

**Safety Assessment of Genetically Modified Food:
Hybrid variety of maize line Bt11 resistant to lepidopteran pests and tolerant to the herbicide
glufosinate and maize line MIR604 resistant to coleopteran pests**

September 2007
Food Safety Commission

Summary

I. Introduction

The Food Safety Commission received a request from the Ministry of Health, Labour, and Welfare in accordance with the Food Safety Basic Law to provide its opinion on the assessment of the effect of food on health related to an investigation of the safety of foods derived from the genetically modified hybrid variety of maize line Bt11 resistant to lepidopteran pests and tolerant to the herbicide glufosinate, and maize line MIR604 resistant to coleopteran pests.

II. Outline of the food to be assessed

Name: Hybrid variety of maize line Bt11 resistant to lepidopteran pests and tolerant to the herbicide glufosinate and maize line MIR604 resistant to coleopteran pests

Properties: Lepidopteran pest-resistance, coleopteran pest-resistance, and glufosinate-tolerance

Applicant: Syngenta Seeds KK

Developer: Syngenta Seeds AG (USA)

The food to be assessed is a hybrid produced using conventional methods to cross one line given the traits of pest-resistance and herbicide-tolerance and one line given the trait of pest-resistance. Safety assessments were completed for each of the pre-hybrid lines – maize line Bt11 resistant to lepidopteran pests and tolerant to the herbicide glufosinate (Ministry of Health, Labour, and Welfare Notice No. 118 of March 30, 2001) and maize line MIR604 resistant to coleopteran pests (Ministry of Health, Labour, and Welfare Notice No. 289 of August 17, 2007) – and both were deemed to pose no risk to human health.

III. Results of the assessment of the effect of food on health

Based on the results of an investigation conducted in accordance with the Approach to the Safety Assessment of Hybrids of Genetically Modified Plants (January 29, 2004 Decision of the Food Safety Commission), it was deemed that there is no need for another assessment of the effect of food on health for hybrid variety of maize line Bt11 resistant to lepidopteran pests and tolerant to the herbicide glufosinate, and maize line MIR604 resistant to coleopteran pests.