

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

Safety Assessment Report

L-Hydroxyproline produced using the AHD strain (Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ) January 2015

ABSTRACT

FSCJ conducted a safety assessment of L-hydroxyproline produced using the AHD strain based on the documents submitted by the applicant.

This additive is produced from L-proline using the AHD strain to which L-proline-4-transhydroxylase gene was introduced to yield L-hydroxyproline. The host strain for this gene introduction was the AHJ 202 strain derived from *Escherichia coli* K-12.

This additive meets the content specification of Japanese Standards of Food Additives, and is estimated to contain no hazardous materials in the inactive ingredients.

The documents was evaluated based on the "Approach to the Safety Assessment on an Additive Produced Using Geterically Modified Microorganisms, which its End Porduct is a Highly Purified Nonprotein Additive, such as Amino Acids¹" (Supplementary Provisions of "Standards for Safety Assessment of Food Additives produced Using Genetically Modified Microorganisms²"). Consequesntly, the safety of the additive has been confirmed.

In conlusion, the assessment based on the "Standards for Safety Assessment of Food Additives produced Using Genetically Modified Microorganisms" is not necessary for this additive.

¹ Decision of the Commission dated April 28, 2005

² Decision of the Commission dated March 25, 2004