What is quality?

- The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs

International Organization for Standardization (ISO) Standard 8402

Wholesome food:

- Nutritious
- Safe
- Palatable
Microbiological testing
- Useful for controlling quality
- Not very useful for controlling food safety

Control procedures
- Inspections
  - Check for compliance with GMP and SOP
- Sampling plans
  - Check for product compliance with quality criteria
- HACCP
  - Focus on process adjustments for controlling food safety hazards

Sampling
Observation of a set amount of product (lot) resulting in the separation of lot units or portions for further testing
Some definitions

- **Sampling**
  - Action of separating a portion of a production lot for further testing
- **Random sampling**
  - Sampling procedure where every unit in a lot has the same chances of being selected for analysis
- **Representative sample**
  - Sample possessing characteristics comparable to the average of the whole lot

Some definitions

- **Sampling plan**
  - Instructions specifying the number of units to be tested and the criteria for accepting or rejecting the lot
- **Risk to the consumer**
  - The risk for consumers that a defective lot be accepted
  - Usually set at 10%
- **Risk to the producer**
  - The risk for the producer that the sampling plan reject a non-defective lot
  - Usually set at 5%

Sampling plans

- **By attribute**
  - Require Normal, Poisson, binomial or hypergeometric distribution
    - Two-class plans
    - Three-class plans
    - Double sampling plans
- **By variables**
  - Require normal distribution
Two-class plans

- $n =$ No. sample units to be tested
- $c =$ No. sample units allowed to yield unsatisfactory results
- Example: $n = 5$, $c = 2$

Two-class plans

- $\bigcirc \bigcirc \bigcirc \bigcirc \bigcirc$
- $\bigcirc \bigcirc \bigcirc \bigcirc$
- $\bigcirc \bigcirc \bigcirc$
- $\bigcirc \bigcirc$
- $\bigcirc$

$n = 5$, $c = 2$

- $+$
- $-$

Three-class plan

- $n =$ No. sample units to be tested
- $c =$ No. sample units allowed $>m$ but $\neq M$
- $m =$ Acceptable level of the test organism
- $M =$ Level above which the sample unit is unacceptable
- Example: $n = 5$, $c = 2$, $m = 10^2$, $M = 10^3$
Multiple plans

- The lot is accepted or rejected on the basis of a sequential decision
- Example:
  - Coliforms in cooked ham (<10 MPN/g)
  - $n_1=10, c_1=0; n_2=6, c_2=1$
  - 10 samples tested
    - Lot rejected if 1 or more samples have $\geq 10$ MPN/g
    - Lot accepted if all 10 have <10 MPN/g
  - If the lot is accepted, 6 more samples are collected
    - Lot rejected if 1 or more have $\geq 10$ MPN/g
    - Lot accepted if all 10 have <10 MPN/g

Double sampling plan

- If the number of detectables found in the first sample:
  - does not exceed $C_1$ of the first sample
  - exceeds the $C_1$ of the first sample but does not exceed the $(C_1 + C_2)$ of the first and second samples combined
  - exceeds the $(C_1 + C_2)$ of the first and second samples combined

- If the number of detectables found in the first and second samples combined:
  - does not exceed $(C_1 + C_2)$ of the first and second samples combined
  - exceeds the $(C_1 + C_2)$ of the first and second samples combined

Pass the lot

Define or reject the lot
Microbiological Criteria

Microbiological criteria

- A criterion is a series of instructions that will let you decide whether a lot is accepted or rejected
Types of criteria

- Standard
  - Specified in a law or regulation
- Guideline
  - Advisory (not mandatory)
  - Used for monitoring the acceptability of a product or process
- Specification
  - Contractual condition of acceptance set in a commercial agreement

Components of a microbiological criterion

- Description of the food or ingredient
- The attribute of interest
- The method of analysis
- The sampling plan
- Microbiological limits

Development and implementation

- Not necessary or practical for all food products
- Establish and implement only when:
  - Recognized need
  - After proving the criterion to be practical and effective
Baseline data surveys - USDA 1994

- **Campylobacter**
  - 4.0%
  - <1.0/cm²
- **Salmonella**
  - 1.0%
  - <1.0/cm²
- **E. coli O157:H7**
  - 0.2%
  - <1.0/cm²

FSIS *E. coli* standards for fresh meats

<table>
<thead>
<tr>
<th>Type of slaughter</th>
<th>m</th>
<th>M</th>
<th>n</th>
<th>c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beef</td>
<td>Negative&lt;sup&gt;a&lt;/sup&gt;</td>
<td>100 cfu/cm²</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>Pig</td>
<td>10 cfu/cm²</td>
<td>10,000 cfu/cm²</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>Chicken</td>
<td>100 cfu/ml&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1000 cfu/ml</td>
<td>13</td>
<td>3</td>
</tr>
</tbody>
</table>

<sup>a</sup> No detection by method with sensitivity ≤ 5 cfu/cm² or ml
<sup>b</sup> Count from liquid resulting from rinsing 13 carcasses

FSIS *E. coli* standards for fresh meats

<table>
<thead>
<tr>
<th>Type of slaughter</th>
<th>Type of sample</th>
<th>Frequency (1 out of):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beef</td>
<td>Brisket, flank and rump</td>
<td>300 carcasses</td>
</tr>
<tr>
<td>Pig</td>
<td>Ham, belly and jowl</td>
<td>1,000 carcasses</td>
</tr>
<tr>
<td>Chicken</td>
<td>Whole carcass</td>
<td>22,000 carcasses</td>
</tr>
<tr>
<td>Turkey</td>
<td>Whole carcass</td>
<td>3,000 carcasses</td>
</tr>
</tbody>
</table>
Salmonella performance standards

<table>
<thead>
<tr>
<th>Type of slaughter</th>
<th>No. samples</th>
<th>Max. positives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steer/heifer</td>
<td>82</td>
<td>1</td>
</tr>
<tr>
<td>Cow/bull</td>
<td>58</td>
<td>2</td>
</tr>
<tr>
<td>Ground beef</td>
<td>53</td>
<td>5</td>
</tr>
<tr>
<td>Pig</td>
<td>55</td>
<td>6</td>
</tr>
<tr>
<td>Chicken</td>
<td>51</td>
<td>12</td>
</tr>
<tr>
<td>Ground chicken</td>
<td>53</td>
<td>26</td>
</tr>
<tr>
<td>Ground turkey</td>
<td>53</td>
<td>29</td>
</tr>
</tbody>
</table>

Procedure for implementation of a criterion

- **Standard**
  - Relevant technical information
  - Consensus for microbiological limits
  - Consulting with experts in all areas involved (industry, academia, government)
  - Consensus for its approval
- **Other criteria**
  - Decision by interested party (es)
  To be meaningful, all criteria must be based upon science