

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

Risk Assessment Report

Anacardic Acid (Exempted Substances¹)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

The FSCJ conducted a risk assessment of anacardic acid (CAS No. 11034-77-8) referring to evaluation documents for a feed additive designation in response to the request from the Ministry of Health, Labour and Welfare (MHLW) in line with the application for a new designation of cashew nutshell liquid (further named CNSL) as a feed additive. Anacardic acid has been designated as an exempted substance by the Minister of Health, Labour, and Welfare. Anacardic acid is a primary substance of CNSL. This substance does not have adverse effects on human health by the provision of Article 13 paragraph (3) of the Food Sanitation Act (Act No. 233 of 1947). Anacardic acid is an alkyl phenol that suppresses methane production in the first rumen of cattle.

The test results used in the assessment include the data on fate in animals (cattle and others), residues (cattle), genotoxicity, acute toxicity (mice), subacute toxicity (mice), and others.

As the study results of fate in animals and residues, most of the anacardic acid was excreted into feces without being degraded or absorbed. Furthermore, as alkyl phenol substances such as anacardic acid were not detected in the tissues, milk, etc., the FSCJ viewed that anacardic acid administered to the cattle would not remain *in vivo* in animals.

In a genotoxicity study, the FSCJ fully examined the reports of the negative results of *in vivo* studies with anacardic acid as well as *in vitro* and *in vivo* studies with CNSL, CNSE, etc. Accordingly, no genotoxicity was observed for anacardic acid.

In a subacute toxicity study, toxicity related to blood and kidneys was not observed up to the administration of 600 mg/kg bw per day. Females only experienced toxicity after being administered 1,000 mg/kg bw per day, while males were unaffected. Subsequently, the FSCJ determined the non-

¹ On May 29, 2006, the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods- the system 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 defined by the MHLW as substances having no potential to cause damage to human health, based on the provision of Article 13, paragraph (3) of the Food Sanitation Act. These substances are not subject to the positive list system.

observed-adverse-effect level (NOAEL) of 600 mg/kg bw per day for females and 1,000 mg/kg bw per day (the maximum dose) for males.

Chronic toxicity and carcinogenicity studies for anacardic acid have not been conducted. Nevertheless, the FSCJ presumed that identifying the concerned chronic effects would be viable using the results of a subacute toxicity study given the low residue of this substance and the edible experience of cashew nuts containing the same substance.

Reproductive/developmental toxicity studies for anacardic acid have not been conducted. Meanwhile, the residue level of this substance is low. No toxicity effects on reproductive function nor on the next generation have been reported regarding the edible experience of cashew nuts including this substance.

In Japan, CNSL containing anacardic acid has been applied as a feed ingredient to livestock since 2012. No safety issue has been reported on livestock or their products due to this feed ingredient. Further, the FSCJ assumed that humans would unlikely take excessive amounts of anacardic acid derived from feed additives through food since alkyl phenol substances such as anacardic acid, etc. were not detected from the tissues, milk, and others after administering this mixed feed additive to the cattle.

Given the above, the FSCJ came to the clear conclusion that anacardic acid would not harm human health by the residues in food as long as it is ordinarily used as a feed additive.