

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**

JUL 02 2019

(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	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) 226-4967	(+632) 226-4967	(+632) 226-4967
Fax No.	-	-	-
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	Stack trait product MON 88302 × MS8 × RF3 and all progenies derived from crosses of the product with any conventionally-bred canola, and canola-	MON 88302: Common soil bacterium MS8: Common soil bacterium RF3: Common soil bacterium	Canola (<i>Brassica napus</i>)	MON 88302 was developed through <i>Agrobacterium</i> -mediated transformation utilizing plasmid vector PV-BNHT267 2.	Molecular characterization of MON 88302 confirmed that one copy of the <i>cp4 epsps</i> expression cassette was integrated into the canola genome at a

	<p>containing registered biotech events.</p>			<p>MS8 was developed through <i>Agrobacterium</i>-mediated transformation utilizing plasmid vector pTHW107.</p> <p>RF3 was developed through <i>Agrobacterium</i>-mediated transformation utilizing plasmid vector pTHW118.</p>	<p>single locus. No backbone DNA sequences from PV-BNHT2672 were detected in MON 88302.</p> <p>Molecular characterization of MS8 confirmed that one copy of <i>barnase</i> and <i>bar</i> expression cassette was integrated into the canola genome at a single locus and that vector backbone sequences are absent.</p> <p>Molecular characterization of RF3 confirmed that one partial copy of T-DNA, in which only part of the <i>Pta29</i> promoter was inserted, flanked by another partial copy in an inverted orientation, which includes a complete <i>barstar</i> gene cassette and a part of the <i>PssuAt</i> promoter. Vector backbone sequences are absent from</p>
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					RF3.
Scientific Name	<i>Brassica napus</i> L.	MON 88302: <i>cp4 epsps</i> : <i>Agrobacterium</i> sp. strain CP4 MS8: <i>barnase</i> : <i>Bacillus</i> <i>amyloliquefaciens</i> <i>bar</i> : <i>Streptomyces</i> <i>hygroscopicus</i> RF3: <i>barstar</i> : <i>Bacillus</i> <i>amyloliquefaciens</i> <i>bar</i> : <i>Streptomyces</i> <i>hygroscopicus</i>	<i>Brassica napus</i> L.	-	-
Trade Name	InVigor® × TruFlex® Roundup Ready® Canola	-	-	-	-
Other Designations	-	-	-	-	-

Country of Origin	Importers of commodities/grains 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)
MUNTINLUPA CITY)s.s

0 2 JUL 2019

SUBSCRIBED AND SWORN TO before me this ___ day of _____ with Affiant exhibiting to me his/her Passport with number P9866316A issued on December 7, 2018 at DFA NCR South.


ELEGOR T. HERNANDEZ
Notary Public

Until December 31, 2019

Appt. NO. 18-009, Attorney's Roll No. **38749**

PTR No. 3244611, Jan. 3, 2019, Muntinlupa City

IBP Lifetime Member No. 05253, TIN: 135478879

MCLE No. VI-0003131, 04/23/2018, Philippines

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