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Small Plant NEWS

Editor: Keith Payne

Production: Sally Fernandez

Design: Rowena M. Becknel

Contact: *Small Plant News*, USDA/FSIS, Aerospace Building, 3rd Floor, Room 405, 14th and Independence Ave., SW, Washington, DC 20250. (202) 690-6520
E-mail: SmallPlantNews@fsis.usda.gov

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What to Do if Your Product Needs to be Recalled



By Jeff Tarrant, LCDR
U.S. Public Health Service

In the last issue of *Small Plant News*, we provided steps that you can take to develop your own facility's food recall plan. This month we go one step further —what to do if your product needs to be recalled.

Before we start, we need to determine how a recall is initiated. Generally speaking, most recalls are identified by the facility, U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) or other sources. In this scenario, let's assume you identified the problem.

So, in the event you are involved in a food recall, what should you do? First, FSIS recommends you read FSIS Directive 8080.1, Revision 4, Attachment 1, *Product Recall Guidelines for Firms*. It provides step-by-step actions FSIS "expects a firm to take to ensure that the maximum

Complete and accurate product identity is essential when initiating a food recall. (USDA photo)

amount of product is recovered in the shortest amount of time." In addition, the directive provides valuable communication information including model press releases and recall notification letters.

Get the Facts

Next, you need to collect information that will allow you to characterize the issue properly and communicate with FSIS, consignees and the public in a timely manner. FSIS' inspector-in-charge, district office and Recall Management Staff will need clear and concise documentation including the following:

- Complete and accurate product identity, including product labels (e.g., digital images);
- Reason for recall and details about the time and discovery of the defect or deficiency;
- Your determination and risk assessment of product consumption;
- Timeframe and volume of the product's production;
- Estimate of how much product is in distribution and for how long;
- Area of geographical distribution of product by state and/or country;

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Food Safety Resources

By Mary Gioglio

Are you setting up a new plant and need guidance to comply with Federal regulations? Or do you want to find a unique way to orient new managers and employees at your plant?

Turn to the *New Plant Orientation: Safe and Easy*, a DVD designed to introduce Sanitation Standard Operating Procedures (SSOPs) and the Hazard Analysis and Critical Control Point (HACCP) system to owners and operators of new meat plants. This informative DVD, developed by New Mexico State University in partnership with FSIS, describes daily activities that occur in meat plants including pre-operational, processing, monitoring and verification procedures. Not only is this a good resource for new plant owners and operators but it can also be used as an orientation for newly hired employees.

To request this item or any other food safety resource, fax the order form found on FSIS' *Food Safety Resources Brochure* to (202) 690-6519, or complete an online version of the form and send it to FoodSafetyResources@fsis.usda.gov. The online form can be found at www.fsis.usda.gov/Science/HACCP_Resources_Order_Form/index.asp.

Briefs By Sheila Johnson

Public Meetings

FSIS held a public meeting titled "E. coli O157:H7 – Addressing the Challenges, Moving Forward with Solutions" on April 9 and 10 in Washington, D.C. Presentations and the transcript from this meeting are now available at www.fsis.usda.gov/News_&_Events/Past_Events/index.asp. To obtain information on any other public meetings, visit FSIS' Web site at www.fsis.usda.gov or call (202) 690-6520.

Web Seminars

As part of FSIS' initiative to enhance outreach to assist small and very small plants outlined in the *FSIS Strategic Implementation Plan for Strengthening Small and Very Small*

Outreach, the agency is holding a series of regulatory education workshops. The workshops include a walk-through of a variety of topics, which may include HACCP system, Sanitation Performance Standards, SSOPs, Rules of Practice, food defense strategies, E. coli O157:H7 workshops and FSIS Notices 65-07, 66-07 and 68-07. Online registration forms are provided. Pre-registration helps FSIS plan for the meetings, but is not required.

An upcoming workshop will focus on E. coli O157:H7, and the sessions will cover prerequisite programs and FSIS Notices 65-07, 66-07 and 68-07. The workshop will be held in Raleigh, North Carolina, on July 15 from 6:30 a.m. to 8:30 p.m.

at the Holiday Inn Crabtree Valley, located at 4100 Glenwood Avenue. For more information and assistance in registering, call FSIS' Office of Outreach, Employee Education and Training at (800) 336-3747.

Feedback

Small Plant News is also posted on FSIS' Web site at www.fsis.usda.gov. If you or your colleagues would like to receive an electronic copy, visit FSIS' Web site today and sign up for a complimentary e-mail subscription. Please continue to submit your comments to SmallPlantNews@fsis.usda.gov or call (202) 690-6389. We look forward to hearing from you on how we can provide the resources you need.

Commonly Asked Question & Answer

Q.

Can a noncompliance report be issued for failing to label product "For export only" when required?

A.

Yes, "For Export Only" or a similar term is a statement of limited distribution required when the labeling does not fully meet FSIS labeling regulations but has been determined to meet the labeling regulations of the receiving country. It's required when a deviation is approved under Title 9 *Code of Federal Regulations*, Parts 317.7 or 381.128 and when generic approval of a direct translation is exercised under Parts 317.5 or 381.133. The term "For Export Only" or a similar term may not be used when the container bears no other label other than an English-only label that meets all domestic requirements.

Measuring Your Needs

FSIS Examines Communication Methods

By Jeff Tarrant, LCDR
U.S. Public Health Service

For over 25 years, FSIS has been searching for ways to communicate better with meat, poultry and processed egg products establishments under its regulatory purview. During that time, industry demographics have changed tremendously.

In an effort to keep up with the ever-changing industry landscape, the agency participated in an informal study in 2005 to help it find more effective ways to communicate with underserved owners, operators and employees of small and very small meat, poultry and processed egg products facilities, in particular African Americans, Hispanics/Latinos, American Indians/Alaska Natives, or Asians/Pacific Islanders.

The informal study was based on interviews of 22 subject matter experts from around the country. These included trade association representatives, government officials, academics and extension agents with experience in getting food safety and regulatory messages across to small and very small plants in communities with special language or cultural needs. The subject matter experts were asked a series of questions about the effectiveness of different vehicles that may be used for FSIS communication. The responses were informative. A sampling of these includes:

How do you think small and very small businesses become aware of FSIS messages related to new regulations and other food safety initiatives?

- FSIS inspection program personnel (55%)
- Rural Development/University Extension programs (45%)
- Trade associations (28%)
- State inspection programs (23%)
- Postal mail/Fax (18%)

What do you think are the best ways for FSIS to get information to small and very small businesses?

- Postal mail (50%)
- E-mail (41%)

- Direct contact between FSIS inspectors and plant owners/operators (41%)
- Fax (36%)
- Regional workshops (32%)
- Workshop webcasts (27%)
- University Extension Service (18%)
- FSIS Web site (18%)

A number of respondents expressed concerns with FSIS' reliance on computer-based communication methods (e.g., e-mail, webcasts, etc.). One interviewee stated, "Many small and very small operators don't have computers and are small family-owned businesses. Direct contact is still the best way to communicate with them." A commonly conveyed phrase was, "All the examples are important, because there is no one-size-fits-all approach to reach the businesses."

Any comments on the best ways for FSIS to communicate?

Fifty percent of interviewees stated that they would like FSIS to develop and foster positive working relationships between its inspectors and the owners and operators of small and very small plants.

One respondent stated, "Since industry is a non-homogeneous population, there is no one-size-fits-all approach for communicating with operators. For some, seminars work well. For others, face-to-face interaction is necessary. Combination methods work best."

Another interviewee commented, "Some of these plants are the primary source of income in their communities. We need to find a way to help them out. The local community and economy depends on it."

FSIS could not agree more. In keeping with the goals set out in the *FSIS Strategic Implementation Plan for Strengthening Small and Very Small Outreach* released in May 2006, the agency is committed to listening to, identifying and addressing the needs of small and very small plant owners and operators across the country. And, that's a promise we plan to keep.

For more information on FSIS small and very small plant outreach efforts, visit FSIS' Web site at: www.fsis.usda.gov/Science/Small_Very_Small_Plant_Outreach/index.asp#plan or call FSIS' Office of Outreach, Employee Education and Training at (800) 336-3747.



Part of the recall effectiveness check methodology includes **physical verification of a product on-hand/in inventory at the time of the effectiveness check.** (USDA photo)

Web site. According to Lisa Volk, director of FSIS' recall management staff, plants are encouraged to issue their press releases in conjunction with FSIS.

In addition, your facility is expected to report regularly, and in a timely manner, ongoing efforts to retrieve recalled product to FSIS in a recall status report. The frequency of updates is determined by the degree of public health hazard. The recall status report should include:

- Number of consignees notified of the recall;
- Dates notifications were made and the method used;
- Number of consignees responding to recall communications;
- Quantity of product each customer had on hand when communication was received;
- Number and identity of consignees who did not respond;
- Quantity of product returned or held by each customer; and
- Estimated time of recall completion.

Effectiveness Checks

FSIS also plays a strong role in the conduct of effectiveness checks. This is a process where the agency verifies the effectiveness of the establishment in carrying out its recall by statistically sampling a percentage of consignees throughout the distribution chain.

Recall Termination

A recall is terminated when FSIS has completed its effectiveness checks and determined that the firm has made all reasonable efforts to recall the product, and that it has either disposed of the recovered product or it is under documented control. In addition, FSIS expects that the firm will notify the agency when the recall is complete through a closeout memorandum containing a list of consignees, the amount of product retrieved and actions taken.

Once a recall action has been completed, you should notify your consignees, thank them for their assistance and provide assurances that the problem has been corrected. In addition, your recall team should evaluate the recall process and determine if changes should be made to your recall plan.

In a future issue of *Small Plant News*, we'll address different food products and the other Federal agencies that may be involved in a recall. For more information on food recalls, visit the FSIS Web site at www.fsis.usda.gov/Fsis_Recalls/index.asp or call (202) 690-6520 if you need assistance in obtaining FSIS Directive 8080.1, Revision 4, Attachment 1, *Product Recall Guidelines for Firms*.

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- Distributor and customer information;
- Copies of any firm correspondence with distributors, brokers or consignees related to recall actions and a copy of any proposed press release; and
 - The name, title and telephone number of your facility's recall coordinator.

Initially this information may be provided orally. However, FSIS recommends you submit confirmation information on a data sheet to the recall management staff once it's collected. Shortly thereafter, FSIS will typically send one of its employees to your facility to review and verify the information.

Communicate Early and Regularly

Once you have the facts, contact your consignees, distributors or brokers (if you haven't yet) by telephone, FAX, e-mail or special delivery and provide them the following information:

- The suspect product subject to a recall;
- The immediate cessation of distribution or use of any remaining product;
- Notification of your consignees of the recall; and
- Your contact information (e.g., name and number).

If your facility provides notice of the recall by telephone or personal contact, FSIS expects you to document it and follow up with a written communication. Furthermore, follow up communications should be sent to those who did not respond to the initial product removal communication within a specified timeframe.

Next, you need to notify the public. Typically, FSIS develops press releases for class I and II recalls. The agency will develop the recall press release based on information you previously provided them. They, in turn, will give you 30 minutes to review and comment on it for accuracy. Then, they will distribute the release to the media, interested constituents and finally post it to FSIS'