

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

Risk Assessment Report Cotton line 281 x 3006 (Genetically modified food)

Food Safety Commission of Japan (FSCJ)
September 2005

Name: Cotton line 281 x 3006
Property: Lepidoptera-resistant, glufosinate herbicide-tolerant
Applicant: Dow Chemical Japan Ltd.
Manufacturer: Mycogen Seeds/Dow AgroSciences, LLC

I. General Description of the Product

The recombinant cotton line 281 x 3006 was produced by conventional crossing between two transgenic lines of cotton which are resistant to Lepidoptera and tolerant of herbicide glufosinate. Risk assessment was already conducted for each parent cotton line 281 and 3006 by the Food Safety Commission of Japan (FSCJ) on August 18, 2005, which concluded that there is no concern about health hazards in humans caused by the consumption of either of them.

II. Results of the Risk Assessment

- (1) The product was derived by crossing of cotton lines 281 and 3006 which contain inserted genes conferring resistance to Lepidoptera and tolerance of herbicide, without affecting host plant's metabolic systems.
The genes *cryIF* and *cryIAc* (both synthetic products) introduced to cotton lines 281 and 3006 express proteins CryIAc and CryIF, respectively. Neither protein has been identified as having any enzymic activity. The PAT protein, an expression of the modified *pat* gene introduced to both cotton lines 281 and 3006, is an enzyme to acetylate glufosinate, but seems unlikely to have any effect on plant's metabolic systems because of its high substrate specificity. Therefore, FSCJ concluded that the protein expressed by crossing of cotton lines 281 and 3006 would not affect host plant's metabolic systems.
- (2) The crossing was conducted between congeneric species.
Both cotton lines 281 and 3006 belong to *Gossypium hirsutum*, the congeneric species.
- (3) No difference exists in amount of consumption, edible parts or processing methods.
There is no difference between cotton lines 281, 3006 and 281x3006 as to their intended uses or application, such as the amount of consumption, edible parts and processing methods.

According to above (1) to (3), on the basis of Safety Assessment for Cross-Breeding of Genetically Modified Plants (January 29, 2004; determined by Food Safety Commission), FSCJ concluded that there is no need for conducting safety assessment of cotton line 281 x 3006, and that there is no concern about health hazards in humans caused by the consumption of the genetically modified cotton line 281 x 3006.