ASSESSORS' CONSOLIDATED REPORT ON MONSANTO PHILIPPINES' APPLICATION FOR DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING CORN MON89034

EXECUTIVE SUMMARY

On April 30, 2018, Monsanto Philippines Inc. submitted corn MON89034 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 MON89034 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 MON89034 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 MON89034.

Furthermore, the Socio-economic, Ethical and Cultural (SEC) Considerations expert also recommended for the issuance of biosafety permit for this regulated article after assessing the socio-economic, social and ethical indicators for the adoption of Genetically Modified Organisms.

BACKGROUND

In accordance with Article VII. Section 20 of the JDC, no regulated article, whether imported or developed domestically, shall be permitted for direct use as food and feed, or for processing, unless: (1) the Biosafety Permit for Direct Use has been issued by the BPI; (2) in the case of imported regulated article, the regulated article has been authorized for commercial distribution as food and feed in the country of origin; and (3) regardless of the intended use, the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart.

The BPI Biotech Office provided the assessors, except for the SEC expert, the complete dossier submitted by Monsanto Philippines. The SEC expert, on the other hand, was provided with a questionnaire on socio-economic, ethical and cultural considerations that have been addressed by Monsanto in relation to their application.

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

STRP ASSESSMENT AND RECOMMENDATIONS

Based on the documents submitted by the applicant:

A. Host Organism

Corn, has been a staple of the human diet for centuries. Corn grain and its processed fractions are consumed in many food and animal feed products.

Corn also produces anti-nutritional factors such as phytic acid, raffinose and trypsin/chymotrypsins. Phytic acid in corn binds ~60-75% of the dietary phosphorus as phytate. Because of this binding, the availability of phosphorus becomes less for consumption by humans and non-ruminants. Ruminants on the other hand, produce the enzyme phytase that can break down phytate and release bound phosphorus for dietary uptake. The level of phytate in corn grain is ~0.45-1.0% of dry matter. Raffinose is present at ~0.21-0.31% of dw in field corn and 0.1% of dw in sweet corn. It is non-digestible by enzymes in the gastrointestinal tract and is considered as an anti-nutrient because of gas production. The resulting flatulence is a source of discomfort. However, raffinose can be removed by methods used in the processing of corn and corn products such as soaking, cooking, enzyme or solvent treatment and by irradiation. The levels of trypsin and chymotrypsin inhibitors in corn are low to be considered nutritionally significant (White and Pollack 1995).

Corn does not produce significant quantities of toxins, allergens or anti-nutritional factors warranting analytical or toxicological tests. Also, corn is not a common allergenic food, although in some case-studies, allergenic reactions were reported.

B. Transgenic Plant

The following countries have approved the use of MON 89034 for direct use as food and/or for feed or for processing: Argentina (2010), Australia/New Zealand (2008), Brazil (2009), Canada (2008), China (2015), Colombia (for food 2010; for feed 2007), European Union (2009), Indonesia (2011 for food; for feed 2013), Japan (2007), Korea (2009), Malaysia (2015), Paraguay (2013, Philippines (2014), Russian Federation (for food 2014; for feed 2013), Singapore (2011), Taiwan (for food 2013; for feed 2017), USA (2007), Vietnam (2014).

The introduction of MON 89034 is not expected to change the consumption patterns because it has been established to be equivalent in terms of nutritional composition to conventional corn varieties.

C. Donor Organism

The Cry 1A.105 and Cry 2AB2 proteins encoded by the genes cry1A.105 and cry 2AB2, respectively, in the plasmid vector PV-ZMIR245 have been adequately described. Both genes came from Bacillus thuringiensis sequences.

The Cry 1A.105 protein was created by assembling the nucleotide sequences that encodes domains I and II of Cry1AB or Cry1AC, domain III of Cry 1F and the C-terminal domain of Cry1 AC. The Cry1AB and Cry1AC proteins are 100% identical at the amino acid sequence level in domains I and II. The three domains (I, II and III) of Cry proteins are active in the gut of target lepidopteran insects that have specific receptors that recognize these proteins.

The Cry2Ab2 protein sequence was derived from Bac. thuringiensis subsp. kurstaki (Btk). However, there was a one amino acid change that is not biologically relevant. Nucleotide sequences for the chloroplast transit peptide (CTP) from corn ribulose 1,5 bisphosphate carboxylase was added in the N-terminus of the cry2Ab2 in order to direct the delivery and accumulation of Cry2Ab2 in MON 89034 into the chloroplast. The CTP is removed from the mature Cry 2Ab2 upon entry into the chloroplast and is rapidly degraded.

Bac. thuringiensis is common in soil and the long history of the safe use of its insecticidal crystal proteins was backed by extensive safety tests for non-target insects, human beings and animals. Acute oral toxicity study in mice did not show any adverse effects at the dose level of 2072 mg/kg body weight for Cry1A.105 and 2198 mg/kg for Cry 2Ab2.

E. Transformation System

MON 89034 was developed through Agrobacterium-mediated transformation of corn to produce the Bt insecticidal proteins Cry1A.105 and Cry2Ab2 using the binary plasmid vector, PV-ZMIR245. Agrobacterium-mediated transformation is a well-documented process for the transfer and integration of exogenous DNA into a plant's nuclear genome. PV-ZMIR245 contains two separate T-DNAs (hereafter referred to as a 2 T-DNA system). The first T- DNA, designated as T-DNA I, contains the cry1A.105 and the cry2Ab2 expression cassettes. The second T-DNA, designated as T-DNA II, contains the nptII expression cassette that encodes the neomycin phosphotransferase enzyme which confers tolerance to certain antibiotics such as neomycin and paromomycin.

F. Inserted DNA

Molecular analyses confirmed that MON 89034 contains a single copy of T-DNA I containing the crylA.105 and the cry2Ab2 expression cassettes that is stably integrated at a single insertion site and no detectable additional genetic elements. The result was demonstrated by Southern blot analysis and PCR and sequence analysis. In addition, molecular analyses also showed one intact copy of the crylA.105 and the cry2Ab2 expression cassettes integrated at a single chromosomal locus in MON 89034. No additional genetic elements, including backbone sequences from the transformation vector PV-ZMIR245, linked or unlinked to the intact DNA insert, were detected in the genome of MON 89034.

Molecular characterization of MON 89034 by Southern blot analysis demonstrated that the genome of corn line MON 89034 does not contain any detectable plasmid backbone DNA.

H. Genetic Stability

The stability of the DNA insert across multiple generations was demonstrated by Southern blot analyses which demonstrated that the MON 89034 single integration locus was maintained through seven generations; confirming the stability of the insert.

Chi square analysis across four generations of backcrosses of MON 89035 showed the expected segregation ratio of the introduced traits. This was confirmed by (1) ELISA for Cry2Ab2 (2) ELISA for Cry1A.105 (3) PCR re-amplification to show the presence of the two inserted genes and (4) lateral flow format immunoassay for the Cry2Ab2. The results were consistent with the single insertion site for the cry1A.105 and cry2Ab2 expression cassettes.

I. Expressed Material

The levels of the Cry1A.105 and Cry2Ab2 proteins in various tissues of MON 89034 that are relevant to the risk assessment were assessed by validated enzyme-linked immunosorbent assay (ELISA). Tissue samples for analysis were collected from five field trials conducted in the U.S. during 2005, which represent the major corn-growing region of the U.S. and provide a range of environmental conditions that would be encountered in the commercial production of corn. At each site, three replicated plots of MON 89034 and a conventional control hybrid were planted using a randomized complete block field design. Overseason leaf, overseason whole plant, overseason root, pollen, silk, forage, forage root, grain, stover, and senescent root tissues were collected from each replicated plot at all field sites.

The mean Cry1A.105 levels across sites were highest in young leaf (520 µg/g dwt), followed by stover (50 µg/g dwt), forage (42 µg/g dwt), silk (26 µg/g dwt), pollen (12 µg/g dwt), forage root (12 µg/g dwt), senescent root (11 µg/g dwt), and grain (5.9 µg/g dwt). On the other hand, the mean Cry2Ab2 levels across sites were highest in young leaf (180 µg/g dwt), followed by silk (71 µg/g dwt), stover (62 µg/g dwt), forage (38 µg/g dwt), senescent root (26 µg/g dwt), forage root (21 µg/g dwt), and grain (1.3 µg/g dwt).

In general, the levels of the two Cry proteins declined over the growing season, and the two novel proteins do not have a metabolic role in the plant.

J. Toxicological Assessment

For the digestibility study using simulated gastric fluid (SGF) that contained the enzyme pepsin, the Cry1A.105 was digested within 30 seconds. There were no proteolytic fragments observed in the SDS-PAGE gel, except for a very faint band of ~4.5 kDa band visible in the first 20 min of digestion but was not visible after 30 min of digestion. This band is unlikely to pose a health risk because of its small size. Western Blot analysis also demonstrated that the Cry 1A.105 was digested below the limit of detection (LOD) of 1 ng within 30 seconds in SGF (see Figure VI.16 of the reference document FDA BNF 00105). On the other hand, in simulated intestinal fluid (SIF) that contained pancreatin, the digestion of Cry1A.105 was assessed by Western blotting (with LOD of 0.1 ng). The full length protein of was digested below the LOD within five minutes. Fragments of 60, 32 and 30 kDa were visible up to 24 h of digestion (Figure VI.17 of the reference document FDA BNF 00105). The 60 kDa fragment was said to be representative of the tryptic core portion Cry1A.105. This is consistent with other Cry proteins with demonstrated safety. The estimated T50 result in SGF is <30 seconds and the estimated T50 in SIF is <5 minutes.

In addition, the effect of heat treatment on the immunologically detectable levels of the Cry1A.105 protein in corn grain from MON 89034 was evaluated using the Western blot method and image analysis of blot films. The amount of immunodetectable Cry1A.105 protein present in buffer extracts of MON 89034 after heating was below the lower limit of detection, or had decreased considerably relative to their original values. These results clearly demonstrate that the heating of ground corn grain, in a manner similar to the conditions employed for commercial processing, results in the loss of immunodetectable Cry1A.105 protein.

Bioinformatics analyses were performed to assess the potential for toxicity of the Cry1A.105 by amino acid sequence alignment to sequences in the TOXIN5 and ALLPEPTIDES databases. The FASTA algorithm was employed to identify structural and sequence similarities where proteins sharing a high degree of similarity are often homologous in function as well. From comparisons with the TOXIN5 database, the results showed significant sequence similarity to Bac. thuringiensis pesticidal crystal protein Cry1Ac (92% identity in 1,182 amino acid residues, E score=0). This was expected because Cry1A.105 has a significant portion similar to Cry1Ac. This protein and Cry1A.105 did not share any match with other proteins that are known as toxic to human beings and animals. From the ALLPEPTIDES database, there was again a 92.1% identity to Cry1A over 1,177 amino acid with E score =0. Other matches with significant E scores were to Cry homologues and the hypothetical amino acid sequence JMP 134 from Ralstonia eutropha. According to the reference document, there are no indications for any adverse biological activity of the Cry protein homologues or the hypothetical protein from the JMP 134 sequences to non-target species.

Further, an acute oral toxicity assessment was conducted to evaluate potential adverse clinical signs or detrimental effects on mice exposed to E. coli-produced Cry1A.105 protein. Cry1A.105 protein was administered by oral gavage (as two doses about 4 hours apart) to 10 male and 10 female CD-1 mice

at a total dose level of 2072 mg/kg body weight. There were no treatment-related effects on survival, clinical observations, body weight gain, food consumption or gross pathology. Therefore, the No Observable Adverse Effect Levels (NOAEL) for Cry1A.105 was considered to be 2072 mg/kg body weight, the highest dose tested.

Lastly, E. coli-produced Cry1A.105 protein was used as the test protein. An acute oral toxicity study conducted with The E. coli-produced Cry1A.105 protein was shown to be equivalent to the plant-produced Cry1A.105 present in MON 89034.

Meanwhile, in SGF with pepsin, the full length Cry2Ab2 (65 kDa) produced in E.coli was rapidly degraded within 30 seconds. At least 99.4 % and 99.0% of the original amount of protein was digested as shown in the SDS-PAGE gel and by Western Blotting, respectively. No other stable fragments were visible at any time point (0.5-60 min). Therefore, the T50 can be considered to be <30 seconds. While, In SIF with a mixture of pancreatin as enzyme, the full length Cry2Ab2 produced in E.coli was digested within 15 min to at least 97.5% of the original amount. Western Blot analysis showed bands of 60, 55, 50, 40, 12 and 10 kDa were observed. The 60 kDa band was not detectable after 1 h of incubation in SIF. The 55 kDa band was undetected at 24 h incubation time point. The 50 kDa band was still present after 24 h incubation in SIF. The 40 kDa band disappeared after 12 h of incubation in SIF. The 12 kDa band was undetectable after 1 h incubation in SIF. New bands of <50 kDa were detected beginning at 4 h incubation time point. These represented the fragments of Cry2Ab2 produced during incubation and were undetected at the 24 h incubation time point as shown in Figure 1 of the reference document Thorp and Goley. The estimated T50 for Cry2Ab2 in SIF is <15 minutes.

Immunologically detectable Cry2Ab2 extracted in CAPS and NLS buffers from MON 89034 powdered grains that were obtained after heating at 204oC for 20 min, was measured to be below the lower limit of detection of the Western Blot analysis. The reduction in the original amount of protein was reported to be 77% and 70% in CAPS and NLS buffers, respectively. The T50 result cannot be accurately determined. However, the Cry2Ab2 was established to be inactivated by heating, as used in common commercial corn processing methods.

Further, using the FASTA sequence alignment tool, a comparison of the Cry2Ab2 protein sequence was performed with the toxin (TOXIN5) and public domain (ALLPEPTIDES) database sequences. The highest similarity observed was to pesticidal crystal protein Cry2Ab, demonstrating 100% identity over 632 amino acids with an E-score of zero. All remaining alignments with significant E-scores were to Cry protein homologues derived from B. thuringiensis, Paenibacillus popilliae or Paenibacillus lentimorbus. Based on these data, the Cry2Ab2 protein does not share structural congruence with any proteins that may cause adverse effects in humans and animals.

An acute oral toxicity assessment was also conducted to evaluate potential adverse clinical signs or detrimental effects on mice exposed to E. coli-produced Cry2Ab2 protein. Cry2Ab2 protein was administered by oral gavage (as two doses about 4 hours apart) to 10 male and 10 female CD-1 mice at a total dose level of 2198 mg/kg body weight. There were no treatment-related effects on survival, clinical observations, body weight gain, food consumption or gross pathology. The NOAEL for Cry2Ab2 was considered to be 2198 mg/kg body weight, the highest dose tested. The source for the Cry2Ab2 used in the acute oral toxicity study in mice was Cry2Ab2 produced in recombinant E.coli. The plant-produced and E.coli-produced Cry2Ab2 have been established to be equivalent in form and function through a battery of physico-chemical and biochemical tests (molecular weight analysis; N-terminal sequence analysis; MALDI-TOF analysis of tryptic peptides; lack of glycosylation; protein stability test) as well as performance in insect bioassays.

K. Allergenicity Assessment

Bioinformatics analyses were performed to assess the potential for allergenicity of the Cry1A.105 by amino acid sequence alignment to sequences in the allergen AD6 database. The FASTA algorithm was employed to identify sequence similarities and no relevant matches were found. Using the algorithm ALLERGENSEARCH for alignment of eight contiguous amino acid residues, again there was no matches found in the AD6 sequences. The Cry2Ab2 sequence was also compared to the allergen AD6 database sequences using the FASTA algorithm. There was no relevant similarity based on amino acid sequences with known allergens. Using an eight amino acid sliding window for the algorithm ALLERGENSEARCH, there were no immunologically relevant sequences when the Cry2Ab2 sequence was compared to the sequences available in the AD6 database. The analyses demonstrated that Cry1A.105 and Cry2AB2 have no amino acid sequence similarities to known allergens, gliadins and glutelins.

The Cry1A.105 protein produced from the plant and that produced in E.coli migrated at 130 kDa in gels and are both non-glycosylated. The Cry1A.105 therefore is not within the 10-70 kDa molecular weight range. Meanwhile, molecular weight of the intact plant-produced Cry2Ab2 migrated in the same manner on the gel as the E.coli-produced Cry2Ab2 at 61.3 kDa. This size is well within the 10-70 kDa range. The Cry1A.105 present in MON 89034 grain was calculated to be 0.0047% of total protein whereas for Cry2Ab2, it was calculated to be 0.001% of total protein.

L. Nutritional Data

The over-all (combined sites) analyses of proximate amounts of ash, carbohydrates, moisture, protein and total fat from grains and forage of MON 89034 were comparable to grain and forage obtained from the non-transgenic isoline (control). There were significant differences in the amount of carbohydrate in MON 89034 grain as compared to the non-transgenic control at two sites, namely, Site IA and Site OH with values lower and higher than in the control, respectively. For forage, there were differences between those derived from MON89034 forage with those from the non-transgenic control in the amounts of moisture, ash and carbohydrates in only one site each. However, the said discrepancies were within the range of the respective parameters in the commercial reference varieties. Taken together, the proximate composition of grain and forage from MON 89034 were substantially the same as in the non-transgenic corn lines.

As for key nutrient combined-site analyses, statistical differences between MON 89034 and control corn were observed for phosphorus in forage, and 18:0 stearic and 20:0 arachidic acids in grain. The differences observed are generally small (3.4 – 19.2%), considering the range of natural variability, and the mean levels and ranges of MON 89034 are well within the 99% tolerance intervals for commercial corn. The mean levels and ranges of phosphorus in forage, and 18:0 stearic and 20:0 arachidic acids in grain, were also within the ranges in the International Life Sciences Institute Crop Composition Database (ILSI-CCD), as well as within published literature ranges. Therefore, it is concluded that MON 89034 and control corn are compositionally equivalent based on analyses of the combined-site data.

The data for anti-nutrients and secondary metabolites were obtained from the summary of combined sites analyses. The value for the anti-nutrient phytic acid was very slightly higher in the transgenic MON 89034 grain than in the non-transgenic control isoline. However, the difference was not statistically significant. The data for raffinose was not included because the values was found to below the limit of quantitation and were then excluded for further statistical analysis. Statistical difference between the amount of p-coumaric acid in MON 89034 grain with that from the non-transgenic isoline was identified in only one site (Site OH). But the value was within the range derived from the commercial reference varieties. Ferulic acid was present in comparable amounts in the transgenic and non-transgenic control corn lines. Therefore, the contents of phytic acid and secondary

metabolites in grain form MON 89034 can be considered substantially equivalent to those in the non-transgenic isoline.

M. Recommendation

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

BPI-PPSSD and BAI ASSESSMENT AND RECOMMENDATION

Based on the assessments of BAI and BPI-PPSSD:

A. Toxicological Assessment

Digestibility was assessed by western blot in simulated intestinal fluid (SIF) with pancreatinin for Cry1A.105 protein. Results showed that at least 99.5% of the protein was broken down within 5 minutes of of digestion.
Since Cry1A.105 is easily digested in SGF and SIF, this indicates that this protein is unlikely to pose a toxicological risk to human health.

In addition, western blot method and image analysis of blot films also indicated that immunodetectable Cry1A.105 present in CAPS and NLS buffer extracts of MON 89034 after heating was below the LOD or had decreased by > 94% and 78% relative to their original values, respectively. The results demonstrated that heating corn grain in the same temperature as in processing of corn results to loss of immunodetectable Cry1A.105 protein.

Furthermore, bioinformatics analyses using FASTA sequence alignment tool showed that no relevant structural similarities were observed between the Cry1A.105 and human and animal tonxins in the TOXIN5 and ALLPEPTIDES databases thus indicating that Cry1A.105 will not cause toxicity or health risk to human health.

Also, Cry1A.105 protein was administered to 10 male and 10 female CD-1 mice at a total dose level of 2072 mg/kg body weight. No Observable Effect Levels was considered to be 2072 mg/kg body weight, the highest dose tested. Escherichia coli was used as the source protein. The E- coli-produced Cry1A.105 protein has been shown to be equivalent to the plant-produced Cry1A.105 present in MON 89034 based on Immunoblot Analysis, MALDI-TOF Tryptic Mass Map Analysis, apparent molecular weight, Glycosylation Analysis and Functional Activity Assay.

Meanwhile, digestibility was also assessed by western blot in simulated intestinal fluid (SIF) with pancreatinin for Cry2Ab2 protein. Results showed that at least 97.5% of the protein was brokendown within 15 minutes of digestion.Since Cry2Ab2 was easily digested in SGF and SIF, it indicates that this protein is unlikely to pose a toxicological risk to human health.

Further, western blot method and image analysis of blot films indicated that immunodetectable Cry2Ab2 present in CAPS and NLS buffer extracts of MON 89034 after heating was below the LOD or had decreased by > 77% and 70% relative to their original values, respectively. The results demonstrated that heating corn grain in the same temperature as in processing of corn results to loss of immunodetectable Cry2Ab2 protein.

Also, bioinformatics analyses using FASTA sequence alignment tool showed that a similarity to a pesticidal protein Cry2Ab, demonstrating 100% identity over 632 amino acids with a E-score of 0. All

remaining alignments with significant similarity were to Cry protein homologues derived from B. thuringiensis, Paenibacillus poppilliae or Paenibacillus lentimorbus but not to toxic proteins that can cause health risk to humans.

Lastly, Cry2Ab2 protein was administered to 10 male and 10 female CD-1 mice at a total dose level of 2198 mg/kg body weight. NOEL was considered to be 2198 mg/kg body weight, the highest dose tested. Escherichia coli was used as the source protein. The E- coli-produced Cry2Ab2 protein has been shown to be equivalent to the plant-produced Cry2Ab2 present in MON 89034 based on Western Blot Analysis, MALDI-TOF Tryptic Mass Map Analysis, N-Terminal Sequence Analysis, apparent molecular weight, Glycosylation Analysis and Functional Activity Assay.

B. Allergenicity Assessment

Bioinformatics analyses using FASTA sequence alignment tool showed that no relevant structural similarities were observed between the Cry1A.105 and Cry2Ab2 and known protein allergens upon evaluation of 6(AD6) database using ALLERGENSEARCH, thus indicating that Cry1A.105 and Cry2Ab2 will not cause allergenicity risk to human health.

The overall mean level of Cry1A.105 protein in MON 89034 grain is 5.9g/g (dwt) or equivalent to 0.0047% of total protein in MON 89034 grain. On the other hand, the mean level of Cry2Ab2 protein is 1.3 µg/g (dwt). The mean % dry weight of total protein in MON 89034 grain is 12.51% (or 125,100µg/g). Therefore, the Cry1A.105 and Cry2Ab2 proteins represents a very small portion of total protein in MON 89034 grain.

C. Nutritional Data

MON 80934 and SE comparator has a statistical differences observed on phosphorus in forage and stearic and arachidic acid in grain however, the observed differences were small and within the tolerance intervals and published literature range for commercial corn. Additionally, no statistically significantly differences were observed for protein, fat, ash and moisture in forage and grain between MON 89034 and the conventional corn. There were also no observed statistically significant differences on the levels of anti-nutirents in grains in the combined site analysis.

There were no observed statistical differences between the proximate, key nutrients, and anti-nutrient analyses in grain and forage of MON 89034 and the conventional corn that can be considered biologically relevant. Thus, MON 80934 and SE comparator are compositionally equivalent with each other.

D. Recommendation

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

DENR ASSESSMENT AND RECOMMENDATION

After a comprehensive review and evaluation of the documents including the scientific evidences from provided references and literature submitted by Monsanto Philippines, Inc., on its application for Direct Use as FFP of Corn MON89034, 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 protein product produced by the transgenic crop will degrade upon exposure to the natural environment and general conditions (i.e_, high temperatures [60°C and above], varying pH, enzyme digestion, etc.).

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.

3. The Bureau of Plant Industry (BPI〕shall ensure the proper and secure packaging of the regulated article for transport and the safety and durability of the transport vehicle, for prevention of any possible spillage or unintended release during transport/import based on BPI's inspection in the port area.

Based on the review and evaluation, the DENR-BC considered the regulated article safe to the environment and non-target organisms and hereby submits the technical report relative to the application of Monsanto Philippines, Inc. Corn MON89034 for Biosafety Permit for direct use as food, feed, or for processing.

DOH ASSESSMENT AND RECOMMENDATION

After a thorough review and evaluation of the documents provided by the proponent, Monsanto Philippines, Inc through the Bureau of Plant Industry (BPI), in support of their application for approval for Direct Use as Food, Feed or for Processing (FFP) of Corn MON 89034 I/We,

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.

5. 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.

6. Based on the above considerations and with the submitted sworn statement and accountability of the proponent, we hereby submit our evaluation to BPI relative to the application of a Biosafety Permit for Direct Use as Food, Feed, or for Processing (FFP) of Corn MON 89034

SEC ASSESSMENT AND RECOMMENDATIONS

The SEC expert has stated that corn is a significant crop in the country. It is the second largest crop of the Philippines, next to rice. A third of the country's farmers grow corn, or slightly over a million

farmers. The area harvested of corn reached 2.625 million hectares. The data mentioned are acceptable. According to PSA, in 2017 we produced 7.91 mln. Tons of corn. Most of that is yellow corn.

Imports, on average, are about 400,000 tons of corn, and virtually all of that would be yellow corn to be used as feeds. Nearly 60% of supply is used for feeds. Feeds are used in producing livestock in the country, which in turn is processed into meats and meat products for the consumption of the population.

The presence of GM corn in our country will not alter the current patterns of production and use of corn in the country. We had used GM corn in the country for more than ten years now and there is no evidence that that its use is hazardous for the health of the population and livestock and even other plants. If food consumption of corn had been reduced over the years, this is likely more because of the increased availability of rice, not because of GM corn. In fact, if there is any change at all, it would be that there is greater demand of farmers for GM yellow corn because it provides them with higher net income. The market of feeds is strong, as the demand for meats and meat products is boosted by strong growth of per capita income.