

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**

November 22, 2016
(Date)

The Director
Bureau of Plant Industry

Sir:
We –

Information	Applicant	Responsible Officer (RO)	Representative of RO (if applicable)
Name	Syngenta Philippines, Inc.	Duong Ba Cau	Felipe S. dela Cruz, Jr.
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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	Bt11 x MIR162 x MIR604 x TC1507 x 5307 x GA21 Corn		Corn	Bt11 transformation plasmid: pZO1502 MIR162 transformation plasmid: pNOV1300 MIR604 transformation plasmid: pZM26 TC1507 transformation plasmid: PHP8999 5307 transformation plasmid: pSYN12274 GA21 transformation plasmid: pDPG434	Bt11: <u>active ingredient cassette</u> <i>cryIAb</i> , 35S promoter, intervening sequences, NOS terminator <u>selectable marker cassette</u> <i>pat</i> , 35S promoter, intervening sequences, NOS terminator MIR162: <u>active ingredient cassette</u> : <i>vip3Aa20</i> , ZmUbi1Int promoter, 35S terminator <u>selectable marker cassette</u> : pmi, ZmUbi1Int

promoter, NOS terminator

MIR604:
active ingredient cassette
mcry3A, MTL promoter, NOS terminator, intervening sequences

selectable marker cassette
pmi, ZmUbiInt promoter, NOS terminator, intervening sequences

TC1507:
active ingredient cassette
cryIF, *Ubi1ZM* promoter, ORF25PolyA terminator

selectable marker cassette
pat, CaMV 35S promoter, CaMV 35S terminator

plasmid backbones of the transformation plasmids

5307:
active ingredient cassette
ecry3.1Ab, CMP promoter, intervening sequences, NOS terminator

selectable marker cassette
pmi, ZmUbiInt promoter, NOS terminator, intervening sequences

GA21:
active ingredient cassette
mepsps, Actin promoter complex, NOS terminator, OTP, intervening sequences

Scientific Name	<i>Zea mays</i> L.	<i>cry1Ab: Bacillus thuringiensis</i> var. <i>kurstaki</i> <i>vip3Aa20: Bacillus thuringiensis</i> strain AB88 <i>mcry3A: Bacillus thuringiensis</i> subsp. <i>tenebrionis</i> <i>ecry3.1Ab: Bacillus thuringiensis</i> <i>cry1F: Bacillus thuringiensis</i> var. <i>aizawai</i> <i>mepsps: Zea mays</i> <i>pat: Streptomyces viridochromogenes</i> strain Tu494 <i>pmi: Escherichia coli</i>	<i>Zea mays</i> L.		
Trade Name	-	-	-	-	-
Other Designations	-	-	-	-	-

Country of Origin	USA / Canada or other countries which will have cultivation approvals in the future
Quantity	The information will be provided by the importers of the commodities/ grains.
Flight/Voyage No	The information will be provided by the importers of the commodities/ grains.
Port of Entry	The information will be provided by the importers of the commodities/ grains.
Proposed Schedule	The information will be provided by the importers of the commodities/ grains.

***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.

DUONG BA CAU

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

Republic of the Philippines)

_____)

SUBSCRIBED AND SWORN TO before me this ____ day of _____, 2016,
affiant exhibiting to me his/her Passport No. N1656336 issued on 28/8/2013 at Singapore.

Doc. No. _____;

Page No. _____; NOTARY PUBLIC Book No. _____;

Series of 200__.