

New Era of Smarter Food Safety Blueprint

Modern Approaches for Modern Times



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The New Era of Smarter Food Safety Blueprint is centered around four core elements:

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

These are the foundational pillars of the New Era of Smarter Food Safety, covering the range of technologies, analytics, business models, modernization and values that are its building blocks. These elements, working together, will help create a safer and more digital, traceable food system.

Below, we explain what we hope to achieve, the principles we abide by, the process we followed, and a list of goals attached to each of the core elements.

Executive Summary

I. Executive Summary

The world around us is changing rapidly, and we are in the midst of a food revolution. Many believe we will see more changes in the food system over the next 10 years than we have over the past several decades. Foods are being reformulated, new foods and new food production methods are being realized, and the food system is becoming increasingly digitized. At the U.S. Food and Drug Administration (FDA), we believe modern times require modern approaches.

While we had originally planned to unveil the blueprint in the spring of 2020, our plans were placed on pause so the FDA could focus on COVID-19 pandemic response efforts. This crisis has highlighted some challenges and has underscored the need for modern approaches as we

respond to unique demands on our food system and work to ensure that the food supply remains safe and strong, now more than ever. With the pandemic have come unprecedented imbalances in the marketplace, changing consumer behaviors and a rise in e-commerce, and challenges in performing inspection and compliance work in FDA's traditional manner. It has demonstrated the need for more real-time, data-driven, nimble approaches to help ensure a strong and resilient food system and keep all Americans safe during a crisis, whether they are federal employees, food industry workers, or consumers.

The New Era of Smarter Food Safety represents a new approach to food safety, leveraging technology and other tools to create a safer and more digital, traceable food system. Smarter food safety is about more than just technology. It's also about simpler, more effective, and modern approaches and processes. It's about leadership, creativity, and culture.

This blueprint outlines the approach FDA will take over the next decade to usher in the New Era of Smarter Food Safety. It will evolve as food technologies and the food system evolve. It builds on work that FDA has done to implement the FDA Food Safety Modernization Act (FSMA), which established science and risk-based protections.

This document represents the thinking of FDA food safety experts, consumers, the food industry, technology firms, federal and state regulatory partners, our regulatory counterparts in other nations, and academia. Together, we envision a framework that will enable food to be traced to its source in seconds and will utilize new data analytical techniques to strengthen prevention of

foodborne illnesses, alerting consumers in real time before contaminated or misbranded foods are consumed. We envision a framework in which education, communication, and democratization of data will enable industry, public health advocates, and government to work in concert to keep the food supply safe.

This document represents achievable goals to enhance traceability, improve predictive analytics, respond more rapidly to outbreaks, address new business models, reduce contamination of food, and foster the development of a food safety culture. It outlines a partnership between government, industry and public health advocates based on a commitment to create a more modern approach to food safety. There is an opportunity to drive the changes needed to create a digital and safer food system. We're in this together.

If you've heard FDA leaders talk about the New Era of Smarter Food Safety, you might understandably be asking yourself how we plan to bring about this sea change. Read on.

Introduction

II. Introduction

Smarter Food Safety to me means always looking to the future. Our destination -- safe food for our families, our children, and our animals -- is unchanged. But how do we

get there more quickly and effectively using modern tools as the world transforms around us?

FDA Commissioner Stephen Hahn

What is the New Era of Smarter Food Safety? While we have made advancements in food safety over the past decade, rates of foodborne disease in the U.S have not changed significantly. Our ultimate goal is to bend the curve of foodborne illness in this country by reducing the number of illnesses. Essentially, we are building on the work we're doing to create a modernized food safety regulatory framework while also leveraging the use of new and emerging technologies and approaches to strengthen our predictive capabilities, accelerate prevention, speed outbreak response, and enhance our ability to swiftly adapt to crises that could affect the food supply.

When we look at how industries track, through digital means, the real-time movement of planes, ride sharing, and packaged goods or how firms are harnessing big data to identify trends, it is clear FDA and our stakeholders should be looking at how to tap into new technologies that include, but are not limited to, artificial intelligence, the Internet of Things, sensor technologies, and blockchain.

That said, while technology is an important part of the New Era of Smarter Food Safety, it's more than that. It's about simpler, more effective, modern approaches and processes. It's about leadership and creativity. It's about fostering a food safety culture that transcends borders

between the public and private sectors. This New Era of Smarter Food Safety is people-led, FSMA-based and technology-enabled.

The tools and authorities granted by FSMA create a flexible framework that is adaptable to the changing food safety environment. We continue to make progress in implementing the seven foundational rules that are the FSMA building blocks, which created standards for the production, transportation and importation of human and animal food. Major compliance dates have arrived, inspections are being conducted, and challenges are being addressed.

Fully implementing the remaining FSMA-mandated requirements will help to further prevent contamination. Yet, our prevention framework must continue to evolve. Advances in detection technologies (e.g., whole genome sequencing and enhanced analytics) mean that more outbreaks are being detected than would have been possible to detect in the past. Recognizing this reality, FDA aims to focus on further modernizing prevention, quickly identifying contaminated food, and helping to ensure that it is removed from the marketplace.

The New Era of Smarter Food Safety is an approach to bending the curve of foodborne illness through the use of new technologies and approaches.

Deputy FDA Commissioner Frank Yiannas

Collectively, FDA and all stakeholders should strive to ensure that we are doing everything possible to quickly incorporate the lessons learned from contamination events into prevention efforts, and to complete our work as expeditiously as possible.

Our world is evolving at a breakneck pace. With this evolution comes new technologies, ranging from new digital tools to new sources of food ingredients. It also comes with new business models, like e-commerce and omni-channel food distribution, which covers a range of online, mobile device, telephone, and brick-and-mortar store shopping platforms. These advances provide new tools and approaches for tackling food safety issues, but also present new issues to consider in determining how to regulate food safety.

FDA has determined that it's time to look to the future of food safety once again, with an approach that builds on the progress that FSMA has made in creating a risk-based, prevention-oriented regulatory framework, but that also leverages the use of new and emerging technologies to create a safer and a more digital, traceable system.

We plan to engage a broad expanse of stakeholders in industry, academia, trade associations, and consumer groups, as well as our state, federal, international and other regulatory partners, and groups that we had not traditionally engaged with before, such as technology companies.

We recognize that building on our food safety approach in a rapidly evolving and interconnected world will require resources and innovation. Continued

investments throughout FDA and the food safety system will be critical to improving public health and reducing supply chain disruption.

Our Principles

III. Our Principles

We are not walking away from, nor are we replacing, FSMA. Instead we are building on the progress we have made in implementing this landmark law.

Susan Mayne, Director of FDA's Center for Food Safety and Applied Nutrition

People-Focused and Led

Enhancing the safety of the foods consumers eat each day, as well as improving consumer trust in the food system, will require heightened focus on prevention, advancements in food traceability, and continued efforts to provide consumers with actionable and accurate information about the foods they consume. To address the growing complexity of the food system we need actions informed by the best expertise. Scientific and regulatory expertise is at the root of our public health mission, and the people of FDA and our stakeholders are critical to future success. FDA will bring diverse groups together to find common ground and identify

smart solutions. Together, we can implement better solutions to protect public health in a way that creates shared value.

FSMA-Based

The prevention-based system that FSMA created is the foundation of the work going forward. Digital innovation and a complex, dynamic global supply chain are re-shaping the future of food and food safety. Realizing the opportunities that come with change will depend on our collective vision and commitment. This approach will layer informational and technological advancements onto the FSMA foundation to further strengthen food safety.

Technology-Enabled

The world is rapidly becoming more digital. Advances in artificial intelligence, the Internet of Things, sensor technologies, and blockchain are improving business processes. New digital technologies offer the potential to help us predict and prevent food safety problems and better detect and respond to problems when they do occur. Whenever possible, we will work with stakeholders to explore low- or no-cost options so that our approaches are inclusive of and viable for food operations of all sizes. As we learned with the FSMA rules, there’s no such thing as one-size-fits-all when it comes to protecting a diverse food system and flexibility in approaches is critical.

Our Process

IV. Our Process

Science, technology, and innovation continue to evolve, and we must constantly think about how we evolve along with them.

FDA Associate Commissioner for Regulatory Affairs
Judy McMeekin

In April 2019, FDA announced the New Era of Smarter Food Safety initiative. In July, FDA's Foods Program leadership took the first step, selecting experts within the agency to provide their insights on how we can really make this happen, starting with ideas and continuing with a vision of how their ideas could potentially be realized. The experts represented the Office of Food Policy and Response, the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the Office of Regulatory Affairs, and the Office of the Commissioner. More than 100 experts participated in brainstorming sessions on these core elements.

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

In the first round of brainstorming sessions, participants were asked to unleash their ideas, unfettered by practical considerations like staff and

resources. The time for practicality came in a second round of sessions, when these experts looked at their ideas with new eyes, considering feasibility and recommending realistic goals for the next decade.

In October 2019, FDA conducted a public meeting to engage stakeholders and foster a dialogue with our domestic and international regulatory partners, industry, consumer advocates, and others. More than 1,300 people participated in person or via Webcast. FDA also opened a docket in the Federal Register inviting public comment. The comment period closed on December 5, after which an FDA team compiled and reviewed all of the input for consideration during our planning.

The release of this blueprint, initially planned in spring 2020, was delayed by the COVID-19 pandemic response, but our experiences thus far in our ongoing response efforts have only reinforced that the New Era of Smarter Food Safety is the right approach for the future. The lessons we are learning are helping us prioritize our goals by highlighting the areas in greatest need of new technologies, tools, and approaches.

This blueprint reflects input from a variety of stakeholders and offers a vision for the new decade, with short and long-term goals that will evolve as we move forward in implementation. Priorities will inform the deployment of resources and can be adapted based on food safety performance metrics and ongoing stakeholder input.

The Four Core Elements

V. The Four Core Elements

These are the foundational pillars of the New Era of Smarter Food Safety, covering the range of technologies, analytics, business models, modernization and values that are its building blocks. There is a lot of synergy; an idea in one element may be relevant to one or more others. For example, analytics crosses over into traceability and new business models. The themes of mutual reliance between federal and state partners and the importance of food safety culture are woven throughout. There are common needs for metrics and reliable third-party audits. These elements, working together, will bring us into the New Era of Smarter Food Safety.

Tech-Enabled Traceability

Whether you're working on the safety of human or animal food, we will all benefit from being able to more rapidly trace a contaminated food to its source.

Steven Solomon, Director of FDA's Center for Veterinary Medicine

The records involved in moving food through the supply chain are still largely paper-based. This creates a system in which it is necessary to take one step forward to identify where the food has gone and one step back to identify the previous source. This, along with insufficient data identifying the product along the supply chain, creates an inability to rapidly track and trace food. During an outbreak, this can cost lives,

millions of dollars in avoidable product loss, and damage to consumer trust. As has been seen with outbreaks in fresh leafy greens and other foods over the past decade, anonymity and lack of traceability in the food system are an Achilles heel that hinders more significant progress in rapid traceback efforts to identify contaminated foods. It also stands in the way of the transparency needed to better understand the supply chain in the event of public health crises, such as the COVID-19 pandemic, and to create a more nimble, resilient, and interoperable food system.

Technology already assists outbreak response: Whole genome sequencing allows us to identify illness clusters when they are smaller. Public health agencies increasingly rely on electronic data in outbreak investigations—e.g., shopper card data; the bar code from a food package; supplier-customer data; purchase orders; bills of lading for shipments of goods. Yet the quality and compatibility of this data is highly variable. We want to tap into new technologies and integrate data streams to identify outbreaks and trace the origin of a contaminated food to its source in minutes, or even seconds, speeding our response when public health is at risk.

Smarter Tools and Approaches for Prevention and Outbreak Response

With better traceback, our ability to conduct root-cause analyses will be greater, and findings from this work can be used to better inform the prevention-based framework that FSMA established. To fully realize a preventive controls system that rapidly incorporates new knowledge, it is important to ask how we can make processes and communications more effective, efficient,

and in some cases, simpler. This will be particularly valuable in our collaborations with the public and private sectors to mitigate the risks presented by foods that are especially vulnerable to contamination. As more data streams and tools for rapidly analyzing data become available, we should also think about how we can best use predictive analytics tools to identify when and where contamination might be likely to occur, to prevent contaminated products from entering the food supply, and target efforts to remove potentially contaminated product from the market. It's also important for us to work with others in new and creative ways, such as leveraging reliable third-party audits and the expertise of our state and local regulatory partners to advance food safety. We must also have alternate approaches when traditional methods cannot be carried out during a public health crisis.

New Business Models and Retail Modernization

Industry is inventing new ways to produce and distribute food, and we strive to prepare for new business models. Before the COVID-19 pandemic, research indicated that online grocery shopping would have a 20 percent share of consumer food spending within the next few years. [1] However, online shopping took on a new importance for consumers sheltering in place, with one survey reporting that 31 percent of U.S. households are already using online grocery services. [2] What approaches can FDA take to help ensure food safety? How do we educate distributors, manufacturers, and retailers on the importance of temperature control, cross-contamination, and other safety issues? We will also explore how to adapt our oversight to help ensure the safety of novel ingredients, new foods, and new food production methods.

Progress should also be made in advancing the safety of foods sold in traditional retail establishments. According to the Centers for Disease Control and Prevention (CDC), restaurants and other retail establishments remain the most common nexus of foodborne illness outbreaks. We will focus on known risk factors to change behaviors and practices.

- 1) FMI/Nielsen: The Digitally Engaged Food Shopper; January 2018 (<https://www.fmi.org/digital-shopper>)
- 2) Brick Meets Click/ShopperKit Online Grocery Shopping Survey conducted March 23-25, 2020

Food Safety Culture

Last, but not least, we should foster, support, and strengthen food safety culture on farms, in food facilities, and in homes. We will not make dramatic improvements in reducing the burden of foodborne disease without doing more to influence and change human behavior, addressing how employees think about food safety and how they demonstrate a commitment to this goal in how they do their job. The importance of a food safety culture has been highlighted during the COVID-19 pandemic with its focus on keeping food workers safe and educating consumers cooking more at home on safe food handling practices. We should also look within to ensure that we, as regulators, are promoting the development of a global food safety culture.

Core Element 1: Tech-Enabled Traceability

Core Element 1: Tech-Enabled Traceability

We are advancing traceability to help protect consumers from contaminated products by doing rapid tracebacks, identifying specific sources and helping to remove products from the marketplace as quickly as possible when necessary. The first step in our work will be completing FSMA Section 204 rulemaking to harmonize the key data elements and critical tracking events needed for enhanced traceability. Establishing this foundation for traceability will allow stakeholders in the supply chain to adopt and leverage digitally-enabled technologies, enable data sharing, and introduce approaches that greatly reduce the time it takes to identify the origin of a contaminated food tied to a recall and/or outbreak. This will also create the transparency needed to anticipate and help prevent supply chain disruptions in a public health emergency, such as a pandemic.

Ultimately, we want to have end-to-end traceability throughout the food safety system. We want to explore ways to encourage firms to voluntarily adopt tracing technologies and ways to harmonize tracing activities, which will support interoperability across a variety of technology solutions, working towards outcomes that are achievable for all sectors.

1.1 Develop Foundational Components

- Help the food system to speak the same traceability language through the use and **standardization of critical tracking events and key data elements.**
- Strive to enable industry compliance with FDA's

traceability regulation **using existing consensus standards**, where possible.

- Expand FDA's capacity to process data quickly for all food commodities, encouraging **the expansion of traceability** to cover the broadest range of commodities on a voluntary basis.
- Play a lead role in promoting and participating in governance and harmonization with U.S. and international regulatory counterparts through bodies such as GS1 and Codex.
- Develop **ways to achieve interoperability**. Specifically, work with standards bodies, technology providers, and users to help ensure systems are designed with interoperability as a foundational component.

1.2 Encourage and Incentivize Industry Adoption of New Technologies

- Demonstrate FDA's commitment to **promote industry adoption** by highlighting the wide-ranging benefits of tech-enabled traceability in outreach to the food industry and engaging in conversation with non-traditional stakeholders (e.g. financial industry, technology firms, insurance companies).
- Consider how to address concerns about how to disclose actions related to traceability in a way that provides any necessary protection of **confidentiality and proprietary interests** while advancing transparency.
- Explore ways for FDA to recognize adoption of **strong traceability systems** in how we approach our **food safety oversight** activities

(e.g., taking traceability into account in risk-based planning for inspections).

- Encourage food traceability technology providers to develop creative financial **models that are low- to no-cost solutions**, proportional to benefits derived from participating, and enabling food producers of all sizes to participate in a scalable, cost-effective way.

1.3 Leveraging the Digital Transformation

- 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.
- Collaborate with federal, state, local, tribal and territorial partners on **new ways of conducting accelerated tracebacks and trace forwards** in a tech-enabled food traceability world.
- Harmonize, where possible, **traceability work already underway at the agency** related to other FDA-regulated products (e.g., drugs and medical devices).
- Work with stakeholders to design and execute **pilots on concepts needed for traceability to further scale**, such as testing interoperability and public-private data sharing. Select commodities that have been subject of recent outbreaks, specifically leafy greens, will be given a high priority.
- Implement **an internal digital technology system**, such as blockchain, to receive critical tracking events and key data elements from industry and regulatory partners.

Core Element 2: Smarter Tools and Approaches for Prevention and Outbreak Response

Core Element 2: Smarter Tools and Approaches for Prevention and Outbreak Response

As modern food safety approaches generate new data streams - and tools for rapidly analyzing big data become available – we are exploring their preventive value. We are looking to enhance and strengthen root cause analyses and predictive analytics. Findings of root cause analyses can be an important step in helping industry modify practices to avoid identified risks and can provide more robust data for predictive analytics.

It's also important for us to work with others in new and creative ways. These include the domestic mutual reliance initiative, in which FDA seeks 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. They also include leveraging reliable third-party audits to advance food safety and having alternate approaches when traditional methods are not feasible.

These tools and approaches will also inform FDA and our regulatory partners' approach to inspections, outbreak response and recall modernization.

2.1 Invigorate Root Cause Analyses

- Collaborate with federal, state, industry,

consumer, and academic stakeholders to advance, standardize, and socialize **root cause analysis protocols for food safety**.

- Consider how to address concerns about how to disclose actions related to data analyses in a way that provides any necessary protection of **confidentiality and proprietary interests** while advancing transparency.
- Strengthen **root cause analysis procedures** - coordinating with federal, state, local, tribal, and territorial partners - to ensure **rapid deployment** as soon as an outbreak is traced to a specific site.
- Standardize **criteria and format for producing reports on root cause analyses** of outbreaks and determine the most expedited process for disseminating information and required actions to prevent a reoccurrence.
- **Enhance communication tools**, for quickly and transparently relaying the outcomes of root cause analyses, both internally and externally, in a timely manner.
- Incorporate root cause analysis data into the agency's risk **ranking and predictive analytical systems** to increase the likelihood of predicting and mitigating future contamination events.

2.2 Strengthen Predictive Analytics Capabilities

- Advance FDA's predictive analytics capabilities through **expanded use of artificial intelligence and machine learning tools**, beginning with expanding the proof of concept

completed by the agency on using AI for screening of imported foods at ports of entry.

- Increase the amount and quality of data FDA has through mechanisms that include expanded use of **information-sharing agreements** with regulatory and public health partners, academic institutions, industry and others.
- Explore methods to create **public-private "data trusts,"** a bank of large volumes of data generated by industry that can be accessed for analytical work to further strengthen preventive approaches. Begin by working with stakeholders to create a **"leafy greens data trust."**
- Work with industry to find the balance between the need for **transparency and concerns about the confidentiality of business data** in advancing predictive analytics, including the development of protocols to establish that requests for data are targeted for a specific purpose.
- Explore technologies to enhance **predictive toxicology tools that identify and characterize food chemical hazards** to further strengthen preventive approaches and to support safe innovative food ingredient and production technologies.
- Working with stakeholders, develop **processes to analyze big data and non-traditional data sources of information**, such as environmental conditions (rain, temperature, wind, etc.), that could be used by the public and private sectors to strengthen foodborne predictive capabilities and make more informed risk management decisions.

2.3 Domestic Mutual Reliance

- Consistent with our legal framework, develop and implement a plan for **state and federal mutual reliance**, which will build on existing efforts to provide an effective approach for FDA and its state regulatory counterparts to work in partnership, one defined by sharing, collaboration and harmonization, as well as supporting activities during a public health crisis.
- Further develop and enhance the mechanisms for appropriate **data and information sharing** to enable FDA and states with comparable regulatory and public health systems to more fully rely on, coordinate with, and leverage one another's work, data, and actions.
- Advance an integrated approach to **work planning and risk prioritization/categorization**, including inspection frequency mandates, comparison/reconciliation of inventories, and sample collection.
- Advance an integrated, 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.
- Collaborate on **training and education**, including training of field staff and industry and consumer education.
- Harmonize **food testing methodologies** used by state and federal laboratories, including sample collection, analysis, and reporting.

2.4 Inspection, Training, and Compliance Tools

- Conduct **proof-of-concepts to evaluate the feasibility of using remote, virtual, and/or component inspections** of foreign and domestic firms with a demonstrated history of compliance for agency prioritization purposes. FDA conducted remote inspections of certain importers during the COVID-19 pandemic.
- Encourage, support, and evaluate the use of **sensor technology** by industry to strengthen monitoring of critical and preventive control points.
- Expand the availability of industry and regulatory training to include, where appropriate, **computer-based and distance learning models**.
- Increase **the use of reliable third-party audits** to help ensure safer food, including exploring the use of reliable audit data in risk-prioritization for FDA regulatory activities, for example, with respect to inspections of both imported and domestically produced foods.
- **Develop online tools** to assist growers in evaluating the risk of their water sources and determine potential management options to help ensure compliance with the Produce Safety Rule.
- Modernize the agency's inspectional and reporting process by leveraging **mobile inspection technology and digital reporting tools**.

2.5 Outbreak Response

- Working with federal partners, explore mechanisms to accelerate **the submission of**

reports of foodborne illnesses from state health departments and state departments of agriculture to federal authorities.

- Work with international, federal, state and academic partners to increase the number of laboratories that can submit sequences of parasites, pathogens and viruses isolated from food samples via **FDA's GenomeTrakr**.
- Continue building capacity to upload FDA's food and environmental sample **sequence data to PulseNet** to facilitate investigations of foodborne outbreaks.
- Explore barriers and mechanisms to better leverage **industry food testing results** to identify possible outbreaks.
- Enhance **early warning mechanisms** by facilitating information exchange with and between other countries on reported foodborne illnesses and pathogens isolated from food samples.
- Increase awareness and training to facilitate opportunities to speed **whole genome sequencing of pathogens by public and private labs**.
- Explore using **artificial intelligence to mine nontraditional sources of information**, such as customer online reviews, medication sales trends, and dining apps to detect outbreaks and as an adjunct to traditional health reporting.

2.6 Recall Modernization

- Explore mechanisms to harmonize how FDA and USDA communicate **recall information** to

consumers.

- 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.
- Explore the use of a **broad spectrum of technologies** to enhance external communications and the effectiveness of recalls.
- Create a **United States Government (USG) app** for alerting consumers about food recalls and advisories to empower them with actionable information in real time.
- 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.
- Enhance connectivity of data from **Reportable Food Registry** submissions and food recalls.

Core Element 3: New Business Models and Retail Modernization

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We are looking to address how to protect foods from contamination as new business models emerge and change to meet the needs of the modern consumer. The evolution of how food gets from farm to table continues

with the emergence of e-commerce and new delivery models. The evolution of how food gets produced continues with the emergence of new business models that advance innovations in novel ingredients, new foods, and new food production systems. These new models include online shopping for meals and groceries, a practice that has surged during the COVID-19 pandemic.

Looking at more traditional business models, we're exploring the best ways to further modernize and help ensure the safety of foods sold at restaurants and other retail establishments.

3.1 Ensure Safety of Food Produced or Delivered Using New Business Models

- In collaboration with regulatory partners, and including a broad array of stakeholders, convene a **new food business model summit** to identify future courses of action to address potential food safety vulnerabilities.
- Work with regulatory partners to address new business models that may not be currently covered by FSMA (e.g. address who "owns" □ the food in the last mile).
- Partner with **food delivery companies** to provide education on the importance of proper food handling, including outreach to delivery services such as the U.S. Postal Service, UPS, FedEx, Uber, Lyft, DoorDash, etc.
- In partnership with the U.S. Department of Agriculture, CDC, industry and consumer stakeholders, develop **educational materials for consumers on the handling of food**

delivered to their home including time/temperature considerations, looking for tamper-resistant packaging, and reducing potential for cross-contamination. These materials are also relevant to creating a food safety culture in the home.

- Encourage the use of **technology that automatically monitors product risk factors** associated with new business models, such as time, temperature, tamper resistance, and traceability information.
- Facilitate the safe development of **new food ingredients and production technologies** to foster product innovation and market access in a safe and timely way.

3.2 Modernize Traditional Retail Food Safety Approaches

- Conduct an **independent review of the traditional retail food safety program's effectiveness** in preventing foodborne illness and communicating effectively across partners.
- Further advance the importance of **facility and equipment design** as preventive controls for retail food safety management (i.e., engineering controls). In particular, encourage the development and use of commercial **smart kitchen equipment** capable of automatically monitoring time and temperature processes.
- Work with the Conference for Food Protection to:
 - increase **uniform adoption of the FDA Food Code** by state, local, tribal, and territorial retail food protection programs,

and

- explore more fully incorporating into the Food Code a **food safety management systems** approach for retail establishments.
- Encourage and explore use of **new digital tools and incentives that prompt desired behaviors**, such as handwashing and manual temperature monitoring (i.e., managerial controls).
- Work with partners to enhance existing **manager certification and food handler education and training requirements** to include principles proven to better influence human behavior.
- Enhance **training curricula for federal, state, local, tribal, and territorial retail regulators** and staff, while increasing engagement with **industry and regulatory partners**, to target food safety practices most effective in preventing foodborne illness.
- Increase the use of **risk-based inspectional approaches** that are consistent with the principles of Annex 5 of the Food Code, which provides guidance on planning, conducting and evaluating risk-based inspections.
- Advance **research related to strengthening retail food safety**, encouraging academic research to fill knowledge gaps in this area.
- Identify and develop **intervention strategies** known to be effective at reducing the occurrence of foodborne illness risk factors and tie incorporation of these strategies to FDA's funding of state and local retail programs to incentivize

implementation.

Core Element 4: Food Safety Culture

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We should foster, support and strengthen food safety cultures on farms, in food facilities, and in homes. We will not make dramatic improvements in reducing the burden of foodborne disease without doing more to influence the beliefs, attitudes, and, most importantly, the behaviors of people and the actions of organizations.

A strong food safety culture is a prerequisite to effective food safety management.

4.1 Promote Food Safety Culture Throughout the Food System

- Review literature and conduct and support **research on challenges, barriers, and opportunities** to influence and modify behaviors related to food safety culture.
- Develop an FDA **food safety culture social marketing plan** to strengthen a culture of food safety in the establishments we regulate and in turn, influence and sustain widespread safe-food behavior changes.
- Encourage **influencers**, such as chefs, bloggers, cooking shows, celebrities, and industry leaders to model desired safe-food behaviors and make smarter food safety part of the national dialogue and social norm.

- Ensure **FDA education, training, and inspectional tools** incorporate established behavioral science principles that foster a food attitudes safety culture.
- Enhance food safety culture and **behavioral science principles** as a critical component of the food safety work we do with federal, state, local, tribal, territorial and international regulatory partners.
- Support the development and harmonization of **tools that companies can use to assess their food safety culture**, working in concert with industry and academia.

4.2 Further Promote Food Safety Culture Throughout the Agency

- Ensure consideration of the central role of **food safety culture as a core tenet** in advancing the agency's food safety mission.
 - Develop procedures to further strengthen and measure the **internal understanding** of food safety culture, including the role of public health and regulatory partners as essential members of our food safety team.
- Strengthen communications from FDA leadership on the **importance of food safety culture** as part of FDA's Foods Program.
- Consider how companies' **positive food safety culture** can factor into reduced inspection frequencies.
 - Educate investigators on **the characteristics** that indicate a facility has a strong food safety culture.

4.3 Develop and Promote a Smarter Food Safety Consumer Education Campaign

- Develop strategies to help consumers access, understand and utilize **new technologies relevant to food safety** and facilitate their adoption of new tools (e.g., apps).
- Engage **new partners in a broad coalition** (consumer groups, industry groups such as technology companies, other government partners, and media groups) to promote food safety culture.
- Use **new, tech-enabled popular mediums and tools**, such as Smart Home devices, smart phones, digital platforms, and more to reach consumers with Smarter Food Safety messages.

Conclusion

VI. Conclusion

We know that FDA cannot embark upon this journey alone and, to be successful, it's equally important for food companies and technology firms, as well as government agencies and consumers, to join us in this effort.

Imagine how different our work and lives would be if we could leverage tools and technologies, as well as modern approaches, to fundamentally change how we keep food safe.

No matter whether you're a food producer or a food regulator, or whether you are in the government, industry or academia, at the end of the day we're all consumers. So, imagine these aspirations becoming the norm:

- Scanning a bag of lettuce and being able to immediately know where it came from to determine if it's tied to an outbreak of foodborne illness.
- Receiving a text message that lets you know you've purchased something that's been recalled.
- Having greater confidence in the safety of the food you share with your family because artificial intelligence has enabled FDA to significantly increase its predictive capability of finding contaminated food.
- Knowing the potential impact of weather events, like hurricanes or floods, on the safety of foods hundreds of miles or more away because of big data analytics.
- Knowing that the water used to grow the produce you're buying is safe because it was monitored by the farmer in real-time using sensor monitoring on a smart device.
- Receiving alerts on your smart phone when your dinner has reached a safe temperature.
- Knowing that the workers in your favorite restaurant use safe-food handling practices, not because they're required to but because the workplace culture has made it second nature for them.

In putting forth the concepts in this blueprint, we're not talking about things that can't be done. We're talking about doing our work differently.

Working together and thinking outside the box, we'll create a more digital, traceable and safer food system that advances food safety, improves the quality of life for consumers in this country and all over the world, and better prepares us for unexpected events that could impact the food supply.

Was this helpful?