

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

## Risk Assessment Report

### A risk assessment of an amendment to standards for Tofu

(Microorganisms and viruses)

Food Safety Commission of Japan (FSCJ)

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#### ABSTRACT

Aseptic-filled tofu needs to be kept refrigerated under the current standards for tofu. While, FSCJ was requested by the Ministry of Health, Labour and Welfare (MHLW) to assess a food safety risk to human health from changing the standards for storage of aseptic-filled tofu from refrigerated to room temperature storage.

When aseptic-filled tofu is produced following the procedure specified by MHLW, the aseptic-filled tofu is supposed to store and remain on markets for a long period at room temperature.

If *Clostridium botulinum* and *Bacillus cereus* both of which were determined as significant hazards would remain in the final products of the relevant foods, the products may have an adverse effect on human health.

Whereas if a manufacturing procedure includes sterilizing processes that the MHLW indicated as a condition, under a full hygienic control based on “Guidelines on Management and Operation Standards to be Observed by Food-Related Business Operators (Notice Shoku-an No. 1014-1 of October 14, 2014)”, *Clostridium botulinum* and *Bacillus cereus* would be killed and thus would not be existing in the final products. Therefore, FSCJ concludes that the food safety risk to human health is not different before and after changing the standards for aseptic-filled tofu from refrigerated to room temperature storage.

As for a soybean soaking process, an appropriate control of the process is necessary to prevent a growth of the bacteria to a number required for producing a highly heat stable toxin.

In addition, the process management for securing a condition to sterilize by heating at 120°C for 4 min or above needs to have a monitoring system, and when the management is found to be inappropriate, the corrective action must be taken immediately.

Aseptic-filled tofu must be packaged in a container or package that is resistant to various physical effects and capable to prevent a damage that may cause contamination with bacteria. Moreover, for a product of tofu that should be kept refrigerated and that can be kept at a room temperature, it should be noted that the relevant information need to be clearly labeled so that the consumers easily recognize it.