Sampling and Sampling plan
Sampling and Sampling plan

Why do we have to set the sampling plan and collect samples?

- Control of microbiological hazard in foods
  - Education and training
  - Inspection of facilities and operations
    - minimize hazard

- Sampling for microbiological analysis
  - sampling plan → quality of batch → release safe food
Sampling plan

Sampling plan: a statement of criteria of acceptance applied to a lot (batch) based on appropriate examinations of a required number of sample units by specific methods

- Number of units
- Sampling procedure
- Decision criteria (Microbiological criteria)
- two or three class plan
Microbiological criteria

- **Mandatory criterion**
  - Microbiological std.
    - Limit for pathogens of public health significance
    - Limit for non-pathogens
  - ICMSF (International Commission on Microbiological Specifications for Foods)
    - Std. is part of a law and regulation
    - Enforceable by regulatory agencies

- **Advisory criterion**
  - Microbiological end product specification
    - Increase assurance of product hygiene
  - Microbiological guideline
    - During or after processing to monitor hygiene
Microbiological criteria

- Codex

- Consists of 5 components:
  - The organisms of concerns and/or toxins
  - The analytical methods for detection and quantitation
  - A sampling plan
    - When and where samples are to be taken
  - Microbiological limits
  - The number of sampling units
Valid samples

- Representative
  - representative of the batch/lot of products
    - batch?
    - lot?
    - Representative samples depend on?
- Aseptically collected
- Sterile equipment
- Stored properly
## Equipment and reagents

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Reagents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrument for opening</td>
<td>Microbicide</td>
</tr>
<tr>
<td>Transfer instrument</td>
<td>Agent for dilution</td>
</tr>
<tr>
<td>Sample container</td>
<td></td>
</tr>
<tr>
<td>Thermometer</td>
<td></td>
</tr>
<tr>
<td>Label supplies</td>
<td></td>
</tr>
<tr>
<td>Shipping container</td>
<td></td>
</tr>
<tr>
<td>Balance</td>
<td></td>
</tr>
<tr>
<td>Blender and mixers</td>
<td></td>
</tr>
</tbody>
</table>
How large a sample is required?

- Physical limitation
  - How many samples can be tested per day

- Population
  - types of samples
    - Heterogeneous
    - Homogeneous

- Estimation \( \rightarrow \) lot size

\[ \sqrt{\text{Number of unit} + 1} \]
Microbiological limit

- Defect acceptability limit
  - Based on microbiological testing
  - Consumer risk:
    - The risk that the consumer takes
    - Lot does not conform the requirement accepted
    - Normally 10%
  - Producer risk:
    - The risk that the producer takes
    - Lot conform the requirement rejected
    - Normally 5%
Steps for choosing sampling plan

- Select the measurement
- Define the sampling unit
- Determine: consumer or producer risk to ensure the lot quality
- Obtain an estimate process
- Select a plan that meet the risk and lot quality
- Calculate operating characteristic curve (probability of acceptance)
- Apply the plan on the lot
- Maintain record on process or make change the plan if necessary
**Sampling plan**

- **Variable sampling plan**
  - The probability distribution is required (normal distribution)
  - Fewer samples are required

- **Attribute sampling plan**
  - Two class plan
  - Three class plan
  - Do not know the distribution
  - Larger samples are required
Two class plan

- Simple plan used to designate acceptable or unacceptable batch/lot of food
- Specification: $n$, $c$, $m$
  - $n =$ the number of sampling units from the lot
  - $c =$ the maximum allowance number of sample units that exceed the microbiological criterion
  - $m =$ the maximum number or level of relevant bacteria (CFU/gm or ml) (std. acceptable criteria)
Two class plan

- Sampling plan in beef

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>c</th>
<th>m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella</td>
<td>20</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Coliform</td>
<td>5</td>
<td>2</td>
<td>10^2</td>
</tr>
</tbody>
</table>

- More stringent plan
  - increasing number of unit (n)
  - reducing the maximum allowance number (c)
Two class plan

- **Salmonella**  \( n=20 \)  \( c=0 \)  \( m=0 \)

- All samples must be negative
- If one sample is positive, entire lot should be rejected
- To make more effective sampling plan
  - increasing number of unit \((n)\)
Three class plan

- Used to designate acceptable/marginally acceptable/unacceptable food

- Specification: $n, c, m, M$
  - $n =$ the number of sampling units from the lot
  - $c =$ the maximum allowance number of sample units that exceed the microbiological criterion
  - $m =$ the maximum number or level of relevant bacteria (CFU/gm or ml) (Threshold value)
  - $M =$ the maximum number that use to separate marginally acceptable/unacceptable quality food (Maximum permitted microbial level)
Three class plan

Sampling plan in raw chicken

<table>
<thead>
<tr>
<th></th>
<th>n=5</th>
<th>c=5</th>
<th>m=5x10^5</th>
<th>M=10^7</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>APC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>E. coli</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Acceptable: C samples have M/O level between \( m \) and \( M \), other samples have level of M/O less than \( m \)
- Satisfactory: All samples have M/O level less than \( M \)
- Unacceptable: If one or more samples have level of M/O more than \( M \)
Three class plan

Aerobic plate count (APC)

\[ n=5 \quad c=5 \quad m=5 \times 10^5 \quad M=10^7 \]

- None of the unit \( n \) more than \( M \)
- If any sample more than, entire lot is rejected
  - unacceptable
- \( c \) units can more than \( m \)
  - acceptable
  - marginally acceptable (Satisfactory)
- To make more effective sampling plan
  - increase \( n \)
  - reduce \( m \)
## Sampling plans and microbiological limit in foods

<table>
<thead>
<tr>
<th>Products</th>
<th>Tests</th>
<th>Case</th>
<th>Class plan</th>
<th>n</th>
<th>c</th>
<th>m</th>
<th>M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precooked breaded fish</td>
<td>APC</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>$5 \times 10^5$</td>
<td>$10^7$</td>
</tr>
<tr>
<td></td>
<td><em>E. coli</em></td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>11</td>
<td>500</td>
</tr>
<tr>
<td></td>
<td><em>S. aureus</em></td>
<td>8</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>$10^3$</td>
<td>$10^3$</td>
</tr>
<tr>
<td>Raw chicken (fresh or frozen), during processing</td>
<td>APC</td>
<td>1</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>$5 \times 10^5$</td>
<td>$10^7$</td>
</tr>
<tr>
<td>Frozen vegetables and fruit, pH 4.5</td>
<td><em>E. coli</em></td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>$10^2$</td>
<td>$10^3$</td>
</tr>
<tr>
<td>Comminuted raw meat (frozen) and chilled carcass meat</td>
<td>APC</td>
<td>1</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>$10^9$</td>
<td>$10^7$</td>
</tr>
<tr>
<td>Cereals</td>
<td>Molds</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>$10^2-10^4$</td>
<td>$10^5$</td>
</tr>
<tr>
<td>Frozen entrées containing rice or corn flour as a main ingredient</td>
<td><em>S. aureus</em></td>
<td>8</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>$10^3$</td>
<td>$10^4$</td>
</tr>
<tr>
<td>Noncarbonated natural mineral and bottled noncarbonated waters</td>
<td>Coliforms</td>
<td>5</td>
<td>2</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>Roast beef</td>
<td><em>Salmonella</em></td>
<td>12</td>
<td>2</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td><em>S. aureus</em></td>
<td>7</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>$10^3$</td>
<td>$10^4$</td>
</tr>
<tr>
<td></td>
<td><em>V. parahaemolyticus</em></td>
<td>8</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>$10^2$</td>
<td>$10^3$</td>
</tr>
<tr>
<td></td>
<td><em>Salmonella</em></td>
<td>10</td>
<td>2</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>APC</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>$5 \times 10^5$</td>
<td>$10^7$</td>
</tr>
<tr>
<td></td>
<td><em>E. coli</em></td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>11</td>
<td>500</td>
</tr>
<tr>
<td></td>
<td><em>S. aureus</em></td>
<td>8</td>
<td>2</td>
<td>5</td>
<td>0</td>
<td>$10^3$</td>
<td>–</td>
</tr>
</tbody>
</table>
## Sampling plans and microbiological limit in foods

<table>
<thead>
<tr>
<th>Poultry product</th>
<th>n</th>
<th>c</th>
<th>m</th>
<th>M</th>
</tr>
</thead>
<tbody>
<tr>
<td>APC</td>
<td>5</td>
<td>3</td>
<td>10^4</td>
<td>10^5</td>
</tr>
<tr>
<td>S. aureus</td>
<td>5</td>
<td>1</td>
<td>10^2</td>
<td>10^4</td>
</tr>
<tr>
<td>E. coli</td>
<td>5</td>
<td>2</td>
<td>10</td>
<td>10^2</td>
</tr>
<tr>
<td>Salmonella</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dried milk</th>
<th>n</th>
<th>c</th>
<th>m</th>
<th>M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesophilic count</td>
<td>5</td>
<td>2</td>
<td>5x10^4</td>
<td>2x10^5</td>
</tr>
<tr>
<td>Coliform</td>
<td>5</td>
<td>1</td>
<td>10</td>
<td>10^2</td>
</tr>
<tr>
<td>Salmonella</td>
<td>15</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>
# Degree of health hazard and conditions of use

<table>
<thead>
<tr>
<th>Type of Hazard</th>
<th>Conditions in Which Food Is Expected to Be Handled and Consumed after Sampling</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reduce Degree of Hazard</td>
</tr>
<tr>
<td><strong>No direct health hazard</strong></td>
<td></td>
</tr>
<tr>
<td>Utility (e.g., general contamination, reduced shelf-life, and spoilage)</td>
<td>Case 1</td>
</tr>
<tr>
<td><strong>Health hazard</strong></td>
<td></td>
</tr>
<tr>
<td>Low, indirect (indicator)</td>
<td>Case 4</td>
</tr>
<tr>
<td>Moderate, direct, limited spread</td>
<td>Case 7</td>
</tr>
<tr>
<td>Moderate, direct, potentially extensive spread</td>
<td>Case 10</td>
</tr>
<tr>
<td>Severe, direct</td>
<td>Case 13</td>
</tr>
</tbody>
</table>

*Source: ICMSF (16); copyright © 1986 by University of Toronto Press, used with permission.*