ASSESSORS' CONSOLIDATED REPORT ON MONSANTO PHILIPPINES INC.'s APPLICATION FOR DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING OF CORN MON 87427

EXECUTIVE SUMMARY

On October 25, 2018, Monsanto Philippines submitted corn MON87427 application for direct use 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 STRP, BAI, and BPI-PPSSD scientific evidence was found that corn MON87427 is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health.

The Department of Environment and Natural Resources – Biosafety Committee (DENR-BC), after a thorough scientific review and evaluation of the accomplished Project Description Report (PDR) and Environmental Risk Assessment (ERA) form along with the submitted sworn statement and accountability of the proponent, reported that the direct use of the regulated article will not cause any adverse effect on the environment (land and water) and biodiversity.

The DOH-BC, after a thorough scientific review and evaluation of documents related to Environmental Health Impact, found scientific evidence that the GM application will not cause significant adverse effects to human and animal health, is unlikely to result in allergenic reaction, and is as safe as food or feed derived from conventional varieties.

Furthermore, the Socio-economic, Ethical and Cultural (SEC) expert, after reviewing thoroughly the accomplished SEC questionnaire, also recommended for the issuance of Biosafety Permit.

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

STRP'S ASSESSMENT

1. Host Organism

a. Maize is a common cereal that is used for food and feed. The grain or endosperm is a source of carbohydrates, fiber, oil, protein and minerals. The anti-nutrients present in maize are phytic acid and raffinose. [1][2].

b. It was reported that maize is not considered as a source of toxicants and has a long history of safe use in food and feed. There has been no reported case of allergenicity for corn. [1][2].

2. Transgenic Plant

a. MON87427 has been reviewed and approved for food and/or feed use in many countries as can be seen in Annex II of this document [1][3].

b. The consumption pattern is not expected to be changed as a result of the introduction of MON87427 because this transgenic product was found to be substantially equivalent to its non-transgenic parental line and also to other conventionally bred maize hybrids. [1].

3. Donor Organism

a. Maize MON87427 was developed by *Agrobacterium tumefaciens*-mediated transformation. Immature maize (*Zea mays* L., line LH198 HiII) embryos were co-cultured with the *A. tumefaciens* strain ABI containing the transformation binary plasmid *PV-ZMAP1043*. [4].

b. The *PV-ZMAP1043* vector contains a single expression cassette consisting of the following transfer DNA (T-DNA): an enhanced 35S promoter from the *Cauliflower mosaic virus*; the *hsp70* intron derived from the maize heat shock protein 70 gene; the chloroplast-targeting sequence from the *Arabidopsis thaliana shkG* gene (encoding the EPSPS protein); the codon-optimized coding sequence of the *aroA* gene from *Agrobacterium* sp. strain CP4 (encoding the *CP4 EPSPS* protein); and the 3′-untranslated region from the *A. tumefaciens nopaline synthase* (*nos*) gene (*T-nos*), which terminates transcription. In addition to these genetic elements, the *PV-ZMAP1043* vector also contains the left-and right-border sequences from A. tumefaciens, which are used for the transfer of the T-DNA to the plant cells. [4].

c. The vector backbone sequence contains the bacterial *aadA* gene from *Escherichia coli* transposon Tn7, which confers resistance to streptomycin and spectinomycin, the origin of replication from the *pBR322* plasmid, the rop coding sequence from the *ColE1* plasmid, and the origin of replication from the broad host range plasmid *RK2.* [4].

d. *Agrobacterium sp*. strain CP4 (Monsanto, 2015). *Agrobacterium* sp. strain CP4 is related to microbes present in the soil and in the rhizosphere of plants. These

microbes are not known for human and animal pathogen and are not commonly allergenic. The microbes are rapidly digested and not toxic. [5][6].

4. Transformation System

The transformation method that was used was *Agrobacterium*-mediated transformation of immature embryos of maize. The target for the genetic modification was the nuclear DNA of immature maize embryos. [3].

5. Inserted DNA

a. The molecular analysis shows that MON87427 contains a single copy of the *cp4 epsps* expression cassette, i.e., the T-DNA is stably integrated at a single locus of the maize genome and is inherited according to Mendelian principles over multiple generations. Southern blot analyses assayed the entire maize genome for the presence of DNA derived from PV-ZMAP1043, and demonstrated that only a single copy of the T-DNA was inserted at a single site and no plasmid vector backbone sequences were detected in MON87427. [3][7].

b. Moreover, the potential for creating novel chimeric ORFs were tested by bioinformatics. The sequences that spanned the 5' and 3' corn genomic DNA, the intervening sequences and intervening T-DNA junctions were translated from stop codon to stop codon. All six possible reading frames were utilized. The sequence of a total of 14 theoretical polypeptides that were generated with eight amino acids or greater was compared to the databases for allergens, toxins and proteins. Results from the FASTA sequence alignment for structural similarity indicated no structurally relevant similarities of the 14 polypeptides to those allergens, toxins or biologically active proteins. [3][8].

6. Genetic Stability

a. The stability of the T-DNA insert across multiple generations was demonstrated by Southern blot analysis. The analysis demonstrated that the MON87427 single integration locus was maintained through five generations of breeding, thereby confirming the stability of the insert. [3][5].

b. On the other hand, segregation data were generated to assess the heritability and stability of the T-DNA present in MON87427 using Chi square (χ^2) analysis over several generations. The Chi square analysis is based on testing the observed segregation ratio to the expected segregation ratio according to Mendelian principles. Three generations of backcrosses were tested. [3][5].

c. The χ^2 value for three generations indicated no significant difference between the observed and expected segregation ratios. These results support the conclusion that the *cp4 epsps* expression cassette in MON87427 resides at a single locus within the maize genome and is inherited according to Mendelian inheritance principles. These results are also consistent with the molecular

characterization data that indicate MON87427 contains a single intact copy of the *cp4 epsps* expression cassette that was inserted into the maize genome at a single locus. [3][5].

7. Expressed Material

a. The presence and stability of the introduced trait was examined in five generations of MON87427. This was determined by means of Southern blot analysis of seed and leaf tissues. The hybridization bands were consistent in all the generations tested. [3][5].

b. Mendelian inheritance of the tissue selective glyphosate tolerance trait and presence of the *cp4 epsps* expression cassette in MON87427 was established in three backcross generations (BcF1, BC2F1 and BC2F2). The presence or absence of the herbicide tolerance phenotype were scored and analyzed by Chi square method. There was no significant difference between the observed and expected segregation ratios. This finding agreed with the result of molecular analysis that the expression cassette has integrated as a single copy in a single locus in the maize genome. [3][5].

8. Toxicological Assessment

a. The CP4 EPSPS protein, as expressed in MON87427, has been assessed for its potential toxicity according to the recommendations of Codex. The inserted *cp4 epsps* gene in MON87427 results in the expression of CP4 EPSPS. The CP4 EPSPS protein has no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals. It does not exert any acute toxic effects to mammals and has a large margin of exposure (MOE). [3].

b. In addition, the rapid digestibility of CP4 EPSPS in simulated gastric fluid provides additional assurance on its safety. [5].

9. Allergenicity Assessment

a. The results showed that CP4 EPSPS was still functional at 25^{o} and 37^{o}C. At 55^{o}C for 15 min, there was a 70% decrease in activity relative to the control, while the activity decreased to 25% after 30 min of heat treatment. The activity that remained after 15 and 30 min at 75^{o}C and 95^{o}C was below the limit of detection. [3][9].

b. SDS PAGE results showed that the protein band remained unchanged after the various heat treatments. The loss of activity at the higher temperature treatments and non-degradation into fragments indicate that the enzyme becomes denatured at high temperatures. The estimated T50, therefore, is below 15 min. [3][9].

c. Amino acid sequence comparison for 35% amino acid identity over 80 amino acids between the CP4 EPSPS from MON87427 and known allergens, gliadins

and glutelins was performed using the FASTA sequence alignment program as well as an eight amino acid sliding window search in the allergen database AD_2010. Both schemes did not yield any biologically relevant similarities. [3][10].

10. Nutritional Data

a. There was no observed statistically significant difference in the values for proximate composition of grain from MON87427 when compared to its non-modified counterpart or with other conventional corn varieties. Any observed differences were well within the range of natural variations reported for corn in the available literature. Thus, the differences in terms of proximate composition of grain from transgenic MON87427 have no biological relevance. [3][11].

b. There was no statistically significant difference in the composition of minerals in grain and forage between the transgenic corn MON87427 with those from its non-transgenic control. Any observed difference in the mineral composition of grain and forage from MON87427 as compared with those from conventionally bred reference varieties already in the market was within the range of natural variations found in samples of corn reported in the literature and crops database. Therefore, the differences are not biologically relevant. [3][11].

c. The amino acid composition of grain derived from MON87427 is substantially the same as those from conventionally bred corn varieties [3][11][12].

d. The statistical difference in the mean values for phytic acid and raffinose in the grain of MON87427 compared with those from the non-modified control have no biological relevance because the mean values were within the range of values obtained from the commercial reference varieties grown simultaneously under the same agronomic and environmental conditions and the range of values reported in the literature and ILSI database. [3][11].

e. The new studies on single-event transgene product levels being able to predict levels in genetically modified breeding stack as well as on stacked genetically engineered trait products produced by conventional breeding reflecting the compositional profiles of their component single trait products have no bearing on safety issues in the direct use of MON87427. [26][27].

STRP'S RECOMMENDATION

STRPs find scientific evidence that the regulated article applied for direct use as food and feed or for processing is as safe as its conventional counterpart and shall not pose greater risk to human and animal health.

BAI'S ASSESSMENT

1. Toxicological Assessment

a. At least 98% of the *E. coli*-produced CP4 EPSPS protein was digested in SGF within 15 seconds. The estimated T50 result for SGF is below 15 seconds that indicated rapid digestion of the said protein. Hence, no protein bands were observed. Further analysis using Western Blot showed that greater than 95% of the immunoreactive *E. coli*-produced CP4 EPSPS protein was degraded in SGF within 15 seconds. [3][11].

b. Furthermore, the sequence of the toxins was obtained from TOX_2010 database and was aligned with CP4 EPSPS using FASTA sequence alignment program. The analysis showed that there is no structurally relevant similarity that exist between CP4 EPSPS protein and any known toxic or other biologically active proteins that would be harmful to human or animal health. [3][8].

c. Acute oral toxicity study was also performed. There were no treatment-related effects on survival, clinical observations, body weight gain, food consumption or gross pathology. Therefore, the No Observable Adverse Effect Level (NOAEL) for CP4 EPSPS was considered to be 572 mg/kg, the highest dose tested. [3][5] [13].

2. Allergenicity Assessment

a. The enzyme used in the digestibility study was pepsin through simulated gastric fluid, while the protein used, CP4 EPSPS, was produced using *E. coli*. At least 98% of the *E. coli*-produced CP4 EPSPS protein was digested in SGF within 15 seconds. The estimated T50 result for SGF is below 15 seconds that indicated rapid digestion of the said protein. Hence, no protein bands were observed. Further analysis using Western blot showed that greater than 95% of the immunoreactive *E. coli*-produced CP4 EPSPS protein was degraded in SGF within 15 seconds. [3][14].

b. The estimated T50 result for functional activity of CP4 EPSPS is below 15 minutes. This was determined using functional assay and SDS-PAGE. The functional assay was used to assess the impact of temperature on activity. The LOD of the assay was above the functional activity when incubated at 75°C or higher for either 15 or 30 minutes. The functional assay result indicates that the CP4 EPSPS protein loses functional activity during heating. Meanwhile, the SDS-PAGE showed no significant change in band intensity. The SDS-PAGE was used to assess the impact of temperature on protein integrity, hence, the insignificant change in band intensity indicates that the protein integrity was not affected with temperature change. [3][14].

c. The allergenicity potential of the CP4-EPSPS was assessed using bioinformatics tools – FASTA sequence alignment program and ALLERGENSEARCH program in conjunction with the Food Allergy Research and Resource Program (FARRP) allergen database. The FASTA sequence alignment program compared the amino acid sequences of CP4-EPSPS present in MON87427 and known

allergens, gliadins, and glutenins. The said program result showed that there are no alignments between the CP4 EPSPS protein and sequences of known allergens, gliadins, and glutenins were observed that are significant for the allergenic assessment. The ALLERGENSEARCH program which is used for eight-amino acid sliding window search showed that CP4 EPSPS protein and proteins from the AD_2010 allergen database does not match any eight amino acids. With the data presented, it is concluded that there are no significant similarities between the CP4 EPSPS protein and pharmacologically active proteins that are known to cause adverse health effects in humans or animals. [3][14].

d. The physico-chemical properties of both MON87427-produced and *E. coli*-produced CP4 EPSPS as reference protein were analyzed through series of tests. One of which is glycosylation analysis that showed that the plant-produced CP4 EPSPS protein is not glycosylated and is equivalent to the *E. coli*-produced CP4 EPSPS protein. [3][10][14].

3. Nutritional Data

a. Proximate analysis of the ash, carbohydrates and moisture, and protein in forage showed no difference, while in total fat, significant difference was observed. However, the mean value obtained for the proximate analysis for the fat was within the 99% tolerance interval, hence, it is concluded that these differences are not biologically meaningful. [3][11][15].

b. Significant differences were also observed in the grain for five fatty acids which are 16:0 palmitic acid, 18:0 stearic acid, 18:1 oleic acid, 18:2 linoleic acid, 20:0 arachidic acid. Nevertheless, the mean values obtained were within the 99% tolerance interval based on literature. As for the other key nutrients, no difference was found in the forage. With the data given, it is concluded that the differences are not biologically meaningful. [3][11][15].

c. Further, the antinutrient phytic acid showed statistically significant difference in the analysis. However, the mean phytic acid values for MON87427 were within 99% tolerance interval level based on literature values. It is concluded that the difference is not biologically meaningful. As for the secondary metabolites, there were no significant differences found. With the data presented, the anti-nutrient components in grain showed that MON87427 is compositionally equivalent to conventional maize. [3][11][15].

d. The applicant provided 2 peer-reviewed literature sources which reported the latest compositional analysis of the single trait event (MON87427) together with several GE stacked trait products. Their result showed that the transgene concentration in the single trait event is similar in breeding stacks containing the single event. Moreover, results showed no issues on feed safety which further confirms the safety of the single trait event MON87427 corn, aside from HOSU. [26][27].

BAI'S RECOMMENDATION

BAI 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 ASSESSMENT

1. ***Toxicological Assessment***

    a. Digestibility study indicated that CP4 EPSPS of MON87427 is rapidly degraded in simulated gastric fluid (SGF). Hence, the estimated T50 result for SGF is within 15 seconds. The susceptibility of CP4 EPSPS protein to proteolytic degradation was evaluated in the simulated mammalian gastric fluid (SGF) containing pepsin using SDS-PAGE Colloidal Blue gel staining and Western Blot Analysis. [16].

    b. Bioinformatics analyses using FASTA sequence alignment program and TOX_2010 protein database indicated that CP4 EPSPS has no significant homology to any known toxin. [3].

    c. Acute oral toxicity study indicated no treatment-related adverse effects on survival, clinical observations, body weight gain, food consumption or gross pathology of mice administered with CP4 EPSPS protein [13].

2. ***Allergenicity Assessment***

    a. The results of the SDS PAGE and western blot assays demonstrate that CP4 EPSPS protein is rapidly degraded in simulated gastric fluid containing pepsin within 15 seconds. The estimated T50 result is <15 seconds. Results from the digestibility experiments show that CP4 EPSPS protein will likely be digested in the typical mammalian gastric environment and it is highly unlikely to pose a safety concern to human and animal health. [3][16].
    b. The SDS-PAGE analysis and functional assay analysis of CP4 EPSPS protein indicated that the functional activity was below the limit of detection (LOD) of the assay when incubated at 75°C or higher for either 15 or 30 minutes. The activity is significantly impacted by heat treatment. [9].
    c. The results of bioinformatics analysis shows that CP4 EPSPS protein has no homology to any known allergens using the FASTA sequence alignment program and an eight-amino acid sliding window search (ALLERGENSEARCH program) in conjunction with the Food Allergy Research and Resource Program (FARRP) allergen database. [3].

3. ***Nutritional Data***

    a. Safety assessment based on the nutritional data indicates that there is no significant difference between the proximate, fiber, mineral, amino acid,

vitamin, fatty acid and anti-nutrient levels of MON87427 corn and conventional corn that can be considered biologically relevant.

b. BPI PPSSD reviewed and found that the new studies submitted by the applicant will not affect the safety of corn MON87427 [26][27].

BPI PPSSD'S RECOMMENDATION

Upon evaluation of the documents provided by the proponent and scientific literature search conducted for the food safety risk assessment of corn MON87427, it was found that it is as safe as its conventional counterpart.

DENR BC'S ASSESSMENT

After a comprehensive review and evaluation of the documents including the scientific evidence from references and literature submitted by Monsanto Philippines, Inc., on its application for Direct Use as FFP of corn MON87427, 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 non-target organisms. The transgenic crop will not increase its weediness potential in case the seeds spill out into the environment because the CP4 EPSPS protein product produced by the transgenic crop will degrade upon exposure to the natural environment and general conditions that is high temperature (65°C and above), varying pH, enzyme digestion, etc. [6].; and
2. The project description report (PDR) discusses the specified environmental management plan indicating the possible risk and harm to the environment and non-target organisms as well as the mitigating measures and contingency plan. 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. [2][17].
3. DENR BC has acknowledged and has no further comments on the new studies submitted by Bayer for corn MON87427 [26][27].

DENR BC'S RECOMMENDATION

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

DOH BC'S ASSESSMENT

The DOH-BC, after a thorough review of the documents, find that the regulated article applied for Direct Use as Food, Feed or for Processing (FFP) is as safe as its conventional

counterpart and shall not pose any significant risk to human and animal health and environment.

The following are the observations:

1. Pieces of scientific evidence from toxicity studies and references find that the regulated article will not cause significant adverse health effects to human and animal health [1][2].
2. Dietary exposure to the regulated article is unlikely to result in allergic reaction [1][2].
3. The regulated article is as safe as food or feed derived from conventional corn varieties [1][2].
4. The regulated article is not materially different in nutritional composition from that of the non-transgenic corn or the conventional corn [1][2].
5. DOH BC found that the new studies submitted by the applicant will not affect the safety of corn MON87427 [26][27].

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. GM maize is widely produced and consumed and is a significant component of global trade of agricultural commodities. In 2016, maize production in the country registered output losses of 3.99%. However, hog and dairy production grew by 5.25 percent and 3.78 percent, respectively. Importation therefore of maize as feeds material has become more important to meet domestic demands. [18][19][20][21][22].

2. The GM maize product is not believed to drastically change current patterns of production, consumption/utilization and trade.

3. The availability of yellow maize as feeds material is vital to the competitiveness of the Philippines livestock and poultry sector. The "Philippine Agriculture: 2020" reports that the country is projected to have deficits of 683,000 metric tons of pork, 308,400 metric tons of broiler and 30,000 metric tons of eggs by 2020. Among other things, maize MON87427 and the rest of the approved GM maize hybrids in the country can aid reduce projected deficit and minimize imports, both in livestock produce and feeds materials when imported in the country for direct use as food, feed or for processing. [18][22].

SEC EXPERT'S RECOMMENDATION

After a thorough review and evaluation of the documents provided by Monsanto Philippines Inc., relevant to corn MON87427, the SEC Expert recommends the approval and issuance of Biosafety Permit for direct use as food and feed or for processing.

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