24, 2018 at DFA NCR South.

Doc. No. 305;
Page No. 61;
Book No. IX;
Series of 20 20.


ATTY. GERARDO P. HERNANDEZ
NOTARY PUBLIC
UNTIL DECEMBER 31, 2021
NOTARIAL COMMISSION NO. 2020-04
PTR: 138-01561-8-2020 BIRAN CITY
IBP LIFETIME ROLL NO. 40717
MCLE COMPLIANCE CERTIFICATE NO. VI.0018065