



NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

GLYPHOSATE TOLERANT CORN, GA21

Health Canada has notified Monsanto Canada Inc. that it has no objection to the food use of the transgenic corn line GA21, which has been developed to be tolerant to glyphosate containing herbicides, specifically Roundup®. The Department conducted a comprehensive assessment of line G21 according to its *Guidelines for the Safety Assessment of Novel Foods* (September 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

The GA21 line of corn (*Zea mays* L.) was developed through a specific genetic modification to be tolerant to glyphosate containing herbicides. The novel variety was developed from the inbred AT corn variety by insertion of an additional copy of the maize 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) encoding gene, which had been modified to be glyphosate tolerant. Glyphosate specifically binds to and inactivates EPSPS, which is involved in the biosynthesis of the aromatic amino acids tyrosine, phenylalanine and tryptophan. This enzyme is present in all plants, bacteria and fungi, but not in animals, which do not synthesize their own aromatic amino acids. Thus, EPSPS is normally present in food derived from plant and microbial sources. The modified corn line permits farmers to use glyphosate containing herbicides, such as Roundup®, for weed control in the cultivation of corn.

2. Development of the Modified Plant

The GA21 corn line was created through direct DNA transformation by microparticle bombardment of plant cells with DNA-coated gold particles and regeneration of plants by tissue culture on selective medium. The DNA restriction fragment used for transformation contained a copy of the EPSPS encoding gene originally isolated from maize and subsequently modified to be insensitive to inactivation by glyphosate. Constitutive expression of the mEPSPS encoding gene was controlled by inclusion of sequences from the rice actin promoter and the 3'-polyadenylation signal of the nopaline synthase (*nos*)

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)

For further information, please contact:

Office of Food Biotechnology	Telephone:	(613) 941-5535
Food Directorate	Facsimile:	(613) 952-6400
Health Protection Branch		
Health Canada		
Tunney's Pasture		
Ottawa, Ontario K1A 0L2		



gene from *Agrobacterium tumefaciens*. Post-translational targeting of this gene product to the chloroplast organelles was accomplished by fusion of the 5'-terminal coding sequence with the chloroplast transit peptide DNA sequence derived from corn and sunflower (*Helianthus annuus*). Data from five generations of backcrossing and one generation of self-pollination demonstrated stable inheritance of the novel trait.

3. Product Information

The production of mEPSPS in both grain and forage (whole plant minus roots) from transgenic GA21 was quantified using Western immunoblot analysis and was estimated to range between 1.4-4.9 and 46.6-210.4 µg/g fresh weight tissue, respectively. No significant differences were observed between hybrids derived using original elite lines and the selected GA21 line for the agronomic traits of yield, moisture at harvest, ear height, plant height or other phenotypic traits. Other than glyphosate tolerance, the disease, pest and other agronomic characteristics of GA21 corn were comparable to non-transgenic lines of corn.

4. Dietary Exposure

The GA21 line of transgenic corn is not a sweet corn, but rather, a field corn intended mainly for use in animal feed. However, some human food uses are relevant for field corn. The GA21 corn hybrids would be either dry- or wet-milled into various processed corn products. The genetic modification of GA21 corn will not result in any change in the consumption pattern for this product. Consequently, the dietary exposure of Canadians to this product is anticipated to be the same as for other lines of commercially available field corn.

5. Nutrition

The analysis of nutrients from transgenic GA21 corn and non-transgenic corn did not reveal any significant differences in the levels of protein, fat, fibre, starch, fatty acids and micronutrients such as calcium and phosphorus. In each case the level of each respective component was within the normal range reported for corn. The consumption of products from GA21 corn will have no significant impact on the nutritional quality of the Canadian food supply.

6. Safety

a) Potential Toxicity:

The amino acid sequence of the mEPSPS enzyme expressed in GA21 corn is 99.3% identical to the sequence of the endogenous corn enzyme. An analysis of the amino acid sequence of the inserted mEPSPS enzyme did not show homologies with known mammalian protein toxins and it is not judged to have any potential for human toxicity. Safety has also been demonstrated in an acute mouse gavage study by feeding with high doses of the purified protein.



b) Potential Allergenicity:

The mEPSPS enzyme expressed in GA21 corn does not possess characteristics typical of known protein allergens. There were no regions of homology when the sequence of this introduced protein was compared to the amino acid sequences of known protein allergens. Unlike known protein allergens, the mEPSPS is rapidly degraded by acid and/or enzymatic hydrolysis when exposed to simulated gastric or intestinal fluids. The mEPSPS protein is extremely unlikely to be allergenic.

CONCLUSION:

Health Canada's review of the information presented in support of the food use of glyphosate tolerant GA21 corn concluded that this corn does not raise concerns related to human food safety. Health Canada is of the opinion that products from GA21 corn are as safe and nutritious as those available from current commercial field corn varieties.

Health Canada's opinion pertains only to the food use of this glyphosate tolerant corn. Issues related to growing glyphosate tolerant corn in Canada and its use as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.