

This is Provisional English translation of an excerpt from the original full report.

Risk Assessment Report Cotton line 281 (Genetically modified feed)

Food Safety Commission of Japan (FSCJ)
December 2005

Abstract

I. Background

On the basis of the Food Safety Basic Law (related documents received on October 17, 2003), the Ministry of Agriculture, Forestry and Fisheries requested that the Food Safety Commission of Japan (FSCJ) to conduct a risk assessment of the genetically modified feed of cotton line 281 (hereinafter referred to as “cotton line 281”).

II. Overview of the investigational feed

Name: Cotton line 281

Property: Lepidoptera-resistant, glufosinate herbicide-tolerant

Applicant: Dow Chemical Japan Ltd.

Manufacturer: Mycogen Seeds/Dow AgroSciences, LLC

Cotton line 281 is produced by inserting pest (Lepidoptera)-resistant *cryIF* (synthetic products) gene (*Bt* gene) and herbicide glufosinate-tolerant modified *pat* gene into the cotton genome.

Cotton line 281 is highly resistant to the larvae of ball worms and tobacco bud worms, the Lepidoptera cotton pests, and unaffected by the herbicide, glufosinate.

III. Results of the risk assessments

- (a) There is no report that the inserted genome or the protein produced by the inserted genome transferred to animal or animal products.
- (b) As a framework of food risk assessment of cotton line 281, FSCJ concluded on August 18, 2005, that there is no concern about health hazards in humans caused by the consumption of the genetically modified cotton line 281.

Based on the findings (a) and (b) above, it seems unlikely that any hazardous substance will be newly produced in cotton line 281, which in turn will transfer to animal products, and that any recombinant related constituents will be transformed into hazardous substances and accumulated in animals, or they will affect animals' metabolic systems to produce new hazardous substances.

Therefore, in the light of the “The Perspective of Safety Assessment for Genetically Modified Feed and Feed Additives (approved by FSCJ on May 6, 2004)” FSCJ came to the conclusion that there is no need to conduct risk assessment of the genetically modified cotton line 281 and that there is no concern about human consumption of animal products derived from animals fed on cotton line 281.