Recall Modernization:

Accelerated Partnering for Effective Recalls

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Executive Summary

Even with stringent protocols and processes used to produce food today, food recalls are still commonplace. To understand why this is so, we need to understand two basic problems associated with food recalls: 1) Consumers continue to become ill from recalled products that are consumed after the issuance of a recall announcement, and 2) the issuance of a recall and communication around it is typically done too late in the outbreak investigation to prevent additional illnesses.

While the U.S. Food and Drug Administration (FDA) has made efforts to address improvements around its recall activities, more is needed to adequately protect consumers. The release of FDA's New Era of Smarter Food Safety Blueprint calls for smarter tools and creative approaches for prevention and outbreak response, including recall modernization. We urge FDA to do just that: creatively explore new perspectives, innovative policies, and out-of-the-box approaches to implement the recommendations included in Table 2 of this paper. The table includes several recommendations related to not only recall policy, but foundational practices that are integral to working with others to carry out quick and effective recalls. These practices include establishing clear expectations and roles/responsibilities with partners, the absolute need for unrestricted information sharing between regulatory partners to limit duplication and maximize recall speed, and training not just on official statute, but providing *standardized* interpretation of FDA guidance, directives, and internal policies for individuals

both internal and external to FDA. Using the data collected from our surveys and expertise from working group members, an argument will be presented here that recalls and FDA's collaborative approach with partners are both in need of transformative change and fresh approaches. While recalls are recognized as complex events with many contributing factors, our goal is to understand these complexities and identify how each contributes to the policy, information sharing, training, communication, and culture challenges summarized above.

We welcome FDA to work with us and other stakeholders, including industry associations, consumer groups, and state, local, tribal, and territorial regulators, to improve understanding of the data and analysis used in this paper and possibly conduct more outreach as it considers recall modernization and effective, two-way partnerships moving forward. FDA should review the recommendations proposed in this paper, as well as those from STOP Foodborne Illness call to action, and take constructive steps to: update its policies, align its staff, develop novel approaches to information sharing that works for all partners, adopt new recall coordination technologies, provide training on both law and guidance, and enhance the transparency of its communications with partners to successfully conduct recalls in a new era of smarter food safety.

Likely, the single most important item that needs to be addressed is a clear and common purpose in effectuating recalls for FDA and State, Local, Tribal, and Territorial (SLTT) partners. We believe that this clear purpose is the public health goal of expeditiously removing product from the marker, providing consumers simple, usable information in identifying the product, and greatly minimizing the post-recall continuation of illness and injury to consumers. This public health approach does not include the regulatory purpose of determining if the recall is effective. While effectuating a recall remains a firm responsibility, ensuring product is off the market is a public health responsibility for all public health agencies. If we, as a public health system, focus on the largely administrative measurement of recall effectiveness as FDA's and SLTT's responsibility and not product removal, we negate our public health mission of mitigating illness and injury to consumers. We can and must do better to collaboratively and effectively recall potentially adulterated products to protect consumers in this smarter and more creative era of food safety.

Note: This paper will not cover recalls pertaining to products regulated by the U.S. Department of Agriculture, animal food, drugs, devices, or biologicals.

Introduction

The first known recall exercised through the Pure Food and Drug Act took place 100 years ago in canned black olives. Between 1919 and 1920, 18 people died from *Clostridium botulinum* in one of the first multistate outbreaks of a processed product. In response to the deaths, the canning industry at the time sought to form partnerships in order to gain the public's trust and confidence in canned goods. Consumers were still weary of commercially canned goods, a novel product for most domestic homes, and critics blamed canned foods for "poisoning and digestive upset".[1] Despite poor public opinion, the canners "quickly sought the help of government agencies and scientific researchers, funding the Botulism Commission".[1] The result of these partnerships led to new regulations to process olives at 240 °F for at least 40 minutes and "changed the view of canned food safety as an issue of public health".[1] California canners went so far to fund a permanent cannery inspection service carried out by the State Board of Health that could regulate and control the production and distribution of canned food products throughout the state.[1] Other canned products followed suit: Standardized methods were developed for tuna, sardines, and all vegetable products and enforced by the California Cannery Inspection Service[1]. These ideas spread to other states, and thus the canning industry overcame their black olive fiasco and forged a lasting image of the safety of canned food products.

Why is a look back at this history important? It is important because this is the way in which the industry leads the charge for regulatory change. Today, 100 years later, recalls are still dominating news headlines. In 2019 alone, the U.S. Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) reported 124 recalls of 20 million pounds[2] of food recalled, and the U.S. Food and Drug Administration (FDA)'s Enforcement Report listed a total of 609 additional Class I and II recalls that were completed that same year.[3] Products like romaine lettuce, onions, caramel apples, and ice cream have been recalled due to adulteration by foodborne pathogens and continue to challenge the current recall processes and mindset. In a similar fashion to the canning industry, the Association of Food and Drug Officials (AFDO) gathered state regulatory agencies and food industry experts to understand why the recall process continues to cause consternation. FDA acknowledged recalls being a pain point as demonstrated by the inclusions

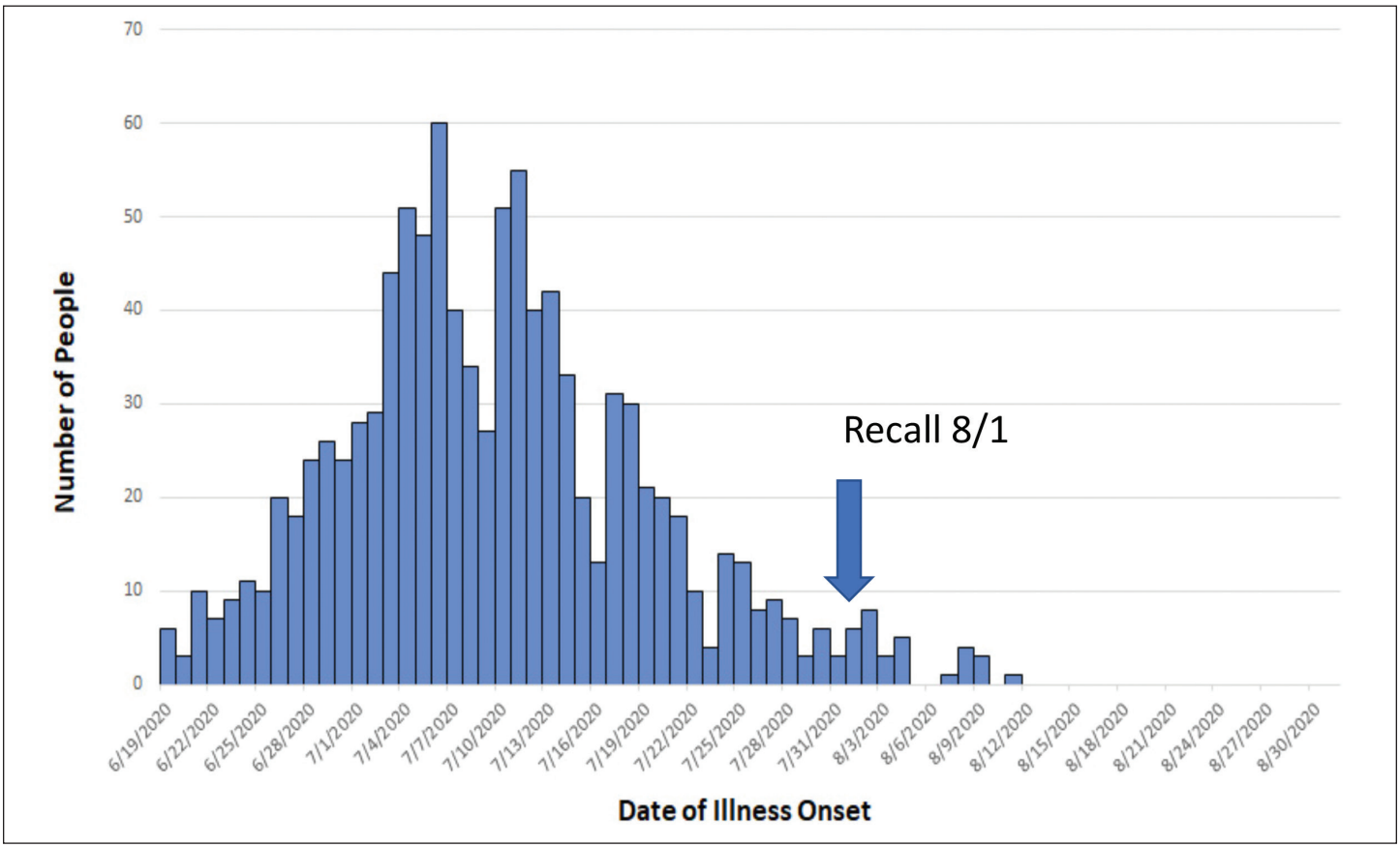

Figure 1. People infected with the outbreak strain of *Salmonella* Newport by date of illness on set as of August 31, 2020.

of recall objectives in FDA's *New Ear of Smarter Food Safety* Blueprint (Sidebar 1).[4] Core Elements 1 and 2, and arguably 3 (if modernizing retail food has a recall approach), all address the need to modernize the recall process.

The reasons AFDO pursued this project are because of two undeniable problems: 1) consumers continue to become ill from recalled products that are consumed after the issuance of the recall announcement, and 2) the issuance of a recall and communication is typically done too late in the outbreak investigation to effectively flatten the curve related to foodborne illnesses associated with the recalled product.

"Why is a look back at this history important? It is important because this is the way in which the industry leads the charge for regulatory change."

To illustrate these problems, consider the following recall example. The recent outbreak of *Salmonella* Newport in onions[5] (Figure 1). The recall was issued when the outbreak was almost over, yet illnesses were still being attributed to the suspect product post-recall announcement four weeks later. This recall support the main problems described in this paper: Recalls are being issued, but new illnesses continue.

Previous recall assessment reports conducted by the Government Accountability Office (GAO) and Office of Inspector General (OIG) have consistently recommended reforms to the recall process. At times, past reports by both offices have overlapped in their recommendations to FDA, which includes a review of GAO reports on recalls in 2000, 2004, and 2012 and an OIG report from 2017[6–8] (Sidebar 2). A survey conducted by AFDO in 2021 was conducted to ascertain how state regulatory agencies' recall procedures, actions, and staff training have changed over time (Sidebar 3). Additionally, AFDO worked with several state partners to widely distribute a 2021 industry survey to measure industry recall activities and training needs due to industry indicating a need for current training on recall regulatory expectations. All data collected from these surveys were consolidated into this paper, which will walk the reader through three significant recall events, discuss the findings of those events, and present recommendations to address the challenges identified.

Watershed Recall Events

Castleberry Recall – 2007

The 2007 Castleberry Brand recall prompted approximately 111 million cans of chili to be recalled, and eight outbreak-associated botulism cases in three states were identified (A Coordinated Response to Food Emergencies: Practice and Execution, V2.0a). In July 2007, public health officials in Texas and Indiana reported four suspected cases of foodborne botulism to the U.S. Centers for Disease Control and Prevention. By mid-July, federal and state inspectors arrived at Castleberry's Food Company in Augusta, GA, finding swollen cans. USDA FSIS and FDA issued recalls that were later expanded and updated. The request from multiple regulatory agencies for records slowed Castleberry's ability to quickly provide requested records.

The North Carolina Department of Agriculture's recall effectiveness checks on the Castleberry products revealed a series of failures: 38 percent of the recalled Castleberry product was still being sold in facilities being visited by state inspectors because a national food distributor had been reselling the recalled product.[9] North Carolina activated 1,000 personnel statewide, visited 16,000 facilities in 15 days, and removed 35,000 plus canned products from shelves.

The ensuing effort executed by state agencies to remove Castleberry products from points of sale was magnified. The product was found in food banks, gas stations, and small grocery stores. Additionally, inspectors continued to find Castleberry brand chili long after the recall ended because canned products have an extended shelf life and are therefore not necessarily used immediately.

A possible contributing factor for recalled product remaining in commerce was that, according to a 2008 case study, FDA had not implemented the recommendations made in the 2004 GAO report[6–8] (Sidebar 2). FDA said "some of the recommendations would be difficult to adapt because of differences in types of food processors and products, in the sizes of companies, and in the distribution practices".[4]

Peanut Corporation of America Recall – 2009

Peanut Corporation of America (PCA) caused one of the largest recalls in history. More than 700 cases in 46 states were reported, with nine deaths (10), and more than 3,600 products were recalled.[11] PCA expanded the recall three times after the initial recall was announced on January 16, 2009.

The development and passing of the 2011 FDA Food Safety Modernization Act (FSMA) can, in part, be tied to the events of PCA. In 2009, FDA did not have legal authority to mandate a recall and was therefore reliant on the company to act. The passage of FSMA resolved mandatory recall authority; however, many significant details were left to be worked out in the future, such as recall communication with state partners (FSMA, 58). In 2011, FDA's Coordinated Outbreak Response and Evaluation (CORE) began leading coordination needs in foodborne illness outbreaks. However, CORE is not the responsible entity for recalls nor do we argue that their role should encompass this activity.

Leafy Greens – 2017–2020

During 2017 and 2018 in the United States and Canada, there were three multistate, multinational foodborne disease outbreaks of *Escherichia coli* O157:H7 associated with the consumption of romaine lettuce that led to 376 illnesses, 158 hospitalizations, and 7 deaths (USDA ERS, 2019). In 2019 and 2020, another *E. coli* O157:H7 romaine outbreak was identified, with the product being sourced from the same region in the United States as the previous outbreaks. These outbreaks highlight the important fact that consumer advisories and FSIS recalls reached the public when the outbreaks were nearly over (Figure 2). For example, in the 2018 and 2019 romaine outbreaks, consumer advisories from FDA were not issued until November 20, 2018 and November 22, 2019, while illnesses began October 7, 2018, and September 24, 2019, respectively.

Complexities surrounding the identification of the source in any leafy green outbreak are known, but the ongoing trends of *E. coli* O157:H7 contamination of leafy greens should lead to quicker traceback processes and thereby faster recall responses through improved traceability of all products back to the field and the maintenance of electronic records. Traceability plays a large part in all recalls but is particularly critical in produce recalls. This is because of the short shelf life of the product and the need to quickly identify the grower

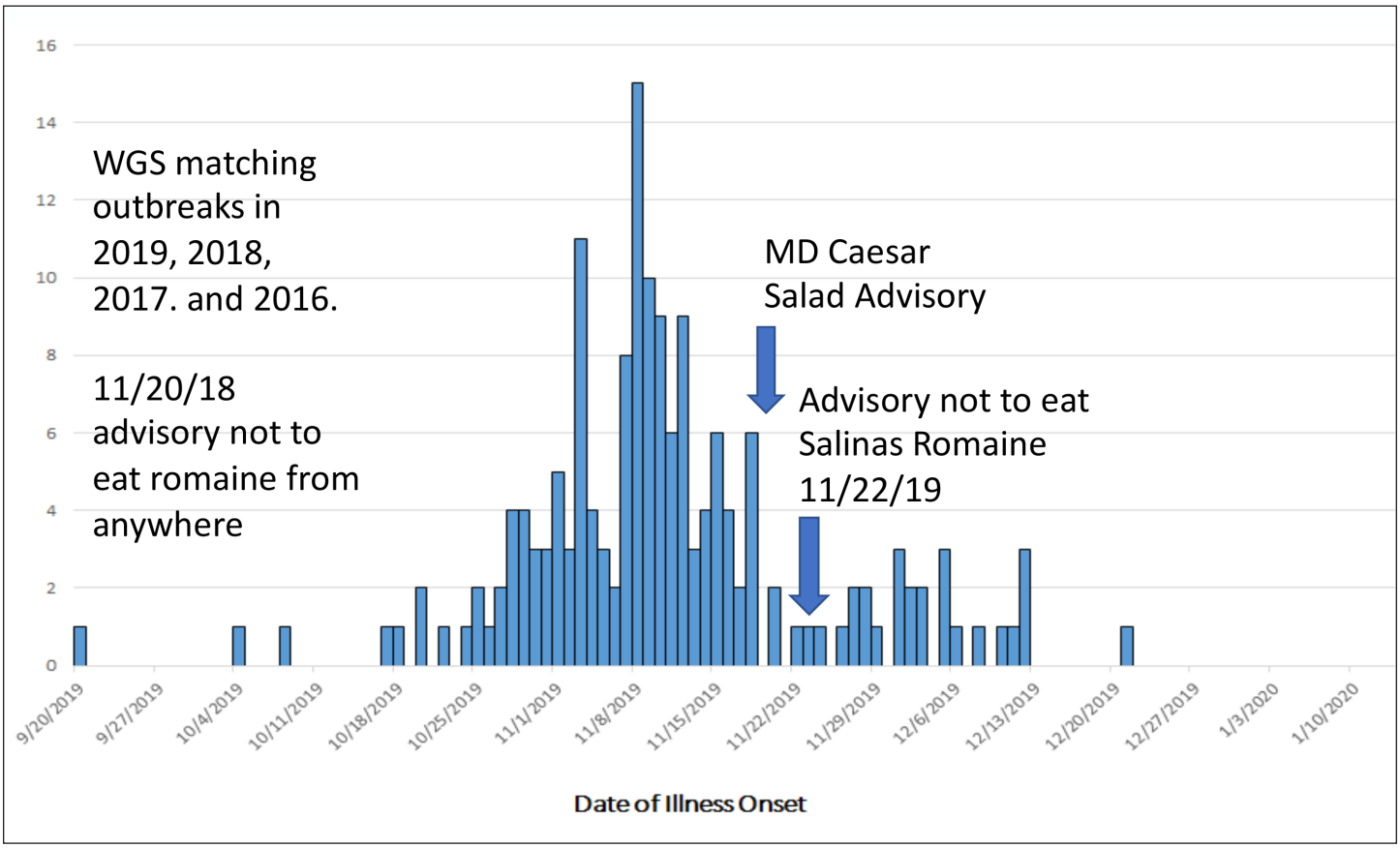

Figure 2. Romaine: People infected with the outbreak strain of *E. coli* O157:H7, by date of illness onset.

where the contamination likely occurred.

Over the last several years, leafy green outbreaks have continued to occur in similar locations with pathogens of similar molecular patterns. This begs the question: Why is FDA not mandating recalls sooner when all the signs point to the same product and the same pathogen?

That said, FDA has actively provided recall guidance, including guidance on leafy green outbreaks. Since 2018, FDA has released several recall guidance documents for industry.[12] These guidance documents provide clarification on topics including mandatory recall authority, retail consignees, and public warnings and notifications of recalls.

The 2020 FDA Leafy Green Shiga toxin-producing *E. coli* Action Plan also gives a variety of response actions, including one specific to recall improvement:

> ***Enhance Outbreak and Recall Communications****: Communications during outbreaks are essential for spurring swift industry action and notifying consumers of potentially contaminated products. In addition, outbreak communications are important for informing industry of ongoing food safety issues within the leafy greens sector. Continuous improvements are* needed to *ensure that communication during outbreaks and recalls is effective in reaching all industry and consumer stakeholders.*

The Action Plan is yet another FDA document addressing the need for recall improvements but does not offer the tools or means to implement them. The need for recall training–not just guidance–is apparent. Guidance serves a purpose but does not go far enough to educate and train both industry and regulatory stakeholders to improve the recall process.

Identifying the Problem: FDA Perspective

In response to the 2017 OIG report, FDA introduced the Strategic Coordinated Oversight of Recall Execution (SCORE) team as a solution to coordinating the most challenging recalls. The goal of SCORE is "to ensure the that FDA acts quickly to investigate and reduce consumer exposure to potentially harmful foods on the market." SCORE's members include leaders from all recall components including compliance, inspection, communication, outbreak investigation, and legal and policy review. FDA reported to Congress in 2018 on SCORE's success and cited several internal improvements being made to the recall process based on the 2017 OIG's report.

While FDA was responding to the OIG report, a new proposed realignment of the FDA organization was underway. During FDA's report to Congress about recalls, the reorganization of FDA was highlighted as a change initiative that would likely improve recall response (Sidebar 4). However, this segregation of responsibilities continues to frustrate communication of recall policies and procedures to the recall coordinators in the field.

One key pain point discussed by industry and states was the delay or misclassification of recalls. The slow classification process may be attributed to scattered recall roles and responsibilities across these FDA offices, which in part can delay a product recall.

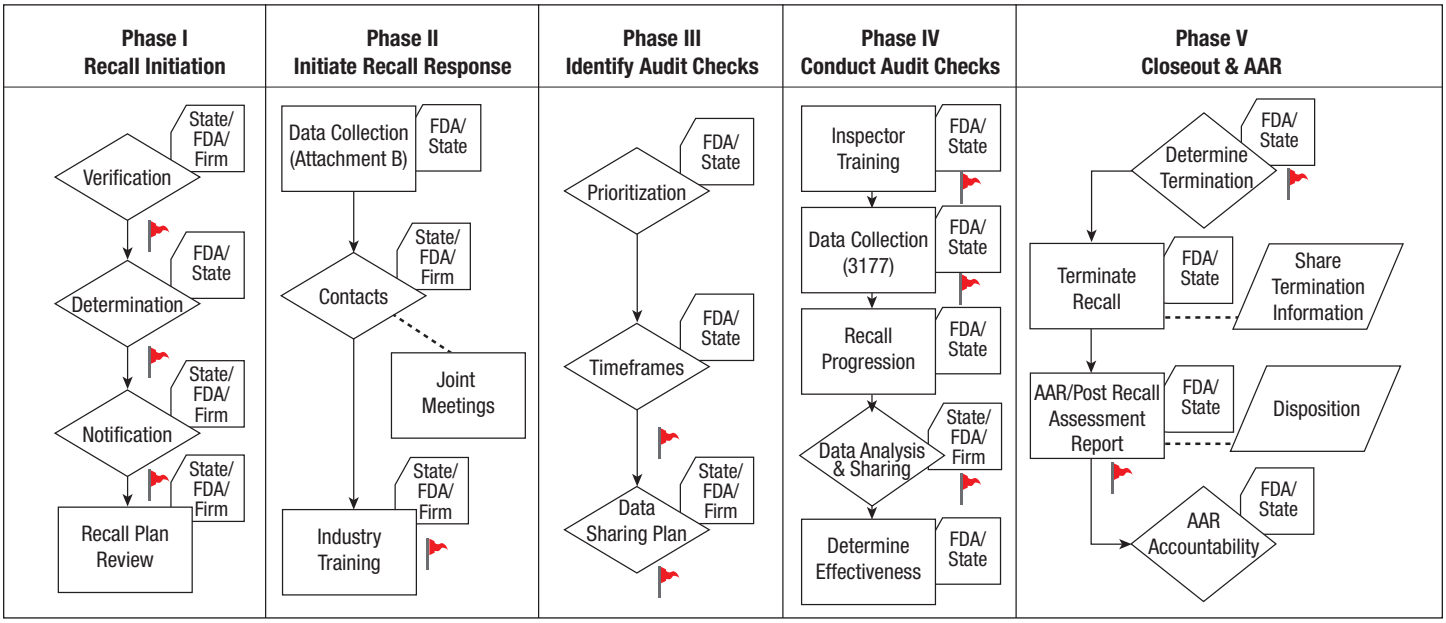

Figure 3. Summary of Recall Response Phases (Decisions, Actions, and Participants).

Identifying the Problem: State Perspective

In 2018, AFDO developed a Recall Working Group. Its goals were to capture the entire recall process, diagram it, and identify the pain points in that process. The outcome of the two face-to-face meetings was a series of recall response flowcharts. The summary flowchart (Figure 3) breaks down a recall into phases. The red flags indicate a pain point experienced by either state regulators, industry, or both. The group was initially composed of six Rapid Response Team (RRT) states, with representatives who came together for a 2-day, face-to-face discussion about recalls. During this meeting, the six states broke apart the recall process from initiation to closure, identifying pain points along the way and developing a recall process diagram. A few months later, key industry leaders joined the six states to review the diagram. The combined state-industry AFDO Recall Working Group confirmed the common challenges in the recall process and discussed potential solutions to alleviate common issues. As stated in the introduction, recalls have two undeniable problems in the recall process: 1) consumers continue to become ill from recalled products after the issuance of a recall announcement, and 2) the issuance of a recall and communication is typically happening after the majority of illnesses are reported. Short shelf-life products may have illnesses coming in after the product is out of the market and in consumers' homes, resulting in the quantification of ongoing illnesses being delayed as confirmed cases. However, the challenge to FDA is whether recalls can be issued earlier to thwart illness or injury.

An attempt to further break down each recall phase's actions by state, federal, and industry was attempted by the Recall Working Group (Table 1) but was not entirely successful due to the complexities, inconsistencies, and

Recall Phase	Recall Process/Decision	Pain Point (Red Flag)	Pain Point: Identified By:
1	Verification	Potential inconsistencies of how and when a recall is triggered	Industry/STOP
1	Determination	Long delays and misclassification of recall	Industry/States
1	Notification	Lack of urgency to notify states of a pending recall and request assistance; delayed or conflicting information with recall notices	States
1	Notification	No directory of industry recall contacts	States
1	Notification	Lack of efficiency in communicating between entities; the RFR lacks key information	STOP/States
2	Industry training	No just-in-time training specific to industry on what to expect from regulators during a recall; this includes a request for training for manufacturing to retail.	Industry
3	Timeframes	Lack of adherence to timeframes for assigning recall audit checks	State
3	Data Sharing Plan	No universal IT system to collect and share recall audit check data in real-time	State/STOP
4	Inspector Training	No universal just-in-time training on conducting recall audit checks	State
4	Data Collection	Not all FDA divisions are equal in the collection RAC data	Industry
4	Data Analysis and Sharing	Lack of understanding of how RAC data is being used from the states due to a lack of communication from FDA	State
4	Determine Effectiveness	Minimal communication on the progress of the RACs or if effectiveness has been reached	State/STOP
5	Determine Termination	Minimal communication to or input from states about the termination of a recall	State
5	Post-recall Assessment/AAR	No clear lesson learned process after the termination of a recall	State

RFR: Reportable Food Registry; RAC: Recall Audit Check; AAR: After-Action Report.

Table 1. Recall Response in Pain Point Table.

unknowns of how recall activities are accomplished across all three entities. This knowledge gap presents an opportunity for further research and development.

The AFDO Recall Working Group was able to successfully conduct the following data collection and outreach activities, done separately from the face-to-face meetings:

1. Re-surveyed all 50 retail and manufacturing state programs on recall response activities (Sidebar 3).
2. Surveyed retail and manufacturing industry partners on facility recall plans and training needs.
3. Piloted a state-based recall audit check tool, "Our Safe Food" with six RRTs (GA, IA, MN, MI, MO, and RI).
4. Submitted a one-page summary to FDA about the similarities and differences between the USDA FSIS and FDA recall processes.
5. Met with STOP Foodborne Illness's Recall Working Group to share a summary of this work.
6. Met with FDA's Recall Working Group to share a summary of this work.

"Information sharing requires a lot of stability and widespread understanding so states feel confident in what they can and cannot do..."

Key takeaways from the state surveys include the following:

1. Sharing of distribution information has improved in the last decade.
2. More training is needed at all levels for all partners on recall response activities.
3. Communication and coordination remain significant pain points for states, including a lack of clarity around roles and responsibilities when responding to recalls; this was a majority response in 2020, while in 2010, it was second to FDA's inability to share distribution information.
4. Development of a technology solution that will be a hub for pertinent recall information and conducting recall audit checks is desired.
5. Timeliness at all phases of a recall is required.
6. Industry needs to be willing to work with state regulators when a recall is impacting their business.
7. The inability of local health departments to see distribution lists in order to conduct recall audit checks at the retail level leaves public health at risk.

The surveys highlight communication as a number one priority to improve the recall process. FDA has directives and procedures about communicating with states during recalls.

Identifying the Problem: Industry Perspective

Industry representatives on the AFDO Recall Working Group included Publix and former U.S. Foods food safety professionals who helped identify various industry challenges and actions during a recall. Several well-recognized state pain points made the industry list too, but the unique industry concerns included the following:

- Not all FDA districts are equal in their collection of recall data.
- In the absence of FDA recall classification, the industry will self-classify.
- FDA/USDA FSIS use different language and descriptions for Class I, II, and III recalls; while it is similar, it is not uniform.
- Small and medium-size firms do not have a "test and hold" process for their products.
- The industry has found that USDA FSIS has a clearer recall process than FDA, especially when it comes to a quicker classification process.
- A central repository for state recall personnel contacts is not widely known (referring to AFDO's Directory of State and Local Officials, or the DSLO).
- A central repository for industry recall personnel is needed, either within the DSLO or as a separate online directory.
- Just-in-time training on what to expect from regulators during a recall is desired by the industry and would benefit an integrated food safety system.
- Attachment B information from FDA should be collected in a centralized IT database and shared with the states to avoid duplicated requests for the same information.
- Industry and state review of final FDA press releases is very important; once the release is out, the tone cannot be changed.
- Industry feels burnout from calls for recall information

from regulators at various levels (local, state, and federal).
- There is a need for a standardized distribution list template across all industries for sharing with regulatory entities in a consistent format.

The decision was made to issue a survey to retail and manufacturing food firms to gather a baseline for recall activities within industry and to measure how and where industry was seeking recall response training. Further, a few questions were added to better understand FDA's Reportable Food Registry (RFR) practices. The findings are presented in Sidebar 5.

Additionally, FDA engaged STOP Foodborne Illness to create a workgroup, composed of experts with food protection backgrounds, focused on recall process improvement. AFDO reached out to STOP and asked them to share their findings. The working group recognized there is need for a fundamental change in food recall processes. STOP stated, "there is no one agency, stakeholder or node in the food chain that controls these processes. An effective recall of a product means that a risky item has been rapidly identified, traced, and communicated about to downstream buyers and, ultimately, to consumers. Our current recall processes have evolved into a patchwork of approaches based on lessons learned from previous events. With hundreds of food recalls a year impacting suppliers, retailers, food service and consumers, the working group believes that a strategic approach is needed to modernize the entire recall system to enhance its effectiveness. To be more effective, recalls must be quicker, more coordinated, better utilize technology, and ensure that consumers better understand and act in response to recall communications by disposing of or returning recalled products."

STOP's working group identified challenges, gaps, and issues (Sidebar 6) related to the current recall processes, many of which align with FDA's *New Era of Smarter Food Safety* Blueprint[4] (Sidebar 1).

Points of Confusion and Potential Steps for Resolution

Information Sharing

US consumers deserve and expect a highly effective recall system that allows for real-time information sharing ensuring recalled products are no longer available. The current recall system has many gaps largely related to a series of federal requirements that limit the ability for FDA to fully and freely share information with state and local public health agencies. Further, the fear of prosecution for the disclosure of confidential information has created a culture within FDA of defaulting to not sharing information with their regulatory partners.

The understanding of information sharing between the states and FDA has shifted in recent years. Information shared by FDA under a general 20.88 Agreement typically must be reviewed and redacted for trade secret information prior to release. Only information shared under the 20.88 can be used by a state for further actions and activities, including inspectional, investigation, sampling, and compliance work. Information shared under an FDA commission can only be shared with a state for its own awareness; it cannot be used by a state for any further purpose or follow-up. Anything shared by FDA under either a 20.88 or commission is considered nonpublic and cannot be further released or shared by a state without first consulting FDA.

"Information shared by FDA under a general 20.88 Agreement must be reviewed and redacted, as needed, for trade secret information prior to release. Only information shared under the 20.88 can be used by a state for further actions and activities, including inspectional and compliance work.…This shift has propelled states and local governments to directly obtain information from the recalling firm."

This shift has propelled states and local health agencies to obtain information directly from the recalling firm because FDA restrictions do not apply if the documentation is received by a state directly from industry. Further, if locals do not have their own 20.88 requirement, states are not allowed to share distribution lists they receive from FDA with any local health agencies conducting retail recall audit checks; therefore, recalled products may be left on store shelves and duplication of efforts may slow down the process and waste resources.

In interviews with industry, many regulatory entities are requesting duplicate recall information, not just distribution lists, and this is causing undue stress to industry recall personnel who are attempting to meet identical information requests from agencies that should all be working together. States choosing to go directly to recalling firms for distribution information or other recall data leads to a frustrated industry and could lead to different versions of information possessed by different regulatory

entities. *In order to unlock the reason why states seek distribution information from industry instead of FDA, we need to not only discuss delays in obtaining distribution information from FDA, but also state and federal informational sharing laws.*

Information sharing requires a lot of stability and widespread common understanding so states feel confident in what they can and cannot do, and what information they can share freely and quickly. Moreso in recent years, states have been provided heavily redacted FDA inspection reports and other key investigatory documents. Redactions have become so invasive that some states stop asking for inspectional reports from FDA because redacted reports provide little to no value to the state to guide appropriate public health follow-up. Inspection reports related to recall events contain less redactions; however, the redacted information in many cases is vital to the active investigation and prevents the state from limiting duplicative efforts, maximizing recall speed, and providing just-in-time training. The recent limitations of information shared to SLTT partners is magnified by lack of will within FDA to make meaningful statutory changes to information sharing laws. FDA submitted A-19, a request to modify existing law to authorize FDA to share confidential information (i.e. trade secret) with domestic partners, but this change does not go far enough. Instead, AFDO will collaborate with FDA and other food safety stakeholders to propose new statuary language to resolve these information-sharing issues. FDA's 2023 Presidential Budget request includes a legislative proposal to expand information sharing disclosure to state, local, and territorial partners. While we appreciate FDA including this request in their budget, a solution is needed now. *FDA and the states need to address current legal restrictions and state workarounds to further integrate their efforts and achieve the goal of mutual reliance and an integrated food safety system.*

"While FDA's recall activities protect consumers from foodborne illness and supporting confidence in the food supply, there is room for improvement."

Policy

In lieu of legislative change, FDA has the ability to adjust existing recall communication and process policies within their agency. Policy changes are a constructive step forward in aligning all partners to a new recall coordination framework that will create effective two-way partnership and communication moving forward. Here are two examples of needed policy changes:

The FDA-State Communication Field Management Directive (FMD-50) was developed to identify specific areas and processes for communication between FDA and state regulatory agency representatives for routine activities, work planning, and emergency situations (i.e., recalls), including the directive that FDA "will" notify and share information. However, the FDA Regulatory Procedure Manual (RPM) states that FDA divisions/districts "should consider" notifying state and/or local officials of recall actions and "should also consider" asking these entities for assistance conducting recall audit checks (13). If FDA is not clear internally on when, how, and what to communicate to their state and local partners, it is not surprising that states continue to find challenges, frustrations, and disparate policy interpretations between divisions/districts during recall communications. *FDA may want to consider harmonizing the language between their recall communications procedures, with the preference being the language in the FMD-50 adopted universally across all FDA documents.*

Another point made by states in the survey is the confusion around the FDA Center for Food Safety and Applied Nutrition (CFSAN)'s role in the recall response. According to the RPM, CFSAN is not given a defined role in the recall procedures; instead, the use of the Center Recall Unit is referred to throughout the manual with no reference back to CFSAN's responsibilities within their procedures. The role of CFSAN is to determine hazard analysis, recall classification, reconditioning, and other important actions (Sidebar 4). States use the RPM to support writing their own procedures and to better understand how FDA will conduct a response within their state. *The inclusion of CFSAN in the roles and responsibilities section of the RPM will clear up misunderstandings and confusion.*

Training

The industry survey data revealed that companies are

Category	Recommendations
Policy	• Create clear timelines for recall classification, hazard analysis, alerts to state partners, and issuance of recall audit checks • Update recall procedures to reflect all organizations conducting recall activities • Update procedures to be consistent in how states should be communicated with before, during, and after a recall • Make terminology consistent between FDA and USDA FSIS • Move class determination up in the process and engage agency leadership quickly in recalls • Institute a clear AAR process for recall response review, including which recalls will be reviewed • Share this process and outcomes with recall partners • Include all recall partners in the AAR • Continue progress on a timely finalizing of the traceability rule to help prevent ongoing foodborne illness from occurring due to poor recordkeeping
Training	• Hire/assign trainers to develop and deliver training on recall response • Create training on FDA guidance documents for industry, field directives, and office/division-level policies related to recalls and information sharing to provide clear, standardized interpretation across FDA divisions and states • Create training for responding to a recall for regulators, specifically on conducting recall audit checks • Create just-in-time training for industry so they understand what to expect from regulators during a recall • Ensure FDA recall coordinators are trained and their supervisors are consistent in management of the work
Communication	• Create a technology solution for sharing data with states • Leverage artificial intelligence for recalls • Implement a set timeframe for classification at FDA to avoid creating challenges for the firm; a firm's recall response is based on the classification type; if the classification is changed after the initial classification, the firm has already set into motion their recall plan and would need either to change course or continue conducting the wrong response activities • Interaction with industry is different depending on the lead agency; procedural consistency needs to be created across all FDA divisions and accountability if procedures are not followed • Update information sharing laws to allow trade secret information to be shared when necessary to rapidly respond to a recall • Leverage public health networks to ensure recalled products are quickly removed from market • Ensure states/locals receive clear communication on expectations during a recall response • Ensure states/locals receive clear communications on roles and responsibilities during a recall response • Ensure state/local partners receive all pertinent recall information in a timely manner • Ensure recall information flows to retail operations • Develop standardized data elements for all recall distribution lists • Require firms to provide standardized data elements for distribution lists • Update data information sharing laws around sharing distribution lists
Recall Management	• Streamline the recall decision-making process by rethinking the FDA organizational structure • Include and ask states/locals to participate in relevant recall response activities • Industry is getting a tremendous number of requests for distribution lists in different formats; thus, development of a standardized format for all distribution lists will alleviate some of the burden on industry • Use technology to track recall audit check data and to quickly identify ineffective firms • Provide recall accountability data to measure improvement • Identify product remaining in commerce and conduct a root-cause analysis as to why the product remains on the shelves • Measure the length of time unaccounted for product is in the market • Measure if existing timeframes are being met and adjust policy/procedures as needed • Track the number of recalls delayed due to incomplete records and identify the reason for the incompleteness • Use above recommendations data to inform traceability process and best practices
Culture	• FDA leadership must create a recall culture based on recalls being a public health emergency • Unify the recall components in ORA, by specializing OSPOP/DE/recall team by program area, and taking the human and animal food part of recalls and putting it in Division of Domestic Human and Animal Food Operations (DDHAFO) • Change federal legal statutes to allow for data sharing of distribution information more freely • Ensure information sharing rules are not causing fear amongst regulatory partners, who are holding back sharing for fear of violating or not understanding the rules • Approach Class I recalls as food safety events and prioritize accordingly, to limit potential additional exposures

AAR: After-Action Report; ORA: Office of Regulatory Affairs; OSPOP: Office of Strategic Planning and Operational Policy; DE: Division of Enforcement.

Table 2. AFDO Recall Modernization Recommendations.

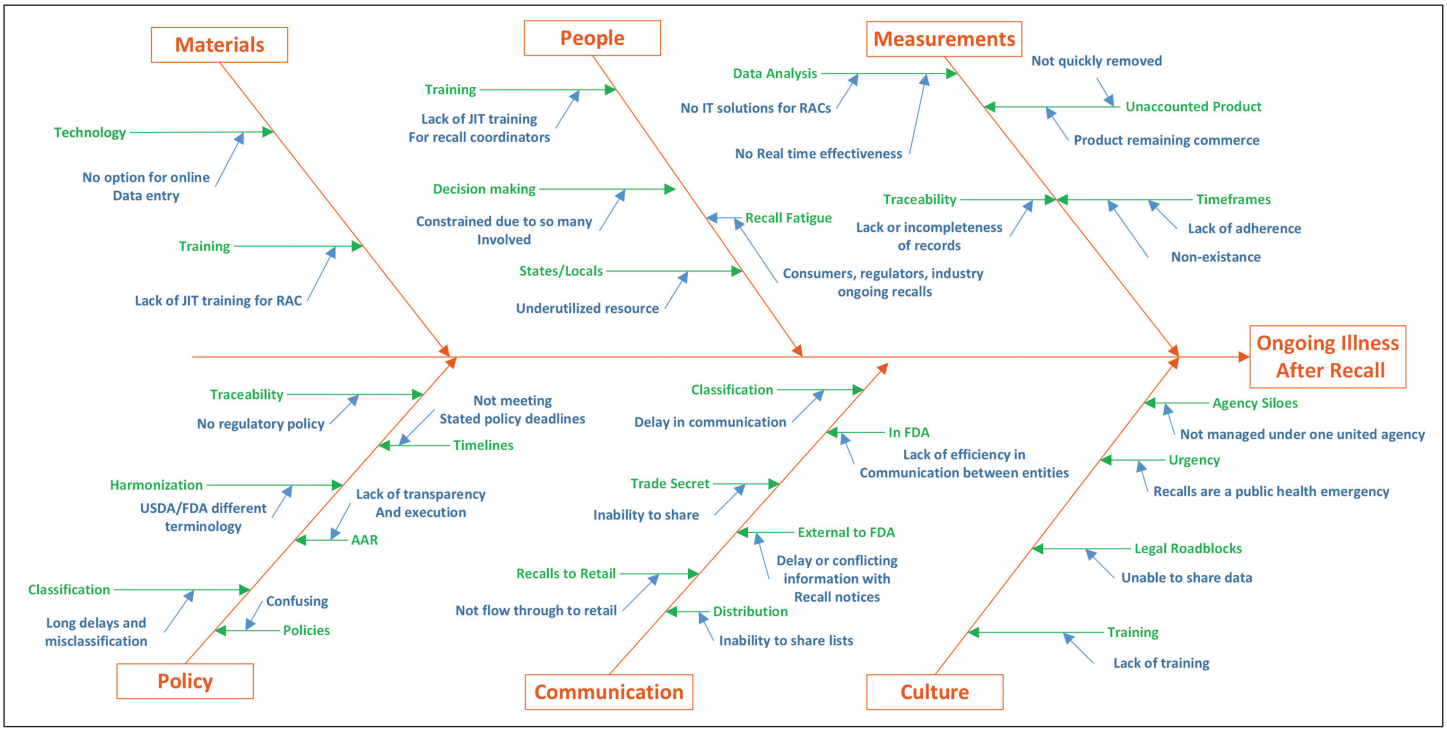

Figure 4.

more likely to seek training from industry/trade associations but are using recall tools or guidance from FDA. The survey questions did not directly ask respondents if free training should come from FDA or states, but the responses indicate that industry clearly wants more training. They are using FDA guidance to build their plans but are not receiving FDA training or exercising the plans once they have been developed. *Thus, FDA should consider providing training both internally and externally on their own guidance, internal policies, and field directives.* Industry/trade associations are doing their best to fill a gap left by their regulatory partners.

The RFR questions revealed that while the majority of companies know what the RFR is, they are not including filing a report as part of their recall plan. Filing a report to the RFR is a requirement "when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious health consequences or death to humans or animals" (14). The disconnect may be due to the lack of specifically including a RFR plan in the required elements specified in 21 CFR 117.139 recall plan. In FDA's "Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C, Guidance for Industry and FDA Staff," the text reads "a significant problem with distributed product may trigger a requirement to make a report to FDA, e.g., a report to the Reportable Food Registry…" (15). *This small subset of data illustrates an opportunity for FDA to include filing reports to the RFR as part of their training for recall response and to possibly clarify that filing reports to the RFR are a part of a complete recall plan.*

AFDO Recommendations

FDA has worked toward addressing several of the findings cited in the GAO and OIG reports. The passage of FSMA gave FDA mandatory recall authority and preventive controls requirements, which include a written recall plan requirement for applicable industry members. FDA instituted SCORE, created several recall guidance documents, and updated their RPM and Inspection Operation Manual, adding clearer direction for recall audit checks and firm status reports and entering data into FDA's Recall Enterprise System database. FDA's *New Era of Smarter Food Safety* is a significant step towards reimaging food safety in its entirety. However, despite the advancements in recall response in the last 10 years, consumers are still getting sick from recalled products every year.

This paper outlines the recall response challenges faced by FDA. Additionally, state and industry surveys and interviews link these challenges to other related pain points being experienced by those responding to and implementing recalls. Table 2 summarizes the needs and opportunities for improving the recall process. A fishbone diagram (Figure 4) is also included to help illustrate the likely causes of ongoing illness after recall, the contents of which are reflected in Table 2.

Call to Action

As a first step toward a collaborative approach to recall

modernization, we urge FDA to consider implementing the recommendations cited in this paper. A working group composed of FDA, AFDO, and other stakeholders would lead to an improved understanding of the data and analysis described, and additional outreach to better understand how best to modernize the recall response would be appropriate.

While FDA's recall activities protect consumers from foodborne illness and supporting confidence in the food supply, there is room for improvement. We are eager to collaborate with FDA in a process to modernize and support recall improvements for the protection of public health. We encourage FDA to engage all stakeholders, including industry associations, consumer groups, and state and local regulators, as it plans and implements recall modernization going forward. After reviewing the recommendations proposed in this paper, steps should be taken to update recall policies and procedures, implement technology solutions and analytics, utilize clear and consistent communication strategies, institute training initiatives, and conduct two-way, effective information sharing as initial steps toward a collaborative approach to modernize and support recall improvements to the benefit of public health and consumer safety.

Acknowledgements

AFDO Recall Working Group
STOP Foodborne Illness Recall Working Group
Publix
US Foods

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Sidebar 1

FDA's New Era of Smarter Food Safety

In 2020, FDA released its *New Era of Smarter Food Safety*, which calls for modernization across all aspects of food safety, including leadership, creativity, and culture.[4] The Blueprint is centered around four core elements, covering the range of technologies, analytics, business models, modernization and values that are its building blocks:

1. Tech-Enabled Traceability
2. Smarter Tools and Approaches for Prevention and Outbreak Response
3. New Business Models and Retail Modernization
4. Food Safety Culture

The key objectives under Core Element 1:3 (Leveraging the Digital Transformation) are "to conduct a review of FDA's current outbreak response and recall protocols to optimize how the agency makes traceback requests of firms and receives information in digital form," and "collaborate with federal, state, local, tribal, and territorial partners on new ways of conducting accelerated tracebacks and traceforward (i.e., recalls) in a tech-enabled food traceability world." Core Element 2:3 (Domestic Mutual Reliance) calls out recall oversight as an objective "advance an intergraded, public health focused approach to emergency and incident response coordination by further expanding our federal-state rapid response teams, including recall oversight, investigations of outbreaks and complaints, and supply chain disruptions." The most significant recall piece in the Blueprint is Core Element 2.6 – Recall Modernization, which contains six objectives:

1. Explore mechanisms to harmonize how FDA and USDA communicate recall information to consumers.
2. Develop best practices guidance on various consumer notification processes ranging from web and social media postings, text messages, email, alerts, and digital scan prompts to ensure that consumers know if they purchased recalled product.
3. Explore the use of a broad spectrum of technologies to enhance external communications and the effectiveness of recalls.
4. Create a United States Government (USG) app for alerting consumers about food recalls and advisories to empower them with actionable information in real time.
5. Explore the ability to create and incentivize the widespread use of protocols and standards to enable register lockdown capabilities to prevent sales of recalled food products.
6. Enhance connectivity of data from Reportable Food Registry submissions and food recalls.

While these objectives may be exciting and important, their achievability in the current environment of recall response is mixed. While the Blueprint calls for working with others in "new and creative ways" to "build on existing efforts to partner with states that have comparable regulatory and public health systems, leveraging each other's data and analytics to ensure optimal use of resources and maximize our food safety reach",[4] there are foundational issues within the recall and information sharing processes that need to be addressed before the broader industry can move forward with Blueprint's objectives.

Sidebar 2

GAO/OIG Reports

GAO Report – 2000

In August 2000, GAO released a report to FDA and USDA regarding industry response time to complete recall activities. GAO's recommendations at the time were based on the facts that neither agency had data to support the claim that industry was conducting recalls in a timely manner. GAO suggested specific guidance be given to industry, including timeframes for quickly initiating and carrying out recalls, and that FDA and USDA maintain key dates—such as the recall start date, when customers in the distribution chain were notified, and when recalls were completed—in their recall database systems to better measure industry response.[6]

GAO Report – 2004

In 2004, the GAO again reviewed FDA and USDA's recall programs. The resulting report noted that, "Weakness in the [federal] recall programs heighten the risk that unsafe food will remain in the food supply and ultimately be consumed."[7] The GAO report also noted that Congress should consider passing legislation requiring companies to notify FDA or USDA if they discover the distribution of unsafe food and to give federal regulatory agencies authority to mandate recalls. The GAO report went on to recommend the Agencies take action to ensure timely, complete recalls with better monitoring.[6]

In response to this report, FDA noted the following:

1. "It is true that FDA recall guidelines do not provide timeframes for companies on recall initiation and termination; it is also true that FDA expectations of a recalling firm are immediate notification, timely removal, and timely disposal."
2. "Specifying workable timeframes for these actions are difficult because of the vast difference in the types of food processors and products, in the sizes of the companies, and in the distribution practices and patterns."
3. "It is primarily FDA district recall coordinators who manage recalls and who use both RES [Recall Enterprise System] and recall folders containing pertinent documents, such as copies of recall notices, letters, press releases, analytical data, and verification reports daily…"
4. "FDA does not see the added consumer safety value in establishing additional fields in RES to record when a firm completes notification to its customers, the date that the district office receives the distribution information, or information documenting when audit checks are assigned and completed."

GAO also recommended revising guidance to FDA staff to include risk-based timeframes for completing audit verification checks and to develop a methodology for FDA districts to verify recalling firms quickly and effectively completed their recalls. FDA responded it was "planning a review of recall operations and application of quality systems principles and controls."

OIG Report – 2017

OIG conducted an independent review of FDA's recall process in 2017 to determine whether FDA had an efficient and effective food recall process that ensured the safety of the nation's food supply. Specifically, the review focused on FDA's oversight of firms' initiation and monitoring of food recalls and maintenance of food recall data in the electronic recall system.[8] The key findings of the OIG report were that "…FDA did not always (1) evaluate health hazards in a timely manner, (2) issue recall audit check assignments at the appropriate level, (3) complete audit checks in accordance with its procedures, (4) collect timely and complete status reports from firms that have issued recalls, (5) track recall data in the RES, and (6) maintain accurate recall data in the RES." These findings reflect that key 2004 GAO recommendations were not fully implemented by FDA; thus, similar issues were rediscovered by the OIG in 2017.

GAO Report – 2012

As required by the Food Safety Modernization Act, GAO provided a 2012 report "FDA's Food Advisory and Recall Process Needs Strengthening," which recommended guidance be issued to industry around the newly released mandatory recall authority. They also identified a number of communication challenges in advising the public about food recalls and outbreaks. In accordance with GAO recommendations, FDA began issuing guidance to industry about the use of mandatory recalls starting in 2018, but as of 2021, the improved information sharing among FDA's databases has not been fully resolved.

Sidebar 3

State Recall Survey Results

In 2010, AFDO issued a survey to state manufactured food programs to better understand the recall response experience at the time. Thirty states responded to the survey, and all but three of those states had participated in a food recall or audit check with FDA within 2 years of the survey. AFDO issued a follow-up survey in 2020 using many of the same questions, adding two new questions to capture additional information not represented in the 2010 survey. The 2020 survey was completed by retail and manufactured human food regulatory programs and animal feed programs for a total of 53 respondents from 44 states. The survey data are represented in the following tables. The similarities and differences between the two surveys in various categories are also compared.

1. In the 2020 survey, the No. 1 recall activity was obtaining a distribution list from recalling firm versus obtaining distribution list(s) from FDA, which ranked No. 4.

Describe your recall activities (please select all that apply) :	
Answer Choices	Responses
Obtained a distribution list from recalling firm	70%
Conducted recall audit checks	63%
Conducted an investigation at the recalling firm	61%
Obtained a distribution list from FDA Division	41%
Issued public health advisory on recall	37%
Other (please identify in comment box)	33%

2. In the 2020 survey, 46 percent of respondents reported conducting recall activities without FDA on Class I recalls.

Did you conduct any recall activities without FDA on any Class I recalls?	
Answer Choices	Responses
Yes	46%
No	54%

3. In 2010 and 2020, 70% and 57% of respondents, respectively, reported conducting recall activities over the last 2 years.

Has your agency coordinated any food recalls in the past 2 years? (2010 Data)	
Answer Choices	Responses
Yes	70%
No	30%

Has your agency coordinated any food recalls in the past 2 years? (2020 Data)	
Answer Choices	Responses
Yes	57%
No	43%

Sidebar 3 continued

State Recall Survey Table

2010 and 2020	State/FDA Challenges
Similarities	• Slowness of information sharing or communication about FDA actions being taken (i.e., press releases, recall audit checks) • Lack of timely notification by FDA to issue a recall notice to states when industry has already released press and/or completed their audit checks • FDA does not support states need to do recall audit checks at the retail level • Clearly understanding roles and responsibilities for all different recall scenarios (i.e., interstate vs. intrastate)
Differences	• Center for Food Safety and Applied Nutrition (CFSAN)'s timeliness to respond to reconditioning proposals (2020) • CFSAN's role is unclear (2020) • Lack of state authority to issue recalls (2010) • Lack of state resources to respond to recalls (2010)
2010 and 2020	**Recommended Improvements**
Similarities	• More and better communication was the #1 category in both 2010 and 2020 • Training is needed for state and locals for recalls as well as small firms • Technology is needed to share information (i.e., distribution lists, lab results) and to capture audit check data electronically • Timeliness of information and work details continue to be a need • Better partnerships between state, local, and federal agencies; states want to be involved in responding to recalls
Differences	• In 2010, 10 of the 13 communication comments were about the sharing of distribution information with states; many wanted the information quicker and in real-time • In 2020, the sharing of distribution information was still relevant but many comments were about communication during the recall event between FDA districts, states and locals; states clearly want more communication at every level about recall in a timely manner
2020	**Barriers**
	• Industry needs to be willing to communicate about recalls occurring at their firms or establishments and be cooperative with state regulators • Industry needs more training about recall regulatory expectations • States lack resources (personnel, equipment, training, etc.) to conduct recall audit checks or respond to the recall • States lack training for recall audit checks and recall response activities • States do not always understand what FDA's expectations are during a recall • States are still not receiving distribution lists to conduct recall audits checks, specifically if the recalling firm is not in their state

Sidebar 4

FDA Reorganization

FDA Division recall coordinators [housed under the FDA Office of Regulatory Affairs (ORA), Office of Human and Animal Food Operations (OHAFO)] are responsible for working with all types of recalls but due to realignment were specialized in specific FDA-regulated products, like human and animal food recalls.

A second organizational change in ORA was the relocation of the Division of Enforcement (DE) from the Office of Enforcement & Import Operations (OEIO) to the Office of Strategic Planning and Operational Policy (OSPOP), which is under the Office of Partnerships and Operational Policy (OPOP). This organizational change seems practical since the DE's primary function is to update and maintain recall policy and procedures, like the Regulatory Procedures Manual (RPM). However, the reorganization did not call for DE to become specialized, like their OHAFO counterparts. DE is responsible for a common operating framework and networking of the division recall coordinators in the field, but the coordinators are not in their direct chain of command, thus making DE's job nearly impossible to complete. ORA recall responsibility is split between OSPOP and OHAFO, and while OHAFO became specialized, DE did not. Since DE is separated from the field recall coordinators, their ability to influence activities in the field is minimal at best.

Furthering the organizational complications are the recall activities that take place in an entirely different center at FDA: the Center for Food Safety and Applied Nutrition (CFSAN). Within CFSAN, three different offices are directly involved in making critical decisions on recall activities (i.e., classification, determination, hazard analysis, and product reconditioning). The decentralization of recall activities continues to slow the effectiveness of the overall recall response.

Sidebar 5

Industry Recall Survey

In total, 1,014 industry members replied to the survey. An average of 35 percent of the questions were skipped by the respondents. The survey contained 20 questions, with 19 multiple choice or yes/no questions and one a narrative question. Across the country, the 21 RRT states were instrumental in helping push this survey out to industry in their states. Several RRTs directly supported the survey's dissemination and, in return, were provided with state-specific survey response data.

Firms were required to provide their residing state. All other questions were optional, including whether the company was a retailer, distributor/warehouse, or processor/manufacturer. The data were analyzed by a Brown University graduate student using Microsoft Excel tools. What follows is only a subset of the data collected, but AFDO will share the entire dataset upon request.

Key Survey Data

The majority of respondents represent the processor/manufacturer sector at 51 percent The remaining 49 percent are nearly evenly split between retailers and warehouse/distributors. Seventy-eight percent of respondents indicated having a recall plan, while 21 percent either do not have a recall plan or do not know if a plan exists. Companies reported their No. 1 use of a recall plan in the past 5 years was a simulated recall event (38 percent), and 22 percent reported using their firm's recall plan for an actual recall event. Another 23 percent reported no use of their recall plan in the past 5 years whatsoever. If the majority of respondents have only used their recall plans during exercises, or not at all, are these firms truly prepared to respond to an active recall event?

Have you used your recall plan in the last 5 years? If yes, select the method(s).	
Answer Choices	Responses
Simulated Recall Event	38%
Actual Recall Event	22%
No Use of Plan	23%

In the following tables, industry was asked where training and guidance for recall response was being sought. The key points are all sectors of industry are seeking training from industry/trade associations, but all sectors are using FDA guidance for help on recalls.

Where are you going as an industry entity to receive training on executing recalls?	
Answer Choices	Responses
Industry/Trade Associations	22%
State Regulatory Agencies	20%
Federal Regulatory Agencies	175

Breakdown by Company	
Retailer	
State Regulatory Agencies	11%
No Active Training	22%
Warehouse/Distributor	
Industry/Trade Associations	26%
State or Federal Regulatory Agencies	15%
Processor/Manufacturer	
Industry/Trade Associations	29%
State Regulatory Agencies	26%
Federal Regulatory Agencies	23%

In reviewing the survey questions related to training,

Sidebar 5 continued

While seeking help for a recall, please select the tools your company uses, if applicable.	
Answer Choices	Responses
FDA Guidance	41%
State Agency Guidance	31%
Industry/Trade Association Guidance	25%

Breakdown by Company	
Retailer	
FDA or State Agency Guidance	18%
Industry/Trade Association Guidance	13%
Warehouse/Distributor	
FDA Guidance	42%
State or Industry/Trade Association Guidance	28%
Processor/Manufacturer	
FDA Guidance	53%
State Agency Guidance	40%
Industry/Trade Association Guidance	31%

22 percent of the aggregated responses report seeking training from industry or trade associations followed by state regulatory agencies (20 percent) and, finally, federal regulatory agencies (17 percent). In segregating the data by company type, retailers were more likely to go to their state regulatory agency for training (11 percent), but the majority (22 percent) have no active training in recalls whatsoever. Warehouses/distributors are more likely to seek training from industry/trade associations (26 percent) with only 15 percent going to either state or federal regulatory agencies. Lastly, processors/manufactures are also seeking training from industry/trade associations (29 percent) followed by state regulatory agencies (26 percent) and federal agencies (23 percent).

When it comes to companies looking for helpful recall tools, the ranking is reversed from training. FDA guidance is ranked first, followed by state guidance and finally industry/trade association guidance. The breakdown of company type for recall tools shows retailers equally reviewing FDA and state guidance (18 percent) with industry/trade associations trailing behind at 13 percent. Warehouses/distributors have 42 percent of respondents reviewing FDA guidance for assistance, while state and industry/trade association guidance are both at 28 percent. Finally, processors/manufactures are more likely than the other two firm types to go to FDA for guidance on recall tools (53 percent) followed by state guidance (40 percent) and industry/trade association guidance (31 percent).

RFR Data

When it came to questions pertaining to the RFR, 35 percent of respondents reported knowing what the RFR is, and 32 percent knew when to submit a report to the RFR, but the same number of respondents (35 percent) did not include filing a report to the RFR in their recall plan.

IT Advances

A key discussion topic among the AFDO Recall Workgroup was how the use of technology could advance recall response. Information sharing was at the center of this conversation. Attachment B, RFR, distribution lists, and Recall Audit Checks (RACs) can all be shared securely online, but no one tool exists to capture and disseminate these data to regulators. AFDO piloted Our Safe Food, a state-focused IT portal where users uploaded distribution information, assigned RACs, inputted RAC data, and instantly generated effectiveness or ineffectiveness RAC maps during a simulated recall response. The question was posed to industry if an online IT option for sharing distribution lists with all responding regulators would make the recall process more efficient. The answer was yes.

Would sharing distribution lists for recalled products via central a centralized electronic system with ALL regulatory partners be preferable and more efficient than sharing the list individually with federal, state, and local regulatory partners?		
Answer Choices	Responses	
Yes	41.93%	426
No	16.44%	167

Sidebar 6

STOP Foodborne Illness Findings

STOP Foodborne Illness Recall Gaps	
FDA Blueprint Element	**Gaps**
Element 1.1 Develop Foundational Components and 2.1 Invigorate Root Cause Analysis	Inconsistencies exist in recall avoidance and limitation strategies (more effective approaches to lot management, clean breaks, sampling).
Element 1.1 Develop Foundational Components	Potential inconsistencies exist in how and when a recall is triggered. Confusion because federal, state, and local agencies may have different approaches to recall management and communication.
Element 2.3 Domestic Mutual Reliance	Inconsistent and inefficient decision-making exists within firms involved in recalls regarding communication and interactions with agencies regarding what should be recalled, how much should be recalled, and what information is communicated.
Element 1.1 Develop Foundational Components	How the use of paper-based methods to share information within the food supply chain slows down the recall process.
Element 1.3 Leveraging the Digital Transformation	There is a lack of utilization of evidence-based risk communication approaches to stakeholders—especially consumers—who receive recalled products.
Element 2.6 Recall Modernization	There is a lack of evaluation of recall effectiveness, including whether consumers have identified, disposed of, or returned recalled products.
Currently outside of the New Era for Smarter Food Safety	to conduct recall audits checks, specifically if the recalling firm is not in their state

AFDO agrees with STOP's identified gaps. STOP also provided other insights as to why the current recall processes are not addressing the core issues of continuing illness after recall and delayed recall advisories. Hilary Thesmar, chief food and product safety officer and senior vice president, food safety program, at the Food Marketing Institute provided this statement: "SCORE and other initiatives have not addressed policy and process issues related to recalls. The pain points are in the [FDA] divisions and how different divisions handle recalls, classify recalls and communicate recalls. Initiatives like SCORE are high level but need to follow up and improve processes at the division level. The issues as I see them are as follows: 1) The need for consistent and transparent processes; 2) Consistent communication on recall notices (especially when there are illnesses); and, 3) Implementation of the findings from the data collected and recommendations from OIG and the FDA audit team."