ASSESSORS' CONSOLIDATED REPORT ON MONSANTO PHILIPPINES INC.'
CORN MON 89034 X NK603 APPLICATION FOR COMMERCIAL PROPAGATION

EXECUTIVE SUMMARY

On September 30, 2016, Monsanto Philippines, Inc.'s corn MON 89034 x NK603 received a biosafety permit for commercial propagation under the DOST-DA-DENR-DOH-DILG Joint Department Circular (JDC) No. 1 Series of 2016. The applicant applied for the renewal of the regulated article on August 6, 2021.

After a thorough review of the Risk Assessment Report and attachments submitted by the applicant, the Scientific and Technical Review Panel (STRP) Expert concurred the regulated article petitioned for renewal continues to be as safe for the human and animal health and environment as its conventional counterpart and that any risks posed could be managed by insect resistance management strategy and monitoring of possible evolution of weeds developing resistance to glyphosate.

Moreover, the Department of Environment and Natural Resources-Biosafety Committee (DENR-BC) and Department of Health-Biosafety Committee (DOH-BC), after a thorough assessment and evaluation of the documents related to Environmental Risk and Environmental Health Impact, recommended the issuance of a biosafety permit for the regulated article, corn MON 89034 x NK603.

The Socio-economic, Ethical and Cultural Considerations (SEC) Expert also recommended for the issuance of biosafety permit for the regulated article after assessing the socio-economic, social and ethical indicators for the adoption of the genetically modified product.

Background

In accordance with 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 BPI Biotech Secretariat.

INFORMATION ON THE APPLIED EVENT

The combined trait maize product MON 89034 × NK603 was developed through conventional plant breeding techniques and each of the individual traits in this product have been approved in the Philippines. It was approved in the country for commercial propagation on September 30, 2016, under the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, series of 2016.

MON 89034 was produced by *Agrobacterium*-mediated transformation system, while NK603 was produced by particle acceleration method. MON 89034 produces two insecticidal proteins (Cry1A.105 and Cry2Ab2) against feeding damage caused by Asian Corn Borer (ACB) and other lepidopteran insects. NK603 produces a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) which confers tolerance to glyphosate.

Counties Where Approvals Have Been Granted

Country	Food direct use or processing	Feed direct use or processing	Cultivation domestic or non-domestic use
Argentina	2012	2012	2012
Brazil	2010	2010	2010
Canada			2008
Colombia	2010	2011	
European Union	2010	2010	
Japan	2008	2007	2008
Mexico	2010		
Nigeria	2018	2018	
Pakistan	2017	2017	2017
Philippines	2009	2009	2011
South Korea	2010	2009	
Taiwan	2009		
Thailand	2013		

Turkey		2011	

Source: https://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=97

STRP's Assessment

1. Scientific Papers

a. The diversity of arthropods in regulated field trial sites (Mindanao and Luzon) suggests that corn MON 89034 × NK603 is not significantly different from conventional corn based on abundance, diversity, and guild structure of non-target organisms. Moreover, corn MON 89034 × NK603 has no significant effects on other herbivorous arthropods, predators, parasites, or parasitoids in the corn agroecosystems.[1].

b. The risk assessment outcomes based on agronomic characterization of corn MON 89034, corn NK603, and corn MON 89034 x NK603 were consistent across multiple regions and were also consistent between breeding stack and single event products.[2].

c. There is no relationship between the preference of maternal oviposition and the positive development of offspring. In addition, moths distinguished between transgenic and non-transgenic plants when infested by larvae, and the transgenic hybrids were preferred for oviposition.[3].

d. The event MON 89034 had the most distinct miRNome profile, followed by the stacked transgenic event. The distinct miRNome was not correlated to the higher expression of CRY transcripts in the Bt single event variety, but the expression and accumulation of CRY proteins suggests alterations in the miRNome of both single and stacked transgenic event varieties. Moreover, 20 novel miRNAs with target transcripts are involved in lipid metabolism in corn. Two miRNAs were observed in the control samples only, one in the NK603 sample only and another in Bt samples only. The remaining 15 novel miRNAs were found in all samples with similar abundance.[4].

e. No statistically significant differences in abundance were detected between GM corn and conventional corn control across the taxa analyzed. This indicates that the single or stacked insect protected and herbicide tolerant GM traits do not exert marked adverse effects on the arthropod populations compared with conventional corn. The distribution of taxa observed provides evidence that regardless of overall biodiversity of a given ecoregion, important herbivore, predatory and parasitic arthropod taxa within the commercial corn agroecosystem are likely similar. This indicates that data generated in one ecoregion can be transportable for the risk assessment (of the same or similar GM crop) in another ecoregion.[5].

2. Permit Conditions

a. An approved insect resistance management (IRM) and monitoring plan for weed resistance management (WRM) were devised by Monsanto Philippines, Inc. IRM was implemented using the 95-5 RIB, monitoring of Cry1A.105 and Cry2Ab2 susceptibility in Asian Corn Borer (ACB), and providing education and training for farmers; while WRM was implemented through monitoring of possible weed resistance to glyphosate, product stewardship, and provision of guidance on planting of NK603 in hilly areas.

b. A proposal was submitted by Monsanto Philippines, Inc. on October 16, 2020 to increase the percentage of non-Bt seed in the seed blend (RIB) of corn MON 89034 x NK603 hybrids from 5% to 10% and results did not indicate any change in the susceptibility of ACB populations to Cry1A.105 and Cry2Ab2 proteins. Moreover, there was no clear indication of possible evolution of weeds that developed resistance to glyphosate.

c. There were no adverse effects observed from the risks being addressed.

STRP's Conclusion

After a thorough and scientific review and evaluation of the documents provided by Monsanto Philippines, Inc. relevant to the petition for renewal of corn MON 89034 x NK603, the STRP found sufficient evidence that the regulated article petitioned for renewal continues to be as safe for the human and animal health and environment as its conventional counterpart and that any risks posed could be managed by the following measures:

1. Insect resistance management strategy; and
2. monitoring plan on possible evolution of weeds developing resistance to glyphosate.

DENR-BC's Assessment

a. Corn has a history of safe use. The regulated article is substantially equivalent to its conventional counterpart, and the likelihood that the regulated article becomes invasive or produces a weedy type of corn is remote.[6].

b. The regulated article showed no significant difference from its conventional counterpart in terms of biologically relevant components, aside from the introduced traits. It also has a history of safe use and had previously been approved for commercial propagation in seven (7) countries: Argentina, Brazil, Canada, Japan, Pakistan, Philippines, and South Africa. Its biosafety permit for commercial propagation has also been previously approved in the Philippines in 2016.[7].

c. The inserted gene, *cp4 epsps* exhibited stable integration into the genome of the host plant, and the compositional analyses and toxicological data show that no unintended and biologically significant effects were conferred by the introduced gene.[8].

d. The genes *cry1A.105* and *cry2Ab2* produce the proteins protecting the plant from lepidopteran insects. It has been commercially used for pest control in other transgenic crops modified using *Bacillus thuringiensis*. It was also shown that no adverse effects were observed when non-target organisms were exposed to the protein products of the inserted genes.[9].

e. Natural crosses of the regulated article with its wild relatives is highly unlikely. In the event of unintended introgression with conventional crops, the regulated article is less likely to alter the biological characteristics of the resulting hybrid.[10][11].

f. The packaging plant in Pulilan, Bulacan, which serves as the seed treatment, packaging and storage facility for corn MON 89034 x NK603, has relevant valid permits including Environmental Compliance Certificate with Reference No. ECC-R03-02012016-3815 issued on February 4, 2016.

DENR-BC's Conclusion

After a comprehensive review and evaluation of the documents and scientific evidence from literature submitted by Monsanto Philippines, Inc. relative to its biosafety permit application for commercial propagation of corn MON 89034 x NK603, the DENR-BC considered that the regulated article poses no significant adverse effect to the environment.

ANNEX V

DOH-BC'S Assessment

a. Corn, the world's third leading cereal crop and widely grown commercial crop, has a history of safe use as it has been grown for thousands of years and used for human consumption.[12].

b. The donor organisms *Agrobacterium* sp. strain CP4 and *Bacillus thuringiensis* or Bt are commonly found in the environment and are not toxic to human beings.

c. The Cry1A.105, Cry2Ab2, and CP4 EPSPS proteins show no amino acid sequence homology to known protein toxins, and are rapidly degraded with loss of functional activity under conditions that simulate mammalian digestion, and during heating.

d. The *cry1A.105*, *cry2Ab2*, and *cp4 epsps* genes were not derived from an allergenic source, and the Cry1A.105, Cry2Ab2, and CP4 EPSPS proteins do not pose immunologically relevant sequence similarity with known allergens or pose the characteristics of known protein allergens.

e. Compositional analysis data confirmed that corn MON 89034 x NK603 was not a major contributor to variation in component levels in corn forage or grain and corn MON 89034 x NK603 plants are as safe and nutritious as conventional corn varieties.

DOH-BC'S Conclusion

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 the commercial propagation of corn MON 89034 x NK603, DOH-BC found that the regulated article applied for commercial propagation is as safe as its conventional counterpart and shall not pose any significant risk to human health.

FPA Plant-Incorporated Protectant (PIP) Registration

The status of Monsanto's application for PIP Registration of corn MON 89034 x NK603 (Trade Name: VT Double PRO®) with Active Ingredients: Cry1A.105 and Cry2Ab2 as Plant Incorporated Protectant (PIP)-Insecticide in corn for the control of Asian Corn Borer, Corn Earworm, Common cutworm and Fall Armyworm is approved for full registration.

The application is approved for full registration in compliance with the provisions stated in the FPA Memorandum Circular No. 10, series of 2017, Guidelines for the Registration of Plant Incorporated Protectants (PIPs) in Pest Protected Plants (PPPs) and other Agricultural Pesticidal Substances Derived from Modern Biotechnology.

As such, this product with FPA PIP Registration No.: PIP-02-03-14 will expire on November 10, 2024 unless sooner revoked by the authority.

Insect Resistance Management Advisory Team (IRMAT) Assessment

December 14, 2021

GEORGE Y. CULASTE
Director
Bureau of Plant Industry
San Andres St., Malate, Manila

Dear **DIR. CULASTE:**

A pleasant day to you.

The DA Insect Resistance Management Advisory Team (IRMAT) reviewed the submission of Bayer CropScience, Inc. (Monsanto Philippines, Inc.) for the renewal application for commercial propagation under the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1 s2016 of Corn MON 89034 x NK603.

Having been mandated by the DA Special Order No. 24 s2017 to provide advice and direction to the BPI in matters relating to Insect Resistance Management (IRM), after a review of the application, the IRMAT therefore finds that the applicant's submitted documents is WITH SUBSTANTIAL COMPLIANCE with the issued DA Memorandum Circular No. 02 series of 2014.

Sincerely yours,

The Insect Resistance Management Advisory Team (IRMAT)

Dr. Candida B. Adalla

Dr. Reynaldo V. Ebora

Dr. Ma. Anita M. Bautista

Dr. Barbara L. Caoili

Dr. Flor A. Ceballo

Dr. Bonifacio F. Cayabyab

SEC Expert's Assessment

a. Corn imports represent less than 10% of total domestic production and consumption. However, the availability of corn will always be important because corn is one of the most critical components in the formulation of animal feed rations to produce pork, poultry meat and eggs.[13][14][15][16].

b. The current pattern of production of GM corn will change slightly due to the expected increase in derived demand from animal feed since it is an important component of the animal feed formulation. The change however is not expected to be drastic. Major factors that are expected to influence the change are the current Covid-19 pandemic and the African Swine Fever that has resulted in stricter rules on meat importation.[17][18].

c. The GM product is expected to increase productivity due to its genetic traits that improve weed management and pest control resulting in increased crop yields and cost reduction from reduced application of pesticides and herbicides.[19].

d. It is not expected to require changes in farm management practices except for reduction of pest and weed management, which is expected to be reduced. This implies a reduction in labor cost.[20].

e. The complementary inputs should be the same for both GM and non-GM corn because as mentioned, what is simply addressed is the ease of weeding and the control of insects that reduces labor cost.[19].

f. The effect would be to lower the cost for labor and material inputs for herbicides and pesticides.[20].

g. It is to be expected that GM products are more expensive, although no comparable data could be given for the non-GM corn product since they are no longer available in the market.[19][20].

h. Given the traits of the GM product, there should be an increase in efficiency due to labor cost savings as well as the economies of scale mentioned.[19][21][22].

i. Given an increase in efficiency and consequent reduction in cost of production, there should be a concomitant increase in profitability. This is clearly shown in the studies that were cited.[23].

j. The farmers are expected to be more competitive with the introduction of GM seeds given the aforementioned increase in production efficiency. This competitiveness may be affected however if there is a lingering public perception that GM crops pose a hidden health risk to humans and that these crops are not being adequately regulated.[20].

k. There should be no additional complementary inputs required to this but rather a decrease in the amounts of pesticides and herbicide applied, and no additional obligations or license cost to be incurred by the farmers.[20].

l. The traditional production techniques and traditional varieties are expected not to be any different from the introduction of non-GM hybrid corn.[20].

m. There is no reason for the social structure of Local Community and Indigenous Peoples to be affected especially in the rural areas given that GM corn has been introduced more than a decade ago. There are no studies to show that the introduction of GM will affect the farmers' social participation in community activities. There is no reason why the adoption of GM will affect the relationship between the GM and non-GM users in the community.[19][20].

n. There are no studies to show that the introduction of GM will adversely affect food availability, accessibility of alternatives, preservation of cultural heritage and other social changes will be affected. In contrast, there could be positive changes for these factors.

SEC Expert's Recommendation

After a thorough and scientific review and evaluation of the documents provided by Monsanto Philippines, Inc. relevant to corn MON 89034 x NK603, the SEC expert recommended for the approval and issuance of biosafety permit of corn MON 89034 x NK603 for commercial propagation.

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