Sampling with a Purpose

Defining a sampling program

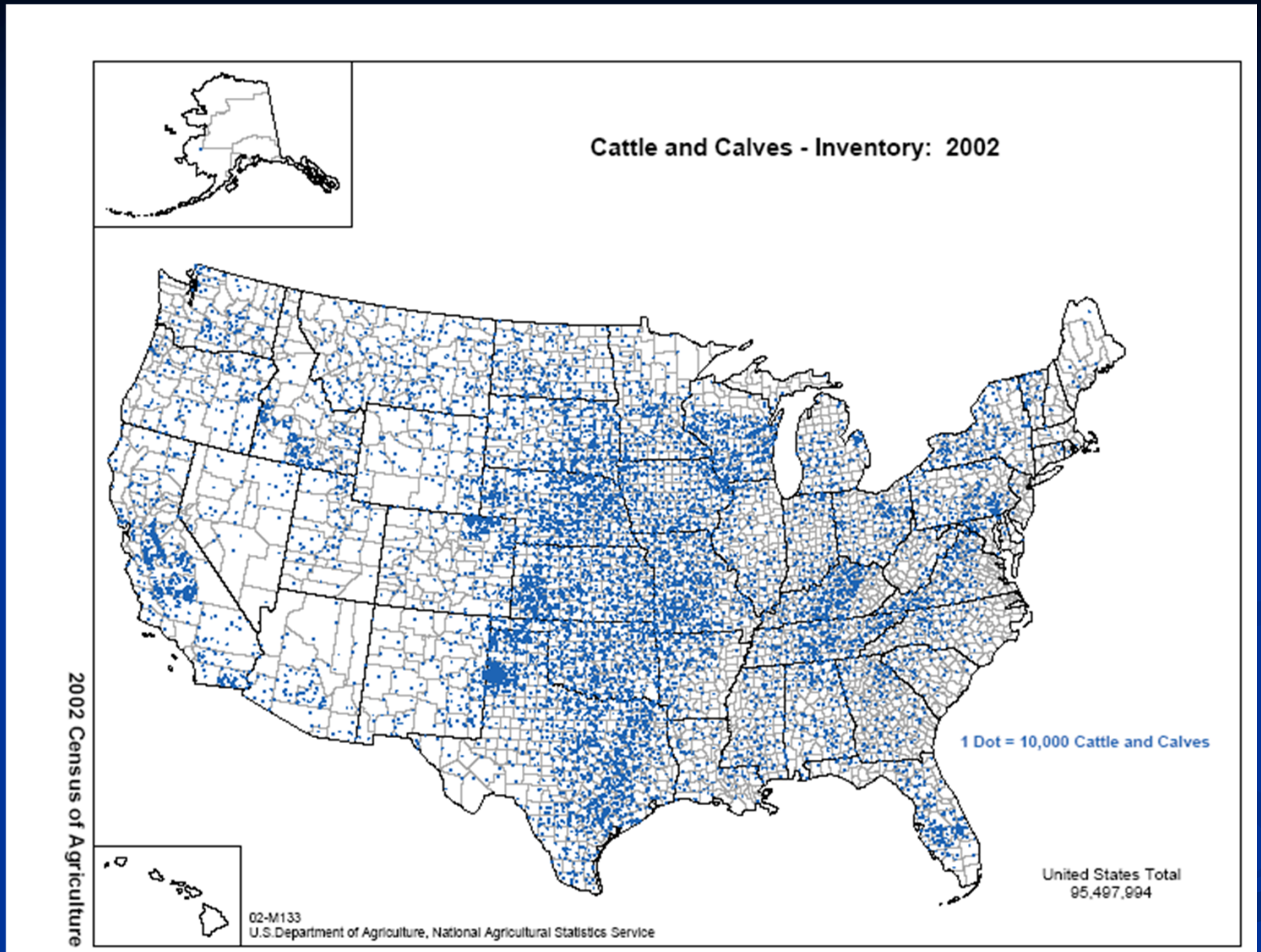
Jose Emilio Esteban, DVM, MBA, MPVM, PhD
Scientific Advisor for Laboratory Services, FSIS

Designing a Surveillance/Monitoring System

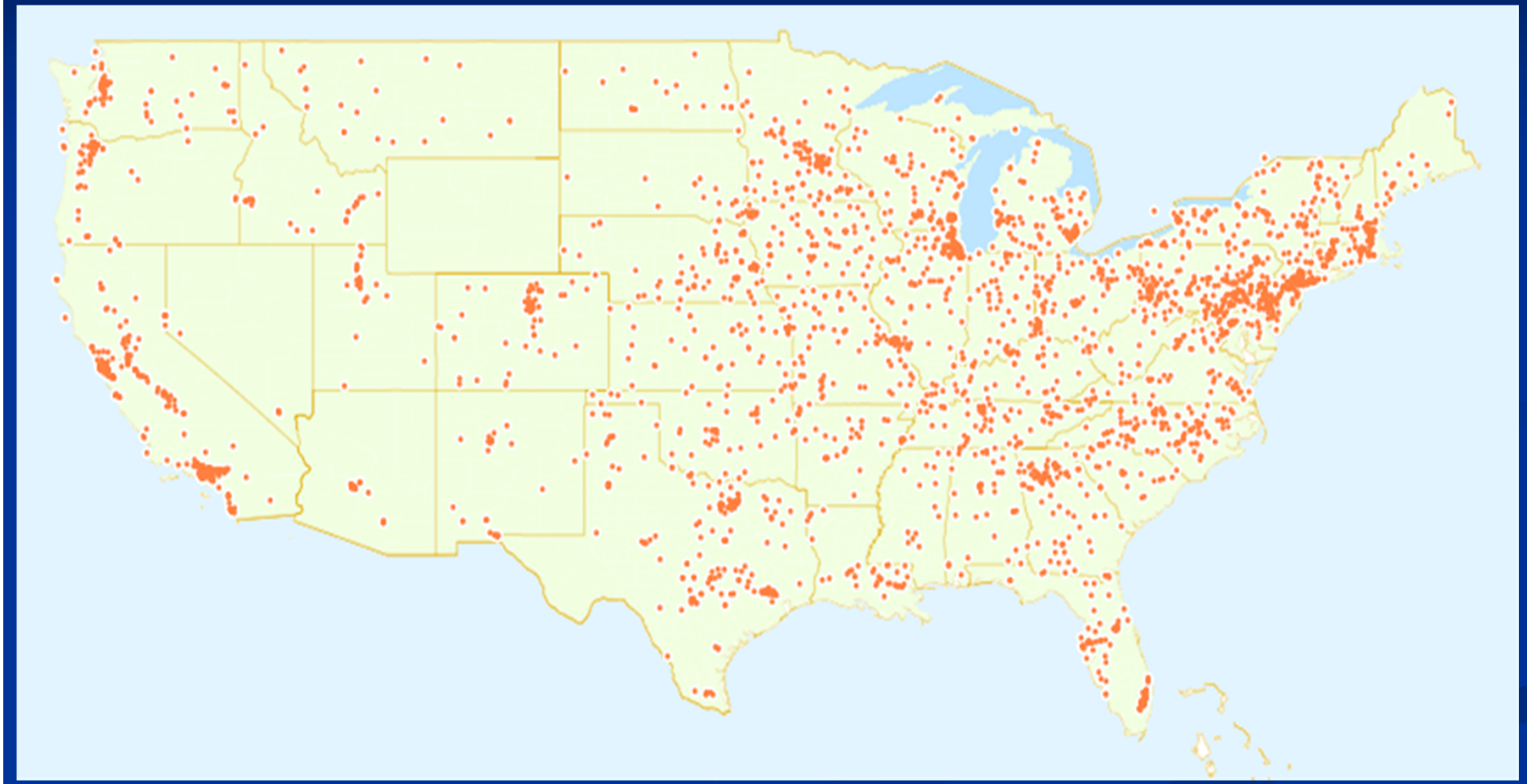
- Purpose
  - Information
    - To demonstrate HACCP system is working
  - Enforcement
    - To demonstrate compliance with statutes
  - "For cause"
    - As a follow up to previous failure
- Active or passive -- active
- Target for surveillance – RTE, HACCP, Residue
- Representative -- ?

Uncertainties

- Plant
  - location, size, intervention, shift, line, item
- Substrate
  - product, component, environment
- Technique
  - single, subs, composite
- Method
  - screen, determinative, confirmatory


Cattle and Calves - Inventory: 2002
1 Dot = 10,000 Cattle and Calves
United States Total
95,497,994
02-M133
U.S.Department of Agriculture, National Agricultural Statistics Service
2002 Census of Agriculture

Beef Plants



Distributing Resources

- Farms
- Slaughter plants or components
- **Grinder**
- **Processing plant**
- **Distributor**
- Retailer
- Consumer

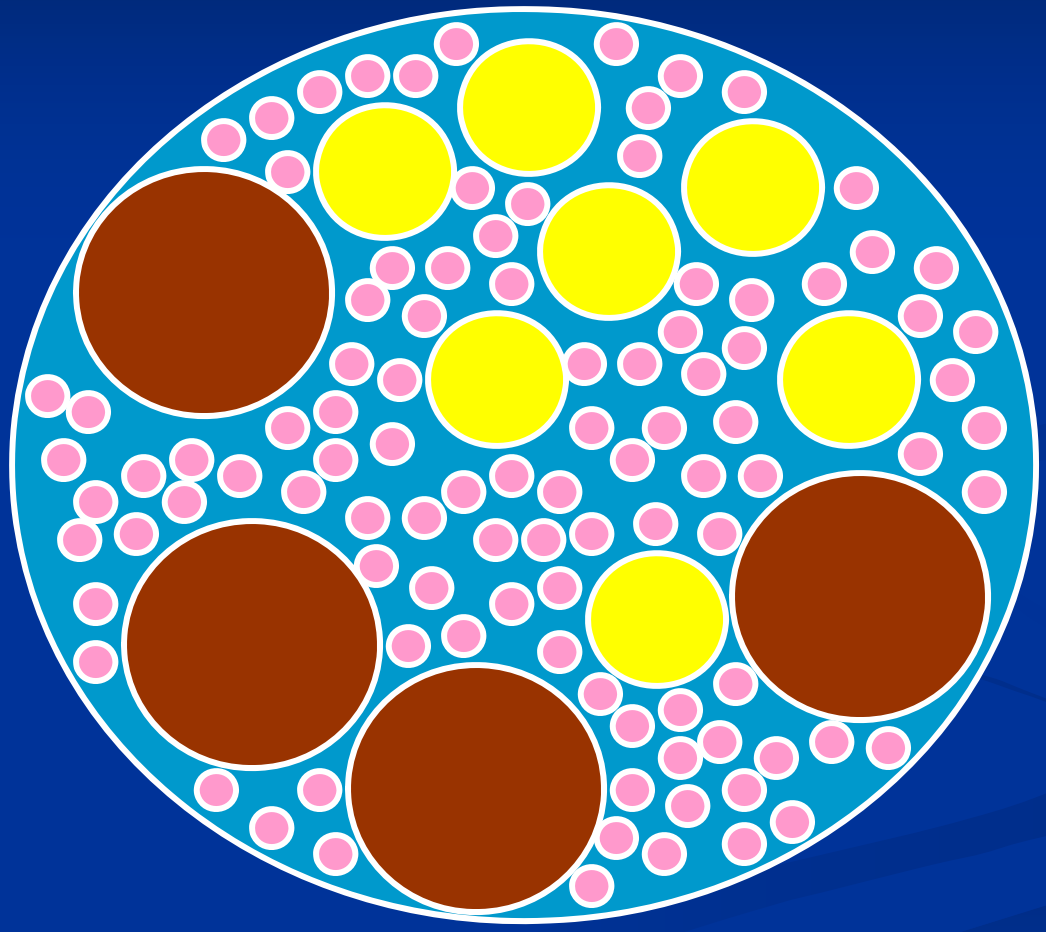
Representative

- Impossible to test all food produced or imported into the US.
- **Verification testing** works
  - Industry (GAP, GMP)
  - Consumer (cooking and handling properly)
  - Government (HACCP, outcome monitoring)
- Outcome feedback
  - Detection
  - Corrective Actions

Where should we sample?

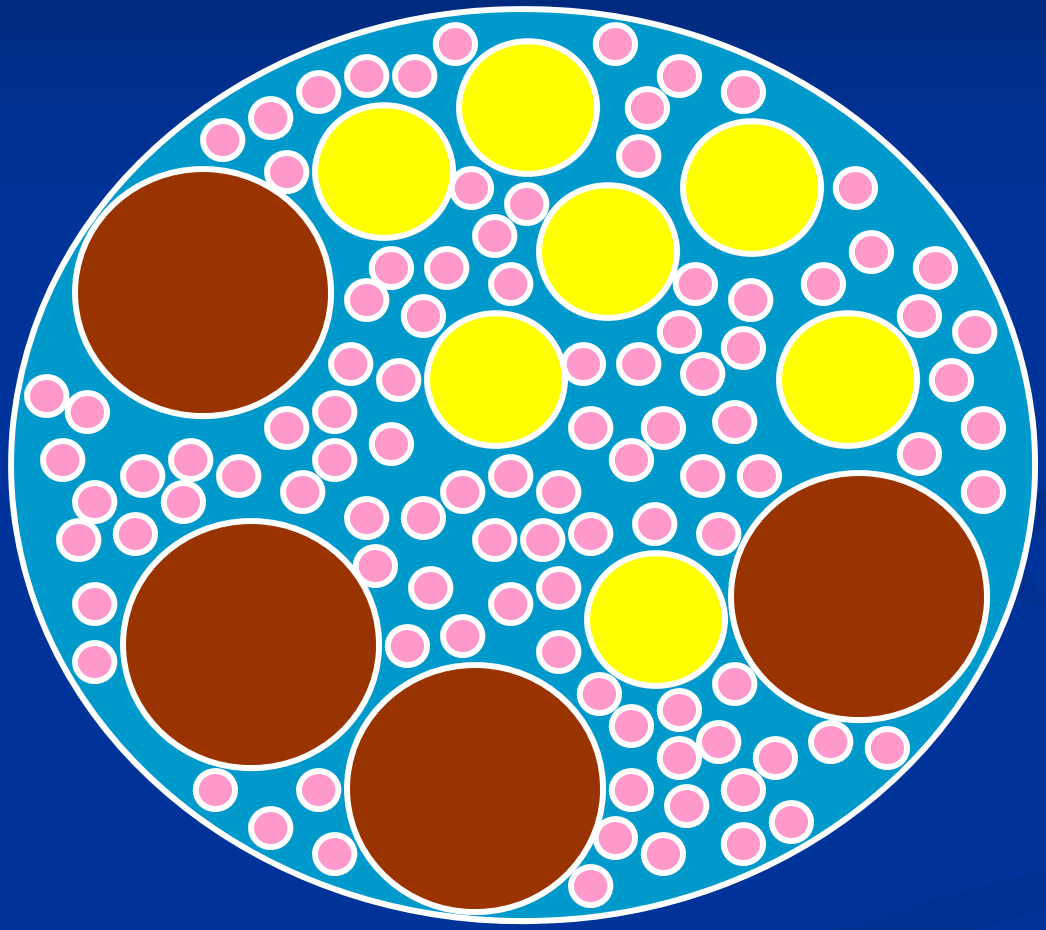
- Sample all plants that manufacture or process a product
- Sample a subset of plants
  - Plant size (production volume)
  - Type of product
  - Type of preventive intervention
  - Prior results
- Random sampling
- Weighted random sampling
- Risk-based sampling
- Combination

Sampling Example



Where

Random



- Define a goal:

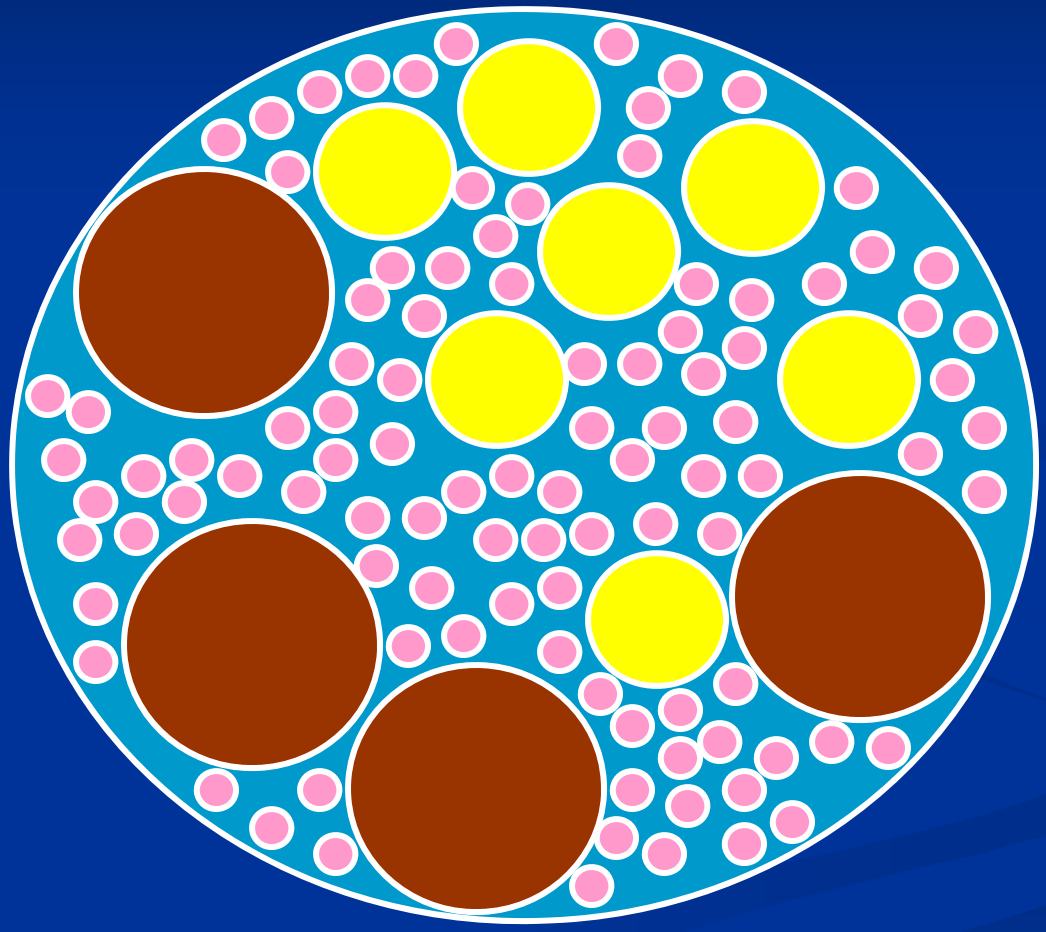
  Detect a 1% failure rate with a 95% certainty.

- Limit by analytical capacity
- Sample without replacement
- True luck of the draw

- Every plant has equal chance of being selected

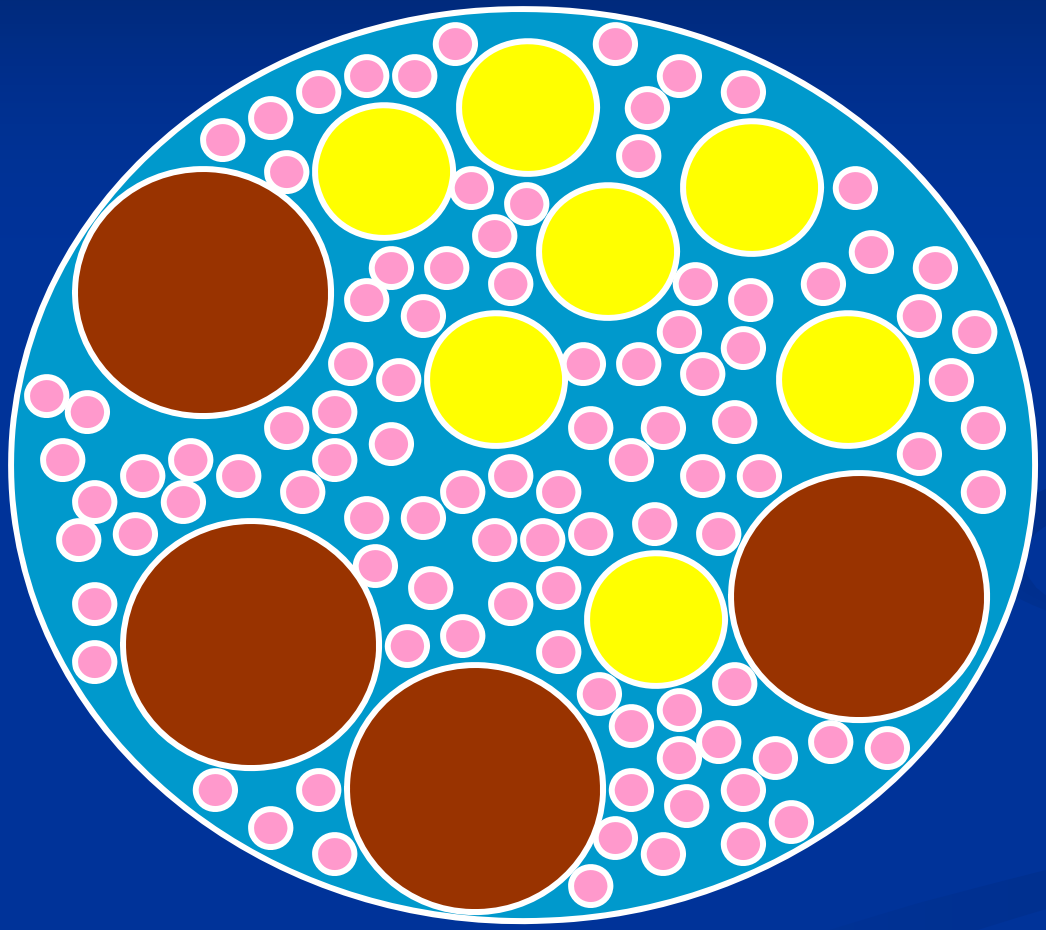
Where

Sampling Example



Where

Weighted Random



- Define a goal:
  Detect a 1% failure rate with a 95% certainty.

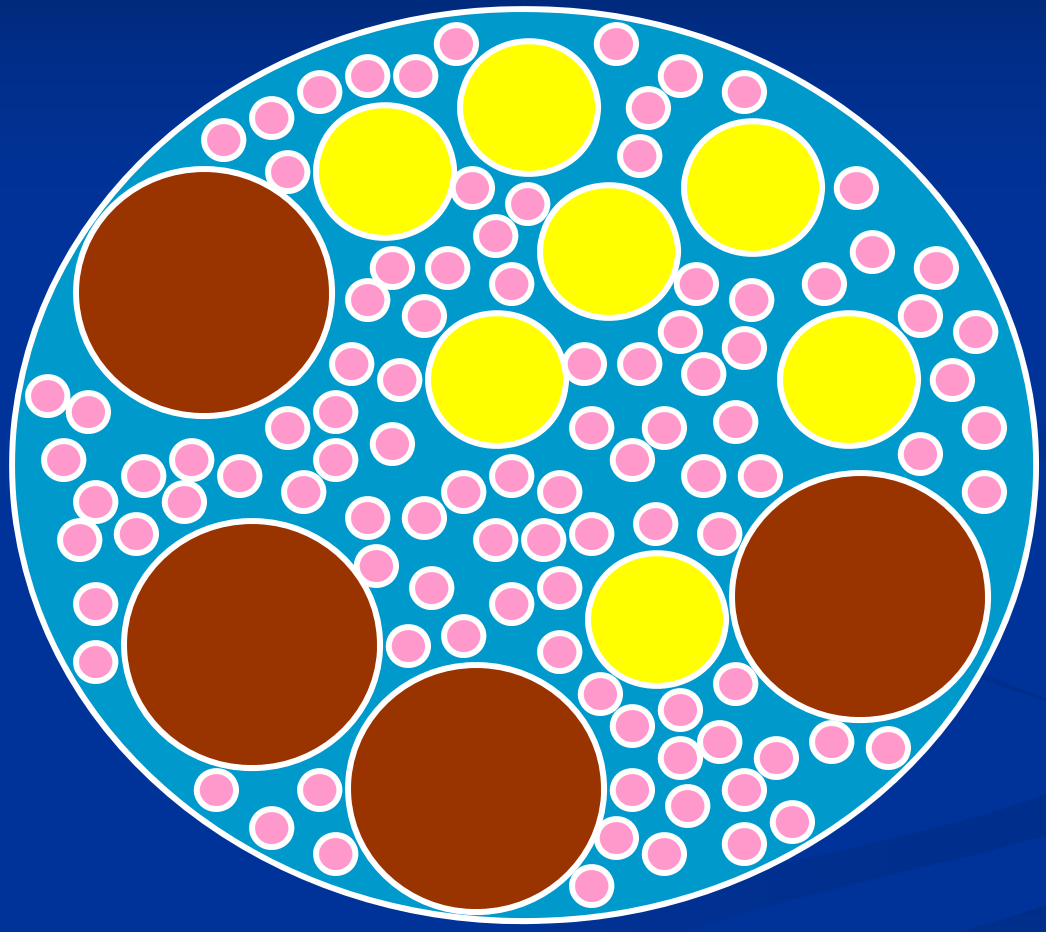
- Limit by analytical capacity
- Sample without replacement
- Assign different weight according to plant size

- Baseline

- The random selection is within a plant size so that we guarantee to have plants from all sizes included in equal numbers.

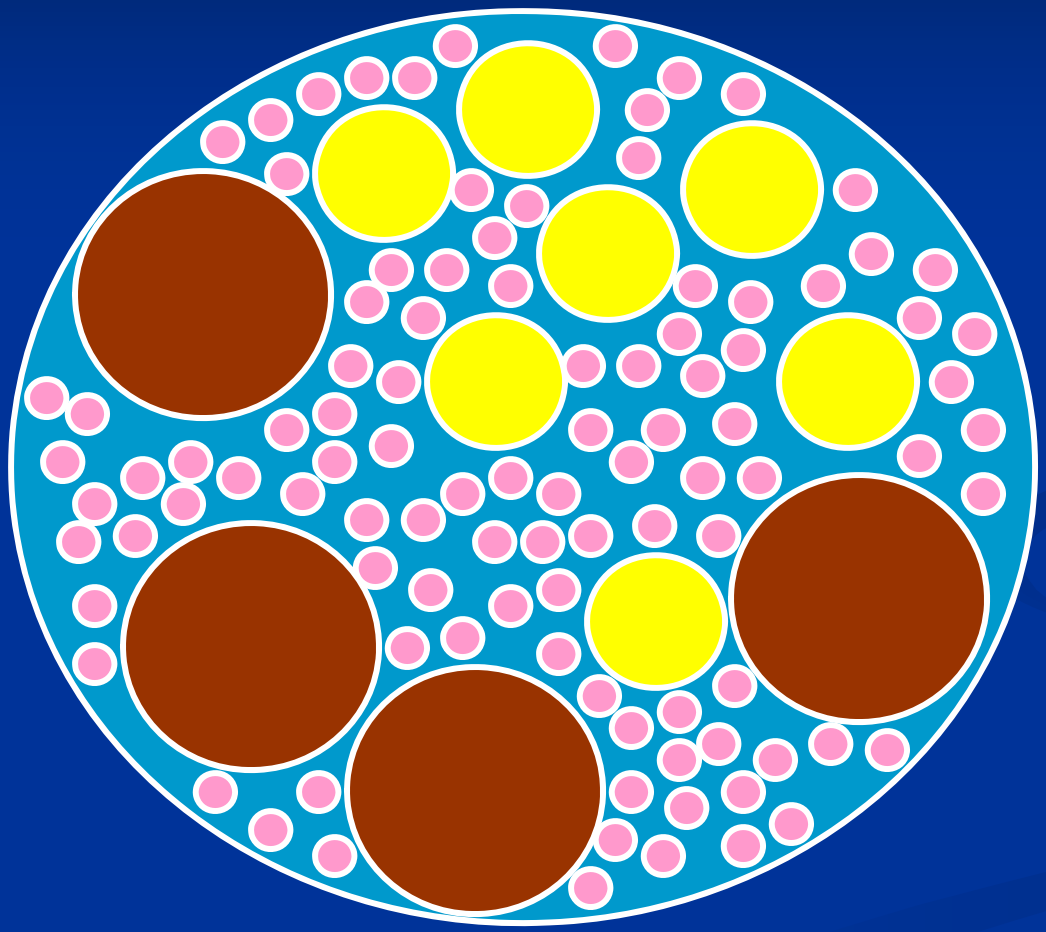
Where

Sampling Example



Where

Risk-Adjusted Weighted Random



- Define a goal
  - Risk driven
- Limit by analytical capacity
- Sample without replacement
- Assign different weight according to plant size
- Assign a weight to plants with prior positive results

- The random selection is within a risk category and plant size so that we guarantee to have plants that present the highest risk.

Where

What do we sample?

- Live animals
- Food component
- Raw product
- Manufactured product
- Food-contact surfaces
- Environment

What

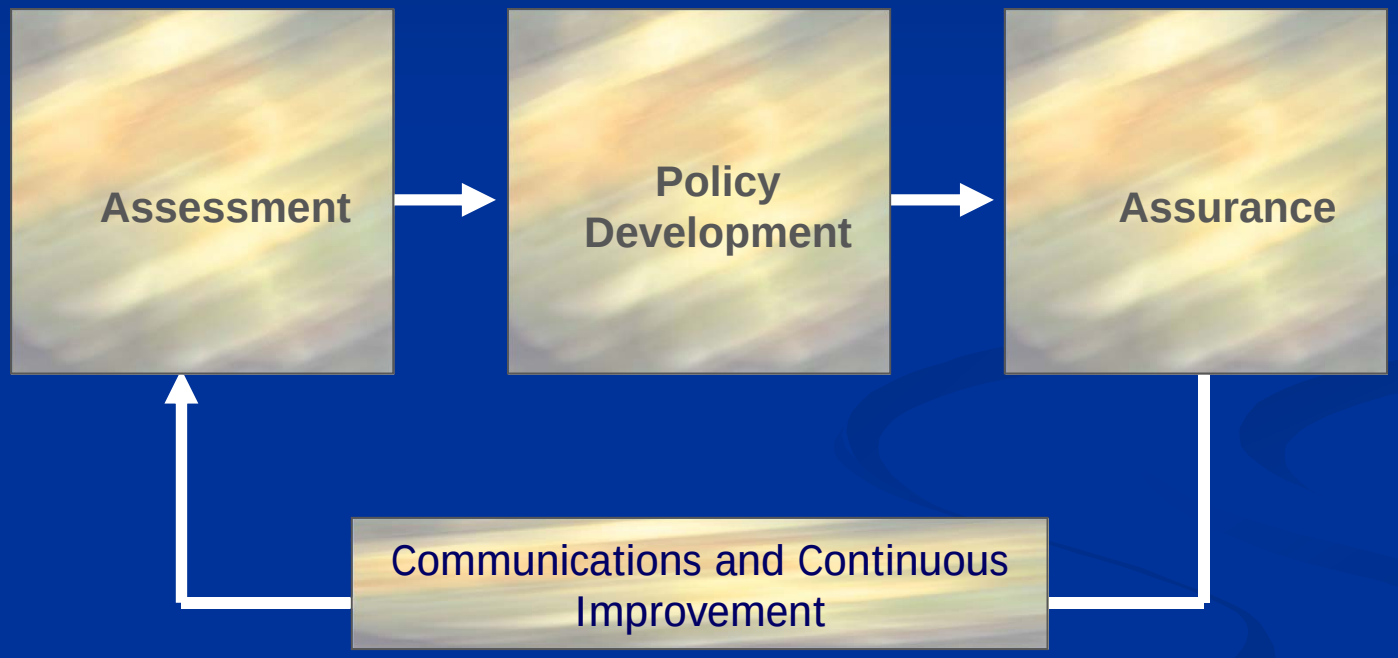
Listeria monocytogenes Sampling Model

- Six sampling approaches
- 25,000 samples
- Random, Risk-based, follow up
- Listeria monocytogenes in processed products
  - Individual final product samples
  - 13,000 samples
  - Sample sets RLm (baseline), IVT (follow up)
    - 80 + ~~ IVT
    - Sample sets RLm (baseline) ~~ complete in 4 years
    - IVT ~~ target within 30 days

Listeria monocytogenes sampling programs

- Product sampling plan
  - Random sampling (ALLRTE) ~ 3000 → 0.6%
  - Risk-Weighted random sampling (RTE001) ~ 9000 → 0.5%
- Environmental sampling plan
  - Risk ranking sampling (RLm) ~ 20 sets/mo
    - Product ~ 0.3%
    - Contact surface ~ 0.6%
    - Environment ~ 1.5%
- Consequential sampling plan
  - Biased by prior results (IVT) ~ variable
    - Product ~ 2.9%
    - Contact surface ~ 1.5%
    - Environment ~ 5.2%

Public Health Model



Application of PH Model

- Hazard Identification
  - Select plant
  - Select line/shift
  - Select lot
  - Product type
- Laboratory result uncertainty
- Exposure Assessment
- Estimate of population exposure
- Outcome estimate (public health partners)

Laboratory Sample Result Uncertainty

- What portion of the sample do we select?*
  - 25g
  - 13 – 25 g samples
- Screen ~ 90%
- Pathogen isolation ~ 100%
- Genetic confirmation
- Quantitative assessment (MPN) ~ currently defining

flow

Assurance

- Monitoring results evaluated
- Actions taken
  - Positive reinforcement
    - Increased line speed or less Agency testing
  - Negative reinforcement
    - Nonconformance incident report
    - Corrective action
    - Enhanced testing
  - Suspension of inspection

Application of PH Model

- Define purpose of sampling
- Select appropriate sampling methodology
- Define the sample prep procedure
- Apply method
- Laboratory result
- Establishment data
  - Compare similar plants to each other (product, size, preventive intervention)
  - Document effectiveness of a particular intervention strategy
  - Communicate with shareholders
- Outcome data
- Policy revision


RUSH


LABORATORY SAMPLES
RUSH
UP
RUSH
UP
UP


PREMOISTENED
CLEANING


MF-WS-27


Olag
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