

MEMORANDUM

From: Joseph A. Levitt
Maile Gradison Hermida
Elizabeth Barr Fawell

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Re: FDA Announces Public Meeting and Docket for Comments on “A New Era of Smarter Food Safety” to Facilitate FSMA Implementation

The Food and Drug Administration (FDA) recently announced it will hold a full day public meeting on October 21, 2019, regarding “A New Era of Smarter Food Safety.” ^{1/} As explained in more detail in this memorandum, as part of FDA’s ongoing implementation of the FDA Food Safety Modernization Act (FSMA), the agency is exploring new and emerging technology to assess risks and prioritize resources, while creating a more digital, traceable, and safer system. The agency’s initial focus areas are traceability, smarter tools and approaches for prevention, the challenges of new business models and retail food safety, and support for the development of food safety cultures. ^{2/} The meeting will be held in Rockville, Maryland, and also will be webcast.

FDA also is opening a docket to receive comments related to this issue, including on several questions set out in the Federal Register notice announcing the meeting. The docket will be open through November 20, 2019. ^{3/}

Background

On April 30, 2019, Acting FDA Commissioner Ned Sharpless and Deputy Commissioner for Food Policy and Response Frank Yiannas issued a statement on the New Era of Smarter Food Safety. ^{4/} With this initiative, the agency articulated its vision of modernizing the approach to the food safety regulatory framework. ^{5/} The approach seeks to incorporate new and emerging technologies, such

^{1/} 84 FR 4911 (September 17, 2019). FDA’s press release about the meeting is available at <https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-public-meeting-discuss-new-era-smarter-food-safety>.

^{2/} To register to attend the in person event or the webcast, visit <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-new-era-smarter-food-safety-10212019-10212019>.

^{3/} Comments can be submitted to docket FDA-2019-N-4187.

^{4/} The statement is available at <https://www.fda.gov/news-events/press-announcements/statement-acting-fda-commissioner-ned-sharpless-md-and-deputy-commissioner-frank-yiannas-steps-usher>.

⁵ See Hogan Lovells memorandum dated May 2, 2019, *FDA Acting Commissioner Sharpless and Deputy Commissioner Yiannas Issue Statement on Steps to Usher the U.S. into a New Era of Smarter Food Safety*, available at <https://www.hoganlovells.com/en/publications/fda-acting-commissioner->

as artificial intelligence and blockchain, to replace paper-based systems for tracking and tracing contamination. The agency also is considering the impact of evolving business models – especially the growth of e-commerce – that give rise to new methods of packaging and delivery, as well as the anticipated acceleration of new and emerging products and ingredients. Finally, the agency aims to support the development of food safety cultures throughout the global supply chain.

In conjunction with announcing the meeting, FDA released “A Conversation with Frank Yiannas,” wherein Mr. Yiannas discusses his vision for this initiative. ^{6/} Mr. Yiannas explains, “Smarter Food Safety is people-led, FSMA-based and technology-enabled.” He also explains that FDA’s efforts are building on FSMA, as a lot has changed since the law was enacted in January 2011. Additionally, he extolls the benefits of better traceability, including blockchain technology.

FDA’s next step will be to publish a strategic blueprint in early 2020 that will outline the actions the agency is planning. A team at FDA is currently brainstorming ideas and considering how to make them a reality.

Meeting and Comment Topics

In the Federal Register notice announcing the meeting, FDA framed a series of high-level areas of inquiry, each of which elaborates a number of questions to direct discussion and input. The four framing subjects and specific questions as stated by FDA are as follows:

- 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 real-time, 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?

[sharpless-and-deputy-commissioner-yiannas-issue-statement-on-steps-to-usher-the-us-into-a-new-era-of-smarter-food-safety.](#)

^{6/} The interview is available at <https://www.fda.gov/food/conversations-experts-food-topics/deputy-commissioner-champions-more-digital-transparent-food-safety-system>.

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?

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Hogan Lovells is planning to attend the public meeting and will stay abreast of developments related to the New Era of Food Safety. Please let us know if we can provide assistance in connection with the public meeting or preparation of comments.