ASSESSORS' CONSOLIDATED REPORT ON MONSANTO PHILIPPINES INC.'s APPLICATION FOR COMMERCIAL PROPAGATION OF CORN MON89034

EXECUTIVE SUMMARY

On August 15, 2019, Monsanto Philippines submitted corn MON89034 as a renewal application for commercial propagation to the Bureau of Plant Industry (BPI) 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), has stated 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 that the conditions set by them are complied.

The Fertilizer and Pesticide Authority has certified that Monsanto Philippines is a licensed PIP handler as importer and national distributor and that the company has a legitimate authority to distribute and import the FPA registered PIP product.

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 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

According to Article VI. Section 15 of the JDC No.1 s2016, no regulated article shall be released for commercial propagation unless: (1) a Biosafety Permit for Commercial Propagation has been secured in accordance with this 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 Foods Derived from the Recombinant-DNA Plants 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 provided the assessors the complete dossier submitted by Monsanto Philippines Inc. The SEC expert, on the other hand, was provided with a questionnaire on socio-economic, ethical and cultural considerations that have been addressed by Monsanto Philippines Inc. in relation to their application. These assessors were given thirty (30) days to submit their independent assessment to the BPI Biotech Secretariat.

STRP'S ASSESSMENT

1. Host Organism

a. Phytic acid is said to be present to maize. Phytic acid reduces phosphorus availability especially in mono-gastric animals. Other reported anti-nutrients include raffinose and trypsin inhibitor; however, these have a minimal effect on nutrition. Maize also contains trace amounts of saponin, phenol, flavonoid, and alkaloids. [1][2].

b. 2,4-Dihydroxy-7-methoxy-2H-1,4-benzoacin (DIMBOA) found in maize leaves and roots has been reported as a potential toxicant; however, there were no reported effect on humans consuming maize [1][2].

2. Transgenic Plant

a. Even if MON89034 was shown to be compositionally equivalent to conventional corn with similar genetic background, there were slight changes in consumption amount by humans or animals due to different beliefs with regards to GMO products [1].

3. The Donor Organism

a. Cry1A.b2 is considered non-toxic and non-allergenic. Cry2Ab2 is also non-toxic and non-allergenic. Neither these proteins show 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. [4][6][7][8][9].

4. Transformation System

a. The transformation protocol has elaborated the steps: insertion to the vector, transformation of *Agrobacterium tumefaciens*, infection of corn embryo, and tissue culture. The materials, reagents, and step-by-step process included in the dossier. [10][11][12][13][14].

5. Inserted DNA

a. Molecular characterization of MON89034 by Southern blot analysis were sufficient to demonstrate that the genome of maize line MON89034 does not contain any detectable plasmid backbone DNA [15][16].

6. Genetic Stability

a. Chi-square analyses were conducted on the plants from four backcrossing generations to determine any difference in performance per generation. It was shown by the Chi-square analysis that there were no significant differences among generations. Some molecular analysis can be done to support the claim for genetic stability. [17].

7. Expressed Material

a. The levels of the expressed proteins were evaluated in young leaves, grain, whole plant and pollen tissues collected from eight field locations using Enzyme Linked Immuno-Sorbent Assay (ELISA) and Western blot analysis. The mean Cry1A.105 level in young leaves was ten times higher than the rest of the plant. These protein levels decline over growing season. [18][19].

b. The expression of the Cry1A.105 and Cry2Ab2 proteins 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. [20][21][22].

8. Toxicological Assessment

a. The digestibility of Cry1A.105 done by simulated gastric fluid containing pepsin was assessed by SDS-PAGE and Western Blot analysis. The protein was almost undetected within 7 seconds after incubation in SGF. The full-length protein degraded rapidly thus impossible to pose a threat in human or animal health. [60][61][62]. After running TOXINS and ALLPEPTIDES databases for protein sequence comparison of Cry1A.105, there is no homology with known toxins [23][24].

b. The digestibility of Cry2Ab2 done by simulated gastric fluid containing pepsin was assessed by SDS-PAGE and Western Blot analysis. The protein was almost undetected within 7 seconds after incubation in SGF. The full-length protein degraded rapidly thus impossible to pose a threat in human or animal health. [62][69][70]. After running TOXINS and ALLPEPTIDES databases for protein sequence comparison of Cry2Ab2, there is no homology with known toxins [23][26].

c. The safety assessment was conducted with produced Cry2Ab2 protein, which is the chemical and functional equivalence of the Cry2Ab2 protein in MON89034 maize plants in terms of molecular weight, immunoreactivity and insecticidal activity. [27][28].

9. Allergenicity Assessment

a. The digestibility of Cry1A.105 done by simulated gastric fluid containing pepsin was assessed by SDS-PAGE and Western Blot analysis. The protein was almost undetected within 30 seconds after incubation in SGF. The full-length protein degraded rapidly thus impossible to pose a threat in human or animal health. [29][30][31].

b. The digestibility of Cry2Ab2 done by simulated gastric fluid containing pepsin was assessed by SDS-PAGE and Western Blot analysis. The protein was almost undetected within 30 seconds after incubation in SGF. The full-length protein degraded rapidly thus impossible to pose a threat in human or animal health. [29][32][33].

c. After running ALLERGENSEARCH database for protein sequence comparison of Cry1A.105, there is no homology with known allergens [34][35][36].

d. After running ALLERGENSEARCH database for protein sequence comparison of Cry2Ab2, there is no homology with known allergens [34][37][38].

10. Nutritional Data

a. The expression of the Cry1A.105 and Cry2Ab2 proteins are independent of each other, and they have different promoter. [39].

b. There are no statistically significant differences in the levels of the proximates in both forage and grain between MON89034 and conventional control [40][41].

c. There are statistical differences between control maize and MON89034 in phosphorus level for forage, and 18:0 stearic and 20:0 arachidic acids for grains. However, these differences in the levels are generally small (3.4-19.2%). [40]. [41]. The statistical differences were not biologically relevant since the differences were small and values are within both observed ranges and reported ranges from literatures. [30][31].

d. The conventional and commercial maize hybrids were grown in the same field site, thus they have the same environmental conditions [40][41].

e. The levels of anti-nutrients in MON89034 are compositionally equivalent to that of the conventional maize. No changes should be anticipated on the amount of material consumed, the characteristics of the edible parts of the plant or in the use pattern and processing procedure of MON89034, compared to conventional maize. [40][41][42].

11. The Host Plant Environment

a. Corn is generally considered as a 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. [43].

b. Possible ways in formation of viable interspecific and/or intergenic hybrids are pollen-mediated gene flow, hybridization with cultivated maize, and hybridization

with wild annual species of subgenus *Zea mays* subsp. *mexicana*. There is also a small possibility to use genome-wide hybridization. [44][45][46].

c. There is no known sexually compatible wild species in the country. Teosinte's distribution is restricted to North, Central and South America and is not reported to Southeast Asia. Same is true with wheat. While *Tripsacum* sp. has been introduced in the Philippines and is sexually compatible with maize, their offspring will still be sterile. [44][47].

d. There are no anticipated changes in habitat or geographic distribution wherein MON89034 seems to be on the same level as the conventional maize based on phenotypic, ecological, and compositional characteristics, except for the introduced trait of insect protection. [48].

e. There is no altered reaction to pests and diseases since MON89034 seems to be on the same level as the conventional maize in its phenotypic, ecological, and compositional characteristics. [48].

12. The Consequences of Outcrossing

a. Corn is generally considered as a 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. [43].

13. Weediness Potential

a. MON89034 maize does not possess weedy tendencies, nor is it listed in standard texts or references as a weed. Hence, the introduced trait is not expected to add any characteristics of weediness to MON89034 maize. [48].

14. Secondary and Non-Target Effects

a. Based on the results presented, no adverse effects were observed on honey bee larvae and honey bee adult. These insects are beneficial as pollinators and source of honey and other bee by products. [49][50].

b. Based on the results presented, no adverse effects were observed on the parasitic wasp. Though this species is a native of Australia, incidence of occurrence in the Philippines has not yet been recorded. [51].

c. Based on the results presented, no adverse effects were observed on the ladybird beetles. The ladybirds are predators and beneficial, though this species of ladybird beetle is a North American species and is not found in the Philippines. [52].

d. Based on the results presented, no adverse effects were observed on the

earthworms. This earthworm is relatively one of the efficient decomposers. However, this species is a native of Europe and records of its occurrence in the Philippines were not recorded. [51].

e. Based on the results presented, no adverse effects were observed on the springtails. Moreover, this species is noted to be beneficial since they feed on plant-pathogenic nematodes and mites. [53].

f. Based on the results presented, no adverse effects were observed on the water flea. They serve as a popular fish food in aquaculture and aquaria. However, this species is broadly distributed throughout the Northern Hemisphere and South Africa and records of its occurrence in the Philippines were not recorded.

g. Based on the results presented, no adverse effects were observed on the minute pirate bug. This species is considered beneficial since they feed on small pest arthropods like thrips and their eggs. However, this species is common throughout the United States, and extends into Canada, Mexico, Central and South America. Occurrence in the Philippines is not recorded. [53].

11. Field Studies

a. Results show that in the field tests 2008 wet season and 2009 dry season planting, MON89034 was able to control ACB, CEW and CCW [54][55].

b. Results showed that in *Bt* and non-*Bt* maize, diversity of arthropods was not affected. Also, there was no adverse impact and no difference observed among the tested functional guilds between *Bt* and non-*Bt* maize. [55].

c. With the literature provided, MON89034 is effective against the fall armyworm, as supported by the data from other countries. However, local data must be generated since the variety will be commercially propagated in the Philippines. In this regard, it is highly recommended to conduct local studies to verify the effectiveness of MON89034 against FAW in the country. There is a possibility that the FAW strain introduced in the country might already have developed resistance to MON89034 from their source of origin. [75][76[77][78][79][80 [81]. [82][83][84][85][86][87][88][89][90][91][92].

STRP'S RECOMMENDATION

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.

DA-IRMAT'S ASSESSMENT AND RECOMMENDATION

1. The DA Insect Resistance Management Advisory Team (IRMAT) reviewed the submission of Monsanto Philippines Inc. for its renewal application for commercial propagation under the DOST-DA-DENR-DOH-DILG JDC No.1 s2016 of corn MON89034 through *ad referendum.*

2. Having been mandated by the DA Special Order No. 1051 s2018 to provide advice and direction to the BPI in matters relating to Insect Resistance Management (IRM), after a review of both applications, the IRMAT therefore finds that the applicant's submitted documents are with substantial compliance with the previously issued DA Memorandum Circulars pertaining to IRM.

SUMMARY AND ANALYSIS OF CORN MON89034 INSECT RESISTANCE MANAGEMENT MONITORING (2013-2019)

In compliance with the DA MC No. 2 s2014, post-approval monitoring of Corn MON89034 for commercial propagation has been complied by the applicant, Bayer Crop Science Inc. (formerly Monsanto Philippines Inc.). MON89034 is marketed with 5% refuge under Refuge-In-a-Bag scheme (RIB). The sentinel sites for this event are located in Barangay Kalabaza, Aurora, Isabela and San Roque, Koronadal City, South Cotabato. The primary objective of this activity is monitoring of target pest incidence, damage, profile of non-target pests and/or beneficial arthropods. The sentinel sites were monitored by the BPI Post Approval Monitoring Group (BPI-PAMG), DA Regional Crop Protection Center, and representatives from Bayer.

As a brief background on the regulated article, MON89034 contains an insect-resistance trait against the lepidopteran pest Asian Corn Borer (*Ostrinia furnacalis).* Corn MON89034 (contains) cry*2Ab2* and *cry1A.105* genes (or produces Cry2Ab delta-endotoxin and Cry1A.105 protein) that target the insect midgut of ACB by lysing the midgut epithelial cells and inserting it into the target membrane and then forming pores. When toxins are activated, they break down their gut and the insect finally die by infection and starvation. Aside from ACB, MON89034 provides moderate control to common cutworm (*Spodoptera litura*) and corn earworm (*Helicoverpa armigera*).

MON89034 was first approved for commercial propagation on November 19, 2010 and the Biosafety Permit was renewed after 5 years (2015). This application was the first renewal under the Joint Department Circular No. 1 s2016.

Analysis of the 10-year monitoring data was submitted to the BPI and reviewed by the DA Insect Resistance Management Advisory Team (IRMAT). Bayer reported that after 8-9 years of cultivation, the less than 1% incidence of ACB larvae or pupae in MON89034 plants in comparison to a 1-11% incidence in refuge plants clearly demonstrates its efficacy**.** No leaf stalk, tassel, or ear damage was observed in Isabela and South Cotabato across all years of planting while comparable insect damage to refuge plants were observed in Isabela than in South Cotabato. To date, there was no significant population indication for common cutworm and corn earworm on MON89034 plants aside from its incidence in 2019. However, corn earworm was present in up to 41% in refuge plants as

observed in the two locations. Based on the analysis of the submitted data, it can be concluded that MON89034 with 5% RIB have provided excellent efficacy against the primary pest, Asian corn borer during the 8-9 years of cultivation. The data on corn earworm and common cutworm also showed the efficacy of MON89034 against these lepidopteran pests. No incidence of common cutworm or corn earworm in MON89034 plants across all years except 1-2% incidence of earworm during WS 2018 and 2019 and 1% incidence of common cutworm during flowering stage of WS 2019. Similarly, cutworm was not present on refuge plants during all years except 7% of the plants showed cutworm incidence during DS 2017 and at vegetative stage. The earworm incidence was observed on 7-12% of the refuge plants during 2017, 2018 and WS 2019, mostly in the flowering stage.

As to other insects present in the sentinel areas, there were no differences in the populations of coccinellids, earwigs, spiders (most predominant in Isabela and South Cotabato), ants (no observed) planthoppers, aphids (40-50%), tachinid flies (no observed), *Trichogramma* sp. (58% on MON89034 and 17% on refuge in 2016), *Cytorhinus*sp (no presence in MON89034 and 10% in refuge in 2017, 9% in MON89034 in 2018), and other beneficial organisms both in the refuge and the Bt crop. Beneficial arthropods were monitored in both the crop growth stages from 2013-2019 on the plants of MON89034 and refuge. Coccinellids, earwigs and spiders are the most predominant predators observed in all the plots at South Cotabato location**.** It can be justified that the population of non-target organisms observed in the location is not altered or affected when corn was planted in the sentinel sites, indicating environmental safety of the said event.

Furthermore, as part of the requirement stipulated in the DA MC No. 2 s2014, the event-specific studies *"Post commercialization monitoring of Bt corn resistance development in Asian corn borer Ostrinia furnacalis Guenee"* were conducted by technology developers to monitor possible breakdown of resistance. The applicant, Monsanto Philippines, is a part of the industry-initiated and funded research, including Dr. Edwin Alcantara of the National Institute of Molecular Biology and Biotechnology, University of the Philippines Los Baños. Baseline susceptibility studies through protein-diet assay of cry proteins Cry1A.105 and Cry2Ab2 on field collected ACB populations were done in 2015-2017. Based on the assay conducted, complete larval mortality was observed in all populations assayed from 2019 to 2020. Thus, the study concluded that there are no changes in the susceptibility of ACB populations to Cry1A.105 and Cry2Ab2 proteins. The findings supported the claims of the technology developer.

The technology developer also submitted its Integrated Pest Management (IPM) plan with a recommendation in the farmer's pest management practice in case breakdown of resistance occurs. This was also reviewed by IRMAT last 2020, along with the IRM Plan. They also submitted the Certificate of Product Registration issued by the Fertilizer and Pesticide Authority for Corn MON89034 against Asian Corn Borer. On the other hand, conditional approval for common cutworm and corn earworm was secured by Bayer.

In conclusion, the BPI-PAMG has found that Bayer Crop Science Inc. (Monsanto Philippines Inc.) complied to the present policy on Insect Resistance Management (IRM), particularly, on the requirements for sentinel site monitoring and refuge testing. Other relevant issues are currently being addressed by Bayer through event stacking,

enhancing awareness on the relevance of refuge system, and introduction of new events. Furthermore, it was concluded that there is no evidence of possible Asian Corn Borer (ACB) resistance on corn MON89034 upon reviewing the monitoring reports. If there has been evidence showing resistance to ACB of corn MON89034, this shall be reported to BPI immediately.

FPA'S ASSESSMENT AND RECOMMENDATION

The protein CrylAb contained in the corn event MON89034 has been issued with a Full PIP Product Registration (Reg. No.: PIP-02-03-04) by FPA on October 25, 2018 and valid until October 25, 2021. This is in compliance with the rules and regulation of the *FERTILIZER AND PESTICIDE AUTHORITY (FPA) PESTICIDE REGULATORY POLICIES AND IMPLEMENTING GUIDELINES 3rd EDITION 2020* or FPA Greenbook.

DENR-BC'S ASSESSMENT

After a comprehensive review and evaluation of the documents and scientific evidence from literature submitted by Monsanto Philippines, Inc. concerning its application for Commercial Propagation of **Corn (MON89034)**, the DENR-BC considered that the regulated article poses no significant adverse effect to the environment on the following basis:

1. The regulated article is considered substantially equivalent to its conventional counterpart for its history of safe use as food in twenty-two (22) countries and as feed in nineteen (19) countries. It has also been approved for cultivation in ten (10) countries.
2. There is low probability that the genetically modified corn will be weedy or invasive to its environment due to the lack of dormancy of its seeds and poor competitive ability of its seedlings. Maize's close relative, teosinte, is not commercially propagated in the Philippines. The risk of introgression between the regulated article and a wild relative is not applicable in the country wherein the crossing of maize and teosinte is limited by the difference in flowering time and the difference in location of the crops. These are temporal and geographical factors limiting the introgression between the two crop relatives.
3. The assessments on environmental interactions indicate that the genetically modified crop is less likely to present risks to the environment more than its conventional counterpart. It is also unlikely to threaten other species of organisms living within its proximity and showed no changes in the natural indicators of its environment. and
4. The genes *Cry1A.105* and *cry2Ab2* that produce the proteins protecting the plant from lepidopteran insects has a history of safe use for human and animal consumption. Additionally, these proteins have no known negative interaction with the abiotic environment, given that proteins are subjected to rapid degradation in soil and is not expected to negatively affect soil or water.

The DENR-BC acknowledged receipt of the documents for the No Adverse Effect statement and its literature attachments. BPI received no further comments from the DENR-BC regarding the new studies for Corn MON89034 for commercial propagation.
[75][76[77][78][79][80][81].[82][83][84][85][86][87][88][89][90][91][92].

DENR BC'S RECOMMENDATION

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

DOH-BC'S ASSESSMENT

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 Commercial Propagation (CP) of Corn MON89034. 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 change in the usual practices as described in the phases/stages of biotechnology project activities. 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. 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.
3. Dietary exposure to the regulated article is unlikely to result in allergic reaction.
4. The regulated article is not materially different in nutritional composition from that of the now-transgenic com or the conventional corn.
5. Scientific pieces of evidence from provided references, i.e., literatures show that regulated article applied for Commercial Propagation is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health and on the environment.
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 Commercial Propagation of Corn MON89034.

The DOH-BC has no further comments on the forwarded no adverse effect statement and literature attachments for CORN MON89034 for commercial propagation

[75][76[77][78][79][80 [81]. [82][83][84][85][86][87][88][89][90][91][92].

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 recommended for use as planting materials.

SEC EXPERT'S ASSESSMENT

1. Using relevant and recent data as support, applicant was able to discuss clearly the relevance of GM maize in terms of production, consumption, and import. As noted by the applicant, maize is a critical feed ingredient—and hence the continued increasing demand for it. [60][61][62][63][64].
2. Using reliable references, applicant was able to affirm that the GM product will not change current patterns of production, consumption, or utilization. Rather, it can help minimize the need to import yellow maize to be used as feed material, thereby possibly reducing the price of animal feeds. Meanwhile, the recent trend of importation was presented in Table 3 (Philippines Maize Import, 2014-2019) in the previous section. [65][66].
3. Using Brookes and Barfoot (2014), applicant reported the global farm income gains from using GM maize. Data shared support the assertion that the GM crop can increase farm income as it lowers pest damage, which results to higher yields. [67].
4. Applicant argued that the use of the GM crop does not require negative changes in farm management. In addition, aside from the elimination of manual weeding and excessive pesticide spray, the farm management practices used for the GM maize product are the same as those of the conventional one. Hence, citing Torres et al. (2013), applicant noted that farmers even find GM maize easier to cultivate. [68].
5. Complementary inputs are the same except that GM maize does not require the farmer to hire labor for weeding and chemical applications [69].
6. The inputs are generally the same. Not factoring the seed cost, production cost would even be less as pesticides will no longer be applied and fewer laborers are required for production. [68].
7. Using Gonzales et al. (2013) and Yorobe and Smale (2012) as references, applicant was able to highlight the advantages and benefits of using GM maize. For instance, citing Gonzales et al. (2013), it was reported that "maize hybrids provided superior performance compared to non-genetically engineered maize hybrids in terms of yield, farm production cost, net farm income, subsistence level carrying capacity, global competitiveness, and return on investment." [70][71][72].
8. Given the data presented, it can indeed be concluded that the GM product can improve farm productivity [67][73][84].
9. Citing Torres et al. (2013), applicant was able to support their assertion that GM maize can benefit small resource-poor farmers [68].
10. Using Torres et al. (2013) as reference, applicant reported that farmers opt to plant GM crop due to lesser expenses for farm input. This implies that the GM maize does not require additional inputs or practices, which supports the applicant's response. [68].
11. Answer is acceptable as concerns regarding contractual obligations or license cost

are the same as non-GM maize hybrids [68].

12. Applicant's argument is acceptable. As noted, farmers have already been using GM crops instead of the traditional varieties for many years due to the economic and psychological benefits. [68].
13. Using Torres et al. (2013) as reference, applicant noted that farming activities are the same regardless of the seed used. However, while there have been no changes in social structure observed, future studies can be conducted to validate such claims. [68].
14. Answer is acceptable. As explained by the applicant, the co-existence of different crops, production systems, and pest management practices in agriculture and the supply chain has long existed. To achieve sustainable agriculture, such co-existence is necessary. [66][69].
15. Applicant was able to cite relevant literature (Torres et al., 2013) to support their answer that GM products can in fact increase social participation in community activities. As farming becomes less laborious as a result of using GM crops that do not require the use of pesticides, it can be assumed that farmers would have more time for other activities. [68].
16. In their literature review, it was reported that the impacts of GM crops on cultural heritage are rarely addressed in research studies on the social impacts of GM crops. This means that there may be no significant evidence yet to support or negate the applicant's response. There is a need for new empirical investigations into the impacts of GM crops in agriculture. Accordingly, the applicant should consider supporting such investigations or research, so that they will have evidence to support their assertion that the GM product, indeed, has no negative effect on LCIPs.

SEC EXPERT'S RECOMMENDATION

The SEC expert recommends for the approval and issuance of the Biosafety Permit of the GM product.

REFERENCES

[1]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105.Monsanto Company. St. Louis, Missouri. Part IV, Section 1 (Page 35).

[2]. OECD. 2002. Consensus document on compositional considerations for new varieties of maize (Zea mays): Key food and feed nutrients, anti-nutrients and secondary plant metabolites. ENV/JM/MONO (2002) 25. Series on the Safety of Novel Foods and Feeds, No. 6. Organization for Economic Co-operation and Development, Paris, France.

[3]. U.S. EPA. 1988. Guidance for the reregistration of pesticide products containing *Bacillus thuringiensis* as the active ingredient. 540/RS-89-023. U.S. Environmental Protection Agency, Washington, D.C.

[4]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part III, Sections 3-3.2.9 (Pages 52-77).

[5]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part VI, Section 5.2 (Pages 149-150).

[6]. Cannon, R.J.C. 1993. Prospects and progress for *Bacillus thuringiensis*-based pesticides. Pesticide Science 37:331-335.

[7]. WHO. 1999. Microbial pest control agent: *Bacillus thuringiensis*. Environmental Health Criteria 217. World Health Organization, Geneva, Switzerland. http://www.inchem.org/documents/ehc/ehc/ehc217.htm [Accessed May 14, 2009].

[8]. Hammond, B.G. and S.K. Koch. 2012. A review of the food safety of bt crops. *Bacillus thuringiensis* Biotechnology pages 305-325 E. Sansinenea (ed.). Springer Science+Business Media, Heidelberg London, New York.

[9]. McClintock, J.T., C.R. Schaffer and R.D. Sjoblad. 1995. A comparative review of the mammalian toxicity of *Bacillus thuringiensis*-based pesticides. Pesticide Science 45:95-105.

[10]. OECD. 2007. Consensus document on safety information on transgenic plants expressing Bacillus thuringiensis-derived insect control proteins. ENV/JM/FOOD (2007)14. Organization for Economic Co-operation and Development, Paris, France.

[11]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part IV, Section 2.1 (Pages 40-41).

[12]. Armstrong, C.L. and R.L. Phillips. 1988. Genetic and cytogenetic variation in plants regenerated from organogenic and friable, embryogenic tissue cultures of maize. Crop Science 28:363-369.

[13]. Eggerling, D.G. 1994. Inbred corn line LH172. Patent 5,276,266, U.S. Patent Office, Washington, D.C.

[14]. Rout, J.R. and C.L. Armstrong. 1997. Factors affecting transfer and integration of T-DNA into corn (*Zea mays* L.) cells. Program issue of congress on *in vitro* biology. Society for *In Vitro* Biology 33:14A.

[15]. Rice, J.F., B.J. Wolff, J.R. Grout, N.K. Scanlon, J.C. Jennings and J.D. Masuci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON89034. Monsanto Technical Report MSL-20311. St. Louis, Missouri.

[16]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional

Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part IV, Section 3.2.9 (Pages 76-77).
[17]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part IV, Section 3.6 (Pages 90-92).
[18]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part VI, Section 2 (Pages 124-128).
[19]. Hartmann, H.J., K.E. Niemeyer and A. Silvanovich. 2006. Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285. St. Louis, Missouri.
[20]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part VI, Section 1.1 (Pages 100-101) and Section 2.1 (Pages 112-113).
[21]. Crickmore, N. 2012. List of Bacillus thuringiensis holotype toxins. University of Sussex, Sussex, United Kingdom. http://www.lifesci.sussex.ac.uk/home/Neil_Crickmore/Bt/holo2.html [Accessed June 26, 2013].
[22]. English, L. and S.L. Slatin. 1992. Mode of action of delta-endotoxins from *Bacillus thuringiensis*: A comparison with other bacterial toxins. Insect Biochemistry and Molecular Biology 22: 1-7.
[23]. McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of DNA Sequences Flanking the 5' and 3' Junctions of the Inserted DNA in MON89034 Corn: Assessment of Putative Polypeptides. Monsanto Technical Report MSL-20306. St. Louis, Missouri.
[24]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part VI, Section 5.4.3 (Page 153).
[25]. McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of DNA Sequences Flanking the 5' and 3' Junctions of the Inserted DNA in MON89034 Corn: Assessment of Putative Polypeptides. Monsanto Technical Report **MSL-20306.** St. Louis, Missouri.
[26]. English, L. and S.L. Slatin. 1992. Mode of action of delta-endotoxins from *Bacillus thuringiensis*: A comparison with other bacterial toxins. Insect Biochemistry and Molecular Biology 22:1-7.
[27]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part VI, Section 2.2 (Pages 113-123).
[28]. Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and *E. coli*-produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071. St. Louis, Missouri.
[29]. Kapadia, S and E.A. Rice. 2005. Assessment of the *in vitro* Digestibility of the Cry1A.105 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19929. St. Louis, Missouri.

[30]. Kapadia, S and E.A. Rice. 2006. Assessment of the *in vitro* Digestibility of the Cry1A.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930. St. Louis, Missouri.
[31]. Thorp, J.J. and M.E. Goley. 2006. Assessment of the *in vitro* Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938. St. Louis, Missouri.
[32]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part VI, Section 4.3.3 (Pages 143-145) and Section 4.3.4 (Pages 146-147).
[33]. McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of DNA Sequences Flanking the 5' and 3' Junctions of the Inserted DNA in MON89034 Corn: Assessment of Putative Polypeptides. Monsanto Technical Report MSL-20306. St. Louis, Missouri.
[34]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part VI, Section 1.2 (Pages 102-111).
[35]. Goertz, B., T. Ganguly, J. Lee, T. Lee and E. A. Rice. 2005. Characterization of the Cry1A.105 Protein Purified from the Corn Grain of MON89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and *E. coli*-Produced Cry1A.105 Proteins. Monsanto Technical Report MSL-19960. St. Louis, Missouri.
[36]. Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and *E. coli*-produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071. St. Louis, Missouri.
[37]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part VI, Section 4.3.2 (Page 142).
[38]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part VI, Section 2.2 (Pages 113-123).
[39]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part VI, Section 1.2.6 (Pages 108-110) and Section 2.2.6 (Pages 119-121).
[40]. Monsanto Petition to U.S. FDA. 2006. Food and Feed Safety and Nutritional Assessment of the Lepidopteran-Protected Corn MON89034. FDA BNF 00105. Monsanto Company. St. Louis, Missouri. Part VII, Section 3 (Pages 165-185).
[41]. Reynolds, T.L., S.M. Drury, M.A. Nemeth, W.A. Trujillo and R. Sorbet. 2006. Amended Report for MSL-20097: Compositional Analysis of Corn Forage and Grain Collected from MON89034 Grown in 2004 US Field Trials. Monsanto Technical Report MSL-20403. St. Louis, Missouri.
[42]. Morris, M.L. 1998. Overview of the world maize economy. Pages 13-34 in Maize Seed Industries in Developing Countries. M.L. Morris (ed.). Lynne Rienner Publishers, Inc., Boulder, Colorado.
[43]. OGTR. 2008. The biology of *Zea mays* L. ssp *mays* (maize or corn). Version 1, September 2008, Australian Government, Department of Health and Ageing, Office

of the Gene Technology Regulator, Canberra, Australia.
[44]. Wilkes, H.G. 1972. Maize and its wild relatives. Science 177: 1071-1077.
[45]. Ellstrand, N.C., L.C. Garner, S. Hegde, R. Guadagnuolo and L. Blancas. 2007. Spontaneous hybridization between maize and teosinte. Journal of Heredity 98: 183-187.
[46]. Russell, W.A. and A.R. Hallauer. 1980. Corn. Pages 299-312 in Hybridization of Crop Plants. W.R. Fehr and H.H. Hadley (eds.). American Society of Agronomy, Inc., Crop Science Society of America, Inc., Madison, Wisconsin.
[47]. OECD. 2003. Consensus document on the biology of *Zea mays* subsp. *mays* (maize). ENV/JM/MONO (2003) 11. Series on Harmonisation of Regulatory Oversight in Biotechnology No.27. Organization of Economic Co-operation and Development, Paris, France.
[48]. Monsanto Petition to USDA. 2006. Petition for the Determination of Non-regulated Status for MON 89034. #06-CR-166U. Monsanto Company. St. Louis, Missouri.
[49]. Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Honeybee Larvae (*Apis mellifera* L.). Monsanto Technical Report CA- 2005-071. St. Louis, Missouri.
[50]. Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Adult Honeybees (*Apis mellifera* L.). Monsanto Technical Report CA-2005-072. St.
[51]. Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, *Ichneumon promissorius* (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20149. St. Louis, Missouri.
[52]. Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on the Ladybird Beetle, *Coleomegilla maculata* (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150. St. Louis, Missouri.
[53]. Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON89034 in a Chronic Exposure Study with Collembola (*Folsomia candida*). Monsanto Technical Report MSL-20169. St. Louis, Missouri.
[54]. Samson, J.A.F., J.O. Manalo, P.L. Borda, E.S. Poliquit, J.A. Fajardo, E.Carlo, E. Ercia, J.J. Garcia and R.M. Leano. 2009. Field Verification of the Agronomic Performance of Transgenic Corn (*Zea mays* L.) Hybrid MON89034 and Stacked Hybrid, MON89034 x NK603, Expressing the *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Proteins for Efficacy Against Lepidopterous Pests of Corn and CP4 EPSPS for Tolerance to the Roundup Herbicide. Terminal Report (Summary of Wet Season, 2008 Results). Monsanto Philippines, Inc.
[55]. Lit, I.L. Jr.. 2010. Studies on Non-Target Organisms on MON89034 and MON89034 × NK603: Aboveground Communities of Arthropods in Regulated Field Trial Sites in Luzon and Mindanao. Terminal Report. University of the Philippines Los Baños (UPLB), Laguna.
[56]. Canadian Food Inspection Agency (CFIA), 2017. DD2008-74: Determination of the Safety of Monsanto Canada Inc.'s Corn (*Zea mays* L.) Event MON89034. Retrieved January 28, 2020 from https://www.inspection.gc.ca/plant-health/plants-with-novel-traits/approved-under- review/decision-documents/dd2008-74/eng/
[57]. *International Service for the Acquisition of Agri-Biotech Applications GM Approval Database.* (2019, May 6). Retrieved January 20, 2020, from International Service for the Acquisition of Agri-Biotech Applications: http://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=95
[58]. USDA, 2008. Monsanto Company; Availability of Determination of Nonregulated

Status for Corn Genetically Engineered for Insect Resistance. Retrieved May 1, 2020 from Federal Register, 73(143).
[59]. US EPA, 2010. *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 Insecticidal Proteins and the Genetic Material Necessary for their Production in Corn. PC Codes 006515
[60]. USDA-FAS. 2019. Philippines: Grain and Feed annual – Philippine grain and feed situation and Outlook. GAIN Report Number: RP 1902. U.S. Department of Agriculture, Foreign Agricultural Service.
[61]. http://www.pcaarrd.dost.gov.ph/home/momentum/cofgin/index.php?option=com_content&view=article&id=213&Itemid=241 (Accessed on September 4, 2019)
[62]. https://www.indexmundi.com/agriculture/?country=ph&commodity=corn&graph=production (Accessed on September 4, 2019)
[63]. https://www.indexmundi.com/agriculture/?country=ph&commodity=corn&graph=imports (Accessed on September 4, 2019)
[64]. https://www.indexmundi.com/agriculture/?country=ph&commodity=corn&graph=feed-domestic-consumption (Accessed on September 4, 2019)
[65]. Benaning, Marvyn. "Biotech Corn now Planted in 831,000 Ha in Philippines". Business Mirror. February 28, 2015.
[66]. National Academy of Science and Technology. "Philippine Agriculture: 2020."
[67]. Brookes, G. and P. Barfoot. 2014. Economic impact of GM crops: The global income and production effects 1996-2012. GM Crops & Food: Biotechnology in Agriculture and the Food Chain 5:65-75.
[68]. Torres, S.S., R.A. Daya, M.T.B. Osalla and J.N. Gopela. 2013. Adoption and uptake pathways of GM/biotech crops by small-scale, resource-poor Filipino farmers. CDC-UPLB, ISAAA and SEARCA: Los Baños, Laguna.
[69]. Gonzales, L.A., E.Q. Javier, D.A. Ramirez, F.A. Cariño and A.R. Baria. 2009. Socio-economic impact of biotech maize adoption in the Philippines. Pages 144-212 in Modern Biotechnology and Agriculture: A History of the Commercialization of Biotech Maize in the Philippines. STIVE/SIKAP Foundation, Los Baños, Philippines.
[70]. Gonzales, L.A. Socio-economic impact of biotech maize adoption in the Philippines. In: Modern Biotechnology and Agriculture: A History of the Commercialization of Biotech Maize in the Philippines. Gonzales, L.A., Javier, E.Q., Ramirez, D.A., Carino, F.A., Baria, A.B. Published by STIVE/SIKAP Foundation. Los Banos, Philippines. 2009
[71]. Gonzales, L.A., Elca, C.C., Paningbatan, B.C., Umali, R.M., Gonzales, A.A., Ignacio, J.L. 2013. Micro-Macro Impacts of Technological Change: The GM (Bt) Corn Experience in the Philippines. Published by SIKAP/STRIVE.
[72]. Yorobe, J.M. and M. Smale. 2012. Impacts of Bt maize on smallholder income in the Philippines. AgBioForum 15:152-162.
[73]. Mutuc, M.E.M., R.M. Rejesus, S. Pan and J.M. Yorobe. 2012. Impact assessment of Bt corn adoption in the Philippines. Journal of Agricultural and Applied Economics 44:117-135.
[74]. Sanglestsawai, S., D.G.P. Rodriguez, R.M. Rejesus and J.M. Yorobe. 2017. Production risk, farmer welfare, and Bt corn in the Philippines. Agricultural and Resource Economics Review 46:507-528.
[75]. Venkatesh et al. (2015). Compositional differences between near-isogenic GM and conventional maize hybrids are associated with backcrossing practices in conventional breeding
[76]. Resende et al. (2016) Does Bt maize cultivation affect the non-target insect

community in the agro-ecosystem?
[77]. Bernardi et al. (2016) Biological activity of Bt proteins expressed in different structures of transgenic corn against *Spodoptera frugiperda*
[78]. Vilperte et al. (2016) Levels of DNA methylation and transcript accumulation in leaves of transgenic maize
[79]. de Sousa AF et al. (2017) Biology of *Trichogramma pretiosum* (Hymenoptera: Trichogrammatidae) fed transgenic maize pollen
[80]. Gampala et al. (2017) Singleevent transgene product levels predict levels in genetically modified breeding stacks
[81]. Thomson JA. (2018) The pros and cons of GM crops
[82]. Wang et al. (2018) Safety of the *Bacillus thuringiensis* derived Cry1A.105 protein: Evidence that domain exchange preserves mode of action and safety
[83]. Agapito- Tenfen et al. (2018) Systematic miRNome profiling reveals differential microRNAs in transgenic maize metabolism
[84]. Acharya et al. (2017) Fitness costs and inheritance of *Cry2Ab2* resistance in *Spodoptera frugiperda* (J.E. Smith)
[85]. Schneider et al. (2017) Impact of Bt sweet corn on lepidopteran pests in midwestern Brazil
[86]. Romeis et al. (2018) Genetically engineered crops help support conservation biological control
[87]. Cocco et al. (2018) First records of *Leucania rawlinsi* Adams and *L. senescens* Möschler (Lepidoptera: Noctuidae) in Brazil: redescription, potential association with Bt maize, larval parasitoids, and spatial and temporal distribution
[88]. Marques et al. (2018) Assessing the efficacy of *Bacillus thuringiensi*s (Bt) pyramided proteins Cry1F, Cry1A.105, Cry2Ab2, and Vip3Aa20 expressed in Bt maize against Lepidopteran pests in Brazil
[89]. Clawson et al. (2019) Consistent risk assessment outcomes from agronomic characterization of GE maize in diverse regions and as single-event and stacked products
[90]. Visser et al. (2019) Preference of Bt-resistant and susceptible *Busseola fusca* moths and larvae for Bt and non-Bt maize
[91]. Fernandes et al. (2019) Species Richness and Community Composition of Ants and Beetles in Bt and non-Bt Maize Fields
[92]. Botha et al. (2019) Efficacy of Bt maize for control of *Spodoptera frugiperda* (Lepidoptera: Noctuidae) in South Africa