Health Canada has notified Calgene Inc. that it has no objection to the food use of the transgenic cotton line BXN™, which has been developed to be tolerant to the herbicide bromoxynil. The Department conducted a comprehensive assessment of BXN™ cotton 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 Calgene Inc. notification to Health Canada and contains no confidential business information.

1. Introduction

The BXN™ line of cotton (Gossypium hirsutum) was developed through a specific genetic modification to be resistant to the activity of oxynil-containing herbicides, such as bromoxynil. The oxynil family of herbicides is active against dicotyledonous plants by blocking electron flow during the light reaction of photosynthesis. The novel variety was developed by insertion of a gene encoding a bacterial enzyme that hydrolyses ioxynil and bromoxynil into non-phytotoxic compounds. The modified cotton line permits farmers to use oxynil-containing herbicides for weed control in the cultivation of cotton.

2. Development of the Modified Plant

The BXN™ cotton line was created by Agrobacterium-mediated transformation in which the transfer-DNA (T-DNA) contained the gene encoding the enzyme for resistance to bromoxynil and a marker gene nptII. There was no incorporation of translatable plasmid DNA sequences outside of the T-DNA region.

3. Product Information

Refined edible cottonseed oil does not contain any detectable protein and consists of purified glycerides. Using a sensitive Western blotting technique that was capable of detecting the enzymes nitrilase and NPTII at levels of 0.1 ppm and 0.01 ppm, respectively, there were no detectable amounts of either of these proteins in refined oil from BXN™ cotton. Other than tolerance to oxynil containing herbicides, the...
disease, pest and other agronomic characteristics of BXN™ cotton were comparable to non-transgenic cotton.

4. Dietary Exposure

The human consumption of cotton products is limited to the refined oil. Typically, cottonseed oils are pooled and blended together and it is anticipated that the oil from BXN™ cottonseed will not be handled or treated any differently than other cottonseed oils. The genetic modification of BXN™ 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 transgenic cotton, there will be no human exposure to these proteins based on normal consumption patterns.

5. Nutrition

The analysis of the fatty acid composition of refined oil from BXN™ cotton did not reveal any significant differences with the parent, non-transgenic, variety and was within the range of the Codex Alimentarius Standard (CODEX STAN 22-1981) for cottonseed oil. The consumption of refined oil from BXN™ will have no significant impact on the nutritional quality of the Canadian food supply.

6. Safety

Since only the processed oil from transgenic BXN™, or lines derived there from, 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 bromoxynil tolerant cotton BXN™ concluded that this cotton does not raise concerns related to human food safety. Health Canada is of the opinion that processed oil from BXN™ cottonseed is as safe and nutritious as that available from current commercial cotton varieties.

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