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5001 Campus Drive
College Park, MD 20740-3835

M-I-17-8

December 5, 2017

TO: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Teat Preparation Protocol GEA In-Liner Teat Preparation

ITEM 13r. MILKING – FLANKS, UDDERS AND TEATS

The Teat Preparation Protocol for GEA In-Liner Teat Preparation has been submitted and evaluated by CFSAN's Milk and Milk Products Branch/Milk Safety Team and has been determined to be in compliance with Item 13r-Milking-Flanks, Udders and Teats, Section 7-Standards for Grade "A" Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging and Item 13r-Milking-Flanks, Udders and Teats, Appendix Q-Operation of Automatic Milking Installations for the Production of Grade "A" Raw Milk for Pasteurization, Ultra-Pasteurization, Aseptic Processing and Packaging or Retort Processed after Packaging of the PMO. Item 13r within Appendix Q of the PMO states:

"AMI manufacturers shall submit data to FDA to show that the teat prepping system employed in their milking system is equivalent to Item 13r., **ADMINISTRATIVE PROCEDURES** #4 of this *Ordinance*: "Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking." Each AMI installer shall provide the dairy producer and the Regulatory Agency with a copy of this FDA acceptance, including a detailed description of the accepted equivalent procedure. Each dairy producer shall keep a copy of the accepted teat prep protocol along with the appropriate AMI manufacturer's teat prep protocol verification procedures on file at the dairy farm."

Compliance with Item 13r of the PMO was based upon the following guidance, provided by GEA-NA (GEA North America) (October 2, 2017) for the Teat Preparation Protocol.

NOTE: While this protocol is specified for use with the GEA In-Liner Teat Preparation Protocol, its acceptance will remain in effect with future versions (models) of this equipment as long as this accepted Teat Preparation Protocol can

be applied as written. If the protocol has not been changed, the manufacturer shall provide this accepted protocol with future versions (models) of their automated milking installations.

Upon the issuance of this M-I, the previously issued teat preparation protocols for GEA MI*one* (M-I-11-4, issued September 21, 2011) and (M-I-11-4 Supplement 1, issued February 11, 2014) and GEA Stall Unit 7820-3001-000, 7820-3003-000, 7820-3004-000 and 7820-5003-000 (M-I-16-12, issued August 12, 2016) will be replaced with this GEA In-Liner Teat Preparation Protocol and all will be classified as "**INACTIVE**".

GEA In-liner Teat Preparation

10/2/2017

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1) Summary

The teat cleaning process takes place within the milking teat cups. Initially, all fluids are routed to a waste line. All teats are located, by the camera if automatic attachment, or by eye, if manual attachment, and then the cups are attached to the teats. A double block and bleed valve arrangement isolates the milk during the teat preparation process. Teat cleaning and sanitizer solution (hereafter referred to as "teat prep solution") is introduced onto the entire teat surface through a passage within the head of the milking liner. Clean oil-free filtered air is used to disperse teat prep solution over entire teat and purge any excess. The teat prepping supply lines are completely isolated through a double block and bleed arrangement of valves. Vented air continues to be admitted to dry the teat. Initial milk flow is used to rinse teat prep solution and foremilk from the system, then valves isolating the teat cups from the milk system are switched and milk is allowed to flow to the milk line. If a block-bleed-block valve fails at any time, the process is halted and the teat cups are detached. All prepping, drying and switching from prep milk to milk are done on an individual teat basis, and may happen at different times.

2) Teat Preparation Procedure

a) **Switchover to the prep process**.
Valves to and from the teat cup begin in a configuration to divert all flow to a waste line. Once the valves are switched to this position, the teats are located and the cups are attached.

b) **Teat prep solution dispensing**
Teat Prep solution is dispensed to deliver cleansing and sanitizer solution into the delivery hose. Approved teat prep solutions are **Oxycide® 5 AMS** and **Qxycide® AMS.**

c) **Teat cleaning**
Teat cleaning is accomplished by flowing liquids past the teat while pulsation is operating. Air flows to push the teat prep solution to the teat, distribute it onto the teat, aid in the removal of dirt, remove excess teat prep solution, and dry the teat. The liquid solution flows into the head of the liner and is directed all around the teat by geometry inside the liner head. Pulsation continues throughout the entire process to enhance movement of solution onto all teat surfaces, to aid in loosening and removal of dirt from the teat and to strip fore-milk.

d) **Teat sanitation**
Teat sanitization time occurs from the moment prep solution arrives to the teat until valves switch to milking mode.

e) **Teat Drying**
Teat drying is accomplished by using both low pressure air and atmospheric air. Low pressure air is used to remove excess prep solution from teat and continues to blow for a minimum of 8 seconds. Then atmospheric air is drawn in for a minimum of 2

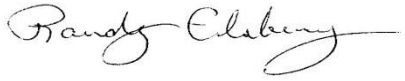
seconds to continue drying teat until switching to milk mode is possible, which is after prep solution purge.

f) **Prep solution purge from milk lines**
To purge the milk hoses of prep solution and foremilk, a small amount of foremilk is used to clean the teat prep solution and solids from the milk line.

g) **Switchover to milking**
Various valve arrangements on a teat-by-teat basis are switched to allow milk to flow to the milk receiver rather than the bad milk receiver. These valve arrangements protect the milk supply.

An electronic version of this memorandum is available for distribution to FDA Milk Specialists, Milk Regulatory/Rating Agencies and Milk Sanitation Rating Officers. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will be available on the FDA Web Site at http://www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.



Randy Elsberry
Senior Milk Sanitation Officer
Milk and Milk Products Branch

Robert Hennes, RS, MPH
CAPT, U.S. Public Health Service
Milk and Milk Products Branch