

**ASSESSOR'S CONSOLIDATED REPORT OF MONSANTO PHILIPPINES AND  
DOW AGROSCIENCES' APPLICATION FOR  
DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING OF  
CORN MON89034 x TC1507 x MON88017 x DAS-59122-7**

**EXECUTIVE SUMMARY**

On October 16, 2019, Monsanto Philippines and Dow AgroSciences submitted corn MON89034 x TC1507 x MON88017 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 MON89034 x TC1507 x MON88017 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 MON89034 x TC1507 x MON88017 x DAS-59122-7s is safe as its conventional counterpart and shall not pose any significant risk to human health.

The Department of Environment and Natural Resources – Biosafety Committee (DENR-BC), after a thorough scientific review and evaluation of documents and scientific evidence from literature of corn MON89034 x TC1507 x MON88017 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 and Dow AgroSciences. 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 and Dow AgroSciences in relation to their application.

## **STRP's Assessment**

### **1. Gene Interaction**

- a. Since there are different modes of action of the proteins, there is no significant likelihood of interaction with one another that would lead to production of a new allergen or toxin in the combined trait product. Furthermore, there is no known mechanism of interaction among the proteins that could lead to adverse effects in humans, animals or environment [1].

### **2. Metabolic Pathways**

- a. Moreover, the mode of action is different for each gene product. Based on the references provided, it can be surmised that CryIA.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins are crystalline intrusions produced by *Bacillus thuringiensis* (*Bt*) which exhibit a highly specific insecticidal activity. These proteins act through a toxic action in the midgut of target insects [2][3][4][5][6][7][8][9].
- b. Also, there is no evidence showing any unexpected effects of the stacked genes on the metabolism of the plant. The stacked genes do not have any unexpected effects on the metabolism of the plant and that expression levels of the different proteins are as expected [1].

### **3. Gene Expression**

- a. All proteins in the combined trait corn product were scientifically assessed and results of these assessments studies revealed that Cry proteins were expressed at low levels typically at the nanogram levels [1].
- b. Furthermore, there is no marker gene transferred and expressed in the plants containing the stacked genes [10].
- c. Additionally, most of the documents submitted with this application are dated. All the evidence presented are from studies conducted in 2006 to 2008. There is no long-term study that was conducted to assess stability and expression level. However, if the basis will be on the expression of the genes via the production of the proteins in various plant parts, there is stability and truly there is expression of the genes [1].
- d. I would like to acknowledge receipt of the latest references relating to Monsanto Philippines' and Dow AgroSciences' corn MON89034 x TC1507 x MON88017 x DAS-59122-7 (SmartStax) application for direct use as food and feed, or for processing. These references would surely help in future assessment on the potential risk associated with the product if any and will definitely highlight the product and the researches that have recently been conducted on them. These references also confirmed my support for the approval of the product and biotech event that goes with it. It shows that there are no safety issues on the product. Only one reference submitted indicated some negative effects on aquatic species which are crayfish

that was directly fed with corn carrying the event in the application. However, crayfish is not found on the Philippines so I do not see any issues with safety of the product. I recommend that these references be part of the portfolio of the MON89034 x TC1507 x MON88017 x DAS-59122-7 (SmartStax) that is submitted for renewal [24][25][26][27][28][29][30][31][32][33].

### **STRP's Conclusions**

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.

After a thorough and scientific review and evaluation of the documents provided by Monsanto Philippines and Dow AgroSciences Inc. relevant to corn MON89034 x TC1507 x MON88017 x DAS-59122-7, the STRP found that the new studies submitted by the applicant will not affect the safety of corn MON89034 x TC1507 x MON88017 x DAS-59122-7 [17][18][19].

### **BAI's Assessment**

#### **Metabolic Pathways**

It is unlikely that there will be interaction among proteins that will create a safety concern. Also, protein expression data shows that the Cry1A.105, Cry2Ab2, Cry1F, PAT, Cry3Bb1, CP4 EPSPS, Cry34Ab1, and Cry35Ab1 proteins are expressed properly indicating that the corresponding genes were inherited and functioning properly. Moreover, the stacked trait event has been in the market for more than ten years as per applicant's documents which means it has already demonstrated a history of safe use [1].

### **BAI's Conclusions**

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.

After a thorough and scientific review of the new studies submitted by Monsanto Philippines, Inc., and Dow AgroSciences for corn MON89034 x TC1507 x MON88017 x DAS-59122-7 (SmartStax) application for direct use as food and feed or for processing, the DA-BAI found that the new studies submitted by the applicant will not affect the safety of corn MON89034 x TC1507 x MON88017 x DAS-59122-7 (SmartStax). [24][25][26][27][28][29][30][31][32][33].

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

#### **Metabolic Pathways**

- a. The proteins in this 5-way stacked event have different mode of actions. The CP4 EPSPS proteins are involved shikimic acid pathway of aromatic amino acids in

plants. The insecticidal activity of Cry proteins is being expressed through a selective receptor-mediated mechanism. PAT protein acetylates the L-phosphinothricin form of glufosinate to produce non herbicidal N acetyl glufosinate [1][2][3][4][5][11].

- b. 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 [1][2][3][4][5][11].

### **BPI PPSSD's Conclusions**

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

After a thorough review of the new studies submitted by Monsanto Philippines and Dow AgroSciences, Inc. for corn MON89034 x TC1507 x MON88017 x DAS-59122-7 application for Direct Use as Food and Feed, or for Processing, BPI-PPSSD found that the new studies submitted by the applicant will not affect the safety of corn MON89034 x TC1507 x MON88017 x DAS-59122-7 [17][18][19].

### **ANNEX IV**

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

After a thorough review and evaluation of the documents provided by the proponent, Monsanto Philippines and Dow AgroSciences, 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 corn MON89034 x TC1507 x MON88017 x DAS59112-7. 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 corn MON89034 x TC1507 x MON88017 x DAS59112-7.~~

## **DOH-BC's Conclusions**

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.

After a thorough review of the new studies submitted by Bayer CropScience, Inc. for corn MON89034 x TC1507 x MON88017 x DAS59112-7 application for Direct Use for Food and Feed, or for Processing, the DOH-BC found that the new studies submitted by the applicant will not affect the safety of corn MON89034 x TC1507 x MON88017 x DAS59112-7 [17][18][19].

## **ANNEX V**

### **SEC Expert's Assessment**

1. As the applicants note, yellow corn is a very important commodity in the country, particularly for the livestock sector, which uses it as a main feed ingredient. Production, consumption and importation projections indicate a continuing need to source yellow corn from overseas in order to meet consumption needs. Issuance of biosafety permit for corn MON89034 x TC1507 x MON88017 x DAS-59122-7 would provide an opportunity to ensure greater availability of raw materials for local feed milling, livestock and other industries along the value chain. The impact on production, consumption and trade goes beyond yellow corn as a commodity. It points to food self- sufficiency and agribusiness competitiveness outcomes, among others [17][18][19][20][21].
2. Issuance of biosafety permit for corn MON89034 x TC1507 x MON88017 x DAS-59122-7 will not be directly affecting production of yellow corn, except for marginal effects on the supply side, should the volumes be coming in push price of the commodity to levels that disincentivize maintenance of current volumes provided by producers to the market. The extent of the effect being drastic will depend on the volume limit. There are however, trade policies that are designed to manage any such possibility of getting the local market flooded by imported yellow corn [22][23].
3. Since the event for which permit is being applied is intended for FFP purposes, other effects on production can't be imagined [22][23].

4. With regard to industrial use, issuance of the biosafety permit can enhance supplemental volumes of raw materials for feed production, which potentially benefits the feed milling industry. The changes in the market that can be perceived are associated with commodities down the value chain of yellow corn [22][23].
5. These changes point to consumption and trade. Increased local production of these commodities ensure food sufficiency as well as enhanced competitiveness of the agribusiness industry [22][23].
6. The applicants' expression of not intending corn MON89034 x TC1507 x MON88017 x DAS-59122-7 to be commercially grown and marketed for propagation and cultivation addresses concerns about any effect on cultural farming practices of a specific ethnic and cultural groups [19].
7. There are groups of consumers who have strong beliefs against use of GMOs, particularly in commodities for FFP use. While the applicants (as other applicants also do) strongly believe in the harmlessness of the GMO to human health, this reviewer still strongly recommends the installation of tracing and labelling mechanisms to protect consumer sovereignty as they are provided sufficient information to enable them to make truly free consumption choices [19].

### **SEC Expert's Recommendations**

The SEC expert recommends for the approval and issuance of the biosafety permit of corn MON89034 x TC1507 x MON88017 x DAS-59122-7.

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