



**U.S. FOOD & DRUG
ADMINISTRATION**

FOOD FOR THOUGHT

Ideas on How to Begin a New Era of Smarter Food Safety



A Letter from FDA's Foods Program Leadership

We recently announced a [New Era of Smarter Food Safety](#).¹

This new initiative is intended to build on FDA's efforts to implement the FDA Food Safety Modernization Act by leveraging, among other things, the use of new and emerging technologies as well as new approaches to some of the food system's biggest food safety challenges. In early 2020, FDA plans to release a blueprint that outlines critical steps to protect public health and keep pace with the ever-changing global food supply chain.

The first step in developing this blueprint was to start this work internally, engaging FDA experts to provide their insights on how to make this vision a reality. More than 100 experts participated in four brainstorming sessions on the following topics:

- Tech-enabled Traceability and Foodborne Outbreak Response
- Smarter Tools and Approaches for Prevention
- New Business Models and Retail Modernization
- Food Safety Culture

Participants in the brainstorming groups represent the Office of Food Policy and Response, the Center for Food Safety and Applied Nutrition, the Office of Regulatory Affairs, the Center for Veterinary Medicine, and several individuals from the Office of the Commissioner. We have also encouraged idea submissions by employees across the Foods Program.

FDA staff were asked to unleash their ideas, unfettered by practical considerations, such as staffing and resources for the agency and the impact on industry. The time for practicality will come in the second round of sessions later this year, when our experts will look at their ideas and ideas gathered from the public with new eyes, considering feasibility and recommending realistic goals.

On October 21, we will conduct a public meeting to engage stakeholders and foster a dialogue on how to most effectively prepare for the work ahead. The blueprint we publish in early 2020 will be a tapestry of wisdom provided by experts in the public and private sectors.

For now, to help stakeholders prepare for the public meeting and for the accompanying public comment period, we would like to share a sampling of the ideas that came out of the brainstorming groups. Opening a window to FDA's preliminary internal thinking may provide food for thought and generate more insights that will enrich the strategic blueprint.



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Melinda Plaisier
Associate Commissioner of Regulatory Affairs

¹<https://www.fda.gov/news-events/press-announcements/statement-acting-fda-commissioner-ned-sharpless-md-and-deputy-commissioner-frank-yiannas-steps-usher>

Tech-enabled Traceability and Foodborne Outbreak Response

Looking at technologies, data streams and approaches that will greatly reduce the time it takes to trace the origin of a contaminated food.



Facilitate End-to-End Traceability Throughout the Food Safety System

- Develop foundational components needed to make full traceability standards operational.
 - Define key data elements and processes that are needed to enable full traceability.
 - Develop strategies to harmonize tracing activities by engaging public (e.g. the U.S. Department of Agriculture, states, international regulatory counterparts) and private partners in discussions on governance for domestic and international voluntary traceability standards, including the role for regulators.
- Encourage industry/company adoption of new technologies.
 - Develop ways to achieve interoperability of traceability systems.
 - Identify and develop incentives to encourage firms to voluntarily adopt tracing technologies (e.g., blockchain).
 - Promote research and innovation by establishing mechanisms to promote shared development of technologies, using cooperative research and development agreements, grants, and other approaches.



Enhance Foodborne Outbreak Response

- Enhance outbreak detection.
 - In partnership with stakeholders, advance efforts to mine data (e.g. reviews of food products on the websites of online retailers and social media, environmental conditions, and illness information) to identify early signals of outbreaks.
 - Explore mechanisms to better leverage industry insights to identify possible outbreaks, potentially using third parties to gather and analyze data.
- Enhance outbreak response activities.
 - Explore new models and approaches for domestic and international outbreak response (e.g. training, sharing lab methodologies, WGS matching, lab collaboration).
 - Make greater use of outbreak information from other countries to prevent contaminated foods from entering the United States.



Innovate Communications Approaches

- Spark new dialogue around traceability.
 - Create forums for dialogue involving interested stakeholders, such as retailers, growers, manufacturers, and IT companies, to address needs and overcome current obstacles for full traceability.
 - Develop communications around traceability. Highlight best practices for traceability, using various forms of communications, such as social media, web, publications, etc.
- Enhance outbreak/recall communication.
 - Create a U.S. Government (USG) app for alerting industry and consumers of recalls and outbreaks.
 - Support development of scannable labels and associated apps to give product information through the supply chain and information on recalls/outbreaks.

Smarter Tools and Approaches for Prevention

Looking at new tools, processes, and communications to inform our prevention efforts.



Invigorate Root Cause Analyses

- Develop new models for conducting root cause analyses, partnering with industry and other stakeholders.
- Improve the standardization of methodologies and guiding principles, including how the findings are reported and communicated.
- Enhance agency readiness for quick deployment of food safety experts to conduct root cause analyses.
- Conduct training and outreach on lessons learned through root cause analyses and through Big Data mining or Artificial Intelligence on inspection and sample findings.
- Work with industry to use food safety data to identify best practices in a non-regulatory framework.



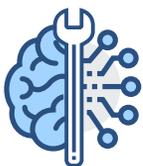
Redefine Data and Data Analytics for Responding to and Preventing Contamination

- Use artificial intelligence and other technologies to scan external information (e.g. product complaints) as tools for detection of potential contamination events. Explore both public sources (such as public forums, consumer reviews, web sites, news reports, and social media) and private sources of data (such as industry and academia).
- Expand how FDA mines data, such as using Big Data mining or Artificial Intelligence to evaluate inspection and sampling findings.
 - Move from descriptive analytics to predictive analytics, mining data to inform future policies, procedures and awareness of risks.
 - Explore greater partnership with academic institutions, and other public/private partnerships, to perform predictive data analytics using both FDA data and other information (e.g., weather events such as flooding in a region) to identify potential risks for contamination events.
- Encourage industry to adopt tools building on traceability to better protect consumers (e.g. an automatic register stop sale in the event of an outbreak).



Develop Innovative Approaches to Inspection and Compliance

- Evaluate the feasibility of conducting remote, virtual, and component inspections of foreign and domestic firms with a demonstrated history of compliance (through previous FDA inspections, reliable third-party audits, etc.).
- Consider establishing a voluntary program for domestic facilities and farms that submit to audits by certification bodies accredited under FDA's Third-Party Program, as we have now for foreign facilities and farms. Possible incentives could be lower inspection frequencies or reduced scope of inspections.
- Further assess the utility of third-party audits as a tool.
- Encourage industry use of real-time remote monitoring of conditions on farms and facilities (e.g., pathogen levels in surface water used for irrigation or within the environment of a food processing plant).



Foster Forward-Thinking Communications for Industry Prevention Efforts

- Enhance communications on compliance trends to encourage firms to self-correct potential food safety concerns.
- Enhance communications internally and externally on trends in top risk factors for food contamination identified during outbreaks.
- Promote education and training to communicate lessons learned from contamination events and how they should inform future preventive controls.
- Publicly share data so that others can use the information by establishing/enhancing templates for reports and communications that can be shared across the public and private sectors.

New Business Models and Retail Modernization

Advancing the safety of both new business models, such as e-commerce and home delivery of foods, and traditional business models, such as retail food establishments.



Develop Approaches to Help Ensure the Safety of E-Commerce

- Work with industry to study new business models (e.g. home delivery, meal kits, etc.) to identify current vulnerabilities and gaps in safety from seller to consumer.
- Identify standards of care based on risks and existing/emerging business models.
- Establish regulatory framework.
 - Given rapid evolution of business models, start a dialogue about flexible tools for considering business models. How can we, as food safety regulators/professionals/etc., bring tools to bear that won't need to be updated every two years?
 - Add section to Food Code or issue guidance for industry regarding handling, packaging, transportation, particularly focused on mail-order meal kits.
- Incentivize the use of technology that automatically monitors product time/temperature/tamper resistant/traceability information.
- Meet with online retailers to better understand their third-party seller models and develop new methods to ensure recalled product information is effectively disseminated and products are removed from the market.
- Foster partnerships with influencers, such as chefs, bloggers, cooking shows and celebrities, to make smarter food safety part of the national dialogue.
- Partner with food delivery companies on how to handle food properly.



Enhance Traditional Retail Food Safety

- Expand the Food Code to require industry food safety management system for retail establishments.
- Enhance the Retail Risk Factor study to measure the occurrence of practices and behaviors known to contribute to foodborne illness outbreaks among different types of foodservice and retail food operations. Champion addressing high priority factors and tie funding to incentivize jurisdictions to implement.
- Develop protocols for retail facilities that have repeated egregious/significant violations and/or outbreaks linked to practices within their facility.
- Improve training curriculum for federal, state, local, tribal and territorial regulators and staff to target food safety practices most effective in preventing foodborne illness.
- Increase engagement with industry and regulatory partnership groups to promote implementation of effective intervention strategies to reduce retail risk factor occurrence.



Navigate the Last Mile

- Crowd-source ideas on developing industry standard of care based on different business models (whether food is delivered hot or cold and by whom—robot or person, for instance).
- Develop best practices for “last mile” food delivery, focusing on packaging, time/temperature control, sensors, tampering, cross-contamination and allergens.
 - Address who “owns” the food in the last mile (e.g., the delivery company/driver? the previous link in the chain?). Target this group for education on safe transport and handling.
- Enhance industry and consumer education on TTTC (temperature, time, tamper resistant, cross-contamination).

Food Safety Culture

Supporting and strengthening cultures that embrace food safety within FDA, on farms and in facilities.



Strengthen FDA's Approach to Recognizing the Critical Importance of Food Safety Culture and Behavior Change in the Agency's Work Processes

- Ensure consideration of the role of culture as a central tenet in advancing the agency's food safety mission.
 - Develop procedures to further strengthen the internal understanding of food safety culture, including the role of public health and regulatory partners as essential members of our food safety team.
 - Conduct internal assessment of current attitudes toward and knowledge about food safety culture and develop and monitor metrics to measure changes in the development of a food safety culture over time.
- Encourage FDA leadership to communicate the importance of Food Safety Culture as part of FDA's Foods program.
- Update staff training and rotational opportunities to ensure they focus on reducing food safety risk as primary responsibility for staff, with compliance/enforcement as one means – but not the only means – to accomplish the goal of preventing foodborne illness.
- Research how inspections might be modified to be used as a tool to strengthen and gauge food safety culture in regulated industry.
 - Train investigators on assessing and promoting food safety culture in facilities.
 - Educate while we regulate 2.0: Encourage industry responsibility, not just accountability, for food safety.

Promote Food Safety Culture Throughout the Food System



- Develop a Food Safety Culture Campaign to foster a new external dialogue on the importance of food safety culture and best practices.
- Develop education, training, and tools to foster and advance industry best practices.
- Review existing literature and conduct, as needed, additional research on challenges, barriers, and opportunities to influence attitudes, behaviors and adopt food safety culture.
- Update FDA's policies and procedures to facilitate industry efforts to adopt food safety culture.
- Enhance food safety culture efforts with international/federal/state/local regulatory partners.

Develop Smarter Food Safety Consumer Education



- Develop a consumer-focused initiative (using full range of media and new technologies) to help consumers create a smarter food safety environment in their daily lives for themselves and their families.
 - Target educational materials to populations that may have the greatest need for food safety education.
 - Target educational materials to focus on emerging food safety concerns.
- Research and test consumer messaging materials.
- Work with a variety of partners (consumer groups, industry, other government partners, and media groups) to promote consumer messaging.
- Develop strategies to help consumers access, understand and utilize new technologies relevant to food safety.