ASSESSORS' CONSOLIDATED REPORT ON SYNGENTA PHILIPPINES INC.'S APPLICATION FOR COMMERCIAL PROPAGATION OF CORN MIR 162

EXECUTIVE SUMMARY

On September 30, 2016, Syngenta Philippines Inc. submitted corn MIR162 for commercial propagation, as original application under the DOST-DA-DENR-DOH-DILG Joint Department Circular (JDC) No. 1 s2016.

Using modern biotechnology methods, Syngenta has developed MIR162 maize to produce the Vip3Aa20 and phosphomannose isomerase (PMI) proteins. The Vip3Aa20 protein is active against a number of significant lepidopteran pests of maize. The pmi gene, also known as manA, encodes the PMI protein, which was utilized as a selectable marker during the development of MIR162 maize. MIR162 maize products can be used in a similar way as those derived from conventionally-produced maize.

This application was assessed in accordance with the Article VI. Commercial Propagation of Regulated Articles of the JDC No.1. This article covers the basic biosafety policies, procedural requirements and guidelines in carrying out the risk assessment of plants carrying single transgene for commercial propagation. Focus of the risk assessment is on food and feed safety of the GM product.

Under the JDC No.1 s2016, the assessors for Syngenta Philippines Inc.'s corn MIR162 for commercial propagation were the following:

- Two (2) members of the Scientific and Technical Review Panel (STRP) - for evaluation of the applicant's submitted risk assessment report.
- Department of Environment and Natural Resources (DENR) – for the determination of the environmental impact of MIR162 application.
- Fertilizer and Pesticide Authority (FPA) – for determination if the applicant is duly licensed as a pesticide handler in accordance with Presidential Decree No. 1144 and if tolerance levels and good agricultural practices have been established for registration for the transformation event.
- Socio-economic, ethical and cultural (SEC) expert – to evaluate SEC impact of the said application

After reviewing the documents submitted by the applicant, the two members of the STRP find scientific evidence that the regulated article applied for commercial propagation is safe for human and animal health, and the environment as its conventional counterpart. Likewise, DOH, DENR, and SEC expert recommended for the issuance of Biosafety Permit for Corn MIR162. In addition, FPA found that Syngenta Philippines Inc. is a duly licensed pesticide importer, exporter, indentor and national distributor of agricultural pesticides.

BACKGROUND

In accordance with Article VI. Section 15 of the JDC, no regulated article shall be released for commercial propagation unless: (1) a Biosafety Permit for commercial propagation has been secured in accordance with the Circular; (2) it can be shown that based on field trial conducted in the Philippines, the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart; (3) food and feed safety studies show that the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart, consistent with CODEX Alimentarius Guidelines on the Food Safety Assessment of Food Derived from the Recombinant-DNA and protocols of the DOH and BAI on feeding trials; and (4)if the regulated article is a pest-protected plant, its transformation event that serves as plant-incorporated protectant (PIP) has been duly registered with the Fertilizer and Pesticide Authority (FPA).

The BPI Biotech Office forwarded the complete dossier to the assessors and its respective agencies for their evaluation on corn MIR162 application submitted by Syngenta 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 ASSESSMENT AND RECOMMENDATION

In the Philippines, maize is the second most important grain crop grown in approximately 2.61 million hectares. According to BAS (2015), the corn production reached 7.7 million MT in 2014, 5.33% above the 2013 output of 7.38 million MT due to the increasing demand for yellow corn which is primarily used as the main ingredient in animal feed following the steady growth of the livestock industry. Domestic yellow corn production has lagged behind this local requirement so the country has to import the deficit to match the demand. In 2014 the Philippines imported 589,650 tons of corn from Thailand, Argentina and other corn exporting countries (Global Trade Atlas, 2015).

I. HOST ORGANISM

Maize as source of key nutrients

Maize contains some amounts of protein, fat, carbohydrates and dietary fiber but it is not typically consumed for specific nutrients. Few anti-nutrients are reported to occur in maize. Phytic acid reduces availability of phosphorus, especially in mono-gastric animals. Other anti-nutrients such as raffinose and trypsin inhibitor are not considered nutritionally significant in maize.

2, 4-Dihydroxy-7methoxy-2H-1, 4-benzoacin (DIMBOA) has been described as potential toxicants in maize leaves and roots; levels vary by varieties and decline as plants grow.

Maize has been listed as a "less common allergenic food" but the presence of a specific food on the list of less allergenic food merely indicates that it has been listed in one or more report as a cause of food allergy and does not indicate the prevalence or potential as an allergenic food.

Maize use as food and feed

About 20% of Filipinos use maize as staple cereal. Food products are derived from wet milling, dry milling and distillery as soups, edible oil, flakes, chips, biscuits, sauces, beer, whisky, etc. Sweet corn is basically for human consumption, although by-products from processing are used as animal feedstuffs.

Field maize is used mainly for animal feeds and for processing, and thus enters the food chain in the form of processed products. Maize is the preferred feedstuff in livestock production as a processed whole grain, as a by-product of the milling industry or as silage (Newcomb, 1995).

Maize consumption pattern

Usual consumption pattern of the product by population subgroups. Maize is widely used as feedstuff; however, a large part of the grain production enters the food chain. Typically, 70-80% of maize grain is used as feed, 15-20% is used for food and the rest for industrial purposes (paper, plastics, and cosmetics).

II. TRANSGENIC PLANT

MIR162 is approved for food use in Argentina, Australia, Belarus, Brazil, Canada, Colombia, China, EU, Indonesia, Japan, Kazakhstan, Korea, Malaysia, Mexico, New Zealand, Philippines, Russian Federation, South Africa, Taiwan, United States, Uruguay, and Vietnam.

It is not expected that consumption pattern would change with the introduction of MIR162 in the market. The amount of maize consumed as food is not likely to change as it is today.

On the other hand, MIR162 is approved as feed use in Argentina, Brazil, Canada, China, Colombia, EU, Japan, Korea, Malaysia, Mexico, Philippines, Russian Federation, South Africa, Turkey, United States, Uruguay, and Vietnam.

III. THE DONOR ORGANISM

The donor organisms used for corn MIR162 were **vip3Aa20 gene**, vegetative insecticidal protein from *Bacillus thuringiensis* and phosphomannose isomerase gene, **pmi** (as selectable marker) from *Escherichia coli*.

According to the STRP, there have been some tests that have indicated that Vip3Aa proteins are non-toxic to humans. Since Vip30Aa isolates are proteins, allergenic potential was also considered. *Bacillus thuringiensis* is not considered to be a source of allergic proteins. A comparison of the amino acid sequence of 80 amino or identity at the level of eight contiguous amino acid residues resulted to minimal allergenicity in Vip30Aa.

All potentially inserted regulatory sequences have been adequately described in the risk assessment report: the locations in the vector, size, function, and origins of the elements. Only the vip3Aa20 gene and phosphomannose isomerase (PMI) gene are the introduced expressible sequences inserted in the vector. No antisense has been identified. Also, the experimental protocol was included.

Bacillus thuringiensis is known to be non-toxic and non-allergenic to mammals. If ingested, the protein will be broken down by enzymes. There are no evidences of sickness or infection after ingestion/exposure.

On the other hand, neither the Vip3Aa20 protein nor the PMI protein shows significant amino acid sequence similarity to known or putative mammalian toxins or to allergenic protein sequences that are biologically relevant or have implications for allergenic potential.

IV. THE TRANSFORMATION SYSTEM

There are three methods of transformation: Agrobacterium tumefaciens-mediated transformation, Biolistics, and Protoplasts. According to Negrotto et al (2000), Agribacterium-mediated transformation yields a maximum success rate of 90% while Biolistics yields a maximum success rate of 50% in corn.

On the target of genetic modification, the STRP stated that nuclear DNA is more appropriate to modify than mitochondrial DNA since it codes for proteins of all functions; unlike the mitochondrial DNA which only codes for metabolic processes. Also, rate of mutation is higher in mitochondrial DNA than in nuclear DNA. Further, the experimental protocol was completely provided. The transformation protocol has elaborated the steps: insertion to the vector, transformation of *Agrobacterium tumefaciens*, infection of corn embryo, and tissue culture.

V. INSERTED DNA

There is only one insertion site for the gene construct: the region between restriction enzymes HindIII and Xmal. Southern blot analyses demonstrated that the T-DNA insert contains the following elements enumerated. Nucleotide sequencing additionally determined that the MIR162 maize TDNA insert did not locate within any known Zea mays gene. Further, no novel open reading frames were created that spanned either the 5′ or 3′ junctions between the T-DNA and Z. mays genomic sequences.

The STRPs also concurred that southern blotting and nucleotide sequencing demonstrated the integrity and order of genetic elements with each insertion site. There are Southern analysis of MIR162 maize with specific probes for each genetic element found in the dossier. The 8.4 kb insert of pNOV1300 used to create transformation Event MIR162 maize, together with the positions of the recognition sequence for KpnI, SphI, HindIII, and XmaI restriction enzymes used in the Sothern Blot analysis with the probes.

Truncations and deletions were identified and determined. The truncations in both left and right borders were briefly described. These occurred during the transformation process. These deletions have no effect on the functionality of the DNA insert, this phenomenon was previously observed in transformations with *Agrobacterium tumefaciens*.

The truncations and deletions have no effect on the functionality of the DNA insert; also, there is no creation of novel chimeric ORFs as determined by ORF analysis. There is no other sources/reference that says there are transgenic crops expressing the main transgene except for Bt cotton. Currently, there are cotton hybrids with the Vip3Aa gene crossed with other cotton varieties.

The STRPs also noted that no hybridization bands were detected for genomic samples, which mean that MIR162 maize does not contain any backbone sequences from the transformation plasmid pNOV1300.

VI. GENETIC STABILITY

Genetic stability can be shown by Southern blot hybridization; a hybrid must have a consistent blotting pattern over several generations before it can be considered stable. After performing Southern blot on generation BC1F1, BC2F1, and BC4F1 using restriction enzyme Acc651 with vip3Aa19 as probe, all three generations have the same blotting pattern and band sizes observed. Thus, MIR 162 is considered genetically stable.

Segregation was assessed by the appearance of a color response in an ELISA which indicates the presence of the target molecule in the sample. ELISAs have been used for detecting various proteins, identifying viruses and bacteria, and determining the presence of low-molecular-weight compounds in a wide range of biological samples. To increase the specificity of the primary antibody and to ensure the reliability of the antibody preparation, monoclonal antibodies are often used for diagnostic ELISAs.

VII. EXPRESSED MATERIAL

Expression levels were measured at seed maturity except for pollen and silk which were taken at anthesis. The expression of the Vip3Aa20 gene and pmi gene did not alter the original metabolism of maize or the other agronomic characteristics of maize. These genes were expressed for the purpose of insect resistance and antibiosis for some Lepidopteran species.

VIII. TOXICOLOGICAL ASSESSMENT

Vip3Aa20

Simulated mammalian gastric fluid was prepared. Pepsin is the enzyme used in the digestibility test. A simulated mammalian gastric fluid without pepsin was prepared as negative control. No more than 60 kDa fragment was detected after 1 minute, but no fragments detected by 2 minutes which mean it takes 2 minutes to breakdown the Vip3Aa20 protein. These results were determined by Western Blot and SDS-PAGE, both methods are used for protein quantification.

Vip3Aa20 protein has denatured and rendered unstable at 65°C. This is determined by bioassay against *Spodoptera frugiperda* (fall armyworm). The higher the mortality rate means that the protein is still intact. An insignificant mortality rate means that the protein became unstable. After running Protein Blast for amino acid sequence comparison of Vip3Aa20, there is no homology with known toxins.

Acute Oral Gavage was also performed on mice. A dose of 1,250 mg Vip3Aa20/kg body weight produced no adverse effects on the mice. On the other hand, the Source of the test protein for MIR162 VIP3A-016 is a bacterial protein. Vip3Aa20 from MIR162VIP3A-016 and MIR162 maize both have the predicted molecular weight of ca. 89 kDa and immunologically cross-react with the same anti-Vip3A antibody, as shown by Western blot analysis. Vip3Aa20 proteins from both sources were also found to have comparable bioactivity against the lepidopteran larvae.

Phosphomannose isomerase (PMI)

Stimulated mammalian intestinal fluid was prepared. Pepsin is used in the digestibility study. No intact PMI detected at immediate sampling time. PMI rapidly degraded in the simulated mammalian intestinal fluid, thus this protein expected to be digested quickly in a mammalian intestines.

PMI protein started to become unstable at 37°C then enzymatic activity decrease at 55°C, as temperature increases up until 95°C where there is complete loss of enzymatic activity. After running Protein Blast, PMI protein had no homology with known toxins.

Furthermore, acute Oral Gavage was performed on mice. A dose of 3030 mg PMI protein/kg body weight resulted no mortality, no clinical signs of toxicity, and no significant difference in weights.

Western blot analysis of PMI proteins extracted from MIR 162 maize leaf tissue and from *E. coli* showed the expected molecular weight for both proteins and also cross-reacted with the same anti-PMI antibody.

The expression of Vip3Aa20 and PMI are independent of each other, and they have separate gene expression cassette in one gene construct. The first gene expression cassette is ZmUbilInt, Vip3Aa20 coding region, and 35S 3' polyadenylation sequences. The second gene expression cassette is ZmUbilInt, PMI coding region, and nopaline synthase (NOS) polyadenylation sequence.

Vip3Aa20 and PMI were expressed in the cytoplasm, thus there was no cellular localization sequences present. In addition, the STRPs concurred that there was no biological interaction between Vip3Aa20 which is an insecticidal protein and PMI which is an enzyme. Vip3Aa20 gene encodes for the Vip3Aa20 protein that disrupts the midgut transmembrane of certain lepidopteran pests and eventually kills the pests. While PMI was used as a selectable marker that helps plant cells to be able to survive and grow on media containing mannose as the primary energy source.

Lastly, Vip3Aa proteins had no enzymatic activities since its function is for insect resistance; while PMI catalyzes the isomerization of Mannose-6-phosphate into Fructose-6-phosphate.

IX. ALLERGENICITY ASSESSMENT

Vip3Aa20

For allergenicity assessment of Vip3Aa20, stimulated mammalian intestinal fluid was prepared. Pepsin is used in the digestibility study. Similar results on toxicological assessment was shown. Vip3Aa20 protein has denatured and rendered unstable at 65°C. This was also determined by bioassay against *Spodoptera frugiperda* (fall armyworm).

After running Protein Blast for amino acid sequence comparison of Vip3Aa20, there is no homology with known allergens. No bands representing glycosylated Vip3Aa20 were visible upon DIG Glycan analysis, same goes for the Vip3Aa20 produced by *E. coli*. There are no other physico-chemical properties shown. The molecular weight of Vip3Aa20 protein is not within 10-70 kDa range, it is 89 kDa.

In addition, the prevalence in food percent of total protein was <=0.01%. Serum screening was not necessary since Vip3Aa20 protein had no significant amino acid sequence identity to known allergenic proteins.

PMI: Phosphomannose isomerase

Stimulated mammalian intestinal fluid was prepared. Pepsin is used in the digestibility study. No intact PMI detected at immediate sampling time. PMI rapidly degraded in the simulated mammalian intestinal fluid, thus the protein was expected to be digested quickly in a mammalian intestines.

As same results on toxicological assessment, PMI protein also started to become unstable at 37°C then enzymatic activity decreases at 55°C, as temperature increases up until 95°C

where there is complete loss of enzymatic activity. After running Protein Blast, PMI protein had no homology with known allergens. Also, PMI protein is not glycosylated and its molecular weight was within 10-70 kDa range, 42.8 kDa.

Serum screening was performed since there was one region of sequence of eight contiguous identical amino acids between PMI and α-paravalbumin from Rana speciesCH2001. Fortunately, the patient's serum did not recognize any region of the PMI protein as an allergenic epitope.

X. Nutritional Data

Proximate Analysis

The levels of the proximates for ash, NDF, and starch are noted to have statistically significant differences. However, the differences observed were small and the average values observed for these proximates in MIR162 were within the ranges of values observed for non-transgenic grain.

Fatty Acid Composition

The differences observed were small (0.65 and 3.21% respectively) and the average values observed for these fatty acids in MIR162 were within the ranges of values observed for non-transgenic grain.

Mineral Composition

Calcium, iron and phosphorus present in corn are noted to have statistically significant differences. However, the differences observed were small and the average values observed for these minerals in MIR162 were within the ranges of values observed for non-transgenic grain.

Vitamin Composition

Vitamin A (β-carotene), Vitamin B6 (Pyridoxine), and Vitamin E (α-tocopherol) present in corn are noted to have statistically significant differences when comparing the MIR162 hybrid and the non-transgenic corn. However, the differences observed were small and the average values observed for these minerals in MIR162 were within the ranges of values observed for non-transgenic grain.

Amino Acid Composition

Biological relevance of statistical difference is not applicable since there are no statistical differences among the 18 amino acids.

For the key nutrients and anti-nutrients, one isogenic hybrid was included in the comparison with SE comparator. They are all grown under the same environmental conditions. The data derived from the test (transgenic) line were within the observed and reported range. The statistical differences were not biologically relevant since the differences were small and values are within both observed ranges and reported ranges from literatures.

XI. THE HOST PLANT ENVIRONMENT

Reproduction Biology

Corn is generally considered as highly cross-pollinated crop. The male part (tassel) is on the top of the plant while the female part (ear shoot) is on the middle part of the plant. Even though both reproductive parts are in the same plant, the flow of pollen is towards the ears of the neighboring plants. It is highly difficult for plants like corn to self-pollinate.

The STRPs also agreed that pollinating agents would include wind and winged insects like bees, butterflies, and other winged insects that may be present in the field. Existing accessions of Teosintes were found in Ilocos Norte and reported as the only wild relative that can cross pollinate with corn easily. According to studies, there are no known sexually compatible cultivated species in the Philippines.

Maize is considered to have evolved from the Mexican annual teosintes (Z. mays ssp. parviglumis). It is the only wild relative that can easily cross pollinate and produce fertile hybrids. Teosinte still has existing accession, no other corn relatives and weed species sexually compatible with corn.

Agricultural Practices

MIR162 maize is for resistance of certain Lepidopteran insect pests. There will be no changes in habitat or geographical distribution across major producing regions in the country since corn cultivation is widely distributed throughout the country.

The genetic modification results in an altered reaction to pests and/or diseases. Since MIR162 maize is only for insect resistance, both MIR162 and non-MIR162 are susceptible to diseases. MIR162 maize shows resistance to only a number of insect pests. It shows high resistance to common cutworm, and moderate resistance to corn semi-looper and leaf feeding by corn earworm.

Non-target pests including corn plant hopper (*Stenocranus pacificus*), *Dalbulus* sp., common grass derbid (*Proutista moestra*), and corn leaf aphid (*Rhapalosiphum maidis*) are commonly found in the test fields in Laoac, Pangasinan and Tampakan, South Cotabato. On the other hand, Curvularia leaf spot is the most prevalent disease in both MIR162 and non-transgenic corn plants across season and across field sites. Southern corn leaf blight, corn rust, brown spot and bacterial stalk rot are the other common diseases in all sites.

XII. CONSEQUENCES OF OUTCROSSING

Outcrossing to related varieties
The potential for gene introgression to occur from MIR162 corn to sexually compatible wild relatives and considered whether such introgression would result in increased weediness.

Outcrossing to wild species
While some teosinte may be considered weeds in certain instances, they are also used by some farmers for breeding improved maize. Teosinte is described as being susceptible to many of the same pests and diseases that attack cultivated corn. In the wild, introgressive hybridization from corn to teosinte is currently limited, in part, by several factors including geographic isolation, differing degrees of genetic incompatibility, differences in flowering time in some cases, developmental morphology and timing of the reproductive structures, dissemination, and dormancy.

Risk mitigating measure
The STRPs agreed that the time isolation of 25 days based on the biology and reproductive cycle of the corn plant is possible in order to prevent out-crossing with other corn varieties planted in adjacent fields.

XIII. WEEDINESS POTENTIAL

The potential for gene introgression to occur from MIR162 corn to sexually compatible wild relatives and considered whether such introgression would result in increased weediness.

Further, the time to maturity was assessed. Maturity depends on the variety of corn.

However, corn seed is already viable 85-90 days after planting. It was recorded in the contained study at UP Mindanao that it takes 103 days to maturity. There are changes in time to maturity in the multilocation trial conducted. Combined analysis showed that Maximus MIR162 reached 50% silking and tasseling earlier than its conventional counterpart. MIR162 reached 50% silking and tasseling at 56 days after planting (DAP).

Corn varieties have been widely cultivated for a many years now; however, there are no records showing that corn plants have become weeds in the wild. It cannot survive without aid from man since it was thoroughly domesticated for years. Both Maximus MIR162 and its conventional counterpart were susceptible to common diseases and insect pests, and were heavily damaged under sever infestation and infection. Only the Maximus MIR162 showed high resistance to common cutworm and moderate resistance to corn semi- looper and corn earworm, compared to the conventional counterpart.

XIV. SECONDARY AND NON-TARGET EFFECTS

Laboratory Studies

Vip3Aa20-Mouse

The assay used in Acute oral toxicity by acute oral gavage of corn oil with a dose as high as 1,250 mg Vip3Aa20/kg body weight. This study was conducted for 15 days. The administration of 1,250 mg Vip3Aa20/kg body weight to mice has produced no adverse effects. In addition, there is no evidence of Vip3Aa20 gene/protein toxicity.

Phosphomanose Isomerase (PMI) -Mouse

The assay used in Acute oral toxicity by acute oral gavage of corn oil with a dose as high as 5,050 mg PMI/kg body weight. This study was conducted for 14 days. The administration of 5,050 mg PMI/kg body weight to mice has produced no adverse effects. Thus, there is no evidence of PMI gene/protein toxicity.

Field Studies

There are two sites in Season 1 and three sites in Season 2. The locations are: Laoac, Pangasinan and South Cotabato for Season 1; and Laoac, Pangasinan, Tampakan, South Cotabato, and Angadonan, Isabela. Experiments were conducted in the greenhouse of Syngenta R&D station in General Station City on June-July 2014. Also, there are two seasons for the field trials: 2011 Dry and 2012 Wet.

Leaf damage rating using BPI harmonized rating scale and laboratory and green-house bioassay using leaf and whole plants are the sampling protocols used.

The results showed that for common cutworm (*Spodoptera litura Fabricius*), additional studies were conducted at Syngenta R&D station in General Santos during 2014, to demonstrate the high dose efficacy of MIR162 against *S. litura.* Results from leaf disc and whole plant bioassays showed that MIR162 hybrids demonstrated 99 to 100% efficacy against *S. litura* when compared to non-Bt control. Overall, field, polyhouse and laboratory data show that the MIR162 is very effective against the common cutworm. In addition, MIR162 showed moderate level of efficacy against corn semi-looper (*Chrysodeixis eriosoma Doubleday*) in both season, observed damage included few to several pinholes on leaves. Further, MIR162 showed moderate resistance to leaf feeding and lower ear damage rating against corn earworm (*Helicoverpa armigera Hubner*) compared to its conventional counterpart.

On the other hand, MIR162 showed no efficacy against true armyworm *(Mythimna separata Walker)* and Asiatic corn borer (*Ostrinia furnacalis*) across locations and across seasons.

With this, MIR162 cannot effectively control Asiatic corn borer and true armyworm. Other means of control must be implemented in order to prevent the reduction of yield but it has

reduced pesticide and input costs to farmers since MIR162 showed moderate resistance to corn earworm, corn semi-looper and common cutworm.

Thus, after a thorough and scientific review and evaluation of the documents provided by Syngenta Philippines, Inc. relevant to Corn MIR162 Application for commercial propagation, the STRPs find scientific evidence that the regulated article applied for propagation is as safe as its conventional counterpart and is not expected to pose any significant risk to human and animal health.

DOH 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 Commercial Propagation (CP) of CORN MIR162. I/We,

Find that the regulated article applied for Commercial Propagation (CP) 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. Find that the regulated article applied for Commercial Propagation (CP) does not require changes in the usual practices as described in the phases/stages of biotechnology project activities: seed production, seed processing and packaging, dispatch of finished goods (corn seeds) to channel. As such, the regulated article is as safe as its conventional counterpart and is not expected to pose any significant risk to human and animal health and environment.
2. On the risk to health matrix, the Syngenta Philippines, Inc., rated the phases/stages of activities a very low incident/exposure potential rating.
3. Scientific pieces of evidences provided references i.e. literatures show that regulated article applied for Commercial Propagation is as safe as conventional counterpart and shall not pose any significant risk to human and animal health and on the environment.
4. It is suggested that the Bureau of Plant Industry (BPI) ensure the following:
    a. Strict monitoring of the regulated article from the port of entry to the trader's/importer's storage/warehouse as stated in Section 32 of the JDC No. 1 Series 2016,
    b. The BPI to include in the issuance of permit for the release of this product the following conditions:
    b.1. Any spillage (during unloading and loading/hauling and transport unloading and storage) shall be collected and cleaned up immediately.
    b.2. Transportation of the consignment from the port of entry to any destination within the country shall be in closed containers.
    b.3. There shall be a clear labeling of the product from the importation down to all levels of marketing stating that it is only for the purpose of commercial propagation and is not to be used as planting materials.
5. 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 Commercial Propagation (CP) of CORN MIR162.

DENR 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 Commercial Propagation of Corn MIR162, here under are the observations:

1. Evaluation of the application and project description report (PDR) submitted by the proponent, including the scientific evidences from provided references, literature and other related studies, the Committee accepts that the commercial propagation of the regulated article will not cause any significant adverse effect on the environment (land, air and water) and on non-target organisms, to wit:

- The regulated article has a history of safe use as food and twenty-three (23) countries and as feed in seventeen (17) countries.
- The genetic stability in the transgenic crop over several generations is ensured under contained use and field trial conditions (conducted year 2011 and 2012), such that no unintended horizontal gene transfer shall occur to unrelated species.
- The protein product produced by the transgenic crop will degrade upon exposure to the natural environment.
- Characterization of the inserted gene has shown that the protein product will not increase the weediness potential of the transgenic crop nor will it give the crop characteristics of a pollutant.
- Corn readily produces hybrids with the other varieties of corn in the *Zea mays* species. However, upon continuous hybridization the resistance to insects gradually decreases. (Hanging and negative statement).
- Diversity analyses from the field trial report showed that there were no significant differences in the non-target arthropod diversity among test sites. Also, no significant differences were observed between the regulated article and conventional hybrids. This indicates MIR162 has no negative effects on the corn-associated arthropod biodiversity of corn fields.
- The adoption of the transgenic plant in agriculture will not result in significant changes in cultivation practices that may adversely affect the environment.

The data evaluated supports the conclusion that the regulated article is as safe as its conventional counterpart.

2. The Bureau of Plant Industry (BPI) to further assist in the dissemination of information on the appropriate Insect Resistance Management (IRM) Plan for Corn MIR162 for proper implementation and adherence by growers of the said crop.

The DENR-BC find scientific evidence that the regulated article applied for Commercial Propagation is as safe as its conventional counterpart, and is not expected to pose any significant risk to the environment and to non-target organisms. Any hazards and risks could be managed by the abovementioned measures. Based on the above considerations and with the proponent's sworn statement of accountability, we hereby submit our evaluation relative to Syngneta Philippines, Inc. MIR162 application for biosafety permit for commercial propagation.

SOCIO-ECONOMIC, ETHICAL, AND CULTURAL ASSESSMENT

For the Filipinos, white corn is one of the most important food crops since it is the staple food of 20% of the population, primarily in the Southern Regions of the Visayas and Mindanao. It is also economically important as it is a major ingredient of feeds and many industrial products. Currently, GM corn is the only biotech crop being planted in the country and it has been commercially available since 2003. In 2013, the Philippines placed at No. 12 in the list of top countries planting biotech crops around the world, with the United States being No. 1. According to the International Service for the Acquisition of Agri-biotech Applications (ISAAA), 415,000 farmers planted GM corn in 831,000 hectares in the Philippines in 2014.

Reference: (http://www.gmanetwork.com/news/story/444997/scitech/science/phl-among-world-s-top-planters-of-gm-crops-in-2014#sthash.Juatcmgb.dpuf)

According to the Department of Agriculture, the Philippines used to import Php28 billion worth of corn a year to meet its domestic requirements but it became self-sufficient in 2013 due to high-yielding varieties and new technology.

Reference: (http://www.gmanetwork.com/news/story/368331/money//agri-dept-says-phi-achieved–corn-self-sufficiency –in -2013)

MIR 162 will not drastically change the production patterns as it requires the same cultural practices as the conventional corn varieties. But since it is a genetically-modified corn whose main characteristic is resistance to damage of lepidopteran insects, a major difference in the production processes for food or for feed is the non-application of insecticides. Consumption/utilization as food and feed will not change drastically. With the commercial propagation of MIR162, the country will be able to meet its domestic requirements continuously as it started in 2013. In 2014, it was reported that due to high-yielding seeds and new technology, corn production increased from 3.4 mt/ha to 4.2mt/ha. This translated to a Php60 billion savings from 2010 to 2013.

In addition, basic human needs refer to food, clothing and shelter. These basic human needs may not be negatively affected by MIR 162. As seen in the literature MIR 162 has been approved for use as food and feed in 2010. The introduction of MIR 162 does not have a negative impact on the social participation of farmers in community activities such as crop production since the farmers are still involved in the production process.

After a thorough and scientific review and evaluation of the documents provided by SYNGENTA relevant to Corn MIR162, I recommend for the approval and issuance of biosafety permit of the said GM product.