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Proper Beverage, Co.'s Product Recall Plan

Policy: Proper Beverage, Co. has an implemented traceability system which tracks raw materials, through processing to the finished goods. This system allows Proper Beverage, Co. to initiate recalls when required.

Purpose: To outline the recall process within Proper Beverage, Co.

Scope: This procedure applies to all receiving, storage, manufacturing, and shipping of:
Cold Filtered Carbonated Formula Acidified Preserved Beverages

Proper. Beverage, Co.

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Section 1 - Recall Concept and Classification

RECALL PROGRAM

Authority

The Food and Drug Administration has established voluntary guidelines for conducting product recalls related to all foods. The product manufacturers or distributors carry out most recalls of products regulated by FDA voluntarily. In some instances, a company discovers that one of its products is defective (adulterated or misbranded) and recalls it entirely on its own. In others, FDA informs a company of findings that one of its products is defective and suggests or requests a recall.

FDA guidelines for companies to follow when recalling defective products under the Agency's jurisdiction are published in Title 21 of the Code of Federal Regulations, Part 117 Subpart B. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=117&showFR=1&subpartNode=21:2.0.1.1.16.2> These guidelines make clear that FDA expects these firms to take full responsibility for product recalls, including follow-up checks to assure that recalls are successful. Under the guidelines, companies are expected to notify FDA when recalls are started, to make progress reports to FDA on recalls, and to undertake recalls when asked to do so by the Agency.

The guidelines also call on manufacturers and distributors to develop contingency plans for product recalls that can be put into effect if, and when needed. FDA's role under the guidelines is to monitor company recalls and assess the adequacy of a firm's action. After a recall is completed, FDA makes sure that the product is destroyed or suitably reconditioned and investigates why the product was defective.

Section 303(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) <http://www.cfsan.fda.gov/~dms/sec-ltr.html#sec303> adds section 304(h) to the Federal Food, Drug, and Cosmetic Act to authorize FDA to detain an article of food for which there is credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to humans or animals. This authority is self-executing and provides an added measure to ensure the safety of the nation's food supply. The Bioterrorism Act also requires FDA to provide by regulation, procedures for instituting on an expedited basis certain enforcement actions against perishable foods subject to a detention order. Section 305 <http://www.cfsan.fda.gov/~dms/sec-ltr.html#sec305> of the Bioterrorism Act requires owners, operators, or agents in charge of domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register their facilities with FDA (unless the facility is exempt).

Definitions

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. A true recall of a food product occurs only when the product violates the law and is a likely candidate for seizure, condemnation or other legal action by the government. A food product may violate the law if it is “adulterated” or “misbranded”. Whether a product defect is likely to result in government action will depend on the particular food product and the potential risk to the consuming public. Recall does not include a market withdrawal or a stock recovery.

1. A food product is **adulterated** if it:
 - Contains a poisonous (e.g. Salmonella, E. coli O157: H7, cyanide) or deleterious substance (e.g. a piece of glass);
 - Contains an unapproved pesticide or a pesticide in excess of a specific legal tolerance set by the FDA and/or the Environmental Protection Agency (EPA);
 - Contains an unauthorized food or color additive;
 - Contains filth (e.g. insect parts, rodent excreta) or a decomposed substance or is otherwise unfit for food;
 - Was produced, prepared, packed, or stored under unsanitary conditions in which it may have become contaminated.
2. A food is **misbranded** if its labeling is false, misleading or does not contain information required by law. A product may be misbranded if:
 - The components of the food are not fully identified in the statement of ingredients;
 - The weight or volume is inaccurate or not declared properly; or
 - The label does not bear the nutritional facts panel.

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, incorrect barcode, tampering without evidence of manufacturing or distribution problems, etc.

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 portions of that lot have been released for sale or use.

A **product safety investigation** is an internal trace of product origin/history prompted by notification by the FDA or a state health department, a customer or quality control/production personnel that there may be a potential food safety or physical defect in a specific product. The facts of the investigation will determine if a product recall, market withdrawal or stock recovery is warranted.

A **mock recall** is an internal exercise to test your company's ability to trace and recall product. Mock recall exercises are scheduled on a semiannual basis (at least) using differing scenarios to ensure the mock recalls run smoothly. This exercise shall be documented to measure the effectiveness of the mock recall process then reviewed to identify and correct any internal problems discovered. *It is the company's mission to conduct mock recalls as a team effort to ensure the recall program has been effectively challenged. The team continually implements new challenges based on current food safety events. It is the company's mission to account for 100% of all recalled product.* Key elements demonstrating effectiveness of the mock recall documentation include scenario, time taken, accounting for affected product, documenting time

line, copies of **supporting** documentation that show the traceback and any lessons learned from the exercise.

Mock recall exercises allow you to "fine-tune" your system. How easily can you trace and recover your products? How long does it take from deciding to carry out a recall to actually being able to inform the affected customers? How easily can you traceback the origin of a particular packaging item? How much product is accounted for? This might include culled materials. If a supplier or grower detects a recall issue, they should contact all affected operations to which they have sold their products. This initiates a trace forward from raw material through to finish. Mocking one of these different scenarios is also useful sometimes.

Have an **emergency management communication strategy** in place as advance preparation for unexpected events e.g. a positive *L. monocytogenes* or Salmonella sample, a food-borne outbreak, a natural disaster, product tampering or a bomb threat. Form a crisis communications team and give each member specific tasks. Designate a leader who will be your media spokesperson. Another person will notify customers (via telephone, letter, and e-mail), another team member will focus on interacting with regulatory personnel. Someone must be carefully trained to answer the calls that come to the company, following a media announcement, who may or may not be legitimately reporting illnesses, or simply regular customers who become irate or overly concerned about the safety of their family. Clearly describe each person's role and designate alternates (in case the designate is unavailable) in the emergency management plan. Keep all the information you need to know in the event of a recall in one place.

A **product code** is required under Good Manufacturing Practices and provides meaningful information regarding product lot number, packing date and packing location. The product code needs to be entered on all appropriate quality control records, production reports, procurement reports and shipping reports so that the product can be traced at a later date if necessary. The out-loading product code(s) is/are usually the first step back in the traceback process through the production and storage processes, through to incoming lot or lots and vice versa in a trace forward scenario

Recall Classification Categories

There are three **FDA recall classification categories**:

Class I: there is a reasonable probability that eating the product will cause death or serious health problems.

Pathogenic organisms such as *Listeria monocytogenes*, *Clostridium botulinum*, *E. coli* 0157:H7, *Salmonella enteritidis*, undeclared peanuts or tree nuts (pecans, hazelnuts, filberts, walnuts, cashews, and brazil nuts), undeclared eggs and undeclared sulfites (10 mg or more per serving), in the product would 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: there is a remote probability that eating the product will cause serious health problems; or products that could cause temporary, reversible health problems.

Examples for this classification would be product that had pathogenic organisms, such as most *Salmonella* species, *Shigella*, *Staphylococcus aureus*, or indicator organisms such as generic *E. coli*, non-FD&C certified colors and undeclared FD&C Yellow #5 and #6, undeclared sulfites (3.7-9.9 mg per serving), undeclared wheat, oats, or corn, undeclared fish, unapproved additives, undeclared pistachios or almonds, undeclared soy (soybeans, soy protein, and soy flour), and undeclared dairy products (milk, cream, dry milk, whey). 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.

Class III: eating the product is not likely to cause serious health problems.

Adulterated or misbranded products that do not involve a health hazard would be given this classification. For example, undeclared certified colors (other than Yellow #5 and #6), undeclared sulfites (less than 3.7 mg per serving) and minor labeling problems (e.g. identification of a container as having 14 ounces of a product when in reality it contains only 10 ounces of product).

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, non-food safety labeling etc.

Section 2 - Traceback Procedure

Notification

The initial notification of a potential health hazard can come from a variety of sources including the FDA, State Health Departments, Proper Beverage, Co.'s customers and Proper Beverage, Co.'s employees, contractors or suppliers (packaging, ingredients, raw materials etc.). In the vast majority of cases, notification of potential foodborne illness or contamination from product in commerce will come from either the FDA or a State Health Department. Regardless of the source, all food safety or health hazard inquiries are routed immediately to the Traceback/Product Recall Coordinator (see Table 1) without exception. Proper Beverage, Co.'s reception is trained to identify these calls and transfer them to the Traceback/Product Recall Coordinator. If the Traceback/Product Recall Coordinator is off site, reception will immediately locate the Traceback/Product Recall Coordinator to apprise him/her of the situation. In those instances when the Traceback/Product Recall Coordinator is unavailable, the alternate Traceback/Product Recall Coordinator (see Table 1) will assume responsibility for addressing the initial notification.

Fact and Data Acquisition

In the initial conversation with the FDA, State Health Department or Proper Beverage, Co.'s customer, contractor or employee, the Traceback/Product Recall Coordinator will ascertain the available facts associated with the potential health hazard. The Customer Contact and Feedback Forms (Figure 3, Figure 7) are used to organize the pertinent facts and create an official record of the issue. Regardless of where the issue originates, the Traceback/Product Recall Coordinator or his/her designate will keep careful, detailed notes of the initial conversation and all subsequent activities associated with the traceback/recall process. The Traceback/Product Recall Coordinator will include in these notations the **time and date of each event** to aid in the preparation of a final report and measure the effectiveness and timeliness of the response. These facts and related information will include **product type and label, product codes, type of defect or health hazard, location(s) involved, invoice numbers, customer(s), number of people affected and their condition**. The Traceback/Product Recall Coordinator will also obtain the name, agency/customer and phone numbers of the person making the notification. A general outline detailing the types of information needed is included in Figure 2. If the notification is coming from the FDA or a State Department of Health, it is important to determine the status of the investigation. Owing to the perishable nature of some products, by the time a state or federal investigation of food safety mobilizes, the product may have moved through the distribution system and been consumed. This situation obviates a product recall but merits swift action to assist the governmental agency in their investigation, so that the cause of the health hazard can be identified and, if found to be a Proper Beverage, Co.'s problem, corrected immediately.

The Traceback/Product Recall Coordinator will also inquire as to whether other products are being investigated as a source of the health hazard and if other companies have been contacted. Often in the initial stages of a food safety or epidemiological study more than one potential source is under consideration. This is especially relevant when dealing with health hazards that trace to restaurants, catering companies or other public food providers. In these cases, cross contamination in the food preparation establishment or contamination by ill food handlers has to be carefully considered.

If the potential health hazard is a physical or chemical rather than biological contamination, i.e. pieces of glass, metal, wood, contamination with petroleum products or other chemical agents, the Traceback/Product Recall Coordinator will attempt to get a sample of the physical hazard to assist in the internal investigation. The sample can be used in tracing the origin of the contamination, determining how the problem arose and developing procedures to mitigate future contamination.

Regardless of the nature of the potential health hazard (physical, chemical or biological), the notification that a potentially widespread health hazard exists and is a concern to the FDA, State Health Department or a customer, will trigger an internal investigation Proper Beverage, Co.'s Traceback/Product Recall Team.

The summary for this phase of the process is as follows:

- Outline of the facts and circumstances related to the potential health hazard.
- Product codes and invoice numbers for product(s) in question.
- Initial evaluation of scope of problem and focus of FDA, State Health Department or customer's ongoing investigative efforts.
- Key contact identification and phone numbers.
- Identification of information needed by investigating agency or customer.

Assemble Traceback/Product Recall Team

The Traceback/Product Recall Coordinator will immediately review the facts and hazard status as determined from the communication with the notifying party. The Traceback/Product Recall Coordinator will then assemble the Traceback/Product Recall Team to inform them of the potential health hazard and to initiate the product trace and accumulate pertinent production, harvesting, cooling, processing, quality, shipping and sales information. Table 1 shows the members of the Traceback/Product Recall team and their alternates. The specific responsibilities for these individuals are outlined in the next section. It is imperative that the Recall Team is composed of individuals who best know their area and product.

The Traceback/Product Recall Coordinator has responsibility for coordinating and managing all aspects of the traceback and recall activity. The Coordinator will keep a log of all actions taken during the traceback/product recall (Figure 9). This log will be used in the preparation of status reports and for measuring the effectiveness of Proper Beverage, Co.'s response. It is understood that each representative on the Traceback/Product Recall Team will use all the personnel and other resources available to them to carry out their responsibilities.

The Traceback/Product Recall Team will trace the product back from the customer to the origin. If possible (based on the time interval from production/distribution to notification of the existence of the problem), an immediate hold will be placed on all suspect products Proper Beverage, Co.'s control. All important documentation will be collected from Production/Sales/Distribution including **invoices, bills of lading, pick tickets, transfers, receiving tags and export documents, customer contact details** (if appropriate). **Supplier details, Inventory listings, production records and harvest schedules** will also be collected. The Traceback/Product Recall Coordinator and the other Team members assemble the necessary documentation and organize it by order. The Team members will also collect pertinent quality control and safety documentation (e.g. GAP, HACCP). Other documents **raw product quality control documents, lot numbers, receiving information, HACCP verification logs and other process control documentation and finished product quality control logs** where relevant will be assembled and evaluated.

The Traceback/Product Recall Coordinator will consider the need for external advice and services e.g. consultants, laboratories, lawyers, public relations/crisis management personnel, etc.

The summary for the initial trace activity is as follows:

- Notification of top management of the potential health hazard.
- Recall Team assembled and knowledgeable of situation
- Hold placed on product that might still be in Proper Beverage, Co.'s control
- Product in question traced to origin.
- Documentation in place to verify origination of product.
- Pertinent QC logs or receiving reports, process control logs, HACCP verification (if appropriate) and GAP audits assembled (if available).
- Outside technical, (e.g. PrimusLabs.com) public relations and legal experts appraised of situation.
- Supplier contact details
- Customer contact details

Traceback Review

The Traceback/Product Recall Coordinator will reassemble the full Traceback/Product Recall Team for a review of the Traceback activity. The review will include the results of the traceback, a summation of the traceback and safety-related documentation and any further communications between the Traceback/Product Recall Coordinator and the investigating agency or customer. This meeting will then move to a discussion and determination of next steps. The issues to be decided include:

- Should current product sales be halted?
- Is a recall, market withdrawal or stock recovery warranted?
- If a recall is necessary, what classification, and what is the appropriate depth of recall?
- If the FDA is not involved at this point, do they need to be notified?
- What further steps does Proper Beverage, Co.'s need to take in its internal investigation?
- Should the corporate insurance carrier be notified?
- What is the message Proper Beverage, Co.'s wishes to convey to the media, customers and employees?

Communications with the media, customers and employees is a critical issue during a food safety or potential health hazard situation. It is important that the message be clear, concise and factual. It is equally important that the company uses a **single spokesperson** so that the message stays consistent.

The summary from this phase will be:

- A summation of the traceback activity
- Traceback documentation from product back to the farm
- A determination if a recall and its depth or other action is warranted.
- A decision to notify the FDA (if appropriate).
- A Proper Beverage, Co.'s position statement to be used for public inquiries and for communication to other Proper Beverage, Co.'s employees
- A priority list for media responses

If A Product Recall Is Not Warranted

A product traceback activity can have a number of different outcomes depending on the nature of the traceback. Some traceback exercises *will not* be followed by a recall activity owing to the highly perishable nature of produce. The following are potential end scenarios of a traceback investigation:

- It is determined that the nature of the potential hazard does not pose a public health risk. An example of this situation might be the detection of a pesticide (due to an inadvertent overspray) not labeled for that particular product, but which is found in other foods and is at a level not above legal tolerances.
- Epidemiologists cannot unequivocally determine the source of the contamination.
- Proper Beverage, Co.'s product is found not to be the source of the contamination. An example might be the determination of cross-contamination at a restaurant by an ill food handler or from another food type.
- Proper Beverage, Co.'s product may or may not be linked to the contamination, but the time interval between the actual event and notification of Proper Beverage, Co.'s precludes a recall since the perishable nature of a product means the product in question would have already been consumed.

In these instances when a recall is not appropriate, the focus of Proper Beverage, Co.'s efforts will be directed toward assisting investigating government agencies and/or customers in isolating the likely source of the contamination and evaluating mechanisms to prevent further occurrences. The Traceback/Product Recall Coordinator will continue to work with growers, suppliers, customers, vendors and government agencies to establish the likely cause of the problem and develop preventative measures. This activity will culminate in a **final report** that will be reviewed with the full Traceback/Product Recall Team. This report will also outline any changes that need to be made to Proper Beverage, Co.'s food safety program.

Section 3 - Recall Procedure

Recall Procedure

Should circumstances warrant a product recall, an **immediate hold** will be placed on all products that may be potentially contaminated or deemed unsafe. Proper Beverage, Co.'s will clearly label all products still in the company's possession as 'On Hold' and place them in an area of the storage facility where they cannot be mistakenly distributed. The Hold Tags will be dated, state the reason for being on hold and the person responsible for placing the product hold. For product outside the company's possession, Proper Beverage, Co.'s will instruct the customer to isolate the product and clearly label the product as 'On Hold' Proper Beverage, Co.'s will tabulate product on hold and evaluate relative to the total amount of potentially contaminated distributed product. Proper Beverage, Co. will strive to recover as much product as possible. A recalled product inventory log is illustrated in Table 2. The Traceback/Product Recall Team will assist FDA and/or other investigative agencies in obtaining samples for microbial or chemical testing. Proper Beverage, Co.'s employees will be present during sampling. Duplicate samples will be taken and Proper Beverage, Co.'s will engage a certified analytical laboratory (e.g. PrimusLabs.com) to replicate any tests performed in government laboratories.

Product disposal will be supervised by Proper Beverage, Co.'s designates in conjunction with the FDA or appropriate state health departments. The Traceback/Product Recall Team will determine whether to ship the product to a central site for disposal or to dispose of product at multiple sites based on the characteristics of the potential hazard.

Proper Beverage, Co.'s will move quickly to notify appropriate government agencies (FDA and State public health departments) and affected customers. The Traceback/Product Recall Coordinator will notify and liaise with the appropriate regulatory agencies while the sales and marketing representatives on the Traceback/Product Recall Team will notify customers that may have received the contaminated product by telephone. The Proper Beverage, Co.'s caller will note the date, time and name of the person contacted. A form to help guide this telephone call is included as Figure 3. Fax or e-mail using a letter formatted similarly to Figure 4 to follow up all telephone calls. The Traceback/Product Recall Coordinator will keep a copy of this written confirmation letter and the telephone record on file. Additionally, a Status Check Questionnaire (Figure 5) will be sent with the follow up letter. The customer will be asked to fill out this questionnaire as soon as possible and return it to Proper Beverage, Co.'s the data collected from this form will assist Proper Beverage, Co.'s efforts in tracking the product.

Throughout the Recall process, the Traceback/Product Recall Team will:

- Update relevant information pertaining to the traceback and recall
- Analyze incoming information and update the Management of Proper Beverage, Co.'s
- Communicate with customers and Proper Beverage, Co.'s employees regarding the recall status
- Update suppliers and other Proper Beverage, Co.'s business partners regarding the recall activities
- Develop messages and strategy for dealing with public/media concerns
- Assist in product recovery/disposal activities
- Assist FDA or other appropriate public health agencies in the outbreak investigation.

Once the product recall has been concluded and the product in question disposed of, the Traceback/Product Recall Coordinator will prepare a report summarizing the events of the traceback and recall activities. This report will be including an evaluation of the efficiency of Proper Beverage, Co.'s response and recommend any improvements that might be needed.

Figure 1. Product Recall Flow Chart

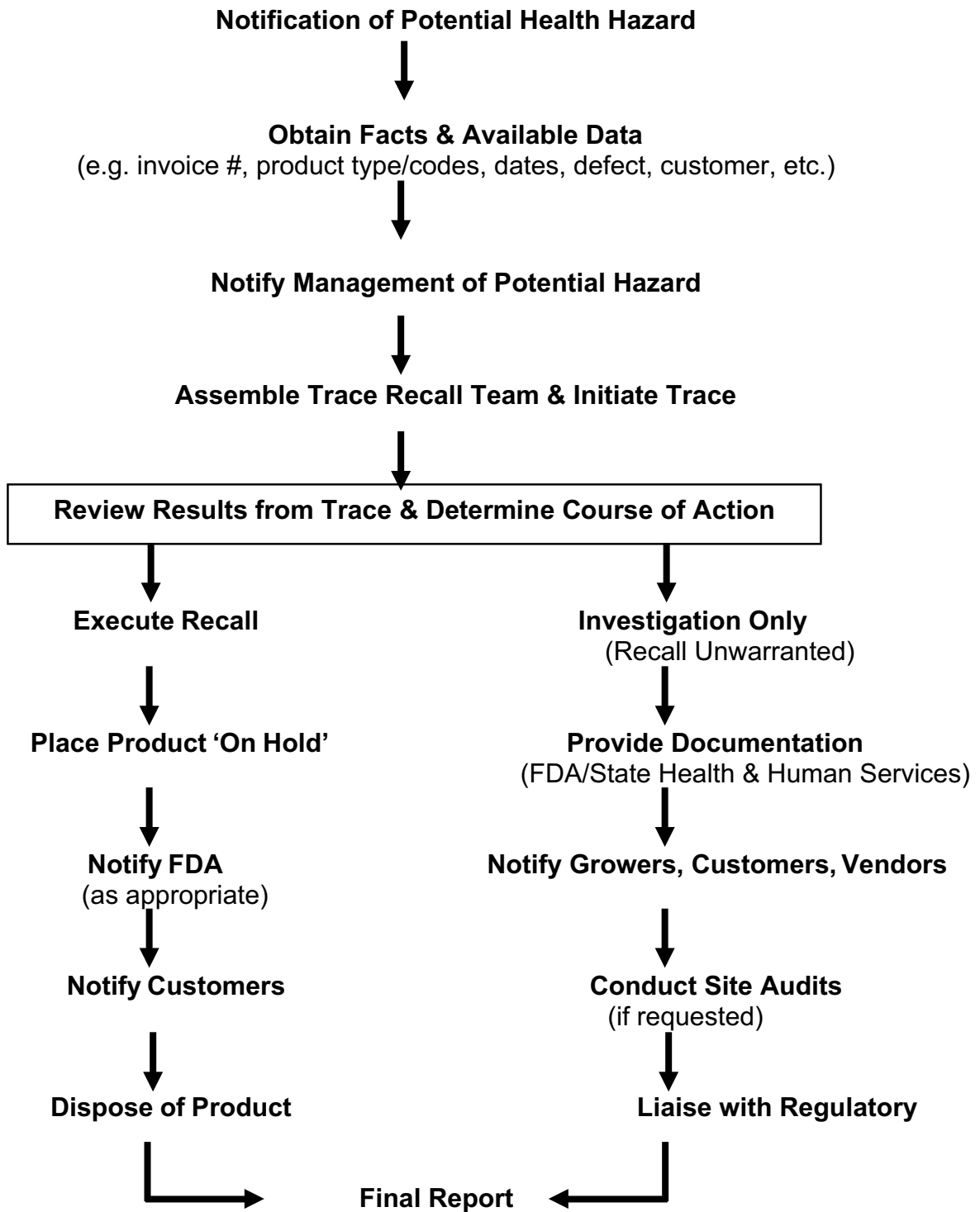
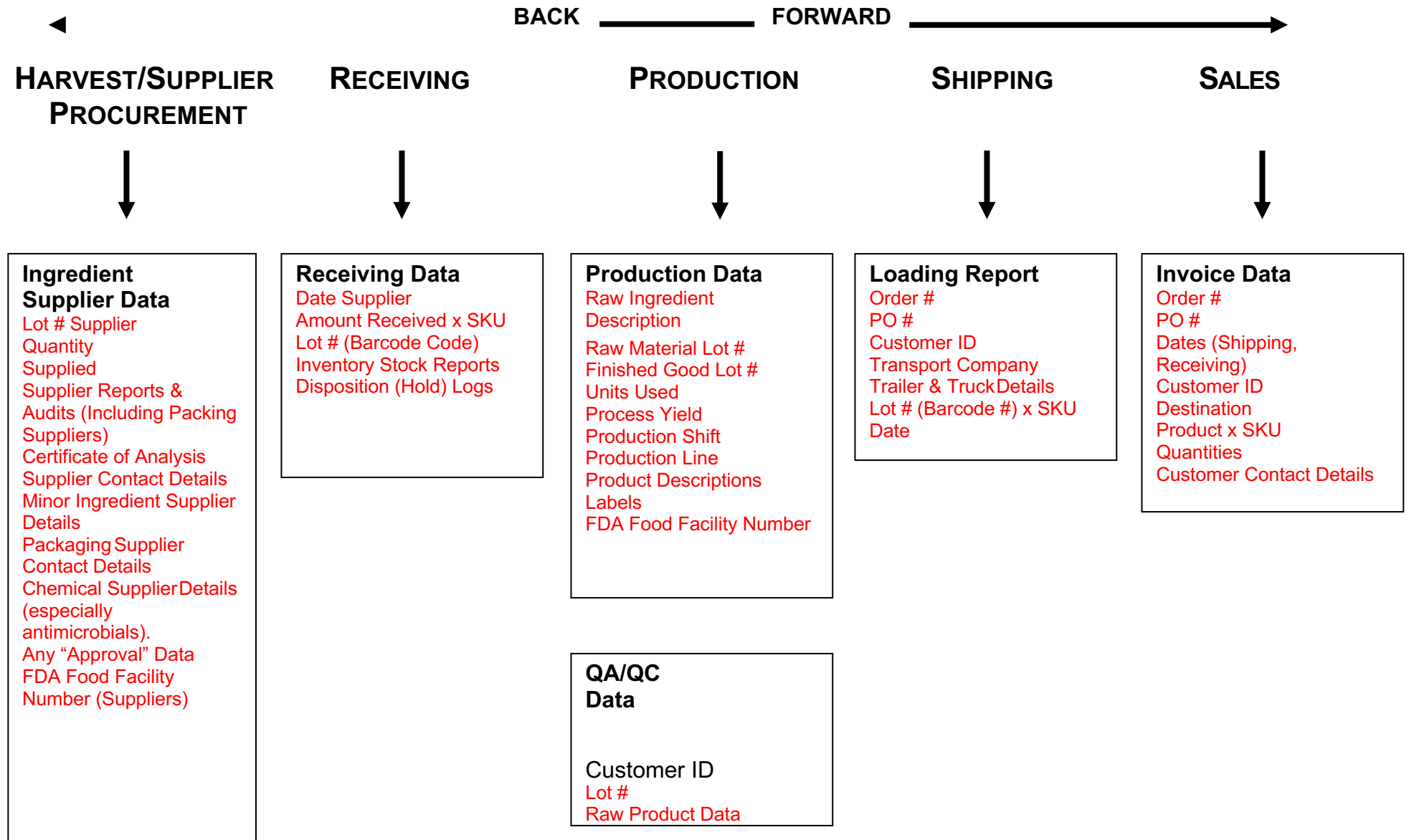


Figure 2. Examples of Data & Documentation Required for Product Traceback & Forward



Section 4 – Individual Responsibilities of Product Traceback/Recall Team

Traceback/Product Recall Coordinator

1. Upon receiving information that a Proper Beverage, Co.'s product may pose a potential health hazard to consumers, or may be defective, the Product Traceback/Recall Coordinator and the Product Traceback/Recall Team 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 Proper Beverage, Co.'s Management immediately, presents all factual data regarding the suspected product, and keeps them informed as events unfold regardless of whether a recall will become necessary or not.
3. Keeps an official record of all activities related to the traceback activity and recall should events move to that level (Figure 8).
4. Obtains and interprets all pertinent data and communicates directly with the Management of the company and all other appropriate individuals on the Traceback/Product Recall Team.
 - Obtains all pertinent production data necessary for the suspected product(s) recall from the Production Manager(s) and Production Supervisor(s).
 - Provides the Shipping/Receiving Manager(s) with the suspected product (s) code date and any other required information necessary for the hold, traceback or recall.
 - Obtains an inventory of the suspected product(s) that may remain at the Proper Beverage, Co.'s cold storage/distribution facilities from the Shipping/Receiving Manager(s) and a complete list of clients who were shipped suspected product(s) from the Production Manager(s), Shipping Manager(s) and/or the Sales Manager(s).
5. 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 includes:
 - 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.
 - FDA Food Facility Registration Number (sometimes referred to as the FDA Food Security Registration Number).
 - Name, title and telephone number of the firm official who is to be contacted concerning the recall.
6. Shall prepare recall status reports as well as a final report at the conclusion of the recall process. See Termination of a Recall (21CFR 7.55 (a) & (b)) for these requirements.
7. Provides the Processing Facility/Packhouse Manager, the Shipping/Receiving Manager, Production Supervisor and/or Proper Beverage, Co.'s Accounting with a Purchase order number, code date or lot number of the suspected product(s) and obtains all the pertinent production data necessary for the product(s) recall to the Traceback/Product Recall Coordinator.

Sales Manager

1. Sales department ensures that the customer contact details are both up to date and available to all key members of the recall team. Contact details are either in the recall program file or referred to in the texts of the recall file.
2. Based on purchase orders and the data provided by Shipping/Receiving/Distribution Manager and other appropriate ordering and shipping forms, co-ordinates the sales staff to contact all clients who received shipment of suspected product(s). Informs clients of the Traceback/Recall effort in progress first by telephone (Figure 3) and confirms by the written communication of a Recall Letter (Figure 4) and follows-up with telephone calls verifying the receipt of the recall letter.
3. If the customer is distributing the suspected product(s), Proper Beverage, Co.'s will have the customer 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, dry storage and 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 facility
 - Work out the necessary arrangement with the client(s) to return suspected product(s) to Proper Beverage, Co.'s or dispose of it in an appropriate manner. If the decision is made to dispose of the suspected product(s), Proper Beverage, Co.'s must send a representative of the company to verify the appropriate disposal of the product. Photographic evidence thereof, or photos and landfill receipts provided by the client shall evidence and verify the appropriate disposal of the suspected product(s).
4. If the customer is **not** distributing the suspected product(s), Proper Beverage, Co.'s will have the client utilize the code date and/or purchase order 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 Proper Beverage, Co.'s or dispose of it in an appropriate manner. Once the decision is made to dispose of the suspected product(s), Proper Beverage, Co.'s will send a representative from the company to verify the appropriate disposal of the product. Photographic evidence thereof, or photos and landfill receipts provided by the client shall evidence and verify the appropriate disposal of the suspected product(s).
5. Provides the information gathered to the Traceback/Product recall Coordinator as it is retrieved.
6. 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 (note that this is not mandated when performing mock recalls). 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.

Distribution/Shipping Manager

1. Utilizing the code date, purchase orders 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 Proper Beverage, Co.'s cooler/distribution facilities.
 - The total volume (cases) of suspected product(s) shipped to each client based on packing lists and bills of lading.
2. Has all suspected product(s) within Proper Beverage, Co.'s distribution facilities gathered together, isolated and then tagged, "Hold - Do not Ship." Any suspected raw materials also be placed on hold.
3. Provides the information gathered to the Traceback/Product Recall Coordinator as it is retrieved.

Production Manager(s) And Production Supervisor(s)

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 Traceback/Product Recall Coordinator.
 - The time period, day(s) during which the suspected product(s) was processed and/or packed.
 - The raw material affected lot(s) (which leads to location(s), suppliers, grower, ranch(es) and production block(s)).
 - The total volume of finished product cases manufactured (and recorded wastage and work in progress if applicable).
 - Process data, HACCP verification logs, sanitation logs, raw and finished product QC evaluations, production shift, trans-shipment information.
 - Any special orders, their total and individual finished product volumes (cases), and the lot(s).
 - The different types of cases and case sizes and identification markings utilized and their individual finished product volumes (cases, pallets, etc.).
 - All pertinent product codes/use by dates used and affected labels.

Provides the information gathered to the Traceback/Product Recall Coordinator as it is retrieved.

Quality Control Supervisor

1. Assists the Processing Plant/Packinghouse Manager with the gathering of Quality Control data:
 - Incoming raw material and final product QC evaluations
 - Process control (monitoring) data/logs (e.g. pH, chlorine or ORP, temperature, etc.)
 - Transfer dates, timing, etc.

Receiving

1. Utilizing the delivery notes, delivery tags, harvest reports and computerized data gathering, 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 Proper Beverage, Co.'s cooler/distribution facilities.
 - The total volume (cases) of suspected product(s) already passed onto the production department (or to shipping if production is not involved, e.g. cross docked, field packed product).
2. Any suspected raw materials are also be placed on hold.
 3. Provides the information gathered to the Traceback/Product Recall Coordinator as it is retrieved.

Procurement/Buyer Manager

1. Maintains and can access the following records as quickly as possible:
 - Up-to-date contact details of all suppliers that are used for raw materials including, commodities, ingredients, chemicals and packaging materials.
 - Records that show any supplier approval system documentation (letters of guarantee, certificates of analysis, third party audit information and contracts).
 - An inventory of goods received, any off-site storage.
2. Informs supplier(s) of their involvement in a recall process.
3. Provides assistance and advice if the recall issue is traced back to the raw materials that are used to produce the products.
4. Is the contact point for the supplier(s), if the supplier is the point of origin for a recall (i.e. a trace forward recall)?

Provides the information gathered to the Traceback/Product Recall Coordinator as it is retrieved.

Management

1. The Proper Beverage, Co.'s Management bears the ultimate responsibility for determining the necessity for a product recall. This decision to be made with the input of the Traceback/Product Recall Team and legal counsel. Upon being informed that a Proper Beverage, Co.'s product poses a potential health hazard to consumers, the Management of the company will work directly with the Traceback/Product Recall Team to determine the necessity for a product(s) recall, its interim classification and depth.
2. Instructs the Traceback/Product Recall Coordinator to initiate a recall.
3. Maintains contact with legal counsel throughout the recall process.
4. Works with legal counsel, the Team, and the PR firm to develop press releases/public statements.



Table 1. Traceback/Product Recall Team Contact Information

<p>Traceback/ Product Recall Coordinator</p> <p>Name: Larry Griesbach Office Phone Number: 616-820-0328 Cellular: 616-414-2463</p>	<p>Alternate: Traceback/Product Recall Coordinator</p> <p>Name: Kevin Clement Office Phone Number: 616-820-0328 Cellular: 248-974-4008</p>
<p>Sales</p> <p>Name: Brian Hirsch Office Phone Number: 616-820-0328 Cellular: 414-731-1663</p>	<p>Alternate: Sales</p> <p>Name: Kevin Clement Office Phone Number: 616-820-0328 Cellular: 248-974-4008</p>
<p>Shipping/Receiving</p> <p>Name: Andrew Vredeveld Office Phone Number: 616-820-0328 Cellular: 616-826-2244</p>	<p>Alternate: Shipping/Receiving</p> <p>Name: Larry Griesbach Office Phone Number: 616-820-0328 Cellular: 616-414-2463</p>
<p>Production</p> <p>Name: Cody VanNoord Office Phone Number: 616-820-0328 Cellular: 616-745-5440</p>	<p>Alternate: Production</p> <p>Name: Andrew Vredeveld Office Phone Number: 616-820-0328 Cellular: 616-826-2244</p>
<p>QA (if different from Recall Coordinator)</p> <p>Name: Dylan Lucas Office Phone Number: 616-820-0328</p>	<p>Alternate QA</p> <p>Name: Cody VanNoord Office Phone Number: 616-820-0328 Cellular: 616-745-5440</p>
<p>Procurement</p> <p>Name: Brian Hirsch Office Phone Number: 616-820-0328 Cellular: 414-731-1663</p>	<p>Alternate: Procurement</p> <p>Name: Kevin Clement Office Phone Number: 616-820-0328 Cellular: 248-974-4008</p>
<p>Legal</p> <p>Name: CBH Attorneys & Counselors Office Phone Number: 616-608-3061</p>	<p>Alternate: Other</p> <p>Name: Mitch Iwan Office Phone Number: 773-821-1943 Cellular: 616-218-3378</p>
<p>:</p>	
<p>Third Party Auditor</p> <p>Name: SQF Office Phone Number: 877-277-2635</p>	
<p>MDARD</p> <p>Name: Casey Wagner Office Phone Number : 616-558-4614</p>	<p>POLICE DEPARTMENT</p> <p>Name: Ottawa County Sheriff Office Phone Number: 616-738-4000 Cellular: 911</p>

FIRE DEPARTMENT

Name: Hudsonville Fire Department
Office Phone Number: 616-669-0200
Cellular: 911

Section 5 - Model Forms

Figure 3. Customer Contact Form Example

Customer Contact Form

Telephone or Personal Visit (circle one)

Date: _____

Time: _____ a.m. / p.m.

Contact Name: _____

Title: _____

Company: _____

Subject: Product Hold and/or Recall Notification via Telephone or Personal Visit

This is (Name of Marketing/Sales Interviewer) with Proper Beverage, Co.'s. I am calling to notify you have that we are requesting that you isolate and hold (product name and description, including the code date). We are calling all of our customers that might have received (product name and code date). We currently believe that this product may represent a public health hazard. We believe the product [ISSUE] (e.g. may have an illegal pesticide residue [NAME], be contaminated with a pathogenic microorganism [NAME], etc.). Please clearly mark the product as on hold and do not distribute this product under any circumstances Proper Beverage, Co.'s will contact you within the next few days with further information regarding compensation for the product and whether to return the product to Proper Beverage, Co.'s or to an alternative site for disposal. If you will allow me, I have a few questions to ask you regarding this product hold and/or recall.

1. 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

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

Yes

No

3. How much product do you have in inventory? _____

4. If the answer to question 2 is **YES**, do you intend to return the product to Proper Beverage, Co.'s if 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. We will follow up this telephone conversation with a written notification and a Status Questionnaire. Please fill out the Questionnaire and return it to Proper Beverage, Co.'s as soon as possible. Instructions are provided with the Questionnaire.

We will be back in touch with you as soon as possible with information regarding the disposition of the product. If you have any questions, please give us a call.

Name of Proper Beverage, Co.'s caller,

Figure 4. Recall Communication Letter Example

Recall Communication Letter

Date: _____

Customer Name: _____

Title: _____

Address: _____

Email (or Fax): _____

Attn: *Customer Name*

Proper Beverage, Co.'s is voluntarily recalling (*product name*), (*container size*), etc. Enclosed is a copy of the original customer invoice, listing the quantity of product shipped to you on (*date*), the product label _____ and the code date _____ which is located _____ on the package (box).

The voluntary recall is being initiated following the discovery of [*ISSUE*] (e.g. *detection of an unregistered ingredient, [NAME] by our analysis-testing program/a potentially pathogenic microorganism, [NAME] by our microbial screening program*) in our [*PRODUCT NAME AND DESCRIPTION*]. Our concern is that your company has received, or may have received, similarly contaminated product. Consumption of this product by consumers represents a potential health hazard.

Proper Beverage, Co.'s requests all consignees (wholesalers and retailers) to hold and discontinue selling their existing stock of this product. Please contact *Proper Beverage, Co.'s* at (*telephone #*) and ask for *CONTACT NAME* for instructions regarding returning or destroying any remaining inventories of the recalled products you may have. 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 *Proper Beverage, Co.'s*.

Enclosed is a recall effectiveness questionnaire. We are requesting that you complete it promptly and return the questionnaire by fax transmission (*fax #*) or scan and e-mail to (*e-mail address*). If you have any questions regarding this request, please call *CONTACT NAME (phone#)*.

Thank you for your cooperation in this matter.

Sincerely,

NAME
TITLE

Figure 5. Status Check Questionnaire Example

Status Check Questionnaire

E-mail or Fax Transmission (circle one)

Date: _____

To: (Name, Title and Company) _____

From: (Name), Proper Beverage, Co.'s _____

Subject: **Recall Effectiveness Check**

E-mail / Fax: _____

Proper Beverage, Co.'s **Product Recall**

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

1. Did your firm receive notification that Proper Beverage, Co.'s is requesting a product hold and/or recalling its (product name and description) product?

Yes

No

2. Who contacted your firm and when? _____

3. Did your firm receive shipments of the product being placed on hold and/or recalled?

Yes

No

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

Yes

No

5. If the answer to question 4 is **YES**, do you intend to return the product to Proper Beverage, Co.'s if so requested?

Yes

No

6. If the answer to question 5 is **NO**, please explain your intentions _____

7. How much of this product do you currently have on hand? _____

8. Have you distributed this product to any of your customers?

Yes

No

9. If the answer to question 8 is YES, to whom (*name, address, telephone*) and how much? _____

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

Yes

No

11. If the answer to question 7 is **YES**, please provide details: _____

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

Return Immediately To:
Proper Beverage, Co.'s
E-mail: NAME@YOUR COMPANY NAME.com
PHONE:

Figure 6. Media Request Form Example

Media Request Form

This form is to be used in the event that a member of the news media requests an interview via telephone, facsimile, e-mail or in person. This information is then be transmitted to *NAME and/or ALTERNATE NAME* for review **prior** to granting the interview. *NAME (Media Firm)* will review the request; research the author with regard to their history/experience in covering food safety issues and provide direction prior to conducting the interview.

Date: _____

Time: _____

Proper Beverage, Co.'s Employee Contacted: _____

Person Requesting Information: _____

Organization Represented: _____

Deadline: _____

Type (e.g. newspaper, radio, television, trade publication, magazine, etc.):

How is the interview to take place? _____

Is background information required? _____

General (e.g. scope of article, angle, etc.):

Forward to:

NAME
MEDIA FIRM
Telephone:
Fax:

Figure 7. Customer Feedback Form Example

Customer Feedback Form

Date/Time of Feedback: _____

Feedback From: _____

Address: _____

Telephone Number: _____

Product Description: _____

Where was product purchased? _____

Amount of Product Involved: _____

Product Code/Date: _____

Issue: _____

Call Back Needed: **Yes** **No** Date: _____

Actions: **Letter** **Notify Managers**
 Money Back **Investigate**
 Coupons

Managers' Notified: _____

Investigative Findings/Comments:

Action taken to correct issue and to prevent its recurrence:

Signature: _____ **Date:** _____

Figure 8. Traceback/Product Recall Information Form Example

Traceback/Product Recall Information Form

Date/time of notification or complaint: _____

Notification or complaint made by: _____

Telephone number/fax/e-mail of contact: _____

Agency or Proper Beverage, Co.'s: _____

Address: _____

Product description/label: _____

Date(s) of occurrence? _____

Purchase Order/Invoice Number(s): _____

Product Code(s) or Use by Date(s): _____

Amount of product involved: _____

Type of health hazard: _____ Sample (physical/chemical) _____

Number of people affected/condition? _____

Location(s): _____

Current status of Agency investigation: _____

Are other products/grower/shippers involved? _____

If so, what/who? _____

Are food handlers or other cross contamination points considered? _____

Are other agencies/companies involved? Who? _____

What action does the Agency/Company recommend? _____

Signature: _____

Mock Recall Summary Form

Mock Recall Initiation Date: _____ Start Time: _____ Finish Time: _____

Product(s) Involved: _____

Shipping Product Code(s) that started the issue: _____ Class of Recall: _____

Personnel Involved: _____

Mock Scenario Description (include cause for the mock recall and where the mock recall originated):

Time taken to discover where the affected product might have been sent: _____

Product Shipping Consolidation	Result Comments
Amount of product shipped	
Amount of product still in inventory	
Amount of product produced	
Amount of product not accounted for	
<i>Where relevant, culls and byproducts sent for further processing into human food and animal feed might need accounting for.</i>	

Lessons learned from the Mock Recall:

Notes:

- 1) ***Attach to the mock recall, copies of records that prove the trace back or trace forward from the given scenario or actual event information leading to which customers and/or suppliers are involved (depending on scenario). Refer to Figure 2.***
- 2) ***Ensure that all key documents used in a mock recall state "Mock Recall" on them, so that no party ever considers these to be documents for a real recall.***
- 3) ***Do not call customers or suppliers when carrying out mock recalls unless they have offered this service. Usually take the mock recall as far as proving that the contact details are on file.***
- 4) ***Choose mock scenarios that are realistic, challenging and vary the mock scenario so that over time the range of products, sources and issues covered test the system in as many ways as possible.***