

Safety Assessment of Genetically Modified Food:

Protease

July 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 protease (protease derived from *Aspergillus niger* GEP-44 strain).

II. Outline of the additive for which an application was submitted

Name:	Protease (protease derived from <i>A. niger</i> GEP-44 strain)
Properties:	Productivity promotion
Applicant:	DSM Nutrition Japan K.K.
Developer:	DSM

Protease derived from *A. niger* GEP-44 strain is a protease produced by GEP-44 strain – the producing microorganism – which was obtained by using homologous recombination to insert the *gepA* gene, which codes protease, at seven locations where the *glaA* gene, which codes glucoamylase derived from *A. niger* GAM-53, had been knocked out. The production method for extracting and purifying protease derived from *A. niger* GEP-44 strain is the same as when using conventional producing strains.

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

It was deemed that since protease derived from *A. niger* GEP-44 strain falls under the “case where the DNA ultimately introduced into the host through recombinant DNA technology is only DNA of a microorganism that belongs to the same taxonomical species as the relevant microorganism” in Section 3 Scope and objective in Chapter 1 General Provisions of the Standards for the Safety Assessment of Additives Produced Using Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission), it is not subject to this standard.