



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

## Risk Assessment Report

### 臙脂茶 *Shushi Cha*<sup>1</sup>

(A beverage containing an enoki mushroom (*Flammulina velutipes*) extract)  
(Food for Specified Health Uses)

Food Safety Commission of Japan (FSCJ)

May 2015

#### ABSTRACT

FSCJ conducted a risk assessment of a food for specified health uses, *Shushi Cha*, based on the documents submitted by the applicant. *Shushi Cha* is a beverage containing an extract of enoki mushroom (*Flammulina velutipes*) as the component relevant to its specified health use, which is described as being “suitable for people who are concerned about body fat or have a tendency to overweight”.

In a 350ml of this product, corresponding to the recommended daily intake, 2.4 mg of an enoki mushroom (*Flammulina velutipes*) extract is contained as a mixture of free fatty acids.

Data used in the assessment include history of safe use as the food, reverse mutation tests using microorganisms, a single oral gavage test in rats, and human trials of 12-week continuous consumption and of 4-week continuous 2.85 fold excessive consumption.

Regarding the mechanism of action, the applicant proclaimed this food to stimulate  $\beta_3$ -adrenaergic receptors of adipocytes from *in vitro* studies. The data presented are, however, insufficient to convince the safety of this food *in vivo*. If the relevant ingredient of this food, as an enoki mushroom (*Flammulina velutipes*) extract, would exert the effects *in vivo* through stimulating  $\beta_3$ -adrenaergic receptors and also through nonspecific stimulation of  $\beta$ -adrenergic receptors as the applicant explain, the submitted data are judged not enough to evaluate the safety of this food.

FSCJ concluded, therefore, that the safety of this food cannot be assessed unless otherwise the additional scientific bases for the mechanism of action and its food safety are appropriately provided.

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<sup>1</sup> “Shushi Cha” is a name romanized the Japanese name using Hepburn's method for this provisional English translation.