

WAC 246-720-080 Milk processing. A milk bank must meet the following milk processing criteria in order to register with the department:

(1) A milk bank must use an electronic inventory system to account for every ounce of donated human milk received, processed, dispensed, discarded, or used for research.

(2) Donated human milk must be traceable to a specific milk donor throughout every step in the collection and donation process.

(3) A milk bank must maintain detailed logistics records, related to donated human milk including, but not limited to, incoming shipping records, receiving date, volume, and the condition of the donated human milk.

(4) Frozen donated human milk must be gradually thawed in a manner that prevents contamination, with careful monitoring and record-keeping documenting adherence to time and temperature requirements.

(5) Donated human milk from multiple donors may be pooled together to create a uniform batch of donor milk. Pooling must be performed with aseptic technique under clean conditions and must be adequately mixed to ensure an even macronutrient distribution throughout the batch.

(6) Donated human milk must be strained with a food grade filter before bottling.

(7) Processed donated human milk must be stored in FDA-approved glass or food-grade plastic containers. Containers must be airtight and leakproof.

(8) Stored donated human milk must be thermally processed, which includes, but is not limited to, pasteurization, prior to storage. Following thermal processing, milk must be rapidly chilled using either processing equipment manufactured to cool milk or ice baths.

(9) Each batch of processed donated human milk or human milk-derived products must be cultured for bacteria. Post-pasteurization or thermal processing, bacteriological testing must be conducted by a third-party accredited lab. Clinical labs must maintain Clinical Laboratory Improvement Amendments (CLIA) or equivalent certification. Food testing labs must meet International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 standards. Donated human milk or human milk-derived products that fail bacteriological testing must not be dispensed.

[Statutory Authority: 2022 c 236. WSR 23-17-149, § 246-720-080, filed 8/22/23, effective 9/22/23.]