Health Canada Santé Canada

NOVEL FOOD INFORMATION-FOOD BIOTECHNOLOGY

IMIDAZOLINONE TOLERANT WHEAT

Health Canada has notified Cyanamid Crop Protection (now BASF Canada) that it has no objection to the food use of grain from the Triticum aestivum line SWP965001 derived through mutation breeding, which is tolerant to imidazolinone herbicides. The Department conducted a comprehensive assessment of this wheat according to its 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 Cyanamid notification to Health Canada and contains no confidential business information.

1. Introduction

American Cyanamid developed a wheat that was tolerant to imidazolinone herbicides with a mutation designated FS2. The basis for the herbicide tolerance is similar to that previously described for imidazolinone tolerant corn and canola.

2. Development and Production of the Tolerant Plant

Wheat is grown widely throughout North America as a food and feed crop. The principal use of wheat grain is the production of flour which, depending on the specific type of wheat, is used in many baked goods.

The imidazolinone tolerant wheat was developed through conventional mutation breeding of Fidel wheat, followed by an initial cross with Grandin wheat and subsequent backcrossing into Grandin. Since recombinant techniques were not used, no foreign DNA was introduced to achieve the herbicide tolerant trait.

The method used for obtaining imidazolinone-tolerant wheat plants was chemical mutagenesis with sodium azide. Four imidazolinone-tolerant seedlings were obtained (FS1-4); SWP965001 was derived from selection line FS2. The FS2 mutation affects the acetohydroxyacid synthase (AHAS) enzyme of wheat at a specific location. The AHAS enzyme catalyses the first step in the biosynthesis of the branched chain amino acids isoleucine, leucine and valine in wheat. The mutation in the AHAS enzyme results in an alteration to the binding site for the imidazolinone class of herbicide, therefore increasing the plant's tolerance to those herbicides. The other properties of the AHAS enzyme are unaffected.

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

A mutation in the AHAS enzyme in wheat could affect the biosynthesis of the essential amino acids isoleucine, leucine, and valine. The amino acid composition of SWP965001 was compared to commercial cultivars, confirming that the AHAS activity of the imidazolinone-tolerant wheat was not affected by the mutation.

4. Dietary Exposure

It is not anticipated that the dietary exposure to wheat-based products will increase as a result of the sale of imidazolinone-tolerant wheat. Many varieties of wheat are available for cultivation in Canada and are assessed for a stringent series of quality parameters before approval. The diversity of wheat available ensures that a wide range of phenotypic traits are available; this, coupled with the normal variation in grain composition resulting from differences in the environmental growing conditions results in a wide variation in the composition of commercial wheat grain. Wheat is mixed during storage, transportation and processing which produces consistency in composition of the commodity grain supply.

5. Nutritional Data

The data presented on the amino acid composition of imidazolinone-tolerant wheat demonstrates that the AHAS mutation does not alter the levels of the amino acids valine, leucine or isoleucine. Proximate analysis confirms that SWP965001 has nutritional composition typical of a spring wheat.

6. Toxicology Data

No toxicity concerns are associated with the expression of the imidazolinone tolerance trait in wheat. No new protein, or significantly altered protein, is produced through this mutation. No allergenicity concerns are associated with the expression of this trait in wheat.

CONCLUSION:

Single amino acid substitutions can affect the binding of AHAS inhibitors, such as imidazolinone herbicides, but there appears to be no significant change in enzyme function, as reflected in enzymes studies of the mutant and wild-type enzymes from wheat. It can be concluded that the single amino acid substitution in the SWP965001 mutation will result in wheat that is unchanged in their nutritional and food safety characteristics when compared to other wheat currently on the market in Canada.

Health Canada's opinion deals only with the food use of imidazolinone tolerant wheat resulting from the FS2 mutation. Issues related to growing imidazolinone tolerant wheat in Canada and its use as animal feed are addressed separately through existing regulatory processes in the Canadian Food Inspection Agency.