

The Food Recall Manual

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Association of Food
& Drug Officials

Recall Team

Date Assigned

ASSIGNMENT

PERSON

CONTACT INFORMATION

Senior Operations Manager

Alt. Manager

Publicity & Public Relations

Alt:

Marketing Specialist

Alt:

Scientific Advisor

Alt:

Logistics and Receiving Specialist

Alt:

Quality Assurance Specialist

Alt:

Accountant

Alt:

Attorney

Alt:

Administrative Support

24-hour Food delivery

Taxi Service

Miscellaneous

Recall Action Flow Diagram

The Diagram below is a quick-use reference tool to help user find pertinent sections in the Recall Binder that describes a given aspect of the recall action. A comprehensive Table of Contents appears on the next page.

Numbers in **Black** type refer to pages on specific topics relevant to the task required.
 Numbers in **Grey** type refer to forms that can be used for the task required.

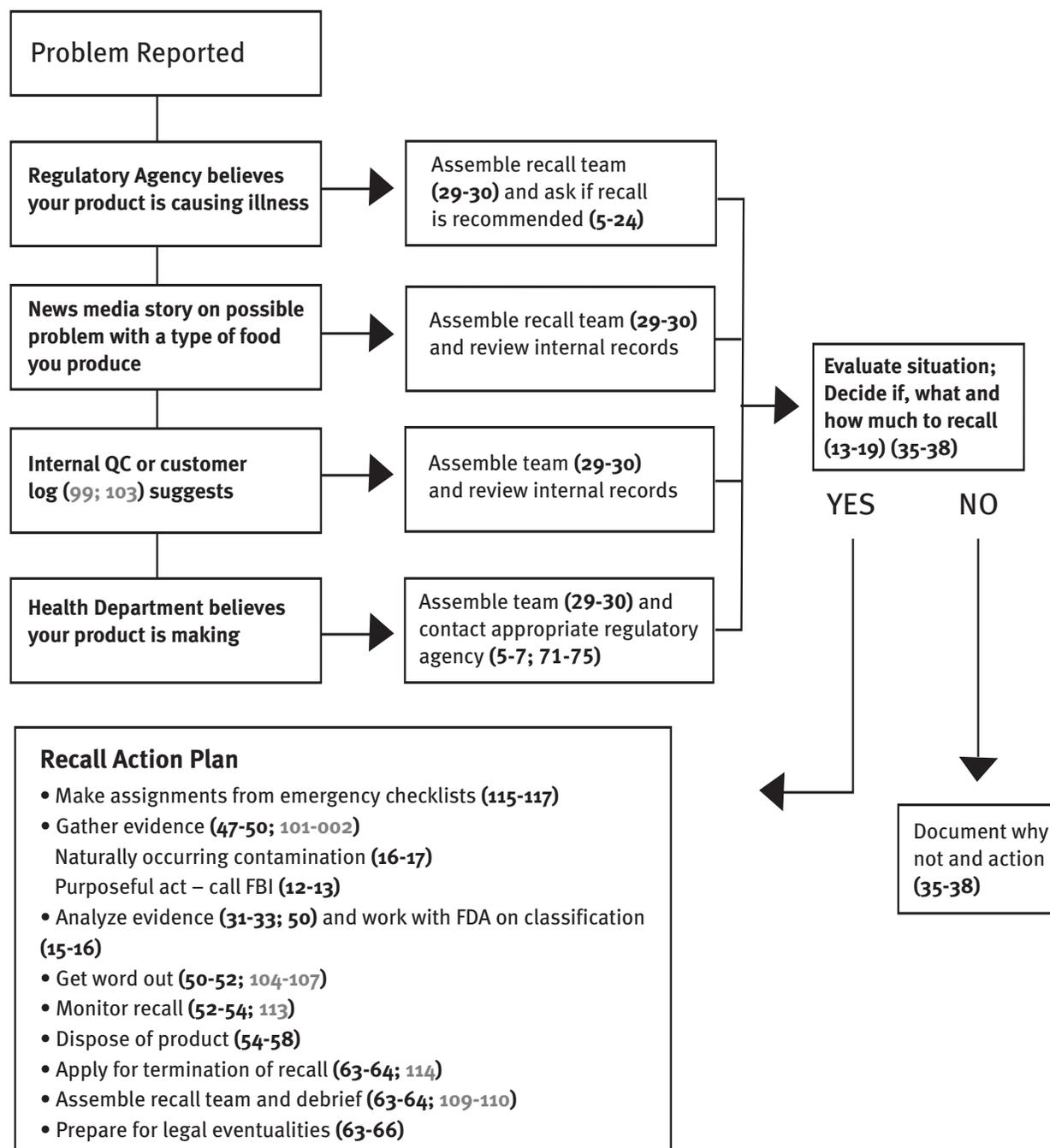


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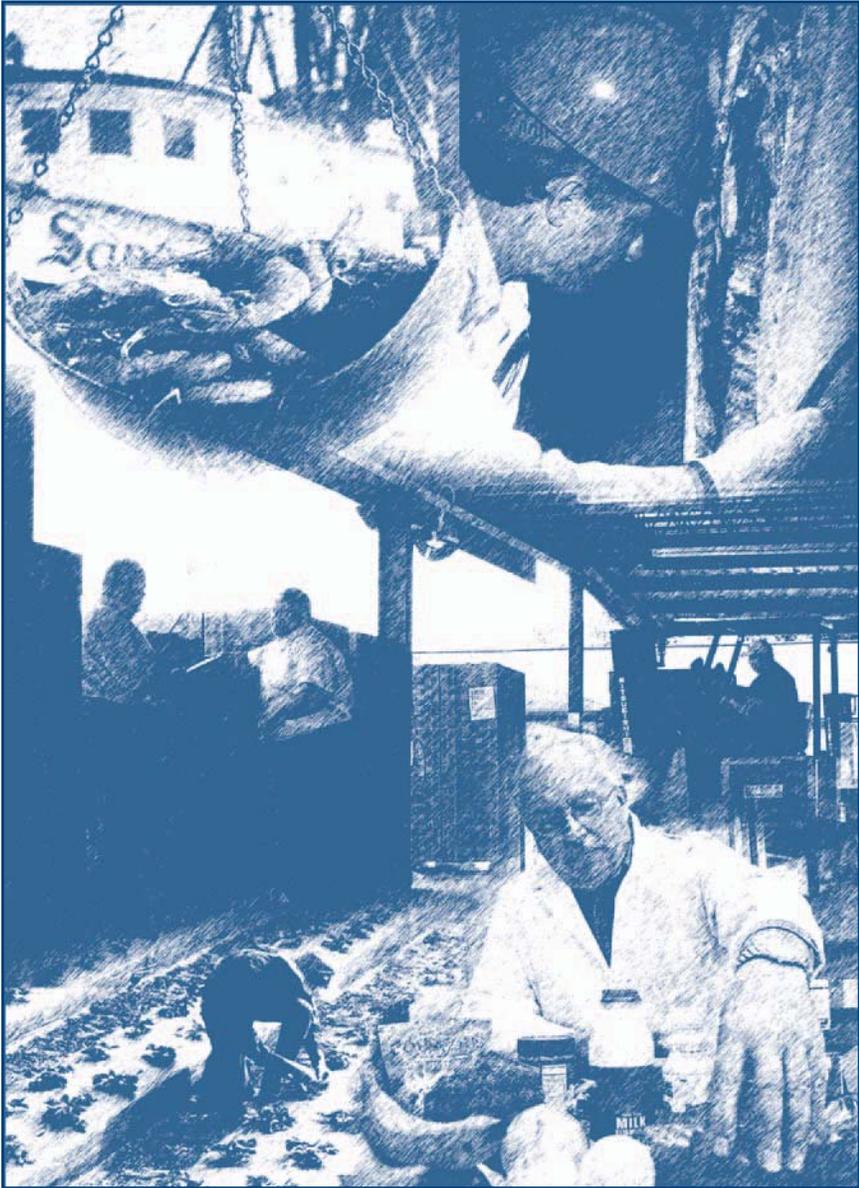
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WHY A FOOD RECALL MANUAL?



Section 1: Why a Food Recall Manual?

Recalls are procedures used to identify and recover potentially adulterated, misbranded, and/or hazardous foods in order to prevent potential food safety problems or economic fraud. The recall procedures outlined in this text are based on traditional industry practices that have proven to be effective for all foods, in all levels of commerce. The procedures comply with the expectations of both the state and federal regulatory authorities in the United States, and they apply to domestic and international commerce for all food products.

The threat of terrorism has now extended to the food supply. The possibility of food being used as a vehicle for biological, chemical, or physical agents of harm has been recognized for several years. There are some parallels between terrorism in the form of purposeful contamination of food, and product tampering. The main difference between the two is intent: the terrorist intends to create fear and economic chaos, with or without adverse effects on human or animal health. When an individual commits product tampering, it is usually with a motive to defraud, extort, or cause harm or death.

Preventing purposeful contamination of food is the ultimate goal, but from the experience gained from years of observing “natural” occurrences of food contamination, prevention is far from 100% achievable. Thus, assuming that total prevention is not possible, containment of an event becomes a worthy goal.

To that end, the Food Science and Human Nutrition Department of the University of Florida has assembled this manual to assist food businesses, at all parts of the food chain, in learning to conduct rapid and effective product recalls, should that become necessary. Quickly removing purposefully contaminated foods from commerce will undoubtedly limit human exposure, and thus, harm.

BACKGROUND

The current federal regulatory reference for recalls is the Code of Federal Regulations, Title 21, Parts 7.10 to 7.59; specifically Section 7.40, the “Recall Policy,” and similar renditions adopted by the respective state authorities. The U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture’s Food Safety and Inspection Service (USDA/FSIS) are the federal authorities that govern food recalls. FSIS has authority over meat and poultry products, and FDA has authority over most other foods. State and local agriculture and/or health authorities may solely possess or share recall authority, depending on the state.

In preparing this manual, the University of Florida’s Food Science and Human Nutrition Department team received invaluable assistance from the Association of Food and Drug Officials. AFDO provided the “Additional Information for Regulators” that appears at the ends of some chapters, and carefully reviewed all the manual contents with the Department team.

WHAT IS A RECALL?

A recall is the procedure(s) conducted by the responsible commercial firm to remove or correct a product in commerce that regulatory authorities (federal, state, or local) consider—or may consider—to be in violation of their food laws. For our purposes in this manual, this includes food that is suspected to have been purposefully contaminated.

In situations involving “naturally occurring” contamination, a company’s decision to remove or correct suspect product will be considered a recall only if:

The regulatory authority considers the marketed product to be in violation of its food laws and...

The regulatory authority concludes that the violation is serious enough to warrant legal action unless a voluntary correction or removal is undertaken by the company.

Newly promulgated federal regulations about bioterrorism give the federal government greater authority than ever before, including the ability to mandate recalls in cases of suspected terrorist acts.

The ability to remove products from the marketplace quickly and effectively has always been vital to businesses, large and small, which grow, pack, process, and distribute foods. Today it takes on added importance, since we have entered an era in which terrorists could use the food supply as a mechanism to disrupt commerce and cause public panic. So the goal of this manual, and accompanying training, is to prepare businesses for the possibility of recalls, and to enhance their ability to conduct rapid and effective removal of foods from the marketplace.

WHAT CAN PROMPT A RECALL?

There are a number of situations that can result in a food product recall. Some are emergency situations; others are not. The following alphabetical list was compiled with the assistance of the AFDO; many of the topics are elaborated on in other parts of this manual.

- **ALLERGENS** - A product or component containing an unlabeled ingredient that may cause an allergic reaction in humans. (The list of common allergens, nicknamed the “Big Eight,” can be found in the glossary of this manual).
- **BACTERIAL CONTAMINATION** - Contamination by spoilage organisms or harmful bacteria, which may be the result of processing equipment malfunction, mistakes in the production process, hygiene issues, etc.

- **CHEMICAL CONTAMINATION** - Use or presence of unapproved pesticide, herbicide, fungicide or animal drugs; and/or residues of these items in amounts that exceed established residue tolerance levels; excessive sanitizer, industrial cleaners, solvents.
- **COMMUNICABLE DISEASES** - Human illnesses that can be transmitted through foods.
- **COMPANY-GENERATED INFORMATION** - Companies find problems with products through their own internal record review and examination processes and decide to recall as a precaution.
- **FOREIGN OBJECTS** - Production line mishaps may introduce foreign objects (such as glass, plastic or metal fragments) into food products; or they may be present in the ingredients a firm receives from a supplier.
- **ILLNESSES IDENTIFIED BY STATE HEALTH DEPARTMENTS OR CDC** - State health departments and/or the Centers for Disease Control and Prevention (CDC) may issue a news release when their epidemiological investigations implicate a particular brand of product, or even a type of food, as causing illness.
- **IN-HOUSE SABOTAGE** - A firm's workers or suppliers might deliberately cause product defects, chemical contamination, etc.
- **MISBRANDING** - Food product labels that do not declare ingredients or misstate nutrient composition. A recall may result if the label claims are false or misleading, net content statements are inaccurate, or if printing errors occur in labels that result in misstatement of facts.
- **PACKAGING DEFECTS** - Includes faulty seams, microscopic leaks, etc.
- **REAL OR FRAUDULENT CONSUMER CLAIMS** - Consumer complaints filed with and investigated by state or federal regulatory agencies may prompt a recall if the complainant was injured or made ill by a product; or if the allegation is serious enough to pull product off the market until a more thorough investigation is done.
- **SCIENTIFIC REPORTS** - Data from government agencies or recognized scientific organizations suggesting a potential problem with a food can prompt regulatory agencies and food firms to take recall action.
- **SUPPLIERS' NOTIFICATION** - Sometimes a company must participate in someone else's recall—an ingredient or equipment supplier that has reason to believe there is a problem with its own product, and needs its customers' and end users' cooperation to round up the affected inventory.
- **TAMPERING AND TAMPERING THREATS** - Federal investigators can help the company determine whether an intentional threat to a company or product warrants the removal of the targeted product from distribution.

- **UNDECLARED INGREDIENTS** - A product or components that contain ingredients not listed on the label; often allergens.

THE DECISION TO RECALL

As you can see from the above list, there are plenty of potential pitfalls in the food processing and distribution process. Most often, a business first learns of a threat or problem from a local, state, or federal government agency, so it is very important that the affected business have the right group of people trained and available to understand the nature of the threat, whether suspected or real, and then to assist in the most critical decision the business will make—whether or not to embark on a product recall.

This group of people is the company's Recall Team. In case of a potential recall, the team must be prepared to document all information that is available to support their decision—either to recall, or not. **IT IS IMPORTANT TO REMEMBER THAT A RECALL IS, UNTIL OTHERWISE DETERMINED BY LAW, A VOLUNTARY ACTION.**

If the initial notification comes from a buyer or a regulatory agency, the decision NOT to recall must be discussed and **AGREED UPON MUTUALLY**. Otherwise, the buyer could discontinue business; a regulatory agency could proceed with punitive actions; and the company could incur greater liability in the event of a health or safety problem.

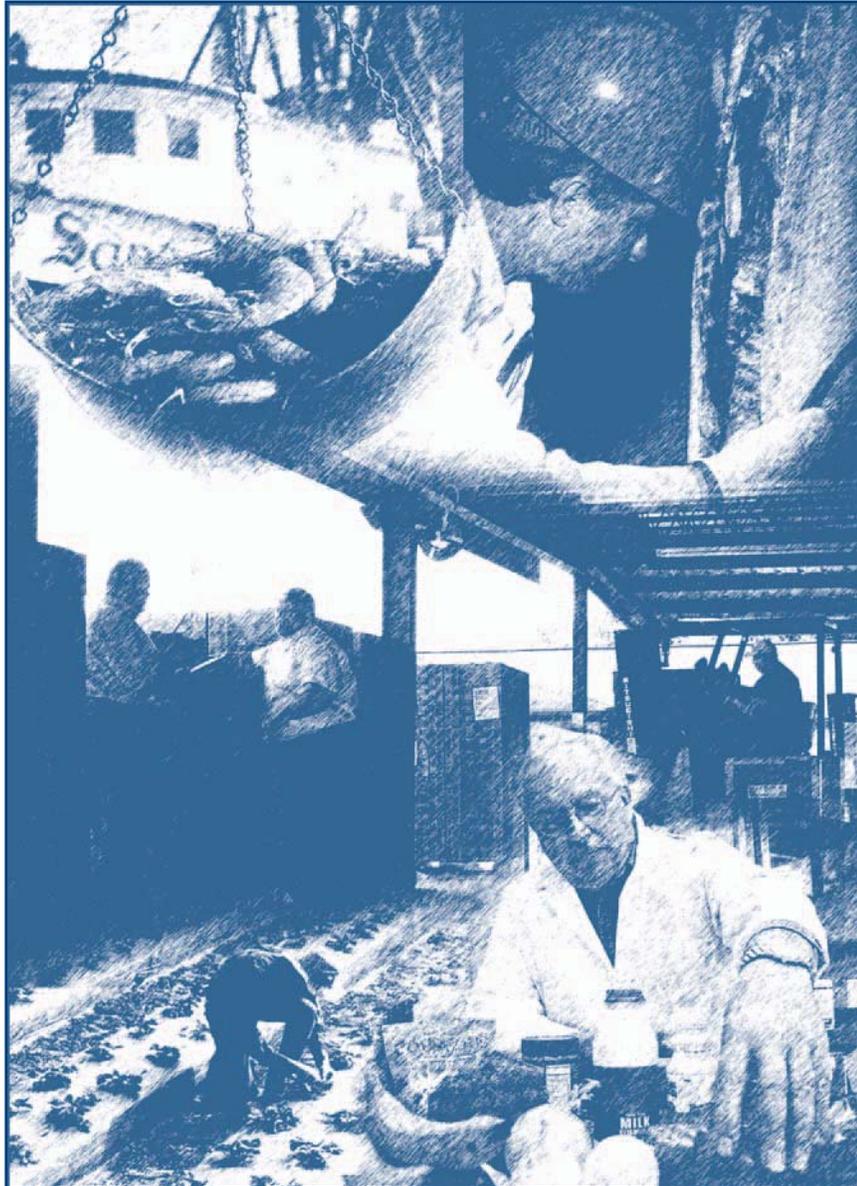
The size of the Recall Team will vary depending on the business. The group is convened as necessary to assess a situation and make the recall decision. Some Recall Teams meet on a regular basis to review the company's recall-related policies—about safety, health, insurance, security, etc.—and to practice mock recalls to test their plans. In this manual, you will learn the process for creating a Recall Team and conducting such exercises.

USING THIS MANUAL

This manual is available in electronic format, for free and open use by anyone. It includes information for companies, and also for employees of regulatory agencies, so that each group or Recall Team member can learn more about what the others expect of them.

As a working manual, it contains decision trees, checklists, a glossary, Internet addresses, and other practical resources that may be useful during an actual recall event.

AN INTRODUCTION: FOOD SAFETY AND YOUR LEGAL RESPONSIBILITY



If you discover, or even suspect, a problem with the food product you are manufacturing, distributing or selling, you have certain duties—both legal and ethical—to do whatever you can to correct the problem. But exactly what do you have to do, and who requires it? That is the topic of this wide-ranging chapter, which is arranged in question-and-answer form to cover some of the most common issues and explain the food safety laws.

The officers and employees of a food manufacturing company have a legal responsibility to ensure that their products are safe, sanitary and accurately labeled. Today, carrying out this responsibility encompasses a lot more than the knowledge and practice of basic sanitation and packaging methods. Issues like prevention of product tampering and bioterrorism by purposeful contamination are also at the forefront, as well as avoidance of consumer or customer lawsuits.

Ironically, the same agencies that can help curb these frightening prospects can also take you to task, or to court. How you handle these events may determine whether your business survives a product recall.

WHICH GOVERNMENT AGENCIES DEAL WITH FOOD SAFETY ISSUES?

State and local agencies that regulate the food industry safeguard the public health and promote public welfare by protecting the consuming public from adulterated or misbranded food products. It is impossible to mention each and every state's specific regulations here. But we can say most food-related businesses are granted licenses or permits by one or more state or local agencies, and are subject to routine safety and sanitation inspections by these agencies, so we'll begin there.

STATE AND LOCAL AGENCIES

Depending on your location, this official regulatory agency could be your state department of agriculture or health department, another state agency, or a local health department. The latter may be a city or county agency.

Regulatory inspections by these agencies may turn up something questionable, and violations of laws or ordinances may result in fines or other actions. Other regulatory officials may visit because an end user of a manufacturer's product (a restaurant, for instance) has reported an illness outbreak, and the agency that regulates the end user needs to rule out the manufacturing process as a possible cause of the illness.

State or local epidemiologists (usually affiliated with county or state health departments) also play a role in identifying foods responsible for illness out-breaks, because often that is where consumers will call to "report" the illness. These experts can link cases that may otherwise appear to be isolated, and should be able to objectively gather data that will help you pinpoint potential problems. The local agencies are sometimes very aggressive in reporting problems to the federal agencies for further investigation. However, a state does not have to ask for federal assistance in investigating a disease outbreak.

Local or state agencies may coordinate voluntary recalls for firms operating within their jurisdiction, or assist federal regulators with recall investigations and effectiveness checks (USDA-regulated products) and audit checks (FDA-regulated products). Many state agencies also have their own state-mandated authority to embargo or seize adulterated or misbranded products if a firm does not adequately remove products from commerce.

To summarize, the local and state agencies are often the public's first line of defense in foodborne illness cases. For their federal counterparts, they serve as an important extra set of eyes and ears in the food distribution chain, so it's probably smart to think of inspections and complaint collection as helpful instead of intrusive.

FEDERAL AGENCIES

On the federal level, the **Centers for Disease Control and Prevention (CDC)** maintains three national networks that receive and coordinate health-related data from all the states. This is another critical step in tracing the distribution of potentially hazardous products. The three networks are:

- The Foodborne Diseases Active Surveillance Network (FoodNet) consists of programs in nine states doing regular surveillance for and tracking of the epidemiology of foodborne illnesses. By “active,” they mean researchers contact health officials and look for prospective problems or outbreaks, instead of relying only on incoming reports.
- The National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS) is a group of public health labs in 28 states and cities that routinely send microbe samples (of *Salmonella*, *Shigella*, *E. coli* O157:H7 and others) to the CDC for susceptibility testing—that is, to see if they are becoming resistant to conventional treatments, like antibiotics.
- The National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet) is a network of public health laboratories in the U.S. and Canada that can perform a specific DNA “fingerprinting” test (called pulsed-field gel electrophoresis, PFGE) on foodborne bacteria. The fingerprint can be used to identify specific strains and origins of bacteria. The labs make the results available on PulseNet for quick comparison.

Several groups work within the CDC, keeping tabs on food safety issues, collaborating on research and reporting their findings. They include a Foodborne Outbreak Response and Surveillance Unit, the Epidemiological Program Office and the Epidemic Intelligence Service (EIS).

Other, external government organizations also collaborate with the CDC. These are the agencies that food processors are likely to come into contact with:

- The **Food and Drug Administration (FDA)**, which is part of the Department of Health and Human Services (HHS). FDA is responsible for the safety and purity of all food products (including chewing gum, shell eggs, and animal feed), with the exception of meat and poultry. By agreement with the USDA, the FDA oversees recalls that involve egg products.
- The **Food Safety Inspection Service (FSIS)**, which is part of the Department of Agriculture (USDA). FSIS is responsible for safety of meat, poultry and egg products and inspects thousands

of processing plants annually. (See the note above about the FDA's responsibility in recalls of egg products.)

- The **Animal and Plant Health Inspection Service (APHIS)** is also part of the USDA. APHIS is charged with protecting against plant and animal pests and diseases.
- The **Environmental Protection Agency (EPA)** regulates pesticide use and is responsible for establishing safe standards for pesticide residue in raw agriculture commodities and in foods sold in interstate commerce. (The FDA, and the USDA agencies, monitor food products for pesticide residues and enforce the EPA tolerance limits).
- And of course, the **Federal Bureau of Investigation (FBI)** gets involved if terrorism, extortion or intentional product tampering is an issue. (More about this later in this chapter of the manual.)

When the CDC or any of its “branches” suspects a disease outbreak, their responsibility is twofold: to identify the source of the problem and—in concert with regulatory agencies—to stop it from spreading as quickly as possible. The CDC has the authority (as part of an epidemiological investigation) to inspect food processing facilities, and homes of people who claim to be victims. They collect medical information, analyze bacteria isolated from patients, and notify state and local officials if necessary. They may investigate multi-state disease outbreaks, if asked by individual states. CDC employees are not legally allowed to testify in court about the data they collect, but the actual data may be used in court, either to prosecute or defend a company accused of manufacturing, distributing or selling unhealthful products.

What do the laws say?

This manual cannot begin to thoroughly cover state and local food safety ordinances, since they vary widely. However, most follow the basic guidelines of the federal food safety laws. The big difference is that, in most jurisdictions, health department personnel have the right to unannounced inspections of food facilities, to check the following items and conditions:

- Food protection—whether containers are properly stored, sealed and labeled.
- Proper food temperatures during storage, preparation, holding and serving.
- Safe handling of food and ice; correct use and sanitation of utensils and food contact surfaces to prevent cross-contamination.
- Hygiene practices of employees, and restriction of any infected or ill employee from working with food.
- Construction and installation of equipment for maximum safety.
- Adequate ventilation, especially in cooking and dishwashing areas.
- Safe water temperatures of dishwashing machines.

- Safe water sources; adequate hot and cold running water.
- Proper disposal of sewage and wastewater.
- Adequate numbers of toilets, sinks and separate hand-washing sinks.
- Clean, covered interior trash receptacles, and exterior dumpster facilities that are properly constructed and enclosed.
- Insect, rodent and animal control (with written records available for inspection).
- Floors, walls, ceilings washable and in good repair; working floor drains in food preparation areas; lighting adequate and fixtures shielded in case of bulb breakage.
- Toxic items (like cleaning materials) properly labeled and stored.
- Proper storage of clean and soiled linens, dishtowels, etc.
- A no-smoking policy, or designated smoking areas, which must be clearly marked.
- If a grease trap is used, its clean-out records must be available to inspectors.
- Emergency procedures (Heimlich maneuver, etc.) must be posted prominently in many foodservice work areas, along with any permits the city, county or state requires of the particular type of business.

Depending on the situation and the inspector, these can be very thorough and time-consuming processes. Think of them as additional eyes and ears, and be open to the findings of the inspectors. More and more often, it is a state health department that initiates a complaint instead of a federal agency.

In addition to your own city and county ordinances and state laws, there are federal laws that govern food-related product quality and/or contamination. The pertinent federal acts and/or legislative activities that involve food safety are summarized on the next few pages.

The Food, Drug and Cosmetic Act (FDCA)

First enacted in 1938, the FDCA replaced the Pure Food and Drug Act of 1906. The primary intent of the FDCA is to prevent adulteration or misbranding of food products in interstate commerce, and it is enforced by the FDA. The FDCA sets the framework for FDA's regulations, which are codified and published under the Code of Federal Regulations (CFR), Title 21. For example, "current Good Manufacturing Practices" (cGMPs) published under 21CFR110 provide the sanitation inspection requirements used by the agency.

Under FDCA, the FDA has several enforcement procedures at its disposal, both judicial and non-judicial:

- Judicial actions involve the U.S. Marshall's Office and the court system. They may include criminal action (which is clearly defined in the FDCA), or a civil action, such as an injunction or a product seizure. More information about these two terms:
- An injunction is a court order which requires a person or company to refrain from certain, specified actions. Thus, an injunction can be used to stop a food manufacturer "in its tracks."
- A seizure, by definition, is an in rem action (that is, an action against the goods involved, and not against any business or business entity), and is used to remove violative products from the marketplace.
- Non-judicial actions include product recalls, the issuance of warning letters, and/or various types of publicity, like including an action in the weekly FDA Enforcement Reports.

The Meat, Poultry and Egg Inspection Acts

The federal acts enforced by FSIS include:

- The Federal Meat Inspection Act (FMIA), enacted in 1906.
- The Poultry Inspection Act (PIA), enacted in 1957.
- The Egg Products Inspection Act (EPIA), enacted in 1970.

The FMIA and PIA were each amended in the 1960s to provide for federal (or equivalent) inspection of those meat and poultry facilities which are not involved in interstate commerce, and they may be referred to by their "newer" names, the Wholesome Meat Act of 1967 and the Wholesome Poultry Act of 1968. FSIS regulations for enforcing these acts are published and codified in the CFR, Titles 7 and 9.

In general, the FMIA and PIA govern safety, sanitation, wholesomeness, packaging and labeling of meat and poultry products. They also include rules about the humane slaughter of animals and safe transporting of food throughout the steps of processing. The EPIA governs pasteurization and sanitation requirements in egg product processing facilities.

The acts enforced by FSIS were among the first to address safety and cleanliness of food processing plants, including equipment, evidence of pests and rodents in every step of production, employee hygiene, and cross-contamination in product handling. They also cover mislabeling of products and require FSIS to enforce product uniformity standards. As an example, a can of "chile con carne" must meet certain standards for specific quantities of meat and fat to ensure product consistency, no matter where it is manufactured.

Plants under FSIS inspection must apply for the inspection program, and must demonstrate their ability to meet the agency's sanitation, facility and operational standards. The plants must also show that they have "preventive systems in place" to ensure the production of safe, unadulterated food. In exchange, the products from these plants are labeled with a "mark of inspection," a sort of seal of approval indicating they have passed federal inspection or the equivalent. The inspections are done by FSIS personnel, who may be resident inspectors with full-time offices located within the inspected facility.

If FSIS inspectors find a problem, they write a Noncompliance Report (NR) or a Process Deficiency Record (PDR) explaining the problem and notifying the plant manager that action must be taken to correct it. For the most part, a plant can continue to operate while the problem is being remedied. However, when there are repeated or serious problems, FSIS Compliance Officers can take any of these more stringent actions:

- Detain products that have already been produced and shipped but may be unsafe—that is, forbid them to be sold. (After a detention, FSIS has 20 days to ask a federal court for permission to seize the product.)
- Issue a Letter of Warning (LOW), telling anyone who makes, distributes, stores or sells the product in question that FSIS “may seek criminal action” based on continued violations.
- Withhold marks of inspection—and without that official mark, the product cannot be sold.
- Suspend inspection of the plant temporarily, which also effectively means part, or all, of a plant’s operations are shut down. The term used in a suspension is that the plant is being “held in abeyance” until the problem is remedied.
- Withdraw inspection entirely, which means the product that comes from the plant is no longer USDA-approved for sale and, therefore, cannot be sold.
- Take judicial or non-judicial actions, using procedures similar to those described earlier for the FDA.

FSIS is also responsible for inspection of imported meat, poultry and egg products. This is a two-part system:

1. FSIS monitors the laws and food safety controls within the exporting country to be certain they are equivalent to those of the United States and grants them the ability to export to the U.S., and...
2. FSIS inspects random lots of incoming product to verify that the exporting country’s system is working.

Violative food that does not meet the U.S. health and safety guidelines is required to be exported back to its source, destroyed or, in some cases, converted to animal food.

Interesting Statistics on Compliance

How prevalent are these problems? In one recent three-month period, the USDA's FSIS Compliance Officers:

- Issued 27,528 NRs and 6,416 PDRs.
- Detained 1.8 million pounds of product in 191 actions.
- Issued 562 Letters of Warning.
- Suspended or withheld inspections at 56 plants.

In the same three-month period, 40,085 lots of imported meat and poultry arrived in the U.S., representing more than 861 million pounds. Of those lots, 6,744 were inspected on arrival, and 2,183 lots (a little over 2 million pounds) were refused entry into the country. Of the 125 lots of eggs that were examined, none was refused entry.

Hazard Analysis of Critical Control Points (HACCP) and Food Regulation

In the 1990s, federal regulatory agencies embarked on programs to require Hazard Analysis of Critical Control Points in certain segments of the food industry. A critical control point is any point in a food manufacturing or preparation process at which a loss of control may result in a health risk. HACCP is a seven-step risk management system:

1. Identify hazards and assess their severity and risk.
2. Determine the critical control points (CCPs).
3. Determine the critical control limits (CCLs) for each CCP.
4. Monitor the CCPs and record the data.
5. Take corrective action whenever the monitoring indicates a CCL has been exceeded.
6. Establish procedures to verify that the HACCP system is working.
7. Keep thorough documentation of these actions.

The FDA has clearly embraced the HACCP system, with requirements for seafood facilities (21CFR120) effective in 1997; and for fruit and vegetable juice facilities (21CFR123) effective in 2002.

In general, the FDA's HACCP rules require facilities to:

- Operate under an acceptable HACCP program—in fact, absence of a HACCP plan is considered adulteration under FDCA.

- Appropriately train all personnel.
- Have specific prerequisite programs in place (like compliance with cGMPs, and sanitation control procedures).

The agency has also initiated a voluntary HACCP program for fluid milk and milk products, and has been involved with pilot HACCP programs with a variety of food industries.

The FSIS HACCP rules for meat and poultry (9CFR417) became effective in 1996. In addition to requiring the HACCP system, this very detailed rule (often termed the “Mega Reg”) requires:

- All meat and poultry plants develop written Standard Operating Procedures (SSOPs)
- Mandatory *E. coli* testing for slaughter plants.
- Specific standards for Salmonella risk reduction for slaughter plants and ground meat producers.
- *Listeria monocytogenes* interventions.

What if bioterrorism is suspected?

There are two relatively new federal laws in the U.S. as a result of today’s heightened awareness of bioterrorism and other types of product scares from external sources. The Federal Anti-Tampering Act (FATA) was passed by Congress in 1983, making it a federal crime to tamper with consumer products, and authorizing the FDA to investigate allegations of product tampering. The law contains five violations:

- Tampering, or attempted tampering, with a consumer product with reckless disregard for the risk of death or bodily injury.
- Tainting a consumer product with intent to cause serious injury to the business of any person.
- Knowingly communicating false information that a consumer product has been tainted.
- Knowingly threatening to tamper with a consumer product.
- Conspiracy to tamper with a consumer product.

Tampering, or even the threat of tampering, is very serious business. It must be reported to the Division of Emergency and Investigational Operations (DEIO) of the FDA. FDA Regional offices will take their probe a step further, notifying their region’s Office of Criminal Investigations (OCI) field staff. The OCI then deals with other law enforcement agencies and keeps them updated as necessary.

In 2002, the U.S. Congress passed PL 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act—most often known simply as the Bioterrorism Act. This legislation, which is especially directed at food imports, will greatly enhance the overall effectiveness of the FDA with regard to protection against food adulteration.

In addition to major budget increases, the FDA now has administrative detention authority for a 30-day time period for food products when there is “credible evidence or information of a threat of adulteration.” It will also require registration of domestic and foreign facilities involved in food manufacture or handling, and it gives the FDA increased access to company records.

The Federal Bureau of Investigation (FBI) is routinely alerted in all product-related investigations that involve:

- Extortion
- Serious injury or death
- Threats of terrorism
- Significant false reports

Protocols may be different if the federal Department of Homeland Security becomes involved. In any case, if these situations are suspected, preservation of evidence becomes another critical element in cooperating with federal investigators. Other important elements in bioterrorism situations such as record keeping state embargo authority will be addressed later in this manual.

What is the regulatory basis for food product recalls?

You often hear or read in the news media that a company has been “ordered” to recall a product. In fact, the federal regulatory agencies such as the FDA or FSIS do not “order” recalls—they “request” them. The only food product for which the FDA has jurisdiction to force a recall is infant formula, when evidence shows it has been “adulterated or misbranded.”

Proposed legislation (termed the Food Safety Enforcement Enhancement Act) was introduced in Congress in 1997 to give federal agencies the additional authority to require the recall of food that presents “a threat to the public health,” notably foods contaminated with foodborne pathogens. However, at this writing, there has been no further action on this legislation.

In general, while recalls are voluntary, it is usually in the best interest of a food facility and its owners or managers to fully cooperate and initiate a recall when requested. Federal agencies can, and probably will, take more stringent actions—such as those described elsewhere in this section of the manual—when a product poses a significant risk to human health, if the manufacturer or distributor is unwilling to launch a voluntary recall, or if the agency decides the company’s voluntary action is ineffective.

The FDA, for instance, is candid about the fact that before it formally requests a recall, it usually already has evidence capable of supporting legal action. And even if a recall takes place—requested or voluntary—the agency can still take legal action against the company at a later date.

The Code of Federal Regulations, Title 21, Part 7 (21CFR7; see Appendix 8) contains the Enforcement Policy for “removing or correcting” food and drug products in the marketplace that are “in violation of laws administered by the FDA,” and it outlines the recall procedures to be used either by the FDA or FSIS. 21CFR7 is a thorough guideline for what can be expected in a potential recall situation.

Here is a summary of what it says:

- Recall is a voluntary action, a way for manufacturers and distributors to carry out their responsibility to public health...from products that present a “risk of injury or gross deception or are otherwise defective.”
- Recall is an alternative to FDA (or FSIS) initiated court action, and a recall may be undertaken with or without a request by the agency.
- The agency appoints a Health Hazard Evaluation Committee to evaluate the potential danger presented by any product being considered for recall. The committee looks at things like whether any disease, injury or death has already occurred, and what documentation there is to associate these occurrences with the product.
- The committee looks at the label directions on the product, and decides whether “any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard.” In short, was it used correctly, or misused? Mislabeled?
- Was it a product malfunction? In the case of a food, adulteration? In the case of a drug or cosmetic, an incorrect formulation? A quality issue, like contamination? Badly designed? All possible problems are taken into account.
- The committee assesses the problem’s potential impact on various segments of the population (such as high-risk individuals: children, senior citizens, immuno-compromised consumers, etc.); the “degree of seriousness” of the health hazard; and its actual likelihood of occurrence.
- The committee also considers the short-term and long-term consequences of the potential hazard. Then, it assigns a classification (Class I, II or III) to indicate the relative degree of danger.

What are the recall classifications?

The recall classifications often involve the presence of bacteria and/or substances that may prompt allergic reactions. For more information about these substances, please refer to the glossary of this manual, under headings like “Allergens,” “Big Eight,” “Sulfites,” or the name of the bacteria type.

The USDA determines the percentage of any undeclared allergen in a particular food product before determining the class of the recall. The degree of decomposed, mold-contaminated or undeclared sulfites affecting a food product may affect the recall classification as well. Therefore, USDA recall classifications can be subject to a case-by-case review. The FDA also has some flexibility, in that every recall is classified based on the individual situation. But there are established precedents where certain situations always fall into the Class I recall category.

CLASS I

A Class I recall means there is “a reasonable probability” that the use of the violative product will cause serious adverse health consequences or death. Examples of Class I recall situations:

- Product tampering or mislabeling of a lifesaving drug.
- Confirmed cases of *Clostridium botulinum* toxin in food.
- *Listeria monocytogenes* in ready-to-eat foods.
- All *Salmonella* in ready-to-eat foods.
- Undeclared allergens—a food that contains an ingredient that is a common cause of serious allergic reactions but is not labeled to indicate these contents. ‘Class I’ recalls may include: peanuts, tree nuts, eggs, dairy products or milk derivatives including casein, fish, shellfish, and soy.
- Undeclared sulfite (also an allergen) content of 10 milligrams or more per serving.

CLASS II

A Class II recall means the use of a violative product may cause temporary or medically reversible adverse health consequences, or the probability of serious adverse health consequences is remote. Examples of Class II recall situations:

- A drug that is below its labeled strength level, but is not used to treat life-threatening conditions.
- Non-FD&C certified colors or undeclared FD&C Yellow #5 or #6.
- Botulinum potential
- Norovirus (Contamination in seafood)
- Undeclared sulfites (3.7 – 9.9 milligrams per serving)
- Undeclared allergen - wheat
- Unapproved additives or ingredients (e.g., coumarin, nitrites in certain species of fish, ponceau 4R, artificial sweetener, alcohol)
- Potentially hazardous products that have been temperature abused for sufficient time that they might potentially pose a risk to consumers.
- A diet product that contains more fat or calories than its label indicates and may be problematic for diabetics.
- A food that requires refrigeration but is not labeled with this precaution.

CLASS III

Class III recalls are for products that violate federal regulations but are unlikely to cause adverse health consequences. Examples of Class III recall situations are:

- Drugs that contain fewer tablets than are advertised on the label.
- So-called “economic fraud,” which includes incorrect weight or volume labeling, or non-organic products being labeled as organic.
- A diet soft drink that is mistakenly labeled as a regular soft drink.
- Minor labeling problems.
- Undeclared certified FD&C colors (other than FD&C Yellow #5 and #6).
- Undeclared sulfites (less than 3.7 milligrams per serving).
- A food that contains yeast or mold contamination (except fresh breads).
- A food product that may have been produced under unsanitary conditions or that is decomposing.

The agencies realize that some types of contamination (dirt, mold, insect or rodent infestation, etc.) are routine occurrences in almost any manufacturing process. Both the FDA and FSIS have set what they call “action levels,” or “defect action levels” (DALs) for these items. If the problem exceeds the action level, it may become subject to regulatory action. However, these action levels are not binding, and are considered on a case-by-case basis by the agencies.

What does the law say about creating a recall strategy?

The Code of Federal Regulations, Title 21, Chapter 7 (21CFR7) outlines steps for a recall strategy, and lists these items as important in creating a strategy:

- The results of the health hazard evaluation.
- The ease (or difficulty) in identifying the product.
- The “degree to which the product’s deficiency is obvious to the consumer or user.”
- The “degree to which the product remains unused in the marketplace.”
- The “continued availability of essential products.”

The CFR states that a company should do everything possible to put the recall into motion promptly; not to wait until the FDA or FSIS reviews or approves its recall strategy. It says a recall strategy “will address” these topics:

- Depth of the Recall—that is, exactly who returns the products? How far (up or down) the distribution chain did the product go?

There are three options here:

1. Wholesale Level: includes wholesalers and distributors, but not retailers.
 2. Retail Level: includes every distribution level EXCEPT the consumer, both wholesale and retail.
 3. Consumer or User Level: a recall to the final consumer or user of the product.
- Public Warnings—A public warning may or may not accompany a recall. How extensive should it be, and how quickly must it be launched? There are general warnings in the news media (national, regional, local); others through the professional or trade press; still others to specific professions or population segments, like doctors, hospitals, schools, nursing homes, etc. The investigating authority will want to see a “public warning and plan for distribution” by the company when it analyzes a recall strategy.
 - Effectiveness Checks—This is a way to measure how well the recall is working, whether everyone who was supposed to has received the proper notification, and how they acted on it. FDA and FSIS rate the levels of effectiveness as “A” through “E,” depending on what percentage of consignees are contacted about their participation in the recall.
 - Level A is 100%.
 - Level B is more than 10% but less than 100% of consignees.
 - Level C is 10% of consignees.
 - Level D is 2% of consignees.
 - Level E indicates no effectiveness checks.

The law says a company that performs a recall is responsible for checking its own effectiveness, but the FDA or FSIS may step in and assist if asked.

When can a recall be requested?

The CFR covers this too, in some detail. The Commissioner of Food and Drugs (or his/her designee, usually an FDA Regional Office) may request a recall when an agency determines:

- A product presents a “risk of illness or injury or gross consumer deception.”

- A company has not initiated its own recall of the product.
- An agency action is “necessary to protect the public health and welfare.”

Notification may begin with a visit or phone call from an FDA regional office representative, but will be followed up with some type of formal, written confirmation that specifies:

- The violation.
- The health hazard classification (Class I, II, or III).
- A suggested recall strategy and any instructions for conducting the recall.

If you don’t want to wait for an official recall request, you can begin what the law terms a “firm-initiated recall”—that is, your company makes a decision on its own to pull product off the market. The FDA or FSIS consider voluntary actions as “recalls” ONLY IF the agency decides the violation involved would otherwise be “subject to legal action,” like a product seizure.

When you initiate your own recall, you do not have to notify the FDA or FSIS. However, it is smart to do so. Here’s the list of details that should be provided to the closest district office:

- The identity of the product, including all brand names and container sizes.
- Copies of all pertinent labels.
- Lot numbers, serial numbers, any type of identifying code number.
- The reason for removal or correction.
- The date and “circumstances under which the product deficiency (or possible deficiency) was discovered.”
- A description of how the “evaluation of risk” was made.
- The total amount of product produced.
- The time period in which it was produced.
- An estimate of how much product is in distribution.
- The number of direct accounts to which it is distributed, and possibly their names and/or contact information.
- A copy of your recall communication, whether or not it has already been issued.
- The proposed recall strategy.
- A contact person at your company who is familiar with the situation and authorized to speak with FDA and other health officials.

When the agency receives these details, it reviews them, decides on a recall classification (Class I, II or III). The FDA places the information in its weekly FDA Enforcement Report. The agency also offers advice to the company about the recall strategy, if necessary.

If a company thinks it MIGHT have a problem but the reason “is not obvious or clearly understood,” the law says the FDA “will assist the firm in determining the nature of the problem.”

What are my company’s responsibilities to our customers?

Pages and pages could be written here about the sense of trust between client and supplier, and the importance of maintaining that relationship—but let’s look instead at what the law actually says. First, if you are communicating recall information to your customers, it must accurately reflect the level of danger that may be involved in using the product, as well as the strategy developed for the recall. By law, the recall communication MUST include the following details:

- The complete identity of the product, along with labels, brand name and code number information.
- That the product is being recalled.
- That “further distribution or use of any remaining product should cease immediately.”
- That this customer should notify any of its own customers, down the line, if they received any of the product.
- Specific instructions for what to do with the product.

It should also include a “ready means” for the customer to report back to the company. The FDA’s suggestions are:

- A self-addressed, postage-paid postcard, or...
- A phone number for customers to call, collect or toll-free.

The law says this information can be imparted by “telegrams, mailgrams, or first class letters conspicuously marked, preferably in BOLD RED TYPE, on the letter and envelope:”

- FOOD (or “drug,” “biologic,” etc.) RECALL (or “correction”).
- For Class I and II recalls, it should also be marked URGENT.

If the recall information is telephoned to customers, the caller should have a written script to work from, to ensure everyone is given the same details. The FDA says it is appropriate to tell customers the reason for the recall and the potential hazard involved. The law also notes that the recall communication “should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message.”

And finally, this section of the law states that the recipient's responsibility should be made clear to them—exactly what is expected of them, and how important it is to immediately carry out the recall instructions and notify other people in the distribution chain as necessary.

Remember, by following the law, you are also helping defend yourself against the possibility of private lawsuits resulting from the recalled product.

What will the federal agency say publicly about my company?

The FDA and the USDA's FSIS deal somewhat differently with the news media when it comes to recall events. FSIS will issue its own news release regarding the recall of any food product under its jurisdiction. The FDA, on the other hand, will want the recalling company to draft a news release, and typically approves the contents of the release for the company to then send out.

The FDA regional office also immediately sends a "24-Hour Alert to Recall Situation" to the appropriate central FDA department (biologics, cosmetics, drugs, devices, foods, or veterinary medicine). This bulletin summarizes the basic facts: the reason for the recall, the product and the company initiating the recall. The FDA also notifies public health authorities in the state(s) in which you do business. The FDA Office of Public Affairs calls its news releases "FDA Talk Papers." They contain separate phone numbers for media inquiries and consumer inquiries, and are available on-line at: www.fda.gov/opacom/hpnews.html.

The FDA puts recall information in its weekly "FDA Enforcement Report." The recalls are grouped by Class (I, II or III), and the FDA mentions whether each was FDA-requested or firm-initiated. It also describes the specific action being taken by the recalling firm. This report is available for public access on-line.

Recalls in the last 60 days can be found at www.fda.gov/opacom/7alerts. The Enforcement Reports are also listed by month, at this Internet address: www.fda.gov/opacom/enforce.html. The USDA's FSIS team also puts a Quarterly Enforcement Report on-line, at www.fsis.usda.gov/OA/haccp/enfrep complete with charts that name companies, dates of notifications and current status or resolution of each complaint.

The FDA does not include product removals or field corrections in the Enforcement Report if it decides they are more accurately "market withdrawals" or "stock recoveries." (See these definitions elsewhere in this manual, in Recalls and Related Actions.) Interestingly, the FDA will also agree to "intentionally delay" public notification about a drug or medical device recall if the agency determines that the news may cause "unnecessary and harmful anxiety in patients." Instead, physicians are allowed to contact their patients first, and inform them individually.

We'll discuss what YOU can say publicly, later in this manual.

What is today's regulatory climate?

At the University of Florida's Department of Food Science and Human Nutrition, we hear from many companies in the throes of product corrections and recalls. Here are our general observations:

There is certainly a heightened concern about the safety of the U.S. food supply in light of terrorist

acts of recent years, as well as the deaths and illnesses that have resulted from contamination by biological agents like anthrax, as well as serious, naturally occurring outbreaks of foodborne illness.

This, combined with the increased sophistication of laboratory testing methods, has the potential to increase the number of product recalls. In short, more people are actively looking for problems, and it is much easier to identify and trace specific causes and sites of foodborne illness outbreaks.

Regulatory programs have enhanced their emphasis on stringent requirements and programs to ensure the safety and sanitation of the entire food system. Thankfully, control systems (like HACCP) are also more sophisticated than ever. Of course, no program or system provides absolute protection against natural forms of contamination in food, and certainly not against purposeful, harmful acts of tampering or terrorism; but having such a program or system in place does provide an extra measure of vigilance that might prevent potential problems before products are released into distribution.

There is also increased emphasis on safe shipment and storage of ingredients and finished products—whether trucks and warehouses are sanitary and adequately refrigerated, for instance—as well as proper care of the products at the retail level where they are displayed and sold. With all this, plus checking imported foods, the inspectors obviously have their hands full.

In our capacities as food safety experts, we have noticed that FDA and FSIS responses vary between regions, so it is difficult to state hard and fast rules about the regulatory agencies' behavior. What seems very important to one FDA official, for example, may not matter as much to another. We feel certain that these differences also exist among various state and local agencies, across jurisdictions.

It does seem to impress every level of official—and any outside consultants you may contract with—when a company is well-organized and responsive to questions and requests. That should be among your primary goals in embarking on a solid recall plan that works for your organization.

ADDITIONAL INFORMATION FOR REGULATORS

The Association of Food and Drug Officials recommends that all regulatory agencies, manufacturers, warehouses, and retailers be prepared to rapidly initiate or respond to a recall situation.

Determining the Lead Agency

Many recall efforts are collaborative, and a crucial initial step between regulatory agencies is to clarify which agency should take the lead in a potential food recall investigation and audit. Then, it is critical to communicate that agency's role and responsibility to other regulatory entities, and thus avoid confusion and duplication of efforts early in the investigation.

The lead regulatory agency is responsible for:

- Overseeing the firm's recall strategy.
- Approving notification to consignees, new releases to the media and any information disseminated to the public and/or consumers.

- Conducting recall effectiveness checks.
- Supervising disposition of product.
- Deciding when the recall may be terminated.

These must all be accomplished while maintaining collaborative communications with other regulatory agencies affected by, or involved in, the recall. Here are some general guidelines for determining Lead Agency status:

Since most food recalls involve products distributed in interstate commerce, the FDA or FSIS are most often the lead regulatory agencies for their respective food product jurisdictions. (Remember, USDA and FDA have agreed that for food recalls involving eggs, the FDA is the lead agency for recall coordination, even though the USDA's FSIS has jurisdiction for food safety compliance of non-shelled egg products). FSIS and FDA may enlist the assistance of state and local health jurisdictions for the recall investigation and audit checks.

If a product is limited to intrastate commerce (in the state it is manufactured), the agency responsible for regulating the food manufacturer would be the appropriate lead agency for the food product recall. If a product is manufactured by a dairy plant appearing in the Interstate Milk Shippers List, the state regulatory agency is normally the lead agency for handling the recall investigation and audit checks, even though the product may be in interstate commerce. The FDA may become involved in IMS product recalls, however, in the event FDA determines that the state(s) are unable to achieve the necessary actions.

When a state regulatory agency collects and analyzes product samples as part of a food safety surveillance program, and the laboratory results warrant a food product recall, that agency takes the lead on the recall even if the food production facility is under the local health jurisdiction. However, it is very important to inform the regulatory entity with jurisdiction over the production facility, maintain collaborative communication with them and conduct the investigation and recall audit jointly.

When a state health agency's epidemiological investigation warrants a food product recall and that state agency is not responsible for licensing or inspecting the manufacturer in question, the agency must contact the appropriate agency responsible for licensing and inspection of the food manufacturer (e.g., other state regulatory agency, FDA, FSIS), which would then assume the lead role for the recall.

Gathering the Facts about the Product or Problem

The lead regulatory agency contacts the company to gather the following information. Depending on the circumstances, the lead agency may already have some of this information on file before contacting the firm:

1. PRODUCT IDENTITY

- Product name, including all brand names and generic names.
- Product code numbers (e.g., lot/unit numbers, expiration dates, use-by dates, UPC codes).

- Product description (e.g., powder, liquid, ready-to-eat, expected shelf-life, packaging type and size).

2. MANUFACTURER IDENTITY

- Firm name, address, city, state, zip code.
- Most responsible individual for firm: name, title, phone, fax, email address.
- Recall contact: name, title, phone, fax, email address.
- Contact for the public: name, title, phone, fax, email address.

3. REASON FOR THE RECALL

- Explanation of cause of problem and date or time it occurred.
- Explanation of how and when the problem was discovered.
- Explain whether the problem affects all products in the lot or quantity being recalled or only a portion of the products being recalled. (If it's a portion, provide as accurate a quantity as possible).
- If firm received a positive microbiological sample laboratory result, get a copy of the confirmed result.
- If firm received complaints associated with the problem, they must provide date(s) of complaint(s), with descriptions that include details of injury or illness, lot numbers, code dates, etc.
- If recall is due to presence of a foreign object, describe the size, composition, hardness and/or sharpness of the object.
- If recall is due to presence of a chemical contaminant, explain level of contamination, and provide labeling, list of ingredients and the Material Safety Data Sheet for the contaminant.
- If recall is the result of a labeling issue, the company must provide and identify the correct and incorrect label(s), description and formulation.

4. FIRM'S ASSESSMENT OF THE HEALTH RISK ASSOCIATED WITH THE PRODUCT DEFICIENCY, INCLUDING ANY SUPPORTING DATA OR INFORMATION.

5. VOLUME OF PRODUCT BEING RECALLED

- Total quantity produced.
- Date(s) produced.
- Quantity distributed.

- Quantity on hold by recalling firm and its distribution centers.
- Description of product quarantine procedures and conditions.
- Estimate amount of product remaining in the marketplace at: distributor level, retail level, and consumer level.

6. DISTRIBUTION PATTERN:

- List of consignees – the direct accounts the firm sells the product directly to. The list should include the name, address, city, state, contact name, phone number, fax number, email address of each consignee.
- Indicate quantity of product shipped to each consignee, including dates.

It is recommended that the regulatory agency clearly communicate the expected timeframes for the exchange of communication with the businesses involved in order to facilitate efficient handling of the recall. A firm's failure to respond may necessitate rapid notification of federal agencies for assistance.

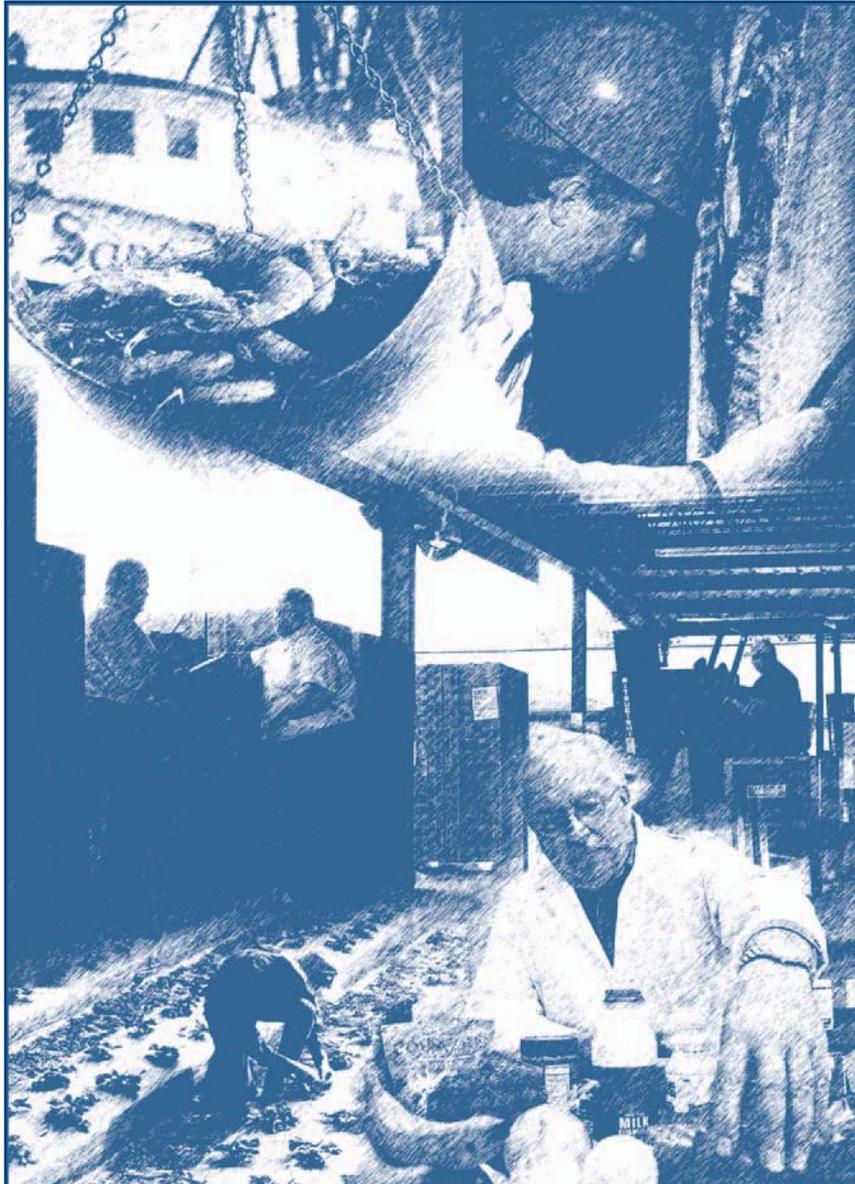
Health Hazard Evaluations

Once the data has been collected, the Health Hazard Evaluation Committee can be assembled by the lead agency to review the documentation and decide on a recall classification. This evaluation takes into account, but is not limited to, the following factors:

- The nature of the violation or defect—adulterated product, misbranded product, improperly labeled product, etc.
- Whether any illnesses or injuries have already occurred from the use of the product.
- The likelihood that illnesses or injuries may result.
- Whether any existing conditions could contribute to a situation that could expose humans to a health hazard, and the types of illnesses or injuries that may result.
- An assessment of the hazard to particular segments of the population— children, elderly, expectant mothers, persons with compromised immune systems, etc.—and the degree of seriousness of this hazard to these specific population segments.
- An assessment of both immediate and long-term consequences of the hazard.

The speed with which the committee must work depends largely on the nature of the alleged violation or defect. The more serious the potential health effects, the greater the need for an urgent response.

**“MY BEST ADVICE”
THE QUALITY ASSURANCE DIRECTOR**



Section 3: “My Best Advice”—The Quality Assurance Director

This person agreed to speak with us on condition of anonymity. After all, there’s no reason to name his company or detail its recall experiences in order for him to share his best advice. He received a Bachelor’s degree in Chemistry, and a Master’s degree in Food Science with a minor in Food Microbiology. He has worked in the environmental field as well as in food laboratory environments, and now serves as Senior Director of Quality Assurance and Technical Services for a major U.S. food processing company. He says his job is very rewarding, because it is, in his words, “a pragmatic application of science.”

Q: HOW DO FOOD RECALL SITUATIONS USUALLY START, IN YOUR EXPERIENCE?

A: The classic way that it starts is from a complaint from our consumer hotline. The initial complaint often doesn’t give us enough information. Then we’ll get a second complaint, or a third—and you see a pattern. Then you start digging and doing your research right away, whether the complaints pinpoint a plant or a line or a process. You’re trying to find out when it happened, exactly what happened and where—to put some boundaries around it.

Q: HAVE YOU EVER DEALT WITH INSTANCES OF PRODUCT TAMPERING OR TAINING?

A: Not directly. It’s usually with a national chain account—somebody will take an order of French fries or some other product and intentionally put something in it at take-out; then they’ll take it back and say, ‘I found this in my French fries and I want to sue.’ Then it comes back to us. We have to show our records and our documentation—why we believe that it’s either possible, or not possible, for this to have happened. Obviously, we try to get hold of the material itself that was allegedly found, and we use an outside lab to determine the heat and history of that product. A lot of times, you can tell if something has been super-heated or not. That’s important because we par-fry some products, and they’re fried at the restaurant as well. So if the foreign material has never seen heat, then it didn’t come through the frying process. We do microscopic analysis of the particles too, to see if the material was ever even exposed to the food. People will say, ‘I bit on this.’ Well, we can test to see if there’s evidence of saliva on it.

Q: WHAT ARE THE BIGGEST AND SMALLEST RECALLS YOU’VE BEEN INVOLVED IN?

A: The smallest probably involved, maybe, 15 cases. It was an allergen labeling problem. The largest was probably 31,000 cases. The problem there was foreign material.

Q: WHAT IN THE WORLD MAKES THE DIFFERENCE BETWEEN A 15-CASE AND A 31,000-CASE RECALL?

A: It's the scope. You do your investigation and go back through your records and decide what happened when. The 15-case one was pretty easy. The record showed the film (printed bags) was put on the line, it was the wrong film, and they took it off the line. The product was put on hold, but a partial pallet got released. It was a simple gap in the production process.

In the other one, the foreign material looked like it was shed on the production line, over a given period of time. What you always try to do with foreign material is determine whether it's an isolated incident, or something that was systemic. When your raw materials are crops dug out of the ground, you've got foreign stuff coming into the plants all the time. We have procedures for containing it, shutting a line down, isolating the problem and cleaning it up. So when you get a complaint about a foreign object, you have to decide if it came in with the raw material, or if it's something that shows a systematic failure of a piece of equipment on the line, like a shard of metal.

An isolated incident doesn't give you much to go after, in terms of correcting a problem. But if you have a bit of metal, and you use that type of metal in six of your machines, and you check them all for wear and find a wear point that matches this type of material, it could have been spread through the product. That's when you look at the maintenance records to see the last time the machine was inspected, and that's how you work backward to establish some time boundaries.

Q: DO YOU HAVE A RECALL TEAM AND A RECALL PLAN?

A: Yes we do, absolutely. We do regular mock recalls as well as responding to complaints. It is critical to do the mock recalls. Without them, you don't know if your system works, and you always find things that don't work! You'll find product that was taken out of inventory in one of your warehouses, but there's no record of what was done with it—was it destroyed? Was it moved? Was it sampled? If even one or two cases can't be accounted for, it's a problem.

Q: ARE CUSTOMERS AND SUPPLIERS PRETTY GOOD ABOUT PARTICIPATING IN RECALL ACTIVITIES?

A: Our customers are more savvy and generally, I'd say they have a greater understanding of recalls and the potential impact of a recall, than our suppliers do. They've got their name on it; whereas the ingredient or packaging suppliers don't have their names on it, so they don't seem as concerned.

Q: WHAT'S YOUR BEST ADVICE FOR PUTTING TOGETHER A RECALL TEAM?

A: I guess the first piece of advice is to take a team approach, and make sure you have a cross-functional recall team. You've got the manufacturing aspect of it, so you have a team and coordinator at the production level. What they look at is all of their ingredient handling records, all their blending records, maintenance records—you'd have a coordinator at the facility level, that has a team of their own, with maintenance, production and quality assurance represented on that team; usually also somebody from

the warehouse, if you have an on-site warehouse. They really are responsible for doing the investigation at the plant level.

Then at the corporate level, you need to have representation from warehousing, customer service, transportation—somebody who understands where the product went, how it moves, who the customers or distributors are and how they manage their inventory. You'll have your public relations person, to approve and screen the news releases. And you want the recall coordinator from the plant-level Quality Assurance department in there as well. We have the recall coordinator deal with the FDA and the P.R. person deal with the media. Just make sure you have someone who understands the whole picture that communicates with the FDA and the media. When someone asks a question, you don't want a spokesperson who'll say, 'I don't know.' That puts your company on the defensive. We also have a corporate attorney on the team.

Q: WHAT ABOUT HAVING RECALL INSURANCE?

A: It depends on what your ability is to self-insure. That's really a financial decision. Recall insurance is extremely expensive, so the company's got to make a decision whether they're going to self-insure, or rely on a second party to insure them. By self-insure, I mean set money aside to use in case of this type of problem.

Q: WHAT'S IT LIKE WORKING WITH THE FDA?

A: I've found them very good to work with. They generally want to do what's right and want to be pragmatic. They're fairly rigid in what they expect. They have their own internal protocol in terms of how decisions are made—like how to classify a recall as I, II or III—so the person you're working with in the field may not be the person who's making the decision, and sometimes that's frustrating.

Recalls are voluntary, so they really can't force us to do one, or can't come in and just take control. What they will do, is ask all sorts of very specific questions and expect you provide them the information, rather than showing up and your plant and saying, 'We're going to investigate.' They WILL come into your facility after a recall, to inspect and decide if they feel comfortable with the safety of the products coming out of there. Most of the flurry of activity is in the containment phase, which has to be done very quickly, within a day or two. The follow-up and verification is done over weeks, and months. On a Class I recall, it may be a year before it's totally done.

Q: IS A RECALL REALLY THE AMAZING HASSLE THAT EVERYONE PAINTS IT AS?

A: It depends on the recall. The biggest nightmare in my situation, if I had a recall, would be if something happened in the field—so it comes in through consumer complaints. We trace it back and find that it is not a line incident-related situation, but let's say an ingredient-related situation. Now, you have

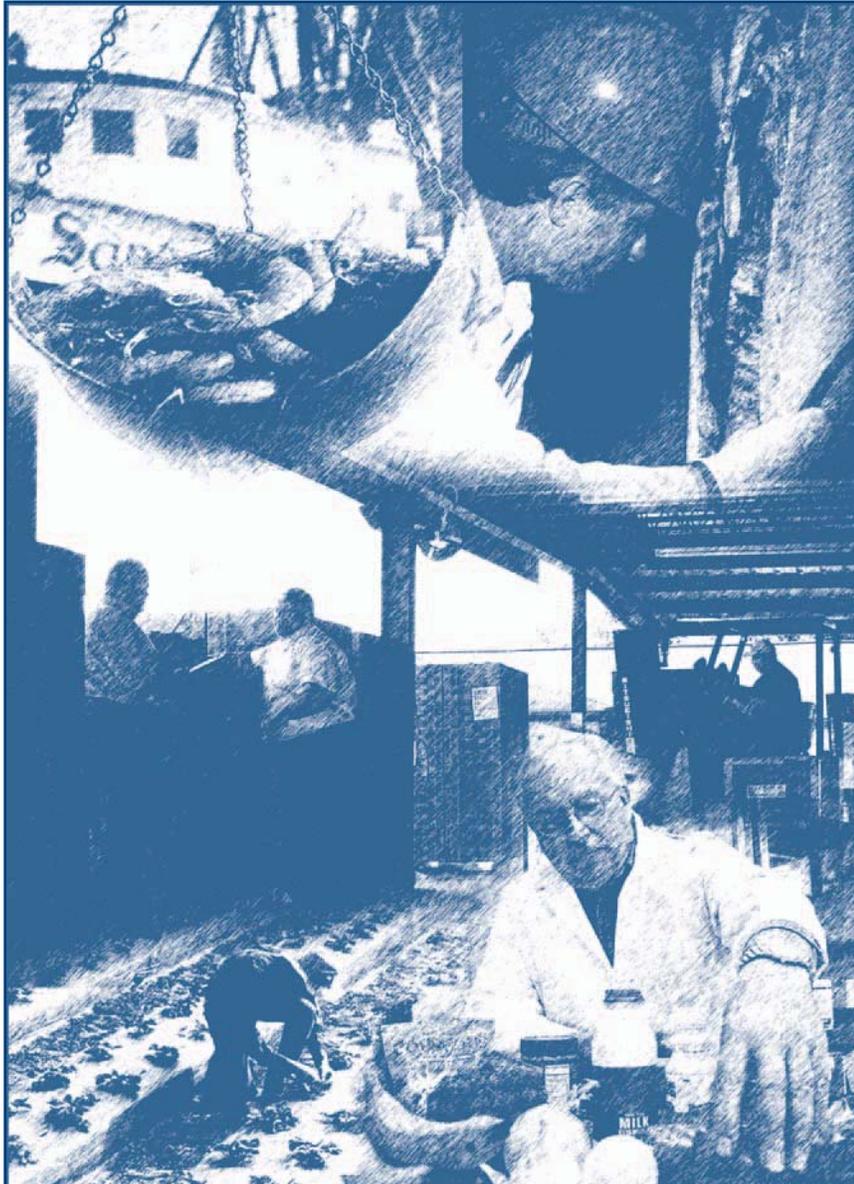
to be able to trace where every pound of that ingredient went; and all the products that are impacted; and then go back up through the process to say, ‘Okay—when was this ingredient used? What lines did it go into? Were those products blended into anything else? Were they used in making a component meal? Which customers did they go to? Were they national accounts that would want to be notified independently?’

The communication piece can get extremely complicated very quickly. Your good customers, you know, don’t want a cold, formal recall notice mailed to them. They also expect a personal call that their product’s been impacted. You’re talking about a large quantity of product, oftentimes with a lot of different customers. Or you’re selling to a distributor, but you don’t know who THEY’RE selling to—and they may be selling to a customer that you also sell directly to, and then the customer is mad because you didn’t call them first. ‘Why did I have to hear this from a distributor?!’ they’ll say. ‘Why do they know about this before I did?’ And of course, the distributor sees them as THEIR customer, and thinks it’s none of OUR business who their customers are! So you can see, it can get complicated very quickly.

Q: BUT OVERALL, WILL PEOPLE SURVIVE A RECALL?

A: Maybe. You have to keep impeccable records, and you have to keep them for 3 to 5 years. They won’t survive if they don’t have good records.

BEFORE THE RECALL: EMERGENCY PREVENTION AND PLANNING



If you are in the business of selling food or beverages—in any form, anywhere on the distribution chain—you must be prepared to deal with product emergencies. The best way to do this is to anticipate them and create a plan for a product recall, should one become necessary.

However, the first step in this process is not planning, but prevention. Why not do everything possible NOW to thwart an emergency? So this chapter focuses first on securing your own manufacturing and distribution processes; then follows with advice on how to draft a product retrieval plan that works for your company.

Some degree of risk is inevitable in business. Your goal is to continuously minimize this risk wherever possible. So let's get started.

THE RECALL TEAM

Call it a recall, a product withdrawal, a retrieval, or crisis management—but **you've got to have a plan to accomplish it**. It takes a team to make a good plan—a team that is familiar with every aspect of your business—and perhaps an outside expert or two who can be helpful in certain specialized areas.

The responsibilities of this committee are to:

- Review existing operating procedures and recommend changes to lessen the probability of a recall, or to make a recall easier if it becomes necessary.
- Develop a Recall Plan, or review and update an existing one.
- Respond to any product quality problem that may require retrieval, including handling all communications about the issue, internal and external.
- Make recommendations to senior management and any government agencies about what to do with remaining product.
- Follow through until the situation is resolved.
- Follow up by assessing the effectiveness of the plan, and making suggestions to prevent similar incidents.

Your Recall Team should be a core group of people who represent all the key departments or functions of the organization. It should include:

- A senior operations manager, who is familiar with the entire manufacturing process. This person serves as team leader and reports directly to the owner and/or president of the company.

- A public relations specialist, who will coordinate all communications activities, both internal and external. This includes media inquiries, updating your Website, issuing news releases, etc. It is important to keep your messages clear and consistent. Coming from one spokesperson, it is easier to achieve this.
- A marketing specialist. This person can instruct the sales force (employees and independent sales contractors) in their dealings with customers and end users; and can coordinate marketing and advertising changes, if necessary.
- A scientific advisor, who can speak to the health and food safety aspects of the problem and help quantify the risks. This person might be a food scientist, an epidemiologist or microbiologist, depending on the type of pathogen and the number of persons affected.
- A logistics and receiving specialist, who is familiar with the shipping, tracking and storage of products and can schedule timely retrieval from wholesalers, retailers, etc.
- A quality assurance specialist, who can start immediately to gather facts (even before inspectors show up) and then can work with them to pinpoint any problem. This person should be familiar with all safety and sanitation rules of the company, and should be able to arrange for laboratory testing of product samples.
- An accountant, to estimate costs of the options the team is discussing, set up account codes to track them, and manage a system for customer reimbursement, if necessary.
- An attorney, who can handle liability questions and help the team deal with government regulators. This person can also help the company collect pertinent oral and written statements; advise about what information may be kept confidential; and help you gather documents that may be needed as evidence in case of litigation.

At this point, you may be scratching your head and saying, ‘That’s more people than we HAVE in our entire company!’ And that’s okay. The public relations person, scientific advisor and attorney can all be hired as outside contractors, and there are also companies that specialize in retrieving recalled merchandise. If one person wears three of the “hats” mentioned on the list of committee members, your team will simply be that much smaller. Just realize—you can’t do it alone.

When the employee members of the committee are in place, your first order of business can be to contact and interview outside experts. You will want to be acquainted with them, and they’ll want to know more about your company, before they are ever needed. They should be prepared to make a short presentation to the committee about their services and prices. These outside experts should be under contract and “on the team” during the recall planning process, if your budget allows this.

Together, the team can create a sensible and workable recall plan that, with any luck, you will never have to use.

IDENTIFY PROBLEM AREAS

The best way for your team to begin is to list the entire sequence of production for the foods or beverages your company prepares. Then, analyze every point in the sequence to identify potential “weak spots.” Strange as it may sound, think like a terrorist (or perhaps a mystery writer!) If YOU wanted to shut a company down or taint its outgoing products, how would YOU go about it without getting caught? If a disgruntled customer, or former employee, decided to “get even” somehow...what might they try?

You can brainstorm as a recall team, but it is smarter to enlist the help of your department heads, or a few trusted employees in this task. As you can see, there’s a broad list of possible areas of concern to consider—and certainly others, depending on the type and size of your operation.

- Identify points at which unauthorized persons might have easy access to your facility—through unlocked doors, gates, vehicles.
- Think about whether employees have unnecessary access to a critical part of your operation.
- Pinpoint any place and method by which a person might bring in, store or move unauthorized materials within your facility.
- How do you approve vendors and suppliers? How do you check THEIR products for safety, sanitation, etc.?
- Is there an inspection process for incoming raw materials and supplies? How does the Receiving staff document incoming shipments, and what is done about discrepancies? Is there a method for refusing goods? For accepting goods that other users have sent back to you?
- What is your lot coding strategy? Do you use the suppliers’ lot codes for incoming goods, or assign your own new codes? Do you assign the same code to an entire shipment, or break it into smaller increments? Does your system correlate the codes, in case a supplier notifies YOU of a recall? You must be able to:
 1. Link all raw ingredients to their original suppliers.
 2. Link raw ingredient codes to finished product codes.
 3. Code finished products by lot.
 4. Link finished product codes to the customers who receive the product.
- Do you have a system in place to clearly mark the code numbers on all outgoing product, and how is the product tracked when it leaves your facility? Experts say it is easier to track product when:
 1. The shipping cartons and individual containers inside them bear the same code numbers.

2. Only ONE code is packed in each case.
 3. Code numbers are changed often, making lot sizes fairly small.
- If your plant premixes raw ingredients for future use, are they coded to allow you to trace the individual ingredients in a batch?
 - If you rework (use “leftover” product from one batch in another), do you code the finished product to be able to trace the “leftover” ingredients?
 - If your products are freshness-dated, is there a standard procedure for stock rotation—in your warehouse, and in the field? Do your customers know and understand it? Do they follow it?
 - Take a look at all your labeling with a critical eye. Could ingredients be listed in terms that would be more easily understood? In your zeal to market the product, have you used any terms or made any claims that aren’t “exactly” true? Can you prove the statements that are there?
 - Does anyone inspect your water system for purity? If so, how often? How are discrepancies reported?
 - Look carefully at how each of your processes is documented. Are there “gaps” in recording the production, processing or distribution history of a product? Who could change the written records if they wanted to? Who has access to the computerized files, and how is that access granted?
 - What kinds of firewalls and virus protection does your computer system have? Is the system backed up regularly, and by whom?
 - What kinds of laboratory testing do your quality control people do, and how secure are those records? How easy would it be for someone to falsify them—either to cover up a problem, or create one as a hoax?
 - What food safety and storage precautions are required at your facility? Are these in writing, and easily accessible to employees? Who monitors them to make certain they are being adhered to?
 - Are criminal background checks conducted on all employment applicants? Drug tests?
 - How are employees trained, and are they motivated to follow the rules?
 - Do you have a photo ID system for employees?
 - How are layoffs and terminations handled? How long does it take to purge a terminated employee from the records? To restrict that person’s access to the property, computers, and filed documents?
 - Is there a process in place for employees to report suspicious or unusual activity? Who investigates these reports?
 - Is there a standard form and/or operating procedure for receiving and handling consumer complaints? Other customer complaints?

- If chemicals or pesticides are used in any of your processes, get the most current safety information about them. Have activist groups targeted any of them, for boycott or other protests? Are the finished products tested for chemical residue, and are these records current and accurate?
- If a terrorist targeted one of your suppliers, vendors or shippers, how would it impact your operation? For an even more thorough inspection, identify the “weak spots” at your vendors’ and shippers’ locations.

A related topic for candid discussion among your recall committee members: How much of a “target” are you? Does your company or industry have a lot of public visibility? Is it in any way seen as controversial? List all the outside interest groups, political parties, labor unions and trade associations your company, and its officers, are associated with. If you were in a crisis, would these groups be supportive? In short, it’s time to think about who your friends are, as well as your detractors.

Another area that’s difficult to quantify is how committed your workforce is to meeting quality standards and putting out the safest, most sanitary product. Company loyalty and ethics are tough to gauge, but you might want to try.

RISK CONTROL AND INSURANCE

Now you should have a very thorough idea of what might happen, even if it never does. When you’ve identified these risks, you can decide how to reduce or eliminate them. Prioritize the list—as high, medium or low risk—and tackle the highest risks first. You are looking for effective risk control measures. An “effective” measure is one that reduces ANY of these three factors:

- The probability of a problem.
- The severity of a problem.
- The exposure to a problem.

Other considerations are the cost of the measure, and how it works (or conflicts with) other measures or day-to-day business processes—in other words, how expensive is it, and how much hassle is it?

As a very simple example, let’s say Company XYZ has an unlocked exterior door that provides easy access for anyone with a desire to sneak in. However, it is a local fire code requirement that the door be kept unlocked during business hours for safety reasons. Company XYZ could:

- Make sure the area outside the door is well-lit to discourage entry.
- Install video surveillance and monitor the door.
- Post NO ENTRY signs and install an alarm on the door that goes off when it is opened.
- Put seals or sensors on the door that will show any attempt made to open it.

- Make sure the employee working nearest the door on every shift knows to keep an eye on it, with a small reward for reporting security breaches.
- Provide an outdoor smoking area, so employees who smoke won't be tempted to use the door to take a quick cigarette break.

As you can see, there are a lot of options for risk controls, even for the simplest situations. Whenever possible, the employees who would be impacted by the decision should be involved in making it.

Another critical part of risk management is insurance. Companies in many industries have recall-related insurance coverage. Now is the time to dig it out, meet with your insurance agent, and take a good look at exactly what the policy covers and whether it meets your needs. If you're not very familiar with this type of coverage, type the words "product recall insurance" on any Internet search engine and start reading. You'll get an eyeful—from companies that want to sell it to you, to expert opinions in trade journals, to attorneys' opinions about which types of insurance are worth the money, and which are not. One of the most helpful sites is that of the International Risk Management Institute, found at www.irmi.com.

It may not exactly be comforting to learn that almost all the major international food and beverage corporations have been through enormous recalls at one time or another. Then again, they're all still in business and you can learn from their experiences.

There are four basic types of insurance coverage that relate to product recall claims. Any of them can be purchased separately, or added as an endorsement to an existing property insurance policy.

1. A **product recall policy** covers the actual costs of a recall: repairing and returning items, costs of publicizing the recall, transportation and storage. Usually, this type of policy will not cover loss of profits, or the cost of rebuilding a company's tarnished image.
2. A **product liability policy** protects the company against claims of injury caused by a defective or hazardous product. It is strictly to cover claims of injured parties, not recall costs.
3. An **accidental contamination policy** covers the company against claims resulting from its own unintentional distribution of an unsafe product. This includes all the related recall costs, plus lost profits.
4. **Malicious tampering insurance** covers criminal actions of sabotage against a company, and also includes all related recall costs and compensation for lost profits.

Each of these is really a form of catastrophic insurance. If your Recall Team ever has to use its insurance coverage, it must be prepared to clearly document all of these expenses and/or losses:

- Cost of investigations – hiring private labs or outside experts.
- Recall costs – for removal, transportation, storage and destruction of the recalled products.

- Repair or replacement costs – not just the cost of giving people new products, but repairing any equipment that might have caused or contributed to the problem.
- Sales losses – not only the product that had to be recalled, but the lingering effects of negative publicity and the losses that will be incurred by the company’s customers.
- Legal and professional fees – attorneys, consultants and accounting assistance to file the insurance claims.
- Public Relations costs – new advertising, special incentives, crisis management and anything else that is needed to get the recalled brand back in good standing with consumers after a recall.

Attorneys warn that the basic Commercial General Liability (CGL) policies held by many companies are not sufficient to compensate for the massive costs that may be associated with a recall. Luckily, as with any other type of insurance, there are policies in many different price and coverage ranges. Premiums can range from \$5,000 to seven figures; deductibles from \$10,000 to \$25 million; for coverage from \$10 million to \$300 million or more! Most insurers have a toll-free hotline for companies to use in case of a product crisis; some offer their own expert consulting services at no additional cost to the policyholder. It is worth shopping around.

THE DECISION TO RECALL

Ironically, the two biggest questions in a product crisis don’t seem as complex as they actually are:

1. Should there be a recall in the first place?
2. What should be recalled?

Even when health inspectors are telling you they have some serious concerns about one of your products, a recall notification will not necessarily follow. Remember, the FDA and FSIS prefer that the action be *voluntary*. This means a responsible company will determine in advance, as much as possible, under what circumstances a recall will take place. An agency may not have been the source of the information in the first place—it may be problems that your own employees, or consumer complaints, have brought to your attention.

A product should be recalled if there is credible evidence that shows it has caused any illness, due to suspected contamination or another unsafe condition. No matter what the circumstances, the decision to recall must always be made quickly. So, when a complaint first comes to your attention, you should be able to pinpoint the source of the complaint or notification, and to confirm the credibility of that source.

1. If the information comes from health inspectors or a federal agency, listen carefully to what they say. Take notes. You have the right to ask for and/or expect:

- Courteous treatment.
- An explanation of the process or findings that linked this product to particular problems or illnesses.
- A specific time period for the records they are requesting.
- A minimal number of individuals or agencies requesting the same information from you.
- Access to supervisors or managers of the agency if a field investigator cannot answer your questions.
- Copies of paperwork, from news releases to the agency’s inspections, lab reports, etc.

Ask if the inspector or agency is making a specific recommendation to recall, or any other recommendations. You will usually receive these in writing, soon after the initial telephone or personal contact. Tell them you will notify your Recall Team immediately before a decision is made—then do it.

2. If the information comes from a member of the public who has called or written to make a complaint:

- You should get as much information as possible from the complainant. This includes:
 - a) All contact information.
 - b) Exactly what they feel the problem is with the food (chemical taste, “off” odor, allergic reaction, object in the food).
 - c) Exact product details (name of product, size of package, code numbers, whether they still have any of it left—in that container, or others like it that are unopened).
 - d) Details of how the product was stored and handled after purchase.
 - e) Name and address of the store where it was purchased, and date of purchase.
 - f) Date and time the product was consumed.
 - g) Amount of product that was consumed.
 - h) Has this person ever consumed this product before?
 - i) Did others consume it too, and do they have the same complaint?
 - j) Names and ages of the people who are affected.
 - k) Symptoms, in the order that they appeared, and approximate time they began.
 - l) Name and contact information for any physician they may have consulted about this incident.

m) Name and contact information of any other agency they may have contacted to report this incident.

- Some experts say it is very important to cover yourself legally by asking the person to fill out a form that lists everything they have eaten in the previous three days, and return it to you. See a sample of this form, as well as a questionnaire for phone-in complaints, in Appendix 1.
- Use this information to begin (or continue) your own, internal investigation and testing.

The second big question, about what should be recalled, refers to exactly which product(s) are affected. The answer may be:

- Particular lots or batches.
- Items made between certain production dates.
- Items made at a certain plant.
- Items that contain a certain ingredient, often an allergen.
- Products that have been mislabeled.
- Items with faulty packaging.
- Products that may be contaminated.

How far these products traveled after they were released from your facility is another important key. Are they in wholesalers' storerooms? On supermarket shelves? Being served in restaurants? In public school cafeterias? Can you find them locally, regionally, or around the nation? Gauging the depth and breadth of the effort will help guide the committee as it decides whether to begin a recall.

ALTERNATIVES TO A RECALL

A company's first reaction is usually to try to limit a recall to include as small an amount of product as possible, to minimize disruption, financial losses and negative publicity. Government agencies will insist on scientifically valid reasons for this kind of limitation, so be ready to justify your decision, whatever it is.

Of course, there are other options short of a recall. They are:

CORRECTION — An action taken to modify a product to cause it to conform to applicable regulations so that it may remain in distribution. Corrective action includes repairing, re-labeling or making an adjustment to a product. With agency approval, a product might even be destroyed under the "correction" banner.

PRODUCT WITHDRAWAL (or MARKET WITHDRAWAL) – The act of removing a product from distribution when it violates federal or state law in a minor or technical way (not posing a health-related risk), or when it doesn't meet the manufacturer's own specifications or quality standards. It does not include products that have been contaminated or adulterated.

In a withdrawal, you can notify your consignees (usually wholesale distributors and retailers) to remove certain products from distribution, and to replace them with new stock that you provide. You can have your own sales force or sales brokers perform the removal and replacement duties.

STOCK RECOVERY — The act of removing a product from potential distribution before it has left the direct control of the manufacturer. It may be in your own warehouse, or on wholesalers' shelves, but has not been released to the public. Your company simply places a "hold" on the merchandise, so it does not leave your direct control.

COMMODITY HOLD AND RELEASE – This system is unique to USDA commodity (bulk) foods given to large foodservice customers, like school districts, which has a completely different set of rules than other types of product retrievals. A school district, for example, is notified to "hold" (stop using and isolate any remaining stock) a product for up to 10 calendar days while the USDA investigates the claim that it might be unsafe. It may be determined to be safe (and "released" for use), or it may be recalled. The State Distributing Agency that distributes commodity foods serves as the clearinghouse for information during a hold-and-release investigation.

Now that you are aware of all the options, it's time for the committee to draft a recall plan. Even if you are convinced that, most of the time, you can use one of the other methods short of recall, it is necessary to have a written plan for more drastic action for two reasons:

1. You may actually need it someday.
2. When you do need it, the regulatory officials are going to ask to see it in writing.

CREATE A RECALL PLAN

What should be in a recall plan? It does not have to be a long and complicated document to serve as a good "blueprint" for crisis management. These suggestions were compiled from the plans and documentation of many well-respected state health departments and university food safety experts.

1. A LOG OF YOUR ACTIONS

One of the MOST IMPORTANT steps is that the recall committee maintains a WRITTEN LOG of the dates and times of any related event or action. This means logging WHEN the complaint was received, WHEN the team met,

WHEN the initial risk was evaluated, WHEN testing was done, WHEN production was stopped, WHEN and HOW wholesalers were notified, etc. This log can help prove your responsiveness and

promptness if later legal battles ensue. One person on the crisis team should be responsible for keeping this log updated. A sample “Action Log” may be found in Appendix 6.

2. A DECISION TREE OR LIST FOR DETERMINING PRODUCT EMERGENCIES

Make a logical list, based on your particular industry and products, of questions you must answer to determine whether the emergency is a health problem or a hoax and, in either case, what should be done about it. The goal of your “decision tree” is to answer the two primary questions: Should there be a recall in the first place? And if so, exactly what should be recalled?

3. MASTER LISTS OF NAMES AND PHONE NUMBERS

All the **committee members’** names and phone numbers must be listed, including a back-up person in each department. Include ALL phone numbers, to facilitate 24-hour contact with the committee.

Compile a list of **regulatory contacts**, including local health department representatives, the police department (in case of a threat or hoax), and the FDA District Office nearest your company headquarters.

Compile a separate list of **outside experts** who may be called upon to assist the company: attorneys, public relations companies, insurance carriers, food scientists and/or laboratories to be used for product testing, trade associations, telephone answering services (for a high volume of calls), trucking companies (for product retrieval).

You may also want to periodically update your list of **wholesalers, retail customers** and/or **sales representatives**, but these do not need to be included in the Recall Plan.

4. A METHOD FOR ROUNDING UP RECORDS

The plan must include ways of accessing the following information within a few hours’ time:

- a) Any routine monitoring or testing records that may pinpoint causes of a problem—equipment servicing or breakdown, deviations on a processing line, HACCP temperature controls, acidity levels of canned foods, etc.
- b) Production (period) codes, lot numbers, production dates (and instructions for locating and deciphering these codes on packaging), and label information for products in question.
- c) Receipts or other Receiving documents for any raw materials used to make the product. (Remember, these are also important in case your company is notified of a potential problem by one of your suppliers.)

- d) The amount of product potentially affected.
- e) Warehouse and distribution records of the finished product, to track its current location(s).

5. A LIST OF BASIC FDA REQUIREMENTS

If you notify the FDA or FSIS that you intend to undertake a recall, the agency will ask you to supply the following information. In your plan, state clearly whose responsibility it is to collect these details:

- a) The identity of the product, including original labels and use-by or sell-by dates, the package size(s), product form, codes, lot numbers and any other identifying data.
- b) The reason for the removal or correction, and the date and circumstances under which the problem was discovered.
- c) An evaluation of the risk associated with the problem.
- d) The time span during which the product was produced, and how much product was produced.
- e) The total amount of product (by package size and case size) estimated to be in distribution channels.
- f) Distribution information—the number of direct accounts (brokers and wholesalers). In some cases, you'll be asked for their names, addresses and phone numbers.
- g) A copy of whatever communication you have sent, or will send, about the recall. (See sample news releases and notifications in the appendices.)
- h) Your proposed strategy for conducting the recall, including measures to correct the problem and what you intend to do with the recalled product.
- i) The name and phone number of a person at your company who will serve as the contact for the regulatory agency. (If you are not a manufacturer, but are recalling a manufacturer's product that you sell or use, you must also supply contact information for the manufacturer.)
- j) Our own addition: It is advisable to add a sentence in the written Recall Plan that the plan itself is not an admission of any kind of guilt or negligence. Your attorney can help you word this statement correctly.

6. A METHOD FOR SECURING PRODUCT

It's not enough to say that the items on this checklist will be done. Your plan must detail HOW they're going to be done, with time estimates for how long each step will take:

- a) The Recall Team must notify all department heads, who in turn notify their employees. (A list of department heads will be helpful here.)
- b) Production of the product should be stopped immediately pending an analysis of the causes of any suspected problem.
- c) Outgoing shipments of all product being recalled should be stopped immediately, even if the production dates are different than those under investigation.
- d) Notify all locations where the product may be to explain the situation and secure all product in warehouses or wholesaler/retailers' stockrooms. (The list of customers and wholesalers will be helpful here.)

7. DRAFTS OF COMMUNICATIONS DOCUMENTS

As facts are determined, the Recall Plan must specify who should be contacted and what information should be dispersed. This includes everyone from employees, to consignees, to state and federal authorities, to the news media.

It is absolutely critical that the team designates a single spokesperson who can handle inquiries from the press and the public, to ensure that a consistent message is being delivered. Your attorney should brief this person before speaking publicly, so as not to say anything that might later turn out to be legally damaging.

With so much to disseminate and so little time, it is smart to have "sample documents" ready, that can be easily adapted to the circumstances. You'll find examples of some of these in the appendices for this manual. Always ask your attorney to read your document drafts BEFORE they are used!

- a) A form for noting complaints and/or threats that come in by phone.
- b) A telephone script for calling consignees (distributors, wholesalers, retailers) to inform them of the recall.
- c) A fax (that can either precede or follow) the initial phone call to consignees, confirming the recall information.
- d) A letter on company letterhead, restating the recall information and providing specific details for destruction or return of the product.
- e) A news release for newspapers, radio and/or television stations.
- f) A Recall Effectiveness Check, which can be done by letter, phone or in person.
- g) A Recall Status Report, which the FDA or FSIS will want to see. It is a written update of progress during a recall. (See the "During a Recall" chapter for details on what it must contain.)

From here, the plan will vary depending on what the disposition of product is—and you have no way of knowing that in advance.

TEST THE RECALL PLAN

A mock food recall is an excellent way to test your plan and your company's response time. How quickly can your team identify and segregate specific product, and disburse information to those who might be affected by selling or consuming the product?

For the test, select product from your actual production records. It should have real-life period codes, lot numbers and production dates. Pick at least one lot that was fairly recently produced—some stock is still on-site or in storage, and some is already out in the marketplace. This allows you to check internal, as well as external, ability to account for the product. The test will only be effective if you also set timed goals.

The Recall Team should convene and “work the plan.” In all communication, however, be sure to stress the fact that this is a mock exercise designed strictly for emergency preparedness, and that nothing is wrong with the actual product!

The mock recall should involve a complete review of company records and, to a certain extent, external sources of information. Brief the employees and perhaps offer an incentive for meeting the research deadlines. Ask your brokers, distributors and retailers to participate, and let them know they are being timed to see how quickly they can locate the product and report back to your sales force. Consider giving them a discount on their next order for helping with the test!

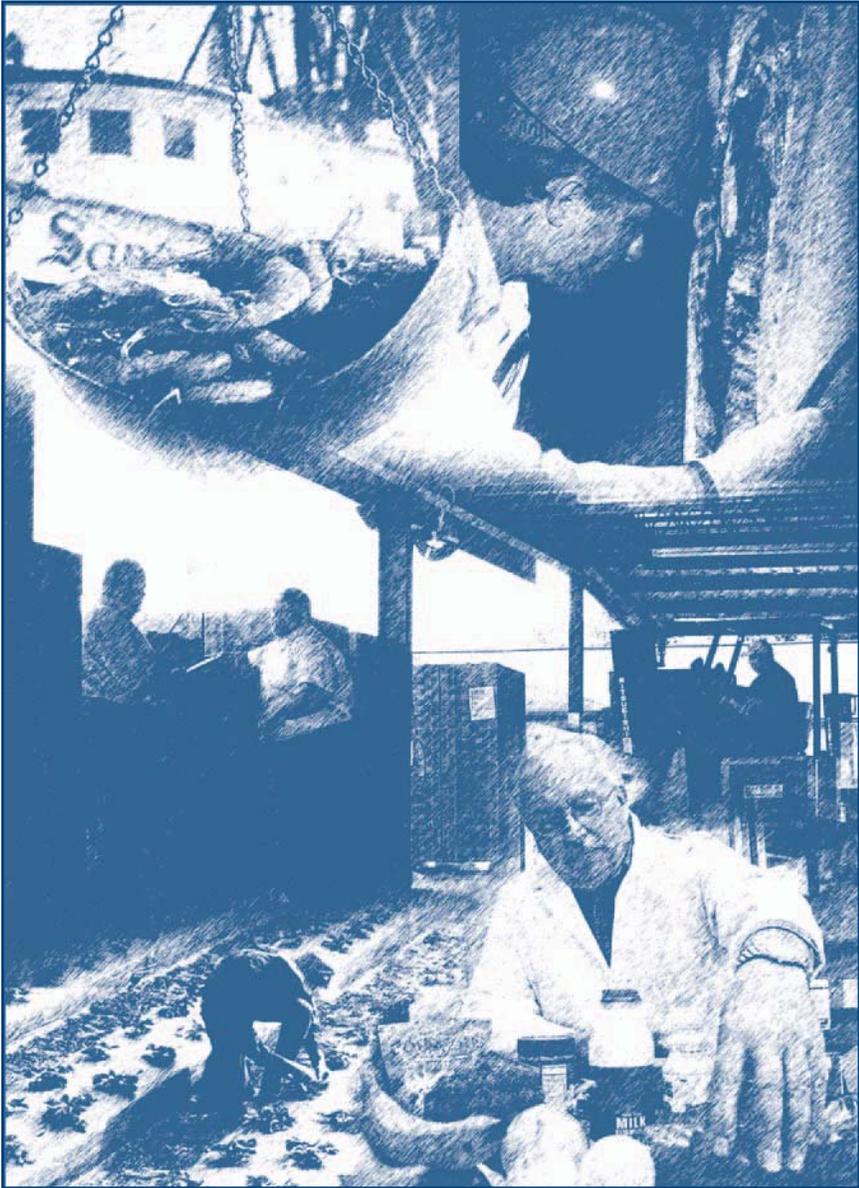
Mock recalls are “mini” versions of real ones. They're supposed to take two or three days, not weeks or months to complete. Therefore, progress should be assessed every few hours.

Some production facilities run exercises similar to a mock recall but not as extensive. They practice tracking every bit of their inventory within a two-hour period, to see how accurately they can pinpoint locations, code numbers and quantities in case of a recall situation.

Perhaps the most important part of a mock recall is the debriefing session at the end. The entire point of the exercise is to prove that the company can effectively trace all raw materials through receiving, production, packaging and storage...and determine the locations to which all product has been shipped. Testing the plan will quickly point out any shortcomings, which can then be revised to work better in case of a real emergency.

The date and results of each mock recall or product-tracking exercise should be documented in writing. If you modified your Recall Plan based on the results, this should also be noted.

**“MY BEST ADVICE”
THE RECALL TEAM LEADER**



Section 5: “My Best Advice”—The Recall Team Leader

Kathy Spear has been an attorney at Kraft Foods North America, Inc. for almost 20 years. After getting her law degree at Northwestern University, she was in private practice in Chicago. She enjoys her job because, in her words, “Every day, something is new and interesting and challenging. Kraft is a leader in the North American food industry, and a wonderful place to work.”

As Vice President and Deputy General Counsel, one of Spear’s myriad responsibilities is to chair the “Special Situations Management Team.”

Q: TELL US WHO SERVES ON THE SPECIAL SITUATIONS TEAM.

A: It’s a cross-functional team. It is divided into a core team which has four members’ and an extended team, where there are people from a number of other functions within the company who are designated as team members and called in if their particular function or expertise is required. The core team consists of myself as the leader; a senior Quality Assurance person; a senior Corporate Affairs (public and press relations) person; and a senior Food Lawyer. The Corporate Affairs person is responsible for both external and internal communications on a situation—our sales force, the media, and working with our Consumer Response group that deals with consumer call-ins.

The team deals with product-related things, but also non-product-related things: environmental matters, worker safety and other employee policies. “Special situations”—it’s an all-encompassing term! The core team is involved in every situation, and the others shift on and off as needed, depending on the type of help and expertise that’s needed. It’s very adaptable, and much, much broader than just product recalls.

Q: DOES THE TEAM MEET REGULARLY, WHETHER THERE’S A “SITUATION” OR NOT?

A: The core team meets every other Friday. We get together to discuss what’s hot and what’s not. And we’re involved in training and other activities to drive home the point, throughout the organization, that we have this management process for a whole variety of special situations. We just completed a major effort last week, where we brought in about 45 of our key customers to talk about food safety and food security. So even if we’re not working on a particular problem, we have plenty to do, and we do meet regularly.

Q: DO YOU HAVE MOCK RECALLS?

A: We do two kinds of exercises. Several times a year, we pretend that we had a problem with a particular product, manufactured at this plant on this day. And we trace it, in terms of our production and everywhere it went, to determine how long it will take us to notify customers. We also do hypothetical

case studies with different groups, to show them how our process works and drive home what their responsibilities would be in a particular situation. It's a very interactive process.

Q: DO YOU HAVE SAMPLE DOCUMENTS ALREADY PREPARED FOR RECALL SITUATIONS?

A: Yes. Our Consumer Response group handles a couple million contacts in a year, and only a tiny fraction of those relate to anything that's a systematic product problem. They have very well-established procedures to deal with people in, let's say, "non-special" matters. But for a special situation, we have template documents for notices to our sales force and to customers, press releases, Q-and-A's for consumers on different kinds of issues. We have a lot of material on the shelf that we can use, and if we are doing a recall, we put it up on both our Internet site, and our intranet (internal) website.

Q: WHAT IS THE BIGGEST RECALL YOU'VE BEEN INVOLVED WITH?

A: The biggest one recently is public knowledge, not anything confidential. You may remember in Fall 2000, there was a recall of corn-containing products, because of the presence of an unapproved variety of corn called Starlink. We started it, when we learned through an anti-GMO (genetically modified organisms) group that they had tested some products of ours and found this unapproved corn in it.

The background is, genetically modified corn and soybeans are controversial in some countries. The EPA, the USDA and the FDA all get involved in the approval of new strains of crops before they can be planted and then used either to feed animals or people. The variety of corn called "Starlink" had been approved for animal feed, but not for human consumption. Some of that corn had entered the human food supply and, unbeknownst to us or anyone else, it was present in some taco shells that we made. This triggered a nationwide recall, not only of the taco shells—but the entire corn-containing food supply in the country was implicated!

It was a very technically difficult situation to manage, as well as being a very sensitive public policy issue. The anti-GMO group had done its testing to make a point, to demonstrate what it felt was the fact that the government wasn't doing a good enough job of regulating the approval of these products. It was quite a complicated situation to manage, and definitely the biggest thing we've been involved in recently.

Q: WHAT ABOUT THE SMALLER SITUATIONS THAT YOU MANAGE?

A: We sometimes get involved even when a single consumer complains, and is quite unhappy, and believes that our product has somehow been involved in an illness and threatens to go to the media, calls a regulatory official, threatens to bring litigation, or makes a demand. We always take all of these contacts very seriously, but if we're absolutely certain that there was nothing wrong with our product and the symptoms or onset of the illness are not consistent with what really happens with a given pathogen, then we'll get involved and usually it'll be over with quite quickly.

The first call we got in one case was from the person's lawyers, who said they were about to convene a press conference and, unless we were willing to pay a great deal of money, they would also bring litigation against us. They explained that their client claimed that they had found a whole mouse in a bottle of salad dressing—which we knew was a physical impossibility, just given the processing equipment. And let's just say the condition of the mouse was not conducive to a mouse who had been through a thousand-bottle processing line. We worked with the FDA's Office of Criminal Investigation on that one and they were very helpful.

Q: WHAT KIND OF ADVICE WOULD YOU GIVE TO COMPANIES THAT HAVE BEEN LUCKY—THEY HAVEN'T BEEN THROUGH ANYTHING LIKE THIS?

A: I'm a good Girl Scout, so I always say, 'Be prepared.' The best insurance you can buy is to form a team and think in advance about what you'd do, before you're in the thick of something—because when you're in the middle of a very sensitive or acute situation, you don't have the time to make it up as you go along. If it's a situation that presents a potential health concern, we may have only a few hours to begin a recall and issue a public announcement. We'll simultaneously be doing a product trace. We've had cases where we've literally had to move within hours. We've had others where the facts are just not clear enough, and whether there really is a problem or not is unclear. In those cases, it may take two or three days to sort things out.

We've met with a lot of other companies over the years, for benchmarking on how they do things. We can learn from them, and we're happy to share information ourselves. It's always amazing to me, the ones who say, 'Yep! We have a crisis management team. See? We have this big, three-inch binder and you know what? We've never had to meet!'

They think that's a GOOD thing! And my reaction to that is, 'Lord help you if something really happens.' Again, I say—be prepared.

Q: HOW IMPORTANT ARE RELATIONSHIPS WITH YOUR SUPPLIERS AND RETAILERS?

A: We've got good linkages with everybody one step up the chain from us, like ingredient suppliers—and one step down the chain, like our customers, either wholesale or retail. But everybody in the whole chain needs to have similar systems in order for a recall to really work.

We have very good relationships with our suppliers, retailers, and what we call "co-manufacturers." We have seminars and sessions with them, partly to make sure we know who are the right people to contact in their businesses. We visit them, or do video conferences, or have meetings that we host. We might also work with a supplier or customer, helping set up their team.

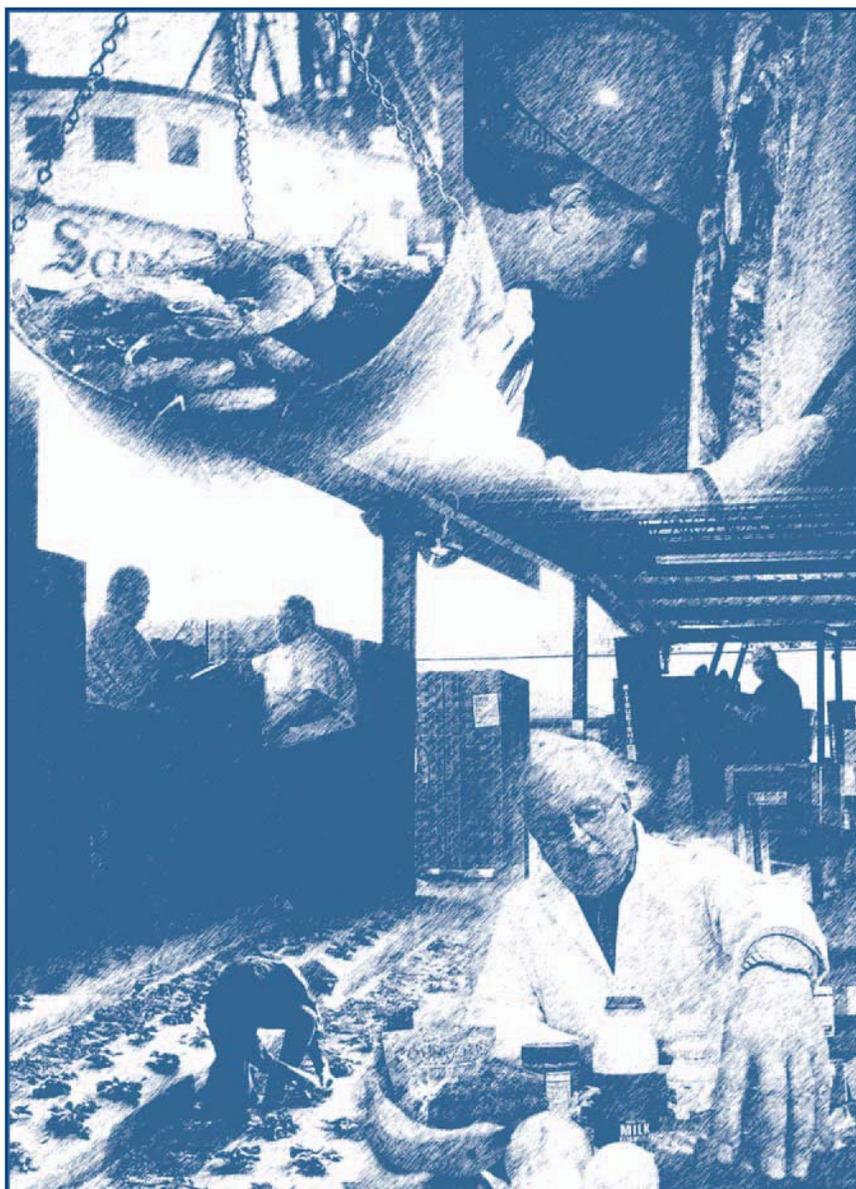
Q: HOW IMPORTANT IS YOUR SALES TEAM IN THESE EFFORTS?

A: We also have the largest sales force of any food company in the U.S., but even they call on only about 25,000 of the 95,000 or so supermarkets and other food stores. So the salesperson's role is very important, and they communicate with our customers and we rely on them a lot—but we also rely on distributors and wholesalers, as well as our public communications, to execute recalls.

Q: WHAT HAS IT BEEN LIKE TO WORK WITH THE NEWS MEDIA?

A: I'm not the person who works specifically with the press—that's our senior Corporate Affairs person on the team, who deals with broadcast and print outlets. But I would say, and I think she would say, they have generally gotten much better at getting the information right, using the information in our press releases or on our website to describe the product, where it was sold, what the problem is. Several years ago, that was not so uniformly the case. But the "mouse in the salad dressing" case? If it's a slow news day in a small market and a consumer has some sensational tale, it's amazing how reporters will bite! I guess that's the beauty of a free press!

DURING THE RECALL: INVESTIGATION AND COOPERATION



Section 6: During the Recall: Investigation and Cooperation

A problem has been called to your company's attention—by consumer complaints, your own quality control monitoring systems, or by a health-related government agency. No matter what the source of the problem, the first step is to COLLECT INFORMATION. You will need it to reach a decision, as a company, about whether to recall product. You will also need it to document whatever actions you take to remedy this problem, and to justify your decisions to authorities, if necessary.

At this point, as an owner or senior manager, you should:

- Convene the Recall Team and brief them on the situation.
- Contact an attorney (preferably part of the Recall Team).
- Ask Production to cease making the suspect product(s) and compile a list of suppliers to contact if necessary.
- Ask Distribution to locate all product that has been shipped to wholesale customers and prepare a list of them.
- Ask Sales force to compile a list of retail customers to alert if necessary.
- Immediately begin to compile all the records to investigate the cause or source of the problem.

Remember, IN SOME CASES YOU WILL ONLY HAVE HOURS in which to do all this! At best, you'll have a couple of days. As mentioned in the "Before a Recall" chapter, the questions you are trying to answer are: Should there be a recall; and if so, WHAT should be recalled? Therefore, you are looking for evidence of the:

- Credibility of the complaints.
- Exact (or alleged) problem and product.
- Degree of actual public health or safety risk.
- Possible cause(s) of the problem—or circumstances that make people ASSUME there is a problem when it may not be. (i.e., mold that occurs naturally on some foods but is harmless, etc.).

GATHERING EVIDENCE

Where do you begin? Think like a lawyer. You want to compile things that show your company is doing a GOOD JOB, as well as searching for weak spots. NEVER discard records during this process!

First, DO NOT OVERLOOK internal e-mail messages. This may mean alerting your Information Technology department (the computer folks) to maintain an archive of the e-mail accounts of those employees who are closely involved in the case. (Ask your attorney about this step, which is primarily for your own internal investigation.) There are many other potential sources of information:

EXTERNAL SOURCES

Brokers and distributors	Newspaper, radio or TV news reports
Regulatory agencies (the actual reports or warning notices)	Suppliers (of your ingredients and/or packaging materials)

YOUR OWN COMPANY RECORDS

Complaint history or complaint log
Compliance (health inspections, anything required by local or industry-specific health agencies including past non-compliance documents and how the company handled them)
Quality assurance (internal data, laboratory test results, in-house rules about food safety or safe manufacturing practices)
Production (equipment maintenance logs, date coding, product specifications, packaging specifications)
Distribution and storage data
Interviews with employees

The time crunch prompts some companies to assign responsibilities by department. In a medium- to large-sized company, the division of duties might look like this in the early stages of a recall:

- **ACCOUNTING** – Set up new account codes to keep track of expenses related to the recall, and assess its overall financial impact. Confirm the status and limitations of any insurance coverage. Set up standard methods of processing refunds or crediting accounts for returned product. Work with Sales and Consumer Affairs to make them aware of these methods.
- **CONSUMER AFFAIRS** – Brief anyone who answers the phones about what to say to callers. Arrange for additional telephone staff and/or a toll-free “hotline” if a large volume of calls and inquiries is expected. (Use the sample form in Appendix 1 to elicit information from callers.) If incoming calls are forwarded to others, create procedures for who receives which type of call. Work with Public Affairs to finalize information released to consumers, or to customers who call to find out what to do with the product they have on hand. Present your findings and suggestions to the Recall Team.
- **DISTRIBUTION** – Locate and immediately stop all shipments of the product, and arrange for their return to specific collection points. List all inventory, where and when it was distributed. Identify, separate and clearly mark any of the product that is still on site. Check storage conditions in company warehouses and delivery vehicles. Start a “Recall Log” to keep track of product as it is returned to the company. Present your findings and suggestions to the Recall Team.

- **LEGAL** – Look at specific complaints or allegations in relation to the laws that impact this industry. Check the wording of any outgoing letters, prepared statements or news releases. Advise the company officers and Recall Team on correct handling of consumer complaints and how to respond to any threat of litigation. Sit in on discussions with regulatory officials. Assist in interviewing employees for evidence-gathering.
- **PRODUCTION** – If your business is a manufacturing plant, gather all production, equipment maintenance, safety and quality assurance records for the product in question. Stop production if necessary. Provide written explanation of any product codes and complete sets of labels. Work with Distribution to locate all the inventory in question. Report on the shelf life of any product that has already been shipped. Present your findings and suggestions to the Recall Team.
- **PUBLIC RELATIONS** – Write statements of facts for employees and shareholders, and news releases for the media (if necessary), explaining the situation. Write letters and faxes to notify customers, and a script for complaints or other consumer contacts by phone. (See the Appendices of this manual for some sample documents.) Work with Sales staff to prepare hand-out and point-of-sale information for retail customers, to help them communicate with their own customers. Work with legal counsel, and perhaps the lead regulatory agency, to approve these documents and/or prepare to speak with reporters.
- **QUALITY ASSURANCE** – Oversee the technical investigation of the problem. Obtain and examine samples of the product in question, and contact outside experts or laboratories for assistance if necessary. Be able to provide and interpret process flow charts for products. Provide technical information and test results to regulatory authorities. Maintain a list of possible experts to contact to help determine the level of hazard. Present your findings and suggestions to the Recall Team.
- **RECALL COORDINATOR** – Convene and chair meetings of Recall Team. Serve as liaison between the company and regulatory agencies. Keep current records of all regulatory agencies' contact names and numbers, and all copies of information (both sent and received) pertaining to the product investigation and Recall Plan. Be available to meet with regulatory officials.
- **RECEIVING** – Organize and submit all records of incoming materials (both food and packaging) and inspections of same. Compile or update list of growers and/or suppliers who ship raw materials (including packaging materials) to you, in case one of their products ends up being part of the problem.
- **SALES** – Serve as a point-of-contact between the company and its customers. Make or update lists of contact information for accounts that may have the product. Present your findings and suggestions to the Recall Team. Later, help customers remove the product from sales and isolate it for later disposition. Distribute any written explanation of the situation to them—letters, flyers, posters, point-of-sale materials. Keep customers informed about financial adjustments, credits, or new product stock they may be offered.

As you might imagine, many of these activities are taking place simultaneously. But NOTHING will happen unless you brief each department about its specific responsibilities, and give department managers a deadline.

ANALYZING EVIDENCE

The Recall Team's next job is to compare the complaints, and the evidence that has been collected, to the pertinent laws. It may mean poring over FDA or FSIS standards; city or county health, safety or sanitation codes. It may require assistance from outside experts. The goal here is to evaluate the seriousness of the allegations—to learn as much as possible about exactly what is being charged and how you can disprove the complaint, offer a reasonable explanation for it, or acknowledge a problem and fix it. Unless a recall is already being requested by the lead agency, the only way to decide on a company-initiated recall is to analyze evidence and compare it to the applicable laws. Your attorney should be especially helpful in this step, as well as outside experts who may be valuable in determining the level of hazard.

This is also the point at which you may want to obtain independent laboratory analysis of product samples, even if you routinely analyze them in-house.

If it is a firm-initiated recall, the FDA or FSIS, and any other appropriate agencies should be notified. At this point, the team spokesperson (with the attorney's review) should be preparing this notification.

Agency-initiated recalls are rare, but when they occur the FDA or FSIS will notify the company with a very thorough written Recall Recommendation (RR). If the company does not have its own recall plan that's found to be acceptable to the lead agency, the agency will draft its own. It will include specific guidelines about what must be stated in any public notice.

GETTING THE WORD OUT

This brings us to the critical point of what, when and how much to say—to inspectors, employees, customers, etc. It is important to adopt the attitude that you will “Inform the Public,” not “Respond to the Crisis.” Good crisis communication will make the difference between a recall that causes some short-term disruption...and one that puts the company out of business because of negative publicity.

Remember what the FDA or FSIS is now deciding: the depth of recall, the extent of public warnings that will be required, and what level of effectiveness checks will be required. Each of these decisions affects the types and quantity of information you will have to write and release.

When a product emergency or recall action is in its initial stages, certain steps must be taken as soon as possible. They are:

- Decide who the “audience” is that needs information immediately. There is almost certainly more than one group, and their information needs will be different. Your prospective audiences may be: incoming callers, your workforce, your shareholders, government agencies, growers, suppliers,

wholesalers, distributors, retailers, specific industries that use your product, news media (including the trade press) and members of the public. Consider your non-English-speaking audience too.

- Decide what is the quickest and most effective way to impart this information: an afternoon of personal phone calls? A news conference? A mandatory meeting at each of your facilities? A fax or e-mail message? Document each contact in writing, no matter how it is made.
- Make a simple statement that says your company is aware of the situation, is investigating further, and will provide more details as soon as they are known. (This is sometimes aptly referred to as the “We’re aware and we care” statement.)
- Give as much detail as you can about the nature or extent of the problem and any actions that are being taken, but focus on the key points. Don’t get bogged down in such minute or scientific detail that the reader or listener won’t understand it, or will be unnecessarily frightened by it.
- Ask the lead regulatory agency if there is a health statement they would prefer you use in your news release or other public statements. This is a short summary (usually only a few sentences) of symptoms, cautions, etc. related to an allergen or foodborne illness.
- Limit your remarks to ONLY what you know to be true. If you don’t know something, it is best to say you don’t have the answer yet. Do not speculate, and keep your temper in check even if you feel some of the endless questions seem like “badgering” or “baiting” when you’ve told them everything you can for the moment. (Watch a couple of White House news conferences for a look at this behavior at its ultimate!)
- Even if you are making contact by phone or in person, work from a written “script” to be sure you are including all the pertinent info—not leaving anything out, and not misstating anything.
- DO NOT forget to include your website! It is one of the first places today’s computer-savvy consumers (and reporters) will look for information. See that it is updated IMMEDIATELY, and often, to reflect the latest progress or developments in crisis situations. It can be a huge help, in that you can refer clients and callers to it for updates and instructions.
- Keep a log of who calls in or e-mails questions, and document exactly what you have told, sent or given them. Also keep a list of which organizations you have sent information to—recall notices, media kits, the news release. The lead regulatory agency will ask to see this list.

The fact is, a TV news reporter standing outside your plant can make the phrase, “No comment,” sound more gruff and less cooperative than anything you could have said on camera. Remember that reporters are only doing their jobs. So here’s a switch—how about calling THEM instead of waiting for them to call you when there’s a problem? There is nothing wrong with contacting local journalists, if you have a statement to make and written background materials to hand them.

Some of this material can be produced in advance, and can also be useful as part of your “press kit” (or “media kit.”) This includes things like:

- A short (1-page) news release about an event or new product.
- A short (1-2 page) summary of your company history and product lines, mission and vision statements, etc.
- Background sheets (1-2 pages) about how your company handles issues like safety, sanitation, quality control, research and development.
- A “position statement” about an interesting topic in your industry that reporters may find newsworthy.
- Short (1-2 paragraph) biographies of company officers, with small photos and bulleted lists of awards or accomplishments.
- And, of course, the name and phone number(s) for your spokesperson.

Companies find press kits handy because they are modular—a folder with a variety of hand-out sheets that can be updated or eliminated as needed. Others prefer to produce a short brochure (or series of brochures) containing this information. The same data should also be part of your website.

Keeping much of the communication in writing, and assigning a single spokesperson, helps ensure that your message is consistent and clear. When the situation calls for some technical explanation, “back up” your spokesperson with an expert or two if necessary, letting them handle questions in tandem. Rely on your Quality Assurance department to select the experts who are most familiar with your operation.

The Recall Team should also meet with senior management, Sales and Accounting to decide how best to replace the recalled product and compensate customers for the inconvenience, as well as the physical loss of inventory. The Sales team’s job is even more difficult in a recall situation, and being able to offer meaningful goodwill gestures and collateral materials to customers are important steps in maintaining or rebuilding the company’s credibility.

During a recall or other type of product emergency, it is hard to see that anything good might come of it. But if you manage to deal honorably with—and gain the trust of—news reporters, business associates and members of the public, you may actually come out ahead long-term.

MONITORING THE RECALL

The FDA or FSIS approves or modifies the company’s recall plan, and the product recall is underway. Your Recall Team members are tending to their responsibilities—and so is the agency that’s watching your progress. For Class I and II recalls, the government agency will call or visit some of your customers at random, just to be sure they’ve been notified and are taking appropriate action.

RECALL STATUS REPORTS

The recalling firm must submit Recall Status Reports to the lead agency (usually an FDA District Office) at intervals of two, three or four weeks. (The agency decides the frequency.) Each report must contain the:

- Number of consignees contacted.
- Dates and methods used to notify them.
- Number who have responded to the Recall contact, and how much product they had on hand at the time of notification.
- Quantity of product returned (or corrected) by each consignee who was contacted.
- Total quantity of product that has been accounted for so far.
- Number of consignees who have not responded. (The FDA may request their identities and contact information.)
- Number and results of any Effectiveness Checks that have been made.
- Estimated time frame in which to complete the recall.

If the agency that reviews the Recall Status Reports decides the recall is not proceeding quickly or smoothly enough, or that a significant quantity of the product remains on the market despite the manufacturer's efforts, the agency may move to legally detain or seize product unless the company is willing to take more effective action.

EFFECTIVENESS CHECKS

The lead regulatory agency will also specify how many of the consignees to contact during the recall period to gauge the effectiveness of the recall. Effectiveness Checks (also sometimes referred to as "Audit Checks") verify that consignees have received their recall notifications and have taken the appropriate action.

These follow-ups are done periodically throughout the recall. They should be done in person if at all possible, but they can also be done by phone, fax, mail, or e-mail. (See sample Effectiveness Check questionnaire forms in the Appendix.) As you've already learned, Effectiveness Checks may be mandated for ALL of the consignees (Level A) or as few as two percent of the consignees (Level D.) At Level E status, for extremely minor problems, they don't have to be done at all. The level is usually based on the class of the recall. You cannot suggest or change the level for your own recall—it is assigned by the lead agency.

The lead agency may entrust Audit Checks to a state health department, and ask the department to report its findings to the FDA or FSIS. Since your company is ultimately responsible for the success of the recall, you may also ask to see the results.

Gauging Public Opinion

In extremely serious or far-reaching cases, your company may also decide to monitor public opinion. Most major cities have “clipping services” that save newspaper and television reports and provide you with copies of them for a fee—provided they know to look for the coverage in advance. It’s a good idea to find out more about the local clipping services before you need them.

Your company’s public relations person should be able to locate a market research firm that can perform consumer opinion research, by telephone or in person, or using mail-in surveys or even e-mailed surveys. (If your company is big enough, it can do this without outside assistance.) It may provide valuable feedback about what to do to rebuild customer trust. Some types of recall-related insurance cover these business-rebuilding expenses.

Remember that the lead agency will also be monitoring news sources, primarily to ensure that you’ve done an effective job of contacting them.

DISPOSITION OF PRODUCT

Now there is the question of what to do with the cases of product that are defective or suspect. This decision must be made jointly between the company and the lead regulatory agency. The most important advice here is to NOT destroy or dispose of ANY product without first:

1. Submitting a written plan to the FDA or FSIS about what do to with the product, AND getting their approval of it.
2. Offering to have a state or federal agency representative there to “witness” whatever action you take.

In most cases, the manufacturer either asks that the products be returned or destroyed. This decision should be made based on whether they can be reconditioned or repackaged and sold safely. If reconditioning is an option, be aware that government supervision will probably be required.

DONATION

Sometimes, in the case of Class III recalls when the problem is related to labeling—the product does not pose any type of health risk—a company may be allowed to donate the recalled merchandise to reputable nonprofit organizations that are authorized to receive it. In this case, be sure the nonprofit group provides written documentation that it understands the recall terms and accepts the product anyway.

RECONDITIONING

If the product is meat or poultry, before it can even be moved to a reconditioning site, the recalling company must request permission from the FSIS District Manager; and then notify the local USDA-

FSIS inspector of its arrival date at a USDA-inspected plant. When it arrives, the inspector checks the product to determine whether, and how, reconditioning can proceed—and may supervise the reconditioning process, or at least re-inspect the reconditioned product before it can leave the plant again. Reconditioned product that still doesn't meet FDA or USDA standards is destroyed.

DESTRUCTION

If the product poses a potentially serious health hazard, the lead agency may require that it be gathered in a single location for destruction. The method of destruction has to comply with all regulations (local, state or federal) about disposal of toxic materials and/or landfill use. The recall team should compile a list of approved landfills and disposal services.

In serious cases, simply throwing the products away is not sufficient—you must prevent them from being retrieved and consumed. The manufacturer must keep records of the code numbers and quantities destroyed. Get a receipt for whatever was paid to the landfill or other site, including the address and date and the method used for product destruction. It's a good idea to document the destruction process by photographing or videotaping it. An inspector from the lead agency may also do this. If the product is located at a number of different locations, you may be authorized to contract with a third party to document the product destruction.

If a product is simply spoiled and/or throwing it away would not pose a health hazard, the consignees may be asked to dispose of the product like any other waste—in their trash dumpsters. Again, ask them to document **WHAT** they did...**HOW MUCH** they tossed out...and **WHEN** they did it. Better yet, have your salesperson on-site, to help with the task.

ADDITIONAL INFORMATION FOR REGULATORS

NOTIFICATION

Your role in the notification process is to ensure that the company gets the word out to its consignees:

- In a timely manner, to ensure quick removal of the product from the marketplace.
- With specific instructions for what to do with the product—how to return it, whom to contact, etc.
- That they include everyone, both “upstream and downstream” on the product distribution chain, including secondary accounts if applicable.

The initial contact may be made by telephone, but a written letter of notification must be required as a follow-up. If the notification is sent by U.S. mail, fax or e-mail, the company should also include a mechanism to verify that the consignee actually received the notice.

CONTENTS OF THE WRITTEN NOTIFICATION

No matter who actually writes it, the components AFDO recommends as part of every written recall notification are:

1. The words “Urgent Food Recall,” typically in a headline and on the envelope in which a document is mailed.
2. The recalling firm’s name, address, contact person, telephone number(s).
3. The date of the recall notification.
4. Exact description of the product(s) being recalled, including name(s), packaging, and container size(s).
5. Any product codes on the container(s) or packaging.
6. Name of manufacturer / distributor (if different than the recalling firm).
7. Reason for the recall.
8. Instructions for disposition of recalled product.
9. Instructions for any further sub-recall action (i.e., notification to secondary accounts and beyond.)
10. A requested response, to verify that the notification has been received, and to document the quantity of product at each account.

ISSUING A NEWS RELEASE

Not every recall situation includes the need to notify news media. It depends on the depth of the recall. But when this is necessary, it is in the company’s best interest to issue its own news release. The lead regulatory agency either:

- Works with the company to word the news release, and must approve the final copy before it is sent out, or...
- Issues its own news release about the recall.

(FSIS always issues its own news release, even if the company chooses not to.) AFDO’s recommendations for what to include in a news release are:

1. The recalling firm’s name, address, contact person, telephone number(s).

2. The date of the news release and, if there are guidelines for when it is to be released, include them. (Usually this means “For Immediate Release.”)
3. A headline that very briefly describes the recall (“Potential Salmonella Contamination,” etc.)
4. Specific product(s) being recalled (e.g., quantity, label names, product codes and where they might be located on the container, container size and type, production dates, expiration dates).
5. Specific reason for the recall.
6. A mention of any particular group of persons who might be at risk.
7. A description of symptoms.
8. Status of the number and types of related illnesses confirmed to date.
9. Area of distribution, naming each state and how it reached consumers (e.g., retail, mail order, direct delivery).
10. A brief description of how the problem was identified (e.g., firm’s quality control processes, regulatory agency’s routine product sampling program, regulatory agency’s epidemiological investigation)
11. Instructions for what consumers should do with the recalled product.
12. Instructions and contact information for consumers to obtain additional information.

DISSEMINATING THE INFORMATION

As a regulator, your agency should compile a list of news sources before it is ever needed. Include newspapers, wire services, television and radio stations—with contact names and phone numbers, fax numbers and e-mail addresses of these media outlets. Do not forget to include Spanish-language stations and publications, or those of other languages common to immigrants in your area. The speed of notification depends greatly on having an updated media list.

Also think about other groups and institutions that might need to know about recalls. Anyone who might have received the food, or who might receive complaints or questions, should be notified. Depending on the product and the situation, this may include:

- Food banks
- State agencies
- Trade associations (for restaurants, caterers, etc.)
- Consumer groups
- Military bases

- School districts
- Hospitals, nursing homes, Senior Citizen Centers
- The state Medical Association
- The Food Allergy and Anaphylaxis Network (FAAN)
- Internet-based sites, like www.recalls.gov

These organizations can then alert their own members, multiplying the reach and impact of your information. The news release must be issued in ALL STATES WHERE THE PRODUCT WAS SHIPPED.

Share the list of contacts with the recalling company. As a regulator, you can request verification from the recalling company that the news release has been sent, and to whom.

OVERSEEING PRODUCT DISPOSITION

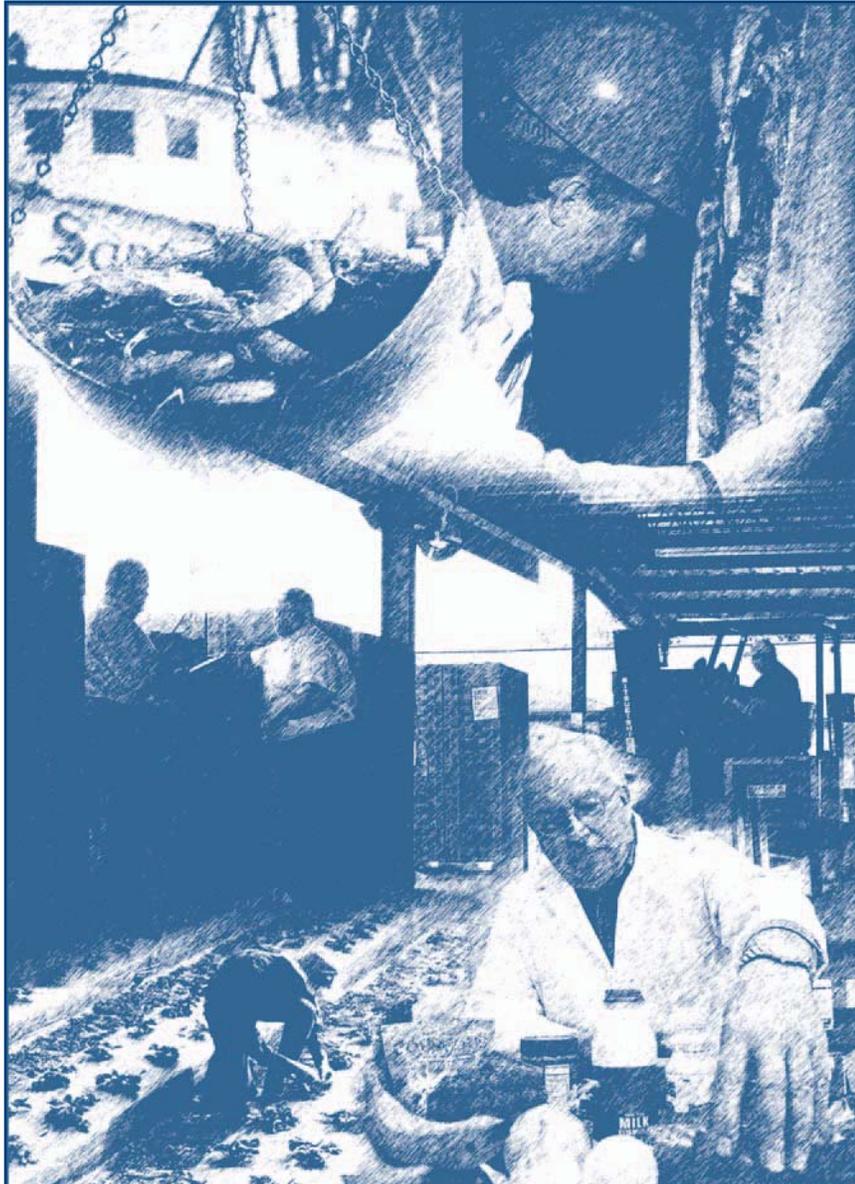
What to do with recalled product is a question that should be resolved jointly by the agency and the recalling company. Remember that reconditioning is only an option if it brings the product into compliance with the law. Methods may include:

- Cleaning
- Reprocessing
- Repackaging
- Relabeling
- Overstamping
- Sorting
- Segregating

When product must be destroyed, the method must ensure that it will not be returned to human food channels. It is not sufficient to assume that down-line users will follow the correct guidelines and do it themselves, so it is important that the manufacturer physically recalls the product, gathers it in as few places as possible, and documents its destruction.

Your agency must have a policy for documenting product reconditioning and destruction. As an inspector, you can observe the procedures and document them, in writing and/or using film or videotape. In some instances (usually when multiple locations are involved), the lead agency and the recalling company may agree to contract with a third party to document product destruction on-site at stores, warehouses, etc.

**“MY BEST ADVICE”
THE PROSECUTING ATTORNEY**



Section 7: “My Best Advice”–The Prosecuting Attorney

Bill Marler of the law firm MarlerClark in Seattle, Washington, is perhaps best known for suing the quickservice restaurant chain Jack In The Box back in 1993 for serving people ground beef contaminated with a deadly strain of *E. coli* bacteria. Since then, his firm has specialized in food-related liability cases on behalf of consumers.

Q: WHEN, IF EVER, SHOULD A COMPANY PROTEST A RECALL REQUEST?

A: If the company refuses a recall, it’s generally not good for business anyway. But if you negotiate with the agency for a couple of days, that is two more days that people could be out there consuming your product. That opens the door, not just for compensatory damages, but for punitive damages for failing to act to protect the public when you know that your product is potentially tainted. So the bottom line from my perspective is, the minute—the second—that you think your product is tainted, you should be recalling it and you should have a recall “Swat Team” and plan right off the bat. It should be completely second nature as to how to do it, who to contact, how to get to your customers, what kinds of faxes and phone calls you should send. Have the whole thing pre-planned. And be on it quick, primarily because you don’t want to sicken any more of your customers, because especially those that you sicken after the recall announcement, it puts you at risk of being hit with punitive damages, which are not covered by insurance.

Q: SPEAKING OF INSURANCE, WHAT KINDS WOULD YOU RECOMMEND A COMPANY GET?

A: As much as they can! (laughs) I’ll give you an example. In the Jack In The Box case back in 1992-93, it had only been about six months before the (*E. coli*) outbreak happened that there was a new board member who was an insurance executive. He looked at the amount of insurance in light of the amount of risk the company had—considering the number of stores and stuff—and said, ‘You guys need at least four times the insurance that you currently have.’ So they increased it from \$25 million to \$100 million. In fact, they spent all \$100 million on liability cases. Without that additional \$75 million, the case would have bankrupted them. As it was, they literally had enough insurance money to pay and they were proactive with their insurance company, so most of the claims were handled relatively quickly.

That’s the power of insurance. The balance is having enough. I can tell you in a lot of cases, especially in small companies, they don’t have insurance and wind up being at high risk of going bankrupt.

Q: HOW OFTEN IS A PRODUCT-RELATED CASE THE RESULT OF A DISGRUNTLED EMPLOYEE?

A: Oh, I've been doing this work for 11 years, and have handled \$110 million of cases for clients. There has not been one case I've been involved in where there was evidence of employee tampering. I've had cases where employees were ill—say, *Salmonella* positive or Hepatitis A positive—who's to blame for that? I've heard defense lawyers claim that employees didn't do a good job, and we're starting to see a few more defense claims that there's a risk of terrorism, or a terrorist act. But I can count on one hand how many actual food illness terrorism acts have occurred in the last 20 years, and there's like, three. Sure, anything can happen, but I think mostly people are all excited about it because the federal government is now funding research in that area, and so far, it's sort-of creating a problem that doesn't really occur.

Q: PERHAPS THE WORST THING IS THAT IT MIGHT EVEN GIVE PEOPLE SOME IDEAS THAT THEY MIGHT NOT OTHERWISE HAVE HAD!

A: I'll tell you a funny story. I had a case where about 100 people got sick from salmonella poisoning at a golf and country club. The owners put out a news release saying, 'We believe it was a criminal act'—that one of the employees did something. It probably was a number of ill employees who contaminated the food or a food item that was not prepared and employees ate it too, and people all got sick. It just kept going and going.

The club owners asked for an FBI investigation. So my partner and I were meeting with the insurance adjuster on the case and she said, "Our defense is that we believe this was an employee terrorist act."

I said, 'Really? What's your basis for that?'

She said, "I've been going through health department files, and there are notations for some of the workers saying, 'Suspect FBI.'"

I said, 'You're an idiot. That means 'Suspect Food Borne Illness!' We see stuff like that!'

Q: WHAT DO YOU TELL COMPANIES TO KEEP, OR NOT KEEP, IN TERMS OF RECORDS?

A: Nobody needs to keep records longer than the statute of limitations, which varies from state to state. My suggestion is to ask your lawyer what the statute of limitation is in your state, and you should have an ongoing document retention policy that does what it's supposed to do. Don't archive or destroy records sporadically—do it on a very consistent basis. Don't start destroying documents the minute you find out you're doing a recall, or you're being sued. That'll just be a disaster for you, because nowadays, there is never one document anywhere. The one you're trying to destroy is always floating around somewhere else, 4 or 5 copies of it that an enterprising fellow like myself will find! So companies need to have a document retention policy that makes logical sense, and follow it. If you destroyed things last Thursday, make sure it's because they were three years old and it was the logical time to destroy them according to your policy. Make a policy and stick with it.

Q: WHAT ABOUT E-MAIL FILES?

A: Same thing. There are innumerable examples I've been involved in where I've gotten courts, in civil cases, to seize hard drives and require the company to pay for somebody to come in and go over those hard drives. I've found many, many, many e-mails that are exceedingly embarrassing. So people need to have both a hard document and electronic document retention policy, and it needs to be consistent. If you have a recall and have four years of files on hand and suddenly decide, 'Gee! I think we can destroy three years of this stuff!' That would be a bad idea.

Q: WHAT ARE THE DUMBEST THINGS YOU'VE SEEN COMPANIES DO? ARE RECALLS, FOR THE MOST PART, A RESULT OF STUPID MISTAKES?

A: Yes. Most of the time, nobody does this because they're evil! Any time there's been a foodborne illness outbreak of any size, usually a number of things have to happen in order for it to occur. You have to have a raw food product that is contaminated. You've got to have inattention to detail about how you're processing it. And you have susceptible people that get sick. There have to be all the right factors—or all the 'wrong' factors—that come into play. But you always look back on these things in hindsight, and you can see exactly where and how the company made the mistake. I can't tell you an outbreak I've been involved in where you'd look back and say, 'Gee, none of us would have ever caught that.' In every one of these cases, there is clearly something that the company failed to do. Repeated days of positive e. coli tests, or months of high bacterial counts, in their finished product. Those are the kinds of mistakes that, frankly, I see all the time. They're just inattention to detail and more attention to marketing, the bottom line, the quota. They're not paying attention.

Q: WHAT'S YOUR ADVICE ON HIRING AN ATTORNEY TO BE ON THE RECALL TEAM FROM THE BEGINNING, TO BE IN THE LOOP AND LEARN THE PROCESSES AND LEARN ABOUT THE COMPANY?

A: Well, most companies in my experience don't have an ongoing relationship with an attorney. Y'know, nobody likes attorneys—hell, I don't even like attorneys! The companies that successfully deal with outbreaks and recalls well, are those that have ongoing relationships with a lawyer who understands his or her role. That role is to advise the clients how to protect themselves—someone who understands a document retention policy, and ongoing compliance issues in whatever form. But in order to save money, most companies don't bring a lawyer in until something goes wrong. And what happens is, when something goes wrong you call your insurance adjuster. The lawyer for the insurance company contacts you and says, 'Oh, I'm your lawyer!' Well, then you need to step back and say, 'Is that person REALLY my lawyer? Who pays his bill? The insurance company! I wonder if he has my best interest at heart, or the insurance company's?'

I've found that those companies that try to be penny wise and pound foolish by not having an attorney and relying on the insurance company attorneys are the ones I absolutely rip apart and leave their bones.

Q: WHAT ARE YOUR THOUGHTS ABOUT THE ENFORCEMENT CLIMATE, IN GENERAL?

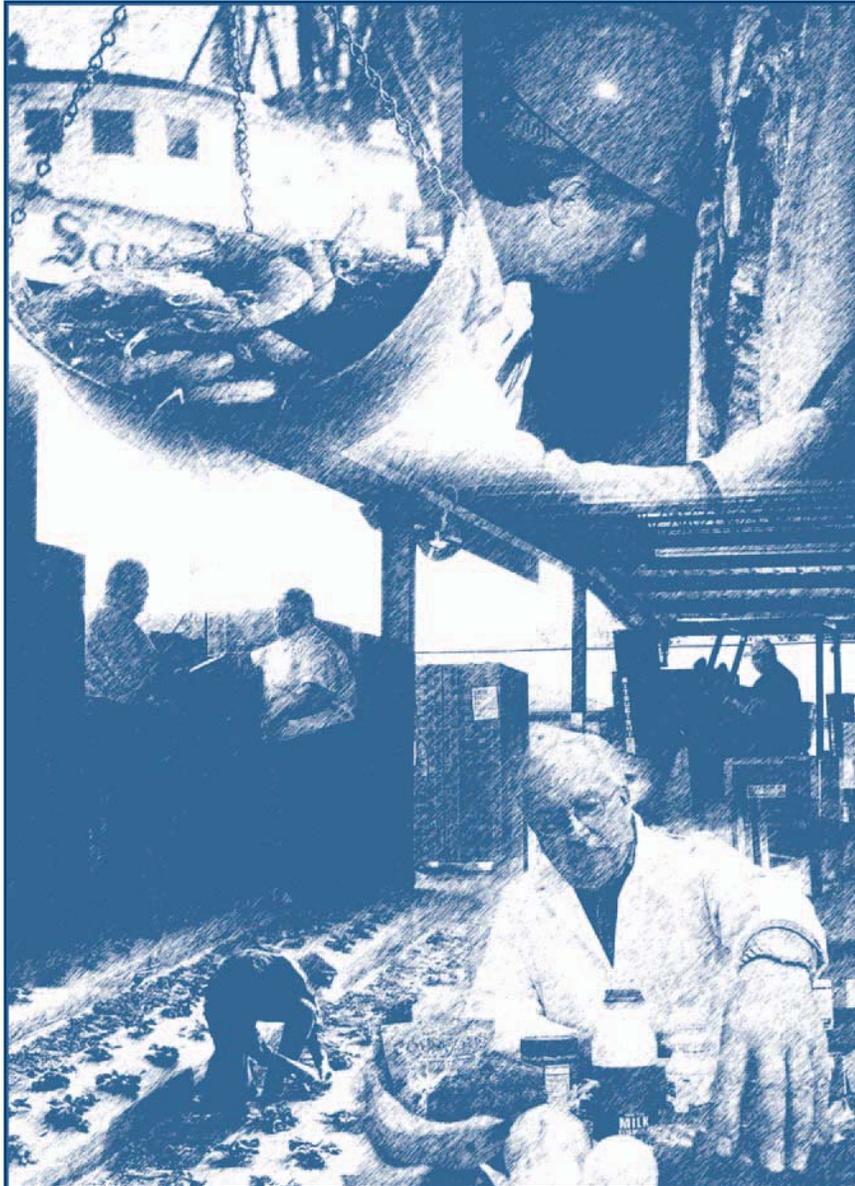
A: If you believe the CDC statistics, there are some 76 million foodborne illness cases every year in the U.S. In the vast majority, maybe 95%, you never figure out what caused them. You might generally know what it might have been, potentially, but there are all kinds of reasons why you can't pin it down. People don't report, they're misdiagnosed, they don't have stool cultures; local agencies not talking to state agencies, who aren't talking to each other, or to federal agencies. So the vast majority of food illness cases are never figured out.

The reality is that there is very little pressure on companies to reform, because there's very little chance they'll get caught. Things are improving—the technology is getting better, the agencies are getting more tools like genetic fingerprinting and sharing more information. But it's like a finger in the dike. If you look at it from a local health department standpoint—understaffed, underpaid, overworked, going in sporadically to look at health issues at plants or restaurants—they are mostly coming in as teachers, to teach these companies why they should be hot-holding this or that. The state health departments are also under-funded and overworked, and now are focused on bioterrorism because that's where their funding is coming from.

All of this comes down to two things, from my perspective. One, there is really a moral reason to not poison customers. They're usually nice little old ladies or children, and you run the risk of killing them or absolutely ruining their lives. I see it every day, and I make multimillion dollar settlements in cases for kids who run the risk of losing their kidneys, or are brain-damaged, or are now diabetic. There's not one of those kids or their parents who would rather have their health back than the money. So to the companies, I say, 'Hey! It could be your kid, or your grandkid, or your neighbor.'

Two, there is a business reason not to do it—and that is, every once in a while, you might get caught. If you want to play the odds, chances are you will get caught. And if you get caught by a lawyer like me, who knows what they're doing, I will do everything in my power to take you to the ground. That's what I do.

AFTER THE RECALL: LEGAL LIABILITY AND TRUST-BUILDING



Section 8: After the Recall: Legal Liability and Trust-Building

A product recall is considered officially complete when all reasonable efforts have been made to correct the violative product or remove it from sale. The Code of Federal Regulations (Title 21, Part 7, Subpart C, Section 7.55) puts it this way:

- a) A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product.

The USDA's FSIS has similar rules. Ultimately, this is the decision of whatever federal agency is involved; however, a company can request in writing that a recall be terminated. (See the sample request for recall termination, Appendix 5 of this manual). This request must be accompanied by:

- The most current recall status report.
- A description of the disposition of the recalled product.

The agency will confirm the recall termination in writing. And even when a recall is over, there is still much to do. The Recall Team should continue to meet to:

1. Review the procedures and discuss how well the plan worked.
2. Make a written report that details the entire recall.
3. Make recommendations for how to avoid the situation in the future, and follow up to see that they are enforced.
4. Decide if follow-up is appropriate—to consumers, retailers, agency personnel, employees and members of the news media.
5. Discuss the actual costs of the recall and file appropriate insurance claims along with documentation of costs and losses.
6. Consult with the attorney about the potential for litigation.

PRODUCT LIABILITY LAWSUITS

Two of the scariest words in the English language for corporate executives are “pending litigation”—and yet, it is always a possibility in recall cases. A recent study indicates the average settlement amount for recall-related litigation is more than \$200,000.

If a lawsuit is filed by an individual in the company’s home state, the laws of that state will apply. If, on the other hand, the product has been recalled nationally and people in other states file lawsuits, the company being sued may have some input about which state’s laws will apply. This is important because state laws vary drastically on almost every important aspect of product liability cases, from statutes of limitation to plaintiffs’ ability to collect punitive damages. As an example, let’s take statutes of limitation. At this writing, for a product liability claim:

- Consumers have one year from the date of illness or injury to file a lawsuit in California, Kentucky and Tennessee...
- two years in Illinois, Indiana and Louisiana.
- three years in Connecticut and New York...and so on.

Another important difference is the type of claim that the consumer can make. Here are some of the issues that consumers, and their lawyers, will be deciding:

- **STRICT LIABILITY OR NEGLIGENCE** – In a strict liability case, the plaintiff does not have to prove that a company was negligent. There are different tests for liability and/or negligence, which vary among states. The “consumer expectations” test is a common-sense approach—that a product is considered defective if “any reasonable person” expects it to be in a certain condition, and it is not.

The “risk-utility” test means the risk involved outweighed the usefulness of the product. Risk-utility is determined by factors like how serious was the problem; what was the probability of the risk occurring; did the consumer take adequate precautions in using the product?

Proving negligence usually requires proving “proximate causation”—that is, the problem was foreseeable by the food manufacturer. But again, different states have different definitions of causation.

- **PUNITIVE DAMAGES** – This is an amount of money added to a judgment or settlement to punish a company for wrongdoing. Some states allow it only when a wrongful death has occurred; others don’t allow punitive damages at all in product liability cases. A few states allow them depending on whether the plaintiff can prove the company showed “reckless disregard” for safety, or had “actual knowledge” of a dangerous condition and failed to act on it.

- **CLASS ACTION CERTIFICATION** – When several (or hundreds) of people file similar complaints or lawsuits, your company may be faced with a Class Action—one case that covers everyone who joins the class. Sometimes, this is the quickest way to resolve a large case. It usually involves a one-time settlement amount and is less complicated than negotiating dozens of smaller suits in different states.

A company may decide to oppose a class certification if it is convinced the claims are not valid, or if the settlements to each plaintiff would be so small that it's not worth wrangling in court about. Your attorney can help you make the decision.

Historically, companies that fight about each and every recall-related issue don't make out as well overall as those that show a desire to cooperate.

CRIMINAL VERSUS CIVIL CASES

Because food-related illnesses can pose serious health hazards, courts have ruled many times that a prosecutor does not have to prove that a company was aware of the problem in order to make a case. In fact, all a company has to do is transport unsafe products across state lines for sale and it becomes a federal case. The U.S. Attorney prosecutes these cases on behalf of either the FDA or USDA.

Food-related lawsuits are most often civil suits. However, a criminal case may be filed if the action itself was deliberate (intentionally tainting or mislabeling food, or using unsafe ingredients). Felony charges could also be filed if the company knew there was something wrong with the product and continued to sell it—or attempted to hide the facts from inspectors, customers or consumers—adding the charges of “willful blindness,” “intent to defraud,” and conspiracy. Criminal liability extends to any employee or company officer who might have been in a position of responsibility, such that they could have prevented the problem. Hefty fines (in the millions of dollars, even for misdemeanors) and imprisonment (for felonies) have been the results of past convictions.

Legal experts say if there is a chance both the company and individual employees will be sued, it is advisable for the employees to retain their own separate legal counsel. This is because there's always a chance that the interests of the individual and the company will conflict as the case progresses.

GAINING GROUND

As strange as it may seem when you're in the middle of a recall, there is some good that should come of it. First, it has forced your company to learn how to do some things better: more safely, with better organization, more accurate record-keeping, etc. It was learning the hard way—but it was learning.

Second, it has opened up a dialogue with members of the news media that can now be used in a positive fashion. Reporters swarm like flies when there's a crisis. (Don't take it personally; it's their job!) Now that you know who they are—and they know something about you—it's time to keep them informed of any new plans, organizational changes, feature topics or other newsworthy issues in your

industry. Let them know they can contact you as an ongoing source of information. Remain accessible, and maintain the level of trust that has been established during the crisis.

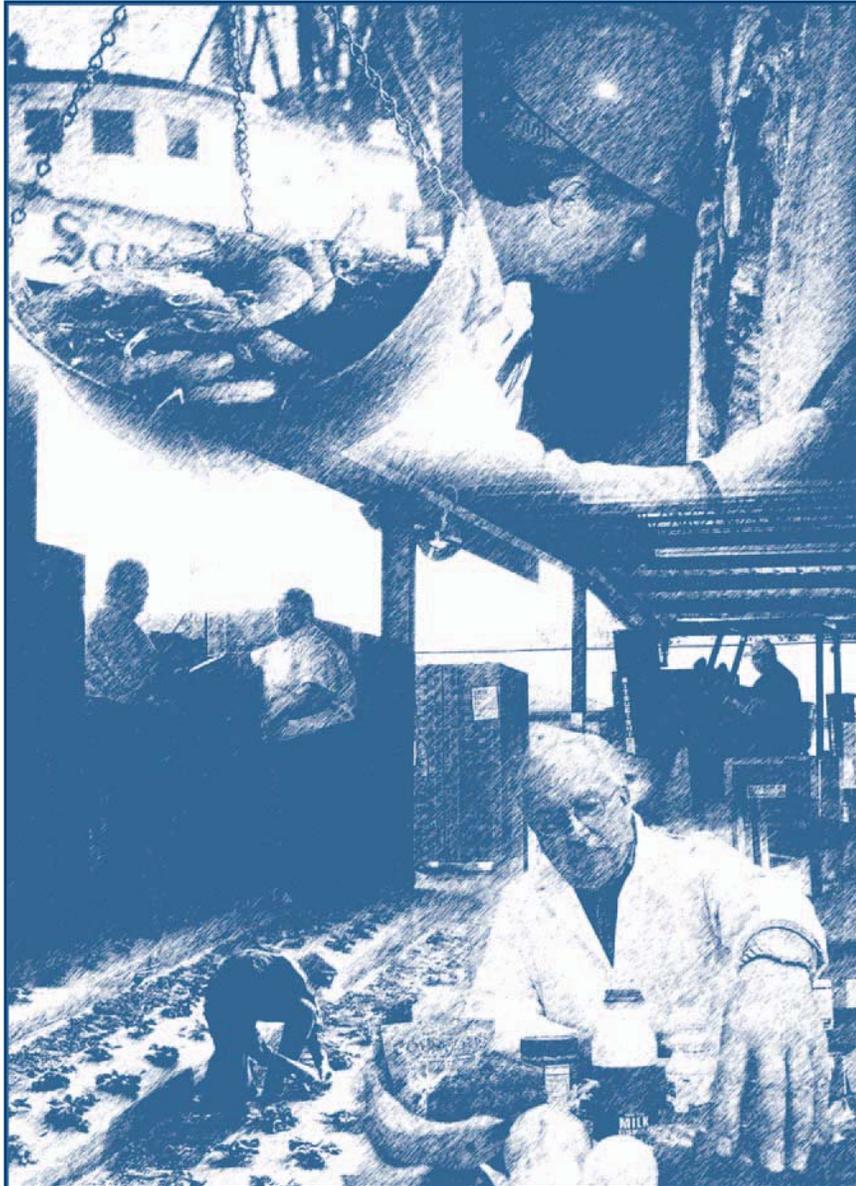
Third, you also have the opportunity to build a new level of trust with your customers. It is time to thank them sincerely for the help they provided during the recall. Let them know your operation is back to normal, and that their continued support is valued. Go beyond the financial costs of the crisis, to determine exactly how it has affected them, and their customers. You might draft a survey form and ask your sales team to deliver it to their accounts so they can give you feedback. Use the feedback to make positive changes, and then inform them of these changes. Stay in touch with them, and keep your website updated with good information.

Fourth, your employees and managers have been put under a great deal of pressure during the recall. There may have been some finger-pointing and infighting about how to handle the various steps, and tempers may have flared as patience ran short. Recognize that your company needs time to heal. Use this period to reward those who made significant contributions to the recall effort—perhaps financially, or with recognition in a newsletter or on a bulletin board. Ask employees for their input about how things can be done better from now on. You might be surprised at their commitment and creativity.

And finally, use your experience to help others in your industry. As a Recall Team, discuss how well your “allies” rallied around you when you needed them—trade groups, civic organizations, suppliers, shareholders. If you see weak links, this is the time to shore them up.

The fact is, no type of food product is immune from problems, or the possibility of a recall. Being proactive and well prepared significantly minimizes your recall risk and improves the chances of doing very effective damage control if it does happen.

**“MY BEST ADVICE”
THE FDA OFFICIAL**



Section 9: "My Best Advice"—The FDA Official

Sandra Whetstone is the Director of the Division of Compliance Management and Operations in the Office of Enforcement of the U.S. Food and Drug Administration in Rockville, Maryland.

Q: HOW MANY RECALLS DOES YOUR OFFICE OVERSEE (IF THAT'S THE RIGHT WORD) IN A YEAR? HOW ABOUT PRODUCT CORRECTIONS, WITHDRAWALS, STOCK RECOVERIES?

A: In Fiscal Year 2002, FDA classified 2,585 industry actions as "Recalls." These industry recalls included 5,105 individual products and recall numbers, recognizing that many recall actions include more than one product. There are also a small, but uncounted, number of industry actions to correct or remove products from the market that are considered market withdrawals. These situations are generally not tracked in our database so no count is available. Market Withdrawals by definition are actions for which FDA would not take regulatory action. "Product correction" is a part of the "recall" definition. A "product correction" may be classified as a recall or a market withdrawal, but is not counted separately from other recalls. Stock recoveries are not reported to FDA and we have no information to provide.

The number of recall events and recalled products by FDA Centers for 2002 are:

- Center for Drug Evaluation & Research – 193 recalls, 437 products
- Center for Food Safety and Nutrition – 423 recalls, 920 products
- Center for Device & Radiological Health – 627 recalls, 1534 products
- Center for Biologics Evaluation & Research – 1307 recalls, 2052 products
- Center for Veterinary Medicine – 35 recalls, 162 products

Q: ARE THERE COMMON PROBLEMS THAT YOU SEE IN THE WAY COMPANIES HANDLE RECALLS—SOMETHING SIMPLE THAT THEY OFTEN OVERLOOK? A DETAIL OR TWO THAT THEY COULD ADDRESS BETTER?

- A:**
1. Failure to communicate with the local FDA district office recall at the out start, giving the FDA recall coordinator the opportunity to review the recall letter before issuance and identify problems that may arise later.
 2. Failure to communicate the level in the distribution chain to which the recall should extend, i.e. retail or consumer level. Firms should make the recall level clear and instruct their consignees to extend the recall to that level. They should then monitor it to that level.

3. Failure to have the customer response form provide needed information. Ask pertinent questions, such as: Did you segregate the product? How much product is on hold? Did you notify your customers? When and how?
4. Failure to carefully proofread recall communications, resulting in incorrect or missing lot or code numbers needed to properly identify the recalled product.
5. Failure to specify clearly what should be done with held and returned recalled product.
6. Failure to send the recall communication to the right person. When products are billed to one address, but shipped to another, the recall communication should be sent to both. The billing address staff may have no idea what to do with a recall communication, resulting in its ineffectiveness at that consignee. If not sent to both locations, then the “shipped-to” address is the better choice.
7. Failure to keep records of customer responses so they know which customers to expect and monitor returns from, and know who to re-contact when no response, or an inadequate response, is received. Failure to maintain log date, responding person, title, and response.
8. Failure to provide the local FDA district office with timely distribution information.
9. Failure to have a Recall Strategy and failure to do a health hazard assessment.

Q: IS LABELING, ESPECIALLY FOR ALLERGENS, A BIG ISSUE?

A: Yes, failure to declare food allergens on labeling is a significant reason for food recalls. Of the 182 Class I food recalls in 2002, 128 were related to undeclared ingredients, including allergens and/or sulfites.

Q: THE CODE OF FEDERAL REGULATIONS SAYS AN FDA "AD HOC COMMITTEE" DECIDES HOW TO CLASSIFY RECALLS (AS CLASS I, II, OR III). WHO MAKES UP THE COMMITTEE? HOW LONG DOES THE DECISION USUALLY TAKE?

A: The CFR does not state that the "ad hoc committee" decides the classification of the recall. It states that "an evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account..." The classification as I, II, or III is done by the Center compliance office in which the recall staff is located and takes into account not only the HHE (abbreviation for Health Hazard Evaluation) but other factors as well.

The "ad hoc committee" varies between the five FDA centers, as each has responsibility for different types of products and may require different degrees and types of expertise. The makeup of the committee is the decision of the Center management. It may be comprised of physicians, engineers, technolo-

gists, compliance officers and other scientists as appropriate for the particular center or product within the Center.

HHE's are done quickly, usually within a few days once the documentation necessary to evaluate the hazard has been provided by industry to the district office and it has been forwarded through the Center recall staff to the committee. There are exceptions when issues are very technical or when regulatory concerns have to be resolved.

Q: CAN YOU TALK A LITTLE ABOUT THE "COLLABORATIVE" NATURE OF A RECALL AND THE IMPORTANCE OF WORKING WITH THE FDA FIELD PEOPLE? ARE THEY CALLED "INSPECTORS," "INVESTIGATORS"?

A: As we mentioned, it is very important that FDA-regulated industry immediately notify the local FDA district recall coordinator as soon as the firm decides that a recall is the appropriate action to take. The district coordinators can work with firms in the preparation of press releases when needed, in the preparation or review of the recall communication, and can provide answers to questions the firm may have. On occasion, district offices send FDA personnel to the recalling firms to assist in the collection of necessary recall background information and to conduct an inspection of the facilities. These persons are usually consumer safety officers (official title) referred to as "investigators". The agency also has consumer safety inspectors (official title) who are referred to as "inspectors" and who, in some cases, might contact recalling firms.

Q: WHEN A COMPANY IS FIRST CONTACTED BY AN FDA PERSON, THEIR FIRST REACTION IS PROBABLY FEAR. ("UH-OH, WE'RE IN TROUBLE NOW...") WHAT CAN YOU TELL THEM ABOUT THE AGENCY THAT MIGHT HELP TO ASSUAGE THAT FEAR?

A: I don't agree with your supposition, although I imagine that a firm does have some concern when an FDA investigator shows up or calls the firm unexpectedly. FDA regulated firms and FDA both should have the health and protection of the American consumer as first priority. When firms live up to that responsibility, they will find FDA as an ally to assist them in taking responsible actions—including, of course, removing or correcting defective, misbranded, or adulterated products from the marketplace. FDA recall coordinators and investigators are simply doing their jobs when requesting information and conducting inspections. Complete cooperation and understanding between firm personnel and FDA expedites and improves the effectiveness of recall actions.

Q: IS BIOTERRORISM A PRIORITY FOR FDA? HAVE YOUR PEOPLE RECEIVED SPECIAL TRAINING IN THIS AREA?

A: Of course it is! FDA has an Office of Bioterrorism at the Commissioner level which is coordinating activities among the FDA centers and field offices. The recall staff has been involved in the activities of

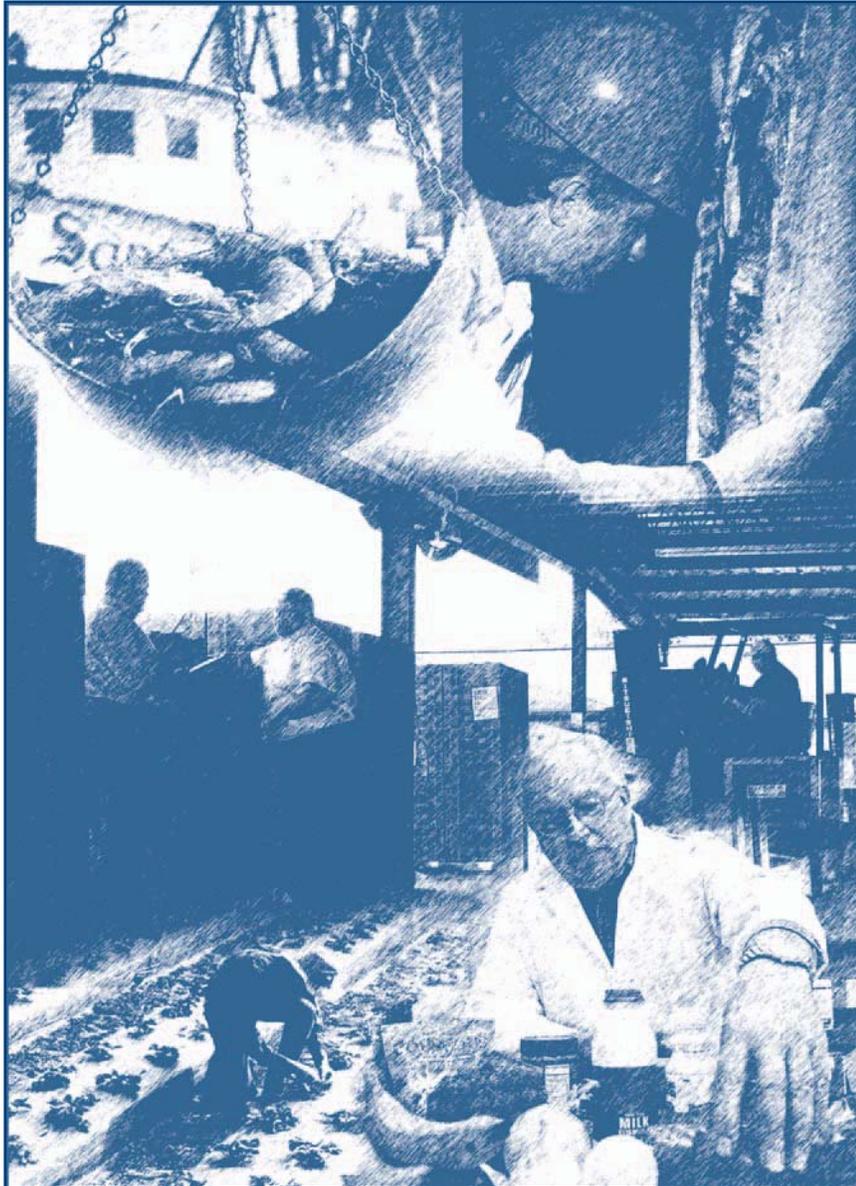
that office. Recalls are occasionally by nature critical operations, such as those in the past in which *E. coli* O157:H7 was involved. The headquarters and field staffs are familiar with and know how to handle emergency situations.

Q: WHAT IS YOUR BEST ADVICE FOR A SMALL COMPANY DEALING, FOR THE FIRST TIME EVER, WITH A PRODUCT EMERGENCY THAT MAY RESULT IN A RECALL?

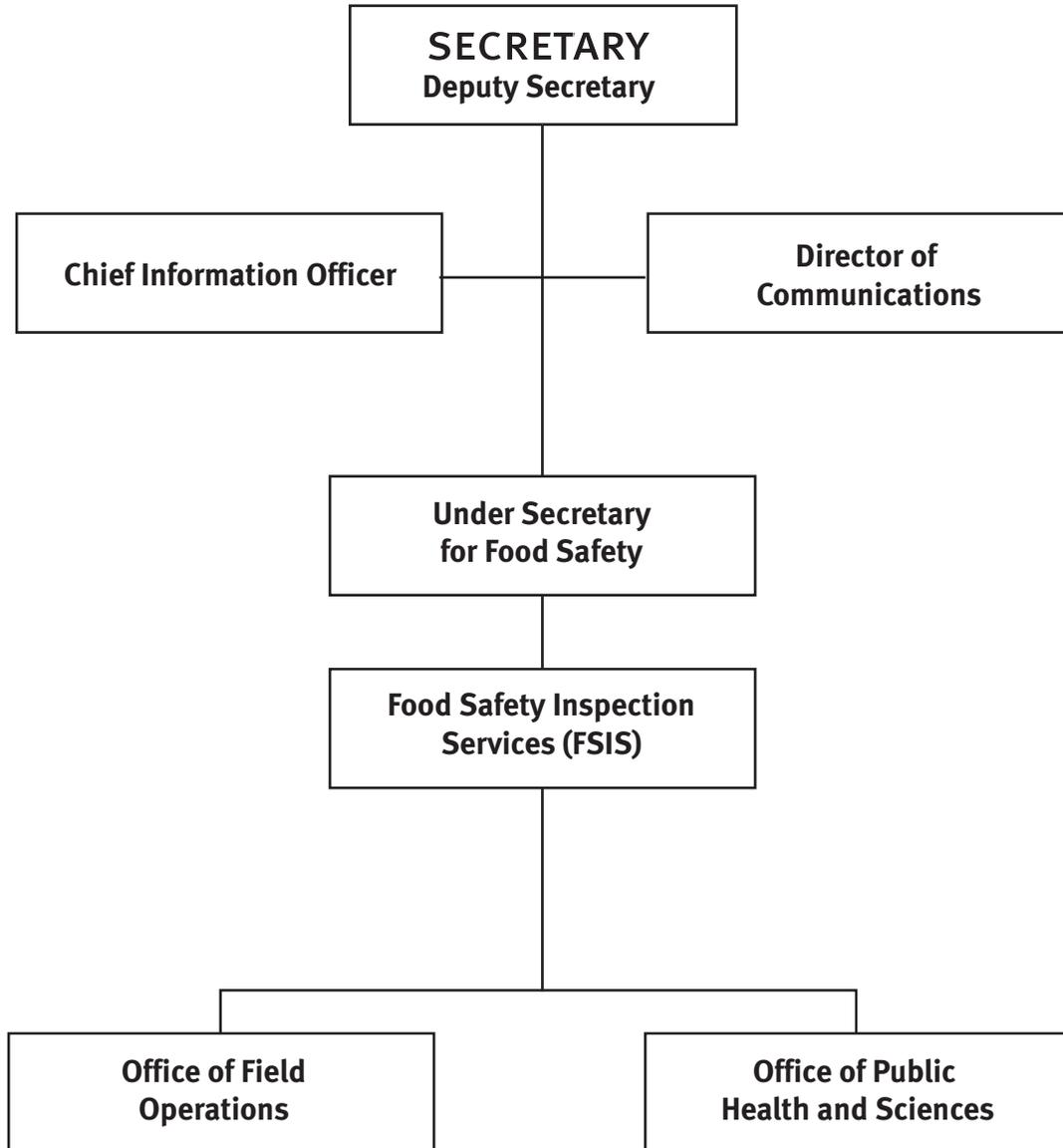
A: Contact the local FDA district office immediately and work them to get the recall implemented as quickly and effectively as possible. But, the important thing for a firm to do is to develop a recall procedure or strategy in advance so that the myriad of questions and problems that develop as a normal part of a recall can be addressed calmly without the pressures of the recall moment.

It might well be of value to all FDA-regulated industry to go to the FDA website and download and review a document called "Product Recalls, Including Removals and Corrections Industry Guidance." This document is intended to assist FDA-regulated industry in the product recall process by providing the information considered by FDA to be essential in the development of a firm's recall strategy, the recall notification to its customers, disposition of recalled products, determination of the reason for recall, and termination of the recall. This guidance also lists the information needed by FDA to assess the significance of the hazard involved, to comment on the recall strategy and recall notifications, including necessary press releases, and to audit the effectiveness of the recall.

ORGANIZATION CHARTS USDA AND FSIS, HHS AND FDA

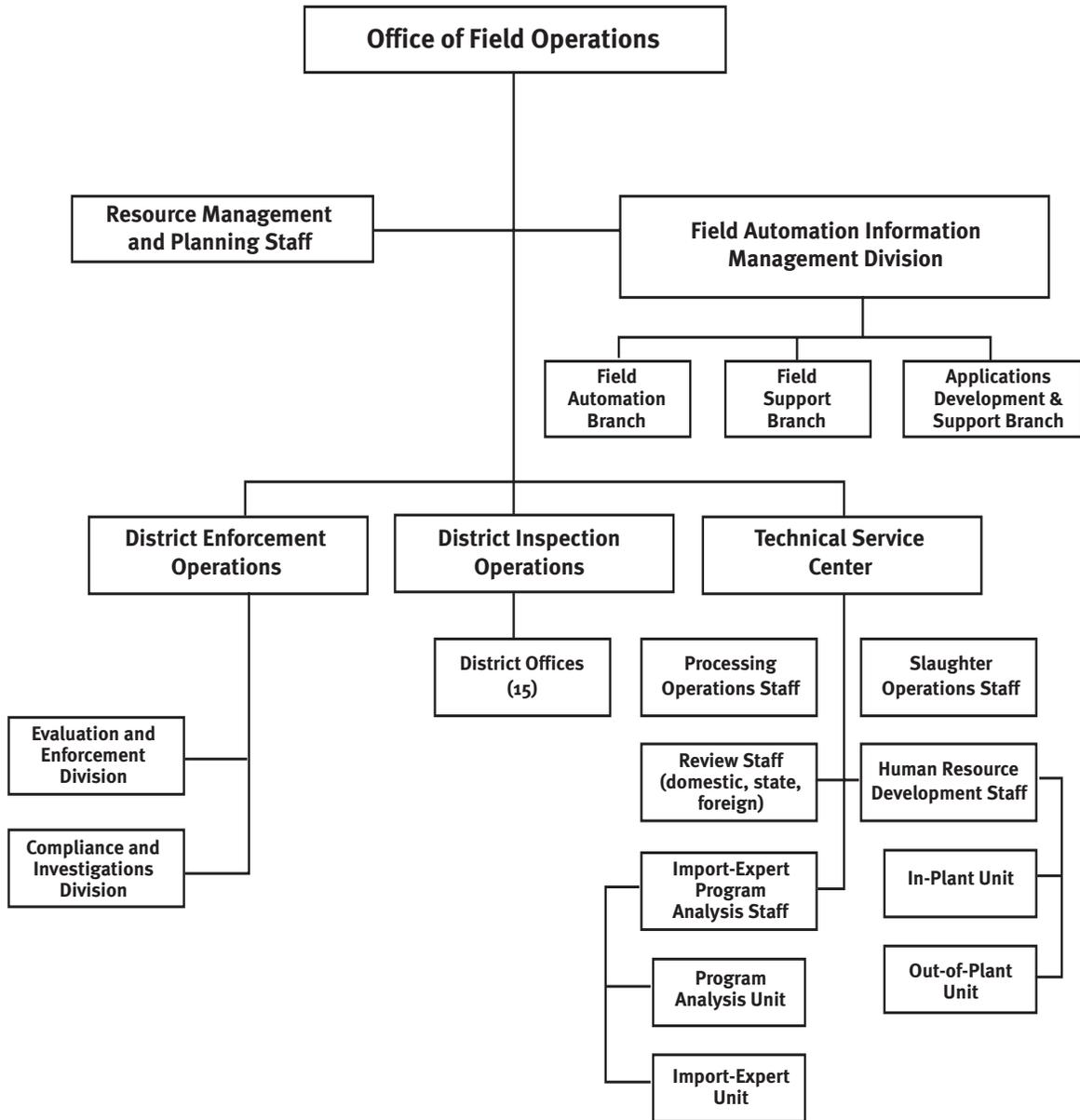


U.S. Department of Agriculture ORGANIZATION CHART



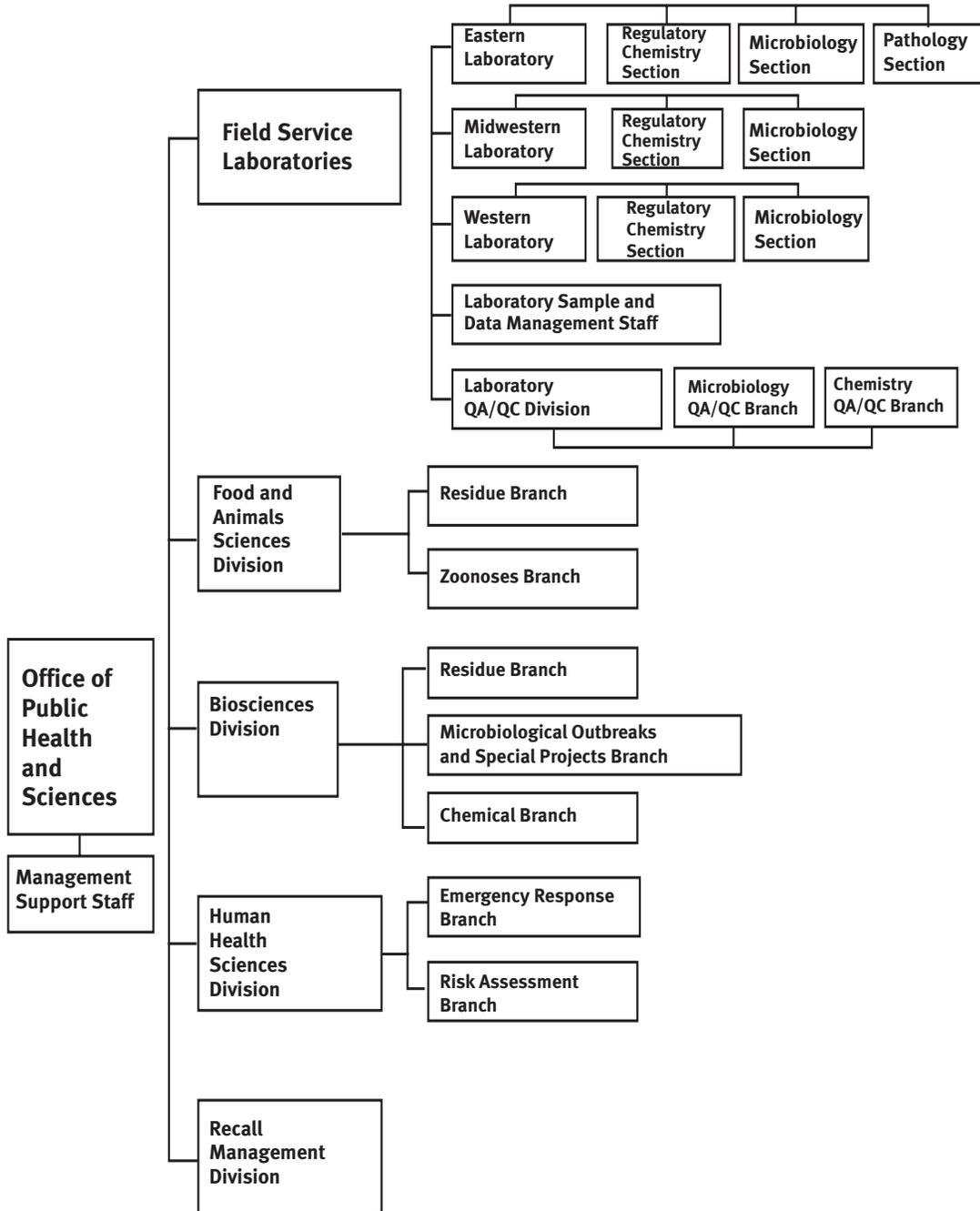
FSIS Office of Field Operations

ORGANIZATIONAL CHART



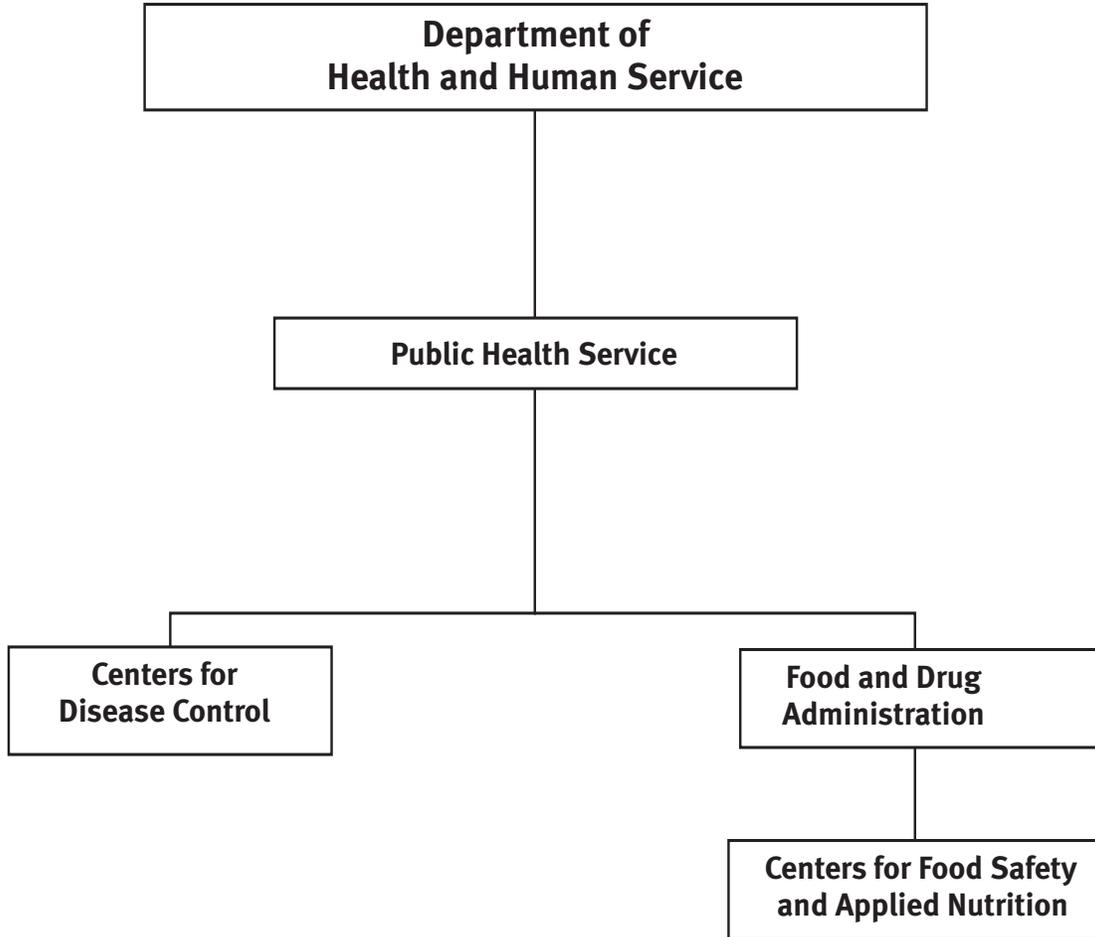
FSIS Office of Public Health and Science

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U.S. Department of Health and Human Service

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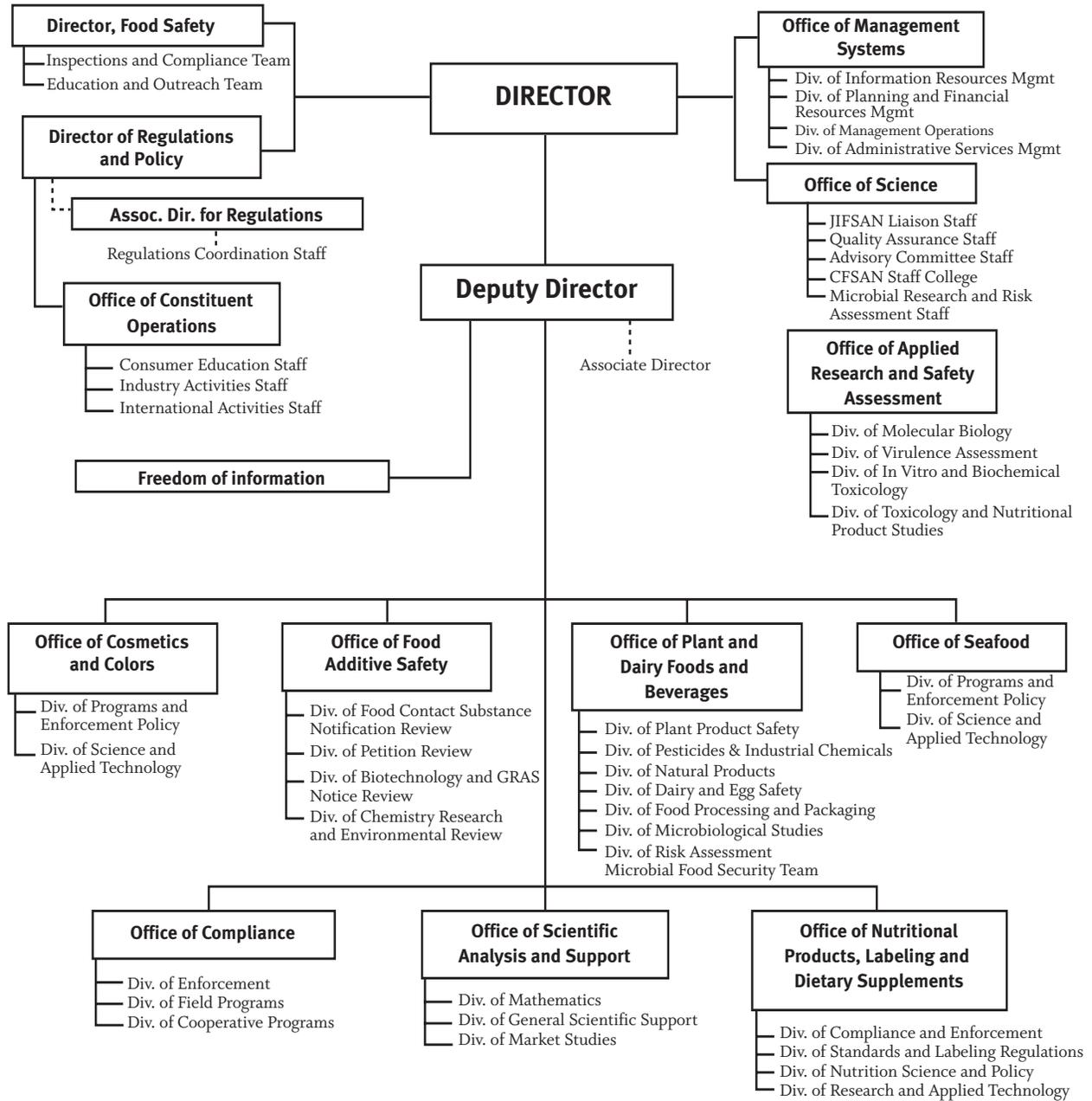


The HHS Public Health Service includes the Food and Drug Administration (FDA); and the Centers for Disease Control (CDC), the primary federal agencies involved with product recalls.

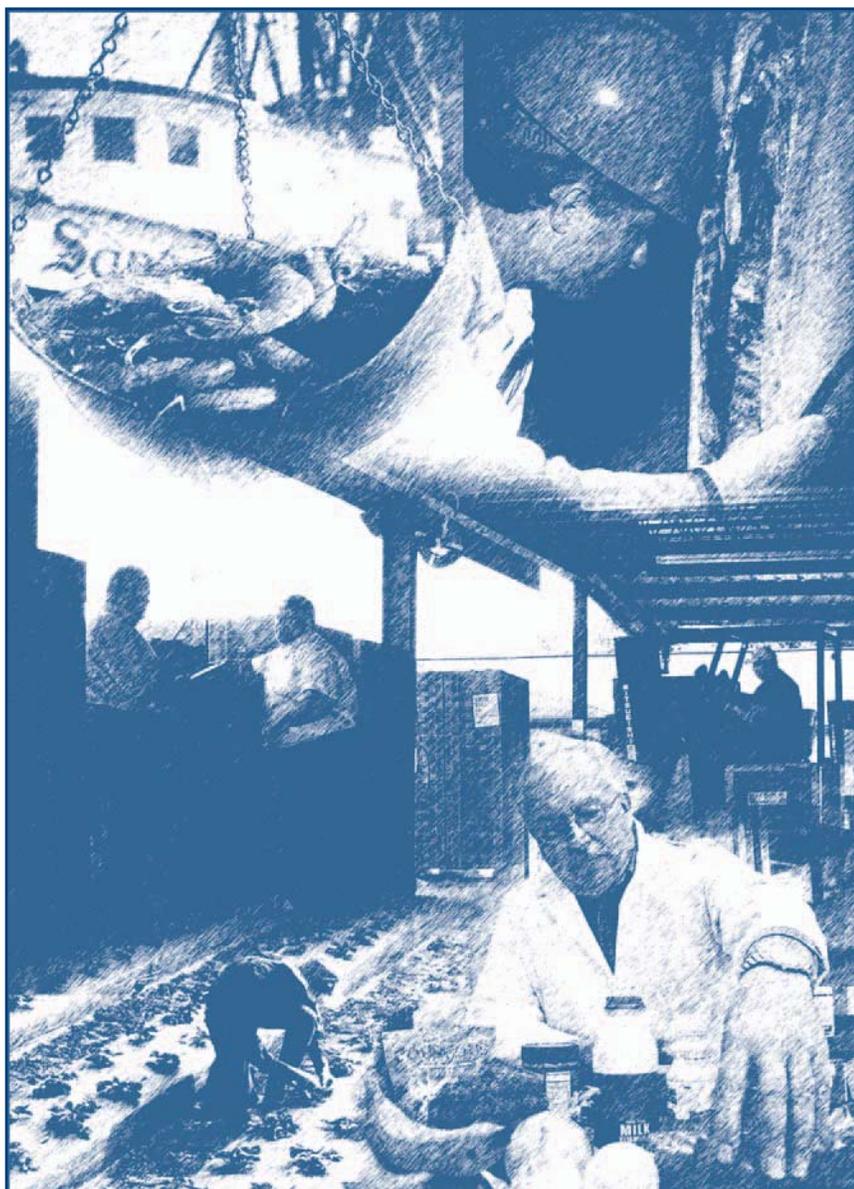
The Center for Food Safety and Applied Nutrition is one of six product-oriented centers, in addition to a nationwide field force, that carry out the mission of the FDA. CFSAN, in conjunction with FDA field staff, is responsible for ensuring the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.

FDA Center for Food Safety and Applied Nutrition

ORGANIZATIONAL CHART



GLOSSARY OF KEY TERMS, INCLUDING WEBSITE ADDRESSES



A

ACTION LEVEL: The level of contamination informally established by the FDA and/or USDA for conditions that are typical in the food manufacturing process, such as mold, insects, rodents, and filth. Also known as “defect action levels” (DALs), an agency may or may not institute enforcement activity based on these non-binding guidelines.

ADULTERATION: In general, this term refers to contamination of a product that makes it unfit for human use and/or not up to expected product standards. It may include products that have valuable ingredients or components omitted, or that contain unsafe or unauthorized ingredients. The term is broadly defined in federal regulations and laws as “filthy,” “putrid,” “unsound,” “unhealthful,” or “unwholesome.” Further defined by some courts as including manufacturing conditions sufficiently unsanitary that contamination is likely.

AGENCY-REQUESTED RECALL: FSIS or FDA can request a product recall as part of their regulatory sanctions. Agency-requested recalls are most often done when the agency determines that an already-distributed product may endanger public health or safety, or involves a “gross consumer deception;” that the producing company hasn’t initiated a recall; and that the agency must act to “protect the public” from exposure to the product. For more details, see www.fda.gov.

ALLERGEN: A food, or substance in a food, that causes an allergic reaction in some people. The substance that makes a food an “allergen” is a protein contained within the food. Food products made without these proteins (peanut oil or soy oil, for instance) do not cause allergic reactions, even though they are made from products typically thought to be allergens. (See also the definition of “Big 8.”) For more information about allergens: www.foodallergy.org (website of the Food Allergen and Anaphylaxis Network, FAAN); www.ift.org (website of the Institute of Food Technologists); and www.aafa.org (website of the Asthma & Allergy Foundation of America). Some preservatives, like sulfites, are also considered allergens. For information about sulfites: www.fda.gov/fdac/features/096_sulf.html.

ALLERGIC REACTION: An exaggerated immune system response to a food, drug or other allergen that the body mistakenly believes is harmful. Symptoms vary widely among individuals, but may include: tingling sensation or swelling of tongue and throat; breaking out in a rash or hives; breathing difficulty; drop in blood pressure; nausea, stomach cramps and diarrhea. In severe cases (see “anaphylaxis”) loss of consciousness or death can result. According to the Food Allergen and Anaphylaxis Network, allergic reactions cause up to 200 deaths and 30,000 emergency room visits annually in the U.S.

ANAPHYLAXIS: Hypersensitivity to an allergen that causes a life-threatening allergic reaction. A severely allergic person may experience anaphylactic shock, and even death. For information, see www.faemi.org (website for Food Anaphylaxis Education).

ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS): This Department of Agriculture (USDA) agency focuses on preventing insect infestations and diseases that affect plants and animals. For details, go to www.aphis.usda.gov.

ANTHRAX: An infectious disease of warm-blooded animals (cattle, sheep) caused by the spore-forming bacterium *Bacillus anthracis*. It is transmissible to humans by handling infected products (including wool). Anthrax infection causes lesions in lungs and external ulcerating nodules.

AUDIT CHECK: See **Effectiveness Check**.

B

BACTERIAL AND MYCOTIC DISEASES, DIVISION OF (DBMD): This agency is part of the National Center for Infectious Diseases (NCID), which is part of the Centers for Disease Control and Prevention (CDC). Its task is to prevent and control emerging, re-emerging, drug-resistant, and other important bacterial and mycotic diseases in the United States and around the world. DBMD branches are responsible for investigation, surveillance, and control of specific groups of diseases, including many foodborne diseases. For more details, go to www.cdc.gov/ncidod/dbmd/.

BACTERIAL CONTAMINATION: Product adulteration by harmful bacteria or spoilage organisms through production errors or equipment malfunctions, human error and other reasons. (Also see contamination).

BENZENE: An aromatic series hydrocarbon most often associated with water contamination. Colorless, volatile and flammable, it is used as a solvent and in some fuels. If ingested, benzene can cause nervous system, liver, renal, and bone marrow damage. Sometimes called *benzol*.

“BIG 8:” The common industry nickname for the eight most common food allergens that are responsible for 90% of all allergic reactions: eggs, fish, shellfish, milk, peanuts, tree nuts (walnuts, cashews, etc.), soy and wheat.

BIOTERRORISM: A deliberate act motivated by a political agenda, that results in harm to humans, animals or agriculture in general. The Centers for Disease Control and Prevention (CDC) has a large database related to bioterrorism, including pathogens and other agents that could be deliberately introduced into food, water and other consumable products and result in recalls. Find more details about these substances on the following websites:

CDC BIOTERRORISM HOME PAGE: bt.cdc.gov.

FACTS ABOUT: Anthrax, Botulism, Pneumonic Plague, Smallpox:
www.bt.cdc.gov/DocumentsAPP/facts_about.pdf.

BIOLOGICAL AND CHEMICAL TERRORISM: a strategic plan for preparedness and response:
www.cdc.gov/mmwr/preview/mmwrhtml/rr4904a1.htm.

ANTHRAX AND INTERIM GUIDELINES FOR MANAGEMENT OF ALLEGED USE:
www.cdc.gov/mmwr/PDF/wk/mm4804.pdf.

For anthrax and bioterrorism questions or comments not addressed above, or in case of emergency, a CDC duty officer can be reached at (404) 639-2807 (8:00am to 4:00pm EST) or (404) 639-7100 (after hours).

BOTULISM: A severe form of food poisoning caused by the neurotoxin *botulin*. Botulin is produced by a spore-forming bacterium called *Clostridium botulinum*, widely found in soil and domestic animal intestinal tracts. Human cases generally arise from bacterial development in raw or improperly canned or preserved foods, especially meats and non-acid vegetables. Botulism can cause cardiac arrest and respiratory paralysis.

BOVINE SPONGIFORM ENCEPHALOPATHY (BSE): An infective protein (known as a prion) which causes plaque formation in certain brain tissue, commonly known as “mad cow disease” when manifested in cattle. First known occurrence was in Great Britain in the early 1990s, when farmers fed sheep brains to their cattle, which then became infected. Humans infected with BSE can experience fatal brain damage without knowing they were ill or what caused it. The number of infected people remains unknown because the disease can take years to show up in humans.

C

CALCIVIRUS: A very common cause of foodborne illness. Also known as a Norovirus (Norwalk-like virus). The unique feature of calcivirus is its transmission from one infected person to another, rather than from animal sources. Rarely diagnosed due to general unavailability of the necessary lab test.

CAMPYLOBACTER: A type of bacteria that lives in the intestines of healthy birds and infects poultry. The most frequent source of this infection is eating undercooked chicken, or other foods contaminated by contact with raw chicken juices.

CAUSATION: A legal term for “causing something to happen.” In the case of recall-based litigation, plaintiffs must not only establish that a manufacturer’s product was defective, but that it actually caused an injury. The causation test varies between states. Some states require proof of “proximate causation”—that the injury was foreseeable to the manufacturer; others require only that the recalled product was a “substantial factor” in causing the plaintiff-suffered harm.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC): This federal agency provides a system of health surveillance to monitor and prevent disease outbreaks (including bioterrorism), implement disease prevention strategies, and maintain national health statistics. Conducts both active and passive foodborne surveillance. It also guards against international disease transmission, with personnel stationed in more than 25 foreign countries. The CDC has more than 8,500 employees and a 2002 budget of \$3.7 billion. For information, go to www.cdc.gov.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FDA (CFSAN): This is one of six product-oriented centers, in addition to a nationwide field force, that carry out the mission of the FDA. CFSAN, in conjunction with FDA field staff, is responsible for ensuring the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled. For more details, go to www.cfsan.fda.gov/list.html or www.cfsan.fda.gov/~1rd/recall2.html.

CENTER FOR VETERINARY MEDICINE, FDA: One of three federal agencies that make up the National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS). The other two agencies are the Centers for Disease Control and Prevention (CDC), and the Food Safety Inspection Service (FSIS).

CHART: The Commodity Hold and Recall Team. Created in 1999 by representatives from the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), state distributing agencies and local school districts, CHART oversees the “hold and recall” process for USDA commodity foods. (**See hold.**)

CHEMICAL CONTAMINATION: Contamination of food products by pesticides, sanitizing or other chemicals, or by the addition of legal additives at higher-than-acceptable levels.

CITATION: A legal document and any attachments thereto that provide notice to a person or company against whom criminal prosecution is contemplated, informing them that they have a chance to present views to the plaintiff regarding an alleged violation.

CLASS-ACTION LITIGATION: A legal action brought by one or more persons on behalf of themselves, or a much larger group, all of whom have the same reasons for taking the legal action.

CLASS CERTIFICATION: A court's decision that multiple lawsuits can be tried together in as a single case instead of individually, when plaintiffs have similar complaints against the same defendant. One of the challenges in class certification is determining (if individuals in more than one state are involved) which state's laws will apply in trying the case. As part of a recall strategy, companies should consider whether or not it is in their best interest to oppose class certification. Typically, companies oppose class action certification when they choose to fight a lawsuit, and accept it when they want to settle expeditiously.

CLINICIANS, INFECTIOUS DISEASE: These individuals, along with epidemiologists, can help companies both communicate better with government agencies and better analyze the details of foodborne illnesses and how the company can best respond. They can assist in outbreak investigations, diagnosis and treatment, and in corroborating the regulatory agency's methodology and results.

CODE OF FEDERAL REGULATIONS (CFR): The CFRs are the body of laws, rules and regulations upon which federal government control and oversight of almost every aspect of American life and business is based. The CFRs relevant to food-based product recalls are contained in Title 21, Food and Drugs, Chapter 1, Food and Drug Administration, Department of Health and Human Services, Part 7, Enforcement Policy; and the FSIS laws on Meat, Poultry and Egg Inspection.

COMMODITY FOODS: The USDA term for bulk food products given by the federal government to schools and state health agencies to prepare for, or distribute to, low-income families through a variety of nutrition programs.

CONSIGNEE: A term for anyone who received, purchased, or used the recalled product.

CONSUMER ASSISTANCE: A mechanism by which, once a recall is initiated, a company readies itself for a deluge of phone calls and e-mails from concerned customers. Many companies hire outside vendors to perform this task, and company recall plans should include "pre-placed" customer assistance assets that can be quickly activated in the event of a recall.

CONSUMER PRODUCT SAFETY COMMISSION (CPSC): The CPSC is an independent federal agency that works to protect the public against unreasonable risks of injuries associated with consumer products. This agency does not enforce regulations about food, alcohol or tobacco, but it does regulate non-food objects (like toys or prizes) that are sometimes included with food items. The CPSC develops voluntary standards with industry, issues and enforces mandatory standards, and/or bans consumer products if no feasible standard would adequately protect the public. The CPSC also seeks product recalls and/or arranges for product repairs, conducts research on potential product hazards, and informs consumers of product hazards. Its website: www.cpsc.gov.

CONTAMINATION: The process, either willful or accidental, of causing a product or substance (in this case, a food product) to become impure, polluted or infected by coming into contact with a contaminant. A **contaminant** may be biological (viruses, parasites), chemical (pesticides, cleaning products), or physical (hair, bits of glass or metal, etc.).

CORRECTION: An alternative to a recall, this means the repair, modification, adjustment, re-labeling, destruction, or inspection (including patient monitoring) of a product without its physical removal from the marketplace.

CRUSTACEANS: This common category of food allergen includes these types of fish: crab, crayfish, lobster and shrimp.

CRYPTOSPORIDIUM PARVUM: A single-celled protozoan parasite monitored by the Foodborne Diseases Active Surveillance Network (FoodNet). It is an obligate intracellular parasite. It has been given additional species names when isolated from different hosts. The species infecting humans is thought to be the same one that causes disease in young calves. The forms that infect birds and mice are not thought capable of infecting humans. *Cryptosporidium sp.* infects many herd animals (cows, goats, sheep among domesticated animals, and deer and elk among wild animals). See www.cdc.gov/foodnet.

CYCLOSPORA CAYETANENSIS: *Cyclospora* is a one-cell parasite monitored by the Foodborne Diseases Active Surveillance Network (FoodNet). *Cyclospora* is spread by people ingesting water or food contaminated with infected stool. The parasite needs days or weeks after being passed in a bowel movement to become infectious, making it unlikely that it's passed directly from one person to another. It is unknown whether infected animals can pass the infection to people. It infects the small intestine and usually causes diarrhea, though some infected people are symptom-free. See www.cdc.gov/foodnet.

D

DEFECT ACTION LEVEL (DAL): See **Action level**.

DEPTH OF RECALL: The level of distribution that will have to be contacted to recall a product:

- The **Wholesale Level** means companies between the manufacturer and the retailer that may have some of the product.
- The **Retail Level** means wholesalers and the retail outlets to whom they sell.
- A **Consumer** or **User Level** recall means people who have already purchased the product for home use must also allow it to be turned in, picked up or destroyed.

DETENTION: An FDA or FSIS action that prevents distribution of a product that is potentially adulterated or misbranded, after it has left the manufacturer’s possession. The agency has 20 days to request a federal court to seize the product, but most detentions result in the product being voluntarily disposed of without court action.

DIVISION OF EMERGENCY AND INVESTIGATIONAL OPERATIONS (DEIO): The branch of the Food and Drug Administration that investigates criminal food-related cases, like tampering, terrorism, extortion and malicious false reports.

DOCUMENTS, COLLECTING: Documents relating to a recalled product should be gathered at the same time interviews and other elements of the investigation are being conducted. These documents may help explain how it became necessary to recall the product—and they may be requested by government agencies or litigants. Having them quickly available makes a company appear organized and, more importantly, cooperative.

DOCUMENTS, DESTROYING: No company documents should ever be destroyed before company officers and attorneys have determined whether it is legal to do so. More importantly, no recall-related documents should be destroyed under any circumstances after a recall has been initiated.

DUTY TO RECALL: Most state laws reject the notion that companies have a “duty to recall.” State courts have generally ruled that legislatures and related administrative agencies have jurisdiction in this area. However, some states do have laws that impose a duty on companies to retrofit or recall defective products. This can complicate recall procedures, and expose the company to greater risk of civil claims and criminal prosecution.

DUTY TO WARN: Companies that discover product defects after manufacture and/or sale have a “duty to warn” their customers of those defects. Failure to do so can result in both civil and criminal legal liability. This manufacturer duty stems from a 1959 Michigan Supreme Court case, *Comstock v. General Motors*. It was precipitated by GM’s lack of warning to consumers about a brake defect it discovered shortly after manufacture. However, “duty to warn” statutes in the several states are based on negligence, not strict liability; they require evidence that the company acted unreasonably, not just that the product was defective.

E

E. COLI: See *Escherichia coli*.

EFFECTIVENESS CHECK: This update is performed to verify that all consignees specified in the recall plan have received notification about the recall and have taken appropriate action. Effectiveness checks

may be accomplished in person, by phone, fax, e-mail, and/or regular mail. The recalling company is usually responsible for conducting effectiveness checks, but the FDA, FSIS, and/or state/local health departments can assist. The FDA publishes a guide, "Methods for Conducting Recall Effectiveness Checks," available upon request from the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 1-23, 12420 Parklawn Drive, Rockville, MD 20857.

EGG PRODUCTS INSPECTION ACT (EPIA): One of the federal laws used by FSIS to inspect egg processing plants for safety, sanitation, labeling and packaging. Find the full text of the law on the FSIS website, at www.fsis.usda.gov.

EMBARGO: An order by a government regulatory agency to seize and prevent the movement of products in commerce.

EMERGING INFECTIONS PROGRAM (EIP): A program of the Centers for Disease Control and Prevention (CDC). The EIP's Foodborne Diseases Active Surveillance Network (FoodNet) actively monitors bacteria and parasites that have recently emerged as human pathogens.

EPIDEMIC INTELLIGENCE SERVICE (EIS): EIS is part of the Centers for Disease Control and Prevention (CDC). It is a two-year post-graduate program of service and on-the-job training for health professionals interested in the practice of epidemiology. Since 1951, more than 2,000 EIS officers have studied and battled the causes of major epidemics within the United States and throughout the world. Its website is www.cdc.gov/eis.

EPIDEMIOLOGICAL PROGRAM OFFICE: A unit of the Centers for Disease Control and Prevention (CDC) tasked with monitoring, preventing and responding to epidemics of all types. For more details, go to www.cdc.gov/ncidod/dbmd.

EPIDEMIOLOGISTS: Individuals concerned with the study and control of epidemic diseases. These persons, along with clinicians, can help companies communicate with government agencies, and better analyze the details of foodborne illnesses and how the company can best respond. They can assist in outbreak investigations, and in corroborating the regulatory agency's methodology and results.

EPIDEMIOLOGY: The science of infectious diseases and the study of their causes, incidence, distribution and control.

ESCHERICHIA COLI (*E. COLI*): A type of bacterium that lives in the intestines of healthy humans and animals, including cattle. Most strains are harmless but one—*E. coli* O157:H7—produces a powerful toxin that can cause severe illness. Infection can occur through contaminated meat or milk products that have not been cooked or pasteurized sufficiently. The infection is diagnosed by testing a stool

sample; symptoms of *E. coli* O157:H7 infection are diarrhea and abdominal cramps. In toddlers and the elderly, it can also cause a complication called *hemolytic uremic syndrome*, in which red blood cells are destroyed and kidneys fail. The CDC estimates *E. coli* O157:H7 causes 73,000 foodborne illness cases and about 60 deaths annually.

EXPERT TESTING: Independent individuals or laboratories that specialize in finding and identifying the presence (or absence) of contamination can be extremely helpful, but their work is generally “discoverable” should the recalling company end up in court. Company officers should consult with legal counsel before hiring outside experts to conduct part or all of any recall-related internal investigation.

F

FEDERAL ANTI-TAMPERING ACT (FATA): The U.S. law that makes it a federal crime to tamper with consumer products and authorizes the Food and Drug Administration to investigate these allegations. They include tampering with, tainting, knowingly communicating false information about tampering or tainting incidents, threatening or conspiring to tamper with a consumer product. Read the full text of the law at www.fda.gov/opacom/laws/fedataact.htm.

FEDERAL MEAT INSPECTION ACT: The Federal Meat Inspection Act governs "animal food manufacturers," meaning any person or company that manufactures or processes animal food derived wholly or in part from partial or whole carcasses of cattle, sheep, swine, goats, horses, mules, or other equines. This Act is found in the Code of Federal Regulations (CFR), Title 21, Food and Drugs, Chapter 12, Meat Inspection. For details, go to www.fda.gov/opacom/laws/meat.htm.

FEDERAL SENTENCING GUIDELINES: These are the guidelines federal judges must follow when imposing criminal penalties on individuals and companies convicted in federal court. For details, go to www.ussc.gov/guidelin.htm.

FIRM-INITIATED RECALL: A recall prompted by the company making or distributing a product, without notification or suggestion by the FDA or FSIS. Even in the case of firm-initiated recalls, the FDA asks that the relevant district office be notified immediately. The FDA deems these company-initiated removals or corrections “recalls” only if the product may represent a violation subject to legal action.

FOOD ALLERGY AND ANAPHYLAXIS NETWORK (FAAN): The FAAN was established in 1991 and now includes more than 25,000 families, dietitians, nurses, physicians, school staff, government agencies, and food and pharmaceutical companies worldwide. Its purpose is increase awareness of food allergy and anaphylaxis issues. FAAN also supports and participates in research studies focusing on the epidemiology of food allergy. For details, go to www.foodallergy.org.

FOOD AND DRUG ADMINISTRATION (FDA): FDA is a scientific regulatory agency responsible for the safety of the nation's foods, cosmetics, drugs, biologics, medical devices, and radiological products (both domestically produced and imported). It is internationally recognized as the world's leading food and drug regulatory and consumer protection agency. The FDA is part of the executive branch of the U.S. government within the Department of Health and Human Services (DHHS) and the Public Health Service (PHS). Many of the agencies dealing with product recall are FDA sub-agencies. For detailed information on the FDA, go to www.fda.gov.

FOOD AND NUTRITION SERVICE (FNS): The USDA agency responsible for administering many of the federal food-related programs for low-income families, including School Breakfast and School Lunch Programs; the Child and Adult Care, Food Stamps and Food Distribution Programs, and the Women, Infants and Children Program. These programs use USDA commodity foods.

FOOD, DRUG AND COSMETIC ACT (FD&C ACT): This Act is the federal law that the CDC and its associated agencies use to oversee the manufacture and sale of food, drugs and cosmetics in the United States. It defines “food” as “articles used for food or drink for man or other animals, and chewing gum.” (21 USC 301), and “drug” as “articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and/or affect the structure or any function of the body of man or other animals.” For a closer look at the FD&C Act, see this portion of the FDA website: www.fda.gov/opacom/laws/fdcact/fdctoc.htm.

FOOD SAFETY AND INSPECTION SERVICE (FSIS): This Department of Agriculture (USDA) agency inspects more than 6,000 processing plants to ensure the proper processing, safe handling and correct labeling of meat, poultry and egg products. This includes humane slaughtering of livestock, sanitation, safe transportation and storage, and proper disposal of condemned product. FSIS oversees approximately 25 percent of all food in the U.S., using many of the same guidelines and methods, and with the same type of legal clout, as the FDA. For more information, go to www.fsis.usda.gov.

FOODBORNE DISEASES ACTIVE SURVEILLANCE NETWORK (FOODNET): This network is the primary foodborne disease element of the Centers for Disease Control and Prevention (CDC) Emerging Infections Program (EIP). FoodNet monitors which foods cause the most foodborne illnesses and actively surveys laboratories for diarrheal illness cases—the most common symptom of foodborne illness. FoodNet also conducts random population surveys on diarrheal illness, and conducts epidemiological studies on targeted pathogens. For more details, go to www.cdc.gov/foodnet.

FOODBORNE OUTBREAK RESPONSE AND SURVEILLANCE UNIT (FORSU): FORSU is a division of the Centers for Disease Control and Prevention (CDC) that investigates specific foodborne illness outbreaks and establishes both short-term control measures and long-term improvements to prevent similar future outbreaks. FORSU works closely with state and local health departments to investigate food-

borne outbreaks and make information available to the public. For details, go to: www.cdc.gov/foodborneoutbreaks.

FREEDOM OF INFORMATION ACT (FOI): The FOI provides the means for individuals and companies to petition the federal government for access to documents not willingly released by federal agencies. It is sometimes used in recall situations by companies seeking Centers for Disease Control and Prevention (CDC) data that may be helpful in defending against consumer complaints and claims; and often used by the news media to obtain government documents.

G

GUARANTY: For each product shipment or other delivery, a designated company representative must guarantee the product, "...as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce." (21 CFR, Chapter 1, Section 7.13 (b) (2)).

Government Printing Office (GPO). Many documents needed to prepare for and execute a product recall are available from the GPO at www.fda.gov.

H

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP): A food safety system developed by NASA (U.S. Space Program) that includes seven (7) steps for identifying potential hazards; critical control points (proper temperatures for storage, cooking, thawing, etc.); monitoring and correcting problems and establishing an effective record-keeping system to document that the system is working. Federally inspected meat and poultry plants, and all producers of fishery products and juices, are required by federal law to develop and implement HACCP plans.

HEALTH AND HUMAN SERVICES, DEPARTMENT OF (HHS): The U.S. government's principal agency for protecting the health of all Americans and providing essential human services, especially for those least able to help themselves. There are more than 300 HHS programs for food and drug safety, disease prevention and response to disease outbreaks. HHS has more than 65,000 employees and a 2002 budget of \$460 billion. The HHS Public Health Service includes the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), two federal agencies involved with product recalls. For detailed information on HHS, go to www.hhs.gov.

HEALTH HAZARD EVALUATION (HHE): This is an assessment conducted by an FDA or FSIS committee to determine the degree of public health hazard presented by a product being recalled or considered for recall; to classify the recall as Class I, II or III.

HOLD: A time period used for investigation after a USDA commodity food has been identified as potentially unsafe. The agency has a maximum of 10 days after receiving a complaint or identifying a product to make its recall decision. During this time, recipients of the food are instructed to isolate and not use it, effectively “holding” it until its safety has been determined. The hold process is unique to USDA commodity foods.

I

INFANT FORMULA: This is the only product for which the Food and Drug Administration (FDA) can demand, not just request, a recall. Infant formula is governed by 21 CFR, Chapter 1, Part 107; infant formula recalls, Subpart E.

INJUNCTION: A court order that prohibits a person, group or company from carrying out an action. When a company refuses to voluntarily recall a potentially dangerous or defective product, an injunction can be sought by the FDA, FSIS, state and/or local regulatory agencies to stop its continued distribution or sale.

INVESTIGATIONS OPERATIONS MANUAL, FDA: The IOM is the primary guidance document on FDA inspection policy and procedures for field investigators and inspectors. The IOM is sometimes supplemented but not superseded by other manuals and field guidance documents. Significant departures from IOM established procedures must have the concurrence of FDA district management. The FDA welcomes suggestions for changes and updates to the IOM. Suggestions can be sent to the Division of Field Investigations (HFC-130), 5600 Fishers Lane, Rockville, MD 20857 or via e-mail to Director, DFI. You can also send e-mails regarding the IOM at IOM@ORA.FDA.GOV For a look at the IOM: www.fda.gov/ora/inspect_ref/iom.

L

LABELING: The written or printed information on a product that contains ingredient and nutrition information. Three critical areas to consider in food labeling are:

1. Whether it is easy for consumers to understand (“milk” instead of *ammonium caseinate*, “cashews” instead of *tree nuts*, etc.)
2. Whether the advisory statements included on the label are understandable and actually helpful to consumers. Manufacturers often use blanket statements (“May contain...”) which gives little useful information and limits the choices for food-allergic customers.
3. Whether low-level ingredients are adequately labeled, instead of being lumped into descriptions like, “flavorings, spices or colors.” There is currently no standard rule about identifying potential allergens that are present in very small amounts.

LEGAL COUNSEL: Attorney(s) hired to represent a company on a regular basis. Pre-established arrangements with recall-knowledgeable attorneys are key to any recall strategy. When a foodborne illness outbreak may spark a product recall, having an attorney already familiar with the company means quicker and more effective legal counsel to help company officers look at options and make decisions. Attorneys can also be valuable as investigators and interviewers because of their legal training. For more information about legal food-related issues, including a list of referrals, see the Food Drug Law Institute website, at www.fdpi.org.

LEGAL COUNSEL, SEPARATE: Depending on the circumstances of a product recall, individual company officers and other associated parties may need to retain legal counsel independent of the recalling company. Part of any company's recall strategy should be a process by which the company assesses the way employee and company interests may conflict in the event of a recall, and whether a company should provide and/or pay for separate counsel for employees.

LETTER OF WARNING (LOW): FSIS issues this notice for minor violations of law. A LOW may be issued to any individual or business, from a restaurant or retail store to a wholesaler, distributor or processor of meat or poultry products. The letters warn that FSIS "may seek criminal action based on continued violations," and indeed, receipt of a series of LOWs may prompt an FSIS District Office to refer the case to the U.S. Attorney for prosecution.

LIABILITY: While liability rules vary widely between the states, a product manufacturer's liability is generally limited to responsibility for defects the manufacturer knew about during production, and not for defects discovered after the product has been distributed and/or sold. Liability definitions vary widely between states, so check with your attorney about the states in which you do business. However, here are a few common terms:

- **Civil liability** usually means harm was done without intent.
- **Corporate officer liability** means company officers can be found criminally liable for violations if they held a "responsible position" from which they could have prevented the violation. These officers include but are not limited to presidents, general managers, and quality control personnel.
- **Criminal liability** indicates the law was deliberately broken or ignored.
- **Strict liability** means a company can be held liable for simply producing a defective product, even if the defects were not a result of negligence or other aggravating factors. Among states, liability thresholds vary from "consumer expectation" to "risk-utility" to "it is in a condition not contemplated by reasonable persons."
- **Strict misdemeanor liability** may be the legal charge if a prosecutor proves only that a product was defective, not that the manufacturer or distributor knew about the defect.

LISTERIA MONOCYTOGENES (L.M.): A soil-associated bacterium that can contaminate both animal- and vegetable-based foods. Carrier animals can be symptom-free and contaminate meat and dairy products; vegetables can be contaminated by soil or manure used as fertilizer. It is found in both uncooked and processed vegetables, meats and dairy products. Listeriosis presents symptoms such as stomach cramps, nausea, vomiting, diarrhea and fever. Infections can also affect a person by means of septicemia, meningitis, encephalitis or meningoenzephalitis. The CDC attributes about 500 fatalities annually to *L.m.*

M

MAD COW DISEASE: The informal name for bovine spongiform encephalopathy (BSE), when manifested in cattle. See **bovine spongiform encephalopathy**.

MARKET WITHDRAWAL: The removal or correction by a company of a distributed product that involves minor violations not subject to FDA legal action, or which involves non-violations such as normal stock rotation practices, routine equipment adjustments and repairs, etc. (also called “product withdrawal”).

MEAT AND POULTRY HOTLINE, USDA: This hotline is open Monday-Friday 10 am-4 pm EST, and recorded messages are available 24 hours per day. (800) 535-4555 (Washington DC area: (202) 720-3333, or send e-mail messages to: myhotline.fsis@usda.gov.

MICROBIOLOGY: The study of microscopic forms of life, including most foodborne pathogens. Relationships with microbiologists and laboratory test facilities should be part of any recall strategy.

MISBRANDING: The incorrect labeling of a food or drug product. A misbranded product may be subject to recall if the label or packaging misstates nutrient composition or excludes ingredients. Action is especially likely if the product in question involves one of the “Big 8” allergens.

N

NATIONAL ANTIMICROBIAL RESISTANCE MONITORING SYSTEM FOR ENTERIC BACTERIA (NARMS): A monitoring collaboration made up of three federal agencies: food and Drug Administration (FDA) Center for Veterinary Medicine, FDA Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA) Food Safety Inspection Service (FSIS). NARMS tests the antibiotic resistance of gastrointestinal bacteria to determine resistance patterns that may be useful in outbreak investigations.

NATIONAL CENTER FOR INFECTIOUS DISEASES (NCID): The National Center for Infectious Diseases (NCID) is part of the CDC. Its goal is to prevent illness, disability, and death caused by infectious diseases in the United States and around the world. It conducts surveillance, epidemic investigations,

epidemiologic and laboratory research, training, and public education programs to develop, evaluate, and promote prevention and control strategies for infectious diseases. For more details, go to: www.cdc.gov/ncidod

NEGLIGENT RECALL: When companies recall products, the courts have generally found that they have a duty to conduct the recalls in a reasonable manner. Companies that do not properly notify their customers or otherwise mishandle the recall can be held liable for substandard actions.

NEWS RELEASE: A written statement released to the news media and/or other groups or organizations that disseminate news to the public. “Press release” is an old-fashioned term for this.

NONCOMPLIANCE REPORT (NR): A document issued by a Compliance Officer for FSIS or the FDA to a company owner or plant manager indicating it must take immediate action to remedy a problem uncovered in an inspection. (Also see **Process Deficiency Report**).

NOROVIRUS: This is the prototype of a family of small round-structured viruses (SRSVs) which may be related to the *calciviruses*. It is also known as a Norwalk or Norwalk-like virus. The family consists of several serologically distinct groups of viruses that have been named after the places where the outbreaks occurred. In the U.S., the Norwalk and Montgomery County agents are serologically related but distinct from the Hawaii and Snow Mountain agents. The Taunton, Moorcroft, Barnett, and Amulree agents were identified in the U.K., and the Sapporo and Otofuke agents in Japan. Their serological relationships are now being studied. Common names of the illness caused by the Norwalk and Norwalk-like viruses are viral gastroenteritis, acute nonbacterial gastroenteritis, food poisoning, and food infection. The disease is self-limiting, mild, and characterized by nausea, vomiting, diarrhea, and abdominal pain. Headache and low-grade fever may occur. The infectious dose is unknown but presumed to be low. For more details, go to: www.vm.cfsan.fda.gov/~mow/chap34.html and also www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus.htm.

NORWALK VIRUS: See **Norovirus**.

O

OFFICE OF REGULATORY AFFAIRS, FDA (ORA): The Office of Regulatory Affairs (ORA) is the lead office for all Field activities of the Food and Drug Administration. There are five ORA regions: Northeast, Central, Southeast, Southwest, and Pacific. The specific duties, functions and components of ORA can be viewed at www.fda.gov/ora/hier/ora_overview.html.

P

PACKAGING DEFECTS: A faulty, damaged or otherwise unsafe container. Product recalls are sometimes precipitated by packaging defects.

PATHOGEN: A bacteria, virus or other substance capable of causing a disease or illness.

PERIOD CODES: This manufacturing data is used by companies to identify the approximate date and time a product was made. Period codes can play a vital role in determining how big a recall must be. A company using one- or two-hour period codes, for example, may be able to significantly reduce the amount of recalled product compared to a company that uses half- or full-day codes, simply because individual production lots can be traced more accurately.

POST-SALE DUTY CASES: These are claims brought against companies by plaintiffs who have purchased allegedly defective products. They are generally based on “duty to warn” failures and are sometimes pursued because they are cheaper and easier to litigate than cases that involve possible design defects (usually in non-food situations).

POULTRY PRODUCTS INSPECTION ACT: Part of USDA Title 21 regulations that authorizes the Secretary of Agriculture (and related government agencies, including states) to regulate the processing and distribution of poultry products with uniform inspection standards. It includes language that the condemnation of products be “supported by scientific fact, information or criteria.” For the full text of the Act, see www.fda.gov/opacom/laws/pltryact.htm.

PRESS KIT: A folder of written materials about a company or event prepared for the news media. It may contain company history, product news, information about topics that may be of interest to reporters for story ideas.

PRESS RELEASE: See **News release**.

PROCESS DEFICIENCY REPORT (PDR): A document issued by a Compliance Officer for FSIS or the FDA to a company owner or plant manager indicating it must take immediate action to remedy a problem uncovered in an inspection. (Also see **Noncompliance Report**).

PRODUCT: Product means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item subject to an FDA quarantine (CFR 21, Chapter I, Part 1240). Product does not include an electronic product that emits radiation (CFR 21, Chapter I, Part 1003, Part 1004).

PRODUCT WITHDRAWAL: See **Market withdrawal**.

PUBLIC WARNING: In the cases of recalls involving an immediate threat to public health, the FDA or FSIS will, in consultation with the recalling company, alert the public that a product being recalled presents a serious health hazard. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate.

PULSENET: A data gathering network of the Centers for Disease Control and Prevention (CDC). Provides supplemental data on food-related pathogens and related diseases.

PUNITIVE DAMAGES: This is an amount awarded by a court in excess of normal compensation, to “punish” a defendant for serious wrongdoing. There are numerous court cases in which companies defeated punitive damage claims because they acted quickly, comprehensively and cooperatively in recalling defective products.

R

RECALL: A company’s removal from distribution and sale of a marketed product that may be unsafe, adulterated, contaminated or mislabeled; or that a government agency considers to be in violation of federal law, and against which the agency could initiate legal action, e.g., seizure. Recall does not include market withdrawals or stock recovery.

RECALL CLASSIFICATION: The federal agency designation (Class I, II, or III), assigned to product recalls to indicate the relative health hazard of the product.

RECALL COORDINATOR: The recall coordinator leads the company’s Recall Team and supervises the making of a Recall Plan. He or she should have comprehensive knowledge of the company and its products, and enough authority to make and execute key decisions quickly and communicate them to the company officers.

RECALL, FDA-REQUESTED: Under CFR 21, Chapter I, Section 7.45, the commissioner of the Food and Drug Administration (FDA), or the commissioner’s designee, may ask a company to initiate a recall when it is determined that the product in question may threaten the public health or safety if not recalled, or be a “gross consumer deception,” if the company has not recalled the product voluntarily.

RECALL NUMBER: The number assigned by the FDA or FSIS to a particular recall action. Separate recall numbers may be assigned if the product in question was reprocessed or used in the manufacture of another product.

RECALL PLAN: A written set of procedures, practices and actions developed and put in place for a particular company or type of product in case a product recall becomes necessary. (See also recall strategy.)

RECALL PROTOCOLS: Each Recall Team member should be provided with documented pre-recall responsibilities and procedures that can be immediately implemented in the event of an actual recall.

RECALL RECOMMENDATION (RR): The official documentation of an FDA District Office that contains the results of the FDA's investigation and the reasons it is requesting the recall of a certain product. It contains copies of the product label(s), FDA laboratory worksheets, quality control records from the company, and the company's proposed recall strategy. It may also include a sample of the product. The RR is sent to the recall coordinator in the appropriate FDA office.

RECALL SPOKESPERSON: The Recall Team member with primary responsibility for all communication with news media, governing agencies, and affected customers. Many times, Recall Coordinators also serve as a spokesperson because they are most familiar with all phases of the recall and all the personnel and issues involved.

RECALL STATUS REPORTS: Companies recalling products are asked by the FSIS or FDA to submit periodic recall status reports to the agency's district office. Status report frequency is flexible and will be specified by the agency depending upon the overall urgency of the recall situation. (21 CFR, Chapter 1, Section 7.53).

RECALL STRATEGY: A company's planned, specific course of action to be taken in conducting a recall, which addresses the depth of recall, need for customer and public warnings, and extent of effectiveness checks for the recall.

RECALL TEAM: A group of key personnel from different areas of a company, along with external experts in other fields. This team should meet regularly to consider possible health and safety hazards, recommend corrections, decide on the company's recall strategy, and draft a written Recall Plan, and conduct mock recall exercises to prepare for the possibility of a product emergency.

RECALL TERMINATION: FSIS or FDA regulators terminate a recall when they determine that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy. Notice of recall termination will be issued in writing by the relevant district office. (21 CFR, Chapter 1, Section 7.55).

RECALLING FIRM: The company initiating a recall or, in the case of a FDA- or FSIS-requested recall, the company with primary responsibility for the manufacture and marketing of the recalled product.

REIMBURSEMENT: A method by which a customer's or client's money is refunded. To maintain good customer relations and reduce the number of possible claims against the company, guidelines for refunding customers' money in the event of a recall should be considered as part of the company recall strategy.

RESPONDENT: A person or company named in an official notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

RESPONSIBLE INDIVIDUAL: The FDA's (or FSIS') term for any person within a company who is in a position of power or authority to prevent, detect, or correct violations of the Federal Food, Drug, and Cosmetic Act.

RISK MANAGEMENT: A company's risk management element must be part of the recall team and, in particular, know the details of the company's recall-related insurance coverage.

S

SABOTAGE: The deliberate destruction of property or the tainting or hindering of a manufacturing process by someone unhappy with a company or employer. In today's world, food supply sabotage must be incorporated as a possible bioterrorism and/or security threat, and included in a safety precautions and recall planning. (See **Bioterrorism**).

SALMONELLA: A bacterial pathogen that lives in the intestines of birds, reptiles and mammals, and spreads to humans through animal-based food. Can enter the bloodstream and cause food poisoning and potentially fatal infections (like typhoid and septicemia) to people at the extremes of age or in poor health.

SANITATION STANDARD OPERATING PROCEDURES (SSOPs): Federally inspected meat and poultry plants are required to develop and implement these safety and sanitation procedures. (Also see **HACCP**).

SEIZURE: A court order that allows a government regulatory agency to take possession of products in order to remove them from the commerce stream. Seizure may be used if an agency's request for a voluntary recall is ignored or not adequately addressed by the target company.

SHELLFISH: A common allergen, this category of seafood includes clams, mussels, oysters and scallops.

SHIGELLA: A group of bacteria that can cause fever, cramps, diarrhea and often bloody bowel movements. It is present in the stool of an infected person for up to two weeks after their illness, which

makes hand-washing extremely important to avoid spreading infection. *Shigella* can be acquired from contaminated food, or by drinking or swimming in contaminated water. With shigellosis, the illness caused by ingesting the *Shigella* bacterium, typically lasts from 5 to 7 days, but the person may still be infectious for another two weeks after symptoms subside.

STATUTES OF LIMITATION: Like liability and duty to recall laws, statutes of limitation vary widely from state to state. Companies can reduce liability exposure by thoroughly understanding statutes of limitation issues related to their products and the states in which they are sold.

STOCK RECOVERY: A company's collecting of a product from its distributors or warehouses that has not yet been marketed or has not left the company's direct control, and of which no portion has been released for sale or use.

SULFITES: Sulfur-based preservatives that are used in many types of cooked and processed foods, and occur naturally in beer and wine. The FDA estimates the consumption of 10 milligrams or more of sulfites in a serving of food or beverage can elicit an allergic reaction in people who are sulfite-sensitive. About 1 in 100 persons are sulfite-sensitive, as well as 5 percent of asthma sufferers, so the FDA requires that sulfite contents be disclosed on food labels. See www.fda.gov/fdac/features/096_sulf.html for more details.

SUSPENSION OF INSPECTION: A disciplinary precaution that may be taken by FSIS inspectors if a food processing plant fails to correct (or at least, propose corrective action) after being informed of a safety or sanitation problem. Since meat and poultry can't be sold without a federal inspection, a suspension effectively shuts the plant down until the problem is resolved.

T

TAMPERING: To interfere with the production, content or labeling of a food, drug or device with the intent of changing it for the worse.

TOXOPLASMOSIS: An illness caused by a parasite, *toxoplasma gondii*, found in animal feces, especially cats. Symptoms include enlarged lymph nodes, severe headaches, muscle pain, and rashes. Pregnant women and their fetuses are at highest risk for this infection, which may be spread by not hand-washing after coming into contact with soil or cat litter boxes; or by consuming contaminated water, or raw or undercooked meats.

TREE NUTS: This common food allergen category includes almonds, Brazil nuts, cashews, filberts or hazelnuts, macadamia nuts, pecans, pine nuts, pistachios and walnuts.

U

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA): An enormous federal agency with wide-ranging responsibilities, that was first created as “the People’s Department” by President Abraham Lincoln in 1862 to help farmers. Today, the USDA administers Food Stamp, school breakfast and lunch programs; serves as a water and soil conservation agency; funds rural housing projects and much more. The USDA is also responsible for the safety of meat, poultry and egg products through its Food Safety and Inspection Service (FSIS). Find more specific information at www.usda.gov.

V

VIBRIO: A type of bacteria found in seawater, one type of which causes cholera. Diarrhea and abdominal cramps are the chief symptoms, but one strain of vibrio, called *Vibrio vulnificus*, can infect the bloodstream. In persons whose immune system or liver are already compromised, a *V. vulnificus* bloodstream infection is fatal about 50% of the time. A less lethal strain, *V. parahaemolyticus*, causes common food poisoning maladies (vomiting, diarrhea, cramps) and lasts about 3 days. Both types of vibrio infection occur by eating raw or undercooked shellfish, particularly oysters. The CDC tracks vibrio infections in the states of Alabama, Florida, Louisiana and Texas, but reporting is spotty elsewhere.

W

WILLFUL BLINDNESS: A legal term meaning that companies or employees intentionally put adulterated food into the commerce stream. Proof of willful blindness can turn possible misdemeanors into felonies, with their attendant increases in criminal penalties and fines.

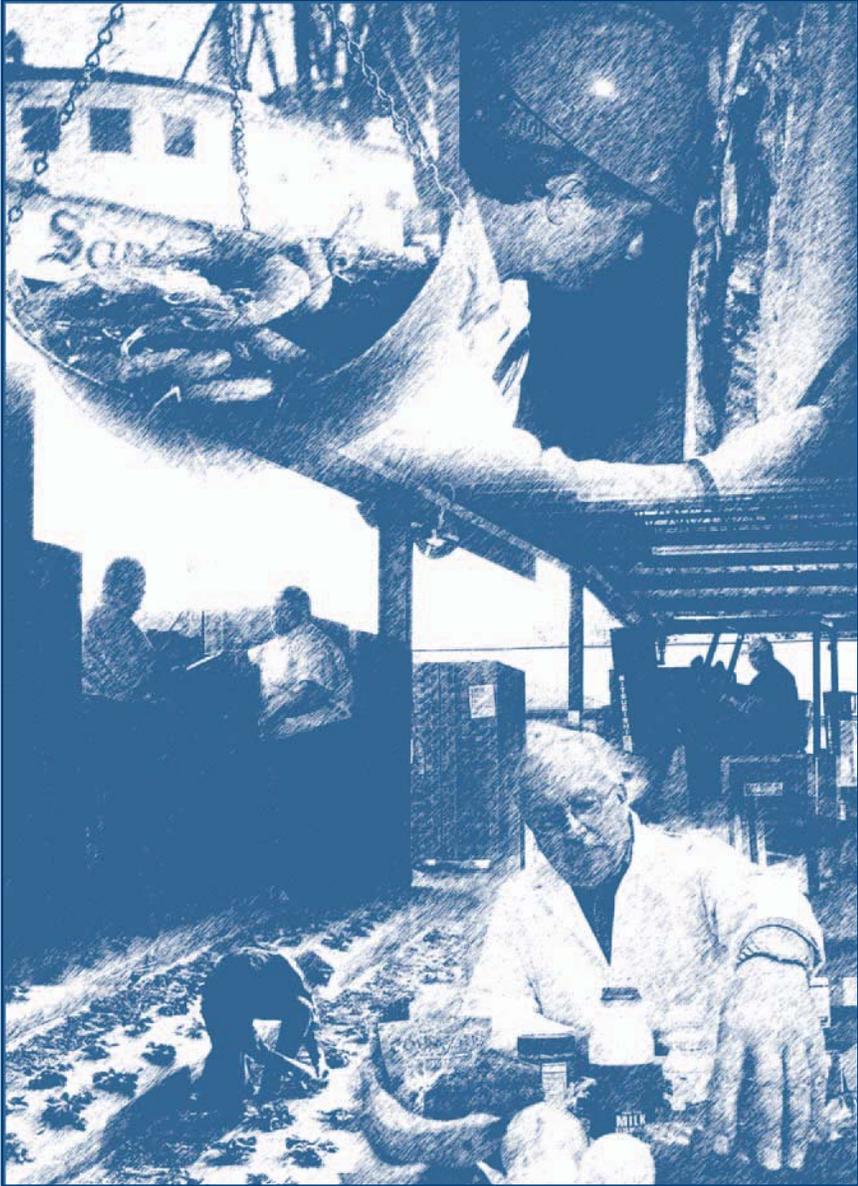
WITHDRAWAL OF INSPECTION: In some severe cases, when a meat or poultry processing plant has been found in violation of health or safety laws and fails to make corrections, FSIS can stop inspections altogether. Inspection can only be withdrawn after a hearing before a USDA Hearing Clerk. The plant can continue to operate in the days before the hearing, unless the reason for the violation is a lack of sanitation. If so, the plant must shut down until the hearing has been held and a decision is made.

WITHHOLDING MARKS OF INSPECTION: The USDA (through FSIS inspectors) can refuse to put its mark of inspection on some meat or poultry products if a processing plant has sanitation or process control problems that go unresolved. This action effectively shuts down sale of the unapproved products, since it is illegal to sell products in interstate commerce that do not bear the USDA mark of inspection.

Y

YERSINIA ENTEROCOLITICA: A bacterium usually acquired by eating contaminated food, often raw or undercooked pork, or by drinking unpasteurized milk or untreated water. Infection with *Y. enterocolitica* causes fever, abdominal pain and diarrhea, and occurs most often in young children. Symptoms typically develop 4 to 7 days after exposure, and may last as long as 3 weeks. Yersiniosis is the illness caused by ingesting *Y. enterocolitica* bacteria.

APPENDICES



Appendix 1: Records of Telephone Calls

Call sheets for incoming complaints or threats

FOR PERSONS CLAIMING AN ILLNESS OR INJURY

(This is a rather lengthy questionnaire, but it covers EVERYTHING. If the person on the phone is frustrated that it's "taking too long," assure them that, "We want to confirm ALL the facts so we can make the best decision about what to do next. I'm sorry that it's going slowly; thank you so much for your patience.")

Who received this call? _____

Date and time of incoming call: _____

Name of person calling: _____

Phone number(s) where they can be contacted: _____

What product did you call to discuss? _____

Specific packaging info (size, any product codes on it) _____

Describe exactly what you think may be the problem: (Odor, color, taste, allergic reaction, object in the food, etc.) _____

Where (and when) was this product purchased? _____

How was it stored before use? _____

How was it used or prepared? _____

Name of person who is ill or injured: _____

Address and phone # of this person, or (if a minor) their parent or guardian: _____

Age of person who is ill or injured: _____

Does this person have any other known illnesses or allergies? _____

What are the person's symptoms? _____

In what order did the symptoms appear? _____

Do you know how much of the product this person consumed? _____

Did anyone else consume the product at the same time? _____

Are they having the same symptoms? _____

Has the person seen a doctor for this problem? _____ If so, when? _____

Was there a diagnosis? _____

Doctor's name and phone number _____

Have you reported the illness/injury to anyone else? _____ If so, whom? _____

Do you still have any of the products? _____ Do you have the original container? _____

(If so, tell them to KEEP these; DO NOT throw them away!) _____

Can we send someone out to pick it up for testing? (get address) _____

Is there something specific you are asking _____ (company) _____ to do or consider doing? _____

FOOD DIARY

(to be mailed to complainant, with a stamped, self-addressed envelope so they can return it promptly.)

NAME: _____ PHONE: _____

Thank you for reporting your recent experience to the _____ (Company Name) _____. In an effort to determine the cause of your complaint, it is important that we know, to the best of your recollection, WHAT you ate on the day you experienced the problem, as well as what you ate for the previous TWO days. Please fill this form out as completely as possible, and return it to us in the enclosed stamped, self-addressed envelope.

DATE: _____ DAY 1 - (TWO DAYS BEFORE SYMPTOMS OCCURRED)

Breakfast

Lunch

Dinner

Between-Meal Snacks and Beverages

DATE: _____ DAY 2 - (ONE DAY BEFORE SYMPTOMS OCCURRED)

Breakfast

Lunch

Dinner

Between-Meal Snacks and Beverages

Food Diary continued

DATE: _____ DAY 3 - (THE DAY THAT SYMPTOMS OCCURRED)

Breakfast

Lunch

Dinner

Between-Meal Snacks and Beverages

FOR TELEPHONE THREATS

Which person received this call? _____

Date and time of incoming call: _____

What did the caller say? _____

What threat was made? _____

What demand was made? _____

Did the caller say they would call again? _____ If so, when? _____

In your opinion, how old was the caller? _____

Did you notice any type of accent? _____

Any other speech characteristics (lisp, stutter, mispronunciation of certain words, etc.)? _____

Did the caller seem to be:

Male? _____

Female? _____

White? _____

Black? _____

Hispanic? _____

Asian? _____

Middle Eastern? _____

Other? _____

Describe any specific background noises you heard. _____

Telephone booth? _____

Cellular phone? _____

How was the caller acting? (Anything NOT on this list? _____)

Calm _____

Intoxicated _____

Irrational _____

Angry _____

Desperate _____

Vulgar _____

Crying _____

Rational _____

Excited _____

Taunting _____

Hostile _____

Laughing _____

Threatening callers often begin with something like, "Listen very carefully. I'm only going to say this once." The caller usually insists on setting the "ground rules" for the conversation. You may be frightened, but it is VERY important that you STAY CALM and give the caller your FULL ATTENTION. Try to obtain as much information as possible from the caller—and ABOUT the caller, as you listen. Complete this form IMMEDIATELY after taking the threatening call, and report the incident IMMEDIATELY, as outlined in your company's emergency policy.

Signature of person who took this call

Given to: _____
or follow-up investigation on

Appendix 2: Recall Notification Templates (Phone, Fax, Letter, News Release, Health Messages for Outgoing Information)

TELEPHONE CALL TEMPLATE/WORKSHEET

For each Recall telephone contact, first be sure you speak with the right person – someone who can personally deal with the recall, or has the authority to designate someone else to deal with it. Then log that person's name and contact information on this sheet. Keeping good records is CRITICAL!

Date: _____
Company name: _____
Company contact: _____
Phone number: _____ Fax number: _____
Email address: _____ Website address: _____

Good morning/afternoon:

This is _____ (caller name) _____ calling from _____ (recalling company) _____ to notify your company that we are voluntarily recalling one of our products.

Do you have a pen and paper handy to write down some information? Great. The product brand is _____ (brand name) _____. The packaging is _____ (size, weight, etc.) _____. The product code is _____ (product code) _____. The recall date code is _____ (date code) _____. The codes are located _____ (describe 'where' on the packaging) _____.

The reason for the recall is: _____ (state it briefly) _____. The product might not meet our company quality standards, and MAY represent a _____ small/moderate/serious (CHOOSE appropriate word) _____ health or safety threat to people who use it.

At this point, there are a few things we'd like you to do right away. First, determine if any of the product in YOUR inventory carries the recall date code(s). If you have any of it in your inventory, please immediately discontinue sale or distribution, and put the product ON HOLD for now. We will contact you with further instructions. In the meantime, DO NOT dispose of this product. When a final decision is made about what to do with the product inventory, _____ (recalling company) _____ will contact you to take care of all issues associated with this recall.

We will also send you written confirmation of this recall notification. Would you like to receive it by fax, regular mail, or e-mail? (Jot down the answer & make sure you have the correct contact info on the top of this sheet to send the confirmation.)

If you have any questions, please call _____ (the recalling company's spokesperson) _____ at _____ (phone number) _____. You can also check for updates to this situation on our website, at _____ (web address) _____. We certainly regret any inconvenience that may be caused by this recall and thank you very much for your assistance.

FAX/Letter Template (Distributors/Wholesalers/Retailers/Restaurants)

(PUT ON COMPANY LETTERHEAD)

URGENT!

FOOD RECALL NOTIFICATION

Date: _____

Our firm is voluntarily recalling _____(product name) _____ due to _____(reason for recall)_____. It may not meet company quality standards, and/or may represent a small/moderate/serious (CHOOSE one word) health or safety threat to people who use it.

PLEASE FOLLOW THESE INSTRUCTIONS TO ENSURE A SUCCESSFUL RECALL:

- Immediately discontinue selling or distributing your existing stock of ___(brand, name, code of product, package size, etc.)____.
- Inform us of the quantity of product you have on hand by completing the bottom portion of this form. Sign the form and return it by FAX to ___(FAX number)___as soon as possible.
- DO NOT dispose of this product! Instead: (Choose one of the two options)
(Wait for further instructions from ___(their sales rep)___) OR
(Return the recalled product to ___(name of firm's contact person)___as soon as possible).

IF YOU HAVE DISTRIBUTED ANY OF THE RECALLED PRODUCTS, PLEASE IMMEDIATELY:

- Contact your consignees by telephone and in writing to advise them about the recall.
- Instruct them to return their unused, undestroyed stock to (recalling firm or supplier).
- Instruct them to also notify any of their consignees, which may have received the recalled product.

Thank you for your cooperation! If you have any questions regarding this recall, please feel free to contact ___(firm's contact person)___ at ___(phone)_____.

Sincerely,

(Recalling Firm Representative)

CUSTOMER NAME: _____

QUANTITY ON HAND: _____ **Cases / Cans / Packages (Circle One)**

OWNER'S NAME – PLEASE PRINT

OWNER'S SIGNATURE

News Release Template – Potential Salmonella Contamination
(PUT ON COMPANY LETTERHEAD)

FOR IMMEDIATE RELEASE

Date: _____

Contact Person's Name (for media inquiries)

Phone: _____

FAX: _____

XYZ RECALLS “SNACKIES” BECAUSE OF POSSIBLE HEALTH RISK

XYZ Inc. of Anywhere, MS, 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 #666666 on the top and with an expiration date of 12/12/04 stamped on the side.

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

The potential for contamination was noted when routine testing by the company revealed the presence of *Salmonella* in some 5-ounce packages of “Snackies.” Production has been suspended while the company continues its investigation into 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 1-800-555-5555.

Representatives of the news media may obtain more information about XYZ, Inc., as well as any updates on this recall notification, on our website:

www.xyzcompanyinc.com, or by contacting ____ (contact person's name)____ at the numbers listed above.

News Release Template – Potential Undeclared Allergens
(PUT ON COMPANY LETTERHEAD)

Date: _____

FOR IMMEDIATE RELEASE

Contact Person's Name (for media inquiries)

Phone: _____

FAX: _____

**XYZ ISSUES AN ALLERGY ALERT
ON UNDECLARED PEANUTS IN “SNACKIES”**

XYZ Inc. of Anywhere, MS, is recalling its 5-ounce packages of “Snackies” food treats because they may contain undeclared peanuts. People who have allergies to peanuts run the risk of a serious or life-threatening allergic reaction if they consume these products.

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 #666666 on the top and with an expiration date of 12/12/04 stamped on the side.

No illnesses or allergic reactions involving this product have been reported to date.

The recall was initiated voluntarily by the company after it was discovered that the peanuts contained in the product were not listed on “Snackies” new packaging labels. New, corrected ingredient labels are being printed; however, production of the product has been suspended until the company is certain that the problem has been corrected.

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 1-800-555-5555.

Representatives of the news media may obtain more information about XYZ, Inc., as well as any updates on this recall notification, on our website:

www.xyzcompanyinc.com, or by contacting ____ (contact person's name) ____ at the numbers listed above.

Health-Related Messages (for Use in News Releases, Websites, etc.)

Fatal foodborne illnesses are rare, but when they do occur, more than 75 percent of them are caused by 3 pathogens: Listeria, Salmonella, and Toxoplasma. So we've included them in these short, very basic descriptions of foodborne illness and/or allergy symptoms. More detailed information is available from a number of excellent resources, including:

Diagnosis and Management of Foodborne Illnesses: A Primer for Physicians and Other Health Care Professionals.

This is a collaboration of the U.S. Food and Drug Association and the American Medical Association, and can be found on the AMA's website: www.ama-assn.org/go/foodborne

ServSafe Essentials, Third Edition. This is the food safety instruction course designed for foodservice industry workers by the National Restaurant Association Educational Foundation. It is very handy, thorough, and easy to understand. It's available from NRAEF at 175 West Jackson Blvd., Suite 1500, Chicago, IL 60604-2814. Cost is \$71; less expensive used copies may be found on amazon.com

The U.S. Centers for Disease Control website also lists every possible ailment on its website. Find most foodborne culprits in the Division of Bacterial & Mycotic Diseases: www.cdc.gov/ncidod/dbmd/diseaseinfo

For allergy-related information, the Food Allergy and Anaphylaxis Network includes more than 26,000 doctors, nurses, dietitians, families, government agency and food and drug industry representatives. Its web address is www.foodallergy.org; or call tollfree, 1-800-929-4040.

Make sure the following 6 paragraphs are not part of the effectiveness checks template.

Allergens and Sulfites

People who have an allergy to a specific type of food, or severe sensitivity to sulfites, run the risk of serious or life-threatening adverse reactions if they consume these products. The “Big Eight” food allergens are peanuts, tree nuts (almonds, Brazil nuts, cashews, chestnuts, filberts, hazelnuts, pecans, pine nuts, walnuts), eggs, dairy (milk derivatives, including casein) fish, shell fish, soy, and wheat.

Clostridium botulinum

This bacteria causes botulism, a potentially fatal form of food poisoning. Symptoms include: fatigue and weakness, vertigo followed by double vision, dizziness, trouble with speaking or swallowing, breathing difficulty. People experiencing these problems should seek immediate medical attention.

E. coli O157:H7

Escherichia coli O157:H7 is commonly known simply as “*E. coli*.” Symptoms appear 12 to 24 hours after ingestion of the bacteria, and may include severe abdominal cramps and diarrhea, dehydration and, in the most severe cases, a kidney failure condition called *hemolytic uremic syndrome* (HUS). People experiencing these problems should seek immediate medical attention. The very young, the elderly, and persons with compromised immune systems are the most susceptible to *E. coli* infection.

Listeria monocytogenes

Consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, with high fever, severe headache, neck stiffness, and nausea as its primary symptoms. In rare cases, listeriosis is fatal; it can also cause miscarriages and stillbirths. People experiencing these problems should seek immediate medical attention. Pregnant women, the very young, the elderly, and persons with compromised immune systems are the most susceptible to this infection.

Salmonella

Healthy persons infected with the *Salmonella* bacteria may experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal cramps. In rare circumstances, if *Salmonella* enters a person’s bloodstream, it can produce more severe illness. It may also cause severe dehydration in infants and elderly persons. People experiencing these problems should seek immediate medical attention. The very young, the elderly, and persons with compromised immune systems are the most susceptible to salmonellosis.

Toxoplasma

Toxoplasmosis is the illness caused by the *Toxoplasma gondii* parasite. It is carried in animal feces (especially cats) and may be passed to humans in raw or undercooked meats and/or contaminated water. Symptoms include severe headaches, muscle pain, and enlarged lymph nodes in the head and neck. People experiencing these problems should seek immediate medical attention. Pregnant women, the very young, the elderly, and persons with compromised immune systems are the most susceptible to toxoplasmosis.

Appendix 3: Recall Effectiveness Check (Letter, On-site Visit)

Letter Template

(PUT ON COMPANY LETTERHEAD)

RECALL EFFECTIVENESS CHECK

Date: _____

To: Consignee name and address _____

Ref: (Recall product name, product code, date code, FDA or FSIS Recall Number) _____

The following checklist has been sent to you as part of a (U.S. Food and Drug Administration (FDA) or USDA-Food Safety Inspection Service) -required Recall Effectiveness Check. Please complete this checklist, sign and date it, and mail or fax to:

____(Recalling company name)____

____(Recalling company address, fax number)____

1. DID YOUR COMPANY RECEIVE NOTIFICATION FROM ____ (RECALLING COMPANY) ____ THAT THE ABOVE-LISTED PRODUCT WAS BEING RECALLED?

____ YES

____ NO

2. DID YOUR FIRM RECEIVE SHIPMENTS OF THE RECALLED PRODUCT? (IF NO, PLEASE SIGN THIS LETTER AND RETURN.)

____ YES

____ NO

3. DO YOU HAVE ANY OF THE RECALLED PRODUCT IN YOUR CURRENT INVENTORY?

____ YES

____ NO

4. IF THE ANSWER TO #3 IS YES, DO YOU PLAN TO RETURN THE RECALLED PRODUCT AS REQUESTED, TO ____ (RECALLING COMPANY) ____ ?

____ YES

Please list quantities and expected return delivery date:

____ NO

Please explain your intentions: _____

5. HAVE YOU RECEIVED ILLNESS OR INJURY REPORTS RELATED TO THE RECALLED PRODUCT?

YES Please provide details _____

NO

6. DID YOU SHIP THE RECALLED PRODUCT TO OTHER DISTRIBUTORS, RETAILERS, OR CONSIGNEES?

YES NO

7. IF THE ANSWER TO #7 IS YES, DID YOU SEND THE CONSIGNEE A RECALL NOTICE?

YES NO

8. IF THE ANSWER TO #8 IS YES, DID THE CONSIGNEE HAVE ANY PRODUCT ON HAND?

YES NO Did not inquire

THANK YOU FOR YOUR COOPERATION. PLEASE SIGN AND DATE YOUR SIGNATURE BELOW.

Signature Title

Date Company

Sincerely,

Signature and title Date

_____(Recalling company name)____

Phone Call/Personal Visit Template/Worksheet

For each Recall telephone or personal contact, first be sure you talk with the right person—one who can personally deal with the recall, or has the authority to designate someone else to deal with it. Then log that person’s name and contact information on this sheet. Keeping good records is CRITICAL!

Date: _____

Company name: _____

Company contact: _____

Phone number: _____ Fax number: _____

Email address: _____ website address: _____

Good morning/afternoon:

I am _____(caller name)_____ from _____(recalling company)_____. I am calling/visiting in reference to our _____(date)____ product recall of _____(brand, type, Product Code, Date Code)_____.

I’m calling/here today for a brief Recall Effectiveness Check with your company, to make sure we’re doing everything possible to meet the FDA (or FSIS) regulations. I’ll need to ask you several questions:

1. DID YOUR COMPANY RECEIVE NOTIFICATION FROM _____(RECALLING COMPANY)____ THAT THE (ABOVE-LISTED) PRODUCT WAS BEING RECALLED?

_____ YES _____NO

2. DID YOUR FIRM RECEIVE SHIPMENTS OF THE RECALLED PRODUCT? (IF NO, THEN “THANK YOU FOR YOUR TIME, WE’RE DONE.”)

_____ YES _____NO

3. DO YOU HAVE ANY OF THE RECALLED PRODUCT IN YOUR CURRENT INVENTORY?

_____ YES _____NO

4. IF THE ANSWER TO #3 IS YES, DO YOU PLAN TO RETURN THE RECALLED PRODUCT TO _____(RECALLING COMPANY)____ AS REQUESTED?

_____ YES Can you tell me the quantities, and the date we can expect them to be returned to the company?

_____NO Please explain your intentions: _____

5. HAVE YOU RECEIVED ILLNESS OR INJURY REPORTS RELATED TO THE RECALLED PRODUCT?

YES Please provide details _____

NO

6. DID YOU SHIP THE RECALLED PRODUCT TO OTHER DISTRIBUTORS, RETAILERS, OR CONSIGNEES?

YES NO

7. IF THE ANSWER TO #7 IS YES, DID YOU SEND THE CONSIGNEE A RECALL NOTICE?

YES NO

8. IF THE ANSWER TO #8 IS YES, DID THE CONSIGNEE HAVE ANY PRODUCT ON HAND?

YES NO Did not inquire

Thank you for your cooperation. (If in person, ask the consignee to sign and date the questionnaire.)

Signature Title

Date Company

Sincerely,

Signature and title Date

_____(recalling company)_____

Appendix 4: Recall Status Report Template

(Put on Company Letterhead)

Date: _____
FDA or FSIS Recall Number _____
Product Brand: _____ Product Code: _____ Date Code: _____
FDA Contact: _____ Phone: _____
Email address: _____

Dear _____:

_____(Recalling company)____ hereby submits the following Recall Status Report regarding the above-listed product.

1. Notification

- a. Total number of Consignees identified: _____
- b. Number of Consignees notified: _____
- c. Method of notification (check all that apply):
 1. Letter _____
 2. Phone _____
 3. FAX _____
 4. Email _____
 5. Other ____ (specify) _____

2. Consignee Response

- a. Total number of Consignees responding: _____
- b. Total number of Consignees not responding: _____
- c. Total quantity of recalled product on hand: _____
- d. Number/amount of product returned or corrected: _____
 1. Consignee 1 _____
 2. Consignee 2 _____
 3. Consignee 3 _____
 4. Consignee 4 _____
 5. Consignee 5 _____

3. Effectiveness Checks

- a. Total number required: _____
- b. Total number completed _____
- c. Completion date _____

4. Estimated Recall Completion Date: _____.

Please let us know if you require additional information.

Sincerely,

Signature and title

Date

_____(Recalling company)_____

Appendix 5: Request for Recall Termination

(Put on Company Letterhead)

Date: _____
FDA or FSIS Recall Number _____
Product Brand: _____ Product Code: _____ Date Code: _____
FDA Contact: _____ Phone: _____ Email: _____
REF: Request for Recall Termination

Dear _____:
_____(Recalling company name)___ initiated a Class ___ recall of the above-listed product on ___(date)-___ that extended to the _____ level. Proper consignee notification was made by phone, fax, email, mail and personal visits, and records of these notifications have been provided to your office.

An Effectiveness Check Level of _____ was assigned to this product. _____(Recalling company)___ therefore contacted a total of _____ consignees, _____ of which replied with the requested information.

All requested Status Reports have been filed within the proper timeframes, and the latest report is being submitted with this Request. _____(Recalling company)___ believes the above-listed product has been successfully recalled in accordance with our recall plan, as well as FDA (or FSIS) requirements.
<ADD additional data here if necessary. >

In light of this successful and conscientiously executed recall, ___(recalling company)___ hereby requests that this product recall be terminated, and that _____(recalling company)___ be provided with written confirmation of the termination.

If you have further questions, please do not hesitate to contact us. Thank you for your assistance.

Signature and title

Date

_____(Recalling Company)_____

Appendix 6: Action Log for Recalling Company

This checklist is designed to be a general “log of actions” that includes all major actions and requirements. It may easily be adapted in greater detail to a company’s specific Recall Plan.

RECALL TEAM AND PRELIMINARY STEPS

Action	Initiated	Completed	Not Done
Recall Team selected & organized			
Recall Coordinator selected			
Outside experts, consultants interviewed			
Outside experts, consultants hired			
Phone list given to all team members			
Team Spokesperson selected & trained			
Communicate with dept. managers about plan & Recall Team’s upcoming tour			
Recall Team tours company facilities & customer sites & makes recommendations			
Prioritize risks and findings from tour as ‘high,’ ‘medium,’ or ‘low’			
Solicit suggestions for improvements			
Assess employee and dept. management morale, commitment to improvements			
FDA or FSIS, pertinent local laws & guidelines reviewed			
Product tracking system reviewed			
For receiving			
For manufacturing			
For distribution			
Approve templates of letters, news releases, other documents			
Internal contact list prepared			
Customer/consignee contact list made			
Create scenario & “rules” for Mock Recall			
Mock Recall exercise performed			
Recall Plan modified as necessary			
Legal review of final plan			

THE RECALL DECISION

Action	Initiated	Completed	Not Done
Recall Team notified of problem			
Recall Team briefed by legal counsel			
Dept. managers briefed on problem and asked for input			
FDA or FSIS rules reviewed			
Dept. managers submit records to Team			
Risk evaluated			
Decision made to initiate a:			
Stock recovery			
Market Withdrawal			
Product Recall			
If decision is internal, FDA or FSIS is notified			
Team Spokesperson prepares information for public release			

Team and legal counsel approves information for public release			
--	--	--	--

IMMEDIATE ACTIONS

Action	Initiated	Completed	Not Done
Product production halted			
Internal investigation begun to determine cause or source			
Product in warehouse secured			
Receptionists, admins briefed on what to tell incoming callers & what info to obtain from them			
Update website with recall info			

INFORMATION GATHERED

Action	Initiated	Completed	Not Done
Identity of product			
Establish use of reworked or blended ingredients & their suppliers			
Product package size(s)			
Product code number(s)			
Production dates			
Quantity per Code Date			
Quantity in controlled warehouses			
Quantity shipped to customers			
Quantity unaccounted for			

PRODUCT LOCATION(S) DETERMINED

Action	Initiated	Completed	Not Done
Location of each shipment established			
Quantity shipped to each location verified			
Quantity of product unaccounted for			

RECALL CLASSIFICATION AND DEPTH

Action	Initiated	Completed	Not Done
Recall Classification assigned by the lead agency			
Recall Number(s) assigned by the lead agency			
Depth of Recall (either established by the lead agency or determined by Recall Team)			
Document templates revised to reflect current situation, recall classification & depth			
Dept. managers updated about recall classification and depth			

NOTIFICATION TO OUTSIDE GROUPS

Action	Initiated	Completed	Not Done
Wholesale distributors notified by phone/fax			
Wholesale distributors notified by mail			
Retailers notified by phone/fax			
Retailers notified by mail			
FDA or FSIS approves news release copy			
News releases sent to media list			

News releases sent to other pertinent contacts			
Sales reps instructed on Recall procedures			
Point-of-sale info prepared for Sales reps to deliver to retail customers			
Continue to update Website as needed			

PRODUCT DISPOSITION

Action	Initiated	Completed	Not Done
Company and lead agency agree on collection and disposition of product			
Decisions made about refund or exchange policies			
Wholesalers informed of product disposition			
Retailers informed of product disposition			
Sales reps assist customers in complying with recall			
Customer Service briefed on refund policy			
Warehouse prepared to receive product			
Warehouse isolating returned product			

EFFECTIVENESS CHECKS

Action	Initiated	Completed	Not Done
FDA Effectiveness Check Level established			
Effectiveness Checks begin			
Finish date established			
Review/evaluate Effectiveness Checks			
Prepare Effectiveness Checks summary			

RECALL TERMINATION

Action	Initiated	Completed	Not Done
Team undertakes review of Recall			
Recall officially concluded			
FDA or FSIS notified of Recall completion			
Team receives written confirmation from FDA or FSIS of Recall completion			
Announcement (and thanks, as needed) to customers about successful end of recall			
Update website; notify news media for follow-up if necessary			

FINAL STEPS

Action	Initiated	Completed	Not Done
Recall Team assembles all documents			
Team reviews all procedures and makes recommendations to Senior Management			
Team decides on exact cause of problem			
Team Coordinator writes summary report			
Necessary corrections made			
Final report reviewed; presented to Senior Management			

Appendix 7: Product Recall Action List for Regulators

These checklist are designed to be a general list that includes all major actions and requirements. They may easily be adapted in greater detail to the specific recall situation.

A Product Sample Report must contain the following information:

- **SAMPLE #** _____
- **TYPE OF SAMPLE**
 - Consumer Complaint
 - Inspection
 - Scheduled
- **PRODUCT INFORMATION**
 - Manufacturer _____
 - Distributor _____
 - Importer _____
- **TYPE OF PRODUCT**
 - Ready to Eat
 - Raw
 - Frozen
 - Perishable
- **PRODUCT LABEL** (must be attached)
- **CONTAINER INFORMATION**
 - Container Type _____
 - Bulk _____
 - Code or lot numbers _____
 - Container _____
 - Other distinguishing marks _____

FIELD INSPECTION

IF AN IN-STATE MANUFACTURER/DISTRIBUTOR, IMMEDIATELY VISIT THE FIRM.

- Sample other product codes or lots, and/or additional products.
- Inspect facilities if warranted.
- Provide copies of:
 - Product Sample Report
 - News Release template
 - Recall Letter template

- Determine amount of product affected.
- Ask to see company's recall plan.
- Request voluntary recall and news release, and set timelines for each.
- Request distribution list and geographic distribution details.
- Seize/Embargo and destroy any existing product from same code/lot.
- Set another meeting or contact time.

IF OUT-OF-STATE MANUFACTURER/DISTRIBUTOR, CONTACT APPROPRIATE FEDERAL, STATE OR LOCAL AGENCIES IN THAT AREA AND BRIEF THEM ON THE SITUATION.

- Contact the out-of-state manufacturer or distributor.
- Let them know a local agency (or local representative of your agency) will also be contacting them.
- By FAX, mail, or e-mail, provide copies of:
 - Product Sample Report
 - News Release template
 - Recall Letter template
- Ask if company has a recall plan in place; suggest they make it available to the local agency representative who will be in contact.
- Request distribution list and geographic distribution details.
- Set another contact time.

AT YOUR LEAD AGENCY'S CENTRAL OFFICE

- Brief your agency director about the situation.
- Check previous enforcement records about the recalling company.
- Convene a Health Hazard Evaluation Committee, if necessary.
- Decide on Class of Recall and Level of Effectiveness Checks, if these are not already obvious based on the situation, and communicate them to the recalling company.
- Recommend a news release if:
 - The Class of Recall requires it.
 - Product is likely to be in commercial channels.
 - Product is already likely to be in the hands of consumers.
 - Product shelf life or other factor makes continued sale and consumption likely.
 - Persons who may have already consumed the product would benefit from medical intervention if notified (i.e., Hepatitis A outbreak).
- Contact affected firms and advise of specific content for news release.
- Set deadline for news release (date & time, normally before 3:00 PM)
- Review the news release prepared by the recalling company.
- Prepare an agency news release if:
 - The company refuses to issue its own.
 - The company's news release is inadequate and/or they will not agree to change it.
 - The company says it cannot produce a press release in a timely manner.
 - For any reason, an agency release might be considered more effective than one issued by the firm.

- Share the news release contents with other appropriate government agencies.
- Share distribution lists (when available) with other appropriate government agencies.
- Share news release contents with industry trade associations.
- Schedule further meetings and communication as necessary.

FOLLOW-UP IN THE FIELD

- Stay in contact with the recalling company to ensure they understand the process and are complying with the agency's requests.
- Recall Tracking Report is submitted by Field Supervisor.
- Recall Audit Checks are coordinated.
- Determine whether in-line swabbing will be done.
- Witness and document product destruction and/or reconditioning efforts.
- Get follow-up reports from other agencies (local, state) that may be involved.
- Recommend strong legal action where appropriate (i.e., temporary restraining orders, injunctions)

RECALL AUDIT REPORT

REGION	COUNTY	INSPECTOR(S) NAME(S)	RECALL N ^o (S)
DISPOSITION OF RECALLED MATERIAL RETURNED			
TO			POUNDS
VIA			CASE COUNT
DATE			WHOLESALE VALUE IN US \$
DESTROYED			
METHOD			POUNDS
DATE			CASE COUNT
<input type="checkbox"/> SEE NARRATIVE			WHOLESALE VALUE IN US \$
RECONDITIONED			
METHOD			POUNDS
DATE			CASE COUNT
<input type="checkbox"/> SEE NARRATIVE			WHOLESALE VALUE IN US \$
ON HOLD			
REASON			POUNDS
DATE			CASE COUNT
<input type="checkbox"/> SEE NARRATIVE			WHOLESALE VALUE IN US \$
SEIZURE			
REASON			POUNDS
DATE		SEIZURE N ^o	CASE COUNT
<input type="checkbox"/> COPY OF DOCUMENTS ATTACHED			WHOLESALE VALUE IN US \$
NARRATIVE			
<input type="checkbox"/> Narrative is continued on report		Copy of report forwarded to: <input type="checkbox"/> USDA <input type="checkbox"/> FDA	
SUPERVISOR SIGNATURE	DATE	INSPECTOR(S) SIGNATURE(S)	CONTACT

Appendix 9: Cities with FDA Facilities (courtesy of FDA)

LOCATION	ACTIVITIES
WASHINGTON, DC AREA:	
Rockville, MD	FDA Headquarters and headquarters operations of the Human Drugs, Biologics, Animal Drugs, Device and Radiological Health products programs and laboratories
Washington, DC	Foods program headquarters and laboratories
Bethesda, MD	Human Drugs and Biologics laboratories
Beltsville, MD	Foods and Animal Drugs Research facilities
FIELD OPERATIONS FACILITIES:	
Jefferson, AR	Arkansas Regional Laboratory
Oakland, CA	San Francisco Regional Office
Alameda, CA	San Francisco District Office and laboratory
Irvine, CA	Los Angeles District Office
Los Angeles, CA	Los Angeles District laboratory
Denver, CO	Denver District Office and laboratory (special emphasis in animal drugs residue testing)
Orlando, FL	Florida District Office
Atlanta, GA	Atlanta Regional Office, Regional laboratory, and District Office
Chicago, IL	Chicago District Office
Lenexa, KS	Kansas District Office and laboratory (special emphasis in pesticides and total diet analysis)
New Orleans, LA	New Orleans District Office
Stoneham, MA	New England District Office
Winchester, MA	Winchester Engineering and Analytical Center (testing of Medical Devices and Radiological Health Research products)- Testing facility for Radionuclides and Radiopharmaceutics.
Baltimore, MD	Baltimore District Office
Detroit, MI	Detroit District Office and laboratory
Minneapolis, MN	Minneapolis District Office
Parsippany, NJ	New Jersey District Office
Jamaica, NY	New York Regional Office, Regional laboratory and District Office
Cincinnati, OH	Cincinnati District Office and Forensic Chemistry Center (elemental analysis)
Philadelphia, PA	Philadelphia Regional Office, District Office, and laboratory
San Juan, PR	San Juan District Office and laboratory (special emphasis in human drugs products testing)
Dallas, TX	Dallas Regional Office and District Office
Bothell, WA	Seattle District Office testing and laboratory (special emphasis in seafood products)
OTHER SPECIALIZED FACILITIES:	
Dauphin Island, AL	Fishery research (CFSAN)
Jefferson, AR	National Center for Toxicological Research (NCTR)
St. Louis, MO	Specialized human drugs product testing laboratory (CDER)

Appendix 10: FDA District Offices

MA, ME, NH, VT, RI, CT:

One Montvale Ave.
Stoneham, MA 02180
(781) 279-1675, ext. 1614

NY City Area:

158-15 Liberty Ave.
Jamaica, NY 11433
(718) 340-7000, ext. 5681

New York (except NY City Area):

300 Pearl St., Suite 100
Buffalo, NY 14202
(716) 551-4461, ext. 3142

NJ (importers contact):

Port Elizabeth Res. Post
1201 Corbin St.
Elizabeth, NJ 07201
(210) 645-2386 or
(210) 645-2389

PA, DE:

900 U.S. Customhouse
2nd & Chestnut Sts.
Philadelphia, PA 19106
(215) 597-4390, ext. 4561

MD, DC, VA, WV:

6000 Metro Drive, Suite 101
Baltimore, MD 21215
(410) 779-5454

GA, NC, SC:

60 Eighth St., N.E.
Atlanta, GA 30309
(404) 253-1163

FL:

555 Winderley Place
Maitland, FL 32751
Import Offices:
Tampa (813) 228-2214
Miami (305) 526-2800

PR:

466 Fernandez Juncos Ave.
San Juan, PR 00901
(787) 729-7793, ext. 2106

MI, IN:

1560 East Jefferson Ave.
Detroit, MI 48207
(313) 226-5249

MN, WI, ND, SD:

240 Hennepin Ave.
Minneapolis, MN 55401
(612) 334-4100, ext. 247

IL:

300 S. Riverside Plaza
Suite 550 South
Chicago, IL 60606
(312) 353-5863, ext. 163

OH, KY:

6751 Steger Dr.
Cincinnati, OH 45237
(513) 679-2700

KS, IA, NE, MO:

11510 West 80th St.
Lenexa, KS 66214
(913) 752-2100

TX, AR, OK:

3310 Live Oak St.
Dallas, TX 75204
(214) 655-5310

CO, WY, UT, NM:

P.O. Box 25087
Denver, CO 80225

Importers in KS, IA, NE, MO, TX, AR, OK, CO, WY, UT, NM:

Southwest Import District
3310 Live Oak St.
Dallas, TX 75204
(214) 655-5310, ext. 334
toll free (800) 991-4881

LA, MS, TN, AL:

6600 Plaza Dr., Suite 400
New Orleans, LA 70127
(504) 253-4519

WA, OR, MT, ID, AK:

22201 23rd Dr., SE
Bothell, WA 98021
(425) 4836-4974

CA (Northern), NV, HI:

1431 Harbor Bay Parkway
Alameda, CA 94502
(510) 337-6786

CA (Los Angeles), AZ:

San Pedro Import Operations
222 W. 6th St., Suite 700
San Pedro, CA 90731
(310) 831-6123, ext. 102

CA (DISTRICT 5)

620 Central Ave.
Building 2C
Alameda, CA 94501
(510) 337-5000
Emergency 24-hour:
1-866-729-9307

**CT, ME, MA, NH, NY, RI, VT
(DISTRICT 65)**

230 Washington Avenue
Extension
Albany, NY 12203-5369
(518) 452-6870
Emergency 24-hour:
(518) 452-6870 ext. 250

**FL, GA, Puerto Rico, Virgin
Islands**

(DISTRICT 85)
100 Alabama St., SW
Bldg. 1924, Suite 3-R-90
Atlanta, GA 30303
(404) 562-5900
Emergency 24-hour:
1-800-282-7005

**DE, MD, VA, WV,
Washington DC**

(DISTRICT 75)
5601 Sunnyside Ave.
Suite 1-2288-B
Beltsville, MD 20705-5200
(301) 504-2136
Emergency 24-hour:
1-800-289-4116

KS, MO (DISTRICT 30)

4920 W. 15th St.
Lawrence, KS 66049
(785) 841-5600
Emergency 24-hour:
(785) 840-0020

KY, NC, SC (DISTRICT 80)

6020 Six Forks Rd.
Raleigh, NC 27609
(919) 844-8400 or
1-800-662-7608
Emergency 24-hour:
(919) 844-8400

**AK, AZ, CO, HI, ID, NM, NV,
OR, UT, WA and
American Samoa, Guam, N.
Mariana Islands**

(DISTRICT 15)
665 S. Broadway, Suite B
Boulder, CO 80303
(303) 497-5411
Emergency 24-hour:
(303) 497-5411

Additional District 15 Office
530 Center St., NE
Mezzanine
Salem, OR 97301
(503) 399-5831
Emergency 24-hour:
(303) 497-5411

IL, IN, OH (DISTRICT 50)

1919 S. Highland Ave.
Suite 115-C
Lombard, IL 60148
(630) 620-7474
Emergency 24-hour
1-888-874-6503

Additional District 50 Office
155 E. Columbus St.
Pickerington, OH 43147
(614) 833-1405
Emergency 24-hour:
1-888-874-6503

TX (DISTRICT 40)

1100 Commerce St.
Room 516
Dallas, TX 75242-0598
(214) 767-9116
Emergency 24-hour:
(214) 767-9116, ext. 250

AR, LA, OK (DISTRICT 35)

Country Club Center
4700 South Thompson
Bldg. B, Suite 201
Springdale, AR 72764
(479) 751-8412
Emergency 24-hour:
(479) 751-8412 IA, NE

IA, NE (DISTRICT 25)

Federal Bldg., Room 985
210 Walnut Street
Des Moines, IA 50309
(515) 727-8960
Emergency 24-hour:
(515) 710-1829

AL, MS, TN (DISTRICT 90)

715 Pear Orchard Road,
Suite 101
Ridgeland, MS 39157
(601) 965-4312
Emergency 24-hour:
(601) 662-3407

MI, WI (DISTRICT 45)

2810 Crossroads Dr.
Suite 3500
Madison, WI 53718-7969
(608) 240-4080
Emergency 24-hour:
1-888-724-3212, code #300267

REGION 4

Miami, FL (Ft. Lauderdale)
(954) 356-7213

REGION 5

Philadelphia, PA
(215) 597-4219, ext. 130

MN, MT, ND, SD, WY

(DISTRICT 20)

Butler Square West, Suite 989-
C, 100 6th Street
Minneapolis, MN 55403
(612) 370-2400
Emergency 24-hour:
1-800-923-9535

NJ, PA (DISTRICT 60)

701 Market St.
Suite 4100-A
Philadelphia, PA 19106
(215) 597-4219
Emergency 24-hour:
1-800-637-6681, ext. 101 or 113

NOTE: The USDA also has 5 regional offices, where the Import Inspection Divisions are located:

REGION 1

Washington, DC
(202) 720-9904

REGION 2

Detroit, MI (Oak Park)
(248) 968-0722

REGION 3

Los Angeles, CA (Diamond Bar)
(909) 396-9518

[Code of Federal Regulations, Title 21, Volume 1, Revised April 1, 2002]

From the U.S. Government Printing Office via GPO Access

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 7--ENFORCEMENT POLICY

Subpart A--General Provisions

SEC. 7.1 SCOPE.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) and other laws that it administers. This part also provides guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

SEC. 7.3 DEFINITIONS.

- (A) Agency means the Food and Drug Administration.
- (B) Citation or cite means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.
- (C) Respondent means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.
- (D) Responsible individual includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.
- (E) [Reserved]
- (F) Product means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. Product does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.
- (G) Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.
- (H) Correction means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

- (I) Recalling firm means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.
- (J) Market withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.
- (K) Stock recovery means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.
- (L) Recall strategy means a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.
- (M) Recall classification means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.
 1. Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
 2. Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
 3. Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.
- (N) Consignee means anyone who received, purchased, or used the product being recalled.

[42 FR 15567, Mar. 22, 1977, as amended at 43 FR 26218, June 16, 1978; 44 FR 12167, Mar. 6, 1979]

SEC. 7.12 GUARANTY.

In case of the giving of a guaranty or undertaking referred to in section 303(c)(2) or (3) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

SEC. 7.13 SUGGESTED FORMS OF GUARANTY.

- (A) A guaranty or undertaking referred to in section 303(c)(2) of the act may be:
 1. Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or
 2. General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.
- (B) The following are suggested forms of guaranty or undertaking under section 303(c)(2) of the act:
 1. Limited form for use on invoice or bill of sale.
(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterat-

ed or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

2. General and continuing form. The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or in the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce. (Signature and post-office address of person giving the guaranty of undertaking.)
- (C) The application of a guaranty or undertaking referred to in section 303(c)(2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the act, or becomes an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.
- (D) A guaranty or undertaking referred to in section 303(c)(3) of the act shall state that the shipment or other delivery of the color additive covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.
- (E) The following are suggested forms of guaranty or undertaking under section 303(c)(3) of the act:
1. For domestic manufacturers: (Name of manufacturer) hereby guarantees that all color additives listed herein were manufactured by him, and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act. (Signature and post-office address of manufacturer.)
 2. For foreign manufacturers: (Name of manufacturer and agent) hereby severally guarantee that all color additives listed herein were manufactured by (name of manufacturer), and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act. (Signature and post-office address of manufacturer.) (Signature and post-office address of agent.)
- (F) For the purpose of a guaranty or undertaking under section 303(c)(3) of the act the manufacturer of a shipment or other delivery of a color additive is the person who packaged such color.
- (G) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.
- (H) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

Subpart B [Reserved]

SEC. 7.40 RECALL POLICY.

Source: 43 FR 26218, June 16, 1978, unless otherwise noted.

- (A) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and dis-

tributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and Secs. 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

- (B) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.
- (C) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

Subpart C--Recalls (Including Product Corrections)--Guidance on Policy, Procedures, and Industry Responsibilities

SEC. 7.41 HEALTH HAZARD EVALUATION AND RECALL CLASSIFICATION.

- (A) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:
 - 1. Whether any disease or injuries have already occurred from the use of the product.
 - 2. Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
 - 3. Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
 - 4. Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.
 - 5. Assessment of the likelihood of occurrence of the hazard.
 - 6. Assessment of the consequences (immediate or long-range) of occurrence of the hazard.
- (B) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

SEC. 7.42 RECALL STRATEGY.

(A) General.

1. A recall strategy that takes into account the following factors will be developed by the agency for a Food and Drug Administration-requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:

(i) Results of health hazard evaluation.

(ii) Ease in identifying the product.

(iii) Degree to which the product's deficiency is obvious to the consumer or user.

(iv) Degree to which the product remains unused in the market-place.

(v) Continued availability of essential products.

2. The Food and Drug Administration will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

(B) Elements of a recall strategy. A recall strategy will address the following elements regarding the conduct of the recall:

1. Depth of recall. Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

(i) Consumer or user level, which may vary with product, including any intermediate wholesale or retail level; or

(ii) Retail level, including any intermediate wholesale level; or

(iii) Wholesale level.

2. Public warning. The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The Food and Drug Administration in consultation with the recalling firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by the Food and Drug Administration. The recall strategy will specify whether a public warning is needed and whether it will issue as:

(i) General public warning through the general news media, either national or local as appropriate, or

(ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

3. Effectiveness checks. The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. A guide entitled "Methods for Conducting Recall Effectiveness Checks" that describes the use of these different methods is available upon request from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. The recalling firm will ordinarily be respon-

sible for conducting effectiveness checks, but the Food and Drug Administration will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

- (i) Level A--100 percent of the total number of consignees to be contacted;
- (ii) Level B--Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees;
- (iii) Level C--10 percent of the total number of consignees to be contacted;
- (iv) Level D--2 percent of the total number of consignees to be contacted; or
- (v) Level E--No effectiveness checks.

[43 FR 26218, June 16, 1978, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14363, Mar. 28, 1994]

SEC. 7.45 FOOD AND DRUG ADMINISTRATION-REQUESTED RECALL.

- (A) The Commissioner of Food and Drugs or his designee under Sec. 5.20 of this chapter may request a firm to initiate a recall when the following determinations have been made:
 - 1. That a product that has been distributed presents a risk of illness or injury or gross consumer deception.
 - 2. That the firm has not initiated a recall of the product.
 - 3. That an agency action is necessary to protect the public health and welfare.
- (B) The Commissioner or his designee will notify the firm of this determination and of the need to begin immediately a recall of the product. Such notification will be by letter or telegram to a responsible official of the firm, but may be preceded by oral communication or by a visit from an authorized representative of the local Food and Drug Administration district office, with formal, written confirmation from the Commissioner or his designee afterward. The notification will specify the violation, the health hazard classification of the violative product, the recall strategy, and other appropriate instructions for conducting the recall.
- (C) Upon receipt of a request to recall, the firm may be asked to provide the Food and Drug Administration any or all of the information listed in Sec. 7.46(a). The firm, upon agreeing to the recall request, may also provide other information relevant to the agency's determination of the need for the recall or how the recall should be conducted.

SEC. 7.46 FIRM-INITIATED RECALL.

- (A) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in Sec. 5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure. In such cases, the firm will be asked to provide the Food and Drug Administration the following information:
 - 1. Identity of the product involved.
 - 2. Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.

3. Evaluation of the risk associated with the deficiency or possible deficiency.
 4. Total amount of such products produced and/or the timespan of the production.
 5. Total amount of such products estimated to be in distribution channels.
 6. Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.
 7. A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.
 8. Proposed strategy for conducting the recall.
 9. Name and telephone number of the firm official who should be contacted concerning the recall.
- (B) The Food and Drug Administration will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not delay initiation of its product removal or correction.
- (C) A firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall. The firm's action also is considered a firm-initiated recall and is subject to paragraphs (a) and (b) of this section.
- (D) A firm that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with the appropriate Food and Drug Administration district office when the reason for the removal or correction is not obvious or clearly understood but where it is apparent, e.g., because of complaints or adverse reactions regarding the product, that the product is deficient in some respect. In such cases, the Food and Drug Administration will assist the firm in determining the exact nature of the problem.

SEC. 7.49 RECALL COMMUNICATIONS.

- (A) General. A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:
1. That the product in question is subject to a recall.
 2. That further distribution or use of any remaining product should cease immediately.
 3. Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.
 4. Instructions regarding what to do with the product.
- (B) Implementation. A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: "drug [or food, biologic, etc.] recall [or correction]". The letter and the envelope should be also marked: "urgent" for class I and class II recalls and, when appropriate, for class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.

(c) Contents.

1. A recall communication should be written in accordance with the following guidelines:

- (i) Be brief and to the point;
- (ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;
- (iii) Explain concisely the reason for the recall and the hazard involved, if any;
- (iv) Provide specific instructions on what should be done with respect to the recalled products; and
- (v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.

2. The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, followup communications should be sent to those who fail to respond to the initial recall communication.

(d) Responsibility of recipient. Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

SEC. 7.50 PUBLIC NOTIFICATION OF RECALL.

The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm. The Food and Drug Administration will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential. The report will not include a firm's product removals or corrections which the agency determines to be market withdrawals or stock recoveries. The report, which also includes other Food and Drug Administration regulatory actions, e.g., seizures that were effected and injunctions and prosecutions that were filed, is available upon request from the Office of Public Affairs (HFI-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

SEC. 7.53 RECALL STATUS REPORTS.

(A) The recalling firm is requested to submit periodic recall status reports to the appropriate Food and Drug Administration district office so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the Food and Drug Administration in each recall case; generally the reporting interval will be between 2 and 4 weeks.

(B) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

- 1. Number of consignees notified of the recall, and date and method of notification.
- 2. Number of consignees responding to the recall communication and quality of products on hand at the time it was received.

3. Number of consignees that did not respond (if needed, the identity of non-responding consignees may be requested by the Food and Drug Administration).
4. Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
5. Number and results of effectiveness checks that were made.
6. Estimated time frames for completion of the recall.

(C) Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

SEC. 7.55 TERMINATION OF A RECALL.

- (A) A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.
- (B) A recalling firm may request termination of its recall by submitting a written request to the appropriate Food and Drug Administration district office stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

SEC. 7.59 GENERAL INDUSTRY GUIDANCE.

A recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect. Notwithstanding similar specific requirements for certain products in other parts of this chapter, the following is provided by the Food and Drug Administration as guidance for a firm's consideration:

- (A) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with Secs. 7.40 through 7.49, 7.53, and 7.55.
- (B) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.
- (C) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention.

Subpart D [Reserved]

Subpart E—Criminal Violations

SEC. 7.84 OPPORTUNITY FOR PRESENTATION OF VIEWS BEFORE REPORT OF CRIMINAL VIOLATION.

(A) (1) Except as provided in paragraph (a) (2) and (3) of this section, a person against whom criminal prosecution under the Federal Food, Drug, and Cosmetic Act is contemplated by the Commissioner of Food and Drugs shall be given appropriate notice and an opportunity to present information and views to show cause why criminal prosecution should not be recommended to a United States attorney.

2. Notice and opportunity need not be provided if the Commissioner has reason to believe that they may result in the alteration or destruction of evidence or in the prospective defendant's fleeing to avoid prosecution.
 3. Notice and opportunity need not be provided if the Commissioner contemplates recommending further investigation by the Department of Justice.
- (B) If a statute enforced by the Commissioner does not contain a provision for an opportunity to present views, the Commissioner need not, but may in the commissioner's discretion, provide notice and an opportunity to present views.
- (C) If an apparent violation of the Federal Food, Drug, and Cosmetic Act also constitutes a violation of any other Federal statute(s), and the Commissioner contemplates recommending prosecution under such other statute(s) as well, the notice of opportunity to present views will include all violations.
- (D) Notice of an opportunity to present views may be by letter, standard form, or other document(s) identifying the products and/or conduct alleged to violate the law. The notice shall--
1. Be sent by registered or certified mail, telegram, telex, personal delivery, or any other appropriate mode of written communication;
 2. Specify the time and place where those named may present their views;
 3. Summarize the violations that constitute the basis of the contemplated prosecution;
 4. Describe the purpose and procedure of the presentation; and
 5. Furnish a form on which the legal status of any person named in the notice may be designated.
- (E) If more than one person is named in a notice, a separate opportunity for presentation of views shall be scheduled on request. Otherwise, the time and place specified in a notice may be changed only upon a showing of reasonable grounds. A request for any change shall be addressed to the Food and Drug Administration office that issued the notice and shall be received in that office at least 3 working days before the date set in the notice.
- (F) A person who has received a notice is under no legal obligation to appear or answer in any manner. A person choosing to respond may appear personally, with or without a representative, or may designate a representative to appear for him or her. Alternatively, a person may respond in writing. If a person elects not to respond on or before the time scheduled, the Commissioner will, without further notice, decide whether to recommend criminal prosecution to a United States attorney on the basis of the information available.
- (G) If a respondent chooses to appear solely by designated representative, that representative shall present a signed statement of authorization. If a representative appears for more than one respondent, the representative shall submit independent documentation of authority to act for each respondent. If a representative appears without written authorization, the opportunity to present views with respect to that respondent may be provided at that time only if the authenticity of the representative's authority is first verified by telephone or other appropriate means.

[44 FR 12167, Mar. 6, 1979]

SEC. 7.85 CONDUCT OF A PRESENTATION OF VIEWS BEFORE REPORT OF CRIMINAL VIOLATION.

- (A) The presentation of views shall be heard by a designated Food and Drug Administration employee. Other Food and Drug Administration employees may be present.

- (B) A presentation of views shall not be open to the public. The agency employee designated to receive views will permit participation of other persons only if they appear with the respondent or the respondent's designated representative, and at the request of, and on behalf of, the respondent.
- (C) A respondent may present any information of any kind bearing on the Commissioner's determination to recommend prosecution. Information may include statements of persons appearing on the respondent's behalf, letters, documents, laboratory analyses, if applicable, or other relevant information or arguments. The opportunity to present views shall be informal. The rules of evidence shall not apply. Any information given by a respondent, including statements by the respondent, shall become part of the agency's records concerning the matter and may be used for any official purpose. The Food and Drug Administration is under no obligation to present evidence or witnesses.
- (D) If the respondent holds a "guaranty or undertaking" as described in section 303(c) of the act (21 U.S.C. 333(c)) that is applicable to the notice, that document, or a verified copy of it, may be presented by the respondent.
- (E) A respondent may have an oral presentation recorded and transcribed at his or her expense, in which case a copy of the transcription shall be furnished to the Food and Drug Administration office from which the notice issued. The employee designated to receive views may order a presentation of views recorded and transcribed at agency expense, in which case a copy of such transcription shall be provided to each respondent.
- (F) If an oral presentation is not recorded and transcribed, the agency employee designated to receive views shall dictate a written summary of the presentation. A copy of the summary shall be provided to each respondent.
- (G) A respondent may comment on the summary or may supplement any response by additional written or documentary evidence. Any comment or addition shall be furnished to the Food and Drug Administration office where the respondent's views were presented. If materials are submitted within 10 calendar days after receipt of the copy of the summary or transcription of the presentation, as applicable, they will be considered before a final decision as to whether or not to recommend prosecution. Any materials received after the supplemental response period generally will be considered only if the final agency decision has not yet been made.
- (H) 1. When consideration of a criminal prosecution recommendation involving the same violations is closed by the Commissioner with respect to all persons named in the notice, the Commissioner will so notify each person in writing.
2. When it is determined that a person named in a notice will not be included in the Commissioner's recommendation for criminal prosecution, the commissioner will so notify that person, if and when the Commissioner concludes that notification will not prejudice the prosecution of any other person.
3. When a United States attorney informs the agency that no persons recommended will be prosecuted, the Commissioner will so notify each person in writing, unless the United States attorney has already done so.
4. When a United States attorney informs the agency of intent to prosecute some, but not all, persons who had been provided an opportunity to present views and were subsequently named in the Commissioner's recommendation for criminal prosecution, the Commissioner, after being advised by the United States attorney that the notification will not prejudice the prosecution of any other person, will so notify those persons eliminated from further consideration, unless the United States attorney has already done so.

[44 FR 12168, Mar. 6, 1979]

SEC. 7.87 RECORDS RELATED TO OPPORTUNITIES FOR PRESENTATION OF VIEWS CONDUCTED BEFORE REPORT OF CRIMINAL VIOLATION.

- (A) Records related to a section 305 opportunity for presentation of views constitute investigatory records for law enforcement purposes and may include inter- and intra-agency memorandums.
1. Notwithstanding the rule established in Sec. 20.21 of this chapter, no record related to a section 305 presentation is available for public disclosure until consideration of criminal prosecution has been closed in accordance with paragraph (b) of this section, except as provided in Sec. 20.82 of this chapter. Only very rarely and only under circumstances that demonstrate a compelling public interest will the Commissioner exercise, in accordance with Sec. 20.82 of this chapter, the authorized discretion to disclose records related to a section 305 presentation before the consideration of criminal prosecution is closed.
 2. After consideration of criminal prosecution is closed, the records are available for public disclosure in response to a request under the Freedom of Information Act, except to the extent that the exemptions from disclosure in subpart D of part 20 of this chapter are applicable. No statements obtained through promises of confidentiality shall be available for public disclosure.
- (B) Consideration of criminal prosecution based on a particular section 305 notice of opportunity for presentation of views shall be deemed to be closed within the meaning of this section and Sec. 7.85 when a final decision has been made not to recommend criminal prosecution to a United States attorney based on charges set forth in the notice and considered at the presentation, or when such a recommendation has been finally refused by the United States attorney, or when criminal prosecution has been instituted and the matter and all related appeals have been concluded, or when the statute of limitations has run.
- (C) Before disclosure of any record specifically reflecting consideration of a possible recommendation for criminal prosecution of any individual, all names and other information that would identify an individual whose prosecution was considered but not recommended, or who was not prosecuted, shall be deleted, unless the Commissioner concludes that there is a compelling public interest in the disclosure of the names.
- (D) Names and other information that would identify a Food and Drug Administration employee shall be deleted from records related to a section 305 presentation of views before public disclosure only under Sec. 20.32 of this chapter.

[44 FR 12168, Mar. 6, 1979]

Appendix 13: Guiding Principles for “Mock” Product Recalls

Mock recalls are the best way to test your company’s readiness should a natural or purposeful contamination of one or more of your food products occur and be detected by your Quality Assurance staff or by a Federal, state or local regulatory agency. Mock recalls can vary from a full blown, start-to-finish exercise that takes the company through every step that would occur in a real recall, to a timed test of your ability to trace forward and trace back and notify your notify your customers (see “My Best Advice” – The Recall Team Leader). Top management of the company should not just be supportive of such exercises, but encourage them, and take an active part in the process and the follow-up. The real purpose of such exercises is to rigorously test the procedures that your company has in place to isolate a problem, and quickly and efficiently remove the problem product from the marketplace.

Mock recalls can and should be conducted by any size company, from the very small to the very largest. Prior to establishing a program that includes mock recall exercises, the company should have its recall team in place with each team member knowledgeable as to his/her role, as well as its emergency plan, and appropriate standardized forms and procedures.

THE FOLLOWING ARE SOME GUIDING PRINCIPLES FOR CONDUCTING A MOCK RECALL:

REGULARITY BUT UNEXPECTEDLY – Mock recall exercises should be conducted with some regularity, but not so regular that they become predictable. They should be unannounced, and the time for conducting the mock recall should be known only by top management. The recall team members should be surprised by the exercise, just as they would be in a real situation, such as when a regulatory agency informs the company of a problem.

INCONVENIENT – Recall situations seldom occur at convenient times. Mock recalls therefore should never be timed to accommodate the schedules of key recall team members or other involved employees or clients. If the recall team is scattered (on vacation, the golf course, etc.), your ability to communicate will be tested, and this is highly desirable.

REALISTIC – The mock recall exercise should be as realistic as it can possibly be, as it must be taken seriously by all participants to be effective.

COMPREHENSIVE – The mock recall exercise should be as comprehensive as possible, meaning that all aspects of the company’s emergency plan should be tested, and all recall team members involved.

RECORDED – The results of the mock recall exercise should become a recorded part of the company’s history. Each exercise should be a baseline from which improvements can be demonstrated.

CRITIQUED – Top management should review the results of each mock recall exercise and constructively critique the performance of each participant (including themselves).

FOLLOWED UP – Any performance deficiencies identified in follow up to the mock recall should be corrected through changes in the emergency plan or additional employee training as appropriate.

Remember, you may truly believe you have the best emergency plan and the best recall team, but if they are not rigorously tested by a realistic, comprehensive mock recall exercise, you will really never know how well they will perform should an emergency occur.

PRODUCT RECALL GUIDELINES FOR FIRMS

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1. Background and Objectives

A recall is an effective method of removing from commerce any product that may be adulterated or misbranded. Firms such as a manufacturer, distributor, or importer take these actions as part of their responsibility to protect the public health and welfare.

A recall can be disruptive to a firm's operation and business; however, there are several steps that a firm can take to minimize this disruption. An operator of an inspected establishment should take measures that will ensure rapid and effective response if products that appear to be adulterated have entered commerce. The operator should prepare and maintain a detailed, written recall plan. This plan should describe, step by step, the procedures the firm will follow in case it becomes necessary to recall a product.

Official establishments are required to have HACCP plans that control hazards reasonably likely to occur and that identify in-plant corrective actions when there is a failure to control a critical control point (9 CFR 417.2-417.3). FSIS believes that establishments can identify corrective actions, including a recall if necessary when violative product has entered commerce. There is no regulatory requirement that an establishment includes this recall plan in its HACCP plan or as a prerequisite program; however, FSIS believes that prudent establishments will.

The guidance presented here is intended for all meat and poultry firms that may need to conduct a recall without regard to plant size or the number of people employed. Some of the recommendations may speak in terms of forming teams of employees to conduct certain activities related to recalls, or may seem to imply that sophisticated analyses of potential health hazard situations be conducted. However, the key activities discussed below can be performed by one or two individuals in circumstances where there are limited resources. For example, in a small plant operation, the owner or manager of the establishment may be the recall coordinator as well as the contact for the Agency, the firm's consignees, and the public. The Agency does not expect smaller establishments to hire personnel simply to prepare for recalls. On the contrary, the Agency strongly encourages the management of all firms to prepare themselves, and their personnel regularly employed, for the potential of having to conduct a recall.

2. The Recall Plan

One person should be identified as the recall coordinator (firms may use other titles as appropriate) to prepare for and coordinate all activities related to recalls. The recall coordinator should be knowledgeable about every aspect of the firm's operations, including purchasing, processing, quality assurance, distribution, and consumer complaints. The recall coordinator should select people to form a recall team. The recall coordinator should be authorized to make decisions in carrying out a recall and should report to top management at regular, specified intervals.

A RECALL PLAN SHOULD ADDRESS THE FOLLOWING ELEMENTS:

- (A) **Identification of Recall Personnel** - All internal and external personnel to be involved in the recall actions, along with their respective telephone and facsimile numbers, e-mail addresses, etc., as appropriate, should be identified. For each identified individual, an alternate to act in his or her absence should be specified. The roles and responsibilities of every person identified should be clearly specified.
- (B) **Recall Procedures** – The recall plan should specify, in detail, actions that the firm will take in deciding whether to recall a product and in effecting the recall should it decide to do so.
- (C) **Evaluation of Health Hazards** – A firm may collect and evaluate any information it has regarding the nature and extent of the associated health risks. A firm may take into account the following factors if it chooses to submit this information to the FSIS Recall Committee during the preliminary recall evaluation:

- Whether any disease or injuries have already occurred from the use of the product.
- Assessment of the hazard to various segments of the population, (e.g., children, the elderly, immuno-compromised individuals, etc.), who are expected to be exposed to the product being considered for recall, with particular attention paid to the hazard to those individuals who may be at greatest risk.
- Assessment of the relative degree of seriousness of the health hazard to which the population at risk would be exposed.
- Assessment of the likelihood of occurrence of the hazard.
- Assessment of the consequences (immediate or long-range) of the hazard's occurrence.

- (D) **Scope of Recall** – The plan should outline how the establishment will assess the amount and kind of product that is implicated in a problem. When the problem involves contamination with microbial pathogens, FSIS generally considers all products produced under a single HACCP plan between performance of complete cleaning and sanitizing procedures (clean-up to clean-up) to be potentially involved. However, sanitation does not necessarily define the scope of all product removal actions.

Some examples of product removal actions where the scope is defined other than by clean-up to clean-up include: the contamination of a vat of product with a foreign object, the use of an incorrect label, or the use of the same source of raw materials in other lots on other days of production. FSIS will consider such factors as the establishment's coding of product; the pathogen of concern; the processing and packaging; the equipment; the establishment's HACCP plan monitoring and verification activities (including microbiological testing); the establishments Sanitation SOP records; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.

If the use of the "clean-up to clean-up" approach does not define the scope of the problem, the firm will have to identify the product involved by defining, for example, when the problem began, and when it ended. The plan should specify how the firm will determine the scope of the implicated product for various scenarios and contingencies.

- (E) **Records** - A system of product coding sufficient to permit positive product identification and to facilitate effective recalls should be in use by all firms. Records should be maintained for a period of time that exceeds the shelf life and expected use of the product and at least the length of time specified in FSIS regulations concerning record retention (9 CFR 320; 381.175).

Distribution records should be maintained as are necessary to facilitate identification and location of products that are recalled. These records can be used to quickly provide FSIS with requested information regarding product

distribution. Records such as bills of sale, invoices, and shipping papers are required to be kept with respect to each transaction in which any livestock, poultry or poultry food, or meat or meat food product is purchased, sold, shipped, received or otherwise handled by the establishment in connection with any business subject to the FMIA. These records should include names and address of consignees, shipment method, date of shipment, etc. It is also useful to note consignees that are hospitals, chains, restaurants, distributors, independent retailers or sellers to the National School Lunch Program or the Department of Defense.

Production records should be maintained that would facilitate the traceback of product ingredients in order to help determine causes of adulteration and define the scope of recalls. In the event that a recall becomes necessary because of an Agency sample testing positive or an outbreak of foodborne illness, verified records could be used to demonstrate limiting factors that may narrow the scope of a recall by a particular plant. Moreover, the records would be essential in facilitating the traceback of the contamination to its source.

In practical terms related to *Escherichia coli* O157:H7 as detailed in FSIS Directive 10,010.1 establishments are expected to maintain records of their suppliers of ground beef raw materials and to make the records available to Agency personnel upon request in order for them, in the event that a sample of ground beef is reported positive, to notify suppliers that their product may have been the source of the contamination. The information inspection program personnel collect includes the name of the supplying establishment, the supplier's lot number, and production date of the product. This information has proven to be an effective tool for initiating tracebacks in an effort to find the source of contamination.

If a recall of ground beef is necessary because of contamination with *E. coli* O157:H7, a prudent establishment may be able to limit the amount of affected product if it has a detailed recordkeeping system in place. Carefully maintained production records can serve a vital public health purpose by providing an establishment and the Agency with an essential means of pinpointing potential sources of contamination and allow for greater accuracy in deciding which products may be affected. The kinds of records comprising such a system include production or grinding logs showing the times of each grind, the formulation or blend of raw ingredients including amounts, supplier lot identification, the finished product lot and subplot identification, and any test results associated with either the raw materials or finished product. The records should indicate and track which lots or sublots of a grinding establishment's ground beef particular raw materials were used and the amounts of each that were used.

For example, establishment 38 is a beef slaughter/fabricating/grinding establishment. It produces approximately 50,000 pounds of ground beef products per day. The raw materials used in the ground beef include its own inhouse generated boneless beef, as well as boneless beef products purchased from other establishments. The establishment tests each lot of raw material it purchases from outside sources as well as those that it generates in-house and does not use any boneless beef that tests positive on the *E. coli* O157:H7 screening test. It also tests its finished ground beef by pulling a sample representing every 2000-pound blender batch and combining those four batches into one composite sample representing an 8000-pound subplot of the day's lot. For example, a given day's ground beef production log might (in part) look like this:

Ground Beef Log Date : November 3, 2003

Product ID	Sublot #	Blend #	Time of Sample	Product Ground	Amt. (lbs)	Sample Result	Date	Initials
GOOD GRIND	1	1	7:50 AM	EST 38 - 103003 LEARN TRIM	1000	NEGATIVE	05-NOV	QC
				EST 42 - 102903 80% TRIM	500			
				EST 38A - 103103 50% TRIM	300			
				EST 38 - 103003 HEAD/CHEEK MEAT	100			
				EST AUST. 38B - 90603 COW SHOULDER	100			

Note: [Blend #2, #3, and #4 making up subplot #1 would be recorded in the same way. The sample result represents the entire subplot.]

Product ID	Sublot #	Blend #	Sample Time	Product Ground	Amt. (lbs)	Sample Result	Date	Initials
BEST GRIND	2	1	9:20 AM	EST 38 - 103003 LEARN TRIM	1000	NEGATIVE	05-NOV	QC
				EST AUST. 38B - 90603 COW SHOULDER	800			
				EST 42 - 102903 80% TRIM	200			

Note: [The next three blends making up the subplot would be recorded in the same way. The sample result represents the entire subplot.]

Product ID	Sublot #	Blend #	Sample Time	Product Ground	Amt. (lbs)	Sample Result	Date	Initials
MEAT LOAF	5	1	2:30 PM	EST 38 - 103103 50% TRIM	700	NEGATIVE	05-NOV	QC
				EST 42 - 102703 BONELESS VEAL	400			
				EST 38 - 103003 LEAN TRIM	200			
				EST 38 - 103103 HEAD/CHEEK MEAT	200			
				EST AUST. 38B - 90603 COW SHOULDER	500			

Note: [The next three blends making up the subplot would be recorded in the same way. The sample result represents the entire subplot.]

In the event of a recall, this establishment will be able to identify the more likely sources of contamination from its production records. To illustrate, suppose subplot 5 from the chart above was the only lot that tested positive for *E. coli* O157:H7. The establishment could review their records and identify two sources of raw materials, Est. 42 boneless veal and Est. 38 head/cheeks (103003), that were not used in the other sublots. These two source materials would be more likely than the others to be the vector of contamination in the finished product.

GIVEN THIS INFORMATION, THE ESTABLISHMENT COULD:

1. Review its dressing procedures and the boning and handling of its head/cheek meat in order to find and eliminate any potential causes of contamination;
2. Confirm the test results for the lot that had the screen test positive;
3. Divert the rest of that lot of head/cheek meat away from ground beef production and into a process with an adequate kill step;
4. Notify its supplier of boneless veal, Est. 42, of its findings regarding that establishment's product; and
5. Inform the Agency of its findings, conclusions, and actions taken.

The establishment may also be able to demonstrate through this type of testing program and thorough recordkeeping that the previous sublots of product were not represented by the positive test from subplot 5. The previous sublots would not need to be removed from commerce if the establishment could adequately demonstrate through additional confirmation testing that they were not adulterated. For production records such as those discussed here to be most useful to an establishment and FSIS, they should be incorporated into an establishment's HACCP plan or be made part of a pre-requisite program.

(F) Depth of Recall – The plan should specify how the depth of recall will be determined for various scenarios and contingencies. The depth is dependent upon the extent of distribution and the level to which the recalled product was distributed. Levels of recall depth may be:

- Wholesale level, the distribution level between the manufacturer and retail or user level;
- HRI level, which includes hotels, restaurants and other institutional type customers and any intermediate wholesale level to reach those users;
- Retail level, which includes retail sellers and any intermediate wholesale level to reach the retail sellers; or
- Consumer level, which includes household consumers and any prior level distribution.

(G) Recall Communications - A recalling firm is responsible for promptly notifying each of its affected consignees about the recall. The plan should specify what means of communication will be used and should include sample communication for various scenarios and contingencies. The format, content, and extent of a recall communication should be commensurate with the hazard associated with the product being recalled, the strategy developed, and the recall plan. In general terms, the purpose of a recall communication (see attached sample letter) is to convey:

- That the product in question is subject to a recall;
- That further distribution or use of any remaining product should cease immediately;
- Where applicable and required as part of the recall strategy, that the direct consignee should in turn notify its consignees that received the product about the recall;
- Instructions regarding what to do with the product; and
- Contact Information for questions (e.g. a name and toll free number).

1. Recall Communication Implementation - As determined by the recall strategy, developed in conformance with

the recall plan, a recall communication can be accomplished by telephone, facsimile transmission, e-mail, or special delivery letters conspicuously marked, preferably in bold red type, on the letter and envelope "URGENT - FOOD RECALL." If firms communicate their recall strategy by telephone calls or other personal contacts, FSIS expects the firms to document and follow-up this communication in some written form (e.g., letter, e-mail message, fax).

2. Recall Communication Content - A recall communication should be written in accordance with the following guidelines:

- Be brief and to the point;
- Identify clearly the product and any other pertinent descriptive information to enable accurate and immediate definition of the product including, as appropriate;

Product/brand name

Product code

Package/case size

Package/case date code

Lot number/expiration date

UPC code

- Provide an explanation of the risk involved in consuming the product;
- Explain concisely the reason for the recall and the hazard involved;
- Provide specific instructions on what should be done with respect to the recalled products;
- Request an official, written response from the firm;
- Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, (e.g., by allowing the recipient to place a collect call to the recalling firm);
- The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message; and
- Provide firm contact information (for questions).

Where necessary, follow-up communications should be sent to those who fail to respond to the initial product removal communication within a specified timeframe (e.g., within 24 hours).

The recall plan should specify what means of communication will be used, including sample communications, for various scenarios and contingencies.

3. Responsibility of Recipient - Consignees that receive a recall communication should immediately carry out all instructions set forth therein and, where necessary, extend the recall to their consignees.

(H) Public Notification - The purpose of public notification is to alert the public that a product is being recalled. A firm should consider the need for and means of public notification upon initiating a recall. The recall plan should

specify what means of public notification will be used, if appropriate, for various scenarios and contingencies such as:

- General public notification by press release through the general news media, either national or local as appropriate; or
- Public notification through specialized media, (e.g., professional, trade or ethnic press, store placards or notification to specific customers (if known)).

A Recall Plan should include contact information for all potential media outlets such as television stations, radio stations, and newspapers and with local, State, and regional coverage areas as well as the national wire services. If the actual contacts are not specified, reference sources of current media contacts for all possible recall scenarios should be specified in the Recall Plan.

NOTE: Regardless of the public notification action taken by the recalling firm, FSIS will generally issue a press release for Class I and Class II recalls. For Class III recalls, generally the Agency will only issue a Recall Notification Report (RNR). The Agency will also post them on the FSIS web site (www.fsis.usda.gov/OA/recalls/rec_actv.htm) for all recalls. In addition, the RNR will be sent, by means of E-mail or facsimile transmission, to public health officials throughout the country.

- (i) **Firm's Effectiveness Checks** - The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The methods for contacting consignees should be specified, for various scenarios and contingencies, and may be accomplished by personal visits, telephone calls, letters, facsimile transmission, or a combination thereof. This is a means of assessing the progress and efficacy of a recall. The method for determining the number of effectiveness checks to be conducted and the manner for conducting them should be determined for various scenarios and contingencies in the recall plan. FSIS will verify the firm's effectiveness checks.

To assess the effectiveness of a recall, a firm needs the following information:

- How much product is implicated in the recall?
- How is this product identified to a customer/retailer (i.e., lot markings)?
- How much product is within a firm's control?
- How much product has left the firm's control?
- How many locations did the firm ship the product to, and where are those locations?
- How did the firm communicate the product removal action to those who received the product; did the firm document this contact; and did the firm ask for and receive a written response acknowledging receipt of the information?
- What actions were taken with the product and by whom?
- If product was destroyed, was destruction witnessed and documented; were Agency personnel present?
- Is there a written record of when the issue was identified, when customers were notified, and when the firm received notification that product was either placed on hold or was no longer in a customer's control?

- Can the firm account for most of the product? Does the math add up? (The firm produced this amount, shipped this amount, had this amount returned, destroyed or determined to be consumed or irretrievable.)

(J) Returned Product Control and Disposition - The means of controlling and disposing of or correcting the defect in the stock returned during a recall should be specified in the recall plan. Remember to check with the Agency before destroying product; FSIS may wish to witness the destruction. (Destroy means to render inedible for humans and animals, and all labeling is made unusable for trade.)

(K) Recall Simulations - In order to evaluate how well its plan will work in the event of an actual recall situation, the establishment should conduct periodic simulations. A simulated recall should involve the selection, without prior notice to personnel involved in the simulated recall, of at least one lot of product that has been distributed in commerce. A hypothetical reason for recalling the product should be specified, and the recall plan should be followed to establish a strategy for recalling the product. Such scenarios may be simple (e.g. one contaminated lot of product) or very complex (e.g. contaminated ingredient used in multiple products and involving rework). A firm may wish to begin with simple scenarios and work up to more complex simulations for their operation. The simulation should proceed at least to the point at which communication is to be made beyond the firm's organizational limits; however, full details of who will be contacted at that point, and how contact will be established, should be specified. Firms, especially those with products distributed by multi-layer distribution systems, may wish to consider conducting at least one simulation in which the product to be recalled has been shipped beyond the firm's initial customer to one or more of the consignee's customers. Taking the simulation beyond the recalling firm's organization could reveal potential problems in the retrieval process that possibly could be addressed before a "live" recall occurs.

A recall simulation file should be maintained to record the details and results of all simulated recalls. The recall simulation file should include the name, address, and telephone number of clients for the test lot, production records, the inventory, and distribution of the test lot. A recall simulation is used to determine whether the recall procedure is capable of identifying and quickly controlling a given lot of potentially affected product and reconciling the quantities produced, quantities in inventory, and quantities distributed. In addition, a recall simulation will identify potential problems and allow personnel to become familiar with recall procedures. If problems are identified during a recall simulation, the recall plan and procedures should be revised to correct the problems.

3. Notifying FSIS of Recalls

FSIS expects that, once it is determined that a recall will be undertaken, the recalling firm will immediately notify FSIS. When doing so, the firm should notify the Recall Management Staff (RMS) or the District Office in the FSIS district where the firm is located. The basic information that should be conveyed to FSIS includes, but is not limited to, the following (see FSIS Directive 8080.1):

- Complete and accurate product identity, including product labels.
- The reason for the recall and details about when and how any defect or deficiency was discovered.
- An evaluation of the risk associated with consumption of the product and how the evaluation was made (although FSIS will make its own determination of risk).
- How much of the product in question was produced and during what period of time.
- An estimate of how much of the product is in distribution and how long it has been in distribution.
- Area of the geographical distribution of the recalled product by State and, if exported, by country.

- Information about which distributors and customers received the product.
- Copies of any firm correspondence with distributors, brokers, or customers relating to the recall strategy or actions, and a copy of any proposed press release.
- The name, title, and telephone number of the recall coordinator for the firm.

This information may initially be provided orally. However, it should be confirmed to the RMS by using the worksheet. For clarity, it is recommended that the worksheet be filled out and submitted via e-mail. Doing so will prevent errors resulting from hard-to-read handwriting or illegibility because of poor fax transmission. Early on in the recall process, FSIS will generally send a program employee designated by the District Office to the establishment to verify distribution records and confirm facts.

4. Recall Assessment

The firm is expected to regularly, and in a timely manner, report the results of checks of the effectiveness of its efforts to retrieve the product to FSIS in order to keep the Agency apprised of the status of recalls in progress. The reporting frequency will be agreed upon by the recalling firm and FSIS. FSIS believes that the higher the degree of public health hazard, the more frequently the firm should report. FSIS will conduct its own effectiveness checks as specified in FSIS Directive 8080.1, Rev. 4. In addition, FSIS expects that the firm will notify the agency when it appears that the recall has been completed.

UNLESS OTHERWISE SPECIFIED, THE RECALL STATUS REPORT SHOULD CONTAIN THE FOLLOWING INFORMATION:

- The number of consignees notified of the recall, the dates notifications were made, and the method of notification that the firm used for each consignee.
- The number of consignees responding to the recall communication.
- The quantity of product each consignee had on hand at the time the communication was received.
- The number and identity of consignees that did not respond.
- The quantity of product returned or held by each consignee.
- An estimated time for completion of the recall.

5. Recall Termination

A recall will be terminated when FSIS has completed the recall effectiveness checks and determined that the recalling firm has made all reasonable efforts to recall the product, and that it has either disposed of the recovered product, or the product is under FSIS control (retention or detention) or has documented control by the firm. To effect a timely termination of the recall, the firm should provide all relevant information to the Agency once the firm has determined that it has retrieved all possible product. The firm should send to the relevant District Office, a “closeout memo” containing a list of customers, the amount of product retrieved, and the actions taken. Once the Agency determines that the firm has made all reasonable efforts to recall the product, the RMS will notify the firm in writing.

6. Recall Follow-up

Once a recall action has been completed, the establishment should notify its customers that the recall action has been completed, thank them for their assistance, and provide assurances that the problem has been corrected. The Recall Team should evaluate how the recall action was conducted to determine whether things should have been handled differently, and what, if any, changes should be made to the plan.

MODEL RECALL NOTIFICATION LETTER

DATE

CUSTOMER FIRM 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 and 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 of the product, please contact us. We will arrange to have the product shipped to our facility. Please do not destroy the product. We will credit your account for product returned.

We are undertaking this action in cooperation with the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture. FSIS 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 Official Name and Title

MODEL PRESS RELEASE – FOREIGN OBJECT

[State] Company Recalls [Product] That May Contain Glass

[City], [Date]—[Company], a [City, State], establishment, is voluntarily recalling approximately [number of pounds] of [product] because the product may contain [hazardous material, e.g., glass]. Consumption could cause [lacerations].

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

Product was distributed [Listing of the states and areas where the product was **distributed and how it reached consumers (e.g., through retail stores, mail order, direct delivery)**].

Status of the number of and types of related illnesses that have been confirmed to date (e.g., “No illnesses have been reported to date”).

Brief explanation about what is known about the problems, such as how it was revealed, and what is known about its source. An example of such a description: “The recall was the result of the plant finding several pieces of glass on routine examination of the product. The company immediately contacted FSIS and has ceased distribution of the product as FSIS and the company continue their investigation as to what caused the problem.”

Because of the potential hazard, [name of company] urges consumers who have purchased these products not to eat them but to return them to the place of purchase.

Information on what consumers should do with the product and where they can get additional information (e.g., “Consumers who have purchased Brand X are urged not to eat the product but to return it to the place of purchase for a full refund).

Consumers with questions about the recall may contact [name and position or company division], at [phone number], or the consumer hotline at [toll free number]. Media with questions may contact [name and position] at [phone number].

MODEL PRESS RELEASE – ALLERGEN

[State] Company Recalls [Product] Because Of Undeclared Allergen

FOR IMMEDIATE RELEASE

DATE

COMPANY CONTACT AND PHONE NUMBER

FOOD CO. ISSUES ALLERGY ALERT ON UNDECLARED ALLERGEN IN PRODUCT

[Company Name] of [City, State] is recalling [Quantity and Type of Product], because it may contain undeclared [specific type of allergen, e.g., egg, milk, etc]. People who have an allergy or severe sensitivity to [specific type of allergen] run the risk of serious or life-threatening allergic reaction if they consume these products.

Specific information on how the product can be identified (e.g., the 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 (e.g., through retail stores, mail order, direct delivery)].

Status of the number of and types of related illnesses that have been confirmed to date (e.g., “The company has received two reports from consumers allergic to [specific allergen] of mild adverse reactions.”).

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 recall was initiated after it was discovered that product containing (the allergen) was distributed in packaging that did not reveal the presence of (the allergen).”

Information on what consumers should do with the product and where they can get additional information (e.g., “Consumers who have purchased Brand X are urged to return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX”).

MODEL PRESS RELEASE – *L. monocytogenes*

[State] Company Recalls [Product] For Possible *Listeria* Contamination

[City], [date]– [Company Name], a [city, state] company, is voluntarily recalling approximately [quantity] of ready-to-eat [product] that may be contaminated with *Listeria monocytogenes*.

Specific information on how to identify the product (e.g., the type of container [plastic/metal/glass], size or appearance of the product, product brand name, flavors, codes and expiration dates, etc.).

Product was distributed [Listing of the states and areas where the product was distributed and how it reached consumers (e.g., through retail stores, mail order, direct delivery)].

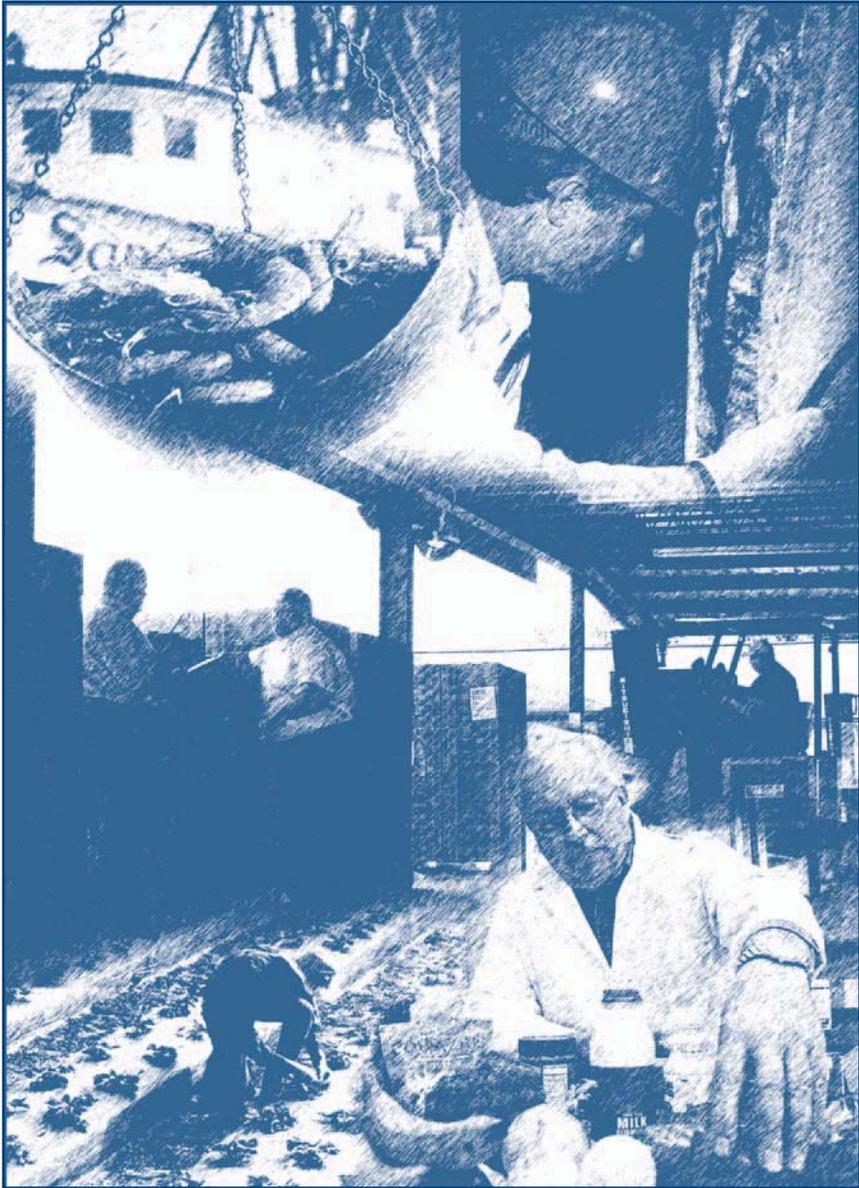
Description of illness: “Consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease. Healthy people rarely contract listeriosis. Listeriosis can cause high fever, severe headache, neck stiffness and nausea. Listeriosis can also cause miscarriages and stillbirths, as well as serious and sometimes fatal infections in those with weak immune systems – infants, the frail or elderly and persons with chronic disease, HIV infection or in chemotherapy.” Status of the number of and types of related illnesses that have been confirmed to date (e.g., “No illnesses have been reported to date. Anyone concerned about an illness should contact a physician.”).

Brief explanation about what is known about the problems, 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 FSIS microbiological testing.”

Information on what consumers should do with the product and where they can get additional information (e.g., “Consumers who have purchased Brand X 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].

Consumers with food safety questions can phone the toll-free USDA Meat and Poultry Hotline at 1-800-535-4555. The hotline is available in English and Spanish and can be reached from 10 a.m. to 4 p.m. (Eastern Time) Monday through Friday. Recorded food safety messages are available 24 hours a day.

LIST OF SOURCES



Section 13: List of Sources

The University of Florida Department of Food Science and Human Nutrition is extremely grateful to the following organizations and individuals for their generous suggestions and expertise, as well as the use of their texts, articles, documents and websites:

Association of Food and Drug Officials, York, PA. (www.afdo.org, 717-757-2888). In particular, three AFDO members worked to merge our original document with AFDO information to add the perspective of regulators:

Marion F. Aller, DVM, DABT, Division of Food Safety, State of Florida Department of Agriculture and Consumer Services, Tallahassee, FL.

John Lattimore, Assistant Director, Retail Foods Division, Texas Dept. of Health, Austin, TX.

The Bad Bug Book (Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, US Food and Drug Administration, 1992).

California Department of Health Services, Food and Drug Branch (“Interim Guidance for Food and Agriculture Safety and Security in California,” November 2001).

Canadian Food Inspection Agency, Office of Food Safety and Recall (www.inspection.gc.ca/English/).

Centers for Disease Control and Prevention, Division of Bacterial & Mycotic Diseases; and Foodborne & Diarrheal Diseases Branch.

Centers for Disease Control and Prevention website: www.cdc.gov

Center for Produce Quality, Alexandria, VA (“Avoiding the Alligators,” 1989).

Design and Equipment for Restaurants and Foodservice, by Costas Katsigris and Chris Thomas, John Wiley & Sons, New York, NY, 1999.

Florida Department of Agriculture and Consumer Services, Division of Food Safety, Bureau of Food and Meat Inspection.

Food Allergy & Anaphylaxis Network, Fairfax, VA. www.foodallergy.org

Food Crisis Management Manual, by James T. O’Reilly, Food and Drug Law Institute, 2002.

Food Marketing Institute, Washington, DC (“Product Tampering – Newsroom Advisory,” 2002).

Food Processing Magazine, Itasca, IL. www.foodprocessing.com

Food Quality Magazine, Carpe Diem Communications, Inc., Yardley, PA. www.foodquality.com

FoodTechSource.com (Internet food technology magazine)

Insurance Brokers Services, Inc., Chicago, IL.

International Risk Management Institute (“Are You Ready for Total Recall? – A Guide to Product Recalls and the Insurance that Covers Them,” November 2000), Dallas, TX. **www.irmi.com**

Law firm of Christie, Pabarue, Mortensen & Young, PC, Philadelphia, PA.

Law firm of Jenner & Block, LLC, Chicago, IL.

Law firm of MarlerClark, PC, Seattle, WA.

National Fisheries Institute (“A Guide for Product Recall Planning and Implementation,” December 1998), McLean, VA. **www.nfi.org**

National Food Processors Association, Washington, DC. **www.nfpa-food.org**

National Food Service Management Institute (“Responding to a Food Recall”), University of Mississippi, University, MS. **www.nfsmi.org**

New York State Department of Agriculture and Markets, Albany, NY.

Ohio State University (“Parasites and Parasitological Resources”), Columbus, OH.
www.biosci.ohio-state.edu

Mary Ann Platt, Executive Vice President, RQA, Inc., Darien, IL.

David Ransom, PhD, microbiologist and food scientist, Boise, ID.

ServSafe® Essentials, Third Edition. Compiled by the National Restaurant Association Educational Foundation, Chicago, IL, 2004. **www.nraef.org**

University of California at Davis (“Recalls – Are You Really Prepared?” September 2000), Davis, CA.

US Department of Agriculture Economic Research Service, and Food Safety and Inspection Service (Quarterly Regulatory and Enforcement Reports).

US Department of Agriculture website: **www.usda.gov**

US Food and Drug Administration, Center for Food Safety and Applied Nutrition (“FDA Recall Policies – Industry Affairs Staff Brochure,” June 2002).

US Food and Drug Administration (“Methods for Conducting Recall Effectiveness Checks,” June 1978), Washington, DC.

US Food and Drug Administration website: **www.fda.gov**

Western Association of Food and Drug Officials, Salem, OR.

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