



Bulk Tank Milk Sample Logistics for HPAI H5N1 Testing

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Introduction

This document describes considerations and resources needed to use Grade "A" bulk tank milk (BTM) samples for HPAI H5N1 testing.

Industry, National Animal Health Laboratory Network (NAHLN) labs and State Animal Health Officials (SAHOs) should use this guidance document to describe a process that works for their infrastructure, farm/lab/state resources and regulatory oversight for animal disease control. The information was created by the NMPF Dairy H5N1 Technical Committee and based on lessons learned from other states who have been testing BTM samples for HPAI H5N1. There is no cost to producers to run this test at NAHLN labs. More information about funding is available from USDA for shipping supplies and shipping costs—click learn more below.

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Key Points

10mL of raw milk needs to be submitted for testing to <u>NAHLN labs</u>.

- 2 Samples should be held at or below 40 degrees Fahrenheit but not frozen.
- NAHLN labs should receive a sample that islabeled with a National <u>Premises Identification</u> <u>Number (PIN)</u> in a secured screw top vial (USDA APHIS will provide 10ml vials; contact your NAHLN lab for other options).
- A NAHLN labs should receive a completed submission form that includes (at a minimum) Region/State, PIN, submitter info, sample date and what the samples are (bulk tank, in line sample, hospital pen, etc.), contact info including phone number, email for whomever represents the dairy and wants to get the results.

States using a NAHLN lab not located in their own state need to describe their result reporting process if different than expected.

Lessons Learned from States Who Have Tested Bulk Tank Milk for H5N1

Keep it simple; use existing processes wherever possible.

- Gather input of producers, cooperatives, processors, NAHLN labs, dairy regulatory, and SAHOs to develop plans for sample collection, labeling, transporting, and result reporting.
- Put individual raw milk samples in bags as flip/
 hinged-top vials may open in transit.
- Ensure that correct contact info for whomever wants the results (owner, dairy manager, local veterinarian, dairy system veterinarian, etc.) is included on the sample submission form/ paperwork. Data reconciliation can take hours to days depending on state databases, human resources, and dairy contact information.
- Initial herd surveillance in states where H5N1 is currently circulating on dairies or poultry operations may only need to submit one sample per herd per week rather than each bulk tank based on disease spread.

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BTM Sample Collection Points

Every bulk tank with salable milk from dairy farms in the Grade "A" program is sampled at a maximum every 72 hours under the guidance in the Pasteurized Milk Ordinance (PMO)—see <u>Appendix A</u> for pertinent excerpts. Samples could be collected:

- On the farm
- At the milk plant—tanker from a single source farm
 - Tanker with multiple farms in one load will not provide herd level data
- At receiving or transfer stations if first collection point in a state
 - Some PMO Appendix N samples are collected here

Resources Needed on the Farm, at Milk Plant, Receiving, Transfer Station

Milk Sample Vials

- Screw top vials are preferred over flip/hinged-top tubes as they decrease contamination and speed up the process to get test results out. Hinged tops pose a high risk for leakage in transit, and contamination via aerosolization when opened at the NAHLN testing laboratory. Milk splatter/spills can contaminate the receiving area and cause downtime to de-contaminate (all milk is assumed to have H5 virus in it until tested negative).
- USDA APHIS can provide sample collection vials to the submitter free of charge (dairy farm, milk plant, receiving, transfer station).
 - -10mL screw top vial
 - 50mL vials are being used for the FDA silo sampling survey; they have the same opening width as hinged top for use with dippers or septum samplers on farm. These are not routinely used for on-farm sampling due to storage capacity limitations.
- Contact the NAHLN lab intended for sample testing to ask about preferred sample vials.
 - Not currently standardized; labs can provide resources on where to purchase if not using APHIS vials and some will provide their preferred screw top vial free of charge to the submitter.
- If a milk sample is collected in a flip/hinged-top tube, which is the standard for certified samples and PMO Appendix N samples, consider transferring to a screw-top vial prior to NAHLN lab submission. Personnel transferring milk should be trained to take precautions to protect themselves from splashes in their eyes, mouth, and prevent cross-contamination between samples from different dairy premises. This transfer could occur at the:
 - Dairy farm premises
 - DHIA lab/PMO Section 6 lab
 - Milk plant
 - Receiving or Transfer station (Appendix N sample)
- It is not recommended to use vials with transport media at this stage of surveillance testing.







Top: Screw top vials come in a variety of sizes.

Middle: 10mL screw top vials, foam racks, plastic bag, absorbent material, and an ice pack are all provided by USDA APHIS for shipment in the cooler within the box.

Bottom: Milk in a flip/hinged-top tube which is commonly used for milk quality testing.

Sample Volume and Temperature

- 10mL of raw milk needs to be submitted for testing to NAHLN labs.
 - Need 5mL to send to USDA NVSL for confirmatory test on samples that are not negative (called "non-negative").
- Samples should be held at or below 40 degrees Fahrenheit but not frozen.
 - Frozen samples can affect virus isolation and sequencing done by USDA on positive samples.

Sample Collection Devices

- Samples may come from stationary bulk tanks on farm (collected with a sanitized dipper or from a sampling port), from direct load tankers (collected with in-line or aseptic samplers), or from tankers at the milk plant (collected with a sanitized dipper). See <u>Appendix A</u> for pertinent excerpts from the PMO for dipper sanitizing steps.
- Sanitized dippers are carried on trucks that go farm-to-farm to pick up milk; some dairy farms have their own; used after agitation to scoop a sample out of top of tank.

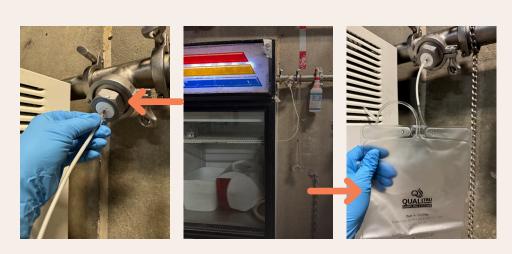
- Pennsylvania recommended a
 50ml conical screw top tube with a string attached and autoclaved (see picture) prior to use to ensure sterility; agitator must be stopped prior to use.
- In-line samples are collected from milk pipelines using certified equipment or direct loads from dairy farms.



- Collects a few drips at a time from the pipeline as cows are milked; samples are collected into a bottle or bag kept in a cooling device and are transferred on farm to a vial by a certified sampler.
- Also referred to as "string samples" indicating a sample of milk is taken from each group or "string" of cows.
- Aseptic samples are collected via a needle inserted into a certified septum device installed in a milk pipeline either into a bag kept in a cooling device or directly into a vial.
 - -Also referred to as "septum samplers."



Licensed weigher-sampler collecting milk from a farm bulk tank using a sanitized dipper into a flip-top tube.



Milk sample being collected using a needle inserted into a septum in the pipeline. The milk travels through tubing that leads to a bag kept in the refrigerator.

Packaging for Transport to Lab

- Minimize contamination on the outside of the vial; wipe it or clean the outside before packaging.
- Communicate with the receiving lab to determine if they prefer sample bagging by single dairy premises/silo or a rack of sample vials bagged.
- Note: Racks will not be returned to the submitter.
- NAHLN labs need to determine what they are capable of unbagging (based on volume of samples to process daily).
 - Large scale sample processing: Recommend bagging each rack that holds 50 samples of 15mL vials
 - Smaller scale sample processing: Each sample could be individually bagged prior to shipment to lab (could slow sample processing at the lab)

Sample Labeling

Bar codes (1D) or QR codes (2D) used for milk quality/component testing provide unique identifiers for whomever provided the labels (milk plant, milk quality lab). They do not include the PIN for the dairy farm.

- Work with the NAHLN lab to ensure label details are provided in a manner they can read.
 - Labs may be able to provide labels that are coded with the dairy farm's PIN which is required for testing and reporting.
 - Bar codes or QR codes are preferred to handwriting.
- Codes may be able to be scanned, and data transferred into a spreadsheet for ease of transfer into the laboratory information management system (LIMS) used by all NAHLN labs.
- USDA NVSL provides bar code stickers for sample vials.
 - For labs that cannot provide labels, request them from NVSL or dairy farms can <u>print their own</u> from National Pork Board.

State Approaches

- Colorado: Wrote name of dairy on sample vial collected by industry and placed in a bag with lab submission sheet (86 dairies).
- Michigan: Lab provides 4 bar code stickers per PIN—one label goes on sample and one on submission form/paperwork.
- New York: Provides tubes but not pre-labeled; that happens at the lab.
- Washington: Bar codes for milk quality testing were not readable by NAHLN lab; Data corrections for farms that had multiple Grade A permits on the same premises/PIN took several hours for 200 dairies.







Top: Sealed plastic bags contain milk vials in a rack for shipping.

Middle: Two flip/hinged-top vials from one farm's bulk tank are bagged prior to transporting in a cooler.

Bottom: Individual milk samples in vials that are bagged with bar code labels and handwritten PINs.

Submission Forms

- Contact the NAHLN lab for their specific submission form and ensure details are provided in a manner they can read if not electronic.
- Paper or electronic forms must accompany the samples.
- Completed submission form should include (at a minimum): Region/State, PIN*, submitter info, sample date and what the samples are (bulk tank, in line sample, hospital pen, etc.), contact info including phone number, email for whomever associated with the dairy wants to get the results (owner, dairy manager, veterinarian of record, dairy system veterinarian, etc.).
 - At a minimum, the address where the cows are physically located must be on the form.
 - Washington: Pre-populated NAHLN form, lab had to match data from cooperative (was time-intensive and only doable because of 200 farms in state).
- Recommend including "blanks" on form to include contact info for the veterinarian of record, dairy system veterinarian, etc. from originating state—this will allow notification of results through various avenues to dairy producers.
- Dairies enrolled in the USDA Herd Status Program are provided guidance for form completion and the veterinarian of record requests the sample testing NAHLN lab.



A *PIN is needed for result reporting; dairy premises that do not know their PIN can contact the office of their State Animal Health Official to request it, free of charge.



NAHLN Laboratories Approved to Conduct Avian Influenza (AI) Testing

Preparing Milk Samples for the Lab

Flip/hinged-tops are pressurized in transit. When opened at the NAHLN lab, they can contaminate the area via aerosolization.

Goal: Somewhere between the dairy farm and the NAHLN lab, transfer milk from a flip/hinged-top vial to a screw top vial.

- California: PMO Appendix N samples from dairies in the Central Valley went to a processor where samples were transferred to a vial then sent to the NAHLN lab (900 dairies in this region; not all under surveillance at the time of this writing).
- Colorado: For cooperative dairies, Colorado Dept of Public Health and Environment sample collector would collect on-farm (76 dairies), bring temperature control samples to satellite office, completed the form, milk remained in hinged-top vial, randomly selected one vial per farm and placed in a sealable bag with lab form, then delivered to NAHLN lab. The NAHLN lab had to open the flip/hinged-tops and that is where issues of contamination via aerosol happened that slowed the process down. Hence why screw tops are being recommended.

• Washington: Haulers collect 3oz milk in 4oz flip-top vial (same process as always).

- Ship samples to PMO Section 6 corporate lab, and lab personnel used a pipette and transferred to screw top conical vials (provided by NAHLN lab in WA) using sterile techniques.
- Initially: Put each vial in a sealable bag and ship to lab; had issues with screw tops not being tightly closed and leaking; no issue in cross-contamination as they were in individual bags.
- Now: They secure the screw top tubes and put them in a rack of 50 and bag the rack for shipping to the lab.

Personnel to Collect BTM Samples

The state dairy regulatory body holds certified sampler info. For H5N1 testing of BTM, there may be other options to collect samples if haulers are not willing/able/allowed.

This varies by state regulatory oversight of salable milk samples and resources available in the state (examples below). Ensuring the sample was collected in a uniform and consistent manner is important to ensure the test results are valid. The list of options for collectors is below, and more than one option may work. Discuss what will work best for the various collection points in your state:

- Certified sampler—various levels—on farm, at plant, at receiving/transfer station
 - Colorado: Some of their farms have certified samplers and collected their own samples using kits provided and mailed into the NAHLN lab
- Licensed milk hauler—from the hauling company or coop/processor or on dairy
 - Used in Colorado, Idaho, Oklahoma, Washington
- State dairy regulatory official (department of public health or agriculture)
 - Used in Colorado (PH), Massachusetts (Ag), Oklahoma (Ag), Utah (Ag)
- Industry Plant Sampler
 - Direct load, single source farms or commingled loads. The latter will need individual farm samples if milk tests positive.
- USDA Category II Accredited Veterinarian
 - Used in Iowa for surveillance testing of dairies around infected poultry premises

- USDA reimburses dairy producers for veterinary costs associated with sample collection. From the date of the <u>Federal Order</u>, April 29, 2024, and up to 120 days total, eligible expenses include:
 - Veterinarian's fees (for example, hourly rate or call fee)
 - Supplies for HPAI-related sample collection
- Someone designated by the accredited veterinarian
 - Used in Iowa for surveillance testing of dairies around infected poultry premises
- Dairy producer/Biosecurity Manager/Farm Personnel trained for collection—under direction of a Category II Accredited Veterinarian with a veterinary-clientpatient relationship (VCPR) with herd owner
 - Used in New Hampshire
- State animal health regulatory staff
- Federal animal health regulatory staff



Industry plant sampler collecting a milk sample using a sanitized dipper from the top of the tanker.

Sample Transport and Resources Needed at Lab

Sample handling is critical. Whatever process is used, make sure the samples are kept at or below 40 degrees Fahrenheit but not frozen.

- If shipping from farm to lab, ensure farm knows which lab will be used if in another state.
- Within a state or region, identify collection points (milk plant, receiving/transfer station) for initial receipt of raw milk samples.
 - Ensure adequate storage exists pending how many dairies, number of samples per dairy, and how long before samples are packaged for transport to lab (days, weeks).
 - This may be where samples are transferred from hinged-top tubes to screw top vials.
- Labeled milk samples should be placed in a cooler (bagged and/or racked as described above), cooling packs on top of tubes, fill with packing material so there is no empty space, including above cooling packs, place paperwork on top of packing material (in sealed plastic bags if concerned it will get wet); tape cooler shut, place shipping labels on outside and mail it.
- Coolers may be shipped back to origin unless contamination cannot be mitigated.
- USDA will pay for the cost of shipping samples to laboratories in the <u>National Animal Health</u> <u>Laboratory Network (NAHLN)</u> for HPAI testing.
 - USDA will pay actual shipping costs, not to exceed \$50 per shipment for up to two shipments per month for each affected premises.

Ideally, samples come in batches to move through accessioning (upfront handling, error checking, paperwork alignment with samples, labeling, and other preparation work to get the samples ready for diagnostic testing).

- Recommend completed and correct submission form with PIN.
- Recommend labeled with barcodes/QR codes readable by lab that aligns with PIN for each dairy.
- Recommend contact information for courier/ submitter so lab can communicate if samples arrive too warm.
- Storage space for samples (40 degrees Fahrenheit) will be necessary for any samples that need to be sent to NVSL for confirmation.
 - Lab differences in lab capacity and storage.
- Recommend using the NAHLN network to support rapid turnaround if the lab of choice does not have resource capacity to manage sample processing, testing, resulting.



The labeled milk samples were placed in a rack and then bagged prior to shipping in a cooler with packing material and cooling packs.

Reporting Results

NAHLN labs are required to report any non-negative results to the SAHO and AVIC. In surveillance programs, all results should be reported to the SAHO.

- Any samples with a Ct of 39 or lower are sent to NVSL for confirmation and should be reported to the submitter as non-negative requiring additional testing.
- Results should also be reported as soon as available to the sample submitters (owner, dairy manager, veterinarian of record, dairy system veterinarian, etc.). Delays could impact disease spread from infected, undetected herds.
- Results should reflect the sample type submitted (bulk tank, individual, sick cow, etc.).
- Recommend this statement on the results from the lab: "Contact your State Animal Health Official and your Herd Veterinarian for Test Result Interpretation and Next Steps" since results may be confusing to producers (the numbers may not have meaning).
 - The veterinarian, if listed on the submission form, can provide a critical communication link for dairy owners, managers, and their employees.
 - In the event the dairy owner or manager is not available, the veterinarian may be able to provide important guidance to the dairy should the SAHO implement movement restrictions or quarantine.



Contact your State Animal Health Official and your Herd Veterinarian for Test Result Interpretation and Next Steps.

- Describe reporting of results from NAHLN lab to SAHO, AVIC, submitters/responsible parties for the dairy (owner, manager, veterinarian of record, dairy system veterinarian) and any differences if:
 - Negative vs. non-negative,
 - Testing samples from suspect dairies (changes in production parameters and/or clinical cows),
 - Testing samples for surveillance (no evidence of disease), and
 - Testing samples from a different state than where NAHLN lab is located.
- Recommend States planning for surveillance testing discuss the role for the NAHLN lab to contact (call, email) the submitters (owner, manager, veterinarian) about non-negative results at the same time they notify the SAHO and submit the sample to NVSL.
 - Note: The regulatory authority for quarantine or movement restrictions resides with the SAHO for non-negative results.
- Recommend states provide NAHLN labs with a single email to send results to; that state can then send out results to whoever needs it (submitter, dairy producer, herd veterinarian, etc.).

Acknowledgements

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Acronyms and Definitions

AVIC: USDA APHIS Area Veterinarian-in-Charge

BTM: Bulk tank milk; this term is used to represent an aggregate sample of raw milk from Grade "A" dairies.

Ct: Cycle threshold; the unit used to report results from polymerase chain reaction (PCR) testing. In the case of bulk tank milk testing via PCR, the lower the Ct number, the more viral particles in the milk.

DHIA: Dairy Herd Improvement Association works with a third-party service to proficiency test, audit and certify laboratories to test raw milk samples for components (fat, protein, solids, etc.) and quality (somatic cell count) which are used for payment. For a complete list, visit: <u>www.quality-certification.com/</u> <u>certifiedlab.asp.</u>

HPAI: Highly pathogenic avian influenza

LIMS: Laboratory Information Management System is used for result tracking and reporting at NAHLN labs

NAHLN: National Animal Health Laboratory Network are laboratories approved by USDA to conduct Influenza A virus testing. For a complete list, visit: www.aphis.usda.gov/labs/nahln/approved-labs/iav-a.

NVSL: National Veterinary Services Laboratories; one located in Ames, Iowa performs the confirmatory testing for HPAI virus to determine if the sample tested at the NAHLN lab is a true positive; they can also do whole genome sequencing to determine the exact strain of virus.

PIN: National Premises Identification Number is a unique alphanumeric national code that is assigned by USDA to a single physical location. The PIN is permanently connected to either a 911 address or latitude and longitude coordinates (geospatial location). USDA, States, and Territories can use a PIN for tracing in the event of an animal health or food safety emergency.

PMO: Pasteurized Milk Ordinance

PMO Appendix N sample: This is the raw milk sample that is taken from each bulk milk tank/direct load tanker destined for Grade "A" processing. This sample is collected by certified samplers and is tested for antibiotic residues under PMO Appendix N: Drug Residue Testing and Farm Surveillance. It can come from a farm bulk milk tank, direct load tanker, milk silo on a dairy premises, or tankers at a transfer or receiving station if single source. The samples are tested by DHIA laboratories for antibiotic residues, quality and milk components.

SAHO: State Animal Health Officials

Excerpts from 2023 Pasteurized Milk Ordinance (PMO)

This language from the <u>PMO 2023</u> describes some of the terms and people involved in collecting milk samples for FOOD SAFETY under the authority of the FDA through responsible regulatory agencies at the state level. Sample collection for HPAI testing of milk is not a food safety test; it is using milk to detect the presence of virus in dairy cattle.

Section 1. Definitions

F. Bulk Milk Hauler/Sampler

A person responsible for the collection of official "Universal" samples for regulatory purposes as outlined in Section 6.; and/or Appendix N. of this Ordinance, including those that are related to reinstatement/clearing samples at dairy farms, if acceptable to the Regulatory Agency, and may transport raw milk from a dairy farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any Regulatory Agency to sample such raw milk and/or raw milk products. This person is evaluated at least once every twenty-four (24)month period, which includes the remaining days of the month in which the evaluation is due, by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

Y. Industry Plant Sampler

A person responsible for the collection of official "Universal" samples that are related to samples collected from direct loaded milk tank trucks, if acceptable to the Regulatory Agency; and/or the collection of Appendix N. samples for regulatory purposes at a milk plant, receiving station or transfer station as outlined in Section 6. and/or Appendix N. of this Ordinance. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every twenty-four (24) month period, which includes the remaining days of the month in which the evaluation is due, by a Sampling Surveillance Officer (SSO) or a properly delegated Sampling Surveillance Regulatory Agency Official (dSSO).

WW. Receiving Station

A Grade "A" receiving station is any place, premises, or establishment where Grade "A" raw milk is received, collected, handled, stored, or cooled and prepared for further transporting.

GGG. Transfer Station

A transfer station is any place, premises, or establishment where milk or milk products are transferred directly from one (1) milk tank truck to another.

Section 6. The Examination of Milk and/ or Milk Products

It shall be the responsibility of the bulk milk hauler/ sampler to collect a representative official "Universal" sample of milk from each farm bulk milk tank and/or silo or from a properly installed and operated in-linesampler or aseptic sampler, that is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring or as transferring milk utilizing an aseptic sampler from a farm bulk milk tank and/or silo, truck or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Regulatory Agency. The industry plant sampler or bulk milk hauler/sampler is a person responsible for the collection of a representative official "Universal" sample related to samples collected from direct loaded milk tank trucks either at the dairy farm or receiving milk plant, receiving station or transfer station, if acceptable to the Regulatory Agency. It shall be the responsibility of the industry plant sampler to collect a representative sample of milk for Appendix N. testing from the following:

- 1. Each milk tank truck or from a properly installed and operated aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring milk from a milk tank truck; and/or
- 2. Each raw milk supply that has not been transported in bulk milk pickup tankers or from a properly installed and operated in-line sampler or aseptic sampler, which is approved for use by the Regulatory Agency and FDA to collect representative samples, prior to transferring the milk from a farm bulk milk tank(s)/silo(s), milk plant raw milk tank(s) and/or silo(s), other raw milk storage container(s), etc. for processing at that location.

Appendix B: Milk Sampling, Hauling and Transportation

I. Milk Sampling and Hauling Procedures

The bulk milk hauler/sampler is a person responsible for the collection of official "Universal" samples for regulatory purposes as outlined in Section 6.; and/ or Appendix N. of this Ordinance, including those that are related to reinstatement/clearing samples at dairy farms, if acceptable to the Regulatory Agency, and may transport raw milk from a dairy farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any Regulatory Agency to sample such raw milk and/or milk products. The bulk milk hauler/ sampler occupies a unique position making this individual a critical factor in the current structure of milk marketing. As a weigher and sampler, they stand as the official, and frequently the only judge of milk volumes bought and sold. As a milk receiver, the operating habits directly affect the quality and safety of milk committed to their care. When the obligations include the collection and delivery of samples for laboratory analysis, the bulk milk hauler/sampler becomes a vital part of the quality control and regulatory programs affecting producer dairies. Section 3. of this Ordinance requires that Regulatory Agencies establish criteria for issuing permits to bulk milk hauler/samplers. These individuals are evaluated at least once every twentyfour (24) month period by a SSO or dSSO using FORM FDA 2399a-BULK MILK HAULER/SAMPLER REPORT. (Refer to Appendix M. of this Ordinance.)

The milk tank truck driver is any person who transports raw or pasteurized milk or milk products to or from a milk plant, receiving station or transfer station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples. If samples are shipped by common carrier, a tamperproof shipping case shall be used, and the top of the case is labeled "this side up".

Evaluation of Bulk Milk Hauler/Sampler Procedures

Universal Sampling System: When bulk milk hauler/ samplers collect raw milk samples, the "universal sampling system" shall be employed, whereby samples are collected every time milk is picked up at the dairy farm. This "universal sampling system" shall also be employed whenever industry plant samplers are authorized by the Regulatory Agency to collect samples from direct loaded milk tank trucks at a milk plant, receiving station or transfer station. This system permits the Regulatory Agency, at its discretion, at any given time and without notification to the industry, to analyze samples collected by the bulk milk hauler/ sampler and/or industry plant sampler, respectively. The use of the "universal sample" puts more validity and faith in samples collected by industry personnel. The following are sampling procedures:

- a. Pick-up and handling practices are conducted to prevent contamination of milk contact surfaces.
- b. The milk shall be agitated a sufficient time to obtain a homogeneous blend. Follow the Regulatory Agency's and/or manufacturer's guidelines or when using an approved aseptic sampling device, follow the specified protocol and Standard Operating Procedure (SOP) (For informational purposes only; refer to the FDA issued M-I) for that device.
- c. While the farm bulk milk tank and/or silo is being agitated, bring the sample container, dipper, dipper container and sanitizing agent for the outlet valve, or single-service sampling tubes into the milkhouse aseptically. Remove the cap from the farm bulk milk tank and/or silo outlet valve and examine the valve outlet for milk deposits or foreign matter. If milk deposits or foreign matter are present, or the bulk tank cap is not present then rinse and sanitize. Protect the hose cap from contamination when removing it from the transfer hose and during storage.
- d. The sample may only be collected after the milk has been properly agitated or when using an approved aseptic sampling device, follow the approved specified protocol and SOP for that device. Remove the dipper or sampling device from the sanitizing solution or sterile container and rinse at least twice in the milk.

Evaluation of Bulk Milk Hauler/ Sampler Procedures Continued

- e. After washing hands with soap and drying, collect a representative sample or samples from the farm bulk milk tank and/or silo by using a sample dipper or other approved aseptic sampling device. (For informational purposes only: Refer to the M-I that is appropriate for the aseptic or inline sampler being used.) When transferring milk from the sampling equipment, caution should be used to assure that milk is not spilled back into the farm bulk milk tank and/or silo. Do not fill the sampling container more than three-quarters (³/₄) full. Close the cover on the sample container.
- f. The sample dipper shall be rinsed free of milk and placed in its carrying container, if provided.
- g. Close the cover or lid of the farm bulk milk tank.
- h. The producer sample shall be identified with the producer's identification, temperature, date and time at the point of collection.
- i. A temperature control sample (TC) shall be taken at the first stop of each load. This sample shall be labeled with collection time (optionally, in military time (24-hour clock)), date, temperature and producer and bulk milk hauler/sampler identification.

Appendix N: Drug Residue Testing and Farm Surveillance

I. Industry Responsibilities

Monitoring and Surveillance: Industry shall screen All Grade "A" Raw Milk Supplies (AGARMS) transported in bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers, regardless of final use, for beta-lactam drug residues, using NCIMS Accepted Drug Residue Test Methods (refer to Section V. of [the PMO] Appendix).

Bulk milk pickup tankers shall be sampled after the last producer has been picked up and before any additional commingling. These bulk milk pickup tanker samples may be collected using an approved aseptic sampler. The sample shall be representative. Samples shall be collected by an Industry Plant Sampler, Dairy Plant Sampler, or a Bulk Milk Hauler/ Sampler who has been evaluated according to the requirements specified in Section 6. and at the frequency addressed in Section 5. of this Ordinance.

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Page 5 Bottom: Washington Animal Disease Diagnostic Laboratory

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Page 8: Danelle Bickett-Weddle

Page 9: Iowa State University Veterinary Diagnostic Laboratory



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