

	Document Number P-263	Issue/Date 12/30/15	Revision #: 6 1.23.23	
Prepared By: QA Manager	PRODUCT WITHDRAWAL & RECALL PROGRAM			Approved By: VP operations

1. PURPOSE:

The purpose of this Product Withdrawal & Recall Program is to safeguard the health and safety of consumers in the event a suspect product is shipped to a customer. As such, this protocol formulates the steps taken to 1) Determine the food safety issue 2) Locate the suspected product 3) Stop the use of the suspected product and 4) Remove the suspected product from distribution.

2. SCOPE:

This protocol also identifies some of the preventative measures in place to guard against a product recall materializing, lists the members of the Recall Team, and specifies their primary areas of responsibility. It also formulates a framework for mock recovery exercises – a scheduled test of the recall program pertaining to the traceability of the shipped product.

3. RESPONSIBLE:

President/General Manager
 QA Manager
 VP Operations
 Production

PRODUCT RECALL CONCEPTS AND PRINCIPLES

PRODUCT RECALL TERMINOLOGY

The term *PRODUCT RECALL* should not be used in a careless or general way by company personnel. It should be used when an actual recall is taking place; otherwise, the misuse of this term can lead to unfounded rumors and misleading inquiries by the customer and/or regulatory agencies. In addition, the differences between a *product recall*, a *market withdrawal*, and a *stock recovery* must be understood by everyone, particularly at the plant and sales level.

DEFINITIONS

- 1) **PRODUCT** – Any food subject to the jurisdiction of the Food and Drug Administration, intended for human consumption.
- 2) **PRODUCT RECALL** – A firm’s correction in the field or removal from the marketplace of products that are subject to regulatory action under the Food and Drug Administration’s current compliance policy.
- 3) **STOCK RECOVERY** – The firm’s removal or correction of a product that has not left the direct control of the firm; the product is located on the premises owned by or under the control of the firm, and no portion of the lot has been released for sale or use.
- 4) **MARKET WITHDRAWAL** – A situation where a firm removes or corrects a product involving a minor violation that would not be subject to legal action by the Food and Drug Administration or that situation which involves no violation (e.g., normal stock rotation practices).
- 5) **FIELD CORRECTION** – The repair, modification, adjustment, re-labeling, or destruction of a regulated product without its physical removal to the recalling firm’s control.
- 6) **CONSIGNEES** – This means anyone who received, purchased, or used the product being recalled.
- 7) **RECALLING FIRM** – The firm that initiated the recall of, or in the case of a Food and Drug Administration’s initiated recall, the firm that the Food and Drug Administration designates and the recalling firm, which may be the manufacturer of the finished product, or where appropriate, the labeler, re-packer, or distributor of the product.

A) **FDA RECALL CLASSIFICATION**

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- B) Class I Recall – This represents an emergency in which the consequences are immediate or long-term, life-threatening, and involve a direct cause/effect relationship. The product recall must be accomplished down to the consumer level as completely and rapidly as possible. The Food and Drug Administration would conduct effectiveness checks of known distribution points, would place the corporation on their need’s public recall list, and probably issue a public warning for the benefit of consumers having the affected product in their possession. Imminent public health problem leading to physical harm or death, 100% recovery, complete in a few hours (e.g., high glass contamination).
- C) Class II Recall – This represents a priority situation in which the consequences of exposure may cause temporary or medically reversible health problems. A life-threatening situation is unlikely. The Food and Drug Administration would place the corporation on a public recall list and possibly issue a press release if they deem it necessary. A possible health problem or regulatory out of compliance, target 100% recovery, complete in a few days (e.g., mislabeling, possible glass contamination).
- D) Class III Recall – This represents a situation involving serious product violations not directly related to any health hazard. The Food and Drug Administration would still place the corporation on a public recall list but would probably not issue a press release. The threat to company reputation, complete in 1 to 2 (e.g., short shelf life, out-of-specification).

ANTICIPATED FOOD AND DRUG ADMINISTRATION REACTIONS TO...

THE THREE DIFFERENT RECALL CLASSIFICATIONS

1. Food and Drug Administration Reactions to Class I Recalls
 - A) Product recall to consumer or end-user level as complete and rapidly as possible.
 - B) One hundred percent effectiveness checks of known direct and sub-distribution points, including the consumer.
 - C) Recall placed on public recall list as Class I Recall.
 - D) Issuance of public warning via press and media.
2. Food and Drug Administration Reactions to Class II Recall
 - A) Product recall to retail level completely and promptly.
 - B) Effectiveness checks on a sliding scale depending on the seriousness of the hazard ranging upward from two to ten percent of known direct distribution points and upward from one to two sub-distribution points for each direct distribution point check.

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- C) Recall placed on public recall list as Class II Recall.
 - D) Possible issuance of the press release as circumstances warrant.
3. Food and Drug Administration Reactions to Class III Recalls
- A) Product recalls generally to a wholesale level only.
 - B) Minimum effectiveness checks.
 - C) Recall placed on public recall list as Class III Recall.
 - D) Ordinarily, no press release was initiated by the Food and Drug Administration; however, they will respond to inquiries from the press and public.

MARKET WITHDRAWAL

- 1. Usually, no effectiveness checks will be made on the adequacy of the withdrawal.
- 2. The withdrawal will not be placed on the Weekly Enforcement Report.
- 3. No press release will be initiated by the Food and Drug Administration; however, they will respond to inquiries from the press and the public.

A PRODUCT RECOVERY

- 1. Will not be placed in the Weekly Enforcement Report.
- 2. Usually, no effectiveness checks will be made on the adequacy of the withdrawal.
- 3. No press release will be initiated by the Food and Drug Administration; however, they will respond to inquiries from the press and the public.

FOOD AND DRUG ADMINISTRATION INITIATED RECALLS

There are two types of Food and Drug Administration-initiated recalls.

- 1. When the Food and Drug Administration determines that a marketed product violated the law and so informs the responsible firm, a later recall of the product by that firm is considered an

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“FDA Initiated Recall,” even though such action has not been specifically requested by the agency.

2. When the use of a product presents an imminent danger to consumer health or a significant consumer deception and immediate action is necessary, the commissioner or his designee will formally notify the firm of this determination and of the need to immediately recall the product.

Notification will ordinarily be by telegram to a responsible official of the firm. Notification may also be given by oral communication or by a visit from a representative of the local Food and Drug Administration District Office, with written confirmation from the commissioner or his designee afterward. The notification will specify the violation, the health hazard classification of the product in violation, the recall strategy, and other appropriate instructions for conducting the recall.

FIRM INITIATED RECALLS

A firm may, of its own volition and under any circumstances, recall a product from the market or correct it in the field. A firm that does so should immediately notify the appropriate Food and Drug Administration District Office when it has evidence confirming that this recall was warranted. Such removal or correction will be considered a recall only in the Food and Drug Administration regards the product in violation and is subject to legal action. In such cases, the firm will be asked to provide the Food and Drug Administration with the following information:

1. Identity of the product (s) involved.
2. Description of the defect in the product, the date, and circumstances under which it was discovered.
3. Evaluation of the risk associated with the defect.
4. Quantity of such product produced at a time span of production.
5. Quantity of such product estimated to be in distribution channels and identity of all consignees.
6. A copy of the firm’s recall communication, if any, has been issued or a proposed communication if none has been issued.
7. Proposed strategy of the firm for conducting the recall.
8. Name and telephone number of the firm’s official who should be contacted concerning the recall.

The Food and Drug Administration will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm’s strategy for recall, and advise the firm that its recall will be placed in the Weekly Food and Drug Administration Enforcement Report.

FACTORS THAT COULD PRECIPITATE A PRODUCT RECALL

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The following is a list of the most often encountered factors, which could precipitate a recall situation:

1. Microbiological and/or Toxigenic contamination (i.e., Salmonella and Staph toxin)
2. Mycotoxins and Aflatoxins
3. Rodent, insect contamination
4. Pesticide contamination
5. Illegal use of food and color additives
6. Product was prepared, packed, or held under unsanitary conditions.
7. Foreign material contamination
8. Product decomposition
9. Leaky and/or swollen containers
10. Label mix-up, illegal or inadequate labeling.
11. Misbranding
12. Faulty manufacturing practices (i.e., mis-formulation)
13. Heavy metals
14. Short weights/slack fill

KEY ELEMENTS OF A PRODUCT RECALL SYSTEM

1. **Depth of a Recall** – This refers to the level of product distribution to which a recall is to extend. There are three basic options.
 - A) Consumer or user level
 - B) Retail-level
 - C) Wholesale level

In cases where a health hazard is imminent, the depth of recall would be at the consumer or user level. This depth of recall also requires removing the product from intermediate distribution levels (e.g., retail and wholesale). For products in violation that pose a lesser hazard or otherwise appropriate, the depth of recall may extend only to the retail or wholesale level, but not to the consumer or user level. In other situations, there may be a recall only at the wholesale level.

2. **Effective Checks** – This involves the verification that consignees have been notified of a recall and have taken appropriate action. The Food and Drug Administration considers such effectiveness checks

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to be a vital part of the overall responsibility of recalling firms. However, to ensure that the recalling firm is fulfilling its responsibilities, the Food and Drug Administration will monitor the efforts of a firm, and, where necessary, initiate its own effectiveness checks.

Effectiveness checks can be carried out by direct visits, telephone, letters, or other verified methods to assure that consignees have been notified of the recall and have taken appropriate action. The magnitude of effectiveness checks, contingent upon the recall classification, are as follows:

LEVEL A – One Hundred percent of the total number of known consignees, and, if necessary, consumers to be contacted.

LEVEL B – Any percentage of the total number of known consignees to be contacted that is greater than LEVEL C but less than LEVEL A.

LEVEL C – Ten percent of the total number of known consignees to be contacted.

LEVEL D – Two percent of the total number of known consignees to be contacted.

LEVEL E – No effectiveness checks.

RECALL COMMUNICATIONS

The importance of timing in communications is essential in a recall situation. One cannot over-emphasize the importance of being ready with advanced procedures and prototype language, which can be customized rapidly with specific and authoritative facts. Prompt execution of the communications program is essential if consumer and customer understanding, and confidence are to be maintained.

A recalling firm is responsible for promptly notifying each of its consignees in the event of a recall. This can be accomplished by telegrams, mailgrams, or first-class letters conspicuously marked, preferably in bold red type on the letter and envelope “URGENT FOOD RECALL.” Telephone and/or personal contacts should be confirmed by one of the above methods.

Regardless of the method used, communication should be brief and to the point. It should clearly identify the product packaging, Lot or code numbers, package size, and any other information to enable accurate identification of the product being recalled and include a concise explanation of the reason for the recall and the nature of the violation and hazard involved, if. The communication should not contain qualifications, irrelevant statements, promotional materials, or other statements that may detract from the message. The recalling firm should also provide instructions and a ready means for the recipients of the communication to report to the recalling firm whether they have any of the product’s g., by sending a postage-paid, self-addressed postcard). Follow-up communications should be sent to consignees that fail to respond to the initial recall communications.

MEDIA/PRESS COMMUNICATION GUIDELINES

Although there is no guarantee that a market withdrawal or product recall will not receive public attention, it does not necessarily follow the placing of a product on the Food and Drug Administration recall list will result in widespread publicity. The most significant factor in pre-judging the probability in this area is

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related to the degree to which the product in question represents a health hazard. Other factors enter the question, such as the breadth of distribution, and familiarity of the public with the product. The point here is that one should be cautious of the possibility of triggering more or unwarranted public notice that would have occurred otherwise.

While neither the Food and Drug Administration nor the press can be expected to protect a company to the detriment of what they believe to be public interest, one should nevertheless avoid, at all costs, letting communications create an adversary relationship. The appearance of secrecy concerning these matters should be avoided. Such action will invariably be given unfavorable interpretations. The patience of all might be tried, but it is important to maintain a positive attitude.

It is important to remember that the Freedom of Information Act makes it mandatory for the Food and Drug Administration to disclose the information if requested, about a firm's contact and dealings with the agency.

In the event of an impending recall situation, a designated Public Affairs individual should prepare a news release containing all essential information. This release should be cleared by the firm's Recall Team, owners, and if necessary, legal counsel. As a rule, the release should contain the following information:

1. Identification of suspect product/package, code/lot number, package sizes, and probable market distribution areas.
2. An Approximate number of cases and packages subject to recall. This is done to put the extent of the problem into proper perspective quantitatively.
3. A concise explanation of the reason for the recall.
4. Embargo and recall steps instituted or being instituted, including coordination with appropriate regulatory agencies and other external organizations (trade, etc.).
5. Investigate steps being taken to determine probable cause.
6. Corrective measures to prevent a recurrence.

In other words, it should be clearly demonstrated that the company is taking vigorous action to protect the consumer. Background information, including prior safety records, a reference to Quality Control, etc., may be appropriate to the subject. The release of a letter containing similar information should also be prepared for simultaneous distribution to the trade, customers, distributors, management personnel, employees, etc.

FOOD AND DRUG ADMINISTRATION/FIRM COMMUNICATION

The recalling firm should submit periodic status reports to the appropriate Food and Drug Administration District Office. This report contains the following information:

1. Number and identity of consignee notified to date and method of communication.
2. Several consignees responded to the recall communication and the number of products on hand at the time it was received.

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3. Number of consignees that did not respond.
4. Quantity of product retrieved or corrected by each consignee contacted and the quantity of product accounted for.
5. Number and results of effectiveness checks that were made.
6. Reconciliation of the number of products accounted for the amount estimated on the market.
7. Time frames for completion of the recall.

PRODUCT CODING AND RECORD KEEPING

Recall of a particular lot of a consumer product is impossible without a legible code. The alternative is a total recall of all similarly labeled products. Plant batch codes help make product recalls or withdrawals possible. They are useless if illegible for any reason.

Plant/batch codes on products are used to identify production dates, production plant, batch, line, shift, hour, and other information of use to the manufacturer in monitoring the product during its entire market life. They are also used by Quality Assurance and other technical personnel in combination with their records of raw material histories, process logs, formulation, and similar production information to relate anything, which happens to the product during its market life with these factors.

Most manufacturers place codes on shipping cartons to assist in inventory controls, stock rotation, and proper identification of product lots throughout the distribution system. In an emergency recall situation, codes on product cases can save valuable time. Consecutive numbering of cases or shipping containers also helps pinpoint a specific lot.

Occasionally a product lot, which is perfectly acceptable during the initial Quality Control test, may show product defect during distribution. Plant/batch coding tied in with distribution records, which show the allocation of that lot, facilitates withdrawal of that lot from the marketplace, if necessary. Coding provides a means of tracking consumer complaints to establish their validity, provides legal protection from false claims, and allows the manufacturer to discover faults due to production, distribution, or retailing.

Any code must be free of redundancy and must be definitive and, in the context of recalls, should be significant in identifying specific segments of production. Regardless of the product coding system used by the manufacturer, the system must have three essential characteristics:

1. Be legible to company personnel.
2. Be legible to regulatory agencies.
3. Be legible to the consumer.

Plant and distribution product coding records should be sufficiently documented and detailed to facilitate the prompt location of products in the event of a recall. Product coding records should be maintained for a period that exceeds shelf life or is expected to use the product.

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DISPOSITION OF RECALLED PRODUCT

All movement, reconditioning, and/or destruction of the recalled product should be monitored by responsible personnel to assure close controls and to avoid inadvertent product release to the public. Also, the recalled product should not be disposed of through commercial salvage operations, charities, institutions, etc. The Food and Drug Administration should be notified of the firm’s method of recalled product disposition prior to its actual disposition so as not to further exacerbate the recall situation.

PRODUCT RECALL DOCUMENTATION

All events, activities, decisions, and communications that occurred prior to and during the recall should be documented in a chronological, concise, objective manner. Specifically, this document should contain the causal factors, which precipitated the recall, administrative/technical successes and failures that occurred during the recall, and a description of the corrective measures that were instituted to prevent a recall in the future. Most importantly, this document will serve as a valuable reference source that illustrates the weakness of the current recall program, which should be strengthened, and deficiencies in the manufacturing operation, which should be corrected.

PROGRAM

STEP ONE

STEP ONE – When an employee of Brooklyn Provisions INC (i.e., plant manager, regional sales manager, customer service, etc.), is alerted to the fact that a regulatory agency (i.e. Food and Drug Administration) is considering a recall of a product or becomes aware that product produced at this facility may be adulterated, misbranded, or contain a health hazard, he/she shall promptly notify the Recall Coordinator. The coordinator shall then convene members of the Recall Team (listed below).

NSF Certification Body

STEP TWO

STEP TWO – The Recall Team must gather accurate and complete information pertaining to the food safety issue utilizing the checklist outlined below. If the product affected is produced for an outside customer, that customer must be notified and consulted for the appropriate action to take. Procedures for recall shall be determined using the affected customer’s policy in this instance.

Recall Procedure Checklist

Before conducting a product recall, the product recall team will make a judgment as to whether the product in question is:

- A) Misbranded
- B) Adulterated
- C) Contains an actual threat to the health and safety of the consumer.

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- E. Quantity of such product estimated to be in distribution channels and identity of all consignees.
- F. Copy of the firm's recall communication, if any has been issued, or a proposed communication if none has been issued.
- G. Firm's proposed strategy for conducting a recall.
- H. Name and telephone number of the firm's official who should be contacted concerning the recall.
 - 2. The product recall team will prepare a statement for the media, if necessary, and will also notify any regulatory agencies that may have jurisdiction over the problem.
 - 3. The team will then coordinate the recall action plan according to the departmental responsibilities listed below. All information as it is gathered is to be transmitted to the Recall Coordinator who is responsible for keeping an accurate log of all events for future reference.

BASIC DEPARTMENTAL RESPONSIBILITIES DURING A PRODUCT RECALL

The following is a list of activities, which each department should carry out on a priority basis to facilitate a product recall. This list is not all-inclusive, but rather just highlights key activities. Additional duties may be assigned, contingent on the magnitude and seriousness of the product recall.

RECALL COORDINATOR – has the absolute authority to enlist the services of all segments of the company during a product recall on a priority basis. Specifically, he/she will:

- 1. Notify management that a product recall is in effect.
- 2. Direct and coordinate all activities associated with the product recall.
- 3. Collate and summarize all pertinent data and information relevant to the product recall to make periodic status reports to the regulatory agencies.
- 4. Notify the Food and Drug Administration that a product recall is to be initiated.
- 5. Act as the primary communications link with the Food and Drug Administration in matters relevant to the product recall.
- 6. Maintain a documented chronological log of product recall activities.
- 7. Function as the central coordinating point for internal and external communications prior to, during, and after the recall.
- 8. Conduct a post-mortem on the product recall to identify causal factors and recommend preventative, corrective measures.

QUALITY CONTROL

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1. Advise, assist, and coordinate all product recall-related activities.
2. Review all pertinent Quality Control and manufacturing records for recall causal factors and recommend corrective measures.
3. Determine, with assistance from the Recall Team, the disposition of the product, and any further testing or sampling that may be necessary upon return of affected items.
4. Advise and assist other functional areas on an as-needed basis.

DISTRIBUTION

1. Stop all in-transit shipments of suspect products.
2. Arrange for the return of all suspected products in the field to a central location and/or designated public warehouses.
3. Prepare inventory and distribution status reports on the suspect product. Show where, when, how much, and to whom the product was shipped.
4. Embargo and segregate all suspect products at the facility and at designated public warehouses.

SALES AND MARKETING

1. Notify Regional Sales Directors.
2. Arrange for proper customer credit to be given, contact all customers, and have shipments of suspect products stopped.
3. Notify all retail outlets to immediately pull the product from shelves and hold it.
4. Utilize sales force in product pick-ups.

MANUFACTURING

1. Hold production of suspect product.
2. Identify lots, batches, codes of the suspect product, and raw materials used therein.
3. Review production schedules and materials inventory with Management and Sales.

PURCHASING

1. Identify alternate sources of ingredients and packaging materials.

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2. Update inventory of ingredients and packaging materials.

FINANCE

Monitor and tabulate all the costs of the recall effort.

1. Alert insurance carrier.
2. Conduct a comparative cost analysis of salvage versus destruction.

LEGAL

1. Audit all recall activities to see that they conform with the legal obligations of the company and yet do not expose the company and its employees to subsequent legal actions on the part of the customer, consumer, or regulatory agencies.
2. Advise and assist the Recall Coordinator on an as-needed basis.

ADMINISTRATION – PUBLIC AFFAIRS

1. Prepare and issue recall notices, recall letters, telegrams, etc., and all subsequent press releases to the media, trade, and customers. This department is the sole contact with the press and other media and may be a designated internal employee or a contracted public relations representative.

If the problem falls under Category Two or Three, the recall team will determine the steps to be taken in each instance, although the responsibilities and steps taken shall be like that of a Category One Recall.

As the product is recalled to a central location, it is imperative to reconcile the amount returned and destroyed with the amount originally produced.

Product Destruction Procedures

1. Inventory all recalled finished cases by lot number and quantity.
2. Compare the actual amount returned to the recall coordinator's report of the amount identified as produced by the recall coordinator.
3. If the product needs further inspection, complete inspection by random samples determined by the recall coordinator.
4. Prior to the discarding of the recalled product, all brand names identified on the shipping case are to be removed or covered up completely. Use black spray paint or a bold print, and black magic marker for smaller prints if applicable.
5. Open all cases of product to begin final contamination, and spray actual product with denaturant (if the product is subject to USDA inspection) where applicable.

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6. Contact the trash hauler to remove the filled bin of contaminants. Either have an employee follow the trash hauler to the dump to verify actual disposal or have the disposal company issue a letter stating the verification of the disposal.
7. Complete Finished Goods Distribution forms and submit them to the recall coordinator.
Notify the recall coordinator that the destruction and disposal of the recalled product are completed.

TERMINATION OF WITHDRAWAL/RECALL

The following must be completed before the termination of the product recall:

- A. All questionable product has either been returned, disposed of, or destroyed.
- B. All pertinent information must be compiled and completed.
- C. Returned product reports must be filed.
- D. If the product is destroyed, USDA must be notified and an MP407 completed.
- E. Confirm that USDA agrees with the determination of the recall.
- F. All information must be on file with the Recall Coordinator. This includes withdrawal and recall tests, root cause investigations into the **actual** recall, and corrective and preventive actions taken.

STEP FOUR

STEP FOUR – follow-up with appropriate good manufacturing practices training, so the situation does not repeat itself.

GMP Training for Food Safety

Brooklyn Provisions Inc. believes regular GMP training is a key preventative measure, and that it safeguards against the possibility of a product recall materializing in the first place. For this reason, Brooklyn Provisions has an ongoing employee-training program for new and annually existing employees in Good Manufacturing Practices (GMPs). Food safety GMPs, moreover, are discussed in crew training meetings, and every effort is made to reiterate the importance of food safety as a paramount component in fulfilling customer expectations. In the event, however, a product recall materializes, the GMPs associated with the situation shall be reviewed (and amended as necessary) with the parties involved, so the situation does not replicate itself.

STEP FIVE

STEP FIVE – Mock Recall Exercises.

Mock recalls are conducted once yearly and during these exercises, a product hypothetically suspected of being adulterated is traced and accounted for. A summary of the mock recall shall be written.

For the exercise, items shall be traced forward to the first customer as well as back to the suppliers from whom the raw ingredients were received. This will be recorded in summary. We have one shift at Brooklyn Provisions, so the mock recall reflects that. Also recorded will be the start and end time for the exercise, the created situation for

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the mock recall, and how smoothly the exercise progressed. If any part of the recall fails, it shall be done again within sixty days.

Brooklyn Provisions Inc. uses lot numbers and code dates for inventory and tracking purposes, as well as purchase order numbers. These systems enable tracking during mock recall exercises and in the event of any incident that could require this Product Recall Program to be exercised.

Testing for root causes for mock recalls has been removed from the SQF program.

The company target for the mock recall is a recall rate of 99.5 – 100% within two hours.

RECALL FORMS

PRODUCT RECALL CHECK-OFF LIST

Recall Number _____ Date _____

- _____ 1) Did the contact document source name, identity, source phone number, product item number, product description, code dates, location of the incident, and reason for the possible recall?
- _____ 2) Did Recall Coordinator contact General Manager?
- _____ 3) Did the Recall Team contact production to verify the product number, code dates, and number of cases packed and retrieve copies?
- _____ 4) Did the Recall Team contact Customer Service/distribution centers to verify the product item number and several cases shipped against inventory records?
- _____ 5) Did Customer Service/Distribution document quantity and product locations?
- _____ 6) Did Customer Service/Distribution contact all applicable distribution warehouses to perform code date inventory, retrieve samples for Quality Assurance if necessary, and product records for locations of the product?
- _____ 7) Did Customer Service/Distribution contact either Buyer or Broker for notification of area sales representatives and brokers?
- _____ 8) Did the President of Sales notify sales representatives/brokers of this?
 - _____ (a) Affected accounts.
 - _____ (b) Reason for recall and potential hazard.
 - _____ (c) Identify product, size, lot numbers, code dates, etc.
 - _____ (d) Further distribution or use of the product should cease.
 - _____ (e) Direct account notification of customers receiving the product about the recall.
 - _____ (f) Instructions about what to do with the product.
 - _____ (g) Sales representatives/brokers are directly involved in pulling the product off store shelves.
 - _____ (h) Continuous follow-up procedures are being completed.
- _____ 9) Did the Recall Requester have a time frame for the completion of a product recall?
- _____ 10) Did the Recall Coordinator notify FDA (if applicable) to discuss recall strategy, provide detailed information recall effort, receive the recall classification number, discuss public warning alert, and discuss recall status reports?

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- 11) Did the Recall Team reconcile all affected products produced and shipped with the product returned?
 _____ 12) Have accurate records been kept documenting the recall effort?

INITIAL SOURCE CONTACT FORM

Recall Number _____

Date _____

CONTACT PERSONNEL:

1. SOURCE NAME	TELEPHONE.
2. IDENTITY	
3. PRODUCT ITEM NUMBER AND DESCRIPTION	
4. CODE DATE(S)	
5. INCIDENT OR REASON FOR POSSIBLE RECALL	
6. COMMENTS / DISPOSITION	

COMPANY MODEL RELEASE

Contact Person: John Jones or Mary Moore at (123) 456-7890
DATE
FOR IMMEDIATE RELEASE

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ANYTOWN, ANYWHERE – Announced today that as a precaution it is recalling _____ processed at its _____ plant because of _____ detected in part of one day’s production. No illness has been reported. The company said its quality assurance personnel found the _____ in cases packed under code number _____ and distributed in _____.

The cases are _____ oz. size. Consumers in these and adjoining states who possess any _____ were asked by the company to _____. Refunds may be obtained by _____. The _____ was detected because of _____. The company’s findings and corrective actions were reported to the Food and Drug Administration. To prevent a recurrence, has _____. It was the first public recall of processed foods in the _____ year history of, a major processor of _____.

The company has packed more than (number) cases of foods since its incorporation in (year).

About _____ cases were affected. In addition to the label, the recall also involved _____ private labels. The company said it had recovered _____ percent of the recalled cases. Grocers and distributors have been advised to withdraw the product from sale and to hold it for pickup by the company.

Note: If the recall should involve a potential health hazard (botulism toxin), it is recommended that the release contain a definition, medical explanation, and some background. Many news media will attempt to define the problem and, moving in deadline speed, will report with greater accuracy if given a reliable source of information. Using botulism as an example, the following language is suggested.

“Most botulism cases result from eating improperly prepared home-canned foods. The incidence is c commercially canned foods estimated to be less than one in 100 billion cans. Botulism is a poisoning of the nervous system, caused by the toxin botulism, which is produced by spores of a one-celled bacterium, Clostridium, Botulism. The germ is widely distributed in the soil but cannot produce as a toxin when exposed to oxygen. In the processing of food, spores are destroyed by careful cooking at a prescribed temperature. for a designated length of time.”

MODEL COMMUNICATION

NOTICE TO CUSTOMERS

Note: Modified from an actual product withdrawal notice to the trade

DATE

TO OUR CUSTOMER:

In compliance with the announcement by Commissioner _____, of the Food and Drug Administration, Brooklyn Provisions Inc. has halted the production and shipment of all products containing _____. Also, in compliance with the Commissioner’s announcement, we have developed a policy for the orderly withdrawal of those products, we have attempted to keep the interests of both our consumers and our customers in mind. We have also taken in to account the protection of our valuable brand franchises.

Accordingly, we have decided upon the following trade policy:

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1. If counterpart products are available which contain no _____, we will replace the _____ products now in inventory with their _____ free counterparts.
2. For other _____ containing products for which there is no suitable counterpart, we will issue credit. Lists of those products will be replaced by counterparts and those for which credit will be issued are attached.

In all instances, the products provided as replacements are equal to or higher than the replaced. Products in invoice cost. The differences in invoice cost will be realized by our customers as an allowance. To expedite the handling of inventories at your warehouse, we ask that you take an immediate inventory of the products listed and provide this information to the Brooklyn Provisions Inc. Distributor, which supplies you. Replacements and credits will be handled promptly upon return of the inventories to the place designated by your Brooklyn Provisions Inc. Representatives. Retail inventories will be handled by our sales organization. A special order will be issued for product replacement. We suggest that you ask those stores served by you to remove the affected products from their shelves and hold them for a company.

MODEL COMMUNICATION

MODEL CUSTOMER ADVERTISEMENT

IMPORTANT SAFETY WARNING

**IF YOU HAVE RECENTLY PURCHASED A PACKAGE OF (product).
READ THIS AD.**

A _____ quantity of the Brooklyn Provisions Inc. brand of _____ now in distribution is being recalled because of a potential health hazard. Only _____ in the _____ package size (Net Weight) bearing embossed codes _____ through _____ are affected by this recall. Codes appear at the bottom of the package. These lots are considered suspect (dangerous) because of _____. Packages bearing the above codes are known to have been distributed to retail stores in the following cities (countries) between and _____, 200_.

Effective _____, all affected product(s) has been withdrawn from retail distribution. You may now purchase any Brooklyn Provisions Inc. product stocked by your grocery or supermarket with absolute safety. However, if you

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bought the product with the above codes, return it unopened to your grocer at once. He will refund your money promptly.

This is an ad we thought we would never have to run. For over _____ years, during which we have processed over _____ billion packages of food. Brooklyn Provisions Inc. has prided itself on hundreds of checks, precautions, and safeguards that have produced its outstanding safety record. Please help us to preserve this record. If you know of anyone who may have bought this product recently, shows them our ad. Thank you.

Brooklyn Provisions Inc.

PRODUCT RECALL CUSTOMER CONTACT FORMS

DATE:

CUSTOMER'S NAME
CUSTOMER'S ADDRESS

Dear _____:

On a date, you were notified by a letter that is recalling (product name), with code numbers.
_____ all products were manufactured by a distributed solely under the manufacturer's label.

The recall is a precaution due to (the reason for the recall).

The recall notice from _____ requested all consignees (wholesalers, retailers, and distributors) to hold and discontinue selling their existing stock of the product being recalled.

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_____ also requests an inventory amount on hand of the product in recall status. _____ will make all arrangements for replacement and pick up of the recalled product as soon as possible.

To advise the Food and Drug Administration about the effectiveness of this _____ recall, you are requested to complete and return the enclosed questionnaire promptly using the prepaid self-address envelope. If you have any questions or problems with the request, please call _____. Thank you for your cooperation.

Sincerely,

Recall Coordinator

PRODUCT RECALL QUESTIONNAIRE

NAME
ADDRESS

Please read each question and check the proper answer you have chosen. Please check with anyone who may have received this notification before answering.

DATE

1. Did your firm receive notification that _____ is recalling its (name) product?
Yes _____ No _____
2. Did your company receive shipments of the product being recalled? (If no, please sign and return.)
Yes _____ No _____
3. Do you now have any of the recalled product on hand? Please check inventories before answering.
Yes _____ No _____
4. If the answer to question 3 is Yes, do you intend to return the product to _____ as requested?
Yes _____ No _____
5. If the answer to question 4 is No, please explain your intentions _____.
6. Have you received any reports of illness or injury related to this product?
Yes _____ No _____

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Name of the person completing questionnaire: _____

DISTRIBUTOR/STORE QUESTIONNAIRE

PLEASE FILL OUT AND RETURN

_____ do
_____ do not have any stock of _____ on hand.
(The product, product number, lot)

We have requested our customers to return any of these products to us.

We currently have _____ of the product on hand.
(amount)

NAME _____

ADDRESS _____

CITY _____

TELEPHONE PRODUCT RECALL EFFECTIVENESS CHECK

Company's names
Company's Address

After contacting the consignee and locating the person responsible for handling recall notification and/or the product involved, an opening like the following may be used:

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This is (name of interviewer). I am calling for _____ to check on the effectiveness of the company recall of (product description, including codes). On (date), we notified (how: By letter, telephone, visit, mailgram, etc.), all firms which may have purchased (product) that all stock should be (returned, destroyed, modified, re-labeled, etc.). I have the following questions to ask you about this recall:

DATE _____

- Did your firm receive notification the (product name) manufactured by _____ are being recalls?
Yes _____ No _____
- Did your firm receive shipments of the product being recalled? (if no, terminate questioning and to the closing)
Yes _____ No _____
- Do you have any of the recalled products on hand? (Please check inventories before answering).
Yes _____ No _____
- If the answer to question 3 is Yes, do you intend to return the product to _____ as requested?
Yes _____ No _____
- If the answer to question 4 is No, please explain your intentions _____.
- Have you received any reports of illness or injury related to this product?
Yes _____ No _____

PRODUCT RECALL TERMINATION FORM

DATE: _____

TO: _____

FROM: Recall Coordinator

SUBJECT: Termination of Recall

Dear _____:

This letter officially informs you that the recall of (product and code numbers) brand has been completed. _____ has exhausted all channels to locate any inventory of the recalled product. All (or a percent of total product produced) recalled product has been located, and either retrieved, destroyed, re-labeled, or modified to _____ standards.

Sincerely,

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Recall Coordinator

FINISHED GOODS DESTRUCTION FORM

PRODUCT

LABEL

QUANTITY

DESTRUCTION METHOD

FINAL DESTINATION OF DESTROYED PRODUCT

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Recall List

SQFI Certification www.sqfi.com
Responsibility: Governs the certification body

NSF Certification Body Siliker

Halal Halal Watch World

Lawyer name: James A. Kridel, Jr., **Law Firm:** Kridel Law Group Phone number:(973) 470-0800
Responsibility: Expert & Legal advice