

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

---

---

# FSIS NOTICE

---

---

15-21

4/7/21

## 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 and/or a nutrition facts panel per eligibility criteria.

### 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. 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 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.

---

**DISTRIBUTION:** Electronic

**NOTICE EXPIRES:** 4/1/22

**OPI:** OPPD

**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
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 bears a nutrition facts panel 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. 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.

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 13.000.2, 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 submit requests for sampling supplies to FSIS EL via Outlook, using the following e-mail address:

[SamplingSupplies-EasternLab@fsis.usda.gov](mailto: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.

E. 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.

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\_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*. If any of the product represented by the soy positive lab results has been shipped into commerce, 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](#). If any of the product represented by the soy positive lab results has been shipped into commerce, IPP are to notify the Recall Management and Technical Analysis Staff (RIMTAD) through their supervisory chain for further guidance regarding their concerns.

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 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, complete the [web form](#) and select Sampling as the Inquiry Type.



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 consumer-ready packaging with the label applied to the package and with a label that contains the label claim that makes the product eligible for sampling. Samples submitted without the label or not in consumer-ready packaging will be discarded.

**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”.

**GROUND BEEF**  
 Raised without added hormones

Nutrition Facts	
Serving Size: 4oz (112g)	
Servings Per Container: 4	
Amount Per Serving	
Calories 210	Calories from Fat 110
	%Daily Value*
<b>Total Fat 13g</b>	20%
Saturated Fat 6g	30%
Trans Fat 0g	
Cholesterol 90mg	27%
<b>Sodium 70mg</b>	3%
Total Carbohydrate 0g	0%
Dietary Fiber 0g	0%
Sugars 0g	
<b>Protein 24g</b>	
Vitamin A 2%	Vitamin C 0%
Calcium 0%	Iron 15%

\* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less Than	65g	80g
Sat Fat	Less Than	20g	25g
Cholesterol	Less Than	300mg	300mg
Sodium	Less Than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:  
 Fat 9 • Carbohydrate 4 • Protein 4

U.S. INSPECTED AND PASSED BY DEPARTMENT OF AGRICULTURE EST. 38

**KEEP REFRIGERATED**

**NET WT. 16 OZ (1 LB)**

Distributed by Mucho Beef, Inc.  
 1234 Common St., Somewhere, MD 54321

### 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”.

