

ASSESSORS' CONSOLIDATED REPORT ON PIONEER HI-BRED'S APPLICATION FOR DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING OF CORN DAS 59122-7

EXECUTIVE SUMMARY

On October 28, 2016, Pioneer Hi-Bred submitted corn DAS 59122-7 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 DAS 59122-7 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 cornDAS 59122-7 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 corn DAS 59122-7.

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, except for the SEC expert, the complete dossier submitted by Bayer. The SEC expert, on the other hand, was provided with a questionnaire on socio-economic, ethical and cultural considerations that have been addressed by Pioneer in relation to their application.

Upon receipt of the individual reports from the assessors, the BPI Biotech staff prepared this consolidated risk assessment report for the information of the public.

STRP ASSESSMENT AND RECOMMENDATIONS

Based on the documents submitted by the applicant:

A. Host Organism

The STRP unanimously agreed that corn is a source of key nutrients both for human and animals. It is a source of carbohydrates, proteins, lipids, minerals and vitamins. However, they also agree that it contains a number of anti-nutrients, such as: phytic acid, DIMBOA, and raffinose, like all other corns in cultivation.

They also unanimously concurred that there are no known toxicants present in corn and that it has a low allergenicity potential. However, some individuals show allergic reaction possibly brought about by the following proteins: 9kDa lipid transfer protein, and 50 kDa protein reduced in soluble fraction (zeins). Some case studies report that in few reported cases of corn allergy, symptoms are mild.

All the STRPs agree that corn is used as food in many parts of the world, even as a staple food in many populations such as in Latin America and Africa. In the Philippines, white corn is consumed as part of the staple in Central Visayas and other parts of Mindanao. It is also a major source of animal feed in the form of grain and forage. The grain is ground and fed directly without shelling. The cob is also used in animal feed. The STRPs cited that according to OECD, 2003, corn is used by industrialized countries for 2 purposes: 1) for animal feed, and 2) as raw material for extractive industries. As for developing countries, the use of corn is variable.

B. Transgenic Plant

All the STRPs are in agreement that the information provided by the applicant on the list of countries that has approved the said transformation both for food and feed event is sufficient. Copies of the authorization documents from the said countries namely: Australia, Canada, China, Colombia, EU, Japan, Korea, Mexico, Philippines, Singapore, South Africa, Taiwan and US were provided to the STRP who requested them. They also are in agreement that the consumption pattern resulting to the introduction of the transgenic food will not change since results of the nutritional assessment show that 59122 maize is comparable to non-GM maize.

C. Donor Organism

The STRPs concur that all the protein-encoding sequences found in the original gene construct with respect to source and potential pathogenic or allergenic properties have been described clearly and adequately as follows: 1) plasmid map of PHP17622 showing locations for the genes cry35Ab1, cry34Ab1 and pat, 2) description of the encoded proteins. The STRP are also in concurrence that all potentially inserted regulatory sequences of promoters, enhancers, termination signals, etc. in 59122 maize have been presented and adequately described, as well as all the expressible sequences (cry35Ab1, cry34Ab1 and pat).

The STRPs agree that the 2 donor organisms, namely: *Bacillus thuringiensis*, donor of cry35Ab1 and cry34Ab1 genes and *Streptomyces viridochromogenes*, donor of the pat gene are both naturally occurring soil bacteria and are not considered toxic or allergenic to humans and animals. They also agree that the information on the expressible proteins are adequately described and listed as follows: CRY34AB1, CRY35Ab1 and PAT. These proteins were also found to be not allergenic and toxic, to which the STRPs also agree.

D. Transformation System

Two of the STRPs concur that the information provided by the applicant on the transformation system of DAS 59122-7 is sufficient, while one of them has expressed that he is not qualified to answer this question which is understandable since the STRP is an expert on food sciences and not in the molecular biology.

The 2 STRPs were in agreement that the method used is the *Agrobacterium*-mediated system, with nuclear DNA as its target. They also stated that all experimental protocols were provided and that the

coding and non-coding regions, as well as the recombinant plasmid maps and its components and source were described and characterized sufficiently. The STRPs also agree that there were no helper plasmids or carrier DNAs used.

E. Inserted DNA

Two of the STRPs concur that the information provided by the applicant on the insertion system of DAS 59122-7 is sufficient, while one of them has expressed that he is not qualified to answer this question which is understandable since the STRP is an expert on food sciences and not in the molecular biology.

The 2 STRPs were in agreement that the characterization of the insert and border sequence of corn DAS 59122-7 were adequately described. They also concurred that there is only a single insertion of the T-DNA from plasmid PHP17662 as demonstrated by southern blot analysis, PCR and DNA sequencing. They also verified that there were deletions in the right and left border detected by sequencing, however, these do not affect the protein coding sequence of the said plasmid. No other changes were detected in the T-DNA. Open reading frames were also analyzed and was found that these have no effect on the ORF of the targeted genes. There were also no backbone sequences were present as shown by southern blot analysis.

F. Genetic Stability

Two of the STRPs concur that the information provided by the applicant on the genetic stability of DAS 59122-7 is sufficient, while one of them has expressed that he is not qualified to answer this question which is understandable since the STRP is an expert on food sciences and not in molecular biology.

The 2 STRPs were in agreement that the evaluation of genetic stability of corn DAS 59122-7 were sufficiently described. They concurred that the evaluation, done by confirming the inheritance of the DNA insertion by genotypic and phenotypic characterization through multigenerational stability, using 4 segregating generations. Segregation analysis were also done and was shown across 4 generations.

G. Expressed Material

All the STRPs concurred that the mean levels of expression in ng/mg tissue dry weight of Cry34Ab1 and Cry35Ab1, and PAT proteins in the leaf, root, whole plant, pollen and grain in corn 59122-7 have been provided by the applicant. The method used was ELISA. The data was collected from corn DAS 59122-7 and commercial counterparts grown in 7 locations in the USA and Canada. A complete description of the experimental protocol and sampling was also presented.

The STRPs also agree that the 3 proteins expressed in corn DAS 59122-7 have no known metabolic role. The Cry34Ab1 and Cry35Ab1 proteins, together comprise an active insecticidal crystal protein conferring resistance to certain coleopteran pests while PAT protein confer tolerance to the herbicidal active ingredient glufosinate-ammonium.

H. Toxicological Assessment

All STRPs are in agreement that all information relative to the toxicological assessment done to the 3 proteins, namely Cry34Ab1, Cry35Ab1 and PAT are sufficiently described. They also agreed that the information on the digestibility studies, heat inactivation studies, Amino acid sequence comparison studies, acute oral gavage studies and protein equivalence to source proteins of the three expressed novel proteins are adequate.

However, 2 of the STRPs has stated that the novel proteins are expressed independently of each other while 1 has stated that they are expressed constitutively and together, however, all three of

them has stated that the proteins are expressed in different tissues. They also agree that independently, Cry34Ab1 and Cry25Ab1 are ineffective since the 2 proteins are binary in nature and do not have significant insecticidal activity independently and that they are not involved in metabolic pathways in plants.

I. Allergenicity Assessment

All STRPs are in agreement that all information relative to the allergenicity assessment done to the 3 proteins, namely Cry34Ab1, Cry35Ab1 and PAT are sufficiently described. They also agreed that the information on the digestibility studies, heat inactivation studies, Amino acid sequence comparison studies including physico-chemical properties, prevalence in food and serum screening studies of the three expressed novel proteins are adequate.

They also concurred that the 3 proteins are easily digested, heat labile and have no known homology to known toxins or allergens as demonstrated by the abovementioned studies enumerated. They also concur that the three proteins are not glycosylated; that protein levels in food are expected to be lower due to reductions that are likely to occur during processing; and that serum screening was not needed since all three proteins are completely degraded, digested in the stomach, hence these proteins are no longer available for absorption and thus are not present in the serum.

J. Nutritional Data

All the STRPs agreed that the information provided by the applicant on the proximate analysis and analysis on key nutrients, anti-nutrients and other secondary metabolites are sufficient. One of the STRP required additional data on the comparison of commercial varieties of all the analysis done, and was provided by the applicant. They also agreed that there were no statistical difference found between corn DAS59122-7 and the near-isoline control in terms of proximate analysis of grain and forage, levels of key nutrients (vitamins and amino acids), and anti-nutrients/secondary metabolites. In terms of mineral phosphorus, there is a statistically significant difference, however, it is still within the literature range and is not meaningful in the context of biological relevance.

K. Recommendation

After a thorough evaluation of the documents provided by the applicant, the STRPs find scientific evidence that the regulated article applied for human food and animal feed use is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health

BPI-PPSSD ASSESSMENT AND RECOMMENDATION

DAS 59122-7 (59122 Maize) was developed by Pioneer Hi-Bred Philippines, Inc. through the use of recombinant DNA technology. The said event was developed through Agrobacterium-mediated transformation of maize cells with PHP17662 plasmid vector carrying, the cry34Ab1 and cry35Ab1 genes that encodes Cry34Ab1 and Cry35Ab1 proteins that provides protection to certain coleopteran pest (WCR, *Diabrotica virgifera virgifera*), and pat gene encoding phosphinothricin-acetyl-transferase (PAT) protein which confers tolerance to glufosinate ammonium herbicides.

Host Organism (*Zea mays* L.)

Maize (*Zea mays* L.) has been widely consumed as staple food for humans and feed ingredient for animals. It is used in food products such as oil, grit, meal, flour, ethanol, syrup and starch as well as feeds such as hulls, gluten and hominy. Humans consume corn mostly in the form of corn-based ingredients such as high fructose corn syrup, starch, sweeteners, cereals, oil and alcohol. In terms of the feeds, it is commonly consumed in the form of corn silage (forage), gluten meal, gluten feed and distillers dried grains.

History of safe use was attributed to maize. It is known to produce no significant amount of toxins and anti-nutrients. It is not a common allergenic food; however, some reports had stated gastrointestinal and respiratory allergenic reactions.

Transgenic Plant (DAS 59122-7 Maize)

DAS 59122-7 Maize has been reviewed and approved for food and/or feed use in many countries including Australia (2005), Canada (2005), China (2006), Columbia (2011), EU (2007), Japan (2005), Korea (2005), Malaysia (2016), Mexico (2004), Philippines (2006), Singapore (2016), South Africa (2011), Taiwan (2005), Turkey (2011), New Zealand (2005) and United States (2005).

DAS 59122-7 Maize was developed to produce Cry34Ab1 and Cry35Ab1 proteins derived from *Bacillus thuringiensis* and phosphinothricin-acetyl-transferase (PAT) protein from a modified *Streptomyces viridochromogenes*. The Cry34Ab1 and Cry35Ab1 proteins together comprise an active insecticidal crystal protein that provides protection against certain coleopteran pests including western corn rootworm (WCR, *Diabrotica virgifera virgifera*) while the PAT protein confers tolerance to the herbicidal active ingredient glufosinate. The transformation method is through *Agrobacterium*-mediated transformation with plasmid PHP17662 (50,321 bp) into the maize line Hi-II. The T-DNA region of PHP17662 (7,390 bp) contains three gene cassettes. The first gene cassette contains the maize-optimized cry34Ab1 gene derived from Bt that is regulated by the *Zea mays* ubiquitin gene 1 (ubiZM1) promoter. This ubiZM1 promoter region also includes the 5' untranslated region (UTR) and intron associated with the native ubiquitin gene 1 promoter. The terminator for the cry34Ab1 gene is the terminator sequence from the proteinase inhibitor II gene (pinII) of *Solanum tuberosum*. The second gene cassette contains the maize-optimized cry35Ab1 gene also from Bt that is regulated by the wheat (*Triticum aestivum*) peroxidase promoter. The terminator for the cry35Ab1 gene is a second copy of the pinII terminator. The simultaneous expression of the Cry34Ab1 and Cry35Ab1 proteins provide protection against damage by certain coleopteran pests. The third gene cassette contains a modified version of the pat gene from *Streptomyces viridochromogenes* that is controlled by the promoter and terminator regions of the cauliflower mosaic virus (CaMV) 35S transcript. The pat gene has been optimized for expression of phosphinothricin acetyltransferase (PAT) enzyme in plants, which confers tolerance to L-isomer of phosphinothricin (L-PPT), the active ingredient in glufosinate-ammonium herbicide.

The results of molecular analyses showed that 59122 maize genome contains only a single insertion of the T-DNA from the plasmid PHP17662. This implies that no other expressible genes are within the inserted material in transformation event 59122-7 maize.

Nutritional and compositional assessment of DAS 59122-7 maize was conducted by Pioneer to determine the substantial equivalence of the transgenic plant to its conventional counterpart. Results of the analyses proved that the modified DAS 59122-7 maize was substantially equivalent to the produced non-transgenic maize varieties and the comparable food and/or feeds derived from it.

Donor Organisms (*Bacillus thuringiensis* and *Streptomyces viridochromogenes*)

Bacillus thuringiensis is a diverse group of Gram-positive, spore-forming bacteria. It occurs naturally in the soil and on plants including vegetables, cotton, tobacco, tree crops, and forest crops. Several Cry proteins have been deployed as safe and effective pest control agents in microbial Bt formulations and has a history of safe use as a pesticide over several decades.

Streptomyces viridochromogenes, a common soil saprophytic bacterium was the donor organism which is the source of pat gene that produces naturally occurring glufosinate ammonium tolerant PAT protein. According to OECD (2007) "Consensus Document on Safety Information on Transgenic Plants Expressing *Bacillus thuringiensis* - Derived Insect Control

Proteins”, *Streptomyces viridochromogenes* is not considered pathogenic to humans or animals. It is not known to be human pathogen nor has it been associated with other properties like production of toxins that is known to affect human health. It was also found that the pat DNA sequence is considered to be safe as any other DNA in food that human usually consumed. Hence, conferring the history of safe use.

Expressed Material (Cry34Ab1, Cry35Ab1 and PAT proteins)

To confirm the identity and functions of the introduced protein, the detailed insert characterization of the transformation event DAS 59122-7 Maize was subjected to a different methods of analyses like Western and Southern blot analysis, sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE), sequence analysis, glycosylation analysis. Through enzyme-linked immunosorbent assay (ELISA), the level of concentrations of the Cry34Ab1, Cry35Ab1 and PAT proteins in various tissues was quantified. Resulting data was used to calculate the dietary exposure and margins of exposure to identified proteins. It indicates that there is no risk to human and animal health that will be associated with dietary exposure to food and feed products derived from DAS 59122-7 maize due to large margins of exposure.

A bioinformatics analysis was also performed using the BLASTP sequence alignment tool of NCBI non-redundant protein database. Result showed no alignments or no sequence homology to any known protein toxins or allergens indicating no apparent toxicity nor allergenicity concerns for any of the proteins produced as a result of the 59122 maize insertion. Rapid digestion of *Pseudomonas fluorescens* produced Cry34Ab1 and Cry35Ab1 and *E. coli* produced PAT to simulated gastric fluid (pepsin) also served as an indicator that the proteins shares similar characteristics among proteins with a history of safe human and animal consumption.

The results of acute oral toxicity study in mice indicated no observed effect level (NOEL) for oral toxicity of Cry34Ab1 (with 2,700 mg/kg bw), Cry35Ab1 (with 1,850 mg/kg bw) and PAT (with 5000 mg/kg bw) in mice. Incorporation of these proteins in the diet resulted to no mortality, no adverse clinical signs were observed and no adverse findings were noted at necropsy during the study. Relatively high dose for this test did not give increase to any toxicity and was found not to be acutely toxic in mice.

Functional assay were conducted by Pioneer to determine the effect of heat treatment on the functional activity of Cry34Ab1, Cry35Ab1 and PAT proteins. It was confirmed by the loss of biological activity, i.e. toxicity against southern corn rootworm (*Diabrotica undecimpunctata howardi*) after being exposed to heat treatment of the Cry proteins. The result of heat lability assessments support that the Cry34Ab1 and Cry35Ab1 proteins are unstable at 60, 75 and 90 °C and on high temperature that these proteins will be inactivated by many of the processes involved in food or animal processing. This indicates that Cry35Ab1 and the Insecticidal Crystal Protein (ICP) demonstrated very significant heat inactive. While the stability of the PAT protein was determined through SDS-PAGE in which the PAT protein was digested in a solution of pepsin. Result showed that there is one major band located around the molecular weight marker at 21.5 kDa, in accordance with the expected molecular weight of the PAT protein. The 10% PAT protein control was still visible although with a much lower intensity. After the various treatments, there were no visible changes to the PAT band with intensity similar to the unheated sample. The SDS-PAGE and western blot analysis has the same results, except for the final time point (60 minutes) at 90°C where band intensity was slightly reduced. In the lanes with only buffer solution, there were no bands visible. Therefore, the PAT protein was not degraded or modified in a way that would affect their migration in SDS-PAGE at up to 90°C for 60 minutes. Additionally, PAT protein has been used for different transformation event which indicates a history of safe use.

Conclusion

For the transgenic DAS 59122-7 maize, enough evidence is provided to support the equivalence of the genetically modified crop, in terms of the nutritional composition, agronomic characteristics and food safety, with the conventional maize other than the protection from corn rootworm damages and tolerance to glufosinate ammonium herbicides. After reviewing the provided material of Pioneer Hi-Bred Philippines, Inc., it is therefore concluded that DAS 59122-7 maize is substantially equivalent as its conventional counterpart.

BAI ASSESSMENT AND RECOMMENDATIONS

Based on the documents submitted by the applicant, BAI made the following assessment:

A. Host Organism

BAI has agreed that corn is a source of key nutrients for food and feed. It is also a source of anti-nutrients and is known to contain DIMBOA found in the roots of corn, however, they stated that the levels of DIMBOA vary from variety to variety and it rapidly drops as the corn plant grows. They also added that corn is not considered a major allergenic food and is likely to have a low allergenic capability.

BAI also has stated that one of the main uses of maize is food, especially in Eastern Africa, Central America and Mexico where it is a staple food, but they also added that one of its major usage is for feed use in the form of whole grains, rolled or ground, or steam flaked, pelleted or extruded.

B. Transgenic Plant

BAI has concurred with the listing provided by the proponent on the countries which approved the transgenic plant for food and feed. They also stated that studies have shown that there were no difference in the nutritional assessment between the transgenic and control maize, and so consumption patterns by subgroups will not change as a result of introducing corn DAS 59122-7.

C. Donor Organism

BAI has stated that the Cry34Ab1 and Cry35Ab1 genes were obtained from *B. thuringiensis* while the Pat gene came from *S. viridochromogenes*. The 3 genes have neither the potential for pathogenicity nor allergenicity. They also stated that the inserted regulatory sequences and the description of the transformation methods and table of genetic elements were adequately described.

They also concur that the three proteins Cry34Ab1, Cry 35Ab1 and PAT and their donor organisms are not known to be toxic or allergenic.

D. Transformation System

BAI has stated that the information provided by the applicant in terms of the transformation system were adequately described. They have stated that corn DAS 59122-7 was transformed using *Agrobacterium*-mediated transformation with plasmid PHP17662 and that the target of the genetic modification is the nuclear DNA.

They also stated that the description of the transformation process, as well as the table of genetic elements, and the map of plasmid vector was provided, They also agree that there were no helper plasmids or carrier DNA used.

E. Inserted DNA

BAI has affirmed the information provided by the proponent that the single insertion site was confirmed by southern blot, PCR and sequence analysis. Southern blot analysis, PCR, DNA sequencing and bioinformatics analysis also demonstrated the integrity and order of genetic elements within the insertion site.

BAI also has stated that the deletions found on the plasmid are not unexpected as they do occur during the *Agrobacterium*-mediated transformation process. These two base changes in the non-coding regions of the inserted TDNA sequence also has no effect on the ORF composition of the

TDNA insert. No novel ORFs also resulted from the TDNA insertion and that there are no vector backbone sequences.

F. Genetic Stability

BAI stated that southern blot hybridization study has demonstrated the stability of the intact T-DNA insert and that four segregating generations follow the Mendelian laws of inheritance, again confirming the stable inheritance of the DNA.

G. Expressed Material

BAI concurred that the levels of expressed protein both in different plant parts and plant forms were determined using specific quantitative ELISAs and were adequately provided by the proponent. They also agree with the proponent that the novel proteins do not have metabolic roles.

H. Toxicological Assessment

BAI has concurred that all information relative to the toxicological assessment done to the 3 proteins, namely Cry34Ab1, Cry35Ab1 and PAT are sufficiently described. They also agreed that the information on the digestibility studies, heat inactivation studies, Amino acid sequence comparison studies, acute oral gavage studies and protein equivalence to source proteins of the three expressed novel proteins are adequate.

I. Allergenicity Assessment

BAI is in agreement all information relative to the toxicological assessment done to the 3 proteins, namely Cry34Ab1, Cry35Ab1 and PAT are sufficiently described. They also agreed that the information on the digestibility studies, heat inactivation studies, Amino acid sequence comparison studies, acute oral gavage studies and protein equivalence to source proteins of the three expressed novel proteins are adequate.

BAI has also agreed that the proteins are easily digested, heat labile and have no known homology to known toxins or allergens as demonstrated by the digestibility and heat inactivation studies, with the amino acid sequence comparison using BLAST.

J. Nutritional Data

BAI has concurred that there are no statistically differences identified between DAS 59122-7 and the control maize in terms of proximate analysis of grains and forage, levels of key nutrients and anti-nutrients and that there is no biological relevance in terms of safety. BAI has also taken note of the level of mineral phosphorus since there is a significant difference but they have expressed that the statistical difference is not meaningful so there is no impact.

K. Recommendation

After a thorough scientific review and evaluation of the documents provided by the Bureau of Plant Industry (BPI) to the BAI-Biotech Team, the Team has found scientific evidence that the regulated article applied for animal feed use is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health

DENR ASSESSMENT AND RECOMMENDATION

After a thorough scientific review and evaluation of the documents provided by the Bureau of Plant Industry (BPI) to the DENR Biosafety Committee within the prescribed period pursuant to the Joint Department Circular (JDC) No. 1 S 2016 on the application of Pioneer Hi-Bred Inc. for direct use for feed, food or processing of Genetically Modified Corn DAS 59122-7, along with the submitted sworn statement and accountability of the proponent, a biosafety permit may be issued to the proponent if the conditions set by DENR are followed.

DOH ASSESSMENT AND RECOMMENDATION

After a thorough scientific review and evaluation of the documents, DOH find sufficient evidence that the regulated article applied for direct use will not pose any significant risk to health and environment and that any hazards could be managed by the measures set by DOH.

SEC ASSESSMENT AND RECOMMENDATIONS

Based on SEC expert review of the SEC questionnaire answered by the applicant:

A. Socio-economic issues

The SEC Expert has stated that although the GM product will not be cultivated in the Philippines, it can be significant in terms of domestic consumption given the increasing trend in country-wide demand for corn and estimated decline in corn production in the last quarter of 2016 based on Philippine Statistics Authority report. The expert also stated that in any event, given the Philippine's history of corn importation vis a vis trends in consumption/utilization, drastic changes are not expected, and even modest changes in use for food and feed do not seem attributable to imports alone.

The expert has expressed that the applicant must address the question regarding any possible impact on income inequality in rural communities especially since cheaper corn from imports have been noted to traditionally result in producers surplus losses, however, the expert has stated that the public participation provisions of JDC 1 s2016 may be a venue to thresh this out.

The expert has also recognized that the GM product, along with other corn imports, is intended to help meet overall domestic demand for corn.

B. Social Issues

The SEC Expert has stated that since the GM product will be for direct use, the possible and/or perceived effects on consumers will still be relevant. According to the expert, in any event, based on the BPI records, the GM product has been previously approved under the old regulatory regime for direct use in the Philippines. Additionally, the expert also stated that the applicant's submissions regarding approvals in other jurisdictions including the more discriminating European Union, as well as published studies cited reveal the subject GM crop's equivalency with non-transgenic corn.

The SEC expert also recognized that the GM crop's introduction is not expected to reduce societal adaptability. The expert has stated that the recent decline in domestic corn production has been attributed largely to typhoons and dry spells and not solely on pests. In addition, the expert also stated that based on submissions and studies, there is no negative impact so far identified given that the GM product is equivalent to conventional corn. The expert has identified the public participation provisions of JDC 1 s2016 to be a venue to thresh out other possible concerns.

C. Ethical Issues

The SEC expert has stated that issues of equity and equality are best understood in the context of engagement and participation, hence, evaluation of the applicant's response should be done alongside results of the procedures for public participation for direct use under Sec. 22 of JDC 1 s2016.

D. Recommendation

The SEC expert has recommended for the approval and issuance of the biosafety permit of the GM product.