Recall Plan

REVIEW DATE	REVIEWER	OWNERS SIGNIATURE

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.

· **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. 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

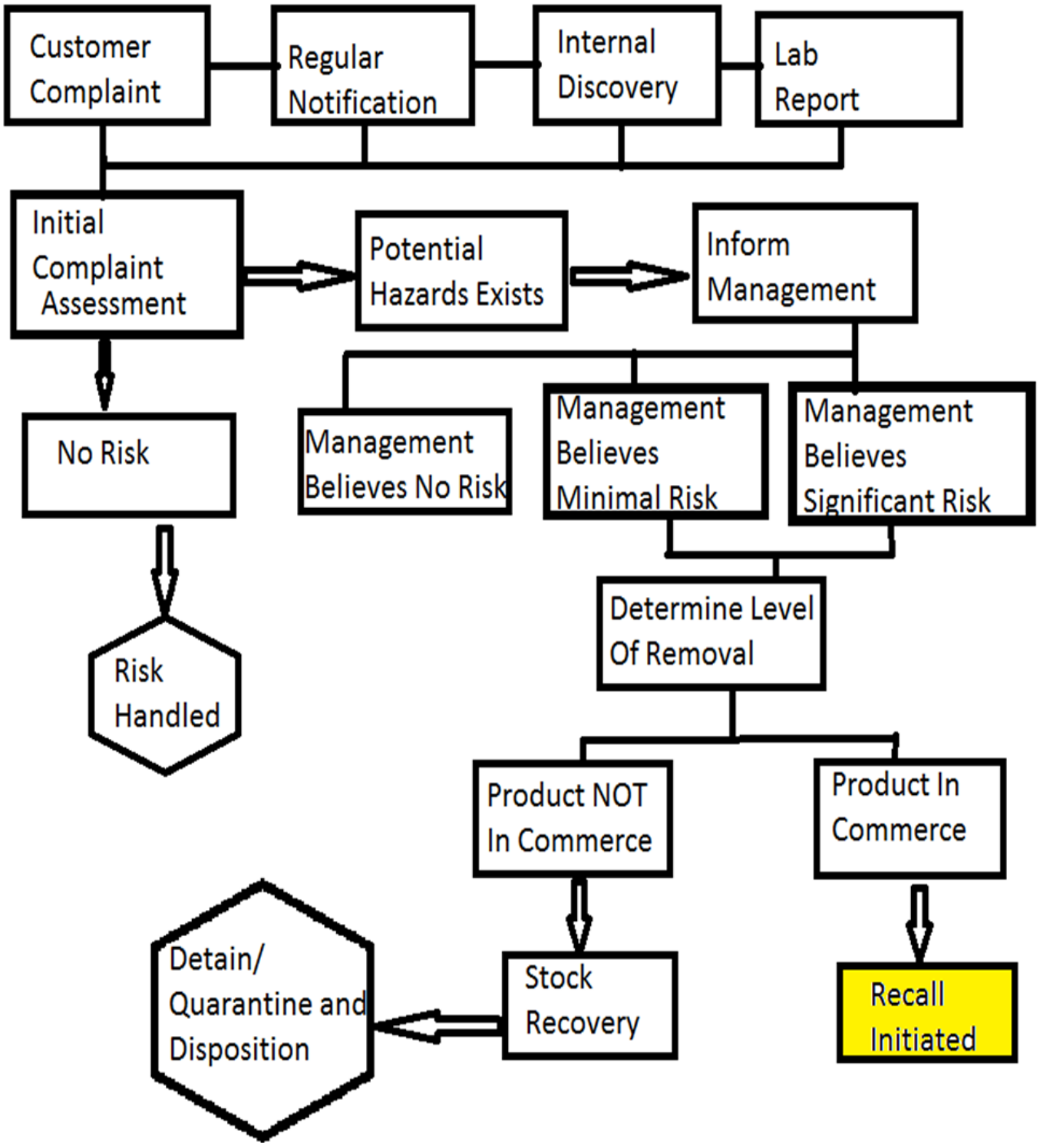
This farm maintains a recall plan which provides specific procedures, defines terms, and assigns roles and responsibilities when a food safety issue arises with any of our products.

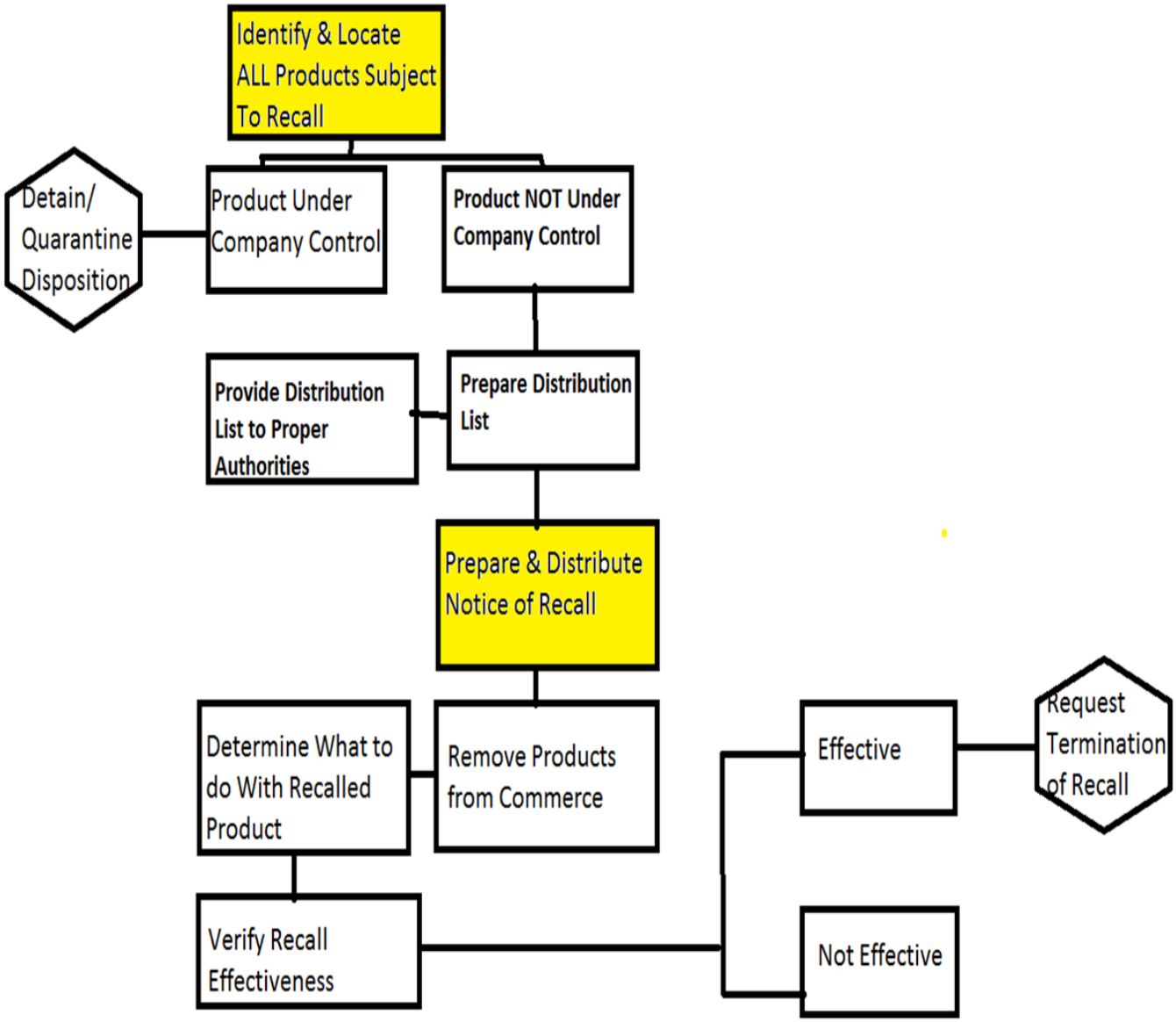
The plan will be activated whenever a potential recall requirement arises. The recall committee members include the business owner and food safety personnel. Food safety personnel are responsible for all recall responsibility assignments. Details of the recall responsibility assignments can be found in the “Recall Procedures” section.

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.


Customer Complaint
Regular Notification
Internal Discovery
Lab Report
Initial Complaint Assessment
Potential Hazards Exists
Inform Management
No Risk
Management Believes No Risk
Management Believes Minimal Risk
Management Believes Significant Risk
Risk Handled
Determine Level Of Removal
Product NOT In Commerce
Product In Commerce
Detain/ Quarantine and Disposition
Stock Recovery
Recall Initiated


Identify & Locate ALL Products Subject To Recall
Detain/ Quarantine Disposition
Product Under Company Control
Product NOT Under Company Control
Provide Distribution List to Proper Authorities
Prepare Distribution List
Prepare & Distribute Notice of Recall
Determine What to do With Recalled Product
Remove Products from Commerce
Verify Recall Effectiveness
Effective
Request Termination of Recall
Not Effective

Recall Procedures

The recall procedure outlines the activities that this operation will take to manage the recall of 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**

· **Evaluation of the Complaint or Condition**

· **Identification of Implicated Products**

· **Notification of Affected Parties**

· **Removal of Affected Products**

Assignment of Roles and Responsibilities

The roles and responsibilities of food safety personnel include the oversight of the recall elements. This includes duties such as but not limited to:

· Assuring the documentation of all recall decisions and actions in a master recall file.

· Activating various components within the company for priority assistance.

· Making recall decisions on behalf of the operation**.**

· Managing and coordinating the implementation of the company's product recall.

· Keeping the owner informed at all stages of the recall.

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

· If an initial assessment indicates a recall may be necessary, the Recall Coordinator will provide 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 the operation'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

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

· 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

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 the operation chooses to retain recalled product, control must be regained to prevent reentry of the product into commerce.

All affected product returned will be identified and not for sale or distribution, then disposed of properly.

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 is destruction. The operation will not try to reuse the product under any circumstance. It will be documented as "damaged goods" and be disposed of properly away from the production area.

Recall Effectiveness

The operation 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 90%, 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.

Mock Recall

In addition to an annual verification of the recall plan, the operation 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 and email address of recall coordinator should be confirmed and updated as often as necessary to assure accuracy.

Contact Information

· Recall Coordinator (24/7):

Name: _____

Phone Number: _____

Email: _____

· Recall Coordinator (24/7):

Name: _____

Phone Number: _____

Email: _____

· Emergency Contact (24/7):

Name: _____

Phone Number: _____

Email: _____