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

FSIS NOTICE

26-19 | 8/20/19

FSIS SAMPLING FOR LABELING CLAIMS VERIFICATION

I. PURPOSE

This notice updates instructions to inspection program personnel (IPP) on verification sampling 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 and have been assigned a directed Label Verification Sample Task in the Public Health Information System (PHIS). This notice has been updated to clarify that IPP are to submit samples in finished packaging with the label applied to the package and with a label that contains the label claim that makes the product eligible for sampling. Examples of labels of product eligible for sampling are included as an attachment to this notice.

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), and 381.129). Labels are also required to display a complete listing of ingredients (9 CFR 317.2(c)(2), and 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 sampling project.

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.

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

bearing the corresponding claim:

Table 1 - Label Verification Sampling Projects and Corresponding Pathogen Sampling Projects

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. IPP are to refer to the attachment for examples of labels bearing claims for products eligible for the sampling projects covered in this notice. IPP are to be aware that the description of the claims on the labels may vary.

D. 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 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 have both the fat **AND** sodium claims on the consumer ready packaging.

E. 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) projects. 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.

F. Products eligible for the EXP_LV_SOY sampling project are ready-to-eat (RTE) products that are eligible for sampling under the RTEPROD_RAND sampling project, 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, 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 the labeling claim verification sampling 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 sampling 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 likely recommend that it be recalled.

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. 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 EL for analysis.

D. Samples for labeling claim verification testing must be submitted to the EL in consumer-ready packaging with a label applied to the package and with the label containing 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.

E. 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 13,000.2 , *Performing Sampling Tasks in Official Establishments Using the Public Health Information System*, 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 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. 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.

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 consumer-ready packaging with a label applied to the packaging and containing 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 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 into consumer-ready packaging in portions larger than 2 lb., IPP can request a slack-filled sample from the establishment, provided the slack-filled sample's packaging includes a label with the labeling claim.

2. Complete the sampling task in PHIS, following the instructions provided in FSIS 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 labeling claim verification sampling projects.

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.

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.

V. TEST RESULTS AND FURTHER ACTIONS

A. 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 "unacceptable" because it is positive for the presence of soy under the EXP_LV_SOY project, IPP are to document the finding in a noncompliance record (NR) and cite 9 CFR 317.8(a) and 317.2(c)(2) (for meat products) or 381.129 and 381.118 (for poultry products). IPP are to conduct a Big 8 Formulation Verification Task and document the findings in PHIS in accordance with FSIS Directive 7230.1, *Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common ("Big 8") Food Allergens*. 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.

B. 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 (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.

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 2). When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter **Notice 26-19.**
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 the Risk Management and Innovations Staff through askFSIS or by telephone at 1-800-233-3935 (press 3). When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter **Notice 26-19.**
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.

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.

Figure 1. – Nutrition Facts Panel and "Raised Without Hormones" Claim

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).

Negative hormone statements can be worded in many ways, including but not limited to:

- "raised without added hormones",
- "no added hormones administered", and
- "raised without steroids".

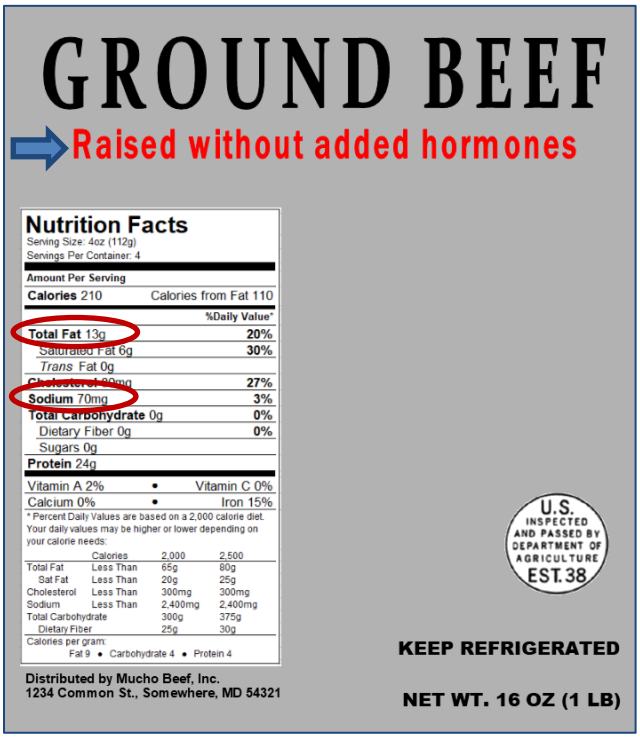

Figure 2. – "Raised Without Antibiotics" Claim

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

Negative antibiotic statements can be worded in many ways, including but not limited to:

- "raised without antibiotics",
- "antibiotics-free",
- "No antibiotics added",
- "no antibiotics ever", and
- "no antibiotics administered".

Figure 3. – "Soy-free" Claim

This label is intended solely to highlight examples of claims for the **EX_LV_SOY** – "Soy-free" sampling project.

Negative soy statements can be worded in many ways, including but not limited to:

- "no soy",
- "no soy added",
- "does not contain soy",
- "this product does not contain soy",
- "soy-free", and
- "free from soy".

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