

**WAC 246-720-010 Definitions.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Adulterated" means the addition of a substance other than human milk to artificially increase the volume of a donation to a milk bank.

(2) "Compensation" means monetary or in-kind payment or donation to either a milk donor or a third party made in exchange for donated human milk.

(3) "Current good manufacturing practice" or "CGMP" means the regulations adopted by the United States Food and Drug Administration (FDA) under Title 21, Chapter 1, Subchapter B, Part 117 of the Code of Federal Regulations.

(4) "Department" means the Washington state department of health.

(5) "Donor human milk" means human milk that has been contributed to a milk bank by one or more donors.

(6) "Food safety plan" or "FSP" means a written plan to significantly minimize or prevent biological, chemical, and physical hazards in a milk bank.

(7) "Human milk derived product" means donor human milk which has been processed to alter or concentrate the nutrient composition including, but not limited to, human milk derived fortifiers.

(8) "Milk bank" means an organization that engages in the procurement, processing, storage, distribution, or use of human milk contributed by donors. This definition does not include hospitals that act as milk collection sites or milk depots, or that procure, store, distribute or use donor milk received from an offsite milk bank.

(9) "Milk depot" means a drop-off or collection site for donor milk that then gets transported to a milk bank.

(10) "Milk donor" means a lactating person who has passed a health screening and voluntarily donates milk.

(11) "Preventive controls qualified individual" or "PCQI" means a person who has completed a formal certification program through the Food Safety Preventive Controls Alliance (FSPCA).

(12) "Processing" means the use of evidence-based methodologies to prepare safe milk for recipients including, but not limited to, pasteurization.

(13) "Unit of alcohol" means a standard drink which contains 0.6 ounces (14.0 grams or 1.2 tablespoons) of pure alcohol.

[Statutory Authority: 2022 c 236. WSR 23-17-149, § 246-720-010, filed 8/22/23, effective 9/22/23.]