Health Canada Santé Canada

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NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

IMIDAZOLINONE HERBICIDE TOLERANT CANOLA LINES NS738, NS1471, NS1473

Health Canada has notified Pioneer Hi-Bred International that it has no objection to the food use of the novel canola varieties NS738, NS1471 and NS1473, which have been developed to be tolerant to imidazolinone herbicides. The Department conducted a comprehensive assessment of NS738, NS1471 and NS1473 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 Pioneer Hi-Bred International notification to Health Canada and contains no confidential business information.

1. Introduction

The NS738, NS1471 and NS1473 lines of canola (*Brassica napus*) were developed through induced mutagenesis to be resistant to the activity of imidazolinone herbicides. The novel varieties were developed from the registered canola variety Topas, and were selected for a mutation within the acetolactate synthase (ALS) encoding gene that resulted in this enzyme being insensitive to the activity of imidazolinone herbicide. ALS is involved in the biosynthesis of essential branched-chain amino acids and the endogenous corn enzyme is inhibited by imidazolinones resulting in accumulation of toxic levels of α-ketoglutarate and subsequent plant death. The modified canola lines permit farmers to use imidazolinone herbicides for weed control in the cultivation of canola.

2. Development of the Modified Plant

The imidazolinone tolerant trait in lines NS738, NS1471 and NS1473 was selected following induced mutagenesis by exposing microspores to a solution of ethylnitrosourea (20 mM) and subsequent regeneration of plants by tissue culture on selective medium. The tolerance to imidazolinone resulted from a single base substitution within the ALS encoding gene, which prevented the binding of imidazolinone to the active site, thus maintaining normal enzyme activity. Data from several generations of backcrossing demonstrated stable inheritance of the novel trait.

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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3. Product Information

Based on the information provided, there are no novel proteins produced in lines NS738, NS1471 and NS1473, and only the refined seed oil will be used as a food. Refined edible canola oil does not contain any detectable protein and consists of purified triglycerides (96-97%). These novel varieties meet 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 imidazolinone herbicides, the disease, pest and other agronomic characteristics of NS738, NS1471 and NS1473 were comparable to the unmodified variety Topas.

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 present in lines NS738, NS1471 and NS1473 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 canola.

5. Nutrition

The consumption of products from NS738, NS1471 and NS1473 canola varieties will have no significant impact on the nutritional quality of the Canadian food supply.

6. Safety

Since only the processed oil from NS738, NS1471 and NS1473, 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 imidazolinone tolerant canola lines NS738, NS1471 and NS1473 concluded that they do not raise concerns related to human food safety. Health Canada is of the opinion that products from NS738, NS1471 and NS1473 are as safe and nutritious as those available from current commercial canola varieties.

Health Canada's opinion pertains only to the food use of these imidazolinone tolerant canola varieties. Issues related to growing imidazolinone tolerant NS738, NS1471 and NS1473 canola in Canada and their use as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.