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Risk Assessment Report
Formic acid
(Mixed formulation of Sodium hydroxide)
(Feed Additive)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

The FSCJ conducted a risk assessment of a feed additive containing an active substance, Formic acid (mixed formulation of Sodium hydroxide) (CAS No.64-18-6) referring to the submitted documents for feed additive designation.

Formic acid dissociates into formate ions and hydrogen ions in an aqueous solution. *In vivo*, each ion is absorbed and circulated, while Formic acid is metabolized and oxidized to carbon dioxide. Formic acid not metabolized *in vivo* is excreted *in vitro* through urine, feces, or exhalation. Consequently, the FSCJ thought that Formic acid administered to animals would be promptly metabolized and excreted without accumulating *in vivo*, and humans would not excessively ingest Formic acid from feed additives.

The FSCJ determined that Formic acid would not have genotoxicity attributing to the negative results of the tests: *in vitro* reverse mutation, gene mutation, abnormal chromosome, sister chromatid exchange, and *in vivo* sex-linked recessive lethal.

From the results of a subacute toxicity study in rats using Formic acid, the FSCJ identified the no-observed-adverse-effect level (NOAEL) of 160 mg/kg bw per day.

Residue and safety studies applying this formulation have not been undertaken. Meanwhile, in the safety study in which formic acid was administered to targeted animals, abnormal findings were not observed in livestock even after the dose of the recommended maximum additive amount or more.

Furthermore, regarding the substances contained in this formulation, the FSCJ presumed that the health effects on humans when consumed through food would be negligible.

The FSCJ has not conducted the Risk Assessment of the Effects of Food on Health for the Formic acid so far. Nonetheless, assessing calcium formate and potassium diformate, the FSCJ determined that it would not affect human health if their optimal amounts could be applied as feed additives.

Given the above, the FSCJ concluded that the probability of causing adversely affecting human health through food would be negligible as long as it is appropriately used as a feed additive.