

Determination of the Safety of Monsanto's  
Corn MON 810 (Insect-Resistant Corn)  
for Direct Use as Food, Feed and for Processing and for Propagation

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**Food and Feed and Environmental Safety**

The product dossier on Yieldgard® (MON810) was 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, the following conclusions were made: Corn MON 810 is as safe as the conventional corn taking into account dietary impact of any changes in nutritional content or value. Corn MON810 is safe to humans, animals, non-target organisms and as nutritious as ordinary corn. Corn MON810 is safer than chemical insecticides. Corn MON 810 is very effective in controlling Asiatic corn borer.

A biosafety permit for Yieldgard® (MON810) and all progenies derived from crosses of the product with any conventionally-bred corn and corn containing approved-biotech events for propagation was issued to Monsanto Philippines Inc. on December 4, 2002. The validity of the permit was only five years. Based on many published local and foreign studies, comprehensive reviews and reports on corn MON 810 event showing no adverse effects on human and animal health, the environment, non target beneficial arthropods; similar nutritional compositions, substantial equivalence, superior performance in terms of corn yield, cost of production, profit and global cost competitiveness compared to non-transgenic or conventional maize, the biosafety permit for propagation for MON810 hybrids was renewed on December 3, 2007. The permit is valid for five years and shall expire on December 2, 2012 subject to the terms and conditions set forth in DA Administrative Order No. 8, Series of 2002, and Memorandum Circular No. 2, Series of 2007. The transformation event approved for propagation is also approved for direct use as food, feed and for processing. The said corn event (MON810) was included in the Lists of Approval Registry (Delisting) prepared by the Department of Agriculture-Bureau of Plant Industry.

*This approval is for propagation which is also approved for Direct use as Food, Feed and for Processing of Insect Resistant Corn Mon 810 in the Philippines. Food, Feed and use of its by-products and cultivation of Corn MON810 is therefore authorized as of December 4, 2002 which was renewed on December 3, 2007. The biosafety permit stated that "Insect-Resistant (ACB) Corn Mon 810 is as safe for human food, livestock feed and for processing as its conventional counterparts" and also safe for the environment.*

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

**Designation:** Yieldgard® (MON 810) corn

**Applicant:** MONSANTO PHILIPPINES, INC.  
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**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, 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 (Biolistic method)
<b>Donor Organism:</b>	<i>Bacillus thuringiensis var kurstaki</i> , source of <i>cry1Ab</i> gene which produces crystal protein effective as insecticide against specific group of insects.
<b>Pathogenicity:</b>	<i>Bacillus thuringiensis var. kurstaki</i> (the donor for Cry1Ab protein) has been shown to be non-toxic to humans, other vertebrates and beneficial insects. <i>B.t.k.</i> based foliar insecticides have been registered for over 30 years and have a long history of safe use
<b>Proposed Use:</b>	For propagation and for direct use as food, feed and for processing

## II. Background Information

Monsanto Philippines, Inc has developed a corn line resistant to the Asiatic corn borer (ACB), a periodic pest of corn. This corn line, designated Yieldgard® (referred to as MON810 in this document), has been transformed using micro projectile bombardment or particle acceleration, to produce an insecticidal protein, from *Bacillus thuringiensis* (subspecies *kurstaki*), active against lepidopteran corn pest, asiatic corn borer (ACB). This corn line was developed to provide a method to control yield losses from insect feeding damage caused by the larval stages of corn borer, without the use of conventional pesticides.

On September 3, 2002, Monsanto Philippines Inc., submitted an application to the Bureau of Plant Industry requesting for biosafety permit under AO#8 for corn MON810 which has been genetically modified for insect resistance (corn borer). Since the validity of the permit is only five years, Monsanto Philippines, Inc. submitted an application for Corn MON 810 renewal to the Bureau of Plant Industry on June 13, 2007.

Monsanto Philippines Inc. has provided data on the identity of line Corn MON 810, 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 MON 810 has been evaluated according to BPI's safety assessment by concerned agencies: [Bureau of Animal Industry (BAI), Bureau of Plant Industry (BPI), Bureau of Agriculture Fisheries and Product Standards (BAFPS) and Fertilizer and Pesticide Authority (FPA)], 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 and environmental issues associated with the modified corn.

The petitioner/applicant published the said application on two widely circulated newspapers (Malaya and Daily Tribune) on October 2, 2002 for public comment/review. BPI received positive comments on the petition supporting the cultivation of Corn MON 810 during the 30-day comment period. The petitioner also published the renewal application in two widely circulated newspapers (Malaya and Daily Tribune) on October 25, 2007. Likewise, BPI received positive comments on the petition supporting the cultivation of Corn MON 810 during the 15-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 810 (Tradename: Yieldgard®) and all corn lines/hybrids derived from this Event contain the *cry1Ab* coding sequence from *Bacillus thuringiensis* sp *kurstaki* strain. The *cry1Ab* gene was modified to produce a protein with enhanced insecticidal activity against the lepidopteran pest, ACB.

The novel variety produces a truncated version of the insecticidal protein, Cry1Ab, derived from *Bacillus thuringiensis*. Delta-endotoxins, such as the Cry1Ab protein expressed in MON 810, act by selectively binding to specific sites localized on the brush border midgut epithelium of susceptible insect species. Following binding, cation-specific pores are formed that disrupt midgut ion flow and thereby cause paralysis and death. The insecticidal properties of Cry1Ab is applicable only to lepidopteran insects, and its specificity of action is directly attributed to the presence of specific binding sites in the target insects. There are no binding sites for delta-endotoxins of *B. thuringiensis* on the surface of mammalian intestinal cells, therefore, livestock animals and humans are not susceptible to these proteins.

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

*Bacillus thuringiensis* var. *kurstaki* HD-1(*B.t.k.*) is a common gram-positive soil-borne bacterium. In its spore forming stage, it produces several insecticidal protein crystals, including the d-endotoxin Cry1A(b) which is active against certain lepidopteran insect pests, such as ACB.

This protein has been shown to be non-toxic to humans, other vertebrates and beneficial insects. *B.t.k.* based foliar insecticides have been registered for over 30 years and have a long history of safe use.

Corn products are an important alternative to wheat flour for individuals afflicted with coeliac disease, an immune mediated food intolerance for which wheat gliadins have been implicated as the causal agent.

The amino acid sequence similarity between the MON 810 Cry1A (b) protein and proteins relevant to allergy and coeliac disease (that were assembled to a sub-database of publicly available sequences) was evaluated. The amino acid sequence similarity between the corn event MON 810 Cry1A (b) protein and toxins or other pharmacological active proteins relevant to animal or human health was also evaluated. The FASTA sequence alignment tool was used to assess structural similarity.

No amino acid sequence homologies between the Cry1A (b) protein and gliadins were detected. It also indicated no amino acid sequence homologies between known toxins and the Cry1A (b) protein, with the exception of homologies to other *B.t.* insecticidal proteins.

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

Studies showed that the ranges for proximate analysis (moisture, protein, ash, fat), calories, crude fiber, carbohydrates, starch, fatty acid profile, sugar profile, amino acid composition, tocopherols and minerals (calcium and phosphorous) showed comparable ranges with commercial corn.

The nutritional equivalence of MON810 corn to conventional corn was confirmed in numerous feeding studies with broiler chickens, quails, rats and catfish which included clinical and histological evaluations. The studies showed that MON810 and the commercial variety are substantially equivalent in composition.

Thus MON810 can be used in food and feed formulations and 100% substitute for commercial 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 Yieldgard® corn fell within the range found in non-transgenic corn.

#### **VI. Environmental Assessment**

Predator arthropods are not susceptible to Bt toxin. Studies confirm that direct feeding on Bt plant materials poses negligible risks for arthropod predators or non target insects. Inclusion of GM plant products at about 12% inclusion level in feed were as safe as the commercially available non GM products in terms of effects on indices and histological parameters of the Atlantic and

Salmon intestinal tract. Similarly, GM products given to salmon diet at a given level poses little or no adverse risk to the health of the first feeding atlantic parr and promote normal growth. Bt corn is not deleterious to the natural enemy population like *Trichogramma* parasitism and high predator population (flowers, bugs, *Orius tantillus*, coccinellid beetle, and spiders). Results in feeding trial of the broiler chicks using yieldgard corn hybrids and their isohybrids with or without insecticide treatment showed that he feed consumption, body weight gain, feed efficiency and dressing percentage at 28 and 42 days of feeding were not significantly affected by the two yieldgard corn varieties and their isohybrid counterpart. Studies conducted shows that Yieldgard (Bt corn) does not appear to have detrimental effects on insect diversity, guild structure and population abundance of predator beetles and lacewings as well as parasitoid *Trichogramma* sp. Studies showed that in general field trial, the transgenic corn producing the Cry1Ab toxin of Bt did not affect the non-target organisms. Field studies have confirmed that the abundance and activity of parasitoids and predators are similar in Bt and non Bt crops.

## **VII. Regulatory Decision**

After reviewing the scientific data and information relevant to the application of Monsanto Philippines Inc., it is concluded that Yieldgard® (MON810) and all progenies derived from crosses of the product with any conventionally-bred corn, and corn containing approved-biotech events for propagation is as safe and substantially equivalent to its unmodified counterpart, and is therefore approved for propagation and is also approved for direct use as food, feed and for processing. The permittee must comply with approved stewardship program consisting of Enhanced Insect Resistance Management (IRM) strategy, other approved monitoring activities, regular report of seed sales and conduct of required technical studies.