CONSOLIDATED REPORT OF MONSANTO'S SOYBEAN MON87708 X MON89788 X A5547-127 APPLICATION FOR DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING

EXECUTIVE SUMMARY

On August 30, 2017, Monsanto Philippines Inc. applied the stacked trait product soybean MON87708 X MON89788 X A5547-127 for direct use as food and feed, or for processing as an original application under the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1 Series of 2016 (JDC No.1, S2016).

After reviewing the Risk Assessment Report and attachments submitted by the applicant; the Scientific and Technical Review Panel (STRP) member, the Bureau of Animal Industry (BAI), and the BPI-Plant Products Safety Services Division (BPI-PPSSD) found no interaction on the resulting gene product of the regulated article applied for direct use as food and feed, or processing based on scientific evidences provided.

The STRP, BAI, and BPI-PPSSD concurred that the likelihood of interaction among the three (3) proteins (DMO, PAT, and CP4 EPSPS) is unlikely because their modes of action are different. In addition, allergen and toxicity analyses of the three proteins have shown that these proteins show no homology to any known mammalian allergen or toxin.

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 that the conditions set by them are complied.

The Department of Health – Biosafety Committee (DOH-BC), after a thorough scientific review and evaluation of documents related to Environmental Health Impact, concluded that soybean MON87708 X MON89788 X A5547-127 will not pose any significant risk to 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 soybean MON89788.

Lastly, after assessing that there will be no negative socio-economic, ethical and cultural concerns that will arise from the adoption of Genetically Modified Organisms, the Socio-economic, Ethical and Cultural (SEC) expert recommended for the approval and issuance of biosafety permit of soybean MON87708 X MON89788 X A5547-127 for direct use as food and feed, or for processing.

BACKGROUND

In accordance with Article VIII, Section 20 of the JDC No.1, S2016, 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. Upon receipt of the individual reports from the assessors, the BPI Biotech Office prepared this consolidated risk assessment report for the information of the public.

STRP, BAI, BPI-PPSSD ASSESSMENT AND RECOMMENDATION

After a thorough review of the documents submitted by the applicant, the STRP made the following assessment and recommendation:

A. Gene Interaction

The assessors confirmed that Monsanto Philippines, Inc. provided sufficient information and references which support that the presence of three proteins (DMO, CP4 EPSPS and PAT) will not interact to produce new allergen or toxins. This is due to the distinct mode of action of each protein which is not likely to interact.

The DMO, CP4 EPSPS and PAT proteins modes and sites of biological activity are different and there is no known or conceivable mechanism of interaction between DMO, CP4 EPSPS and PAT which could lead to adverse health effects in animals or humans.

B. Metabolic Pathways

The mode of action of each gene product, according to the assessors, was completely described.

Dicamba monooxygenase (DMO) is encoded by the *dmo* gene which was originally derived from the bacterium *Stenotrophomonas maltophilia*. DMO is the terminal Rieske oxygenase of a three-component system that also includes a ferredoxin and a reductase. In *S. maltophilia*, the first chemical step in the mineralization of dicamba is catalyzed by the O-demethylating enzyme DMO, which oxidizes the herbicide dicamba to the herbicidally inactive compounds, 3,6-dichlorosalicylic acid (DCSA) and formaldehyde. The presence of the gene and its gene product makes the stacked hybrid resistant to dicamba because of its ability to convert dicamba into DCSA.

The gene *cp4 epsps* which encodes for CP4 EPSPS (5-enoylpyruvyl-shikimate-3-phosphate synthase) was derived from *Agrobacterium tumefaciens* strain CP4. EPSPS catalyzes the reversible reaction of shikimate-3-phosphate (S3P) and phosphoenolpyruvate (PEP) to produce EPSP and Pi. EPSPS is an enzyme which catalyzes the penultimate step of the shikimate pathway of aromatic amino acid biosynthesis. In plants, EPSPS is localized in the chloroplast. The herbicide glyphosate is an inhibitor of the native plant EPSPS but the CP4 EPSPS is far less sensitive to the inhibitory effects of glyphosate, hence conferring tolerance to glyphosate.

The *pat* gene encodes the enzyme phosphinothricin acetyl transferase. The *pa*t gene from A5547-127 is a synthetic version based on the coding sequence of the *pat* gene of *Streptomyces viridochromogenes*, a non-pathogenic bacterium. The PAT protein acetylates phosphinothricin thereby inactivating phosphinothricin compounds such as the herbicide glufosinate ammonium. The presence of the *pat* gene allows plant selection of transformed plants and provides tolerance to glufosinate ammonium herbicides. The PAT protein in A5547-127 is highly specific for the acetylation of L-phosphinothricin (L-PPT, L-glufosinate) and does not acetylate other L-amino acids.

C. Gene Expression

The STRP reported that previous assessments have shown the safety of each of the three single events. DMO, CP4 EPSPS and PAT are structurally and functionally different and they are independent from each other. Thus, even if they are bred together in a single hybrid, it is highly likely that they will function independently as in single events.

Genetic and molecular analyses showed that all three genes are inherited, expressed and functioning properly in MON 87708 x MON 89788 x A5547-127, as they did similarly in

single events. The possibility of occurrence of an unexpected effect of the stacked genes on the metabolism of the hybrid in highly unlikely.

It was also reported that DMO, CP4 EPSPS and PAT are all expressed at low levels in MON 87708 x MON 89788 x A5547-127. In addition, protein expression level analysis did not show any indication that the marker genes were transferred and expressed in plants containing the combined genes.

The STRP, BAI and BPI-PPSSD found scientific evidence that soybean MON87708 x MON 89788 x A5547-127 applied for direct use has no evidence of interaction on the resulting gene products.

DENR-BC ASSESSMENT AND RECOMMENDATION

After thorough and scientific reviews and evaluation of the document provided by the Bureau of Plant Industry (BPI) to the DENR Biosafety Committee within the prescribed period pursuant to Joint Department Circular (JDC) No. 1 s2016 on the application of Monsanto Philippines, Inc. for direct use for feed, food or processing of Genetically Modified soybean MON87708 X MON89788 X A5547-127, the following are the observations and recommendations:

1. From the evaluation of the application submitted by the proponent, including the scientific evidence from provided references and literature, as well as other related studies, the Committee finds that the direct use of the regulated article whether for food and/or for processing will not cause any significant adverse effect on the environment (land, air, and water) and non-target organism, to wit:

    a. Genetic stability in the transgenic crop is ensured such that no unintended horizontal gene transfer shall occur to unrelated species.
    b) The protein product produced by the transgenic crop will degrade upon exposure to the natural environment and general conditions (i.e. high temperatures (60C and above), varying pH, enzyme digestion, etc); and
    c) The protein product will not increase the weediness potential of the transgenic crop.

The data evaluated support the conclusion that the regulated article is as safe as its conventional counterpart.

2. 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 of the proponent. Upon evaluation of the submitted PDR and environmental risk assessment (ERA), the Committee notes that 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 is not conducive for plant growth/germination.

3. The importer shall ensure the proper and secure packaging of the regulated article for transport and the safety and durability of the transport vehicle, for prevention of any possible spillage or unintended release during transport/import. The Bureau of Plant Industry (BPI) shall conduct inspection of the shipment at the port of entry.

The DENR-BC finds scientific evidence that the regulated article applied for Direct Use as Food and Feed or for Processing is safe as its conventional counterpart and is not expected to pose any significant risk to the environment and to non-target organisms.

DOH-BC ASSESSMENT AND 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 MON 87708 × MON 89788 × A5547-127. I

The DOH-BC concluded 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:

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 allergic reaction.
3. The regulated article is as safe as foo or feed derived from conventional soybean varieties.
4. The regulated article is not materially different in nutritional composition from that of the non-transgenic soybean or the conventional soybean.
5. There shall be a clear instructions that the product is only for the purpose of direct use and is not be used as planting materials to be used as planting materials.

SEC EXPERT ASSESSMENT AND RECOMMENDATIONS

After thorough review of the documents submitted by the applicant/proponent, the SEC Expert made the following assessment and recommendation:

According to the SEC Expert, domestic production of GM soybeans is non-existent since no GM Soybean has been approved for planting or propagation in the Philippine. Thus, approval of this event would not alter the domestic production of soybeans in the Philippines since the application is just for direct use as food and feed ingredients. However, approval of this event may improve our domestic consumption of food products whose main ingredient is soybeans. Allowing this product to be imported for direct use for food would help stabilize prices of soybeans in the Philippines. Domestic soybean production cannot meet the demand of soybean for food and for feeds (The total areas planted to soybean in the Philippines remained at a very insignificant hectarage, maybe a little more than a 1000 hectares). Stable price of raw materials (e.g. soybean) would be beneficial to producers of food products whose main ingredient is soybean and would also stabilize prices of these food products.

Stable demand of soybean would increase importation of soybeans. Thus, approval of this event may affect our patterns of agricultural trade (imports). However, since the share of our soybean imports is insignificant to the total agricultural imports, its effect might be minimal. The increasing imports of soybean may reflect the continuous growth of our livestock industry. In addition, importation of soybeans would help stabilize local prices of food products whose main ingredient is soybeans.

Likewise, the approval of this event would also stabilize process of feeds as soybeans is also a main ingredient in feed formulation for poultry and livestock sub-sector. The approval of this event may also help develop the feed milling sub-sector in the Philippines, assuring them of continued supply of feed ingredient at a stable price.

With the data provided by Monsanto, Philippines, Inc., approval of this event MON 87708 × MON 89788 × A5547-127, will not drastically change the current pattern of production since it will not be grown locally. For consumption, approval of this event may slightly affect (improve) our consumption pattern. However, since the share of soybeans and soybeans products to the total food consumption of Filipinos is very minimal, the change would be negligible.

With regards to utilization, approval of this event would improve our current utilization due to availability of raw material (e.g. soybean). With the availability of soybeans for food and feeds formulation, producers and millers will be encouraged to use soybeans as one of the ingredients.

In terms of patterns of trade, approval of this event would increase our importation of soybeans. However, since its share to the total agricultural imports, it may have insignificant effect to the overall patterns of agricultural trade.

Recommendation

Based on the assessment of the above indicators, the SEC expert does not have any socio-economic, social, and ethical issues to raise regarding the approval of the applicant's application for biosafety permit for direct use as food and feed, or for processing of soybean MON 87708 × MON 89788 × A5547-127. The expert recommends for the approval of said application.