

CONSOLIDATED RISK ASSESSMENT REPORT OF MONSANTO PHILIPPINES INC.'S CORN NK603 APPLICATION FOR COMMERCIAL PROPAGATION

EXECUTIVE SUMMARY

On March 29, 2019, Monsanto Philippines submitted corn NK603 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 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 proponent, recommended the issuance of a biosafety permit for this regulated event provided that the conditions set by them 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 NK603 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 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

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 BPI Biotech Secretariat.

INFORMATION ON THE APPLIED EVENT

1. Corn NK603 contains two genes from *Agrobacterium* sp. strain CP4 that expresses CP4 EPSPS protein to confer tolerance to glyphosate (N-(phosphonomethyl)-glycine), the active ingredient in the Roundup® brand of agricultural herbicides. Corn NK603 was produced by particle acceleration technology using a linear DNA restriction fragment from the plasmid vector PV-ZMGT32.
2. Corn NK603 has already undergone the risk assessment for field trial. Moreover, the biosafety permit for propagation of corn NK603 was released by BPI on 8 February 2005 and renewed on 16 March 2010 and 16 March 2015.
3. Corn NK603 was fully characterized to confirm the integrity and stability of the inserted gene. The source of the *cp4 epsps* coding sequence, a soil bacterium, which is not a known human or animal pathogen and for which there are no reports of allergies; CP4 EPSPS protein has been reviewed and approved by numerous independent international regulatory agencies worldwide.
4. Based on bioinformatics searches of amino acid sequence databases, no evidence was observed to indicate that the CP4 EPSPS protein shares similarities with known toxins or allergens. The CP4 EPSPS protein in Corn NK603 is rapidly degraded by simulated gastric fluid, lost activity after heating at temperatures above 75°C, and has no adverse toxicity in mice at the levels tested. A comprehensive compositional analysis demonstrated that maize corn NK603 grain and forage are substantially equivalent to grain and forage from conventional maize.
5. An extensive evaluation of corn NK603 phenotypic and agronomic characteristics and environmental interactions demonstrated corn NK603 has no increased plant pest potential compared to conventional maize and does not negatively affect non-target organisms differently from conventional maize under normal agricultural practices.
6. Corn NK603 is substantially equivalent to the conventional corn, except for its ability to tolerate glyphosate herbicides. The well characterized modes of action, physico-chemical properties, and a history of safe use demonstrate that the CP4 EPSPS protein present in corn NK603 present no risk of harm to the environment.

Countries Where Approvals Have Been Granted (for FFP; for Commercial Propagation)[2]

Country	Food direct use or processing	Feed direct use or processing	Cultivation domestic or non-domestic use
Argentina	2004	2004	2004
Australia	2002		

Brazil	2008	2008	2008
Canada	2001	2001	2001

**Countries Where Approvals Have Been Granted
(for FFP; for Commercial Propagation) (cont.)[2]**

Country	Food direct use or processing	Feed direct use or processing	Cultivation domestic or non-domestic use
China	2002	2002	
Colombia	2004	2006	2007
Cuba			2011
European Union	2005	2004	
Honduras			2001
Indonesia	2011	2012	
Iran	2016		
Japan	2001	2003	2004
Malaysia	2010	2010	
Mexico	2002		
New Zealand	2002		
Nigeria	2019	2019	
Pakistan	2017	2017	2017
Paraguay	2012	2012	2012
Philippines	2003	2003	2010
Russia	2008	2004	
Singapore	2014	2014	
South Africa	2002	2002	2002
South Korea	2002	2004	
Taiwan	2003		
Thailand	2013		
Turkey		2011	
United States	2000	2000	2000
Uruguay	2011	2011	2011
Vietnam	2014	2014	2014 *

STRP'S ASSESSMENT

1. Host Organism

- a. Generally, corn does not contain known allergens or produce significant toxins or antinutrients warranting analytical or toxicological tests. However, in some case-studies, allergenic reactions were reported [3][4].
- b. Maize or corn is being consumed in varied forms. It can be eaten raw. Most of the human consumption of maize is in the form of maize-based ingredients such as high fructose corn syrup, starch, sweeteners, cereals, oil and alcohol [3].

2. Transgenic Plant

- a. Corn NK603 has been reviewed and approved for food and/or feed use in many countries which were listed by the applicant. In terms of food and feed safety, results from compositional studies support the overall conclusion that corn NK603 was not a major contributor to variation in component levels in maize grain and forage and confirmed the compositional equivalence of corn NK603 to the conventional control in levels of these components [3][4][5].
- b. Since corn NK603 was found to be substantially equivalent to conventional maize with similar genetic background, there is no anticipated change in the use pattern for the product [3][5].

3. The Donor Organism

- a. *Agrobacterium sp.* strain CP4 is the donor organism for corn NK603 and is not known to be toxic or allergenic [3].
- b. CP4 EPSPS protein is not known to be toxic or allergenic. CP4 EPSPS protein produced in corn NK603 is also present in many commercial biotechnology-derived crops and that a history of the safe use of CP4 EPSPS protein has been demonstrated [3].

4. Transformation System

- a. Plasmid vector PV-ZMGT32 developed by Monsanto Company, was used for the transformation of maize to produce NK603 and a detailed description of the expression cassette was adequately provided by the applicant [3][6] [8].
- b. Particle acceleration transformation was the method used and the complete experimental protocol was provided by the applicant [3].

5. Inserted DNA

Validation of the results from molecular analyses confirmed that corn NK603 contains a single copy of T-DNA containing the *cp4 epsps* expression cassettes that is

stably integrated at a single insertion site and no detectable additional genetic elements. The result was demonstrated sufficiently by Southern blot analysis and PCR and sequence analysis [3][8].

6. Genetic Stability

- a. The potential for creating novel chimeric ORFs were tested by PCR and DNA sequencing which verified the 5' and 3' ends of the insert in corn NK603. The sequences flanking the insert were confirmed to be native to maize. Western blot confirmed the expression of the full-length CP4 EPSPS proteins in corn NK603 and results indicate that the two CP4 EPSPS proteins are indistinguishable in Western blot analysis with the available polyclonal antibody, since the proteins are essentially identical. The reported data support the conclusion that only the two full-length CP4 EPSPS proteins are encoded by the insert in corn NK603 [3][8].
- b. The reported data show that corn NK603 does not contain backbone sequences from the backbone sequences. This was sufficiently demonstrated by *SacI* restriction enzyme digestion, hybridization and Southern blotting. [3][7].
- c. The reported results from Southern blot analysis demonstrated the stability of the DNA insert across multiple generations on F₁ generation and the fifth generation of back-crossing of corn NK603. The analysis confirmed that a single integration locus was maintained through five generations of breeding, thereby confirming the stability of the insert [3][7].

7. Expressed Material

The reported mean level of CP4 EPSPS proteins in forage was 25.6 $\mu\text{g/g}$ tissue on a fresh weight basis while the level of CP4 EPSPS proteins in grain from event NK603 was 10.9 $\mu\text{g/g}$ tissue. This was measured by performing a double antibody sandwich enzyme-linked immunosorbent assay (ELISA) from the collected forage and grain tissues from the field sites treated with glyphosate in the U.S. Other relevant information in this methodology was provided by the applicant [3][9].

8. Toxicological Assessment

- a. SDS-PAGE and Western blot methods were used in assessing the digestibility of corn NK603 CP4 EPSPS proteins (CP4 EPSPS and CP4 EPSPS L214P) in simulated gastric fluid (SGF, containing pepsin). Results from these experiments demonstrated that CP4 EPSPS produced from *E. coli* were rapidly digested after incubation in SGF. The SDS-PAGE Colloidal Blue gel staining method demonstrated that at least 98% of the *E. coli*-produced CP4 EPSPS proteins were digested in SGF within 15 seconds and the estimated T₅₀ result for SGF is below 15 seconds. There were no observed protein bands due to degradation of the CP4 EPSPS. Western blot analysis confirmed that greater than 95% of the *E. coli*-produced CP4 EPSPS proteins were digested in SGF within 15 seconds [3][10][11].
- b. The estimated T₅₀ CP4 EPSPS is less than 15 minutes and was determined in the

temperature dependence studies which demonstrated that the enzymatic activity is eliminated after 15 minutes incubation at 65°C. The impact of heating and *in vitro* digestibility of CP4 EPSPS has also been confirmed by Okunuki et al. (2002).[12][13].

- c. Upon comparison of amino acid sequences of the CP4 EPSPS to protein sequences in the toxin database using the FASTA sequence alignment tool, the protein shared sequence similarities to homologous EPSPS proteins which have not been described as toxins relevant to human health. No other significant structural homology was observed [3][11][14].
- d. Acute oral toxicity study was conducted with *E. coli*-produced CP4 EPSPS protein and was administered as a single dose by gavage to three groups of 10 male and 10 female CD-1 mice at dose levels up to 572 mg/kg. Results show that there were no treatment-related effects on survival, clinical observations, body weight gain, food consumption or gross pathology. Therefore, the No Observable Adverse Effect Level (NOAEL) for CP4 EPSPS was considered to be 572 mg/kg [3][15].

9. Allergenicity Assessment

- a. The amino acid sequence of the CP4 EPSPS protein was compared to a database of protein sequences associated with allergy and celiac disease using the sequence alignment tool FASTA and demonstrated that CP4 EPSPS shared no structurally significant sequence similarity to sequences within the allergen database.
- b. In addition, the CP4 EPSPS sequence was compared to the allergen database using an algorithm that scans for a window of eight linearly contiguous identical amino acids and results showed that The CP4 EPSPS protein sequence does not share eight linearly contiguous amino acid identities to any sequence in the allergen database.
- c. These results confirm that the CP4 EPSPS protein does not share any relevant amino acid sequence similarities with known allergens, gliadins, or glutenins. Further analysis of the physicochemical and functional properties provides a detailed characterization of the corn NK603-produced CP4 EPSPS and CP4 EPSPS L214P proteins and establish its equivalence to the *E. coli*-produced CP4 EPSPS proteins [3][11][14][16].

10. Nutritional Data

- a. Results of the study provided shows that there were no statistically significantly differences observed for proximate analysis in forage grain and antinutrients between corn NK603 and the conventional control [3][17][18][19][20].
- b. Reference grain and forage samples from the E.U. field trials also included 19 conventional, commercial hybrids (five hybrids per site with one hybrid planted at two sites), planted under the same environmental conditions. All test values of proximate were within the 99% tolerance interval established from the

commercial varieties [3][17][18][19][20].

- c. The studies provided by the applicant show that all test values of forage, grain and antinutrients were within or similar to literature range or historical range [3][19][20]
- d. Differences observed in key nutrients were not biologically relevant and meaningful from a food and feed safety perspective [3][17][18][19][20].

11. The Host Plant Environment

- a. Maize is a wind pollinated species with plant morphology that facilitates cross pollination [21].
- b. The references provided by the applicant on hybridization with cultivated *Zea mays* L., wild annual species of subgenus *Zea mays* subsp. *mexicana*, wild perennial species of subgenus *Tripsacum* have described the possible formation of viable interspecific and/or intergeneric hybrids. From the studies provided, there are no scientific reports confirming the transfer of genetic material from maize to other species with which maize cannot sexually interbreed. Thus, the probability for horizontal gene flow to occur is negligible [22][23][24].

12. The Consequences of Outcrossing

- a. In the Philippines, there is no known sexually compatible wild species. This among other factors reported by the applicant support that the assessment that the risk of loss of this wild species due to the development of the GM variety is very low [22][25].
- b. There are no anticipated changes in habitat or geographic distribution. Corn NK603 has been shown to be no different from conventional maize in its phenotypic, ecological, and compositional characteristics, except for the introduced trait of glyphosate tolerance [6].

13. Weediness Potential

- a. There is no adverse environmental impact is expected from the introduction of Corn NK603 to pests and/or diseases on current cultivation and management practices for maize. As shown by previous studies, corn NK603 has been shown to be no different from conventional maize in its phenotypic, ecological, and compositional characteristics, except for the introduced trait of glyphosate tolerance [6].
- b. Mode of dissemination is through seeds. Plant produces a male (tassel) and female (ear) flower borne on the same plant but different positions. A well-developed ear shoot has 750 to 1,000 ovules (potential kernels), each producing a silk. However, under good conditions only 400 to 600 ovules will be fertilized and eventually produce kernels. Under favorable conditions, a pollen grain upon landing on a receptive silk will develop a pollen tube containing the male genetic material, develop and grow inside the silk, and fertilize the female ovary within 24 hours.

Pollen grains are borne in anthers, each of which contains a large number of pollen grains. The anthers open and the pollen grains pour out after dew has dried off the tassels. Pollen is light and can be carried considerable distances by the wind. However, most of it settles within 6 to 15 meters (20 to 50 feet). Pollen shed is not a continuous process. It stops when the tassel is too wet or too dry and begins again when temperature conditions are favorable [21].

STRP'S RECOMMENDATION

Find sufficient evidence that the regulated article applied for direct use will not pose any significant risk to health and environment as its conventional counterpart and that any risks posed to health and environment could be managed by the following measures;

1. Continuous monitoring of planted sites for weed shifts and herbicide resistance development.
2. Product stewardship.
3. Provision of guidance on the planting of corn NK603 in hilly areas.

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 (NK603), hereunder are the observations and appropriate actions:

1. The regulated article is considered substantially equivalent to its conventional counterpart for its history of since use as food in twenty-six (26) countries and as feed in twenty-one (21) countries. It has also been previously approved for commercial propagation in fourteen (14) countries (International Service for the Acquisition of Agri-Biotech Applications GM Approval Database, 2019) [28].
2. The genetic stability of the transgenic crop was tested over multiple generations wherein the hybrids of the regulated article crossed and backcrossed with inbred were tested for glyphosate herbicide tolerance. Therefore, it is proven stable in molecular structure and trait expression [28].
3. The glyphosate herbicide tolerance traits of the regulated article do not alter nor enhance the persistence, invasiveness, or weediness of the crop relative to its conventional counterpart [28].
4. The CP4 EPSPS protein has no significant potential toxicity to wildlife or non-target organism because agronomic evaluations such as plant vigor, plant habit characteristics, general disease susceptibility has no significant difference relative to its conventional counterpart [29].

DENR BC'S RECOMMENDATION

Based on the evaluation and review of literature cited, the DENR-BC considered the regulated article safe to the environment and 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 (CP) of Corn NK603. I/We,

Find that the regulated article applied for Commercial Propagation (CP) is safe as its conventional counterpart and shall not pose any significant risk to human and animal health and environment.

The following are the observations and recommendations:

1. Find that the regulated article applied for Commercial Propagation (CP) does not require changes in the usual practices as described in the phases/stages of biotechnology project activities. 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 evidences 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 allergic reaction.
4. The regulated article is riot materially different in nutritional composition from that of the non-transgenic or the conventional corn.
5. Scientific pieces of evidences from provided references i.e. literature 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.

DOH BC'S RECOMMENDATION

It is suggested that the Bureau of Plant Industry (BPI) ensure the following:

- a. Strict monitoring of the regulated article from port of entry to the trader's/importer's storage/warehouse as stated in Section 32 of the JDC No. 1 series, 2016.
- b. The BPI to include in the issuance of permit for the release of this product the following conditions:
 - i. Any spillage (during unloading and loading/hauling and transport unloading and storage) shall be collected and cleaned up immediately.
 - ii. Transportation of the consignment from the port of entry to any destination within the country shall be in closed containers.
 - iii. There shall be a clear instructions that the product from importation down to all levels of marketing is only for the purpose of commercial propagation.

SEC EXPERT'S ASSESSMENT

As a percentage of total agricultural trade, maize is not very significant. However, maize importation is increasingly becoming important because of the increasing requirements of a growing animal industry. This is reflected in the increasing importation dependency ratio that is provided. [30][31][32][33].

It is not expected to require changes in farm management practices except for weed. [34]. The complementary inputs should be the same for both GM and non-GM maize because as mentioned, what is simply addressed is the ease of weeding that reduces labor cost. [35].

SEC Expert agrees that this will not affect the traditional production techniques. If any, it should be beneficial to farmers given the reasons given previously. [36].

There is no reason for the social structure of LCIPs to be affected especially in the rural areas. [36].

SEC EXPERT'S RECOMMENDATION

The SEC expert recommends for the approval and issuance of the biosafety permit of the GM product.

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