

TRACE RECALL PROGRAM

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TRACE RECALL PROGRAM

INTRODUCTION

AUTHORITY

The Food and Drug Administration receives its authority to recall adulterated or misbranded product from sections 301(Prohibited Acts), 402 (Adulterated Food) and 403 (Misbranded Food) of the Federal Food Drug and Cosmetic Act.

GUIDELINES

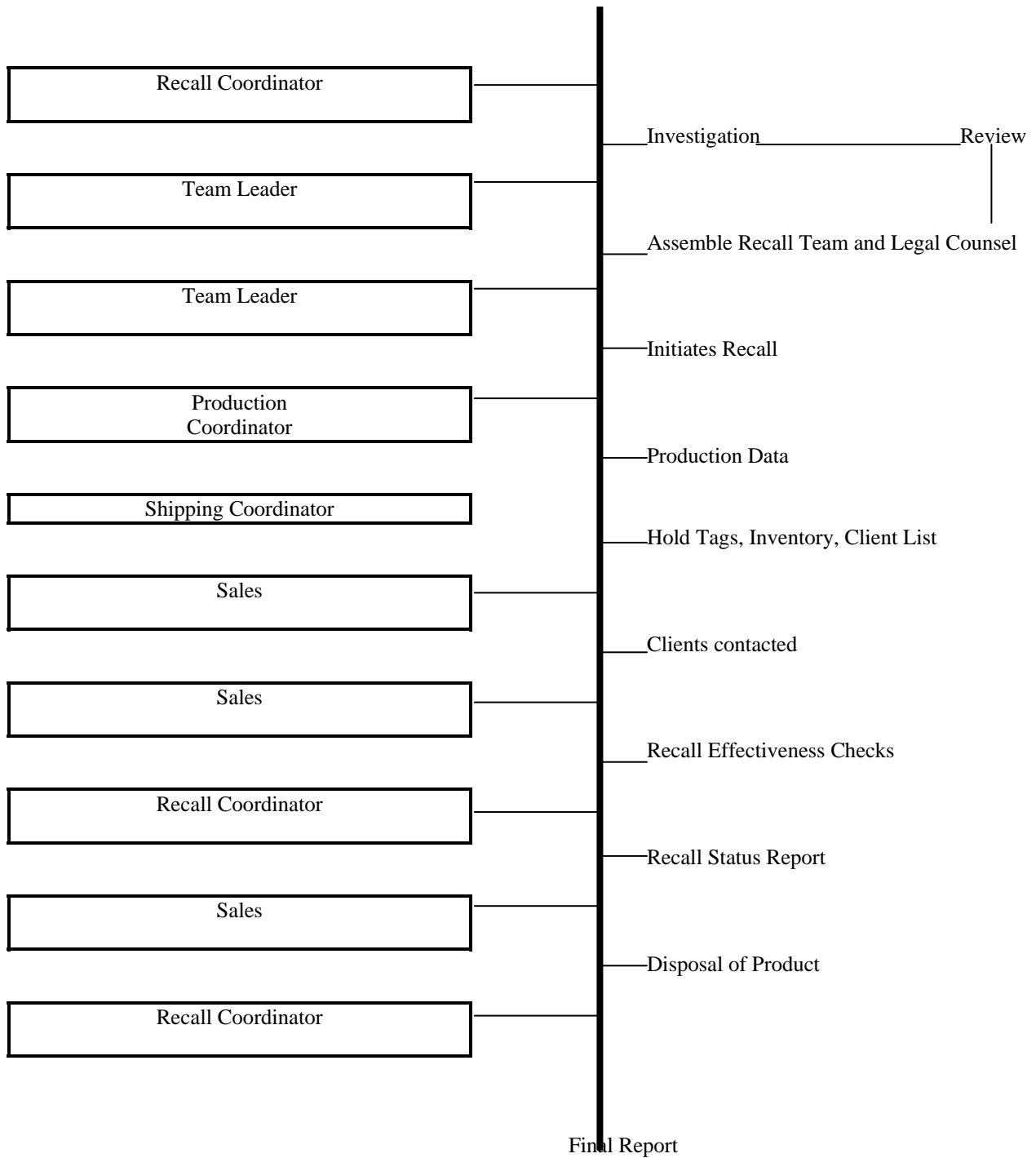
The Food and Drug Administration established voluntary guidelines for conducting product recalls related to all foods in 1979. These guidelines may be found in the Federal register Vol. re. No. 117 - Friday, June 16, 1978, Recall Enforcement Policy. Subsequent amendments to these guidelines may be found in 21CFR7.41 (refer to Appendix A). This is recommended reading for all persons on the product recall team.

DESCRIPTION OF PRODUCT RECALL

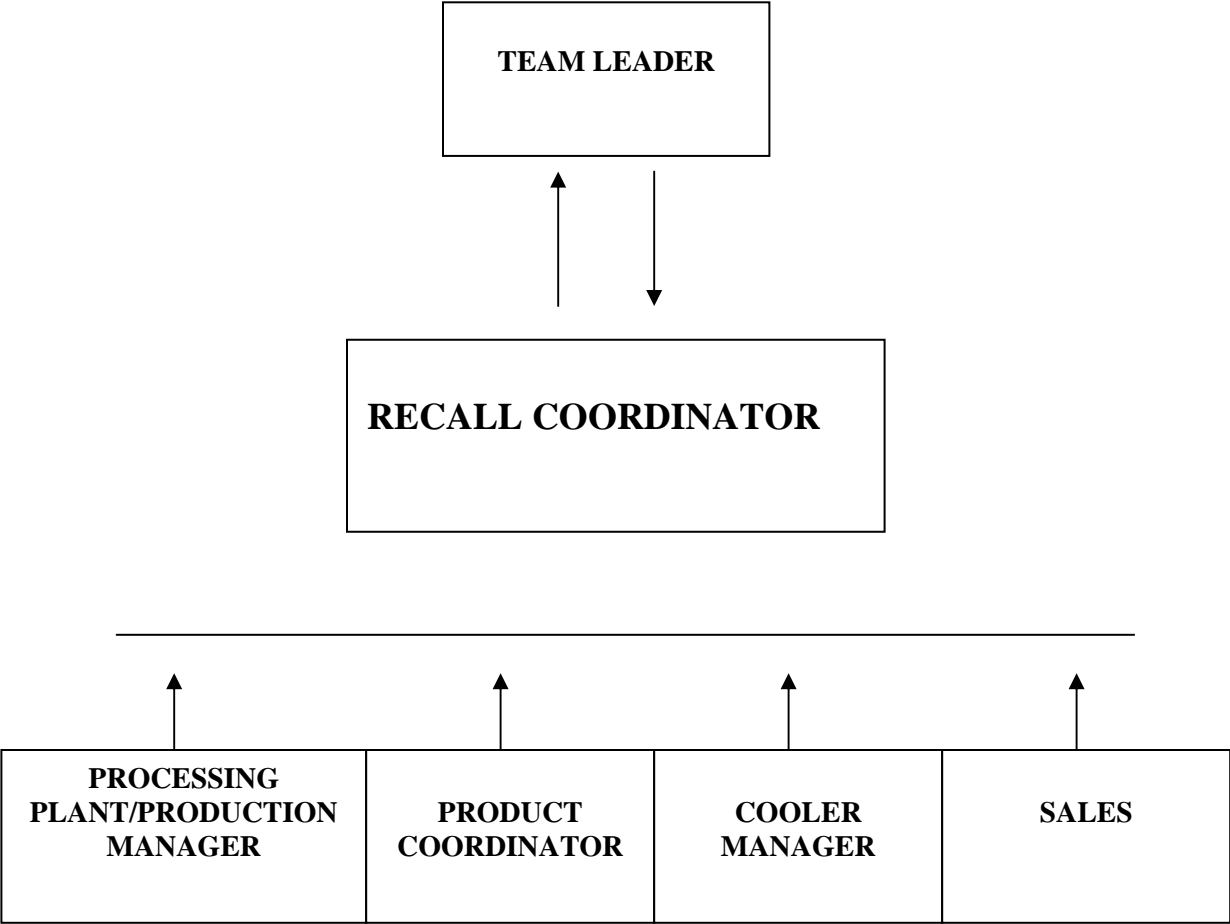
1. A product recall is the removal or correction from the channels of distribution and consumption of any product deemed to be potentially hazardous or defective.
2. Market withdrawal of a product is the removal or correction from channels of distribution and consumption of any product where no legal violations have occurred, or only minor violations that under normal circumstances would not be subject to legal action, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.
3. Stock recovery is 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. For example, the product is located on the premises owned by, or under the control of, the firm and no portion of that lot have been released for sale or use.

PROCEDURAL FLOW CHART

Potential Health Hazard



INFORMATION FLOW CHART



INDIVIDUAL RESPONSIBILITIES

TEAM LEADER

1. The president bears the ultimate responsibility for determining the necessity for a product recall. This decision should be made with the input of appropriate organizational personnel and legal counsel. Upon being informed that a FRESH KIST PRODUCE, LLC. product poses a potential health hazard to consumers, the president of the company will summon the Recall Team to determine the necessity for a product(s) recall, its interim classification and depth.
2. Instructs the recall coordinator to initiate the Trace/Recall Program.
3. Maintains contact with legal counsel throughout the recall process. Only the president is to issue statements or release communications to the media, relative to the situation, if it should become necessary. See Appendix A, Public Warning (CFR21, Pg. 26219, Part 7.42 (b), (2)).

RECALL COORDINATOR

1. Upon receiving information that a FRESH KIST PRODUCE, LLC. product may pose a potential health hazard to consumers, or may be defective, the Recall Coordinator and Processing/Production Manager will immediately begin investigating the suspected product and the events leading to its suspected status. They will determine if the product(s) is indeed a potential health hazard to the consumer.
2. Informs the president immediately and presents all factual data regarding the suspected product, and keeps him informed as events unfold when there is a suspicion that a product recall may become necessary.
3. Obtains and interprets all pertinent data and communicates directly with the president of the company and all other appropriate individuals involved in the recall effort.
 - Obtains all pertinent production data necessary for the suspected product(s) recall from the Processing/Production Manager.
 - Provides the cooler manager with the suspected product (s) code date and any other required information necessary for the recall.
 - Obtains an inventory of the suspected product(s) that may remain at the FRESH KIST PRODUCE, LLC. cold storage facilities and a complete list of clients who were shipped suspected product(s) from the Processing/Production Manager.
 - Provides Sales with the complete list of clients who were shipped suspected product(s).
4. Is the primary contact if it becomes necessary to involve the FDA in the product(s) recall. FDA notification of your intent to initiate a product recall must include:
 - Identity of the product involved.
 - Reason for the removal or correction, and the date and circumstances under which the product (s) deficiency or possible deficiency was discovered.
 - Evaluation of the risk associated with the deficiency or possible deficiency.
 - Total amount of suspected product produced and/or times span of the production.
 - Total amount of the suspected product estimated to be in distribution channels.
 - Distribution information, including number of direct accounts and, where necessary, the identity of the direct accounts.
 - A copy of the firm's Recall Communication if any has been issued, or a proposed communication if none has been issued.
 - Proposed strategy for conducting the recall.
 - Name, title and telephone number of the firm official who should be contacted concerning the recall.
5. Shall prepare recall status reports as well as a final report at the conclusion of the recall process. See Appendix A, Termination of a Recall (CFR 21, Pg. 26221, Part 7.55 (a) & (b)) for these requirements.

PRODUCT COORDINATOR

1. Provides the Processing Plant/Production Manager with a code date of the suspected product(s) and obtains all the pertinent production data necessary for the product(s) recall to the recall coordinator.
2. Provides the Recall Coordinator with all the pertinent production data necessary for the product(s) recall.
3. Obtains an inventory of the suspected product(s) that may remain at the Fresh Kist Produce, LLC. cold storage facility and a complete list of clients who were shipped suspected product(s).

4. Provides the Recall Coordinator with daily Recall Status reports.
5. Provides a log of all pertinent data and events relating to the product recall for Recall Coordinator.

PROCESSING PLANT/PRODUCTION MANAGER

1. Utilizing the code date of the suspected product(s) and appropriate production forms, obtains all the pertinent production data necessary as quickly and as accurately as possible for the recall coordinator
 - The time period, day(s) during which the suspected product(s) was processed.
 - The affected lot(s), location(s), ranch(es) and block(s).
 - The total volume of finished product cases manufactured.
 - Any special orders, they're total and individual finished product volumes (cases), and the lot(s), locations(s), ranch(es), and block(s) where they were harvested.
 - The different types of cases, case sizes and identification markings utilized and their individual finished product volumes (cases, pallets, etc.).
2. Provides the information gathered under item 1 to the Recall Coordinator as it is retrieved.

COOLER MANAGER/DISTRIBUTION

1. Utilizing the code date and the appropriate shipping forms, determines the following information as quickly and as accurately as possible:
 - The current location(s) and total volume (cases) of all suspected product(s) within FRESH KIST PRODUCE, LLC. cold holding facilities.
 - The total volume (cases) of suspected product(s) shipped to each client.
2. Has all suspected product(s) within FRESH KIST PRODUCE, LLC. cold holding facilities gathered together, isolated and then tagged, "Hold - Do not Ship."
3. Provides the information gathered under item 1 to the Production Manager as it is retrieved.

SALES

1. Utilizing the client list provided by the Cooler Manager/Distribution and other appropriate ordering and shipping forms, coordinates the sales staff to contact all clients who received shipment of suspected product(s). Make the clients aware of the Trace/Recall effort in progress by the facsimile transmission of a Recall Letter and follow-up with telephone calls verifying the receipt of the recall letter.
2. IF THE CLIENT(S) IS DISTRIBUTING THE SUSPECTED PRODUCT(S), have the client utilize the code date and their own appropriate shipping forms to determine the following information, and perform the following tasks as quickly and accurately as possible:
 - The current location(s) and total volume (cases, pallets, etc.) of all suspected product(s) within the client's cold storage distribution center(s).
 - The total volume (cases) of suspected product(s) shipped and a list of affected clients.
 - The individual total volume (cases) of suspected product(s) shipped to each client.
 - Have the client(s) cease all further distribution of the suspected product(s).
 - Have the client(s) gather together and isolate all suspected product within their cold holding
 - Work out the necessary arrangement with the client(s) to return suspected product(s) to FRESH KIST PRODUCE, LLC.. or dispose of it in an appropriate manner. If the decision is made to dispose of the suspected product(s), FRESH KIST PRODUCE, LLC.. must send a representative from their company to verify the appropriate disposal of the product. Photographic evidence thereof, or photos and land fill receipts provided by the client shall evidence and verify the appropriate disposal of the suspected product(s).
3. IF THE CLIENT IS NOT DISTRIBUTING THE SUSPECTED PRODUCT(S), have the client utilize the code date and their own appropriate receiving forms to determine the following information and perform the following tasks as quickly and as accurately as possible.
 - The current location(s) and total volume (cases, pallets, etc.) of all suspected product(s) within the client's store(s).
 - The total volume (cases) of suspected product(s) sold at consumer level.
 - Have the client(s) cease all further distributing and use of the suspected product(s).

- Have the client gather together and isolate all suspected product(s) within their store(s) and tag it, "Hold - Do Not Use."
 - Work out the necessary arrangements with the client to return the suspected product(s) to FRESH KIST PRODUCE, LLC.. or dispose of it in an appropriate manner. Once the decision is made to dispose of the suspected product(s), FRESH KIST PRODUCE, LLC.. must send a representative from their company to verify the appropriate disposal of the product. Photographic evidence thereof, or photos and land fill receipts provided by the client shall evidence and verify the appropriate disposal of the suspected product(s).
4. Provides the information gathered under items 2 and 3 to the Product Coordinator as it is retrieved.
 5. Recall effectiveness checks may be carried out by telephone calls, facsimile transmissions, or personal visits as often as is necessary to accomplish their intended purpose. The objective of the follow-up is to verify that all the consignees are taking the appropriate actions and that all, or as much as is humanly possible, of the suspected product(s) has been accounted for.

PRODUCT CODE DATE

REQUIREMENTS

1. Good Manufacturing Practices require the meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or re-packing activity.
2. The code date is utilized to facilitate positive lot identification and the isolation of specific food lots that may have become contaminated or otherwise unfit for their intended use.
3. Records should be maintained for a period of time beyond the expected shelf life of the product, but need not be retained for longer than two years.

CODE DATE

1. The product code contains 4 important pieces of information:
 - The Shipper code.
 - The Julian date the product was processed.
 - The location (Salinas, Yuma or Heron).
 - The lot number.
2. The FRESH KIST PRODUCE, LLC., code date is composed of the Julian date. The first and second digits comprise the Shipper code; the third, fourth and fifth digits are the reverse Julian Date and indicate the month and the day of the product's use by date; the sixth digit is the location code (1=Salinas, 2=Yuma and 3=Heron)
3. The FRESH KIST PRODUCE, LLC. lot number comprises a unique three digit ranch number.

PLACEMENT

1. Every package and/or case of product will be identified with the appropriate code date. It will be legible, easily located, and preceded by the words "CODE DATE", so as not to confuse it with any other sequence of numbers or letters placed on the package and/or carton.
2. The code date will be entered on all appropriate quality control records, production reports, and shipping forms, so that the product can be traced at a later date if necessary.

RECALL CLASSIFICATIONS

CLASS I RECALL

An emergency situation in which there is a reasonable probability that the use of, or exposure to, a volatile product will cause serious adverse health consequences or death. Pathogenic organisms such as *Clostridium botulinum* and *Listeria monocytogenes* in the product would be given this classification. Abiotic materials such as leachable lead at 400 parts per billion in the product would also be given this classification. Other pathogenic organisms may also be considered in this classification depending upon the specific situation, amount of product distributed, extent of product consumed, age and health of the individuals exposed, etc.

CLASS II RECALL

A priority situation is the use of, or exposure to, a volatile product may cause temporary or medically reversible adverse health consequences. Or when the probability of serious adverse health consequences is remote. For example, pathogenic organisms exclusive of *Clostridium botulinum* or *Listeria monocytogenes* in the product. Other pathogenic organisms, such as *Salmonella*, *Shigella*, *Staphylococcus aureus*, or indicator organisms such as *E. coli* in the product are candidates for this classification. Again, depending on the specific situation, amount of product distributed, extent of the product consumed, age, and health of the individuals exposed, other pathogenic organisms may also be considered in this classification. Abiotic materials such as leachable lead in this product at 10 parts per billion would be considered in this classification.

CLASS III RECALL

A situation in which the use of, or exposure to a violative product is not likely to cause adverse health consequences, for example, adulterated or misbranded products that do not involve a health hazard. Identification of a container as having 14 ounces of a product when in reality it contains only 10 ounces of product would fall into this category.

AN UNCLASSIFIED OR VOLUNTARY WITHDRAWAL

Any Unclassified and Voluntary situation of product withdrawal in which no violations are involved, or are of such a minor nature, will not place them under FDA guidelines. Examples may include product quality, packaging, etc.

Real situation interpretation of the Recall Classifications is not always simple or straightforward. The Food and Drug Administration should be contacted when any doubt exists as to the classification of a specific situation.

DEPTH OF RECALL

1. The depth of recall is situation specific. There are many variables to consider, but generally it depends on the degree of the hazard and the extent of the product distribution. Research of this subject suggest the following guidelines:
 - Class I Recall shall be made to the consumer or user level (if possible), including any intermediate wholesale or retail level.
 - Class II Recall shall be made to the retail level, including any intermediate wholesale level.
 - Class III Recalls shall be made to the wholesale level.
2. It becomes clear that the success of a product recall may also hinge upon the ability of distributors, wholesalers and retailers to initiate a sub product recall. It behooves FRESH KIST PRODUCE, LLC. to audit its own ability, as well as the ability of the other entities in the product chain, to perform this task satisfactorily.

RECALL STATUS REPORTS

1. The information received from the Recall Effectiveness Checks should be reported periodically to the President and other appropriate entities and individuals involved in the recall effort, so that its progress may be assessed.
2. The frequency of such reports will be determined by the relative urgency of the recall and the entities involved in the recall effort.
3. Unless otherwise specified or inappropriate in a given recall case, the status report should contain the following information:
 - Number of consignees notified of the recall, and the date and method of notification.
 - Number of consignees responding to the recall communication and the quantity of the product(s) on hand at the time it was received.
 - Number of consignees who did not respond (the identity of the unresponsive consignees may be requested by the FDA).
 - Number of products(s) returned or disposed of by each consignee contacted and the quantity of products accounted for.
 - Number and results of effectiveness checks that were made.
 - Estimated time frames for completion of the recall. (21CFR7.53, Refer to Appendix A)

RECONDITIONING & DISPOSAL

1. Generally, "Value Added" fresh processed food cannot be considered as salvageable, although each specific situation must be reviewed for this possibility. The following applicable information was taken from the Model Food Salvage Code drafted by the Food & Drug Administration in 1984.
 - Salvaged food shall be labeled to indicate that the merchandise has been salvaged. Replacement labels must disclose the name and address of the salvaging outfit as well as the date of reconditioning.
 - Potentially hazardous foods that require freezing or refrigeration must be discarded after standing for over 4 hours at a temperature above 45 degrees Fahrenheit.
 - Food contaminants and/or adulterated with pesticides or other chemicals are non-salvageable.
 - Good manufacturing practice regulations are specified for all salvage operations including: equipment, buildings, plumbing, garbage and refuse, insect and rodent control, employee hygiene, housekeeping, lighting and ventilation.
 - Salvage
 - Estimated time frames for completion of the recall. (21CFR7.53, Refer to Appendix)

RECALL COMMUNICATION - MODEL LETTER

Date _____

Consignee
Name, title, and Address

Attn: John Doe

Fresh Kist Produce, LLC., P.O. Box 3617, Salinas, CA 93912 is recalling (product name), (container size), (zippered or unzipped), etc. This product is produced by FRESH KIST PRODUCE, LLC., and may be distributed under different manufacturer's labels. Enclosed is a copy of the original client invoice, listing the quantity of product shipped to (consignee), on (date), the product label _____ and the code date _____ is located _____.

The recall is being initiated following detection of an unregistered pesticide, (name of pesticide) by our pesticide residue analysis-testing program, in our (product name and description). Our concern is that this same product, already in distribution channels, may also be contaminated with the same pesticide. Consumption of this product by consumers represents a potential health hazard.

FRESH KIST PRODUCE, LLC., requests consignees (wholesalers and retailers) to hold and discontinue selling their existing stock of this product, and return any remaining inventories of the recalled products to FRESH KIST PRODUCE, LLC., P.O. Box 3617, Salinas, CA 93912. If you have redistributed or sold this product to other retailers, please notify your clients as to the status of this product and whom they may contact for further information at FRESH KIST PRODUCE, LLC..

Enclosed is a RECALL EFFECTIVENESS QUESTIONNAIRE. We are requesting that you complete it promptly and return the questionnaire by fax transmission. If you have any questions regarding this request, please call _____ at (877) 886-7650.

Thank you for your cooperation in this matter.

Sincerely,

(name and title)

MODEL EFFECTIVENESS CHECK QUESTIONNAIRE

Fax Transmission

Date _____

ATTN: Name, Title, and Company

Subject: Recall Effectiveness Check

Fax Transmission To: _____

FRESH KIST PRODUCE, LLC..
Product Recall

Please read each question, check the appropriate answer, and return immediately.

Date _____

1. Did your firm receive notification that FRESH KIST PRODUCE, LLC.. is recalling its (product name and description) product?

Yes _____ No _____

2. Did your firm receive shipments of the product being recalled?

Yes _____ No _____

3. Do you now have any of the recalled products on hand? Please check your inventories before answering. This is very important.

Yes _____ No _____

4. If the answer to question 3 is YES, do you intend to return the product to FRESH KIST PRODUCE, LLC.. As requested?

Yes _____ No _____

5. If the answer to question 4 is NO, please explain your intentions.

6. Have received any reports of illness or injury related to this product?

Yes _____ No _____

7. If the answer to question 6 is YES, please provide details.

8. Name and title of the person completing this questionnaire.

MODEL EFFECTIVENESS CHECK QUESTIONNAIRE

Telephone or Personal Visit

Date _____

Consignee Name and Address

Name and Title of Interviewee

SUBJECT: Recall Effectiveness Check
Telephone and/or Personal Visit

This is (Name of Interviewer) with FRESH KIST PRODUCE, LLC.. I am calling to confirm that you have received our product recall notification for (product name and description, including the code date). On (day and date) FRESH KIST PRODUCE, LLC. sent a letter by fax transmission, notifying all firms, which may have purchased our (product name) that all remaining stock should be (held, returned, destroyed, relabeled, etc.). If you will allow me, I have a few questions to ask you regarding this recall.

1. Did your firm receive notification of the product being recalled?

Yes _____ No _____

2. Did your firm receive shipments of the product being recalled/ (If the answer is no, terminate the questioning and go to the closing statement).

Yes _____ No _____

3. Do you have any of the recalled products on hand? Please check your inventories before answering. This is very important.

Yes _____ No _____

4. If the answer to question 3 is YES, do you intend to return the product to FRESH KIST PRODUCE, LLC.. 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? If the answer to question 6 is YES, please provide details.

Yes _____ No _____

Thank you for your cooperation in this matter,

And your name is? _____

What is your title, please? _____

Interviewer _____

If you have any further questions, you may direct them to (Name and Title), FRESH KIST PRODUCE, LLC., P.O. Box 3617, Salinas, CA 93912; Phone (877) 886-7650-; Fax:(831) 757-2357.

FRESH KIST PRODUCE, LLC..

**TRACE /RECALL PROGRAM
RECALL EFFECTIVENESS CHECK LOG**

Name of Consignee	Ship Date	Total Cases, Pallets	Cases Shipped			Cases Shipped		
			Item #	Item #	Item #	Lot #	Lot #	Lot #
			Lot #	Lot #	Lot #			
TOTAL								

FRESH KIST PRODUCE, LLC..

**TRACE/RECALL PROGRAM
PRODUCT COMPLAINT FORM**

Date/Time of Complaint: _____ **Code Date:** _____

Complaint Made By: _____

Product Description: _____

Amount of Product Involved: _____

Nature of Complaint: _____

Managers Notified: _____

Investigative Findings:

Action Taken to Correct Complaint and to Prevent its Recurrence:

Date of Response to Complaint: _____

Signature: _____ **Date:** _____

Signature: _____ **Date:** _____

APPENDIX A

Code of Federal Regulations

Title 21, Volume 1, Parts 1 to 99
Revised as of December 2003

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 7--ENFORCEMENT POLICY

Subpart A--General Provisions

Sec.

7.1 Scope.

7.3 Definitions.

7.12 Guaranty.

7.13 Suggested forms of guaranty.

Subpart B--[Reserved]

Subpart C--**Recalls** (Including Product Corrections)--Guidelines on Policy, Procedures, and Industry Responsibilities

7.40 Recall policy.

7.41 Health hazard evaluation and recall classification.

7.42 Recall strategy.

7.45 Food and Drug Administration-requested recall.

7.46 Firm-initiated recall.

7.49 Recall communications.

7.50 Public notification of recall.

7.53 Recall status reports.

7.55 Termination of a recall.

7.59 General industry guidance.

Authority: Secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-393); secs. 301, 351, 354-360F, 361 of the Public Health Service Act (42 U.S.C. 241, 262, 263b-263n, 264).

Source: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A--General Provisions

Sec. 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) and other laws that it administers. This part also provides guidelines for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory

practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978]

Sec. 7.3 Definitions.

(a) Agency means the Food and Drug Administration.

(b) Citation or cite means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.

(c) Respondent means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

(d) Responsible individual includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) [Reserved]

(f) Product means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. Product does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.

(g) Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration 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.

(h) Correction means repair, modification, adjustment, re-labeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

(i) Recalling firm means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

(j) Market withdrawal means 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 Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

(k) Stock recovery means 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.

(l) Recall strategy means a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

(m) Recall classification means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

(1) Class I is 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.

(2) Class II is 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.

(3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

(n) Consignee means anyone who received, purchased, or used the product being recalled.

[42 FR 15567, Mar. 22, 1977, as amended at 43 FR 26218, June 16, 1978; 44 FR 12167, Mar. 6, 1979]

Sec. 7.12 Guaranty.

In case of the giving of a guaranty or undertaking referred to in section 303(c)(2) or (3) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

Sec. 7.13 Suggested forms of guaranty.

(a) A guaranty or undertaking referred to in section 303(c)(2) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or (2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303(c)(2) of the act:

(1) Limited form for use on invoice or bill of sale.

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce. (Signature and post-office address of person giving the guaranty or undertaking.)

(2) General and continuing form.

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or in the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce. (Signature and post-office address of person giving the guaranty of undertaking.)

(c) The application of a guaranty or undertaking referred to in section 303(c)(2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the act, or becomes an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303(c)(3) of the act shall state that the shipment or other delivery of the color additive covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303(c)(3) of the act:

(1) For domestic manufacturers:

(Name of manufacturer) hereby guarantees that all color additives listed herein were manufactured by him, and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act. (Signature and post-office address of manufacturer.)

(2) For foreign manufacturers:

(Name of manufacturer and agent) hereby severally guarantee that all color additives listed herein were manufactured by (name of manufacturer), and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act. (Signature and post-office address of manufacturer.) (Signature and post-office address of agent.)

(f) For the purpose of a guaranty or undertaking under section 303(c)(3) of the act the manufacturer of a shipment or other delivery of a color additive is the person who packaged such color.

(g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(h) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

Subpart B [Reserved]

Subpart C--**Recalls** (Including Product Corrections)--Guidelines on Policy, Procedures, and Industry Responsibilities

Source: 43 FR 26218, June 16, 1978, unless otherwise noted.

Sec. 7.40 Recall policy.

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and Secs. 7.41 through 7.59 recognize the voluntary nature of recall by providing guidelines so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

Sec. 7.41 Health hazard evaluation and recall classification.

(a) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:

(1) Whether any disease or injuries have already occurred from the use of the product. (2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

(b) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

Sec. 7.42 Recall strategy.

(a) General. (1) A recall strategy that takes into account the following factors will be developed by the agency for a Food and Drug Administration-requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:

(i) Results of health hazard evaluation.

(ii) Ease in identifying the product.

(iii) Degree to which the product's deficiency is obvious to the consumer or user.

(iv) Degree to which the product remains unused in the market-place.

(v) Continued availability of essential products.

(2) The Food and Drug Administration will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

(b) Elements of a recall strategy. A recall strategy will address the following elements regarding the conduct of the recall:

(1) Depth of recall. Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

(i) Consumer or user level, which may vary with product, including any intermediate wholesale or retail level; or

(ii) Retail level, including any intermediate wholesale level; or

(iii) Wholesale level.

(2) Public warning. The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The Food and Drug Administration in consultation with the recalling firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by the Food and Drug Administration. The recall strategy will specify whether a public warning is needed and whether it will issue as:

(i) General public warning through the general news media, either national or local as appropriate, or

(ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

(3) Effectiveness checks. The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. A guide entitled "Methods for Conducting Recall Effectiveness Checks" that describes the use of these different methods is available upon request from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but the Food and Drug Administration will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

- (i) Level A--100 percent of the total number of consignees to be contacted;
- (ii) Level B--Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees;
- (iii) Level C--10 percent of the total number of consignees to be contacted;
- (iv) Level D--2 percent of the total number of consignees to be contacted; or
- (v) Level E--No effectiveness checks.

[43 FR 26218, June 16, 1978, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14363, Mar. 28, 1994]

Sec. 7.45 Food and Drug Administration-requested recall.

(a) The Commissioner of Food and Drugs or his designee under Sec. 5.20 of this chapter may request a firm to initiate a recall when the following determinations have been made:

- (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.
- (2) That the firm has not initiated a recall of the product.
- (3) That an agency action is necessary to protect the public health and welfare.

(b) The Commissioner or his designee will notify the firm of this determination and of the need to begin immediately a recall of the product. Such notification will be by letter or telegram to a responsible official of the firm, but may be preceded by oral communication or by a visit from an authorized representative of the local Food and Drug Administration district office, with formal, written confirmation from the Commissioner or his designee afterward. The notification will specify the violation, the health hazard classification of the violative product, the recall strategy, and other appropriate instructions for conducting the recall.

(c) Upon receipt of a request to recall, the firm may be asked to provide the Food and Drug Administration any or all of the information listed in Sec. 7.46(a). The firm, upon agreeing to the recall request, may also provide other information relevant to the agency's determination of the need for the recall or how the recall should be conducted.

Sec. 7.46 Firm-initiated recall.

(a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in Sec. 5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure. In such cases, the firm will be asked to provide the Food and Drug Administration the following information:

- (1) Identity of the product involved.
- (2) Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.
- (3) Evaluation of the risk associated with the deficiency or possible deficiency.
- (4) Total amount of such products produced and/or the timespan of the production.
- (5) Total amount of such products estimated to be in distribution channels.
- (6) Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.
- (7) A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.
- (8) Proposed strategy for conducting the recall.
- (9) Name and telephone number of the firm official who should be contacted concerning the recall.

(b) 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 the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not delay initiation of its product removal or correction.

(c) A firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall. The firm's action also is considered a firm-initiated recall and is subject to paragraphs (a) and (b) of this section.

(d) A firm that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with the appropriate Food and Drug Administration district office when the reason for the removal or correction is not obvious or clearly understood but where it is apparent, e.g., because of complaints or adverse reactions regarding the product, that the product is deficient in some respect. In such cases, the Food and Drug Administration will assist the firm in determining the exact nature of the problem.

Sec. 7.49 Recall communications.

(a) General. A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

- (1) That the product in question is subject to a recall.
- (2) That further distribution or use of any remaining product should cease immediately.
- (3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.
- (4) Instructions regarding what to do with the product.

(b) Implementation. A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: "drug [or food, biologic, etc.] recall [or correction]". The letter and the envelope should be also marked: "urgent" for class I and class II **recalls** and, when appropriate, for class III **recalls**. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.

(c) Contents. (1) A recall communication should be written in accordance with the following guidelines:

- (i) Be brief and to the point;
- (ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;
- (iii) Explain concisely the reason for the recall and the hazard involved, if any;
- (iv) Provide specific instructions on what should be done with respect to the recalled products; and
- (v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.

(2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, follow up communications should be sent to those who fail to respond to the initial recall communication.

(d) Responsibility of recipient. Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

Sec. 7.50 Public notification of recall.

The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm. The Food and Drug Administration will intentionally delay public notification of **recalls** of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential. The report will not include a firm's product removals or corrections which the agency determines to be market withdrawals or stock recoveries. The report, which also

includes other Food and Drug Administration regulatory actions, e.g., seizures that were effected and injunctions and prosecutions that were filed, is available upon request from the Office of Public Affairs (HFI-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Sec. 7.53 Recall status reports.

(a) The recalling firm is requested to submit periodic recall status reports to the appropriate Food and Drug Administration district office so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the Food and Drug Administration in each recall case; generally the reporting interval will be between 2 and 4 weeks.

(b) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

- (1) Number of consignees notified of the recall, and date and method of notification.
 - (2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
 - (3) Number of consignees that did not respond (if needed, the identity of non-responding consignees may be requested by the Food and Drug Administration).
 - (4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
 - (5) Number and results of effectiveness checks that were made.
 - (6) Estimated time frames for completion of the recall.
- (c) Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

Sec. 7.55 Termination of a recall.

(a) A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.

(b) A recalling firm may request termination of its recall by submitting a written request to the appropriate Food and Drug Administration district office stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

Sec. 7.59 General industry guidance.

A recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect. Notwithstanding similar specific requirements for certain products in other parts of this chapter, the following is provided by the Food and Drug Administration as guidance for a firm's consideration:

(a) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with Secs. 7.40 through 7.49, 7.53, and 7.55.

(b) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.

(c) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention.

FRESH KIST PRODUCE, LLC.

Trace/Recall Program

Appendix B

TEAM LEADER Name (805) (Work) (805) (Mobile) (805) (Home)	Alternate: TEAM LEADER Name (805) (Work) (805) (Mobile) (805) (Home)
RECALL COORDINATOR Name (805) (Work) (805) (Mobile) (805) (Home)	Alternate: RECALL COORDINATOR Name (805) (Work) (805) (Mobile) (805) (Home)
LEGAL Name (805) (Work) (805) (Home)	Alternate: LEGAL Name (805) (Work) (805) (Home)
PRODUCTION Name (805) (Work) (805) (Mobile) (805) (Home)	Alternate: PRODUCTION Name (805) (Work) (805) (Mobile) (805) (Home)
SHIPPING Name (805) (Work) (805) (Mobile) (805) (Home)	Alternate: SHIPPING Name (805) (Work) (805) (Mobile) (805) (Home)
SALES Name (805) (Work) (805) (Home)	Alternate: SALES Name (805) 7 (Work) (805) (Home)