

**ASSESSORS' CONSOLIDATED REPORT ON PIONEER HI-BRED PHILIPPINES AND
DOW AGROSCIENCES PHILIPPINES' APPLICATION FOR COMMERCIAL
PROPAGATION OF CORN MON89034 X TC1507 X NK603**

EXECUTIVE SUMMARY

On June 14, 2019, Pioneer, Hi-Bred Philippines and Dow AgroSciences submitted corn MON89034 x TC1507 x NK603 for commercial propagation 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 MON89034 x TC1507 x NK603 is as safe for human food, animal feed and commercial propagation as its conventional counterpart.

The Department of Environment and Natural Resources – Biosafety Committee (DENR-BC), after a thorough scientific review and evaluation of the accomplished Project Description Report (PDR) and Environmental Risk Assessment (ERA) form along with the submitted sworn statement and accountability of the proponent, reported that the propagation of the regulated article will not cause any adverse effect on the environment and biodiversity.

The DOH-BC, after a thorough scientific review and evaluation of documents related to Environmental Health Impact, found scientific evidence that the GM application will not cause significant adverse health effects to human and animal health and is not materially different in nutritional composition from that of the non-transgenic corn.

On the other hand, the Socio-economic, Ethical and Cultural (SEC) expert, after reviewing the accomplished SEC questionnaire, raised issues on the commercial propagation of the aforementioned event and did not recommend for the issuance of permit.

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, except for the SEC expert, the complete dossier submitted by Pioneer, Hi-Bred Philippines and Dow AgroSciences. The SEC expert, on the other hand, was provided with questionnaire on socio-economic, ethical

and cultural considerations which has been addressed by the applicant in relation to their application.

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

STRP'S ASSESSMENT

A. Gene Interaction

Cry1A.105, Cry2Ab2, Cry1F, PAT and CP4 EPSPS proteins expressed in MON 89034 x TC1507 x NK603 maize showed no characteristics associated with allergenic proteins.

The potential for interaction between the combination of the Cry1A.105, Cry2Ab2 and Cry1F proteins was assessed using the European corn borer, *Ostrinia nubilalis* larvae. The larvae were exposed to fed lyophilized leaf tissue concentrations of corn varieties MON 890324 (for Cry1A.105, Cry2Ab2); TC1507 (for Cry1F) or MON 89034 x TC1507 x NK603 (for the above-mentioned Cry proteins including CP4 EPSPS) and the correct control tissues in 7-day diet-incorporation bioassay. Bioassay data showed no interaction among the three proteins.

Cry1A.105, Cry1F, and PAT proteins will accumulate in the cytoplasm while the Cry2Ab2 and CP4 EPSPS are targeted to and accumulated in the chloroplast of the cells in the corresponding MON 89034, TC1507, and NK603 maize events.

B. Metabolic Pathways

The mode of action of each gene product is different. The Cry1A.105, Cry2Ab2 and Cry1F proteins bind to specific receptors in the midgut of susceptible Lepidopterous insects. Whereas the PAT protein confers tolerance to exposure to glufosinate-ammonium herbicide and the CP4 EPSPS protein confers tolerance to exposure to glyphosate herbicide.

No interaction among proteins Cry1A.105, Cry2Ab2, and Cry1F within the same metabolic pathways. PAT and CP4 EPSPS are both specific for different compounds such that PAT is for L-Phosphinothricin particularly for glufosinate ammonium herbicide, and CP4 EPSPS for phosphoenolpyruvate (PEP) and shikimate-3-phosphate which are part of the shikimate metabolic pathway.

There are no possible unexpected effects as MON 89034 x TC1507 x NK603 has been produced through conventional breeding methods. It uses three different progenies of corn that are genetically modified and the corresponding transgenes have individual modes of action. The single events have been proven to be safe since its approval. The stacked GM events likewise were produced through the same conventional methods thus it is unlikely that there will be possible unexpected effects on the metabolism of the plant.

C. Gene Expression

The expression levels of the proteins Cry1A.105, Cry2Ab2, Cry1F, PAT and CP4 EPSPS in the grain from MON 89034 x TC1507 x NK603 corn are the same to the individually approved transformations events.

There is a controlled gene expression in the individual corn lines that provide for constitutive expression of the Cry1A.105, Cry2Ab2, Cry1F, PAT and CP4 EPSPS proteins in MON 89034 x TC1507 x NK603 corn.

D. Field Performance

Trait corn product MON 89034 X TC1507 x NK603 is tolerant to the herbicide glyphosate and glufosinate and did not exhibit any biologically meaningful differences in its plant response to herbicides containing glyphosate, glufosinate-ammonium, or sequentially applied glyphosate and glufosinate-ammonium compared to their respective herbicide tolerant controls.

The combined-site analysis showed MON 89034 x TC1507 x NK603 had statistically higher yield (8.9 vs 7.4 tonnes/ha) as opposed to the conventional control. The mean amount for yield of MON 89034 x TC1507 x NK603 was higher than the non-GM commercial corn hybrid data range and may have been related to less injury from target pests that could be attributed to the insect-protection trait in MON 89034 x TC1507 x NK603.

E. Agricultural Management

Bt maize and its stack trait with herbicide tolerant maize are widely cultivated in the Philippines. Agricultural management practices are not expected to change with the introduction of MON 89034 x TC1507 x NK603 maize.

STRP'S RECOMMENDATION

The STRP find scientific evidence that the regulated article applied for propagation has no evidence of interaction on the resulting gene products.

DENR BC'S ASSESSMENT

After a comprehensive review and evaluation of the documents including the scientific evidence from references and literature submitted by Dow AgroSciences and Pioneer Hi-Bred Inc, on its application for Commercial Propagation of Com MON89034 x TC1507 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 eleven (11) and as feed in six (6) countries. It has also been previously approved for commercial propagation in five3 (5) countries;
2. The individual events of the gene stacked Com MON89034 x TC1507 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, biodiversity, and 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 [2].

DOH BC'S ASSESSMENT

After a thorough review and evaluation of the documents provided by the proponent, Dow AgroSciences and Pioneer Hi-Bred Inc, through the Bureau of Plant Industry (BPI), in support of their application for approval for Commercial Propagation (CP) of Corn MON89034 X TC1507 X NK603. The DOH-BC 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 not materially different in nutritional composition from that of the non-transgenic corn or the conventional corn.
5. Scientific pieces of evidences 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. 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:

- Any spillage (during unloading and loading/hauling and transport unloading and storage) shall be collected and cleaned up immediately.
- Transportation of the consignment from the port of entry to any destination within the country shall be in closed containers. b.3. There shall be a clear instruction that the product from importation down to all levels of marketing is only for the purpose of commercial propagation and is not to be used for direct use as food, feed or for processing.

SEC EXPERT'S ASSESSMENT

The SEC Expert reported that from 2014 to 2019, corn production has always been lower than consumption, and the average difference is -780,000 metric tons (MT). This implies the need to increase corn production to meet the demand for consumption.

Based on Table 1, the Philippines' importation of corn varied through the six-year period from 2014 to 2019, but the average import is 7,753MMT. Basically, the Philippines is importing corn for feeds purposes. Increase in local corn production may help in reducing corn importation for feeds.

Table 1. Philippines' corn importation in 2014-2019

Year	Import (1,000MT)	% Growth Rate
2014	7,671	1.85
2015	6,966	-9.19
2016	8,087	16.09
2017	8,084	-0.04
2018	7,608	-5.89
2019	8,100	6.47
Ave	7,753	

<https://www.indexmundi.com/agriculture/?country=ph&commodity=corn&graph=imports>

A study conducted on GM herbicide tolerant maize (largely tolerant to the broad-spectrum herbicide glyphosate) has shown that in the Philippines, the use of GM herbicide tolerant technology gives a farmer an average farm income benefit of US\$40 per hectare. The benefit is realized from cost savings plus yield gains of +5% to +15%. MON 89034 x TC 1507 x NK603 maize also possesses these characteristics in addition to its resistance to lepidopteran insect pests. The main way in which GM HT technology has impacted on farm incomes has been through lowering the levels of pest damage and hence delivering higher yields.

However, based on the research of the expert, the price of GM seeds per bag is P5000-6000. For one hectare, a farmer needs 2 bags which is equivalent to P10,000-12,000 per hectare [3][4]. To a small farmer, this is a significant cost.

Corn MON 89034 x TC 1507 x NK603, as claimed by the applicants, will be planted and managed as the conventional maize and with its ability to resist lepidopteran maize pests such as Asiatic corn borer, the use of pesticides may be reduced and the subsequent cost reduction can be realized from less use of insecticides against Asian Corn Borer (ACB).

In addition, the ability of MON 89034 x TC 1507 x NK603 maize to tolerate glyphosate herbicide may offer effective and economical weed control to ensure yield and increase farmers' income. Likewise, its resistance to the destructive lepidopteran pests like ACB can also increase corn yield. These two characteristics of this GM corn will improve the profitability of farms compared to conventional corn.

In terms of competitiveness of small-scale farmers, it was reported by the expert that the small farmers will be affected by the introduction of GM corn. Since GM corn is hybrid, the seeds from harvested GM crops cannot be planted again without experiencing a drastic reduction in harvested yield by as low as 50% the original yield. GM corn seeds being sold for P5,000 per bag can be costly to small-income farmers if they have to keep buying seeds every harvest season.

In another report, former DA Secretary Piñol gave a directive to investigate the report he received that GM seeds are being sold at P6,000 per bag or equivalent to P12,000 per hectare [4]. Thus, the price of the seeds may limit the competitiveness of the small farmers.

The same cultural practices as the conventional will be done for GM corn. These include land preparation (plowing, harrowing and furrowing), seed sowing, water management, pesticide application, fertilizer application, harvesting, post-harvest management, transport of seeds to seed plant, and cleaning, processing, and bagging of seeds.

The SEC Expert added that since the product is patented, then the farmers may incur license cost. Hence, the farmers specially the small-scale ones may have limited access to the technology. They may not afford to buy the license to use the GM corn seeds. Only the patent owner and those big farmers or corporations who can afford to buy the license to use the GM corn seeds can benefit from the product.

The SEC expert also reported that the use of GM may affect the relationship between the GM and non-GM users in the community who do not favor the use of GMOs, specially the activists. People have different perceptions of GMOs. According to Behrokh Mohajer Maghari and Ali M. Ardekani, the current food biotechnology debate pictures the serious conflict between two groups: 1). Agri-biotech investors and their affiliated scientists who consider agricultural biotechnology as a solution to food shortage, the scarcity of environmental resources and weeds and pests infestations; and 2) independent scientists, environmentalists, farmers and consumers who warn that genetically modified food introduces new risks to food security, the environment and human health such as loss of biodiversity; the emergence of superweeds and super pests; the increase of antibiotic resistance, food allergies and other unintended effects[5].

The SEC expert also believes that the introduction of GM product affect farmers' social participation in community activities especially those who are anti-GMOs. As a sign of protest, they may not participate in community activities in relation to GM corn.

The expert also perceived a differential effect of the technology on the small-scale farmers who may lack the capital to provide the needed inputs particularly the seeds.

As defined, small-scale farmers are resource-poor farmers who are constrained in terms of capital and labor. Because of the financial limitations, the small-scale farmers may not be able to avail of the technology and as such the promised increase in yields and income may not be realized, thus affecting food availability.

The book *Genetically Engineered Crops: Experiences and Prospects* published by the National Academies of Sciences, Engineering, and Medicine; Division on Earth and Life Studies; Board on Agriculture and Natural Resources; Committee on Genetically Engineered Crops: Past Experience and Future Prospects in 2016 devoted Chapter 6 on the social and economic effects of GM crops. On or near farm, these socio-economic factors include income effects, benefits to small farmers, farmers' knowledge, gender, rural communities, and seed availability and cost. The effects of GM crops on these aspects are very variable, hence, the authors recommend for more research to be undertaken which would show more consistent results[6].

The above concerns have to be looked into to ascertain the good or bad effects of GM crops.

SEC EXPERT'S RECOMMENDATION

The SEC expert did not recommend for the approval and issuance of the biosafety permit of the GM product.

INSECT RESISTANCE MANAGEMENT ADVISORY TEAM (IRMAT) RECOMMENDATION

The Insect Resistance Management Advisory Team (IRMAT), upon review of the submitted IRM Plan of corn MON89034 X TC1507 X NK603 application for commercial propagation, found that it is compliant with Memorandum Circular No.2, series of 2014 "Enhancing the IRM Strategy for Bt corn Targeting Asian Corn Borer" and therefore recommends for the issuance of its biosafety permit.

PLANT-INCORPORATED PROTECTANT (PIP) REGISTRATION UNDER FERTILIZER AND PESTICIDE AUTHORITY (FPA)

The stacked product, MON89034 X TC1507 X NK603 (Tradename: PowerCore®) by Pioneer Hi-Bred Philippines and Dow AgroSciences is registered and approved for full registration as PIP product at FPA, with Registration No. PIP-03-07-08 on January 17,2020.

NK603 was not classified and evaluated as PIP, thus it was not included in the issued Certificate of Product Registration.

REFERENCES

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