Florida Department of Agriculture and Consumer Services Division of Food Safety Bureau of Dairy Industry

BATCH (VAT) PASTEURIZATION REQUIREMENTS Rev. 06/2018

Please note: These are basic requirements put together for processors who wish to legally pasteurize dairy products using a batch or vat pasteurizer. The full set of regulations a processor will need to abide by can be found in the documents listed below:

- Grade "A" Pasteurized Milk Ordinance (PMO) 2015 Revision
- Chapter 502, Florida Statutes http://www.flsenate.gov/Laws/Statutes/2014/Chapter502
- Chapter 5K-10, Florida Administrative Code <u>https://www.flrules.org/gateway/ChapterHome.asp?Chapter=5k-10</u>

INTRODUCTION

You have received this information because you have been identified or chose to use batch (vat) pasteurization to legally pasteurize your product. Due to the importance of this process, it is imperative that it be done using approved, tested equipment that includes all of the necessary public health controls outlined in the *Grade "A" Pasteurized Milk Ordinance*.

There are many small batch pasteurizers on the market that do not meet the regulations, especially some of foreign design. One-way dairy and frozen dessert manufacturers can protect themselves is to purchase pasteurization equipment that carries a 3A Sanitary Symbol. Another way is to have our agency review the equipment prior to purchase. Please understand that physically inspecting the equipment prior to purchase may not be feasible due to its location. Specialist can only review the information provided in those scenarios which a physical inspection.

This document contains all the requirements for batch or vat pasteurization, sometimes referred to as "low heat" pasteurization, and is the type of process most small manufacturers will use. Your assigned Sanitation & Safety Specialist will answer any questions you may have regarding this material.

PASTEURIZATION EQUIPMENT TESTING

Prior to initial use and once every three (3) months thereafter, the Bureau of Dairy Industry will perform all required tests on your pasteurization system and, where applicable, apply public health seals.

PUBLIC HEALTH SEALS

Some of the equipment in a pasteurization system is required to be sealed by Bureau personnel after testing. If a seal is broken for repair, maintenance or by accident, the dairy and/or frozen dessert manufacturer must notify their inspector and the Bureau of Dairy Industry immediately. Your assigned inspector will provide further information regarding broken seals during the permitting process. A pasteurizer shall not operate with any public health controls not in place or compromised.

BATCH PASTEURIZATION (aka Vat, Low Heat Pasteurization)

DEFINITION

The terms "batch pasteurization", "vat pasteurized" and "low heat pasteurized" shall mean the process of heating every particle of milk or milk product, in properly designed and operated equipment, to a minimum temperature of 69°C (155°F) and held continuously at or above that temperature for at least 30 minutes.

PUBLIC HEALTH REASON

Unless the temperature-control instruments and devices used on pasteurization equipment are accurate within known limits, there can be no assurance that the proper pasteurization temperature is being applied. Pasteurization must be performed in equipment, which is properly designed and operated and which insures that every particle of milk or milk product will be held continuously at the proper temperature for the specified period of time.

Recording thermometers are the only known means for furnishing the Regulatory Agency with a record of the time and temperature of pasteurization. Experience has shown that recording thermometers, due to their mechanical complexity, are not entirely reliable. Therefore, mercury indicating thermometers or equivalent, which are much more reliable, are needed to provide a check on the recording thermometer and assurance that proper temperatures are being applied.

The recording thermometer shows the temperature of the milk or milk product immediately surrounding its bulb, but cannot indicate the temperature of the milk or milk product in other portions of the batch pasteurizer. Similarly, it shows the holding time in manual-discharge vats, but not in automatic-discharge systems. The pasteurizer must; therefore, be so designed and so operated and, where necessary, provided with such automatic controls, as to assure that every

portion of the milk or milk product will be subjected to the proper temperature for the required length of time.

Unless the outlet valve and connections to the vats are properly designed and operated, cold pockets of milk or milk product may be held in the outlet valve or pipeline and raw or incompletely pasteurized milk or milk product may leak into the outlet line during the filling, heating or holding period.

Tests have shown that when foam is present on milk or milk product in vats or pockets during pasteurization, the temperature of the foam may be well below the pasteurization temperature. In such cases, pathogenic organisms that may be in the foam will not be killed. Experience indicates that some foam is present at some time in all vats, particularly at certain seasons.

Furthermore, in filling vats, milk or milk product frequently are splashed on the surfaces and fixtures above the milk or milk product level, as well as on the underside of the vat cover.

Droplets of this splash may drop back into the body of the milk or milk product, and since they may not have been at pasteurization temperature for the required time, they may contain pathogenic organisms. Heating the air above the milk or milk product, above pasteurization temperature, remedies these conditions. When air heating is not provided, its need may frequently be demonstrated by swabbing milk or milk product from the upper vat walls and from the underside of the cover, at the end of the holding period, and running phosphatase tests on the swab samples.

Many milk plant operators have reported that the use of airspace heaters, especially with partly filled vats with un-insulated lids, makes it easier to maintain the milk or milk product at a uniform and sufficiently high temperature. It also helps to prevent the growth of thermophilic organisms and promotes easier cleaning.

Obviously, if the design and construction of pasteurization vats and pocket covers do not prevent leakage, condensation and the entrance of water and dust, the milk or milk product may become contaminated with material containing disease bacteria. Keeping the covers closed during operation will decrease the chance of contaminants such as dust, insects, drip and splash from entering the milk or milk product.

Pasteurization: The term "pasteurization", "pasteurized" and similar terms shall mean the process of heating every particle of milk or milk product, in properly designed and operated equipment to (1) of the temperatures give in the following chart and held continuously at or above that temperature for at least the corresponding specified time:

TemperatureTime63°C (145°F*)>30 minutes*If the fat content of the milk product is ten percent (10%) or greater, or a total solids of 18%or greater, or if it contains added sweeteners, the specified temperature shall be increased by3°C (5°F)

Egg Nog

Temperature	Time
69°C (155°F)	>30 minutes

Airspace Temperature must be $\geq 5^{\circ}F$ above the minimum pasteurization temperature

ITEM 16p. BATCH PASTEURIZATION

TIME AND TEMPERATURE CONTROLS

- *Temperature Difference*: The pasteurizer shall be so designed that the simultaneous temperature difference between the milk or milk product, at the center of the coldest milk or milk product in the vat, will not exceed 0.5°C (1°F) at any time during the holding period. The vat shall be provided with adequate agitation, operating throughout the holding period. No batch of milk or milk product shall be pasteurized unless it covers a sufficient area of the agitator to insure adequate agitation.
- 2) Location and Required Readings of Indicating and Recording Thermometers: Each batch pasteurizer shall be equipped with both an indicating and a recording thermometer. The thermometers shall not read less than the required pasteurization temperature throughout the required holding period. The milk plant operator shall check the temperature shown by the recording thermometer against the temperature shown by the indicating thermometer at the start of the holding period. This comparison shall be noted on the recording thermometer chart. The recording thermometer shall not read higher than the indicating thermometer. No batch of milk or milk product shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometer.
- 3) Assurance of Minimum Holding Periods: Batch pasteurizers shall be so operated that every particle of milk or milk product will be held at not less than the minimum pasteurization temperature continuously for at least thirty (30) minutes. When milk or milk products are raised to pasteurization temperature in the vat, and cooling is begun in the vat simultaneously with or before the opening of the outlet valve, the recording chart shall show at least thirty (30) minutes, at not less than minimum pasteurization temperature. When milk or milk products are preheated to pasteurization temperature before entering the vat, the recording chart shall show a holding period of at least thirty (30) minutes, at not less than the minimum pasteurization temperature plus the time of filling from the level of the recording thermometer bulb. When cooling is begun in the batch pasteurizer, after opening the outlet valve, or is done entirely outside the batch pasteurizer, the recording chart shall show at least thirty (30) minutes at not less than the minimum pasteurizer plus the time of emptying to the level of the recording thermometer bulb.

When the recording time interval on the recording chart at the pasteurization temperature includes filling and/or emptying time, such intervals shall be indicated on the recording chart, by the operator, by removing the recording thermometer bulb from the milk or milk product for a sufficient time to depress the pen; or by turning cold water into the vat jacket at the end of the holding period; or by inscribing the holding time on the recording chart. The filling time and the emptying time for each batch pasteurizer, so operated, shall be determined by the Regulatory Agency, initially and after any change, which may affect these

times. No milk or milk product shall be added to the batch pasteurizer after the start of the holding period.

AIRSPACE HEATING

- 1) Means shall be provided and used in batch pasteurizers to keep the atmosphere above the milk or milk product at a temperature not less than 3°C (5°F) higher than the minimum required temperature of pasteurization, during the holding period. (Refer to Appendix H.)
- 2) Each batch pasteurizer shall be equipped with an airspace thermometer. The surface of the milk or milk product shall be at least 25 millimeters (1 inch) below the bottom of the thermometer bulb when the vat is in operation.
- 3) The temperature shown by the airspace thermometer shall be recorded on the recording thermometer chart at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the recording chart.

NOTE: Small volume batch pasteurizers may not require an airspace heater to maintain proper airspace temperature. Larger vessels used for pasteurization usually require airspace heaters to quickly heat the air and to maintain an appropriate pasteurization temperature of the head space.

INLET AND OUTLET VALVES AND CONNECTIONS

The following definitions shall apply to inlet and outlet valves and connections:

- 1) "**Valve Stop**" shall mean a guide which permits turning the valve plug to, but not beyond, the fully closed position.
- 2) "**The Fully Open Position**" shall mean that position of the valve seat that permits the maximum flow into or out of the pasteurizer.
- 3) "**The Closed Position**" shall mean any position of the valve seat that stops the flow of milk into or out of the pasteurizer.
- 4) "**The Fully Closed Position**" shall mean that closed position of the valve seat which requires the maximum movement of the valve to reach the fully open position.
- 5) "**The Just-Closed Position**" shall mean that closed position of a plug-type valve in which the flow into or out of the holder is barely stopped, or any position within 2 millimeters (0.078 inches) thereof as measured along the maximum circumference of the valve seat.
- 6) "Leakage" shall mean the entrance of unpasteurized milk or milk product into a batch pasteurizer during the holding or emptying period, or the entrance of unpasteurized milk or milk product into any pasteurized milk or milk product line at any time.
- 7) "Leak-Protector Valve" shall mean a valve provided with a leak-diverting device, which when the valve is in any closed position, will prevent leakage of milk or milk product past the valve.
- 8) "Close-Coupled Valve" shall mean a valve, the seat of which is either flush with the inner wall of the pasteurizer or so closely coupled that no milk or milk product in the valve is more than 0.5°C (1°F) colder than the milk or milk product at the center of the pasteurizer at any time during the holding period.

A close-coupled valve, which is not truly flush, shall be considered as satisfying this requirement when:

- a) The vat outlet is so flared that the smallest diameter of the large end of the flare is not less than the diameter of the outlet line, plus the depth of the flare; and
- b) The greatest distance from the valve seat to the small end of the flare is not greater than the diameter of the outlet line; and
- c) In the case of batch pasteurizers, the outlet and the agitator are so placed as to insure that milk or milk product currents will be swept into the outlet.

DESIGN AND INSTALLATION OF VALVES AND CONNECTIONS

All valves and connections shall comply with the following requirements:

- 1) Valves and pipeline connections shall meet the requirements of Item 10p.
- 2) All pipelines and fittings shall be so constructed and so located that leakage will not occur.
- 3) To prevent clogging, and to promote drainage, all leak-protection grooves in plug-type outlet valves shall be at least 5 millimeters (0.187 inches wide) and at least 2.3 millimeters (0.094 inches) deep at the center. Mating grooves shall provide these dimensions throughout their combined length, whenever the valve is in, or approximately in, the fully closed position. All single leak grooves, and all mating leak grooves when mated, shall extend throughout the entire depth of the seat, so as to divert leakage occurring at all points throughout the depth of the seat and so as to prevent air binding. Washers or other parts shall not obstruct leakprotector grooves.
- 4) A stop shall be provided on all plug-type outlet valves in order to guide the operator in closing the valve so that unpasteurized milk or milk product may not inadvertently be permitted to enter the outlet line. The stop shall be so designed that the plug will be irreversible when the plug is provided with any grooves or their equivalent, unless duplicate, diametrically opposite grooves are also provided. Stops shall be so designed that the operator cannot turn the valve beyond the stop position, either by raising the plug or by any other means.
- 5) Outlet valves, in addition to the requirements listed above, shall be so designed as to prevent the accumulation of unpasteurized milk or milk product in the milk or milk product passages of the valve when the valve is in any closed position.
- 6) All outlets from vat pasteurizers shall be equipped with close-coupled leak-protector valves or be otherwise similarly protected during filling, holding and emptying periods.
- 7) All leak-protector grooved outlet valves shall be installed in the proper position to insure the function of the leak-protector groves and the drainage of the leak-detector valve.
- 8) All outlet valves shall be kept fully closed during filling, heating, and holding periods.
- 9) Close-coupled vat pasteurizer outlet valve bodies and plugs shall be made of stainless steel or of other materials that have heat transfer properties at least equal to stainless steel.
- 10) All inlet pipelines are disconnected during the holding and emptying periods.

PASTEURIZATION PROCESSING RECORDS

All temperature recording charts shall be preserved for a period of three (3) months. The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this Item. The following information shall be entered on the charts:

1) Batch Pasteurizers:

- a. Date;
- b. Number or location of recording thermometer when more than one is used;
- c. A continuous record of the product temperature;
- d. Extent of holding period, including filling and emptying times when required;
- e. Reading of airspace thermometer, at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart;
- f. Reading of indicating thermometer, at the start of the holding period, at a given time or reference point as indicated on the chart;
- g. Quarterly, the initials of the Regulatory Agency, or in the case of milk plants regulated under the NCIMS HACCP Program, a qualified industry person acceptable to the Regulatory Agency, opposite the required readings of the indicating thermometer and airspace thermometer;
- h. Quarterly, the time accuracy of the recording thermometer, as determined by the Regulatory Agency, or in the case of milk plants regulated under the NCIMS HACCP Program, a qualified industry person acceptable to the Regulatory Agency;
- i. Amount and name of the pasteurized milk or milk product, represented by each batch or run on the chart;
- j. Record of unusual occurrences;
- k. Signature or initials of the operator; and
- 1. Name of the milk plant.

INDICATING THERMOMETER SPECIFICATIONS

Type:

1) Mercury-Actuated; Direct-Reading:

- a. Contained in a corrosion-resistant case, which protects against breakage and permits easy observation of the column and scale.
- b. Filling above mercury nitrogen or other suitable gas.
- c. The mercury column shall be magnified to an apparent width of not less than 1.6 millimeters (0.0625 of an inch).

2) *Digital*:

- a. No more than 0.2°C (0.5°F) drift over three (3) months use on a batch pasteurizer compared to a certified temperature source.
- b. Self-diagnostic circuitry, which provides constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry should be capable of detecting "open" circuits, "short" circuits, poor connections and faulty components. Upon detection of failure of any component, the device shall blank or become unreadable.
- c. The electromagnetic compatibility of this device for this use shall be documented and available to the Regulatory Agency. The device must be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device must comply with the requirements for performance level characteristics of industrial devices. Vendors shall develop protocols for these tests with FDA concurrence.
- d. The effect of exposure to specific environmental conditions shall be documented. The device must be tested to determine the effects of low and high temperatures, thermal

shock, humidity, physical shock and salt fog. Vendors shall develop protocols for these tests with FDA concurrence.

- e. Both the probe and the display case shall be constructed so that they may be sealed by the Regulatory Agency.
- f. Calibration of the device shall be protected against unauthorized changes.
- g. The device shall be protected against unauthorized component or sensing element replacement. Replacement of any component or sensing element shall be regarded as a replacement of the indicating thermometer and subject to Regulatory Agency inspection and all application tests under Appendix I. of this *Ordinance*.
- h. The sensing element shall be encased in appropriate material constructed in such a way that the final assembly meets the conditions of Item 11p of this *Ordinance*.
- i. The device must be tested from the sensing probe through the final output.

Scale: Shall have a span of not less than fourteen (14) Celsius degrees (twenty-five (25) Fahrenheit degrees), including the pasteurization temperature, $\pm 2.5^{\circ}$ C ($\pm 5^{\circ}$ F); graduated in 0.5°C (1°F) divisions, with not more than nine (9) Celsius degrees (sixteen (16) Fahrenheit degrees) per 2.54 centimeters (1 inch) of span; and protected against damage at 105°C (220°F). Provided, that on batch pasteurizers used solely for thirty (30) minute pasteurization of milk and milk products at temperatures above 71°C (160°F), indicating thermometers with 1°C (2°F) scale graduations, with not more than six (6) Celsius degrees (twenty-eight (28) Fahrenheit degrees) per 2.54 centimeters (1 inch) of scale, may be used.

Accuracy: Within $\pm 0.2^{\circ}$ C ($\pm 0.5^{\circ}$ F), through the specified scale span. Provided, that on batch pasteurizers used solely for thirty (30) minute pasteurization of milk and milk products at temperatures above 71°C (160°F), indicating thermometers shall be accurate to within $\pm .5^{\circ}$ C ($\pm 1^{\circ}$ F). (Refer to Appendix I., Test 1)

Submerged Stem Fitting: A pressure-tight seat against the inside wall of the holder; no threads exposed to milk or milk products; and the location of this seat to conform to the 3-A Sanitary Standard for a wall-type fitting or other equivalent sanitary fitting. *Bulb*: Corning normal or equally suitable thermometric glass.

AIRSPACE THERMOMETER SPECIFICATIONS

Type:

1) Mercury-Actuated; Direct-Reading:

- a. Contained in a corrosion-resistant case, which protects against breakage and permits easy observation of the column and scale.
- b. The bottom of the bulb chamber shall not be less than 51 millimeters (2 inches) and not more than 89 millimeters (3.5 inches), below the underside of the cover.
- c. Filling above mercury nitrogen or other suitable gas.
- d. The mercury column shall be magnified to an apparent width of not less than 1.6 millimeters (0.0625 of an inch).

2) Digital:

- a. No more than 0.2°C (0.5°F) drift over three (3) months use on a batch pasteurizer compared to a certified temperature source.
- b. Self-diagnostic circuitry, which provides constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry should be capable of detecting "open"

circuits, "short" circuits, poor connections and faulty components. Upon detection of failure of any component, the device shall blank or become unreadable.

- c. The electromagnetic compatibility of this device for this use shall be documented and available to the Regulatory Agency. The device must be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device must comply with the requirements for performance level characteristics of industrial devices. Vendors shall develop protocols for these tests with FDA concurrence.
- d. The effect of exposure to specific environmental conditions shall be documented. The device must be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog. Vendors shall develop protocols for these tests with FDA concurrence.
- e. Both the probe and the display case shall be constructed so that they may be sealed by the Regulatory Agency.
- f. Calibration of the device shall be protected against unauthorized changes.
- g. The device shall be protected against unauthorized component or sensing element replacement. Replacement of any component or sensing element shall be regarded as a replacement of the indicating thermometer and subject to Regulatory Agency inspection and all application tests under Appendix I of this *Ordinance*.
- h. The sensing element shall be encased in appropriate material constructed in such a way that the final assembly meets the conditions of Item 11p of this *Ordinance*.
- i. The device must be tested from the sensing probe through the final output.
- j. The bottom of the bulb chamber is not less than 51 millimeters (2 inches) and not more than 89 millimeters (3.5 inches), below the underside of the cover.

Scale: Shall have a span of not less than fourteen (14) Celsius degrees (twenty-five (25) Fahrenheit degrees), including the pasteurization temperature of 66°C (150°F), ± 2.5 °C (± 5 °F); graduated in not more than 1°C (2°F) divisions, with not more than nine (9) Celsius degrees (sixteen (16) Fahrenheit degrees) per 2.54 centimeters (1inch) of scale; and protected against damage at (105°C) 220°F.

Accuracy: Within \pm 0.5oC (\pm 1oF), throughout the specified scale span. (Refer to Appendix I., Test 1)

Stem Fittings: A pressure-tight seat or other suitable sanitary fitting with no threads exposed.

RECORDING THERMOMETER SPECIFICATIONS

UTILIZING TEMPERATURES LESS THAN 71oC (160oF)

Case: Moisture proof under normal operating conditions in milk plants.

Scale: Shall have a span of not less than eleven (11) Celsius degrees (twenty (20) Fahrenheit degrees), including pasteurization temperature, $\pm 2.5^{\circ}$ C ($\pm 5^{\circ}$ F); and graduated in temperaturescale divisions of 0.5° C (1° F), spaced not less than 1.6 millimeter (0.0625 of an inch) apart between 60° C (140° F) and 69° C (155° F). Provided, that temperature-scale divisions of 0.5° C (1° F), spaced not less than 1millimeter (0.040 inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line; graduated in time-scale divisions of not more than ten (10) minutes; and having a chord of straight-line length of not less than 6.3 millimeters (0.25 inches), between 63° C (145° F) and 66° C (150° F).

Temperature Accuracy: Within $\pm 0.5^{\circ}$ C ($\pm 1^{\circ}$ F), between 60°C (140°F) and 69°C (155°F). (Refer to Appendix I., Test 2)

Time Accuracy: The recorded elapsed time, as indicated by the chart rotation, shall not exceed the true elapsed time, as compared to an accurate watch, over a period of at least thirty (30) minutes at pasteurization temperature. Recorders for batch pasteurizers may be equipped with spring operated or electrically operated clocks. (Refer to Appendix I., Test 3) *Pen-Arm Setting Device*: Easily accessible and simple to adjust.

Temperature Sensing Device: Protected against damage at a temperature of 105°C (220°F). *Submerged Stem Fitting*: A pressure-tight seat against the inside wall of the holder; no threads exposed to milk or milk products; and the distance from the underside of the ferrule to the sensitive portion of the bulb to be not less than 76 millimeters (3 inches).

Chart Speed: A circular chart shall make one (1) revolution in not more than twelve (12) hours. Two (2) charts shall be used if operations extend beyond twelve (12) hours in one day. Circular charts shall be graduated for a maximum record of twelve (12) hours. Strip-charts may show a continuous recording over a twenty-four (24) hour period.

Chart Support Drive: The rotating chart support drive shall be provided with a pin to puncture the chart in a manner to prevent its fraudulent rotation.

UTILIZING TEMPERATURES GREATER THAN 71° (160°F)

Batch pasteurizers used solely for thirty (30) minute pasteurization of milk and milk products at temperature above 71°C (160°F) may use recording thermometers with the following options:

Scale: Graduated in temperature scale divisions of $1^{\circ}C$ ($2^{\circ}F$), spaced not less than 1 millimeter (.040 inch) apart between 65°C (150°F) and 77°C (170°F); graduated in time-scale divisions of not more than fifteen (15) minutes; and having a chord of straight-line length of not less than 6.3 millimeters (0.25 inch) between 71°C (160°F) and 77°C (170°F).

Temperature Accuracy: Within $\pm 1^{\circ}$ C ($\pm 2^{\circ}$ F), between 71°C (160°F) and 77°C (170°F). *Chart Speed*: A circular chart shall make one (1) revolution in not more than twenty-four (24) hours and shall be graduated for a maximum record of twenty-four (24) hours.