NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

BXN PLUS BT COTTON

Health Canada has notified Monsanto Canada Inc. that it has no objection to the food use of refined oil from BXN Plus Bt cotton (*Gossypium hirsutum* L.), which is resistant to lepidopteran insects and tolerant to the herbicide, bromoxynil. The Department conducted a comprehensive assessment of BXN Plus Bt cotton according to it’s *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

BXN Plus Bt cotton was developed through genetic modification to be tolerant to bromoxynil and resistant to lepidopteran insects. The modification permits farmers to use the bromoxynil herbicide for weed control and offers protection against damaging lepidopteran insect pests.

2. Development and Production of the Modified Plant

BXN Plus Bt cotton was produced by *Agrobacterium*-mediated transformation to introduce DNA into cotton plant cells. Molecular analysis of the resultant cotton line, identified as BXN Plus Bt cotton, established that the line contains the *cryIAc*, *bxn*, and *nptII* genes. Genetic analysis data confirms the stable integration of one DNA insert into the cotton genome.
The cryIAc gene was derived from the common soil bacterium *Bacillus thurgiensis* subsp. *kurstaki*. This gene encodes for the production of the CryIAc protein which imparts protection from certain lepidopteran insects. The *bxn* gene was derived from the soil bacterium *Klebsiella pneumoniae* subsp. *ozaenae*. The gene encodes for the production of the nitrilase enzyme which degrades the herbicide bromoxynil, imparting bromoxynil tolerance. Also introduced into cotton is the *nptII* gene, which encodes a selectable marker, neomycin phosphotransferase (NPTII), used to identify cotton cells that contain the introduced genes during the transformation process.

3. **Product Information**

Cottonseed oil is used primarily in baking shortening due to its high palmitic acid content. Refined cottonseed oil does not contain any detectable protein and consists of purified triglycerides. Only the refined oil from BXN Plus Bt cotton will be available for human consumption.

4. **Dietary Exposure**

The human consumption of cotton products is limited to the refined oil. Commercial processing of refined cottonseed oil removes all proteinaceous materials. The genetic modification of BXN Plus Bt cotton 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 the modified cotton, there will be no human exposure to these proteins based on normal consumption patterns.

5. **Nutrition**

BXN Plus Bt cotton seed was compared with other commercial available cottonseed varieties. Compositional components (nutritional fibre, fatty acid compositions, moisture, crude fat/oil, protein-kjeldahl, ash, amino-acid profile) commonly found in cottonseed were demonstrated to be equivalent for both modified and unmodified crops. Levels of fatty acids found in BXN Plus Bt cotton refined oil are within the normal range reported for conventional cottonseed oil and within the levels specified by Codex for cottonseed oil. The use of refined oil from BXN Plus Bt cotton would have no significant impact on the nutritional quality of the Canadian food supply.

6. **Toxicology**

CryIAc, nitrilase and NPTII proteins did not show any meaningful amino acid sequence homology when compared to known allergens or protein toxins. In addition, they are ubiquitous in nature and do not possess proteolytic or heat stability. No adverse effects have been reported to be associated with these proteins. As mentioned in section 4, all proteinaceous material is removed from cotton seed oil during processing.
Levels cyclopropenoid fatty acids in BXN Plus Bt cotton that are naturally present in cotton are similar to those found in non-transgenic lines. The processing in the production of refined cottonseed oil degrades the cyclopropenoid fatty acids contained in cottonseed lipids. Other potential natural toxins such as aflatoxins and gossypols were not detected in the refined cotton seed oil.

CONCLUSION:

Health Canada’s review of the information presented in support of the food use of refined oil from BXN Plus Bt cotton concluded that such refined oil does not raise concerns related to safety. Health Canada is of the opinion that refined oil from BXN Plus Bt cotton is as safe and nutritious as refined oil from current commercial varieties.

Health Canada’s opinion deals only with the food use of refined oil from the genetically modified cotton line. Issues related to growing BXN Plus Bt cotton in Canada and its use as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.