ASSESSORS' CONSOLIDATED REPORT ON BAYER CROP SCIENCE GLUFOSINATE HERBICIDE AND LEPIDOPTERAN INSECT RESISTANT COTTON T304-40 APPLICATION FOR DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING

EXECUTIVE SUMMARY

On December 7, 2016, Bayer Crop Science Philippines Inc.'s application for cotton T304-40 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 cotton T304-40 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 cotton T304-40 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. The DOH-BC also recommended for the issuance of biosafety permit for soybean cotton T304-40

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 Crop Science. The SEC expert, on the other hand, was provided with a questionnaire on socio-economic, ethical and cultural considerations that have been addressed by the applicant 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:

Host Organism
The STRPs reported that cotton is a key source of nutrients and farms animals as presented in a science-based consensus document from OECD. Adequate data was presented on the typical levels of antinutrients that are present, with the expert remarking that free gossypol in cottonseed is highly reduced to very low or undetectable amounts in oil and that appropriate control measures are given to ensure the safety of consumers. They also reported that the host organism is not a known source of allergens. Cottonseed products consumed as feeds for animals

Transgenic Plant
Cotton is not a known source of allergens. According to the STRP, adequate onformation on the final form of the consumed food product has been provided by the applicant, together with a list of countries that have approved the use of this transgenic plant as food and as feed

Donor Organism (*Bacillus thuringensis sp., Steptomyces hygrospicus*)
Adequately documented in both cross references was provided to describe the donor organism. The inserted regulatory sequences were adequately described.

Cry1Ab the overall homology search with general protein database showed mainly similarities with other acetyltransferases from various bacterial origin. No allergic nor toxicological in silico findings associated with PAT/bar proteins was found. It was noted by the STRPs that the Cry1Ab protein has been in use for more than ten years in genetically modified crops.
The source of bar protein with which he overall homology search with general protein database showed mainly similarities with other and no allergenic or toxicological homology were associated with the protein. The donor organism have no known allergenic and pathogenic effects on human, animals and non-target organisms.

Transformation System
The STRPs reported that transformation was agrobacterium mediated and that the nuclear DNA was the target of modification. The genetic description of calli production experimental protocol including cali production and cell suspension was described by the applicant. A complete map of the plasmid vector is provided including the restriction site location of genetic elements

Inserted DNA Genetic Stability

Southern blot analysis sufficiently demonstrated the integrity of the inserted DNA sufficiently demonstrating that there were no truncations deletions and rearrangements. Bioinformatic analysis indicated that there were were no potential novel chimeric ORFs therefore, eliminating the possibility of creating a new protein and that the absence of the vector backbone was also demonstrated using this technique

Multi generational stability of the induced trait was presented by the banding patterns of southern blots from plants from different generations. Inheritance for single gene locus and stability of the T304-40 insert was demonstrated.

Expressed Material
The mechanism of action of the Cry1Ab is apply described and in a similar to the known mechanism of action on lepidopteran larvae. The presented study by the applicant has described and characterized the metabolic pathways involved in the expression of the Cry1Ab protein. It was noted by the STRP that Cry1Ab has received regulatory approval by several countries in the late 1900s.

The PAT protein was present in all plant parts at different growth stages which is due to the action of the constitutive promoter driving the constitutive expression of the protein in all plant tissues. The provided reference by the applicant sufficiently provides data on the characterization and mode of action of the PAT proteins.

Toxicological Assessment
The STRPs noted that the Cry1Ab protein was degraded very rapidly in human simulated gastric fluid, within 2 minutes of incubation in the presence of pepsin. SDS-PAGE analysis sufficiently demonstrated the rapid degradation of Cry1Ab protein in SGF. When the protein was subjected to high temperatures, the STRP noted that the the observed bands after heating can be explained in terms of partial denaturation and agglutination and that supporting evidence was cited with respect to non-correlation of possible allergenicity/toxicity with protein stability. Homology search on the protein databases was sufficient to show no known homology with toxins

Allergenicity Assessment

Cry1Ab

SDS-PAGE analysis shows that the Cry1Ab protein was rapidly degraded in the presence of simulated gastric fluid and simulated intestinal fluid. Homology search performed was sufficient to show that there is no homology with known allergens. The data provided shows that the protein is not glycosylated and that the protein is not detectable or present on the cottonseed oil.

PAT

The STRPs reported that the data presented sufficiently shows that the PAT protein was completely and rapidly degraded after a few second incubation in SGF and SIF. The protein was inactivated but not degraded by high temperatures. The use of three databases showed no similarities with known allergens. The data provided also shows that the PAT protein is not detectable or present in cottonseed oil.

Nutritional Data

The mean values obtained for proximate and fiber compounds in fuzzy cottonseed of T304-40 falls within the reference range. Transgenic cotton values obtained for proximate fiber compounds fell within the range reported for commercial varieties. Biological relevance was shown by comparing values obtained with the reference commercial values. The STRPs support the findings that the processing of cottonseed to oil removes the CPFs and that values reported for the same antinutrients from transgenic cotton were within the range reported in literature.

Recommendation

After thorough and scientific review and evaluation of the documents provided by the Bureau of Plant Industry relevant to the transformation event Cotton T304-40 of Bayer CropScience, Inc., STRPs did not find any information pertaining to relevant differences between the the safety and nutritional quality of the said event in comparison with its conventional counterpart. There were no evidence of potential toxic or allergenic attributes to cotton T304-30 as food, feed or for processing.

BPI-PPSSD ASSESSMENT AND RECOMMENDATION

Upon evaluation of the documents provided by the proponent for the food safety risk assessment of Cotton T304-40 the following assessments were made:

Host Organism (*Zea mays* L.)

The developer provided sufficient data that cotton is a source of nutrients, as well as source of oil derived from cottonseed which can be consumed by humans and proteins present in cottonseed cake and meal making it appropriate as livestock feed. Antinutrients are also present cotton as a host organism and contains cyclopropenoid fatty acids like sterculic, malvic and dihydrosterculic acids. Sufficient information was also provided on cotton's use as food and feed. The presence of cottonseed meal is an excellent source of protein for ruminant animals, most often used in dairy feed than in beef and sheep feed. Cotton seed hulls are very palatable for ruminant animals and are commonly used in combination with limited amounts of corn silage or hay.

Transgenic Plant (Cotton T304-40)

The developer provided sufficient data and reference regarding the list of countries that have approved cotton as food which are Australia/New Zealand, Brazil, Canada, Japan, Korea, Mexico, Taiwan and the United States of America. The developer has provided sufficient that the consumption pattern will not change.

Donor Organisms (*Bacillus thuringensis, Streptomyces hygroscopius***)**

The developer provided sufficient information and reference about the protein encoding sequences found in the original gene construct and it was described with respect to source and potential pathogenic or allergenic properties. Inserted regulatory sequences of the cry1Ab gene and the bar gene were adequately described. *Bacilllus thuringiensis subsp. Berliner* is a common bacteria in the environment and its naturally occurring isolates have been used for insect control for decades with no safety concerns. *Streptomyces hygroscopicus* is not known to be a human, animal or plant pathogen nor has it been associated with other properties known to affect human health. History of safe use was attributed to both donor organisms.

Expressed Material (Cry3Bb1 and CP4 EPSPS)

The developer presented researches on the level of expression of the Cry1Ab and PAT in different plant parts like roots, stems, leaves, whole plant, squares, bolls, pollen, nectar, flowers and grains. . The amounts of PAT/bar protein and Cry1Ab protein were measured in these plant parts from T304-40 and Coker 315.

Toxicological Assessment

Digestibility study was performed in human simulated gastric fluid containing pepsin with varying incubation time at pH 1.2 and SDS-PAGE analysis was used to show the degradation of the protein. The Cry1Ab protein was degraded very rapidly with no residual protein being visible at 2 minutes of incubation with SGF, in presence of pepsin, at pH 1.2. There was no significant digestion at pH 1.2 in the absence of pepsin, showing that digestion requires pepsin. Heat inactivation studies demonstrated that Cry1Ab protein was markedly degraded after 60 minutes at 90°C.

The PAT/bar protein was degraded very rapidly in human simulated gastric fluid. Results of Western Blot Analysis showed that 90% of the PAT protein is readily digested in less than a minute upon incubation with pancreatin. After heat treatments, there were no visible changes to the PAT/bar band intensities similar to the unheated sample. As a conclusion, there are no toxicological in silico finding associated with PAT protein. Acute oral gavage was performed and no mortalities, no treatment-related clinical signs, no effects on body weight and food consumption parameters and no macroscopic changes that were observed on the mice after acute oral administration of PAT protein at 2000 mg/kg body weight. The PAT protein purified from T304-40 cotton leaves and from *E. coli*,was assessed for comparability by means of SDS-PAGE and was found to similar.

The BPI-PPSSD has reported that the novel proteins are expressed independently of each other. As in the case of majority of the plant proteins, both proteins were translated in the cytoplasm. There are no expected interaction between the insect resistance and herbicide tolerance traits due to their differences in mode of actions and metabolic pathway.

Allergenicity Assessment

Cry1Ab protein was also subjected to digestibility study using SIF with pancreatin at pH 7.5. Results showed that Cry1Ab protein is readily digested at 30 seconds upon incubation with pancreatin. Cry1Ab protein was markedly degraded after 60 minutes at 90°C.The Cry1Ab protein may be only slightly degraded up to 60 minutes at 90°C, and may be agglutinated and become insoluble after 30 to 60 minutes at 90°C. The developer provided sufficient information and presented a bioinformatics study to evaluate potential amino acid sequence similar to Cry1Ab with known allergens using in silico method.

The PAT protein was very rapidly and completely degraded in human simulated gastric fluid, within few seconds of incubation, in the presence of pepsin, at pH 1.2. The PAT protein was completely thermo-inactivated after 10 minutes at 55oC and higher temperatures despite the fact that the protein was not degraded. There are no allergenic in silico findings associated with the PAT/bar protein. The main product derived from cottonseed in human consumption is cottonseed oil. Last traces of protein in the crude oil are removed in the alkali treatment and deodorization steps of the oil refining. This was confirmed by the absence of any detectable or quantifiable PAT/bar protein amounts in crude and food grade oil produced from T304-40 cotton seeds.

The main product derived from cottonseed in human consumption is cottonseed oil. Last traces of protein in the crude oil are removed in the alkali treatment and deodorization steps of the oil refining. This was confirmed by the absence of any detectable or quantifiable Cry1Ab protein amount in crude and food grade oil produced from cotton event T304-40 seeds. No serum screening was performed.

Nutritional Data

The composition of T304-40 cotton is evaluated to determine if it is nutritionally equivalent to its non-GM cotton variety Coker 315 as well as other varieties available in the market. Proximate

analysis was done for the comparison of nutritional values. The developer provided sufficient data with regards to the comparison of key nutrients of GM and non-GM groups.

Comparisons included the results from reference ranges compiled from cotton literature. Substantial equivalence in the chemical composition is established, if the levels and variations of the nutrients and anti-nutrients of the GM crop are within the natural or experimental variability for the respective nutrients and anti-nutrients in the non GM comparator grown under the same regimes and environmental conditions.

The differences that were detected for phytic acid either in the over-all sites or in the by-site statistical analyses have no biological and nutritional relevance because the mean values calculated for the GM groups are inside or in good compliance with the references ranges for commercial cotton seeds, the estimated differences between treatments are very small for most compounds and the content of the anti-nutrients is slightly lower in the GM samples, so that nutritional deficiencies cannot be expected.

After heat treatment, anti-nutrients notably decrease up to 90%. Only the oil moiety and to some extent the linters of the seeds will, after processing, enter the human food chain since cotton is not used for direct consumption. The biological and nutritional relevance of some statistically significant differences found between the non-GM control and T304-40 cotton were negligible.

There is no safety issue related to the consumption of T304-40 seed since the contents of all nutrients are comparable to the contents in seeds from other commercial cotton varieties.

Conclusion

Various tests were conducted to evaluate if T304-40 cotton is compositionally and nutritionally comparable to its non-GM counterpart such as variety of Coker 315 and other commercially available cotton varieties. Proximate and fiber analysis was done, micro-nutrients analysis such as minerals and alpha tocopherol, anti-nutrients free and total gossypol, phytic acid and cyclopropenoid fatty acids, total amino acid and total fatty acids percentage were also gathered.
Average values determined from composition analyses of T304-40 and Coker 315 cotton seeds were compared to reference ranges taken from different chemistry reference guidelines. Most of the values obtained were within the reference ranges obtained from the literatures.
For most of the analyzed components no differences between the GM and non-GM control products were observed. If differences were noticed this has no nutritional impact, for various reasons. Most analyzed values for the GM products are inside the reference range for the commercial products. If differences to the reported ranges are noticed this is in most cases also true for the non-transgenic product and therefore not an effect of the genetic modification of the cotton seeds. Differences in nutrient levels were only found in one product, but not in the raw agricultural commodity and in the intermediate. Differences in nutrient levels are too small for having a nutritional.

According to the presented statistical evaluation of the analytical data and an assessment of the nutritional impact of the different observations, the seeds from T304-40 cotton and the products

derived from them are found to be nutritionally equivalent to their traditional non-GM counterpart. There is no impact on the nutritional value of the cotton seeds as a result of the genetic modifications.

BAI ASSESSMENT AND RECOMMENDATIONS

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

Host Organism

Cotton is a source of key nutrients for both human & livestock and cottonseed oil is the main product for human consumption. The by-product from oil extraction is cottonseed meal that contains large amounts of protein and is the main product for use as feed for livestock. Cotton contains anti-nutrients including several cyclopropenoid fatty acids and other compounds like flavonoids, tannins, and anthocyanin. Most of these are inactivated during processing.

Cotton is not a source of allergens and cottonseed oil has a long history of safe use. The main cotton by-product used as food for human consumption is cottonseed oil which is a pure source of fatty acids. Raw cotton products contain non-glyceride materials and other genetic materials or proteins and are mostly inactivated or removed during processing. Whole cottonseed and cottonseed hulls are used as feed for ruminant animals. One of the by-products from cottonseed processing is cottonseed meal which is an excellent source of protein and is the main cottonseed product used as feed for livestock.

Transgenic Plant

The countries that have authorized T304-40 cotton for use as food are Australia, New Zealand, Brazil, Canada, Japan, Korea, Mexico, Taiwan, and the U.S. BAI states that consumption patterns are not expected to change across popu;ation sub groups as a result of introducing the novel food. The countries that have authorized T304-40 cotton for use as feed are Brazil, Canada, Japan, Korea, Mexico, and the United States of America.

Donor Organism (Scientific name: *Bacilllus thuringiensis, Streptomyces hygroscopicus)*

BAI reported that protein-encoding sequences and inserted regulatory sequences were adequately described. *Bacillus thuringiensis subsp. berlineris* known to have toxic properties mainly directed to a particular group of insects making it useful as a source of biological pest control agents. *Streptomyces hygroscopicusis* not known to be pathogenic, toxic, or allergenic. Both proteins are not known to be toxic or allergenic

Transformation System

The *Agrobacterium tumefaciens* transformation system was used in this event with the Nucleus cotton variety Coker 315 as recipient. The experimental protocols are completely provided and each genetic elements in the plasmid map were adequately described.

Inserted DNA

The obtained data from the Southern Blot analysis has sufficiently demonstrated that the inserted transgenic sequence in the transformation event T304-40 consist of only one insertion site. Aside from cotton and other cotton stacks, Cry1Ab is also expressed in several GM maize products that have been given approval by various regulatory authorities, while the PAT protein is expressed in several other transformation events in eigth species of plants namely sugarbeet, oilseed rape, bird rape,chicory, soybean, rice, and corn.

Genetic Stability and Expressed Material

Southern blot analysis confirmed the molecular stability of event T304-40 across four generations. As mentioned in the documents presented, the novel proteins do not have a metabolic role.

Toxicological Assessment

Cry1Ab

Pepsin enzyme was used in the digestibility study in human Simulated Gastric Fluid (SGF). After 2 minutes of incubation, Cry1Ab protein was rapidly digested after incubation in SGF. SDS-PAGE analysis was used to determine the fragments remaining after digestion. Within two minutes was degraded rapidly with no residual protein being visible. Pancreatin enzyme was also used in the digestibility study in Simulated Intestinal Fluid (SIF) and the Western Blot analysis revealed that the degradation is stable after 60 minutes of incubation. Bioinformatic analysis was conducted to evaluate the potential amino acid sequence. and No toxicological findings were found. Acute oral toxicity of Cry1Ab was administered to mice by oral gavage 2000mg/kg bodyweight and there were No signs of systemic toxicity in the mice observed.
Escherichia coli was the source of protein and its equivalency was assessed for comparability by means of SDS-PAGE and Western blot.

PAT protein

Pepsin was the enzyme used in the digestibility study in human Simulated Gastric Fluid (SGF). After 30 seconds of incubation PAT protein was degraded rapidly in SGF. The samples were analyzed by Coomassie blue-stained SDS-PAGE and Western blot. Pancreatin enzyme was also used in the digestibility study using Simulated Intestinal Fluid and results show the complete

digestion of PAT protein in less than 30 seconds upon incubation. Heat inactivation studies have reported that PAT protein was heat stable up to 60 minutes of incubation at 90°C. By means of Coomassie blue-stained SDS-PAGE and Western blot. Bioinformatic analysis led to a finding that no biologically relevant identities were found with any toxic proteins.

Escherichia coli used as the source of test protein and comparability was assessed by means of SDS-PAGE, Western blot, glycostaining, peptide mapping, N-terminal sequencing and activity measurement. The proteins are expressed independently of each other with their respective functional activity maintained. Both proteins are expressed in the cytoplasm, do not interact to express the phenotypes and do not interact in a metabolic pathway.

Allergenicity Assessment

The digestibility study of Cry1Ab protein in SGF using the enzyme pepsin, and in SIF using the enzyme pancreatin showed different results. The half-life of Cry1Ab in SGF using pepsin at pH 1.2 is 2 minutes with complete, rapid degradation of the protein. The result in SIF with pancreatin at pH 7.5 demonstrated incomplete degradation of the protein. Both SDS-PAGE and Western Blot analysis revealed the largest size of remaining fragments to have a molecular weight of 66.3 kDa.

Both SDS-PAGE and Western Blot analysis have similar results demonstrating that Cry1Ab protein is heat stable up to 75oC in 30 minutes with only slight degradation of the protein in higher temperatures. The homology of the protein sequence with that of sequences with the similarities are not biologically significant to known allergens from the AOL database. Cry1Ab protein has an identity match with Cry proteins from Bacillus thuringiensis with a best score of only 31.7% identity over 60 amino acids. Therefore, these results did not meet the matching criterion for an allergen based on a 35% identity over an 80 amino acid segment. Cry1Ab has 7 potential N-glycosylation sites identified but are not necessarily predictive of glycosylation and therefore not conclusive to identify Cry1Ab as a glycosylated protein. There is no detectable or quantifiable Cry1Ab protein amount in crude and food grade oil produced from cotton event T304-40 seeds.

PAT protein

DS-PAGE and Western blot analysis both have similar half-life results of 30 seconds for the digestibility study of PAT protein in SGF using the enzyme pepsin at pH 1.2 and in SIF using the enzyme pancreatin at pH 7.5 with complete degradation of the protein after digestion. SDS-PAGE and Western Blot analysis both demonstrated an observed half-life of PAT protein at 90oC in 60 minutes. PAT protein has no relevant homology with any known allergen.

No detectable PAT protein amounts in both crude and food grade oil produce from event T304-40 cottonseed. Statistical difference is not biologically relevant.

Nutritional Data

Statistically significant differences were found either in the over-all sites or in the by-site analyses for ash, calcium, dihydrosterculic acid, and a number of fatty acids. The estimated differences between treatments are very small for most compounds and very often lower than the variation inside the transgenic control group.

Comparison with a range of four varieties were done and the data derived from the transgenic line were within the observed range. Levels of gossypol are reduced in food and feed products. Gossypol is detoxified by combination of heat and moisture during processing steps.

Recommendation

orough and scientific review and evaluation of the documents provided by __Bayer Crop Science, relevant to Cotton T304-40 the undersigned BAI Biotech Team find scientific evidence that the regulated article applied for human food 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 and scientific review and evaluation of the documents provided by the Bureau of Plant Industry (BPI) on the application of Syngenta Philippines, Inc. for Direct Use as Food and Feed or for Processing of cotton T304-40, here under are the observations and appropriate actions:

1. From the evaluation of the application submitted by the proponent, including the scientific evidences 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, feed and or for processing will not cause any significant adverse effect on the environment (land_ air_ and water) and non-target organisms, 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 (60 C and above), varying pl-I, 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) discuss .t-s 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 damairir_ and lasting effects because the receiving environment (areas near the port. roads, railways. etc.) is not conducive for plant growth/germination.

3. The Bureau of Plant Industry (BPI) 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 as per BPI' s inspection in the port area.

The DENR-BC finds scientific evidence that the regulated article applied for Direct Use as Food and Feed or Processing is safe as its conventional counterpart and is not expected to pose any significant risk to the environment and to non-target organisms. Based on the above considerations and with the proponent's sworn statement of accountability, we hereby submit our evaluation relative to Syngenta Philippines, Inc. MON87411 application for biosafety permit for food, feed, and/or processing.

DOH ASSESSMENT AND RECOMMENDATION

After a thorough review and evaluation of the documents provided by the proponent, Syngenta Philippines, Inc., through the Bureau of Plant Industry (BPI), in support of their application for approval for Direct Use as Food, Feed or for Processing (FFP) of cotton T304-40, the DOH Biosafety Committee find that the regulated article applied for Direct Use as Food, 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. They have also forwarded the following observations and recommendations :

1. 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.
2. Dietary exposure to the regulated article is unlikely to result allergic reaction.

3. The regulated article is as safe as food or feed derived from conventional corn varieties.
4. The regulated article is not materially different in nutritional composition from that of the non-transgenic corn or the conventional corn
5. It is suggested that the Bureau of Plant Industry (BPI) ensure the following :

a. Clear labeling of the regulated article from the source down to all levels of marketing stating that it is only for the purpose of direct use as food, feed or processing and is not to be used as planting materials.

6. Based on the above considerations and with the submitted sworn statement and accountability of the proponent, this recommendation is being submitted to BPI related to the processing and issuance of a Biosafety Permit for Direct Use as Food. Feed or for Processing (FFP) of cotton T304-40.

SEC Assessment and Recommendation

While PSA statistics confirm use of cottonseed oil and oil-cake, as well as cotton linters pulp in the Philippines, the figures corroborate applicant's submission that cottonseed product imports are minor and insignificant in the country. Based on the compiled PSA data, the annual average of cottonseed oil imports from 2011 to 2015 is only around 6,000 kilograms.

Changes in the patterns of production are not expected since the application is only for direct use as food and feed, or for processing of insect resistant and herbicide tolerant T304-40 cotton. The applicant does not intend to produce or grow cotton in the Philippines. Patterns in utilization as food and feed, and for processing as well as patterns in trade are not expected to be drastically changed by the issuance of the biosafety permit.

After a thorough and scientific review and evaluation of the documents provided by the Bureau of Plant Industry relevant to Transformation Event T304-40 of Bayer Crop Science, Inc. the SEC expert recommend for the approval and issuance of biosafety permit of the said GM product