# Food Recalls: Essentials for Action

Presented By:  
California Department of Public Health  
Food and Drug Branch  
Phone: (916) 650-6660 Fax: (916) 650-6650  
FDBtraining@cdph.ca.gov

## 2015

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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)

<table>
<thead>
<tr>
<th>Ways that food can become contaminated or “adulterated”</th>
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<tbody>
<tr>
<td><strong>Physical</strong></td>
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<tr>
<td>Glass – jars, bottles, light fixtures, thermometers</td>
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<td>Metal – machinery, wire, staples</td>
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<tr>
<td>Plastic – packaging materials</td>
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<tr>
<td>Stones – from plant surroundings</td>
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<td>Wood – boxes, bins, pallets</td>
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<tr>
<td><strong>Chemical</strong></td>
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<tr>
<td>Chemical adulteration includes pesticides, cleaners and paint, toxic elements such as lead or mercury</td>
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<tr>
<td><strong>Biological</strong></td>
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<tr>
<td>Viruses or bacteria from food-borne pathogens (i.e., Salmonella, E. coli O157H7, Hepatitis A)</td>
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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

Prevention

Enhanced Partnerships

Inspections, Compliance, and Response

Import Safety

Proposed Rules

<table>
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<tr>
<th>Rule</th>
<th>Date</th>
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<tr>
<td>Preventative Controls for Human Food</td>
<td>8/30/15</td>
</tr>
<tr>
<td>Preventative Controls for Animal Food</td>
<td>8/30/15</td>
</tr>
<tr>
<td>Produce Safety Standards</td>
<td>10/31/15</td>
</tr>
<tr>
<td>Foreign Supplier Verification Program</td>
<td>10/31/15</td>
</tr>
<tr>
<td>Accreditation of Third Party Auditors</td>
<td>10/31/15</td>
</tr>
<tr>
<td>Sanitary Transportation</td>
<td>3/31/16</td>
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<tr>
<td>Intentional Adulteration</td>
<td>5/31/16</td>
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</tbody>
</table>
Food Safety Modernization Act

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

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

RECALL ACTION PLAN
Support Personnel

   Accounting
   Customer Service
   Public Relations
   Legal
   Information Technology
   Scientific Support
   Records Management
   Regulatory Affairs
RECALL ACTION PLAN
Essential Plan Elements

1. EVALUATE the hazard

Complaint/Condition Evaluation Flow Chart

Is there a PROBLEM?
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
RECALL ACTION PLAN

Essential Plan Elements

1. Recall Notice
2. Press Release
3. NOTIFY affected parties
URGEN

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

Don’t Be THAT Guy!

RECALL ACTION PLAN
Essential Plan Elements

1
2
3
4
5 REMOVE affected product
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

4 Hours
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
<table>
<thead>
<tr>
<th>Business Type</th>
<th>Customer May Use Product as an Ingredient? (Yes/No)</th>
<th>Customer Name/Address/Telephone</th>
<th>Contact Person/Email Address</th>
<th>Product Ship Date</th>
<th>Amount of Product Shipped</th>
<th>Lot No.</th>
<th>UPC</th>
<th>Brand Name of Manufactured Products</th>
</tr>
</thead>
</table>

**Mock Recall Exercise**
If You Have Questions Contact:

**State Government**
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
California Department of Food and Agriculture
1220 N Street
Sacramento, CA 95814
www.cdfa.ca.gov
Phone: (916) 654-0466 (Sacramento)

**Federal Government**
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)
U.S. Department of Food and Agriculture
620 Central Avenue, Building 2C
Alameda, CA 94501
www.fsis.usda.gov
Phone: (510) 337-0000 (Alameda District)

Questions?