

Consolidated Technical Report of Monsanto's corn MON810 X NK603 for Direct Use as Food and Feed, or for Processing

EXECUTIVE SUMMARY

On July 10, 2018, Monsanto Philippines Inc. submitted corn MON810 x NK603 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 STRP, BAI, and BPI-PPSSD find scientific evidence that corn MON810 x NK603 is as safe for human food and animal as its conventional counterpart and that there is no evidence of gene interaction on the resulting gene products.

The Department of Environment and Natural Resources – Biosafety Committee (DENR-BC), after a thorough scientific review and evaluation of the accomplished Project Description Report (PDR) and Environmental Risk Assessment (ERA) form along with the submitted sworn statement and accountability of the proponent, considered corn MON810 X NK603 safe to the environment and biodiversity, particularly to non-target organisms.

The DOH-BC, after a thorough scientific review and evaluation of documents related to Environmental Health Impact, found scientific evidence that the GM application will not cause significant adverse effects to human and animal health, and is unlikely to result in allergenic reaction.

Furthermore, the Socio-economic, Ethical and Cultural (SEC) expert recommended for the issuance of biosafety permit for this regulated article after assessing the SEC impact of corn MON810 x NK603 for direct use.

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 accomplished 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

MON 810 x NK603 contains *cry1Ab* gene encoding Cry1Ab protein and *cp4 epsps* gene encoding CP4 EPSPS protein. These proteins have different mode of actions and metabolic pathways and are not likely to interact to produce any known mammalian allergen or toxin (Monsanto, 2018).

CP4 EPSPS in NK 603 and Cry1Ab in MON 810 have been assessed individually using different bioinformatics analyses and showed that these proteins have no significant homology and similarity to any known allergen and toxins that could lead to potential adverse effect on human and animal health. The proteins will accumulate in different subcellular compartments of plant parts. Cry1Ab is likely to accumulate in the cytoplasm while CP4 EPSPS is expected to accumulate in the chloroplast.

B. Metabolic Pathways

The products are not involved in the same metabolic pathways. The Cry1Ab proteins are shown to be selectively toxic to lepidopteran species and act through a toxic action in the gut of specific lepidopteran insects. The CP4 EPSPS protein, on the other hand, are enzymes involved in the penultimate step of the biochemical shikimic acid pathway producing aromatic amino acids in the chloroplasts of plants.

Data provided indicates 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 maize plant tissue from stacked MON810 x NK603 is similar to the corresponding levels in single events based on ELISA. Results showed that the proteins are expressed properly to the combined trait product as in its relevant single events.

C. Gene Expression

Validated Enzyme-Linked Immunosorbent Assay (ELISA) provided by the developer indicated no significant change in the expression levels of Cry1Ab and CP4 EPSPS proteins in their respective single events and MON 810 x NK603 (Monsanto, 2018). Furthermore, the data on the expression of the novel proteins in the corresponding single events, MON 810 and NK603 indicates that the proteins which were expressed similarly in the combined trait product are present at low level in plant. This indicates that the presence of two proteins (Cry1Ab, and CP4 EPSPS) will not interact to produce new allergen or toxins.

D. Recommendation

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

DENR ASSESSMENT AND RECOMMENDATION

After a comprehensive review and evaluation of the documents including the scientific evidence from references and literature submitted by Monsanto Philippines, Inc., on its application for Direct Use as FFP of corn MON810 x NK603, hereunder are the observations and recommendations of the DENR-BC:

1. The Corn MON810 x NK603 individual event 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 and biodiversity, particularly non-target organisms. 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 genetically modified parents is similar with that of non-genetically modified parents. This method does not introduce any greater variation in the genome beyond what is obtained (Weber, et al., 2012).

The project description report (PDR) discusses the specified environmental management plan indicating the possible risk and harm to the environment and non-target organisms 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.

DOH ASSESSMENT AND RECOMMENDATION

The DOH-BC found 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 corn or the conventional corn,
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.

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 MON810 x NK603.

SEC ASSESSMENT AND RECOMMENDATIONS

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

Philippine became a marginal importer of corn in the past six years. Based on the data (Table 1), corn imports of the Philippines increase from 66,193.10 MT in 2011 to 806,118.6 MT in 2016. However, in terms of growth rate, it decreased from 51.53% in 2011-2012 to only 11.62% in 2015-2016. The above data shows that corn is a significant commodity in agricultural trade.

Table 1. Maize: Quantity Imports (in Metric Tons)

	2011	2012	2013	2014	2015	2016
Maize	66,193.10	136,574.60	341,604.60	575,138.70	712,423.70	806,118.6
Source: Agriculture Indicator System (AIS) on Agricultural Exports and Imports. Report No. 2017-4. Philippine Statistics Authority. September 2017						

Although, corn production slightly decreased in 2015 (7.5000 mt) and 2016 (7.2000mt) as compared to 2014 (7.8000 mt), on the average, domestic production increased by 0.61 % from 2012-2016. In the last five years also, Philippines' corn importation increased from 137 mt in 2012 to 812 mt in 2016, ut on the average, the rate of importation declined from about 52 percent in 2012 to only 12 percent in 2016 (PSA).

In terms of production, Philippine corn experienced a decline from 7,406,830 MT in 2012 to 7,218,817 MT in 2016. However, poultry and livestock industry expanded which causes corn importation to increase. In terms of consumption, corn and its components are valuable raw materials for the food, processing and feed industries in the Philippines. It is considered a major ingredient for the feed formulation for the poultry and livestock industry. Domestic corn production constituted an average of 78.7% of the total com utilization of the country from 2012-2016 (Food Balance Sheet, PSA). Significant portion of corn supply (both domestic production and imports) is utilized as feed ingredient for livestock and aquaculture industries. The per capita consumption of corn increased from 17.55 kg./year in 2012 to 22.52 in 2016 kg./year (PSA).

B. Recommendation

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