

NOVEL FOOD INFORMATION: FOOD BIOTECHNOLOGY
GLUFOSINATE AMMONIUM TOLERANT SUGAR BEET (EVENT T120-7)

Health Canada has notified Aventis CropScience Canada that it has no objection to the food use of sugar beet event T120-7, which is tolerant to the broad spectrum herbicide glufosinate ammonium. The Department conducted a comprehensive assessment of this sugar beet event according to the *Guidelines for the Safety Assessment of Novel Foods*. These Guidelines are based upon internationally accepted principles for establishing the safety of foods with novel traits.

BACKGROUND:

The following provides a summary regarding the Aventis CropScience Canada notification to Health Canada and contains no confidential business information.

1. Introduction

Sugar beet transformation event T120-7 was developed through a specific genetic modification to be resistant to the activity of glufosinate ammonium herbicide. Sugar beet transformation event T120-7 will be used for the same food uses as conventional sugar beets. Sugar beet is grown primarily for the root, from which sucrose is extracted and processed into refined sugar for human consumption.

2. Development and Production of the Modified Plant

The transformation event T120-7 was produced by *Agrobacterium*-mediated transformation to introduce DNA into sugar beet plant cells. The introduced DNA includes the *pat* gene which was originally isolated from a common soil bacterium, *Streptomyces viridochromogenes*, and encodes for the enzyme, phosphinothricin-N-acetyl transferase (PAT). The PAT enzyme detoxifies L-phosphinothricin, the active ingredient in the herbicide glufosinate ammonium. Also included with the introduced DNA is the *nptII* gene which encodes for resistance to the antibiotic kanamycin. The *nptII* marker gene was originally obtained from *Escherichia coli* Tn5 transposon and is commonly used as a selectable marker for transformed cells. The biological marker allows researchers to identify the modified plants. Molecular analysis indicated that one copy of the transferred DNA has been incorporated into the sugar beet genome. Analysis of segregation data confirms the stable integration of the DNA into the sugar beet genome.

3. Product Information

The genetic modification results in the addition of two novel genes into the sugar beet genome and the expression of their protein products PAT and NPTII. The PAT protein mediates the rapid metabolism of glufosinate ammonium. The amount of PAT protein is in the range of 0.1% to 0.025% of total protein in the leaves and between 0.01% and 0.0013% in the roots. The amount of detectable NPTII protein was one order of magnitude lower in leaves and roots. Refined sugar and molasses from the modified sugar beet destined for human consumption do not contain detectable

amounts of either the PAT or NPTII proteins.

4. Dietary Exposure

Glufosinate tolerant sugar beets are expected to be used in similar applications as traditional sugar beet varieties by the food industry. As indicated above (section 3), PAT and NPTII proteins are not detected in refined sugar. As such no human exposure to the introduced PAT and NPTII protein is expected as a result of the consumption of refined sugar from sugar beet event T120-7.

5. Nutrition

Compositional analysis for T120-7 sugar beet roots and tops indicated that no significant differences were noted between glufosinate tolerant T120-7 sugar beet and the unmodified counterpart. The major contribution of sugar beet to the food supply is refined sugar. Since sugar contributes negligible levels of essential nutrients to the diet, the use of foods produced from T120-7 sugar beet should have no significant impact on the nutritional quality of the Canadian food supply.

6. Safety

The petitioner has provided data to demonstrate that the presence of the two novel proteins in T120-7 sugar beet, at the levels expressed, are not a toxicological concern. The PAT and NPTII proteins did not show any meaningful amino acid sequence homology when compared to known allergens or protein toxins. Both enzymes have been demonstrated to be highly substrate specific. In addition, they are ubiquitous in nature and do not possess proteolytic or heat stability. No adverse effects have been reported to be associated with either enzyme.

CONCLUSIONS

Health Canada's review of the information presented in support of the food use of glufosinate tolerant sugar beet (event T120-7) concluded that event T120-7 does not raise concerns related to human food safety. Health Canada is of the opinion that sugar beet event T120-7 is as safe and nutritious as traditional sugar beet varieties.

Health Canada's opinion deals only with the food use of glufosinate tolerant sugar beet event T120-7. Issues related to growing sugar beet event T120-7 in Canada and its use as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.