

## NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

### SULFONYLUREA TOLERANT FLAX, CDC TRIFFID – FP967

Health Canada has notified the Crop Development Centre, University of Saskatchewan, that it has no objection to the food use of the transgenic flax line CDC Triffid - FP967, which has been developed to be tolerant to sulfonyleurea herbicides, specifically triasulfuron and metsulfuron-methyl. The Department conducted a comprehensive assessment of CDC Triffid – FP967 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 Crop Development Centre, University of Saskatchewan, notification to Health Canada and contains no confidential business information.

#### **1. Introduction**

The CDC Triffid – FP967 line of flax (*Linum usitatissimum*) was developed through a specific genetic modification to be resistant to the activity of sulfonyleurea herbicides. The novel variety was developed from the NorLin flax variety by insertion of a sulfonyleurea tolerant mutant of the acetolactate synthase (ALS) gene. The ALS gene encodes an enzyme involved in the biosynthesis of branched-chain amino acids and the endogenous flax enzyme is inhibited by sulfonyleurea resulting in accumulation of toxic levels of  $\alpha$ -ketoglutarate and subsequent plant death.

#### **2. Development of the Modified Plant**

The CDC Triffid – FP967 flax line was created by *Agrobacterium*-mediated transformation in which the transfer-DNA (T-DNA) contained the ALS gene from a chlorsulfuron tolerant line of *Arabidopsis thaliana*. This mutant ALS gene contains a single base-pair substitution resulting in a single amino acid change in the sequence of this protein when compared with the wild-type enzyme. The expression of this gene in transgenic flax was regulated by the native promoter and terminator sequences from *A. thaliana*. In addition, the T-DNA contained sequences encoding the enzymes nopaline synthase from *Agrobacterium tumefaciens*, neomycin phosphotransferase II (NPTII) from the Tn5 transposon of *Escherichia coli*, strain K12, and two other selectable marker genes that encode bacterial resistance to ampicillin and spectinomycin/streptomycin, respectively. These latter two genes were under the control of

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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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bacterial promoters and were not expressed in plant tissue. The expression of NPTII and nopaline synthase activity were used as selectable traits to screen transformed plants for the presence of the mutant ALS gene. There was no incorporation of translatable plasmid DNA sequences outside of the T-DNA region as verified by Southern blot analysis. Data from 8 generations of backcrossing demonstrated stable inheritance of the novel trait.

### **3. Product Information**

The activities of ALS, NPTII and nopaline synthase were measured in various transgenic flax tissues. The activity of ALS in CDC Triffid – FP967 flax was slightly higher than that measured in non-transgenic control plants. The *neo* gene product, NPTII, was found in the seeds, cotyledons and leaves of transgenic flax and its presence has been judged to be insignificant with respect to any human health risk due to exposure. Nopaline synthase activity, as evidenced by the presence of nopaline, was demonstrated in root, stem and leaf tissue but not in seeds from CDC Triffid – FP967. In addition, the cyanogenic glucoside content of CDC Triffid – FP967 was found to be similar to that of the non-transgenic flax, NorLin, and within the normal range of 6.0 – 9.2 mg/g for Canadian cultivars. Other than tolerance to sulfonylurea herbicides, the disease, pest and other agronomic characteristics of CDC Triffid – FP967 were comparable to non-transgenic NorLin flax.

### **4. Dietary Exposure**

The human consumption of flaxseed from CDC Triffid – FP967 will be mostly via specialty baked goods such as flax/multigrain breads. Additionally, smaller amounts will be made available for human consumption as either milled flaxseed or as flaxseed oil. Flax consumption in Canada is small and direct human consumption has been estimated by the Flax Council of Canada to be on the order of 4,000 tons annually. The genetic modification of CDC Triffid – FP967 will not result in any change in the consumption pattern for flaxseed. Consequently, the dietary exposure of Canadians to this product is anticipated to be the same as for other lines of commercially available flaxseed.

### **5. Nutrition**

The analysis of nutrients from transgenic CDC Triffid – FP967 flax and non-transgenic flax did not reveal any significant differences in the levels of macronutrients, minerals, amino acids or fatty acids. The consumption of this product will, therefore, have no significant impact on the nutritional quality of the Canadian food supply.

### **6. Safety**

#### **a) Potential Toxicity:**

The amino acid sequence of the mutant form of ALS introduced into CDC Triffid – FP967 flax is identical, except for a single amino acid substitution, with the wild-type form of this enzyme from *A. thaliana*. In addition, this sequence did not show homologies with known mammalian protein toxins and is not judged to have any potential for human toxicity.



b) Potential Allergenicity:

The ALS protein does not possess characteristics typical of known protein allergens. There were no regions of homology when the sequence of this introduced protein was compared to the amino acid sequences of known protein allergens. The sulfonylurea tolerant form of ALS is extremely unlikely to be allergenic.

**CONCLUSION:**

Health Canada's review of the information presented in support of the food use of sulfonylurea tolerant flax CDC Triffid – FP967 concluded that this flax does not raise concerns related to human food safety. Health Canada is of the opinion that flaxseed from CDC Triffid – FP967 is as safe and nutritious as that available from current commercial flax varieties.

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