

NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

INSECT RESISTANT COTTON LINES 531 and 757

Health Canada has notified Monsanto Canada Inc. that it has no objection to the food use of the transgenic cotton lines 531 and 757 which have been developed to be resistant to lepidopteran pests such as the cotton bollworm, pink bollworm and tobacco bollworm. The Department conducted a comprehensive assessment of lines 531 and 757 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 531 and 757 lines of cotton (*Gossypium hirsutum*) were developed through a specific genetic modification of cultivar Coker 321 to be resistant to lepidopteran insects. The novel varieties produce a version of the insecticidal protein, CryIA(c), derived from *Bacillus thuringiensis*. Delta-endotoxins, such as the CryIA(c) protein expressed in these transgenic cotton lines, act by selectively binding to specific receptors localized on the brush border midgut epithelium of susceptible insect species. Following binding, cation-specific pores are formed that disrupt midgut ion flow and thereby cause paralysis and death. CryIA(c) and related endotoxins are insecticidal only to lepidopteran or coleopteran insects and their specificity of action is directly attributable to the presence of specific receptors in the target insects. There are no receptors for delta-endotoxins of *B. thuringiensis* on the surface of mammalian intestinal cells, therefore, livestock animals and humans are not susceptible to these proteins.

2. Development of the Modified Plant

The 531 and 757 cotton lines were created by *Agrobacterium*-mediated transformation in which the transfer-DNA (T-DNA) contained a copy of the *cryIA(c)* gene from *B. thuringiensis* subsp. *kurstaki*. The expression of neomycin phosphotransferase II (NPTII) activity was used as a selectable marker to screen transformed plants for the presence of the *cryIA(c)* gene. There was no incorporation of translatable

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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plasmid DNA sequences outside of the T-DNA region. Data from 2 or 4 generations of backcrosses confirmed stable inheritance of the novel trait in lines 757 or 531, respectively.

3. Product Information

Refined edible cottonseed oil does not contain any detectable protein and consists of purified triglycerides. The transgenic and parental lines were assayed for the presence of potential toxins, including gossypol, dihydrosterculic acid, sterculic acid, malvalic acid and aflatoxins B1, B2, G1 and G2. At detection thresholds of 0.002% or 1 ppb, respectively, neither free gossypol nor any of the four aflatoxins were detected in the oil from transgenic cottonseed. Similarly, the respective levels of the cyclopropanoid fatty acids (dihydrosterculic, sterculic and malvalic) were statistically identical in cottonseed samples from transgenic and control lines. Other than resistance to lepidopteran insects, the disease, pest and other agronomic characteristics of 531 and 757 cotton lines were comparable to non-transgenic Coker 321 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 531 and 757 cottonseed will not be handled or treated any differently than other cottonseed oils. The genetic modification in 531 and 757 cotton lines 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 531 and 757 cotton did not reveal any significant differences with the parent, non-transgenic, variety and was within the normal range reported for cottonseed oils. In addition, the levels of α -tocopherol in refined oil from transgenic and control lines were similar. The consumption of refined oil from 531 and 757 cottonseed will have no significant impact on the nutritional quality of the Canadian food supply.

6. Safety

Since only the processed oil from transgenic 531 and 757 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 insect resistant cotton lines 531 and 757 concluded that they do not raise concerns related to human food safety. Health Canada is of the opinion that processed oil from 531 and 757 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 these insect resistant cotton lines. Issues related to the use of insect resistant cotton lines 531 and 757 in Canada as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.