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

FSIS DIRECTIVE

5000.3
Rev. 1

2/11/16

IDENTIFICATION AND SEGREGATION OF PRODUCT

I. PURPOSE

This directive provides inspection program personnel (IPP) with instructions for verifying that meat and poultry establishments and egg products plants identify, segregate, and properly hold adulterated product that has been returned to the establishment or plant or has been received by the establishment or plant for further processing. Also, this directive addresses IPP's responsibility to verify that an establishment or plant holds products in an appropriate manner pending receipt of FSIS laboratory results.

KEYPOINTS:

- *Updated to reflect that FSIS will withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received*
- *Updated to remove PBIS procedure codes and include Public Health Information System (PHIS) Inspection Task names*
- *Updated to include egg products plants*

II. CANCELLATION

FSIS Directive 5000.3 *Identification and Segregation of Product,* 12/21/06

III. BACKGROUND

A. This directive focuses on products that are considered to be adulterated and that have been returned to an establishment or plant because of a recall or that have been received at an establishment or plant for other reasons (e.g., product produced at another establishment or plant that needs to receive further treatment so that it is no longer adulterated). Properly identifying and segregating product considered to be adulterated is necessary to prevent shipment of adulterated product into commerce.

B. The directive also addresses products that an establishment or plant holds pending FSIS or establishment or plant test results that, if positive, will evidence that the product is adulterated. The establishment or plant is responsible for identifying what it determines to be the sampled lot that will be held, and justifying why that product is considered to be a lot. To ensure that the sampled lot maintains its identity, the establishment or plant needs to segregate the sampled lot.

IV. VERIFICATION ACTIVITIES FOR PRODUCTS WHEN THERE IS REASON TO BELIEVE THEY ARE ADULTERATED OR MISBRANDED, AND THEY ARE RETURNED TO, OR RECEIVED AT, A MEAT OR POULTRY ESTABLISHMENT

A. IPP are to verify that an establishment implements controls to segregate and to maintain the identification of adulterated or misbranded product that is returned to the establishment as a result of a recall or other reason until the planned disposition of the product is completed.

B. IPP are to verify that when a meat or poultry establishment receives product produced at another establishment for purposes of further processing, that receiving establishment has addressed the treatment of the product in its HACCP plan. Among other measures, the establishment needs to identify the measures that it will take to segregate and to maintain the identity of product, so that it does not enter commerce until it has been appropriately processed.

C. If an establishment plans to hold the adulterated product while it decides how to dispose of or process that product, IPP are to verify that the establishment's controls are sufficient to ensure that the product will be appropriately segregated from non-adulterated product, and that the product is prevented from entering commerce.

NOTE: IPP are to also follow the instructions found in FSIS Directive 10,010.2, *Verification Activities for Shiga Toxin-Producing* Escherichia Coli *(STEC) in Raw Beef Products,* for STEC positive product.

D**.** IPP are to accomplish the above verifications by performing a routine or directed HACCP Verification Task under the appropriate product category.

E. If an establishment fails to maintain the segregation of the product from non-adulterated product or fails to implement controls to prevent the product from entering commerce, IPP are to retain the product by taking a regulatory control action in accordance with 9 CFR 500.2, Product Adulteration or Misbranding. IPP also are to document noncompliance as set out in FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System.*

F. If IPP find the product has entered commerce, they are to contact their supervisor or the District Office (DO) to inform them that product that may be adulterated or misbranded has entered commerce. The DO will contact the Recall Management and Technical Analysis Staff (RMTAS) and follow the Recall Procedures per FSIS Directive 8080.1, *Recall of Meat and Poultry Products*.

G. Product is in commerce if it is out of the producing establishment's direct control and is in distribution (e.g., in a warehouse or distribution center not owned by the establishment, retail facility, restaurant, or other institution).The Agency will consider product under the producing establishment's direct control if it is:

1. At the establishment;
2. Located on the premises owned by the producing establishment;
3. At a sister establishment owned by the same establishment or corporation;
4. At a warehouse owned by the establishment or corporation;
5. On a truck or other conveyance owned or operated by the establishment or corporation; or
6. Offsite under company control or FSIS control (FSIS seal accompanied by FSIS Form 7350-1).

V. VERIFICATION ACTIVITIES FOR EGG PRODUCTS WHEN THERE IS REASON TO BELIEVE THEY ARE ADULTERATED OR MISBRANDED, AND THEY ARE RETURNED TO, OR RECEIVED AT, AN EGG PRODUCTS PLANT

A. IPP are to verify that the plant implements controls to segregate and maintain the identification of adulterated or misbranded egg products returned to a plant as a result of a recall or other reason until the disposition of the product.

B. IPP are to verify that when egg products that were produced at another plant and that may be adulterated are received for the purposes of further processing, the receiving plant has in place measures to segregate and maintain the identity of the product, so that it does not enter commerce until it has been appropriately processed.

C. If a plant plans to hold the adulterated product while it decides how to dispose of or process the egg product, IPP are to verify that the plant's controls are sufficient to ensure that the product will continue to be appropriately segregated from non-adulterated product, and that the product is prevented from entering commerce.

D. If an egg products plant fails to maintain the segregation of adulterated product from non-adulterated product or fails to implement controls to prevent the product from entering commerce, IPP are to retain the product by placing a retention tag in accordance with 9 CFR 590.426. IPP are to also document noncompliance as set out in FSIS Directive 5030.1, *Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants.*

E. If IPP find the product has entered commerce, they are to contact their supervisor or the DO to inform them that product that may be adulterated or misbranded has entered commerce. The DO will contact the RMTAS and follow the Recall Procedures per FSIS Directive 8080.1.

VI. VERIFICATION ACTIVITIES FOR PRODUCTS BEING HELD BY AN ESTABLISHMENT OR PLANT PENDING TEST RESULTS THAT, IF POSITIVE, WILL SHOW THAT THE PRODUCT IS ADULTERATED

When an establishment or plant is holding product (either by holding the product on premises or by moving the product off-site under company control) pending FSIS test results or its own test results, IPP are to verify that the establishment or plant has identified the sampled lot, has segregated the lot from other product, and has maintained the sampled lot's identity. If the establishment or plant moves this product to another official establishment or plant, renderer, or landfill operation, IPP are to examine establishment or plant records to verify that the product received appropriate disposition.

VII. QUESTIONS

Refer questions regarding this directive to the Policy Development 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 **Directive 5000.3**
Question Field:	Enter question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **Regulations/Agency Issuances** from the drop-down menu. 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.

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