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November 20, 2019

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2019-N-4187: "A New Era of Smarter Food Safety"

Dear Sir or Madam:

The Pew Charitable Trusts (Pew) is pleased to offer these comments for the Food and Drug Administration's (FDA) docket on "A New Era of Smarter Food Safety." Pew is an independent, nonpartisan research and policy organization with a longstanding focus on public health, which includes assuring food safety.

We appreciate this opportunity to submit comments, most of which address issues raised in FDA's brainstorming document entitled "Food for Thought,"[1] which the agency published in advance of the October 21st public meeting.

FSMA must remain the foundation of any new initiative focused on food safety

While FDA has emphasized the important foundational role the FDA Food Safety Modernization Act (FSMA) will play in its new food safety strategy, this role cannot be overstated. FSMA represents a sea change in how food safety is ensured by food producers and overseen by the government. The fundamental shift the law embodies – a shift from reaction to prevention -- must inform every aspect of "smarter food safety."

While much progress has been made, this important law is not yet completely implemented: just a few weeks ago, the agency finally released proposed regulations on food laboratory certification, and it has a team drafting a proposal to implement section 204, which requires FDA to identify hi-risk foods and establish enhanced record-keeping requirements for them.

Regarding metrics, we commend FDA for its recently unveiled "Food Safety Dashboard,"[2] which provides transparency on FSMA implementation status. It does not, however, provide information that would -- on its own -- constitute the metrics that demonstrate progress towards FSMA's ultimate goal of reducing foodborne illnesses linked to FDA-regulated food. FDA is

[1] https://www.fda.gov/media/131682/download
[2] https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-food-safety-dashboard

working with the Centers for Disease Control and Prevention (CDC) to develop a methodology for identifying illness reductions related to FSMA, and we support this effort. We urge FDA not to treat activities and process metrics – such as the number of inspections completed and the number of test results that are positive for contamination – as ultimate metrics demonstrating the food safety law's effectiveness in lieu of completing work with CDC to develop a methodology to identify FSMA's impact on foodborne illness.

As the food industry, FDA, and other stakeholders evaluate the role that new technologies like block-chain, artificial intelligence, and machine learning can play – the primary question to ask should be whether a particular technology can improve public health by helping reduce foodborne illness.

Food safety culture should be the beginning, not the end, of any blueprint for "A New Era of Smarter Food Safety"

The "Food for Thought" document addresses the role of "food safety culture" in creating and maintaining an effective food safety program on a farm or in a food processing facility.

There is increasing recognition of the importance of developing and sustaining a culture of food safety. The Global Food Safety Initiative (GFSI) convened a technical working group in 2017 that defined food safety culture as "shared values, beliefs and norms that affect mindset and behavior toward food safety in, across and throughout an organization."[3] To elaborate further:

> A culture of food safety is built on a set of shared values that operators and their staff follow to produce and provide food in the safest manner. Maintaining a food safety culture means that operators and staff know the risks associated with the products or meals they produce, know why managing the risks is important, and effectively manage those risks in a demonstrable way.[4]

To foster wider adoption of food safety culture, the agency could, for example, convene a group of experts to develop materials on food safety culture to be used by food companies, especially for smaller operations that may not have the resources to develop their own.

One example of how to communicate the importance of food safety to people working in food production was developed by the Leafy Green Marketing Agreement (LGMA) in partnership with STOP Foodborne Illness, an advocacy group made up of foodborne illnesses victims and their family members. Together they produced a video[5] for produce workers that features two young women who were seriously sickened after eating fresh spinach contaminated with *E. Coli*

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[3] https://mygfsi.com/2018/07/03/a-culture-of-food-safety

[4] Douglas A. Powell, Casey J. Jacob, Benjamin J. Chapman "Enhancing food safety culture to reduce rates of foodborne illness," *Food Control* 22 (2011) https://www.sciencedirect.com/science/article/pii/S0956713510004378.

[5] https://youtu.be/AE9G818uJsQ

O157:H7. FDA should work with LGMA and STOP to assess the effectiveness of this video and determine if it might be appropriate in other settings.

The blueprint for smarter food safety should prioritize use of root cause analysis both by the government and the private sector

Root cause analysis (RCA) is a systematic method of problem-solving that can be used to determine the underlying reasons for how and why an event (such as product contamination or a foodborne illness outbreak) occurred. It also helps clarify what steps are needed to correct the cause of the problem so that it will not recur.[6] As such, it is an indispensable component of any truly prevention-based system.[7]

RCA intersects with the other core components of FDA's strategy for a "New Era of Smarter Food Safety." For example, it has been shown to improve food safety culture. Moreover, effective traceability enables quicker and more efficient RCA. For this reason, FDA should introduce root cause analysis very early in the Blueprint for Smarter Food Safety it is developing, and it should be characterized as the foundational approach and philosophy that it is, not as a discrete tool among many others.

Because RCA is not an academic exercise but a real-world undertaking, FDA should provide guidance of how companies can operationalize strategies and approaches to implement impactful changes based on RCA findings. The agency should also consider developing meaningful metrics to track and evaluate the food safety improvements gained through RCAs.

Data, data, and more data is key to smarter food safety

Important insights can be obtained from analysis of data generated and collected by food companies. These data include findings from root cause analyses as well as results of product and environmental testing. However, there are many obstacles to data sharing, both technical and legal. Companies are concerned that sharing information with the regulator will expose them to possible enforcement action or private litigation.

FDA's priority in this area should be to identify ways to get access to data while addressing company concerns about sharing it. One solution worth considering is for FDA to partner with an

[6] Melanie J. Firestone, Karin Hoelzer, Craig Hedberg, Carol A. Conroy, and John J. Guzewich, "Leveraging current opportunities to communicate lessons learned from root cause analysis to prevent foodborne illness outbreaks" Food Protection Trends 38, no. 2 (2018), https://www.foodprotection.org/publications/food-protection-trends/archive/2018-03-leveraging-current-opportunities-to-communicate-lessons-learned-from-root-cause-analysis-to-/.

[7] Pew, in conjunction with a wide range of stakeholders, will soon publish *A Guide for Conducting a Food Safety Root Cause Analysis*, the purpose of which is to improve food safety by encouraging the use of RCA in food operations and by safety regulators, and the sharing of information and lessons learned from these investigations. We will add a copy of the guide to this docket once it is finalized

academic institution, or other third party, which could establish a data clearinghouse that would anonymize company data in a way that preserves its value in identifying food safety problems and revealing trends while adequately addressing industry's concerns.

FDA must do more to facilitate end-to-end traceability throughout the food supply

Multiple foodborne illness outbreak investigations involving romaine lettuce over the past two years have illustrated how the inability to trace a potential food vehicle slows down – or even thwarts – investigators' ability to stop further illnesses.

Pursuant to a court settlement, FDA is now working on a proposed rule implementing section 204 of FSMA, which requires the agency to designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health. However, since FSMA was drafted in 2009, traceability systems have progressed substantially beyond what section 204 requires.

At multiple public meetings and conferences on traceability in recent years, including one that Pew convened in October 2018, stakeholders have indicated that the most helpful thing FDA could do to improve traceability would be to provide some guidance on some foundational components, such as key data elements (KDEs) the agency needs in an outbreak investigation and the core characteristics of an effective traceability system.

Low-tech" tools that improve food safety

While new technologies often garner most of the attention, FDA should include "low-tech" approaches to improving food safety that have proven effective. One such example is "the Supply Chain Consultative Process," (SCCP) developed as part of the Collaborative Food Safety Forum, cosponsored by Pew and the Robert Wood Johnson Foundation.[8] Through a series of meetings focused on ways to enhance early outbreak investigations, participants developed protocols for early hypothesis development during the beginning of an outbreak investigation. The SCCP facilitates more efficient information exchange among government agencies and the private sector, which can provide investigators with helpful information such as growing seasons or distribution channels. The information can lead to more rapid narrowing of hypotheses, faster identification of the food vehicle, and quicker intervention.

FDA reliance on third-party audits in its inspection and compliance duties is problematic

As Pew's previous comments on FSMA proposed rules have noted, FDA reliance on third-party private sector audits, funded by the company being audited, raises concerns. Any use of third-party audits must be accompanied by a robust system to ensure the quality of the audits as well as transparency regarding what information will be made public, shared only with the FDA or

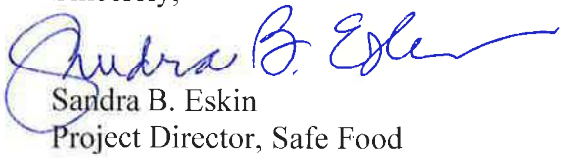
[8] https://www.resolve.ngo/site-foodsafety/early-outbreak-investigations-forum.htm

shared with the company that is paying for the audit. At a minimum, the public should have access to the same information it has for inspections conducted by the agency.

Conclusion

We commend FDA for its sustained effort over almost a decade implementing FSMA. The blueprint it plans to create for a "New Era of Smarter Food Safety" should complement, not supplant, the agency's efforts to tie up the loose ends of FSMA implementation, as well as to develop effective and efficient inspection protocols and meaningful metrics for FSMA. We look forward to continuing to work with FDA to improve food safety.

Sincerely,



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