

**ASSESORS' CONSOLIDATED REPORT ON MONSANTO PHILIPPINES INC.'S STACKED
INSECT RESISTANT AND HERBICIDE TOLERANT CORN MON87427 x MON89034 x
MIR162 x NK603 APPLICATION FOR DIRECT USE AS FOOD AND FEED, OR FOR
PROCESSING**

EXECUTIVE SUMMARY

On February 22, 2018 Monsanto Philippines Inc.'s filed for application of corn MON87427 x MON89034 x MIR162 x NK603 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 MON87427 x MON89034 x MIR162 x NK603 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 MON87427 x MON89034 x MIR162 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 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 Monsanto Philippines, Inc. Upon receipt of the individual reports from the assessors, the

BPI Biotech Secretariat prepared this consolidated risk assessment report for the information of the public.

STRP, PPSSD AND BAI ASSESSMENT

Gene Interaction

The protein products (CP4 EPSPS, Cry1A.105, Cry2Ab2, Vip3Aa20, and PMI) have different modes of action and belong to different metabolic reactions. 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. CP4 EPSPS and Cry2Ab2 are expected to accumulate in the chloroplast while Cry1A.105, Vip3Aa20 and PMI are expected to accumulate in the cytoplasm.

Metabolic Pathways

The assessors have determined that the mode of action is different for each gene product. They have individual roles, different specificities and do not share same targets or substrates. Genetic and molecular analyses showed that all genes are inherited, expressed and functioning properly in MON 87427 x MON 89034 x MIR 162 x NK 603, as they did similarly in single events.

Gene Expression

Enzyme-Linked Immunosorbent Assays (ELISA) was used to quantify and determine the level of proteins. The result showed that CP4 EPSPS, Cry1A.105, Cry2Ab2, Vip3Aa20 and PMI proteins are expressed properly in the combined product MON 87427 x MON 89034 x MIR162 x NK603 as in its relevant single events.

The expression of the proteins in maize plant tissue from stacked MON 87427 x MON 89034 x MIR162 x NK603, MON 87427, MON 89034, MIR162 and 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. Compositional analyses provided by the developer indicated that the stacked MON 87427 x MON89034 x MIR162 x NK603 is substantially equivalent to the control substance MPA640B which has similar background genetics.

Conclusion

After a thorough and scientific review and evaluation of the documents provided by Monsanto Philippines, Inc. relevant to combined trait corn MON87427 x MON89034 X MIR162 X NK603 the BPI-PPSSD, BAI and STRP find scientific evidence that the regulated article applied for direct use has no evidence of interaction on the resulting gene products.

DENR RECOMMENDATION

The DENR-BC has reported that the direct use of the regulated article whether for food, feed or for processing will not cause any significant diverse effect on the environment and biodiversity.

The individual events or the gene stacked corn MON8742 7 x MON90 34 x MIR16 2 x NK603 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, biodiversity, and non-target organisms. Similarly, it is less likely to pose any significant adverse effect on the environment.

The incorporation of gene stacked event is through conventional breeding, which is regarded 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 (Weber et al., 2012); and

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, corns are very highly domesticated and does not survive well without human intervention (FAO, 2014).

After a comprehensive review and evaluation of the documents including the scientific evidence from references and literature submitted by Monsanto Philippines Inc. its application for Direct Use as food and feed or for processing of corn MON87427 x MON89034 x MIR162 x NK603, the DENR-BC considered the regulated article safe to the environment particularly on biodiversity, and hereby recommends for the approval of application of Monsanto Philippines, Inc. for Biosafety Permit for direct use as food, feed or for processing of corn MON87427 x MON89034 x MIR162 x NK603.

DOH RECOMMENDATION

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 of corn MON87427 x MON89034 x MIR162 x NK603, the DOH Biosafety Committee 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.

The DOH-BC has reported that 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. Dietary exposure to the regulated article of unlikely to result in allergic reactions.

The regulated article is not materially different from nutritional composition from that of the non-transgenic potato or the conventional corn.

Based on the above considerations and with the submitted sworn statement and accountability of the proponent, the DOH-BC has submitted the evaluation to the BPI relative to the application of a Biosafety Permit for direct use as food and feed or for processing (FFP) of corn MON87427 x MON89034 x MIR162 x NK603.

SOCIO-ECONOMIC CONSIDERATIONS EXPERT RECOMMENDATION

According to the SEC Expert, domestic corn production is very minimal relative to the demand for corn by various industries. Thus, the Philippines is importing a significant quantity of corns to meet the demand. The approval of this product (corn MON 87701 x MON 897880) and its entry into the Philippine market would help stabilize its prices as it is not expected to affect the local production since the Philippine is not a major corn producer.

The SEC Expert further states that the approval of importation of this corn MON 877010 x MON 89788 and its product contain component will not affect the cultural practices of any ethnic and cultural group.

After a thorough and scientific review and evaluation of the documents provided by Monsanto Philippines, Inc., combined trait corn MON87427 x MON89034 X MIR162 X NK603, the SEC Expert recommends for the approval and issuance of biosafety permit of the said GM product.