

FSIS DIRECTIVE

10,100.1
Revision 1

10/29/19

FSIS CECAL SAMPLING UNDER THE NATIONAL ANTIMICROBIAL RESISTANCE MONITORING SYSTEM (NARMS) SURVEILLANCE PROGRAM

I. PURPOSE

This directive provides changes and updates to cecal sampling instructions to Public Health Veterinarians (PHVs) at slaughter establishments selected under the FSIS National Antimicrobial Resistance Monitoring System (NARMS) surveillance program. The changes in this revision consist of updating the results reporting vehicle (to implement calendar year 2020) and the replacement of pulsed-field gel electrophoresis (PFGE) characterization with Whole Genome Sequencing (WGS).

II. CANCELLATION

FSIS Directive 10,100.1 *FSIS Sampling for the National Antimicrobial Resistance Monitoring System (NARMS)*, 6/9/14

III. BACKGROUND

A. The NARMS is an interagency, collaborative partnership with state and local public health departments, the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA). This national public health surveillance system was established in 1996 to track antimicrobial susceptibility among foodborne enteric bacteria from humans, retail meats, and food animals. The CDC NARMS program focuses on bacterial isolates from case-patients. FDA's Center for Veterinary Medicine (CVM) NARMS program focuses on retail meats, and the USDA FSIS NARMS program focuses on food animals at slaughter and processing through two sampling points—the non-regulatory samples that are collected from intestinal (cecal) content and selected regulatory programs to include carcass and food commodity samples. The FSIS and CVM NARMS programs include isolations of *Salmonella*, *Escherichia coli* (*E. coli*), *Campylobacter*, and *Enterococcus spp.* Additional information and web links are available on the [FSIS NARMS](#) web page.

B. In addition to monitoring antimicrobial susceptibility, the NARMS partners collaborate on epidemiologic and microbiologic studies and conduct research to better understand the emergence, persistence, and spread of antimicrobial resistance among foodborne bacteria. Additional information on the FDA NARMS program is available at [The National Antimicrobial Resistance Monitoring System](#). Information on the CDC NARMS program is available at [National Antimicrobial Resistance Monitoring System for Enteric Bacteria \(NARMS\)](#).

C. The FSIS NARMS sampling program provides data on the presence and antimicrobial resistance profile of selected enteric microorganisms in food animal slaughter classes. As part of this sampling program, FSIS's Office of Public Health Science (OPHS) laboratory in Athens, Georgia processes samples of cecal contents collected by PHVs and tests for the presence of *Salmonella*, *E. coli*, *Campylobacter*, and *Enterococcus spp.* This FSIS laboratory performs the primary isolation and identification of these microorganisms and completes further characterization of the isolates to include

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serotyping, antimicrobial susceptibility testing and Whole Genome Sequencing (WGS). The resulting NARMS data is used to monitor trends in antimicrobial resistance and susceptibility among enteric bacteria in food animals and in FDA's CVM animal antimicrobial drug approval and evaluation processes.

NOTE: The routine PFGE approach for cecal and regulatory isolates was discontinued in March 2019.

D. PHVs will collect samples of cecal contents from the large intestines of swine (Market Swine and Sow), cattle (Dairy Cow, Beef Cow, Steers, and Heifers), Young Chickens, and Young Turkeys in FSIS-regulated livestock and poultry slaughter establishments. Additional slaughter classes may be included as determined through collaboration with FSIS's NARMS public health partners. Samples are to be shipped to the FSIS Eastern Laboratory for testing, as described in Section XI of this directive.

IV. ESTABLISHMENT ELIGIBILITY FOR THE FSIS NARMS SAMPLING PROGRAM

A. Livestock and poultry slaughter establishments are eligible for the NARMS sampling program based on data in the FSIS Public Health Information System (PHIS): by establishment size; the animal classes slaughtered; and annual slaughter volumes. Sampling tasks for the NARMS sampling program will be assigned at the following frequencies, using the previous 12 months of slaughter data:

Slaughter Volume	Maximum Number of Sampling Tasks per Month per Sampling Project
Top 25% of Slaughter Establishments	4
Second 25% of Slaughter Establishments	2
Lowest 50% of Slaughter Establishments	1

B. PHVs will receive sampling tasks through PHIS and are to order supplies for each sampling event from the Eastern Laboratory (see Section VI). PHVs are to respond to each sampling task using the instructions provided in this directive.

V. REFERENCES AND REVIEW OF TRAINING MATERIALS

PHVs assigned to establishments eligible for the FSIS NARMS sampling program are to be familiar with the following FSIS issuances and the information provided in this directive:

1. [FSIS Directive 13,000.2](#), *Performing Sampling Tasks in Official Establishments Using the Public Health Information System*
2. [FSIS Directive 7355.1](#), *Use of Sample Seals for Laboratory Samples and Other Applications*; and
3. [NARMS Training video](#) (level 2 e-Authorization is needed to access this site).

VI. SAMPLING TASK ASSIGNMENT

A. PHVs will receive a PHIS alert when the NARMS sampling task(s) has been distributed. The sampling tasks are directed tasks on the establishment task list with one or more of the following sampling project codes:

Project Code	Slaughter Class To Sample
NARMS_YC	Young Chicken
NARMS_YT	Young Turkey
NARMS_DC	Dairy Cow
NARMS_BC	Beef Cow
NARMS_ST	Steer
NARMS_HF	Heifer
NARMS_MS	Market Swine
NARMS_SW	Sow

B. The sampling task can be located on the task list in PHIS by using the “sampling” filter. PHVs are to refer to [FSIS Directive 13,000.2](#) for instructions on how to add the task to the task calendar, enter the sample information, submit the sample information to the lab, and print a finalized sample collection form in PHIS.

C. The sample collection window for each NARMS sampling project is 37 days. PHVs are to schedule sample collection as soon as possible to reserve laboratory capacity. Samples cannot be scheduled once the laboratory has met its daily testing capacity. For extenuating scheduling circumstances (e.g. intermittent producers in which there is short notice for a sampling opportunity), the PHV may contact the Eastern Laboratory in order to obtain a solution. PHVs may use the laboratory inquiry mailing list to reach the NARMS point of contact: [FSIS – Laboratory Inquiry – Eastern Lab](#).

VII. ORDERING SAMPLING SUPPLIES

A. The Eastern Laboratory will not automatically send sampling supplies. The PHV is to request NARMS sampling supplies necessary for the slaughter class scheduled for sampling at least 72 hours before the scheduled sample collection date. The PHV is to use only the sampling supplies provided by the Eastern Laboratory that are specific to the slaughter class scheduled for sample collection.

B. The PHV is to refer to the Sampling Supply List in the [Appendix](#) for a list of sampling supplies provided by the Eastern Laboratory. These supplies do not include isopropyl alcohol, isopropyl alcohol wipes or pads, or a caddy, which must be procured locally. The PHV is to contact the Frontline Supervisor (FLS) for guidance on obtaining these supplies.

C. The PHV is to order sampling supplies through the PHIS task calendar. To order sample supplies, PHVs are to right-click on the scheduled NARMS sampling task and select **Order Supplies** from the drop-down menu. A pop-up window will appear that displays the project code

and the name of the FSIS Laboratory that will fill the sampling supply request. When necessary, PHVs are to enter requests for specific supplies (e.g., extra gloves) in the **Comments** field and click **Submit Request**. A confirmation message will appear.

D. As an alternative in situations where the PHV is unable to order supplies through the task calendar (e.g., because of PHIS connectivity issues), the PHV may send a request for sampling supplies using Outlook to the [FSIS - Sampling Supplies - Eastern Lab](#) mailbox.

E. The PHV is to use the Subject heading “NARMS Sampling Supplies” in the email and include the establishment name and number; the project code; the PHV’s contact name and telephone number; and a list of the supplies needed.

VIII. SAMPLE SELECTION

A. The PHV is to refer to the NARMS sampling task for information on the slaughter class to be sampled.

B. The PHV is to randomly select from the lots of animals presented for slaughter on the scheduled sampling day that have passed ante-mortem inspection. The PHV is to select a carcass post mortem for each scheduled sampling event. The PHV is to note the lot information and animal identification information for the animals selected and record this information in the appropriate data fields in the Sample Collection screen in PHIS for the sampling task.

C. The PHV is to work with establishment management to identify:

1. The point in the slaughter process where the viscera/large intestines will be retrieved for sampling;
2. The location in the establishment where the sample selection will be performed;
3. The establishment employee designated to retrieve the selected viscera and transport it to the pre-determined sample collection location in the livestock slaughter establishment; and
4. A cleanable work surface (i.e., table) in the sample collection location for staging the sampling supplies and sample collection.

D. The number of cecal samples to collect per sampling task is as follows:

Project Code	Slaughter Class	Number of Cecal Samples
NARMS_YC	Young Chicken	5 (composited)
NARMS_YT	Young Turkey	5 (composited)
NARMS_DC	Dairy Cow	1
NARMS_BC	Beef Cow	1
NARMS_ST	Steer	1
NARMS_HF	Heifer	1
NARMS_MS	Market Swine	1

NARMS_SW	Sow	1
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E. The PHV is to perform sample collection in a location and in a manner that ensures their personal safety, maintains sanitary conditions, prevents the contamination of edible product, and does not interfere with inspection activities. Examples of sampling locations may include, but are not limited to, the veterinary disposition area on the kill floor or the intestine harvesting area (in an establishment that harvests intestines for edible purposes).

IX. SAMPLE COLLECTION PREPARATION (ALL SLAUGHTER CLASSES)

- A. PHVs are responsible for collecting the NARMS cecal samples.
- B. PHVs are not to delegate this task to a Consumer Safety Inspector (CSI) or any establishment employee.
- C. In preparation for cecal sampling, the PHVs are to review the [NARMS Training video](#) to understand how to use the sampling supplies to retrieve and ship cecal samples to FSIS's Eastern Laboratory.
- D. Cecal sampling instructions are available via IPP Helpdesk and in the [Appendix](#).

X. COMPLETING THE SAMPLING TASK IN PHIS

- A. The PHV is to follow the instructions provided in [FSIS Directive 13,000.2](#) and in the [PHIS User Guide](#) for accepting, scheduling, and completing the sampling task using PHIS. To assist in the sampling task, the PHV may choose to print a copy of the sample form from PHIS for use during sample collection and to document lot information to enter into PHIS.
- B. The PHV is to enter lot information, the owner/producer name and address, and animal identification information into the appropriate Sample Collection data fields in PHIS for each sample collected. The PHV is to ensure that all requested information is entered into PHIS. When sample collection data entry is completed, the PHV is to click the **Submit to Lab** button, print a finalized form, and sign and date the form. PHIS will display a message stating that the sample collection information has been successfully submitted. The PHV is to place the signed sample form in the sample box with the corresponding sample.

XI. SHIPPING THE SAMPLE

- A. The PHV is to use only the shipping materials provided by the FSIS laboratory specific to the NARMS sampling program and refer to [FSIS Directive 7335.1](#), for complete instructions on the proper use of sample seals.
- B. For samples collected from Monday to Wednesday morning, the PHV is to ship the sample no later than Wednesday afternoon to ensure its arrival at the FSIS Eastern Laboratory before Friday. For samples collected between Wednesday afternoon and Friday afternoon, or collected on Saturday or Sunday, IPP are to store and maintain the sample under refrigeration and under FSIS control and ship on Monday morning. Do not freeze the samples.

C. Upon completion of the sample collection, the PHV is to perform the steps below.

1. Apply one small barcode label from FSIS Form 7355-2A/2B, Laboratory Sample Container Seal Set, to the sample collection container;
2. Place the sample collection container in a quart-size zipper lock bag. Expel excess air from the bag and close the bag using the zipper lock closure. Place the bagged specimen into the gallon-size zipper lock bag, expel the excess air from the bag, and close the bag using the zipper lock closure;
3. Apply the medium sized bar-coded FSIS Laboratory Sample Identification Label (FSIS Form 7355-2B) to the gallon-size zipper lock bag;
4. Affix one small bar-coded sample label from FSIS Form 7355-2A/2B sample seal set to the completed and signed printed sample form;
5. Affix the bar-coded label in the space provided at the top center of the sampling form;
6. Place the completed sample form in the plastic sleeve provided;
7. Retrieve the frozen gel coolant packs from the freezer and retrieve the pre-chilled shipping container;
8. Place the cardboard separator and absorbent pad on the bottom of the shipping container;
9. Place the frozen gel coolant pack on top of the absorbent pad and then place the corrugated cardboard pad on top of the frozen gel coolant pack. Place the bagged sample on top of the corrugated cardboard pad;

NOTE: When needed, place a second frozen gel coolant pack in the shipping container to ensure that the sample arrives at the laboratory at an acceptable temperature.

10. Review the information on the pre-printed carrier shipping airbill (e.g., FedEx airbill) provided with the sampling supplies, **and ensure that the sample is addressed to the FSIS Eastern Laboratory.** Enter the return address information on the airbill;
11. Place the completed sample form and any unused sample seals in the container;
12. Insert the foam plug and press down to minimize the space between the sample and foam plug. If the shipping container does not have a foam plug, place the insulated lid on the container. Do not overfill the shipping container;

NOTE: Do not tape or wrap the samples or use any newspaper or similar material as packing material. Use of such materials may result in the sample being discarded by the laboratory.

13. Complete the information on the large bar-coded seal from the same FSIS Form 7355-2A/2B sample seal set, sign the seal, and affix the signed, large bar code seal across the seam of the closed sample box flap;

- a. For shipping containers with self-sticking closures, apply the seal across the closed inner flap of the box parallel to the edge of the closed flap. Then close the outer flap over the seal.
- b. For shipping containers without self-sticking closures, apply the seal across the closed outer flaps. Fasten the outer flaps with clear packaging tape.

14. Affix the carrier shipping airbill on the shipping container and remove any old stamp receipts and carrier shipping bar codes from the container; and

15. Ensure that the sample remains under FSIS control until pickup by the carrier (e.g., FedEx).

D. The PHV is to ensure that the sample container lid is securely closed prior to shipping. If the sample container is leaking upon arrival, the laboratory may discard the sample. The PHV is to avoid storing shipping containers near heaters or in areas exposed to excessive heat.

E. Regarding the return of unused sample supplies:

1. The PHV is to hold any unused sample supplies for future NARMS sampling tasks unless otherwise advised that no additional NARMS sampling tasks will be assigned to the establishment.
2. If at any time there is a need to return unused sampling supplies, the PHV is to send a request for a Ground shipping label by email through the [FSIS - Sampling Supplies - Eastern Lab](#) mailbox in Outlook.
3. The PHV is to include the establishment name, establishment number, mailing address, and project code in the email request. The PHV is to return any unused sampling supplies for the FSIS NARMS sampling program via ground shipping to the address below.

USDA/FSIS/Eastern Laboratory
Attn: NARMS-Microbiology Russell Research Center
950 College Station Rd.
Athens, GA 30605-2720

XII. SAMPLE RESULTS

Results of individual samples collected will be posted in the Laboratory Information Management System (LIMS)-Direct and PHIS for individual establishment access. Sample results from the FSIS NARMS sampling program are non-regulatory; therefore, establishments do not need to hold products pending the receipt of results.

XIII. QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 10,100.1**.
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Sampling** as the main category then select **General** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.

Assistant Administrator
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