

Determination of the Safety of Monsanto's  
Corn MON 863 (Insect-Resistant Corn)  
for Direct Use as Food, Feed and for Processing

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**Food and Feed Safety:**

The product dossier on Corn MON 863 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 corn event MON 863 is as safe as the conventional corn taking into account dietary impact of any changes in nutritional content or value.

A biosafety permit for Corn MON 863 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 and for processing were issued to Monsanto Philippines Inc. on October 7, 2003. The permit is valid for five years and shall expire on October 6, 2008 subject to the terms and conditions set forth in DA Administrative Order No. 8, Series of 2002. The said corn event (MON 863) was included in the Lists of Approval Registry (Delisting) being prepared by the Department of Agriculture-Bureau of Plant Industry.

*This approval is for Direct use as Food, Feed and for Processing only. This does not include cultivation of Insect Resistant Corn MON 863 in the Philippines. Food, Feed and use of its by-products is therefore authorized as of October 7, 2003. The biosafety permit (No.03-005) stated that "Insect-Resistant (rootworm) Corn MON 863 is as safe for human food, livestock feed and for processing as its conventional counterparts".*

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

<b>Designation:</b>	Corn MON 863
<b>Applicant:</b>	MONSANTO PHILIPPINES, INC. 7 <sup>th</sup> Floor, Ayala-FGU Center Alabang-Zapote Rd. cor Acacia Avenue Madrigal Business Park Alabang 1770, Muntinlupa City Philippines
<b>Plant Species:</b>	
Name:	Corn ( <i>Zea mays</i> L.)
Parent Material:	Inbred line of corn A634
Center of Origin:	Mexico, Central America and South America

Toxic Factors/Allergen(s):	Trypsin inhibitor, phytic acid, and secondary metabolites such as raffinose, ferulic acid and p-coumaric acid are present in low amount 2-4 dihydroxy-7-methoxy-2H-1, 4 benzoxazin- 3(4H)- one (DIMBOA) a potential toxicant but declines rapidly as the plant grows
<b>Trait Description:</b>	Insect Resistance
<b>Trait Introduction Method:</b>	Particle bombardment transformation
<b>Donor Organism:</b>	<i>Bacillus thuringiensis</i> subsp <i>kumamotoensis</i> , source of <i>cry3Bb1</i> gene which produces a protein with enhanced insecticidal activity against the coleopteran pest, corn rootworm.
<b>Pathogenicity:</b>	<i>Bacillus thuringiensis</i> subsp. <i>kumamotoensis</i> is a non-pathogenic spore-forming gram positive bacterium that is found naturally in soil. Bt strains have been used commercially in the US since 1958 to produce microbial-derived products with insecticidal activity.
<b>Proposed Use:</b>	For direct use as food, feed and for processing

## II. Background Information

Monsanto Philippines, Inc has developed a corn line resistant to the corn rootworm, a periodic pest of corn. This corn line, designated Corn Event MON863, has been transformed using Particle Bombardment Transformation, to produce an insecticidal protein, from *Bacillus thuringiensis* (subspecies *kumamotoensis*), active against coleopteran corn pest, corn rootworm. This corn line was developed to provide a method to control yield losses from insect feeding damage caused by the larval stages of corn rootworm, without the use of conventional pesticides

On May 6, 2003, Monsanto Philippines Inc. submitted an application to the Bureau of Plant Industry requesting for biosafety permit under AO#8 for corn event MON863 which has been genetically modified for insect resistance (rootworm) corn.

Monsanto Philippines Inc. has provided data on the identity of line Corn MON863, a detailed description of the transformation method, data and information on the gene insertion sites, copy number and levels of expression in the plant, the role of the inserted genes and regulatory sequences in donor organisms and full nucleotide sequences. The novel proteins were identified, characterized and compared to the original bacterial proteins, including an evaluation of their potential toxicity to livestock and non-target organisms. Relevant scientific publications were supplied.

Corn MON863 has been evaluated according to BPI's safety assessment by concerned agencies Bureau of Animal Industry (BAI), Bureau of Agriculture Fisheries and Product standards (BAFPS), and a Scientific Technical Review Panel (STRP). The process involves an intensive analysis of the nature of the genetic modification together with a consideration of general safety issues, toxicological issues and nutritional issues associated with the modified corn.

The petitioner/applicant published the said application on two widely circulated newspapers (Malaya and Daily Tribune) on June 6, 2003 for public comment/review. BPI received no comment on the petition during the 30-day comment period.

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 Event MON 863 (Tradename: Yieldgard Corn Rootworm) and all corn lines/hybrids derived from this Event contain the *cry3Bb1* coding sequence from *Bacillus thuringiensis* sp *kumamotoensis* strain. The *cry3Bb1* gene was modified to produce a protein with enhanced insecticidal activity against the coleopteran pest, CRW, and was codon optimized for expression in monocotyledonous plants.

#### **Safety of the Expressed Proteins**

No biologically relevant structural similarities were observed between any known allergen or toxin and the Cry3Bb1 protein produced in corn event MON 863. Further, no immunological relevant sequence similarities were observed between the Cry3Bb1 protein and proteins in the allergen and gliadin database.

Bioinformatics analyses indicate that the Cry3Bb1 protein produced by corn event MON 863 is not similar to known allergens, toxins or other pharmacologically active proteins relevant to animal or human health. In addition, Cry3Bb1 from MON863 can be easily degraded to a small transient peptide fragment (MW=2Kda) within 15 seconds under simulated gastric conditions.

### **IV. Nutritional Composition (Compositional Analysis)**

Statistical analysis of the compositional data using randomized complete block model analysis of the variance for multiple replicated trials showed that the ranges for proximate analysis, neutral detergent fiber, amino acids, vitamins and minerals (calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium, and zinc showed comparable ranges with published data for commercial corn). Thus MON 863 can be used in food and feed formulations and 100% substitute for commercial corn.

The nutritional equivalence of MON 863 corn to conventional corn was confirmed in numerous feeding studies with broiler chickens and rats which included clinical and histological evaluations. The environmental impact of MON 863 corn is also comparable to conventional corn.

### **V. Anti-Nutritional Factors**

There are no toxic or anti-nutritional factors present in corn which would need to be controlled by a specification. Though trypsin inhibitor, phytic acid, and secondary metabolites such as raffinose, ferulic acid and p-coumaric acid have been established as anti-nutrients in corn, they are present in very low amount and are below the thresholds considered to raise a food safety concern. The amount of anti-nutrients present in Bt176 corn fell within the range found in non-transgenic corn.

## **VI. Regulatory Decision**

After reviewing the scientific data and information relevant to the application of Monsanto Philippines Inc., it is concluded that Corn MON863 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 and for processing is as safe and substantially equivalent to its unmodified counterpart, and is therefore approved for direct use as food, feed and for processing. Monsanto shall duly inform the public of this approval by way of publishing in any one (1) of the top three (3) leading newspapers in the country that imports of this product is covered by conditions for approval as provided in Department of Agriculture Memorandum Circular No. 8, Series of 2003.