

ASSESSORS' CONSOLIDATED REPORT ON MONSANTO PHILIPPINES INC.'
CORN MON 810 X NK603 APPLICATION FOR COMMERCIAL PROPAGATION

EXECUTIVE SUMMARY

On October 16, 2019, Monsanto Philippines Inc. submitted corn MON 810 x NK603 for commercial propagation, as an original application under the DOST-DA-DENR-DOH-DILG Joint Department Circular (JDC) No. 1 Series of 2016.

After reviewing the Risk Assessment Report and attachments submitted by the applicant, the Scientific and Technical Review Panel (STRP), concurred that corn MON 810 x NK603 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 applicant, 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 [EVENT NAME] 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 MON 810 x NK603.

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 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

A combined trait maize MON 810 × NK603 confers resistance to key lepidopteran insect pest like Asian corn borer (*Ostrinia furnacalis*) and addresses the needs of farmers in their insect resistance management systems as well as weed resistance management systems as demonstrated by the adoption of Roundup Ready maize with the following benefits: (1) a broad-spectrum weed control option in maize, (2) a novel herbicidal mode of action for in-season maize weed control, (3) increased flexibility to treat weeds on an “as needed” basis, (4) cost-effective weed control, and (5) an excellent fit with reduced-tillage systems. In turn, a number of environmental benefits arise from the use of conserved tillage, including improved soil quality, improved water infiltration, reductions in erosion and sedimentation of water resources, reduced runoff of nutrients and pesticides to surface water, improved wildlife habitat, increased carbon retention in the soil, reduced fuel use, and encouragement of sustainable agricultural practices.

Counties Where Approvals Have Been Granted

Country	Food	Feed	Cultivation
	direct use or processing	direct use or processing	domestic or non-domestic use
Argentina	2007	2007	2007
Brazil	2009	2009	2009
Canada			2001
Colombia	2009	2007	2008

Source: <https://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=92>

STRP'S Assessment

1. Gene Interaction

- a. The gene products can be accumulated at different subcellular compartments: Cry1Ab accumulates in the cytoplasm while CP4 EPSPS is directed to the chloroplast. The gene construct for NK603 (*CP4 epsps* gene) is designed to encode a chloroplast transit peptide (CTP) directed to the chloroplast for the site of action of CP4 EPSPS protein, particularly deposited in the plastid. In contrast, the Cry1Ab protein does not have an amino terminal transit peptide, therefore it will just be accumulated in the cytoplasm.[1].
- b. The possibility of interaction of the resulting products, Cry1Ab and CP4 EPSPS proteins, is unlikely to happen due to their different modes of action. Cry1Ab and CP4 EPSPS are accumulated at different subcellular compartments of the plant parts (Cry1Ab accumulates in the cytoplasm and CP4 EPSPS is directed to the chloroplast), thus interaction between these two resulting gene products is very unlikely to occur. Moreover, these proteins are expressed at a very low level, which do not pose any adverse effect to humans and animals. Based on literature search, since the product's approval in 2005, there were no adverse effects documented/reported.[1][2].

2. Metabolic Pathways

- a. The gene products of the events MON810 and NK603 are CP4 EPSPS and Cry1Ab proteins, respectively. The mode of action of each gene product is already established and completely described in several literatures.[3][4][5][6][7][8][9][10].
- b. *Bacillus thuringiensis* insecticidal Cry1Ab toxin does not affect the membrane integrity of the mammalian intestinal epithelial cells.[6][11].
- c. The protein modes of action in both MON810 and NK603 are different, thus the possibility of interaction in the stacked genes (MON810 x NK603) is unlikely and it is not expected to affect plant metabolism.[12][13][14][15].

3. Gene Expression

- a. Based on Monsanto report (2018), the expression of the combined trait product of MON810 x NK603, with similar expression level of the gene products in the individual events of MON810 and NK603, was reported at low levels. Cry1Ab and CP4 EPSPS proteins, expressed at low levels, are unlikely to interact. Hence, no possibility to produce new allergen or toxin.[16].
- b. Similarly, Monsanto Europe-Africa (2007) reported that the level of protein expression of Cry1Ab and CP4 EPSPS in forage and kernels in the single-trait

maize (MON810 and NK603) was similar to the expression level in the stacked maize. In the U.S., a field trial of the stacked MON810 x NK603 was also conducted in 2002. The compositional analyses of the single- trait maize as well as the conventional maize were compared to the stacked maize and found that no statistically significant differences in forage and grain.[16][17][18][19].

4. Field Performance

The field trials of the stacked plant were conducted at different locations: Isabela, Pangasinan, Camarines Sur, Misamis Oriental, Bukidnon and South Cotabato, and were found to be equivalent to the field performance of the individually approved transformation events, MON810 and NK603.[21][22].

5. Agricultural Management

MON810 x NK603 was approved for commercial planting in the Philippines since 2005. Eighty-five percent (85%) of the total biotech maize, cultivated in 2012, accounts to the stacked traits (Bt/Ht). This signifies that most farmers preferred planting maize with stacked traits. The Czech Republic Ministry of the Environment (2007) reported that the management and harvesting techniques of the stacked event, MON810 x NK603, have the same environmental impact as compared to the conventional cultivation practices for traditional maize. Furthermore, the utilization and dispersion of the stacked event in the cultivation environment is considered similar to the case of traditional maize. Hence, stacked traits will not cause alteration in the cultural management of crop, which includes planting, harvesting and processing techniques.[23][24][25].

STRP's Conclusion

After a thorough review of the new studies submitted by Bayer CropScience Inc. for MON810 x NK603 application for commercial propagation, the STRP found that the new studies submitted by the applicant will not affect the safety of MON810 x NK603.

Upon checking the materials submitted by Bayer CropScience, Inc., the references were found substantial to conclude that the corn event MON810 x NK603 has no adverse effect and safe for commercial propagation, specifically the study of Tufarelli et al. (2015), which demonstrated that genetically modified corn is substantially equivalent & safe as existing conventional corn; as well as of Castan et al. (2017) that investigated the genetic stability of the entire construct of NK603 utilizing the stacked variety MON810 x NK603, however, it was recommended to further investigate the genetic stability of the whole genome of GM crops versus commercial crops without genetic modifications. [43][44][45][46].

The STRP found no scientific evidence of gene interaction in the regulated article applied for propagation.

FPA Plant-Incorporated Protectant (PIP) Registration

The status of Monsanto's application for PIP Registration of MON 810 x NK603 (Trade Name: YieldGard® Corn Borer with Roundup Ready® Corn 2), with the Active ingredients: Cry1Ab as Plant Incorporated Protectant (PIP)-Insecticide in corn for the control of Asian Corn Borer (*Ostrinia furnacalis* Guenee) 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-02-02-13 will expire on November 5, 2024 unless sooner revoked by the authority.

DENR-BC'S Assessment

After a comprehensive review and evaluation of the documents including the scientific evidence from references and literature submitted by Monsanto Philippines Inc. on its application for commercial propagation of corn MON810 x NK603, hereunder are the observations and appropriate actions:

- 1.The regulated article is considered substantially equivalent to its conventional counterpart for its history of safe use as food in twelve¹ (12) countries and as feed in eleven² (11) countries. It has also been previously approved for commercial propagation in nine³ (9) countries;
- 2.The individual events of the stacked corn MON810 x NK603 have biosafety permits for commercial propagation, which were previously issued. Therefore, each event has undergone rigorous safety assessment, and is considered safe to the environment and biodiversity, particularly on non-target organisms. Similarly, it is less likely to pose any significant adverse effect on the environment; and
- 3.The incorporation of gene stacked event is through conventional breeding, which is regarded as innocuous for its long history of safe use. Furthermore, the method of crossing individual transgenic parents is similar with that of non-transgenic parents. This method does not introduce any greater variation in the genome beyond what is obtained.

¹Argentina, Brazil, Colombia, European Union, Japan, Mexico, Pakistan, Philippines, South Africa, South Korea, Taiwan, and Uruguay

²Argentina, Brazil, Colombia, European Union, Japan, Pakistan, Philippines, South Africa, South Korea, Turkey, and Uruguay'

³Argentina, Brazil, Canada, Colombia, Japan, Pakistan, Philippines, South Africa, and Uruguay

The DENR-BC acknowledged receipt of the new studies and references and has no further comments. [43][44][45][46].

DENR-BC'S Conclusion

Based on the 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 commercial propagation of corn MON 810 x NK603, the DENR-BC considered the regulated article safe to the environment, particularly on biodiversity.

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 for commercial propagation of corn MON 810 x NK603. The following are the observations and recommendations:

1. Scientific evidence from toxicity studies and references, find that the regulated article will not cause significant adverse health effects to human 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.

After a thorough review of the new studies submitted by Bayer CropScience, Inc. for corn MON810 x NK603 application for commercial propagation, the DOH-BC found that the new studies submitted by the applicant will not affect the safety of corn MON810 x NK603. [43][44][45][46].

DOH-BC'S Conclusion

The 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.

IRMAT Assessment

June 30, 2020

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

Dear Dir. Culaste:

A pleasant day to you.

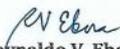
The DA Insect Resistance Management Advisory Team (IRMAT) reviewed the submission of Monsanto Philippines Inc. for the new application for commercial propagation under DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1 s2016 of **Corn MON810 x NK603** through *ad referendum*.

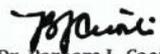
Having been mandated by the DA Special Order No. 24 s2017 to provide advice and direction to the BPI in matters relating to Insect Resistance Management (IRM), after a review of the application, the IRMAT therefore finds that the applicant's submitted document is with **SUBSTANTIAL COMPLIANCE** with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

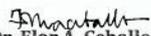
Sincerely Yours,

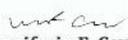
The Insect Resistant Management Advisory Team (IRMAT)

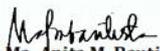

Dr. Candida B. Adalla


Dr. Reynaldo V. Eboria


Dr. Barbara L. Caoili


Dr. Flor A. Ceballo


Dr. Bonifacio F. Cayabyab


Dr. Ma. Anita M. Bautista

SEC Expert's Assessment

- a. Relevant data from PSA were provided to supplement the assertion that GM maize is a significant component of global trade of agricultural commodities.[41][42][43][44].
- b. Relevant and up-to-date data were provided to support response and to assert that the availability of yellow maize as feed material is in fact vital to the competitiveness of the Philippines' livestock and poultry sector.[41][45].
- c. Applicant noted that while the inputs required are the same as those of conventional seeds, production cost is less for weed elimination as fewer laborers are required.[46].
- d. Applicant asserted that the inputs applied to maize cultivation are the same for GM and conventional seeds. Using Torres, et al. (2013) as reference, applicant reported that 73% of the farmer' s gross income from biotech crop went to farm expenses. Of these expenses, 60% are for farm inputs such as seeds, fertilizers, and weedicides. [23].
- e. Applicant noted that as per their market survey, there are no conventional/non-GM maize seeds available in the market. The average price of a GM maize seed is PHP

4500, while the last stock of conventional maize seed was from Pioneer in 2012 with a price range of PHP2500-3000 per bag. In addition, applicant cited a 2009 STRIVE foundation study which states that despite the relatively high price of GM maize seed compared to the price of non-GM hybrid seeds, GM maize has a cost advantage over conventional maize.[23][46].

- f. Generally, the applicant asserts that small-scale farmers will become more competitive as they are assured of high yield and better income with the use of GM seeds.[23].
- g. Applicant noted that different agricultural production systems have been successfully practiced in proximity to one another for many years and in many parts of the world, which implies the likelihood of a peaceful co-existence between GM and non-GM users in the community.[46].

SEC Expert's Recommendation

After a thorough and scientific review and evaluation of the documents provided by Monsanto Philippines, Inc. relevant to corn MON810 x NK603, the SEC expert recommended for the approval and issuance of biosafety permit of the said GM product.

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