

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

Risk Assessment Report Maize MON810 x MON863 (Genetically modified food)

Food Safety Commission of Japan (FSCJ)
February 2004

Name: Maize MON810 x MON863
Property: Lepidoptera-resistant, herbicide-tolerant (glufosinate, glyphosate)
Applicant: Monsanto Japan, Ltd.
Manufacturer: Monsanto Company (U.S.)

I. General Description of the Product

The maize MON810 x MON863 was produced by conventional crossing between two transgenic lines of maize which are resistant to Lepidoptera and tolerant of herbicide. Risk assessment was already conducted for each parent maize line MON810 and MON863 by the Food Safety Commission of Japan (FSCJ), 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 the two lines of maize both containing inserted genes that confer resistance to Lepidoptera without affecting host plant's metabolic systems.
The gene *cry1Ab* introduced to MON810 expresses protein Cry1F_{Ab} and the gene *cry3Bb1* introduced to MON863 expresses protein Cry3Bb1 which both have been identified as not having any enzymic activity, thus would not affect host plant's metabolic systems.
- (2) The crossing was conducted between congeneric species.
Both MON810 and MON863 belong to *Zea Mais L.*, the congeneric species.
- (3) No difference exists in amount of consumption, edible parts or processing methods.
There is no difference between MON810, MON863 and MON810 x MON863 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 FSCJ), FSCJ concluded that there is no need for conducting safety assessment of maize MON810 x MON863, and that there is no concern about health hazards in humans caused by the consumption of the genetically modified maize MON810 x MON863.