

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

Risk Assessment Report

Distilled liquid smoke flavouring acetic acid (Exempted Substances¹)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

The FSCJ conducted a risk assessment of a fungicide, distilled liquid smoke flavouring acetic acid² referring to various documents. The purpose of this assessment is to apply to a designated exempted substance defined by the Ministry of Health, Labour and Welfare (MHLW). This substance does not have adverse effects on human health in accordance with the provision of Article 13 paragraph (3) of the Food Sanitation Act (Act No. 233 of 1947).

From the result of various toxicity studies, the FSCJ found that the LD₅₀ value of the rat which distilled liquid smoke flavouring acetic acid was administered, was over 2,000 mg/kg bw in acute toxicity study. Genotoxicity in the organism was not observed.

Concerning food intake via the residues in crops in normal dietary life, the possibility to increase the amount of the distilled liquid smoke flavouring acetic acid would be low in case that it is used as pesticide.

Given the above, the FSCJ thought that there is no concern about human consumption of substances in the residues as long as the distilled liquid smoke flavouring acetic acid is normally applied as pesticide in line with the registered standards of use. The FSCJ drew a conclusion based on the assumption that the mixtures of original constituents are controlled within the specified range.

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 11, paragraph (3) of the Food Sanitation Act. These substances are not subject to the positive list system.

² Distilled liquid smoke flavouring acetic acid is a purified wood vinegar containing acetic acid as an active substance. It was developed by Taiko Pharmaceutical Co., Ltd.