ASSESSORS' CONSOLIDATED REPORT ON SYNGENTA PHILIPPINES INC.'s APPLICATION FOR DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING OF CORN 5307

EXECUTIVE SUMMARY

On June 21, 2019, Syngenta Philippines Inc. submitted corn 5307 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 5307 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 corn 5307 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 5307.

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 the complete dossier submitted by Syngenta Philippines Inc. The SEC expert, on the other hand, was provided with a questionnaire on socio-economic, ethical and cultural considerations that have been addressed by Syngenta Philippines Inc. in relation to their application. These assessors were given thirty (30) days to submit their independent assessment to BPI Biotech

Secretariat

STRP'S ASSESSMENT

1. Host Organism

a. Corn has been a staple food in many countries for centuries, and its leaves/stalks, grain are also used to feed animals. It is a source of key nutrients carbohydrates, protein, oil, magnesium and potassium, beta-carotene and vitamin E, phytochemicals, antioxidants and many secondary metabolites [1]

b. The genus Zea is reported not to be associated with significant native toxins. However, 2-4 dihydroxy-7-methoxy-2H-1, 4-benzoxazine-3 (4H)-one is considered a potential toxicant in the leaves of corn and root tissue. The toxicant declines rapidly as the plants grow. [2] Corn grain is also not considered a potential allergenic food [3]

2. Transgenic Plant

Corn 5307 is approved for food and feed use in Australia, Canada, China, Columbia, Indonesia, Japan, Korea, Malaysia, Mexico, Nigeria, Philippines, Russian Federation, Singapore, Taiwan, United States and Vietnam. [8] It was also not expected that the consumption pattern will change in any population sub-group with the introduction of corn 5307 as it is substantially equivalent to non-transgenic corn. [41]

3. Donor Organism

a. The *eCry3.Ab* gene is described as a fusion between the 5' end of a modified *cry3A* gene (mcry 3A) derived from *Bacillus thuringiensis subsp. tenebrionis* and the 3 end of a synthetic cry1Ab gene from *Bacillus thuringiensis subsp. kurstak*i strain HD-1. On the other hand, the *pmi* gene was derived from *Escherichia coli* strain K-12. The *pmi* gene encodes PMI, the enzyme phosphomannose isomerase (PMI). The PMI enzyme catalyzed the isomerization of mannase-6-phosphate to fructose-6-phosphate.

b. Both ECRY3.1AB and PMI are not derived from a known source of allergenic proteins and do not have any significant amino acid sequence similarly to known putative allergenic proteins. Their donor organisms are also not known to be toxic or allergenic. The proteins encoded by expressible sequences, *eCry3.1Ab* and *pmi* are not known to be toxic or allergenic. [42-45]

4. Transformation System

Agrobacterium mediated transformation was used to insert the plasmid into immature embryos of corn. [46] The target of the genetic modification was nuclear DNA. [46] A complete description of the method used to transform corn 5307 via *Agrobacterium tumefaciens* was given.[43] The list of genetic elements plus the plasmid map were presented. The active ingredients or structural gene cassette,

selectable marker cassette and plasmid backbone were described with respect to number of base pairs, position in the plasmid and description/function. Coding and non-coding regions were also included. [43]

5. Inserted DNA

There is only one insertion site and this was demonstrated by using the Southern blot analyses where the T-DNA insert in corn 5307 contains single copies of *ecry3.1Ab, pmi*, the CMP promoter sequence and the ZmUbilin promoter sequence, and two copies of the NOS terminator sequence. There were no extraneous DNA fragments of the functional elements elsewhere in the corn 5307 genome. Also, the corn 5307 is free of backbone sequence from transformation plasmid pSYN12274. [5][6]

6. Genetic Stability

a. The integrity and order of genetic elements within each insertion site were demonstrated using the Southern blot analyses where it was shown that there were no extraneous DNA fragments of the functional elements on the corn 5307 genome and that the corn 5307 is free from backbone sequence from transformation plasmid pSYN12274. [4]

b. Potential for creating novel chimeric opening reading frames were analyzed using bioinformatics, which is sufficient for detecting any possible allergen or toxin in the novel protein. As reported, the results showed that that no possible allergen/toxin can be produced. [7]

c. A Chi-square analysis of *ecry3.1ab* and *pmi* inheritance data over three generations of Event corn 5307 based on a comparison of observed and expected gene segregation ratios from each generation, showed that both *ecry3.1ab* and *pmi* are inherited according to Mendelian principles, indicating stable integration of the T-DNA as a single locus in the genome. [8]

7. Expressed Material

a. On maturity, the levels of ECRY3.1AB in leaves, roots, whole plant and kernels gave a mean of 25.33 ug/g FW, 2.98 ug/g FW, 8.86 ug/g FW, and 4,56 ug/g FW, respectively. On maturity, the levels of expression of PMI in roots, whole plant, and kernels gave a mean of 0.45 ug/g FW, 0.96 ug/g FW, and 1.36 ug/g FW, respectively. [9] The ECRY3.1AB is not an enzyme, and therefore has no metabolic role.

b. Meanwhile, expression of the *pmi* gene does not appear to adversely affect plant metabolism, as shown by the established substantial equivalence of corn 5307 with non-transgenic corn. [10] [11]

8. Toxicological Assessment

a. The enzyme pepsin in simulated mammalian gastric fluid (SGF) study was used to degrade ECRY3.1AB protein. No intact ECRY3.1AB or derived fragments were

observed when the protein was incubated in SGF for 30 seconds as demonstrated in the Western blot analysis. [12] It was also demonstrated that ECRY3.1AB protein is deactivated and denatured upon heating at temperature of 95°F and above. [13]

b. ECRY3.1AB is not a toxic protein, nor does ECRY3.1AB shows significant sequence similarity with other known or putative protein toxins. This was assessed using comparison of the ECRY3.1AB amino acid sequence and Syngenta custom toxin database. [14] The oral administration of 2000 mg of ECRY3.1AB protein/kg bodyweight as a single dose resulted in no treatment related effects as demonstrated in an acute oral toxicity study of ECRY3.1AB in mice. [16]

c. Meanwhile, the enzyme pepsin in simulated mammalian gastric fluid (SGF) study was used to degrade PMI protein rapidly. Following incubation of the novel protein in SGF for 1 minute, no intact PMI or degradation products were observed using the Western Blot Analysis. [18]

d. Heat stability of PMI was then determined by incubating solutions of test substance PMI-0105 for 30 minutes ranging from 25oC to 95oC. The incubation at 25oC and 37oC showed no loss of immunoreactivity. At 65oC, there was a 94% loss of immunoreactivity, and at 95oC, there was a complete loss of immunoreactivity. [20]

e. PMI is not a toxic protein nor does it share significant sequence similarity with other known or putative protein toxins based on the assessment of the PMI amino acid sequence using a comprehensive similarity search of a non-redundant NCBI Entrez® protein database and a Syngenta custom toxin database. [21] The oral administration of 2000 mg PMI protein/kg bodyweight as a single dose resulted in no treatment related effects as demonstrated in an acute oral toxicity study of PMI in mice. [23]

9. Allergenicity Assessment

a. The ECRY3.1AB protein comprises 0.0077% of the total protein in the kernels, which is a very low level of expressions for ECRY3.1AB protein in corn. The potential for dietary exposure to ECRY3.1AB proteins via corn 5307 seed is insignificant. [25] On the other hand, PMI protein is 0.0025% of the total protein of the kernel, and given this very low level of PMI protein expressed in corn, the dietary exposure to PMI protein via corn 5307 is also considered insignificant.[27]

b. The serum screening performed in the sequence identity between PMI and α - parvalbumin from Rana species CH2001 is not biologically meaningful and have no implications for the potential allergenicity of PMI. [26]

10. Nutritional Data

a. For proximate analysis, in 6 locations, there was one location where results showed that the protein, ash and starch in grain only differed significantly between the non-modified control and corn 5307. However, across locations,

there were no significant differences seen in grain and forage. Results showed that the values obtained for the genetically modified corn 5307 were within the range reported in the literature. [28]

b. Similarly, data for mineral content of corn grain across locations did not differ significantly. Ten minerals were measured, calcium, copper, iron, magnesium, manganese, phosphorus, potassium, selenium, sodium and zinc. For some locations, significant differences were observed for zinc (L4), magnesium and phosphorus (L7) and manganese (L8). All values regardless of location did not differ from those reported at the ILSI database. [30]

c. In addition, vitamin composition of grain of corn 5307 and non-transgenic across locations differed statistically between corn 5307 and the non-transgenic line for Vitamins A, B6 and B9. This is to be expected because vitamin biosynthesis could be responsive to growing conditions. Grain from specific locations also showed some significant differences with respect to vitamin content. Non-transgenic and corn 5307 grains from corn grown in location 4 and 8 differed significantly in Vitamin A, while grains also differed for Vitamin B6. These variations were within the ranges of natural variation reported in the literature. [31]

d. Meanwhile, data for the levels of 18 amino acids (except for glutamine and asparagine) measured in grain were shown to be not statistically different between non-transgenic near isogenic line and corn 5307 across locations, while there were significant differences in 8 amino acids in one location (L2). However, all values for amino acid concentration were within published values. [32]

e. Furthermore, data for fatty acid levels of nine fatty acids were presented. Data shows that across locations, there were significant differences between non-transgenic control and corn 5307 with respect to palmitic, stearic, linolenic, and eicosonoic acids. The 2 genotypes showed differences in palmitic acid at locations 4 and 7, stearic acid at locations 1 and 4, linoleic acid at locations 2 and 4, and eicosenoic at location 4. All levels were within the range of the ranges in the ILSI database. The differences were deemed of no biological significance. [33]

f. Lastly, no significant differences in the antinutrients of the grain in comparison with SE Comparator were found. Levels of antinutrients, namely, phytic acid, trypsin inhibitor and raffinose did not differ significantly between the corn 5307 and the non-transgenic corn. [34]

STRP'S RECOMMENDATION

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

BAI'S ASSESSMENT

1. *Toxicological Assessment*

a. The enzyme used in the digestibility study was pepsin in simulated mammalian gastric fluid. The results provided by the applicant showed that the protein ECRY3.1AB was digested in less than 30 seconds. Furthermore, there were no fragments of ECRY3.1AB detected by Western blot analysis. [12] The ECRY3.1AB protein inactivated and denatured when subjected to treatment at 95°C for 30 minutes. This was determined by subjecting the substance at different temperatures and using an insect bioassay to determine the loss of insecticidal activity with Colorado potato beetle. [13]

b. ECRY3.1AB protein showed no homology with known toxins based from the assessment through BLASTP using NCBI and Syngenta toxin databases. There was no significant similarity found between ECRY3.1AB protein and reported toxins. [14] Acute oral gavage was then performed and showed that there were no effects on the mice tested with a dosage up to 2000 mg/kg. Based from the results given by the applicant, the No Observable Adverse Effect Level of ECRY3.1AB was 2000 mg/kg which was the highest dose tested. [16] The source of test protein was recombinant *E. coli.* ECRY3.1AB produced in the said source of test protein is proved to be substantially equivalent to the ECRY3.1AB produced in corn 5307. [18]

c. The PMI protein was incubated in simulated mammalian gastric fluid (SGF) containing pepsin. It was determined PMI was readily digested in 1 minute, as assessed by SDS-PAGE analysis. Using western blot analysis, it was confirmed that no intact PMI or degradation products were observed after incubation in simulated mammalian gastric fluid for one minute. [18]. It was also determined that incubating the protein at 65 °C resulted in a 94% loss of immunoreactivity and incubating it at 95 °C resulted in a complete loss of immunoreactivity. Therefore, PMI loses it immunoreactivity upon heating at temperatures of 65 °C and above. [20]

d. PMI was subjected to amino acid sequence similarity search using the non-redundant NCBI Entrez® protein database and Syngenta custom toxin database. Results showed that PMI does not share significant sequence similarity with any known or putative toxins. This means that PMI is unlikely to be a toxin. [21] The PMI protein was also administered to mice 0 or 2000 mg active ingredient/ kg bw in a single oral gavage dose and was observed for 14 days. Results of their study showed no test substance-related clinical observations or effects in the biological samples. Therefore, NOEL is considered to be 2000 mg PMI protein/kg body weight. The result of this study further implies that the PMI protein will unlikely cause adverse toxicological effects in animal health. [23]

e. Recombinant *Escherichia coli* is the source of the test protein. The recombinant *E. coli*- produced (test substance PMI-0105) PMI protein was found to be biochemically and functionally equivalent to the PMI produced in corn 5307. [24]

2. Allergenicity Assessment

a. Protein in corn is comprised of ~0.0077% ECRY3.1AB protein. [25] While PMI protein constitutes only ~0.0025% of the total protein in the kernel, which implies that the protein has very low level of expression in corn, meaning there is only a minimal dietary exposure to corn 5307 seed PMI proteins. [27]

b. Serum screening was also performed for PMI. The test showed one region of sequence homology of eight contiguous identical amino acids between PMI and α-parvalbumin. To further know if the homology to a known allergen will make PMI a potential allergen, a sensitive serum screening was done. Results showed that there is no cross-reactivity between PMI protein and serum from individual with lgE-mediated allergy to this specific α-parvalbumin, also, the serum did not recognize any portion of PMI protein as an allergenic epitope. Thus, it can be concluded that the homology is not biologically meaningful which implies that PMI is not considered as an allergen nor a potential allergen. [26]

3. Nutritional Composition

a. For proximate analysis on grain: at one location, levels of protein, ash, and starch differed significantly between corn 5307 and conventional corn. However, the mean values obtained were within the reported ranges in the ILSI database except for starch. Meanwhile, for forage, proximate analysis results given showed that levels of moisture, protein, fat, ash, carbohydrates, ADF, NDF did not differ significantly between corn 5307 and conventional corn. The levels of moisture and protein each differed significantly at one location, however, all the mean levels were within the reported ranges in the ILSI database. [28]

b. No significant differences in the levels of calcium, copper, iron, magnesium, manganese, phosphorus, potassium, and zinc between the corn 5307 grain and the non-transgenic corn grain were observed. Levels of magnesium, manganese, phosphorus, and zinc, on the other hand, showed a significant difference at one location. For selenium that are quantifiable and not below limit of quantitation (LOQ), no significant differences were observed. Moreover, all mean levels of quantifiable components were within the ILSI database range. [30]

c. Meanwhile, across-location comparisons, calcium and phosphorus levels have no significant differences between the corn 5307 forage and the non-transgenic corn forage. However, at each location, levels of both minerals calcium differed significantly at one location. Nonetheless, all mean levels across and each location were still within the ILSI database range. [30]

d. Significant differences were found in levels of vitamins A, B6, and B9. However, all the mean values obtained were within the ranges reported in the ILSI database except for vitamin B2. [31] Amino acid levels did not differ between the corn 5307 and the conventional corn. However, the levels of asparagine, threonine, glutamic acid, glycine, alanine, valine, leucin, and histidine significantly differed at one location. Based on the data provided, all obtained values were within the ranges

reported in the ILSI database. [32]

e. Statistically significant differences were found in proportions of various fatty acids based from the results provided by the applicant. However, all the obtained mean values were within the ranges reported in the ILSI database. [33]

f. Lastly, levels of phytic acid, trypsin inhibitor, and raffinose in the across-location comparisons between the corn 5307 and the non-transgenic corn have no significant differences. Also, the anti-nutrients levels do not differ at any of the six locations. [34]

BAI'S RECOMMENDATION

Find 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.

BPI-PPSSD'S ASSESSMENT

1. Toxicological Assessment

a. SDS-PAGE and Western blot analysis demonstrated the digestibility of ECRY3.1AB protein in simulated gastric fluid (SGF). The results showed that more than 99% of the full-length ECRY3.1AB was digested within 30 sec. of incubation in SGF. Western blot analysis confirmed that there were no intact ECRY3.1AB protein fragments observed upon incubation in SGF for 30 seconds. [12] Western Blot Analysis also demonstrated the effect of heat treatment on the immunologically detectable level of the ECRY3.1AB protein. The results showed that ECRY3.1AB protein is inactivated, and therefore, denatured upon heating at 95℃ and above. [13]

b. Amino Acid Sequence Comparison with non-redundant protein sequences database using BLASTp showed no significant homology of ECRY3.1AB to any known toxin (BLAST). [14] [15] Acute oral gavage demonstrated that administration of 2000 mg/kg BW ECRY3.1AB protein in mice did not result in any treatment-related effects on survival, clinical observations, body weight gain, food consumption or gross pathology. The No Observable Effect Level (NOEL) for the ECRY3.1AB protein is 2000 mg/kg BW. [16] [17]

c. *E. coli* was the source of test protein. Comparative analyes on structure, immunoreactivity, glycosylation and functional activity showed that *E. coli*-produced ECRY3.1AB protein is equivalent to the plant-produced ECRY3.1AB present in corn 5307 [18] [19].

d. Meanwhile, SDS-PAGE and Western blot analysis demonstrated the digestibility of the PMI protein in simulated gastric fluid. The results showed that PMI was digested within 1 min of incubation in SGF. No other bands were detected in the lanes corresponding to the 2 min through 60 min digestion time points. The

estimated T50 result for SGF is below 1 minute. [18] ELISA also demonstrated the effect of heat treatment on the immunologically detectable level of the PMI protein in corn 5307. Samples were heated at 25°C, 37°C, 65°C and 95°C. Results showed that at 95°C, complete loss of immunoreactivity was observed. [20]

e. Amino Acid Sequence Comparison with non-redundant protein sequences database using BLASTp showed no significant homology of PMI to any known toxin [21] [22]. Acute oral toxicity study demonstrated that the administration of 2000 mg/kg BW PMI protein to mice did not result in any treatment-related effects on survival, clinical observations, body weight gain, food consumption or gross pathology. The No Observable Effect Level (NOEL) for the PMI protein is 2000 mg/kg BW. [24]

f. *E. coli*-produced PMI protein was also used for the safety assessment. The *E. coli*-produced PMI protein has been shown to be equivalent to the plant-produced PMI present in corn 5307. [24]

2. Allergenicity Assessment

a. Amino Acid Sequence Comparison with non-redundant protein sequences database using BLASTp showed no significant homology of ECRY3.1AB to any known toxin or allergen. [14] [15] Same is true for PMI protein. [21] [25]

b. The mean level of PMI protein and the mean dry weight of total protein in corn 5307 kernels indicates that PMI comprises 0.0025% of total corn kernel protein. [27] Serum screening showed no cross reactivity between PMI and the serum from single individual known to have demonstrated IgE mediated allergy to specific a-parvalbumin. [26] On the other hand, the mean level of ECRY3.1AB protein and the mean dry weight of total protein in corn 5307 kernels indicates that ECRY3.1AB comprises 0.0078% of total corn kernel protein. [25]

3. Nutritional Composition

a. Compositional analysis indicated no significant difference between the proximate levels of corn 5307 and the conventional control forage and grains. [28] [29] It also indicated no significant differences observed on amino acid, fatty acid, vitamin and mineral content of corn 5307 and the non-transgenic corn except for vitamin A, vitamin B6, vitamin B9, palmitic acid, stearic acid, linolenic acid and eicosenoic acid. [29] corn 5307 exhibited higher levels of vitamin B9, palmitic acid, linolenic acid and eicosenoic acid, and lower levels of vitamin A, vitamin B6 and stearic acid. [31] [32] [33] [29] All test values were within the range of literature values. [29]

b. Lastly, compositional analysis indicated no significant difference between the anti-nutrient levels of corn 5307 and the conventional control. [29] [34]

BPI-PPSSD'S RECOMMENDATION

Find scientific evidence that the regulated article applied for human food use is as safe as its conventional counterpart and shall not pose any significant risk to human and animal

health.

DENR BC'S ASSESSMENT

After a comprehensive review and evaluation of the documents including the scientific evidences from provided references and literature submitted by Syngenta Philippines, Inc., on its application for Direct Use as FFP of Corn 5307, hereunder are the observations and appropriate actions:

1. The direct use of the regulated article whether for food, feed or for processing will not cause any significant adverse effect on the environment (land and water) and biodiversity, particularly on nontarget organisms. The transgenic crop will not increase its weediness potential in case the seeds spill out into the environment because the resistance trait is unrelated to sexual compatibility and it behaves similarly to the conventional counterpart [35];

2. The donor organism for ECRY3.1AB protein, is ubiquitous to the environment and biodiversity particularly on non-target organisms and does not pose significant risk of pathogenicity to animals. Also, based on the bioinformatics analysis, it has no structural similarity to any putative toxins to mammals; and

3. The project description report (PDR) discusses the specified environmental management plan indicating the possible risk and harm to the environment and biodiversity particularly on 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, corn is a highly domesticated plant that requires human intervention for it to persist in the environment. [35] [36]

DENR BC'S RECOMMENDATION

Based on the evaluation and review of literatures cited, the DENR-BC considered the regulated article safe to the environment, particularly on biodiversity and non-target organisms.

DOH BC'S ASSESSMENT

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.

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 in 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.

DOH BC'S RECOMMENDATION

It is suggested that the Bureau of Plant Industry (BPI) ensure that there shall be clear instructions that the product is only for the purpose of direct use for FFP and is not to be used as planting materials.

SEC EXPERT'S ASSESSMENT

1. Corn is a significant crop in the Philippines given its widespread use as food and feed. Country- wide consumption of corn, although with slight fluctuations in recent five years, has shown a generally increasing trend since 2002. [37] FAO data, which Applicant cited, confirms a similar demand trend with a notable increase of more than 500,000 MT of corn imports in 2017-2018, with a 200,000 MT drop in local corn production. The Philippine Statistics Authority observed a continued decrease in domestic corn production in the recent quarter (April to June 2019) as harvest areas contract and yields per hectare decline. [38]

2. The US Department of Agriculture however projects an increase in local corn production in 2020 especially with the use of better quality, including genetically modified, seeds. While use of corn as food is expected to decrease next year due to cheaper food alternatives like rice and wheat, feed- corn demand is expected to rise.

3. The subject application is only for direct use as food and feed, or for processing. Given the Philippine's history of corn importation [39] vis a vis trends in consumption/utilization, drastic changes are not expected, and even modest changes are not attributable to imports alone.

4. Moreover, it is noted that the subject application is a renewal, given the previous Philippine approval of the GM crop for food, feed and processing. Since then, there has been no dramatic change in the corn production, consumption and importation trends in the country.

5. The subject GM product, including its compositional content, has also been found through various scientific studies (and from approval issued in other jurisdictions) to be substantially equivalent to non- GMO/conventionally grown maize.

6. In any case, possible effects on the use of the GM crop for food, feed and processing on specific ethnic or cultural groups should be best understood in the context of engagement and participation. [40] Evaluation of Applicant's response should be done alongside results of the procedures for Public Participation for Direct Use under Sec. 22 of JDC 1-2006.

SEC EXPERT'S RECOMMENDATION

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

REFERENCES

[1] Section 1.A, Corn as a Source of Key Nutrients, pp.13-14 of the dossier

[2] Section 1.B, Corn as Source of Anti-nutrients, p. 14-15 of dossier

[3] Section 1.C, Corn as Source of Toxicants, p. 15 of dossier

[4] Section 5, The Inserted DNA, pp. 24-45 of dossier

[5] Section 5.B, Copy Number of Functional Elements, pp. 24-37 of dossier

[6] Section 5.E, Absence of Backbone Sequence in 5307 Corn, pp. 42-45 of dossier

[7] Section 5.D, Novel Chimeric ORFs, p. 40-41 of dossier

[8] Section 6.B, Mendelian Inheritance of Transgene Insert, p. 55 of dossier

[9] Section 7, Expressed Material, pp. 56-59 of dossier

[10] Section 7.B, The Metabolic Pathways, pp. 59-60

[11] Section 10, Nutritional Data, pp. 72-96 of dossier

[12] Section 8.A.1, In vitro Digestibility of ECRY3.1AB, pp. 60-63 of dossier

[13] Section 8.A.2, Heat Stability of ECRY3.1AB, pp. 64 of dossier

[14] Section 8.A.3, Amino acid sequence homology with known toxins, p. 64-65 of dossier

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[17] Section 8.A.5, Characterization of ECRY3.1AB Produced in Event 5307 Corn and Comparison to ECRY3.1AB Produced in Recombinant *E.coli*, p. 65-66 of dossier

[18] Section 8.B.1, In vitro Digestibility of PMI, p. 66 of dossier

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[20] Section 8.B.2, Heat stability of PMI, p. 66-67 of dossier

[21] Section 8.B.3, Amino acid sequence homology with known toxins, p. 67 of dossier

[22] BLAST: https://blast.ncbi.nlm.nih.gov/Blast.cgi

[23] Section 8.B.4, Acute oral mouse toxicity study of PMI protein, p. 67-68 of dossier

[24] Section 8.B.5, Characterization of PMI Produced in Event 5307 Corn and Comparison to PMI Produced in Recombinant *E.coli,* p. 68-69 of dossier

[25] Section 9.A.2, Prevalence of ECRY3.1AB and PMI protein in Food, p. 69-70 of dossier

[26] Section 9.B.1, Homology of PMI to known or putative allergens, pp. 70-71 of dossier

[27] Section 9.B.2, Prevalence of ECRY3.1AB and PMI protein in Food, p. 71 of dossier

[28] Section 10.A.1, Proximate analysis, p.74 of dossier

[29] Launis, K. 2010. Compositional analysis of forage and grain from event 5307 hybrid maize grown during 2008 in the USA. Syngenta Biotechnology, Inc. Report No. SSB-170-09 A1.

[30] Section 10.A.2, Minerals, p. 74-75 of dossier

[31] Section 10.A.3, Vitamins, p. 75 of dossier

[32] Section 10.A.4, Amino acids, p. 75 of dossier

[33] Section 10.A.5, Fatty acids, p. 75 of dossier

[34] Section 10.A.6, Anti-nutrients, p. 76 of dossier

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