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 (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, $c_m = c$ ($c_M = 0$)
- $p_a = \sum_{i=0}^{i=c} C_i^n \,(p_m)^i (1 - p_d - p_m)^{n-i}$
  - $C_i^n = \frac{n!}{i!(n-i)!}$
  - $p_m = p(m < X \leq M)$
  - $p_d = p(X > M)$

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) = 99.5th %ile ($p_d = 0.5\%$)
- Specify $\log_{10}(M/m) = 1$ 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~Lognormal($\mu_{log10,}\sigma_{log10}$)
- Given p_d and σ_{log10}, 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 μ and percentile of m will vary depending on the process variability σ.
- $\mu_{log10} = \log_{10}(M) - \Phi^{-1}(F(M), 0,1)\sigma_{log10}$
- $F(m) = \Phi(\log_{10}(m), \mu_{log10,}\ \sigma_{log10})$
- $p_m = F(M)-F(m)$
- $FAR_m = FAR - FAR_M$

Three-Class Sampling Plans

n	c	log(M/m)	σ_{log10}	m percentile	FAR(%)	FAR_M(%)	FAR_m(%)
5	2	1	0.25	7.7	99.6	2.5	97.1
			0.50	71.8	15.8	2.5	13.3
			0.80	90.8	3.1	2.5	0.6
			1.20	95.9	2.5	2.5	0.0
5	2	2	0.25	0.0	100.0	2.5	97.5
			0.50	7.7	99.6	2.5	97.1
			0.80	53.0	45.2	2.5	42.8
			1.20	81.8	6.6	2.5	4.1

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) = 50th percentile.
- Then specify M based on additional risk of lot rejection (a) attributable to M.
- For a = 0.01, p(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 $\log_{10}$ cfu/g; F(M) = 99.9^{th} percentile
  - $FAR_M = 0.5\%$
  - $\sigma_{log10} = 0.8$ $\log_{10}$ cfu/g ($\mu_{log10} = 2.5$)
  - FAR = 1%
- Solve for m,
  - s.t. $FAR_m = 0.5\% = (1-p_a = 1\%) – (FAR_M = 0.5\%)$
  - m = 3.63 $\log_{10}$ cfu/g (91.6^{th} 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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