

**ASSESSORS' CONSOLIDATED REPORT ON MONSANTO PHILIPPINES INC.'S CORN
MON 95379 APPLICATION FOR DIRECT USE AS FOOD AND FEED, OR FOR
PROCESSING**

EXECUTIVE SUMMARY

On May 19, 2021, Monsanto Philippines Inc. submitted corn MON 95379 for direct use, 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 Scientific and Technical Review Panel (STRP), Bureau of Animal Industry, and BPI Plant Products Safety Services Division concurred that corn MON 95379 is as safe as its conventional counterpart.

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 MON 95379 is safe as its conventional counterpart and shall not pose any significant risk to human health.

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 Monsanto Philippines, Inc. The SEC expert, on the other hand, was provided with special questionnaire on socio-economic, ethical and cultural considerations that have been addressed by Monsanto Philippines, Inc. in relation to their application.

INFORMATION ON THE APPLIED EVENTS

The purpose of this corn MON 95379 biosafety permit application is for Direct Use as Food, Feed or Processing (FFP).

The transgenic corn MON 95379 produces Cry1B.868 and Cry1Da_7 proteins from *Bacillus thuringiensis* which protect against feeding damage caused by targeted lepidopteran insect pests, including fall armyworm (FAW; *Spodoptera frugiperda*), sugarcane borer (SCB; *Diatraea saccharalis*), and corn earworm (CEW; *Helicoverpa zea*).

Corn event MON 95379, which was developed through *Agrobacterium*-mediated transformation. This transgenic corn had prior approval in Brazil last 2020 for use as food, feed and cultivation.

Approval of the permit for direct use for food, feed and for processing of corn event MON 95379, will enable the entry of this product into the Philippines for food, feed, and processing purposes.

STRP's Assessment

1. Host Organism

- a. Corn has a long history of safe use for food and feed. It is a source of key nutrients such as carbohydrates, amino acids, fatty acids, beta-carotene, B-vitamins, minerals, and linoleic acid.[1][2][3].
- b. Antinutrients such as 2,4-dihydroxy-7-methoxy-2H-1,4-benzoxazin-3-one (DIMBOA), phytic acid, raffinose, chymotrypsin and trypsin inhibitors are present in corn. These antinutrients are in amounts that have not been shown to adversely affect human and animal nutrition. Furthermore, levels of these components in corn MON 95379 are comparable with the conventional corn.[1][4].
- c. Corn does not produce significant quantities of toxins, allergens or antinutritional factors. Although few cases of allergic reaction were reported when corn is consumed in extremely high amounts.[1][2]
- d. Traditionally, corn has been consumed as food in different forms, usually cooked or processed. In the Philippines, corn accounts for about 3% of the total food consumption on a per capita basis.[5][6].
- e. Corn is also used as material for livestock feed in raw or processed form, as it has high nutritional value and low cost.[1][5].

2. Prior Safety Approval

Corn MON 95379 is approved in Brazil for use as food, feed and propagation. This transgenic corn was developed to produce two insecticidal proteins Cry1B.868 and Cry1Da_7, which protect corn against feeding damage caused by lepidopteran insect pests, including fall armyworm (FAW; *Spodoptera frugiperda*), sugarcane borer (SCB; *Diatraea saccharalis*), and corn earworm (CEW; *Helicoverpa zea*).[4][7][8].

3. Donor Organism

- a. *Bacillus thuringiensis* is the donor organism of genes *cry1B.868* and *cry1Da_7*. [8].
- b. Bt has a long history of use for pest control. Extensive toxicity assessments have not shown any adverse effect of Bt to human health.[8][9][10][11][12][13][14][15].
- c. Cry1B.868 and Cry1Da_7 proteins expressed in corn MON 95379 are of similar structure with Bt Cry proteins which have been attested by several studies and literature to be safe for food and feed. These proteins are described as non-contact insecticides that cause osmotic shock and cell lysis leading to the death of the target insects.[8][9][10][11][12][14][15][16].
- d. No relevant similarities with allergens, toxins and other biologically active proteins was observed in the protein-encoding sequences. The expression cassettes are noted to be stable in a single locus in the corn genome.[7][8][9][10][11][12].

4. Transformation System

- a. *Agrobacterium tumefaciens*-mediated transformation utilizing plasmid vector PV-ZMIR52223 was utilized in the development of corn MON 95379. This plasmid vector has a size of 21.6 kb and has a single T-DNA (transfer DNA) delineated by the right and left border regions.[7].
- b. The T-DNA contains the *cp4 epsps*, *cry1B.868*, and the *cry1Da_7* expression cassettes. During the transformation the T-DNA was inserted into the corn genome. Integration of the *cry1B.868* and *cry1Da_7* expression cassettes with the nuclear genome of corn was the target of

genetic transformation. No carrier DNA or helper plasmids were used in the transformation event.[7][41][42].

- c. Immature embryos from post-pollinated corn ears (LH244) which were co-cultured with *A. tumefaciens* carrying the plasmid vector, were excised and were placed in a selection medium containing glyphosate and carbenicillin sodium salt. Upon callus formation, the embryos were transferred to a shoot and root promoting medium. Afterwards, plants exhibiting phenotypic characteristics were transferred in soil and subjected to further evaluation and selection.[7][17][41][42].
- d. Subsequently, traditional breeding, segregation, selection, and screening were used to isolate those plants that contained the *cry1B.868* and *cry1Da_7* expression cassettes, and lacked the *cp4 epsps* selectable marker and any sequences from the *cre* gene containing plasmid, PV-ZM00513642.[7][41].
- e. Multigenerational stability of the T-DNA present in corn MON 95379 was evaluated using the Next Generation Sequencing (NGS) and bioinformatics analysis. Results demonstrated the stability of the DNA insert in a single locus of integration for over five breeding generations.[7][18][41].

5. Food and Feed Safety

- a. Digestibility of Cry1B.868 was assessed using pepsin and pancreatin. About 99.8% of the intact Cry1B.868 was degraded by pepsin within 0.5 minutes while about 99.6% was degraded by pancreatin, T_{50} is estimated at below 5minutes.[19][20].
- b. Pepsin and pancreatin were also used to assess the digestibility of Cry1Da_7 protein. Results have shown that about 99.4% of the intact Cry1Da_7 was degraded within 0.5 minutes by pepsin while about 96.9% was degraded by pancreatin, T_{50} is estimated at below 5minutes.[19][20].
- c. Cry1B.868 and Cry1Da_7 proteins were degraded when treated by pepsin and pancreatin. This showed that under the animal digestion process the proteins will be degraded and will not likely pose safety concerns to human and animal health.[19][20].
- d. Cry1B.868 and Cry1Da_7 proteins were heated to 25°C, 37°C, 55°C, 75 °C, and 95 °C for either 15 or 30 minutes. Loss of functional activity was noted at temperatures above 75°C. T_{50} was estimated within 15

minutes.[21].

- e. Toxicity study through acute oral gavage was performed on mice, no observable adverse effect level (NOAEL) for Cry1B.868 and Cry1Da_7 protein was established at 5000 mg/kg body weight. Treatment-related effects on animal survival, clinical signs, body weight gain, food consumption or gross pathology were not observed.[19][22].
- f. The bioinformatic analyses of the protein sequence showed no relevant structural similarity to allergens, toxins or other biologically active proteins that could be harmful to human or animal health.[18].
- g. Statistically significant difference was observed between MON 95379 and the conventional control for the protein content in grain. The mean protein content (% dry weight) of MON 95379 grain (9.61) is within the range of protein contents described in literature (8.27 to 13.33) and ILSI (5.72 to 17.26). Differences noted are not biologically relevant in terms of safety.[7][8].
- h. Statistically significant difference between corn MON 95379 and conventional corn was noted for the following proximates:
 - i. For carbohydrates by calculation, the difference was 0.50% dw.
 - ii. For nine amino acids (alanine, glutamic acid, isoleucine, leucine, methionine, phenylalanine, serine, threonine, and valine) the mean difference was between 0.011% and 0.096% dw.
 - iii. For copper, iron, zinc, manganese, and phosphorus the mean differences were 0.18 mg/kg dw, 0.81 mg/kg dw, 1.46 mg/kg dw, 0.62 mg/kg dw and 0.010% dw, respectively.
 - iv. For linolenic acid, the difference was -0.023% total fatty acid. For vitamin A, the difference was 0.082 mg/kg dw.

The difference for these proximates was less than the corresponding conventional control range value and within the natural variability. Thus, are not biologically relevant or significant in terms of food and feed safety.[7][8].

STRP's Conclusion

After a thorough and scientific review and evaluation of the documents provided by Monsanto Philippines, Inc., relevant to corn MON 95379, the STRP found scientific

evidence that the regulated article applied for Direct Use as Food and Feed or for Processing (FFP) is as safe as its conventional corn counterpart and shall not pose greater risk to human and animal health.

BAI's Assessment

1. Toxicological Assessment

- a. Digestibility assessment of the novel proteins Cry1B.868 and Cry1Da_7, has shown that the T_{50} when subjected to pepsin is less than 0.5 minutes and when pancreatin was used T_{50} resulted to be below 5 minutes. This indicates that the protein is rapidly digested, thus will not pose any safety concern to animal health.[20].
- b. The heat inactivation of Cry1B.868 is within 15 minutes at above 75°C, while for Cry1Da_7 it is within 0.5 minutes. Loss of protein integrity and functional activity was observed.[19][21].
- c. FASTA and TOX_2010 database showed no structural relevant similarities between Cry1B.868 and Cry1Da_7 protein sequences with other known toxic or other biologically active proteins that would be harmful to human or animal health.[18].
- d. Acute oral gavage was performed in mice. NOAEL is established at 5000 mg/kg body weight. No mortalities, no treatment-related clinical signs, no effects on body weight parameters, change in food consumption and no macroscopic changes at necropsy were observed. Since no evidence of mammalian toxicity has been reported, the protein is highly unlikely to pose a risk to animal health.[19][22].

2. Allergenicity Assessment

- a. Digestibility and degradation using pepsin and pancreatin enzymes was evaluated, and results have shown the T_{50} is below 0.5 min. Thus, the protein will be likely rapidly digested in gastric and intestinal digestion and will likely not pose animal health concern.[19].
- b. When the novel proteins were subjected to heat inactivation, T_{50} for Cry1B.868 and Cry1Da_7 is within 15 minutes at above 75°C. Decline in the functional activity of the proteins was observed.[19].

- c. Results using FASTA sequence alignment tool demonstrate lack of structural and immunological relevant similarities with known allergens, gliadins, and glutenins.[18][21][23].

3. Nutritional Data

- a. Grain compositional analyses has shown no statistical differences in ash, total fat, and antinutrients between grains of corn MON 95379 and its conventional counterpart.[7][6].
- b. Forage compositional analyses have shown no statistical differences in carbohydrates, fiber and mineral levels.[7][6].
- c. Statistically significant differences for protein and proximate composition (alanine, glutamic acid, isoleucine, leucine, methionine, phenylalanine, serine, threonine, valine, linolenic acid, carbohydrates by calculation, copper, iron, manganese, phosphorus, zinc, and vitamin A) were noted between corn MON 95379 and its conventional counterpart. However, the levels of analyte are within the 99% tolerance intervals, thus differences are not biologically relevant.[7][6].

BAI'S Conclusion

After a thorough and scientific review and evaluation of the documents provided by Monsanto Philippines, Inc., relevant to corn MON 95379, BAI found scientific evidence that the regulated article applied for Direct use as food, feed, and or processing is as safe as its conventional counterpart and shall not pose any significant risk to animal health.

BPI PPSSD's Assessment

1. Toxicological and Allergenicity Assessment

- a. Bt-produced Cry1B.868 and Cry1Da_7 proteins were used for the safety assessment. The Bt-produced proteins are structurally and functionally equivalent to the plant-produced proteins present in corn MON 95379 based on the N-terminal sequence analysis, peptide mass mapping, functional activity assay, Western blot analysis and glycosylation analysis.[24][25].

- b. The *in vitro* assay and the SDS-PAGE analysis showed that both Cry1B.868 and Cry1Da_7 proteins are rapidly degraded in gastric fluid which implies that these proteins are unlikely to be toxic and allergenic.[19].
- c. It was observed that both Cry1B.868 and Cry1Da_7 at 75°C and above lost its functional activity to >98% with respect to the control heated at 15 and 30 minutes. The SDS-PAGE also showed the visible evidence of fading bands indicating the denaturation.[21]
- d. Bioinformatics analysis and tools confirmed that Cry1B.868 and Cry1Da_7 proteins have no significant homology with any known toxins and allergens.[26].
- e. Assessment of toxicity through acute oral gavage in mice resulted to NOAEL at 5000 mg/kg bw, no treatment related effects on survival, clinical observation, body weight gain, food consumption or gross pathology was observed.[25].
- f. It was observed that the Cry proteins were present in all plant tissue and are highest in the grains of the plant. The percentage of Cry1B.868 in the grains is 0.0271% or 271 ppm and for Cry1Da_7 is 0.00026% or 2.6 ppm of the total grain protein.[27].

2. Nutritional Data

- a. Grain and forage compositional analyses of samples from corn MON 95379 demonstrated statistical differences in terms of protein and carbohydrates. The difference noted is within the range of the literature values and ILSI database and can be attributed to the natural variation within the conventional control grown at multiple locations.[8].
- b. Nine amino acids found in corn grains namely: alanine, glutamic acid, isoleucine, leucine, methionine, phenylalanine, serine, threonine, and valine, were found significantly different from the conventional control. However, the difference is not biologically relevant since all values are within the range of literature value.[8]
- c. Safety assessment based on the nutritional data indicates that there is no significant difference between the proximate, fiber, amino acid, fatty acid, mineral, and vitamin levels of corn MON 95379 and conventional corn that can be considered biologically relevant.[8].

BPI-PPSSD's Conclusion

After a thorough and scientific review and evaluation of the documents provided by Monsanto Philippines, Inc., relevant to corn MON 95379, BPI-PPSSD found scientific evidence that the regulated article applied for direct use as food, feed, and or processing is as safe as its conventional counterpart with regards to substantial equivalence and food safety.

DENR-BC's Assessment

- a. It is less likely that the regulated article would persist in the environment in case of unintended release. Corn does not grow in unmanaged or uncultivated habitats.[28][29][30][31].
- b. Corn has a history of safe use, the regulated article is substantially equivalent to its conventional counterpart, and the likelihood that the regulated article becomes invasive or produces a weedy type of corn is remote.[28][29][30][31].
- c. The introduced gene products are not harmful if ingested by non-target organisms and other wildlife, since the endotoxin derived from the *cry* genes in *Bacillus thuringiensis* is only harmful to its target lepidopteran insect pests.[28][29][30][31].
- d. The project description report (PDR) indicates the environmental management plan indicating the possible risk and harm to the environment particularly on biodiversity, as well as mitigating measures and contingency plan.[28][29][30][31].

DENR-BC's Conclusion

After a comprehensive review and evaluation of the documents and scientific evidence from literature submitted by Monsanto Philippines, Inc. concerning its application for direct use for food, feed, or for processing of corn MON95379, the DENR-BC considered that the regulated article poses no significant adverse effect to the environment and non-target organism.

DOH-BC's Assessment

- a. Corn has a long history of safe use and is one of the world's leading cereal crops. Its products are used in food, products (oil, grits, meal, flours,

ethanol, syrup, starch) and feed (hulls, gluten, hominy).[1].

- b. Corn MON 95379 was developed through an *Agrobacterium*-mediated transformation. This insect protected corn produces two insecticidal proteins Cry1B.868 and Cry1Da_7 which confers lepidopteran insect pest resistance.[4].
- c. *Bacillus thuringiensis*, the donor organism is not toxic or allergenic, use of Bt as pest control in agriculture has a long history of safe use. The Cry proteins produced have undergone rigorous and extensive toxicity and allergenicity studies showing no adverse effect to human health.[4].
- d. Assessment of digestibility showed that at least 99.8% of the intact Cry1B.868 and Cry1Da_7 proteins were completely digested within 0.5 minutes. This indicates that the protein is highly unlikely to pose any safety concern to human or animal health.[6]
- e. Heat treatment on the Bt-produced proteins demonstrate that Cry1B.868 and Cry1Da_7 proteins are heat labile and behave with a predictable tendency toward protein denaturation and loss of functional activity at elevated temperatures.[19].
- f. Potential toxicity of Cry1B.868 and Cry1Da_7 proteins was assessed through the FASTA sequence alignment tool using the TOX_2020 database, results showed that there is no alignment with an E-score of ≤ -5 . [18].
- g. The amino acid sequence of Cry1B.868 and Cry1Da_7 proteins produced in corn MON 95379 was found to have no similarities to any anti-nutritional proteins or any known protein toxins.[19].
- h. As confirmatory evidence to support safety of corn MON 95379 an acute oral mice toxicity study was conducted, Cry1B.868 and Cry1Da_7 proteins were administered by oral gavage. There were no treatment-related effect on survival, clinical observation, body weight gain, food consumption or gross pathology noted. NOAEL for Cry1B.868 and Cry1Da_7 proteins was considered to be 5000 mg/kg bw.[19].

DOH-BC's Conclusion

Based on the evaluation of available literature and supporting documents presented, corn MON 95379 applied for direct use as food, feed or for processing (FFP) is safe as its conventional counterpart except for its herbicide tolerance and hybridization traits.

Use of this event in its usual context is not expected to pose any new or additional risk to human health.

SEC Expert's Assessment

- a. Recent and relevant data on corn production, consumption and trade show that corn is a critical feed ingredient, thus demand is expected to rise.[32][33][34][35][36][37].
- b. The GM product will not drastically affect the current patterns of production, consumption and trend, rather it can aid in the reduction of projected deficit in livestock produce and feeds materials in the country.[38][39].
- c. The product is not intended to be commercially grown, thus it is less likely that it would affect the cultural practices of a specific ethnic group.[84].

SEC Expert's Recommendation

After a thorough and scientific review and evaluation of the documents provided by Monsanto Philippines, Inc., relevant to corn MON 95379, the SEC expert recommends the approval and issuance of biosafety permit due to socio-economic, ethical and cultural impact concerns of the said GM product.

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