

FOOD RECALL OPERATIONS FOR INDUSTRY

The impact of a recall on your business can be minimized by having an efficient, organized and expedited response. In cooperation with the Florida Department of Agriculture and Consumer Services (FDACS) and the U.S. Food and Drug Administration (FDA) and/or the U.S. Department of Agriculture (USDA) you will be able to work through the recall process. This document is intended to provide general guidance on executing and recovering from a recall. Several steps may take place concurrently.

Important Contacts:

<u>Florida Department of Agriculture and Consumer Services:</u>	<u>U.S. Food and Drug Administration:</u>	<u>U.S. Department of Agriculture:</u>
Serena Giovinazzi FDACS Recall Coordinator 850-245-5541 850-245-5520 Serena.Giovinazzi@FDACS.gov	District Office Maitland, FL 407-475-4700 ORAFLARecalls@fda.hhs.gov	District Office Orlando, FL 407-648-6651 MPHotline.fsis@usda.gov

Reporting the Recall

- ☐ If you have reasonable probability that a food you manufacture and/or distribute will cause serious adverse health consequences, you are required to report within 24 hours:
 - Contact FDACS by phone or email.
 - Complete a [Reportable Food Registry \(RFR\)](#). You will need a valid Food Facility Registration Number and the filing takes 20-45 minutes. Some fields may be left blank initially and amended later, as more information becomes available.
- ☐ The Recall Coordinator will work with you on recall operations and will provide assistance in drafting a public notification about the recall. Things to include: Product descriptions, distribution, sizes, lot codes, types of packaging, etc.



The Recall Investigation

Prompt identification of any affected products and source(s) of contamination may reduce the scope of the recall and time to withdraw the product from commerce. Working with your regulatory officials will help ensure an efficient and effective recall that protects the public health.

- ☐ Help the federal and state inspectors obtain the following:
 - Scope of the recall, which ensures the recall is not too broad (leading to additional losses) or too narrow (requiring subsequent or expanded recalls).
 - Up-to-date inventory for finished product, in-process material and/or raw materials present in your facility.
 - Up-to-date distribution, including a list of customers who received the product (could be sales records, shipping manifests, invoices or other business documents).
- ☐ Provide assistance and education to the federal and state regulatory personnel about the meaning of product or lot codes used in your facility. The more rapidly specific products or lots affected are catalogued, the more rapidly the recall can be concluded.

Public Notification

Your public notification campaign will be an integral part of the product correction/withdraw. Prompt, forthcoming communication with the public will protect your business and hasten the recovery process.

- ☐ Work with the FDACS, FDA or USDA Recall Coordinator to draft a recall press release notifying the public.
- ☐ Include as much information as possible about:
 - *Product name*
 - *Lot codes and UPC*
 - *Package description and size*
 - *Photo of product label*
 - *Reason for the recall - adulteration with a pathogen, misbranding, etc.*
 - *Distribution information*
 - *Recall instructions*
 - *Contact information*
- ☐ While FDA and USDA may release their own press release, every opportunity will be given to allow the food establishment to release the information first.

Restoration and Recovery

Once the recall is initiated, begin planning your strategy for preventing future occurrences. FDACS will provide support, approval and verification for your restoration and recovery. FDA and USDA may also be available during this phase and throughout the recall process.

FOOD RECALLS

Background

Recalls are actions taken by a food establishment to remove a product from the market and warn consumers who may have the product in their homes.

There are a number of situations that could result in a recall. Some examples might include undeclared allergens, bacterial or chemical contamination, or foreign objects.

It is the legal responsibility of the food manufacturing company to ensure that their products are safe, sanitary, and accurately labeled.

While the food establishment is encouraged to voluntarily issue a recall of potentially affected products, many recall efforts are collaborative and are often overseen by more than one regulatory agency; such as the Florida Department of Agriculture and Consumer Services (FDACS,) the Food and Drug Administration (FDA,) and the United States Department of Agriculture (USDA.)

Reporting and Issuing a Recall

If finished product samples have tested positive for a pathogen, or are otherwise adulterated or misbranded, please contact FDACS by phone or e-mail. Likewise, please contact FDACS if any environmental samples, from a food contact surface, test positive for a pathogen. In the event that samples obtained and analyzed by FDACS have been found adulterated/misbranded, you will be notified. The FDACS recall coordinator will assist you in determining if a recall is needed.

Once the determination has been made that a recall is warranted, you will need to:

1. Gather all pertinent information about the product subject to recall. This includes:
 - a. *Product Name*. What product is being recalled, specifically.
 - b. *Lot Codes*. What lots are subject to recall, and how they can be identified on the product packaging.
 - c. *Container(s) size(s)*. All affected sizes by volume or weight.
 - d. *Photo*. When possible, provide a photo of the product/label.
 - e. *Reason for the Recall*. What prompted the recall - adulteration with a pathogen, misbranding, etc. Include details informing customers of the risks, signs, and symptoms.
 - f. *Distribution Information*. Where was the implicated product shipped to.
 - g. *Recall Instructions*. What should customers do with the implicated product - hold for return, destroy, etc.
 - h. *Contact*. A valid contact name and number for anyone with further questions.
2. Complete a Reportable Food Registry (RFR) with the FDA. This is required if any of the product was shipped or left your control. <http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>
3. Draft *Recall Communication* which will be used to notify your customers. Once the draft is complete, please forward to FDACS for review and approval before issuing. The recall communication shall include all of the information in 1. above, and be free of extraneous or promotional material. An example and template have been provided in Attachment A.
4. Draft a *Recall Press Release*, if it is determined that the scope of your recall needs to include the general public. This shall contain many of the same elements as your recall communication and will be provided to local media/news outlets. As with the recall communication, please forward to FDACS for review and approval before issuing. Please provide FDACS proof that the *Press Release* was issued - this can be in the form of copying FDACS on any e-mails sent to press contacts; or providing the name and contact number for press sources contacted. Examples and a template have been provided in Attachment B.

Recall Effectiveness

The recalling food establishment will be responsible for ensuring that all customers who received the implicated product are made aware of the recall. You may be required to reconcile the amount of implicated product shipped, versus the amount sold to your customers to ensure that all of the recalled product is accounted for.

FDACS, FDA, and/or USDA will work with you and provide guidance if necessary to promote an effective recall. Once the recall communication has been issued, FDACS will conduct an *effectiveness check*, by contacting the customers who received the implicated product, to ensure that the recall was successful.

1-800 HELP FLA
www.FDACS.gov

Model Company Recall Notification Letter Template

Date

Customer Food Establishment Name & Address
ATTN: Contact Person Name & Title

Re: Recall of Type of Product

Dear Sir or Madam:

This letter is to confirm our telephone conversation that (Company Name) is recalling the following product because (Specify Recall Reason).

Describe the product, including name, brand, code, package size & type, establishment number, etc.

We request that you review your inventory records and segregate and hold the above product. If you have shipped any of this product we request that you contact your customers and ask them to retrieve the product and return it to you. Once you have retrieved all the product, please contact us.

We are undertaking this action in cooperation with the Florida Department of Agriculture and Consumer Services (FDACS.) FDACS officials may contact you to confirm that you have received this notice and are cooperating in this action.

Your prompt action will greatly assist (Company Name) in this action. If you have any questions, please do not hesitate to contact (Company Recall Coordinator) at (Phone Number).

Thank you for your cooperation.

Sincerely,

Company Office Name & Title

Model Press Release—Microbial Pathogen Contamination

Florida Company Recalls (Product) For Possible (Pathogen) Contamination

(City, date)--(Company Name) a (City, Florida) company is voluntarily recalling approximately (quantity) of (product) that may be contaminated with *pathogen*.

Specific information on how to identify the product can be identified (i.e. type of container (plastic, metal, glass), size or appearance of the product, product brand name, establishment number and location on package, flavors, codes, expiration dates, etc.

Product was distributed (listing of the states and areas where the product was distributed and how it reached consumers (ex: through retail stores, mail order, or direct delivery)).

Description of illness: “Consumption of food contaminated with (*Pathogen*) can cause (Symptoms and who is most likely affected.) Status of the number of and types of related illness that have been confirmed to date (ex: “No illnesses have been reported to date. Anyone concerned about an illness should contact a physician.”).

Brief explanation about what is known about the problem, such as how it was revealed, and what is known about its source. An example of such a description: “The problem was discovered through routine microbiological testing conducted by the Florida Department of Agriculture and Consumer Services.

Information on what consumers should do with the product and where they can get additional information. ex: “Consumers who have purchased (Product) are urged to return it to the place of purchase for a full refund. Media with questions about the recall may contact (name and position) at (phone number). Consumers with questions about the recall may contact (name and position) at (phone number.)

Sample Press Release—*Listeria monocytogenes*

XYZ Inc.
123 Smith Lane
Anywhere, FL

FOR IMMEDIATE RELEASE

DATE

Sam Smith /555-555-5555

XYZ RECALLS "SNACKIES" BECAUSE OF POSSIBLE HEALTH RISK

XYZ Inc. of Anywhere, FL, is recalling its 5 ounce packages of "Snackies" food treats because they have the potential to be contaminated with Listeria monocytogenes, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, listeria infection can cause miscarriages and stillbirths among pregnant women.

The recalled "Snackies" were distributed nationwide in retail stores and through mail orders.

The product comes in a 5 ounce, clear plastic package marked with lot # 1111111 on the top and with an expiration date of 12/12/99 stamped on the side.

No illnesses have been reported to date in connection with this problem.

The potential for contamination was noted after routine testing by the company revealed the presence of Listeria monocytogenes in 5 ounce packages of "Snackies."

The production of the product has been suspended while FDA and the company continue to investigate the source of the problem.

Consumers who have purchased 5 ounce packages of "Snackies" are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.

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Sample Press Release--Salmonella

XYZ Inc.
123 Smith Lane
Anywhere, FL

FOR IMMEDIATE RELEASE

DATE

Sam Smith /555-555-5555

XYZ RECALLS "SNACKIES" BECAUSE OF POSSIBLE HEALTH RISK

XYZ Inc. of Anywhere, FL, is recalling its 5 ounce packages of "Snackies" food treats because they have the potential to be contaminated with *Salmonella*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis and arthritis.

The recalled "Snackies" were distributed nationwide in retail stores and through mail orders.

The product comes in a 5 ounce, clear plastic package marked with lot # 111111 on the top and with an expiration date of 12/12/99 stamped on the side.

No illnesses have been reported to date in connection with this problem.

The potential for contamination was noted after routine testing by the company revealed the presence of *Salmonella* in some 5 ounce packages of "Snackies."

Production of the product has been suspended while FDA and the company continue their investigation as to the source of the problem.

Consumers who have purchased 5 ounce packages of "Snackies" are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.

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