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Inside

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Developing a Recall Plan

By Natasha Williams

Yes, you've heard it right! All meat and poultry plants, including small and very small plants, are required to have a recall plan based on the 2008 Farm Bill final rule. Large plants are required to have a plan in place by November 5, 2012, and small and very small plants by May 8, 2013.

If you own or operate a small or very small plant, you're probably wondering, "What does this mean for me?" Well, this means you'll have to devise a plan that will prepare your plant to act quickly and efficiently in case of a recall.

The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) is developing a resource for the *Small Plant News* guidebook series titled "How to Develop a Recall Plan" that you can use to help develop a recall plan. However, in the meantime, FSIS Directive 8080.1, Revision 6, *Recall of Meat and Poultry Products*, contains an attachment that provides product recall guidelines for plants and includes suggested components of a recall plan. To summarize the guidebook and to inform you of what is now expected, the following is a list of items you should consider when developing a recall plan.

First, you want to identify your recall team. This team should consist of the people who will be involved in a product recall, internal or external, and include their

Continued on Page 2 ...

... Continued from Page 1

responsibilities and contact information. A "backup" should be appointed for each individual in case the person is absent when a recall occurs. If you only have a few employees, a person can have multiple roles.

Second, you'll need to choose someone from the team to be the Recall Coordinator. This person is responsible for managing the recall and involving each member of the recall team. The Recall Coordinator should have access to the detailed recall plan and be authorized to make decisions regarding recall implementation. In addition, the Recall Coordinator should be knowledgeable about the firm's operations, including purchasing, processing, quality assurance, distribution, and consumer complaints.

Third, you'll need to establish procedures for determining whether to implement a recall and, if you decide to conduct one, how the recall will be accomplished. Some questions you may want to ask yourself include:

1) Has adulterated or misbranded product been produced?
2) Has adulterated or misbranded product been shipped?
3) Is the product in commerce? (In commerce refers to product that has been shipped from an establishment without any agency or establishment controls or restrictions and is free to be moved to any consignee or consumers.)
4) Where has the product been shipped?
5) Is the product available to consumers?

In addition, you may want to include a health hazard evaluation in your recall procedures. This evaluation will help you determine the health risk to the public if the product is in commerce. Below are questions you can ask to determine the health risk:

1) What injuries or illnesses may occur if the product is used?
2) How serious is the health hazard?
3) How likely is the hazard to occur, and what will happen if it does occur?

Fourth, you need to outline how to determine the scope of a recall — the product and the amount of product. It will be your responsibility to determine when the problem began, when it was resolved, and what products were affected. This is how you'll determine the product and the amount to recall.

The fifth step in your recall plan should explain how you will decide on the depth of the recall. Depth refers to the level of product distribution that will be included in the recall. The depth depends on the seriousness of the hazard, the extent of the product distribution, and the level of product distribution. Levels of distribution include wholesale, retail, hotel/restaurant/institutional (HRI), and household consumers. For more information on determining the depth of a recall and a complete description of the levels of distribution, refer to FSIS Directive 8080.1, Revision 6.

The sixth step is recordkeeping. It's vital to maintain all records because they will aid in tracing the product. These records include bills of sale, shipping documents, and invoices. The following are immediate records you should have on deck:

1) Records for positive identification of products produced (e.g., labels, lot numbers, Julian codes, etc.);
2) Production records such as records of raw materials used in each lot of ground beef; and
3) Distribution information for recalled products. These records may include names/addresses of consignees, methods of shipment, dates of shipment, etc.

The seventh step is to outline your plant's recall communication tools. Examples of recall communication tools include your plant's recall notice to your consignees and methods of public notification. When drafting your recall notice to your direct consignees, consider the following guidelines:

1) Be brief and direct;
2) Explain the reason for the recall and the associated hazard;

Continued on Page 3 ...

... Continued from Page 2

3) Clearly describe the product and provide sufficient information to enable accurate and immediate identification of the product, including:
   - product/brand name
   - product code
   - package/case size
   - package/case date code
   - lot number/expiration date
   - UPC code
4) Provide an explanation of the consumer's risk if the product is consumed;
5) Provide instructions on what to do with the recalled product;
6) Provide ready means for the recipient of the communication to report to the recalling firm whether it has any of the products. Consider allowing the recipient to place a collect call to the recalling firm;
7) Provide instructions on what to do with the recalled products. These instructions can include anything from the destruction of the product at the consignee location; to returning the product to the official plant;
8) Provide recall communication that does not include irrelevant qualifications, promotional materials, or any other statement that may detract from the message; and
9) Provide plant contact information (for questions).

After you have notified your consignees, you may also need to notify the public. FSIS recommends that you identify if and how the public will be notified of the recall. Recalls are often announced by a press release to national or local news media. The class of a recall and the extent to which the product was distributed in commerce will determine the type of notification you will use. Your recall plan should include contact information for all potential media outlets such as television stations, radio stations, and newspapers with local, state, and regional coverage areas as well as the national wire services.

The eighth step in your recall plan is to outline the procedures you will use for conducting effectiveness checks. Effectiveness checks verify that your consignees received notification of the recall and have taken the appropriate action to return or dispose of the recalled product. You should include the methods you will use to determine the number of effectiveness checks you will conduct, as well as the manner in which you will conduct them.

The ninth step in your recall plan should specify the means you will use to control, dispose of, or correct defects in the product that is returned to your plant as a result of the recall.

The tenth and final step in developing your plant's recall plan is to create recall simulations. A recall simulation is very similar to a fire or tornado drill. Conducting these simulations is the best way to test the effectiveness of your recall plan. These drills will help you identify glitches in your plan and stay current on vital contact information for consignees. Additionally, these drills will keep your recall personnel prepared and familiar with the plant's recall procedures. If problems are identified during a recall simulation, the recall plan should be revised.

Although it does not have to be included in your recall plan, you may wish to include a step about notifying your FSIS District Office (DO). Remember, if adulterated product is in commerce, you must notify the DO within 24 hours.

If you have any questions or concerns about developing your recall plan or need additional resources, call the Small Plant Help Desk at 1-877-FSISHelp (1-877-374-7435) or email *Infosource@fsis.usda.gov*. For additional information on developing a recall plan, access FSIS Directive 8080.1, Revision 6, *Recall of Meat and Poultry Products*, at *www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1.pdf*.

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

FSIS DIRECTIVE	8080.1, Revision 6	10/26/10

RECALL OF MEAT AND POULTRY PRODUCTS

I. PURPOSE

This directive provides the terminology, responsibilities, and public notification procedures regarding the voluntary recall of FSIS-inspected meat and poultry products.

II. CANCELLATION

FSIS Directive 8080.1, Revision 5, dated 11/17/08

III. REASON FOR REISSUANCE

This directive is being reissued in its entirety. The only change is a revised attachment 3, Effectiveness Checks.

IV. REFERENCES

Federal Meat Inspection Act (FMIA)
Poultry Products Inspection Act (PPIA)
9 CFR Parts 329; 381, Subpart U
FSIS Directive 8091.1, Procedures for the FSIS Health Hazard Evaluation Board
FSIS Directive 8410.1, Detention and Seizure

V. BACKGROUND

A recall is a firm's action to remove product from commerce (e.g., by manufacturers, distributors, or importers) to protect the public from consuming adulterated or misbranded products. Although it is a firm's decision to recall product, the Food Safety and Inspection Service (FSIS) coordinates with the firm to ensure it has properly identified and removed recalled product from commerce by verifying the effectiveness of the firm's recall activities. FSIS also notifies the public about product recalls.

Commonly Asked Questions & Answers

Q. *In a dual-jurisdiction establishment, is the establishment required to conduct a full/complete cleanup prior to manufacturing an FSIS-inspected product after producing a U.S. Department of Health and Human Services' Food and Drug Administration (FDA) product?*

A. Not necessarily. There is nothing in the regulations that mandates a complete cleanup when an establishment switches from FDA to FSIS products. In most cases, dual-jurisdiction establishments first manufacture FSIS-regulated products and then switch to FDA-regulated products. However, this production practice is not a regulatory requirement. Regardless of whether they start the day producing FSIS or FDA products, establishments must comply with the Sanitation Performance Standards and Sanitation Standard Operating Procedures (SSOP) requirements prescribed in Title 9 of the *Code of Federal Regulations* (9 CFR) 416 when they produce FSIS-regulated products. To verify that dual-jurisdiction establishments are meeting these requirements, Inspection Program Personnel (IPP) review the establishment's written SSOP prior to the production of the FSIS products to determine how the establishment intends to maintain sanitary conditions when it starts with FDA product and then switches to FSIS product. IPP should also verify that the establishment has not created any insanitary conditions while producing the FDA product. If the establishment maintains sanitary conditions during the production of the FDA-regulated product, the establishment may be able to move to producing the FSIS-inspected product without conducting a complete cleanup, if it has also addressed cross-contamination or other adulteration or misbranding concerns in its hazard analysis. For example, the establishment is producing an FDA product (cheese pizza) and will switch to an FSIS-inspected product (cheese and sausage pizza). The production process for the FSIS-regulated product is essentially the same as the production process for the FDA-regulated product. In addition, the establishment's hazard analysis did not identify any potential food safety hazards associated with switching from the FDA-regulated process to the FSIS-regulated process without conducting a cleanup. Therefore, if no insanitary conditions are observed during the FDA process, the establishment can transition over to the FSIS- inspected product without conducting a full cleanup. In addition, as a consequence of the hazard analysis conducted by the establishment, it determined that no new food safety hazards are created. As a result, there is no need to conduct a full/complete cleanup prior to producing the FSIS-inspected cheese and sausage pizza.

Q. *If an establishment is monitoring its critical control points (CCP) more frequently than is identified in the Hazard Analysis and Critical Control Point (HACCP) plan, can an establishment say the extra monitoring checks are "unofficial" and, therefore, not subject to FSIS review?*

A. No. When an establishment conducts HACCP monitoring more frequently than specified in the HACCP plan, all monitoring results generated are subject to review by FSIS personnel in accordance with 9 CFR 417.5(f). In addition, any deviation observed during any CCP monitoring check is subject to the corrective action requirements of 9 CFR 417.3(a), including documentation in accordance with 9 CFR 417.5(a)(3).

If inspection program personnel (IPP) have questions regarding whether "unofficial" HACCP records are being maintained by the establishment, they should, in accordance with the instructions in FSIS Directive 5010.1, periodically ask the establishment if it is maintaining records of its HACCP monitoring that it is storing with its other HACCP records. IPP are to include the establishment's response when documenting the weekly meeting in a Memorandum of Interview (MOI).