



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-4187]

A New Era of Smarter Food Safety; Public Meeting, Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled "A New Era of Smarter Food Safety" to get input from a broad cross-section of stakeholders on a modern approach the Agency is taking to strengthen its protection of the food supply. The purpose of this meeting is to foster a dialogue with our domestic and international regulatory and public health partners, industry, consumers, academia, and others. The input received at this meeting, and in comments submitted to the docket, will be used to shape an FDA Blueprint for a New Era of Smarter Food Safety. This Blueprint will outline how this modern approach will address public health challenges, ranging from being able to trace sources of contaminated foods, to using new predictive analytics tools like artificial intelligence to assess risks, and help prioritize the Agency's work and resources.

DATES: The public meeting will be held on October 21, 2019, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by November 20, 2019. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at the Hilton Washington DC/Rockville Hotel and Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852. For more

information on the hotel see <https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 20, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 20, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No.FDA-2019-N-4187 for "A New Era of Smarter Food Safety." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made

publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential."

Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For questions about registering for the meeting or to register by phone: Mark Gifford, SIDEM, 1775 Eye St. NW, Suite 1150, Washington, DC 20006, telephone: 240-393-4496, Fax: 202-495-2091, email: EventSupport@sidemgroup.com.

For general questions about the meeting or for special accommodations due to a disability:

Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, telephone: 240-402-1731, email: Juanita.yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On April 30, 2019, FDA released a joint statement from Acting FDA Commissioner Ned

Sharpless, M.D., and Deputy Commissioner for Food Policy and Response Frank Yiannas on the New Era of Smarter Food Safety. (<https://www.fda.gov/news-events/press-announcements/statement-acting-fda-commissioner-ned-sharpless-md-and-deputy-commissioner-frank-yiannas-steps-usher>). This is a modern approach to food safety that incorporates the use of new and emerging technologies, considers the challenge of evolving business models, and works to support the development of food safety cultures throughout the global supply chain. The New Era of Smarter Food Safety will enhance the Agency's ongoing efforts to implement the FDA Food Safety Modernization Act (FSMA) by creating a more digital, traceable, and safer system to help protect consumers from contaminated food.

FDA continues to build a modernized regulatory framework that can help ensure the safety of the food supply, including innovations in food ingredients and processes. At the same time, FDA will leverage the use of new and emerging technologies to strengthen predictive capabilities, support the implementation of preventive controls, and speed outbreak response.

Today's technology-focused world has changed the way our society operates, creating a highly complex and globally interconnected landscape. The food system has evolved from a system that sources foods from around the corner to a system that brings in foods from around the world and travels an ever-changing "last mile" with the emergence of direct-to-home delivery models. Technology and market forces have redefined how foods go from farm to table as shown by the expansion of e-commerce and the use of new technologies to track foods and their storage conditions along the supply chain.

There will be significant innovation in the agriculture, food production, and food distribution systems in the next 10 years, which will continue to provide an even greater variety of food sources, food ingredients, and delivery conveniences for American consumers. With this

ever-changing landscape, FDA must continue preparing to take advantage of new opportunities and address potential risks.

Since FSMA was signed into law in 2011, FDA has proposed and finalized critical regulations that have established science- and risk-based standards for the production, importation, and transportation of foods. FDA has also had great success leveraging technology to advance food safety, especially in the use of new analytical tools like Whole Genome Sequencing. However, a lot has changed since 2011.

When it comes to food traceability, many in the food system still utilize a largely paper-based system of taking one step forward to identify where the food has gone and one step back to identify the source. The use of new and evolving digital technologies envisioned in the New Era of Smarter Food Safety 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. Access to information during an outbreak about the origin of contaminated food will facilitate more timely root cause analyses and enable FDA to prevent future contamination incidents.

The Agency will look at technologies and approaches that include those being used in society and business sectors all around us, such as distributed ledgers, sensors, the Internet of Things, and artificial intelligence. FDA will assess how these technologies could create a more digital, transparent, and safe food system while also addressing consumer demands for quick access to information about where their foods come from, how they are produced, and if the food is the subject of an ongoing recall.

As consumers are increasingly asking for food to be delivered to their homes, there are new methods, packaging materials, temperature control approaches, and delivery models in the e-commerce system. These 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.

The New Era of Smarter Food Safety is about more than technology. It is also about working within and outside of FDA to foster a food safety culture that transcends borders between the public and private sector, as well as geographic and commodity divides. The New Era of Smarter Food Safety is also about enhancing existing processes to make them more effective and efficient. FDA looks forward to participation in this effort by food companies and technology firms of all sizes, as well as state, territorial, local, and federal agencies and other stakeholders.

II. Topics for Discussion at the Public Meeting

The public meeting will begin with a plenary session, followed by breakout sessions that will discuss key topics relating to the New Era of Smarter Food Safety. These topics will include technologies and data streams that have the potential to greatly reduce the time it takes to trace the origin of a contaminated food to its source and how we might best use this information. We will talk about how we can use lessons learned from outbreaks to better inform and enhance our prevention efforts.

No matter how consumers get their food, whether they are ordering online or at their favorite restaurant, they deserve to have confidence in the safety of the food supply. We will talk about 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. Perhaps the most fundamental topic that we will address is the need to support and strengthen food safety culture throughout the supply chain from farms to facilities through retail, which is the foundation of food safety management.

We encourage public comments and presentations at the public meeting. In submitting comments, data, and information to the docket, please identify available references for the data and information, as well as the general category area and, if appropriate, the specific question listed below. We are starting with several focus areas: 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.

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?
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?

Approximately two weeks before the meeting, we will post the public meeting agenda and additional meeting materials on the Internet at: <https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements>. In addition to the opportunity to comment at the public meeting, there will be an opportunity for interested stakeholders to submit written comments following the meeting.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: <https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability. Persons interested in attending this public meeting must register by 11:59 p.m. Eastern Time on October 11, 2019. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be

provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting.

For questions about registering for the meeting or to register by phone, please contact Mark Gifford (see FOR FURTHER INFORMATION CONTACT).

If you need special accommodations due to a disability, please contact Juanita Yates, (see FOR FURTHER INFORMATION CONTACT) no later than October 2, 2019.

Requests for Oral Presentations: During online or telephone registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants. All requests to make oral presentations must be received by October 2, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting. Persons notified that they will be presenters are encouraged to arrive at the meeting room early and check in at the on-site registration table. Actual presentation times may vary based on how the meeting progresses in real time.

Persons attending FDA's meetings are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the public meeting: This public meeting will also be webcast. Webcast participants are asked to preregister at <https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements>.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at <https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements>.

Dated: September 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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