

**CONSOLIDATED REPORT FOR SYNGENTA PHILIPPINES INC.'S CORN BT11 x MIR162 x
MON89034 x GA21**

(APPLICATION FOR COMMERCIAL PROPAGATION)

EXECUTIVE SUMMARY

On November 29, 2018, Syngenta Philippines Inc. Inc.'s filed for application of Corn Bt11 x MIR162 x MON89034 x GA21 commercial propagation, as original application under the DOST-DA-DENR-DOH-DILG Joint Department Circular (JDC) No. 1 Series of 2016.

This application was assessed in accordance with *Article VI. Commercial Propagation of Regulated Articles* of the JDC No.1. This Article covers the basic biosafety policies, procedural requirements and guidelines in carrying out the risk assessment for GM applications for Commercial Propagation.

Under the JDC, the assessors for Syngenta Philippines Inc.'s corn Bt11 x MIR162 x MON89034 x GA21 for Commercial Propagation were the following:

- One member of the Scientific and Technical Review Panel (STRP) – for evaluation of the Applicant's submitted risk assessment report.
- Department of Environment and Natural Resources (DENR) – for the determination of the environmental impact of the said application.
- Department of Health (DOH) - for the determination of the environmental health impact of the said application.
- Insect Resistance Management Team (IRMAT) – for review and evaluation of the application for any IRM related concerns and issues.
- Fertilizer and Pesticide Authority (FPA) – for the determination if the applicant is duly licensed as a pesticide handler in accordance with Presidential Decree No.1144 and if tolerance levels and good agricultural practices have been established for registration for the transformation event.
- Socio-economic, ethical and cultural (SEC) Expert – to evaluate SEC impact of the said application

After reviewing the documents submitted by the applicant, the STRP find scientific evidence that the regulated article applied for Commercial Propagation is as safe for human and animal health, and the environment as its conventional counterpart. Based on the assessment of the DENR BC and DOH BC, the regulated article is not expected to pose greater risk to the environment and health, respectively, than its conventional counterpart. IRMAT and SEC expert recommended for the approval and issuance of a biosafety permit of the said GM product. Furthermore, the plant-incorporated protectant (PIP) in the regulated article has been duly registered with FPA.

BACKGROUND

In accordance with Article VI. Section 1. No regulated article shall be released for commercial propagation unless: (1) a Biosafety Permit for Commercial Propagation has been secured in accordance with this Circular; (2) it can be shown that based on field trial conducted in the Philippines, the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart; (3) food and feed safety studies show that the regulated article does not pose greater risks to biodiversity, human and animal health than its

conventional counterpart, consistent with CODEX Alimentarius Guidelines on the Food Safety Assessment of Foods Derived from the Recombinant-DNA Plants and protocols of the DOH and BAI on feeding trials; and (4) if the regulated article is a pest-protected plant, its transformation event that serves as plant-incorporated protectant (PIP) has been duly registered with the Fertilizer and Pesticide Authority (FPA).

The BPI Biotech Office provided the assessors the complete dossier submitted by Syngenta Philippines, Inc. Upon receipt of the individual reports from the assessors, the BPI Biotech Secretariat prepared this consolidated risk assessment report for the information of the public.

STRP ASSESSMENT

1. GENE INTERACTION

The STRP has stated that there is no interaction of the resulting products such that a new allergen or a new toxin could be produced. The proteins (Cry1Ab, PAT, Vip3Aa20, PMI, Cry1A.105, Cry2Ab2 and mEPSPS) show no homology to any known mammalian allergen or toxin. There is no evidence suggesting that the 7 proteins will interact to form some new allergens or toxin since each has a distinct mode of action and are not likely to interact. Reports on allergenicity and toxicity about the individual proteins in each event were provided earlier when the single events were submitted for biosafety assessment and all of which received biosafety approvals for feed, food, processing and for commercial propagation.

The STRP also reported that gene products will not accumulate in the same or different subcellular compartments of the plant parts.

For Bt 11, the *cry1AB* and *par* gene expression are both driven by the *35S* promoter, no cellular localization sequences are present, so the cytoplasm is the location for accumulation.

For MIR162, the *vip3Aa20* and *pmi* gene expressions are both driven by *ZmUbilnt* promoter; no cellular localization sequences are present, so the cytoplasm is the location for accumulation.

For MON 89034, the Cry1A.105 protein is likely to accumulate in the cytoplasm of corn cells while the Cry2Ab2 protein is expected to accumulate in the chloroplasts of corn cells. This is because the gene construct encoding the Bt protein, Cry1A.105, does not include a sequence for targeting its transport to a specific sub-cellular location like organelle and would thus accumulate in the cytoplasm of corn cells. The Cry2Ab2 protein is targeted to the plastids by the addition of a chloroplast transit peptide (CTP).

The modified EPSPS enzyme, whether modified (as in GA21) or otherwise, is known to be directed in the chloroplast using the CTP. This transit peptide is cleaved off of the protein when it is imported into the chloroplast. When isolated from the plant, only the cleaved version of the protein can be found indicating that all of the protein is immediately imported into the chloroplast upon synthesis.

2. METABOLIC PATHWAYS

The STRP has also reported that the mode of action are different and no interaction has been detected based on protein expression levels. Further, The Cry1Ab, Cry1A.105, Cry2b2 and Vip3Aa20 proteins have no enzymatic activities, therefore they are not involved in any

metabolic pathways in the corn plant's metabolism, while PAT protein has an enzymatic activity, but no endogenous substrate for the PAT protein has been identified in the corn plant. The selectable marker PMI is not involved in the same metabolic pathway as PAT and there is no endogenous substrate for PMI in the corn plant except when the plant is exposed to mannose. The modified EPSPS enzyme is involved in the production of the aromatic amino acids such as tyrosine, phenylalanine and tryptophan.

3. GENE EXPRESSION

Upon review of data presented, the STRP confirmed that the protein expression in single events is similar to that in the stack product implying that there have been no detectable unexpected effects on the corn plant's metabolism.

On the overall, the concentrations of Cry1Ab, PAT, Vip3Aa20, PMI, Cry1A.105, Cry2Ab2 and mEPSPS in tissues of the Bt11 x MIR162 x MON 89034 x GA21 corn hybrid were similar to those of the corresponding single-event corn hybrids namely: Bt11, MIR162 MON 89034 and GA21. This shows that the proteins mentioned are expressed and they are functioning properly in the stacked trait corn as in the corresponding single-event corn hybrids.

4. AGRICULTURAL MANAGEMENT

The STRP commented that agricultural management for the corn hybrid is essentially the same as its conventional counterpart, except for its built-in resistance against certain lepidopteran insect pests and glyphosate and glufosinate tolerances. Therefore, except for these intended changes, planting of Bt11 x MIR162 x MON 89034 x GA21 corn would not change the cultural management practices in corn that could affect adversely the environment.

After a thorough and scientific review and evaluation of the documents provided by Syngenta Philippines Inc. relevant to Corn Bt11 x MIR162 x MON89034 x GA21, the STRP found scientific evidence that the regulated article applied for commercial propagation has no evidence of interaction on the resulting gene products.

DENR BIOSAFETY COMMITTEE RECOMMENDATION

After a comprehensive review and evaluation of the information provided by Syngenta Philippines, Inc., on its application for Commercial Propagation of Corn Bt11 x MIR162 x MON89034 x GA21, the DENR-BC finds that the regulated article is considered substantially equivalent to its conventional counterpart for its history of safe use as food in twelve countries namely Argentina, Brazil, Colombia, European Union, Japan, Mexico, Paraguay, Philippines, South Africa, South Korea, Taiwan, and Uruguay and as feed in nine countries namely Argentina, Brazil, Colombia, European Union, Japan, Paraguay, Philippines, South Africa, and South Korea. It has also been previously approved for commercial propagation in six countries namely Argentina, Brazil, Canada, Japan, Paraguay and Uruguay. (International Service for the Acquisition of Agri-Biotech Applications GM Approval Database, 2017);

Further, the individual events of the gene stacked Corn Bt11 x MIR162 x MON89034 x GA21 have biosafety permits for commercial propagation, which were previously issued. Therefore, each event has undergone rigorous safety assessment, and is considered safe to the

environment, biodiversity, and non-target organisms. Similarly, it is less likely to pose any significant adverse effect on the environment;

The incorporation of gene stacked event is through conventional breeding, which is regarded as innocuous for its long history of safe use. Furthermore, the method of crossing individual transgenic parents is similar with that of non-transgenic parents. This method does not introduce any greater variation in the genome beyond what is obtained (Weber et al., 2012).

DOH BIOSAFETY COMMITTEE RECOMMENDATION

After a thorough review and evaluation of the documents provided by the proponent, Syngenta Philippines, Inc., through the Bureau of Plant Industry (BPI), in support of their application for approval for Commercial Propagation of Corn Bt11 x MIR162 x MON89034 x GA21.

The DOH-BC finds that regulated article applied for Commercial Propagation does not require changes in the usual practices as described in the phases/stages of biotechnology project activities. As such, the regulated article is as safe as its conventional counterpart and is not expected to pose any significant risk to human and animal health and environment.

Further, scientific pieces of evidences from toxicity studies and references, find that the regulated article will not cause significant adverse health effects to human and animal health. Dietary exposure to the regulated article is unlikely to result allergic reaction. The regulated article is not materially different in nutritional composition from that of the non-transgenic corn or the conventional corn.

The DOH-BC find that the regulated article applied for Commercial Propagation is safe as its conventional counterpart and shall not pose any significant risk to human and animal health and environment.

DA-IRMAT'S RECOMMENDATION

The DA Insect Resistance Management Advisory Team (IRMAT) reviewed the application of Syngenta Philippines Inc., for the commercial propagation of corn Bt11 x MIR162 x MON89034 x GA21 under the Joint Department Circular No.1 s2016.

The IRMAT finds the IRM plan compliant with the DA Memorandum Circular No. 2 series of 2014 and recommends the approval of the aforementioned application.

FPA PIP REGISTRATION

The Fertilizer and Pesticide Authority provided a certification that the regulated articles Corn Bt11, MIR162 and MON89034 are registered in their office as PIP products with registration number PIP-01-06-07 on October 28, 2019.

In addition, the BPI was also informed that the GA21, was not classified as PIP and hence was not included in the certificate of product registration.

SEC CONSIDERATIONS

The SEC Expert has affirmed that aside from control measures against certain insect pests and tolerance to glyphosate and glufosinate herbicides, there are no significant differences in agricultural practices for Bt11 x MIR162 x MON 89034 x GA21 corn cultivation when compared with the cultivation of conventional corn varieties. Therefore, no impact in production, consumption/utilization and trade would be expected.

Farm management will be the same except for reduced pesticide application for the control of Asian corn borer and common cutworm. The hybrid Bt11 x MIR162 x MON 89034 x GA21 corn will be grown in the typical corn-growing regions of the Philippines. Trends in total land use of corn cultivation in the Philippines will not be altered. Therefore, LCIPs, in accordance with the Indigenous People's Right Act, will not be impacted nor cause negative effects on social structures especially in rural areas.

Furthermore the expert has confirmed that Bt11 x MIR162 x MON 89034 x GA21 corn and food and feed derived from Bt11 x MIR162 x MON 89034 x GA21 corn, are not materially different from conventional corn, other than its ability to resist insect feeding and tolerate glyphosate application. Therefore, no impact on farmers' participation in community activities is foreseen.

After a thorough and scientific review and evaluation of the documents provided by Syngenta Philippines, Inc. Relevant to Corn BT11 x MIR162 x MON89034 x GA21, the SEC Expert recommended for the approval and issuance of biosafety permit of the said GM product.