NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

COLORADO POTATO BEETLE RESISTANT POTATO LINES BT06, BT10, BT12, BT16, BT17, BT18, BT23

Health Canada has notified Monsanto Canada Inc. that it has no objection to the food use of the transgenic cultivar Russet Burbank NewLeaf™ potato lines BT06, BT10, BT12, BT16, BT17, BT18 and BT23, which have been developed to be resistant to the Colorado potato beetle (CPB). The Department conducted a comprehensive assessment of Russet Burbank NewLeaf™ potato 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 Monsanto Canada Inc. notification to Health Canada and contains no confidential business information.

1. Introduction

The BT06, BT10, BT12, BT16, BT17, BT18 and BT23 lines of potato (Solanum tuberosum) were developed through a specific genetic modification of cultivar Russet Burbank to be CPB (Leptinotarsa decemlineata Say.) resistant. The novel lines produce a version of the insecticidal protein, CryIIIA, derived from Bacillus thuringiensis. Delta-endotoxins, such as the CryIIIA protein expressed in Russet Burbank NewLeaf™ potato, act by selectively binding to specific receptors localized on the brush border midgut epithelium of susceptible insect species. Following binding, cation-specific pores are formed that disrupt midgut ion flow and thereby cause paralysis and death. CryIIIA and related endotoxins are insecticidal only to lepidopteran or coleopteran insects and their specificity of action is directly attributable to the presence of specific receptors in the target insects. There are no receptors for delta-endotoxins of B. thuringiensis on the surface of mammalian intestinal cells, therefore, livestock animals and humans are not susceptible to these proteins.

2. Development of the Modified Plant

The BT06, BT10, BT12, BT16, BT17, BT18 and BT23 potato lines were created through Agrobacterium-mediated transformation in which the transfer DNA (T-DNA) contained the gene encoding the CryIIIA
protein from *B. thuringiensis* subsp. *tenebrionis*. In addition, the T-DNA contained sequences encoding the enzyme neomycin phosphotransferase II (NPTII). The expression of NPTII activity, under the control of the CaMV 35S promoter, was used as a selectable trait for screening transformed plants for the presence of the *cryIIIA* gene. The data from at least 4 generations of vegetative propagation demonstrated the stability of the novel trait.

3. **Product Information**

The average expression levels of the CryIIIA protein in the leaves and tubers from each of seven NewLeaf™ Russet Burbank lines were estimated to be 16.8 and 0.8 µg/g fresh weight tissue, respectively. Likewise, constitutive expression of NPTII was quantified in both leaf and tuber tissue at levels of 0.34 and 0.2 µg/g fresh weight tissue, respectively. The presence of NPTII protein has been judged to be insignificant with respect to any human health risk due to exposure. Solanine and chaconine are the principal glycoalkaloids commonly found in potato tubers. Analyses of total glycoalkaloid (TGA) levels in each of the transgenic lines demonstrated that in each case the level was below the administrative guideline of 20 mg/100g fresh weight that has previously been established for TGA in potato. Other than resistance to CPB, the disease, pest and other agronomic characteristics of the NewLeaf™ Russet Burbank lines were comparable to non-transgenic Russet Burbank potato.

4. **Dietary Exposure**

Potatoes are considered to be a staple food for many Canadians, constituting up to 37% of the total average vegetable intake. The genetic modification present in the BT06, BT10, BT12, BT16, BT17, BT18 and BT23 transgenic lines will not result in any change in the consumption pattern for potatoes. Due to their protection from CPB damage, the NewLeaf™ Russet Burbank cultivars are expected to replace some existing commercial potato cultivars in all potato product applications. Hence, they will provide an alternate or additional choice to consumers and food manufacturers.

5. **Nutrition**

The analysis of nutrients from each of the seven transgenic potato cultivars and non-transgenic potato did not reveal any significant differences in the levels of protein, fat, ash, fibre and starch. Similarly, the levels of micronutrients and trace elements, including thiamine, niacin, riboflavin, vitamin C, calcium, iron and zinc, were comparable to those of unmodified Russet Burbank. In each case, the measured concentration was within the range normally reported for potatoes. The consumption of products from NewLeaf™ Russet Burbank potatoes will have no significant impact on the nutritional quality of the Canadian food supply.
6. **Safety**

a) **Potential Toxicity:**

The amino acid sequence of the CryIIIA protein expressed in NewLeaf™ potatoes is closely related to the sequence of the same proteins that are present in strains of *B. thuringiensis* that have been used for over 30 years as commercial organic microbial insecticides. An analysis of the amino acid sequence of the inserted CryIIIA protein did not show homologies with known mammalian protein toxins and it is not judged to have any potential for human toxicity. Additionally, acute oral toxicity studies with purified CryIIIA protein did not reveal any deleterious effects when mice were administered a dose of 5220 mg/kg body weight.

b) **Potential Allergenicity:**

The CryIIIA 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. Unlike known protein allergens, the CryIIIA protein is rapidly degraded by acid and/or enzymatic hydrolysis when exposed to simulated gastric or intestinal fluids. The CryIIIA protein is extremely unlikely to be allergenic.

**CONCLUSION:**

Health Canada's review of the information presented in support of the food use of CPB resistant BT06, BT10, BT12, BT16, BT17, BT18 and BT23 potato lines concluded that they do not raise concerns related to human food safety. Health Canada is of the opinion that products from NewLeaf™ Russet Burbank potato are as safe and nutritious as those available from current commercial potato cultivars.

Health Canada's opinion pertains only to the food use of these CPB resistant potato lines. Issues related to growing NewLeaf™ Russet Burbank potatoes in Canada and their use as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.