CONSOLIDATED REPORT ON PIONEER HI-BRED PHILIPPINES, INC.'S SOYBEAN DP305423 X 40-3-2 APPLICATION FOR DIRECT USE AS FOOD, FEED OR FOR PROCESSING (FFP)

EXECUTIVE SUMMARY

On October 30, 2018, Pioneer Hi-Bred Philippines Inc.'s filed for application of soybean DP305423 x 40-3-2 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 soybean DP305423 x 40-3-2 is as safe as its conventional counterpart for use as human food and animal feed.

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 the regulated article 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 soybean DP305423 x 40-3-2.

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 the regulated article.

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 Pioneer Hi-Bred Philippines, Inc. Upon receipt of the individual reports from the assessors, the BPI Biotech Secretariat prepared this technical report for the information of the public.

Summary of Assessment

A. STRP, PPSSD AND BAI ASSESSMENT

Gene Interaction

Based on the documents provided by the developer, the STRP, PPSSD and BAI concurred that the two proteins will not produce new or identified allergen or toxin because they are unlikely to interact due to the different mode of action of each protein. The safety of each protein were assessed using different comprehensive 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 differences in the modes of action of the CP4 EPSPS and GM-HRA proteins, and the localizations of these proteins in the plant cells indicates no likelihood of interaction with one another which could lead to production of a new allergen or toxin.

In terms of accumulation, the gene products will accumulate in different subcellular components of the corn with GM-HRA accumulates in the cytoplasm while CP4-EPSPS accumulates in the chloroplast.

The molecular data presented by the applicant for soybean DP305423 showed that a 597 bp *gm-fad2-1* fragment (in the sense orientation) corresponding to about 40% of the middle of the open reading frame (ORF) of the *fad2-1* gene and driven by seed-preferred KTi3 promoter was used to silence the endogenous *fad2-1* gene. DP305423 soybean is characterized by a decreased content of polyunsaturated fatty acids and elevated levels of monounsaturated (oleic) acid in seeds. Decrease in the level of the desaturase encoded by *fad2-1* inhibits the conversion of oleic acid to linoleic acid, thus elevating the oleic acid level in soybean seed.

Metabolic Pathways

The applicant was able to provide a complete description of the mode of action of each gene product. With the two proteins having different substrate and modes of biological action and being structurally and functionally different, each protein function independently and are not expected to interact nor will affect the metabolism of the plant.

The CP4 EPSPS protein are enzymes are involved in the penultimate step of the bioehemical shikimic acid pathway producing aromatic amino acids in the chloroplasts of plants. The gm-fad2-L gene is involved in fatty acid biosynthesis while GM-HRA and CP4 EPSPS proteins have high substrate affinities: GM-HRA for pyruvate and 2-ketobutyrate as part of a branched-chain amino acid biosynthetic pathway, and CP4 EPSPS for biochemical shikimic acid pathway producing aromatic amino acids. With the two proteins having different substrate and modes of biological action and being structurally and functionally different, each protein function independently and are not expected to interact nor will affect the metabolism of the plant. No gene products are produced by the *GM fad2-1* gene due to the silencing mechanism.

Gene Expression

The genetic stability of each genes, in the single events were already demonstrated in the previous evaluations and has been approved by the Bureau of Plant Industry for Biosafety Permit for food and feed, or for processing. Since the inserted DNA are combined in soybean DP305423 x 40-3-2 through conventional breeding, the genetic stability of the genes in the combined trait

product was assessed through determining the concentration of each protein using Enzyme-linked Immunosorbent Assay (ELISA) to determine if the combined genes are present. ELISA results provided by the developer indicated that the expression of GM-HRA and CP4 EPSPSproteins in DP 30542 3 x 40-3-2 soybean is similar to the corresponding levels in single events DP305423 and 40- 3-2. The data also shows that both proteins EPSPS and GM-HRA are expressed in very low levels in the different plant tissues

Conclusion

The STRPs, PPSSD and BAI concluded that after a thorough and scientific evaluation of the documents provided by Pioneer Hi-Bred Philippines Inc. and other related literature, scientific evidence indicates that the stacked genes of soybean DP305423 x 40-3- 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 its conventional counterpart.

B. DENR RECOMMENDATION

Based on the evaluation and review of literature cited, the DENR-BC considered the regulated article safe to the environment and to the biodiversity. The project description report discusses the specified environment management plan indicating the possible risk and harm to the environment and biodiversity 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 port, roads, and railways among others, is not conducive for plant growth. Also noted by the committee is that soybeans are generally very highly domesticated and do not survive well without human intervention.

C. DOH RECOMMENDATION

After a thorough review and evaluation of the documents provided by the applicant, the DOH-BC finds that the regulated article applied for direct use as Food, Feed or for processing is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health and environment.

D. SEC RECOMMENDATION

The SEC expert has stated that the approval to import DP305423-1 x 40-3-2 soybean will not affect the domestic production since it will not be propagated domestically but will be used as one of the raw materials for food and feed processing only. Current production pattern will not be affected since DP305423-1 x 40-3-2 soybean will not be produced locally. On the other hand, allowing DP305423-1 x 40-3-2 soybean to enter into the country for utilization in the food and feed industries may stabilize prices thus, current consumption of products containing soybean as an ingredient may improve.

After a thorough and scientific review and evaluation of the documents provided by Pioneer Hi-Bred Philippines relevant to DP305423 x 40-3-2, the SEC expert recommends for the approval and issuance of biosafety permit of the said GM product.