

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

Risk Assessment Report

2,3-Dimethylpyrazine

(Food Additive)

Food Safety Commission of Japan (FSCJ)
July 2008

Executive summary

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of 2,3-dimethylpyrazine [CAS No. 5910-89-4], a food additive used as a flavor, using various test results.

The test results used in the assessment are related to the repetitive dose toxicity and genotoxicity.

In a 90-day repetitive dose toxicity study, mucosal membrane hyperplasia was observed in the large intestine (colon). However, since the substance is unlikely to have genotoxicity relevant to human health, it is evaluated that threshold of the toxicological effects can be determined. Therefore, 2,3-dimethylpyrazine seems to have no toxicity relevant to human health at least within a low-dose range normally used for a flavor. In addition, FSCJ confirmed that the substance was categorized into structural class II based on the safety assessment method compiled and used in Japan for flavoring agents commonly used in the world, and that the safety margin (10,000–40,000) exceeds 1,000, which is regarded as the appropriate safety margin for a 90-day repetitive dose toxicity study and the predicted amount of intake (4–16 µg/person/day) is lower than the acceptable daily intake of Structure Class II (540 µg/person/day).

Thereby FSCJ concluded that there is no safety concern with 2,3-dimethylpyrazine when it is used for the purpose of flavoring food.