



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

Risk Assessment Report

Foods highly containing diacylglycerol (Novel Foods and Food Additives)

Food Safety Commission of Japan (FSCJ)
March 2015

ABSTRACT

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment on foods highly containing diacylglycerol (DAG) (hereinafter referred to as DAG foods), based on results from various studies.

The safety of DAG foods, 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 September 11, 2003, FSCJ approved the evaluation of the MHLW's council to be appropriate.

Subsequent MHLW's two-stage carcinogenicity studies on edible oils highly containing DAG (hereinafter referred to as DAG oils) conducted from September 2005 to February 2009 supported the MHLW's judgment "No concern relevant to human health even though all the edible conventional oils were substituted with DAG oils". FSCJ continued to conduct also a risk assessment of DAG oils focusing on the minor constituent, glycidol fatty acid esters (GE).

DAG oils and related products have been, however, retracted from the market in September 2009 in Japan. DAG foods are thus unlikely to expose people, and no further data necessary for the assessment are available on the consumption of DAG foods (period, amount, age, etc.) and varieties of confounding factors in lifestyle. Lack of individual data on the exposure makes it difficult from the reliable estimation of lifetime cancer risk. The food safety assessment thus could not be completed.

Current scientific considerations on the possible adverse effects of DAG oils and GE as contaminants in food oils are summarized in the appendices.

Appendix 1: On DAG oils

- DAG oils showed no tumor promoting activity after the oral administration in the oral cavity and tongue, esophagus, forestomach and colon of mice.
- DAG oils showed no carcinogenicity in the mammary gland in animal studies.
- Both the experiments described above were done at much higher doses compared with human daily consumption.



- As the results, the tumor promoting activity of DAG oils, once concerned, was denied. Adverse effects of DAG oils were not confirmed in animal experiments, although DAG oils contain GE as contaminants.
- Hence, FSCJ judged that tumor promoting risk in human is negligible from the daily consumption of DAG oils in foods.

(Full version is available in Japanese at: <http://www.fsc.go.jp/fsciis/attachedFile/download?retrievalId=kya20050920001&fileId=200>.)

Appendix 2: On Glycidol and its fatty acid esters (GE)

- DAG oils were suspected to contain trace amounts of GE as contaminants. The genotoxic carcinogenicity was not denied for the metabolite of GE, glycidol.
- Studies, however, showed the rather weak genotoxicity of GE than glycidol. The incidence and multiplicity of tumors in carcinogenicity studies were rather lower with GE than glycidol.
- The level of GE in the currently available edible oils and food products is maintained as minute. For this exposure estimation, all of the GE were assumed to be converted to the equimoles of glycidol in the body. Even though the possible overestimation, a certain level of margin of exposure (MOE), slightly lower than 10,000, was allocated.
- These data suggest no apparent adverse effects due to the consumption of edible oils currently available. GE exposure levels, however, should be kept as low as possible according to the principle of ALARA (As Low As Reasonably Achievable).
- For future risk assessments, detailed data on GE such as the toxicokinetics and toxicity on individual GE substances, as well as human exposure, would be helpful.

(Full version is available in Japanese at: <http://www.fsc.go.jp/fsciis/attachedFile/download?retrievalId=kya20050920001&fileId=200>. The executive summary is available in the accompanying annex.)