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MEMORANDUM

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Date: October 25, 2019

Re: FDA Holds Public Meeting on "A New Era of Smarter Food Safety" to Further FSMA Implementation

On October 21, 2019, the U.S. Food and Drug Administration (FDA) held a public meeting to engage stakeholders on the agency's initiative, "A New Era of Smarter Food Safety," to build on the advances that have been and are being made in FDA's implementation of the FDA Food Safety Modernization Act (FSMA). 1/ FDA will use input from the meeting and written comments to the docket to develop a Blueprint for a New Era of Smarter Food Safety, which the agency plans to release in early 2020. The Blueprint will outline the agency's vision for a modern approach to food safety that includes technology-enabled traceability and the use of predictive analytic tools to assess risk and set agency priorities. FDA has opened a docket for written comments, which are due by November 20, 2019. 2/ The specific questions on which FDA has requested input are included as an appendix to this memo and provide insight into FDA's current thinking on these issues. The discussion below provides a high-level summary of the agency statements and stakeholder comments made during the meeting.

Background

Through this initiative, FDA is exploring the use of new and emerging technologies to strengthen predictive capabilities, support the implementation of preventive controls, and increase the speed of outbreak response. The impetus for the initiative is rooted in the rapid innovation in food products, processes, and delivery modes alongside the emergence of transformational technologies such as blockchain, machine learning, sensors, and the Internet of Things. FDA believes that these technologies offer the potential to dramatically alter the speed and effectiveness of preventing, tracing, and responding to outbreaks.

There are four priority areas that will be the focus of FDA's efforts:

1/ See our memo on FDA's notice of the public meeting at https://www.hoganlovells.com/en/publications/fda-announces-public-meeting-and-docket-for-comments-on-a-new-era-of-smarter-food-safety-to-facilitate-fsma-implementation.

2/ Comments can be submitted to FDA docket number FDA-2019-N-4187.

- **Tech-Enabled Traceability and Foodborne Outbreak Response**: Looking at technologies, data streams, and processes that will greatly reduce the time it takes to track and trace the origin of a contaminated food and respond to public health risks.
- **Smarter Tools and Approaches for Prevention**: Enhancing the use of new knowledge from traceback, data streams, and other tools for rapidly analyzing data. The ability to use new data analysis tools and predictive analytics will help FDA and stakeholders better identify and mitigate potential food safety risks and advance the preventive controls framework that FSMA established.
- **Adapting to New Business Models and Retail Food Safety 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.
- **Food Safety Culture**: Promoting and recognizing the role of food safety culture on farms and in facilities. This involves doing more to influence what employees and companies think about food safety and how they demonstrate a commitment to this work. Strengthening food safety cultures also extends to the home and FDA is working to educate consumers on safe food handling practices.

Meeting Scope

Prior to the meeting, groups of FDA experts were asked to generate big-picture ideas and proposals, without considering practical constraints such as staffing and resources, on how the agency can leverage new technologies, as well as new approaches to the food system's safety challenges. The results of these discussions are found in "Food for Thought: Ideas on How to Begin a New Era of Smarter Food Safety," which was released as background information prior to the public meeting. 3/ In his opening remarks, FDA's Deputy Commissioner for Food Policy and Response, Frank Yiannas, charged the assembled stakeholders to contribute to these brainstorming efforts using "imagination" to ask "what if" as part of an ongoing dialogue to eventually reach actionable solutions. Yiannas emphasized that the initiative is FSMA-based and reported that the agency is making significant progress on a proposed rule on traceability under FSMA § 204, which is expected sometime next year. 4/

In his remarks, Yiannas flagged traceability as a critical issue. The challenges around devising a scalable, flexible, interoperable system based on effective data management practices elicited commentary throughout the day. FDA is not planning on building its own platform, but does see a role for the agency in creating the conditions for interoperability, industry adoption, and scale.

The at-capacity meeting (both in-person and webcast) included representatives from food and technology companies, public officials from other government agencies (including state, local, and international), media, and consumer advocates. Two all-inclusive sessions offered "Visions for" and

3/ "Food for Thought: Ideas on How to Begin a New Era of Smarter Food Safety," available at https://www.fda.gov/media/131682/download.

4/ Section 204 of FSMA requires FDA to 1) establish and publish a list of high-risk foods; and 2) engage in rulemaking setting forth additional traceability recordkeeping requirements related to such foods. Two consumer groups brought a lawsuit against FDA for failing to implement these provisions within the statutorily prescribed timeframe. FDA ultimately entered into a settlement agreement committing to issuing a proposed rule establishing recordkeeping requirements for high-risk foods. For a summary of the settlement agreement regarding FSMA Section 204, see our memo at https://www.hlfoodlaw.com/wp-content/uploads/sites/357/2019/06/HL-Memo-Settlement-Reached-in-Lawsuit-Seeking-to-Compel-FDA-to-Implement-FSMA-Traceability-Provisions.pdf.

"Perspectives on" a "New Era of Smarter Food Safety," which were then followed by repeat breakout sessions on the four topics for discussion, which are discussed in more detail below.

Key Issues Addressed

The simultaneous breakout sessions were structured to gather input from participants on four focus areas: traceability, smarter tools and approaches for prevention, challenges of new business models and retail food safety, and food safety culture. A recurring theme across most of the sessions was the tension between FDA's dual roles of compliance enforcer and public health collaborator. Participants frequently queried how to collaborate with the agency in information sharing and education in an experimental environment without invoking enforcement risks that might chill exploration of solutions. Other recurring issues concerned the need for consistent standards, interoperability, costs associated with development and implementation, and clearly defined rubrics for data governance and analysis.

Following are brief summaries of the issues raised by stakeholders in the specific breakout sessions:

Tech-Enabled Traceability & Foodborne Outbreak Response

- It is critical for FDA to establish and clearly communicate the minimum data elements needed for any traceability technologies.
- The focus of any standards should be on foundational elements, and using that information to integrate, communicate, and implement traceability with and through members of the supply chain.
- FDA should establish standards for assuring that data can be shared effectively through a common language and interoperable systems.
- Considerations for sensitive data sharing (e.g., proprietary, liability, and regulatory risk) are integral to gaining industry buy-in.
- Firm size, complexity of various industries, and complex processes at different points in the supply chain may require flexibility in establishing regulatory frameworks.
- Cost may be a barrier to adoption; for smaller firms, it could be difficult to adopt or invest in new technologies without a clearly articulated return on investment.
- There are additional challenges with implementing technologies at the grower level and ensuring data integrity all the way to retail, such as cost, complicated supply chains, and educating growers. Any research undertaken should consider all of these challenges.

Smarter Tools & Approaches for Prevention

- Data already exists that could be utilized immediately, but consideration must be given to:
    - safeguards for information sharing, including around potential liability, the Freedom of Information Act (FOIA), and retroactive enforcement, and
    - precise definitions for types of data to be analyzed, consistent data management standards, and whether and when the data should be aggregate or firm-specific.
- Root cause analyses are fundamental to a truly preventive system, and there is a need for FDA to help companies perform root cause analyses effectively. Environmental assessments and root cause analysis need clarity around timeliness and required outcomes.
- FDA should promulgate a laboratory accreditation regulation under FSMA § 202. 5/

5/ For a summary of FSMA's laboratory accreditation provisions and associated lawsuit, see our memo at https://www.hlfoodlaw.com/2019/08/lawsuit-seeks-to-compel-fda-to-implement-fsmas-laboratory-accreditation-provisions/.

Adapting to New Business Models & Retail Food Safety Modernization

- Global research to understand potential health risks posed by foods should be leveraged versus discrete analyses at the domestic level.
- There are challenges with the assumptions that all business models are the same or could implement the same standards. Flexibility is needed regarding how standards are developed.
- Research is needed to identify the landscape of new business models and to clarify specific emerging issues, such as reusable containers, models for shelf life, best practices for tamper resistant containers, and the impact of shared kitchens.
- Other countries have developed best practices on "the last mile" that could be adopted. Thinking globally across the supply chain is crucial.
- Industry focus groups should be convened to develop collaboration models, potentially to include instituting agency resources, e.g., FSIS's "askKaren" resources.
- Standards must take into consideration privacy issues when it comes to notifications and traceability.

Food Safety Culture

- Culture is really about "behavior" and needs to focus on all levels across organizations.
- Education is critical to ensure that everyone fully understands and embraces food safety behaviors, but can come up against countervailing business and operational imperatives.
- Reminders in the form of real stories of the human impact of foodborne illness can have significant impact.
- Existing standards can be leveraged – there is no need to invent new ones.
- FDA can provide communication and guidance to industry constituents to translate technical legal and regulatory material into information that is applicable in the field.

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We will continue to monitor FDA's updates related to this public meeting, as well as other guidance and rulemaking generally related to food safety and FSMA. Please contact us if you are interested in submitting comments to FDA's docket or if you have any questions regarding this or other matters.

Appendix: Topics for Discussion

FDA is encouraging the public to submit detailed comments. At the meeting, agency officials repeatedly underscored the desire to collaborate with industry to develop regulatory strategies that will facilitate and incentivize industry adoption of technology-enabled food safety approaches. FDA will continue to accept comments through November 20, 2019 to docket number FDA-2019-N-4187.

Following are the specific questions for discussion:

A. New and Evolving Digital Technologies Will Play a Pivotal Role in Tracing the Origin of a Contaminated Food to Its Source in Minutes, or Even Seconds, Instead of Days or Weeks

1. What are the most significant actions FDA could undertake to enable industry to enhance traceability across the entire global food supply chain?
2. How could FDA make it more likely that companies utilize new technologies to enhance the traceability of their products?
3. What can FDA do to facilitate and expedite outbreak-related communications between government agencies, industry, and consumers?
4. Are there mechanisms FDA could employ to incentivize adoption of realtime, end-to-end food traceability throughout the food sector?
5. What are the challenges to creating a more digital, traceable global food supply, and how might FDA approach this in a manner that creates shared value for all participants?

B. To Fully Realize a Preventive Controls System That Rapidly Incorporates New Knowledge, We Must Also Ask if We Can We Make Processes and Communications More Effective, Efficient, and in Some Cases, Simpler

1. What are the most significant actions FDA could undertake to promote and support the use of smarter tools for prevention?
2. What predictive analytical tools and data streams are best suited to helping identify a potential contamination event?
3. What further steps can be taken to advance the safety of domestic and foreign commodities that have been the subject of frequent contamination incidents?
4. In what ways can FDA support the use of environmental assessments and root cause analyses in industry prevention efforts?
5. Are there changes that FDA can and should make in the way in which it conducts environmental assessments and root cause analyses, and reports its findings to industry, to better facilitate their use in industry prevention efforts?

C. Evolving Business Models Present Food Safety Challenges as Well as Novel Considerations Around Regulatory Framework and Oversight at the Federal, State, Territorial, and Local Level

1. What are the most significant actions FDA could undertake to help ensure the safety of foods delivered under a variety of new business models, such as e-commerce?
2. What research is available or should be conducted to understand the potential health risks posed by foods provided by new business models, such as e-commerce?
3. Are there specific collaborations between FDA and industry that would help to ensure the safety of these foods?
4. What are the most significant actions that FDA, state, territorial, and local agencies, and industry could take to change practices in the retail food industry that present risks to public health?

D. We Want To Do More To Use and Leverage Proven Organizational Culture and Behavioral Science Principles and Techniques To Enhance Organizational and Employee Compliance With Desired Food Safety Practices and Behaviors

1. What are the most significant actions FDA could undertake to foster and support the development of food safety cultures globally?
2. How can FDA encourage and support companies in the development of food safety cultures throughout the supply chain?
3. What are the obstacles to creating food safety cultures throughout the supply chain?
4. Are there changes that FDA can and should take in how it approaches food safety to place further emphasis on prevention?