Quantitative Risk Assessment of *Bacillus cereus* Growth during the Warming of Thawed Pasteurized Human Banked Milk Using a Predictive Mathematical Model

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<u>Abstract</u>

Bacillus cereus is relatively resistant to pasteurization. We assessed the risk of *B. cereus* growth during warming and subsequent storage of pasteurized banked milk (PBM) in the warmed state using a predictive mathematical model. Holder pasteurization followed by storage below –18 °C was used. Temperature maps, water activity values, and B. cereus growth in artificially inoculated PBM were obtained during a simulation of manipulation of PBM after its release from a Human Milk Bank. As a real risk level, we chose a B. cereus concentration of 100 CFU/mL; the risk was assessed for three cases: 1. For an immediate post-pasteurization B. cereus concentration below 1 CFU/mL (level of detection); 2. For a B. cereus concentration of 10 CFU/mL, which is allowed in some countries; 3. For a B. cereus concentration of 50 CFU/mL, which is allowed in some countries; 3. For a B. cereus concentration of 50 CFU/mL, which is approved for milk formulas. In the first and second cases, no risk was detected after 1 h of storage in the warmed state, while after 2 h of storage, B. cereus concentration of 102 CFU/mL could be regularly expected after 2 h of storage. Based on these results, we recommend that post-pasteurization bacteriological analysis be performed as recommended by the European Milk Bank Association (EMBA) and using warmed PBM within 1 h after warming (no exceptions).

Keywords: Bacillus cereus; human pasteurized milk; predictive microbiology; mathematical growth model

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