

Food Recall Guidance for State and Local Agencies

This Food Recall Guidance for State and Local Agencies has been developed by the California Department of Public Health (CDPH), Food and Drug Branch (FDB), in collaboration with the California Conference of Directors of Environmental Health (CCDEH). The procedures contained in this Guidance document are designed to facilitate communication and improve the coordination between state and local health departments during food safety recalls.

The Food Recall Guidance for California State and Local Agencies provides recommendations in the following areas:

- Responsibilities of industry.
- Roles and responsibilities of state, federal, and local regulatory agencies.
- Procedures and mechanisms to disseminate recall information to local health departments.
- Potential response to recalls by local health departments.

Background

Contaminated or misbranded food products entering into the marketplace may result in serious illness, injury, or death. When contaminated or misbranded foods are identified, the food industry has primary responsibility for:

- 1) notifying regulatory agencies when recalls are initiated¹.
- 2) notifying consumers and down-stream clients,

¹ Pursuant to Health and Safety Code Section 110806, firms involved in USDA Class I or Class II meat and poultry recalls are required to notify CDPH. Firms involved in non-meat and poultry recalls are not legally obligated to notify authorities concerning recalls; however, regulatory agencies expect notification from responsible firms and progress reports when requested.

- 3) identifying and containing suspect product(s), and
- 4) adequately conducting recalls to ensure removal of suspect food(s) from the marketplace.

Regulatory agencies at the federal, state, and local level have the authority and public health responsibility to monitor product recalls to assure the recall is effective. CDPH and U.S. Food and Drug Administration (FDA) have oversight responsibility for recalls involving general food products (non-meat and non-poultry). CDPH and U.S. Department of Agriculture (USDA) oversee meat and poultry recalls. CDPH coordinates recall efforts affecting California industry and consumers with the appropriate federal agencies and serves as primary contact for local health departments.

Guidance concerning general food recalls, regulated by FDB and FDA may be obtained at [21 Code of Federal Regulations \(CFR\), Part 7](#) and [21 CFR and Part 107](#) (infant formula). Guidance for meat and poultry recalls may be obtained from [FSIS Directive 8080.1](#).

Food Safety Conditions Requiring Recalls

Food safety failures may occur at any point in the food supply continuum. These conditions can result from intentional acts, or from loss of control within the normal food processing environment. Conditions typically associated with recalls are listed below:

Table 1: Conditions That May Require Recalls of Food Products

Category	Description
Bacterial Pathogens	Unintentional introduction of pathogens during growth, harvest, processing, or storage. Pathogens can also grow to unacceptable levels in adequately processed products if the products are not properly maintained during distribution and retail storage.
Chemical Contaminants	Unintended contamination during food production
Drug Residues	Presence of unapproved drugs or concentrations of drugs in excess of tolerance levels
Problematic reports	Inaccurate reports of injury, illness or contamination
Foreign Objects	Unintended introduction of glass, metal, plastic, wood, etc.
Packaging Defects	Undetected defects in packaging such as faulty seams or leaks.
Pesticides	Use of improper pesticides or concentrations of pesticides in excess of tolerance levels
Misbranding	Untruthful or inaccurate declarations of ingredients, especially allergens.
Tampering/Bio-Terrorism	Intentional introduction of any contaminant designed to inflict injury, illness, psychological stress, or economic harm to the industry.

Product Removals in Response to Food Safety Failures

Recalls: The removal of marketed products that are in violation of federal/state law. Processors or distributors that do not take action to remove affected products from the marketplace may force regulatory agencies to initiate legal action to execute their removal.

Product / Market Withdrawal: The removal from the marketplace of products that fail to meet a company's quality standards or specifications. These products typically contain technical or minor violations of federal or state provisions.

Stock Recovery: The recovery of product that is under the direct control of the responsible firm and has not entered into commerce.

Recall Classifications

Industry has primary responsibility for conducting recalls. Regulatory agencies may assist by evaluating and classifying recalls based on the real or potential impact to public health. FDA and USDA generally classify recalls as Class I, II or III.

- Class I recalls involve a reasonable expectation that exposure to the product will cause serious adverse health consequences or death.
- Class II and Class III have less severe, temporary public health consequences.

Recent outbreaks have emphasized the importance of providing timely, accurate, and detailed information to the food industry, regulatory agencies, media, and consumers. The majority of

recalls are initiated by processors and distributors regulated by FDB. Therefore, effective communication must be established between the state and local health agencies to assure proper oversight of each recall. FDB intends to notify local health jurisdictions concerning product recalls with the most significant public health threat. However, notification may also be required during lower level threat events.

Roles and Responsibilities:

United States Food and Drug Administration (FDA): Responsible for recall activities involving general food (non-meat and poultry) products shipped in interstate commerce. Many of the activities conducted by FDA will be in concert with FDB. FDA may issue recall information independently to the state and media sources. FDB may elect to send the recall notice to local health agencies in the absence of or in addition to FDA notices.

United States Department of Food and Agriculture (USDA): Responsible for recall activities involving meat and poultry products shipped in interstate commerce. Many of the activities conducted by USDA will be in concert with FDB. USDA may issue recall information independently to the state and media sources. FDB may elect to send the recall notice to local health agencies in the absence of or in addition to USDA notices.

Food and Drug Branch (FDB) and federal agencies have principal oversight responsibilities over the manufacturers and distributors which are conducting recalls. FDB receives food recall notifications from multiple sources and is often the principal source of information for local health departments. Information received by FDB may include:

- sales and distribution within California

- nationwide sales and distribution, with likely distribution within California
- sales and distribution within a particular state or region, other than California
- little or no details regarding distribution and/or sale.

The information provided by FDB can assist local agencies in determining an appropriate response. FDB will endeavor to provide recall information in a timely manner and make available any additional information (e.g., recommended disposition of the product, need for product samples, etc.) not contained in the formal recall notice. However, there may be delays in transmitting recall information to local health departments because FDB has not received information from suppliers or from other regulatory agencies.

FDB activities may include:

- Coordinating recall activities statewide.
- Acting as primary contact between the FDA, USDA, the recalling firm, and local health departments
- Disseminating recall information to local health departments. FDB notifications to local programs will be confined to recalls in which affected products are known or reasonably expected to be distributed within California.
- Maintaining systems to notify Directors of Environmental Health and other identified environmental health program leads through fax and/or e-mail.
- Coordinating activities with CDPH's, Division of Communicable Disease Control (DCDC) and disease control labs to monitor illnesses/injuries and assure communications with local public health control programs.

- Releasing statewide consumer or industry recall notifications and posting recall information on the FDB webpage.
- Addressing statewide requests for information from consumers, local jurisdictions, or the media.
- Conducting inspections and/or investigations of processing and distribution facilities during recalls.
- Assuring that specific product information is communicated to local health departments (size, lot codes, amounts of product affected, distribution information, etc.) as it becomes available.
- Notifying local health departments when it is determined that the recalls are a result of tampering or terrorist events.
- Conducting recall effectiveness checks throughout the wholesale distribution chain.
- Reviewing and approving/rejecting reconditioning or destruction proposals.
- Conducting recall effectiveness checks at manufacturers, processors, and distributors.
- Compiling recall effectiveness checks from local jurisdictions, analyzing the results, recommending additional actions to industry and local jurisdictions when necessary, and forwarding information to federal agencies.
- Providing FDB contact information to local health departments.

California Department of Public Health

Food & Drug Branch

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Office of Emergency Services

(916) 262-1621.

<http://www.oes.ca.gov/>

Local Health Agencies (LHA): Responsible for engaging in follow-up activities that protect public health at retail food facilities within their jurisdictions. In addition, local health agencies will respond to inquiries from consumers, regulated facilities, and media within their jurisdiction. Response to media inquiries and issuance of press releases regarding recalls should be coordinated with the CDPH Office of Public Affairs when possible, to ensure a consistent message to consumers.

LHA activities may include:

- Developing and utilizing mechanisms to communicate recall information quickly to all retail food facilities within the local jurisdiction and/or to sub-categories of retail food facilities (ie. seafood restaurants).
- Coordinating activities with local disease control programs and laboratories
- Addressing information/media requests within the local jurisdiction and ensuring consistent messages with state and federal regulatory agencies, where possible,
- Conducting inspections and/or recall effectiveness checks at retail facilities as necessary to assure that food facilities have received the recall notification, removed the affected product from sale, and executed the recommended disposition of the product.

- Notifying FDB when recalls are deemed ineffective, and providing documentation of the checks completed.
- Impounding or overseeing the voluntary destruction of affected products within retail facilities.
- Issuing public and industry notifications within their jurisdiction, as necessary. This may include the development of press releases in non-English languages. FDB encourages the sharing of non-English language press releases and other consumer information with other jurisdictions to assist in the overall recall effort statewide. Local programs may wish to develop model press releases to facilitate the dissemination of information during a recall. Response to media inquiries and issuance of press releases regarding recalls should be coordinated with the CDPH Office of Public Affairs when possible, to ensure a consistent message to consumers.
- Communicating information about the effectiveness of recall efforts to FDB. Information obtained during the effectiveness checks should be documented using CDPH provided formats, so that FDB can compile and evaluate checks from multiple jurisdictions.
- Maintaining and updating, as necessary, a list of contact numbers, e-mail addresses, fax numbers, after hour's telephone numbers for retail food program managers and supervisors within local environmental health programs to assist FDB in the dissemination of information. Additionally, local jurisdictions should provide a single 24/7 duty officer/emergency contact number for their county. Local health departments are encouraged to notify FDB of any changes within their respective organizations.
- Providing notification to FDB when there is evidence that the food safety emergency may have resulted from a tampering/terrorist act.

Recall Notifications to Local Health Agencies (LHA)

FDB will provide recall notifications to LHAs. Notifications will be confined to those representing the most significant public health risk, generally classified by FDA or USDA as Class I.

Notification Processes

FDB will use an array of systems to assure adequate and timely notification to local health departments. Primary notification will be provided to the Directors of Environmental Health and other identified local program personnel via e-mail and fax and phone alerts. To assure that appropriate program leads receive the information, local jurisdictions are responsible for providing to FDB a current list of program staff who should receive these notifications.

E-mails will be transmitted through a distribution list obtained from the CCDEH website. FDB recommends that CCDEH: 1) notify FDB when changes occur within local health departments, and 2) maintain a current list of Environmental Health Directors and food program leads on the CCDEH webpage.

FDB also utilizes a "Message Blaster" system for immediate and widespread notification of information to regulatory agencies, industry, and the public. The messages are transmitted through multiple electronic formats (including fax, phone, e-mail, and pager). Subscription to the "Message Blaster" is free of charge and can be accessed at the following web address: <http://www.envoyprofiles.com/CDOHS/>. FDB strongly encourages local agencies to establish similar electronic notification systems within their jurisdictions for all licensed facilities.

Recall Effectiveness Checks

Recalling firms are required to conduct effectiveness checks to assure that all consignees have been contacted concerning the recall and that appropriate action has been taken to remove affected products from commerce. Regulatory agencies may also conduct evaluations to assure that the recall has been effective; however, electronic communications through phone, e-mail, or fax may be utilized in lieu of on-site inspection where appropriate. FDB is providing a model "Product Recall Effectiveness" (See Page 14) verification form that can be sent to businesses by fax or used by staff when conducting telephone contacts.

The decision to conduct recall effectiveness checks is influenced by a number of factors, including; the severity of health risk (e.g. recall classification), amount of product in commerce, extent of distribution, and level of consumer or industry awareness of the recall. For recalls classified as Class I, FDA and FDB recommend 100% of food establishments be contacted to assure receipt of recall information and compliance with recall directives. However, FDB recognizes that circumstances will arise that will restrict agencies from conducting effectiveness checks at all facilities. Moreover, distribution data may be incomplete or delayed. Under these circumstances, local health agencies are urged to assess the level of risk associated with an ineffective recall and initiate appropriate follow-up activities as deemed appropriate.

When the number of affected firms is prohibitively large, statistical sampling may be used in determining whether the recall is effective. Table 2 provides guidance on the minimum number of firms to contact for recalls of varying sizes. For example, in a Class I recall in which

250 consignees have been identified as receiving the affected product, a minimum of 132 firms should be randomly selected and contacted. If all 132 firms confirm they have been contacted about the recall, we may conclude that the recall was effective with a 95% statistical confidence level (\pm 5% margin of error). When a local jurisdiction determines that a recall is not effective, FDB requests prompt notification.

Table 2:

Number of Firms Necessary to Assure a Reliable Estimate of Recall Effectiveness *	
Number of Affected Firms	Minimum Number of Firms to Contact at Projected Recall
<13	100%
13-19	13
20-39	19
40-59	36
60-79	52
80-99	66
100-199	79
200-299	132
300-399	168
400-499	196
500-599	217
600-699	234
700-799	248
800-899	259
900-999	269
1,000-1,999	277
* 95% Confidence Interval, 5% Margin of Error	

Recall Effectiveness Reports:

FDB may also request local health agencies to provide summary information on the effectiveness of recalls. This may include verbal reports or written documentation, which summarize the findings of recall effectiveness within the local jurisdiction.

Recall Coordinator

California Department of Public Health

(916) 650-6650, or

(916) 650-6651

PRODUCT RECALL EFFECTIVENESS

Retailer Information:

Date: _____

Name: _____

Address: _____

City/Zip _____

Phone/e-mail: _____

Product Description:

Product: _____ Manufacturer: _____

Brand: _____ Product Code: _____

Date Code: _____ UPC Code: _____

Container Size: _____ Shipping Dates: _____

1) Did you receive any of the recalled product codes or during the identified shipping dates?

Yes: _____ No: _____ (Please sign and return form)

2) Did you receive notification from your supplier concerning the referenced recall?

Yes: _____ No: _____

3) Do you have any of the recalled product in inventory?

Yes: _____ No: _____ (Please skip to question 4)

a. How much product is being held? _____

b. What do you intend to do with the detained product?

4) Have you received any illness or complaints concerning the recalled product?

Yes: _____ No: _____

a. What was the nature of the complaint? _____

b. In case of illness, was the complainant referred to the local health department?

Yes: _____ No: _____

Company Representative

Signature

Title

Date

Please fax form to: (XXX) YYY-ZZZ