

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

## **Safety Assessment Report**

### **L-Citrulline produced using CPR strain**

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)  
October 2017

#### **ABSTRACT**

FSCJ conducted a safety assessment of L-Citrulline produced using CPR strain, based on the documents submitted by the applicant.

The CRP strain was generated through deletion of genes involved in suppression of L-citrulline production, byproduct amino acids production and L-citrulline metabolism, introduction of genes involved in suppression of byproduct amino acids production, and modification of genes involved in suppression of L-citrulline production into *Escherichia coli* KY8227 as a host to enhance the L-citrulline productivity.

This food product is highly purified as L-citrulline by crystallization during the production process where the producing strain and byproducts are eliminated by resin treatment. Amounts of non-active ingredients existing in the conventional L-citrulline products have not increased to a level that could cause a safety issue, and no new non-active ingredient suggested to be harmful is included in this product.

Documents were evaluated applying the “Stance on Safety Assessments of Additives Produced Using Generically Modified Microorganisms, whose End Product is regarded as a Highly Purified Nonprotein Additive, such as Amino Acids<sup>1</sup>” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms<sup>2</sup>”). Consequently, the safety of this food product was confirmed to be the same as that of the conventional product for comparison as long as it is used in the same way as the current use. Hence, FSCJ considered that the assessment based on the “Standards for Safety Assessment of Genetically Modified Foods (Microorganisms)<sup>3</sup>” is unnecessary.

By this assessment, FSCJ confirmed only the fact that the risks of “L-citrulline produced using CPR strain” were not higher than those of the conventional L-citrulline. Therefore, the risk management organizations should thoroughly instruct related business operators to provide consumers the precautions for use, and to collect information on the adverse effects of this food product, as well as request them to ensure compliance to the product standards, when the organizations take the risk management measures for this food product.

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<sup>1</sup> Decision of the Commission dated April 28, 2005

<sup>2</sup> Decision of the Commission dated March 25, 2004

<sup>3</sup> Decision of the Commission dated June 26, 2008