

# **Consolidated Risk Assessment Report of Syngenta Philippines, Inc.'s Corn GA21 x T25 Application for Direct Use as Food, Feed or for Processing (FFP)**

## **EXECUTIVE SUMMARY**

On May 6, 2019, Syngenta Philippines Inc.'s filed for application of corn GA21 x T25 for direct use as food and feed, or for processing, as original application under the DOST-DA-DENR-DOH-DILG Joint Department Circular (JDC) No. 1 Series of 2016. After reviewing the Risk Assessment Report and attachments submitted by the applicant, the assessors namely: Scientific and Technical Review Panel (STRP), BPI Plant Products Safety Services Division (BPI-PPSSD) and Bureau of Animal Industry- Biotech Team (BAI-BT), concurred that corn GA21 x T25 is as safe for human food and animal feed as its conventional counterpart.

The Department of Environment and Natural Resources – Biosafety Committee (DENR-BC), after a thorough scientific review and evaluation of the documents related to Environmental Risk along with the submitted sworn statement and accountability of the proponent, recommended the issuance of a biosafety permit for this regulated event provided the conditions set by DENR are complied. Also, the Department of Health – Biosafety Committee (DOH-BC), after a thorough scientific review and evaluation of documents related to Environmental Health Impact, concluded that corn GA21 x T25 will not pose any significant risk to the health and environment and that any hazards could be managed by the measures set by the department. DOH-BC also recommended for the issuance of biosafety permit for the transformation event.

Furthermore, the Socio-economic, Ethical and Cultural (SEC) Considerations expert also recommended for the issuance of biosafety permit for this regulated article after assessing the socio-economic, social and ethical indicators for the adoption of Genetically Modified Organisms.

## **BACKGROUND**

In accordance with Article VII. Section 20 of the JDC, no regulated article, whether imported or developed domestically, shall be permitted for direct use as food and feed, or for processing, unless: (1) the Biosafety Permit for Direct Use has been issued by the BPI; (2) in the case of imported regulated article, the regulated article has been authorized for commercial distribution as food and feed in the country of origin; and (3) regardless of the intended use, the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart.

The BPI Biotech Office provided the assessors the complete dossier submitted by Syngenta Philippines Inc. The SEC expert, on the other hand, was provided with a questionnaire on socio-economic, ethical and cultural considerations that have been addressed by Syngenta Philippines Inc. in relation to their application. These assessors have thirty (30) days to submit their independent assessment to BPI Biotech Secretariat.

### Information on the Applied Events

GA21 x T25 is a corn stack hybrid developed by conventionally crossing GA21 and T25 corn. GA21 and T25 are transgenic corn events developed through modern biotechnology.

GA21 contains the *mepsps* (modified 5-enolpyruvylshikimate-3-phosphate synthase) gene which confers tolerance to glyphosate herbicide.

T25 produces a phosphinothricin acetyltransferase (PAT) enzyme that confers tolerance to glufosinate herbicides. Table 1. Status of FFP approvals of the single events of the stacked corn MON87427 x MON89034 X MIR162 X NK603.

Source: *Public Information Sheet of corn MON 89034 x TC1507 x NK603 for direct use*

### Countries Where Approvals Have Been Granted (for FFP; for Commercial Propagation)

Country	Food direct use or processing	Feed direct use or processing	Cultivation domestic or non-domestic use
Japan	2016	2016	2016
Mexico	2015		
Philippines	2014	2014	
South Korea	2014	2014	
Taiwan	2014		

Source: <https://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=376>

## **STRP'S ASSESSMENT AND RECOMMENDATION**

### *Gene Interaction*

The protein products (mEPSPS and PAT) have different modes of action and belong to different metabolic reactions. Bioinformatic analyses have shown that both the mEPSPS and PAT proteins have no homology to known or putative protein toxins and allergens. In addition, there is no known mechanism of interaction of the protein products. Therefore, they are not expected to interact in the stacked hybrid; hence, no new allergen and toxin could be produced [1][2][3][4].

The modified EPSPS is expected to accumulate in the chloroplast while PAT is expected to accumulate in the cytoplasm [5][6].

### *Metabolic Pathways*

The gene *mepsps* encodes for a modified or mutated form of EPSPS (5-enoylpyruvyl-shikimate-3-phosphate synthase). EPSPS catalyzes the reversible reaction of shikimate-3-phosphate (S3P) and phosphoenolpyruvate (PEP) to produce EPSP and P<sub>i</sub>. EPSPS is an enzyme which catalyzes the penultimate step of the shikimate pathway of aromatic amino acid biosynthesis. In plants, EPSPS is localized in the chloroplast. The herbicide glyphosate is an inhibitor of the native plant EPSPS but the modified form of EPSPS (mEPSPS) is less sensitive to glyphosate thereby conferring tolerance to herbicide products containing glyphosate. [7][8]

The gene *pat* encodes for the enzyme phosphinothricin acetyltransferase (PAT) which acetylates the free NH<sub>2</sub> group of phosphinothricin (PPT). PPT is a potent inhibitor of glutamine synthetase in plants and is used as a non-selective herbicide. Any organism which produces PAT can essentially detoxify PPT. A genetically modified plant which possesses the transgene *pat* and produces the enzyme PAT is tolerant to PPT-containing herbicides. [7][8]

Modes of action of the mEPSPS and PAT proteins are different, and no interaction has been detected based on protein expression levels. [7][8]

### *Gene Expression*

Southern blot analysis and protein expression analysis showed that the *mepsps* and *pat* genes are inherited and expressed properly in GA21 x T25 hybrid, as they did similarly in single events GA21 and T25 [5][9].

mEPSPS and PAT proteins have similar expressions and at low levels in GA21 x T25 stack hybrid and the two single event maize plants, GA21 and T25 [9]. There are no possible unexpected effects or possible interaction of the stacked genes and their products on the metabolism of GA21 x T25.

### *Conclusion*

Find scientific evidence that the regulated article applied for direct use has no evidence of interaction on the resulting gene products.

## **BAI'S ASSESSMENT AND RECOMMENDATION**

### *Gene Interaction*

mEPSPS and PAT proteins mode of action and location/accumulation in the plant cells have no known interaction that could possibly lead to production of new allergens or toxins nor could lead to adverse effects in animals, further any likelihood of interaction with each other is not considered to be significant [1][2].

Occurrence of possible interaction among proteins will not lead to production of any putative allergens or toxins, nor could cause an adverse effect in animals [5].

### *Metabolic Pathways*

mEPSPS and PAT proteins have different modes and sites of biological activity. They have different specificities and do not share biological targets or substrates. mEPSPS is likely to accumulate in chloroplast while PAT accumulates in cytoplasm [5].

There are no possible unexpected effects of stacked genes on the metabolism of plant and that the individual proteins were expressed as anticipated in the combined trait product or stacked event. Also, the single events were substantially equivalent to its conventional counterpart and will not cause changes in the plant's metabolic activity [9].

### *Gene Expression*

mEPSPS and PAT proteins were expressed properly and in similar levels as their respective individual events in the combined trait product GA21 x T25 which means the proteins were functioning properly in the stacked trait corn [9].

### *Conclusion*

Find scientific evidence that the regulated article applied for direct use has no evidence of interaction on the resulting gene products.

## **BPI-PPSSD'S ASSESSMENT AND RECOMMENDATION**

### *Gene Interaction*

The presence of mEPSPS and PAT proteins will not interact to produce any new allergen or toxins. This is due to the different mode of action of each protein which are not likely to interact and its single events having received biosafety approval [1][2].

Based on the protein expression analysis and the difference of mode of action of the novel proteins, the presence of mEPSPS and PAT proteins will not likely to cause interaction that can affect the stability and expression level of either one of the genes [7][9].

### *Metabolic Pathways*

The products involved are significantly different in metabolic pathways. Modes of action of the mEPSPS and PAT proteins are different and there is no interaction has been detected based on protein expression levels [7][8].

#### *Gene Expression*

The expression of the proteins in corn from stacked GA21 x T25 has been developed from traditional breeding techniques and is similar to the corresponding levels in single event. Results showed that the proteins are expressed properly to the combined trait product as in its corresponding single events [8][9].

The protein expression analysis provided by the developer indicated that the proteins in GA21 x T25 are being expressed at low levels in the plant [9].

#### *Conclusion*

Find scientific evidence that the regulated article applied for direct use has no evidence of interaction on the resulting gene products.

### **DENR Biosafety Committee (Environmental Safety)**

After a comprehensive review and evaluation of the documents including the scientific evidence from references and literature submitted by the applicant on its application for Direct Use as FFP of corn GA21 x T25, hereunder are the observations of the DENR BC:

1. The individual events of the gene stacked Corn GA21 x T25 have biosafety permits for direct use, which were previously issued. Therefore, each event has undergone rigorous safety assessment, and is considered safe to the environment, particularly on biodiversity. Similarly, it is less likely to pose any significant adverse effect on the environment.
2. 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 [10]; and
3. The project description report (PDR) discusses the specified environmental management plan indicating the possible risk and harm to the environment particularly on biodiversity as well as the mitigating measures and contingency plan. Furthermore, the chances of unintended release or planting of the regulated article is very minimal and will not cause any damaging and lasting effects because the receiving environment (areas near the port, roads, railways, etc.) is not conducive for plant growth. Also, corn is a highly domesticated plant that requires human intervention for it to persist in the environment [11][12].

### **DOH Biosafety Committee (Environmental Health Safety)**

The DOH BC, after a thorough review of the application, find that the regulated article applied for Direct Use as Food and Feed, or For Processing is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health, and environment. The following are the observations and recommendations of the DOH BC:

1. Scientific pieces of evidence from Toxicity studies and references, find that the regulated article will not cause significant adverse health effects to human and animal health. [1]
2. Dietary exposure to the regulated article is unlikely to result in allergic reaction. [2]
3. The regulated article is as safe as food or feed derived from conventional corn varieties.
4. The regulated article is not materially different in nutritional composition from that of the non-transgenic corn or the conventional corn. [1][2][3][4]
5. It is suggested that the Bureau of Plant Industry (BPI) ensure that there shall be clear instructions that the product is only for the purpose of direct use for FFP and is not to be used as planting materials.

### **SEC Expert (Socio-Economic Considerations)**

Corn is a significant crop in the Philippines given its widespread use as food and feed. Country-wide consumption of corn, although with slight fluctuations in recent five years, has shown a generally increasing trend since 2002. FAO data, which Applicant cited, confirms a similar demand trend with a notable increase of more than 500,000 MT of corn imports in 2017-2018, with a 200,000 MT drop in local corn production. The Philippine Statistics Authority observed a continued decrease in domestic corn production in the recent quarter (April to June 2019) as harvest areas contract and yields per hectare decline.

The US Department of Agriculture however projects an increase in local corn production in 2020 especially with the use of better quality, including genetically modified, seeds. While use of corn as food is expected to decrease next year due to cheaper food alternatives like rice and wheat, feed-corn demand is expected to rise. Although wheat feed substitutes compete with corn-feed imports, corn (especially imported ones which are more reliable and uniform) remains to be “the preferred feed grain of local end-users [13][14][15][16][17].

The application is only for direct use as food and feed, or for processing. Given the Philippine’s history of corn importation vis-a-vis trends in consumption/utilization, drastic changes are not expected, and even modest changes are not attributable to imports alone.

As mentioned above, while use of corn as food is expected to decrease next year due to cheaper food alternatives like rice and wheat, feed-corn demand is expected to increase. Wheat-feed substitutes compete with corn-feed imports and imported corn posts higher prices than locally produced ones due to import tariffs. However, corn (especially imported ones which are more reliable and uniform) remains to be “the preferred feed grain of local end-users.” Any decrease in corn importation this year and next would likely be an effect of demand stabilization after the significant 500MT increase in corn imports from 2017 to 2018.

Moreover, it is noted that the application is a renewal, given the previous Philippine approval of the GM crop for food, feed and processing. Since then, there has been no dramatic change in the corn production, consumption and importation trends in the country.

#### *Recommendation*

The SEC expert recommend for the approval and issuance of the biosafety permit of the GM product.



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