I. Food Safety Law and Regulatory Agencies
II. Essential Elements of a Recall Action Plan
III. Mock Recall Exercise
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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 0157H7, 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

Food Safety Modernization Act

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Date</th>
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<tbody>
<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>
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<td>Produce Safety Standards</td>
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<td>Foreign Supplier Verification Program</td>
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<td>Accreditation of Third Party Auditors</td>
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<td>Sanitary Transportation</td>
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<td>Intentional Adulteration</td>
<td>5/31/16</td>
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Food Safety Modernization Act

Title 21 – Code of Federal Regulations
Part 117.139 (a, b)

Recall Plan
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

Title 21 CFR Part 7.3

Removal of Products from
Commerce

<table>
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<tr>
<th>Violation</th>
<th>Minor / No Violation</th>
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<tr>
<td>Control</td>
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<tr>
<td>No Control</td>
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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
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

2

3

4

5

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 IDENTIFY product and scope
2
3
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. Notify affected parties

2. 

3. 

4. 

5. 

6. 

7. 

8. 

9. 

10. 

11. 

12. 

13. 

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15. 

16. 

17. 

18. 

19. 

20.
URGENT FOOD RECALL

ABC Company Inc Date: Today
California CA
1-800-123-4567

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 to 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 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 or recall coordinator, John Smith, at 1-800-123-4567.

Thank you for your cooperation,

Sincerely,

Company President
**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

**REMOVAL**
**RECONCILIATION**
**EFFECTIVENESS**
**DISPOSITION**
**TERMINATION**
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

- 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
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Resources

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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, California, U.S.A. 95814
www.cdfa.ca.gov
Phone: (916) 653-4966 (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
520 Central Avenue, Building 2C
Alameda, CA 94501
www.fsis.usda.gov
Phone: (510) 357-0000 (Alameda District)

Questions?