

Collaborative Plan to Achieve Customer-Focused Recall Modernization

Background

On August 20, 2020, the Alliance to STOP Foodborne Illness convened a group of food safety experts (working group) to outline how food recall processes in the United States can be improved. This working group recognized that there is a need for fundamental change in food recall processes to protect consumers from harmful products and decrease the burden of foodborne illness. With as many as 500 food recalls a year impacting suppliers, retailers, food service, and consumers, the working group recommends a strategic approach to modernize the entire recall system and enhance its overall effectiveness for the consumer.

The working group benchmarked the current system(s) and defined an effective product recall as an item(s) rapidly identified, traced, and removed from the supply chain/commerce by downstream businesses/organizations and ultimately, communicated to consumers. Currently, there is not a singular federal or state agency, stakeholder, or node in the food chain that controls these processes. This has been identified as a major problem, as the current recall processes of the U.S. evolved due to a patchwork of approaches based on learnings from previous recall events.

Recalls are preventable. Although industry has become more proactive and there have been advances in technology and techniques to identify issues that require a product recall, the number of annual recalls has not decreased. The working group's philosophy is to have an action-focused plan for modernizing the U.S. food recall system; specifically, to not rely on consumers' vigilance.

To realize significant improvements for recall effectiveness, they must be timely, coordinated, technology must be deployed appropriately, and outcomes must be consumer focused. Providing language that consumers understand and measuring whether they take appropriate action responding to recalls is essential.

The working group is focused on taking evidence-based action to identify and assess the current U.S. recall system. The existing structure depends on consumers' internal motivation to monitor recalled products. This deems the recall system as dysfunctional due to its reliance on consumers' diligence to determine whether a product has been recalled.

We identified research gaps needing to be filled and evaluated the current system. This work is critical to create the political will to improve the broken aspects in the recall structure. This applied research may be used to develop better metrics and mechanisms for measuring success. There is potential to specifically create an educational framework to support the food systems and identify who is best suited to conduct this research.

These challenges, gaps, and issues need to be addressed to achieve real modernization of the recall system. This group sees the opportunity to work collaboratively with industry partners, consumer advocacy organizations, federal agencies (CDC, USDA-FSIS, FDA) and state and local regulators to attain this goal. The group is particularly interested in working jointly to meet the needs of consumers to identify effective methods of communication to limit the consumption of recalled foods.

Goal of collaborative project of this working group: Develop an action plan that can be implemented by federal agencies (FDA, USDA-FSIS, CDC), state and local regulators, the food industry, consumer advocacy organizations, and public health organizations to improve recall execution and consumer communications to protect public health.

Identification of Points in the U.S. Food Recall System that Need Improvement and Recall System Related Research Gaps

Specific Research Questions and Tasks Identified by the Working Group

Communication

- **Inventory** what industry is currently doing to manage and communicate recalls and investigate what it would take to move forward.
- **Investigate** how communication between businesses work to remove recalled products; include information on available alert systems and identify if legal and privacy issues are associated with these alert systems, and if yes, how are they being addressed?
- **Probe** how regulatory agencies can notify consumers and other stakeholders about recalls efficiently through technological advances.
- **Determine** who is helping unregulated food entities, (e.g., food banks, cottage foods, youth sports/scouts) do their part to assure that recalls are effective/communicated. Do consumers react by disposing or returning contaminated food? What are potential areas of improvement?
- **Investigate** challenges and solutions to recalls of food sold at farmers' markets and aggregators: what is the best way to conduct and communicate this type of recall? Should there be a feedback loop to the consumer at a farmers' market/aggregator?

Recall Execution

- **Collect** food industry, regulatory and consumers perspectives as to what would make food recall execution more efficient. Specifically, have individuals address the barriers and hurdles that should be removed.
- **Probe** how recalls are handled through secondary market sales, online retailers/third party sellers. Is there an opinion if regulators should expand recall effectiveness to such parties? How might this be done to address confidentiality concerns?
- **Identify** what would motivate stakeholders to effectively execute and respond to recalls. Are there incentives at various nodes in the supply chain (including the consumer) that might be put in place?
- **Capture** how recalls are handled by federal and state agencies and how recall systems work in an international context.

Consumer-Focused Research Needs

The major research gap(s) is understanding how the consumer is receiving and reacting to information about food recalls. The following research must be conducted:

Consumer Motivations

- **Gain** an understanding of what consumers say they do versus actually do; when consumers currently receive different types of recall messaging and experience different modes and/or methods of message delivery (e.g. social media, local news, websites, etc.)
- **Investigate** what would motivate consumers to respond appropriately, (e.g., dispose of food, not consume food) when they are notified of a food recall.
- **Investigate** barriers and interventions for consumers to act on recall notifications.
- **Identify** potential solutions to consumer recall fatigue.

Consumer Messaging

- **Determine** what messages and modes of message delivery are most effective.
- **Research** whether recall messages should differ based on whether the recalled product is shelf stable or perishable.
- **Determine** how to easily notify consumers about an evolving recall.

Consumer Tools, Technology, and Response

- **Develop/expand** implementation of consumer tools such as QR codes/SKU codes for immediate consumer feedback on whether a product has been recalled.
- **Conduct** basic research of how to improve recalls.gov to allow data to be more readily accessible for third parties to use (APIs, UPC code linking).
- **Conduct** basic research on how recalls.gov can be more user-friendly for individuals who have limited access to technology or those who are technologically naïve.

Consumer Data Privacy/Trust

- **Research** how big data of consumer purchases can be used to identify and target recall notices.
- **Investigate** balancing trust, while ensuring privacy and not misusing information on sales/products. Who does what and who controls what?

Additional Opportunities to Explore

- **Investigate** what role health care providers could play in executing recalls. Are there existing communication systems that could be tapped?

The release of the U.S. Food and Drug Administration's (FDA) *New Era for Smarter Food Safety* catalyzed discussions among the working group. In this blueprint, the FDA has stated the way the Agency addresses recalls should be modernized. The working group recognizes that Core Element 2.6: Recall Modernization calls for the Food Safety and Inspection Service (FSIS) and FDA to harmonize communications of recall information and develop guidance documents on notification processes for consumers.



The following opportunity areas directly align and support multiple topics identified in FDA *New Era for Smarter Food Safety* – FDA's *Blueprint for the Future* listed according to the Blueprint Core Element

Element 1.1 Develop Foundational Components related to Tech Enabled Traceability

- Identify and address inconsistency in recall avoidance and limitation strategies. Best practices are needed to develop more effective approaches to lot management, clean breaks, and sampling.
- Identify best practices in information sharing throughout the food supply chain to facilitate the recall process.

Element 1.3 Leveraging the Digital Transformation

- Review current outbreak and response protocols to identify ways to accelerate information sharing. Align RFR and recall process to share information digitally.
- Identify causes and propose solutions to inconsistencies in how and when a recall is triggered.
- Identify the cause and impact of inconsistent and inefficient decision-making within firms involved in recalls regarding communication and interaction with agencies on what, how much should be recalled, and what information is communicated.

Element 2.3 Domestic Mutual Reliance

- Identify and implement consistent policies that can be implemented by federal, state, and local partners for outbreak investigation and recall initiation.
- Streamline information sharing between federal, state, and local agencies to share relevant information about investigations and recalls. Recall effectiveness checks are often done at the state and local level, but investigators do not have access to information provided to FDA. Sharing information would make the current process more efficient. Technology should be evaluated to increase the efficiency and information sharing. Providing states with direct access to information would facilitate the process. Focus should be on consumer perceptions and actions and not on counting packages and cases.

Element 2.6 Recall Modernization

- Explore mechanisms to harmonize FDA and USDA recall communications to consumers.
- Apply consistent policies for recalls, recall communications, recall effectiveness checks, and classification of recalls.
- Explore use of technologies to enhance recall communication and effectiveness.
- Enhance connectivity of data from Reportable Food Registry submissions to inform food recalls and sharing of data.
- Evaluate ways consumers receive and access information and develop tools to provide real time recall notifications. Leverage public/private information sharing.
- The blueprint encouraged the use of register lockdowns. This is a widely used practice at the point of sale. The action blocks sale of any product sharing the same SKU. Lot specific blocking is not currently supported. This is often one of the first steps in recall execution and happens within minutes to hours of recall notification from suppliers. FDA and FSIS should work with the food industry and support commonly adopted practices.

RFR system should be linked to the recall system to avoid duplicate data entry and delays in recall initiation. Connectivity of data is imperative to streamlining the process and allowing for sharing of information for speed and accuracy.



Additionally, there are opportunity areas that fall outside the scope or are not directly addressed in the *New Era for Smarter Food Safety – FDA’s Blueprint for the Future*

- Create a consumer-focused risk communications strategy.
- Obtain information and evaluate research on consumer perceptions and behavior related to recalls.
- Create an Oak Ridge Institute for Science and Education (ORISE) Research Fellowship to evaluate effective recall modernization and consumer communication tools to drive change.
- Promote evidence-based risk communication approaches and apply to recall communications.
 - Precautionary language is not appropriate in recall communications, especially when the recalled product is subject to a foodborne illness investigation.
- Investigate social media and the impact on recall communications.
 - How to address misinformation?
 - How to counter misinformation?
 - Who monitors it?
 - How does industry identify it?
 - How do we access social networks of differing cultural groups/ethnicities?
- Develop evaluation tools for recall effectiveness, including knowing if consumers have disposed of or returned recalled products.
 - How do we drive action?

Prioritized List of Topics for Action with Proposed Plans to Support the New Era Blueprint

1. Conduct an evaluation of recall effectiveness (including consumer actions) across federal agencies. Standardize recall coordination and execution across federal agencies.

FDA should lead an effort to gather data specific to recall effectiveness beginning at firm decision-making through consumer actions. FDA and FSIS should develop an interagency team to discuss best practices and align on recall policies and procedures. FDA to provide leadership in developing consistency in recall management, policies, and communications across FDA, FSIS and state and local regulators. The agencies currently use different models (decentralized and centralized) and there are valuable parts of each that can be shared and implemented. Consistent policies are needed for timely recall classifications that apply across jurisdictions. This applies to recall identification and initiation as well as communications.

Who: FDA and FSIS co-lead this initiative related with significant stakeholder input.

Timeline: Evaluation begins immediately . Interagency recall modernization team begins immediately.

2. Support technology application in recall execution, management, and communications with a specific focus on SME.

FDA should continue the New Era-supported focus on collaborating on implementing new technologies to support the timely identification, tracking and tracing of food to support recall systems. FDA should be focused on helping SMEs to implement low-cost technologies and support programs that lead to education, toolkits and practical application of technology in the food systems.

Integration of systems is needed for the RFR and the division recall coordinators. Toolkits for food businesses of various sizes to be created, shared and implemented.

Who: FDA leads this initiative related to the blueprint with significant stakeholder input from industry partners and service providers.

Timeline: FDA has already begun this work with The FDA New Era of Smarter Food Safety Low- or No-Cost Tech-enabled Traceability Challenge, continue through 2022.

3. Develop and implement a risk communication strategy for regulatory and industry partners. Drive programs resulting in timely, accessible and effective information to protect consumers.

Sometimes these are simple actions (changes in language used in recall notices) and some will require more complex development (policy changes across agencies and guidance to the food industry).

Who: A regulatory coalition, FDA/FSIS and outside experts in risk communication

Timeline: Evaluation of evidence-based risk communications should begin immediately with an ORISE Fellow and consumer research.

Collaboration Tools

Working groups or task forces should be established to collaborate among agencies, industry and public health organizations through meetings, forums, webinars, and research/surveys. Ideas include initiating a special project with a focus on evaluation, implementation, communication, and continuous improvement to implement changes in recall initiation and management.

Next Steps

- Continued engagement with both regulatory agencies to create a joint recall modernization action plan.
- Recruit members (industry, advocacy, and consumers) into a regulatory coalition

Summary

The working group of the Alliance to STOP Foodborne Illness with external stakeholders recognizes that FDA's *New Era for Smarter Food Safety*, Core Element 2.6: Recall Modernization calls for harmonization in communications of recall information to consumers for both FSIS and FDA. This document provides guidance on future research and priorities to achieve this goal and aligns with the blueprint.



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