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

# Safety Assessment Report

## L-ornithine monohydrochloride produced using ORN-No.1 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)
September 2019

## ABSTRACT

FSCJ conducted a safety assessment of L-ornithine monohydrochloride produced using ORN-No.1 strain, based on the documents submitted by the applicant.

The food product is L-ornithine monohydrochloride produced using the ORN-No.1 strain, which was generated from *Escherichia coli* K-12 as a host through introduction of genes involved in L-ornithine biosynthesis and sugar utilization as well as mutation of genes involved in L-ornithine degradation.

This food product is highly purified by crystallization during the manufacturing process, where its producing strain and fermentation byproducts are eliminated. Amounts of non-active ingredients existing in the conventional L-ornithine monohydrochloride products have not increased to levels that could cause safety issues, and no new non-active ingredient suggested to be harmful is included in this product.

The 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[1]". As a result, it was considered that the safety of this food product was confirmed to be equivalent to that of the conventional product for comparison as long as it is used in the same way as the current use. Consequently, it was concluded that the assessment based on the "Standards for Safety Assessment of Genetically Modified Foods (Microorganisms)[2]"is not necessary for this food product.

However, FSCJ confirmed only the fact that the risk of "L-ornithine monohydrochloride produced using ORN-No.1 strain" was not higher than that of the conventional L-ornithine mononydrochloride product in this assessment. Therefore, the risk management organizations should instruct related business operators to comply with the product specification that was set, and additionally to provide consumers with the precautions for use and to collect information on the adverse effects of this food product as the need arises, when the organizations take the risk management measures for this food product.

[1] Decision of the Commission dated April 28, 2005
[2] Decision of the Commission dated June 26, 2008