

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

Risk Assessment Report

Vaam Smartfitwater

(Food for Specified Health Uses)

Food Safety Commission of Japan (FSCJ) May 2019

SUMMARY

FSCJ conducted a risk assessment of *Vaam Smartfitwater* as a food for specified health uses based on the documents submitted by the applicant. This product is a beverage containing alanine, arginine and phenylalanine as relevant ingredients which accelerate body activity of fat decomposition and burning resulting in increased fat metabolism. This product is thus described as being suitable for people who are concerned about body fat.

The recommended daily intake of this product, 500 ml, contains the relevant ingredients consisting of alanine 375 mg, arginine 375 mg and phenylalanine 750 mg (as 1,500 mg of a mixture of three amino acids).

The assessed data include history of use as the food, reverse mutation tests using microorganisms, chromosomal aberration tests in cultured mammalian cells, micronucleus tests in rats, single dose oral administration tests in rats, 13-week repeated dose oral administration tests in rats, 13-week repeated dose oral administration tests in ZDF spontaneous diabetic rats, and human trials of 12-week continuous consumption in individuals having BMI score of 25 to 30 and of 4-week continuous three fold excessive consumption.in individuals having BMI score of 18.5 to 30.

Based on the above results and the presented documents, FSCJ concluded that *Vaam smartfitwater* has no concern relevant to human health as long as the presented documents concern.