

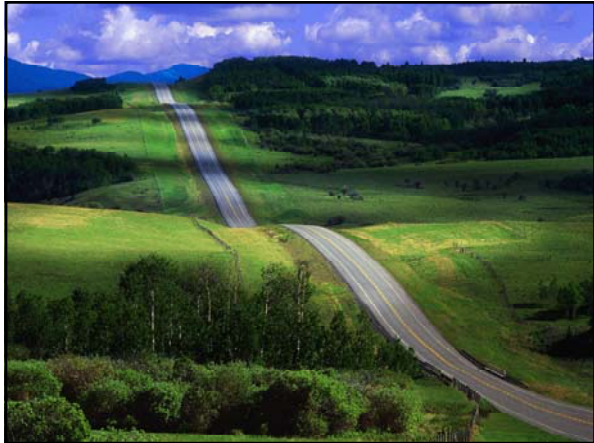
Food Recalls: Essentials for Action



Presented By:
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Food and Drug Branch

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2015

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Training Agenda 

- I. Food Safety Law and Regulatory Agencies
- II. Essential Elements of a Recall Action Plan
- III. Mock Recall Exercise
- IV. Resources

 **California Law: Sherman Food, Drug, and Cosmetic Act**


The **Sherman Food, Drug and Cosmetic Act** is the state law that prohibits the manufacture or sale of food that is adulterated, misbranded, falsely advertised or misleading.

Text of the Sherman Law can be found at:
<http://www.cdph.ca.gov/services/Documents/fdbSFDCA.pdf>

 **Adulteration**
 (Health and Safety Code, Sections 110545-110610)

Ways that food can become contaminated or “adulterated”

- Physical**
 - Glass - jars, bottles, light fixtures, thermometers
 - Metal - machinery, wire, staples
 - Plastic - packaging materials
 - Stones- from plant surroundings
 - Wood - boxes, bins, pallets
- Chemical:** Chemical adulteration includes pesticides, cleaners and paint, toxic elements such as lead or mercury
- Biological:** Viruses or bacteria from food-borne pathogens (i.e., *Salmonella*, *E. coli* O157H7, Hepatitis A)



Misbranding

(Health and Safety Code, Section 110660)

Requires that all packaged foods list specific information on labels to avoid misbranding due to false, misleading or missing information.

Food labels must include:


- > Food Name
- > Responsible Firm
- > Address (if not listed in local Yellow Pages)
- > Ingredient Listing (in order of predominance by weight)
- > Net Quantity



Allergen Labeling Law: FALCPA

The **Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)** applies to all foods labeled on or after January 1, 2006.

- > Food labels must list the food source names of all ingredients that contain any protein derived from the eight most common food allergens, which FALCPA defines as "major food allergens."



FALCPA Major Allergens

Eight foods are designated as major food allergens by FALCPA:

- Milk
- Eggs
- Fish (e.g., bass, flounder, cod)
- Crustacean shellfish (e.g., crab, lobster, shrimp)
- Tree nuts (e.g., almonds, walnuts, pecans)
- Peanuts
- Wheat
- Soy

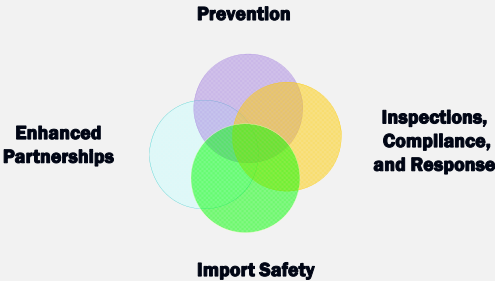
Bioterrorism Registration

To protect the public from a threat or actual terrorist attack on the nation's food supply, the **Public Health Security and Bioterrorism Preparedness Response Act** requires food facilities to register with the FDA.

Register at: www.fda.gov



FSMA: Main Themes of the Law



Proposed Rules

Preventative Controls for Human Food	8/30/15
Preventative Controls for Animal Food	8/30/15
Produce Safety Standards	10/31/15
Foreign Supplier Verification Program	10/31/15
Accreditation of Third Party Auditors	10/31/15
Sanitary Transportation	3/31/16
Intentional Adulteration	5/31/16

Food Safety Modernization Act







Food Bill Aims to Improve Safety

Regulatory reform, enhanced oversight, and improved food safety are the focus of the Food Safety Modernization Act (FSMA), the most comprehensive food safety legislation in decades. The bill is expected to be signed into law by President Obama in the next few weeks. The bill will give the FDA the authority to prevent food safety problems before they happen, rather than just reacting to them after the fact. It will also give the FDA the authority to require food safety plans for certain food facilities, and to require food safety training for food workers. The bill will also give the FDA the authority to require food safety audits for certain food facilities, and to require food safety records for certain food facilities. The bill will also give the FDA the authority to require food safety inspections for certain food facilities, and to require food safety testing for certain food facilities. The bill will also give the FDA the authority to require food safety recalls for certain food facilities, and to require food safety labeling for certain food facilities. The bill will also give the FDA the authority to require food safety labeling for certain food facilities, and to require food safety labeling for certain food facilities.

Check the FDA website at:
www.fda.gov/fsma
 for information on FSMA.

A subscription service for updates is available.
 Contact:
FSMA@fda.hhs.gov.

General Foods	Fresh Produce	Meat & Poultry	Disease Investigation
			

Removal of Products from Commerce



Removal of Products from Commerce

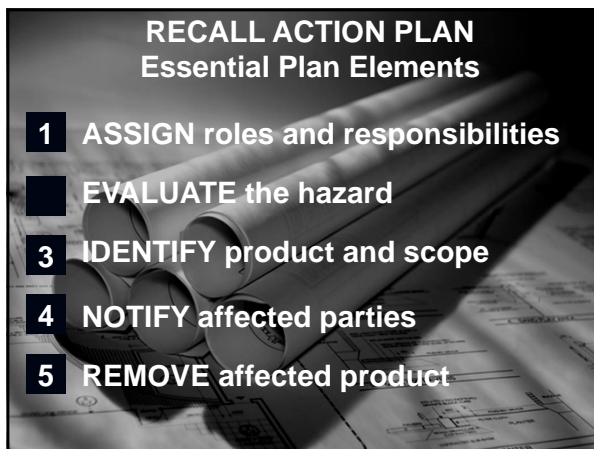
Stock Recovery
Market Withdrawal
Recalls





RECALL ACTION PLAN
Essential Plan Elements

- 1** ASSIGN roles and responsibilities
- 2** EVALUATE the hazard
- 3** IDENTIFY product and scope
- 4** NOTIFY affected parties
- 5** REMOVE affected product



RECALL ACTION PLAN
Essential Plan Elements

- 1** ASSIGN roles and responsibilities
- 2**
- 3**
- 4**
- 5**



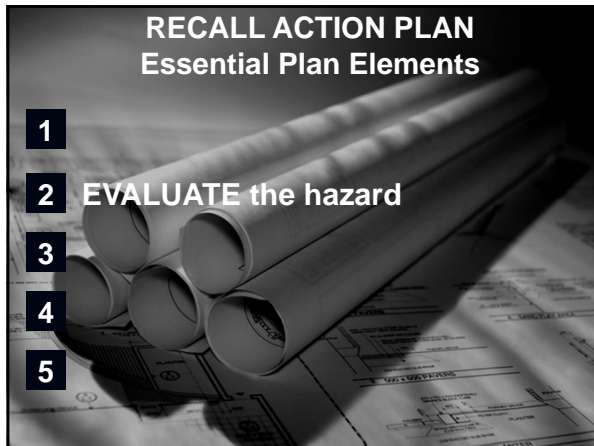
RECALL ACTION PLAN
Recall Team

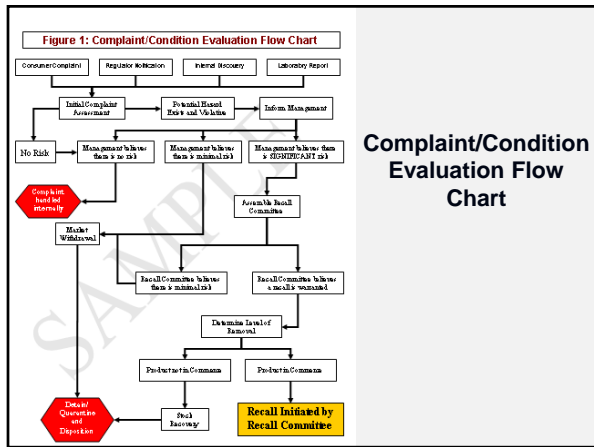


- Management
- Distribution/Sales
- Production/Purchasing
- Quality Assurance
- Recall Coordinator

RECALL ACTION PLAN
Support Personnel

Accounting	Information Technology
Customer Service	Scientific Support
Public Relations	Records Management
Legal	Regulatory Affairs







RECALL ACTION PLAN
2. Evaluate the hazard

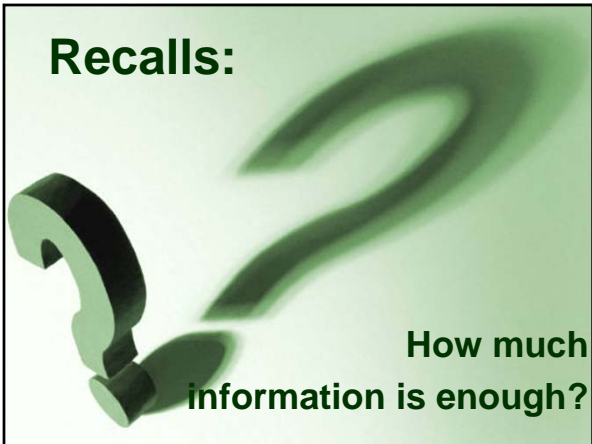
Is it **MY** problem?

RECALL ACTION PLAN
Preparation
2. Evaluate the hazard



How **bad** is my problem?

Recalls:



How much information is enough?

RECALL ACTION PLAN
Essential Plan Elements

- 1
- 2
- 3 **IDENTIFY product and scope**
- 4
- 5



SOURCE
PRODUCT(S)
LOCATION





REPORTABLE FOOD REGISTRY

<http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>

U.S. Food and Drug Administration
Protecting and Promoting Your Health

Reportable Food Registry for Industry

For Industry/Regulators Submit a Report
For Consumers Contact FDA

RECALL ACTION PLAN
Essential Plan Elements

- 1
- 2
- 3
- 4 **NOTIFY affected parties**
- 5

Recall Notice
Press Release

Recall Action Plan

Header
Firm Contact Information and Date
Statement of Recall
Production Information – Problem – Stop Sale Statement
Detailed Product Information – Statement of Illnesses
Consumer Directives
Regulatory Notification and Information Request
Firm Contact Information
Standard Closure



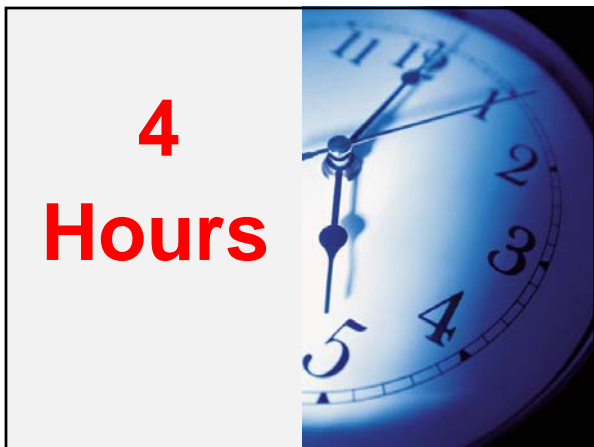
RECALL ACTION PLAN
Essential Plan Elements

- 1
- 2
- 3
- 4
- 5 REMOVE affected product

**REMOVAL
RECONCILIATION
EFFECTIVENESS
DISPOSITION
TERMINATION**

**RECALL ACTION PLAN
Essential Plan Elements**

- 1** ASSIGN roles and responsibilities
- 2** EVALUATE the hazard
- 3** IDENTIFY product and scope
- 4** NOTIFY affected parties
- 5** REMOVE affected product



Recall Coordinator Resources

Recall Coordinators are a useful resource in the event of a food recall. To contact the recall coordinator nearest you,

- **State:** CDPH-FDB – send email to: fdberu@cdph.ca.gov; view food recalls at: <http://www.cdph.ca.gov/HealthInfo/Pages/fdbFr.aspx>
- **Federal:** U.S. FDA - list of regional recall coordinators can be found at: <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>

Be prepared to advise the recall coordinator on the reason for the recall, list of consignees, and areas of distribution.

Requested Documents

- Affected Product
- Product Information
- Labels
- Draft Recall Notices
- Draft Press Releases



Requested Documents

- Amount of Product Made or Received
- Amount Distributed
- Distribution List



Distribution List

E-mail: FDICER@fdi.gov, With subject line "Re: **Source** for Name of Recall"

Company Name: _____ *(insert your company name & DSA here)* **Date Form Completed:** _____

Business Type (Retail, Manufacturer, Distributor, etc.): _____

Customer May Use Product as an Ingredient? (YES, NO): _____

Customer Name: _____

Customer Ship to Address: _____

City: _____

State: _____

Zip Code: _____

Telephone: _____

Contact Person: _____

Contact Email Address: _____

Product Ship Date: _____


Amount Product Shipped: _____

Lot No.: _____

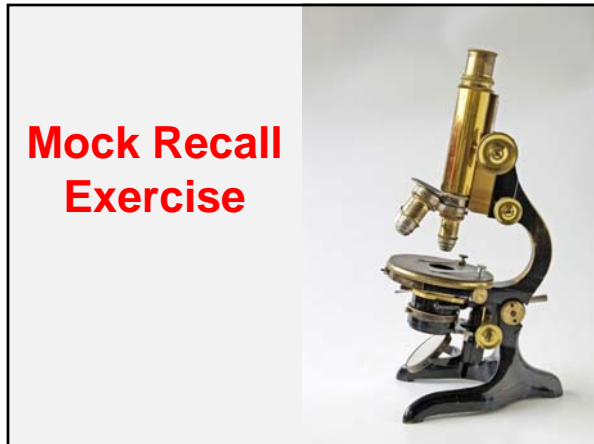
UPC: _____

Brand Name of Manufactured Products: _____

Distribution List



- ✓ **Business Type**
- ✓ **Customer May Use Product as an Ingredient? (Yes/No)**
- ✓ **Customer Name/Address/Telephone**
- ✓ **Contact Person/Email Address**
- ✓ **Product Ship Date**
- ✓ **Amount of Product Shipped**
- ✓ **Lot No.**
- ✓ **UPC**
- ✓ **Brand Name of Manufactured Products**





If You Have Questions Contact:



<p><u>State Government</u></p> <p>CDPH-Food and Drug Branch P.O. Box 997435, MS 7602 Sacramento, CA 95899-7435 E-mail: FDBtraining@cdph.ca.gov Phone: (916) 650-6500</p> <p>California Department of Food and Agriculture 1220 N Street Sacramento, California, U.S.A. 95814 www.cdffa.ca.gov Phone: (916) 654-0466 (Sacramento)</p>	<p><u>Federal Government</u></p> <p>U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 www.fda.gov Phone: 1-888-INFO-FDA (1-888-463-6332)</p> <p>U.S. Department of Food and Agriculture 620 Central Avenue, Building 2C Alameda, CA 94501 www.fsis.usda.gov Phone: (510) 337-5000 (Alameda District)</p>
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Questions?
