



## NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

### POLLINATION CONTROL SYSTEM FOR CANOLA, MS1/RF1

Health Canada has notified Plant Genetic Systems N.V. that it has no objection to the food use of the transgenic canola lines MS1, RF1 or hybrids derived therefrom (PGS1), which have been developed to be tolerant to phosphinothricin containing herbicides, specifically glufosinate ammonium. The Department conducted a comprehensive assessment of MS1 and RF1 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 Plant Genetic Systems N.V. notification to Health Canada and contains no confidential business information.

#### **1. Introduction**

The MS1 and RF1 lines of canola (*Brassica napus*) were developed through a specific genetic modification of cultivar Drakkar to display the traits of nuclear male sterility and fertility restoration, respectively, and to be tolerant to glufosinate ammonium herbicide. The induction of male sterility (MS) was accomplished by insertion of the gene encoding barnase ribonuclease (RNase), an enzyme that disrupts RNA production and thus normal cell functioning resulting in arrested anther development. The trait of restored fertility (RF) was due to the introduction of the gene encoding a specific inhibitor of the barnase RNase. Only hybrids derived from the crossing of MS1 and RF1 are fertile. Both of the novel varieties, MS1 and RF1, contain a gene encoding the enzyme, phosphinothricin N-acetyl transferase (PAT), from *Streptomyces hygroscopicus*. Phosphinothricin containing herbicides, such as glufosinate ammonium, act by inhibiting glutamine synthetase resulting in the accumulation of toxic levels of ammonia. The PAT enzyme detoxifies phosphinothricin by acetylation into an inactive compound. Hybrids derived from MS1 and RF1 crosses permit farmers to use phosphinothricin containing herbicides for weed control in the cultivation of canola.

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

The MS1 and RF1 canola lines were created by *Agrobacterium*-mediated transformation in which the transfer-DNA (T-DNA) contained either the *barnase* or *barstar* genes from the common soil bacterium,

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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)

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



*Bacillus amyloliquefaciens*, under the control of the PTA29 anther-specific promoter from *Nicotiana tabacum*. In addition, each T-DNA contained a copy of the *bar* gene from *S. hygrosopicus*, which encodes the PAT enzyme, and sequences encoding the enzyme neomycin phosphotransferase II (NPTII) from the Tn5 transposon of *Escherichia coli*, strain K12. Expression of the *bar* gene was regulated by the PSsuAra promoter from *Arabidopsis thaliana* and post-translational targeting of the gene product to the chloroplast organelles was accomplished by fusion of the 5'-terminal coding sequence with the chloroplast transit peptide DNA sequence from *A. thaliana*. The expression of NPTII activity, under control of the nopaline synthase promoter from *A. tumefaciens*, was used as a selectable trait for screening transformed plants for the presence of the *barnase* and *barstar* genes, respectively. There was no incorporation of translatable plasmid DNA sequences outside of the T-DNA region as verified by Southern blot analysis. Data from several generations of backcrossing have demonstrated stable inheritance of the novel traits.

### 3. Product Information

Transcription of the *bar* gene was detected in both leaf and flower bud tissue by Northern blot analysis. Similar analyses demonstrated that the *barnase* and *barstar* genes were only transcribed in the flower bud tissue of MS1 and RF1 plants, respectively. These novel varieties meet the standards for canola oil in Canada of containing less than 2% erucic acid and less than 30 µmoles/g glucosinolates in the oil-free meal. Other than the traits of glufosinate herbicide tolerance and either male sterility or fertility restoration, respectively, the disease, pest and other agronomic characteristics of MS1 and RF1 canola were comparable to non-transgenic Drakkar canola.

### 4. Dietary Exposure

The human consumption of canola products is limited to the refined oil. Refined edible canola oil does not contain any detectable protein and consists of purified triglycerides (96-97%). As the introduced gene products are not detectable in the refined oil produced from transgenic canola, there will be no human exposure to these proteins based on normal consumption patterns.

### 5. Nutrition

The analysis of nutrients from transgenic MS1 and RF1 canola and non-transgenic canola did not reveal any significant differences in the levels crude protein, crude fat, crude fibre, ash and gross energy in either whole seed or processed meal. The fatty acid composition of oils extracted from both transgenic and non-transgenic canola was statistically identical and within the normal range for canola oil. The consumption of refined oil from MS1, RF1 or hybrids derived therefrom will have no significant impact on the nutritional quality of the Canadian food supply.

### 6. Safety

Since only the processed oil from transgenic MS1, RF1, 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 glufosinate herbicide tolerant canola lines MS1 and RF1 concluded that they do not raise concerns related to human food safety. Health Canada is of the opinion that processed oil from MS1, RF1, or hybrids derived therefrom, 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 glufosinate herbicide tolerant canola lines. Issues related to growing glufosinate herbicide tolerant canola lines, with either male sterility or fertility restoration traits, in Canada and their use as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.