

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

Risk Assessment Report

Aflatoxin M1 in Milk and Aflatoxin B1 in Feeds

(Natural toxins and mycotoxins)

Food Safety Commission of Japan (FSCJ)

July 2013

ABSTRACT

FSCJ conducted a risk assessment of aflatoxin M1 (AFM1) in milk and aflatoxin B1 (AFB1) in feeds, based on the studies on toxicokinetics, acute toxicity, genotoxicity, chronic toxicity and carcinogenicity, and the contamination survey in feeds and livestock products.

AFB1 is a secondary metabolite of fungi and may contaminate agricultural crops. AFM1 is a metabolite of AFB1 and is contained in the milk of animals that ingested AFB1.

Carcinogenicity of AFB1

As shown in the risk assessment report “Total Aflatoxins (aflatoxin B1, B2, G1, and G2)” published in March 2009, AFB1 is a genotoxic carcinogen with the strongest carcinogenicity among all the aflatoxins, and animal experiments showed that AFB1 caused liver cancer in most animal species. Based on the epidemiological studies, the risk for liver cancer in a human population has been estimated to be 0.01/100.000/year/ng AFB1/kg bw in the hepatitis B surface antigen (HBsAg) negative individuals and 0.3/100.000/year/ng AFB1/kg bw in HBsAg positive individuals. The International Agency for Research on Cancer (IARC) reported that there was sufficient evidence for the carcinogenicity of AFB1 in humans and experimental animals, being classified to IARC carcinogenicity group 1.

Carcinogenicity of AFM1

Like the AFB1, it is known that the target organ of the AFM1 toxicity is the liver. The genotoxicity of AFM1 was demonstrated by both in vitro and in vivo tests. The toxicity is weaker than that of AFB1. Although AFM1 induces liver cancer in experimental animals, the tests in rats showed that the carcinogenic potency of AFM1 was 2 to 10 % of that of AFB1. IARC reported that there was sufficient evidence for the carcinogenicity of AFM1 in experimental animals. It also reported that, although there was inadequate evidence in humans for the carcinogenicity of AFM1, the carcinogenicity of AFM1 was classified to the IARC’s carcinogenicity group 2B due to its similarity with AFB1 in structure, activity, and other relevant evidence.

Therefore, FSCJ considered that there was sufficient evidence for the carcinogenicity involving genotoxicity of AFM1, and that it was appropriate to conduct a risk assessment of AFM1 as a carcinogen for human health. Based on the findings that the cancer inducing mechanism of AFM1 is the same as that of AFB1 and that the carcinogenicity of AFM1 in rats is about one tenth of that of

AFB1, the risk for liver cancer in a human population has been estimated to be 0.001/100.000/year/ng AFB1/kg bw in the hepatitis B surface antigen (HBsAg) negative individuals and 0.03/100.000/year/ng AFB1/kg bw in HBsAg positive individuals.

AFM1 contamination in foods

The survey of the AFM1 contamination level of commercially available pasteurized milk and raw milk in Japan showed that the average concentration \pm standard deviation of AFM1 was 0.009 ± 0.0004 $\mu\text{g/kg}$ in commercially available milk and 0.0074 ± 0.0047 $\mu\text{g/kg}$ in raw milk. The survey of the AFM1 contamination level of powdered infant formula indicated that the average concentration of AFM1 was 0.002 $\mu\text{g/kg}$ when converted to the concentration in the formula. Estimation of the carcinogenic risk based on the lifetime exposure to AFM1 calculated from these values suggests that the risk is extremely low in the present situation.

AFB1 in feeds and AFB1 metabolites in livestock foods

The regulatory level of AFB1 in formula feeds has been designated by the Ministry of Agriculture, Forestry and Fisheries of Japan. The contamination survey of the formula feed conducted in Japan showed that the average AFB1 concentration in formula feeds remained lower than the regulatory level.

The study on the transfer of AFB1 from formula feeds to milk indicated that the AFM1 concentration in milk increased in proportion to the amount of AFB1 taken by cows. From this finding, FSCJ considered that suppression of the AFB1 contamination of formula feeds would reduce the AFM1 concentration in milk.

Based on the findings of feeding experiments, the risks of the residues of AFB1 and its metabolites observed in tissues of various livestock and poultry are estimated to be at negligible levels. Also the survey of contamination of foods in Japan has demonstrated that the residues of AFB1 and its metabolites in livestock products remain below detectable levels in the current situation where AFB1 concentrations in feeds are controlled to be lower than the regulatory level.

Conclusion

Hence, FSCJ concluded that the potential that AFB1 in formula feeds would affect human health through milk or other livestock products is extremely low.

However, considering that AFM1 and some of its metabolite which might be contained in livestock products are genotoxic carcinogens, the AFB1 contamination in feeds and the AFM1 contamination in milk need to be suppressed to an ALARA (as low as reasonably achievable) level. In particular, attention should be paid to the fact that the intake of milk per 1kg of body weight by infants is higher than that by other age groups.