

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

## Risk Assessment Report

### **A feed additive containing an active substance, L-Histidine Monohydrochloride Monohydrate produced using *Corynebacterium glutamicum*** (Feed Additive)

Food Safety Commission of Japan (FSCJ)  
December 2022

#### ABSTRACT

The FSCJ conducted a risk assessment of a feed additive containing an active substance, L-histidine monohydrochloride monohydrate (CAS No. 5934-29-2), produced using *Corynebacterium glutamicum*, referring to the submitted documents for feed additive designation.

This formulation contains 98% or more of L-histidine monohydrochloride monohydrate produced by fermentation with a non-genetically modified strain of *Corynebacterium glutamicum*.

The FSCJ evaluated as follows in the assessment report of Exempted Substance “L-histidine” published in October 2022:

- “The amount of histidine in the edible part (muscle, etc.) of the animal dosed L-histidine was equivalent to that of intrinsic histidine in this part of the same animal. For this reason, L-histidine administered as a feed additive is unlikely to increase human intake of L-histidine significantly.”
- “It is obvious that L-histidine is unlikely to cause adverse effects on human health via residues in food as long as it is used normally as a veterinary medicinal product or a feed additive.”

*C. glutamicum*, a production strain, is classified into EFSA’s QPS. The safety of amino acids and other products is affirmed.

Considering the existing assessments, usage, and dosage of this formulation, the FSCJ determined that the effects on human health could be negligible in case that the person consumes its contained substance via food.

Although residual tests using this formulation or safety tests in respective animals were not conducted, there was no concern about safety from the findings of L-histidine administered to those animals.

Given the above, the FSCJ concluded that a feed additive containing an active substance, L-histidine monohydrochloride monohydrate produced using *Corynebacterium glutamicum* has negligible potential to cause adverse effects on human health through food as long as it is appropriately used as a feed additive.