FSPCA WEBINAR

How to Be Ready for a Recall: Working with FDA and Preparing for the Unexpected

December 12, 2024

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS TECH
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WELCOME AND INTRODUCTIONS

Amy Philpott, APR

Founder and Chief Brand Protector
Philpott PR Solutions, LLC

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Agenda

DESCRIPTION	PRESENTER	TIME
Housekeeping	Amy Philpott	12:00 – 12:05 ET
FSPCA News and Webinar introduction	Amy Philpott	12:05 – 12:15 ET
How to Be Ready for a Recall: Working with FDA and Preparing for the Unexpected	Anh Trinh Nguyen Maile Gradison, Elizabeth B. Fawell	12:15 – 1:15 ET
Q&A	All	1:15 – 1:30 ET

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NEWS

SAVE THE DATE! FSPCA 2025 Annual Conference

- The **9th Annual FSPCA Conference** will be held in person in the Chicagoland area on November 18-19, 2025
- Presentations from the 2024 FSPCA Annual Conference will be posted on the FSPCA website upon presenter approval

FSPCA Events webpage: https://www.fspca.net/events

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FSPCA Technical Assistance Network (TAN) Restructure

FDA FSMA RULE QUESTIONS	The FDA FSMA TAN will continue to address questions related to FSMA rule interpretation, applicability, programs, and implementation.
FSPCA SCIENTIFIC QUESTIONS	University Extension Specialists are volunteering to provide support by answering scientific and/or technical questions related to food safety. Inquirers can choose from the list of volunteer experts and interact directly with that expert.
FSPCA CURRICULA	You can submit questions related to FSPCA Animal Food, FSVP, Intentional Adulteration and Food Traceability curricula and training, or request FSPCA Administrative Support for any of your FSPCA-related needs.
FSPCA PCHF V2.0 QUESTIONS	Experts are on hand to assist V2.0 Human Food Lead Instructors with their future participant course delivery questions or answer general questions about V1.2 and V2.0.

FSPCA TAN: https://fspca.my.site.com/FSPCA/s/?language=en_US

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FSPCA Preventive Controls for Human Food Version 2.0 Lead Instructor Refresher Training

- The FSPCA Preventive Controls for Human Food (PCHF) Version 2.0 curriculum was finalized and recognized by FDA in October 2024.
- FSPCA Preventive Controls for Human Food Version 2.0 Lead Instructor Refresher Training began on October 29, 2024.
- The FSPCA Preventive Controls for Human Food (PCHF) Version 1.2 curriculum will be retired on June 30, 2025. Beginning July 1, 2025, FSPCA will only allow PCHF Version 2.0 participant course registration and deliveries.
- If Human Food Lead Instructors intend to continue to register and deliver FSPCA Human Food participant courses, this FSPCA Preventive Controls for Human Food Version 2.0 Lead Instructor Refresher Training Course is mandatory.

FSPCA webpage: https://www.fspca.net/pchf-v2-li-refresher-training

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2025 FSPCA Lead Instructor (LI) Courses

- The 2025 FSPCA Lead Instructor course schedule has not been determined.
  - All approved Lead Instructor applicants will be notified once the schedule is determined.
  - Find complete Lead Instructor course details on the FSPCA website.

FSPCA Preventive Controls for Human Food V2.0 Lead Instructor Course

FSPCA Preventive Controls for Animal Food Lead Instructor Course

FSPCA Foreign Supplier Verification Programs (FSVP) Lead Instructor Course

FSPCA Intentional Adulteration Vulnerability Assessment Combination Course

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Upcoming 2025 FSPCA Webinar for FSPCA Lead Instructors

- **Free FSPCA Webinar:** FDA's Data Dashboards
- **Date:** Wednesday, February 12
- **Time:** 11:00 am – 12:00 pm U.S. Central
- **Registration:** Open to all FSPCA Lead Instructors

Presenter: Robert Bughman

Operations Research Analyst
Regulatory Business Informatics Branch
ORA/OBISM/DRBIS/RBIB
U.S. Food and Drug Administration (FDA)

Moderator: Kathy Gombas

Principal
FSMA Solutions

REGISTER*

**FSPCA Lead Instructor status will be verified*

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HOW TO BE READY FOR A RECALL: WORKING WITH FDA AND PREPARING FOR THE UNEXPECTED

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Requirements for a Recall Plan PCHF (21 CFR 117.139) and PCAF (21 CFR 507.38)

For food with a hazard requiring a preventive control

(a) Establish a written recall plan

(b) Include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions:

(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;

(2) Notify the public about any hazard presented by the food;

(3) Conduct effectiveness checks to verify that the recall is carried out; and

(4) Appropriately dispose of the recalled food.

Recall communications: Common target audiences

Regulators (federal, state, local)

Direct consignees, received recalled product

Direct consignees, did NOT receive recalled product

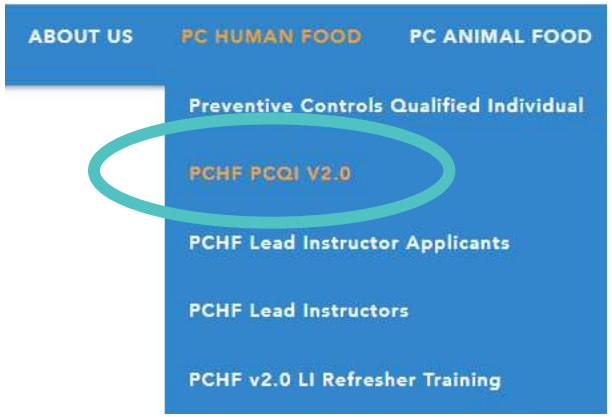
Consumers:

- press release
- consumer call center
- website
- social media accounts
- media interviews

- Employees (office, facility, field, etc.)
- Suppliers
- Brand owners
- Business partners
- Shareholders
- SEC if publicly held company
- Others...

FSPCA Recall Plan Resources

- Visit: www.fspca.net
- Choose "PCHF PCQI V2.0" from the dropdown menu under PC Human Food
- Click on the "Materials and Resources" tab
- Scroll to "PCHF Workaids" on the lower left of the page



An Animal Food Recall Plan Template is available on the PC Animal Food Materials and Resources webpage

Webinar Presenters

Anh Trinh Nguyen

Recall Coordinator

U.S. Food and Drug Administration

Maile Gradison

Partner

Hogan Lovells

Elizabeth B. Fawell

Partner

Hogan Lovells

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HOW TO BE READY FOR A RECALL: WORKING WITH FDA AND PREPARING FOR THE UNEXPECTED

Anh Trinh Nguyen

Division Recall Coordinator
U.S. Food and Drug Administration

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Food Safety Preventive Controls Alliance (FSPCA)

How to Be Ready for Recall Webinar

December 12, 2024

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Office of Human Food Inspectorate
Division of Human Food Inspectorate West 3
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FDA/OII Recall Coordinators

As of October 1, 2024, FDA's reorganization is in effect. The inspection and investigation function (including recall management) of the Office of Regulatory Affairs is now the Office of Inspections and Investigations (OII). Most of the CFSAN Staff are part of the Human Foods Program (HFP).

Firm should locate the Division Recall Coordinator (DRC) in their state to report a new recall.
https://www.fda.gov/safety/industry-guidance-recalls/oii-recall-coordinators

Agenda

- Recall Initiation Types
- Voluntary Recall Process & Timeframe Overview
- Voluntary Recall - Ready in 24 hours
- Recall Strategy - Letter vs. Press Release
- Attachment A, Attachment B, Recall Classification
- Recall Audit Checks - Effective vs. Ineffective
- Firm’s Recall Status Report and Termination
- New Recall, Recall Averted, Sub-Recall
- Undeclared Allergens and Recall Guidance

Recall Initiation Types

Voluntary Recall per 21 CFR 7.46.

-Firm initiates recall based on firm's finding or based on FDA or state's recommendation.

-Recall means a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action.

FDA Requested Recall per 21 CFR 7.45:

FDA send the formal FDA Requested Recall Letter when the following determinations have been met:

1) Firm has not initiated a voluntary recall

2) Distributed product presents a risk of illness or injuries or gross consumer protection

3) FDA action is necessary to protect public health

Recall Initiation Types

Mandatory Recall 21 USC 3501:

The FDA's mandatory food recall authority went into effect when FSMA was enacted on January 4, 2011. Section 423 of the FD&C Act, was added by section 206 of FSMA, gives the FDA the authority to order a responsible firm to recall. FSMA's mandatory recall authority allows the FDA to mandate a recall when all four conditions below are met:

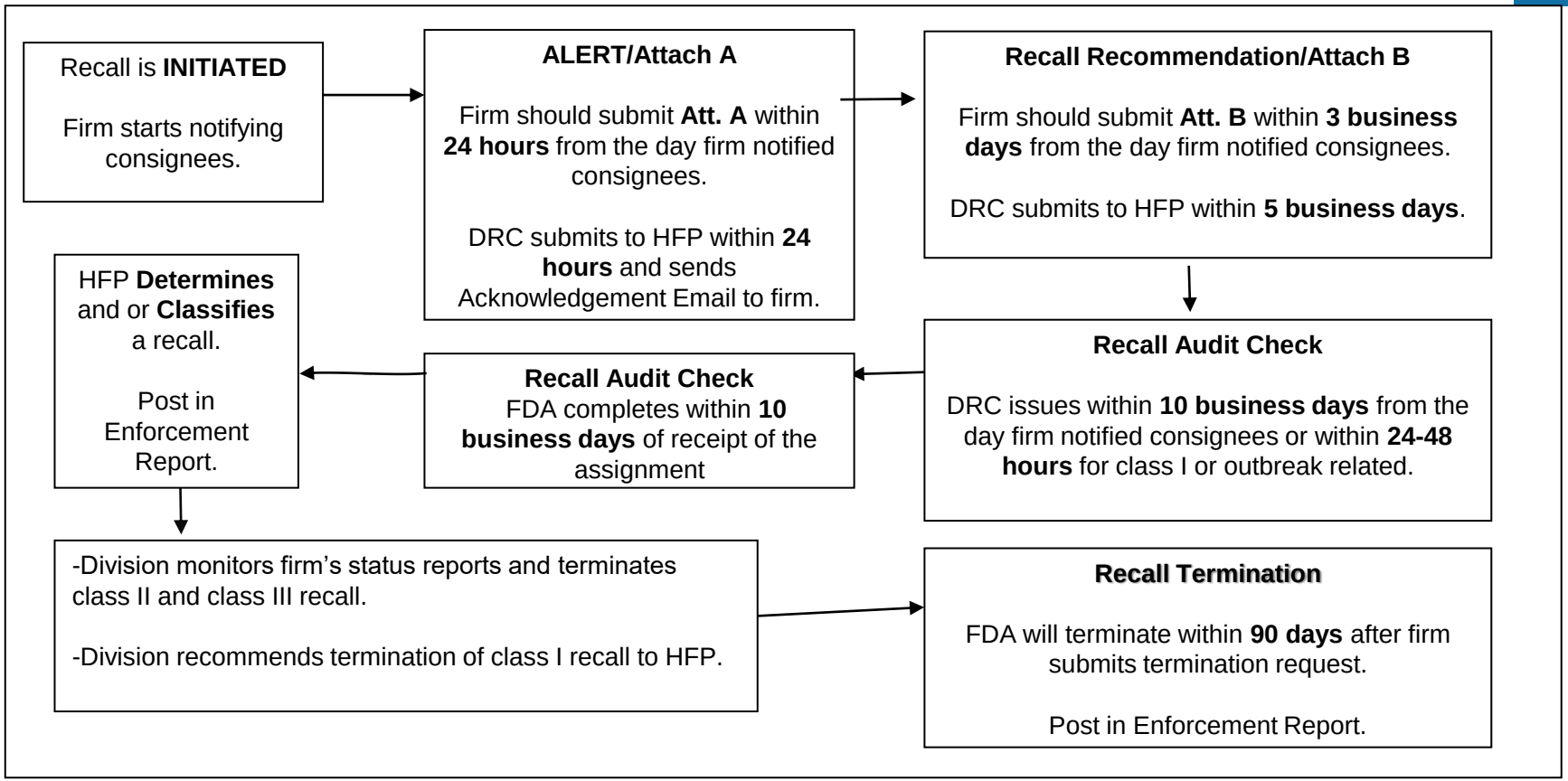
1) the FDA determines that there is a reasonable probability that an article of food is adulterated under section 402 and/or misbranded under section 403(w) of the FD&C Act

2) there is a reasonable probability that the use of or exposure to such food would cause SAHCODHA

3) when a responsible firm is food facility that is required to register under 415(a) of the FD&C Act

4) when a responsible firm chooses not to conduct a voluntary recall

Voluntary Recall Process & Timeframe



FDA Voluntary Recall – Ready in 24 Hours

Firms should have the following items ready to initiate a recall:

-Identify impacted product and label

-Recall scope (production dates and lot codes)

-Distribution (amount, shipping dates, states)

-Consignees list (types of consignee and contact information)

-Reportable Food Registry (RFR) report

-Draft notification letter

-Draft press release for class I

Reportable Food Registry Report (RFR)

- The RFR requires a responsible party to file a report when there is a reasonable probability that the use of, or exposure to, a **reportable food** will cause serious adverse health consequences or death to humans or animals.
- The RFR report must be filed **no later than 24 hours** at this portal www.safetyreporting.hhs.gov.
- Responsible party is a **registered food facility** that manufactures, processes, packs, or holds food for human or animal consumption in the U.S.

When Not to File RFR

- Responsible party is not required to registered with FDA (e.g. retailer).
- Article of food is infant formula or dietary supplement.
- A responsible party meets ALL of the following three conditions:
  1. The adulteration *originated* with the responsible party; AND
  2. The responsible party *detected* the adulteration prior to any transfer to another person of the article of food; AND
  3. The responsible party *corrected* the adulteration or *destroyed* or caused the destruction of the article of food.

Recall Strategy - Notification Letter

Per **Recall** definition 21 CFR 7.3(g), **Recall** means a firm's removal or correction (re-labeling or re-conditioning) of a marketed product that the FDA considers to be in violation of the laws it administers.

Per **Recall Communication** 21 CFR 7.49(a), Recalling Firm is responsible for promptly sending direct accounts a **Food Recall Letter** with the following:

1) Product Name & Lot number subject to recall
2) Reason for Recall
3) Hazard of the product being recalled
4) Provide specific instructions to consignees such as ceasing further distribution or use of any remaining product
5) Ask distributor to notify their downstream accounts who received the affected product (sub-recall)
6) Tell customers how to reply to a recalling firm

Recall Strategy – Press Release

The FDA's policy is to evaluate each individual recall in determining whether a public warning is needed. For Class I and signification class II recalls where a press release should be issued within 24 hours:

1. When product poses a serious adverse health consequences or death to humans or animals (SAHCODHA).
2. When impacted product was sold to consumers, and it may be still be available at consumers' home.
3. When firm cannot notify direct consignees effectively or in case of ineffective recall.
4. Products intended for infant use.
5. All recalls that involve injury or illness, consumer complaint, related to outbreak.

Justification for No Press

Press is NOT necessary or issued:

- Recalled product has not yet been sold to consumers (distributed to warehouse DC only).
- Product was distributed to manufacturers for further processing.
- Product was distributed in bulk case to foodservice accounts only.
- Recalling firm is able to notify direct consumers via email or phone, and can determine whether email is opened, read, or delivered. Consumers did not further distribute or sold products to anyone else.

Attachment A

Firm should submit Attachment A information to DRC **within 24 hours:**

- Label of impacted ingredient which was used in recalled finished product
- Label of impacted product subject to recall
- Lot code(s) of recalled product
- Brief reason for recall and brief root cause if known
- Name and physical address, city, state of Recalling Firm, Manufacturer, and Responsible Firm (may have contributed to the adulteration or misbranding)
- Recall initiation date and method of notification
- Distribution chain notification date
- Final recall notification letter
- Final press release

Attachment B

- Firm should submit Attachment B information to DRC **within 3 working days** from the day the firm notified consignees.
- Attachment B provides information for Affected Product, Codes, Firms, Firm Officials, Detailed Reason for Recall, Volume of Affected Product, Distribution Pattern, Recall Strategy, Root Cause and Preventive Actions.
- Templates for Attachment A/B, recall letter, and press release can be obtained from OII DRC.

Recall Classification

Recall Classification means the numerical designation, i.e., I, II, or III, assigned by the FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

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

Recall Audit Check (RAC) - Effective

- Consignee received formal notification from recalling firm.
- Product was quarantined for destruction, return, or correction.
- Consignee destroyed or corrected product.
- Consignees notified downstream customers if product has been distributed.

RAC – Ineffective By Recalling Firm

- Consignee did not receive formal notification from recalling firm.
- FDA will provide the firm's recall notification letter and/or the press release during audit check to consignee.
- FDA may consider to send the Ineffective Recall Letter to recalling firm.

RAC – Ineffective by Consignee

- Consignee did not follow the instructions provided by the notifying firm and affected product is still held for sale/use.
- Consignee distributed affected product but did not conduct a sub-recall (did not notify downstream accounts).
- Consignee cannot determine whether they received the specific recalled lots or further distributed the product, and did not conduct a sub-recall.

Recall Status Report and Termination

- Firm should submit status report monthly (or bi-weekly upon request). Questions are found in the Acknowledgment email.
- Firm may send request termination via email to DRC.
- Per 21 CFR Part 7.55, FDA will terminate a recall when it is determined that all reasonable efforts have been made to remove or correct affected product, 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.

What is a New Recall?

- When a firm changes the recalled product (e.g., used the product as a component of a new product, re-labeled the product to obscure the original product name and/or lot code, repackaged the product), a new product recall is warranted.

- Firm should submit recall Attachment A/B information when a new product recall is initiated.

New Recall is Averted

- A new recall is averted if the consignee re-labeled the product or made new product, but allergens declared correctly on label.
- A new recall is not warranted if consignee applied a kill step (heat treatment) adequately to eliminate a pathogen hazard in product.
- Consignee does not need to submit recall Attachment A/B information to DRC.
- Firm should provide new finished product labels or kill step information to FDA for evaluation.

What is Sub-Recall?

- A Sub-Recall is when a consignee notified their own downstream customers about a recall of product they distributed.
- FDA will ask consignee for a sub-distribution list and downstream customer’s recall notification when FDA conducts sub-account recall audit checks.
- Consignee does not need to submit Attachment A/B information to FDA.

Allergens Recall

Undeclared major allergens:

-Milk, Egg, Fish, Crustacean Shellfish (crab, lobster, or shrimp), Tree Nuts (including coconut), Peanuts, Wheat, Soy, and Sesame (effective since 1/1/2023).

*Press is recommended when a certain allergen is NOT declared in Ingredients Statement and Contains statement.

Gluten-free product:

-Product is labeled gluten-free but found to contain wheat gluten (>20ppm). Press is recommended.

-Supporting Evidence: Affected ingredient's label and Finished Product's incorrect and correct labels.

Total Food Recalls events FY 2024

Data published from 10/1/2023 to 9/30/2024 on https://datadashboard.fda.gov/ora/cd/recalls.htm

- 465 food recall events initiated
- 1908 food products were recalled from 465 events

Recall Classifications for 465 events

- 179 class I
- 244 class II
- 42 class III

Resources

- 21 CFR Part 7
- Industry Guidance For Recalls
- Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C (March 2022).
- Guidance for Industry and FDA Staff: Questions and Answers Regarding Mandatory Food Recalls
- Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C
- Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls
- Food Defense

Resources

Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food | FDA

- Chapter 4: Preventive Controls (PDF: 499KB)
- Chapter 15: Supply-Chain Program for Human Food Products (PDF: 920KB)
- Chapter 14: Recall Plan (Draft Guidance)

Enforcement Report:

http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

RFR and Food Registration

- **RFR At A Glance**: https://www.fda.gov/files/food/published/Reportable-Food-Registry-(RFR)-At-a-Glance.pdf
- **File RFR or Create Account at Safety Reporting Portal**: www.safetyreporting.hhs.gov
- **Online Food Firm Registration**: https://www.fda.gov/food/registration-food-facilities-and-other-submissions/online-registration-food-facilities.
- **FIS Create New Account**: https://www.fda.gov/food/online-registration-food-facilities/fda-industry-systems-user-guide-create-new-account.
- **Food Firm Registration Step-by-Step Instructions**: https://www.fda.gov/food/online-registration-food-facilities/food-facility-registration-user-guide-step-step-instructions
- **Food Facility Registration Renewal**: https://www.fda.gov/food/online-registration-food-facilities/food-facility-registration-user-guide-biennial-registration-renewal.
- **Questions and Answers Regarding Food Facility Registration**: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-facility-registration-seventh-edition.

Food Registration

There is no fee for registration, registration renewal, or updates to a registration. Steps to register a food facility:

Obtain a DUNS number

- Register the facility name and physical address associated with your FFR (Food Facility Registration) (Section 2) with D&B to obtain a DUNS number. Note – Name and address details must match with the FFR section 2.
- Visit D&B's Import Safety Registration Portal to search for an existing registration(s) and submit update requests, or to obtain new DUNS number(s). See user guide for details – Import Safety Registration Portal D-U-N-S® (DUNS) Number Quick User Guide.

Create a FDA Industry Systems account

- Once created, the same account will be used to update or renew your registration, which is required every two years during the registration period.
- Step by Step Guide FDA Industry Systems User Guide: Create New Account | FDA

Add a Food Facility Registration to your FDA Industry Systems account.

- Step by Step Guide Food Facility Registration User Guide: Step-by-Step Instructions | FDA

HOW TO BE READY FOR A RECALL: WORKING WITH FDA AND PREPARING FOR THE UNEXPECTED

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Additional Considerations for Recalls

Initial Stages

- Fact gathering
- Are the criteria for a recall met?
- Who makes the decision?
- Do you need to report to the Reportable Food Registry?
- Who is gathering the data on scope, amounts, and where product is located?
- Have you stopped distribution?

Additional Considerations for Recalls

Manufacturing & Food Safety

- Scope of Recall
- Root Cause Investigation and Corrective Actions
- Continuing, Pausing, and/or Resuming Production

Additional Considerations for Recalls

Communications

- Internal Stakeholders
- Consumer Contacts
- Customer Contacts
- Business Partner Notifications
- Media Strategy

Additional Considerations for Recalls

Legal

- Legal Claims
- Insurance Coverage
- FDA Regulatory Legal Counsel

Additional Considerations for Recalls

Additional FDA Engagement

- Permission for lawyer to engage with FDA
- Reconditioning
- Recall Close Out Request
  - Effectiveness Checks
  - Product Returns and Destruction
  - Root Cause Investigation and Corrective Actions
- Resuming Production

Contact Information

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Reminder: Webinar Presentation and Recording

- Along with a PDF of the presentation, a portion of this webinar will be recorded and posted to the FSPCA website post-event.
  - The webinar recording is **view only**, download is not available
  - The Q&A portion of the webinar will **not** be recorded

- Please allow 5 business days for the presentation and recording to be published

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Questions?

If you have any questions,
please contact the FSPCA at
fspca@iit.edu
or or visit the FSPCA website at
https://www.fspca.net/
for resources on preventive controls, lead instructor applications, and details of other FSPCA activities.

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THANK YOU!

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