

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

Risk Assessment Report

Tocopherol (Exempted Substances)

Food Safety Commission of Japan (FSCJ)
March 2018

SUMMARY

FSCJ conducted a risk assessment of tocopherol that was designated as Exempted Substances¹ based on reports of JECFA or of EFSA.

The bioavailability of orally administered tocopherol was 70 ~ 80 % in humans, however various values of bioavailability (10 ~ 80 %) were reported. Results of studies on its distribution and residues suggested that tocopherol once absorbed were distributed and accumulated mainly in the liver or adipose tissues. The main excretion of tocopherol was considered to be the excretion into stools through the bile.

FSCJ judged that tocopherol has no genotoxicity.

No carcinogenicity was observed in chronic toxicity and carcinogenicity studies.

No teratogenicity was observed in reproductive developmental study.

FSCJ estimated the maximum intake of tocopherol from livestock and aquatic products in Japan to be 2.9 ~ 9.2 mg/person/day, considering that tocopherol has been used as a veterinary medicinal product or a feed additive, and livestock and aquatic products derived from food animals exposed to it have been in circulation as foods.

When compared this estimated maximum intake to values specified in the report from Study Group for Development of Dietary Reference Intakes for Japanese (2015), it was 58 ~ 142 % of the adequate intake of Vitamin E and was 0.74 ~ 2.3 % of the no tolerable upper intake level (UL). Hence FSCJ considered that tocopherol intake would hardly exceed the UL even if the intake from foods other than livestock and aquatic products was included.

In addition, FSCJ considered that the source of excessive intake of tocopherol would be hardly derived

¹ On May 29, 2006 the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods to prohibit the distribution of foods that contain agricultural chemicals above a certain level if maximum residue limits (MRLs) have not been established. Exempted Substances are designated as substances having no potential to cause damage to human health by the Minister of Health, Labour and Welfare, based on the provision of Paragraph 3, Article 11 of the Food Sanitation Act, and these substances are not subjected to the positive list system.

from daily foods based on the estimated maximum intake mentioned above.

Therefore, FSCJ concluded that it was unnecessary to specify the ADI for tocopherol.

Consequently, FSCJ concluded that risks of tocopherol to human health through residues in foods are negligible as long as normally used as veterinary medicinal products and feed additives.