

## **ASSESSORS' CONSOLIDATED REPORT PIONEER HI-BRED'S APPLICATION FOR COMMERCIAL PROPAGATION OF CORN MON810 x TC1507 x NK603**

### **EXECUTIVE SUMMARY**

On October 11, 2018 Pioneer Hi-Bred Philippines Inc. submitted corn MON810 x TC1507 x NK603 for commercial propagation, 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) concurred that corn MON810 x TC1507 x NK603 is as safe for human food, animal feed and commercial propagation 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 MON810 x TC1507 x NK603 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 corn MON810 x TC1507 x NK603.

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 Section 15 of the JDC No.1, S2016, 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, except for the SEC expert, the complete dossier submitted by Pioneer Hi-Bred 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 Pioneer in relation to their application.

Upon receipt of the individual reports from the assessors, the BPI Biotech staff prepared this consolidated risk assessment report for the information of the public.

## **STRP ASSESSMENT AND RECOMMENDATIONS**

Based on the documents submitted by the applicant:

### **A. Gene Interaction**

The STRP stated that the claim on no interaction of the resulting products is supported by (Maxwell, 2008) data for April 14 to October 2, 2009 growing seasons of 5 separate sites. The study was on nutritional composition of forage and grain tissues that showed that the level on multi-stacked maize was comparable to the near-isoline controlled maize. Secondary metabolites and anti-nutrient composition is much lower than the tolerance level.

The STRP also concurred that Cry 1 F & PAT are in the cytoplasm. TC 1507, Mon 810 and NK603 maize events integrated into the genome of multi-stacked products in the same way as individual maize as confirmed in corresponding protein expression levels in stacked and in individual maize event. Results of ELISA (Enzyme-linked, ImmunoSorbent Assay) showed that Cry 1F protein concentrations in tissues derived from stacked, herbicide-treated stack maize were comparable to Cry 1F protein concentrations in tissues derived from 1507 maize.

The Cry 34Ab1 protein concentrations in leaf, stalk root and grain tissues from 59122x Mon810 maize, herbicide-treated 59122x Mon810 maize, 15007x 59122x Mon810x NK603 and herbicide treated stacked maize were comparable to Cry 34Ab1 protein concentration in tissues derived from 59122 maize. For all tissue samples (leaf, stalk, root, grain tissue) derived from controlled maize, results of ELISA for Cry 1F, 34Ab1, Cry 35Ab1, PAT, Cry1Ab, and Cp4EPSEPS were < LLOQ (Lower limit of quantitation).

### **B. Metabolic Pathways**

The STRP has concurred that complete description of the mode of action of each gene product was provided. For Cry1F, Cry1Ab, mode of action as characterized as given in Abstract page 127 of paper on ("Pore Formation by Cry Toxin" by Soberon et.al, Chapter 11 In : Proteins: Membrane binding and pore formation ed. Anderluh, G. and Laky, J. 2010 and in conclusion page 138, supported by data Table 2 page 133).

The STRP also stated that Cry protein action by selectively binding to specific sites on the lining of the midgut of susceptible species is well discussed in general. It is expected that if single events are safe, multi-stacked products generated by general breeding will not result in unexpected effect.

### **C. Gene Expression**

The STRP stated that expression levels of the individual protein products in tissues from TC1507xMON810xNK603 maize are the same as the individually approved transformation events. She also concurred that all three proteins in the combined trait product are expressed in the same level in different tissues as supported by results of ELISA and that PAT gene was transferred and expressed through conventional breeding.

### **D. Field Performance**

The STRP stated that efficacy on ACB is supported by the results of multi-location field trials as reported by Samson, J et al. (2012) under contained and open field study. Results of field trials claimed to support tolerance to herbicide and yield performance and safety to non-target arthropods were noted in Samson J, et.al (2012).

## E. Agricultural Management

The STRP has agreed with the information provided by the applicant and has concurred that the presence of the traits will not cause a change in cultural management of the crop, except for its intended changes.

## F. Recommendation

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

## **DENR ASSESSMENT AND RECOMMENDATION**

In accordance with Section 15 of the JDC No.1, S2016, 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, except for the SEC expert, the complete dossier submitted by Monsanto. 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 in relation to their application.

Upon receipt of the individual reports from the assessors, the BPI Biotech staff prepared this consolidated risk assessment report for the information of the public.

## **DOH ASSESSMENT AND RECOMMENDATION**

Find that the regulated article applied for Commercial Propagation does not changes in the usual practices as described in the phases/stages of biotechnology 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.

1. 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.
2. Dietary exposure to the regulated article is unlikely to result allergic reaction.
3. The regulated article is not materially different in nutritional composition from that of non-transgenic corn or the conventional corn.
4. Scientific pieces of evidences from provided references i.e. literatures show that regulated article applied for Commercial Propagation is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health and on the environment.

5. It is suggested that the Bureau of Plant and Industry (BPI) ensure the following :
  - i. Strict monitoring of the regulated article from port of entry to the trader's/importer's storage/warehouse as stated in Section 32 of the Joint Department Circular Number 1, series of 2016.
  - ii. The BPI to include in the issuance permit for the release of this product the following conditions :
    - a) Any spillage (during unloading and loading/hauling and transport, unloading and storage) shall be collected and cleaned up immediately.
    - b) Transportation of the consignment from the port of entry to any destination within the country shall be in closed containers.
    - c) There shall be a clear labeling of the product from importation down to all levels of marketing stating that it is only for the purpose of commercial propagation and is not to be used for direct use as food, feed or for processing.

Based on the above considerations and with the submitted sworn statement and accountability of the proponent, this recommendation is being submitted to BPI related to the processing and issuance of a Biosafety Permit for Commercial Propagation (CP) of Corn TC1507 x MON810 x NK603 (Intrasect).

### **SEC ASSESSMENT AND RECOMMENDATIONS**

Based on SEC expert review of the SEC questionnaire answered by the applicant:

Maize is extensively cultivated worldwide and has a long history of safe use. Maize grain and maize-derived products represent staple food and feed for a large portion of the global population (CFIA, 1994). In 2003, the Organization for Economic Cooperation and Development (OECD) published a consensus document on the biology of maize (OECD, 2003) which describes the uses of maize as a crop plant in many regions of the world. Industrialized countries use maize primarily for two purposes. One is as feed to animals, either directly in the form of grain and forage or sold to the feed industry, and the other is as raw material for extractive industries (OECD, 2003). The use of grain as human food has little significance in these countries (Galinat, 1988; Morris, 1998; OECD, 2003; Shaw, 1988). The use of maize in developing countries is variable. In Mexico, one of the main uses of maize is for food. Similarly, maize is consumed as food in Africa and Latin America but in Asia, it is generally used to feed animals (OECD, 2003).

TC1507 maize has been developed to express the Cry1F and PAT proteins. The Cry1F protein confers resistance to certain lepidopteran pests, including Asian corn borer (*Ostrinia furnacalis*), a major insect pest of maize. The PAT protein confers tolerance to glufosinate herbicide which was used as a selectable marker in the development of TC1507 maize.

In countries where above-ground lepidopteran pests such as the Asian corn borer cause significant reductions in maize yield, TC1507 maize provides farmers with an economical and effective means to control these pests. It is an important tool to help farmers keep pace with increasing demand for maize globally for multiple downstream uses for feed, food and fuel.

TC1507 was not commercialized as a single product but rather as a component of stacks, including Intrasect® (MON810XTC1507XNK603). Corn containing TC1507 is expected to help protect the yield and help prevent decrease in productivity due to more effective control of Asiatic corn borer, the most destructive insect pest of corn in the Philippines, as well as certain secondary lepidopteran corn pests. The benefits of planting Intrasect was already evident from the results of regulated trials conducted to verify the field performance of Intrasect (Samson et al., 2012; Samson and Caasi-Lit, 2012)

The comparative performance of non- GM P3774 and its GM counterpart P3774YHR is summarized in Table 1 (South Cotabato) and (Table 2 (Isabela). The yield presented are data from the 2014 trials but

the prices of production inputs and grain were adjusted to 2018 average to better reflect the present scenario. Inputs, labor and seed cost vary from region to region. Yield indicated is the mean from 14 locations. More recently, in a paper presented by Gonzales (2016) on the socio-economic and environmental impact of Bt corn in the country, it was revealed that the average yield advantage of Bt corn over non-GM corn was 19% from 2003 to 2011 and the yield difference was attributed largely to more effective control of corn borer. Moreover, it was reported that Bt corn required 54% less pesticides than conventional corn.

Corn varieties containing event TC1507 can be planted like any other corn varieties in areas where corn is grown. Its inherent ability to ward off Asian Corn Borer (ACB) is not expected to affect current corn planting practices, except that corn varieties containing event TC1507 are expected to have a reduced need for spraying of chemical pesticides to control ACB. It is not expected to affect preservation of cultural heritage.

#### B. Recommendation

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

### **INSECT RESISTANCE MANAGEMENT ADVISORY TEAM (IRMAT) RECOMMENDATION**

The DA Insect Resistance Management Advisory Team (IRMAT) reviewed the submission of Pioneer Hi-Bred Philippines Inc. for the new application for commercial propagation under the DOST-DA-DENR-DOH-DILG JDC No.1 s2016 of Corn TC1507 and Corn MON810 x TC1507 x NK603 through ad referendum.

Having been mandated by the DA Special Order No.24 s2077 to provide advice and direction to the BPI in matters relating to Insect Resistance Management (IRM), after a review of both applications, the IRMAT therefore finds that the applicant's submitted documents is WITH SUBSTANTIAL COMPLIANCE with the previously issued DA Memorandum Circulars pertaining to IRM.