

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

FSIS NOTICE

26-18

5/7/18

FSIS SAMPLING FOR LABELING CLAIMS VERIFICATION

I. PURPOSE

This notice instructs inspection program personnel (IPP) at establishments that produce products in consumer-ready packaging that bear certain labeling claims or raw ground beef in consumer-ready packaging that bears a nutrition facts panel that have been assigned a directed Label Verification Sample Task in the Public Health Information System (PHIS) to collect product samples for verification testing. This notice updates previous instructions from FSIS Notice 77-16, FSIS Sampling of Raw Ground Beef Products for Nutrient Content, and expands sampling to include verification of certain labeling claims.

II. BACKGROUND

A. On March 1, 2012, the final rule titled "Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products" ([75 F 82148](#)) became effective. This rule amended the Federal meat and poultry products inspection regulations to require nutrition labeling of the major cuts of raw, single-ingredient meat and poultry products on labels or at point-of-purchase, unless an exemption applies. FSIS also amended its regulations to require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies. FSIS verifies whether establishments meet the requirements through the procedures in [FSIS Directive 7130.1](#), *Verifying Nutrition Labeling for the Major Cuts of Single-Ingredient, Raw Meat and Poultry Products and Ground or Chopped Meat and Poultry Products*.

B. Purpose of the sampling: FSIS is conducting this exploratory sampling program in order to verify industry's compliance with the Agency's labeling regulations. Labeling claims described above are required to be truthful and not misleading (9 CFR 317.8(a), 381.129). Labels are also required to display a complete listing of ingredients (9 CFR 317.2(c)(2), 381.118) to protect consumers from misbranded and economically adulterated meat and poultry products.

C. To verify compliance with nutrition labeling requirements, FSIS began sampling raw ground beef products and conducting nutrient analysis on September 29, 2014. FSIS intends to continue the nutrient content sampling program at Federal establishments as a directed sampling task under the EXP_LV_NUTR project code.

III. ELIGIBILITY CRITERIA FOR LABEL VERIFICATION SAMPLING

A. Establishment eligibility for this sampling program is determined based on information collected through multiple data sources. FSIS will continue to evaluate eligibility annually based on information collected through an annual label claims questionnaire.

B. Eligible products are those in consumer-ready packaging with a label bearing a labeling claim. The products eligible for each sample project code are the same as those eligible for the corresponding pathogen sample project code as identified in Table 1, if the product is in consumer-ready packaging with

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a label bearing the corresponding claim:

Table 1 - Label Verification Sample Task and Corresponding Pathogen Sampling Task

Type of Labeling Claim	Sample Project Code	Sample To Collect	Analysis	Corresponding Directed Pathogen Sampling Project Code
Nutrition facts panel	EXP_LV_NUTR	Raw ground beef	Fat and sodium content	MT43
Soy-free	EXP_LV_SOY	Ready-to-eat products	Soy	RTEPROD_RAND
Raised without antibiotics	EXP_LV_ABX	Raw chicken parts	Antibiotic residues	HC_CPT_LBW01 HC_CPT_QH01
Raised without hormones	EXP_LV_HORM	Raw ground beef	Hormone residues	MT43

C. Products eligible for the EXP_LV_NUTR and EXP_LV_HORM sampling projects are raw ground beef products that are eligible for *Escherichia coli* O157:H7 sampling under the MT43 project code and meet the standards of identity [9 CFR 319.15\(a\)](#) (“chopped beef”, “ground beef”) or [319.15\(b\)](#) (“hamburger”).

D. Products eligible for the EXP_LV_ABX sampling project are raw chicken parts that are eligible for sampling under the HC_CPT_LBW01 (raw chicken parts – legs, breasts, wings) and HC_CPT_QH01 (raw chicken parts – quarters, halves) project codes. A description of eligible products for these projects is available in the Raw Poultry Sampling Guidance which can be accessed through the [IPP Help](#) button.

E. Products eligible for the EXP_LV_SOY sampling project are ready-to-eat (RTE) products that are eligible for sampling under the RTEPROD_RAND project code, as described in [FSIS Directive 10,240.4, Verification Activities for the Listeria monocytogenes \(Lm\) Regulation and the Ready-to-Eat \(RTE\) Sampling Program](#).

NOTE: IPP are not to select jerky for sampling under the EXP_LV_SOY sampling project code, due to the financial hardship to the establishment, even if the product is selected for RTEPROD sampling and meets the eligibility criteria described in this notice.

IV. IPP RESPONSIBILITIES

A. IPP are to be familiar with the establishment’s production schedule to determine when it is producing product eligible for this sampling program. IPP are to notify establishment management before collecting the samples. The establishment is not required to hold or control product selected for sampling under this program. However, IPP are to inform establishment management that RTE product with a “soy-free” or similar labeling claim that tests positive for soy under the EXP_LV_SOY project would be deemed adulterated and misbranded and the product lot represented by the sample would be subject to regulatory action. If the adulterated and misbranded product has been shipped into commerce, FSIS will recommend that it be recalled.

B. Samples will be assigned under the project codes listed in Table 1 and will appear as directed tasks on the establishment task list. The samples will be analyzed by the FSIS Eastern Laboratory (EL).

C. In situations where the label verification sampling tasks are assigned during the same collection window as the pathogen sampling projects listed in Table 1, IPP are to schedule and complete both sampling tasks during the same sampling event and for the same production lot. However, IPP are to

package and ship the samples for each project in separate shipping containers using the sampling supplies provided by the EL, even if both samples are assigned to the same EL for analysis.

D. IPP are to request sampling supplies at least 72 hours before the day of scheduled sample collection. IPP are to follow the instructions provided in [FSIS PHIS Directive 13,000.2](#) for ordering sampling supplies through the PHIS. As an alternative, IPP may submit requests for sampling supplies to FSIS EL via Outlook, using the following e-mail address:

SamplingSupplies-EasternLab@fsis.usda.gov

When requesting sampling supplies by email, IPP are to include the sampling project code, establishment number, establishment name, physical address, IPP's name and contact phone number in the e-mail request. Supplies needed for each sampling event include:

- 1 – Shipping Box (M-USDA20) with packing materials
- 1 – Two gallon zipper lock bag, non-sterile
- 1 – 6"x12" Plastic Bags
- 1 – FedEx Billable Stamps
- 1 – FSIS Form 7355-2A/2B

NOTE: The FSIS Laboratory will not automatically send sampling supplies at the time the sample is scheduled.

E. On the scheduled day of sampling, IPP are to determine if the establishment is producing eligible product in consumer-ready packaging that bears the labeling claim that can be sampled. As described in Section III, IPP are to use a method for randomly selecting the production lot for sampling. If the product is available for sampling, IPP are to:

1. Collect a 2 lb. sample of product in consumer-ready packaging with the labeling claim. IPP are to collect as many packages of product as necessary to meet the 2 lb. sample size and are to collect a frozen sample only if a fresh sample is not available. IPP are to place the product collected in its final packaging in the large, non-sterile bag provided with the sampling supplies;

NOTE: In situations where product is packaged in portions larger than 2 lb., IPP can request a slack-filled sample from the establishment, provided the slack-filled sample's packaging includes the labeling claim.

2. Complete the sampling task in PHIS, following the instructions provided in FSIS PHIS Directive 13,000.2. When the sample data entry is completed, click the "Submit to Lab";

NOTE: There is no sampling questionnaire to complete for this sampling project.

3. Print, sign and date the sample form. Place the completed sample form in the plastic sleeve provided; and
4. Pack and ship the sample via overnight shipping to the FSIS EL, using the instructions provided in [FSIS Directive 7355.1](#), *Use of Sample Seals for Program Samples and Other Applications*. IPP are to use only the shipping materials provided by the laboratory.

F. If on the scheduled day of sampling, IPP determine that product eligible for label verification sampling, as described in Section III., is not available for sampling, IPP are to reschedule the sampling task for another day within the sample collection window.

G. IPP are to cancel the sampling task and provide the appropriate justification for canceling if:

1. Eligible product is not being produced during the assigned collection window, or
2. The establishment does not produce product eligible for label verification sampling, as described in Section III.

V. TEST RESULTS AND FURTHER ACTIONS

A. Test results for the EXP_LV_NUTR, EXP_LV_ABX and EXP_LV_HORM sampling projects **will not** be reported in LIMS-Direct or PHIS. These test results will be reported by the EL to the Office of Policy and Program Development's Labeling and Program Delivery Staff (LPDS) and Policy Analysis Staff (PAS). LPDS and PAS will review the results for consistency in meeting labeling requirements. If there is a discrepancy between the test result and the labeling claim, LPDS will issue a letter to the establishment and copy the Inspector-in-Charge (IIC) and the Office of Field Operations District Office (DO) informing them of the results. The establishment will have 30 days to provide a written response to LPDS on actions taken in response to the test result to demonstrate that it is fulfilling the claim stated.

B. Test results for the EXP_LV_SOY sampling project will be reported in PHIS as acceptable or unacceptable. In the event that FSIS testing of RTE product with a "soy-free" labeling claim reports as positive for the presence of soy under the EXP_LV_SOY project, IPP are to document the finding in a noncompliance record (NR) in accordance with [FSIS Directive 5000.1](#) and notify their supervisor of the noncompliance. IPP are to conduct a Big 8 Formulation Verification Task and document the findings in PHIS. IPP are to verify that the establishment has accounted for all product in the affected lot and has taken appropriate corrective actions under [9 CFR 417.3](#).

C. If the establishment fails to take appropriate action or fails to demonstrate that it is fulfilling the claim stated, FSIS may take further action, including but not limited to, scheduling additional label verification sampling tasks, recommending a recall of affected product, rescinding label approval for labels bearing the claim and not approving any labels with similar claims until the establishment can demonstrate its ability to ensure the accuracy of its labels.

D. Data collected for this program will be used to inform future label verification sampling programs.

VI. QUESTIONS

Refer labelling questions to LPDS through [askFSIS](#) or by telephone at 1-800-233-3935 (press 4). When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter Notice 26-18
Question Field	Enter question with as much detail as possible
Product Field	Select Labeling from the drop-down menu
Category Field	Select Nutrient Content and Health Claims
Policy Arena:	Select Domestic (U.S.) only from the drop-down menu

Refer sampling and all other questions to RIMS through [askFSIS](#) or by telephone at 1-800-233-3935 (press 5). When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter Notice 26-18
Question Field	Enter question with as much detail as possible
Product Field	Select Sampling from the drop-down menu
Category Field	Select Sampling - General
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.

A handwritten signature in black ink that reads "Sabrina J. Wagner". The signature is written in a cursive style with a large initial 'S'.

Assistant Administrator
Office of Policy and Program Development