Health Canada Santé Canada

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NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

GLYPHOSATE TOLERANT CANOLA, GT73

Health Canada has notified Monsanto Canada Inc. that it has no objection to the food use of the transgenic canola line GT73, which has been developed to be tolerant to broad-spectrum glyphosate containing herbicides, specifically Roundup®. The Department conducted a comprehensive assessment of GT73 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 GT73 line of canola (*Brassica napus*) was developed through a specific genetic modification to be resistant to the activity of glyphosate herbicides. The novel variety was developed from the Westar canola variety by insertion of two genes, one of which is a glyphosate tolerant mutant of the endogenous 5-enolypyruvylshikimate-3-phosphate synthase (EPSPS) and the other, a bacterial enzyme involved in the degradation of glyphosate to aminomethylphosphonic acid (AMPA) and glyoxalate. 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 canola line permits farmers to use glyphosate-containing herbicides, such as Roundup®, for weed control in the cultivation of canola.

2. Development of the Modified Plant

The GT73 canola line was created by *Agrobacterium*-mediated transformation in which the transfer-DNA (T-DNA) contained the EPSPS encoding gene from the common soil bacterium, *Agrobacterium* sp. CP4, and the gene encoding glyphosate oxidoreductase. The same constitutive promoter controlled the expression of both of these genes. Southern blot analysis demonstrated that line GT73 contained a single

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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genetic insert, consisting of single copies of the Roundup-Ready® genes. There was no incorporation of translatable plasmid DNA sequences outside of the T-DNA region.

3. Product Information

The expression of both CP4 EPSPS and glyphosate oxidoreductase was detected in the leaves and seeds of transgenic GT73 canola. Refined edible canola oil does not contain any detectable protein and consists of purified triglycerides (96-97%). There were no detectable amounts of CP4 EPSPS or glyphosate oxidoreductase in the refined oil of GT73 canola. This novel variety meets the standards for canola oil in Canada of containing less than 2% erucic acid and less than 30 μmoles/g glucosinolates in the oil-free meal. Other than tolerance to glyphosate herbicides, the disease, pest and other agronomic characteristics of GT73 canola were comparable to non-transgenic Westar canola.

4. Dietary Exposure

The human consumption of canola products is limited to the refined oil. Typically, canola oil is used by itself as a salad oil or cooking oil, or blended with other vegetable oils in the manufacture of margarine, shortening, salad oil and cooking oils. The genetic modification of GT73 canola will not result in any change in the consumption pattern for this product. As the introduced gene products are not detectable in the refined oil produced from transgenic canola, there will be no human exposure to these proteins based on normal consumption patterns.

5. Nutrition

The analysis of nutrients from transgenic GT73 canola and non-transgenic canola did not reveal any significant differences in the levels crude protein, crude fat, crude fibre, ash and gross energy in either whole seed or processed meal. The fatty acid composition of oils extracted from both transgenic GT73 and non-transgenic canola was statistically identical and within the normal range for canola oil. The consumption of refined oil from GT73 will have no significant impact on the nutritional quality of the Canadian food supply.

6. Safety

Since only the processed oil from transgenic GT73, or lines derived therefrom, will be available for human consumption and the processing removes proteinaceous material, there are no additional toxicity or allergenicity concerns with this product.

CONCLUSION:

Health Canada's review of the information presented in support of the food use of glyphosate tolerant canola GT73 concluded that this canola does not raise concerns related to human food safety. Health Canada is of the opinion that processed oil from GT73 canola is as safe and nutritious as that available from current commercial canola varieties.

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