



NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

IMAZETHAPYR TOLERANT CORN, EXP1910IT

Health Canada has notified Zeneca Seeds that it has no objection to the food use of the novel corn hybrid EXP1910IT, which has been developed to be tolerant to imidazolinone herbicides, specifically Pursuit® which contains imazethapyr as the active ingredient. The Department conducted a comprehensive assessment of EXP1910IT 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 Seeds notification to Health Canada and contains no confidential business information.

1. Introduction

The EXP1910IT line of corn (*Zea mays*) was developed through chemical mutagenesis to be resistant to the activity of imidazolinone herbicides. The novel variety was developed from ICI Seed's inbred line UE95 and was selected for a mutation within the acetolactate synthase (ALS) gene that resulted in this enzyme being insensitive to the activity of imazethapyr, the active ingredient of the herbicide Pursuit®. ALS is involved in the biosynthesis of essential branched-chain amino acids and the endogenous corn enzyme is inhibited by imazethapyr resulting in accumulation of toxic levels of α -ketoglutarate and subsequent plant death. The modified corn line permits farmers to use imidazolinone herbicides for weed control in the cultivation of corn.

2. Development of the Modified Plant

The imazethapyr tolerant trait in line EXP1910IT was selected following chemical mutagenesis by exposing pollen to ethyl-methane sulfonate. Mutagenized pollen was then used to fertilize the parent line, UE95, and progeny plants were screened for tolerance to imazethapyr. Ethyl-methane sulfonate is a commonly used chemical mutagen that affects DNA by chemically altering base pairs. The tolerance to imazethapyr resulted from a single nucleotide substitution within the ALS encoding gene. This substitution resulted in a single amino acid change (serine₂₁ to asparagine₂₁) in the sequence of the

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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enzyme, which prevented the binding of imazethapyr to the active site, thus maintaining normal enzyme activity. Data from several generations of backcrossing demonstrated stable inheritance of the novel trait.

3. Product Information

Based on the information provided, there are no novel proteins produced in line EXP1910IT. The single amino acid change within the active site of the ALS enzyme did not otherwise affect its activity except to provide tolerance to the herbicide Pursuit® at concentrations up to 500 µM. Other than tolerance to imidazolinone herbicides, the disease, pest and other agronomic characteristics of EXP1910IT were comparable to unmodified UE95 corn.

4. Dietary Exposure

The EXP1910IT line of corn is not a sweet corn, but rather, a field corn intended mainly for use in animal feed. However, some human food uses are relevant for field corn. The EXP1910IT corn hybrids would be either dry- or wet-milled into various processed corn products. The genetic modification present in EXP1910IT corn will not result in any change in the consumption pattern for this product. Consequently, the dietary exposure of Canadians to this product is anticipated to be the same as for other lines of commercially available field corn.

5. Nutrition

The analysis of nutrients from EXP1910IT corn and the parental UE95 corn did not reveal any significant differences in the levels protein, fat, fibre and starch. Similarly, the levels of micronutrients including calcium, phosphorus, potassium and magnesium were within the established ranges for corn. The consumption of products from EXP1910IT corn 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 mutant form of ALS present in EXP1910IT corn is identical, except for a single amino acid substitution, with the wild-type form of this enzyme. The mutated form of this enzyme is not judged to have any potential for human toxicity.

b) Potential Allergenicity:

The ALS protein does not possess characteristics typical of known protein allergens. There are no regions of homology between the amino acid sequence of the mutated form of the enzyme and the amino acid sequences of known protein allergens. The imazethapyr tolerant form of ALS is extremely unlikely to be allergenic.

CONCLUSION:

Health Canada's review of the information presented in support of the food use of imazethapyr tolerant corn hybrid EXP1910IT concluded that this corn does not raise concerns related to human food safety. Health Canada is of the opinion that products from EXP1910IT corn are as safe and nutritious as those available from current commercial field corn varieties.

Health Canada's opinion pertains only to the food use of this imazethapyr tolerant corn. Issues related to growing imazethapyr tolerant corn in Canada and its use as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.