



Modernizing Recalls Project

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The Association of Food & Drug Officials



A HISTORICAL PERSPECTIVE

THE EARLY YEARS

Commissioner
Blackburn



Cadillac Hotel — Detroit, Michigan



● 1896

Foundation for the organization to promote uniform application of food and drug regulation

National Association of State Dairy and Food Departments, later became AFDO.

● 1897



● 1904-1905

AFDO passed a resolution supporting the Pure Food and Drug Act

President Theodore Roosevelt signs Pure Food & Drug Act

● 1906



Dr. Harvey Wiley



President Theodore Roosevelt



● 1913

AFDO passed a motion establishing an Office of State Cooperation

AFDO produced the Model Uniform Food Law

● 1927



Sulfanilamide

● 1937

Sulfanilamide episode drives push to strengthen FDA authority

→ TIMELINE
CONTINUED
ON BACK.



President Franklin Roosevelt signs Food Drug & Cosmetic Act

● 1938



● 1939

AFDO passes resolution to support uniformity and state adoption of uniform legislation

George Burditt published "AFDO the First Hundred Years"

● 1996



● 1997

AFDO recommends the federal government develop a fully integrated national food safety system

● 2011

President Obama signed the Food Safety Modernization Act (FSMA) supporting an integrated food system

● 2017



AFDO moves to new headquarters



Ribbon cutting at new AFDO headquarters



Recall Workgroup



- Regulators
 - Nancy Beyer, Missouri
 - Lisa Hainstock, Michigan
 - Alida Sorenson, Minnesota
 - Michelle Boyd, Iowa
 - Katie Silvia, Rhode Island
 - Jessica Badour, Georgia
- Industry Members (Phase 2)
 - Michael Roberson, Publix
 - Cody Herndon, Publix
 - Amber Wenzler, Kroger
 - Kimberly Rice, Rose Acres (formerly USFoods)
 - Lenora Howard, ConAgra Foods
- IT Advisor
 - Eric Hoffman (FoodSHIELD)
- Facilitators
 - Brooke Benschoter, AFDO
 - Steven Mandernach, AFDO
 - Jennifer Pierquet, AFDO

Why do recalls need modernization?



- People continue to become ill after product is removed from the market
- Product continues to be sold after recall is initiated
- Delay between identification of need for recall and implementation of recall can cause additional ill people
- Recalls are confusing for industry, regulators, and public

Project Goals



- Identify performance criteria for effective removal of product from the marketplace (with metrics) that measures the effectiveness of food recalls
- Identify best practices in recall management among regulatory agencies such as FSIS, FDA, state, and local governments
- Determine what would be the characteristics of a highly effective regulatory recall system
- Determine challenges exist and potential ways to address challenges to achieve a highly effective regulatory recall system
- Develop a sustainable national registry of key food industry recall contacts
- Consider how any proposed changes would impact program standards

Stages of a recall



- Phase 1-Recall Initiation
- Phase 2-Initiate Recall Response
- Phase 3-Identify Audit Checks
- Phase 4-Conduct Audit Checks
- Phase 5-Closeout and After Action Review

Information Technology as a Tool



- Distribution list information
 - Changing into a common form
 - Automatic distribution
- Recall Audits
 - Use technology such as computers, smart phones, and tablets
 - UPC codes
 - Geolocation
 - Photos
- Analysis of data

Training needs



Needs to be brief, uniform, and just-in-time as recalls are not a routine activity

- Training for industry
- Training for regulators
 - Recall audits

Industry Survey



The goal is to get a baseline of dataset on the training needs of industry concerning the execution of recalls.

- Key Questions
 - What type of training is industry using?
 - How many use their recall plans?
 - Where is industry finding their training?
 - Are they interested in regulatory JIT training opportunities?




<https://www.oursafefood.com/>







Our Safe Food

 Dashboard

 Recalls

 Alerts

 Support

 Log Out

Welcome!

[Introduction](#)

[Overview](#)

[Activity](#)

[Meetings](#)

Welcome!

Our Safe Food: Recalls

OSF is structured to be a centralized resource of information pre, during, and post recalls, along with tools to support states, locals, industry, and federal stakeholders. Information on this system is considered confidential and is secured appropriately. Do not disseminate details without authorization.

How do I get started?

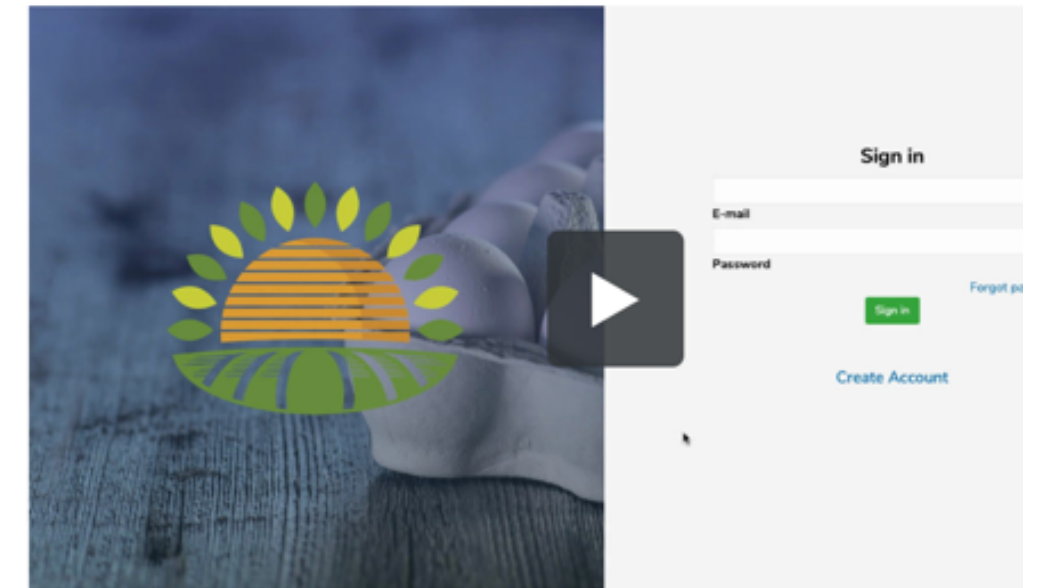
To get started, watch the overview video at the right. Or try this! Go ahead and check the two landing page options, before going into the recall:

 [Personalized](#)  [Busy System](#)

Top Tip:

Thinking about your process and how you may use the system is most helpful to determining best workflows.

Overview



More Information



[Quick Guide](#)



[Knowledgebase & FAQs](#)



Distribution List Template

This is the template file required to be used for automated data submission to the Portal of distribution lists.

[Download Template](#)

Search Distribution Lists

To review existing distribution list data for your state, follow the button below.

[Search Register](#)

Upload Distribution List

To upload a distribution list from a consignee in your state, select this option.

[Upload](#)

Enter a Distribution List Online

If you do not wish to enter your report using the template and then upload it, you may record your information directly into the online web form.

[Enter Online](#)



Recalls Admin

You are in control. Have at it!



Teams

Create or review team breakouts to coordinate data.

[Review](#)



All Submissions

Quick list of all submissions for distribution lists & products.

[Show All](#)



Group Membership

Manage members and roles for the Recalls application.

[Manage](#)



Recall Details Admin

Administer the settings, questions, reports, and security.

[Manage](#)



Group Analytics

(Beta) Review access counts, types, and requested usage analytics.

[Review](#)



Group Settings

Manage the settings for the group including email and design options.

[Settings](#)



Create Assignments

The first step for a State Coordinator is to assign effectiveness checks to inspectors. Click the button below to review your list.

Create Assignments

Review Assignments

Review all listed assignments to inspectors, whether accepted or declined.

Review Assignments

Audit Check Template

This is the FDA 3177 blank template file required for use by FDA inspectors, and **optional for states that elect not to use the web form**, for automated audit check submission to the Portal.

DOWNLOAD PDF

Upload Forms

This allows a completed PDF to be uploaded for auto-submission. (Deprecated?)

3177 Online Entry



Sabra Hummus Recall Input

Take Offline

Sync

Recall Information

Recall Number:

Sabra Hummus

Recalled Code(s):

50001

Product:

Audit Accounts

Direct:

Fareway #089

Phone NO:

Sub-Account (Secondary):

Phone NO:

Sub-Account (Tertiary):

Phone NO:

Consignee Data:

Contacted By:

☐ Phone

☐ Visit

☐ Other:

Name of Person Contacted, Title & Date:

Type of Consignee:

☐ Distributer

☐ Physician

☐ Retailer

☐ Hospital

☐ Processor

☐ Pharmacy

☐ Consumer

☐ Restaurant

☐ School

☐ Other:

Does (did) the Consignee Handle Recalled Product?

☐ Yes

☒ No

Notification Data:

Formal Recall Notice Received:

☐ Yes

☒ No

☐ Cannot Be Determined

(If "No" skip to item 6c.)

Recall Notification Received From:

☐ Recalling Firm

☐ Direct Account

☐ Sub-Account



Proposed Project Outcomes

- *Recommendations for best recall management practices* that minimize required resources, reduce recall execution cycle time, and enhance the integration of state, federal, and local resources. Those recommendations include:
 - Software solutions that *automate the required regulatory tasks* associated with conducting recalls
 - Delegating execution of calling lists
 - Using a software solutions *to consolidate, process and share distribution lists to states*
 - Enhancing recall communication models that would *disseminate recall information* across all regulatory stakeholders more effectively and efficiently
 - Developing a national registry database of key industry recall contacts

Output Timetable



- White Paper
- Recall Tool
- Industry Survey

Thank You & Contact

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