Technical Brief
Ensuring The Safety Of Human Milk–Based Products—Comparing Pasteurization And Processing

Delivering safe, high-quality donor human milk (DHM) products requires careful consideration during collection, testing, and processing. Similar to human blood and plasma, human milk carries with it the risk of pathogen transmission. At the same time, protecting the bioactivity and bioavailability of human milk is vital to ensure the greatest nutritional and health benefits for the vulnerable premature infants who rely on human milk nutrition for survival.

There are several different pathogen inactivation methods in use by providers of human milk–based products. Pathogen inactivation seeks to reduce the number of viable harmful bacteria, fungi, and viruses which can be present in the milk. Each method impacts pathogen inactivation and bioactivity differently.

Vat Pasteurization

Pasteurization fulfills a crucial role of pathogen inactivation in DHM. Vat pasteurization (also known as batch pasteurization) is one of the methods accepted by the US Food and Drug Administration's (FDA's) Pasteurized Milk Ordinance (PMO) to ensure pathogen inactivation.[1] It is a widely used national standard in the dairy food industry, a close analogue to human milk in terms of fat/protein content. Vat pasteurization holds a large volume of fluid in a qualified processing tank before filling final containers under aseptic conditions.

Prolacta Bioscience chose vat pasteurization because it provides effective pathogen inactivation while preserving important bioactive components in human milk. These bioactive components play vital roles in the immune system, nutrient absorption, and growth stimulation, all important to infants' health outcomes, especially those born prematurely.[2]

Holder Pasteurization

Holder pasteurization is used by milk banks belonging to the Human Milk Banking Association of North America (HMBANA). Similar to vat pasteurization, Holder pasteurization involves heating the milk to a set temperature and time. Instead of heating the milk in a large vat, the bottles of milk are heated in small volumes in a water bath, typically the bottles that will be used for distribution. Holder pasteurization is atypical in the food industry (the category under which the FDA currently holds DHM).

In the human blood and plasma industry, the potential risk for product contamination is high and requires close regulation. While contamination risks are similar for human milk–based products, milk banks are not subject to the same level of regulation. The FDA PMO provides guidance for companies using vat pasteurization, but it does not provide similar guidance for companies using Holder pasteurization.

Retort Sterilization/Commercial Canning

Retort sterilization is very different from pasteurization. Some human milk companies, such as Ni-Q and Medolac, use a commercial canning process of pathogen inactivation known as "retort sterilization" which typically involves heating the milk in a sealed pouch. Milk that is commercially canned is shelf stable, similar to canned cow milk, processed foods, and juice products. Pathogens are inactivated using a combination of high temperature and high pressure.

While retort sterilization is effective at destroying pathogens in milk, studies have shown that it also destroys bioactive compounds that are recognized for their importance in immunity, growth and development, and overall long-term health.[3,4] Furthermore, retort sterilization doesn't eliminate bacterial enterotoxins which are produced by certain spore-forming bacteria, including *Bacillus cereus (B. cereus)*, and remain in the milk which could be deadly to a premature infant. Retort sterilization also does not eliminate all medications or other harmful small molecules like THC.

Why is it important to know which pathogen inactivation process is followed?

B. cereus and enterotoxins

B. cereus is a ubiquitous, environmental, spore-forming bacteria known to cause many cases of toxigenic food poisoning each year. It is found in milk donations and represents a special concern for human milk banks and companies that produce human milk–based products. These bacteria are capable of producing heat-resistant toxins, including cereulide, and forming spores that are resistant to pasteurization. These toxins contribute to the pathogenicity of *B. cereus* in emetic or diarrheal syndromes. *B. cereus* is recognized as an infrequent cause of serious non-gastrointestinal infections, particularly in neonates and other immunocompromised patients.[5]

It is important to maintain the proper storage temperature of milk at all stages of collection, handling, and processing to ensure no *B. cereus* growth, even after initial screening. Whenever *B. cereus* is allowed to grow, toxins can be produced. Current findings have postulated the inability of any heat treatment applicable in food processing to eliminate the *B. cereus* toxin, cereulide. Heat sterilization under retort conditions, while having the ability to destroy *B. cereus* spores, will not eliminate cereulide.[6]

The FDA's Center for Food Safety and Applied Nutrition Molecular Methods and Subtyping branch has expressed significant concern about cereulide in human milk–based products and infant formulas. In conversation with the FDA, Prolacta validated and implemented an analytical method to detect cereulide in finished products. It is unknown if cereulide testing is conducted throughout the industry.

Preservation of bioactive components

A study has shown that the macronutrients (total protein and fat), immune-protective proteins, and human milk oligosaccharides (HMOs) of human milk are significantly less in commercially retort sterilized human milk compared to vat pasteurized human milk.[4] Clinicians should consider the bioactivity of donor milk including lactoferrin,[7] lysozyme,[2] sIgA,[8] milk fat globules,[8-10] and others, when deciding on the appropriate nutrition for immunocompromised, critically ill, and premature infants.

Why do collection, testing, and processing standards matter?

At this time, there are no federal-level quality and safety standards specific to human milk and human milk–based products in the US. Collection, testing, and processing vary widely from company to company.

In addition to considering products based on their pasteurization and processing methods, addressing potential risks should start when donors express and store their milk. For example, *B. cereus* is a bacterium commonly found in milk that should be addressed through collection practices before the milk enters a processing facility and thus reducing the overall potential of contamination. If *B. cereus* is present in the milk when it is donated, there is a risk of cereulide contamination regardless of how effective a method is at destroying *B. cereus* itself. Addressing the risks posed by these bacteria should follow a full end-to-end approach starting with donors taking precautions as they express their milk, all the way through the final product testing to confirm there is no presence of cereulide.

Some new human milk providers are promoting clinically unproven and untested manufacturing processes, with no product-specific data, posing potential risk to neonatal intensive care units (NICUs) and the fragile premature infants who rely on human milk nutrition. It is imperative that critically ill and premature infants are provided with the safest, clinically proven, and most nutritionally beneficial diet available.

Preserving bioactivity naturally found in human milk benefits growth and development, immunity, and long-term health of preterm infants.[3,4]

What is the take-away?

Being aware of the impact various pathogen inactivation processing techniques may have on the components of human milk and their functions can help guide decisions when choosing the most appropriate nutrition for the preterm infant population. Pathogen inactivation is critical for the safety of DHM products to protect these most vulnerable patients; however, it is also vital to preserve as much of the bioactivity naturally found in human milk as possible to benefit the growth and development, immunity, and long-term health of these infants.[3,4]

New pathogen inactivation methods are continually being developed and implemented. Current and new methods require stringent evaluation to understand their full impact on both the nutrition and bioactivity of DHM products.

References:

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