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

Risk Assessment Report

Chlorpromazine

(Veterinary medicinal products)

Food Safety Commission of Japan (FSCJ)
July 2014

ABSTRACT

FSCJ conducted a risk assessment of chlorpromazine (CAS No. 50-53-3), a tranquillizer, based on documents such as assessment reports from the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the European Medicines Agency (EMEA).

Data used in the assessment include pharmacokinetics (rats, dogs, goats, pigs, horses and humans), genotoxicity, acute toxicity (mice, rats, rabbits and dogs), and reproductive and developmental toxicity (mice and rats).

Some *in vitro* data were positive in studies on genotoxicity of chlorpromazine, suggesting that chlorpromazine has genotoxic potential. Most of the *in vivo* data were negative on genotoxicity.
However, since chromosomal aberration was observed in humans treated with chlorpromazine, FSCJ concluded that the potential of chlorpromazine to have genotoxicity relevant to human health could not be excluded. Detailed reports of carcinogenicity studies were not available, and therefore based on the available data, FSCJ concluded that it was not possible to judge the pontential whether chlorpromazine has carcinogenic potential or not.

On the basis of the above findings, it was not possible to exclude the potential to have genotoxicity, nor to judge the potential to have carcinogenicity. Consequently, FSCJ concluded that an ADI of chlorpromazine should not be specified.