

**CONSOLIDATED REPORT OF MONSANTO PHILIPPINES' Corn MON 87427 x MON 89034 x TC1507 x MON 87411 x DAS-59122-7 APPLICATION FOR DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING**

**EXECUTIVE SUMMARY**

On October 16, 2019, Monsanto Philippines submitted corn MON 87427 x MON 89034 x TC1507 x MON 87411 x DAS-59122-7 for direct use, 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 Scientific and Technical Review Panel (STRP), Bureau of Animal Industry, and BPI Plant Products Safety Services Division concurred that corn MON 87427 x MON 89034 x TC1507 x MON 87411 x DAS-59122-7 is as safe as its conventional counterpart.

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 MON 87427 x MON 89034 x TC1507 x MON 87411 x DAS-59122-7 is safe as its conventional counterpart and shall not pose any significant risk to human health.

The Department of Environment and Natural Resources (DENR BC), after a thorough scientific review and evaluation of documents and scientific evidence from literature of corn MON 87427 x MON 89034 x TC1507 x MON 87411 x DAS-59122-7, considered the regulated article safe to the environment, particularly on biodiversity and non-target organisms.

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 Monsanto Philippines. The SEC expert, on the other hand, was provided with special questionnaire on socio-economic, ethical and cultural considerations that have been addressed by Monsanto Philippines in relation to their application.

## INFORMATION ON THE APPLIED EVENTS

MON 89034 was developed through *Agrobacterium*-mediated transformation of maize to produce the *Bacillus thuringiensis* (*Bt*) insecticidal proteins Cry1A.105 and Cry2Ab2 using the binary plasmid vector PV-ZMIR245. This vector contains the *cry1A.105* and *cry2Ab2* expression cassettes.

TC1507 was produced via microprojectile bombardment of maize, using a *PmeI*-linearized portion of plasmid PHP8999 containing two expression cassettes: *cry1F* and *pat*.

MON 87411 was developed through *Agrobacterium*-mediated transformation of maize line LH244 utilizing plasmid vector PV-ZMIR10871.

DAS-59122-7 was produced by the *Agrobacterium*-mediated transformation of maize using plasmid PHP17662, which contained three expression cassettes: *cry34Ab1*, *cry35Ab1* and *pat*.

### Countries Where Approvals Have Been Granted

| Country | Food                     | Feed                     | Cultivation                  |
|---------|--------------------------|--------------------------|------------------------------|
|         | direct use or processing | direct use or processing | domestic or non-domestic use |
| Brazil  | 2019                     | 2019                     | 2019                         |
| Canada  | 2017                     | 2017                     | 2017                         |
| Japan   | 2017                     | 2017                     | 2017                         |
| Mexico  | 2018                     |                          |                              |

Source: <https://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=521>

## **STRP's Assessment**

### **1. Gene Interaction**

- a. Based on the distinct mode of action of the CP4 EPSPS, Cry 1A.105, Cry2AbAb2, Cry 1F, PAT, Cry Bb1, Cry 34Ab1 proteins, any likelihood of interaction with one another is not considered significant to affect the stability and expression level of each gene. Their interaction does not lead to the production of new allergen or toxin in the combined trait product. According to Delaney et al., (2008), no tested transgenic proteins used in GM crops have demonstrated adverse effects in acute toxicity tests even at extreme high doses. No indication of similarity to known toxins or allergens was revealed on PAT protein [1][2].
- b. The CP4 EPSPS protein belongs to the family of EPSP synthases. These are enzymes involved in the penultimate step of the biochemical Shikimic acid pathway producing aromatic amino acids present in plants fungi and bacteria and are localized in the chloroplasts of plants. No significant differences were observed among stacked products for any of plant tissue types [1][3][4].

### **2. Metabolic Pathways**

According to Wang et al., (2018), commercialized stacked GM crops are mainly stacked with different Bt genes and herbicide tolerance genes. In transgenic plants, Bt genes are not native to plants. These insecticidal proteins are not targeted to chloroplasts and exert no known metabolic activity in plant. The herbicide tolerance is created by introducing a gene that encodes EPSPS enzyme related to shikimate pathway. So, Bt protein and EPSPS protein are not physiologically related, not active in the same metabolic pathway and share no common metabolites. There is no testable possibility for the gene interaction [5].

### **3. Gene Expression**

- a. Comparison between single and stacked GE products showed that there was no significant difference in CP4 EPSPS expression levels on any plant tissue type. There was also no significant difference among stacked products regardless of the number of traits [4].
- b. Cry proteins are contained only within plant tissue in microgram quantities and are produced at low levels in the pollen [6].
- c. Genetic transformation is an important technology for engineering transgenic organisms including plants. Selectable Marker Genes (SMG) have been very useful to enable plant transformation, yet for a number of regulatory concerns of retaining SMGs in commercialized transgenic plants. Ideally, the SMGs should be removed, after transformation. Several strategies have been developed to remove SMGs from GM products while retaining the transgenes of interest. Specificity is one of the most

important characteristics of protein molecules. An enzyme is specific for a reaction because its active site is constrained to react only to its own substrate. Likewise, specificity of peptide hormones is based on the interaction with specific receptor proteins. These proteins have distinct modes of action and so the possibility of interaction is not observed. Stacking cp4 epsps with one or more GE traits like different herbicide tolerance, insect protected and/or nutritionally-enhanced trait, did not impact CP4 EPSPS expression. With CP4 EPSPS found in many GE crops whether single or combined traits, the safety and efficacy of this introduced protein is not affected by the variability in protein expression ensuring consumers of the safety of their food [4].

## STRP's Conclusion

Find scientific evidence that the regulated article applied for direct use is as safe as its conventional counterpart and is not expected to pose greater risk to human and animal health.

## Metabolic Pathways

- a. Each gene product has a complete description found in the provided appendices supporting this application and even in published literature that can be cited [1]
- b. Each gene product has their own function and thereby enumerated to further elucidate its mechanisms:
  - *Cp4 epsps*—is a gene that produces the protein *3-phosphoshikimate 1-carboxyvinyl transferase* which reduces the affinity of the plant to glyphosate, making it herbicide-tolerant.
  - *Cry2Ab2* – gene from the *Bacillus thuringiensis* subsp. *kumamotoensis* that confers lepidopteran- resistance.
  - *Cry1A.105*, *Cry2Ab2*, *Cry1F*, *Cry3Bb1*, *Cry34Ab1* and *Cry35Ab1* from *B. thuringiensis* – genes that produce toxins specific to insects (lepidopteran) by targeting their midgut.
  - *PAT* protein – tolerance to glufosinate-ammonium herbicides.
  - *DvSnf7 dsRNA* – sourced from Western Corn Rootworm, this double-stranded RNA confers to coleopteran-resistance.

[10][11][12][13][14].
- c. Each mode of action previously mentioned further explains that these gene products have different mechanisms in the plant and genetically engineered stacks are unlikely to commence a novel biological pathway that can alter the plant's normal physiology [1][8].
- d. It is highly unlikely for unexpected effects to emanate from the stacked genes since the developer conducted strenuous screenings to determine which among the progenies will be able to express the intended genes without producing a

novel allergen or toxin. Also, protein expression in single events of transgenic parental lines was assessed rigorously for safety [1][8].

### **BAI's Conclusion**

Find scientific evidence that the regulated article applied for animal feed use is as safe as its conventional counterpart and shall not pose greater risk to animal health.

### **BPI PPSSD's Assessment**

#### **Metabolic Pathways**

- a. The developer provided a complete description of the mode of action of CP4 EPSPS, PAT, and Cry proteins [1][5][6][7][19][20][21].
- b. The proteins have different mode of actions. The CP4 EPSPS proteins are involved in the penultimate step of the biochemical Shikimic acid pathway producing aromatic amino acids in the chloroplasts of plants. *Bacillus thuringiensis* (Bt) Cry proteins exert their insecticidal activity via receptor-mediated mechanisms and are highly selective in terms of the organisms they affect. The PAT protein acetylates phosphinothricin, and confers tolerance to chemically synthesized phosphinothricin compounds such as the herbicide glufosinate-ammonium. The expression of the DvSnf7 suppression cassette results in the formation of a dsRNA transcript containing a 240 bp fragment of the western corn rootworm (WCR) Snf7 gene (DvSnf7) [1][5][6][7][19][20][21].
- c. The developer provided sufficient information that there are no possible unexpected effects of the stacked genes on the metabolism of the plant as supported by weight of evidences encompassing the distinct mode of action of introduced proteins and the protein expression analysis. The expression of the proteins in corn from stacked MON 87427 × MON 89034 × TC1507 × MON 87411 × DAS-59122-7 has been developed from conventional 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 [1][6][16][17][25][26][27].

### **BPI PPSSD's Conclusion**

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

### **DOH-BC's Assessment**

After a thorough review and evaluation of the documents provided by the proponent Monsanto Philippines, Inc., through the Bureau of Plant Industry (BPI), in support of their

application for approval for Direct Use as Food, Feed or for Processing (FFP) of Stacked trait product MON 87427 x MON 89034 x TC 1507 x MON 87411 x DAS-59122-7. The DOH-BC,

Find that the regulated article applied for Direct Use as Food, Feed or for Processing (FFP) is 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.

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.
2. Dietary exposure to the regulated article is unlikely to result in allergic reaction.
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 or the conventional corn.
5. Based on the above considerations and with the submitted sworn statement and accountability of the proponent, we hereby submit our evaluation to BPI relative to the application of a Biosafety Permit for Direct Use as Food, Feed, or for Processing (FFP) of Stacked trait product MON 87427 x MON 89034 x TC 1507 x MON 87411 x DAS-59122-7.

### **DOH-BC's Recommendation**

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's Assessment**

1. Corn commodity is well known in terms for Philippine corn trade production and consumption. This new multiple cross GM corn is evaluated for its direct use, particularly for feed use for commercial feed production.
2. The positive socio-economic impacts of domestic GM corn production are well documented in terms of productivity, cost, efficiency, profitability and positive macro-economic impacts. Despite the success of the GM corn technology in the Philippines, trade data will tell us that we are still dependent on corn imports which are vital to the domestic livestock and poultry industries.

### **SEC Expert's Recommendation**

The SEC expert recommends for the approval and issuance of the biosafety permit of corn MON 87427 x MON 89034 x TC 1507 x MON 87411 x DAS-59122-7.

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