## 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

NOV 1 3 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<br>Country Lead                                       | MS. SHEMAINE O. CASTILLO<br>Regulatory Affairs Lead                      |
| Address          | 2/F Bayer House,<br>Canlubang Industrial Estate,<br>Calamba, Laguna 4028 | 2/F Bayer House,<br>Canlubang Industrial Estate,<br>Calamba, Laguna 4028 | 2/F Bayer House,<br>Canlubang Industrial Estate,<br>Calamba, Laguna 4028 |
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| Fax No.          | N/A  | N/A  | N/A  |
| Email<br>address | www.bayer.com  | erwin.vibal@bayer.com  | shemaineocheda.castillo@b<br>ayer.com                                    |

hereby request for issuance of Biosafety Permit for Direct Use for the genetically modified (GM) plant/plant product described below.

| Designation    | Regulated<br>Article   | Donor<br>Organism        | Host Organism | Vector or<br>Vector Agent  | Constituents of<br>the Regulated<br>Article  |
|----------------|--|--------------------------|---------------|--|--|
| Common<br>Name | MON 88913 and all progenies derived from crosses of the product with any conventionally- bred cotton, and/or cotton containing | Common soil<br>bacterium | Cotton        | MON 88913 was developed through Agrobacterium- mediated transformation utilizing binary vector PV- GHGT35. | Molecular characterizatio n demonstrated that MON 88913 contains a single copy of the T-DNA at a single locus that contains two intact cp4 epsps |

| 3.2019                | registered<br>biotech events.    |                              |                          |   | gene cassettes in the cotton genome. There were no additional genetic elements, including backbone sequences from PV-GHGT35 detected, linked or unlinked to the intact T-DNA present in MON 88913. |
|-----------------------|----------------------------------|------------------------------|--------------------------|---|--|
| Scientific<br>Name    | Gossypium<br>hirsutum L.         | Agrobacterium sp. strain CP4 | Gossypium<br>hirsutum L. |   |  |
| Trade Name            | Roundup<br>Ready® Flex<br>Cotton | Jan a Alikania               |                          |   |  |
| Other<br>Designations |                                  |                              |                          | - |  |

| 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

- 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) MUNTNLUPA CITY IS.S

NOV 13 2019

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

**NOTARY PUBLIC** 

BONCAYAO, JR.

A ALABANG, MUNTINLUPA CITY COMPLANCE NO. VI-0008192 D ON 04-23-18

D UNTIL 4-14-22

IFETIME MEMEBR NO. 1010785-11-06-75

AY CITY # 3252088-01-03-19 18-007, MUNTINI UPA CITY

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