resulting in various forms of paralysis and therefore can be a serious, potentially fatal, disease.

**[0005]** Many human milk banks use pasteurization during human milk processing. As applied to human milk, pasteurization typically involves heating the milk at 62.5°C for 30 minutes ("Holder pasteurization"). *See* Guidelines of the Establishment and Operation of a Donor Human Milk Bank, Human Milk Banking Association of North America, 2015. Methods that eliminate *B. Cereus* and *C. Botulinum* employ more extreme processing conditions. These extreme processing conditions, as well as the conditions employed for Holder pasteurization, often have a detrimental effect on the quality of the sterilized human milk. Namely, the process irreversibly damages nutritional proteins, lipids, and carbohydrates (e.g., oligosaccharides). Therefore, although the sterilized human milk is cleared of pathogens and is safe for consumption, the nutritional content is also substantially altered, such that the benefits rendered by consumption of the sterilized human milk are lost. Moreover, some processes used to reduce *B. Cereus* and *C. Botulinum* content include direct injection of heated steam into the milk, which risks introduction of contaminants and necessitates the downstream separation of water from the milk.

**[0006]** Accordingly, there is a need for a human milk sterilization process that reduces or eliminates harmful pathogens, such as *B. Cereus* and *C. Botulinum*, while also maintaining the nutritional qualities of the human milk.

## 4. SUMMARY

**[0006a]** In one aspect, provided herein is a method of sterilizing an unpasteurized volume of human milk to produce a sterilized human milk product, the method comprising:

homogenizing an unpasteurized volume of human milk;

heating the homogenized human milk volume in a tube to within a temperature range of 130˚ C and 150˚ C while flowing the human milk through the tube, the tube heated by flowing heating fluid in a direction counter to the direction of flow of the human milk, wherein the heating fluid is in contact with an exterior surface of the tube;

holding the temperature of the human milk volume within the temperature range for a duration of 3 to 15 seconds; and

cooling the heated human milk volume to produce the sterilized human milk product,

wherein the sterilized human milk product retains greater than 88% of human immunoglobulin A (IgA) compared to the unpasteurized volume of human milk.

## CLAIMS

What is claimed is:

1. A method of sterilizing an unpasteurized volume of human milk to produce a sterilized human milk product, the method comprising:

homogenizing an unpasteurized volume of human milk;

heating the homogenized human milk volume in a tube to within a temperature range of 130˚ C and 150˚ C while flowing the human milk through the tube, the tube heated by flowing heating fluid in a direction counter to the direction of flow of the human milk, wherein the heating fluid is in contact with an exterior surface of the tube;

holding the temperature of the human milk volume within the temperature range for a duration of 3 to 15 seconds; and

cooling the heated human milk volume to produce the sterilized human milk product, wherein the sterilized human milk product retains greater than 88% of human immunoglobulin A (IgA) compared to the unpasteurized volume of human milk.

2. The method of claim 1, wherein a length of the tube and the flow rate of the human milk are each chosen to hold the temperature of the human milk within the temperature range for the duration.

3. The method of claim 1, wherein the tube has a diameter between 0.25 and 10 inches.

4. The method of claim 1, wherein the flow rate of the human milk through the tube is between 0.25 gallons per minute and 25 gallons per minute.

5. The method of claim 1, further comprising a step, prior to homogenizing the human milk volume, of:

eliminating pathogens from a raw human breast milk sample through one or more clarification processes to obtain a clarified human milk volume, wherein the one or more clarification processes comprises centrifugal filtration.

6. The method of claim 5, further comprising, after eliminating pathogens from a raw human breast milk sample and prior to homogenizing the human milk volume, steps of:

separating the clarified human milk volume into a cream sample and a skim sample;

generating a retentate by performing a concentration process on the skim sample; and

engineering a standardized human milk volume by combining a portion of the cream sample with a portion of the generated retentate.

7. The method of claim 6, wherein combining a portion of the cream sample with a portion of the obtained retentate comprises:

detecting an initial characteristic of the cream sample;

comparing the detected initial characteristic of the cream sample to a target characteristic for the standardized human milk volume; and

determining the portion of the cream sample and the portion of the generated retentate based on the comparison.

8. The method of claim 1, further comprising subsequent to producing the sterilized human milk product, a step of packaging, through an aseptic process, the sterilized human milk product.