

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
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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	Stacked trait product KK179 × J101 and all progenies derived from crosses of the product with any conventionally-bred alfalfa,	KK179: Alfalfa J101: Common soil bacterium	Alfalfa	KK179 was developed by <i>Agrobacterium</i> -mediated transformation using the plasmid vector PV-MSPQ1263 3.	Molecular characterization of each constituent event confirmed that: KK179 contains one copy of the <i>CCOMT</i> gene suppression

Designation	Regulated Article	Donor Organism	Host Organism	Vector or Vector Agent	Constituents of the Regulated Article
	and alfalfa-containing registered biotech events.			J101 was developed through <i>Agrobacterium</i> -mediated transformation using the double border, binary vector PV-MSHT4.	<p>cassette (T-DNA I) 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.</p> <p>J101 contains 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 and intact.</p>
Scientific Name	<i>Medicago sativa</i> L.	KK179: <i>Medicago sativa</i> L. J101: <i>Agrobacterium</i> sp. strain CP4	<i>Medicago sativa</i> L.	-	-
Trade Name	HarvXtra® with Roundup Ready® Technology	-	-	-	-
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.
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***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)
BIÑAN CITY)s.s

JUN 21 2020

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

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Book No. IX
Series of 20 20


ATTY. GERARDO P. HERNANDEZ
NOTAR / PUBLIC
UNTIL DECEMBER 31, 2021
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IBPLIFETIME ROLL NO. 40717
NCLE COMPLIANCE CERTIFICATE NO. VI-0018065