



## NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

### NOVEL HYBRIDIZATION SYSTEM FOR CANOLA (MS8/RF3)

Health Canada has notified Plant Genetics Systems (Canada) Inc. that it has no objection to the food use of refined oil from canola derived from a new hybridization system based on male sterility (MS8) and fertility restoration (RF3), developed using genetic modification. The Department conducted a comprehensive assessment of the MS8/RF3 system 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 Genetics Systems (Canada) Inc. notification to Health Canada and contains no confidential business information.

#### **1. Introduction**

A novel hybridization system for canola (*Brassica napus*) has been developed by Plant Genetic Systems N.V. This system involves the use of two inbred parental lines. The first line (female) is male sterile and therefore does not produce pollen. The second line (male) codes for restoration of fertility. The hybrid plants resulting from the cross of these two lines are fully fertile and produce seed. Linked to this hybridization system is tolerance to the non-selective herbicide glufosinate ammonium, the active ingredient in Liberty® herbicide.

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

The MS8 and RF3 transformants were produced by transforming a double-zero *B. napus* cultivar to introduce DNA with disarmed *Agrobacterium tumefaciens* vectors. The MS8 transformant contains the *barnase* gene isolated from the common soil bacterium *Bacillus amyloliquefaciens*.

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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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The introduced *barnase* gene encodes a ribonuclease (RNAse) enzyme and is linked to an anther-specific promoter which directs expression of the gene to the anther of the plant flower where pollen is produced. The RF3 transformant contains the *barstar* gene also isolated from *B. amyloliquefaciens*. The *barstar* gene encodes the barstar protein which inhibits the barnase enzyme.

Both transformants contain the *bar* gene isolated from the common soil microorganism *Streptomyces hygroscopicus*. The *bar* gene codes for the enzyme phosphinothricin acetyl transferase (PAT).

### 3. Product Information

Expression of the introduced *barnase* gene in MS8 canola plants results in the expression of the RNAse enzyme which disrupts cell development by affecting cellular RNA. When expressed in the anther as directed by the specific promoter, this enzyme disrupts pollen development. The expression of the *barstar* gene in the RF3 plants results in the expression of a protein which inhibits the RNAse enzyme expressed by *barnase*. In MS8/RF3 crosses where both introduced proteins are expressed, the RNAse enzyme is therefore inhibited, ensuring the restoration of pollen development.

The expressed PAT enzyme, resulting from the introduced *bar* gene, mediates the rapid metabolism of glufosinate ammonium, permitting the plants to tolerate application of the herbicide.

The introduced genes have been sequenced and their functions are well characterized. Detailed molecular analyses and analysis of segregation data demonstrated that the introduced DNA has been incorporated into the *Brassica* genome as a single locus. The expression of the introduced genes is essentially limited to the leaves and flowers of the plants.

MS8/RF3 hybrid canola differs from non-transgenic canola only in the insertion of three new genes, *barnase*, *barstar* and *bar*, and in the expression of three new proteins, RNAse, barstar and PAT.

### 4. Dietary Exposure

Human consumption of canola products is limited to the refined oil. The processing of the oil removes the proteinaceous material. The refined oil derived from MS8/RF3 canola is expected to be used in similar applications to the refined oil from traditional canola varieties. Therefore, there would be no dietary exposure to the proteins introduced into MS8/RF3 canola.

### 5. Nutrition

The composition of refined canola oil from MS8/RF3 hybrid canola was compared to that for refined oil from traditional canola. Some statistical differences in fatty acid composition was noted in the comparison of the transgenic lines to the control lines tested. However, the data for the transgenic lines were within the normal range for canola oil fatty acids. Processing as per protocols emulating industrial practices (including tempering, flaking, cooking, pressing, desolventizing oil and meal, oil blending, degumming, oil refining, water washing, bleaching, hydrogenation and deodorizing) further demonstrate that the composition and physical characteristics of the oil from MS8/RF3 hybrids and control canola varieties are equivalent.



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The use of refined oil from MS8/RF3 canola hybrids would therefore have no significant impact on the nutritional quality of the Canadian food supply.

**CONCLUSION:**

Health Canada's review of the information presented in support of the food use of refined oil from the novel hybridization system for canola based on male sterility (MS8) and fertility restoration (RF3) concluded that this refined oil does not raise concerns related to safety. Health Canada is of the opinion that refined oil from MS8/RF3 hybrid canola is as safe and nutritious as refined oil from current commercial canola varieties.

Health Canada's opinion deals only with the food use of refined refined oil from the MS8/RF3 hybrid canola. Issues related to growing MS8, RF3 and MS8/RF3 hybrids in Canada and their use as animal feed have been addressed separately through existing regulatory processes in Agriculture & Agri-Food Canada.