



Extension FactSheet

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What Can You Do to Be Ready for a Recall?

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What can you do to avoid a recall?

Companies should establish practices to prevent a recall. Such preventive practices may include the following actions:

- Have a Hazard Analysis and Critical Control Point (HACCP) plan that lists hazards most likely to occur, and also provides in-plant corrective actions when there is a failure at a critical control point (Regulations 21 CFR Part 123 and Part 120 are for seafood and fruits/vegetables, respectively). FDA/FSIS suggests that establishments should use their HACCP plans to identify situations where recalls may be necessary. Based on the information part of a HACCP plan, an establishment could determine what recall action would be necessary if a product in violation is released to the channels of commerce. There is no regulatory requirement for an establishment to include the recall plan in its HACCP plan; however, it would be a rational approach.
- Comply with FDA's current Good Manufacturing Practices (cGMPs) regulations (21 CFR Parts 110, 113, and 114) (recommended for companies that manufacture, pack, or store food materials).
- Develop and maintain quality management systems covering quality assurance and control to prevent adulteration, substandard quality, and to ensure safety.
- Develop a food security and tampering prevention policy. The FDA's Bioterrorism/Food Safety Security Act became law in 2003. The Food Safety Inspection Services division of the USDA has published guidelines for holding and transportation of meat, poultry, and eggs. Both FDA and USDA rules cover manufacturers, suppliers, and distributors. The FDA also requires all "persons who manufacture, process, pack, transport,

distribute, receive, hold, or import food intended for human or animal consumption in the United States" to be registered with the FDA (see Reference #1) (<http://www.cfsan.fda.gov/~dms/ffregui4.html>).

- Ensure the quality of raw materials by working with credible suppliers. A company's quality and safety program depends on its suppliers' related programs. You have the risk of recalling your product if you purchase adulterated or defective ingredients from your suppliers. The suggested procedures to avoid a recall because of suppliers' related problems are:
 - Setting specifications for all incoming goods including raw materials, packaging materials, ingredients, chemicals, and processing aids to comply with legal and additional internal requirements. Product dating, lot identification, microbial pre-testing, shipping and storage temperature could be included in the specifications.
 - Inspecting all incoming products.
 - Requesting written guarantees and copies of HACCP programs from your suppliers.
 - Conducting supplier audits.
- Develop procedures for checking and maintaining records of storage temperature and humidity.

What can you do to be prepared for a recall?

Even when the best preventive practices are in place, a need for a recall may arise. Companies have the responsibility to remove any product that is adulterated, misbranded, or hazardous to the consumer from commerce promptly. A "recall" is an effective and efficient approach for accomplishing this objective. The disruption of a recall to a company's operation and business can

be minimized by planning in advance to be ready for a recall so that rapid and effective removal of a product of concern is ensured.

The actions necessary to be ready to implement a recall are:

- Select a recall coordinator and establish a recall committee.
- Prepare a recall action plan.
- Keep the contact information in the recall plan up-to-date.
- Conduct mock recalls to test the effectiveness and promptness of the recall plan.
- Revise the recall plan based on mock recalls.
- Establish a product identification and tracking system.
- Conduct timely stock rotations, and maintain good records for the supplied products, invoices, and bills for purchased and sold products.
- Develop a customer inquiry and complaint database to identify major problems. The questionnaire for collection of information from consumers should be designed to get as much information as possible regarding the problem. The frequency of the calls related to the same problem should be recorded.

To be able to implement the necessary actions in the event of a recall, you need to have a well-considered recall plan.

What should you include in a recall plan?

A recall plan is prepared in order to act quickly and effectively to **locate** the product, to **remove** the product from the market, to **quarantine** the product, to **identify** and to **correct** the root cause in order to prevent recurring, and to **reassure** the consumers about the establishment's commitment to consumer safety. Therefore, the *recall plan* should describe in detail the procedures that the establishment will follow and the responsibilities of individuals during the recall. The *recall committee* selected and managed by the *recall coordinator* prepares the recall plan.

A recall plan should include the following items:

- I. Purpose.
- II. Definitions.
- III. Responsibilities.
- IV. Fact gathering about the defective product.
- V. Health hazard evaluation and recall classification.
- VI. Notification of the regulatory agency.
- VII. Recall communications.
- VIII. Recall status reports.
- IX. Returned product.

X. Recall termination.

XI. Appendices.

Each item in a recall plan outlined above is discussed in detail to guide any establishment in preparing its own recall plan.

- I. **Purpose:** This step includes statements defining the company objective for preparing the recall plan. It should define the scope of the products covered under the recall plan. As a starting point, all products produced under a single HACCP plan, including cleaning and sanitation procedures, could be included in the recall plan. The scope of the recall may expand or contract from this point.
- II. **Definitions:** In this section, the terms related to the recall and the level of recalls are defined. The terms include: *recall*, *market withdrawal*, *stock recovery*, *recall classification*, *class I*, *class II*, and *class III recalls*. The terms are defined in OSU Extension Fact Sheet AEX-251 (see Reference #2) (<http://ohioline.osu.edu/aex-fact/0251.html>).
- III. **Responsibilities:** The roles and responsibilities of every individual participating in the execution of the recall should be clearly specified in the recall plan. The recall plan is prepared and implemented by the recall coordinator and the members of the recall committee. The recall plan should include all current contact information (office and home telephone numbers, fax numbers, mobile phone numbers, e-mail addresses) for members of the recall committee and their deputies and should be updated frequently. OSU Extension Fact Sheet AEX-252 defines the responsibilities of the recall committee members (see Reference #3) (<http://ohioline.osu.edu/aex-fact/pdf/0252.pdf>).
- IV. **Fact gathering about the defective product:**
 - A. **Internal discovery:** A defective product may be spotted internally (company plants, warehouses, co-packers). The seriousness of the problem should be rapidly evaluated by the plant manager and the quality assurance manager in the plant and/or the supply chain. If the problem is considered to be serious, the recall coordinator should be alerted ***immediately***.
 - B. **External discovery:** Every complaint about a product should be investigated by consumer services, sales and marketing department, and regional technical management to evaluate the seriousness of the problem. If the problem is judged to be serious, or even if there is an element of doubt, the recall coordinator should be alerted ***immediately***.

A questionnaire, which may incorporate the following questions, should be included as an appendix to the recall plan to document the facts about the suspicious product.

- What are the product identification numbers?
- What is the source of the complaint?
- When was the complaint received?
- What is the reason for the complaint?
- What tests have been carried out that support the complaint?

V. Health hazard evaluation and recall classification:

The recall plan should state the potential defects and hazards for the products in scope of the recall plan and the corresponding recall class. At a minimum, this evaluation should take into account the following factors:

- Whether any disease or injuries have already occurred from the use of the product.
- Assessment of the relative degree of seriousness of the health hazard to which the population is at risk.
- Assessment of the consequences (immediate or long-range) of the hazard.
- Assessment of the ability to identify and quantify the defective product in the marketplace.

The seriousness of the problem will determine the **depth** of recall, which is the distribution chain level at which the recall will be implemented. Depth of recall depends on the classification of recall, based on the degree of hazard, the extent of distribution, and the level to which the recalled product was distributed. Recall depth is based on the following levels of product removal:

- **Consumer level** includes household consumers, as well as all other levels of distribution to reach the household consumer for Class I recalls.
- **Retail level** includes retail sellers and any intermediate wholesale level to reach the retail sellers for Class II recalls.
- **Wholesale level** includes the distribution level between the manufacturer and retail or user level for withdrawals or Class III recalls.

A document describing the level of defect associated with the class of recall may be included in the recall plan as an appendix (see Appendix A).

VI. Notification of the regulatory agency: After the recall coordinator makes the decision to initiate the recall, he or she contacts the regulatory agency. Therefore, the contact information for the individual

in the appropriate regulatory agency should be included in the recall plan. The recall coordinator provides the following information for the regulatory agency to classify the recall:

- A. Product ID (name, code number, lot number, size).
- B. Reason for recall.
- C. How the problem was discovered.
- D. Quantity manufactured and distributed.
- E. Distribution records.
- F. Copy of recall communication.
- G. Recall strategy and depth.
- H. Public warning.

Based on the information, the regulatory agency determines the depth of the recall.

VII. Recall communications: Appropriate and effective communication during recall is essential for a successful recall process. The person(s) in charge of consumer affairs and public relations on the recall committee, together with the recall coordinator, handle the recall communications by setting up a communications center. The recall plan should include the following documents regarding communications with suppliers, customers, and consumers:

- A. A generic press release (see Appendix B): The purpose of a press release is to alert the public that a product presents a serious hazard to health. A press release is required for Class I recalls. The FDA will advise the company when a press release is necessary. Where the FDA is not in agreement with a press release prepared by the firm, the FDA may issue a separate press release.
- B. A generic communication letter for its affected affiliates about the recall: The format, content, and extent of a recall communication should be appropriate with the hazard associated with the product being recalled, the strategy developed, and the recall plan.
- C. Information specifying the means of communication that will be used, including contact information for all potential media outlets such as television stations, radio stations, and newspapers and with local, state, and regional coverage areas as well as the national wire services and sample communications.
- D. The name and contact information for the designated spokesperson.

VIII. Recall status reports: The reports are intended to periodically summarize recall effectiveness checks during the recall. The recall plan should include a policy to document the number of consignees notified, number

of responses versus non-responses, and quantity of product accounted for, all of which are necessary for recall effectiveness checks.

- IX. **Returned product:** The recall plan should include the following statements to clearly define the strategies regarding the returned product:
- Returned products will be quarantined until the termination of the recall.
 - Quarantined products will be reprocessed or disposed of after receiving the approval of technical management.
 - FDA will be notified for approval of planned method of disposition because FDA may wish to witness final destruction of Class I articles.
- X. **Recall termination:** The recall plan should clearly define the policy to be implemented to end the recall process. The following statements should be in the recall plan regarding the termination of the recall:
- The recall coordinator officially decides when the recall is to end.
 - Sales management undertakes the replacement or reimbursement of recalled goods.
 - All returned goods must be controlled and registered by distribution and the producer plant. The plant quality assurance manager will report the amount of product, control results, and defect ratio to the recall coordinator.
 - The recall coordinator prepares the final report for general management. The final report includes:
 - The reason for the recall.
 - The extent of the recall.
 - The percentage of the defective product retrieved.
 - The handling of the recalled products in coordination with the regulatory agency.
 - The total cost of the recall.
- XI. **Appendices:** The following documents are suggested to be included as appendices in the recall plan:
- A. The definition of level of defect (Appendix A).
 - B. A press release template and a sample press release from FDA (see Reference #4) (Appendix B).
 - C. A product withdrawal form template (Appendix C).
 - D. Recall plan flow sheet: This document will provide an overview of the recall plan including the

flow of information and decision-making steps (Appendix D).

Once a recall plan is established, the recall team should conduct practice or “mock” recalls to ensure the plan’s effectiveness and to detect pitfalls in the plan. Mock recalls should be conducted without prior knowledge of the personnel involved. A mock recall assesses the recall team’s ability to use the plan to conduct a review of records related to processing, raw product, ingredients, and containers, and to determine the distribution of the product with the given lot code. Such exercises can also determine the distributors’ (including brokers) ability to locate product rapidly. If there are major problems or it is taking too long to obtain the necessary information, it is strongly suggested that the recall team get help from external organizations and/or consultants.

Conclusions

While it is hard to predict recalls, having a tested recall plan and taking all the preventive cautions can protect a company from costly recalls. The company should appoint a recall coordinator, establish a recall team, select a recall contact at each facility (plants, warehouses, brokers, distributors, stores), have a recall contact at each supplier and customer, and prepare a recall plan. A communication plan to make sure that recall/market removal notices are relayed to the responsible employees should also be part of the recall plan. In addition, simulation of a recall based on the recall plan can evaluate the effectiveness of the plan and ensure that the organization will be ready for a recall.

References

- 1) FDA Center for Food Safety and Applied Nutrition, *Questions and Answers Regarding Registration of Food Facilities*, <http://www.cfsan.fda.gov/~dms/ffregui4.html>
- 2) Kaletunç, G., and Ozadali, F. 2002. *Understanding the Recall Concept in the Food Industry*. Ohio State University Extension Fact Sheet AEX-251, <http://ohioline.osu.edu/aex-fact/pdf/0251.pdf>
- 3) Kaletunç, G., and Ozadali, F. 2002. *Who Should Be Involved in Food Recall Planning and Execution?* Ohio State University Extension Fact Sheet AEX-252, <http://ohioline.osu.edu/aex-fact/pdf/0252.pdf>
- 4) Model press release, FDA. http://www.fda.gov/ora/compliance_ref/recalls/listeria.htm#SAMPLE

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Appendix A. LEVEL OF DEFECT

Class I Recall

The product may harm the consumer for any of the following reasons:

- Presence of contaminants or toxins in critical amounts.
- Presence of pathogenic micro-organisms.
- Non-integrity of packaging.
- Presence of undeclared critical allergens.
- Packaging error (e.g. milk powder in infant formula pack).
- Product tampering and adulteration.
- Presence of broken glass or other foreign bodies that may harm the consumer.

Class II Recall

The product has a serious organoleptic defect or does not comply with federal regulations in respect to any of the following:

- Labeling.
- Packaging.
- Composition (ingredients).
- Contains pesticides, mycotoxins, veterinary drug residues, heavy metals, nitrates, or other contaminants in excess of regulatory limits.
- Falls outside the norms for food additives.
- Falls outside microbiological norms (excluding pathogens).
- Net weight.
- Nutritional claims.

Class III –or– Market Withdrawal

The product complies fully with FDA regulations, but does not meet company internal quality standards in respect to any of the following:

- Composition.
- Microbiological quality.
- Physical properties (solubility, wettability).
- Appearance (e.g. color, texture, foreign bodies).
- Labeling.
- Packaging.
- Physical appearance of the pack or shipping carton/case.
- Organoleptic defect.

Appendix B. PRESS RELEASE TEMPLATE (see Reference #4)

FOR IMMEDIATE RELEASE

DATE

COMPANY CONTACT AND PHONE NUMBER

FOOD CO. RECALLS PRODUCT BECAUSE OF POSSIBLE HEALTH RISK

Company Name of **City, State** is recalling **Quantity and/or type of Product**, because it has the potential to be contaminated with *Listeria monocytogenes*, an organism that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, *Listeria* infection can cause miscarriages and stillbirths among pregnant women.

Information on product distribution (**listing** of the states and areas where the product was distributed and how it reached consumers, e.g. through retail stores, mail order, direct delivery).

Specific information on how to identify the product (e.g. the type of container [plastic/metal/glass], size or appearance of the product, product brand name, flavors, codes and expiration dates, etc.).

Status of the number of and types of related illnesses that have been CONFIRMED to date (e.g. “No illnesses have been reported to date.”)

Brief explanation about what is known about the problem, such as how it was revealed, and what is known about its source. An example of such a description—“the recall was the result of a routine sampling program by the company, which revealed that the finished products contained the bacteria. The company has ceased the production and distribution of the product as FDA and the company continue their investigation as to what caused the problem.”

Information on what consumers should do with the product and where they can get additional information (e.g. “Consumers who have purchased Brand X are urged to return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.”)

SAMPLE PRESS RELEASE

XYZ Inc.

123 Smith Lane

Anywhere, MS

FOR IMMEDIATE RELEASE

DATE

Sam Smith /555-555-5555

XYZ RECALLS “SNACKIES” BECAUSE OF POSSIBLE HEALTH RISK

XYZ Inc. of Anywhere, MS, is recalling its 5-ounce packages of “Snackies” food treats because they have the potential to be contaminated with *Listeria monocytogenes*, an organism that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, *Listeria* infection can cause miscarriages and stillbirths among pregnant women.

The recalled “Snackies” were distributed nationwide in retail stores and through mail orders.

The product comes in a 5-ounce, clear plastic package marked with lot #666666 on the top and with an expiration date of 12/12/99 stamped on the side.

No illnesses have been reported to date in connection with this problem.

The potential for contamination was noted after routine testing by the company revealed the presence of *Listeria monocytogenes* in 5-ounce packages of “Snackies.”

The production of the product has been suspended while FDA and the company continue to investigate the source of the problem.

Consumers who have purchased 5-ounce packages of “Snackies” are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.

Appendix C. PRODUCT WITHDRAWAL FORM

Date:

PRODUCT RECALL/WITHDRAWAL FORM

(Product identified with the following information has to be recalled/withdrawn according to “Product Recall Plan.”)

1. What is the product?.....

2. What is the source of the complaint?

- Manufacturer Customer Consumer Regulatory agency Co-packer

Name and Surname.....

Company/Department

Address (No., Street, P.O. Box, City).....

Telephone

Fax

3. When was the complaint received?

Month/Day/Year

Time.....

4. What is the reason for the complaint?

- Product quality Illness Packaging Foreign body

Provide details

.....

.....

.....

5. What tests have been carried out that support the complaint?

External (give results).....

.....

Internal (give results).....

.....

6. What is the detailed information about the product involved?

Product.....

Lot code.....

Date of manufacture.....

Expiration date.....

Quantity.....

(Destination for withdrawn products)	
(Aimed recalling/withdrawing duration)	

7. What is the depth of the recall?

- Class 1 Class 2 Class 3

Comments.....

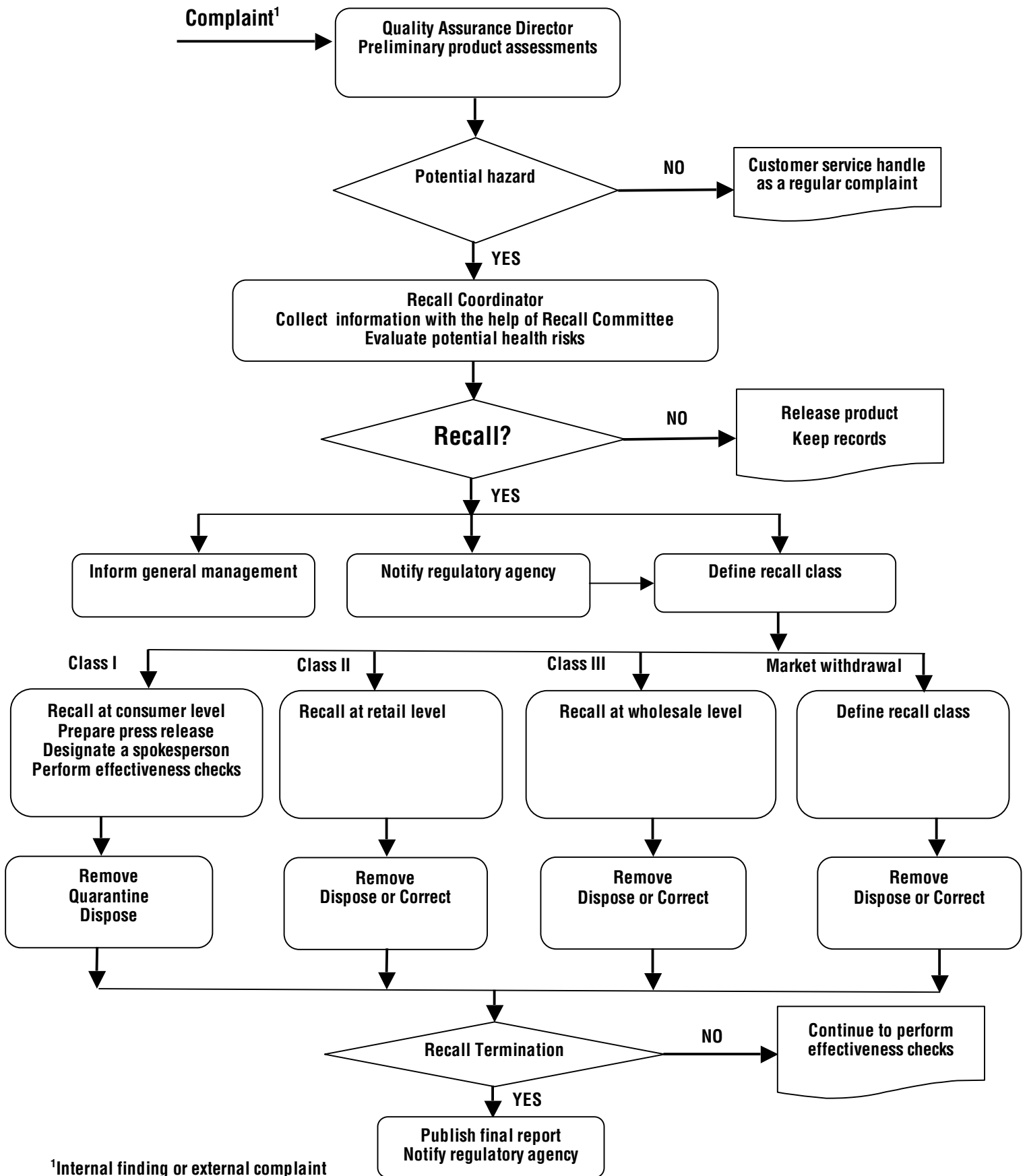
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Quantities and destinations product distributed

Destination	Date	(Quantity sent)	
		Unit	Size/Weight

Appendix D. RECALL PLAN—FLOW SHEET



¹Internal finding or external complaint