

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

Safety Assessment Report

L-Citrulline produced using CIT-No.1 strain (Genetically Modified Food)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

The FSCJ conducted a safety assessment of a nutritional supplementary food, L-citrulline produced using CIT-No.1 strain.

This nutritional supplementary food is L-citrulline produced using CIT-No.1 strain. The strain was generated through the introduction of genes, etc. involved in the biosynthesis of L-citrulline into mutant strain No.55 (host) derived from *Escherichia coli* K-12 strain.

L-citrulline produced using CIT-No.1 strain is highly purified by crystallization in the manufacturing process removing the producing bacteria and fermentation byproducts. Compared to the conventional L-citrulline, the amount of existing inactive substances is not so large for the safety concern. Further, it is deemed that additional inactive substances for probable adverse effects are not contained, either.

This nutritional supplementary food was assessed applying mutatis mutandis to “Stance on Safety Assessments of Additives Produced Using Generically Modified Microorganisms, whose End Product is a Highly Purified Nonprotein Additive, such as Amino Acids¹”. As a result, the FSCJ concluded that it is unnecessary to assess this food based on “Standards for the Safety Assessments of Genetically Modified Foods (Microorganisms)²” and that its safety equivalent to the conventional food is confirmed as long as the use pattern is the same as the current practice.

This assessment confirms that the risk of “L-citrulline produced using CIT-No.1 strain” is not higher than that of the conventional food. Meanwhile, it is necessary for risk management organizations to provide business entities with their full guidance to ensure compliance with the specified product standards and to collect the cases of consumers’ adverse health effects.

¹ Decision of the FSCJ dated April 28, 2005

² Decision of the FSCJ dated June 26, 2008