

ASSESSORS' CONSOLIDATED REPORT ON MONSANTO'S APPLICATION FOR COMMERCIAL PROPAGATION OF COMBINED TRAIT PRODUCT CORN MON89034 X NK603

EXECUTIVE SUMMARY

On April 15, 2016, Monsanto Philippines applied the combined trait product corn MON89034 x NK603 for commercial propagation as an original application under the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1 Series of 2016 (JDC No.1, S2016).

The said transformation event had obtained Biosafety Notifications under the Department of Agriculture Administrative Order No. 8, Series of 2002 for propagation and for food and feed, or for processing on March 3, 2011 and July 10, 2014 (renewal), respectively. The said Biosafety Notification for propagation was expired last March 3, 2016, hence this application represents Monsanto's submission for renewal of these permits under the JDC.

Furthermore, the individual events comprising the said combined trait product were also assessed and approved for commercial propagation. Corn MON89034 was approved last November 19, 2010 and was renewed on November 19, 2015 while NK603 was approved last March 16, 2010 and was renewed on March 16, 2015. The biosafety notifications of corn MON89034 and NK603 are still valid until November 18 and March 15, 2020, respectively.

This application was assessed in accordance with the DA Memorandum Circular No. 6, Series of 2004, Subject: Risk Assessment of Plants Carrying Stacked Genes for Release into the Environment. This Memorandum Circular covers the basic biosafety policies in carrying out the risk assessment of plants carrying stacked genes particularly for applications for commercial release into the environment. Focus of the risk assessment is on the possible adverse interactive effects of corn MON89034 x NK603 which may be indicated by gene expression in common subcellular compartments, sharing metabolic intermediates, targets, and/or pathways, changes in expression levels of single traits.

Under the JDC No.1, S2016, the assessors for Monsanto's MON89034 x NK603 for commercial propagation were the following:

- Two (2) members of the Scientific and Technical Review Panel (STRP) – for evaluation of the Applicant's submitted risk assessment report
- Department of Environment and Natural Resources (DENR) – for the determination of the environmental impact of the said application
- Department of Health (DOH) - for the determination of the environmental health impact of the said application
- Insect Resistance Management Team (IRMAT) – for review and evaluation of the application for any IRM related concerns and issues
- Fertilizer and Pesticide Authority (FPA) – for the determination if applicant is duly licensed as a pesticide handler in accordance with Presidential Decree No. 1144 and if tolerance levels

and good agricultural practices have been established for registration of the transformation event

- Socio-economic, ethical and cultural (SEC) Expert – to evaluate SEC impact of the said application

After reviewing the documents submitted by the applicant, the two members of the STRP find scientific evidence that the regulated article applied for commercial propagation has no evidence of interaction on the resulting gene products while DOH, DENR, IRMAT, and SEC expert recommended for the issuance of Biosafety Permit for corn MON89034 x NK603. On the other hand, FPA found that Monsanto Philippines, Inc. is a duly licensed pesticide importer, exporter, indenter and national distributor of agricultural pesticides

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 Monsanto. The SEC expert, on the other hand, was provided with special questionnaire on socio-economic, ethical and cultural considerations that have been addressed by Monsanto 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 ASSESSMENT AND RECOMMENDATIONS

Based on the STRPs review of the documents submitted:

A. Gene Interaction

The STRPs agrees that, since based on the modes of action of Cry1A.105, Cry2Ab2 and CPS EPSPS proteins, there will be no possibility that the genes or the gene products will interact, such that a new allergen or toxin will be produced. This is because, according to the documents submitted,

there is no known reported mechanism that will allow for interaction that will produce new products that will result to adverse effects especially to other animals and the environment.

They also agreed that the gene products will not accumulate in the same sub-cellular compartments of the plant parts. Cry1A.105 is expected to accumulate in the cytoplasm while, Cry2Ab2 and CP4 EPSPS will accumulate in the chloroplast. The gene constructs of *cry2ab2* and *cp4 epsps* includes a region that allows targeting and transport specifically to the plastids while Cry1A.105 does not have any signal peptide that will make it possible to be exported to any other part of the cell. The difference in the sites of accumulation also point to the unlikely event that the gene products will interact because they are produced and expressed in different sub-cellular compartments of the cell.

B. Metabolic Pathways

The STRPs also agree that the gene products of the inserted novel genes are not involved in the same metabolic pathway. Similarly, they also have different mode of actions, description of which were completely provided by the applicants. The Cry proteins have been found toxic only in the gut of specific lepidopteran insect species and not to mammals (Betz et al., 2000), while CP4 EPSPS is a member of the EPSP synthase enzyme family, whose enzymes catalyze the second to the last step of shikimate pathway that produces aromatic amino acids, and is localized in plant chloroplasts.

Furthermore, they also agree that there is a very low probability or very unlikely that unexpected effects of the stacked genes on the metabolism of the plants will take place. They can be considered to be independent of each other.

C. Gene Expression

The STRPs agree that the Cry proteins and CP4 EPSPS are expressed at low levels, and are properly expressed in MON89034xNK603. They also agree that since the marker genes were not transferred, they are not expressed in the plant. Any likely possible interaction between the two proteins may be considered to be insignificant and will not affect the stability and expression level of either one of the genes.

D. Field Performance

The field performance of stacked corn hybrid MON89034xNK603, was determined during the 2008 wet season (Samson et al., 2009a) and 2009 dry season (Samson et al., 2009b) across six different locations representing the major corn growing areas. The agro-phenotypic characteristics and disease tolerance of the said hybrid was tested in comparison to MON89034, NK603, MON810 and MON810 x NK603. The STRPs agree that the results of this test showed that the stacked MON89034 x NK603 hybrid has the same disease tolerance as the single event MON89034. They also agree that the results of this test showed that the agro-phenotypic characteristics of MON89034 and MON89034 xx NK603 were generally similar to NK603, MON 810 and MON810 x NK603, based on the following parameters (1) seedling emergence and

vigor, (2) stand counts, (3) stalk and root lodging, (4) plant and ear height, (5) stay green rating, (6) % barren plants, and (7) % dropped ears.

E. Agricultural Management

The STRPs also agree that, aside from the expected and intended changes, the presence of traits in the stacked MON89034 x NK603 hybrid will not cause any cultural management changes.

Based on the documents submitted, both STRPs find scientific evidence that the regulated article applied for commercial propagation has no evidence of interaction on the resulting gene products.

DENR BIOSAFETY COMMITTEE ASSESSMENT AND RECOMMENDATIONS

Based on the documents submitted, and augmented by their own separate literature review, the DENR Biosafety Committee concluded that: (a) from the positive results of previous Environmental Risk Assessment, field trial report and monitoring report, that there is no significant risk and negative impact to the environment; and (b) from the scientific pieces of evidence gathered from literature, that the regulated article show that it is as safe as its conventional counterpart, and that it shall not pose any significant risk to non-target organisms, air, water and soil because of the reduction in pesticide use.

Because of these considerations, along with the submitted sworn statement and accountability of the proponent, they recommended for the issuance of a biosafety permit for commercial propagation subject to the following: (a) approval of the concerned local government units where it may be used; (b) limitation of planting and/or commercial propagation within agricultural lands, those of which are classified as Alienable and Disposable (A & D lands); and (c) no planting and/or commercial propagation done in forest, timber lands, protected areas and critical habitats.

DOH ASSESSMENT AND RECOMMENDATIONS

After the scientific review of the DOH Biosafety Committee, they have found that the evidence provided for by the applicant was sufficient and that the regulated article applied for commercial propagation is as safe as its conventional counterpart. Further, they also stated that the said regulated article was not expected to pose any risk to human and animal health and environment.

Along with this, they have made the following observations in support of their above conclusion: (a) on the description of the phases or stages (per EHRA Form No. 3) of the biotechnology project, the applicant, claimed that there was no predicted and potential environmental health impact that was expected to arise from unloading/loading, hauling/transport, storage and harvest/post-harvest of corn MON89034 x NK603. It was further stated that the safety of individual single products and proteins produced in the product had been extensively assessed through standardized protocols including molecular characterization, nutritional and compositional analyses, toxicity studies and environmental assessment; (b) on the risk to health matrix, the applicant rated the activities of the phases of project a very low incident/exponential potential rating; (c) scientific pieces of evidence from literature show that the regulated article applied for commercial propagation is as safe as its conventional counterpart and shall not pose any significant risk to non-target organisms, air, water,

and soil because of the reduction in pesticide use, and has a very favorable environmental, health and safety profile.

Therefore, the DOH BC submitted this recommendation for the consideration of the DA Biosafety Committee, subject to: (a) approval of the concerned local government units where it may be used; (b) the Environmental Health Monitoring Plan (EHMP) will be submitted within 3-6 months period after the issuance of the Biosafety Permit; (c) focusing mainly on the identified highly exposed individuals or groups as stated in Section III.a; (d) detailed health assessment as indicated in the guidelines as post-Biosafety Permit requirement.

IRMAT ASSESSMENT AND RECOMMENDATIONS

The group met on August 8, 2016 held at PCAARRD, Los Baños, Laguna, to evaluate the submission of Monsanto's application for renewal of MON89034 x NK603 for commercial propagation.

Based on the provision of the existing DA AO8 that covers the importation and release into the environment of plants and plant products derived from the use of modern biotechnology, the members present during the meeting posed no objection and endorsed the approval of the request.

FPA ASSESSMENT AND RECOMMENDATIONS

The MON 89034 event expresses a plant-incorporated protectant in the form of the Bt proteins Cry1A.105 and Cry2AB2, and as such went through an evaluation of the FPA. Based on the submitted documents and their own records, the FPA found that Monsanto Philippines, Inc. is a duly licensed pesticide importer, exporter, indenter and national distributor of agricultural pesticides with License No.02-116-495 valid until February 1, 2017.

In addition, necessary documents were attached to the evaluation that in corn MON89034 x NK603 event, MON89034 contained the *Bacillus thuringiensis* (Bt) proteins Cry1A.105 and Cry2Ab2 which expresses the trait as plant-incorporated protectant (PIP). Then, it has been issued with PIP registration on July 4, 2015 and certification on July 1, 2016. Furthermore, *Bacillus thuringiensis* (Bt) proteins Cry1A.105 and Cry2Ab2 residues in or on the food and feed commodities of corn were exempted from the requirement of tolerances pursuant to the US Environmental Protection Agency's Electronic Code of Federal Regulations (EPA e-CFR) dated May 5, 2015 (80 FR 25604) and May 6, 2015 (80 FR 25950).

SEC EXPERT ASSESSMENT AND RECOMMENDATIONS

Based on their review of the documents submitted:

A. Socio-economic Issues

The SEC expert agreed that, in terms of production, consumption and trade, the impact made by GM corn planting is significant. They agreed that in recent years after the commercialization of GM corn, the country became self-sufficient in yellow corn. This self-sufficiency in yellow corn may have influenced the stabilization of feed prices and ultimately stabilized the prices of meat products. In addition, the expert also agreed that the commercialization of GM corn in the country is expected to drastically improve the patterns of production, consumption and trade of

yellow corn, which would also improve the performance of livestock, poultry and aquaculture sub-sector. This improved productivity will also result to the increase in farmer's income, ultimately enhancing the development of rural areas.

The expert agreed that there is an increase in the yield of yellow corn, as exhibited in empirical studies (e.g. Yorobe et .al). They also said that the introduction of GM corn does not necessarily alter the farm management requirement significantly in order to attain higher yield since it will only reduce the activities and inputs used in the production of yellow corn, and that cultural practices being done in conventional corn farming is the same as GM corn farming.

The expert agreed that the introduction of GM corn significantly lower the inputs used by yellow corn farmers and at the same time increases its production. This effect of GM corn, as stated in the documents submitted, significantly improved the overall resource efficiency of yellow corn farms in the Philippines.

B. Social Issues

The expert also agreed that with the reduction of pesticide use in GM corn, there will be a positive effect to the health of not only yellow corn farmers but to most people living in corn producing communities. In addition, the expert also stated that even with the possibility of being dependent to a specific type of herbicide, there will be minimal risk of choice due to the strong and effective regulatory framework. However, he also agreed that there will be alteration in the traditional supply chain of yellow corn because, instead of using recycled seeds from previous season, the farmers will be forced to purchase GM corn seeds if choose to use it.

The expert also agreed that planting GM corn will not cause any negative effects on the social structures in the rural areas because most yellow corn farmers are small, thus, increasing their income from adoption of GM corn will improve the income distribution in the rural areas. However, he also agreed that there might be risk of conflict to occur between adaptors of GM corn and non FM corn due to risk of contamination by unintentional gene flow. This coexistence, as reported is at risk, especially to some non GM corn farmers who intend to sell their products in specific markets (e.g. organic). On the other hand, the expert listed some measures to overcome this risk of conflict, as suggested by literature: (a) introduction of rigid or flexible refuge or buffer areas for corn production; (b) traceability of products; and (c) voluntary or mandatory cooperative GM free zones. He also noted that since the country also has a very strong regulatory framework for GM products, this may also help in minimizing the risk of conflict.

C. Ethical Issues

The expert agreed that although there were no ethical principles of the population at large being violated, some sectors perceived GM products to be morally unethical. This perception, the expert added, is not widely accepted among Filipinos. The expert also agreed that GM corn does not require special requirements in marketing and sales, thus, GM corn does not alter ethical norms and values in marketing.

D. Recommendation

The expert, after the above observations and scenarios of the consequences of MON89034 x NK603, recommends the issuance of the permit of Corn MON89034 x NK603 for commercial propagation. He stated that the introduction of GM corn would increase production without the need to convert more land to corn production. He also added that with the very high population growth rate, GM is the inevitable technology that would have enormous potential positive impact to the rural population. However, he noted that concerned agencies, both government and non-government should monitor and regularly assess the risk of any GM products introduced in the country.