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

Safety Assessment Report

Valencene produced using Rhodobacter sphaeroides 168 strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

June 2020

ABSTRACT

FSCJ conducted a safety assessment of a flavor, valencene, produced using *Rhodobacter sphaeroides* 168 strain based on the documents submitted by the applicant.

Rhodobacter sphaeroides 168 strain was generated through the introduction of an expression vector p-m-Pppa-MBP-ValC-mpmii alt into *Rhodobacter sphaeroides* 35053 strain as a host. The expression vector was constructed by insertion of the gene cluster involved in mevalonate synthesis derived from *Paracoccus zeaxanthinifaciens* ATCC 21588 strain, the genes encoding isopentenyl diphosphate isomerase and others derived from *Escherichia coli* DH5α, and Modified valencene synthase gene derived from *Callitropsis nootkatensis*. This additive is used as a flavor in food and drink such as juice and chewing gum.

Safety of the inserted gene, toxicity and allergenicity of the proteins produced from the inserted gene and so on were evaluated based on the "Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms[1]". As the result, FSCJ considered that there was no change bringing out adverse effects on humans in the flavor produced using recombinant technology compared with the conventional counterpart.

Hence, FSCJ concluded that no concern relevant to human health is raised on the flavor, valencene, produced using *Rhodobacter sphaeroides* 168 strain.

[1] Decision of the Commission dated 25 March 2004.