

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

Safety Assessment Report

Reduced lignin Alfalfa KK179 line (Genetically modified food)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

FSCJ conducted a risk assessment of reduced lignin alfalfa KK179 line based on the documents submitted by the applicant.

This line was generated through introduction of repeated segment of *CCOMT* gene encoding alfalfa caffeoyl CoA 3-O-methyltransferase (CCOMT protein), in the inverted order to DNA sequence of alfalfa. This insertion results in the suppression of endogenous *CCOMT* gene expression via RNA interference (RNAi), and reduced production of lignin in the stems of alfalfa.

Antibiotic resistance gene (*nptII*) originated from transposon Tn5 of *Escherichia coli* was introduced initially. A clone without carrying *nptII* (KK179) was, however, selected during classical hybridization..

The documents, evaluated based on the “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)¹”, included the safety of the inserted gene, toxicity and allergenicity of the protein produced from the inserted gene, post-insertion analysis of the nucleotide sequence, stability of the inserted gene in the successive generations, influences on metabolic pathways in the plants, comparative characterization of nutrients and toxic ingredients in the plants and others. Consequently, newly produced adverse effects on humans derived from this KK179 line are unlikely based on the comparison of this line with the conventional counterpart.

In conclusion, no concern relevant to human health is raised on the reduced-lignin Alfalfa KK179 line.

¹ Decision of the Commission dated 29 January 2004.