COVINGTON

A New Era of Smarter Food Safety

October 25, 2019

Food, Beverage, and Dietary Supplements

FDA hosted a public meeting on October 21, 2019 entitled "A New Era of Smarter Food Safety." The purpose of the meeting was to obtain stakeholder input on the Agency's food safety initiative launched in April 2019 and inform a strategic blueprint expected to be issued in early 2020. Ned Sharpless, MD, Acting Commissioner of Food and Drugs, FDA, provided remarks emphasizing the initiative's focus on "strengthening predictive capabilities, accelerating prevention, speeding response, and using and analyzing data," through leveraging new technologies and approaches. At the conclusion of the meeting, Frank Yiannas, Deputy Commissioner, Office of Food Policy and Response, called it a "historic day" and a "major milestone" on the journey of smarter food safety. Below are our key takeaways from the meeting.

FDA continues to focus on four priority areas, motivated by transformations in food supply and demand

FDA officials and panelists pointed to major developments in the food system as necessitating smarter food safety. Acting Commissioner Sharpless noted that foods are increasingly grown and manufactured outside the United States, and are being produced and delivered differently, such as through online ordering. Several speakers identified changes in demand: consumers are increasingly knowledgeable and empowered, making trust and transparency especially important.

The meeting included breakout sessions on the four priority areas listed below, plenary remarks, panel discussions, and an open public comment period. The breakout discussions were largely guided by the questions set forth in the Federal Register notice of public meeting and request for comments. The panel presentations and remarks by FDA officials similarly focused on these themes.

1. Tech-Enabled Traceability and Foodborne Outbreak Response
2. Smarter Tools and Approaches for Prevention
3. Adapting to New Business Models and Retail Food Safety Modernization
4. Food Safety Culture

In advance of the meeting, internal workgroups of FDA staff held brainstorming sessions on these topics. FDA released preliminary ideas from the workgroups in a document entitled "Food for Thought: Ideas on How to Begin a New Era of Smarter Food Safety."

Tech-Enabled Traceability and Foodborne Outbreak Response

Deputy Commissioner Yiannas reiterated that the lack of traceability and transparency is the "Achilles' heel" of the food system. He encouraged participants to ask "what if?" instead of "what about?" and to imagine if the industry standard of care allowed a customer to scan lettuce in a grocery store and be able to know where it came from with speed and precision, or receive a text message on a device that they have purchased a product that has been recalled rather than a paper flyer. From the industry standpoint, he gave the example of having access to monitor the critical control points in a facility from outside the office.

Participants in the meeting expressed optimism about technological solutions – including existing approaches and newer developments such as blockchain – and panelists presented case studies of successes. However, stakeholders also raised concerns about the complexity and cost of implementing traceability technology end-to-end across supply chains. The Food Safety Modernization Act (FSMA) authorizes FDA to impose enhanced recordkeeping requirements on "high risk foods," but prohibits FDA from requiring specific technologies. During his remarks, Deputy Commissioner Yiannas indicated that the Agency is not currently planning to build its own technological platform, but that he believes there is a role for FDA to work on issues such as interoperability and harmonizing the data element requirements. He also stated that there is a role for the public sector in creating incentives for adoption and scaling of these solutions. Yiannas also said that FDA is working on the FSMA section 204 requirement to designate foods for which additional records are needed, and anticipates proposing a rule sometime next year.

FDA officials recognized interoperability and data standards as key issues with tech-enabled approaches. Industry participants asked for help understanding the minimum elements and what is required for traceability, as well as actionable guidance about how to get started. Many have concerns about complexity and costs of traceability for various industries and small firms, and urged providing flexible options and incentives. FDA officials also acknowledged concerns about sharing sensitive data. Stakeholders also urged FDA to provide regular and frequent meetings, as well as timely communications and sharing of data, especially during outbreaks.

Smarter Tools and Approaches for Prevention

Similar to the tech-enabled traceability session, this breakout group discussed themes including data and related safeguards. FDA acknowledged input about challenges and constraints related to data sharing, including fear of retroactive investigations based on self-reported data. While recognizing there is a "veritable treasure trove of existing data," questions remain about what types of data should be collected, *e.g.*, aggregate or firm-specific data, as well as data standards and interoperability. In summarizing the session, FDA also noted issues related to environmental assessments and root cause analyses, including timeliness and dialogue between FDA and industry.

Adapting to New Business Models and Retail Food Safety Modernization

This discussion addressed evolving food business models such as e-commerce, home delivery, and meal kits. FDA focused its discussion questions on four specific areas: (1) actions FDA can take, (2) research, (3) collaborations, and (4) actions the food safety community can take. Themes from the breakout groups included thinking globally and using existing best practices. Several stakeholders encouraged FDA to learn from companies that are already successfully navigating the "new last mile" or other new business models, from other existing groups with

relevant expertise, and from best practices in other countries. Participants expressed a desire for FDA to identify the landscape of existing research, and proposed potential areas for further research. Some also raised concerns about establishing consistent standards, clearly defining regulatory jurisdiction, and having consistency in auditing. Stakeholders also emphasized last-mile food safety training, rewarding positive food safety culture behavior, and educating consumers.

Food Safety Culture

Themes from the food safety culture breakout groups included the importance of collaboration, partnerships, education, and responsibility at all levels of an organization. Participants also discussed humanizing the work and remembering the people who have suffered foodborne illness. Reflecting common themes across all four topics, participants emphasized leveraging existing best practices and data standards, as well as learning from each other. In summarizing the breakout session, FDA acknowledged stakeholders' requests for as much guidance as possible, particularly for smaller producers.

Next steps

Interested stakeholders may wish to submit comments to FDA on a New Era of Smarter Food Safety. The comment period is open through November 20, 2019. FDA indicated that the internal brainstorming groups will meet again soon, and that development of the blueprint will be informed by the feedback from the meeting and written comments. Where applicable, written comments should reference the specific questions listed in the Federal Register notice for each of the four focus areas described above. During the public meeting, FDA officials specifically asked for more information on incentives, challenges stakeholders are facing (especially "real-life examples"), and what approaches FDA might take.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Beverage, and Dietary Supplements practice:

Miriam Guggenheim	+1 202 662 5235	mguggenheim@cov.com
Jessica O'Connell	+1 202 662 5180	jpoconnell@cov.com
Jeannie Perron	+1 202 662 5687	jperron@cov.com
Marienna Murch	+1 415 591 7016	mmurch@cov.com