

NOVEL FOOD INFORMATION – FOOD BIOTECHNOLOGY

INSECT PROTECTED CORN Cry3Bb1 EVENT MON 863

Health Canada has notified Monsanto Canada Inc. that it has no objection to the food use of insect protected corn line MON 863, which is resistant to certain Coleopteran insects. The Department conducted a comprehensive assessment of this corn according to its Guidelines for the Safety Assessment of Novel Foods. These Guidelines are based upon internationally accepted principles for establishing the safety of foods with novel traits.

BACKGROUND:

The following provides a summary regarding the Monsanto Canada Inc. notification to Health Canada and contains no confidential business information.

1. Introduction

Corn line MON 863 was developed through genetic modification to express two novel proteins, a modified Cry3Bb1 and neomycin phosphotransferase type II (NPTII). The Cry3Bb1 protein has activity against corn rootworm species (Coleoptera, Chrysomelidae, *Diabrotica* sp.). The enzyme expressed by the *nptII* gene confers resistance to aminoglycoside antibiotics and is used as a selectable marker in the development of the MON 863 corn line.

2. Development and Production of the Modified Plant

Corn line MON 863 was produced using particle mediated transformation to introduce a plasmid DNA sequence (ZMIR13L) into corn cells. The introduced sequence consisted of the *cry3Bb1* and *nptII* genes and the associated gene regulatory components necessary for their expression in the corn plant.

The *cry3Bb1* gene is derived from the common soil microorganism *Bacillus thuringiensis* subspecies *kumamotoensis*. The wild-type *cry3Bb1* gene was modified to improve its insecticidal activity and expression in plants without altering function (designated *cry3Bb1.11098*). The *nptII* gene is derived from the prokaryotic transposon Tn5 and confers resistance to aminoglycoside antibiotics. It functions as a selectable marker in the initial laboratory stages of plant cell selection following transformation.

One copy of the ZMIR13L DNA sequence was detected at a single locus in corn line MON 863. This information was obtained by Southern blot analysis of MON 863. No additional DNA, other than that associated with the intact *cry3Bb1* and *nptII* cassettes, was

detected in MON 863. Stability of the introduced traits was confirmed using Southern blot analysis over multiple generations. Polymerase Chain Reaction (PCR) analysis and DNA sequencing were used to verify the junction sequences of the insert with the plant genome as well as the intactness of the 5' and 3' ends of the insert.

3. Product Information

Corn line MON 863 differs from its parental counterpart in the addition of the novel cry3Bb1 and nptII gene sequences into the genome, and the expression of two proteins (Cry3Bb1 and NPTII). The proteins encoded by these genes are expressed at different levels throughout the plant tissue and throughout the life of the plant.

4. Dietary Exposure

Little whole kernel or processed field corn is directly consumed by humans worldwide when compared to corn-based food ingredients. Corn is a raw material for the manufacture of starch. The majority of corn starch is converted to a variety of sweetener and fermentation products, including high fructose corn syrup and ethanol. Corn oil is commercially processed from the germ. These materials are components of many foods including bakery and dairy goods. The human food uses of grain from MON863 are not expected to be different from the uses of non-transgenic field corn varieties. As such, the dietary exposure of Canadians to grain from insect resistant hybrids will not be different from that for other commercially available field corn varieties.

5. Nutrition

The major components of corn grain harvested from field trials were analysed. Compositional data for protein, fat, ash, carbohydrates, calories, moisture, amino acids, fatty acids, vitamins, minerals, and anti-nutrients for line MON863 grain were comparable to the data from the non-modified control line and within published ranges for commercial corn hybrids.

6. Toxicology

The lack of acute toxicity in animal studies and lack of homology to known protein toxins suggest that any MON 863 Cry3Bb1.11098 protein present in food products derived from the novel corn variety would not exhibit toxic activity. The unlikelihood of the MON 863 Cry3Bb1.11098 protein being a potential food allergen or toxin is indicated by its lack of homology to known protein allergens or toxins, and its rapid digestion in the stomach. Data demonstrating that the concentration of Cry3Bb1.11098 protein in the edible grain was very low relative to total plant protein, and that it was degraded during typical baking processes, adds support to the conclusion that

Cry3Bb1.11098 protein expressed in corn event MON 863 is unlikely to be a mammalian toxin or food allergen.

CONCLUSION:

Health Canada's review of the information presented in support of the food use of insect-resistant corn line MON 863 concluded that this corn does not raise concerns related to safety. Health Canada is of the opinion that MON863 is as safe and nutritious as current commercial corn varieties.

Health Canada's opinion deals only with the food use of insect-resistant corn. Issues related to growing insect resistant corn in Canada and its use as animal feed have been addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.

This Novel Food Information document has been prepared to summarize the opinion regarding the subject product provided by the Food Directorate, Health Products and Food Branch, Health Canada. This opinion is based upon the comprehensive review of information submitted by the petitioner according to the Guidelines for the Safety Assessment of Novel Foods.

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