Considering the Design of Three-Class Sampling Plans for Process Control

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Three-Class Sampling Plans

• Attribute sampling plans where quantitative microbiological concentration data are divided into three classes:
  – acceptable: $X \text{ (cfu/g)} \leq m$
  – marginal: $m < X \leq M$
  – unacceptable: $X > M$

• Used for food safety lot acceptance sampling and recommended for process control
Three-Class Sampling Plans

- Defined by sample size \( (n) \) and maximum number of analytical units allowed in the marginal class, \( c_m = c \ (c_M = 0) \)

- \( p_a = \sum_{i=0}^{c} C_i^n (p_m)^i (1 - p_d - p_m)^{n-i} \)

\[ C_i^n = \frac{n!}{i!(n-i)!} \]

- \( p_m = p(m<X\leq M) \)
- \( p_d = p(X>M) \)
Three-Class Sampling Plans

• Existing microbiological criteria intended for three-class sampling plans (e.g., ICMSF) do not consider process variability

• When applied for statistical process control, this results in highly inconsistent false alarm rates (FAR) for detecting out-of-control processes
Three-Class Sampling Plans

• Specify $F(M) = 99.5^{\text{th}} \, \% \text{ile (} p_d = 0.5\% \text{)}$
• Specify $\log_{10}(M/m) = 1 \text{ or } 2$
• $FAR = 1 - p_a$
• $FAR = FAR_M + FAR_m$
• $FAR_M = 1 - (1 - p_d)^n$
• For $n = 5$ and $p_d = 0.5\%$, $FAR_M = 2.5\%$
• $FAR = 2.5\% + ?$
Three-Class Sampling Plans

- Assume $X \sim \text{Lognormal}(\mu_{\log_{10}}, \sigma_{\log_{10}})$
- Given $p_d$ and $\sigma_{\log_{10}}$, we can calculate $p_m$ from existing sampling plans based on the ratio of the limits ($M/m$).
- Given a fixed $M$ percentile, the implied $\mu$ and percentile of $m$ will vary depending on the process variability $\sigma$.

$$\mu_{\log_{10}} = \log_{10}(M) - \Phi^{-1}(F(M), 0,1)\sigma_{\log_{10}}$$

$$F(m) = \Phi(\log_{10}(m), \mu_{\log_{10}}, \sigma_{\log_{10}})$$

$$p_m = F(M) - F(m)$$

$$\text{FAR}_m = \text{FAR} - \text{FAR}_M$$
# Three-Class Sampling Plans

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<tr>
<th>n</th>
<th>c</th>
<th>log(M/m)</th>
<th>$\sigma_{\log 10}$</th>
<th>m percentile</th>
<th>FAR(%)</th>
<th>FAR$_M$(%)</th>
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Three-Class Sampling Plans

• Dahms and Hildebrandt (1998) proposed starting with assuming marginal limit (m) based on an “indifferent lot” – a lot with probability of acceptance = 0.5.
• For \( n = 5, c = 2 \), \( F(m) = 50^{\text{th}} \) percentile.
• Then specify M based on additional risk of lot rejection (a) attributable to M.
• For \( a = 0.01 \), \( p(\text{lot acceptance}) = 0.5 - 0.01 = 0.49 \).
• For process control, this implies FAR = 51\%.
Three-Class Sampling Plans

- Various approaches to design for process control
- For example, for \( n = 5, c = 2 \), given:
  - \( M = 5 \log_{10} \text{cfu/g}; F(M) = 99.9^{\text{th}} \text{ percentile} \)
  - \( \text{FAR}_M = 0.5\% \)
  - \( \sigma_{\log_{10}} = 0.8 \log_{10} \text{cfu/g} \) (\( \mu_{\log_{10}} = 2.5 \))
  - \( \text{FAR} = 1\% \)
- Solve for \( m \),
  - s.t. \( \text{FAR}_m = 0.5\% = (1-p_a = 1\%) - (\text{FAR}_M = 0.5\%) \)
  - \( m = 3.63 \log_{10} \text{cfu/g} \) (91.6\(^{\text{th}} \text{ percentile} \))
Three-Class Sampling Plans

• If the limits (m and M) are set based on microbiological considerations (e.g., shelf-life, hazardous levels) rather than statistical design specifications, then the three-class sampling plans may continue to serve a useful food safety function by indicating marginal and unacceptable microbiological quality.

• However, this function is distinct from that of sampling plans with limits derived from observing a process under control where exceedances of the limits indicate a potential loss of statistical control.
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