Collaborative Food Safety Forum

Successful Implementation of FSMA: Metrics for Public Health-Related Outcomes and Improved Food Safety Culture

Participants in the Collaborative Food Safety Forum:

Attached, please find the finalized summary of the June 25-26 meeting. Thanks to those of you who provided comments and feedback. In addition to the summary, the following documents are attached:

1) CFSF Metrics Outline: An outline of some next steps to further advance the discussion begun during the June meeting, which includes preliminary questions to shape proposed conference calls on top-tier metrics for FSMA overall, as well as for Preventive Controls and Produce.

2) Top-Tier Metrics Draft Language: Based on the June small group sessions, revised language on the top-tier metrics for Preventive Controls and Produce.

These documents will serve as background and working outlines and ideas for additional deliberations. We are proposing to hold a series of two-hour conference calls, one each on the top-tier metrics for FSMA overall and then program-specific metrics for Preventive Controls and Produce. As a first step, refinement and prioritization of the questions will be done in preparation for the calls, and then the calls can focus on delving into the questions. The work conducted on the calls will then help shape the agenda for a large group meeting in November (dates to be proposed shortly).

Please review the CFSF Metrics Outline and provide feedback on the wording or types of questions asked (please don’t respond with answers to the questions themselves – that will be the purpose of future discussion) and/or additional questions to include by September 4th to Kim Rustem (krustem@resolv.org). In the meantime, we will schedule the calls and provide information so that anyone who wants to participate can do so. We want to ensure we have a good cross-section of stakeholders on each call so will work with some of you to find a viable time to hold the calls. Summaries of the calls will be distributed as part of the preparatory information for the November meeting.

If you have any questions, please let us know.

Best regards,

Abby, Erin and Kim
RESOLVE
The CFSF convened a meeting on June 25-26 to discuss public health-related metrics, including drawing on other oversight systems, understanding FDA’s current thinking, and exploring potential top tier metrics. To build on the conversation, we propose an initial step of three conference calls, with the first including a discussion of the Public Health-Related Outcomes – specifically a discussion about reduction of illnesses or risk of illnesses or both. Following that first discussion, calls to explore program-specific questions will be convened. Ideally, we will schedule these in the next 6 weeks to continue the momentum forward and with the expectation the results of the deliberations will be shared and further advanced with the large group in mid- to late-fall. Below outlines some of the questions around which we would like to organize these next discussions. Please review the questions and provide feedback on the wording or types of questions asked and/or additional questions to include by September 4th to Kim Rustem (krustem@resolv.org). Also, attached is the “Top-Tier Metrics Draft Language” document on the “results” and the “tasks” that emerged from the discussions during the June meeting and to consider for further deliberations.

**Public Health-Related Outcomes**

**Very Top-Tier Metric: Reduced Illnesses and Deaths**

1. Is it reduction in illnesses or in risk of illnesses, or both?
   a. When we talk about “risk,” what do we mean, and how are we measuring it?
   b. Should this metric differ for:
      i. Processed foods and produce?
      ii. Domestically produced and imported foods?
      iii. Food from covered and non-covered establishments?
   c. Depending upon whether the metric is reduction in illnesses and/or risk of illnesses, what are the strategies used to collect information (i.e., do we use hard numbers, modeling, other approaches)?
2. What data do we need (i.e., consumption patterns to calculate exposure, hospitalizations and other diagnoses of illness, severity of illness data, contamination data, testing data, etc.)?
   a. What do we have, who has it, and is it accessible?
   b. For those data that are priorities, but currently not available, how do we gather it?
3. What pathogens are we considering or targeting?
   a. Are there indicator organisms that could also be important to track?
   b. Should we include emerging pathogens and if so, how?
4. What time frame should we use to evaluate change against the metric or metrics? Will time frames be different for the different programs, as well as for combined impact of FSMA?
5. How can confounding factors and biases be accounted for? For instance, can, and if so how, the impact of improved outbreak investigations be differentiated from the impact of FSMA rules?

**Program/Rule Specific Measures**

**Preventive Controls**

Participants from the June working group concurred that a mix of measures most likely will be necessary – ones that measure improved public health outcomes, as well as those activities considered essential for achieving progress toward the ultimate public health goals of FSMA, and including progress in developing a food safety culture across all sectors. Below are suggestions that were offered during the June meeting, for preliminary measures for activities or processes, evaluation of which could indicate
progress toward the longer-term public health outcomes, and are proposed for discussion as part of next steps. Refinement and prioritization will be part of shaping future conversations. The questions are sorted in categories specific to lead entities for action.

**Top-Tier Metric: Preventive Controls**

A. Industry – activities that demonstrate strong food safety culture  
   1. Number/Percentage of firms that made corrections to address positive test results  
   2. Number of contamination events self-reported by firms (RFR and recalls)  
   3. Percentage of foreign firms on import alert as a result of violations detected by inspections  
   4. Percentage of firms (domestic and international) that are fully implementing an adequate PC plan as defined by the regulation.  
   5. Percentage of firms that address critical violations of the PC Rule within a set timeframe.  
   6. Number/Percentage of firms that follow best practices?  
   7. Number/Percentage of firms that complete a root-cause analysis and use the results to improve their processes  
   8. Should private audit results be tracked as a metric and if so, how?

B. Regulatory agencies – activities that relate directly to improved public health  
   1. Percentage of foreign firms on import alert as a result of violations detected by inspections

C. Joint activities  
   1. Participation in joint training for inspections  
   2. Conducting root cause analyses  

**Produce**

The June meeting highlighted a number of topics relevant for evaluating progress toward improved public health-related metrics, including the small amount of data of directly attributable foodborne illnesses – making measurement of change challenging; challenges with and necessity of quality data; and ideas for how to achieve data quality and quantity to evaluate progress.

Below are some additional ideas for measuring progress with regard to produce.

**Top-Tier Metric: Produce Safety**

A. Industry – activities that demonstrate strong food safety culture  
   1. Number/Percentage of farms that follow best practices (GAPs?)  
   2. Number/Percentage of farms that made corrections to address positive test results (e.g. for ag water)  
   3. Number of contamination events self-reported by farms (RFR and recalls)  
   4. Percentage of farms that address critical violations of the Produce rule within a set timeframe.  
   5. Number/Percentage of farms that complete a root-cause analysis and use the results to improve their operations.  
   6. Should private audit results be tracked as a metric and if so, how?  
      i. Quality of data provided in self-reported audit?  
      ii. Participation in data collection with second party and third party audits?

B. Regulatory agencies – activities that relate directly to improved public health  
   1. Percentage of foreign farms on import alert as a result of violations detected by inspections

C. Joint activities  
   1. Participation in joint training for inspections  
   2. Participation in root cause analyses and implementation of lessons learned
The Collaborative Food Safety Forum Deliberations on FSMA Public Health-Related Metrics

Top-Tier Metrics Draft Language

Draft Language from June 25-26 Workshop

Preventive Controls

Top-Tier Metric: Preventive Controls Rule

Based on the discussions from the June 25-26 meeting, the language from the Top-Tier Metrics for Preventive Controls is the following:

(Note: Regular text is what FDA’s preliminary thinking was at the time of the meeting and green language indicates group suggested changes during the June meeting.)

Results

- Reduced Contamination of Food from Facilities Subject to the PC Rule
  - Tasks
    - Number of samples collected by regulatory agencies that test positive for agents that have previously been identified in foodborne illness outbreaks (over emphasis on testing – any other revised task that could be positive?)
    - Number of contamination events self-reported by firms (RFR and recalls)
    - Percent of foreign firms on import alert as a result of manufacturing/processing contamination

- Increased Implementation by the Industry of the PC Rule Requirements
  - Tasks
    - Percentage of firms (domestic and international) that are fully implementing an adequate PC plan as defined by regulation
    - Percentage of firms that address critical violations of the PC Rule within an expected timeframe

Participants concurred that a mix of measures most likely will be necessary – ones that measure improved public health outcomes, as well as those activities considered essential for achieving progress toward the ultimate public health goals of FSMA.
Produce

**Top-Tier Metric: Produce Safety Rule**

Based on the group discussion, the proposed Results and Measures are the following:

**Results**

- **Reduce Microbiological Contamination of Fresh Produce that could Pose Risk to the Consumer**
  
  **Tasks**
  - Number of farms with a contamination event (separate out by samples, outbreaks, *identified pathogens known to pose risk, emerging pathogens* etc.)
  - Percentage of on-farm samples from inspections found to be contaminated
  - Number of new farms and countries added to import alert for contaminated produce
  - Number of firms/farms and countries taken off import alert for contaminated produce

- **Increase Compliance with the Rule by Covered Farms, Non-Exempt Farms** (*Need more and better data – define quality data and “reliable audit”; also expand scope to all farms and promote to encourage all farms to participate in uptake of good practices for producing safe food*)
  
  **Tasks**
  - Number/percentage of farms in compliance with key parts of the rule (ex, water)
  - Aggregate compliance score or rate for produce industry
  - Number of violations corrected upon a subsequent inspection