# Ingredients and Finished Product

## An Overview of Current Testing Strategies and Technologies

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Wisconsin Association for Food Protection Meeting

November 9, 2016

# Hey Rocky ..Watch me pull a rabbit out of my hat !!!


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# Foodborne Outbreaks 2016

- Good Earth Egg Company Shell Eggs – *Salmonella* Oranienburg
- Beef Products – *E. coli* O157:H7
- Frozen Strawberries – Hepatitis A
- Frozen Scallops – Hepatitis A
- Alfalfa Sprouts – *Salmonella* Reading and *Salmonella* Abony
- Flour – *E. coli* O121 and O26
- Frozen Vegetables – *Listeria monocytogenes*
- Raw Milk – *Listeria monocytogenes*
- Wonderful Pistachios – *Salmonella* Montevideo
- Jack & The Green Sprouts Alfalfa Sprouts – *E. coli* O157
- Alfalfa Sprouts – *Salmonella* Muenchen and *Salmonella* Kentucky
- RAW Meal Organic Shake & Meal Products - *Salmonella* Virchow
- Packaged Salads – *Listeria monocytogenes*

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**“An element of chance enters into every measurement ; hence every set of measurements is inherently a sample of certain more or less unknown conditions.**

**Even in those few instances where we believe that the objective reality being measured is a constant, the measurements of this constant are influenced by chance or unknown causes.”**

**W.A. Shewart**

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# Overview

- The food value chain is complex
- The value chain can be characterized by addressing consistent stages for all product types
- This supply is global and increasingly complex
- Testing can generate in depth knowledge of the products as they move through the supply chain.
- Understanding is created through measurement and in depth data analysis.

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# Overview Cont.

- FDA doesn't "mandate" testing but it gives strong guidance on what needs to be done to verify the safety of food ingredients and additives
- The regulatory climate is changing and FDA's greater enforcement authority through FSMA will help drive testing
- Testing should extend well beyond the regulatory baseline.

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# Programs

- Supplier Certification
- Supplier Verification
- Transportation Audits
- Cold Chain / Warehousing

Systems are built to monitor the quality in these areas. Testing could occur at any of these stages.

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# Where in the Chain Does Testing Occur

- Harvest /Farm – raw material
- Preshipment from primary processor/supplier
- Manufacturer receipt
  - COA
  - Screening and Verification
- Preprocessing
- In process
  - Specification verification
- Finished Product for Release
- Verification
  - Formula
  - Performance

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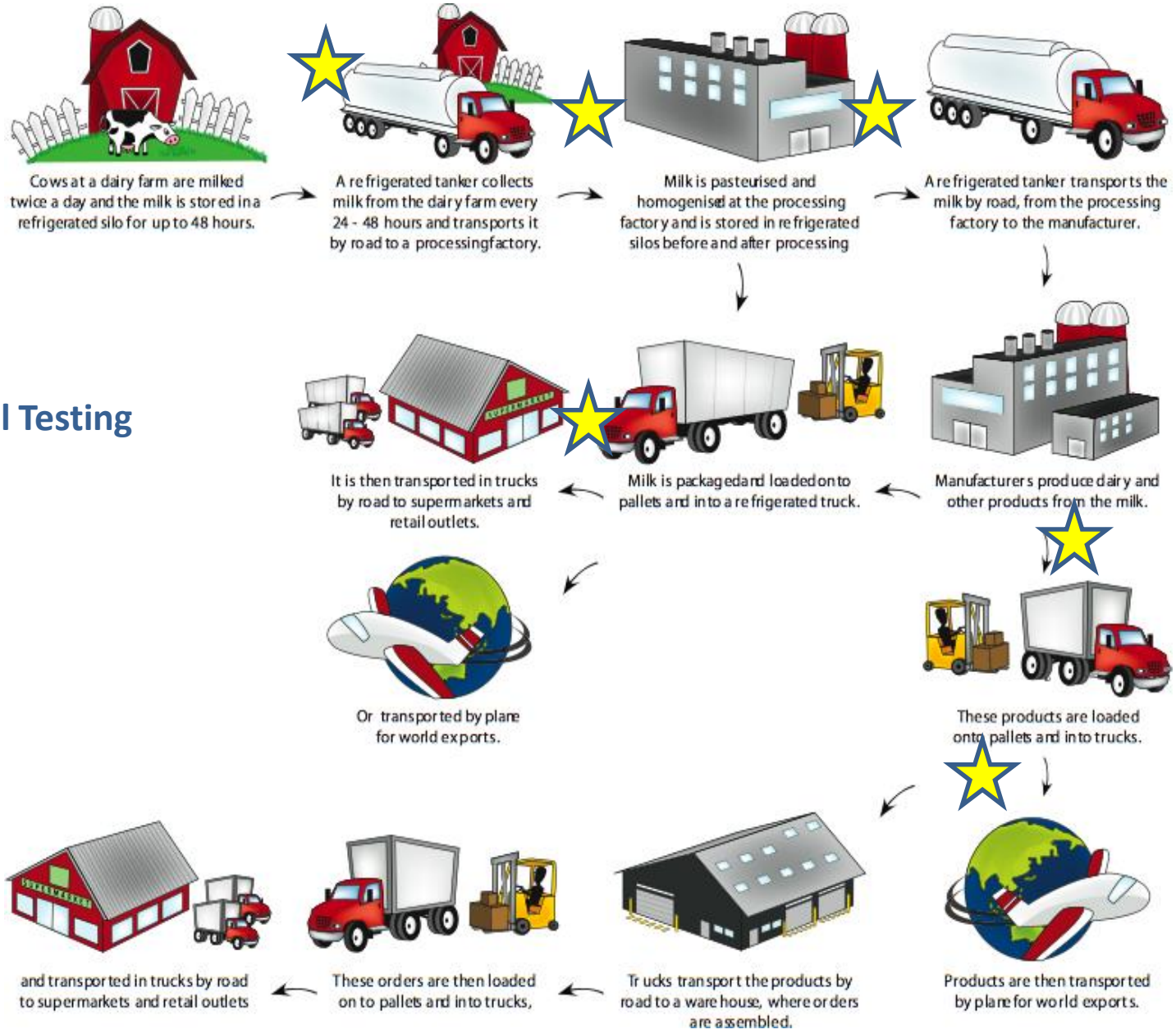
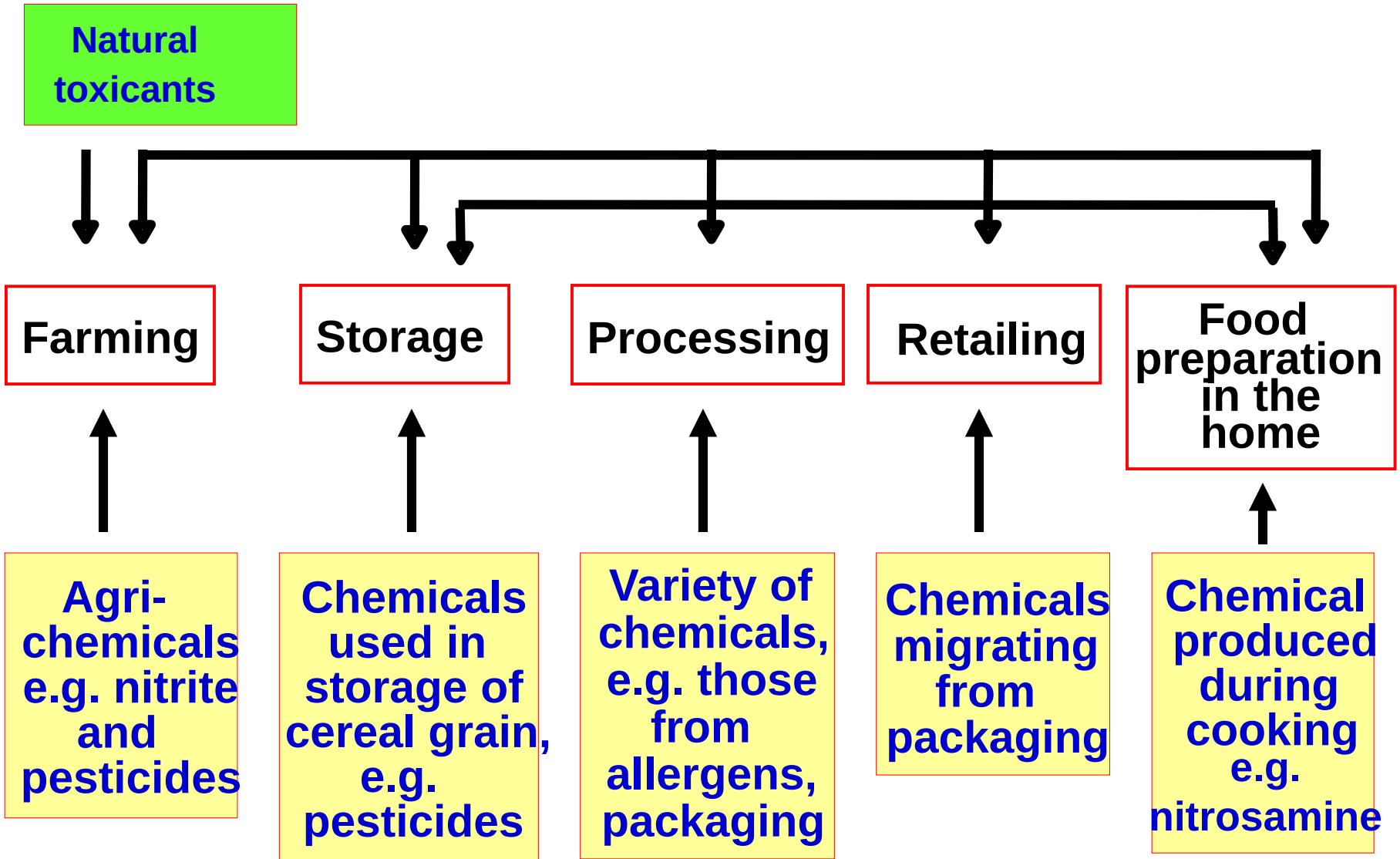
# Dairy Supply Chain Example

rightmoves.tdtvictoria.org.au




## Potential Testing

# Possible Test Points and Chemical Analyte Example



# Specifications

- Required for all components of a food process
  - Ingredients, food stuff , packaging , etc.
- Microbiological
- Used to describe the “product”
- Chemical
- Physical
- All specs should measure
  - Quality
  - Safety
  - Performance

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# How is testing determined ?

- Specification verification drives testing
- Many of the tests are NOT safety related
- Agreements formed between supplier and purchaser often prescribe the test regimens
- Regimens can include physical, chemical and microbiological tests
- Methods for are described in many places by FDA , USDA , AOAC, ISO , etc….

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# Potential Test Frequency

- Determined by risk for safety sensitive ingredients and additives
- Determined by specification
- Determined by purchasing contract
- Determined by company policy
- Determined by regulatory compliance needs
  - Some mandated frequencies (FSIS)

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# Business Challenges

- Do I have enough people to sample ?
- How do I administer the plan ?
- How do I communicate this with suppliers ?
- How much will it cost me ?

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# Challenges

- Performing quantitative risk assessments
  - Criteria development
- Performing economic studies to understand impact
- Conformance to international quality and safety standards
- Development an understanding of material conformance and performance
- Validation and verification of sampling and testing
  - Sample size and accompanying statistics
  - Method development and validation
- Understanding the costs of quality

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# Analysis

- Method Selection and Performance
  - inherent accuracy and precision of the method assuming all procedures are done perfectly
- Analyst Performance
  - training
  - proficiency
- Laboratory Performance
  - quality systems
  - proficiency

# Food Testing Growth Drivers

- Increased consumer awareness
- Significant Regulatory environment
- Food supply globalization
  - Increasing scrutiny of imports and exports
  - New pathogens

- Food microbiology testing expected to grow at 11-14 % CAGR through 2018

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# Selection Criteria

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# What is the test purpose

- **Distinguish good from bad**
  - **Lots**
  - **Pieces**
- **Determine process changes**
- **Determine process approaching control limits**
- **Rate product quality**
- **Understand product performance**

# What is the test purpose ?

- Determine inspection accuracy
- Check precision of the measuring instrument
- Acquire product design information
- Measure process capability

# Selection Criteria

- Measures what it is supposed to measure
- Measurement correlates to a desired outcome
- Results are easily interpreted
- Data is easy to manage

# Situational Assessment

- Assess a problem/situation
- Determine your measurement needs
- Identify critical parameters
- Select measurement tool that gives the best indication of significant change

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# What is Measurement

- 4 scales
  - Nominal , Ordinal, Interval, Ratio
- Relationship to some property
  - Direct or indirect
- Production process
  - Sampling through to Decision making
- Performance characteristics
  - Rugged, Practical, Specific, Reliable

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# Measurement Considerations

- Measurement unit reflects variation
- Consistent over time
- Unbiased
- Characterize product relative to spec limits
- Reflect product that has not been measured

# Measurement Considerations

- Usefulness in process control
- Detects differences in materials
- Technique comparison
- Product information from measurement that can be used to make in depth decisions.

# Statistical performance

- Standard deviation
- Repeatability
- Reproducibility
- Operator bias
- Operator error
- Test bias
- Test error

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# Technical Assessment

# Technical: Food Testing Overview

- Sampling and testing of food is a complex challenge
- There is great diversity in the types of foods that are tested
- The process is virtually the same for all target organisms regardless of detection technology
- 3 categories for screening
  - Quantitative , Semi-Quantitative and Qualitative

- **Challenge – Getting enough target captured to create reliable detection scenarios that deliver results faster than existing methods**

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# Sampling Risks and Hazards

- All sampling plans involve risk
  - Risk of accepting "bad" food:
    - Consumers risk
  - Risk of rejecting "good" food
    - Producers risk
- Two hazard characteristics influence the stringency of the sampling plan
  - Severity of the hazard
  - Whether the normal conditions of handling and preparing the food after sampling will
    - Reduce,
    - Not change, or
    - Increase

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# FDA Guidance on Sampling – BAM Chapter 1

The adequacy and condition of the sample or specimen received for examination are of primary importance. If samples are improperly collected and mishandled or are not representative of the sampled lot, the laboratory results will be meaningless. Because interpretations about a large consignment of food are based on a relatively small sample of the lot, established sampling procedures must be applied uniformly. A representative sample is essential when pathogens or toxins are sparsely distributed within the food or when disposal of a food shipment depends on the demonstrated bacterial content in relation to a legal standard.

- http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm063335.htm

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# FDA Guidance on Sampling – BAM Chapter 1

- In certain instances, it may not be possible to fully conform to the sampling plan. Nonetheless it is still important to ascertain whether or not Salmonella is present in the suspect food. Therefore, the analyst should still try to analyze as many analytical units as is required for the food of interest, i.e., 60 analytical units for Category I foods, 30 analytical units for Category II foods, and 15 analytical units for Category III foods. Individual 25 g analytical units may be combined into 375 g composites as described above unless otherwise indicated in Chapter 5 or the OMA.
- Specific guidance for sampling variances are included in Chapter 1

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# FDA Guidance on Sampling – BAM Chapter 1 cont.

- 100 g for each sample unit
- Sample to an appropriate level
  - As many samples as possible based on the food

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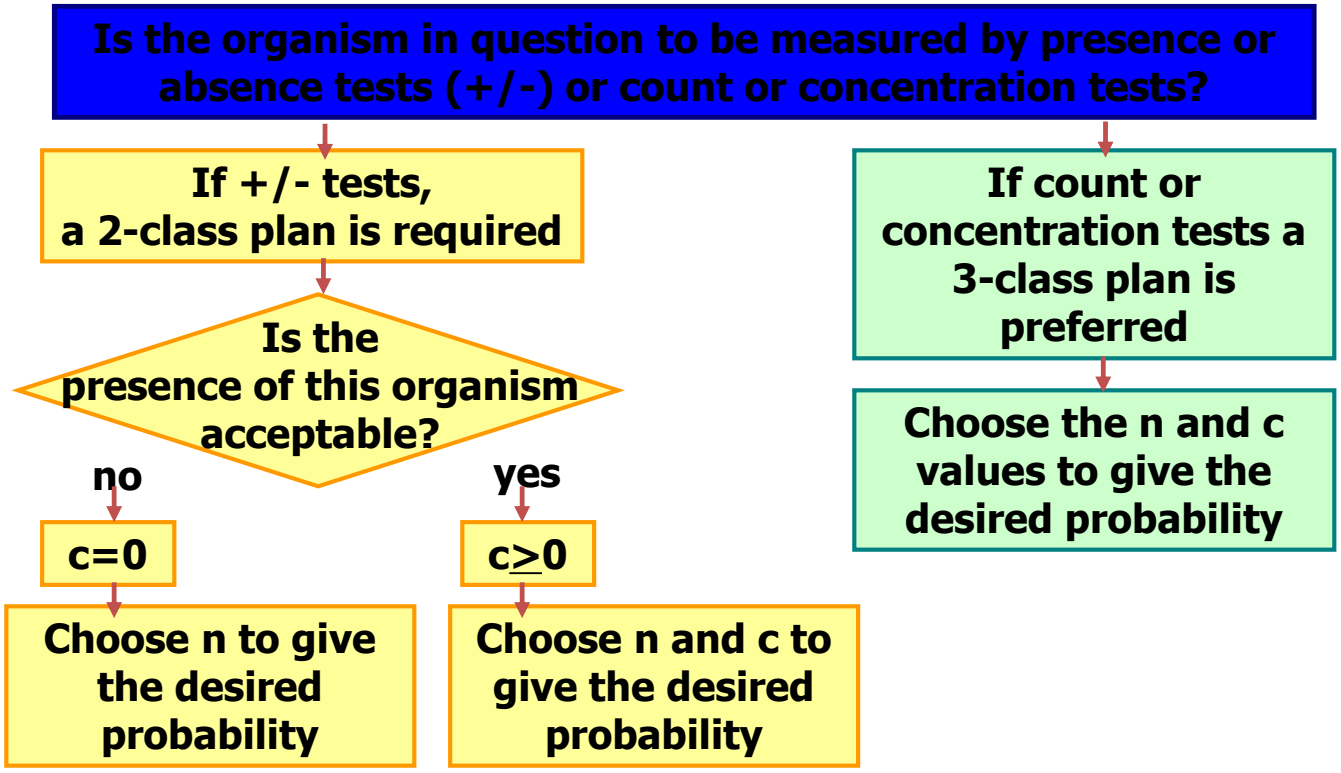
# Choosing a Sampling Plan for a Specific Application

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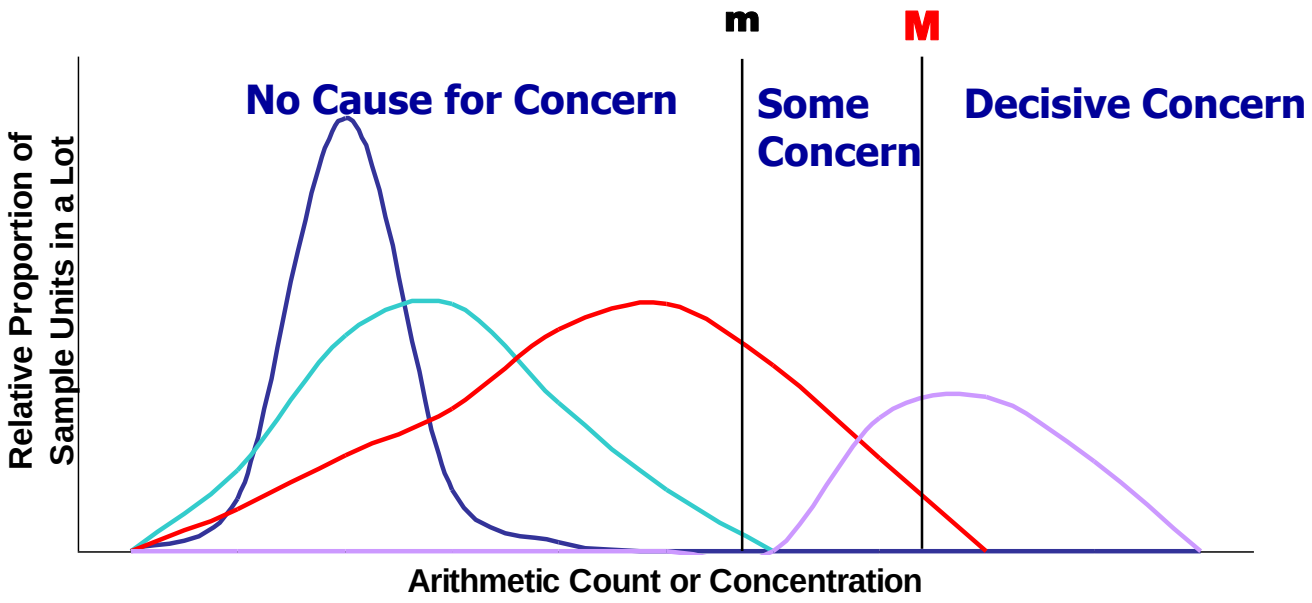
# Quantitative Assessment

## Counting

# Considerations in Choosing m and M

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# Utility and Indicator Testing

Species or groups or microorganisms whose presence may indicate the potential for the presence of pathogens or the extent to which good manufacturing and hygiene practices were adhered to during manufacture

- Examples
  - Aerobic plate count
  - Coliforms or Enterobacteriaceae
  - *Escherichia coli*
  - Yeast and mold count

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# 3 Class Criteria Example

| Analyte | n | c | m | M | Analytical Unit in Grams | Total Analyzed |
|---|---|---|---|---|---|---|
| SPC | 5 | 2 | 1000 | 5000 | 10 | 50 |
| Coliform | 5 | 2 | 10 | 100 | 10 | 50 |
| E. coli | 5 | 2 | | 10 | 10 | 50 |
| Staph | 5 | 2 | 100 | 1000 | 10 | 50 |
| Salmonella | 30 | 0 | | | 25 | 750 |

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# Qualitative Testing

# Challenges of Pathogen Testing

- Performing quantitative risk assessments
  - Criteria development
- Performing economic studies to understand impact
- Conformance to international quality and safety standards
- Development and acceptance of alternative processing / sterilization technologies
- Validation and verification of sampling and testing
  - Sample size and accompanying statistics
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# Where to sample

- Ingredients, Finished Product and Environmental
  - Lot management is important
- Ingredient testing when you do not have an internal kill step is a verification of your supplier's CCP
- Finished product testing is a verification of your CCP.
- Environmental monitoring is a verification of zoning and GMPs

- Testing is not a control point. Testing a raw material without a robust supplier quality program is not sufficient control.
- Testing is appropriate as a verification step. The frequency of verification should be based on knowledge of the process.

# What to look for

- Environmental testing for both indicators and pathogens is appropriate.
  - The target organisms should be determined by the ingredients as well as the processing environment
- Indicator data is more effectively applied if trends are monitored vs. actual target limits
- Finished product testing is not effective when
  - contamination is not homogeneous or
  - low levels of contamination exist
- Ingredients and finished product should be held when testing for pathogens

# What the results may indicate

- Negative results can be misleading
  - Critical to encourage culture of aggressive investigation
  - Avoid internal policies that are disincentive to find and fix
- When a failure occurs, negative finished product results do not provide appropriate assurance to release product
- Careful not to imply that negative results are equivalent to safe product
- See positive results as opportunity to find a problem
  - Continuous improvement vs. blame culture

# Two Hazard Characteristics Influence the Stringency of the Qualitative Sampling Plan

- Severity of the hazard
- Whether the normal conditions of handling and preparing the food after sampling will
  - Reduce,
  - Not change, or
  - Increase

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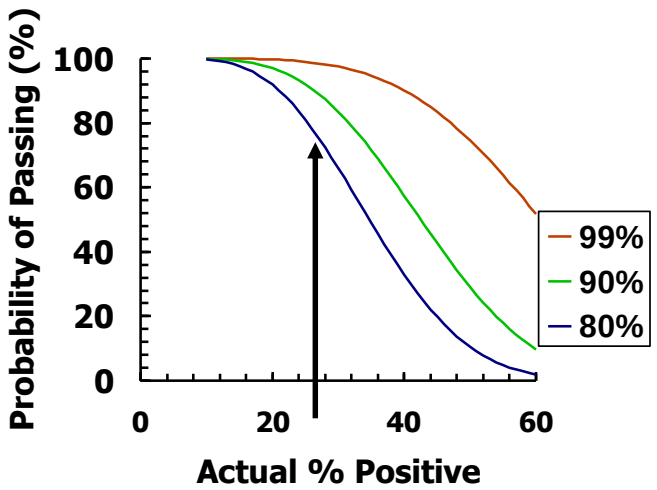
# Setting Stringency

- Set stringency of sampling plan by
  - Number of samples
  - Size of the moving window
- Generate operating characteristics curve

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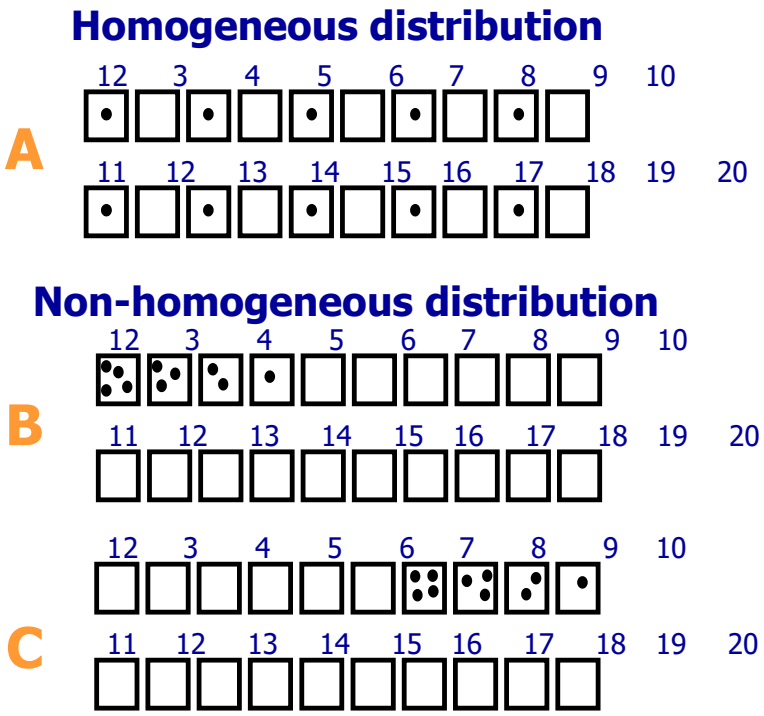
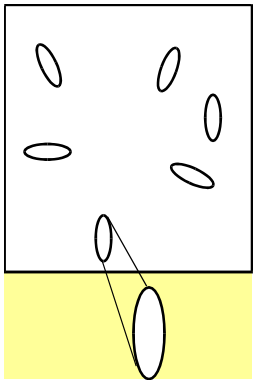
# Distribution of Microorganisms



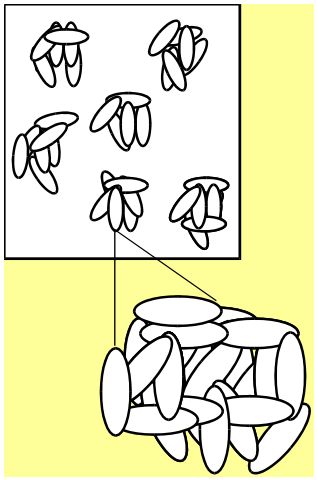
# Incidence vs. Level



**Example A**

**Incidence =**
**6 pos. per 100 x 1 lb. samples**

**Level = 6 cells per 100 lbs.**



**ca. 100 cells /clump**

**Example B**

**Incidence =**
**6 pos. per 100 x 1 lb. samples**

**Level = 600 cells per 100 lbs.**

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# Available Pathogen Detection Tools

- Conventional
- Differential
- Immunoassay
  - Antibody
  - Phage
  - Phage Protein
- Molecular
  - PCR
  - TMA
  - Sequencing and Subtyping ( WGS , 16s, GSS)
- Chemical

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# Our Challenges – Paradigm Shifts

- For microbiologists to accept new technologies we must do several things
- Understand that Koch was “kind of right”
  - Is the presence or absence of an organism an indication of a true result
- Understand different measurement standards
  - Current methods “confirmed” by phenotypic expression
  - Expression of target measurement – copies or concentration of target
- Understand that we must return to our “chemist” roots
  - These are chemistry tests
- Understand how this affects your business decisions
  - Specifications
- Understand possible regulatory effect

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# Summary

- Testing is necessary to understand the condition of a material.
- Safety is a base testing requirement. We assume
- Companies can create significant value by measuring more than safety attributes
- Higher levels understanding comes from focused testing regimens

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# Summary

- Economic factors must be evaluated along with technical merit
- Validations and verifications are a key part of the testing process
- Quality systems must be in place to monitor changes in the system
- There is no perfect method !

# Summary

- Methods need to be chosen that deliver the most reliable , relevant and cost effective information to a process

- Rigorous but relatively simple ,statistically valid protocols can be developed and run

# References


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- FDA Bacteriological Manual
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# Thank You !!

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