THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 1700 215 575 9050 Phone
Philadelphia, PA 19103-7077 215 575 4939 Fax

901 E Street NW, 10th Floor 202 552 2000 Phone
Washington, DC 20004 202 552 2299 Fax
www.pewtrusts.org

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

RE: The FDA Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards
[Docket No. FDA-2015_N_0797]

The Pew Charitable Trusts (Pew) appreciates this opportunity to comment on the agency's draft plan for implementing the FDA Food Safety Modernization Act (FSMA). Pew applies a rigorous, analytical approach to improve public policy, inform the public and stimulate civic life. Through our Safe Food Project, we seek to reduce health risks from foodborne pathogens by strengthening federal government authority and the enforcement of food safety laws.

FSMA will bring about the most comprehensive reform of our food safety system in more than 70 years. This will be a tremendous step forward in assuring the continuing safety of the U.S. food supply. Implementing such fundamental reforms is a challenging task, and Pew commends the agency's efforts to insure constructive stakeholder engagement. In particular, Pew appreciated the chance to participate in the recent public meeting on FSMA implementation, and welcomes the opportunity to provide additional written comments.

One area central to successful FSMA implementation is the development of accurate metrics to track implementation success and measure progress towards public health goals. Pew commends the agency for actively seeking stakeholder input on this important and complex topic, and for sharing the agency's initial thinking during the public meeting.

Pew believes that FDA should adopt the following principles as it develops FSMA implementation metrics:

1. **Improving public health should be the guiding principle for FSMA implementation.** Therefore, the ultimate metrics to determine successful implementation should be based on outcomes that are directly linked to public health, such as statistically significant reductions in the number of outbreaks, recalls, and sporadic cases attributable to FDA-regulated products covered by FSMA.

   However, Pew recognizes the formidable challenges associated with the use of such public health metrics for measuring the impact of FSMA implementation; the need for multiple years of surveillance data to detect disease trends; and the need for improvements in public health surveillance systems and data analysis methodology before such metrics can be applied consistently and reliably. Areas in particular need of improvement include:

- The collection of adequate foodborne illness surveillance data, including the widespread use of DNA fingerprinting and other novel, powerful diagnostic techniques such as full-genome sequencing, to improve the ability to identify and trace outbreaks.

- Protecting public health system capacity that may be threatened by funding deficits and the increasing reliance on culture-independent diagnostic tests (which require different surveillance platforms).

- Continued technological improvements that allow federal and state agencies, as well as other key stakeholders, to readily share the data necessary for the expeditious detection and investigation of outbreaks.

- Enhancements in the investigation of outbreaks and sporadic cases that lead to an increased number being successfully resolved so that the causative agent and associated food vehicles are clearly determined.

- Advancements in the development of robust and valid source-attribution methods, in particular a move towards attribution methods that do not exclusively rely on outbreak data.

- Productive collaboration among stakeholders, including federal and state authorities, the food industry, healthcare providers and other key stakeholders.

Pew urges FDA to continue its efforts to invest in these critical areas and to maintain fruitful collaborations with federal, state and local agencies, industry, and other relevant stakeholders. Pew also recognizes that reliance on public health metrics to measure progress in FSMA implementation may be a mid- to long-term strategic goal. Metrics to use in the short-term are clearly needed to track early phases of FSMA implementation.

2. **Performance metrics should track product-contamination rates.** Tracking product contamination rates over time will provide an indirect measure of FSMA's public health impact, and allow for a direct and almost instantaneous assessment of industry performance. Pew recognizes the following challenges regarding product contamination data:

   - Baseline data on product contamination are currently scarce for many FSMA-covered foods, including many fruits and vegetables; these data are critically important for the detection of trends in contamination rates but may be costly and potentially time-consuming to collect.

   - Industry may have collected product testing data historically, but logistical, technological and other challenges may limit the accessibility and usefulness of these data as metrics for FSMA implementation.

The agency should invest in the collection and analysis of such contamination data now. Better data on product contamination rates is clearly crucial for evaluating FSMA implementation, particular during the relatively early stages. In addition, a better understanding of food contamination patterns may directly improve public health, for instance by contributing to the expeditious resolution of foodborne outbreaks. The baseline data may also allow the agency to set performance standards or food safety objectives for selected foods. The establishment of contamination-based performance metrics may have important ancillary public health benefits beyond the measure of FSMA implementation success, such as an increased understanding of foodborne illness and resulting more effective control strategies.

3. **Industry's level of control over its own food-production processes should be part of meaningful FSMA performance metrics.** A central component of FSMA's prevention-based food safety approach is that food processors must adequately control their food- production chains, from ingredients or agricultural inputs to finished products. On an individual farm, firm or establishment level, data demonstrating this control are crucial to assess compliance. On a broader level, such data are a valuable indicator of FSMA implementation.

   Because the required data will be collected and recorded by firms as part of their normal operations under FSMA, and the data and relevant metrics will likely already be considered as part of the inspection process (be it routine or for cause) in individual operations, these performance metrics are feasible to collect. However, storing such data as text in individual inspection reports, for instance, would make the data almost impossible to retrieve for further analysis. Therefore, practicality will dictate that these data and metrics be recorded in an accessible format at the appropriate time (e.g., during inspection), and in an appropriate, centralized database so that they will be readily available for statistical analysis.

   A variety of metrics may be useful in evaluating the degree of industry control over its processes. The most useful metrics may differ by industry sector, and the optimal way of assessing industry performance will likely rely on a combination of metrics rather than on a single one. Pew recommends the agency consider, in consultation with industry groups, state regulatory agencies, and other key stakeholders, which metrics will be most relevant for assessing the adequate level of industry control; how these data can be most appropriately collected, recorded and analyzed; and what challenges will have to be overcome to achieve successful execution. Some measures to consider may include:

   - **Recall performance** (e.g., time to recall; reason for recall initiation; company's ability to trace contamination along the production chain). Even though the goal of FSMA is to prevent contaminated product from reaching the market, occasional recalls will likely continue. However, a company in control of its processes should be able to detect this contamination (as opposed to contamination being detected during regulatory inspection, routine sampling, or as part of an outbreak investigation); expeditiously implement the recall; have the necessary level of control to efficiently trace contamination along the production chain; and modify processes

and procedures to prevent the issue from reoccurring. Therefore, industry-wide trends in these performance measures over time may provide valuable insights into how an industry is performing with regard to the implementation of FSMA's goals.

- **Data on 'near misses'** (e.g., industry testing data for finished products, ingredients, or environmental samples, as well as deviations at critical control points). 'Near-misses' are expected to occur occasionally during normal operation and, if handled swiftly and appropriately, are actually a characteristic of a functioning food safety system capable of detecting errors before product reaches the consumer. On an individual- operation level, these metrics are reviewed to assess compliance. On an industry-wide level, trends in these metrics will provide insights into how effectively FSMA is being implemented.

- **Performance on internal and third-party audits** (e.g., frequency and type of audits, number and type of infractions detected, time to correction, performance on repeat audits). These data can provide information about how well an establishment (and an entire industry segment) is implementing FSMA's prevention-based requirements.

- **Data on supplier verification programs and other types of data that will be considered during inspections.** Depending on the industry sector and type of operation, various other data may be considered during inspection because they are deemed to provide insights into operational performance. Trends in some of these data can also provide valuable information on an industry's performance with regard to FSMA implementation.

In summary, the agency should take a holistic approach to the development of performance metrics, consider all relevant aspects of an industry's food safety systems as potential metrics, and consult stakeholders with extensive experience in the design, implementation, and audit of food safety systems, such as competent state authorities, food safety certification bodies, and the food industry.

4. **Performance metrics should measure the impact of regulatory inspections on industry compliance**. Inspections are a central component to FSMA's prevention-based food safety approach because they verify the appropriateness of industry's food safety systems, support the correction of infractions, and provide important incentives for effective implementation. A variety of metrics may measure this compliance, including the number of organizations that correct infractions in response to inspections; the time between inspection and corrective action; trends in the prevalence of infractions recorded over time; and the number of repeat infractions (in the same establishments) during subsequent routine inspections. Data and knowledge from other relevant food safety areas (e.g., inspections of meat and poultry slaughter and processing plants and of restaurants) or other areas where FDA has a long history of regulatory inspections (e.g., pharmaceutical manufacturing, clinical trials) may prove valuable for the identification of such metrics.

5. **Performance metric selection should consider research and experiences from other relevant industries.** Meaningful metrics for assessing success are a central issue in many industries, and a considerable body of research exists across industries that may help identify additional meaningful FSMA implementation metrics. It is not immediately clear which other industry or industries are the best to examine for metrics that inform FSMA implementation success. However, the food industry shares important traits with other industries, which may be reasonable starting points. For example, for most parts of the food industry, outbreaks, recalls and finished product contaminations are exceedingly rare but potentially devastating events. This characteristic is shared with other industries, such as the commercial airline and the nuclear power industries. These industries, similar to the food industry, are complex industries tasked with the successful implementation of safety measures to further reduce the frequency of accidents that are characterized by potentially high impact but extremely low probability (Leveson *et al.* 2009). The exceedingly low probability of accidents in these industries poses real measurement challenges that have been studied in some detail, and that may provide constructive ideas for the selection of meaningful FSMA implementation metrics, even though the similarities and differences among the industries have to be considered carefully.

   Other research has explored the relevance of lessons learned in these 'ultra-safe' industries to improving safety in healthcare settings. Some lessons learned from this research may also provide valuable insights for the development of meaningful FSMA performance metrics, such as the increasing body of support for a positive correlation between worker safety and patient safety in healthcare settings (Yassi and Hancock 2005). Similarly, risk-based approaches in other manufacturing areas, such as the pharmaceutical industry, may provide valuable insights for the selection of meaningful FSMA implementation metrics. The agency should take a 'comparative systems approach' to developing meaningful metrics that aims to consider all relevant research and knowledge, regardless of whether the data was collected in the food area or in other relevant industry sectors. Consultations with experts from other sectors, for instance, may be helpful for identifying relevant 'lessons learned.'

In conclusion, Pew commends the agency for seeking input on the important subject of FSMA implementation metrics. Meaningful, science- and public health-based, robust metrics, which are developed based on constructive input from all relevant stakeholders, and which consider recommendations from experts with relevant insights, will be instrumental for achieving FSMA's objective of improving food safety and reducing foodborne illness. The agency should consider input, not only from food safety professionals, but also from experts in other relevant industries. These metrics must be sufficiently flexible and resilient to consider differences among industry sectors and between early and later stages of FSMA implementation.

We would welcome the opportunity to meet with FDA staff to further discuss the points raised in these written comments.

Sincerely,

Sandra B. Eskin
Director, Food Safety

Karin Hoezler, DVM, Ph.D
Officer, Safe Food Project

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