UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

31-23 | 6/29/23

UPDATED-CELL-CULTURED MEAT AND POULTRY FOOD PRODUCTS SAMPLING PROGRAM

I. PURPOSE

A. This notice cancels FSIS Notice 27-23, *Cell-Cultured Meat and Poultry Food Products Sampling Program*, dated 6/23/23. The notice has been updated to reflect sampling of ready-to-eat (RTE) products. No other changes have been made to the instructions.

B. This notice provides instructions to inspection program personnel (IPP) on how to collect cell-cultured meat and poultry food products and send samples to the FSIS Eastern Laboratory (EL) for microbiological, chemical residue, speciation testing, and pathology.

C. This notice provides instructions to Enforcement, Investigations and Analysis Officers (EIAOs) on how to collect food contact surface (FCS) and environmental swab samples at cell-cultured meat and poultry food product establishments and submit the samples to the FSIS Western Laboratory (WL) for testing.

II. BACKGROUND

A. The Food and Drug Administration (FDA) and FSIS jointly oversee the production of cell-cultured meat and poultry. FSIS has jurisdiction during harvest and post-harvest production of cell-cultured meat and poultry products. FSIS Directive 7800.1, *FSIS Responsibilities in Establishments Producing Cell-Cultured Meat and Poultry Products*, provides instruction to FSIS IPP about their roles and responsibilities for inspection and verification activities in cell-cultured meat and poultry establishments.

B. FSIS will conduct sampling of cell-cultured meat and poultry food products, FCS swabs, and environmental swabs to verify establishment food safety programs and assess process control.

1. Raw product samples will be tested for Aerobic Count (AC), *Salmonella*, chemical residues, speciation, and pathology (microscopic anatomy and histologic examination).

2. Environmental and FCS swab samples at establishments producing raw products will be tested for AC and *Salmonella*.

3. RTE product samples will be tested for Aerobic Count (AC), *Listeria monocytogenes* (*Lm*), chemical residues, speciation, and pathology (microscopic anatomy and histologic examination).

4. Environmental and FCS swab samples at establishments producing RTE products will be tested for AC and *Lm*.

C. IPP will collect product samples and EIAOs will collect FCS and environmental swab samples.

D. FSIS will collect final product samples for testing with a volume of at least 60 grams (g) to 454g (1 pound). Initially, FSIS will collect a minimum of 60g per sampling event.

E. FSIS intends to collect samples from every other batch until at least 10 samples are collected. FSIS will evaluate the results and determine the future rate of sampling based on the results of those tests.

F. All microbiological analyses and speciation will be carried out using FSIS Microbiology Laboratory Guidebook methods. Chemical residue analyses will be carried out using FSIS Chemistry Laboratory Guidebook methods.

III. AWARENESS MEETING WITH ESTABLISHMENT MANAGEMENT

A. Prior to sampling at the establishment, the inspector-in-charge (IIC) is to schedule an awareness meeting with establishment management (or at the next weekly meeting prior to sampling) to inform them that the establishment will be part of the sampling program.

B. The IIC is to make establishment management aware of this notice (by providing a web link or printed copy) and review the notice during the awareness meeting.

C. FSIS requires establishments to hold or maintain control of raw and RTE products that FSIS has tested for residues and RTE products that FSIS has tested for *Lm*. The IIC is to inform the establishment management that the establishment must hold and control product pending residue and, for RTE products, pending *Lm* test results.

D. The IIC is to inform the establishment management that establishments are not required to hold product when only AC, *Salmonella,* speciation, and pathology results are pending.

E. If an establishment does not hold or maintain control of product tested by FSIS for residue testing or *Lm* testing, IPP are to document a noncompliance record (NR) because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as required in 9 CFR 417.5(c). In this situation, IPP are to immediately contact the district office (DO).

F. If a product speciation sample collected by IPP is determined not to be the species claimed on the label, then IPP are to consider the product misbranded and are to issue an NR under 9 CFR 381.1 or 301.2. If the product is no longer within the establishment's control, IPP are to notify the DO through supervisory channels.

G. IPP are to document the awareness meeting in a memorandum of interview (MOI) as described in FSIS Directive 5,010.1, *Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management*, Section IV.

IV. IPP RESPONSIBILITIES FOR SAMPLE COLLECTION

A. IPP are to ship all cell-cultured food product samples to the EL in Athens, Georgia. Raw samples will be tested for AC and *Salmonella*, chemical residues, speciation, and pathology (microscopic anatomy and histologic examination). RTE samples will be tested for AC and *Lm*, chemical residues, speciation, and pathology (microscopic anatomy and histologic examination).

B. For this sampling program, IPP are to collect product samples in the final package, where possible, or as close to final packaging as possible, using sampling tasks assigned through the Public Health Information System (PHIS).

C. IPP are not to collect product samples from those products labeled "For Further Processing" when all the product goes to another establishment to be further processed or cooked and does not enter commerce until after further processing and cooking.

D. The sampling supplies provided in the box, include:

1 – Pair of gloves
2 – 24 oz. lined Whirl Pak bags
1 – 2 gallon resealable zip-lock type bag
1 – 6” X 12” plastic sleeve or zip-lock type bag for sample form
1 – FedEx (pre-printed) billable stamp
1 or 2 – Gel coolant packs
1 – Cardboard separator
1 – Absorbent pad
1 – Foam plug

E. For sample handling prior to collection, IPP are to complete the following steps to maintain proper temperature during sample collection and shipment:

1. Place gel coolant packs into the freezer for at least 24 hours before sample collection; and

2. On the day of sample collection, pre-chill shipping containers by placing two pre-frozen gel packs on top of the absorbent pads. The absorbent pads are used to line the bottom of the shipping containers.

NOTE: During the summer months from April through October, FSIS laboratories will include additional gel packs in the sampling supplies to assist in maintaining proper sample temperature. This effort is to reduce the number of samples that the laboratories receive above the acceptable temperature 15°C (59°F) during the warmer months. IPP are to use all the gel packs provided in the supply kit to pack samples for shipment. IPP do not need to contact the laboratories for extra gel packs if they only receive two gel packs. For more information, IPP Help Sample Handling and Packaging is available on IPP Help.

F. IPP are to coordinate sample collection using the task calendar. IPP will receive sampling assignments for the sampling project for cell-cultured meat and poultry products projects through PHIS.

1. At a minimum, IPP are to collect and ship one 60g sample to the EL where laboratory personnel will divide the sample to conduct microbiological, chemical, and pathological tests. IPP are **not** to divide the sample.

2. IPP are to use the following sampling task codes to schedule and collect cell-cultured product samples:

    a. Raw product: CC_PROD_NRTE; and

    b. RTE product: CC_PROD_RTE

G. To request sampling supplies via PHIS, IPP are to right-click a scheduled lab sampling task on the Task Calendar, then select “Order Supplies” from the drop-down menu. If requesting supplies via PHIS is unavailable, IPP may request sampling supplies via Outlook, IPP are to select the following address: SamplingSupplies-EasternLab@usda.gov.

H. IPP are to collect product samples as follows:

1. IPP are to collect from every other batch (i.e., production run); and

2. IPP are to collect the appropriate number of final packages so that the sample contains at least 60g. IPP are to place the product collected in its final packaging in the larger, non-sterile zipper lock bag provided with the sampling supplies.

NOTE: IPP are not to use the roll-top bags when collecting product in its final packaging.

3. For raw finished product not available in final packaging, IPP are to collect the sample aseptically and use the sterile roll-top bags as instructed below. When using roll-top bags, IPP are to:

    a. Randomly select product to sample, if more than one production lot is available;

    b. Collect sufficient product in the provided roll-top bag. The total weight of the sample is to be at least 60 grams;

    c. Ensure the roll-top bag is properly closed. IPP are to carefully squeeze out the air remaining in the bag and tightly fold over the top at least four times as trapped air and loose closures may lead to leakage. To secure the folds in place, fold over the side tabs, but do not tie the ends together; and

    d. IPP are to place the roll-top bag in the zipper-lock bag, expel excess air from the bag, and close the containment bag using the zipper lock closure.

4. For RTE finished product not available in final packaging, IPP are to ask the establishment to slack-fill a product for a 60g sample, at a minimum, and send it in the usual establishment packaging, if the product is too large (greater than 60g). IPP are not to slack-fill the sample and are not to supply the establishment with a laboratory-supplied bag as the primary wrap or container for the sample. The establishment is responsible for slack-filling the product in packaging they supply.

NOTE: IPP are to use only the sampling materials provided by the FSIS laboratory. IPP are not to use supplies from the establishment to collect a sample. Only FSIS-provided sampling supplies should be used.

V. IPP RESPONSIBILITIES FOR SAMPLE HANDLING, PACKAGING, AND SHIPPING

A. IPP are to use only the shipping materials provided by the laboratory and refer to FSIS Directive 7355.1, *Use of Sample Seals for Laboratory Samples*, for instructions on the proper use of sample seals.

B. On the day of sample shipping, IPP are to:

1. Retrieve the pre-chilled shipping container with the frozen gel coolant packs from the freezer;

2. Place the absorbent pad on the bottom of the shipping container and place the frozen gel coolant pack on top of the absorbent pad. Place one of the included cardboard separators on top of the gel pack in the pre-chilled shipping container;

3. Place the bagged and sealed sample in a 13” x 18” zipper-lock bag, expel the excess air from the bag, and close the bag using the zipper lock closure;

4. Apply the medium sized bar-coded FSIS Laboratory Sample Identification Label (FSIS Form 7355-2B) to the zipper lock bag as described in FSIS Directive 7355.1;

5. Place the bagged and sealed sample inside the insulated sample shipping box as soon as possible;

6. Place the completed, signed, and dated sample form in the plastic sleeve provided. Place the completed sample form and any unused sample seals in the shipping container;

7. Place a cardboard separator on top of the sample. When available, place the second frozen gel pack on top of the cardboard, and finally add the foam plug to the box.

NOTE: Sample temperatures must be properly maintained during collection and shipment. IPP are to avoid storing shipping containers near heaters or in areas exposed to excessive heat. Proper use of the packing materials provided for sample collection will help ensure that an appropriate temperature is maintained during shipping.

8. Close the inner flap of the shipping container;

9. Complete the information on the larger bar-coded seal from the same sample seal set (FSIS Form 7355-2A/2B) and sign the seal. Apply the 7355-2A across the closed inner flap of the shipping container as described in FSIS Directive 7355.1. Fasten the outer flap shut using the self-sticking closure. IPP are not to tape the box; and

10. IPP are to ship the sample via overnight FedEx courier the same day the sample is collected, when possible. Samples collected prior to FedEx arrival are to be shipped the same calendar day the samples were collected. IPP are to hold the sample overnight if they collect a sample after FedEx has picked up. For example, samples collected from late production or second shifts are to be held overnight under refrigeration and sent by overnight courier the next calendar day. Samples collected on Friday are to be scheduled, collected, and shipped the same day for arrival at the laboratory on Saturday. IPP are not to ship a sample on Saturday or the day before a Federal holiday.

VI. EIAO ENTRANCE MEETING WITH ESTABLISHMENT MANAGEMENT

A. Prior to sampling at the establishment, the EIAO is to hold an entrance meeting with the establishment. The EIAO is to verbally discuss:

1. The sampling purpose (see Background);

2. Sample collection procedures;

3. That the establishment is not required to hold raw product pending swab test results;

4. That the establishment is required to hold RTE product pending FCS swab test results; and

5. That it is not necessary to rinse the swabbed surfaces after samples are collected.

B. The EIAO is to confirm that the establishment will be producing product on the day sampling is scheduled, and that the establishment is planning to implement its documented routine production, Sanitation Standard Operating Procedures (Sanitation SOP), and food safety practices.

C. The EIAO is to inform the establishment that, if it intends to modify its documented routine production, sanitation, or food safety practices before FSIS sampling, it should inform the EIAO as soon as possible so that the EIAO can determine whether sampling should be rescheduled. The EIAO is also to advise the establishment that if it changes its practices temporarily during sampling without notifying the EIAO in advance, and cannot provide a justifiable reason for having done so, the sampling may be rescheduled and further regulatory actions may be taken.

D. The EIAO is to notify the establishment at least 48 hours before sample collection. The EIAO is to document the notification and outcome of the verbal discussion in an MOI.

VII. DO AND EIAO RESPONSIBILITIES FOR SAMPLE SCHEDULING

A. *DO Responsibilities for Scheduling*

1. After the DO becomes aware that a cell-cultured meat and poultry food product establishment is to begin production, it is to assign a Public Health Risk Evaluation (PHRE) for that establishment following the instructions in FSIS Directive 5100.4, *Public Health Risk Evaluation Methodology*

2. The DO is to select the Food Safety Assessment (FSA) Workflow Category of "Instructed in FSIS Notice or Directive" as shown in Figure 1 below.

3. The DO is not to perform an FSA at this time.

NOTE: The DO is to use the PHRE functionality in PHIS to collect samples during the production of every other batch until at least 10 samples have been collected by assigning additional criteria as described below.

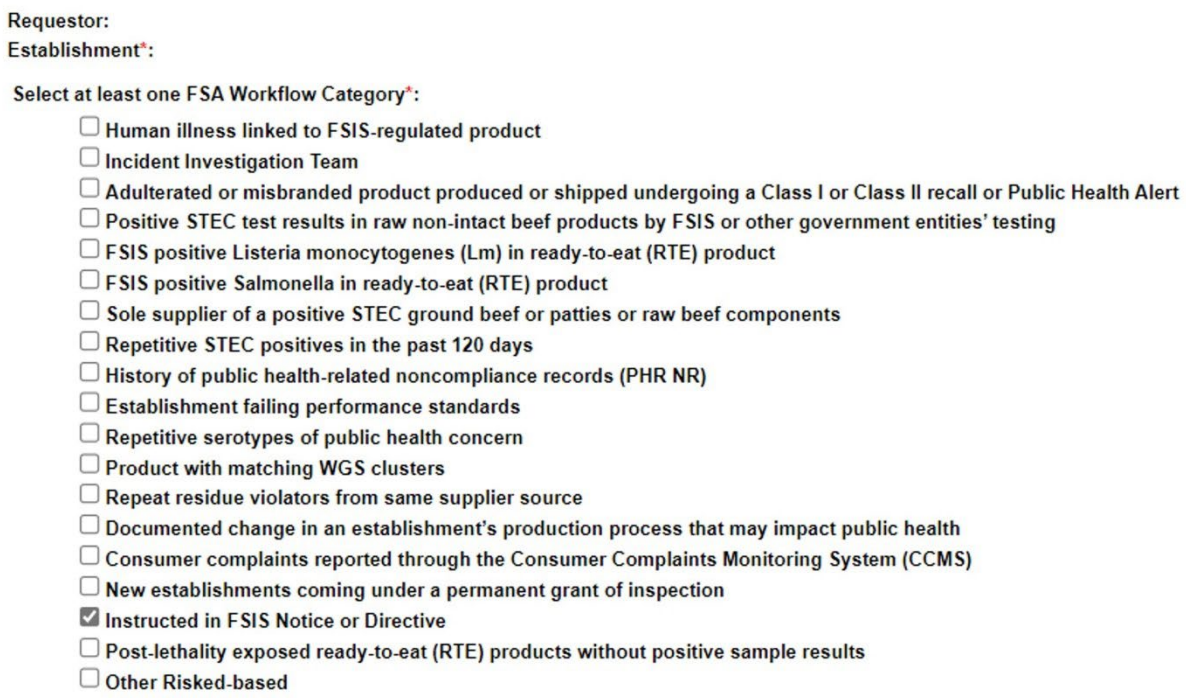
4. The DO is to select "Samples will be collected as part of the FSA" in PHIS. Scheduling of FCS and environmental samples by EIAOs is only possible through the PHIS PHRE FSA module.

5. This PHRE will be used by the EIAO for FCS and environmental sample collection only. An FSA is not to be completed at this time.

6. A separate PHRE is to be assigned by the DO when the establishment appears on the PHRE Scheduling Spreadsheet as a "New establishments coming under a permanent grant of inspection."

7. If during the sample collection the establishment appears on the PHRE scheduling spreadsheet as a new establishment, the DO may assign the additional FSA Workflow Category of "New establishments coming under a permanent grant of inspection." Additional criteria may be added to the PHRE until the DO finalizes the outcome.

Figure 1. FSA Workflow Category



B. *EIAO Responsibilities for Scheduling*

1. The EIAO is to complete up to 10 sampling events under the PHRE (i.e., a separate PHRE is not to be opened for each sampling event). During each sampling event, the EIAO will collect samples under two project codes. The EIAO will add sampling projects to the same PHRE until 10 of each project code have been collected.

2. The EIAO is to add sampling projects to the PHRE by adding Lab Sample Collections under the Sample Collections tab. The EIAO is to select the following projects during each sampling event based on whether the establishment produces raw or RTE products.

    a. For raw products, EIAOs are to select:

        1. **CC_FCS_NRTE** for FCS swab analyses;

        2. **CC_ENV_NRTE** for environmental swab analyses;

    b. For RTE products, EIAOs are to select:

        1. **CC_FCS_RTE** for FCS swab analyses; and

        2. **CC_ENV_RTE** for environmental swab analyses.

3. After 10 sampling events, the EIAO is to complete the PHRE in PHIS. The EIAO is not to complete the PHRE tool unless the DO adds the FSA Workflow Category of "New establishments coming under a permanent grant of inspection" to the PHRE assigned for this sample collection. Otherwise, the PHRE tool will be completed when the PHRE is assigned with the FSA Workflow Category of "New establishments coming under a permanent grant of inspection.

VIII. EIAO SAMPLE COLLECTION RESPONSIBILITIES

A. All FCS and environmental samples collected for this sampling program are to be shipped overnight to the WL in Albany, California.

B. The sampling supplies provided in the box, include:

1 – Hand sanitizer
1 – Marker
20 – 10 mL Dey/Engley (D/E) sponge samplers (SpongeSicle)
5 – 2 gallon zip-lock type bags
20 - 6" X 12" plastic sleeve or zip-lock type bag for sample forms
20 – 1 gallon zip-lock type bag
20 – Pairs of gloves
1 – FedEx (pre-printed) billable stamp
2 – Gel coolant packs
2 – Cardboard separator
2 – Absorbent pad
1 – Foam plug

C. To request sampling supplies via Outlook, EIAOs are to contact SamplingSupplies-WesternLab@usda.gov.

D. EIAOs are to refer to FSIS Directive 10,300.1, *IVT Protocol for Sampling of Product, Food Contact Surfaces, and Environmental Surfaces for Lm or Salmonella,* for background information and relevant information. However, EIAOs are to be aware that product is not to be collected and this collection is not an IVT.

E. EIAOs are only to collect FCS and environmental swab samples. EIAOs are **not** to collect product samples.

F. For this sampling program, during each sampling event, a collection unit consists of:

1. 5 FCS samples; and

2. 8 environmental samples.

G. EIAOs are to collect the swab samples with a D/E SpongeSicle using the procedures described in FSIS Directive 10,300.1, section titled *Sampling Methodology: Food Contact and Environmental Swab Samples.*

H. Samples are to be collected during the production of every other batch during the initial processing after harvest that is representative of the FSIS-regulated process and across the time and space that processing and packaging occurs.

1. For example, if the FSIS-regulated operations occur over 3 days because the establishment's batching process requires 3 days, the EIAO is to collect representative samples over that 3-day timeframe (i.e., rotate sample collection of each unit throughout the day/time, rooms, and equipment).

2. The process may also occur within several rooms over multiple days and the EIAO is to sample different rooms, environments, equipment, and FCS over time to evaluate the process in its entirety. For example, the first sample set may be collected on day 3 of the establishment's process in room 2. The second sample set may be collected on day 2 of the establishment's process in room 1, and so on.

3. Each day of the process and each room of the process should be sampled at least once in a random manner.

NOTE: EIAOs may have to collect FCS and environmental swab samples at multiple establishments if the harvest occurs at one establishment and processing and final packaging occurs at a second establishment.

I. The EIAO is to finalize the actual sites for FCS and environmental sampling once the EIAO is on location and are to use their judgement when selecting sampling sites. Recommended FCS sites include:

1. Vessel used to hold product upon entry into FSIS jurisdiction;

2. Spatula or device to move product;

3. Vessel for rinsing and combining cells;

4. Mesh screen or silicone screen for pressing cells;

5. Tables;

6. Tools;

7. Employee gloves*;

8. Employee protective wear/aprons*;

9. Molds or forms for “drying” process;

10. Forming equipment;

11. Other FCS equipment or tools.

**Could be considered either an FCS or a non-FCS, depending on if the surface comes in direct contact with the product.*

J. EIAOs are to collect most swabs during operations, ideally at the start of routine breaks scheduled by the establishment. EIAOs are to follow “lock-out, tag-out” procedures for equipment. “Lock-out, tag-out” is controlling energy sources while working on or around equipment.

1. EIAOs may collect some swabs at the end of pre-operational sanitation activities and before the start of production. Taking swabs at this time will allow EIAOs to sample areas that are hard to reach or unsafe to sample during operations (e.g., blades);

2. EIAOs are to take post-operational samples as quickly after operations end as practical and before the implementation of establishment sanitation procedures;

K. EIAOs are to complete the sampling task questionnaire within each task.

IX. EIAO SAMPLE HANDLING AND DELIVERY

A. After sampling, EIAOs are to maintain samples in a secure location under refrigeration (at or below 40°F), but not freezing. EIAOs are to use sufficient frozen coolant to keep samples cold during transit.

B. EIAOs are to ship the samples on the day of sample collection using the overnight courier billable stamp included with the sampling supplies. EIAOs are to ship samples Monday through Friday so that they arrive at the laboratory overnight.

NOTE: EIAOs are not to ship samples on Saturdays or on the day before a Federal holiday.

X. RESULTS

A. *Salmonella* (for raw products), *Lm* (for RTE products), chemical residue, speciation, and pathology results will be posted in LIMS-Direct as soon as results are available. Establishments <u>are required to hold</u> the sampled production lot pending the sample results for adulterants in product. FSIS requires establishments to hold or maintain control of products that FSIS has tested for *Lm* (for RTE products) and residues (raw and RTE).

B. After receiving the residue results, IPP are to advise an establishment that is holding product that it does not need to continue to hold that product if it has tested negative for residues and *Lm* (for RTE products). IPP are to be aware that establishments are not required to hold product when only *Salmonella,* speciation, and pathology results are pending. For raw products, if IPP receive *Salmonella*, speciation, and pathology results before the residue results, they are to wait to notify the establishment until after receiving the residue results. For RTE products, if IPP receive speciation and pathology results before the residue and *Lm* results, they are to wait to notify the establishment until after receiving the residue results.

C. Establishments are <u>not</u> required to hold the sampled production lot when EIAOs collect FCS and environmental swabs for AC and *Salmonella*. Establishments **are required to hold** the sampled production lot pending *Lm* results for FCS swabs. IPP and EIAOs are to be aware that repetitive positive sample results over time may indicate a concern with respect to process control and HACCP system support. IPP and EIAOs are to seek guidance from their supervisor for further instruction

regarding these or other concerns.

XI. REPORTING OF RESIDUE AND LISTERIA MONOCYTOGENES TEST RESULTS AND FSIS ACTIONS

A. An establishment that determines in its hazard analysis that chemical residues are a hazard not reasonably likely to occur (NRLTO) reassess its HACCP plan each time a violative chemical residue is found by FSIS. IPP are to verify that an establishment takes corrective actions in response to violative test results that meet all applicable requirements of 9 CFR 417.3(b) for an unforeseen hazard, including performing a reassessment of the hazard analysis and documenting the reassessment.

B. If IPP verify that appropriate corrective actions were followed including adequate measures to prevent recurrence, and the establishment has a history of having an adequate residue control, IPP are NOT to issue an NR.

C. If IPP determine that the establishment has failed to take corrective actions, IPP are to document an NR in PHIS and cite 9 CFR 417.5(a)(1) and 417.3(b).

D. IPP are to verify that the establishment performs the appropriate corrective actions, using a directed HACCP Verification Task.

E. When performing a directed HACCP Verification Task in response to an *Lm* positive result, IPP are to verify that the establishment took the appropriate corrective actions according to 9 CFR 417.3(a) or 417.3(b), or 9 CFR 416.15. FSIS considers RTE products to be adulterated if products or FCS test positive for *Lm*. Therefore, establishments are required to take corrective actions in response to positive results and to reassess their HACCP plan if *Lm* is addressed in the Sanitation SOP or prerequisite program (e.g., *Listeria* control program). If IPP determine that the establishment has failed to take corrective actions, IPP are to document an NR in PHIS and cite 9 CFR 417.3(a), 417.3(b), or 416.15.

XII. DATA ANALYSIS

The FSIS Office of Public Health Science and Office of Planning, Analysis, and Risk Management will analyze the data collected from cell-cultured meat and poultry food products sampling. Results from the sampling may be used to inform future sampling programs and rulemaking.

XII. QUESTIONS

Refer questions regarding this notice to your supervisor or as needed to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select **Sampling** as the Inquiry Type.

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS*, for additional information on submitting questions

Assistant Administrator
Office of Policy and Program Development