

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

Risk Assessment Report

Pertaining to the proposed revision of the Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc. (Microorganisms and viruses)

Food Safety Commission of Japan (FSCJ)
December 2023

1. Background

In response to a request by the Minister of Health, Labour and Welfare as described in the Ministry's notification No. 0831-11 issued August 31, 2023, the FSCJ conducted a risk assessment pertaining to the proposed revision of the Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc. (Ministry of Health and Welfare Ordinance No. 52 of 1951, hereinafter referred to as "the Ministerial Ordinance.") The outcome is summarized below in "2. Results of risk assessment by the FSCJ."

This latest proposed revision of the Ministerial Ordinance includes updates and additions to the existing compositional standards, manufacturing standards, storage standards, and record-keeping standards (hereinafter referred to as "proposed updates to risk management measures") etc. for cow's milk, composition modified milk, low fat milk, skimmed milk, processed milk, liquid infant formula, and milk drink (hereinafter referred to as "Milk, etc.") as provided by the Ministerial Ordinance for products that do not require storage below 10 °C (products that are either aseptically filled into pre-pasteurized containers and packaging after continuous pasteurization or products that are pasteurized after filling into containers and packaging).

2. Results of risk assessment by the FSCJ

Control and manufacture of Milk, etc. which require storage at 10 °C or lower (refrigeration) are already subject to the regulation standards set forth by the existing version of the Ministerial Ordinance. The purpose of the proposed updates to risk management measures is to add or change sterilization conditions for ensure commercial sterility of products intended to be stored at room temperature for an extended period of time.

Assuming sanitation management of Milk, etc. based on the current provisions of the Ministerial Ordinance, no additional risk factor is reasoned to emerge as a result of the proposed updates to risk management measures.

Likewise, pertaining to Milk, etc. defined under the existing version of the Ministerial Ordinance, introduction of the proposed updates to risk management measures will very unlikely result in adverse health risks to humans because of following reasons.

- The proposed revisions to the Compositional Standards shall verify that no microbial growth is found in the products and that the products are manufactured under appropriate control.
- Pertaining to products that are either aseptically filled into pre-pasteurized containers and packaging after continuous pasteurization or products that are pasteurized after filling into containers and packaging, the proposed amendments to manufacturing and storage provisions clearly prescribe the conditions that ensure commercial sterility. “Sterilization by heating at a temperature of 120°C or higher for 4 minutes or alternative methods that guarantee the equivalent or level of sterilization or higher” is sufficient to effectively sterilize microorganisms in products.
- The proposed revisions to record-keeping standards consider the characteristics of products intended to be stored at room temperature for an extended period of time.

It should be noted that evaluation of the effectiveness of each individual heat sterilization method employed for milk and milk products is not subject to this particular assessment.

Since this evaluation result is based on the premise that sanitation management is to be conducted in compliance with the current version of the regulations under the Ministerial Ordinance, risk management organizations should pay sufficient attention to ensure that appropriate sanitation management is carried out including the portion of the new control measures that are planned to be introduced, and should continue to inform all concerned parties of the importance of such management.

The result of this evaluation is based on the knowledge currently available for discussion, and therefore emerging knowledge and new technologies should be monitored continuously going forward.