

NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

SUPPRESSED POLYGALACTURONASE ACTIVITY TOMATO HYBRIDS, 1401F, H282F, 11013F, 7913F

Health Canada has notified Zeneca Plant Science that it has no objection to the food use of the transgenic tomato hybrids 1401F, H282F, 11013F and 7913F which have been developed to exhibit reduced pectin degradation through a suppression of polygalacturonase activity. The Department conducted a comprehensive assessment of these novel hybrids 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 Zeneca Plant Science notification to Health Canada and contains no confidential business information.

1. Introduction

The 1401F, H282F, 11013F and 7913F hybrids of tomato (*Lycopersicon esculentum*) were developed through hybridization with a transgenic inbred line, F, that was the product of a specific genetic modification designed to decrease polygalacturonase (PG) activity. Transgenic line F was developed from the commercial inbred line of processing tomato, TGT7, by the introduction of a truncated PG gene resulting in "downregulation" of the endogenous PG gene. The PG enzyme is the chief mechanism of pectin degradation in tomato fruit leading to fruit softening. The new hybrids ripen normally but experience less pectin breakdown and, therefore, have increased thickness and consistency that benefits all stages of harvesting and processing.

2. Development of the Modified Plant

The inbred line F tomato was created by *Agrobacterium*-mediated transformation in which the transfer-DNA (T-DNA) contained a 3'-truncated open reading frame corresponding to the sequence of the 5'-terminal 731 nucleotides from the PG gene from the Alisa Craig variety of tomato. The expression of this truncated PG gene was controlled by inclusion of sequences from the 35S promoter of cauliflower mosaic virus and the 3'-polyadenylation signal from the nopaline synthase (*nos*) gene from *Agrobacterium tumefaciens*. In addition, the T-DNA contained sequences encoding the enzyme neomycin

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

phosphotransferase II (NPTII) from the Tn5 transposon of *Escherichia coli*, strain K12, under the control of the *nos* promoter from *A. tumefaciens*. The expression of NPTII activity was used as a selectable trait to screen transformed plants for the presence of the truncated PG gene. There was no incorporation of translatable plasmid DNA sequences outside of the T-DNA region.

3. Product Information

While not completely understood, the mechanism of “downregulation” of the endogenous PG gene is likely linked to the coordinate suppression of transcription of both the endogenous gene and the introduced truncated PG gene. Accumulation of these transcripts was reduced in red ripe fruit from the modified tomato hybrids. The NPTII protein was detected in raw tomatoes from two of the hybrid lines, 1401F and H282F, at levels of $2.63 \pm 0.89 \mu\text{g/g}$ and $3.46 \pm 0.72 \mu\text{g/g}$ fresh tissue, respectively, but was not detected in tomato sauce following processing of either of these hybrids. The presence of NPTII protein has been judged to be insignificant with respect to any human health risk due to exposure. Alpha-tomatine is the principal naturally occurring glycoalkaloid in tomato, and the level of α -tomatine decreases as the fruit matures so that the amounts in vine-ripened red tomatoes are negligible. Solanine and chaconine, which are the main glycoalkaloids occurring in potato, have been found in tomato in lesser amounts. The level of α -tomatine in tomato paste prepared from transgenic line F was 58 ppm as compared with 74 ppm for the unmodified TGT7 parental line. The additional glycoalkaloids, solanine and chaconine, were undetectable in either the transgenic or unmodified lines. An analysis of the levels of biogenic amines (tyramine, tryptamine and serotonin), which are considered as potential toxins in tomato, did not reveal any significant differences in the respective concentrations of these compounds in raw tomatoes from either transgenic line F or the unmodified parental line. Tomatoes from the novel hybrid lines 1401F and 282F contained undetectable levels of histamine and nicotine, as did their unmodified counterparts. Other than reduced polygalacturonase activity, the disease, pest and other agronomic characteristics of the 1401F, H282F, 11013F and 7913F hybrids were comparable to the unmodified hybrids.

4. Dietary Exposure

The human consumption of the 1401F, H282F, 11013F and 7913F hybrids will be mainly as processed tomato product in the form of soups, preserves, ketchup, paste and prepared sauces. The genetic modification of these novel hybrids will not result in any change in the consumption pattern for processed tomato products. The novel hybrids are expected to replace other tomato cultivars currently in use due to improved quality and handling characteristics. Hence, they will provide an alternate or additional choice to consumers and food manufacturers.

5. Nutrition

The analysis of nutrients from the novel 1401F hybrid line and non-transgenic 1401 hybrid did not reveal any significant differences in the levels of macro- and micronutrients in either fresh tomatoes or processed tomato paste. The consumption of this product will, therefore, have no significant impact on the nutritional quality of the Canadian food supply.

6. Safety

The reduced synthesis of native PG arising as a result of the coordinate suppression of PG gene transcription by introduction of a truncated PG gene sequence is not judged to have any potential for additional human toxicity or allergenicity.

CONCLUSION:

Health Canada's review of the information presented in support of the food use of reduced polygalacturonase activity tomato hybrids 1401F, H282F, 11013F and 7913F concluded that these hybrids do not raise concerns related to human food safety. Health Canada is of the opinion that the products from tomato hybrids 1401F, H282F, 11013F and 7913F are as safe and nutritious as those available from current commercial tomato cultivars.

Health Canada's opinion pertains only to the food use of tomato hybrids 1401F, H282F, 11013F and 7913F. Issues related to growing tomato hybrids 1401F, H282F, 11013F and 7913F in Canada and their use as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.