Risk-Based Sampling: Perspective from CFSAN, USA

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FDA CFSAN, College Park, MD

IAFP European Symposium on Food Safety, May 11-13, 2016, Athens, Greece

Outline

- Microbial sampling in the context of risk-based preventive controls

- FDA strategic sampling and stakeholders engagement

- Criteria and data to consider to inform risk-based sampling

Microbiological Sampling in the context of Preventive Controls

- Food safety principally ensured by implementation of scientifically valid preventive control measures throughout the food chain

- Risk-based sampling can play an important role in food safety systems

- Product testing and environmental monitoring in FSMA PCHF final rule

FDA FOOD SAFETY MODERNIZATION ACT

Purpose of Product Testing

- "Product testing" means testing of any food product (raw materials, ingredients, in-process foods, or finished products)

- Have many purposes, main ones are

Acceptability of individual lots

Filling critical data gaps

Verification testing (Process control testing)

Product Testing in a Food Safety System

- Testing is used in conjunction with other verification measures, such as audits of suppliers, observations of whether activities are being conducted according to the food safety plan, and reviews of records to determine whether the food safety plan is being implemented appropriately to control hazards.

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Product Testing in a Food Safety System

- The nature of the food facility, the food product, and the control measures used in the production of the food determine

  - What hazards to test for (e.g., a particular pathogen or indicator organism);

  - Where/when to test for a hazard (e.g., testing raw materials/ingredients versus testing finished product); and

  - Frequency of testing.

Process Control Testing

- Can be a powerful tool to evaluate food safety systems and correct system problems, often before product presents a food safety issue.

- Beneficial as part of ongoing verification activities

Establishing Process Control Sampling Plans

- Use data from process capacity study

- Develop microbiological limits and sampling plans such that

  - frequency of detecting a positive result or a specific number of organisms is unlikely to occur due to chance alone, and thus

  - indicates the system is out of control

Example: Product Testing for Indicators Leading to Pathogen Testing

Sampling plans and limits for a low a_w food

Microorganism	n	c	m	M
Aerobic colony count	5	2	10^3	10^4
Enterobacteriaceae	5	2	10	10^2
Salmonella	10	0	0	-

- Test food for APC or Enterobacteriaceae (EB) to verify control of the process;

- When process indicators suggest a loss of control, e.g., EB counts >100, product should be tested for *Salmonella.*

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FDA strategic sampling and stakeholders engagement

Types of Sampling

- **Finished (or Ingredient) Product Sampling**

  - Used to detect the presence of the contaminants in a food, dietary supplement or cosmetic

  - Product collected at some point in the supply chain

  - Can be analyzed for pathogens, chemical contaminants, filth , nutrient content, etc.

  - Used for both import and domestic sampling activities

  - Example: Microbiological Surveillance Sampling Approach

- **Environmental Sampling**

  - Used to detect the presence of pathogens in a facility

  - Primarily used in packing or processing facilities, in particular for RTE foods exposed to the environment

  - Uses swabs to collect samples primarily from food contact surfaces or areas near them

- **Emergency Response/For Cause**

  - Could be any type of sample (product and environmental are most common)

  - Can be analyzed for pathogens, chemical contaminants, filth, etc.

  - Typically unplanned collections, could be part of inspections

Background:
Microbiological Surveillance Sampling Approach

Collect statistically significant data that can **proactively** identify public health risks

Focus surveillance sampling resources on those foods that pose the potential public health risk

Establish standardized, transparent, and collaborative **processes and communications**

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New, More Robust
Surveillance Sampling Approach

Began in 2014

- Collect statistically determined number of samples of targeted foods

- Sampling design targets foods U.S. consumers likely to find in marketplace and that present a risk

- Consider: volume of food, import and domestic products, number of states/countries/businesses that produce the target food

Commodities Sampled

- **Pilot focused on**
  - Sprouts
  - Whole fresh avocados
  - Raw milk cheese (aged 60 days)

  Over 800 samples, tested for

  Salmonella,
  L. monocytogenes,
  E. coli O157:H7

- **FY 2016 will sample**
  - Cucumbers (1600 samples)
  - Hot peppers (1600 samples)

  Test for

  Salmonella,
  E. coli O157:H7,
  STEC (for hot peppers)

Using Data from Sampling

- Use data to inform agency's short- and longer-term decision making, taking certain steps, such as

  - Decreasing sampling if few positives are obtained

  - Implementing more targeted sampling if trends are identified

  - Follow-up inspections

  - Working with state or international partners to take corrective actions

  - Develop new or enhanced industry guidance

  - Conducting outreach and information sharing to better protect consumers

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Example: Using Data to Inform Strategy

Avocados

- Research completed on internalization of pathogens based on high rate of skin contamination
  - Next Steps: Consider how puree, paste, and guacamole processors control for *L. monocytogenes* and *Salmonella* in their facilities
  - Next Steps: Target foreign inspections to determine what practices could be contributing to high contamination rates in some imported avocados

Whole Genome Sequencing

- Expands and improves robustness of reference WGS library
- Can lead to clinical matches, leads for outbreak traceback, and insight on attribution

Example - Enhancing Practices

Public Health Impact

- Identified sprout outbreak early in the signal stage
- 13 class 1 recalls to remove contaminated product from market
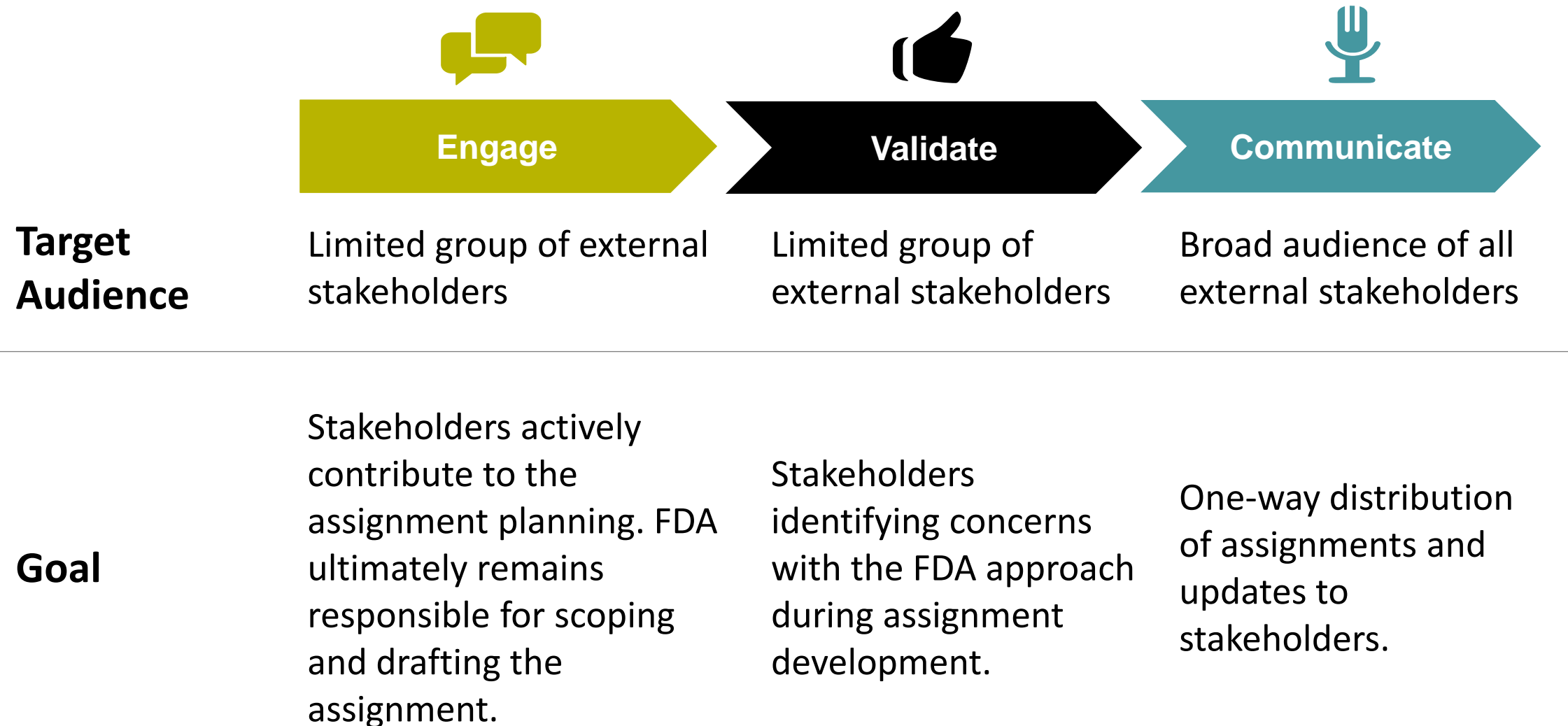- 10 Import Alerts to control imported contaminated product from entering

Collaboration

- Leveraging state partners for case monitoring and utilizing the FERN labs on food safety assignments

Communication

- Quarterly meetings with interested trade groups to share assignment updates
- Working with Trade Assoc. to accommodate collections from shippers before product is on market to decrease impact on trade

Greater Communication and Engagement with External Stakeholders

	Engage	Validate	Communicate
Target Audience	Limited group of external stakeholders	Limited group of external stakeholders	Broad audience of all external stakeholders
Goal	Stakeholders actively contribute to the assignment planning. FDA ultimately remains responsible for scoping and drafting the assignment.	Stakeholders identifying concerns with the FDA approach during assignment development.	One-way distribution of assignments and updates to stakeholders.

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Criteria and data to consider in risk ranking to inform risk-based sampling

Defining Risk

- Factors to consider
  - Hazards (e.g., pathogen characteristics, level, persistence in environment)
  - Foods (e.g., supporting pathogen growth or not, ingredient matrix effect, intended use)
  - Firms (e.g., validated process, credible environmental monitoring program in place or not, records)
  - Consumers (e.g., susceptibility, handling practices)

- Evolving concept

FDA Risk Ranking Portfolio

- FDA/FSIS *L. monocytogenes* in Ready-to-Eat Foods Quantitative Risk Assessment (2003)

- FDA/IFT Risk Ranking Prototype (cooperative agreement; 2005)

- FDA/RTI Produce Risk Ranking Tool (2009)

- FDA-iRISK®, a web-based comparative risk assessment tool (latest version 2015)

- Risk Ranking Model for Product Tracing (under development)

- Decision Analysis Tools
  - Pilot case study projects
  - Data-driven risk prioritization system

These tools primarily rank products & hazards (and firms) based on public health metrics; capacity to evaluate impact of sampling

FDA Process for Risk Ranking and Prioritization using Multi-Criteria Decision Analysis

- Identify hazards, foods, and sectors/firms of interest

- Identify public-health criteria for risk ranking

- Collect data, develop scoring definitions & assign weights

- Calculate risk score & rank the food-hazard pairs, firms, etc.

- Prioritize: Apply resources, consider constraints and other factors

Example Data and Sources to Consider

- Outbreak and illness data from gov't databases

- Surveillance and sampling data

- Data from Gov't surveys and investigations

- Reportable Food Registry (RFR) and recalls data

- Inspection and compliance records

- Published literature

- Other data and information

Some of the Challenges

1. What is the granularity of food classification needed and supportable by data?

2. What approaches to consider to combine data and expert opinions in scoring and ranking of food-hazard pairs?

3. How best to identify the "right" criteria and how to obtain consensus on weights

4. Data: sources, quality and quantity

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Example Criteria to Consider in Risk Ranking

- Frequency of outbreaks and occurrence of illness

- Severity of illness

- Likelihood of contamination

- Growth potential/shelf life

- Manufacturing process contamination probability /intervention

- Consumption

- Firm specific factors, e.g., compliance history, inspection results, sampling results consumer complaints, recalls

Risk Prioritization Issues

- Public health metrics alone are not sufficient to allocate resources & make policy decisions

    – For example: Is the hazard controllable through agency action or influence?

- Important to know the context of the prioritization exercise: which products, which hazards, and which populations

Risk Prioritization

- Take into account additional factors such as,
  - Feasibility of implementing control measures
  - Practicality of control measures
  - Level of public concern
  - Level of certainty in the estimates
  - Policy imperative
  - Cost of interventions or control measures

Process for Developing & Using a Risk Prioritization Model
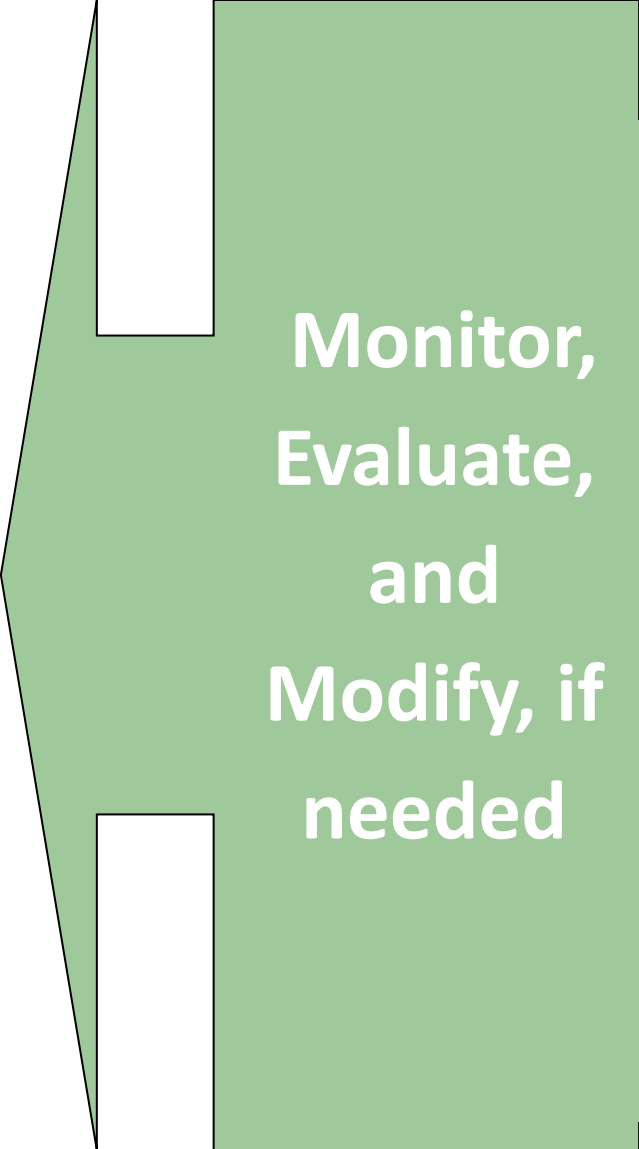
Develop the Risk Prioritization Model

* Assemble a team to develop the model
* Identify the criteria and data sources to be used
* Define the scoring for each criterion
* Define weights for the criteria
* Specify the firms to be evaluated

Conduct the Assessment (using the Model)

* Collect and link the data to the criteria
* Score each firm with respect to each criterion
* Document the justification for each score
* Calculate the total risk score for each firm
* Sort the firms in descending order of score

Evaluate the Results

* Review scores and adjust as necessary
* Based on the scores, determine level(s) of priority
* Allocate resources & Implement Recommendations

Monitor, Evaluate, and Modify, if needed

Example 1: Microbiological Sampling

Criteria

- – Frequency of problems
- – Incidence rate
- – Severity of public health consequences
- – Societal impact
- – Capability to intervene
- – Cost benefit ratio
- – Current knowledge
- – Utility of Project
- – Policy imperative

Top 10 Areas to Address

- New Egg Rule
- Produce: domestic and import
- Spices and dried herbs
- *Salmonella* Enteritidis in Eggs
- *L. monocytogenes* in RTE Foods
- *Listeria* in soft cheeses
- *Salmonella* environmental sampling
- Cold smoked fish
- RTE Foods; seafood sandwiches
- Crab meat; crab pickers

Example 2:
Salmonella Environmental Sampling

Criteria

- Incidence rate
- On-going or sporadic
- Capability to intervene
- Morbidity and mortality severity
- Societal impact
- Cost benefit ratio
- Sufficiency of current knowledge
- Policy imperative

Top 5 Facility Types to Address

- Spices, flavorings, seasonings producers/blenders/processors
- Tree nut/ edible seed processing plant
- HVP processing plant
- Nutritional bars
- Nut/seed butters producers/processors

[low moisture foods only]

Summary

- Risk-based sampling is part of industry's responsibility under the new preventive control requirements for human (and animal) food

- Risk-based sampling is part of FDA's efforts to keep contaminated products from reaching consumers and to facilitate a greater understanding of hazards to minimize risks.

Acknowledgements

- Amy Barringer, CFSAN Office of Compliance

- Sherri Dennis, Jane Van Doren, CFSAN Division of Risk and Decision Analysis