

Food Recalls: Essentials for Action



Presentation Materials

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

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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

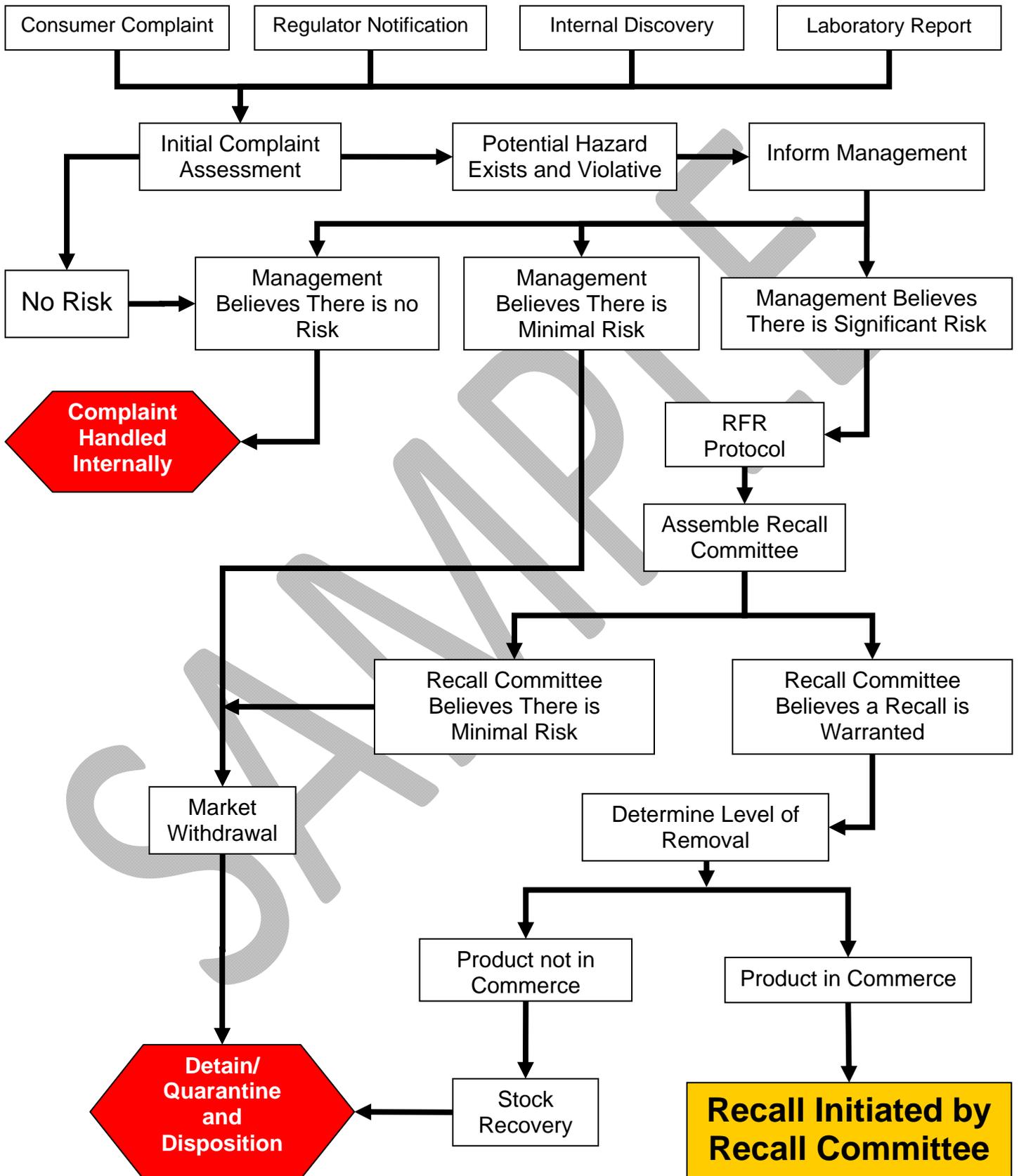
Consumers are advised not to consume 6 ounce containers of Nature's Nest Brand, "Yummy Yuckies" cereal because it has the potential to be contaminated with *Salmonella*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened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

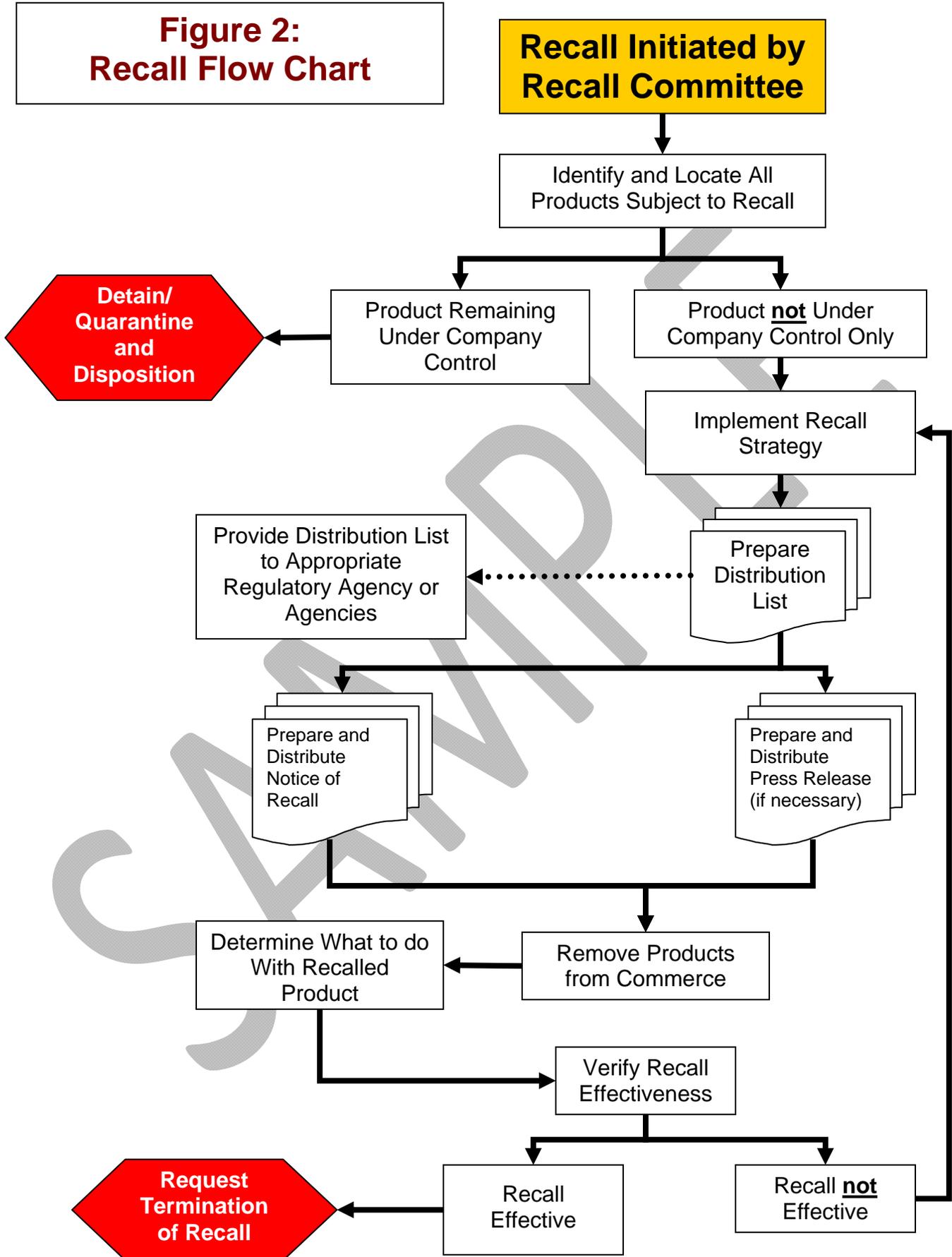
The product was distributed to retailers in CA, AZ, NV and OR, and may have been sold through the internet.

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 Department of Public Health, Food and Drug Branch (FDB) – Industry Education and Training
<http://www.cdph.ca.gov/services/Pages/fdbETU.aspx>
2. FDB – Food Recall Resources
<http://www.cdph.ca.gov/services/Pages/fdbRlgde07.aspx>
3. FDB – Home Page
<http://www.cdph.ca.gov/FDB>
4. FDB – Food Industry Training Information
<http://www.cdph.ca.gov/CAFoodTraining>
5. United States – Food and Drug Administration (FDA) – Reportable Food Registry
<http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>
6. FDA – Home Page
<http://www.fda.gov/>
7. FDA – Termination of a recall – Title 21, Code of Federal Regulations Part 7
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=7.55>
8. FDA – Recall policy – Title 21, Code of Federal Regulations, Part 7
http://edocket.access.gpo.gov/cfr_2004/apr_qtr/21cfr7.40.htm
9. FDA – Industry Guidance: Information on Recalls of FDA Regulated Products
<http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm>
10. FDA – District Recall Coordinators
<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>
11. United States Department of Agriculture – Food Safety Inspection Service (FSIS)
<http://www.fsis.usda.gov/wps/portal/fsis/home>
12. Center for Disease Control
<http://www.cdc.gov/>

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:

1. Identify, isolate and stop selling the affected product (s).
2. 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](#)

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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

FSMA FACTS

Final Rule on Preventive Controls for Human Food

Summary

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule is now final, and compliance dates for some businesses begin in September 2016.

This final rule is the product of an unprecedented level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local and tribal regulatory counterparts, academia and other stakeholders. This outreach began before the rule was proposed in January 2013.

In response to input received during the comment period and during hundreds of engagements that included public meetings, webinars, listening sessions, and visits to farms and food facilities across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective for industry, while still advancing the FDA's food safety goals.

The final rule has elements of both the original and supplemental proposals, in addition to new requirements that are the outgrowth of public input received during the comment period for both proposals. For example, flexibility has been built into key requirements, including

control of the supply chain, and the definition of farms— which are exempt from these regulations— has significantly changed to reflect modern farming practices.

Below are the key requirements and compliance dates.

1. **Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes:**
 - **Hazard analysis:** The first step is hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).
 - **Preventive controls:** These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented. They include process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan.

Final Rule on Preventive Controls for Human Food

- **Oversight and management of preventive controls.** The final rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise.

- **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 actual temperature values and be more frequent than monitoring preventive maintenance activities used to minimize metal hazards, which could be a simple record of the date on which the activity took place.

- **Corrective actions and corrections:** Corrections are steps taken to timely identify and correct a minor, isolated problem that occurs during food production. Corrective actions include actions to identify a problem with preventive control implementation, to reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent it from entering commerce. Corrective actions must be documented with records.

- **Verification:** These activities are required to ensure that preventive controls are consistently implemented and effective. They include validating with scientific evidence that a preventive control is capable of effectively controlling an identified hazard; calibration (or accuracy checks) of process monitoring and verification instruments such as thermometers, and reviewing records to verify that monitoring and corrective actions (if necessary) are being conducted.

Product testing and environmental monitoring are possible verification activities but are only 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 generally would be required if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control.

2. The definition of a 'farm' is clarified to cover two types of farm operations. Operations defined as farms are not subject to the preventive controls rule.

- **Primary Production Farm:** This is an operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of

Final Rule on Preventive Controls for Human Food

crops, the raising of animals (including seafood), or any combination of these activities. This kind of farm can pack or hold raw agricultural commodities such as fresh produce and may conduct certain manufacturing/processing activities, such as dehydrating grapes to produce raisins and packaging and labeling raisins.

The supplemental rule proposed, and the final rule includes, a change to expand the definition of “farm” to include packing or holding raw agricultural commodities (such as fresh produce) that are grown on a farm under a different ownership. The final rule also includes within the “farm” definition companies that solely harvest crops from farms.

- **Secondary Activities Farm:** This is an operation not located on the Primary Production Farm that is devoted to harvesting, packing and/or holding raw agricultural commodities. It must be majority owned by the Primary Production Farm that supplies the majority of the raw agricultural commodities harvested, packed, or held by the Secondary Activities Farm.

This definition for a Secondary Activities Farm was provided, in part, so that farmers involved in certain formerly off-farm packing now fit under the definition of “farm,” as the packing is still part of the farming operation. In

addition to off-farm produce packing operations, another example of a Secondary Activities Farm could be an operation in which nuts are hulled and dehydrated by an operation not located at the orchard before going to a processing plant. If the farmer that owns the orchards and supplies the majority of the nuts is a majority owner of the hulling/dehydrating facility, that operation is a Secondary Activities Farm.

- Primary Production and Secondary Activities Farms conducting activities on produce covered by the Produce Safety Rule will be required to comply with that rule.

3. Supply-chain program is more flexible, with separate compliance dates established.

- The rule mandates that a manufacturing/processing facility have a risk-based supply chain program for those raw material and other ingredients for which it has identified a hazard requiring a supply-chain applied control. Manufacturing/processing facilities that control a hazard using preventive controls, or who follow requirements applicable when relying on a customer to control hazards, do not need to have a supply-chain program for that hazard.

Final Rule on Preventive Controls for Human Food

- Covered food facilities are responsible for ensuring that these foods are received only from approved suppliers, or on a temporary basis from unapproved suppliers whose materials are subject to verification activities before being accepted for use. (Approved suppliers are those approved by the facility after a consideration of factors that include a hazard analysis of the food, the entity that will be controlling that hazard, and supplier performance.)
 - A facility will not be required to implement a preventive control when an identified hazard will be controlled by a subsequent entity such as a customer or other processor. The facility will have to disclose that the food is “not processed to control (identified hazard)” and obtain written assurance from its customer regarding certain actions the customer agrees to take.
 - Another entity in the supply chain, such as a broker or distributor, can conduct supplier verification activities, but the receiving facility must review and assess that entity’s documentation of the verification of control of the hazard.
 - Separate compliance dates have been established for the supply-chain program provisions so that a food facility will not be required to comply with the supply-chain program provisions before its supplier is required to comply with the preventive controls for human food rule or the produce safety rule.
- 4. Current Good Manufacturing Practices (CGMPs) are updated and clarified.**
- The final rule does not include nonbinding provisions, which are more appropriate for guidance.
 - Some of the previously nonbinding provisions, such as education and training, are now binding.
 - Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.
 - Such employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food. Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene.
 - Note that there are similar requirements related to preventive controls.

Final Rule on Preventive Controls for Human Food

- The FDA’s longstanding position that CGMPs address allergen cross-contact is now explicit in the regulatory text.

Compliance Dates

Compliance dates for businesses are staggered over several years after publication of the final rule.

- **Very small businesses** (averaging less than \$1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale): Three years, except for records to support its status as a very small business (January 1, 2016).
- **Businesses subject to the Pasteurized Milk Ordinance** (compliance dates extended to allow time for changes to the PMO safety standards that incorporate the requirements of this preventive controls rule): Three years
- **Small businesses** (a business with fewer than 500 full-time equivalent employees): Two years
- **All other businesses**: One year

Compliance dates after publication of the final rule for the requirements of the supply chain program:

- **Receiving facility is a small business and its supplier will not be subject to**

the human preventive controls rule or the produce safety rule: Two years

- **Receiving facility is a small business and its supplier will be subject to the human preventive controls rule or the produce safety rule**: Two years or six months after the supplier is required to comply with the applicable rule, whichever is later
- **Receiving facility is not a small or very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule**: 18 months
- **Receiving facility is not a small or very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule**: Six months after the supplier is required to comply with the applicable rule

Assistance to Industry

The FDA is developing several guidance documents on subjects that include:

- Hazard analysis and preventive controls,
- Environmental monitoring,
- Food allergen controls,
- Validation of process controls,

Final Rule on Preventive Controls for Human Food

- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.

Plans for training and technical assistance are well under way. They include:

- Establishing a Food Safety Technical Assistance Network within the agency to provide a central source of information to support industry understanding and implementation of FSMA.
- Collaborating with the Food Safety Preventive Controls Alliance (<http://www.iit.edu/ifsh/alliance/>) to establish training and technical assistance programs.
- Partnering with the National Institute of Food and Agriculture in the U.S. Department of Agriculture to administer a grant program to provide technical assistance to small and mid-size farms and small food processors.

More Information

Federal Register

www.regulations.gov

FDA Food Safety Modernization Act

www.fda.gov/fsma

FDA's FSMA Technical Assistance Network

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