

SUMMARY REPORT

**RISK ASSESSMENT OF GENETICALLY MODIFIED – PROTECTED
CORN MON 810 TO HUMAN AND LIVESTOCK**

© 2019 Monsanto Company. All Rights Reserved.

This document is protected under national and international copyright law and treaties. This document and any accompanying material are for use only by the regulatory authority to which it has been submitted by Monsanto Company and its affiliates, collectively “Monsanto Company”, and only in support of actions requested by Monsanto Company. Any other use, copying, or transmission, including internet posting, of this document and the materials described in or accompanying this document, without prior consent of Monsanto Company, is strictly prohibited; except that Monsanto Company hereby grants such consent to the regulatory authority where required under applicable law or regulation. The intellectual property, information and materials described in or accompanying this document are owned by Monsanto Company, which has filed for or been granted patents on those materials. By submitting this document and any accompanying materials, Monsanto Company does not grant any party or entity any right or license to the information, material or intellectual property described or contained in this submission.

I. General Information

1. Name of Applicant: Dekalb Vietnam Company Limited

Applicant's representative: Aruna Rachakonda, Country Lead

Applicant's contact point: Nguyen Thuy Ha, Regulatory Affairs Lead

Address: Unit 1606, Centec Tower, 72-74 Nguyen Thi Minh Khai Street, Ward 6, District 3, Ho Chi Minh City, Vietnam

Tel: +84 8 3823 3474

Fax: +84 8 3823 3473

Email: ha.thuy.nguyen@monsanto.com

2. Name of GM plants

Common name: Corn or Maize

Scientific name: *Zea mays* L.

Trade name: YieldGard Corn Borer Corn

Gene transfer event: Insect-protected corn, MON 810

Introduced trait related to the transformed gene: Corn borer resistance

The only identified code (if yes): MON-ØØ81Ø-6

3. Brief Description of Phenotypic Effect(s) of the Transgene:

MON 810 corn contains *cry1Ab* gene from *Bacillus thuringiensis* that encodes Cry1Ab protein which confers resistance to corn borer.

4. Method of Transformation used:

Particle acceleration transformation

II. Executive Summary and Overall Conclusions

Using modern biotechnology, Monsanto Company has developed insect-protected YieldGard® Corn Borer corn event MON 810 (hereafter referred to as MON 810 corn) that produces the naturally occurring *Bacillus thuringiensis* (*B.t.*) protein, Cry1Ab. MON 810 corn is protected from feeding damage by the European corn borer (ECB, *Ostrinia nubilalis*), the southwestern corn borer (SWCB, *Diatraea grandiosella*), and the pink borer (*Sesamia cretica*).

The benefits of planting insect-protected corn include: 1) a reliable means to control these corn pests; 2) control of target insects while maintaining beneficial species; 3) reduced use of chemical insecticides (Rice and Pilcher, 1999); 4) reduced applicator exposure to chemical pesticides; 5) a fit with integrated pest management (IPM) and sustainable agricultural systems; 6) reduced fumonisin mycotoxin levels in corn kernels (Munkvold et al., 1999; Masoero et al., 1999); and 7) no additional labour or machinery requirements, allowing both large and small growers to maximise hybrid yields.

The development of corn transformation methodology (Fromm et al., 1990) created the opportunity to protect corn plants from insect feeding damage using genes isolated from the bacterium *B. thuringiensis*. The *cry1Ab* coding sequence (Höfte and Whiteley, 1989) was isolated from the *B. thuringiensis* var. *kurstaki* (*B.t.k.*) HD-1 strain present in DIPEL, the leading microbial insecticide in agricultural use.

MON 810 corn was produced by microprojectile bombardment of embryogenic corn tissue with plasmid PV-ZMBK07. Southern blot analysis of MON 810 corn demonstrated that a single functional copy of the *cry1Ab* coding sequence was integrated into the corn genome and that the *cry1Ab* coding sequence is inherited in the expected Mendelian pattern.

The Cry1Ab protein shows no amino acid sequence homology to known protein toxins, other than other Cry proteins, and is rapidly degraded with loss of insecticidal activity under conditions that simulate mammalian digestion. There were no indications of toxicity as measured by treatment-related adverse effects in mice administered Cry1Ab protein by oral gavage. The *cry1Ab* gene was not derived from an allergenic source, and the Cry1Ab protein does not possess immunologically relevant sequence similarity with known allergens or possess the characteristics of known protein allergens. These studies support the safety of Cry1Ab protein and are fully consistent with the extensive history of safe use for the Cry1Ab protein that has high selectivity for insects, with no deleterious effects on other types of organisms, such as mammals, fish, birds or invertebrates (U.S. EPA, 1988; McClintock et al., 1995).

Compositional analyses were performed on grain from MON 810 field trials. The compositional values of MON 810 corn were compared to that of the control line, as well as to published literature values. The compositional parameters measured on grain

samples included proximates (protein, fat, ash, carbohydrates, crude fibre, neutral detergent fibre, acid detergent fibre and moisture), amino acids, fatty acids, calcium, phosphorus, and tocopherol (vitamin E). Compositional data confirmed that MON 810 corn is substantially equivalent to the parental hybrid as well as traditional corn hybrids, and that MON 810 corn plants are as safe and nutritious as conventional corn varieties.