

Risk Assessment Report

Benzoic acid (Exempted Substances)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of benzoic acid (CAS No. 65-85-0) based on the documents of the request for designating it as a feed additive and the reports of EFSA (European Food Safety Authority).

It is generally accepted that benzoic acid after absorbed is rapidly metabolized to hippuric acid in the liver through glycine conjugation, and excreted in the urine as hippuric acid. Studies on the distribution and excretion of ¹⁴C-benzoic acid in rats have clarified that sodium benzoate and benzoic acid do not accumulate in the body.

As for genotoxicity of sodium benzoate and benzoic acid, the both were negative in *in vitro* reverse mutation test using bacteria regardless of the presence or absence of metabolic activation. In addition, results of *in vivo* studies with chromosomal aberration test, comet assay, dominant lethal test, and host-mediated assay were all negative. Therefore, FSCJ concluded that benzoic acid has no genotoxicity relevant to human health and there is the toxicological threshold.

FSCJ considers that toxicity of benzoic acid is not high based on the results of toxicity studies in experimental animals and of human studies so that benzoic acid is a relatively safe substance.

Although limited findings from subacute toxicity study, chronic toxicity study and carcinogenicity study are available, toxic effects such as decreased body weight or hepatic disorder were observed at the high dose.

Regarding reproductive developmental toxicity, NOAEL of 500 mg/kg bw/day has been obtained in multi-generation reproductive toxicity study with dietary administration in rats.

From among various toxicity studies, FSCJ specified the NOAEL of 500 mg/kg bw/day for parent and offspring in multi-generation reproductive toxicity study in rats that can be adopted as POD (Point of Departure) in the risk assessment.

JECFA and EFSA have specified the ADI of benzoic acid as a food additive to be 5 mg/kg bw/day based

on the NOAEL of 500 mg/kg bw/day obtained in the above multi-generation reproductive toxicity study in rats.

Benzoic acid is naturally contained in foods, and has sufficient food experience because of a long history of use as a food additive.

As an estimation based on the average pork intake, FSCJ considered that the intake of benzoic acid through the food derived from the animal (pigs) fed with benzoic acid has a large exposure margin compared to the ADI specified by JECFA if benzoic acid is used appropriately as a feed additive. Moreover, supposing that a large amount of benzoic acid are ingested from other foods, FSCJ considered that the effect is only a small even if meat derived from pigs fed with feed containing benzoic acid is further ingested a lot.

Hence, consideration of an ADI is not necessary in the assessment of benzoic acid as a feed additive, and FSCJ concluded that risks of benzoic acid on human health through remaining in foods are negligible as long as used normally as a feed additive.