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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Data and Technology in the New Era of Smarter Food Safety
Docket FDA-2024-N-1744

Dear Sir or Madam:

FMI-The Food Industry Association (FMI) appreciates the opportunity to comment on recall modernization and U.S. Food and Drug Administration's (FDA) "Virtual Public Meeting on Data and Technology in the New Era of Smarter Food Safety." We are pleased that FDA is seeking stakeholder input on the new era initiative. We encourage the agency to continue to work with multiple stakeholders and seek public input on FDA initiatives.

As the food industry association, FMI works with, and on behalf of, the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as a wide variety of companies providing critical services — to amplify the collective work of the industry. Read more about us at www.FMI.org.

Comments about the Public Meeting Process
Public meetings play an important role when soliciting stakeholder input. To be meaningful, these public meetings need to be interactive and easily accessible. While the intent of having a virtual format for public meetings to broaden the audience participating, use of YouTube for public meetings is a challenge as companies limit or restrict use during work hours and on company owned devices. We encourage the agency to investigate alternative ways for stakeholders to participate in public meetings using widely used business appropriate software.

Additionally, it appeared that some of the presentations were pre recorded which does not foster stakeholder engagement. We realize that schedules are challenging but watching a video is different from watching a live virtual presentation.

Tech-enabled traceability
It is not clear to industry where the tech enabled traceability initiative under New Era ends and where the Food Traceability Final Rule begins. The regulation is very different than the traceability initiative and the approach to each is not clear. We recommend clarity when speaking about the regulation as well as the initiative. There is a lot of confusion about the requirements of the regulation in light of FDA's encouragement of tech enabled traceability.

FDA should be mindful that businesses differ and have significantly varying resources available to adopt new technologies. Regardless, companies will always implement technologies and systems that support business needs and desired outcomes.

Consistent with FSMA section 204, FDA should not prescribe use of a particular technology. Instead, FDA should articulate what needs currently are not being met by industry, as well as its desired outcomes and goals. From there, FDA should provide entities flexibility to adopt whatever technologies are necessary to achieve those outcomes. By focusing on outcomes and rather than the use of technology, FDA should avoid promoting the use technology and encourage industry to choose the best methods for their business for achieving the desired outcomes. Furthermore, it is not FDA's responsibility to promote collaboration and information sharing between technology providers and the food industry. FDA should focus traceability efforts as it relates to protecting public health and encouraging practices, adoption of technology and potential benefits gained is beyond the scope of what Congress authorized.

Regarding the question about SSLT partners, we encourage FDA to engage associations representing SSLT partners by having in-depth discussions regarding the food traceability regulation to learn how to best integrate and collaborate.

Inspections and Investigations
FDA should enhance and streamline foodborne illness investigations through implementation of clear and consistent protocols which include communication with public health partners from other regulatory agencies. Seamless sharing of information across agencies is not only helpful for efficiency and speed, but is necessary to protect public health.

We encourage FDA to remove barriers to risk-based inspection models (addressing international inspections) and implement measures necessary to protect public health to ensure all food (i.e., domestic and imported) meets safety standards. FDA's existing regulations are powerful, and the Agency should use the authority and tools provided under FSMA to ensure these regulations are upheld and enforced.

We encourage FDA to share foodborne illness outbreak findings post event so that the industry can learn and advance food safety management programs. While we think there would be

benefit to FDA sharing more information with industry throughout the entire investigation process, we encourage FDA to focus on ensuring that root cause analysis findings are routinely communicated to industry. The root cause analysis is rarely shared and should be made available after major foodborne illness outbreaks. More transparency is needed for sharing event data and findings. This information is important so that industry can focus on addressing and preventing the identified risks in the future.

Recall Modernization
FDA should integrate the reportable food registry and recall coordinators to streamline recall management.

FDA should modernize recalls by updating FDA systems to allow for easy sharing of information. The Reportable Food Registry (RFR) system is completely separate from the recall coordinators in the divisions. The RFR and recall systems present a clear example of an integration challenge that creates issues for FDA as well as the regulated industry. Integrating the RFR with the recall system would allow divisions to address recalls more consistently. There are multiple opportunities to include seamless communication tools between collaborating departments and agencies.

For industry to report a problem to the FDA, the establishment must enter information into the RFR and if the event turns into a recall, they must separately provide the same information to the recall coordinator. The industry is required to submit the same information multiple times to multiple different offices within FDA, as well as to other public health agencies such as state agencies. The agencies should be able to share information and access the same information submitted once by the industry to FDA. The initial RFR notification occurs before many details are known. There should be a process to provide additional or updated information to the RFR portal which should then be available to all regulatory officials needing the information.

The industry sees the RFR as the required step in notifying the agency of a public health issue. There is no coordination between the RFR, and the recall coordination teams and there should be seamless communication. We strongly believe that FDA should coordinate and streamline that process inside the agency.

Information should also be shared with other public health agencies working to protect public health. Duplicate requests from multiple agencies take time away from executing the recall, results in delays and increases the chance of inaccurate information or mistakes in conveying information. Integrating these systems and facilitating information sharing would streamline the process and establish a more efficient and effective recall process.

Many recalls involve multiple agencies at the state and federal levels. It is essential for all stakeholders to have a comprehensive understanding of what happened or is happening throughout the recall process. Establishments are required to provide the same information to multiple agencies because the agencies do not have the ability to share information with one another. We encourage the agency to seek opportunities that ensure seamless communication and coordination between public health agencies with authority over food recalls.

Data Sharing
The FDA Food Safety Data Sharing Platform is a great tool for the agency to be able to collect and access data from other stakeholders. FMI met with the team leading the project and shared information about the platform with members. We encourage FDA to continue to innovate and allow for novel data sharing tools. The agency should ensure that data used for decision making is fit for purpose. We also encourage the agency to evaluate ways to utilize data for science-based policy development beyond data trends.

Confidentiality and privacy issues with data sharing are the biggest challenges for industry engagement. The industry is willing to share information with FDA but does not want the data to be identified. We encourage FDA to continue to clarify CCI related to data sharing and facilitate seamless sharing of information.

Whole Genome Sequencing
The NCBI Pathogen Database has been a powerful tool due to its open access and the ability for the industry to monitor trends in samples collected and even to track specific isolates of concern.

We encourage FDA to be transparent by making the procedures available for utilizing whole genome sequencing data in outbreak investigations. The applications of sequences in GenomeTrakr are not clear and the agency should continue to advance methodology for the genetic tools as well as the epidemiological tools and criteria.

Open access to NCBI data is critical and much appreciated by the food industry.

E-Commerce
E-commerce models will continue to change. Innovation is part of the business and practices continuously evolve to meet consumers' needs. We encourage FDA to focus on food safety management practices needed to prevent foodborne illness.

We do not believe that additional regulations are needed for e-commerce because they are covered by existing food safety regulations. Food facilities and retail establishments are regulated by FDA, USDA or by local, state and/or tribal authorities. We strongly encourage FDA

to take a risk- and data-driven approach to new and emerging business models and suggest FDA consider ways in which the agency and its state partners can enhance their oversight of existing retail business models. Awareness of existing food safety regulations is needed and one of the greatest areas for improvement would be to achieve greater consistency in food retailer inspections and more consistent adoption of the FDA Food Code.

Food Safety Culture

The agency's efforts on food safety culture should be outcome driven. The questions posed focus on data and predictors for food safety culture. Because food safety culture looks different from business to business and each company approaches the goal differently, standardizing food safety culture is not realistic or even possible. We encourage FDA to explore the ways in which the agency can act as a resource in this area to help companies enhance their food safety culture, without setting prescribed metrics or standards. Furthermore, the focus should be on the outcomes of the food safety management system and identifying opportunities to incentivize stakeholders—both industry and regulatory—to enhance the food safety culture. For this reason, we encourage FDA to support the development of food safety cultures by providing resources to industry about ways in which companies can foster a food safety culture. Sharing success stories will be more effective than creating a new regulatory scheme or component of inspections, as food safety culture must be authentic to be effective.

Summary

We encourage FDA to evaluate the scope of the "new era" work to ensure it is cost effective, not duplicative, and aligns with the goal of protecting public health. Thank you for the opportunity to share our comments and we look forward to continued engagement with the agency.

Sincerely,

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