Sample Recall Plan
Table of Contents

OUR COMPANY'S Recall Plan
Version Verification

OUR COMPANY'S Recall Plan shall be reviewed annually and revised as necessary when personnel, procedures, processes, suppliers, or as other factors change. The Plan will also be reviewed after any company recall.

Version _(mmddyy)_

Approved by _____
Name of Approver

_____
Title

Date Approved _____

Introduction

The primary goal of a food recall is to protect public health by removing products from commerce that have been determined to be unsafe. A recall plan can aid in the execution of a recall by apportioning duties, centralizing current contact information, and providing prewritten templates for communications. Key Individuals that will be participating in a company recall should review the recall plan and be familiar with the execution of the plan.

Definitions

- **Class I Recall** – A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- **Class II Recall** - A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III Recall** - A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.
- **Depth of Recall**: The level of product distribution for the recall (consumer, retail, institutional, wholesale).
- **Distribution List** - A product specific distribution list which identifies accounts that received the recalled product. Requested information includes type of business, account name, addresses, and contact information.
- **FDB** – California Department of Public Health, Food and Drug Branch
- **Market Withdrawal** - A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the regulatory agency or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.
- **Press Release** - A notice that alerts the public (including regulators, retailers, consignees, other distributors, processors, and consumers) that a product presents a serious hazard to health. Not all recalls require a press release; the regulatory agency will advise the firm when a press release is necessary.
- **Recall** - A firm's removal or correction of a marketed product that the regulatory agency considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.
- **Recall Committee** – The group comprised of key staff with the expertise, authority, and responsibility to manage the recall.
- **Recall Plan** - A written contingency plan for use in initiating and implementing a recall in accordance with 21 CFR Sec. 7.40 through 7.49, 7.53, and 7.55. The Recall Plan should be reviewed annually and revised as necessary when personnel, procedures, processes, suppliers, or as other factors change.
- **Recall Strategy** - A planned specific course of action to be taken in conducting a specific recall, which addresses the depth and scope of recall, need for public warnings, and extent of effectiveness checks for the recall.
- **Scope of Recall**: Defines the amount and kind of product in question.

- **Stock Recovery** - A firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

Statement of Recall Plan

OUR COMPANY maintains a recall plan which provides specific procedures, defines terms, and assigns roles and responsibilities when a food safety issue arises with any of our products.

The plan will be activated whenever a potential recall requirement arises and includes the following elements:

1. Recall committee member designations
2. Recall responsibility assignments
3. Key personnel and external contact information
4. Recall procedures
5. Communication templates

Success of the plan relies on the proper execution of plan elements and up-to-date information.

Recall Plan Flow Charts

The following two diagrams are graphical representations of the various steps of a recall. Figure 1, illustrates the typical evaluation of complaints or conditions which may lead to a recall. Figure 2, outlines the various steps of a recall.

Figure 1: Complaint/Condition Evaluation Flow Chart

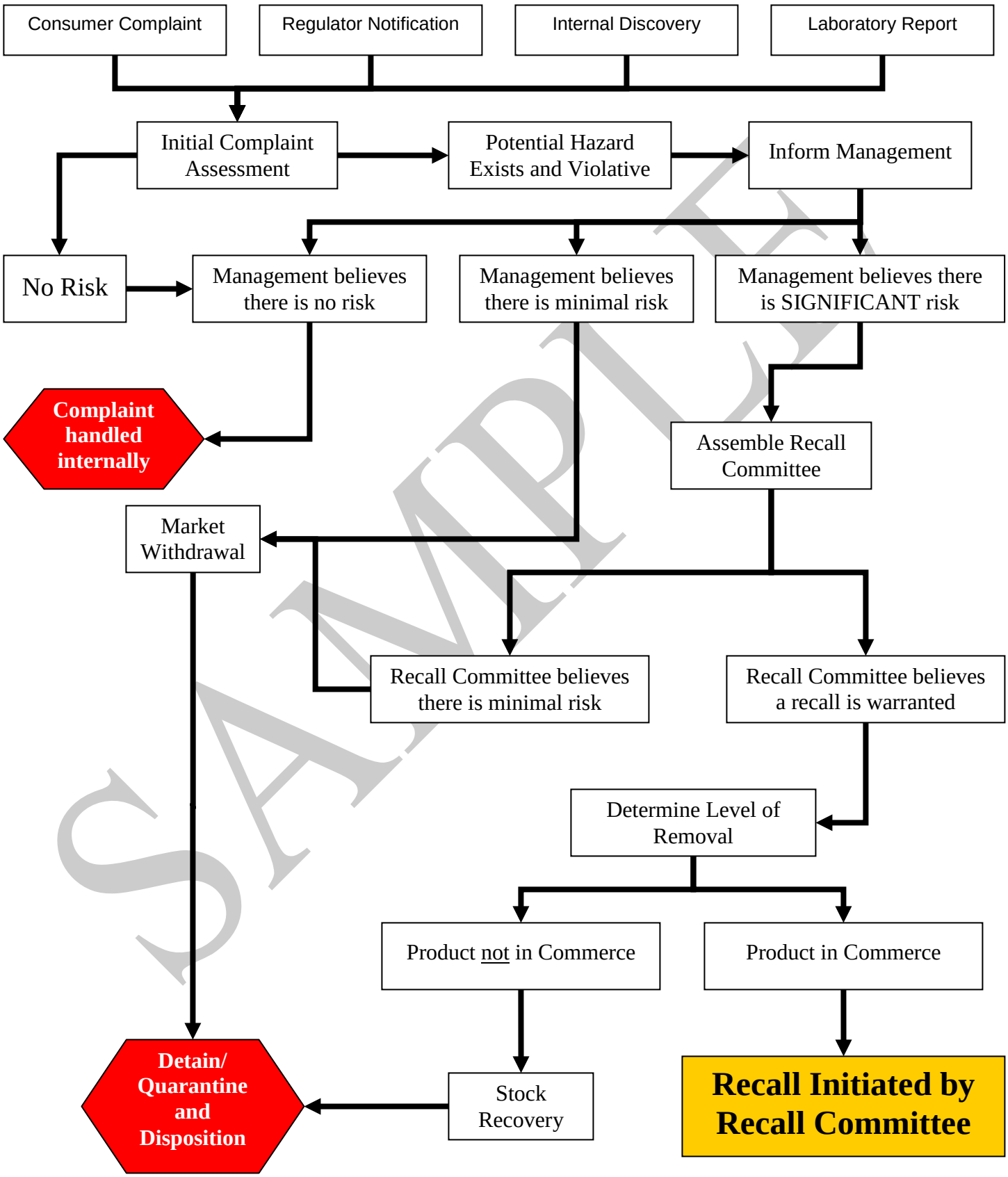
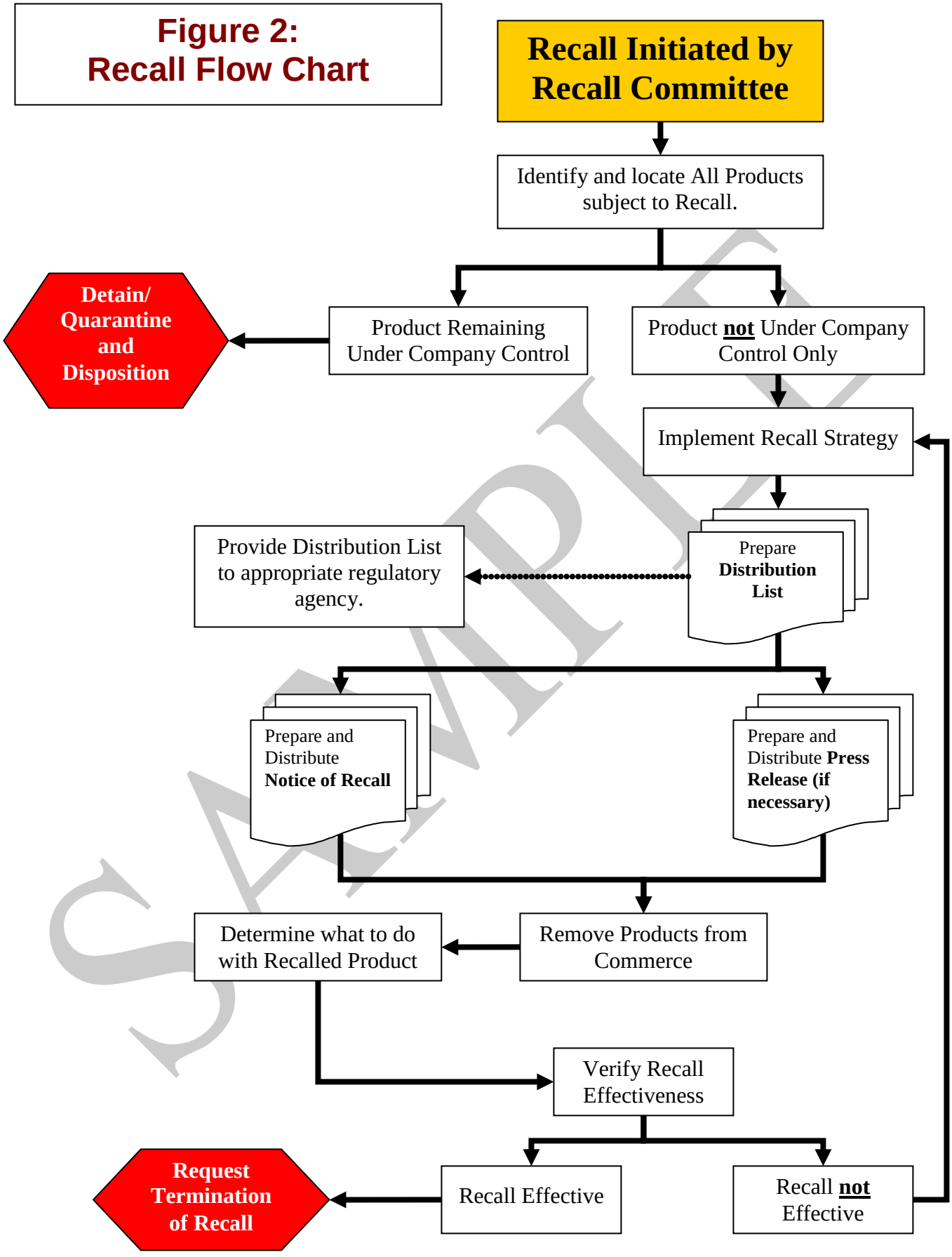


Figure 2:
Recall Flow Chart



Recall Procedures

The recall procedure outlines the activities that **OUR COMPANY** will take to manage the recall of our product(s) which has/have been determined to be unsafe and/or subject to regulatory action. The procedure contains the major recall elements below:

Assignment of Roles and Responsibilities

The roles and responsibilities of every individual on the Recall Committee should be clearly defined in the recall plan. Oversight of the following recall elements should be assigned to a member of the Recall team. Note that individuals may be responsible for more that one recall element.

Recall Coordinator

The recall co-coordinator, has been given authority by the management of **OUR COMPANY** to execute the activities of the recall. Responsibilities of the Recall Coordinator include, but are not limited to:

- Assure the documentation of all recall decisions and actions in a master recall file.
- Initiate the formation of the recall committee.
- Activate various components within the company for priority assistance.
- Make recall decisions on behalf of **OUR COMPANY.**
- Manage and coordinate the implementation of the company's product recall.
- Keep management informed at all stages of the recall.

Recall Committee

OUR COMPANY'S Product Recall Committee is composed of the various components of the company's organization. The following functions should be represented on the committee (an individual may be responsible for more than one function):

- Management (Administration)
- Recall Coordinator
- Accounting
- Consumer Affairs/Public Relations
- Customer Service
- Distribution and Supply
- Information Technology
- Legal Counsel
- Marketing
- Operations
- Production
- Purchasing
- Quality Assurance
- Sales
- Maintenance
- Records Management
- Regulatory Affairs
- Sanitation

Note: Outside resources may need to be obtained for some of the functions.

Responsibilities

Individual recall activities should be assigned prior to a recall event to avoid confusion during a recall. Assignment of the recall responsibilities are found in Appendix D (assign an individual to each activity).

Evaluation of the Complaint or Condition

Complaint receipt, processing, and evaluation are the first steps in the recall process. The steps involved in the evaluation process are:

- Receive the complaint – A file should be maintained containing any product complaints the company receives. Information that should be maintained in the product complaint file is:
    i. Complainant contact information
    ii. Reported problem with the product
    iii. Product Identification
    iv. Product Storage
    v. Product purchase date and location
    vi. Illness and Injury details
- Provide the complaint to knowledgeable staff for initial evaluation. If an initial assessment indicates a recall may be necessary, the Recall Coordinator assembles the Recall Committee for a full evaluation.
- Determine the hazard and evaluate the safety concerns with the product.
- Determine the product removal strategy appropriate to the threat and location in commerce.
- Contact the appropriate regulatory authorities.
- Alert legal counsel, insurance, etc. as appropriate.
- Maintain a log of the events of the recall including information such as dates, actions, communications, and decisions.

Identification of Implicated Products

It is **OUR COMPANY'S** responsibility to ensure the identification of all products and quantities of products implicated in the recall. In addition, determination should be made if any other codes, brands or sizes of product handled by the company are affected.

A distribution list should be prepared as part of the Identification process. The distribution list should at minimum identify:

- Account name (consignees) that received the recalled product(s)
- Account addresses
- Contact names
- Contact telephone numbers
- Type of account (e.g., manufacturer, distributor, retailer)

Additional information relating to product information may include:

- Amount of product received/shipped
- Product ship date(s)
- Amount of product returned
- Amount of product consumed

A link to the FDB Distribution Template can be found in Appendix B.

Notification of Affected Parties

Notifications during a recall must be done in a timely manner and should include the appropriate regulatory agencies, the product distribution chain, and consumers when necessary. Recall notices are typically used to notify regulatory agencies and those businesses in the distribution chain. Press releases are generally oriented to consumers, but may be used to notify any affected party.

- Regulatory Agencies should be notified at the earliest opportunity after the decision has been made to conduct a recall. Regulatory guidance may be found at: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm.
    - Subsequent to the initial notification, the regulatory authority should be updated throughout the recall process.
- Distribution Chain contacts will be notified by appropriate means (telephone, fax, email, letter, etc.). It is recommended that a written recall notice be provided to all consignees. The Recall Notice **must** include all relevant recall information (see Appendix B, section (a)(ii)).
    - Confirm receipt of the Notice of Recall with all accounts. A record of all account communications should be maintained.
- Consumers should be notified by the most effective method available. If appropriate, a press release can be used to notify consumers. Considerations for preparing a press release include:
    - Issuance of a press release should be the highest priority and should be issued promptly.
    - The local FDA District Recall Coordinator should be consulted before issuance of a press release whenever possible.
    - All relevant information should be included in the press release (see sample templates in Appendix B).

Removal of Affected Product

The procedure for product removal can be divided into five components including: removal, control, and disposition of affected product, recall effectiveness, and recall termination.

Removal

All reasonable efforts must be made to remove affected products from commerce.

- Products in commerce should be detained, segregated, and handled in a manner determined by the recalling firm.
- Products that are still in the recalling firm's control (e.g. inventory located onsite, in transit, in off-site storage, and in offsite distribution) should be detained, and segregated.
- All quantities and identification codes shall be documented to assist in the reconciliation of product amounts.

Control of Recalled Product

When **OUR COMPANY** chooses to retain recalled product, control must be regained to prevent reentry of the product into commerce.

- All affected product returned will be clearly marked, not for sale or distribution, and stored in an area that is separated from any other food products.

All quantities and identification codes shall be documented to assist in the reconciliation of product amounts.

Product Disposition

The final disposition of the recovered product must be determined. The final disposition must be reviewed and approved by the regulatory agency. Options include:

- Redirection – Products may be redirected for uses other than human consumption.
- Destruction - Products determined to be unsafe for human consumption may be destroyed or denatured, and disposed by appropriate means.
- Recondition – Products may be reworked to remove the safety risk. For example, would be relabeling a product to declare an allergen originally omitted from the label.

All quantities, identification codes, and disposition shall be documented.

Recall Effectiveness

OUR COMPANY is responsible for determining whether the recall is effective. Recall Effectiveness Checks verify that all consignees have been notified and have taken the appropriate action. Steps include:

- Verifying that all consignees have received the notification.
- Verifying that consignees have taken appropriate action.
- If the response from our consignees is less than 100%, then the recall should be deemed ineffective and the recall strategy should be reassessed. Certain circumstances (e.g. amount of product actually returned vs. expected, potential for consumption, shelf-life, etc.) may also require a reassessment of the recall strategy.

All verifications shall be documented.

Termination of a recall

Termination of the recall may be considered after all reasonable efforts have been made to remove the affected products from commerce, including reconciliation, recall effectiveness, and disposition.

A termination of the recall may be requested by submitting a written request to the regulatory authorities. Guidance for the termination of a recall is provided in Appendix C.

Mock Recall

In addition to an annual verification of the recall plan, **OUR COMPANY** will conduct a mock recall annually or whenever there are significant changes to the plan or personnel. The mock recall will include the following elements:

- Selecting a product which has reached the consumer market.
- Tracing the product from the raw ingredient (e.g. source) level to the finished product in the marketplace.
- Verifying communications systems (e.g. contact information, test emails and faxes, etc.) to outside contacts.
- Modifying the recall plan to correct any problems encountered during the test.

Records of these mock recalls will be documented and filed appropriately.

Appendix A – Contact Information

Recall Committee and Key Personnel Contact Information

The contact information including phone number, fax number, email address, and alternate 24/7 information of all committee members, their alternates, and "outside" key personnel should be confirmed and updated as often as necessary to assure accuracy.

Contact Information

- Recall Committee (24/7)
  - i. Recall Committee Members (insert phone number)
  - ii. Alternate Committee Members (insert phone number)
- Regulatory Contacts
  - i. CDPH Emergency Contact (insert phone number)
  - ii. FDA District Recall Coordinator (insert phone number)
  - iii. USDA (if applicable) (insert phone number)
- Technical Consultants
  - i. Laboratory (insert phone number)
  - ii. Food Safety Consultant(s) (insert phone number)
  - iii. Sanitation Consultants (insert phone number)
  - iv. Engineering (insert phone number)
  - v. Information Technology (IT) (insert phone number)
  - vi. Legal Counsel (insert phone number)
- Distribution Chain Contacts
- Associated Press
  - San Francisco Bureau (insert phone number)
  - Los Angeles Bureau (insert phone number)
  - Internet http://www.ap.org/California/
- Secondary Language Media Contacts (e.g. radio, TV, print, etc. to reach appropriate ethnic populations) (insert phone number)

Appendix B – Templates

1. Communication Templates
    i. Model Press Releases(FDA)
        a. Allergens (Allergy Alert)
        http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129262.htm
        b. Listeria monocytogenes
        http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129267.htm
        c. Clostridium botulinum
        http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129273.htm
        d. Salmonella (all serotypes)
        http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129275.htm
        e. E. coli 0157:H7
        http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129287.htm
    ii. FDA Guidance for Written Recall Notification Letters
    http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm
    iii. FDB Distribution List Template
    http://www.cdph.ca.gov/pubsforms/Guidelines/Documents/fdb%20eru%20Gde%20DistListTemp.xls
2. Recall Events Log (should include the following information):
    i. Name of the person creating the action
    ii. Dates
    iii. Actions
    iv. Communications
    v. Decisions
    vi. Product disposition
3. Recalled Product Information Data Sheet (should include the following information):
    i. Product description: brand, product name, size, etc.
    ii. Lot codes
    iii. Quantity of recalled product
    iv. Date of the action
    v. Action taken for each product
4. Model Product Complaint Report
    http://www.cdph.ca.gov/pubsforms/Documents/fdbRIgde04.pdf

Appendix C – Additional Resources

1. California Food and Drug Branch – Industry Education and Training Unit
   http://www.cdph.ca.gov/services/Pages/fdbETU.aspx

2. Termination of a recall – 21 CFR Sec. 7.55
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=7.55

3. Industry Guidance: Information on Recalls of FDA Regulated Products
   http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm

4. Recall policy – 21 CFR Recall Regulations Sec. 7.40
   http://edocket.access.gpo.gov/cfr_2004/aprqtr/21cfr7.40.htm

5. California Food and Drug Branch
   http://www.cdph.ca.gov/programs/Pages/FDB.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

APPENDIX D – Assigned Responsibilities

Sample Assignments (may include, but not limited to the following)

Assignment

1. Management of the Recall – (**Insert Name, Title**) is responsible for the coordination of all recall activities.
2. Assemble the Recall Committee – (**Insert Name, Title**) is responsible for communicating the decision to recall to the members of the Recall Committee and that each member knows their responsibilities.

Evaluation

1. Management Approval of the Recall – (**Insert Name, Title**) is responsible to decide if the recall should go forward.

Identification

1. Create a Product Recall Log – (**Insert Name, Title**) is responsible to create and maintain a product recall log to document all events, when they occur and the company's response to each.
2. Identify all Products to be Recalled – (**Insert Name, Title**) is responsible for identifying all products which need to be recalled.

Notification

1. Notify the Appropriate Regulatory Authority – (**Insert Name, Title**) is responsible for notifying the appropriate regulatory authority (use the contact information in the Recall Plan). Contacts shall only be made through the designated committee member. Recommended information to be submitted can be found in the FDA guidance document at: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm
2. Prepare the Press Release (if required) – (**Insert Name, Title**) is responsible for the recall press release if the decision to prepare a press release is made. Considerations for preparing a press release include:
    a. Issuance of a press release should be the highest priority and it should be issued promptly.
    b. Consult with your local District Recall Coordinator before issuance of a press release whenever possible.
    c. If the company decides to prepare the press release, include all relevant information (see sample templates in Appendix B)
3. Prepare the Distribution List – (**Insert Name, Title**) is responsible for preparing the recalled product distribution list. The FDB distribution list template requests account type, name, address, phone number, and contact name.
4. Prepare the Notice of Recall – (**Insert Name, Title**) is responsible for preparing the written notice includes all recall relevant information (see FDA Guidance for Written Recall Notification Letters in Appendix).
5. Distribute the Notice of Recall – (**Insert Name, Title**) is responsible for distribution of the Notice of Recall to all accounts that received the recalled product. Responsibilities include:
    d. Confirm receipt of the Notice of Recall with all accounts.
    e. Contact accounts that have not responded to the request for conformation.
    f. Maintain records of the account communications.

Removal

1. Detain and Segregate all Products to be Recalled which are in your Firm's Control – (**Insert Name, Title**) – is responsible to ensure that all products to be recalled in the firm's control are not distributed (identify, detain, and segregate products on-site, in transit, off-site storage, and off–site distribution).
2. Control the recalled product(s) – (**Insert Name, Title**) is responsible to ensure that recalled products do not re-enter commerce. Responsibilities include:
    a. Quarantine and clearly identify recalled products.
    b. Reconcile quantities, identification codes, and monitor recalled products.
    c. Document the returned products.
3. Decide what to do with the recalled product(s) – (**Insert Name, Title**) is responsible for determining the action to be taken on the recalled product (destruction, reworking, and redirection). Other related responsibilities include:
    a. Determine if the regulatory authority requires actions such as witnessing destruction of the recalled product.
    b. Verify that the action taken has been effective.
    c. Document the action(s) taken.
4. Verify Recall Effectiveness – (**Insert Name, Title**) – is responsible for verifying the effectiveness of the recall. Responsibilities include:
    a. Verify that distribution of recalled products has ceased.
    b. Verify that all consignees at the recall depth specified by the recall strategy have received notification about the recall.
    c. Verify that consignees have taken appropriate action.
    d. Document all verifications.