Health Canada Santé Canada

FD/OFB-096-100-A
October 1999

NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

HIGH LAURIC ACID CANOLA LINES 23-198, 23-18-17

Health Canada has notified Calgene Inc. that it has no objection to the food use of the transgenic canola lines 23-198 and 23-18-17, which have been developed to produce oil with significant lauric acid content. The Department conducted a comprehensive assessment of 23-198 and 23-18-17 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 23-198 and 23-18-17 lines of canola (*Brassica napus*) were developed through a specific genetic modification to produce oil that contains significant levels of lauric acid. The novel varieties were developed from the 212/86 canola variety by introduction of a gene from the California bay tree, the leaves of which are an alternative source of the spice “bay leaf” which is commercially harvested from *Laurus nobilis*. The introduced gene encodes a thioesterase enzyme that is active in the fatty acid biosynthetic pathway of the developing seed resulting in the accumulation of triacylglycerides containing esterified lauric acid (12:0) and, to a lesser extent, myristic acid (14:0). The processed oil derived from these novel varieties has a level of lauric acid similar to that of coconut ant palm kernel oil.

2. Development of the Modified Plant

The 23-198 and 23-18-17 lines were created by *Agrobacterium*-mediated transformation in which the transfer-DNA (T-DNA) contained the gene encoding the enzyme 12:0 ACP thioesterase (bay TE) from the California bay tree (*Umbellularia californica*). In addition, the T-DNA contained sequences encoding the enzyme neomycin phosphotransferase II (NPTII). The expression of NPTII activity was used as a selectable trait to screen transformed plants for the presence of the bay TE gene. No other translatable DNA sequences were incorporated into the plant genome. The data from several generations of backcrossing demonstrated that the ACP thioesterase encoding gene was stably inherited.

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)

For further information, please contact:

Office of Food Biotechnology
Food Directorate
Health Protection Branch
Health Canada
Tunney's Pasture
Ottawa, Ontario K1A 0L2

Telephone: (613) 941-5535
Facsimile: (613) 952-6400

3. Product Information

Expression of the bay TE gene was limited to developing seeds since transcription of the promoter is restricted to the time of seed maturation. Using Western blot analysis, the expression of bay TE was monitored over the seed maturation process and was detectable only in samples of mid-maturity seeds at a level of 0.015% of the total protein. The expressed protein, NPTII, was found in seeds and other tissues of transgenic canola and its presence has been judged to be insignificant with respect to any human health risk due to exposure. Refined edible canola oil does not contain any detectable protein and consists of purified glycosides. No detectable bay TE protein was found in samples of refined oil at a detection threshold of 0.05 ppm. Other than the traits of significant lauric acid content and to a lesser extent, myristic acid content in the seed oil, the disease, pest and other agronomic characteristics of the 23-198 and 23-18-17 canola lines were comparable to other commercially available canola varieties.

4. Dietary Exposure

The human consumption of canola products is limited to the refined oil. The presence of lauric acid in this oil will allow it to be used as a replacement for other lauric acid oils such as coconut and palm kernel oil in products such as confectionery coatings and fillings, margarines, spreads, shortenings and commercial frying oils. It will also substitute for cocoa butter, lard, beef fats, palm oil and partially- or fully-hydrogenated soybean, corn, cottonseed, peanut, safflower and sunflower oils. There is no anticipation that the overall amounts of saturated and unsaturated fatty acids in products formulated with this lauric acid containing canola oil will be different from current values.

5. Nutrition

The modified fatty acid composition of the oil from transgenic canola lines 23-198 and 23-18-17 does not raise any nutritional concerns regarding the intended use of the subject oil. The analysis of levels of erucic acid, tocopherols and sterols did not reveal any significant differences when compared with the respective amounts of these compounds in other commercially available canola oils. The consumption of products formulated with this oil will have no significant impact on the nutritional quality of the Canadian food supply.

6. Safety

Since only the processed oil from 23-198 and 23-18-17, 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 high lauric acid canola lines 23-198 and 23-18-17 concluded that these lines do not raise concerns related to human food safety. Health Canada is of the opinion that processed oil from 23-198 and 23-18-17 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 these high lauric acid lines of canola. Issues related to growing high lauric acid lines of canola in Canada and their use as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.