

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

FSIS NOTICE

21-17

4/21/17

QUESTIONNAIRE FOR CERTAIN LABELING CLAIMS ON RAW GROUND BEEF, RAW CHICKEN PARTS AND READY-TO-EAT PRODUCTS

I. PURPOSE

A. Upon issuance of this notice, inspection program personnel (IPP) in establishments that produce raw ground beef products, raw chicken parts, and ready-to-eat (RTE) products are to complete the "Labeling Claims Questionnaire" in the Public Health Information System (PHIS). The purpose of this questionnaire is to collect information on certain labeling claims made on various products in order to direct future sampling efforts related to verification of these claims.

B. IPP are to complete the questionnaire in PHIS no later than June 5, 2017. IPP have an hour of official time to read this notice and complete the questionnaire. If IPP are unable to complete other tasks due to time constraints imposed by this questionnaire, they are to follow the instructions in [FSIS Directive 13,000.1, Scheduling In-Plant Inspection Tasks in the Public Health Information System \(PHIS\)](#), for marking those tasks as "not performed."

II. BACKGROUND

A. FSIS has observed through its label approval system an increase in the application of labeling claims highlighting the absence or limited content of various substances from products. Labeling claims indicate that an establishment is marketing its products to consumers who seek specific qualities or attributes. Consumers typically pay a higher price for these value added products.

B. FSIS is collecting information from an establishment profile questionnaire, based on the establishment's eligibility for sampling under existing microbiological programs (identified below) to identify which establishments produce products bearing specific labeling claims. FSIS is seeking to identify:

1. Establishments producing raw, ground beef bearing a statement on the label claiming that hormones are not administered to the beef used in the product (FSIS collects samples of these products under the code MT43);
2. Establishments producing raw chicken parts bearing a statement on the label that antibiotics are not administered to the chicken used in the product (FSIS collects samples of these products under the code HC_CPT_LBW01); and
3. Establishments producing RTE products bearing a statement on the label that the allergen soy is not present in the product (FSIS collect samples of these products under the code RTEPROD_RISK).

DISTRIBUTION: Electronic

NOTICE EXPIRES: 5/1/18

OPI: OPPD

C. The questionnaire results will assist FSIS in assigning directed sampling tasks to IPP at establishments producing products bearing certain labeling claims. The sampling tasks will be part of an exploratory sampling program. This program is designed to verify such claims are truthful and not misleading. Additional instructions regarding sampling will be issued in future FSIS issuances.

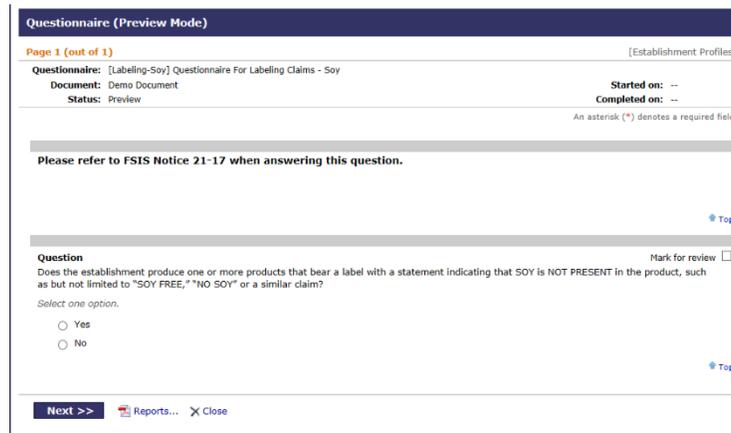
III. IPP RESPONSIBILITIES

A. The questionnaire appears in PHIS as a PHIS Profile Questionnaire and can be found on the left navigation menu under “Establishment Profile”. IPP are to complete and submit the questionnaire during their next scheduled PHIS establishment profile task as instructed in [FSIS Directive 5300.1](#), *Managing the Establishment Profile in the Public Health Information System*.

NOTE: Instructions for accessing and completing the PHIS profile questionnaire are available in the [PHIS Questionnaires Quick Reference Guide](#), on the FSIS intranet, (level 2 e-Authentication is required to view this site).

B. IPP may view or print the questions before completing the questionnaire. To view or print the questions IPP are to:

1. Open the “Labeling Claims” questionnaire;

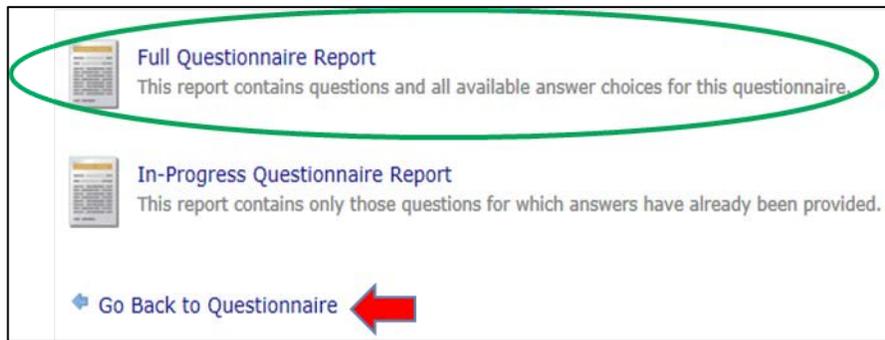


NOTE: There are three different questionnaires, “Labeling Claims Questionnaire – Hormones,” “Labeling Claims Questionnaire – Antibiotics,” and “Labeling Claims Questionnaire – Soy.” Most establishments will only be assigned one of the three questionnaires. Some establishments will be assigned two of the three questionnaires in PHIS.

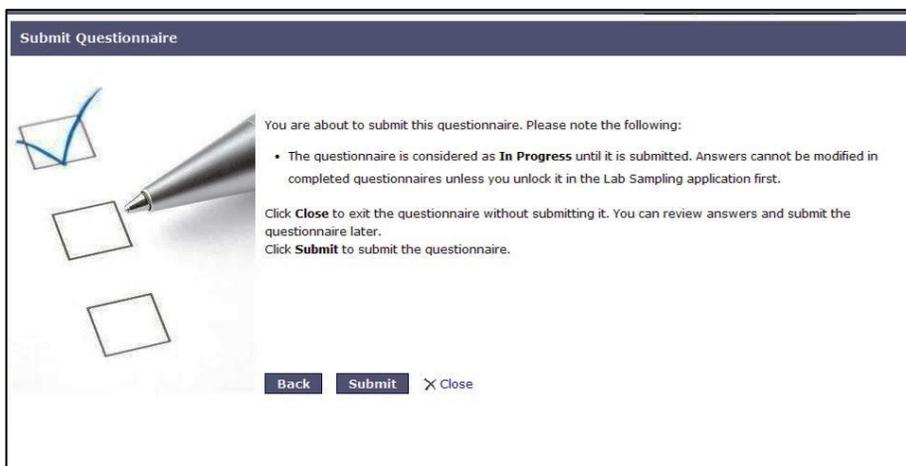
2. Select Reports;



3. Select Full Questionnaire Report (green oval) to generate a PDF file for viewing or printing. Next select Go Back to Questionnaire (red arrow);



4. Select “YES” or “NO” for the question;
5. Select Save & Close; and
6. Submit the questionnaire in the PHIS Profile Questionnaire.



NOTE: Some establishments may be assigned more than one questionnaire. Repeat the instructions starting with Step 1 if assigned a second questionnaire.

IV. QUESTIONNAIRES

A. One or more of the following questionnaires will appear under the Profile Questionnaire tab based on the microbiological sampling program identified for the establishment, as explained in Section II.B. Each labeling claim questionnaire contains one “YES” or “NO” question regarding a specific labeling claim. IPP are to keep in mind that the product with the labeling claim may only be produced infrequently and are to respond to the question if the product is produced at the establishment, even if it is not being produced on the day the questionnaire is being completed.

1. “Labeling Claims Questionnaire – Hormones” (MT43)

1a) The following are examples of claims stating the absence of HORMONES in raw ground beef products:

- i. “No antibiotics administered, no growth stimulants or added hormones;”

- ii. "No Antibiotics – Hormones;"
- iii. "Raised without antibiotics, pesticides, or added growth hormones;"
- iv. "No added antibiotics or added hormones;"
- v. "No Added Hormones;"
- vi. "No Added Growth Hormones;"
- vii. "No added steroids or hormones;"
- viii. "No added antibiotics or added hormones;"
- ix. "No growth promoting substances, injected, fed, or consumed in water;"
- x. "Grass Fed beef without hormones and antibiotics added;" and
- xi. "Raised without Added Hormones."

1b) Does the establishment produce one or more raw ground beef products that bear a label with a statement indicating that HORMONES are **NOT PRESENT** in the finished product, such as, but not limited to, the ones presented above in 1a)?

- i. YES; or
- ii. NO.

2. "Labeling Claims Questionnaire – Antibiotics" (HC_CPT_LBW01)

2a) The following are examples of claims stating the absence of antibiotics in raw poultry products:

- i. "No antibiotics;"
- ii. "No Antibiotics Ever;"
- iii. "No antibiotics added;"
- iv. "No antibiotics administered, no growth stimulants or added hormones;"
- v. "No antibiotics administered;"
- vi. "No Antibiotics – Hormones;"
- vii. "Raised without antibiotics;"
- viii. "Raised without antibiotics, pesticides, or added growth hormones;" and

ix. "No added antibiotics or added hormones."

2b) FSIS allows labels to bear several negative antibiotic claims which allow for a limited use of antibiotics. These claims fall outside the scope of those products targeted in the "Labeling Claims Questionnaire – Antibiotics." If the establishment produces product with labels bearing limited use of antibiotics claims, IPP should disregard these claims when answering the question in 2c below. Limited use of antibiotics statements include, but are not limited to, the following examples:

- x. "No Antibiotics Administered in the last 150 days" (this number can range from 30-200 days).
- xi. "Raised Without Sub-therapeutic Antibiotics."
- xii. "No Growth Promoting Antibiotics, Antibiotics responsibly used only when needed for treatment or prevention of illness."
- xiii. "No Antibiotics Used Important To Human Medicine As Defined By World Health Organization."
- xiv. "Responsible Use of Antibiotics. Only Ionophores. No Antibiotics Used Important to Human Health as defined by the World Health Organization in 2011."
- xv. "NO ANTIBIOTICS*" *Antibiotics responsibly used only when needed for treatment or prevention of illness.
- xvi. "No Sub-Therapeutic Antibiotics, Antibiotics only given in case of illness."

2c) Does the establishment produce one or more raw poultry products that bear a label with a statement indicating that ANTIBIOTICS are NOT PRESENT in the finished product, such as, but not limited to, the ones presented above in part 2a)? NOTE: IPP should answer "NO" to the question if the establishment ONLY produces product bearing any of the limited use of antibiotics statements listed in 2b).

- i. YES; or
- ii. NO.

3. "Labeling Claims Questionnaire – Soy" (RTEPROD_RISK)

Does the establishment produce one or more products that bear a label with a statement indicating that SOY is **NOT PRESENT** in the product, such as but not limited to "SOY FREE," "NO SOY" or a similar claim?

- a. YES; or
- b. NO.

V. DATA ANALYSIS

The Office of Policy and Program Development will analyze the data collected from this questionnaire. The data will primarily be used to direct future surveillance sampling programs related to certain labeling claims.

VI. QUESTIONS

Refer questions regarding this notice to the Labeling and Program Delivery Staff 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 21-17**
Question Field: Enter question with as much detail as possible.
Product Field: Select **Labeling** from the drop-down menu.
Category Field: Select **Labeling Regulations Policies and Claims, Special Claims** 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