Collaborative Implementation of FSMA Workshop

Public Health-Based Metrics

Top-Tier Metrics* Conference Call

October 7, 2015

Draft Summary and Proposed Next Steps

Overview:

A conference call to further discuss “top-tier” metrics* for FSMA was held on October 7th from 2-4 pm Eastern. Twenty-one people participated (see roster below). The goals of the call were as follows:

- Build on the June 2015 meeting deliberations to develop ideas for the “top-tier” public health metrics for FSMA.
- Determine possible next steps for additional dialogue for a future CFSF in-person meeting.

The discussion focused primarily on the questions of what to measure and how, and next steps for advancing the discussions. Below is an overview of key themes that emerged during the call. The summary begins with proposed next steps. Please note the deadline for comments on the summary, as well as the opportunity to participate in developing frameworks.

* During the discussion, participants concluded that better language is to use “top-tier public health outcomes” and a “web of metrics.” Explanation for this change is below in the summary of key themes.

Next Steps:

Participants concurred that a next step for advancing the discussions should include the development of a small number of frameworks for establishing metrics or a combination of metrics. Based on the discussion, possible frameworks could include:

1. **Pathogen-Specific Metrics**: Tracking overall incidence rates for key (but not all) foodborne pathogens, such as *Salmonella*, *Listeria*, and *E. coli* 0157:H7.
2. **Total Cost Metrics**: Tracking economic indicators (e.g., DALYs — which factor in the severity of the illness) to estimate the total cost of foodborne illness linked to FDA-regulated foods, and to track changes in that cost over time.
3. **Pathogen-Food Combinations Metrics**: Tracking foodborne illness by focusing on selected pathogen-food combinations to assess specific impacts of FSMA — e.g., *Cyclospora illnesses* as a measure of the safety of imported fresh fruits and vegetables.
4. **Process Failures or Root-Cause Analysis Metrics**: Tracking rates of foodborne outbreaks linked to identified process failures (e.g., inadequate separation of pasteurized and non-pasteurized product) and/or selected root causes (e.g., failure to adequately monitor a process).

Following feedback on these and other suggested frameworks, RESOLVE will be reaching out to participants to develop 2-4 frameworks around which to structure the next CFSF deliberations. **Please provide comments on this summary and any additional ideas for frameworks by Friday, October 23rd.** Also, if you are willing to dedicate time developing a framework, please let us know right away. Communications on these requests can be sent to Kim Rustem (krustem@resolv.org), who will then compile the information. We will be organizing who is doing what to move forward productively, and will circulate a final call summary to the full CFSF group involved in these metrics discussions.

**Key Themes:**

**General Themes:**

- **“Web of Metrics” and “Top-Tier Public Health Outcomes” rather than “Top-Tier Metrics”** – Over the course of the discussion, participants determined that the language “top-tier metrics” was too confusing and proposed a more conceptually appropriate term- “Web of Metrics.” “Web of Metrics” describes the interconnected, rather than an implied hierarchical, relationship between public health-related measures and other measures (e.g., rates of illnesses and compliance rates); all of these metrics may be considered in measuring improved public health outcomes and the success of FSMA. Multiple metrics considered together can provide a more complete picture of FSMA success than a single metric can. While FSMA’s success and improvements in public health outcomes will be reflected in a variety of different metrics, it is important to keep in mind that each metric may be impacted by external factors (e.g., more outbreaks may be detected because of wider use of whole genome sequencing and not increased contamination). The fact that metrics will likely vary in importance or impact over time is another reason why a fixed or hierarchical set of metrics may not be the right conceptual framework. Some factors that will become much less important or relevant should be phased out, while other factors may become increasingly important and, therefore, should be phased in. In addition to dynamic metrics we also have very dynamic food production and processing sectors. Some of the possible specific measures discussed during the call are outlined in the section titled, “What to Measure and Why,” below.

- **Public health measures in combination with other measures that are not directly linked to public health.** In addition to public health measures, other factors, such as reduced process failures, increased compliance, and other variables should be part of the evaluation. Further, public health outcomes can be challenging to use alone due to
external factors influencing those outcomes. Therefore, including other measures can help provide a clearer picture of trends and insights regarding the impact of FSMA.

- **Communicating about how FSMA success will be evaluated.** For example, increased data and improved metrics will result in detection of more outbreaks. Therefore, an apparent increase in outbreaks does not necessarily indicate declining food safety – but rather, may be attributable to better detection, analysis, and reporting. Consequently, numbers may go up before they go down in the course of improving food safety and improving public health outcomes. It is critical that the communications around FSMA implementation and evaluation be carefully and effectively crafted.

- **Some metrics need to be high-level enough to span across the various programs of FSMA, while others may be more program-specific.** Ultimately, evaluating the success of FSMA in achieving better public health outcomes requires measures relevant across the number of different programs, as well as metrics that may be applicable only to a specific program.

- **Using current data from existing collection mechanisms and data bases, while collecting additional, prioritized data, can support more robust and effective measures.** Some data and information have been and continue to be collected from systems such as FoodNet (Foodborne Diseases Active Surveillance Network), which has tracked trends since 1996 for infections transmitted commonly through food; PulseNet, which tracks clusters of outbreaks from the same pathogen through DNA “fingerprinting” and other surveillance tools; and pathogen-specific monitoring, which should be used to the extent relevant and particularly in the near-term.

**What to Measure and Why:**

The following principles for selecting metrics, as well as specific metrics were highlighted:

- **Criteria/Principles:**
  - As much as possible, use data in hand, even when there may be a need to collect additional types of data.
    - Sets baselines pre-FSMA implementation.
    - Can provide information necessary to conducting trend analyses.
  - Where possible, use measures that can be measured relatively easily.
  - Select measures that have public health relevance or meaning (e.g., impact on burden of disease, vulnerable populations, or higher risk foods)

Several potential measures were identified and briefly discussed, including the following:

- **Specific Possible Measures:**
  - Rates of illnesses.
- Change in number of illnesses is a readily available public health indicator, even though difficult to interpret.
- Incidence data, which is already analyzed annually (FoodNet). However, this system does not track other relevant information such as food type. Although not currently being analyzed by age group, this information could be generated, at least for some pathogens, with data already available.
- Number of foodborne pathogen-related outbreaks.
  - Tracked annually.
  - Eliminate those outbreaks determined to be from sources other than facilities (e.g., sick food handler in a restaurant).
- Size or extent of outbreaks.
  - As detection improves, the size or extent of exposure may be found to be higher, but the extent of the outbreak may decrease.
  - If the health impact decreases in size and extent, this could be the result of more rapid response and, ultimately, reduction in total illnesses, and therefore improve public health outcomes.
- Incidence of illnesses linked to a limited number of pathogens – possible criteria for selection could include:
  - Known foodborne pathogen with few if any non-foodborne exposure routes.
  - Causes severe health impacts (i.e., *E. coli* 0157:H7).
  - Associated with multiple FSMA-regulated foods (e.g., *Salmonella* may be more relevant than *Campylobacter*).
  - Associated with certain sectors of the food supply (e.g., imported produce and *Cyclospora*).
  - Sufficient data exist to assess incidence/prevalence, risk factors, etc.
  - Potential pathogens include:
    - *Salmonella* – have data and linked to foodborne illnesses.
    - *Listeria* – have data and linked to foodborne illnesses.
    - *E. coli* 0157 – known pathogen with severe health impact.
    - *Cyclospora* – associated with imported produce
- Disability adjusted life years (DALYs).
  - Measures impact or severity of disease – a public health measure, as well as an economic one.
  - Is a common, established metric.
  - Can track along with rate of illnesses.
  - Can provide information regarding impact on specific populations.
- Food/pathogen combinations or food/hazard pairs.
  - Could possibly use food categories (e.g., dairy products and *Listeria*).
- Food processing failures.
  - Root cause analyses, whole genome sequencing and other advances and tools will improve analysis of processing failures.
Consumption patterns for establishing exposure, as well as analysis of impacts on different populations.

**How to Measure, Evaluate and Report:**

- Use data in hand for near-term evaluation while additional data sets are developed.
- Some measures are collected and reviewed annually, while others can be used to generate trends if reviewed over a longer period of time and on a rolling basis (e.g., 3-5 year periods.).
- Reporting on and communicating about the evaluation of FSMA’s impact on food safety must be thought through, developed carefully and communicated appropriately.

**Participants**

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Will Daniels, Consultant  
Sandra Eskin, The Pew Charitable Trusts  
Donna Garren, American Frozen Foods Institute  
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**RESOLVE Facilitation Team**

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COLLABORATIVE FOOD SAFETY FORUM
Collaborative Implementation of FSMA Workshop
Public Health-Based Metrics

Produce Conference Call

Summary

November 20, 2015
12:00 – 2:00 pm Eastern

Overview:

A conference call to further discuss Produce Safety program-specific metrics for FSMA was held on November 20th from 12-2 pm Eastern. Twelve people participated (see roster on page 4). The goals of the call were as follows:

- Build on the June meeting deliberations, and follow up conference calls to develop ideas for the produce public health metrics for FSMA.
- Determine possible next steps for additional dialogue for the December 3rd CFSF in-person meeting.

The agenda for the call is attached and helped provide a list of topics and associated questions to structure the conversation, which were generated from the June meeting discussions and input by participants. The overall discussion focused primarily on: (1) what to measure for evaluating the success of FSMA implementation in improving public health outcomes and produce safety, (2) how to measure these metrics, and (3) next steps for advancing the discussions during the December 3rd in-person meeting. Below is an overview of key themes that emerged during the call. The summary begins with proposed next steps. Please note the deadline for comments is quick as we would like to send the summary as background information for the December 3rd meeting.

Next Steps:

1) Provide comments on the draft summary by **COB Tuesday, December 1st** (revisions to the summary will be made and the summary will be distributed to the full group).
2) Develop a possible logic model or models connecting different metrics, such as leading, lagging, and core metrics, not only for progress with Produce Safety, but also with some that link to FSMA-wide measures.
3) Develop ways for tracking “near misses” (as these are important data), as well as understand the differences between those circumstances/factors that prevent an outbreak and those that are “near misses.”
Key Themes:

General Themes:

➢ The group acknowledged that metrics and data collected with an element of human judgement are prone to variability in interpretation. However, what to do about this was determined to be outside the scope of this particular conversation and proposed for a future discussion.

➢ Within the context of metrics and what makes for a good measure (i.e., Glen Mays’ criteria):
  - **Relevance** to program or policy goal
  - **Health impact**: prevalence & severity
  - **Economic impact**: costs and resource use
  - **Distributional impact**: equity and disparities in impact
  - **Tractability**: able to be influenced by relevant actors/actions
  - **Degree & velocity of change**
  - **Attribution**: vulnerability to confounding, selection
  - **Measurement quality**: validity, reliability, sensitivity, specificity
  - **Feasibility**: data availability, collection/reporting burden
  - **Public values/preferences**: what matters most to the public), the group identified the following additional considerations:
    - Meaningful metrics should include multi-dimensions, some of which are particular to the produce industry, some of which are part of a FSMA-wide set of metrics, and some of which are lagging (measures that “look back,” such as trends of foodborne pathogens and outbreaks per commodities, per capita consumption, etc.) and leading (measures that forecast, such as number of people trained in requirements, etc.) indicators. The challenge is prioritizing a select number of meaningful measures that in combination, will provide insights for whether and how FSMA implementation is successful.
    - Meaningful metrics should promote improved public health outcomes along with a food safety culture among all stakeholders. What is measured is done, so how does this translate to improving public health outcomes and supporting the development of a food safety culture?

➢ The group identified the need to be mindful of the overall cost/benefit analysis of implementing each metric as well as how the evaluation of FSMA implementation success is communicated.
  - What changes are happening within the produce industry and why they are important to improving food safety?
  - Preventing unintended consequences is important because we don’t want consumers to think it is unsafe to eat produce. However, if we have more information about certain populations having greater risk for certain foodborne
illnesses or the potential for greater impact on their health, communicating that targeted, evidence-based information is important to improving public health outcomes.

- Successful communications could be an important metric for FSMA implementation success.

**Categories of Metrics for Produce Safety Program Progress**
Following the outline and categories of questions, the group discussed the topics below:

**1) Potential metrics for the produce industry to measure progress in developing a strong food safety culture:**

- Number/Percentage of domestic and international farms that adopt FSMA requirements.
  - A deeper level of analysis is needed along compliance across different key categories, such as water quality, soil amendments, worker hygiene, wildlife etc.
  - Data should be collected on all farms, not just those covered by FSMA. This is important for evaluating progress of institutionalizing a food safety culture, as well as understanding whether practices are more or less being adopted.
  - Employee surveys could provide a different lens for evaluating food safety culture (see the attached example provided by Frank Yiannas).
    - How could other models be adapted to a relevant survey for the produce industry sector?
    - What can be learned from the processed food industry (i.e., closed facilities) and translated to the farm/produce industry?
  - Potential base line data “on farm readiness” should include review of readiness prior to inspection, and evaluated based on progress from where started with readiness. This is also relevant for topic #2 below.
- Percentage of farms that address corrective actions related to the Produce Rule within a decreasing timeframe.
- Track “near misses” and factors contributing to them – both what leads up to the potential problem and what prevented it from turning into a bigger problem (i.e., root cause analyses of near misses).

**2) Potential metrics for private audits/FDA/state inspectors/CDC to directly measure progress in achieving improved public health:**

- Combination of hazards, exposures, and outcomes. For example, a select number of food-pathogen combinations compared against consumption patterns and the outcomes (i.e., who got sick, at what level of intensity, etc.).
- Number of contamination events reported and root-cause analyses conducted.
  - CDC data on contamination across the supply chain.
  - Illnesses attributed to FSMA-covered foods.
• Are there trends that indicate particular areas of focus (i.e., particular pathogens, foods, pathogen/food combinations, and particularly vulnerable populations)?
• Those areas require increased root-cause analyses to reveal associated factors, their interconnectedness, and what can be changed to reduce trends.
• Information to conduct these analyses is required from both directions within the supply chain, from farms to retailers to consumers, as well as those with oversight.
  o Speed with which information is acted upon, including interventions to prevent or contain a problem.
  ▪ Requires improved traceability/tracking.
  ▪ Requires known, evidence-based interventions.
  ▪ Involves thoughtful cost/benefit analysis for translating insights from root-cause analyses to changes in practice, improved public health outcomes, and costs for adoption.

3) Potential metrics for joint activities to measure how well FSMA training activities are being implemented:
• Data collection and sharing (i.e., diversity and sources of quality data and analyses).
  o Opportunities are needed for farmers/growers to talk with one another, gather useful information, and contribute to the wider pool of shared information. These opportunities should:
    ▪ Provide safe environments (i.e., no punitive repercussions).
    ▪ Allow farmers to gain something from the exchange (i.e., trends that others are seeing and ways to address any problems).
    ▪ Coincide with GAP process and groups that are developing platforms and infrastructure to share information.
• Participation in joint training should:
  o Assist with reducing the variability of interpretation of requirements, information and data.
  o Promote a food safety culture.
• Number/Percentage of farms that complete a root-cause analysis and use the results to improve their operations.

Participants:
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Karin Hoelzer, The Pew Charitable Trusts
Dara Lieberman, Trust for America’s Health
David Plunkett, Center for Science in the Public Interest
Fazila Shakir, U.S. Food and Drug Administration
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Steve Warshawer, La Montanita Cooperative/ Beneficial Farms CSA
Frank Yiannas, Walmart

**RESOLVE Facilitation Team:**
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Process Failures or Root-Cause Analysis Framework of Metrics

11.24.2015

Overview of Preliminary Thinking and for Discussion

Process Failures or Root-Cause Analysis Metrics: Tracking rates of foodborne outbreaks linked to identified process failures (e.g., inadequate separation of pasteurized and non-pasteurized product) and/or selected root causes (e.g., failure to adequately monitor a process). Joe Scimeca and Karin Hoelzer and Steve Warshawer

Two overarching questions are:

1) How can we capture data on root causes of outbreaks or ‘near misses’ that are meaningful and sufficiently detailed? And,
2) What specific information or measures in those data should be tracked to evaluate FSMA success?

In considering the various aspects of a general definition of “root-cause analyses” – “Identification of the most basic causes reasonably considered to contribute to a problem and such that if fixed or addressed, will prevent that problem” – it was noted that there are, most always, a combination of factors that contribute to a food safety problem and that when an outbreak occurs, it can be considered a “perfect storm” or convergence of multiple system failures. Collecting the right data and performing the appropriate analyses can determine what combination of factors may make the difference between a near miss and an outbreak. For example, in a salmonella outbreak in leafy greens, there may be a combination of 1) Insufficient food worker training, 2) Failure of critical control points to increase safety (e.g., a “kill” step such as effective use of antimicrobial washes or other interventions is rendered inefficient by some external cause), and 3) Insufficient or no surveillance, monitoring or detection along the food supply chain to prevent or mitigate contaminated product from reaching consumers. Understanding what factors contributed to a near miss or an outbreak and, given the relative same circumstances, what may be the distinction between a near miss or outbreak, can provide important information and opportunities for improvements.

Root causes that could be considered for evaluating progress of FSMA, include:

A) Adequate technical expertise
B) Training failures
C) Equipment-related issues
D) Inadequate communication channels
E) Poor food safety culture and associated lack of leadership and/or management support
F) Supply Chain Management issues, such as
a. Contaminated ingredients
b. Inadequate implementation of post-harvest interventions
c. Critical Control Points inappropriately determined and/or monitored
d. Insufficient surveillance along supply chain to test, verify, or intervene

Based on data gathered, outbreaks or near misses that root-cause analysis attributes to requirements or systems put into place by FSMA (such as training, maintenance of equipment, and supply chain management) should decline over time. These trends should result in fewer foodborne illness outbreaks associated with FSMA-regulated foods and, thus, indicated FSMA is having a positive impact on public health outcomes. If these metrics were used and tracked, it may not only provide information on FSMA progress overall (i.e., foodborne pathogen-related outbreaks reduction) but also which parts of FSMA may be having relatively more or less success. For example, if fewer and fewer outbreaks are occurring due to lack of improper or insufficient training but outbreaks due to other causes are staying the same, then training promoted by FSMA is having a positive impact. On the other hand, the other portions of FSMA that are not reflected by a decrease in the number of associated outbreaks (e.g., equipment failures) could benefit from closer scrutiny AND problem-solving and dissemination of information could be facilitated. These benefits are predicated on “measurability” or the collection of data and appropriate analyses of the data to be able to measure changes over time in the root causes of near misses, process failures and foodborne outbreaks.

Another relevant area is supply chain complexity, particularly as it relates to:

1) Correlation between complexity and risk (i.e., for some supply chains, the more people or equipment that come in contact with the food, and the greater the length of time in transit, the greater the associated public health risks); how is complexity captured in root-cause analyses and how does it impact data collection?
2) Correlation between the economic impact of root-cause analyses and producer size? If smaller producers are disproportionately burdened, how can this be addressed so that all are engaged, no matter size?

Given the potential benefits of using process failures, near misses and root-cause analyses information, the group recommended the following steps for further deliberations:

1) What data are necessary to collect for evaluating near misses, process failures and root-cause analyses, and who can provide it and how?
   a. What is the potential role of state-level outbreak investigations and industry assessments (e.g., root-cause analysis after a near-miss)?
   b. What factors prevented a near-miss from becoming a recall or outbreak, and what can that information tell us about the status of FSMA implementation?
   c. What are potential barriers to conducting root-cause analyses (e.g., funding, priorities, access to proprietary data, and other factors)?
d. How can root causes be classified in a way that is meaningful for evaluating FSMA implementation (e.g., describing root causes in terms of a set of pre-specified factors)?

2) How can collection, provision and sharing of data be incentivized?

3) How can the burdens and benefits of providing and sharing these data be stakeholder and scale neutral to advance an overall increase in food safety culture?

4) Are there any models for root-cause outbreak investigation or the evaluation of the causes of near misses to learn from to consider adapting for FSMA (i.e., the aeronautics industry)?

5) What are the roadblocks to conducting root-cause analysis as well as analyzing near misses and process failures? How can they be overcome?