When Randomness is Not Enough
An Introduction to GOODSamples

AAFCO Midyear Meeting, 2014
New Orleans, LA
Feed Sampling

Some Questions

- Is our data consistent between agencies?
- Does the current sampling guidance meet everyone’s objectives?
- Is our data defensible?
- Do we know the total error in our final analytical results?
Uniformity in sample collection is essential to achieve consistent laboratory analytical results between multiple federal, state and local food/feed safety agencies.
Types of Samples

- Official
- Investigation
- Surveillance
- Documentary
- Emergency Response
- Convenience
- Import
- Monitoring
- Compliance
- Law Enforcement
Critical Element 1. The sampler has policies, procedures, and records to assure sample integrity, security, accountability, and chain of custody

Critical Element 2. The sampler has a statistically appropriate sampling plan

Critical Element 3. The sampler has a training program

Critical Element 4. The sampler is prepared to develop “incident specific” sampling plans prior to beginning collection
FDA Cooperative Agreement
U18FD004710

SPECIFIC AIM #2: Identify, pilot test, and implement nationally the policies and procedures necessary to establish equivalency between federal, state, and local food and feed testing laboratories.

Activity 1: Convene a Sampling and Sample Handling Working Group
PFP Laboratory Task Group

Uniformity in sample collection is essential to achieve consistent laboratory analytical results between multiple federal, state and local food/feed safety agencies.

• How do we accomplish this?
  • make everyone buy the same sampling tools
  • make every state follow the same SOP

• Just because we are consistent does not mean we are correct

• How do we ensure consistency and correctness???

  Hint: It starts with objectives

  Hint: It requires a common sampling theory
PFP Laboratory Task Group

- Are there really 10 types of samples or are there actually 10 objectives?
- Only two types of samples
  - samples that meet your objectives
  - samples that don’t
- Designing a SOP or selecting a SOP that directly meets the objectives is the only way to ensure consistency and correctness. It is the objectives that are critical, not the commonality of SOPs
Critical Element 1. The sampler has policies, procedures, and records to assure sample integrity, security, accountability, and chain of custody
Critical Element 2. The sampler has a statistically appropriate sampling plan
Critical Element 3. The sampler has a training program
Critical Element 4. The sampler is prepared to develop “incident specific” sampling plans prior to beginning collection

- CE1 is important and currently the most developed
- Our workgroup’s current focus is CE2 (includes CE1)
- Our workgroup’s next focus is CE3 - very important!
- With adequate technical expertise, CE4 is addressed
So What Needs to Be Done?

- Consistency and equivalency
  - represent the same material
  - same confidence (or error) in result
- Develop methods to measure and control sampling errors
- Consistent sampling strategy
  - common objectives--data equivalency
  - common sampling theory--data “correctness”

How do we accomplish this?
Answer is Always:
Form a Workgroup

- State, FDA, and industry representatives
- Developing a document - GOODSamples
- Provide training - very important!
Philosophy of GOODSamples

- Have plenty of SOPs but no direction to determine which ones should be used
- Need consistency among agencies without compromising individual agency needs
- Need to know the total estimation error in our final decision, especially sampling error
- Need to know what to consider when developing or evaluating SOPs
Philosophy of GOODSamples

- Flexible enough to address
  - emerging contaminants
  - changing priorities
  - new products, expansion of program
  - unanticipated field conditions
- Need sound scientific basis for all decisions
- Facilitate communication
- Need the power to find a problem when there is one
- Need a system/strategy for sample collection not just a bunch more SOPs
SOPs Are Like Recipes

- We have thousands of recipes in our kitchen, but we still don’t know what to make for dinner!
- We need criteria to pick out just the right recipe
  - ingredients on hand/available
  - allergies
  - health concerns/dietary needs
- We have “thousands” of SOPs
- We need criteria to pick out just the right SOP
  - question
  - decision unit
  - confidence
Most Important Part of Sampling - SQC

• What is the question?
  • analyte
    • container type
    • tool construction
  • levels of concern
    • sampling technique
    • handling/preservation

• What is the decision unit?
  • where sample is collected from
  • what needs to be accessible
  • material in question

• What is the confidence?
  • how are you going to make decisions (be sure you get enough of the right type of data)
  • controlling error in the measurement system
Lab vs Field Methods (SOPs)
They are developed differently

• Lab analytical methods
  • certifying body
  • lots of research, performance criteria
  • quality control to demonstrate performance

• Field sampling methods
  • none of the above
  • selection of method is more difficult
  • there are many more possibilities in the field than in the lab
How Does the Laboratory Address Analytical Methods?

- Verify the science
- Validate the method
- Control chart
- Reference materials
- Check sample programs
- Accreditation and auditors
- and the list goes on
How Does the Field Address Sampling Methods?

• Give them a control number--make it official
• Have Fred tell Ann tell Bill what to do--training
• Don’t provide the proper equipment--need the money for the lab equipment
• Just fill up the bag; how hard can that be!--motivation
• The only bright spot for the field is you get to blame the lab when there are problems

Since the majority of the error is in the field, sampling should get more attention than the lab--but management hates to go outside and get dirty!
How Do We Improve?

- What needs to go into a SOP to make it scientific
- How to evaluate a SOP to see if it is adequate for your objectives
- How to evaluate sampling to determine if you can use the data for your project
- How to ensure consistency and “correctness”
- Standardized terminology (facilitates communication between groups)

Answer: GOODSamples
GOODSamples Strategy

• Determine objectives (SQC)
• Develop sampling and analytical “plan” to meet objectives (collect a representative sample)
  • integrate quality control
  • use sampling theory
• Implement plan
  • preservation
  • handling/shipping
  • chain of custody
  • documentation
• Assessment of data - are objectives met?
Representative Sample

- Some of everything in the Decision Unit is in the sample
- Everything is in the same proportion in the sample as in the Decision Unit
- The act of sampling (and sample handling, processing, etc.) has not changed any of the characteristics
  - contamination
  - losses
- We can document how this is achieved

How is this accomplished?
Important Elements of Sampling Theory

- Enough mass
- Enough increments
- Proper tools to ensure equiprobable selection of all the particles
- Maintain integrity of analyte from the field to the instrument
Mass

- Minimum mass to represent all the particles of different concentration (compositional heterogeneity)
- It is a function of the heterogeneity of the material
- “Usually” trace analytes are more heterogeneous
- Cannot take less than the required mass and expect the right answer
What about a trace amount (0.1%) of AAFCO M&Ms?

What is the minimum number of M&Ms we need?

What about a trace amount (0.1%) of AAFCO M&Ms?
Increments

• One discrete point will not work
• AAFCO inspectors manual states minimum of 10
• Ten increments will not be enough for many materials
• Access is the problem with selection of increments
  • sometimes real, sometimes unwilling to do the work
  • compromises our ability to obtain objectives
  • can only make inference to the portion of the decision unit you collected increments from
Sampling Tools

• What are the critical design elements
  (equiprobable selection of all the particles)
  • reach all the particles
  • no discrimination based on size, shape, location, etc.
• Does the tool or use of the tool affect the analyte?
  • contamination of analyte
  • loss of analyte
  • physical form of analyte
• Use
  • safety
  • ability to decontaminate
  • easy to use
  • durable
Maintaining Integrity

- **Analyte integrity** (chemical, physical, biological)
  - contamination from outside sources (containers, seals)
  - loss of analyte (preservation, holding times)
    - volatilization
    - organisms
    - degradation (form) of analyte

- **Sample integrity**
  - documentation
  - chain of custody
  - “rules of evidence”
What About Field Quality Control?

- It is the “proof of performance”
- Need QC when we want to determine
  - our sampling process is in control
  - what is the magnitude of the error
- If it is important in the lab, it is even more important in the field

Knowledge of the potential sampling error is important since if the sampling error is already more than about 2/3 of the total error...

William Horwitz
Types of Quality Control

- Contamination checks
  - containers
  - environment
  - tools
- Precision measurement
  - replicate field samples
  - all precision error in entire measurement system
Adding Error

Sampling error 80%
Analytical error 20%
reduce analytical error by 1/2
reduce sampling error by 1/2

\[ \sqrt{.80^2 + .20^2} = 82\% \quad \text{total error} \]

\[ \sqrt{.80^2 + .10^2} = 81\% \quad \text{reduce analytical error} \]

\[ \sqrt{.40^2 + .20^2} = 45\% \quad \text{reduce sampling error} \]
In essence

Trippin’ Over Dollars to Pick up Pennies!
GOODSamples: Guidance on Obtaining Defensible Samples

Sampling and Sample Handling Working Group
FDA, AAFCO AFDO, APHL,
JANUARY 2014
web url
**Sampling Terms Illustrated - Grain**

- **Decision Unit**
  - Truck load of grain

- **Increments**
  - Individual probes of grain

- **Primary Sample**
  - All increments combined to provide sufficient mass

- **Laboratory Sample**
  - Package sent to/received by Laboratory

- **Analytical Sample**
  - Grain processed for testing

- **Test Portion**
  - Mass taken for analytical test
Summary

• Status quo is not acceptable
  • uniformity
  • “correctness”

• More of the same is not the solution

• Need to change the paradigm of sample collection
New Paradigm

- Start with objectives
  - question
  - decision unit
  - confidence
- Plan to meet objectives based on sound science
  - sampling theory (bulk materials)
  - quality control
- Assessment
  - determination of error
  - confidence of correct decision

Everybody is involved
How Do We Achieve This?

• Complete GOODSamples document
• Provide training - very important!
  • shifting paradigms, not just providing information
  • need to interact with participants
• Continuous feedback and experimentation
Sampling

- About objectives, not about
  - the perfect sampling tool
  - the perfect sampling technique
  - the universal SOP
- Estimating parameters
  - average
  - percentage
  - presence/absence
- Making decisions
  - no universal/perfect statistics
  - consequences of bad decisions
Workgroup

Photo
needs, issues and day-to-day challenges. Inspector/sampler shadowing has occurred in the following states: MN, SD, FL, OR and ID.

- Ramsey made oral presentations to the AAFCO Laboratory Methods and Services and Inspection and Sampling Committees. His presentation “When Randomness is Not Enough” was an introduction to the Theory of Sampling.
- Sections for the Guidance document have been established, with consensus on the content of each section.
- Title of Guidance document proposed to be: *Guidance On Obtaining Defensible Samples* (GOODSamples). A subtitle will capture the collaborative effort. Suggested subtitle: A collaborative effort of FDA, AAFCO, AFDO, APHL and Industry to provide guidance for the defensible sampling of food and feed materials.
- Writing of first drafts of the Sections is underway.

**Products**

GOODSamples, a guidance document with the following sections is in preparation. The document is expected to be in complete first draft form by February 2014.

- Introduction and Background.
- Definitions
- Flow Charts
- Management Considerations
- Theory of Sampling
- Sampling Quality Criteria
- Quality Control
- Data Interpretation
- Sampling Tools
- Sampling Design
- Targeting
- Maintaining representativeness

- Maintaining legal integrity
- Health & Safety
- Laboratory Sampling, Handling and Preparation
- References

Piloting will occur in two phases

- Training talks/events at national meetings (highest priority)
- Training talks/events at regional meetings (as funding allows)
- In-state piloting in 2-3 states.

**Impact**

It has become apparent that this project is a massive, but critically needed, undertaking. The scope and volume of work is much greater than originally anticipated. However, the work is extremely important and the most overlooked component of establishing equivalency of data necessary for inter-agency data sharing. The group is approaching the project as if the guidelines might eventually be used as guidelines for accreditation. The outcomes promise to be very exciting and productive, with very significant impact.

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Preparation of Food and Feed Laboratories for ISO 17025 Accreditation

Through a cooperative agreement with FDA's Office of Partnerships, APHL, AFDO and AAFCO are preparing food and feed regulatory testing laboratories to achieve, maintain and enhance ISO/IEC 17025:2005 accreditation. Objectives of the work include:

- developing laboratory training programs around accreditation
- building a mentoring program for laboratories at various stages of accreditation
- reaching national consensus on equivalency
- enabling direct electronic sharing of analytical data
- improving communication among federal, state, and local testing laboratories and with their associated regulatory and public health programs
- building a framework for unified laboratory response to food/feed safety emergencies
- expanding a proficiency testing program for feed laboratories
- improving the rapid submission of isolates to the public health system

Specific Aim #2: Harmonized Polices and Procedures for Equivalency of Data

Identify, pilot test, and implement nationally the policies and procedures necessary to establish equivalency between federal, state, and local food and feed testing laboratories.

Under this Specific Aim, AAFCO is leading efforts to:

- Establish harmonized policies and procedures for sample collection, shipment, analysis, storage, and retention of food and feed materials.

Initiatives

- A contract between AAFCO and Envirotstat, Inc. was developed and signed on November 13, 2012, bringing Chuck Ramsey on as a technical consultant.
- The Working Group established a Foodshield Work Group "FDA CoAg Sampling and Sample Handling WorkGroup" for webinars, reference document repository and document control.
- The Organizational Conference call was held December 20. Biweekly working conference calls were held January 3, January 17, January 25, February 14, February 28, March 14, April 11, April 24, May 9, May 30, June 14, June 27, July 11, July 27, August 8, and August 22.
- Face-to-face meeting held January 25 in Albuquerque, NM and August 14-15 in St. Pete Beach, FL.
- Training in Sampling for Defensible Decisions: Food and Feed was held April 2-5, 2013 in Dallas, TX.
- A State Contact List containing contact information for points of contact in the states for food and feed testing has been developed.
- A nationwide survey has been conducted of state personnel involved in sampling regarding issues and concerns with sampling processes and availability of in-house documents that might be shared with our working group.
- Ramsey and Thiex have initiated conference calls on a state-by-state basis to capture sampling needs and issues.
- "Spend a day with an inspector/sampler" was initiated for Chuck Ramsey and Nancy Thiex to spend a day in a few different states to capture the diversity of sampling

Member Involvement

AAFCO, via its Laboratory Methods and Services and Inspection and Sampling Committees, will convene a Sampling and Sample Handling Working Group to establish policies and procedures for sample collection, handling and preparing for analysis. Members have been drawn from AAFCO, AFDO, APHL, FDA and industry, and is chaired by Nancy Thiex and represent laboratory and inspection staff. The charge to this group was to establish harmonized policies and procedures for food and feed sample collection and handling. The procedures should be science based, internationally acceptable and lead to equivalent and defensible analytical results.