

NOVEL FOOD INFORMATION - FOOD BIOTECHNOLOGY

IMIDAZOLINONE TOLERANT CORN, 3417IR

Health Canada has notified Pioneer Hi-Bred Production Ltd. that it has no objection to the food use of the novel corn hybrid 3417IR, which has been developed to be tolerant to imidazolinone herbicides. The Department conducted a comprehensive assessment of 3417IR in accordance with internationally accepted principles for establishing the safety of foods derived from genetically modified organisms.

BACKGROUND:

The following provides a summary regarding the Pioneer Hi-Bred Production Ltd. notification to Health Canada and contains no confidential business information.

1. Introduction

The 3417IR line of corn (*Zea mays* L.) was developed through selection of a somaclonal variant that was resistant to the activity of imidazolinone herbicides. The novel variety was selected for a mutation within the acetolactate synthase (ALS) gene that resulted in this enzyme being insensitive to the activity of imidazolinone. ALS is involved in the biosynthesis of the branched-chain amino acids valine, leucine and isoleucine, and the endogenous corn enzyme is inhibited by imidazolinone 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 imidazolinone tolerant trait in line 3417IR was selected by tissue culture of somatic embryos on imidazolinone enriched media. The regenerated somaclonal variant, XA17, was subsequently crossed with the inbred corn line B73 and the resulting progeny were subsequently backcrossed into each of two proprietary Pioneer hybrids, which were then crossed to produce the hybrid 3417IR. The tolerance to imidazolinone resulted from the selection of a mutation within the ALS encoding gene. Apart from tolerance to imidazolinone, the activity of the ALS enzyme in 3417IR was not affected as evidenced by the accumulation of normal levels of valine, leucine and isoleucine. Data from several XA17 crosses with inbred corn lines demonstrated regular Mendelian segregation of the novel trait in the progeny.

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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3. Product Information

Based on the information provided, there are no novel proteins produced in line 3417IR. The mutation within the active site of the ALS enzyme did not otherwise affect its activity except to provide tolerance to imidazolinone. Other than tolerance to imidazolinone herbicides, the disease, pest and other agronomic characteristics of 3417IR were comparable to its unmodified counterpart.

4. Dietary Exposure

The 3417IR 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 3417IR corn hybrids would be either dry- or wet-milled into various processed corn products. The genetic modification present in 3417IR 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 3417IR corn and other commercial corn hybrids did not reveal any significant differences in the levels of 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 3417IR corn will have no significant impact on the nutritional quality of the Canadian food supply.

6. Safety

a) Potential Toxicity:

The mutation within the ALS enzyme is not judged to add 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 ALS and the amino acid sequences of known protein allergens. The imidazolinone 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 imidazolinone tolerant corn hybrid 3417IR concluded that this corn does not raise concerns related to human food safety. Health Canada is of the opinion that products from 3417IR 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 imidazolinone tolerant corn. Issues related to growing imidazolinone tolerant corn in Canada and its use as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.