

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

FSIS NOTICE

65-20

12/8/20

RAW PORK PRODUCTS SAMPLING PROGRAM

I. PURPOSE

This notice is being reissued to inform inspection program personnel (IPP) of the continuance of sampling under the Raw Pork Products Sampling program. All raw pork samples will continue to be analyzed for *Salmonella* and for aerobic counts (AC), which will serve as indicator organisms. The project codes and sampling instructions to IPP at establishments that produce raw pork products remain unchanged.

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.

B. The Agency continued to collect and analyze raw pork products in an interim phase before implementing Phase II of the Raw Pork Product Exploratory Sampling Program. In Phase II, sampling focused on *Salmonella* and indicators in both slaughter and processing establishments and STEC in slaughter establishments only. A summary of the sample results can be viewed online at: [Quarterly Sampling Results for FSIS-Regulated Products](#), and further analysis of the data can be viewed online at: [Nationwide Raw Pork Product Sampling Study](#).

C. The Agency will continue to analyze raw pork product samples for *Salmonella* and indicator organisms only and the sampling data will be used to continue to develop future policies designed to reduce the levels of *Salmonella* in raw pork products.

III. ESTABLISHMENT SAMPLING ELIGIBILITY AND PHIS SAMPLING TASK ASSIGNMENT

A. IPP will continue to see the raw pork PHIS sampling tasks ([Table 1](#)) appear in PHIS for eligible establishments.

DISTRIBUTION: Electronic

NOTICE EXPIRES: 12/1/21

OPI: OPPD

Table 1: Raw Pork Products Sampling Eligibility			
Raw Pork Products	Project Code	Establishment Volume	Task Frequency
Comminuted	HC_PK_COM01	> 6000 lbs./day	5/month
Comminuted	HC_PK_COM01	1001 - 6000 lbs./day	Random
Intact and Non-Intact Cuts	HC_PK_CUT01	> 50,000 lbs./day	5/month
Intact and Non-Intact Cuts	HC_PK_CUT01	1001 - 50,000 lbs./day	Random

B. FSIS will schedule five (5) samples per month for eligible establishments producing greater than 6,000 pounds of comminuted product and five (5) samples per month for those eligible establishments producing greater than 50,000 pounds per day of pork cuts (intact and non-intact). IPP are to be aware that establishments producing 1,001 to 6,000 pounds of comminuted pork products or 1,001 to 50,000 pounds of pork cuts will be randomly selected for sampling tasks.

C. IPP at eligible 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 2 and 3 of this notice. Descriptions and examples of products not eligible for sampling are available in [Table 4](#). Instructions on how to calculate the production volume information are listed in Section VIII, Production Volume Information of [FSIS Directive 5300.1 Managing the Establishment Profile in the Public Health Information System \(PHIS\)](#).

D. IPP are to notify official establishment management before collecting a sample. Establishments are not required to hold the sampled production lot pending the sample results.

Table 2. Eligible Raw Intact and Non-Intact Pork Cuts
Finished Product Category: Raw intact and Raw non-intact pork

Sampling Task Name	HACCP Category	PHIS Product Group & Definitions	Finished Product Examples
(HC_PK_CUT01) Verification Sampling for Pork Cuts (non-intact and intact)	Raw – Intact	<p align="center">Cuts (including bone in and boneless)</p> <p>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.</p>	<p>Examples of Portioned Cuts: Butt, Cap Meat, Chops, Cubes/Cutlets/Slices/Strips, Leg/Hock/Shank (no feet attached), Picnic, Rib (including riblets and rib ends), Roasts, Rump, Sirloin, Steak, Stew Meat, Tenderloin</p>
	Raw – Non – Intact	<p align="center">Cuts (Tenderized, injected pumped or vacuum tumbled – including bone in and boneless)</p> <p>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.</p>	<p>NOTE: NRTE Heat-treated cuts (e.g. bacon) are not considered raw for this program.</p> <p>Examples of Portioned Cuts: Butt, Cap Meat, Chops, Cubes/Cutlets/Slices/Strips, Leg/Hock/Shank (no feet attached), Picnic, Rib (including riblets and rib ends), Roasts, Rump, Salt Pork, Sirloin, Steak, Stew Meat, Tenderloin</p>

Table 3. Eligible Raw Comminuted Products

Finished Product Category: Raw ground, comminuted, or otherwise non-intact pork

Sampling Task Name	HACCP Category	PHIS Product Group & Definitions	Finished Product Examples
<p>(HC_PK_COM01) – Verification Sampling for Pork - Comminuted (Ground, Mechanically Separated, and Other Comminuted)</p>	<p>Raw – Non – Intact</p>	<p align="center">Ground Product</p> <p>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,”</p>	<p>Examples include: Ground Pork, Fresh Ground Pork, Course Ground Pork, 80/20 Ground Pork, Pork Patties (without the addition of spices, cures, or flavorings)</p>
		<p align="center">Sausage, Patties, or Other Formed Products</p> <p>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.</p>	<p>Examples include: Bratwurst, Breakfast, Sausage/Sausage Links, Chorizo, Country Style Sausage, Hot/Spicy Sausage, Italian Sausage, Meat Loaf Mix, Mild Sausage, Pork Patties (with spices, cures, or flavoring added)</p> <p>NOTE: This product group does not include sausages that have had a fully lethality process administered through curing, smoking, or cooking (i.e. Kielbasa, Longaniza, etc.).</p>
		<p align="center">Mechanically Separated</p> <p>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.</p>	<p>Mechanically separated pork is the only acceptable finished product name for MS pork</p>
		<p align="center">Advanced Meat Recovery (AMR)</p> <p>Finely comminuted pork products resulting from mechanical separation and removal of all bone from attached skeletal muscle per 9 CFR 318.24.</p>	<p>Examples for AMR include finished products labelled as: AMR pork lean, Finely ground pork, Lean pork finely, textured, Pork trim finely textured</p>
		<p align="center">Other Comminuted</p> <p>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.</p>	<p>Examples include: Coarse chopped pork, Pork cut or sliced less than ¾ inch in all dimensions, Diced pork less than ¾ inch in all dimensions</p> <p>NOTE: The Other Comminuted product group is different from the Ground product group, in that these products are further processed via chopping or dicing rather than processed through a grinder.</p>

Table 4: INELIGIBLE PRODUCTS– DO NOT SAMPLE:

<p>Carcass (including carcass halves or quarters)</p>	<p>For the purpose of PHIS classification, “carcass” includes a carcass half, a carcass quarter.</p>	<p>Examples: a whole roasting pig, a “packer style” dressed carcass (head and kidneys removed and practically free of internal fat).</p>	<p>Ineligible- do not collect samples</p>
<p>Raw Primals and Subprimals (Intact and Non-Intact)</p>	<p>A “pork primal” is a primary cut derived from the carcass (typically larger than two pounds). They are considered raw intact if they have not been tenderized, injected, pumped, or vacuum tumbled. For pork commodities, once primals are fabricated into smaller, whole muscle portions they should be considered “cuts” and not subprimals.</p> <p>They are considered raw non-intact if they have been tenderized, injected, pumped, or vacuum tumbled.</p>	<p>Examples: the ham, belly, loin, shoulder, and jowl are pork primal parts as defined in 9 CFR 316.9(b).</p> <p>Examples (that have been processed as non- intact):</p> <p>The ham, belly, loin, shoulder, and jowl are pork primal parts as defined in 9 CFR 316.9(b).</p>	
<p>Trimmings from Intact or Non-intact pork</p>	<p>“Trimmings” are prepared from pork product. They exceed ¾” in any dimension and are not typically available for consumer purchase.</p>	<p>Examples: Pork Trimmings</p> <p>Examples (that have been processed as non- intact): Pork Trimmings</p>	
<p>Edible Offal:</p>	<p>“Edible Offal” is a raw variety meat generated primarily from the viscera and head.</p>	<p>Examples: Liver, heart, chitterlings, and brain.</p>	
<p>Head Meat:</p>	<p>“Head meat” is a group of muscle tissue in both the head and the base of the tongue that remains after removal of the cheek muscle. Head meat excludes the muscle tissue in the snout, lips and ears.</p>	<p>Examples: Head Meat</p>	
<p>Cheek Meat:</p>	<p>“Cheek meat” is a group of muscles lying external to the upper and lower jawbones. Cheek meat should be practically free of lip material, lymph nodes, ear canal, and salivary glands.</p>	<p>Examples: Cheek Meat</p>	
<p>Other Intact and Non-Intact</p>	<p>Includes all other whole muscle, fat, feet, or skin pork products not included under the Intact Cuts pork product group. The product is considered raw intact if it has not been tenderized, injected, pumped, or vacuum tumbled.</p> <p>Covers all other whole muscle, fat, feet, or skin pork products not included under the Non-Intact Cuts pork product group. They are considered raw non-intact if they have been tenderized, injected, pumped, or vacuum tumbled.</p>	<p>Examples: Feet, Tails, Skin, Fat</p> <p>Examples include (that have been processed as non- intact): Fat, Feet, Neck bones, Skin, Tail, Tongues</p>	

E. [IPP Help](#) has a menu item, **Sampling**, which houses the **Raw Pork menu**. The **Raw Pork** menu contains sample collection instructions, in-depth product descriptions and product examples of the PHIS pork product groups to help IPP update the establishment profile. IPP can access IPP Help by double-clicking the **FSIS Applications** icon from the desktop of their government-issued computer.

F. 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.

G. IPP are to complete all requested sample information and complete any sample questionnaires in PHIS. The list of questions for each sampling task is included in IPP Help. IPP are to ensure that all questions in the PHIS questionnaire are answered accurately.

H. IPP are to collect and submit the sample to the FSIS laboratory within the sample collection window assigned to the sampling task.

I. If sampling tasks remain in the task list at the end of the sampling window, IPP are to cancel them from the task list and provide the correct reason, as shown in the image below. If none of the listed reasons are appropriate, IPP are to select “Not collected for miscellaneous reasons” and provide additional details in the text box provided. IPP are not to allow sampling tasks to remain at the end of the sampling window.

The image shows a screenshot of a software interface. On the left, there are two labels: "Select Reason:" and "Describe, If Other:". To the right of "Select Reason:" is a dropdown menu. The dropdown menu is open, showing a list of reasons. The first option, "Requested sample unavailable during sampling timeframe", is highlighted in yellow. Below the dropdown menu is a text box for providing additional details.

Select Reason:	Requested sample unavailable during sampling timef
Describe, If Other:	

- Requested sample unavailable during sampling timeframe
- Requested sample/product never slaughtered/produced
- Not collected for miscellaneous reasons
- Plant closed/no kill
- FedEx did not pickup sample
- Inspection withdrawn
- Insufficient time to collect sample
- Inspection suspended officially
- Other

J. If an establishment does not produce eligible product, IPP are to cancel any remaining product verification sampling tasks. IPP are to cancel these tasks from both the “Establishment Task List” (Delete this task from the Task List) and, if scheduled, the “Task Calendar,” using the correct option (i.e., cancel this task and remove it and all other instances of this task from the Task List). In addition, IPP are to provide the reason for canceling the task: “requested sample/product never slaughtered/produced,” as shown in the image below. IPP are also to update the PHIS Establishment Profile accordingly, if the profile does not include accurate or complete information about the products the establishment produces.



IV. INFORMATION SHARING WITH PLANT MANAGEMENT

At the next routine weekly meeting after sampling tasks are assigned, the Inspector-in-Charge (IIC) is to inform establishment management at establishments producing products eligible for the Raw Pork Products Sampling Program about the following:

1. IPP will continue sampling eligible raw pork products under the Raw Pork Products Sampling Program; and
2. *Salmonella* sample results will continue to be posted in LIMS-Direct as soon as results are available. FSIS still plans only to report indicator organism data in aggregate. FSIS will continue to include individual *Salmonella* results for Raw Pork Products Sampling Program samples on a quarterly basis in the Quarterly Establishment Information Letters, and aggregate results will continue to be posted online at: [Quarterly Sampling Results for FSIS-Regulated Products](#).

V. SAMPLE SELECTION AND ELIGIBILITY CRITERIA

A. IPP are to refer to the sampling tasks for information on the product to collect. At establishments producing more than one eligible product group, IPP may be assigned more than one sampling task with more than one sample project code during the same sampling window.

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 that the establishment operates. When possible, IPP are to collect samples under each project code at a frequency of no more than once per week. In the case that there are more samples than weeks in the sampling window, IPP should schedule sample collection evenly throughout the month. If necessary, more than one sample can be taken in a given week.

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 products are **not** to be included in 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.

F. If the establishment meets the requirements in D. 3 and E. 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;
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; or
3. Reviewing the establishment's HACCP plan and hazard analysis for the intended use of the products and verifying that the establishment has procedures incorporated in its food safety system that effect the movement of all product from that product class to another official establishment at which the product is further processed into RTE product.

VI. RAW INTACT AND NON-INTACT PORK CUTS

A. [Table 2](#) identifies which product groups and products are eligible for sample collection under the HC_PK_CUT01 sampling task.

B. 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. \pm 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.

C. 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.

D. For intact and non-intact pork cuts that are processed in a frozen state only (e.g., 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.

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

F. IPP are to access the [IPP Help](#) menu item, **Sampling**, then **Raw Pork Sampling Program**

Guidance, for more detailed information for collecting samples of raw pork products sampling.

VII. COMMINUTED PORK PRODUCTS

A. [Table 3](#) identifies which product groups and products are eligible for sample collection under the HC_PK_COM01 sampling task.

B. 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 2 lbs. 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.

C. 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.

D. For comminuted pork products that are processed in a frozen state only (e.g., 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.

E. 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 HC_PK_COM01 supplies plus: one 4-ounce sterile scoop, one sterile spatula and two towelettes.

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

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

IPP are to use the e-mail subject heading “Enhanced Raw Pork Products Sampling Program 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).

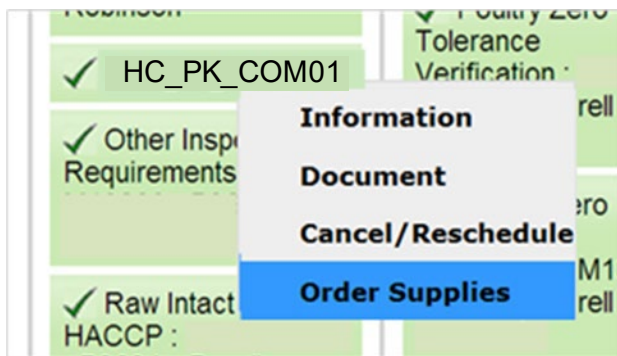
G. IPP are to access the [IPP Help](#) menu item, **Raw Pork Sampling Program Guidance**, for more detailed information on collecting samples of comminuted pork products and the enhanced sampling supplies.

VIII. SAMPLING SUPPLIES FOR RAW PORK PRODUCTS SAMPLING PROGRAM

A. The FSIS laboratories will ship the sampling supplies automatically to the IIC at the establishments selected for sampling. Supplies will arrive in a shipping container labeled with either the HC_PK_COM (comminuted products) or the HC_PK_CUT (cuts) sorting label. IPP are to refer to [IPP Help](#) for a list of sampling supplies that they should receive. IPP are to use only the sampling supplies provided by the laboratories. Sampling boxes and supplies from the exploratory sampling project (EXP_PK_COM02, EXP_PK_ICT02, EXP_PK_NCT02) may be used to collect samples under the verification sampling program (HC_PK_COM01 and HC_PK_CUT01), as the supplies have not changed. Shipping boxes will be relabeled as they are repacked by the receiving laboratories.

B. If IPP do not receive sampling supplies by the first day of the collection month, or need to request replacements for damaged or lost supplies, they are to request Raw Pork Product Sampling Program sampling supplies. For example, if raw pork products sampling tasks are assigned in PHIS in late October, IPP are to request replacement supplies only if they have not arrived by November 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., “HC_PK_COM01,” “HC_PK_CUT01”) on the Task Calendar, then select “Order Supplies” from the drop-down menu.



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

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

C. IPP are to use the subject heading “Raw Pork Product Sampling Program Sampling Supplies” in the e-mail and include the establishment name and number, the project code (“HC_PK_COM01”, “HC_PK_CUT01”) the IPP’s contact name, establishment number, telephone number, and a list of the supplies needed.

D. IPP are to return any unused shipping containers and sampling supplies for these projects to the FSIS Field Service Laboratories. IPP are to send a request for a pre-addressed return FedEx ground shipping label to one of the email addresses listed in Section VII.F. of this notice.

IX. RESULTS

Salmonella results will be posted in LIMS-Direct as soon as results are available. Individual sample results will not result in regulatory control actions. Therefore, establishments are not required to hold the sampled production lot pending the *Salmonella* sample results. However, repetitive positive sample results over time may indicate a concern with respect to process control and HACCP system support. IPP are to seek guidance from their supervisor for further instruction regarding these or other concerns.

X. DATA ANALYSIS

The FSIS Office of Public Health Science (OPHS) and Office of Planning, Analysis, and Risk Management (OPARM) will analyze the data collected in the Raw Pork Product Sampling Program to monitor *Salmonella* in raw products.

XI. QUESTIONS

Refer questions regarding this notice 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 **Notice 65-20**.
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
Office of Policy and Program Development