

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

FSIS NOTICE

30-17

5/26/17

RAW PORK PRODUCTS SAMPLING PROGRAM PHASE II

I. PURPOSE

A. This notice cancels and reissues the content of FSIS Notice 20-17 to provide clarification (see table below) on modifications to the next phase of the nationwide Raw Pork Products Exploratory Sampling Project (RPESP). The main change is that FSIS will not analyze samples collected from non-slaughter establishments for Shiga-toxin producing *E. coli* (STEC). The only samples FSIS will analyze for STEC will be those collected from slaughter establishments. FSIS will analyze all samples for *Salmonella* and indicator organisms. Also, FSIS has added one question to the sampling questionnaire to identify products produced by the in-house slaughter operation. This notice provides new sampling instructions to inspection program personnel (IPP) at establishments that produce raw pork products. The next phase of exploratory pork sampling will begin on June 1, 2017.

	RPESP Phase I			RPESP Phase II		
Laboratory Analysis	Indicator Organisms	<i>Salmonella</i>	STEC (<i>E. coli</i> O157:H7 and non O157 STECs)	Indicator Organisms	<i>Salmonella</i>	STEC (<i>E. coli</i> O157:H7 and non O157 STECs)
Establishments that Slaughter, including those that Process as well	Yes	Yes	Yes	Yes	Yes	Yes
Establishments that Process Only	Yes	Yes	Yes	Yes	Yes	No

B. The following changes are being implemented for the next phase of pork sampling:

1. All samples collected under the new phase will be analyzed for *Salmonella* and for two indicator organisms: aerobic count (AC) and generic *E.coli*;
2. Samples collected at slaughter establishments that were produced with in-house source materials will also be analyzed for Shiga toxin-producing *E. coli* (STECs), including *E. coli* O157:H7 and six STEC serogroups – O26, O45, O103, O111, O121, and O145;
3. Updated instructions for IPP to review and update the Public Health Information System (PHIS) pork product group entries in the establishment profile, by May 30th so that PHIS can generate new sampling tasks based on the most current product group information;

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4. Changes to products eligible for sampling;
5. Updates to questions in PHIS for IPP to answer for each sample collected; and
6. The updated PHIS questionnaire will contain an essential question designed to determine which analyses are performed on the sample.

C. IPP are to inform establishment management about the changes at the next weekly meeting.

II. BACKGROUND

A. As explained in the January 26, 2015 [Federal Register Notice *Changes to the Salmonella and Campylobacter Verification Testing Program: Proposed Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Related Agency Verification Procedures and Other Changes to Agency Sampling* \(80 FR 3940\)](#), FSIS implemented exploratory sampling of raw pork products to test for pathogens of public health concern, as well as for indicator organisms in May 2015. The Agency analyzed approximately 1,200 samples and evaluated the sampling results. The Agency continued to collect and analyze raw pork products in an interim phase. A summary of the sample results can be viewed at the following link: [FSIS Quarterly Sampling Results](#).

B. Based on the pork sampling data collected, the Agency has decided to begin analyzing pork product samples collected at slaughter establishments for STECs in addition to *Salmonella* and indicator organisms. The sampling data will be used to determine the prevalence of *Salmonella* for potential future policy and help develop a Risk Profile for STECs in pork.

III. SAMPLING PLAN CHANGES

A. FSIS is modifying the sampling plan. During the beginning phase, all pork product samples were analyzed for *Salmonella* and a subset of samples were sampled for STECs, regardless if the establishment was a slaughter facility or only a further processing facility. During the new phase, all samples will be tested for *Salmonella* and indicator bacteria, and a subset of these samples, which are collected at slaughter establishments, will also be analyzed for STECs. Sample results from an individual sampling event will not result in regulatory control actions during the new phase.

B. Changes have been made to the scheduling method to take into account the number of days in a calendar month that the establishment produces eligible product. During the initial exploratory sampling phase, establishments were exempt if the average daily volume range was 1 - 1,000 pounds per day for an eligible product group. During the new phase, pork establishments producing eligible pork products in the average daily volume range of 1 – 100 pounds will not be sampled. Pork establishments producing eligible pork product in the average daily volume of 101 - 1,000 pounds per day are eligible for sampling if the number of days of production is 21 or more days in a calendar month.

C. IPP at selected pork establishments will receive sampling tasks based on the establishment's **average daily volume (pounds per day)** and the **number of days of production** that are entered into the PHIS profile for the eligible product groups listed in Tables 1 and 2 of this notice. Instructions on how to calculate the production volume information are listed in Section VIII. Production Volume Information of [FSIS Directive 5300.1 Rev 1 *Managing the Establishment Profile in the Public Health Information System \(PHIS\)*](#).

D. For all eligible pork product groups, the scheduling method will ensure that no more than 8 samples per month will be scheduled for each establishment. IPP are to be aware that not all establishments producing eligible product will receive new sampling tasks under the new phase of sampling.

IV. UPDATING THE RAW PORK PRODUCT GROUPS IN THE ESTABLISHMENT PROFILE

A. IPP are to review the updated product group definitions listed in Tables 1 and 2 of this notice and update the product groups in PHIS based on the new product group definitions. PHIS product group definitions for pork products were revised based on IPP feedback from the initial exploratory phase. The new product group definitions were clarified to help IPP better determine which products are eligible for sampling under this project. IPP will receive sampling tasks on their PHIS task list based on the product groups listed in the establishment profile.

B. IPP will receive sampling tasks based on the average daily production volume and the number of days produced that they have entered into the PHIS profile for the eligible product groups listed in Tables 1 and 2 of this notice.

C. IPP, who have not already done so, are to update the PHIS pork product groups in the profile based on the revised product definitions by May 30, 2017. The sampling tasks for the new phase of sampling will appear on the establishment task list based on the revised product group information on or about June 1, 2017. IPP are to refer to the PHIS User Guide or the IPP Help Button for instructions on making these changes.

1. IPP are to complete a scheduled "Update Establishment Profile Task" from the PHIS task list to update the PHIS product groups if they must update the PHIS pork product groups.
2. IPP are to create a directed "Update Establishment Profile Task" if they no longer have a scheduled "Update Establishment Profile Task" available because they have completed the routine task prior to the issuance of this notice.

A. IPP are to notify official establishment management before collecting a sample. IPP are to collect samples that represent actual production practices. Establishments are not required to hold the sampled production lot pending the sample results. IPP are to be aware that FSIS does not require establishments to hold or maintain control of raw pork products that FSIS has tested for *Salmonella* or STEC pending sample results. However, if the establishment voluntarily holds product, IPP are to provide advanced notice to hold the sampled lot. The amount of time needed for establishment notification is not to impede FSIS's ability to collect samples that are representative of the establishment's actual production practices.

V. INFORMATION SHARING WITH PLANT MANAGEMENT

At the next routine weekly meeting after 5/31/17, the Inspector-in-Charge (IIC) is to inform establishment management at establishments producing products eligible for the RPPESP about the following:

1. IPP will continue sampling eligible pork products under the RPPESP and;
2. *Salmonella* and STEC samples results will be posted in LIMS – Direct as soon as results are available. STEC results will be reported to LIMS-Direct when all STEC analyses (*E. coli* O157:H7 and non-O157 STEC) for the sample are complete. *Salmonella* results will only be reported to LIMS-Direct when all analyses for the sample are complete. Individual sample results will not result in regulatory control actions. Indicator organisms will not be reported for individual establishments. FSIS plans only to report indicator organisms in aggregate at the end of the study. FSIS will continue to post *Salmonella* results, and begin posting STEC results, for RPPESP samples in aggregate on a quarterly basis in the Quarterly Establishment Information Letters as described in FSIS Notice 97-16 [Quarterly Establishment Information Letters about Sample Results](#).

VI. UPDATED SAMPLING TASK ASSIGNMENTS

A. The IPP Help Button has a new menu item, **Raw Pork Products Sampling Program Guidance**, which contains sample collection instructions and in-depth product descriptions and product examples of the PHIS pork product groups to help IPP update the establishment profile. IPP can access the IPP Help Button by double clicking the **FSIS Applications** icon from the desktop of their government-issued computer.



Table 1. Eligible Raw Intact and Non-Intact Pork Cuts

Sampling Task Name	HACCP Category	Finished Product Category	PHIS Product Group	PHIS Product Group Definitions
(EXP_PK_ICT02) Exploratory Sampling for Pork – Intact Cuts	Raw – Intact	Raw intact pork	Cuts (including bone in and boneless)	An intact cut is a smaller cut derived from primal cuts that are in portions equal to or larger than ¾ inch in size in at least one dimension and has not been subjected to processing that renders the product non-intact (e.g., needle or blade tenderized, injected, pumped or vacuum tumbled). This group includes bone-in and boneless cuts.
(EXP_PK_NCT02) Exploratory Sampling for Pork – Non- Intact Cuts	Raw – Non – Intact	Raw, ground comminuted, otherwise non-intact pork	Cuts (Tenderized, injected pumped or vacuum tumbled – including bone in and boneless)	A non-intact cut is smaller cut derived from primal cuts that are in portions equal to or larger than ¾ of an inch in size in at least one dimension that has been subjected to processing that renders the product non-intact (e.g. mechanically tenderized, injected, pumped or vacuum tumbled). This group also includes bone-in and boneless cuts.

Table 2. Eligible Raw Comminuted Pork Products

Sampling Task Name	HACCP Category	Finished Product Category	PHIS Product Group	Description of PHIS Product Group
(EXP_PK_COM02) - Exploratory Sampling for Pork - Comminuted (Ground, Mechanically Separated, and Other Comminuted)	Raw – Non – Intact	Raw, ground comminuted, otherwise non-intact pork	Ground Product	Pork processed through a grinding system designed to reduce the size of muscle pieces to less than ¾ an inch in all dimensions <u>without the addition of seasonings, flavorings, and/or cures.</u> Ground pork that contains seasonings are to be listed in the “sausage patties or other formed products,”
			Sausage, Patties, or Other Formed Products	Raw pork products, such as sausage or ground pork patties made with comminuted pork, and the predominant species is pork and <u>with</u> added seasonings, flavorings, and/or cures. This group also contains cubed or diced pork <u>with added seasonings</u> that are less than ¾ of an inch in all dimensions.
			Mechanically Separated	Finely textured pork products resulting from mechanical separation and removal of most of the bone from attached skeletal muscle that does not qualify as “pork” per 9 CFR 319.5.
			Advanced Meat Recovery (AMR)	Finely comminuted pork products resulting from mechanical separation and removal of all bone from attached skeletal muscle per 9 CFR 318.24.
			Other Comminuted	Pork products <u>without</u> the addition of seasonings, flavorings, and/or cures with a particle size reduced by a process other than grinding. This includes cubes or diced products that are less than ¾ of an inch in all dimensions.

C. IPP are to refer to [FSIS Directive 13,000.2, Performing Sampling Tasks in Official Establishments Using the Public Health Information System](#), for instructions on how to add the task to the task calendar, enter the sample information, submit the sample information to the laboratory, and print a finalized sample collection form in PHIS.

D. IPP are to complete all requested sample information and complete the sample questionnaire in PHIS. The list of questions for each sampling task is included in the IPP Help Button. IPP are to ensure the following question in the PHIS questionnaire is answered accurately as it will determine which analyses are performed on the sample: Does the sampled lot contain pork from swine slaughtered on-site at this establishment? If the answer is no, the sample will only be analyzed for *Salmonella* and indicator organisms. If the answer is yes, the sample will be analyzed for STEC in addition to *Salmonella* and indicator organisms.

E. IPP are to collect and submit the sample to the FSIS laboratory within the sample collection window

assigned to the sampling task.

VII. SAMPLE SELECTION AND ELIGIBILITY CRITERIA

A. IPP are to refer to the sampling tasks for information on the product sample to collect. IPP may be assigned more than one sampling task with more than one sample project code during the same sampling window in an establishment that produces more than one eligible pork product group.

B. IPP are to use a method for randomly selecting the production lot for sampling. IPP are to randomly select a day, shift, and time within the sampling window shown in PHIS. IPP are to collect samples from all shifts the establishment operates and include Fridays in the random selection.

C. The following practices **do not** exempt the product from routine sampling:

1. Addition of ingredients such as spices, seasonings, rosemary extracts or fruits/vegetables to eligible pork products;
2. Application of an antimicrobial treatment or intervention (other than a treatment that achieves full lethality); and
3. Addition of meat or poultry products from a different species to eligible pork products.

D. The following practices **do** exempt the product from routine sampling:

1. Battered or breaded pork product. For example, dumplings, egg rolls, or pot stickers;
2. Not ready-to-eat (NRTE) products containing pork. For example, products in the HACCP processing category "Heat-treated but not Fully Cooked - Not Shelf Stable" such as partially cooked products or products that contain cooked pork and raw dough such as potpies and;
3. Raw pork products intended for use in ready-to-eat (RTE) products at the establishment or another official federally inspected establishment.

E. FSIS does not sample product that will receive full lethality treatment at a federally inspected establishment, provided that the establishment's hazard analysis and flow chart show that the product is intended for such a use. Examples of full lethality treatments other than cooking can include high pressure processing and irradiation, provided that the establishment has supporting documentation that shows that the treatment achieves a 5-log reduction for *Salmonella*, and that the establishment applies the treatment in a manner that is consistent with its critical operational parameters.

F. If the establishment meets the requirements in D. 3 of this section, IPP are to verify during the performance of the associated HACCP verification task that the intended use of all the product the establishment produces is for processing into RTE product (9 CFR 417.2(a)(2)). IPP are to verify that all product will be processed into RTE product by:

1. Observing that all the product moves to be further processed into RTE product in the establishment; or
2. Reviewing records to ensure that all products are further processed into RTE products in the establishment. Records may include those containing production codes or production lot codes.
3. IPP are to review the establishment's HACCP plan and hazard analysis for the intended use of the products and are to verify that the establishment has procedures incorporated in its food

safety system that effect the movement of all product from that product class to another federally-inspected establishment at which the product is further processed into RTE product.

VIII. RAW INTACT AND NON-INTACT PORK CUTS AS SHOWN IN TABLE 1 SAMPLE COLLECTION

A. IPP are to collect fresh, not frozen, raw pork samples in final packaging, whenever possible and an appropriate number of packages to equal 2 lbs ± 10%. IPP are to place the product collected in its final packaging in the larger, non-sterile bag provided with the sampling supplies.

NOTE: IPP are not to use the Whirl-Pak® bags when collecting products in final packaging.

B. For intact and non-intact pork cuts that are not available in their final packaging, IPP are to use the single larger Whirl-Pak® bag and aseptically collect one or more cuts to fill the Whirl-Pak® bag leaving 2 to 3 inches of space at the top of the bag. IPP are to expel as much air as possible from the bag before closing.

C. For intact and non-intact pork cuts that are processed in a frozen state only (i.e., all product received frozen and processed frozen; product further processed in frozen state only, etc.), IPP are to collect a frozen 2 lbs. sample if the establishment does not produce any other eligible pork product. IPP are to indicate whether the sample is fresh or frozen in the PHIS questionnaire.

D. Individual whole pork cuts (intact or non-intact) larger than 2 lbs. should not be collected by IPP.

E. IPP are to access the PHIS Help Button menu item, **Raw Pork Products Sampling Program Guidance**, for more detailed information for collecting samples of raw pork products sampling.

IX. COMMINUTED PORK PRODUCTS AS SHOWN IN TABLE 2 SAMPLE COLLECTION

A. IPP are to collect fresh, not frozen, comminuted pork product samples in their final packaging, whenever possible, and an appropriate number of packages to equal 2lbs. IPP are to place the product collected in its final packaging in the larger, non-sterile bag provided with the sampling supplies.

NOTE: IPP are not to use the Whirl-Pak® bags when collecting products in final packaging.

B. For all comminuted pork product samples not available in their final packaging, IPP are to use the two Whirl-Pak® bags when collecting aseptic grab samples. The Whirl-Pak® bags have fill lines to help IPP collect the desired sample weight of two pounds. IPP are to collect a sufficient quantity of product to fill each of the two Whirl-Pak® bags to the fill-line.

C. For mechanically separated or AMR (finely textured pork) product samples, IPP are to fill each of the two Whirl-Pak® bags by using the sanitized scoop and spatula contained in the enhanced sampling supplies. When needed, IPP are to request enhanced sampling supplies via Outlook at least 3 business days before the scheduled day of sampling. The enhanced sampling supplies will contain all EXP_PK_COM02 supplies plus: one 4-ounce sterile scoop, one sterile spatula and two towelettes.

D. To request enhanced sampling supplies via Outlook, IPP are to select one of the following addresses:

SamplingSupplies-EasternLab@fsis.usda.gov
SamplingSupplies-MidwesternLab@fsis.usda.gov
SamplingSupplies-WesternLab@fsis.usda.gov

IPP are to use the e-mail subject heading “Enhanced RPESP sampling supplies.” IPP are to request one set of enhanced sampling supplies for each sample collection event. IPP are to include in their request the establishment name and street address (no P.O. Box).

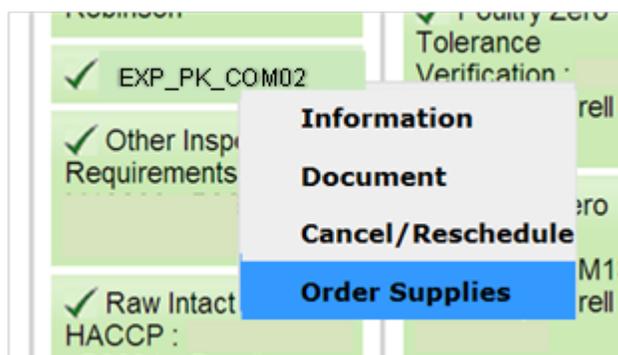
E. IPP are to access the PHIS Help Button menu item, **Raw Pork Products Sampling Program Guidance**, for more detailed information on collecting samples of comminuted pork products and the enhanced sampling supplies.

X. SAMPLING SUPPLIES FOR RPPESP SAMPLING

A. The FSIS laboratories will ship the sampling supplies automatically to the IIC at the establishments selected for sampling. IPP will receive sampling supplies within one week prior to the first day of the collection month. Sampling supplies will arrive in a shipping container labeled with either the EXP_PK_COM02 (comminuted products) or the EXP_PK ICT02/EXP_PK_NCT02 (intact or non-intact cuts) sorting label. IPP are to refer to the IPP Help Button for a list of sampling supplies that they should receive. IPP are to use only the sampling supplies provided by the laboratories that are specific to this sampling project.

B. If IPP do not receive sampling supplies by the first day of the collection month, or to request replacements for damaged or lost supplies, IPP are to request RPPESP sampling supplies. For example, if RPPESP sampling tasks are assigned in PHIS in late May, IPP are to request replacement supplies only if they have not arrived by June 1. IPP requiring sampling supplies are to request them through PHIS or Outlook three business days (not including weekends and holidays) before they intend to collect the sample.

1. To request sampling supplies via PHIS, IPP are to right-click a scheduled lab sampling task (e.g., “EXP_PK_COM02,” “EXP_PK ICT02” or “EXP_PK_NCT02”) on the Task Calendar, then select “Order Supplies” from the drop-down menu.



2. To request sampling supplies via Outlook, IPP are to select one of the following addresses:

SamplingSupplies-EasternLab@fsis.usda.gov

SamplingSupplies-MidwesternLab@fsis.usda.gov

SamplingSupplies-WesternLab@fsis.usda.gov

C. IPP are to use the subject heading “RPPESP Sampling Supplies” in the e-mail and include the establishment name and number, the project code (“EXP_PK_COM02”, “EXP_PK ICT02” or “EXP_PK_NCT02”), the IPP’s contact name, establishment number, telephone number, and a list of the supplies needed.

XI. RESULTS

Salmonella and STEC samples results will be posted in LIMS – Direct as soon as results are available. STEC results will be reported to LIMS-Direct when all STEC analyses (*E. coli* O157:H7 and non-O157 STEC) for the sample are complete. *Salmonella* results will only be reported to LIMS-Direct when all analyses for the sample are complete. Individual sample results will not result in regulatory control actions; therefore, establishments need not hold product. However, repetitive positive sample results

over time may indicate a loss in process control and a HACCP system lacking support. In this case, IPP are to seek guidance from their supervisor for further instruction.

XII. DATA ANALYSIS

The FSIS Office of Public Health Science (OPHS) and the Office of Data Integration and Food Protection (ODIFP) will analyze the data collected in the RPPESP to determine the percent positive for *Salmonella* and to help develop a Risk Profile for STEC in pork. The Agency will use this data to inform food safety policies for pork products.

XIII. QUESTIONS

Refer questions regarding this notice to the Risk, Innovations, and Management Staff (RIMS) 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 **Notice 30-17**
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 - Salmonella** 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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