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

Risk Assessment Report

Butylated hydroxyanisole

(Feed Additives)

Food Safety Commission of Japan (FSCJ)
January 2018

ABSTRACT

FSCJ conducted a risk assessment of butylated hydroxyanisole (CAS No. 25013-16-5), an antioxidant, based on the assessment reports by JECFA and EFSA and others.

The data used in the assessment are the followings; pharmacokinetics (mice, rats, dogs and humans); residues (pigs, chicken, rainbow trouts, carps, and ayus); genotoxicity, acute toxicity (mice and rats); subacute toxicity (dogs and pigs); chronic toxicity and carcinogenicity (mice, rats, hamsters and dogs); reproductive developmental toxicities (mice, rats, rabbits, pigs and monkeys); and effects on stomach (mice, rats, hamsters, rabbits, guinea pigs and monkeys).

While FSCJ considered that butylated hydroxyanisole (BHA) and/or its metabolites such as tert-butylhydroquinone (TBHQ) induce chromosomal aberration, the influence on the chromosomal aberration is likely associated with production of reactive oxygen species by the metabolites, quinone compounds. Therefore, FSCJ considered that BHA and its metabolite(s) have no genotoxicity relevant to human health, thus judged it possible to specify an ADI for BHA.
Although BHA was carcinogenic in the forestomach of rodents, this effect was specific in rodents so that FSCJ considered this effect not relevant to humans.
In subacute and chronic toxicity studies, proliferative changes in the forestomach and chronic interstitial nephritis in the kidney of rats, and suppressed body weight and hepatocellular degeneration in dogs were observed.
Teratogenicity was not observed in reproductive developmental studies, although adverse effects such as increased mortality at weaning and changes of behavior were observed in offspring.
Among NOAELs obtained in various toxicity studies with endpoints other than proliferative changes in the forestomach, the lowest NOAEL was 50 mg/kg bw/day obtained in 15-month chronic toxicity study in dogs. Accordingly, FSCJ specified the ADI for BHA as 0.5 mg/kg bw/day, based on this LOAEL and applying a safety factor of 100.