



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

Safety Assessment Report

Disodium 5'-ribonucleotides produced using RN-No.3 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

September 2019

ABSTRACT

FSCJ conducted a safety assessment of disodium 5'-ribonucleotides produced using RN-No.3 strain, based on the documents submitted by the applicant.

The RN-No.3 strain was generated through introduction of purine nucleoside phosphorylase gene variant into the parental strain RN-No.2. The RN-No.2 strain has been previously obtained from *Escherichia coli* K-12 as a host by recombinant technology, and its safety has been confirmed. Disodium 5'-ribonucleotides is a mixture of disodium inosine-5'-monophosphate and disodium guanosine-5'-monophosphate.

This additive meets the content specification of Japanese Standards of Food Additives. Amounts of known non-active ingredients were not increased to levels that could cause a safety issue, compared to those of the corresponding conventional disodium 5'-ribonucleotides products. In addition, no new harmful ingredients suggested to be harmful are thought to be included in this additive.

Documents were evaluated based on 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 Acids¹” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms²”). As the result, it was considered that the safety of the additive has been confirmed from the documents.

Consequently, it was concluded that the assessment based on the “Standards for Safety Assessments 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