CONSOLIDATED REPORT ON MONSANTO PHILIPPINES, INC.'S SOYBEAN MON87701 X MON 89788 APPLICATION FOR DIRECT USE AS FOOD, FEED OR FOR PROCESSING (FFP)

EXECUTIVE SUMMARY

On October 10, 2018, Monsanto Philippines Inc. submitted soybean MON87701 X MON89788 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 soybean MON87701 X MON89788 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 soybean MON87701 X MON89788 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 soybean MON87701 X MON89788 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 Monsanto in relation to their application.

Upon receipt of the individual reports from the assessors, the BPI Biotech staff endorsed to the DA-BC the application together with the summarized technical report and technical assessment from concerned agencies, STRP, and SEC expert.

STRP, BPI-PPSSD AND BAI ASSESSMENT AND RECOMMENDATIONS

Gene Interaction

The developer provided sufficient information and references which support that the presence of two proteins (Cry1Ac and CP4 EPSPS) will not interact to produce any new allergen or toxins. This is due to the different mode of action of each protein which is not likely to interact. Since the two proteins have different modes of action, any interaction will not lead to production of new allergen or toxin nor will affect the stability and expression of each gene. There has been no reported cases where the two proteins interacted with each other.

Cry1Ac protein does not contain a sequence that targets a specific subcellular location thus is accumulated in the cytoplasm of soybean cells, and expressed as an inclusion and as part of the spore coat while CP4 EPSPS accumulates in the chloroplast since it is involved in the plant chloroplast-localized pathway.

Metabolic Pathways

The developer provided sufficient information that the mode of action is different for each gene product and that the products involved are significantly different in metabolic pathways. The Cry1Ac protein involves binding of the Cry protein to specific receptors in the intestinal tissues of susceptible insect species while CP4 EPSPS protein belongs to the family of EPSP synthases, which are enzymes involved in the penultimate step of the biochemical shikimic acid pathway producing aromatic amino acids in the chloroplasts of plants. It has been stated by BPI-PPSSD, BAI and STRP that it is highly unlikely for protein products to interact since the mode of actions of Cry protein and CP4EPSPS are different.

Gene Expression

Based on the data provided by the developer, the levels of CP4 EPSPS and Cry1Ac in stacked MON 87701 x MON 89788 were similar to the corresponding single events based on the results of ELISA. The protein expression analysis provided by the developer and the previous assessments of the single events, have indicated that the proteins are expressed at low level in plant. It has been concurred by the BPI-PPSSD, BAI and STRP that there is no possible interaction that could affect the stability and expression level of either one of the genes. The genes in the stacked trait MON 87701 x MON 89788 are expressed properly and similar to the corresponding single event.

Conclusion

After a thorough and scientific review and evaluation of the documents provided by Monsanto Philippines, Inc. relevant to combined trait Soybean MON 87701 × MON 89788, 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-BC 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 Soybean MON87701 x MON89788, hereunder are the observations and appropriate actions of the DENR-BC:

1. The individual events of the gene stacked Soybean MON87701 x MON89788 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.

2. 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

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

DOH-BC 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 for Food and Feed or for Processing (FFP) of Soybean MON 87701 x MON89788. The-DOH-BC finds that the regulated article applied for Direct Use for Food and 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 of the DOH-BC:

1. Find that the regulated article applied for Direct Use for food and feed or for processing (FFP) is as safe as its conventional counterpart and is not expected to pose any significant risk to human and animal health and environment.

2. 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.

3. Dietary exposure to the regulated article is unlikely to result in allergic reaction.

4. The regulated article is as safe as food and feed derived from conventional soybean varieties.

5. The regulated article is not materially different in nutritional composition from that the non-transgenic soybean or the conventional soybean.

SEC RECOMMENDATION

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

The SEC Expert further states that the approval of importation of this soybean MON 87701x 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 soybean MON87701 x MON 89788, the SEC expert recommends for the approval and issuance of biosafety permit of the said GM product