Recall Preparedness

Food Protection Taskforce
Alaska Department of Environmental Conservation
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Product Recall

- Violative under the FD&C Act
  - Adulterated or
  - Misbranded

- Product has been distributed in commerce

- FDA has jurisdiction
  - Product moved in interstate commerce
  - A component of the product (raw ingredient) moved in interstate commerce.

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FSMA PCHF Recall Plan Requirements

- Required for any food with a hazard requiring a preventive control
- Must be written
- Must describe steps to take and assign responsibility to:
  - Notify direct customers and consignees
  - Notify the public, when appropriate
  - Conduct effectiveness checks
  - Execute disposition of food

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18 AAC 34.047 & 18 AAC 34.706 - Recall plans

(a) A food processing establishment/seafood processor shall develop, maintain, and make available for ADEC review written procedures sufficient to notify consignees & consumers of a product recall and remove affected product from commerce.

These written procedures ***must describe the steps to be taken***, and ***assign responsibilities for taking those steps***, to perform the following actions as appropriate to the facility/establishment:

1. notify each direct consignee of the recalled food/seafood product, including how to return or dispose of the affected product;
2. notify the public about the hazard presented by the recalled food/seafood product;
3. appropriately dispose of the recalled food/seafood product by reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food/seafood product; and
4. verify, by means such as personal visits, telephone calls, written communications, or a combination of those means, that each consignee received notification of the recall and has taken the appropriate action.

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18 AAC 34.047 & 18 AAC 34.706 - Recall plans

(b) The operator of a food processing establishment/seafood processor shall notify the ADEC immediately if the operator/processor knows or has reason to believe that a product released into commerce might be adulterated or misbranded.

(c) The operator of a food processing establishment/seafood processor shall implement the recall procedures developed in (a) of this section either at the direction of the ADEC or of the operator's/processor's own accord if the operator/processor knows or has reason to believe that a product released into commerce might be adulterated or misbranded.

(d) The operator of a food processing establishment/seafood processor shall maintain records relating to implementation of recall procedures, including notifications to the ADEC, consignees, and the public, and product disposition.

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Recall Plan Common Elements

- Defined roles and responsibilities
- Contact lists for external notification
  - Regulators, customers, public
- Lot identification and verification information
- Effectiveness check procedures during a recall
- Product disposition procedures

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Define Recall Roles

- Identify and document a recall coordinator and recall team
- Describe duties and roles of the team in the recall plan

- Recall team may include:
  - Recall coordinator
  - Operations manager
  - Publicity and public relations
  - Sales and marketing
  - Logistics and receiving
  - Quality assurance
  - Accountant
  - Scientific advisor
  - Attorney
  - Administrative support
  - FDA recall coordinator
  - State recall coordinator

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Define and Assign Responsibility

- Define details of each step in the recall process and person responsible for each item
  - Scope of recall
  - Regulatory agency communication
  - Recall initiation
  - Customer notification
  - Information and data compilation
  - Document gathering
  - Securing inventory of affected lot(s) in your control
  - Product disposition
  - Documentation

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External Notification

- Notify regulatory agencies
  - FDA and state recall coordinator
- Contact customers affected by the recall
  - Identify product and how to return or dispose of it
- Notify the public when appropriate
  - Required for Class I and some Class II recalls
    - SAHCODA*

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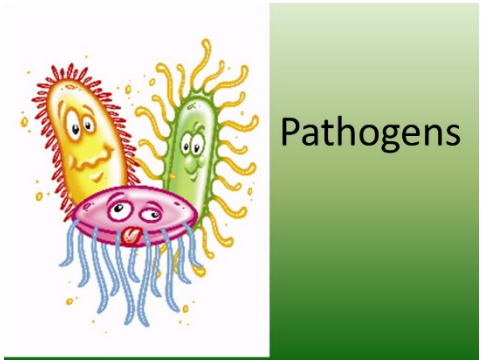
SAHCODHA*

- Serious
- Adverse
- Health
- Consequences or
- Death to
- Humans or
- Animals



Hazards associated with a Class I Recall

- Pathogens
- Allergens

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Identification and Verification of Lot Information

- Identify product involved in a recall with specific markings
  - Inner packaging (where appropriate)
  - Outer packaging (where appropriate)
  - Case

- Identify quantities of product involved in a recall
  - Facilitates metrics involved in the recovery of suspect product

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Effectiveness Checks

- Daily reconciliation of quantity recovered versus total
- Consignee response and follow up
- Recall effectiveness
  - 100 × (# cases recovered / total cases shipped)
- Regulatory effectiveness audits

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Product Disposition

- Determined based on the hazard, the food and other factors

- May include:
  - Reconditioning
  - Reworking
  - Relabeling
  - Diverting to a use that does not present safety concern
  - Destruction

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Corrective Action Related to Recalls

- Reanalysis of the Food Safety Plan is required
- May result in:
  - Modification of the Food Safety Plan
  - Retraining to enhance implementation effectiveness
  - Other actions to prevent recurrence of the problem
- Maintain a log of decisions made throughout recall
- After recall is completed, conduct review meeting

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Periodically Test the System – Mock Recall

- Verify information in the recall plan
  - Contact information, product descriptions, templates, customer lists, supplier lists, etc.
- Test the recall team
  - Can they determine if a recall would be needed?
  - Are the right people on the team and are there alternates?
  - Do they know how to contact technical help if needed?
  - Can they trace product one-step forward and one-step back?
  - Can they create records, logs, product descriptions, press releases, etc.?

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Recall Classifications

- Actions taken by a firm to remove a violative product from the market
  - **Class I recall**: reasonable probability of serious adverse health consequences or death
  - **Class II recall**: may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote
  - **Class III recall**: not likely to cause adverse health consequences
- May be conducted on a firm's own initiative, by FDA or state request, or by FDA or state order

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Examples of Class I Recalls

- Pathogen Contamination
  - *Listeria monocytogenes*
    - cantaloupe
  - *Salmonella*
    - shell eggs
  - *Escherichia coli (E. coli)* O157:H7
    - raw spinach/romaine lettuce
  - *Clostridium botulinum* (toxin)
    - canned chili

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Examples of Class I Recalls

- Undeclared Allergens
  - **Peanuts** (peanut butter, peanut flour, peanut protein)
  - **Tree Nuts** (almonds, chestnuts, macadamias, pecans, walnuts, hazelnuts or filberts, cashews, brazil nuts, hickory nuts, pistachios and pine nuts)
  - **Egg** (egg yolk, egg white/albumin, meringue, ovalbumin)
  - **Milk** (butter, buttermilk, casein, cheese, cottage cheese, curds, whey, lactose, caseinate)
  - **Fish** (fresh or saltwater)
  - **Crustacea** (shrimp, lobster, crab, crayfish)
  - **Soybeans** (miso, tofu, soy flour)

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Examples of Class I Recalls

- Other
  - Undeclared Sulfites
    - equal to, or greater than, 10 mg/serving
  - Foreign objects
    - metal (classification depends on shape and size)
    - glass

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Typical Actions for a Class I Recall

- Issuance of public warning/Press Release and post a placard at point of sale (POS) when applicable

- Immediately notify consignees and direct them to immediately notify their consignees/customers.

- Do not forget internet sales - immediately notify those customers as well.

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Typical Actions for a Class I Recall

- The purpose for this notification is to:
  - Immediately remove product from consumers
  - Immediately remove product from store/retail shelves
  - Immediately stop product from further distribution

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Typical Action for a Class I Recall

- 100% effectiveness checks (calling and/or e-mailing consignees to verify recall)
- Provide written weekly status (progress) reports to the State/FDA recall coordinator

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Reportable Food Registry

- You are required to file electronically in the Reportable Food Registry (RFR) if consumption of your product could result in a serious adverse health consequence or death to humans or animals.

- Infant formula and dietary supplements are exempt.

- http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm

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Examples of Class II Recalls

- Undeclared Allergens
  - **wheat**
  - **coconut**
  - **An ingredient such as butter is listed, but milk is not listed as a sub-ingredient of butter (or listed anywhere else)**

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Allergen Labeling – Class II

- Sources of allergens (ingredients) must be must be declared in the ingredient statement.

- Example: “Ingredients: semolina (wheat), rice flour, rolled oats, pine nuts, tomato juice, whey (milk), sodium caseinate (milk) and natural flavoring (peanuts).”

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Allergen Labeling – Class II

- If you also choose to use a “Contains” statement, all the allergen ingredients must be listed.

- The following “Contains” statement could appear at the end of, or immediately adjacent to, the list of ingredients:

- Example: “Contains wheat, milk, pine nuts and peanuts.”

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Examples of Class II Recalls

- Undeclared Colors
  - FD&C Yellow No. 5
  - FD&C Yellow No. 6

- Undeclared Sulfites
  - Equal to 3.7 mg/serving, or greater, up to 9.9 mg/serving

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An example of sulfite levels

Start with the detected sulfite level of 50 ppm. The product's label reads one serving size is 3 ounces (85 g).

50 mcg/g X 85 g = 4250 mcg (4.25 mg) sulfite per serving.

4.25 mg/serving would be a Class II Recall

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Example of Class II Recalls

- Foreign objects
  - metal
  - classification depends on shape and size

- Under pasteurized products
  - Example: Cheese manufactured from under pasteurized raw milk that may be contaminated with *Salmonella, Listeria monocytogenes*, or *E. coli*

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Typical Actions for a Class II Recall

- No issuance of a public warning/Press Release (though a placard may be considered in some instances)
- Notify all consignees (usually via e-mail or telephone)
- 10 – 50% effectiveness checks
- Monthly status (progress) reports to State/FDA Recall Coordinator

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Examples of Class III Recalls

- Filth in foods
- Minor labeling error
- Undeclared sulfite levels, below 3.7mg/serving
- Food spoilage caused by mold/yeast (unless linked to illness, then upgraded)

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Typical action for Class III Recall

- No issuance of public warning/press release
- Notification to wholesale/retail level
- Limited or no effectiveness checks
- Monthly status (progress) reports to State/FDA Recall Coordinator

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Market Withdrawal

- A marketed product
- Product is in distribution channels
- Not in violation of the FD&C Act
- Not subject to legal action by the State/FDA

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Stock Recovery

- Non-marketed product
- Product has not left direct control of the company.

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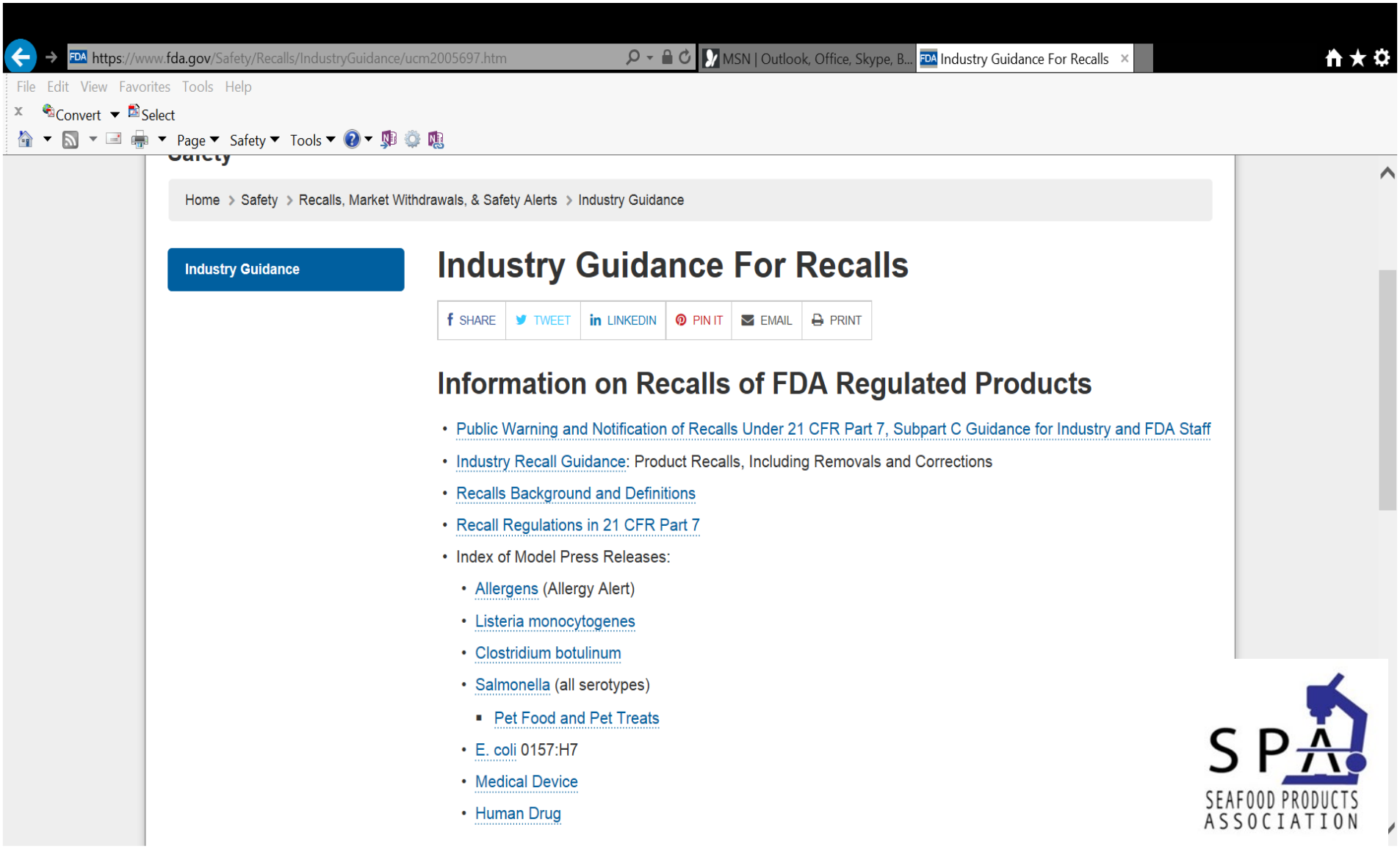
FDA WEBSITES



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WEBSITES

- **Industry Guidance: Information on Recalls of FDA Regulated Products:**

  https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls

  - Recalls Background and Definitions

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WEBSITES

- Index of Model Letter Exhibits in FDA Regulatory Procedures Manual:
  - 7-1 - Effectiveness Check Letter
  - 7-2 - Effectiveness Check Response Format
  - 7-3 - Effectiveness Check Questionnaire
  - 7-4 - Recall Letter (generic)
  - 7-5 - Recall Return Response Form
  - 7-6 - Recall Envelope

- Assisting Interested Parties in Addressing Marketplace Confusion Over the Identity of Products Subject to Recall

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WEBSITES

- **21 CFR Part 7 (Recall):**
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=7

- **Enforcement Report:**
  http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

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WEBSITES

- **Food Allergen Labeling and Consumer Protection Act (FALCPA):** FALCPA http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm

- **Reportable Food Registry (RFR):** http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm

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WEBSITES

- **FDA Recall Coordinators nationwide:**

https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators

- GENERAL: http://www.fda.gov

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ADEC Recall Coordinator:

- Noelani Thompson

Email: Noelani.Thompson@alaska.gov

FDA OHAF-6W Recall Group

- Recall Coordinator - Anh Trinh Nguyen

Email: orasearecalls@fda.hhs.gov

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https://www.ifsh.iit.edu/fspca/fspca-materials

[Company Name]

Recall Plan

Reviewed by: *Signature*, Title

Date: September 1, 2016

This model Recall Plan identifies information that is either required or recommended to facilitate an effective and efficient recall. While a Recall Plan is required by the *Preventive Controls for Human Food* regulation when a hazard requiring a preventive control is identified, no specific format and content is specified. This model contains questions and templates that can be used to develop an individualized Recall Plan. A Recall Plan must be developed as part of your Food Safety Plan records if you identify a hazard requiring a preventive control

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THANK YOU!

QUESTIONS?

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