Microbiological Testing and Performance of Sampling Plans

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Probability that no contamination is found

1 % defectives of 100,000 products, means 1,000 products

\[ P_{accept} = (1 - P_{defective})^n \]
Probability of accepting a lot, \( c=0 \)

With 5 times more samples probability of acceptance 7.7 times lower!

**MISCONCEPTION**

Using a realistic sampling scheme, it is possible to test for absence of a pathogen in a batch of food.
MISCONCEPTION
Current sampling plans assume that microorganisms follow the binomial distribution.

\[ P \text{ (accepting batch): depends on } n, c, P_{\text{defective sample}} \]

If \( c \neq 0 \) \( P_{\text{accept}} = \text{binomial}(k \leq c, n, P_{\text{defective}}) \)
**MISCONCEPTION**

Current sampling plans assume that microorganisms are homogeneously distributed in a batch.

![Table and Diagram]

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**Heterogeneous high-level contamination**
\[ P_{\text{defective}} = P_{\text{normal}}(\log_{10} C > m, \mu_{\log C}, \sigma_{\log C}) \]
\[ = 1 - P_{\text{normal}}(\log_{10} C \leq m, \mu_{\log C}, \sigma_{\log C}), \]
\[ P_{\text{accept}}(c, n, P_{\text{defective}}) = \text{binomial}(k \leq c, n = n, P = P_{\text{defective}}) \]

\[ n=5 \]
$n=10; \sigma = 1.2$ (brown), $1.0$ (blue), $0.8$ (purple), $0.6$ (red), $0.4$ (orange), and $0.2$ (yellow) $\log_{10}$ CFU/g.
\( n=10; \sigma = 1.2 \) (brown), \( 1.0 \) (blue), \( 0.8 \) (purple), \( 0.6 \) (red), \( 0.4 \) (orange), and \( 0.2 \) (yellow) \( \log_{10} \) CFU/g.
\[ P_{detect} = 1 - Poisson(0, \hat{n}_{cells}) \]

\[ P_{defective} = \int_{-\infty}^{\infty} [P_{concentration} \cdot P_{detect}] d \log C \]

\[ = \int_{-\infty}^{\infty} [P_{normal}(\log C, \mu_{\log C}, \sigma_{\log C}) \cdot (1 - Poisson(0, \hat{n}_{cells}))] d \log C \]
$n=60; \sigma = 1.2$ (brown), 1.0 (blue), 0.8 (purple), 0.6 (red), 0.4 (orange), and 0.2 (yellow) log$_{10}$ CFU/g.
Three statistical phenomena are relevant:

1. the actual spatial distribution of microorganism in the food batch,
2. the statistical process of taking a sample unit and it being defective
3. the acceptance of the lot based on $n$ sample units, of which $c$ are accepted to be positive and $P_{\text{defective}}$

For example
1. organism lognormally distributed in product
2. taking one sample is a Poisson process
   $P_{\text{defective}}$ is a Poisson-lognormal distribution of contaminant in the sample unit
3. $P_{\text{accept}}$ of a lot based on $P_{\text{defective}}$, $n$ sample units, and $c$ is a binomial process
   $P_{\text{accept}}$ is then a Binomial(Poisson(LogNormal)) distribution!
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This sampling plan would provide 95% confidence that a lot of food containing a median concentration of 1 organism in 177.7 g and an average concentration of 1 organism in 32.8 g (and having a standard deviation of 0.80 log cfu/g), would be rejected (i.e. more than 0 out of 10 samples of 25 grams giving detection of the organism).
Conclusions

• Control of safety is only to a very limited extend supported by end-product testing
• Distributions can be relevant for performance of sampling plans
• As function of the arithmetic mean the effect of the spread is limited
• Tools exist!

see [http://www.icmsf.org](http://www.icmsf.org)