

Consolidated Risk Assessment Report of Monsanto Philippines, Inc.'s Corn NK603 x T25 Application for Direct Use as Food, Feed or for Processing (FFP)

STRP, PPSSD AND BAI ASSESSMENT

Gene Interaction

The differences in the modes of action, metabolic pathways and enzymatic activities of the CP4 EPSPS, and PAT proteins in the plant cells indicates no likelihood of interaction with one another. PAT protein has no specific cellular localization, hence, it will accumulate in the cytoplasm. CP4 EPSPS protein is being directed to the chloroplast via chloroplast transit peptide (CTP).

Metabolic Pathways

The gene products, CP4 EPSPS in NK603 and PAT in T25 have their different modes of action, are not involved in the same metabolic pathway and did not manifest any interaction based on protein expression.

CP4 EPSPS protein belongs to the family of EPSP synthases involved in the penultimate step of the biochemical shikimate pathway producing aromatic amino acids in the chloroplasts of plants. PAT protein acetylates phosphinothricin, inactivating the compound, and confers tolerance to chemically synthesized phosphinothricin compounds such as the herbicide glufosinate-ammonium.

Gene Expression

Enzyme-Linked Immunosorbent Assay (ELISA) provided by the developer indicated that the level of expression of the proteins in corn plant tissue from NK603 x T25 is similar to the corresponding single events, NK603 and T25. CP4 EPSPS represents 0.01% of the total protein in NK603 grains while PAT protein could represent 0.000022% of the crude protein in whole corn grain.

Protein expression analysis also showed that the CP4 EPSPS and PAT proteins were expressed as expected in the combined trait product NK603 x T25 indicating that the inserted genes, cp4 epsps, and pat were inherited and functioning properly when combined in the breeding stack.

Conclusion

After a thorough and scientific evaluation of the documents provided by Monsanto Philippines, Inc. and other related literatures, scientific evidence indicates that the Combined Trait Product, NK603 x T25 applied for direct use as food and feed or for processing has no evidence of interaction on the resulting gene products and as safe as it's conventional counterpart.

DENR RECOMMENDATION

Upon extensive review and evaluation of the application for direct use as food and feed or for processing, including the scientific evidences from provided references, literature and other studies the DENR-BC finds that the regulated article is sae as its conventional counterpart and is not expected to pose any significant risk to the environment.

DOH RECOMMENDATION

After a thorough and scientific evaluation of the documents provided by the applicant in support for their application for a biosafety permit for direct use as food and feed or for processing, the DOH-BC finds that the regulated article is as safe as its conventional counterpart and shall not pose any significant risk to human health and the environment. The regulated article does not require changes in the usual practices in unloading, and loading, hauling transport, storage and processing.

SEC RECOMMENDATION

The SEC Expert has stated that the GM product will not change drastically the current patterns of production, consumption, utilization, and trade as there is already an existing demand for maize hybrids for direct use as food, feed, or processing in the country.

After a thorough and scientific evaluation of the documents provided by the applicant for the application for direct use as food and feed or for processing of corn NK603 x T25, the SEC Expert recommends for the approval and issuance of biosafety permit for the said GM product.