

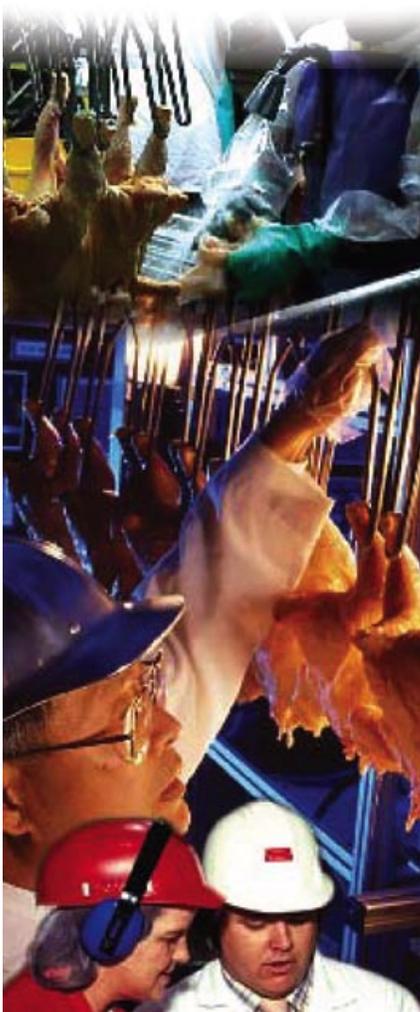
A Recall Program



Hazard Analysis Critical Control Point

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Outline

1. What is a recall program?
2. Written parts of the recall program
3. Evaluating the recall program
4. Inspection agency's role during recall
5. Action steps for the processor

On average, 41 Class I recalls (cases posing the highest health threat) involving 24 million pounds of food occur each year. Class II recalls average 10 per year, involving about 4 million pounds of food. The United States produces approximately 45 billion pounds of meat and poultry products annually.

(Data from USDA-Economic Reporting Service)

Introduction

Recall of an adulterated food product can be a very traumatic and trying experience for a small meat or poultry processor. Preparation beforehand can make the difference between a recall becoming a learning experience or a company nightmare. This fact sheet examines the needed parts of a recall program and explains how to create a recall program.

1. What is a recall control program and why do we need one?

All processing facilities, regardless of size, should have a recall program in place.

There are several potential ways that product can become adulterated and subject to a voluntarily recall, such as:

Problem/Issue	Reason for recall
Microbial tests indicate failure to meet performance standards	Critical control point did not control pathogens of concern
Failure to ensure HACCP critical limits have been met; inadequate pre-shipment approval; incomplete records	Inspection agency assumes product is adulterated
Adulterated ingredients	Safety or suitability problems with ingredients, leading to adulterated final product
Inaccurate labeling	Potential allergens could be included

A strong recall program may reduce a food company's liability, while a nonexistent or poor recall program can be a death blow for a company. Although not currently required by USDA's Food Safety and Inspection Service regulations, a recall program may soon be required to satisfy traceability mandates in the Federal Bioterrorism Act of 2002, Section 306 (www.cfsan.fda.gov/~dms/sec-ltr.html - sec306).

The recall program is the safety net that prevents consumers from obtaining an adulterated or potentially harmful product.

2. Written parts of the recall program

The written recall program will include many parts, all of which must be established and tested with mock recalls. Each part should be carefully constructed and completed. Here is a list of the parts.

1. Designate the primary person responsible as the recall coordinator. For a small facility, this individual usually will be the supervisor or a manager. Other responsible persons should aid the recall coordinator as part of a recall team. All necessary contact information for these individuals should be in the written recall program. Also, a designated media spokesperson should be identified. This often is the company owner or legal counsel.
2. Develop written traceability procedures that should be followed to locate shipped products. These procedures will include all necessary emergency contact information (phone, e-mail, fax) for persons in freight companies, warehouses, stores, etc. who are required to stop a recalled product from reaching consumers.

A note on traceability: A small processor must establish procedures to locate product. There are two forms of traceability: backward and forward. Forward traceability allows processors to determine the number of cases produced on a given date and where those cases were shipped. Backward traceability allows managers to determine the supplier and lot number of all ingredients included in a finished product code.



3. Establish procedures for how and whom to contact at the appropriate regulatory agency, either FSIS or FDA. These procedures should be written and include potential scope of the recall, adulteration issues, and steps that the company is taking to recall the product.
4. Be sure your written recall program includes all necessary contact information for your legal counsel and insurance adjusters.
5. Prepare sample statements for the media. Statements should be addressed for both print and television media coverage. They should attend to the concerns and the steps being taken to protect consumers' safety as well as instructions for consumers who may have purchased the recalled product. These statements should be made in consultation with legal counsel.
6. Prepare form letters to notify retailers that have received a recalled product what to do with pulled and/or returned product.
7. Compile a list of all other customers.

3. Evaluating the recall program through mock recalls

Just as school children conduct practice fire drills, the recall program should be tested and evaluated through mock recalls. The owner or plant manager should randomly pick a particular product or product lot and then test the recall coordinator and recall team's ability to locate and recapture all of the product. This drill will evaluate the effectiveness of the written plan and highlight areas where improvements should be made. The frequency of mock recalls should be determined by the owner or plant manager, depending on the training experience of the recall team and past effectiveness of the recall plan. A company may also hire a third party expert or a process authority, who is

an expert recognized by the FDA, to assess the written recall plan and mock recall procedures.

4. What is the inspection agency's role during recall?

There are three levels of food product recall. The type of recall depends upon the potential risk to consumers and is categorized by the inspection authority. Procedures recommended for recall of meat, poultry, and egg products are followed according to FSIS Directive 8080.1 (www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4.pdf).

Class I: The recall involves a health hazard where there is a reasonable probability that eating the food will cause health problems or death.

Example: Meat that is contaminated with pathogenic bacteria, such as *Listeria monocytogenes* in a ready-to-eat product such as lunchmeat.

Class II: The recall involves a potential health hazard where there is a remote probability of adverse health consequences from eating the product.

Example: Dry milk, a Class II allergen, is an ingredient in sausage without mention of dry milk on the label.

Class III: The recall involves a situation when eating the product will not cause adverse health consequences.

Example: Improperly labeled processed meat where water is added but is not listed on the label as required by federal regulations.



The role of the inspection agency is to notify the public of the recall through a press release and to monitor the effectiveness of the plant's recall procedures. Thus, a well-formulated and tested recall program greatly improves the ability of the plant to demonstrate that a successful recall was completed. The inspection agency conducts a sufficient number of "effectiveness checks" to ensure that the food plant is locating, retrieving, controlling, and disposing of the product according to regulatory requirements.

After the regulatory agency has determined that the plant has made all reasonable efforts to retrieve and appropriately dispose of the recalled product, the plant is officially notified by letter that the recall is completed and no further action is required.

5. Action steps for the small processor

- ✓ Select a recall coordinator and assemble a recall team.
- ✓ Determine the methods for traceability, both forward and backward, and write procedures necessary to locate product from either avenue.
- ✓ Write all necessary forms for the media, customers, etc. in preparation for interaction with the public.
- ✓ Contact a third party expert or process authority who can evaluate your recall plan for completeness and effectiveness.
- ✓ Conduct periodic mock recalls and retrain based on areas requiring improvement.

Other publications in this series

FS-20-W, Small Meat Processing Plants: Overview of HACCP (Hazard Analysis Critical Control Point)

▶ www.ces.purdue.edu/extmedia/FS/FS-20-W.pdf

FS-21-W, Small Meat Processing Plants: SSOP and GMP Practices and Programs (Sanitation Standard Operating Procedures and Good Manufacturing Practices)

▶ www.ces.purdue.edu/extmedia/FS/FS-21-W.pdf

FS-22-W, Small Meat Processing Plants: A Pest Control Program

▶ www.ces.purdue.edu/extmedia/FS/FS-22-W.pdf

FS-24-W, Small Meat Processing Plants: Verification Programs

▶ www.ces.purdue.edu/extmedia/FS/FS-24-W.pdf

FS-25-W, Small Meat Processing Plants: Selection and Maintenance of Temperature Measurement Devices

▶ www.ces.purdue.edu/extmedia/FS/FS-25-W.pdf

Additional resources

Purdue Department of Food Science,
▶ www.foodsci.purdue.edu/outreach

Food Safety and Inspection Service of the USDA,
▶ www.fsis.usda.gov

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