

Determination of the Safety of Monsanto's
Combined Trait Product Corn: MON 89034 x NK603
for Direct Use as Food or Feed or for Processing

Food and Feed Safety:

The product dossiers of Combined Trait Product Corn: MON 89034 x NK603 were reviewed for safety and nutritional differences compared with the conventional corn. The focus of the review was on any new or altered expression trait and changes in composition and nutritional content or value relative to the conventional corn. At the end of the safety assessment, a conclusion was made that the combined trait product corn: MON 89034 x NK603 is as safe as the conventional corn taking into account dietary impact of any changes in nutritional content or value.

A biosafety notification for combined trait product corn: MON 89034 x NK603 and all progenies derived from crosses of the product with any conventionally-bred corn and corn containing approved-biotech events for direct use as food, feed or for processing was issued to Monsanto Philippines, Inc. on July 22, 2009. The notification is valid for five years and shall expire on July 21, 2014 subject to the terms and conditions set forth in DA Administrative order No. 8, Series of 2002, and Memorandum Circulars Nos. 6 and 8, Series of 2004. The said combined trait product corn was included in the Lists of Approval Registry being prepared by the Department of Agriculture-Bureau of Plant Industry.

This approval is for use as Food, Feed and Processing only. This does not include cultivation of combined trait product corn: MON 89034 x NK603 in the Philippines. Food and Feed use of combined trait product corn: MON 89034 x NK603 and its by-products is therefore authorized as of July 22, 2009. The biosafety notification (No. 09- 019) stated that combined trait product corn: MON 89034 x NK603 is as safe for human food, livestock feed and for processing as its conventional counterparts”.

I. Brief Identification of the Genetically Modified Organism (Living Modified Organism)

Designation:	Combined Trait Product Corn: MON 89034 x NK603
Applicant:	Monsanto Philippines, Inc.
Plant Species:	
Name:	Corn (<i>Zea mays</i> L.)
Parent Material:	Inbred corn lines (and/or isolines) developed and produced by Monsanto
Center of Origin:	Mexico and Central America
Toxic Factors/Allergen(s):	Corn is not a common allergenic food. Phytic acid raffinose are antinutrients included in corn.
Trait Description:	Insect resistance and glyphosate herbicide tolerance
Trait Introduction Method:	Conventional breeding

Donor Organism: *Bacillus thuringiensis* - a source of (Bt) *cry1A.105* and *cry2Ab2* genes which confers resistance to lepidopteran insects

Agrobacterium sp. Strain CP4, source of *cp4 epsps* gene which encodes only for the naturally glyphosate-tolerant EPSPS protein

Pathogenicity: *Bacillus thuringiensis (Bt)* has been used commercially in the US for over four decades to produce microbial pesticides. Cry proteins produced from Bt have a history of safe use since 1958 as active ingredients either in Bt microbial pesticides or in biotechnology derived food and feed crops.

The assessment of potential allergenicity and toxicity showed there was a reasonable certainty of no harm to mammals from exposure to the Cry1A.105 and Cry2Ab2 proteins.

The *cp4* gene, which was derived from the common soil bacterium *Agrobacterium sp.* Strain CP4, encodes only for the naturally glyphosate-tolerant EPSPS protein. No other protein is produced or introduced which may bring about toxicity, allergenicity or may be anti-nutritional in nature. Proven to be a safe source. No known pathogenicity in humans and animals because of the absence of the shikimic acid pathway in animals.

Proposed Use: For direct use as food, feed or for processing

II. Background Information

Monsanto Philippines has filed an application with attached technical dossiers to the Bureau of Plant Industry on April 30, 2009 for a biosafety notification for direct use as food, feed and for processing under Administrative Order (AO) No. 8 Part 5 for combined trait product corn: MON 89034 x NK603 which has been genetically modified for insect resistance and herbicide tolerance.

A safety assessment of combined trait product corn: MON 89034 x NK603 was conducted by Scientific and Technical Review Panel (STRP) as per Department of Agriculture Administrative Order No. 8 Series of 2002. The focus of risk assessment is the gene interactions between the transgenes.

Review of results of evaluation by the BPI Biotech Core Team in consultation with DA-Biotechnology Advisory Team (DA-BAT) completed the approval process.

III. Description of Novel (Introduced) Traits

Corn MON89034 produces the Bt insecticidal proteins Cry1A.105 and Cry2Ab2 through *Agrobacterium*-mediated transformation. The introduction of corn MON 89034 is expected to provide enhanced benefits for the control of lepidopteran insects pests such as *Ostrinia furnacalis* (Asian corn borer) and *Spodoptera frugiperda* (fall army worm) and *Helicoverpa zea* (corn ear worm) compared to existing products.

Corn NK603 produces CP4 EPSPS protein from the *Agrobacterium* sp., strain CP4, conferring tolerance to glyphosate herbicide

The transgenic traits from Event MON89034 and Event NK603 were combined through conventional breeding to produce the MON89034 x NK603 corn. This stacked hybrid produces the three (Cry1A.105, Cry2Ab2, and CP4 EPSPS) transgenic proteins present in MON89034 x NK603 corn plants.

Safety of Expressed Proteins

Based on the modes of action of Cry1A.105, Cry2Ab2 and CP4 EPSPS proteins, any likelihood of interaction with one another is not considered to be significant that could lead to production of a new allergen or toxin. There is no known mechanism of interaction among these proteins that could lead to adverse effects in humans or animals.

Thus, bioefficacy data demonstrate that the insect control proteins (Cry1A.105, Cry2Ab2) and herbicide tolerance (CP4 EPSPS) proteins produced in MON 89034 x NK603 do not interact in the plant. There was no evidence of altered insecticidal activity against key target insects or altered efficacy of the glyphosate tolerance traits in the combined trait product.

IV. Nutritional Composition (Compositional Analysis)

Based on the modes of action of the Cry1A.105, Cry2Ab2, and CP4 EPSPS proteins expressed in MON 89034 x NK603, there is no known mechanism of interaction among the gene products that could lead to adverse effects in human and animals. The prior safety assessments of these individual events are directly applicable to the combined trait product. Compositional assessments of the corn from MON 89034 and NK603 demonstrated that MON 89034 and NK603 are nutritionally and biologically equivalent to their conventional counterpart.

V. Anti-Nutritional Factors

There were no synergistic or antagonistic interactions identified in MON 89034 x NK603, the prior safety assessments of these individual events are directly applicable to the combined trait product. Compositional assessments for the antinutrients in the corn from MON 89034 and NK603 demonstrated that they are nutritionally and biologically equivalent to their conventional counterpart.

VI Regulatory Decision

After reviewing the scientific data and information relevant to the combined trait corn MON 89034 x NK603 application of Monsanto Philippines Inc. it is concluded that no interaction found between/among the combined traits, hence this plant product was found to be as safe as its conventional corn and can substitute for its traditional counterpart for direct use as food, feed and for processing. Monsanto is hereby notified that it may proceed with the activities for the above product for direct use as food and feed or for processing following all existing rules and regulations consistent with DA AO #8.