



## NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

### ROUNDUP READY™ CORN LINE MON 832

Health Canada has notified Monsanto Canada Inc. that it has no objection to the food use of grain from the genetically modified Corn line MON 832, which is tolerant to glyphosate herbicide. The Department conducted a comprehensive assessment of Corn line MON 832 according to its *Guidelines for the Safety Assessment of Novel Foods* (Sept. 1994). These guidelines are based upon internationally accepted principles for establishing the safety of foods derived from genetically modified organisms.

#### **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 MON832 was developed through genetic modification to be tolerant to the glyphosate herbicide. The modified corn line permits farmers to use the herbicide for weed control in the cultivation of corn.

#### **2. Development and Production of the Modified Plant**

A commercial corn line was transformed by particle gun acceleration technology using a DNA solution containing two plasmids, PV-ZMBK07 and PV-ZMGT10. Molecular analysis of the resultant corn line, identified as MON 832, established that the line contains CP4 EPSPS, *gox* and *nptII* genes and does not contain the *cryIA(b)* gene. While the *nptII* gene was incorporated into the genome of MON 832 corn, it is not expressed in the plant since its bacterial promoter is only active in bacteria. Western blot analyses have confirmed that the *nptII* protein is not expressed in the modified corn plant. Segregation and stability data were consistent with a single active site of insertion into the genomic DNA of line MON 832.

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This Novel Food Information document has been prepared to summarize the opinion regarding the subject product provided by the Food Directorate, Health Protection 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*.

(Également disponible en français)

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The CP4 EPSPS gene was derived from the soil bacterium *Agrobacterium* sp. strain CP4. The CP4 EPSPS protein produced by this gene is highly tolerant to inhibition by glyphosate, and allows the modified corn plant to be treated with levels of the glyphosate herbicide that control competing weed species.

The *gox* gene was cloned from *Achromobacter* sp. strain LBAA and was also inserted to provide glyphosate tolerance. The GOX enzyme accelerates the normal degradation of glyphosate into aminomethylphosphonic acid (AMPA) and glyoxylate. This provides an additional mechanism for the modified corn's tolerance to applications of the glyphosate herbicide.

### 3. Product Information

Corn is a cultivated species with a long history of safe food and feed use. Animal feeding is by far the largest use of corn with the majority of annual production fed to cattle, poultry, and swine. Corn is readily consumed by livestock and because of its high starch-low fibre content. Corn does not normally contain toxins or antinutritional factors. A significant quantity of corn is fed to livestock directly or in formulated feeds. In addition to corn grown for grain, a portion of annual corn acreage is utilized as whole plant corn silage with consumption confined almost entirely to ruminants. The low price and ready availability of corn has also resulted in the development of large volume food and industrial uses.

Roundup Ready corn line MON 832 differs from its parental counterpart in the insertion of the aforementioned genes, CP4 EPSPS and *gox*. The proteins encoded by these genes are expressed throughout the plant tissue and throughout the life of the plant. Average levels of the expressed protein from field trials are as follows:

COMPONENT	PROTEIN LEVEL (Fg/g fresh wt.)	
	CP4 EPSPS	GOX
Leaf	49.61	4.92
Forage	21.32	3.32
Grain	5.83	1.97

### 4. Dietary Exposure

Corn grain is composed of approximately 61% starch, 19.2% protein and fibre, 3.8% oil, and 16% water (U.S. National Corn Growers Association, 1997). Although an ideal source of energy, little whole kernel or processed corn is consumed by humans worldwide when compared to corn-based food ingredients. Corn is an excellent raw material for the manufacture of starch, not only because of price and availability, but also because the starch is easily recovered in high yield and purity. A portion of corn starch is sold as starch products while the majority of the starch is converted to a variety of sweetener and fermentation products



including high fructose corn syrup and ethanol. Additionally, corn oil is commercially processed from the germ. Each of these materials is a component of many foods including bakery and dairy goods, beverages, confections, and meat products. By-products of the wet and dry milling process for corn, primarily corn gluten meal and feed, are fed to livestock.

## 5. Nutrition

The major components of corn grain and forage were analysed on plant material harvested from field trials. Compositional data for protein, fat, ash, carbohydrates, calories, moisture, amino acids, and fatty acids for line MON 832 grain were comparable to the data from the control line and within published ranges for commercial hybrids. Similarly, proximates (protein, fat, ash, carbohydrates, calories, and moisture), acid detergent fibre (ADF) and neutral detergent fibre (NDF) analyses were performed on forage for line MON 832 and an appropriate control. Based on these compositional data, it was concluded that the forage from line MON 832 and the control line were substantially equivalent.

## 6. Toxicology Data

The safety assessments of the CP4 EPSPS and GOX proteins were confirmed in experiments which included protein characterization, digestive fate studies in simulated gastric and intestinal fluids and acute oral toxicity in mice. The CP4 and GOX proteins are rapidly degraded and their enzymatic activity lost under conditions that simulate mammalian digestion. There were no indications of toxicity as measured by the absence of treatment related adverse effects in mice administered CP4 EPSPS or GOX proteins by oral gavage. Using sophisticated computerized search capabilities, the evidence showed that the CP4 and GOX proteins did not show meaningful amino acid sequence homology when compared to known allergens or protein toxins. These studies support the safety of the proteins and are consistent with the history of safe presence and ubiquitous distribution of *Agrobacterium* and *Achromobacter* spp. in the soil.

## CONCLUSION:

Based on the data and information submitted by Monsanto Canada, and a thorough comparison of insect-protected Roundup Ready corn line MON 832 with an appropriate control line and published ranges for other corn varieties, Health Canada has concluded that corn line MON 832 is as safe and nutritious as current commercial corn varieties.

Health Canada's opinion deals only with the food use of grain from the genetically modified corn line MON 832. Issues related to growing corn line MON 832 in Canada and its use as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.