

Biotechnology Consultation

Note to the File

BNF No. 000073

Date: June 8, 2001

Subject: Mycogen Seeds BNF 000073 (*B.t.* Cry1F maize line 1507)

Background

In a submission dated June 28, 2000, Mycogen Seeds (c/o Dow AgroSciences LLC) and Pioneer Hi-Bred International, Inc., provided summary information to support their safety and nutritional assessment of insect resistant, glufosinate tolerant maize line 1507 containing transformation event TC1507.

Intended Effect/Food Use

The maize line 1507 was derived from a hybrid line designated Hi-II, by transformation with DNA containing the plant-optimized *cry1F* gene derived from the *Bacillus thuringiensis* (*B.t.*) var. *aizawai* strain PS811 (NRRL-B18484), the *pat* gene from *Streptomyces viridochromogenes*, and regulatory sequences necessary for expression of both genes. The *cry1F* gene encodes the Cry1F protein that is effective in controlling certain lepidopteran larval pests common to maize, such as European corn borer and black cutworm. The *pat* gene encodes the enzyme phosphinothricin acetyltransferase (PAT) that confers resistance to the herbicide glufosinate-ammonium. The presence of PAT protein in the transformed maize cells enables selection of these cells for further development and makes line 1507 tolerant to glufosinate-ammonium. Corn products derived from the 1507 line are intended for use in human food and animal feed.

Regulatory Considerations

The use of the Cry1F protein as a pesticidal substance and the use of the PAT protein as a pesticidal inert ingredient in the development of the insect resistant and herbicide resistant corn are under the regulatory purview of the Environmental Protection Agency (EPA). EPA also regulates the genetic material introduced into the transgenic 1507 maize line. Therefore, this memorandum does not summarize the information on the safety of the Cry1F protein and the PAT enzyme as well as the information related to the introduced DNA. The focus of this summary is the unintended changes as measured by the compositional comparison between the transgenic line and the control line. According to the notice, the control line has the same genetic background as the test line.

Compositional Analysis

Forage Analysis

Mycogen analyzed forage from the transgenic and control lines for protein, fat, ash, acid detergent fiber (ADF), and

neutral detergent fiber (NDF). The levels of protein, fat, NDF, and ash were not significantly different in the test and control lines and were within the range of published values (FDA Center for Veterinary Medicine ^CVM| also noted values were within the ranges noted in previous BNF submissions). The level of ADF in the maize 1507 line was lower than the control line, but CVM notes it was within the range of values noted in previous BNF submissions. Calcium and phosphorus levels for 1507 line and the control line, respectively, were 0.22 and 0.23 percent, and 0.25 and 0.24 percent. (CVM noted that these values were within the range of values noted in previous BNF submissions.)

Grain Analysis

The levels of protein, ADF, NDF, and ash were not significantly different in the grain from the transgenic 1507 line and the control line and were within the ranges reported in the literature for maize grain. The level of fat in line 1507 was significantly lower than the control line, but was within the range of values in the literature.

The levels of seven minerals (calcium, phosphorus, copper, iron, magnesium, manganese, and zinc) in the maize line 1507 were not significantly different from the control and within the ranges reported in the literature or as reported by Pioneer Brand Hybrids for 22 commercial varieties. The level of potassium was significantly higher in line 1507 than in the control, but was well within the range of literature values.

The level of the fatty acid, palmitic acid, was not significantly different from the control and was within the range of literature values. The levels the fatty acids, stearic and oleic, were lower in line 1507 than the control; and, the levels of linoleic and linolenic acids were higher in the in the maize line 1507 than the control line. All fatty acids levels for the line 1507 and the control line were within the literature ranges reported for grain from maize. Amino acids from the maize grain were analyzed. There were no significant differences between the individual amino acids in line 1507 and control, except for cysteine where the level was lower in line 1507 than the control. All of the levels of the essential amino acids were within the ranges reported in the literature, as determined by the analysis of 22 commercial Pioneer Hybrid maize lines (or as CVM noted within ranges as reported in previously submitted BNF's).

The level of vitamin B1 was significantly lower in line 1507 than in the control; and the total tocopherol level was higher in line 1507 than the control. The levels of B1, B2, and tocopherol were within published ranges. Folic acid levels for both line 1507 and control were not different but were different from the literature for which only a single level was reported.

Mycogen seeds attempted to measure two potential anti-nutrients, trypsin inhibitor and phytic acid. Trypsin inhibitor levels in the 1507 and control line were below the level of quantitation of 2000 TIU/g. Phytic acid level in the 1507 line was not significantly different from the level in the control line and was within the range of levels reported in the literature.

Conclusion

Mycogen Seeds has concluded that the *B.t.* Cry1F maize line 1507 is as safe and nutritious as maize products already on the market. At this time, based on Mycogen's discription of its data and analysis, the Agency considers maize line 1507 not to be materially different from maize already on the market and Mycogen's consultation on this product to be complete.

/s/
Vincent Zenger, Ph.D.

+ The Office of Premarket Approval became the Office of Food Additive Safety on June 18, 2001.

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