

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

FSIS DIRECTIVE	7000.5	7/24/24
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FSIS SAMPLING FOR LABELING CLAIMS VERIFICATION

I. PURPOSE

This new directive provides instructions to inspection program personnel (IPP) on labeling claims verification sampling at establishments that produce products in consumer-ready packaging bearing certain labeling claims or a nutrition facts panel per eligibility criteria. This directive issues the content of FSIS Notice 06-24, *Reissue of FSIS Sampling for Labeling Claims Verification*, with the exception of soy claims sampling (EXP_LV_SOY). Sampling for soy claims verification will now be conducted under the new allergen verification sampling program and announced in a separate notice.

II. CANCELLATION

FSIS Notice 06-24, *Reissue of FSIS Sampling for Labeling Claims Verification*, 2/2/24

III. 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. FSIS is conducting this sampling program to verify industry’s compliance with the Agency’s labeling regulations. Labeling claims 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 will continue the nutrient content sampling program at Federal establishments as a directed sampling task under the EXP_LV_NUTR sampling project.

D. To verify compliance with labeling claims related to soy and antibiotics, FSIS expanded the sampling program to ready-to-eat (RTE) products and raw chicken parts on May 7, 2018. At this time FSIS also began sampling raw ground beef for hormones.

DISTRIBUTION: Electronic

OPI: OPPD

IV. 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 evaluate eligibility as necessary.
- B. Eligible products are those in consumer-ready packaging with a label that contains the labeling claim or a nutrition facts panel for the specific product type that corresponds with the labeling feature as described in Table 1.

Table 1 - Label Verification Sampling Projects

Type of Labeling Feature	Sample Project Code	Sample To Collect	Analysis	Corresponding Pathogen Sampling Project Code
Nutrition facts panel	EXP_LV_NUTR	Raw ground beef	Fat and sodium content	MT43
Raised without antibiotics	EXP_LV_ABX	Raw chicken parts	Antibiotic residues	HC_CPT_LBW01
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 Shiga toxin-producing *E. coli* (STEC) sampling under the MT43 sampling project and meet the standards of identity [9 CFR 319.15\(a\)](#) (“chopped beef,” “ground beef”) or [319.15\(b\)](#) (“hamburger”). Product eligible for the EXP_LV_NUTR bears a nutrition facts panel on the consumer-ready packaging. Product eligible for the EXP_LV_HORM bears a label that claims no hormone use.
- 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) project and are labeled with a claim stating no antibiotic use. A description of eligible products for this project code is available in the Raw Poultry Sampling Guidance that can be accessed through the [IPP Help](#) button.
- E. IPP are to refer to the attachment below for examples of labels bearing claims for products eligible for the sampling projects covered in this directive. IPP are to be aware that the description of the claims on the labels may vary.

V. 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 the labeling claim verification sampling program.
- B. Samples will be assigned under the sampling projects 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. Samples for labeling claim verification testing must be submitted to the EL in fully labeled consumer-ready packaging bearing the claim that corresponds to the sampling project; otherwise, the sample will be discarded by the lab. IPP are to refer to the attachment for examples of labels with claims that are eligible for this sampling project.

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 Directive 13000.2](#), *Performing Sampling Tasks in Official Establishments Using the Public Health Information System*, for ordering sampling supplies through the Public Health Information System (PHIS). As an alternative, IPP may send a request for sampling supplies using Outlook to the FSIS - Sampling Supplies - Eastern Lab mailbox. When requesting sampling supplies by e-mail, 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.

E. Sample supplies for the label verification sample:

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

NOTE: The FSIS Laboratory will not automatically send sampling supplies at the time the sample is scheduled. IPP are to follow instructions in Section D to request sample supplies.

F. On the scheduled day of sampling, IPP are to determine if the establishment is producing eligible product in consumer-ready packaging that bears a label with the labeling claim that corresponds to the assigned sampling project (see [Table 1](#)). 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 fully labeled consumer-ready packaging bearing the labeling claim that corresponds to the sampling project (see [Table 1](#)). IPP are to collect as many packages of product as necessary to meet the 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;
2. Complete the sampling task in PHIS, following the instructions provided in [FSIS Directive 13000.2](#). When the sample data entry is completed, IPP are to click the "Submit to Lab";

NOTE: There is no sampling questionnaire to complete for labeling claim verification sampling projects.

3. Print, sign, and date the sample form. Place the completed sample form in the plastic sleeve provided; and 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.

G. 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.

H. 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.

VI. TEST RESULTS AND FURTHER ACTIONS

A. Test results for the three sampling projects, EXP_LV_NUTR, EXP_LV_ABX, and EXP_LV_HORM 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, the Office of Field Operations District Office (DO), and the Executive Associate for Regulatory Operations overseeing the 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. 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.

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

VII. QUESTIONS

Refer questions regarding this directive to your supervisor or as needed to the Office of Policy and Program Development through [askFSIS](#) or by telephone at 1-855-444-9904. When submitting a question, complete the [web form](#) and select **Labeling** for 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

ATTACHMENT – Examples of Labels with Claims and Corresponding Sampling Project

The following images are sample labels with claims for products that are eligible for labeling claim verification sampling. These labels are examples and do not necessarily bear all the required features for an approved label, because of lack of space. In addition, FSIS has approved the claims included on these labels in a variety of ways; therefore, multiple variations of the claims are included with each example.

NOTE: IPP must submit all samples in fully labeled consumer-ready packaging bearing the claim that makes the product eligible for sampling. Samples submitted without the label or not in consumer-ready packaging will be discarded.

Figure 1. Label eligible for EX_LV_HORM and EXP_LV_NUTR sampling programs

Note: eligibility for each sampling program is determined independently. For example, the label would still be eligible for EXP_LV_NUTR if the hormones claim was not present.

This label is intended solely to highlight examples of a claim for the **EX_LV_HORM** – “Raised Without Hormones” (blue arrow) and for the **EXP_LV_NUTR** – “Nutrition Facts Panel” (sodium and fat content) sampling projects (circled in red).

Statements claiming the absence of hormones can be worded in many ways, including but not limited to:

- “raised without added hormones”,
- “no added hormones administered”, and
- “raised without steroids”.

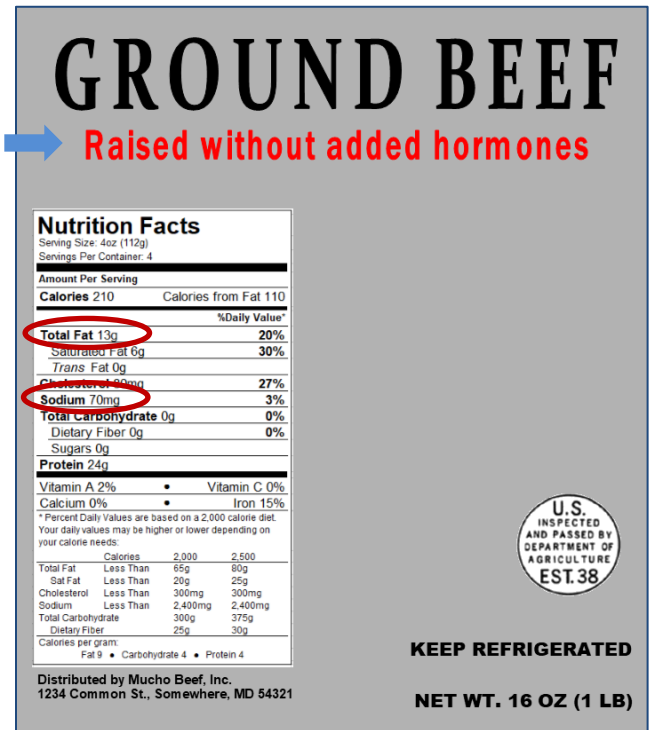


Figure 2. Label eligible for EX_LV_ABX sampling program

This label is intended solely to highlight examples of a claim for the **EX_LV_ABX** – “Raised without Antibiotics” sampling project.

Statements claiming the absence of antibiotics can be worded in many ways, including but not limited to:

- “raised without antibiotics”,
- “antibiotics-free”,
- “No antibiotics added”,
- “no antibiotics ever”, and

