Measuring Success: FSMA Implementation

Food and Drug Administration
June 25, 2015
Overview

• Setting the Stage
• Current Approach - General
• Status of Performance Measurement Development
• High Level Results and Measures
• Challenges
• Current Approach – specific
The Call for an Improved, Risk-Informed Food Safety System

The Food Safety Modernization Act and a 2010 Institute of Medicine (IOM) report both provide strong impetus for the Food and Drug Administration (FDA) to build a more methodical food safety system as it continues on its path to protect public health.

The 2012-2016 Strategic Plan for the Foods and Veterinary Medicine (FVM) Program outlines how the program will continue to increase its focus on risk-informed and science-based decision making.
FVM’s Vision for an Improved Risk-Informed Food Safety System

- Develop Strategic Goals
- Set High-Level Priorities
- Formulate Budget
- Set Specific Risk-Informed Priorities
- Execute Activities – Resource allocations
- Strategic Data Integration and Management
- Measure Progress of Activities
Current Approach:

STRATEGIC PROGRAM PLANNING
Strategic Program Planning (ROM) = Focus on Results

✓ Emphasize results, i.e. we care not just about what we do (activities), but also about what we achieve (results)

✓ Planning process focuses on cause and effect (strategic) linkages

✓ Monitoring tracks progress towards results

✓ “Results data” informs planning, management, and reporting
Managing for Results

Outcome focused approach to FSMA implementation using Strategic Frameworks:

✓ Brings results to the center of the planning and decision-making process

✓ When considering what we do (i.e., activities) and we want to answer the question – Why is this important…Results identified

➢ Measures show progress in achieving results
Strategic Program Planning: 6 STEPS

1. Define Results
2. Identify Performance Indicators
3. Develop a Performance Monitoring Plan
4. Collect Performance Data
5. Analyze Performance Data
6. Use Analysis to Inform Mgmt Decisions

1.a. Identify activities. How we’ll get there.

How we’ll know we got there.
• Performance measures align with the Results in the Strategic Framework

• Performance indicators must meet a set of criteria:
  – Direct
  – Objective
  – Adequate
  – Practical
Criteria for Selecting Measures

• *Direct* measure of the result

• *Objective* - stated in a way that is measurable, is precise and unambiguous

• *Practical* - that the data for the indicator can be collected in a reliable, timely and cost-effective manner

• *Adequate* - that the set of measures for any particular result is sufficient to understand whether progress is being made toward the achievement of the result.
Strategic Program Planning: STEP 3

A performance monitoring plan (PMP) will:

- Facilitate the collection of comparable data over time;
- Assist with managing the data collection process;
- Inform analysis of performance data.
Strategic Program Execution: Monitor & Evaluate

• Moving from “planning to implement” to “implementing”
• Collect Baseline Data
• Collect Performance Data
• Analyze and report on progress
• Use Analysis to Inform Mgmt Decisions
Status:

PERFORMANCE MEASUREMENT DEVELOPMENT
General

• Draft Frameworks developed for 3 teams

• Measuring Progress
  – Activities and Performance measures associated with Results are not independent of each other

• Preventive Control further along

• Focus has been measures for mid-to-lower level Results
LOOKING ACROSS FRAMEWORKS
PC, PRODUCE, AND IMPORTS
PC Framework

Reduced Risk of Illness Attributed to Food From Facilities Subject to the PC Rule

1: More Rapid and Effective Recall Actions by Facilities Subject to PC Rule

2: Reduced Contamination of Food From Facilities Subject to PC Rule

3: Increased Implementation by Industry of PC Rule Requirements

4: Increased Transparency/Info Exchange Related to PC Rule for Emerging Issues Between Regulatory Agencies, Public Health Orgs & Industry

5: Increased Acceptance by Firms of their Responsibility for Meeting PC Standards (for Food Safety)

6: Expanded non-Enforcement incentives

7: Increased Industry Understanding of PC Rule and the Underlying Science

8: More Effective and Efficient Regulatory Activities Related to the PC Rule

5.1: Increased Availability of PC Training, Guidance Materials, and Technical Assistance for Food Safety Staff and Industry (learning resources)

8.1: Increased Knowledge by Food Safety Staff of PC Rule & Underlying Science

8.2: More Effective Inspection & Enforcement Program/Protocol Established

8.3: Expanded Risk Based Management of Regulatory Resources

8.3.1: Increased Capture, Analysis, Management, and Sharing of Enforcement Relevant Info

8.3.2: Improved Analytics to Assess Risk

Foundational Results

A: Improved and Integrated IT Infrastructure and Systems
B: Increased Availability of Information Related to US Safety Standards
C: Improved Collaboration and Integration Between FDA and Regulatory Partners
D: Improved Coordination & Information Sharing between FDA Offices
E: Research Better Targeted to PC Priorities
F: Change in Culture of FDA & Regulatory Partners from Response to Prevention
G: Increased Support for Preventive Approach by Stakeholders
Produce Framework

SO: Reduced Risk of Illness and Death Associated with Produce

R1: Reduce microbiological contamination on farm (US & Foreign)

R2: Increase use of science based GAP that are not required by rule
R3: Increase compliance with the rule by covered, non-exempt farms
R4: Increase voluntary adherence with rule by all other farms

R5: More effective enforcement outcomes by regulatory agencies
R6: Increase incentives to comply with rule
R7: Increase knowledge of the rule and how to apply it by farmers
R8: Increase demand by buyers that farms comply with rule
R9: Increase farmer buy-in & support for rule
R10: Increase availability of technologies & equipment to support implementation of the rule
R11: Increase ability of farms to purchase and use technologies that will facilitate implementation of GAPs and compliance

R12: Better execution of an expanded set of farm related activities that facilitate compliance by FDA & regulatory partners
R13: Increase availability of core produce rule training
R14: Increase effectiveness of technical assistance provided to farmers by FDA & partners
R15: Increase dissemination of inspection findings (trends, emerging issues, good practice)
R16: More effective engagement with consumer/trade groups on produce safety issues
R17: Expanded communication of scientific research that supports the rule

R18: Improve data collection strategy
R19: Increase adoption of the rule by states, local and tribal
R20: Increase knowledge & skills of food safety staff of FDA & partners
R21: Establish and utilize enforcement strategy
R22: Improve working relationship with farms (inspectors, district level, FDA level)
R23: Increase capacity of partner orgs (state, ag extension, etc.) to educate farmers
R24: Improve risk informed decision making
R25: Increase leveraging of information from non-FDA organizations (3rd party audit)

Foundational Results

Result A: Improved and Integrated IT Infrastructure and Systems
Result B: Increased Availability of Information Related to US Safety Standards
Result C: Improved Collaboration and Integration Between FDA and Regulatory Partners
Result D: Improved Coordination & Information Sharing between FDA Offices
Result E: Increase understanding of the science and risk associated with produce
Focus:
PUBLIC HEALTH OUTCOMES
Strategic Objective: Results

- **Long term – End goals**

<table>
<thead>
<tr>
<th>Strategic Objective</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC</td>
<td>• Reduced Risk of Illness Attributed to Food from Facilities Subject to the PC Rule</td>
</tr>
<tr>
<td>Produce</td>
<td>• Reduced Risk of Illness or Death Associated with Produce</td>
</tr>
<tr>
<td>Imports</td>
<td>• Reduced Risk of Illness or Injury from Imported Foods</td>
</tr>
</tbody>
</table>
### Top-Tier Results cont.

<table>
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<tr>
<th>PC</th>
<th>Produce</th>
<th>Imports</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Reduced Contamination of Food from Facilities Subject to the PC Rule</td>
<td>□ Reduce microbiological contamination on farms (U.S. and Foreign)</td>
<td>□ Reduced Food Safety Problems in the Foreign Supply Chain (Pre-entry)</td>
</tr>
<tr>
<td>□ More Rapid and Effective Recall Actions by Facilities Subject to the PC Rule</td>
<td>□ Increase Voluntary Adherence with the Rule by all other Farms</td>
<td>□ More Effective Interdiction of Unsafe Food at Port of Entry</td>
</tr>
<tr>
<td>□ Increase Compliance with the Rule by Covered, Non-Exempt Farms</td>
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<td>□ Increase Compliance of the Foreign Supplier with FDA Safety Standards</td>
</tr>
<tr>
<td></td>
<td>□ Increase use of science based GAP that are not required by rule</td>
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Ideal Public Health Measures

• Able to link progress to actions taken (implementation of the rules)
• Aligns with criteria
  – direct, practical, objective, adequate
• Risk focused
• Supportive building blocks
• Enables program changes upon analysis
General Challenges

• General (not all inclusive):
  – Data limitations
    • Illness/outbreak – reporting, limited data in food categories (CDC likely covered other issues)
    • Food sampling targeting versus “true” surveillance
  – Rarely tells the whole story
  – Measuring prevention
  – Availability of data from different sources
Monitor and Evaluate:

EXECUTING STRATEGIC PROGRAM PLANNING
Review of Approach

• Infuse risk informed approach to measures where applicable
  – Ex. disaggregate by hazard or product type, or component of rule

• Apply consistent criteria for selection of measures; aim for 2-3 measures per result
  – Direct, practical, adequate, objective

• Recognize iterative process; “dry runs”
Status of Metrics Development

- PC: refined, close to completion on narrowing and conducting “dry run”

- Produce – early stages: developing new, refining original and narrowing

- Imports - Currently refining, adding risk component, narrowing and selecting
### Strategic Objectives & Draft Measures: All Rules

<table>
<thead>
<tr>
<th>Results</th>
<th>Draft Measures</th>
</tr>
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</table>
| **PC: Reduced Risk of Illness Attributed to Food From Facilities**     | • # of reported illnesses attributed to food produced at facilities subject to the PC rule  
|                                                                        | • # of reported outbreaks attributed to food produced at facilities subject to the PC rule |
| **Produce: Reduced Risk of Illness or Death Associated with Produce**  | • # of illnesses and deaths associated with produce  
|                                                                        | • % of illness and death attributed with RAC  
|                                                                        | • scope/ scale of the outbreak or illness events  
|                                                                        | • # of outbreak events/ frequency of outbreak events |
| **Imports: Reduced Risk of Illness or Injury from Imported Foods**      | • # of outbreaks where the implicated food source was originally contaminated before entering the US  
|                                                                        | • % of illness and injury attributed to priority chemicals and pathogens where the contaminated source was imported foods |
Draft Top Tier Measures: PC

**Results**

- **Reduced Contamination of Food from Facilities Subject to the PC Rule**

- **Increased Implementation by the Industry of the PC Rule Requirements**

**Draft Measures**

- # of samples collected by regulatory agencies that test positive for agents that have previously been identified in foodborne outbreaks
- # of contamination events self-reported by firms (RFR & recalls)
- # of foreign firms on import alert as a result of a manufacturing/processing contamination

- % of firms that are fully implementing their PC plans (Plan developed, staff trained, and monitored)
- % of firms that address critical violations of the PC rule within expected timeframe

NOTE: there is another Result dealing with Recalls. It’s not listed here since we want to focus on prevention at the firm level for CFSF discussion.
Top Tier Measures: Produce

Results

Reduce Microbiological Contamination on Farms (U.S. and Foreign)

- # of farms with a contamination event (separate out by samples, outbreak, etc)
- % of on-farm samples from inspections found to be contaminated
- # of new farms and countries added to import alert for contaminated produce
- # of firms/ farms and countries taken off import alert for contaminated produce

Increase Compliance with the rule by covered, non-exempt farms

- #/% of farms in compliance with key parts of rule (ex, water)
- Aggregate compliance score or rate for produce industry
- # of violations corrected upon a subsequent inspection
Challenges:
Linking to FSMA specific rules

• Overlapping in activities
• Hazards:
  – PC: chemical (incl allergens), microbial, etc.
  – Produce – microbial pathogens only
  – Imports: many different components
• Products and practices
  – Products not covered creates challenges for selecting foods/hazards to measure
• Distinguishing covered & not, compliance dates
  – Difference in Rules
HIGH LEVEL MEASURES
Measuring Illness/Outbreaks

• What are the key areas of public health concern?
• Are the foods/ingredients associated with illness/outbreak captured in such a way to measure reduction or reduction of risk?
• What’s the best way to measure reduction of “risk”? 
PC: Measuring Illness/Outbreaks

• Hazards:
  – Chemical (incl allergens), microbial, etc

• Focus on Microbial:
  – Illness and outbreak data categorized by food

• Products:
  – Not covered or under another rule:
    • Ex. seafood, juice, shell eggs
  – Covered: many complex foods, dairy, etc
PC: Measuring Illness/Outbreaks

• Foods and microbial hazards:
  – Salmonella and Low moisture foods (is that a category?)
  – Is there enough data in a category to measure this? “reduction of risk” or “reduction”
  – Listeria, Salmonella and cheese?
  – Others?
PC: Measuring Reduced Contamination of Foods

• Risk informed approach

• Similar questions:

• Existing Data sources:
  – FDA sampling data, other govt sources
  – Data generated by non-govt entities

• New streams of data?
PC and Produce Results dealing with Compliance (or Implementation)

• Draft measures focused on compliance
• How do we make the measures more positive?
• What would make this more risk/public health focused?
  – Focus on certain violations and subsequent correction, IT needs to be able to capture
  – Specified practices and conditions more useful
• Other data sources? Audit info? Sharing data
• Other approaches?
Produce: Measuring Illness & Outbreaks

• May be more applicable, amenable
  – only microbial pathogens
  – foods often single ingredient or simple food

• Challenges remain in data limitations

• What will it tell us? Story lies under the strategic objective for measuring

• Can we tie reductions or reduced risk to the produce safety rule?
Produce: Reduce Microbiological Contamination on Farms (covered by rule)

• Draft measures focus on sampling results
  – Unintended consequences?

• What pathogens & foods would we focus? Align with measure illness/outbreaks?
  – How does this mesh with rule’s focus on practices? What can we measure?

• Baseline?

• Methods? Sharing data? Govt & non-govt

• More useful or complementary measures?
Building on Lower Level Results

• Critical component of the Strategic Program Planning; building blocks
  – PC and imports most challenging for illness/outbreak links
  – Produce may be more amenable to use of illness/outbreak data for part of the picture
  – If rely greater on mid-tier results then strengthen data gathering and measurement
    • External data sources, new methods for applying data, expertise, sharing data
Performance Management

- The right expertise needed
- Tools to visualize progress
- IT tools to gather, mash-up data
- Leadership Champions
- Routine monitoring and evaluation leading to better management decision and resource allocation
  - Is there more than FSMA😊
EXTERNAL INPUT
External Stakeholder input

• Opportunities:
  – Improve data to measure progress, improved measures, partnerships in building a preventive food safety system

• Impact:
  – greater understanding by stakeholders of FDA approach to FSMA implementation
  – Potential delay finalization of measures & monitoring
  – Increased success in public health protection
Summary

• Outcome oriented approach
• Results build on each other and not solely relay on illness/outbreak data to measure success
• Iterative process, being more positive
• Stakeholder input and data contribution will enhance ability to measure progress
• Prevention is the goal but hard to measure