



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

Risk Assessment Report

Safety of foods containing high levels of diacylglycerol (Novel Foods and Food Additives)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment on foods containing high levels of diacylglycerol (DAG), (hereinafter referred to as DAG-rich foods), based on results from various studies.

The safety of DAG-rich food, as foods for specified health use, was once evaluated by the Pharmaceutical Affairs and Food Sanitation Council of the Ministry of Health, Labour and Welfare (MHLW). On 11 September 2003, FSCJ notified MHLW the conclusion of the council to be appropriate.

Additional data on two-steps carcinogenicity tests of edible oils containing high levels of DAG, (hereinafter referred to as DAG-rich oils), conducted in the period from September 2005 to February 2009, were presented from MHLW afterward.

FSCJ judged that the DAG-rich food was of no cancer-promoting property relevant to human health as long as they were ingested appropriately. FSCJ decided to conduct also a safety assessment of glycidol fatty acid esters (GE) with which DAG-rich oils were contaminated as minor constituents, which occurrence was found during the assessment described above.

Domestic suppliers of the subjects of this assessment, DAG-rich foods and related products, were, however, suspended in September 2009. Thus DAG-rich foods, already refrained from marketing, are unlikely to expose people and additional data for the assessment are unavailable in the situation. Reliable lifetime risk of cancer is not estimated individually from their broadened history of exposure to DAG-rich foods, confounding varieties of life style and consumption of DAG-rich foods (period, amount, age etc.). Hence, the food safety assessment could not be completed, due to the shortage of the exposure information on the DAG-rich foods.

In this assessment, potential tumor promoting activity of DAG-rich oils and properties of GE, a possible contaminants in food oils are summarized in the appendix for the related information.

Reference 1: Data of studies on DAG-rich oils, presented for the current food safety assessment.

- Oral administration of DAG-rich oils to mice showed no cancer-promoting activity in the oral cavity including tongue, esophagus, anterior stomach and colon.
- DAG-rich oils showed no carcinogenicity in the mammary gland in animal studies.
- These findings were obtained with the doses higher than the recommended daily consumption for



human.

- As the results, potential of cancer-promoting activity of orally intaked DAG-rich oils was denied. Harmful effects of DAG-rich oils was not confirmed in animal experiments, although DAG-rich oils contain GE as a contaminant.
- Hence, FSCJ considered that cancer-promoting risk in human is negligible from the consumption of DAG-rich oils in ordinary foods.

Reference 2: Observations on glycidol and glycidol fatty acid esters (GE) in foods.

- DAG-rich oils are likely to contain trace amounts of GE as contaminants. The possibility of genotoxic carcinogenicity of glycidol, a metabolite of GE, cannot be denied.
- Genotoxicity of GE is less potent than that of glycidol. The incidence rate and degree of tumor in carcinogenicity study with subcutaneous administration were rather lower with GE than glycidol.
- On the assumption that the level of GE in the currently distributed edible oils and food products is maintained as minute and all of the GE is converted to the equimoles of glycidol in the body, margin of exposure (MOE) was estimated to be slightly lower than 10,000. A certain level of margin is still exist even if the exposure was overestimated.
- While these data do not suggest directly the adverse effects of consumption of currently distributed edible oils on human health, GE levels should be kept as low as reasonably achievable according to the principle of ALARA (As Low As Reasonably Achievable).
- More data on GE such as data of toxicokinetics and toxicity studies on individual GE substances, information of human exposure and scientific data on epidemiological studies are needed for the further risk assessment.