

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

## Risk Assessment Report

### Canthaxanthin

(Food Additives)

Food Safety Commission of Japan (FSCJ)

October 2014

#### ABSTRACT

FSCJ conducted a risk assessment of canthaxanthin (CAS No. 514-78-3 as canthaxanthin) which is used as a food coloring agent, based on results from various studies.

The data used in the assessment include genotoxicity, repeated dose toxicity, carcinogenicity, reproductive and developmental toxicity of canthaxanthin as the test substance, and human data also.

Reviewing of the pharmacokinetics of canthaxanthin indicates particularly high accumulation of canthaxanthin in retina in human. Levels of accumulated canthaxanthin in retina was 100 to 500 times higher in humans than in monkeys, and intraocular distribution of [6,7,6',7'-<sup>14</sup>C] canthaxanthin in rats was one hundredth of that in monkeys. Clear species differences are thus observed on the retinal level and intraocular distribution. The accumulation was prominent in humans, then in monkeys, and least in rodents. It is therefore necessary to evaluate carefully the safety of canthaxanthin particularly to retina or eyeballs.

FSCJ reviewed the allergenicity of canthaxanthin and its general pharmacology. None of the data, however, showed their concern for the food safety. In addition, FSCJ concluded that canthaxanthin has no genotoxicity relevant to human health.

FSCJ reviewed the acute toxicity, repeated dose toxicity, carcinogenicity, reproductive and developmental toxicity in experimental animals, and also on human studies of canthaxanthin. In a human intervention study, reduced scotopic b-wave amplitude was observed with the dose of 60 mg/person/day, and was considered due to the ingested canthaxanthin. FSCJ concluded that 15 mg/person/day (0.25 mg/kg bw/day) is the no-observed-adverse-effect level (NOAEL) of canthaxanthin. No apparent carcinogenicity was granted on the basis of its review of canthaxanthin.

Taking the observed toxicological effects and estimated intake of canthaxanthin (0.52 mg/person/day (0.0094 mg/kg bw/day) as the national average, 0.33 mg/person/day (0.02 mg/kg bw/day) for children, 0.39 mg/person/day (0.0067 mg/kg bw/day) for pregnant women) after its approval in Japan into account, FSCJ considered that it is necessary to specify an acceptable daily intake (ADI) for canthaxanthin. FSCJ specified the ADI of 0.025 mg/kg bw/day, based on the NOAEL in a human intervention study (25 mg/kg bw/day) and applying a safety factor of 10 (10 for individual differences).