



What Do I Need to Know Before Submitting Samples for Microbiological Testing?

Today's Speakers:

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Webinar Housekeeping

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Webinar Housekeeping

- It is important to note that all opinions and statements are those of the individual making the presentation and not necessarily the opinion or view of IAFP.
- This webinar is being recorded and will be available for access by IAFP members at www.foodprotection.org within one week.

A Moment of Silence



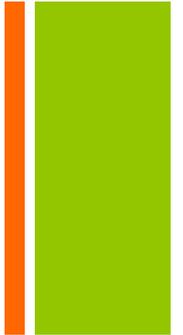
Preparing to take “GOOD” Samples

International Association for Food Protection Webinar: What Do I Need to Know Before Submitting Samples for Microbiological Testing

April 16, 2020 11:00 AM CT



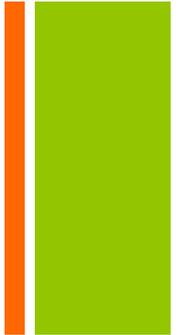
Purposes of Sampling and Testing for Microbial Analytes



- Determine if a product or process meets regulatory requirements?
- Validation of a control measure
- Verification of process control
- Verification of sanitation control
- Agreement between customer and supplier
- Continuous improvement of processes
- Protect public and be an advocate for food safety



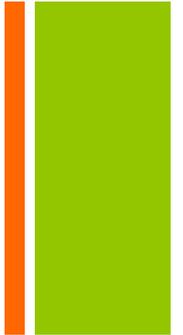
Outcome of Sampling and Testing for Microbial Analytes



- To make a decision
 - To accept or reject incoming material (based on previously established acceptance criteria)
 - To release outgoing product (against quality control criteria)
 - To destroy or rework a defective lot
 - About quality control criteria limits
 - About the production environment (does it meet sanitation requirements?)
- How confident do you want to be in your decision?



What do I need to know before collecting laboratory samples?

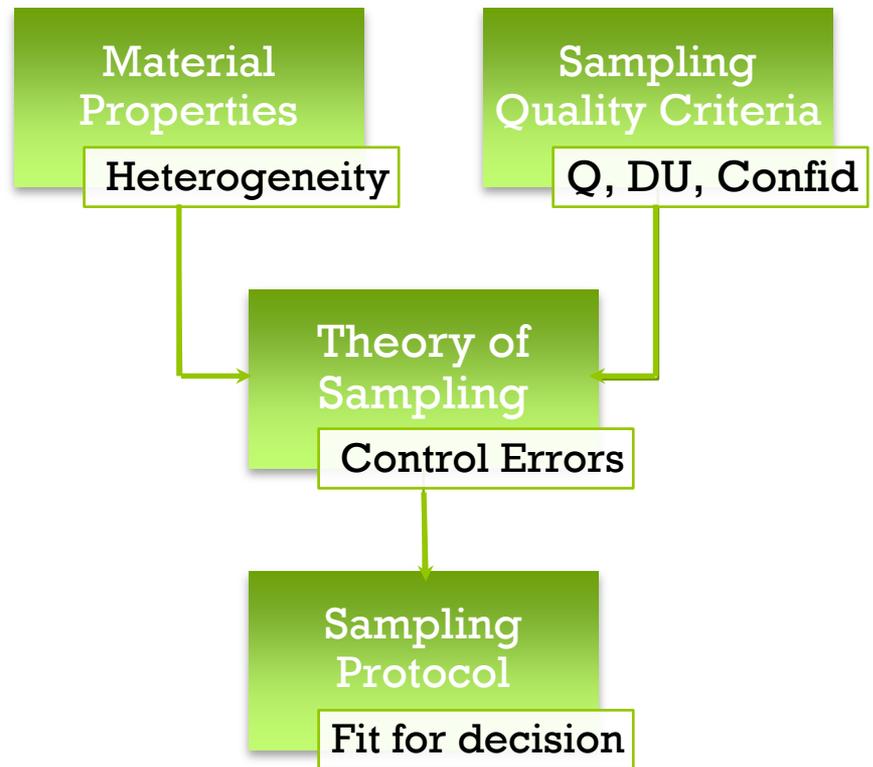


- The most important consideration before submitting a laboratory sample is to have an understanding of the factors that yield a “fit for decision” sample.
 - The primary sample must be “fit for decision” for the laboratory sample to be “fit for decision” and for the test result to be “fit for decision”
 - A representative sample is achieved through sufficient control of error to meet “fit for decision” criteria
 - Same principles are applicable for primary sampling and laboratory sampling.

+ Sampling Protocol

The foundations (three-legged stool) are:

- Sample Quality Criteria
- Material Properties
- Theory of Sampling



+ Key Terms



- **Decision Unit:** Material from which the primary sample is collected and to which inference is made
- **Increment:** Individual portion of material collected by a single operation of a sampling tool and combined with other increments to form a primary sample.
- **Inference:** Estimating a concentration or characteristic about a larger amount of material from data derived from a smaller amount of material.
- Always use an adjective with “sample”!



Decision Unit
• Field of tomatoes



Increments
• Individual selected tomatoes



Primary Sample
• All increments combined to provide sufficient mass



Laboratory Sample
• Package sent to/received by Laboratory



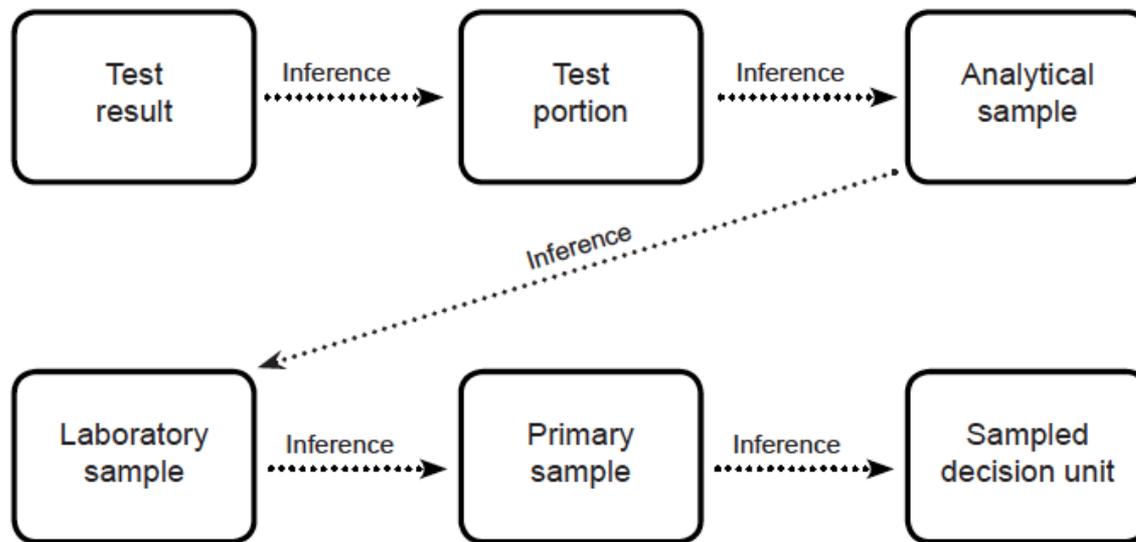
Analytical Sample
• Tomatoes processed for testing



Test Portion
• Mass taken for analytical test

+ Sampling to Test Results is a Single Measurement Process

Sampling/inference pathway. To be able to make inference, the test portion must be representative of the decision unit.

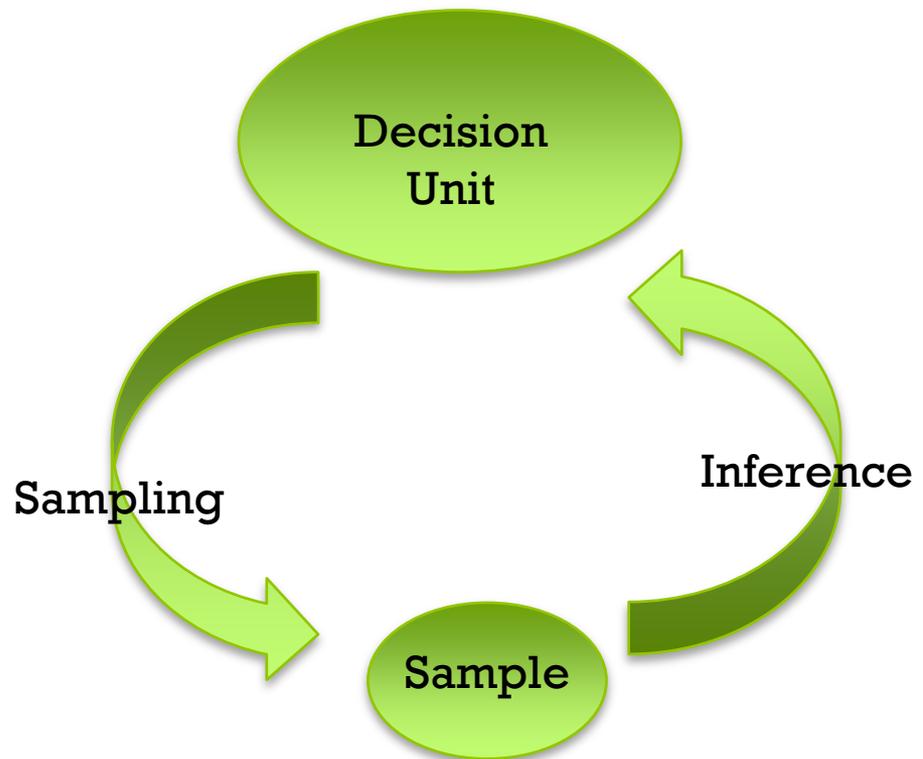


GOOD
Samples

GOOD
Test Portions

+ What is a Representative Sample

- A sample is representative only if:
 - It is “correct” - systematic error is controlled to a negligible level
 - Random error is within “fit for decision” criteria



GOODSamples: Guidance On Obtaining Defensible Samples



Sample Quality Criteria

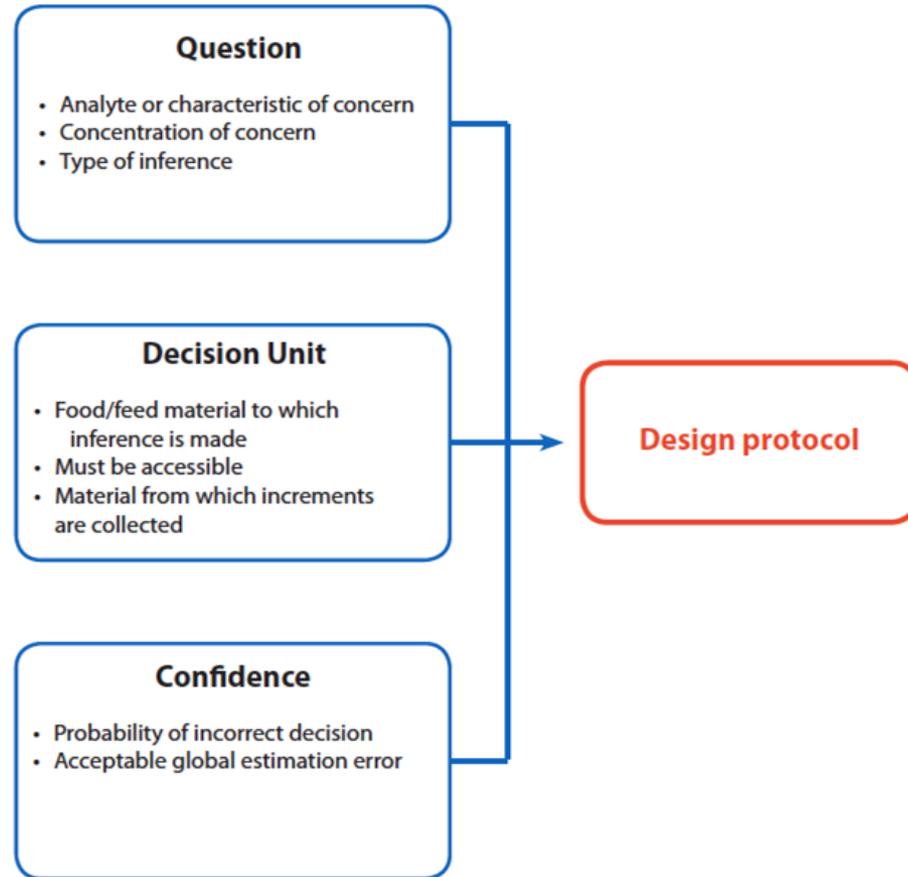
What is the question?

What is the decision unit?

What is the desired confidence?

+ Sample Quality Criteria (SQC)

- A series of statements that clarify technical and quality needs to support defensible decisions (fit for purpose decisions)
- Three inputs: Question, Decision unit, Confidence



+ 1. What is the question to be answered?

- What information is required?
 - What is the analyte?
 - What is the level of concern?
- What type of data will be collected?
 - Characteristic of the decision unit?
 - Concentration of analyte(s) in the decision unit?
- How in the inference from the sample to the decision unit going to be made?
 - Direct inference (single result)?
 - Probabilistic inference (single result)?
 - Statistical inference?

- Analyte or characteristic of concern
- Concentration of concern
- Type of inference



2. What is the decision unit?

- The decision unit is the material from which the primary sample(s) is collected and to which the inference(s) is made.
- Maybe one or multiple decision units
- The decision unit establishes the scale of observation

- Food material to which inference is made
- Must be accessible
- Material from which sample is collected

- Example: 10 pallets of 100 cases of 24 heads of lettuce are present.
 - Is the average value of all 10 pallets of interest? All 10 pallets comprise a single decision unit (1)
 - Must each pallet be within spec? Each of the 10 pallets is a decision unit (10)
 - Must each case on every pallet be within spec? Each case is a decision unit (1000)
 - Must each head of lettuce be within spec? Each head is a decision unit (24000)

+ 2. Decision unit cont'd.

- Example: Food in a deli.
 - Are all food present at a given point in time of interest? All foods comprise a single decision unit (1)
 - Is all the food present each day for a week of interest? (7)
 - Is each type of food of interest (there are 15 types of food present) (15)
 - Are only the sandwiches of interest? (1)
 - Is each type of sandwich present (5 types) of interest (5)
 - Is each of the 12 ingredients in one type of sandwich of interest (12)

- Example: Environmental surfaces in a plant.
 - Are all the surfaces in the plant of interest? All surfaces comprise a single decision unit (1)
 - Are all the surfaces each of 10 work areas of interest (10)
 - Are all the tabletop surfaces in one area of interest? (1)
 - Is a 12" x 12" square in one corner of one table a decision unit? (1)

2. Decision unit cont'd.

- ◆ Specific, definable, accessible
- ◆ Easy in the lab; difficult in the “field”
- ◆ Example coffee beans: + individual bean, small package, shipping bag, or shipload of coffee beans.

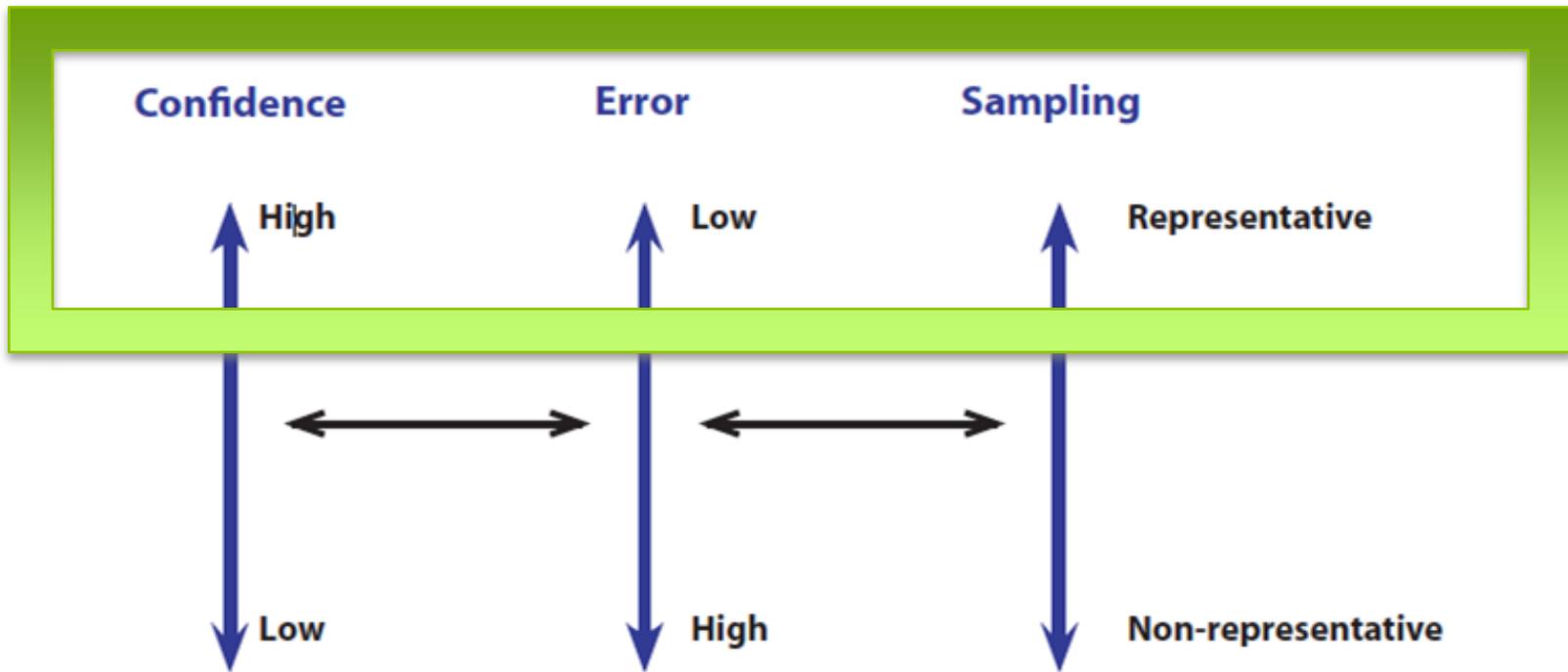


+ 3. What is the required confidence?

- If the risk related to an incorrect decision is high (e.g., people die), more confidence in the inference is required.
- To achieve more confidence in the inference, error must be controlled to a greater extent.
- To reduce error and increase confidence, may collect more increments and/or more mass and include more quality control.
- Note: Can never make a statement with 100% confidence unless you test the entire decision unit.... Then nothing left!

- Probability of an incorrect decision.
- Acceptable global estimation error

+ Relationship among confidence, error & representativeness





Material Properties

Types of materials

Finite or Infinite?

Types of heterogeneity

Compositional and distributional

**GOODSamples:
Guidance On Obtaining
Defensible Samples**



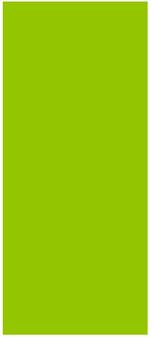
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Types of material elements – finite

- Finite Element Materials: consists of a finite number of discernible elements which can be individually identified and selected at random from the decision unit.





Types of material elements - infinite

- Infinite Element Materials: consists of a practically infinite number of indiscernible elements that cannot be individually identified nor collected individually.



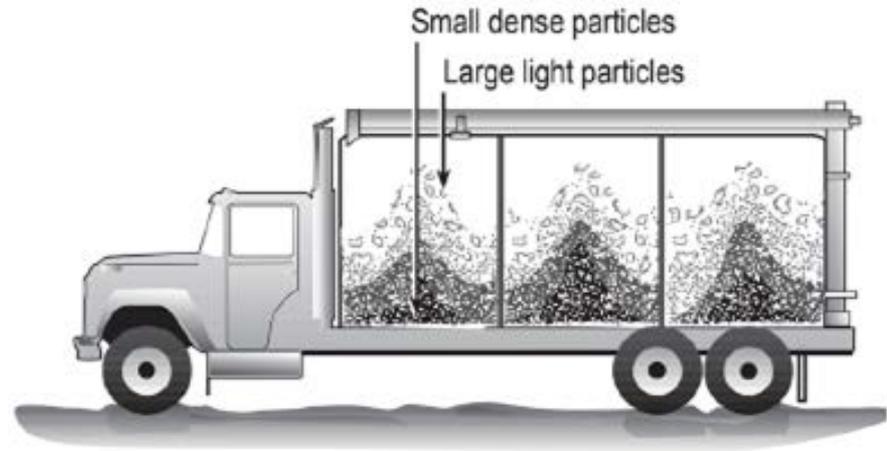
+ Types of heterogeneity



- Compositional heterogeneity: exists when individual elements exhibit differing concentrations of the analyte of interest.

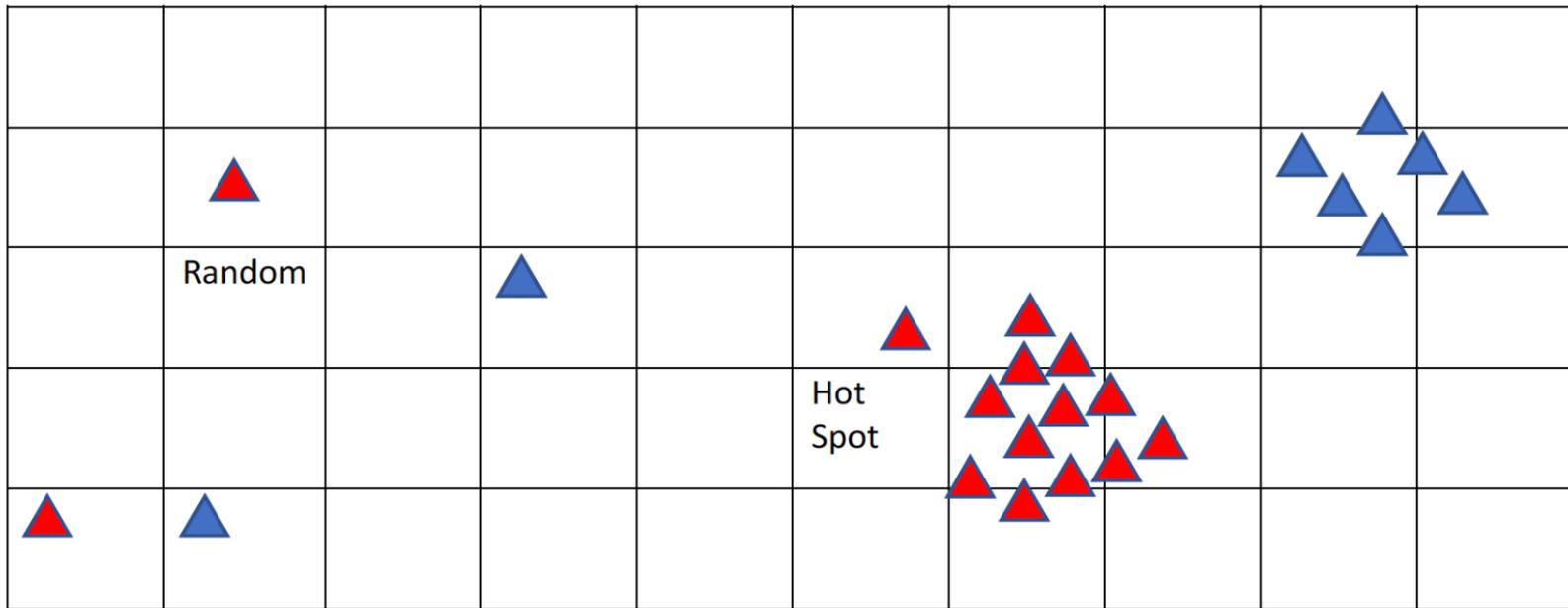
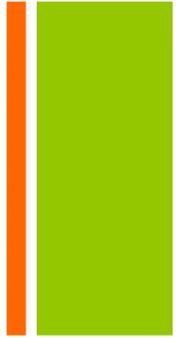


- Distributional heterogeneity: results from non-random distribution of elements.

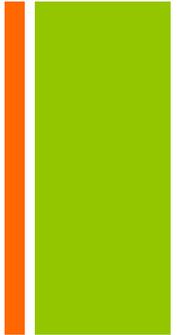




Heterogeneity in pathogen contamination on a surface (both compositional and distributional)



+ Heterogeneity Considerations



- Compositional heterogeneity is a state of nature.
 - CH **cannot** be changed by mixing and moving of the material
 - Compositional heterogeneity can be changed by comminution (crushing, chopping, and grinding) the material
- Distributional heterogeneity is a transient state of nature.
 - DH **can** be changed by mixing and moving the material
 - Distributional heterogeneity is changed every time a material is stirred, blended, poured, piled, etc. It can be increased (harder sampling problem) or decreased (easier sampling problem) during these operations.



GOODSamples: Guidance On Obtaining Defensible Samples



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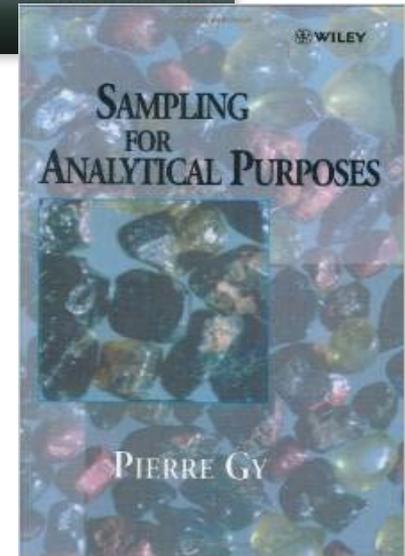
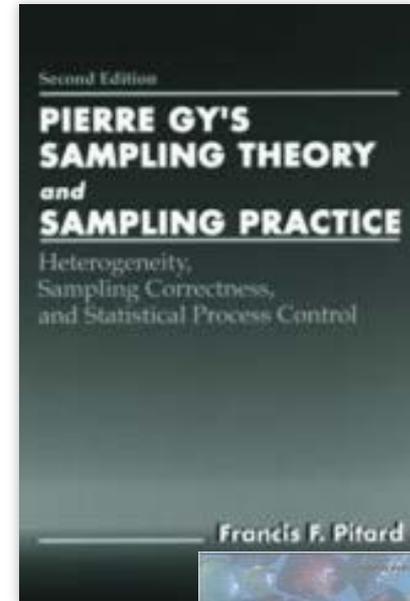
Theory of Sampling

Systematic & scientific process for designing sampling protocols to meet the SQC

Provides techniques for mitigating and estimating error

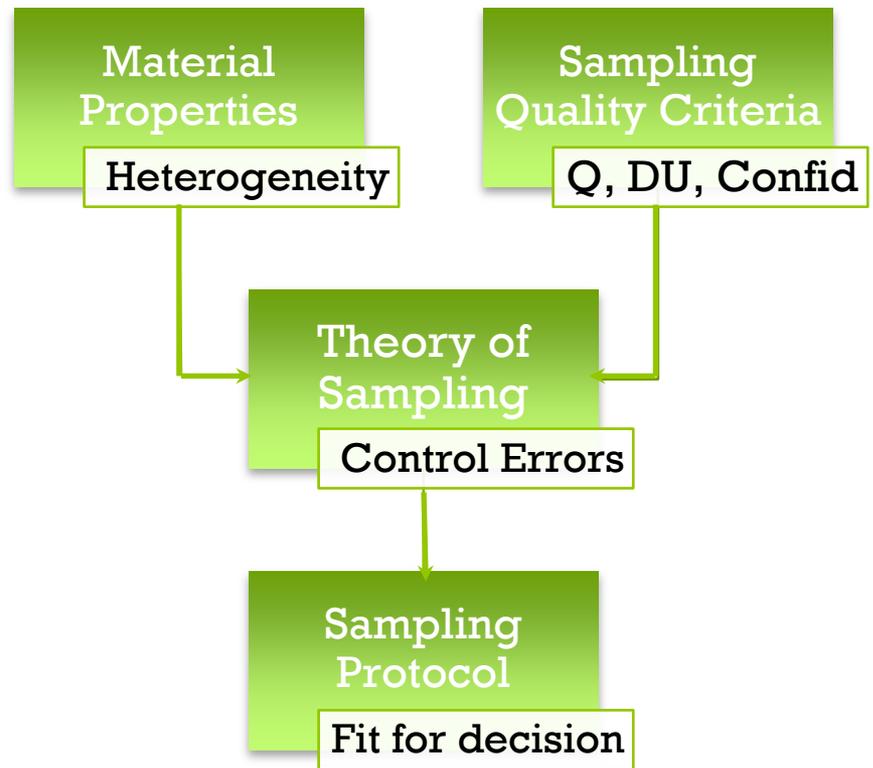
+ Theory of Sampling (TOS)

- Developed by Pierre Gy from the 1950's to the early 2000's
- With finite element material you can use TOS or “classical statistics”
- TOS is essential for infinite element material
 - individual elements that made up the decision unit cannot be individually selected at random—elements are selected in groups, called increments
- TOS describes
 - The final sample mass (combination of all increments)
 - How many increments need to be collected
 - The increment shape (correctness)



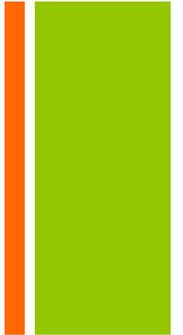
+ Sampling Protocol

- SQC and Material Properties are inputs into TOS to determine the proper sampling protocol





Relationship of error to mass



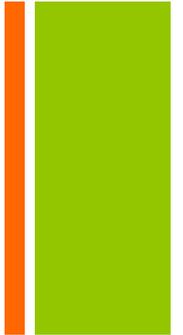
- Presence of Compositional Heterogeneity (CH) leads to the **Fundamental Sampling Error (FSE)**
- FSE is related to: the magnitude of compositional heterogeneity, mass and particle size distribution of the material.

$$s_{FSE}^2 \propto \frac{\text{compositional heterogeneity} * \text{diameter}_{max}^3}{\text{mass}_{sample}}$$

- To control FSE for a given CH, the mass must be increased, the diameter of the particles must be reduced or both. Note: particle size is cubed.



Relationship of error to increments



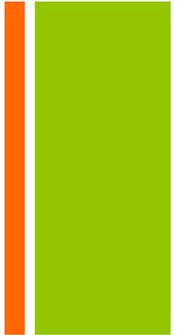
- Presence of Distributional Heterogeneity (DH) leads to the **Grouping and Segregation Error (GSE)**
- GSE is related to: the magnitude of distributional heterogeneity and the number of increments selected.

$$s_{GSE}^2 \propto \frac{\text{distributional heterogeneity}}{\text{number of increments}}$$

- GSE is typically not measured, rather controlled to less than 1/3 of the FSE so it becomes a relatively insignificant source of error. GSE controlled by selecting sufficient increments to reduce until GSE contribution is negligent.
 - increments must be at random
 - increments must be the correct shape
 - 50 increments generally sufficient



Relationship of error to sample correctness



- Control of systematic errors (e.g., **increment delimitation error and increment extraction error**) are collectively referred to as *sample correctness*.
- Sample correctness is a function of
 - properly designed tools and equipment
 - appropriate use of the properly designed tools and equipment
 - **tools and equipment must ensure that all elements have an equiprobable chance of being selected**
- Failure to adhere to principles of sample correctness result in systematic error (bias) that cannot be estimated – therefore critical to adhere to principles



GOODSamples!

Working Group Members
(AAFCO, AFDO, APHL,
FDA)

FREE download:

<http://www.aafco.org/Publications/GOODSamples>

GOODSamples: Guidance On Obtaining Defensible Samples



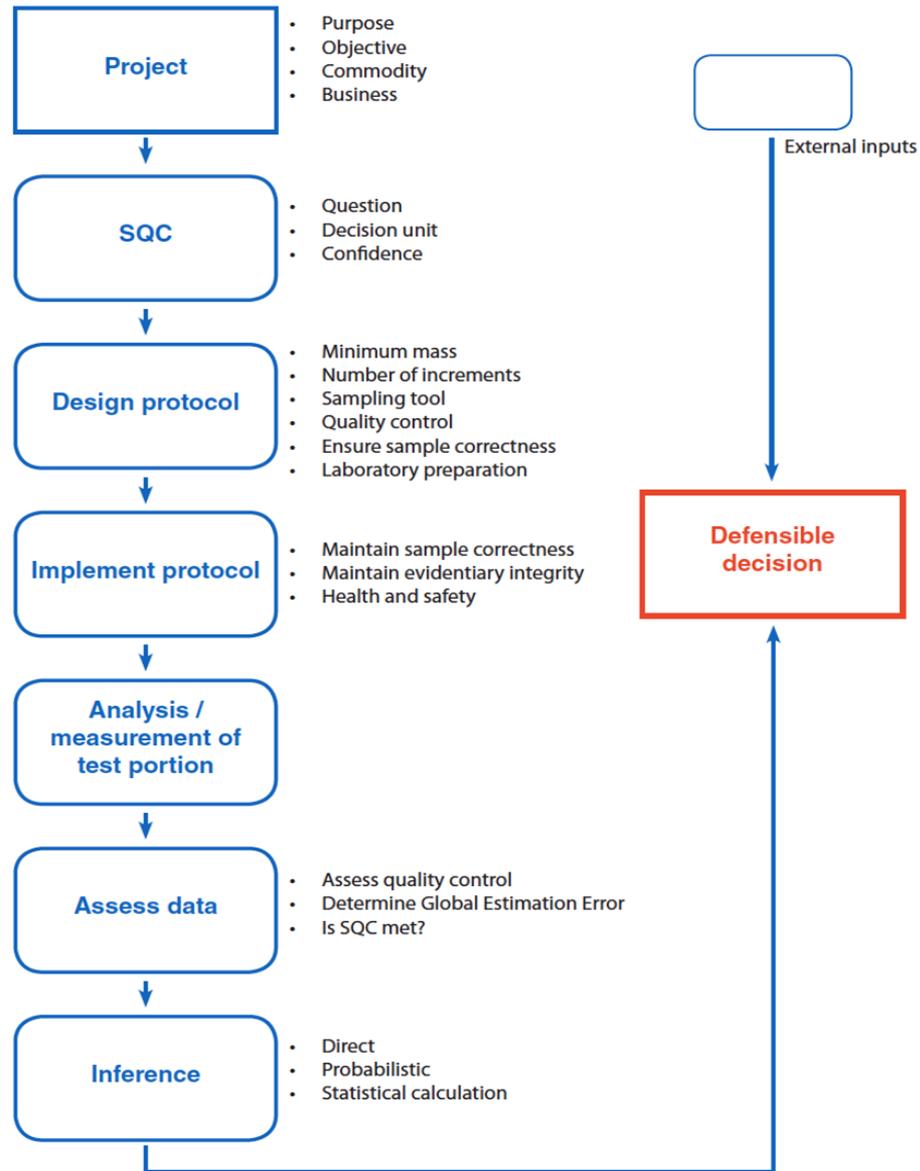
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Sampling and Sample Handling Working Group
FDA, AAFCO, AFDO, APHL, and Industry
October 2015
<http://www.aafco.org/Publications/GOODSamples>

+ GOODSamples

- Pathway to a defensible decision





GOOD Test Portions

FREE download:

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Now also available in French!

GOOD Test Portions: Guidance On Obtaining Defensible Test Portions

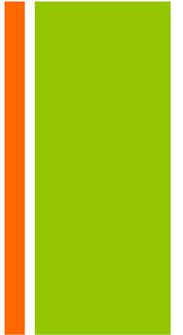


GOOD 
Test Portions

Laboratory Sampling Working Group
AAFCO, AFDO, and APHL
June 2018

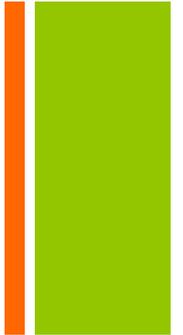
<http://www.aafco.org/Publications/GOODTestPortions>

+ Primary and Laboratory Sampling Protocols – Validation and QC



- Must first understand the source of errors and how to mitigate them to develop fit for purpose protocols.
- Validation of protocols must establish
 - Within the tolerable error (within performance specifications?)
 - Confirm sample correctness (absence of systematic errors)
 - Validate sufficient mass (to control FSE)
 - Validate sufficient number of increments (to control GSE)
- Incorporate Quality Control Checks into laboratory sampling
 - Bias checks
 - Replicates

+ GOODSamples and GOOD Test Portions



- GOODSamples
 - <http://www.aafco.org/Publications/GOODSamples>
- GOOD Test Portions
 - <http://www.aafco.org/Publications/GOODSamples>
 - Go to <http://www.aafco.org>, Publications tab, scroll to Free Manuals





JAOAC Special Guest Editor Section

Open access publications

- Esbensen, K.H. and Paoletti, C. and Thiex, N, *Representative Sampling for Food and Feed Materials: A Critical Need for Food/Feed Safety* (2015) *J. AOAC Int.* **98**, 229–251. http://dx.doi.org/10.5740/jaoacint.SGE_Esbensen_intro
- Kuiper, H. and Paoletti, C., *Food and Feed Safety Assessment: The Importance of Proper Sampling* (2015) *J. AOAC Int.* **98**, 252–258. <http://dx.doi.org/10.5740/jaoacint.15-007>
- Thiex, N, Esbensen, K.H. and Paoletti, C., *Towards a Unified Sampling Terminology: Clarifying Misperceptions* (2015) *J. AOAC Int.* **98**, 259–263. <http://dx.doi.org/10.5740/jaoacint.14-290>
- Ramsey, C., & Wagner, C., *A Systematic Approach to Representative Sampling* (2015) *J. AOAC Int.* **98**, 264. <http://dx.doi.org/10.5740/jaoacint.14-239>
- Ramsey, C., & Wagner, C., *Sample Quality Criteria* (2015) *J. AOAC Int.* **98**, 265–268. <http://dx.doi.org/10.5740/jaoacint.14-247>
- Esbensen, K.H., *Materials Properties: Heterogeneity and Appropriate Sampling Modes* (2015) *J. AOAC Int.* **98**, 269–274. <http://dx.doi.org/10.5740/jaoacint.14-234>
- Wagner, C., & Esbensen, K.H., *Theory of Sampling—Four Critical Success Factors Before Analysis* (2015) *J. AOAC Int.* **98**, 275–281. <http://dx.doi.org/10.5740/jaoacint.14-236>
- Esbensen, K.H., & Ramsey, C., *Quality Control of Sampling Processes—A First Foray; From Field to Test Portion* (2015) *J. AOAC Int.* **98**, 282–287. <http://dx.doi.org/10.5740/jaoacint.14-288>
- Ramsey, C., *Considerations for Inference to Decision Units* (2015) *J. AOAC Int.* **98**, 288–294. <http://dx.doi.org/10.5740/jaoacint.14-292>
- Paoletti, C., and Esbensen, K.H., *Distributional Assumptions in Agricultural Commodities— Development of Fit-for-Decision Sampling Protocols*, (2015) *J. AOAC Int.* **98**, 295–300. <http://dx.doi.org/10.5740/jaoacint.14-250>
- Wagner, C., *Critical Practicalities in Sampling For Mycotoxins in Feed* (2015) *J. AOAC Int.* **98**, 301–308. <http://dx.doi.org/10.5740/jaoacint.14-235>
- Ramsey, C., *Considerations for Sampling Contaminants in Agricultural Soils* (2015) *J. AOAC Int.* **98**, 309–315. <http://dx.doi.org/10.5740/jaoacint.14-268>
- Ramsey, C., *Considerations for Sampling of Water* (2015) *J. AOAC Int.* **98**, 316–320. <http://dx.doi.org/10.5740/jaoacint.14-251>





Resources <https://www.aafco.org/Laboratory>

Laboratory Sampling Resources

GOODSamples or Guidance on Obtaining Defensible Samples

GOOD Test Portions or Guidance on Obtaining Defensible Test Portions

Gy. P. Sampling and Analytical Processes (1988)

Pitard, FF. *Pierre Gy's Sampling Theory and Sampling Practice, Second Edition: Heterogeneity, Sampling Correctness, and Statistical Process Control* (1993) CRC Press, Boca Raton, FL.

Listing of Comminution Equipment

Analytical Results Can Only be as Good as the Test Portion!

Taking and Testing GOODSamples: A Systematic Approach for Representative Sampling from Field to Test Portion. Journal of Regulatory Science, vol. 4, no. 2 (2016). Nancy J Thieux and Charles A Ramsey.

JAOAC Special Section on Sampling

A collection of 13 open access papers (introduction plus 12 manuscripts) published in 2015 serve as an initial effort to create a platform to present critical issues related to sampling of human and animal food products. A listing of the [individual papers with DOI](#) for each is linked.

Journal of Agriculture and Food Chemistry. Lehotay SJ, Cook JM. *Sampling and sample processing in pesticide residue analysis.* 2015 May 13;63(18):4395-404.

Theory and Practice of Sampling for Pesticide Residue Analysis, Jo Marie Cook, Arpad Ambrus, [Food Safety Assessment of Pesticide Residues](#), pp327-403, World Scientific, 2017

TOS Forum

TOS Forum is a free publication for the sampling community, providing a communications platform for all interested in the theory and practice of representative sampling and blending. Papers of particular interest are listed in the [attached file](#).

Information on State Sampling Pilots

1. Florida Department of Agriculture and Consumer Services Sampling Pilot
2. Minnesota Department of Agriculture Sampling Pilot
3. Oregon Department of Agriculture Sampling Pilot
4. Michigan Department of Agriculture and Rural Development Sampling Pilot

Allen, T., & A. A. Kahn. (1970). Critical evaluation of powder sampling procedures. *Chem. Eng.* **238**, 108–112.

Fussell, R. J., Hetmanski, M. T., MacArthur, R., Findlay, D., Smith, F., Ambrus, A., & Brodesser, P. J. (2007a). Measurement Uncertainty Associated with Sample Processing of Oranges and Tomatoes for Pesticide Residue Analysis. *J. Agric. Food Chem.* **55**, 1062–1070.

Fussell, R. J., Addie, K. J., Reynolds, S. L., & Wilson, M. F. (2002). Assessment of the Stability of Pesticides During Cryogenic Sample Processing. 1. Apples. *J. Agric. Food Chem.* **50**, 441–448.

Fussell, R. J., Hetmanski, M. T., Colyer, A., Caldow, M., Smith, F., & Findlay, D. (2007b). Assessment of the Stability of Pesticides During the Cryogenic Processing of Fruits and Vegetables. *Food Addit. Contam.* **24**, 1247–1256.

ISO (International Organization for Standardization). (2012). Animal feeding stuffs—Guidelines for sample preparation. Standard no. 6498. ISO, Geneva, Switzerland.

Maestroni, B., Ghods, A., El-Bidaoui, M., Rathor, N., Jarju, O. P., Ton, T., & Ambrus, A. (2000). Testing the Efficiency and Uncertainty of Sample Processing Using ¹⁴C-Labelled Chlorpyrifos: Part I and Part II. Pages 49–72 in *Principles and Practices of Method Validation*; Fajgelj, A., Ambrus, A., eds. Royal Society of Chemistry, Cambridge, United Kingdom

Peterson, L., Dahl, C. K., & Esbensen, K. H. (2004). Representative mass reduction in sampling—A critical survey of techniques and hardware. *Chemom. Intell. Lab. Syst.* **74**, 95–114.

APHL (Association of Public Health Laboratories). (2017). Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories. APHL, Silver Spring, MD.

FDA (Food and Drug Administration). (XXXX). Investigations Operations Manual. FDA, Washington, DC.

ISO (International Organization for Standardization). (2012). Animal feeding stuffs Guidelines for sample preparation. Standard no. 6498. ISO, Geneva, Switzerland.

Partnership for Food Protection (PFP)-FDA. (XXXX). Human and Animal Food Testing Best Practices Manual (in press).

Leah S Riter, Chad E Wujcik, Novel Two-Stage Fine Milling Enables High-Throughput Determination of Glyosate Residues in Raw Agricultural Commodities (2018) JAOAC 101

Sud Sushant, Kamath Archana. Methods of Size Reduction and Factors Affecting Size Reduction in Pharmaceuticals. *Int. Res. J. Pharm.* 2013 4(8): 57-64.

GOOD
Samples

GOOD
Test Portions

Practical Considerations for the Food Industry

“Bringing Food Safety Across the Globe”

GRAB

FOOD

SAFETY

CONSULTING

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Establishing a Food Microbial Testing Program

- Budget allocation
- Purpose of testing
- Desired Outcome
- Develop microbial testing program
 - ❖ Establish a test plan
 - ❖ Action when an unfavorable result is obtained

Establishing a Food Microbial Testing Program

- Type of sample
 - ❖ Finished product
 - Single unit quantities – e.g. pouch, packets, bottles, etc.
 - Bulk packaging – e.g. super sacks, drums, pails, 50-lb boxes/bags, etc.
 - ❖ In-process material/ingredient
 - ❖ Water
 - ❖ Packaging material
 - ❖ Premiums/Inserts
 - ❖ Environmental samples

Intrinsic Properties of a Material that Can Affect Test Results

- Physical state of material being sampled
 - ❖ Dry
 - ❖ Refrigerated (4°C)
 - ❖ Frozen
- Inherent characteristics of the material
 - ❖ Mucilaginous material
 - ❖ pH of the material
 - Adjust pH of slurry to recommended pH of recovery medium, if necessary; volume of acid or base not to exceed 2% of total volume
 - ❖ pH measurement

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=114.90>
https://2ucloq3z4wn48w1h11mb5302-wpengine.netdna-ssl.com/wp-content/uploads/odb_guide_to_ph_measurement_in_food_v1-0.pdf

"Bringing Food Safety Across the Globe"



Intrinsic Properties of a Material that Can Affect Test Results

- Natural colors/dyes
 - ❖ Annatto – Red, orange or yellow
 - ❖ Spirulina – Green; pH 8-11
 - ❖ Turmeric – Yellow; retains color at pH <7.4
 - ❖ Beet powder – Bluish red (pH 4-5); blue violet (pH > 7)
 - ❖ Cocoa – Light brown (pH 5-8) ; Brownish red (6.8 - 8.1)

Intrinsic Properties of a Material that Can Affect Test Results

- Inhibitory property

Degree of Inhibition	List of Spices
Most Inhibitory (>75%)	Garlic, onion, allspice oregano, thyme, cinnamon, tarragon, cumin, cloves, lemon grass, bay leaf, capsicums, rosemary, marjoram, mustard, *mace, *juniper, *chamomile (English, Roman, German, Hungarian), *lavender, *paprika, *vanilla balm (lemon), *chervil, *chives, *cilantro, *peppermint, *savory, *spearmint, *galangal, *horseradish, *fenugreek seed, *poppy seed, *sesame
Intermediate Inhibition (50% to 75%)	Caraway, mint, sage, fennel, coriander, dill, nutmeg, basil, parsley
Less Inhibition (<50%)	Cardamon, pepper (black/white), ginger, anise seed, celery seed, lemon/lime

**In the absence of other data, the spices which are included in the ASTA list but not in the scientific literature are placed in the "most inhibitory" category.*

<https://www.astaspice.org/food-safety/validation-studies/>

Properties of a Material that Can Affect Test Results

- Type of environmental samples
 - ❖ Food residue – dependent on analyte
 - ❖ Environmental samples
 - Zone 1 : Dependent on the product
 - Zones 2-4 : Use appropriate diluent
 - ❖ Type of diluent in environmental collection device (swabs, spongesicle, sponges, etc.)
 - Avoid use of distilled water
 - Use appropriate diluent
- Segregate food residues and Zone 1 samples from Zone 2-4 samples during shipment.

How Much Lab Sample Should be Submitted for Testing?

- Has the sample collection procedures been established?
- Has proper training on aseptic sampling been provided?
- Does the plant facility have the appropriate sampling tools and shipping containers?
- Is there a unique sample attribute that needs to be communicated to the lab?
- How much lab sample to ship?
- Is there regulatory guidance on how to collect the samples?

How Much Lab Sample Should be Submitted for Testing?

- **How do you define a “lot”?**

FDA – Lot means the food produced during a period of time and identified by an establishment's specific code.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=117&showFR=1>

USDA - has defined a lot as the amount of ground raw beef produced during particular dates and times, following clean up and until the next clean-up (9 CFR 320.1(b)(4)(iii)). In accordance with this definition, the actual size of each lot will depend on the production practices of an official establishment or retail store.

<https://www.fsis.usda.gov/wps/wcm/connect/931c84b3-cc2e-4a10-9108-806bfab661b0/75-16.pdf?MOD=AJPERES>

CFIA - A defined quantity of a commodity (including food animals and livestock carcasses) that has been produced or manufactured under the same basic conditions, and has identified under the same code.

<https://inspection.gc.ca/food-safety-for-industry/compliance-continuum/guidance-for-inspectors/sip/general-principles-of-sampling/eng/1540234969218/1540235089869#a4>

Considerations

- Target analyte
 - ❖ Indicators
 - Plate count method or MPN?
 - Test portion mass/volume (e.g., 25g, 11g, etc.)
 - Frequency
 - ❖ Pathogens
 - Enrichment broth
 - Incubation temperature
 - Test portion - 25g or 375g?
- Appropriate sampling technique – targeted or random sampling?
 - ❖ Pulverize/grind
 - ❖ Blender/ stomacher
 - ❖ Rinsing of test material

Where will testing be performed?

■ Testing Laboratory

❖ Location

- In-house
- Third-party laboratory

❖ Accreditation – ILAC

- Is the method listed in the accreditation certificate?
- Maintain on file current certificate of accreditation

❖ Proficiency result

- Has the method listed in the accreditation certificate included in a testing proficiency program?
- Is the proficiency test provided accredited?

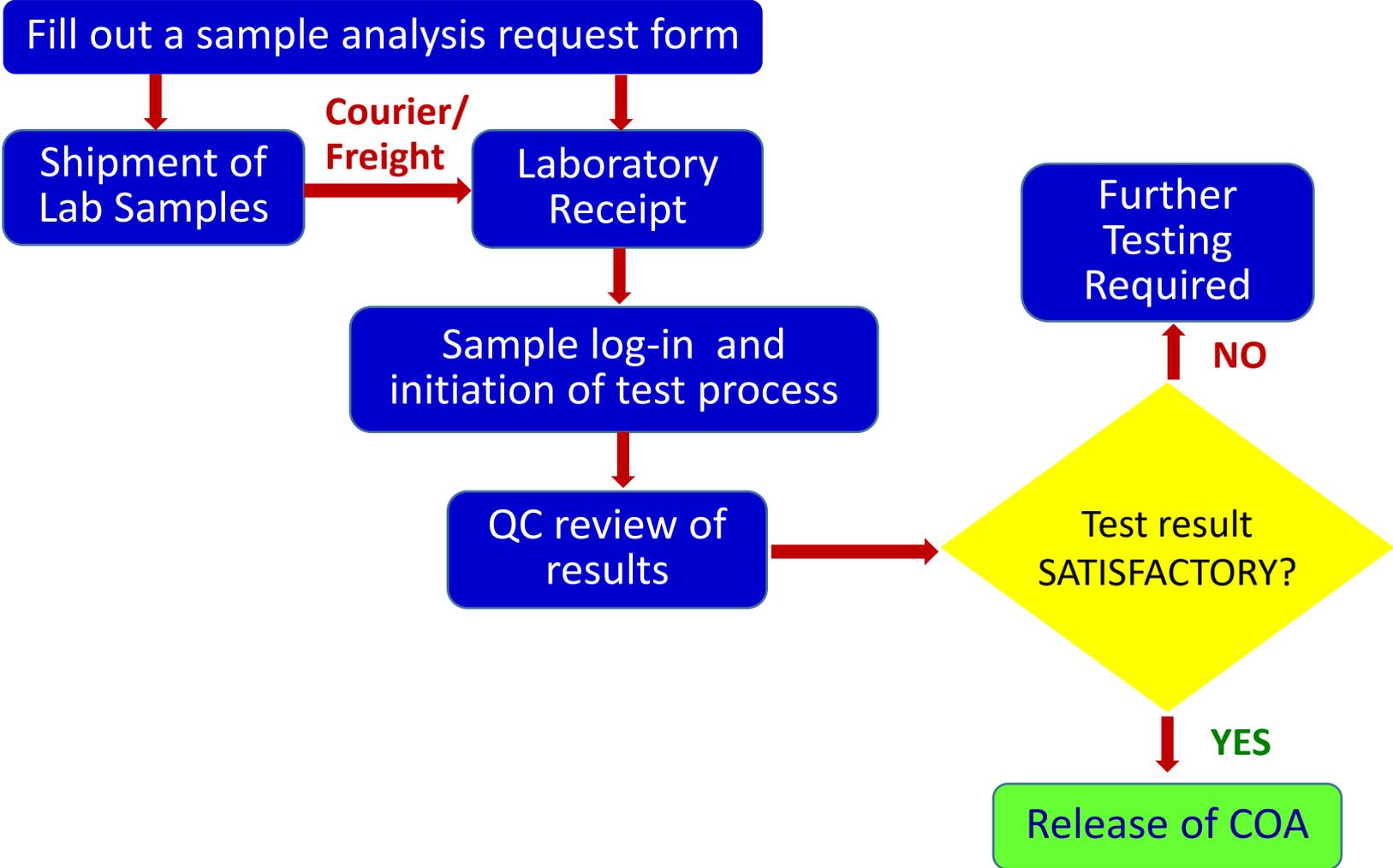
https://www.aplh.org/programs/food_safety/laboratory-accreditation/Documents/Proficiency-Testing-Provider-List.pdf

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Simplified Process for Lab Sample Submissions and Reporting of Results



Which Method to Use?

- Test Method
 - ❖ Has it been validated for the food matrix?
 - ❖ What is the laboratory sample mass?

Bacteriological Analytical Manual (BAM)

<https://www.fda.gov/food/laboratory-methods-food/bacteriological-analytical-manual-bam>

Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds, Edition 3.0

U.S. Food and Drug Administration Foods Program, October 2019

<https://www.fda.gov/media/83812/download>

Official Methods for the Microbiological Analysis of Foods

<https://www.canada.ca/en/health-canada/services/food-nutrition/research-programs-analytical-methods/analytical-methods/compendium-methods/official-methods-microbiological-analysis-foods-compendium-analytical-methods.html>

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Which Method to Use?

Foodborne Pathogen Test Kits Validated by Independent Organizations

FSIS is making available a list of test kits that have been validated for detection of relevant foodborne pathogens (i.e., Salmonella, Campylobacter, Listeria spp. including *L. monocytogenes*, *E. coli* O157:H7 and non-O157 STEC). The list is intended to be informational and is not an endorsement or approval of any specific test kit, regardless of its inclusion in the list. Intended to be informational and are not an endorsement or approval of any particular method, regardless of its inclusion in the list.

FSIS does not specifically endorse any of the mentioned test kits or products and acknowledges that equivalent test kits or products may be available for laboratory use. Likewise, FSIS does not require the use of any specific test kit, including those incorporated into FSIS's Microbiology Laboratory Guidebook methods. Instead, establishments and laboratories should choose test kits that are:

1) Validated for testing relevant foods by a:

- a) Recognized independent body (i.e., AOAC, AFNOR, MicroVal, NordVal),
- b) U.S. regulatory body (i.e., FSIS MLG or FDA BAM), or
- c) International Organization for Standardization (ISO) process

2) In addition, the validated method should be:

- a) Fit for the intended purpose and application (e.g., validated for the appropriate matrix and sample size to detect the appropriate foodborne pathogen), and
- b) Performed per the conditions of the validated protocol by a laboratory that assures the quality of the analytical results.

The table below contains a list of foodborne pathogen test kits that are validated by recognized independent organizations (i.e., AOAC, AFNOR, MicroVal, NordVal) and therefore meet criterion 1a above. However, the test kits in this list are not necessarily equivalent or appropriate for all testing applications.

FSIS intends to update validated test kit lists on a quarterly basis.

#	Method Name	Target Organism(s)	Manufacturer	External Validation	Validated Matrices	Validated Test Portion Size**
S001a	3M™ Molecular Detection Assay Salmonella	Salmonella spp.	3M Health Care	AFNOR # 3M 01/11 - 11/12	All human food products (except spices, aromatic herbs, instant coffees and teas, bouillon cubes/concentrates, milk powders and cocoa powders) and environmental samples (except primary production stage environment)	25g
S001b	3M™ Molecular Detection Assay	Salmonella spp.	3M Food Safety	AOAC-PTM # 031208	Pasteurized liquid whole egg, raw ground beef, cooked breaded chicken, raw shrimp, bagged spinach, wet pet food (375g)	25g except where noted in "Validated Matrices"
S001c	3M™ Molecular Detection Assay (MDA) Salmonella Method	Salmonella spp.	3M Food Safety	AOAC-OMA # 2013.09	Raw ground beef, processed breaded chicken (325g), liquid egg (100g), shrimp, fresh spinach, and wet dog food (375g)	25g except where noted in "Validated Matrices"
S002a	3M™ TECRA™ Salmonella Visual Immunoassay	Salmonella spp.	3M Microbiology	AOAC-OMA # 989.14	All foods	25g

[https://www.fsis.usda.gov/wps/wcm/connect/f97532f4-9c28-4ecc-9aee-0e1e6cde1a89/Validated-Test-Kit-Spreadsheet.pdf?MOD=AJPERES'](https://www.fsis.usda.gov/wps/wcm/connect/f97532f4-9c28-4ecc-9aee-0e1e6cde1a89/Validated-Test-Kit-Spreadsheet.pdf?MOD=AJPERES)

Which Method to Use?

EPA Approved Drinking Water Analytical Methods

<https://www.epa.gov/dwanalyticalmethods/approved-drinking-water-analytical-methods>



AACC Approved Methods of Analysis • 11th Edition

<http://methods.aaccnet.org/toc.aspx>

OFFICIAL ANALYTICAL METHODS
OF THE
AMERICAN SPICE TRADE ASSOCIATION

FOURTH EDITION
1997

AMERICAN SPICE TRADE ASSOCIATION, INC.
WASHINGTON, DC 20038

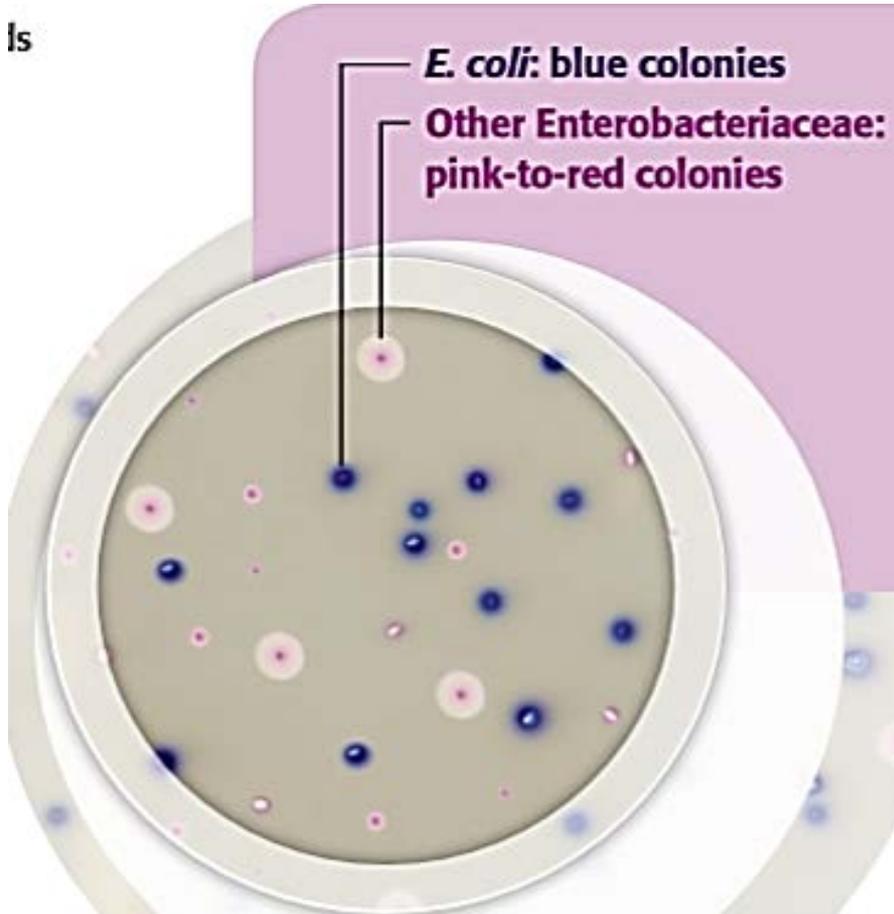
<https://www.astaspice.org/food-safety/astas-analytical-methods-manual/>

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Which Method to Use?

Is



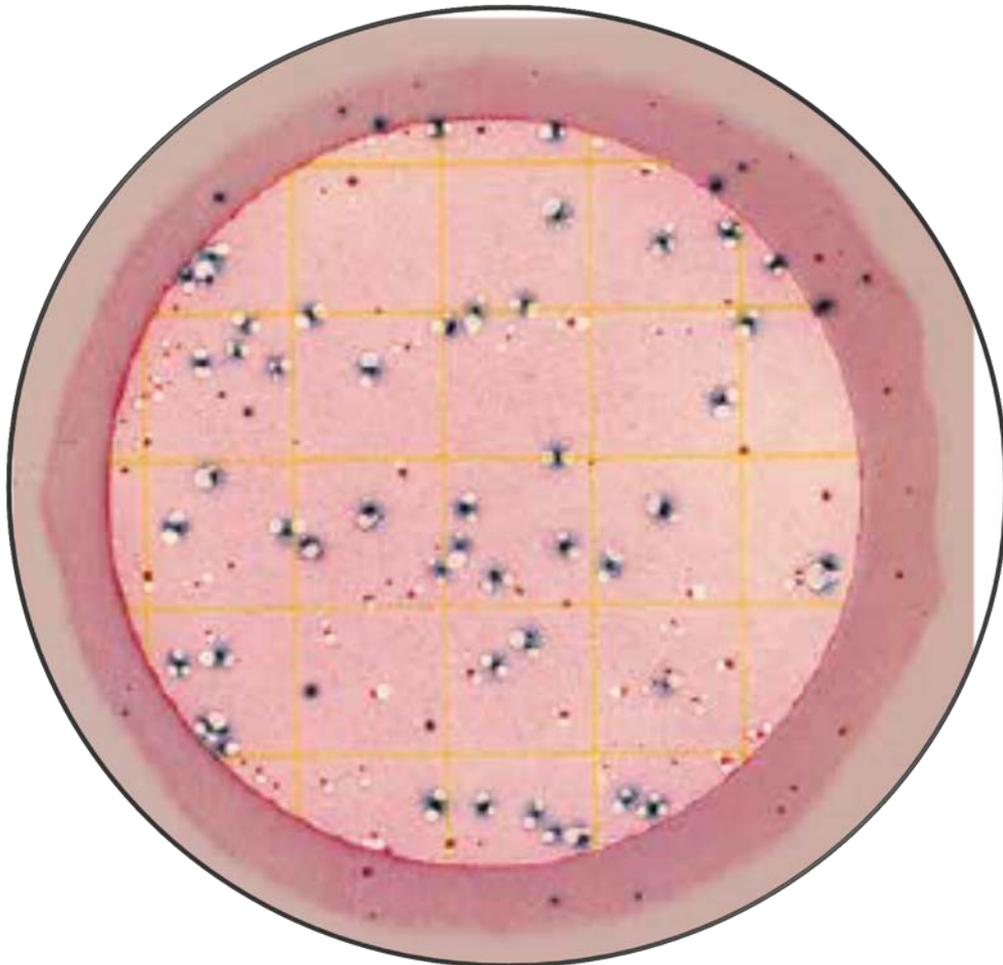
Validated media

- ▣ AFNOR validated following ISO 16140 for both surface-inoculation and pour-plate methods
- Certificate number: AES 10/06-01/08

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Which Method to Use?



- For optimal recovery, adjust pH of the test suspension or slurry to 6.6 – 7.2
- Do not use diluent with citrate, bisulfite, or thiosulfate

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Considerations

- What is the turn around time (TAT) for the method of choice?
- Notification process if the lab sample is compromised
- Notification for out-of-spec results
- What is the lab sample retention time?
- What is the retention time for enrichment broths?
- Does the laboratory use control cultures?
- Can the laboratory perform confirmation testing?
- Does the lab have an environmental monitoring program?
- What is the lab's record retention policy?

What Information Should be on a Certificate of Analysis for Microbial Results?

The report should include the following:

- Title
- Report ID/COA Number
- Laboratory name and location where the test was performed
- Customer name and contact information
- Receipt date
- Test item description
- Test item condition
- Testing date(s)
- Test results and units of measurement
- Clear reference to the method
- Report date
- Identification of person authorizing the test report

Note: If a report must be amended, changed or re-issued, any changed information should be clearly identified and explained and include a statement that clearly indicates that the report is an amendment or correction to “Report ID #XXX (or similar statement). If a new report is issued, should meet all the requirements of the original report as stated above.

Thank you!



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Questions?

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Slides and a recording of this webinar will be available for access by IAFP members at www.foodprotection.org within one week.