

Food Recalls: Essentials for Action



Presentation Materials

California Department of Public Health
Food and Drug Branch
Industry Education and Training Unit

Phone – (916) 650 – 6500

Email – FDBtraining@cdph.ca.gov

Resource 1

Sample Recall Plan

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Yummy Yuckies

URGENT FOOD RECALL

**ABC Company, Inc.
California, CA
1-800-123-4567**

Date: Today

National Recall of Nature's Nest Brand, "Yummy Yuckies"

ABC Co., of California, CA, is recalling 6 ounce containers of Nature's Nest Brand, "Yummy Yuckies" cereal because they may have been contaminated with *Salmonella*. *Salmonella* can cause serious illness in individuals if consumed. ABC Co. requests that you immediately cease all sales and distribution and segregate the affected product.

No illnesses have been reported in connection with this product and no other Nature's Nest products are affected by the recall.

Yuckies are sold 12 – 6 oz boxes per case, labeled under the "Yummy Yuckies" brand and identified with the code "YUCK123" that is printed in black letters on the top of the case. The affected product was manufactured and distributed from May through August, 2013.

We request that you notify your customers and provide them with this notice if they have received this product or any product processed by your firm that contains the affected Yuckies as an ingredient. Direct your accounts to retrieve the product and return to your facility. The ABC Co. will arrange for shipping to our plant in California, CA.

ABC Co. has notified the appropriate federal and state health authorities about the recall. These agencies may be contacting you to confirm that you have received this notice and are complying with our requests. Your firm's records (regarding the receipt and distribution of the products) will likely be requested.

Your prompt attention to this recall will assist ABC Co. in removing the product from the marketplace. If you have any questions or concerns, please contact our recall coordinator, John Smith, at 1-800-123-4567.

Thank you for your cooperation,

**Sincerely,
Company President**

Yummy Yuckies

FOR IMMEDIATE RELEASE:

**ABC Company, Inc.
California, CA
1-800-123-4567**

Date: Today

ABC Co., Announces National Recall of Nature's Nest Brand, "Yummy Yuckies" Because of Possible Health Risks

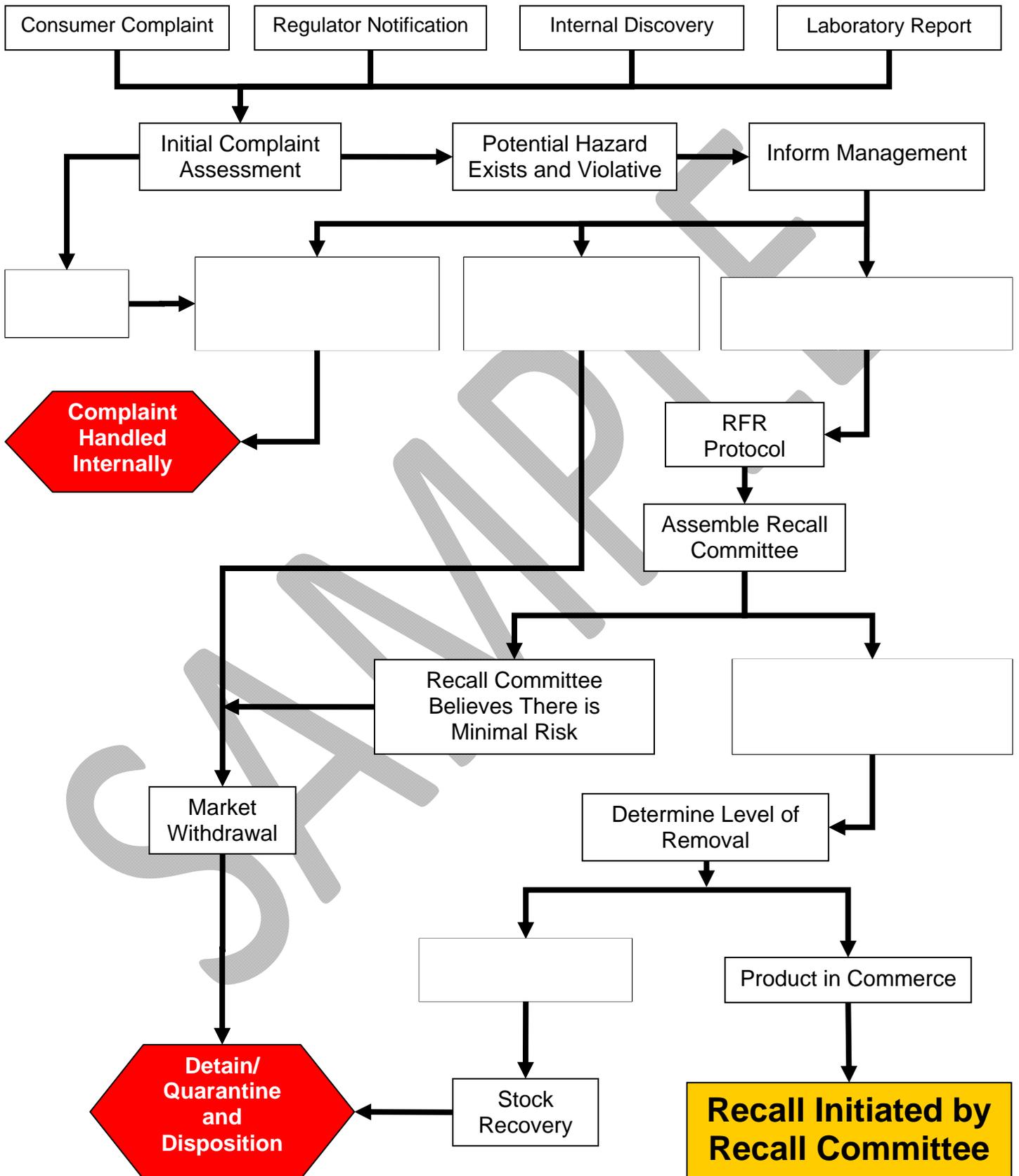
Consumers are advised not to consume 6 ounce containers of Nature's Nest Brand, "Yummy Yuckies" cereal because it has the potential to be contaminated with *Salmonella*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened 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.

Nature's Nest Brand "Yummy Yuckies" are sold in white boxes with the name "Yummy Yuckies" printed in black letters. The 6 oz. boxes have our trademark "Yuckies Yodeler" on the front panel, there is also a blue star with the words "Free toy inside" printed in yellow letters. The top of the boxes have the code "YUCK123" printed in black letters. No illnesses have been reported to date in connection with this product.

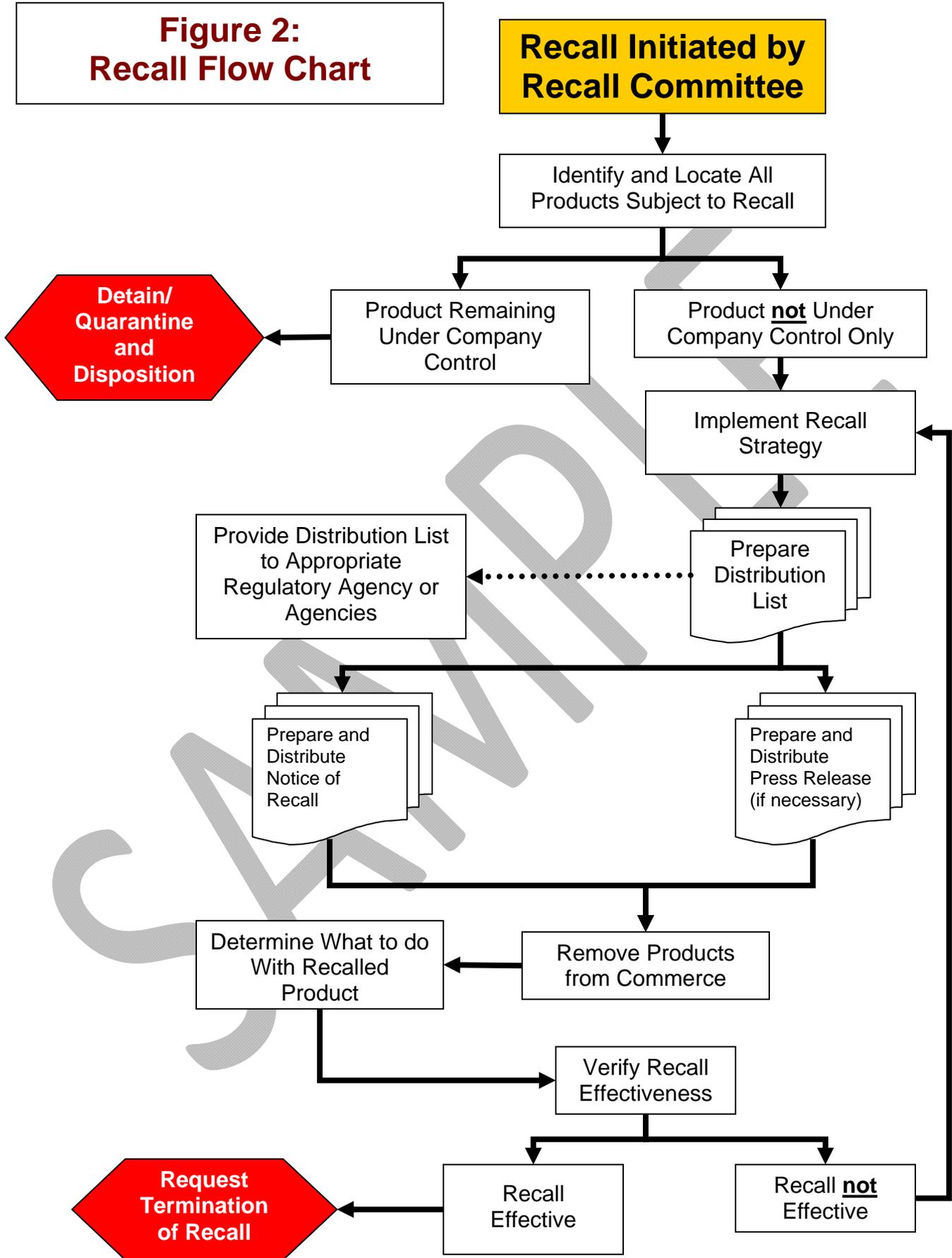
The product was distributed to retailers in CA, AZ, NV and OR, and may have been sold through the internet.

Consumers who have purchased the affected Nature's Nest Brand Yuckies are urged to return them to the place of purchase for refund or dispose of them. The ABC, Co. can be contacted at 1-800-123-4567.

Figure 1: Complaint/Condition Evaluation Flow Chart



**Figure 2:
Recall Flow Chart**



Appendix C – Additional Resources

1. California Food and Drug Branch – Industry Education and Training Unit
<https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/FoodIndustryTraining.aspx>
2. Termination of a recall – 21 CFR Sec. 7.55
https://www.ecfr.gov/cgi-bin/text-idx?SID=dcf3c54c27244b08cfcb031632caeb52&mc=true&node=se21.1.7_155&rqn=div8
3. Industry Guidance: Information on Recalls of FDA Regulated Products
<http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm>
4. Recall policy – Title 21, CFR Recall Regulations Sec. 7.40
<https://www.ecfr.gov/cgi-bin/text-idx?SID=49e51ce57dd0ee8a873d8a236a3856e9&mc=true&node=sp21.1.7.c&rqn=div6>
5. California Food and Drug Branch
<https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FoodandDrugBranch.aspx>
6. US Food and Drug Administration
<http://www.fda.gov/>
7. USDA (FSIS)
<http://www.fsis.usda.gov/wps/portal/fsis/home>
8. Center for Disease Control
<http://www.cdc.gov/>
9. FDA District Recall Coordinators
<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>
10. FDA Guidance: Action levels for Poisonous or Deleterious Substances in Human and Animal Feed
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/chemicalcontaminantsmetalsnaturaltoxinspesticides/ucm077969.htm>
11. FDA Defect Levels Handbook
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/sanitationtransportation/ucm056174.htm>

Resource 2



What Are My Responsibilities During A Food Recall?

A food recall is the removal of an adulterated or misbranded product from commerce. A food recall is undertaken voluntarily by the manufacturer or distributor of a product; however, once a recall has been initiated every firm that has received or distributed the affected product must take action. The California Department of Public Health - Food and Drug Branch (CDPH-FDB) recommends firms prepare in advance for a food recall by developing and implementing a formal Recall Plan. You can access a sample “Food Recall Plan” template at: [Sample Recall Plan](http://www.cdph.ca.gov/pubsforms/Documents/fdbRlgde23.pdf) (<http://www.cdph.ca.gov/pubsforms/Documents/fdbRlgde23.pdf>)

If your firm does not currently have a Recall Plan, it is recommended that you take the following actions identified below, at a minimum to assure the efficient and effective removal of the recalled product from commerce:

If your company is the recalling firm:

1. Identify, isolate and stop selling the affected product(s). You must consider all products that could be involved in the event. For instance, if a problem is found in a single lot of product, are you reasonably assured other lots are not affected?
2. Prepare a Press Release and send it to the Associated Press or other appropriate media agency. If needed, firms may request CDPH-FDB’s assistance with drafting a Recall Notice and/or Press Release. CDPH- FDB requests a review of your draft Recall Notice and/or Press Release before they are issued.
3. Within 24 hours, develop a Recall Notice to inform all customers who received the recalled product. Your customers must be advised of the reason for the recall and the specific product(s) affected. Instruct your customers to isolate and stop selling the product and to notify all their customers who have received the recalled product. The Recall Notice should include a method to contact you to confirm that the Recall Notice was received and appropriate actions taken.
4. Conduct a “root cause analysis” to investigate the cause of the recall and initiate steps to prevent further recurrence of the problem. You may be required to submit a safety report to the Federal Food and Drug Administration (FDA) at:
<http://www.fda.gov/Food/ComplianceEnforcement/RFR/UCM2019388.htm>
 - Infant formula and dietary supplements are excluded from the requirements of the Reportable Food Registry (RFR). Firms recalling formulas and supplements should seek additional information regarding FDA’s requirements for reporting any serious adverse events from FDA’s website at: www.fda.gov.



State of California – Health and Human Services Agency
California Department of Public Health



5. Prepare a Customer Distribution List (e.g., Excel or other database) that identifies all customers to whom your firm shipped the recalled product. CDPH-FDB recommends that a distribution list be prepared within four hours after the recall has been initiated. A template may be obtained at: fdberu@cdph.ca.gov or call (916) 650-6500 and ask for the Food Recall Team.
6. Return the completed “Customer Distribution List” template to CDPH–FDB at fdberu@cdph.ca.gov or fax to (916) 650-6650. The list must include the following information:
 - Type of customer (Distributor, Manufacturer, Wholesaler, Retailer, Retail Distribution Center, Food Service etc.)
 - Customer name
 - Customer street address, city, state, zip code, telephone and fax numbers, contact person’s name and email address
 - Date and quantity shipped
 - Brand Names, Lot Codes and/or UPC Codes
7. Efforts should be taken to reconcile production and/or distribution amounts with products returned. This information will be included in your reports to CDPH-FDB.
8. As the recalling firm you have the responsibility to assure the effectiveness of the recall by monitoring responses from all customers who have received the recall notice.
9. Contact CDPH-FDB concerning requests for product disposition. Requests may include: destruction, reconditioning or redirection to non-food usage.
10. Contact CDPH-FDB to discuss formal termination of the recall.
11. For additional information including sample Press Releases and Customer Distribution Lists, refer to CDPH-FDB at: (<http://www.cdph.ca.gov/services/Pages/fdbRlgde07.aspx>)

For your convenience, a reference sign has been included on the last page of this memo. Please post the document in a visible location for reference during a food recall.



If your firm received a recalled product from a supplier:

- Identify, isolate and stop selling the affected product (s).
- You may be required to submit a safety report to the Federal Food and Drug Administration (FDA) at: <http://www.fda.gov/Food/ComplianceEnforcement/RFR/UCM2019388.htm>

Infant formula and dietary supplements are excluded from the requirements of the Reportable Food Registry (RFR). Firms recalling formulas and supplements should seek additional information regarding FDA's requirements for reporting any serious adverse events from FDA's website at: www.fda.gov.

3. Notify your customers of the recall as soon as possible, but within 24 hours upon notification from the recalling firm.
4. Prepare a "Customer Distribution List" (e.g., Excel or other database) that includes all customers to whom your firm shipped the recalled product. CDPH-FDB recommends that a distribution list be prepared within four hours upon notification from the recalling firm. A template can be obtained at: fdberu@cdph.ca.gov or call (916) 650-6500 and for the Food Recall Team. The list must also include the following information:
 - Type of customer (Distributor, Manufacturer, Wholesaler, Retailer, Retail Distribution Center, Food Service etc.)
 - Customer name
 - Customer street address, city, state, zip code, telephone and fax numbers, contact person's name and email address
 - Date and quantity shipped
 - Brand Names, Lot Codes and/or UPC Codes
5. Return the completed "Customer Distribution List" template to CDPH-FDB at: fdberu@cdph.ca.gov or fax to (916) 650-6650.
6. All firms involved in a recall have the responsibility to assure the effectiveness of the recall by monitoring responses from all customers who have received the recall notice.
7. Efforts should be taken to reconcile production and/or distribution amounts with products returned. This information will be included in your reports to CDPH-FDB.
8. Contact your supplier for disposition instructions.
9. Contact CDPH-FDB to discuss formal termination of the recall.
10. For additional information, refer to CDPH-FDB at: <http://www.cdph.ca.gov/services/Pages/fdbRlgde07.aspx>

For your convenience, a reference sign has been included on the next page of this memo. Please post the document in a visible location for reference during a food recall.



What Are My Responsibilities During A Food Recall?

1. Identify, isolate and stop selling the affected product(s).
2. Refer to your firm's Recall Plan.
3. Notify your customers about the recall as soon as possible, but within 24 hours upon notification.
4. Prepare a Distribution List (e.g., Excel or other database) that includes all customers to whom your firm shipped the recalled product. CDPH-FDB recommends that a distribution list be prepared within four hours after a firm has initiated a recall or is notified of a recall. A template can be obtained at: fdberu@cdph.ca.gov or call (916) 650-6500 and ask for the Food Recall Team.
5. Return the completed "Customer Distribution List" template to CDPH-FDB at fdberu@cdph.ca.gov or fax to (916) 650-6650.
6. You may be required to submit a safety report to the Federal Food and Drug Administration (FDA) at: [FDA Reportable Food Registry](http://www.fda.gov/Food/ComplianceEnforcement/RFR/UCM2019388.htm) (<http://www.fda.gov/Food/ComplianceEnforcement/RFR/UCM2019388.htm>) for more information. Infant formula and dietary supplements are excluded from the requirements of the Reportable Food Registry. Firms recalling formula or supplements should seek additional information regarding FDA's requirements for reporting any serious adverse events from FDA's website at: www.fda.gov.
7. Assure the effectiveness of the recall by monitoring responses from all customers who have received the recall notice.
8. Efforts should be taken to reconcile production and/or distribution amounts with products returned. This information will be included in your reports to CDPH-FDB.
9. Contact CDPH-FDB concerning requests for product disposition. Requests may include: destruction, reconditioning or redirection to non-food usage.
10. Contact your supplier for disposition instructions.
11. Contact CDPH-FDB to discuss formal termination of the recall.
12. For additional information, refer to the CDPH –FDB [Food Recall Resources](http://www.cdph.ca.gov/services/Pages/fdbRlgde07.aspx) (<http://www.cdph.ca.gov/services/Pages/fdbRlgde07.aspx>)

Resource 3

FDA 101: Product Recalls

From First Alert to Effectiveness Checks



First Alert

FDA hears about product problems through company notification, agency inspections and adverse event reports, and through CDC.

Alerting the Public

FDA posts regular updates about recalls to its Web site, and all recalls appear in the agency's weekly Enforcement Reports.

Effectiveness Checks

FDA reviews all of a company's corrective actions to determine when a recall is complete.

Once a product is in widespread use, unforeseen problems can sometimes lead to a recall. Contaminated spinach, for example, led to the recent recall of spinach products under multiple brand names. Contaminated peanut butter led to the recall of thousands of jars of two popular brands. In both cases, FDA responded immediately to minimize harm.

When an FDA-regulated product is either defective or potentially harmful, recalling that product—removing it from the market or correcting the problem—is the most effective means for protecting the public.

Recalls are almost always voluntary. Sometimes a company discov-

ers a problem and recalls a product on its own. Other times a company recalls a product after FDA raises concerns. Only in rare cases will FDA request a recall. But in every case, FDA's role is to oversee a company's strategy and assess the adequacy of the recall.

First Alert

FDA first hears about a problem product in several ways:

- A company discovers a problem and contacts FDA.
- FDA inspects a manufacturing facility and determines the potential for a recall.
- FDA receives reports of health problems through various reporting systems.
- The Centers for Disease Control and Prevention (CDC) contacts FDA.

When it comes to illnesses associated with food products, Dorothy J. Miller, Director of FDA's Office of

RECALL CLASSIFICATIONS These guidelines categorize all recalls into one of three classes, according to the level of hazard involved:



- Class I** Dangerous or defective products that predictably could cause serious health problems or death. Examples include: food found to contain botulinum toxin, food with undeclared allergens, a label mix-up on a lifesaving drug, or a defective artificial heart valve.
- Class II** Products that might cause a temporary health problem, or pose only a slight threat of a serious nature. Example: a drug that is under-strength but that is not used to treat life-threatening situations.
- Class III** Products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws. Examples include: a minor container defect and lack of English labeling in a retail food.

Emergency Operations, says that FDA generally first hears of these kinds of problems from CDC.

“CDC hears about such problems from state health departments that have received and submitted illness reports,” she says. “An ongoing outbreak means that we have an emergency, and when there’s a public health crisis like this, you need to tell the public immediately.”

Alerting the Public

FDA seeks publicity about a recall only when it believes the public needs to be alerted to a serious hazard. When a recalled product has been widely distributed, the news media is a very effective way to reach large numbers of people. FDA can hold press conferences, issue press releases, and post updates to its Web site regularly, to alert people.

“It’s about being as transparent as possible,” says Catherine McDermott, public affairs manager in the Division of Federal-State Relations in FDA’s Office of Regulatory Affairs. “If we feel there is that much of a health risk, we will offer media updates

FDA-regulated Products Subject to Recall

- *human drugs*
- *animal drugs*
- *medical devices*
- *radiation-emitting products*
- *vaccines*
- *blood and blood products*
- *transplantable human tissue*
- *animal feed*
- *cosmetics*
- *about 80 percent of the foods eaten in the United States*

every day to give new information, and all that we know gets posted to FDA’s Web site.”

Not all recalls are announced in the media. But all recalls go into FDA’s weekly Enforcement Report. This

document lists each recall according to classification (see “Recall Classifications” box), with the specific action taken by the recalling firm.

Effectiveness Checks

FDA evaluates whether all reasonable efforts have been made to remove or correct a product. A recall is considered complete after all of the company’s corrective actions are reviewed by FDA and deemed appropriate. After a recall is completed, FDA makes sure that the product is destroyed or suitably reconditioned, and investigates why the product was defective in the first place. [FDA](#)

Find this and other Consumer Updates at www.fda.gov/ForConsumers/ConsumerUpdates

Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumernews.html

Resource 4

<http://www.fda.gov/ReportableFoodRegistry>

Reportable Food Registry (RFR): At A Glance

- ▶ The RFR was established by section 1005 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-085) to provide a reliable mechanism to track patterns of adulteration in food in order to support efforts by FDA to target limited inspection resources to protect the public health.
- ▶ The RFR covers all foods regulated by FDA except infant formula and dietary supplements.
- ▶ The RFR requires a responsible party to file a report through the RFR electronic portal when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. Such foods are "Reportable Foods."
- ▶ "Responsible party" is defined as the person who submits the registration information to FDA for a food facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States. Federal, state, and local public health officials may also use the portal to voluntarily report information that may come to them about reportable foods.
- ▶ As of May 24, 2010, The RFR electronic portal became part of the Department of Human Services' Safety Reporting Portal. The entire set of data elements can be accessed at www.safetyreporting.hhs.gov.

Responsible parties:

- Must report as soon as practicable, but in no case later than 24 hours after a responsible party determines that an article of food is a reportable food
- Must submit certain data elements in the initial report
- Must investigate the root cause of the adulteration if the reportable food originated with the responsible party
- Will be issued a unique number after report submission, called the Individual Case Safety Report (ICSR) number, that identifies the report and allows FDA to properly link associated reportable food reports in the Registry
- May be required to provide notification to immediate previous sources (suppliers) and immediate subsequent recipients (customers) of the reportable food and share information including the ICSR number, after consultation with FDA
- Must provide amended reports as necessary- for example, FDA understands that it may take more than 24 hours to perform investigation activities and obtain information such as the results of any investigation of the root cause of the adulteration (when applicable) and the disposition of the reportable food
- Must consult with FDA to follow up as necessary
- Must maintain records related to each report received, notification made, and report submitted to FDA for 2 years

- ▶ Failure to report a reportable food is a prohibited act under the Federal Food, Drug, and Cosmetic Act.
- ▶ A responsible party is not required to submit a reportable food report if ALL of the following three conditions are met:
 1. The adulteration originated with the responsible party; AND
 2. The responsible party detected the adulteration prior to any transfer to another person of the article of food; AND
 3. The responsible party corrected the adulteration or destroyed or caused the destruction of the article of food.
- ▶ Data elements that a responsible party may include in initial and follow-up RFR reports to FDA:
 - Food Facility Registration Number
 - Date the article of food was determined to be reportable
 - Description of the food, including quantity and amount
 - Extent and nature of the adulteration
 - Results of investigation of the root cause of the adulteration if it may have originated with the responsible party, when known
 - Disposition of the article of food, when known
 - Product information typically found on packaging sufficient to identify the article of food
 - Contact information for the immediate previous sources (suppliers) and/or immediate subsequent recipients (customers) of the article of food, when required by FDA
- ▶ A record in the RFR is subject to Freedom of Information Act (FOIA) rules, with appropriate redactions to protect proprietary information and the reporting facility's Food Facility Registration Number.
- ▶ RFR submissions will not be viewable by any other submitters.

Contact FDA about the RFR

The **RFR Center** answers questions about Reportable Food Registry policies, procedures and interpretations. Email questions to:

RFRSupport@fda.hhs.gov

The **SRP Service Desk** for technical and computer-related questions about about the Reportable Food Registry electronic portal Email questions to:

Support.srp@jbsinternational.com



For additional information, please visit FDA's RFR homepage:
www.fda.gov/ReportableFoodRegistry

Resource 5



Key Facts about Preventive Controls for Human Food

Preventive controls are steps that you, a domestic or foreign food facility, must take to reduce or eliminate food safety hazards. The rule on Preventive Controls for Human Food is mandated by the 2011 FDA Food Safety Modernization Act. The rule also incorporates the Current Good Manufacturing Practice (CGMP) requirements, which have been updated.

- **DO THE REQUIREMENTS FOR PREVENTIVE CONTROLS FOR HUMAN FOOD APPLY TO ME?**
- **DO THE REQUIREMENTS FOR CURRENT GOOD MANUFACTURING PRACTICES (CGMPs) APPLY TO ME?**
- **WHEN DO I HAVE TO BE IN COMPLIANCE WITH THE RULE?**
- **WHAT CURRENT GOOD MANUFACTURING PRACTICES WERE UPDATED UNDER THIS RULE?**
- **WHAT ARE THE REQUIREMENTS REGARDING FOOD SAFETY PLANS?**
- **WHAT DO I DO IF A HAZARD COULD FIT UNDER DIFFERENT PREVENTIVE CONTROLS?**
- **WHAT IS THE FOOD SAFETY PLAN BUILDER? HOW DO I USE IT?**
- **ARE THERE ANY OTHER RESOURCES TO HELP ME FOLLOW THIS RULE?**

■ **DO THE REQUIREMENTS FOR PREVENTIVE CONTROLS FOR HUMAN FOOD APPLY TO ME?**

In general, the requirements apply to you if you manufacture, process, pack, or hold human food for consumption in the United States, whether your facility is domestic or foreign. The requirements apply to you if you are required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic (FD&C) Act. Entities defined as “farms,” retail food establishments, and restaurants are some of the entities that are not subject to the preventive control requirements because they are not required to register. In addition, there are several exemptions or modified requirements that may apply.

■ **DO THE REQUIREMENTS FOR CURRENT GOOD MANUFACTURING PRACTICES (CGMPs) APPLY TO ME?**

In general, the requirements apply to you if you manufacture, process, pack or hold human food. As with the preventive controls requirements, there are exemptions and modified requirements, but they are not identical.

■ **WHEN DO I HAVE TO BE IN COMPLIANCE WITH THE RULE?**

September 18, 2017: Small businesses (businesses with fewer than 500 full-time equivalent employees)

September 17, 2018: Very small businesses (averaging less than \$1 million per year (adjusted for inflation) in annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale)

September 17, 2018: Facilities subject to the Pasteurized Milk Ordinance (PMO) (for their Grade “A” milk and milk products); compliance date was extended to allow time for changes to the PMO to incorporate the requirements of this preventive controls rule)

* *All other businesses (also known as “large” businesses) were required to be in compliance on September 19, 2016. Note that compliance dates for some facilities and activities have been extended.*

SEE ALL FSMA COMPLIANCE DATES
<https://www.fda.gov/food/guidanceregulation/fsma/ucm540944.htm>

■ WHAT CURRENT GOOD MANUFACTURING PRACTICES (CGMPs) WERE UPDATED UNDER THIS RULE?

Now you are required to be in compliance with some provisions that were optional before.

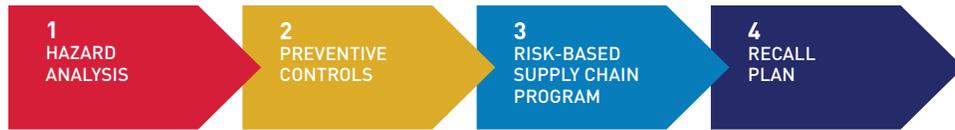
- **Training:** Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties. The employees must be trained in the principles of food hygiene and food safety, including the importance of employee health and hygiene as appropriate to the food, the facility, and the individual's assigned duties. Records of training must be maintained.
- **Allergen cross-contact:** FDA's longstanding position that CGMPs address allergen cross-contact is now explicit in the regulatory text. You are required to employ practices and procedures to control allergen cross-contact.
- **Human food by-products used for animal foods:** The updated CGMPs contain provisions for holding and distributing human food by-products that are used for animal food.

Human Food By-Products for Use as Animal Food (Guidance for Industry - Draft)

<https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdf>
<https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdf>

■ WHAT ARE THE REQUIREMENTS REGARDING FOOD SAFETY PLANS?

You, a domestic or foreign food facility, must (1) have and implement a written food safety plan that identifies food safety hazards that require a preventive control and (2) implement preventive controls to significantly minimize or prevent the hazard. The plan is required to include the following:



1 HAZARD ANALYSIS: You are required to identify any known or reasonably foreseeable (i.e., potential) biological, chemical, and physical hazards, and determine if any of those hazards require a preventive control.

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

<https://www.federalregister.gov/documents/2015/09/17/2015-21920/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human>

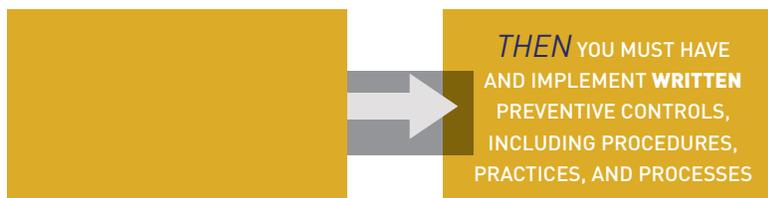
Hazard Analysis and Risk-Based Preventive Controls for Human Food

<https://www.federalregister.gov/documents/2017/08/31/2017-18464/hazard-analysis-and-risk-based-preventive-controls-for-human-food-guidance-for-industry-availability>

Hazard analysis and risk-based preventive controls for human food [Draft Guidance for Industry]

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517394.pdf><https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517394.pdf>

2 PREVENTIVE CONTROLS: If the hazard analysis identifies a hazard that requires a preventive control, you are required to develop and implement a control to significantly minimize or prevent the hazard.



The rule outlines preventive controls and associated requirements that could include:

- process controls
- food allergen controls
- sanitation controls
- other controls

- **Process controls:** procedures, practices, and processes to control parameters during operations. Examples of process controls are cooking and refrigeration, and product formulation.
 - Associated requirements for process controls include, as appropriate, parameters (and minimum or maximum values) associated with the control of the hazard, monitoring, corrective actions, verification including validation as necessary, records
- **Food allergen controls:** procedures, practices, and processes to control allergen cross-contact within a facility and procedures to ensure all food allergens are correctly labeled.
 - Associated requirements for food allergen controls include, as appropriate, monitoring, corrective actions, verification, and records
- **Sanitation Controls:** procedures, practices, and processes to make sure the facility is maintained in a sanitary manner to control hazards such as environmental pathogens. Environmental monitoring is required if contamination of a ready-to-eat food with an environmental pathogen such as *Listeria monocytogenes* is a hazard requiring a preventive control.
 - Associated requirements for sanitation controls include, as appropriate, monitoring, corrective actions, verification (including environmental monitoring for an environmental pathogen or appropriate indicator organism as necessary), and records

See Control of *Listeria monocytogenes* in Ready-to-Eat Foods (Draft Guidance for Industry)

<https://www.fda.gov/RegulatoryInformation/Guidances/ucm073110.htm>

- **Other Controls:** preventive control procedures that are not process, food allergen, or sanitation controls, but are necessary to ensure that a hazard requiring a preventive control will be significantly minimized or prevented.
 - Associated requirements for other controls include, as appropriate, monitoring, corrective actions, verification, and records

Explaining the Oversight and Management of Preventive

Controls: Once a facility has identified a preventive control for a hazard, the facility must make sure that the controls are being met using the following actions:

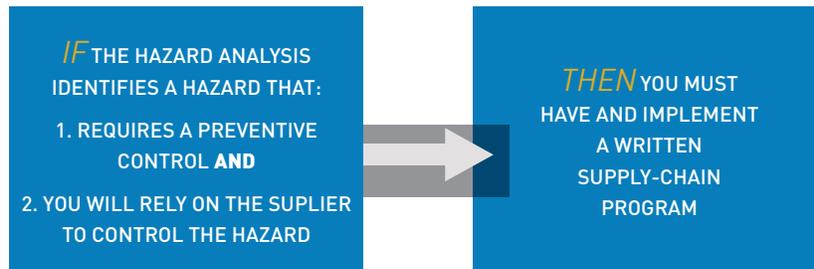
- **MONITORING:** These procedures are designed to provide assurance that preventive controls are consistently performed. Monitoring is conducted as appropriate to the preventive control. For example, monitoring of a heat process to kill pathogens would include recording temperature values. Monitoring must be documented.
- **CORRECTIONS:** These are steps taken, in a timely manner, to identify and correct a minor, isolated problem that occurs during food production.

(continued)

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- **CORRECTIVE ACTIONS:** These include actions to identify and correct a problem implementing a preventive control, reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent that food from entering commerce if you cannot ensure that the affected food is not adulterated. Corrective actions must be documented with records.
- **VERIFICATION:** These activities are required to ensure that preventive controls are consistently implemented and effective in minimizing hazards. Examples of verification activities include scientifically validating process preventive controls to ensure that the control measure is capable of effectively controlling an identified hazard and calibrating (or checking the accuracy of) process monitoring and verification instruments such as thermometers. Verification activities also include reviewing records to ensure that monitoring and corrective actions (if necessary) are being conducted. Verification activities must be documented.
- Product testing and environmental monitoring are also possible verification activities, required as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility's food safety system. Environmental monitoring is required if the contamination of a ready-to-eat food with an environmental pathogen is a hazard the facility identified as requiring a preventive control.

3 Risk-Based Supply Chain Program: If you are a manufacturer and identify a hazard related to ingredients you receive from a supplier and will depend on the supplier to control that hazard, you must have and implement a supply-chain program with appropriate verification activities.



Supply chain program must include:

- Using approved suppliers
- Determining appropriate supplier verification activities and frequency of those activities. They may include:
 - On-site audit
 - Sampling and testing of raw material
 - Review of suppliers' relevant food safety records
 - Other appropriate verification activities
- Conducting supplier verification activities
- Documenting supplier verification activities

When do I NOT need a supply-chain program?

- If you control the hazard at your own facility OR
- If the hazard will be controlled by a subsequent entity (such as another processor). Certain requirements are specific to this situation.

4 Recall Plan: If the hazard analysis identifies a hazard that requires a preventive control, you must have a written recall plan that includes the procedures that describe the steps to perform the recall and at minimum assigns responsibility for:

- Notifying the direct consignees of the food being recalled, including how to return or dispose of the affected food;
- Notifying the public about hazards in the food;
- Conducting effectiveness checks; and
- Appropriately disposing of the recalled product.

■ WHAT IS THE FOOD SAFETY PLAN BUILDER? HOW DO I USE IT?

The Food Safety Plan Builder is a software program that can help you develop a customized food safety plan for your facility. The program can be downloaded for free.

■ Food Safety Plan Builder Resources:

Download the **Food Safety Plan Builder**

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm>

Read the **User Guide**

https://www.accessdata.fda.gov/scripts/foodSafetyPlanBuilder/FoodSafetyPlanBuilderUserGuide_v1.0.pdf

How to use the Food Safety Plan Builder (**videos**)

<https://www.youtube.com/playlist?list=PLEy4Qe-Uxcxb9AGNwFj-oGIquHDZ-tkqo>

■ ARE THERE ANY OTHER RESOURCES TO HELP ME FOLLOW THIS RULE?

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

You can also use the **FSMA TAN Popular Topics**

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM551983.pdf>

FSMA Rules & Guidance for Industry

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm>

Training & Materials on Preventive Controls for Human Food (FSPCA)

<https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food>