Wiskerchen Cheese Inc. SOP

Title: Incoming Raw Milk Antibiotic Testing | # 2.036

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Purpose:
To ensure that Wiskerchen Cheese Inc. is manufacturing cheese from milk at or below the US safe/tolerance for beta lactam drugs.

Scope:
Every load of milk shall be tested for the detectable presence of beta lactam drugs prior to unloading, as regulated by the State of Wisconsin and the Federal Food and Drug Administration.

Responsibility:
Milk receiving personnel are responsible for the testing of incoming raw milk. Milk receiving personnel are also responsible for insuring no milk is unloaded until a safe test (NF) has been achieved. Milk receiving personnel are further responsible for the calibration and testing of the Charm Rosa SL beta lactam screening equipment.

Materials:
Milk load schedule
Milk receiving log
Charm Rosa SL beta lactam test strips
Disposable polypipets
5ppb Penicillin G positive tablets
Previously tested negative raw milk
Charm SL beta lactam tester
Charm SL Rosa reader
Incubator heated to 55-57^{o}C

Start-up and Calibration Procedure:
1. Prepare milk calibration samples using previously tested negative, raw milk. The positive is prepared by adding 5 ml milk to one 5ppb Penicillin G positive tablet. Shake vigorously and allow the positive sample to stand for at least 10 minutes. The sample expires after 2 days. The negative sample is a portion of the previously tested negative, raw milk.
2. Label 2 test strips to identify the milk samples; one positive (-) and one NF.
3. Open the incubator lid and place the test strip in with the flat side facing up.
4. While holding the strip flat on the incubator, use the tab to peel back the edge of the white label to expose the sample pad.
5. Shake the milk samples thoroughly and slowly pipette 300 microliter of milk onto either side of the sample well.
6. Reseal the tape over the sample pad compartment.
7. Close the lid of the incubator and latch. The incubator will automatically time out 8 minutes. A solid red light will automatically start when the lid is properly closed.
8. A 2 minute beeper will start after 8 minutes and a flashing yellow light will start. Remove the test before the beeper stops or the test is invalid. The test strip may only incubate for a maximum of 10

minutes. Turn the strip over and visually interpret results using the posted interpretation guide. If the C line is missing, smeared or uneven, or if the milk is obscuring either the C or T lines, the test is invalid. Re-test the sample. Do not put invalid tests into the reader.

9. Press the "esc 5" key, and then the <ENTER> key on the Rosa reader.
10. Locate the reader test strips that are provided with the reader. Be sure the reader ID# on the back of the unit matches the ID# on the test strips.
11. Follow the instructions given by the Rosa Reader to insert either the reader test strips or the milk test strips, and hit enter after each is inserted into the unit. The unit will tell you whether or not the test is valid and it will also be on the print out. If any tests are not valid, the process needs to be repeated until valid tests are obtained. This may include making fresh samples. No milk may be tested until this is completed.
12. Once the unit has been calibrated, truck samples may be tested. Press the <ESC> key to return to the testing menu of the reader. No truck may be unloaded until an "NF" test has been obtained.
13. Truck samples are to be taken from the top of the truck by receiving personnel only. Temperature of the load is to be taken at this time and recorded on the receiving log.
14. Prepare and label a test strip.
15. Shake sample well then follow steps 3-8 above to test load. Once the samples have been incubated, insert them into the reader and press the <ENTER> key. Loads may not be unloaded until an "NF" test has been obtained.
16. Document all results on the milk receiving log. Positive samples are recorded as "POS" and negative samples are recorded as "NF" (none found).
17. Notify the area Department Head or Quality Assurance Manager immediately upon obtaining positive truck load sample.
18. When a POS sample is obtained, the same sample must be tested in duplicate with positive and negative controls.
19. If the controls read properly (positive is positive and negative is negative) and one or both of the milk strips test positive, the load is considered "Presumptive Positive" and may not be unloaded. The original sample, along with a "Positive Load Report" must be sent to a certified lab. A certified technician must confirm the results in a certified lab.

Reporting:

Wiskerchen Cheese Inc. plant management is responsible for reporting the presumptive positive load to the fieldman for the source plant. This should be done before sending the sample to the certified lab, if possible, as the source plant may have a certified lab and may want to do the confirming in-house.

Wiskerchen Cheese Inc. quality assurance is responsible for faxing the "Positive Load Report" to the state, at the fax number listed on the form. This needs to be accomplished within 24 hours.

Approved By: _____ Date: _____