

Microbiological Testing and Performance of Sampling Plans

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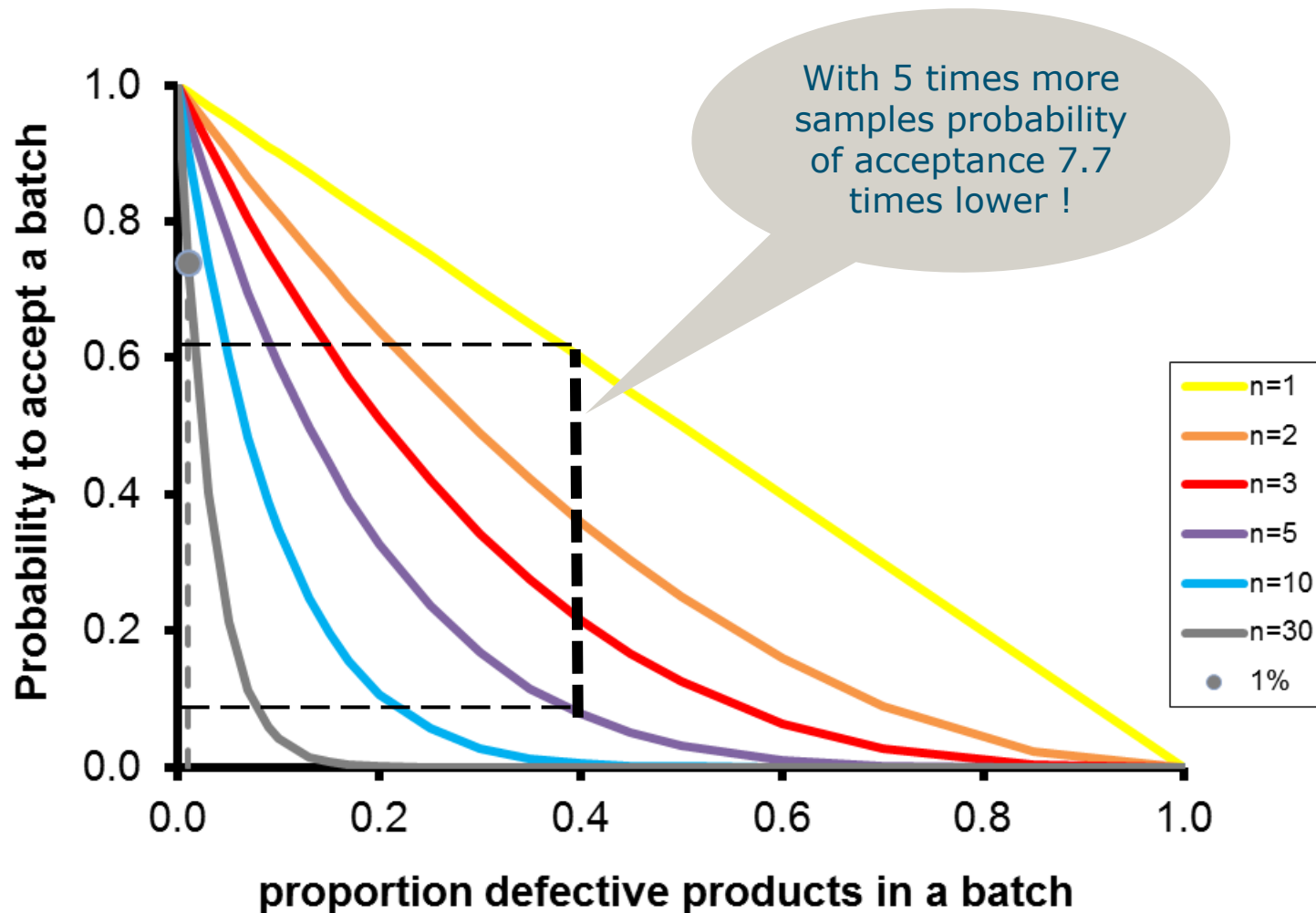
Probability that no contamination is found

$P_{\text{defective}}$	$n=1$	$n=2$	$n=5$	$n=30$
	$1 - P_{\text{def}} =$	$(1 - P_{\text{def}})^2 =$	$(1 - P_{\text{def}})^5 =$	$(1 - P_{\text{def}})^{30} =$
0.00	1.00	1.00	1.00	1.00
0.01	0.99	0.98	0.95	0.74
0.05	0.95	0.90	0.77	0.21
0.10	0.90	0.81	0.59	0.04
0.15	0.85	0.72	0.44	0.01
0.20	0.80	0.64	0.33	0.00
0.25	0.75	0.56	0.24	0.00
0.30	0.70	0.49	0.17	0.00

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

$$P_{\text{accept}} = (1 - P_{\text{defective}})^n$$

Probability of accepting a lot, $c=0$

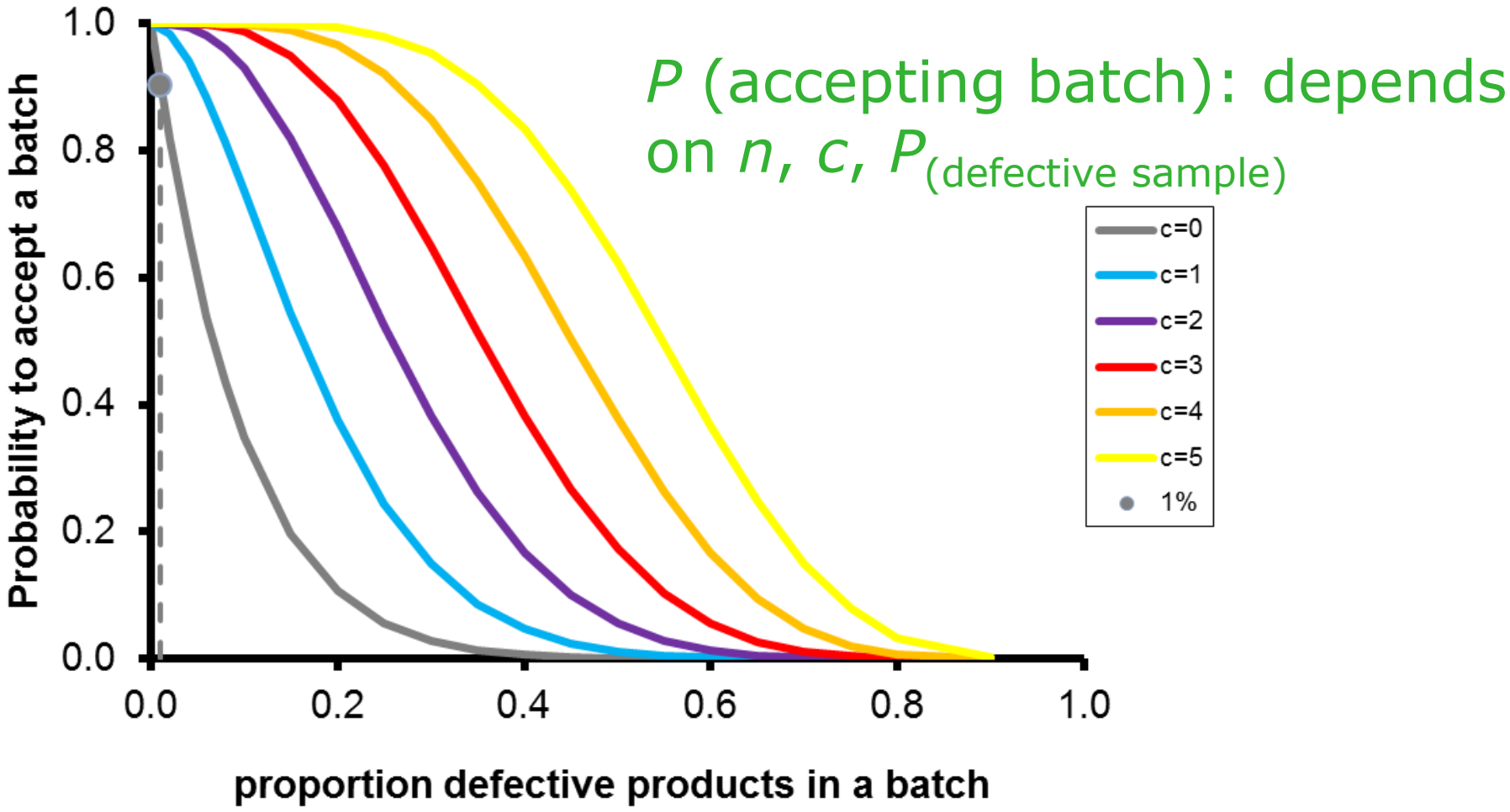


MISCONCEPTION

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.



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

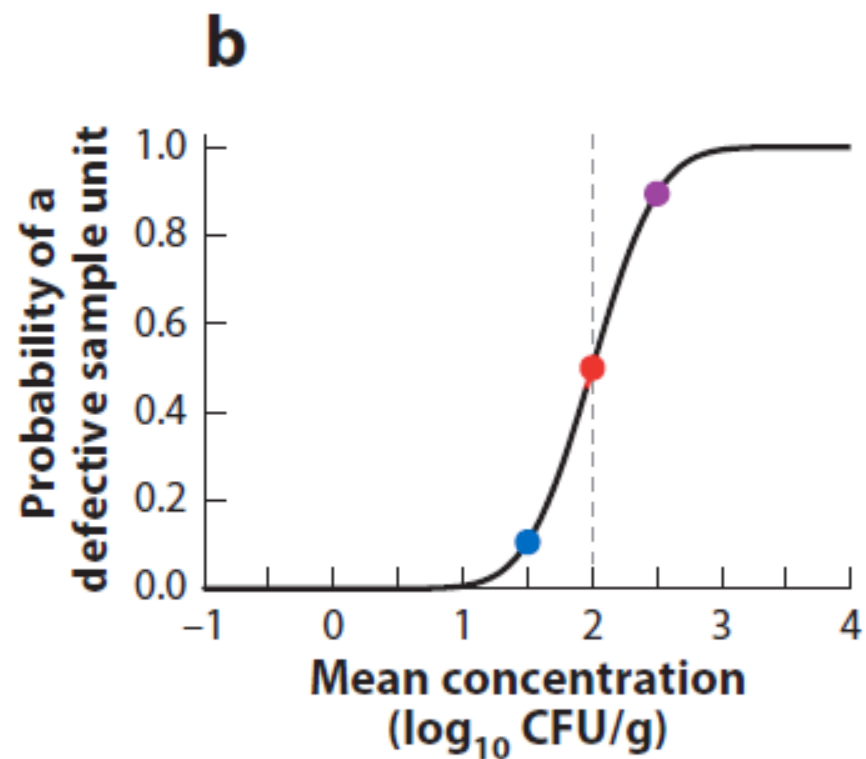
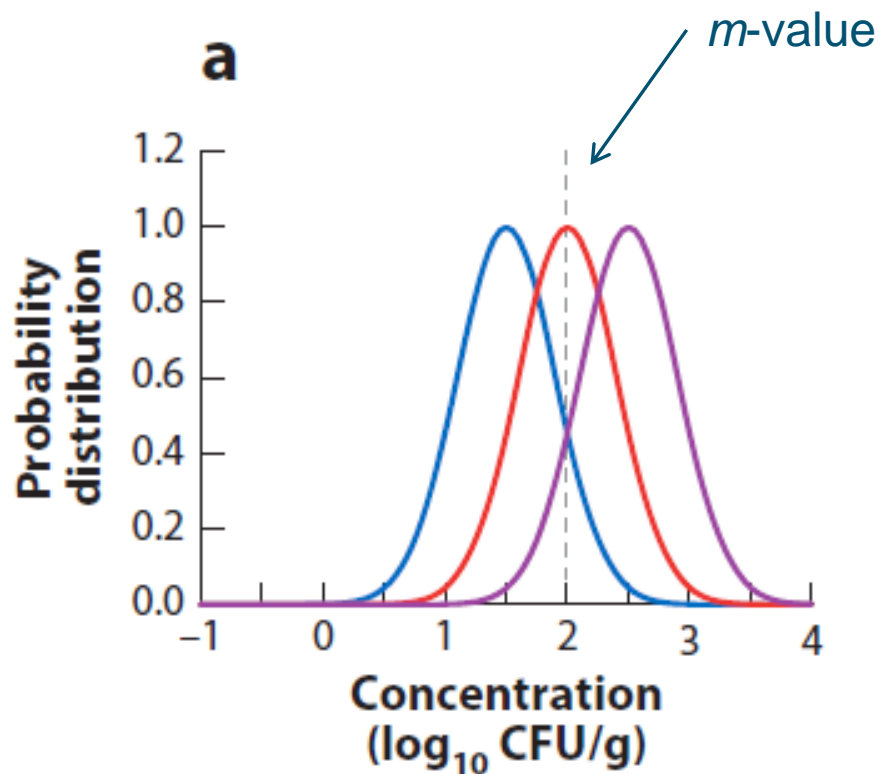
b

22	113	94	49
8	10	93	105
520	59	81	17
19	101	36	33

Heterogeneous
high-level
contamination

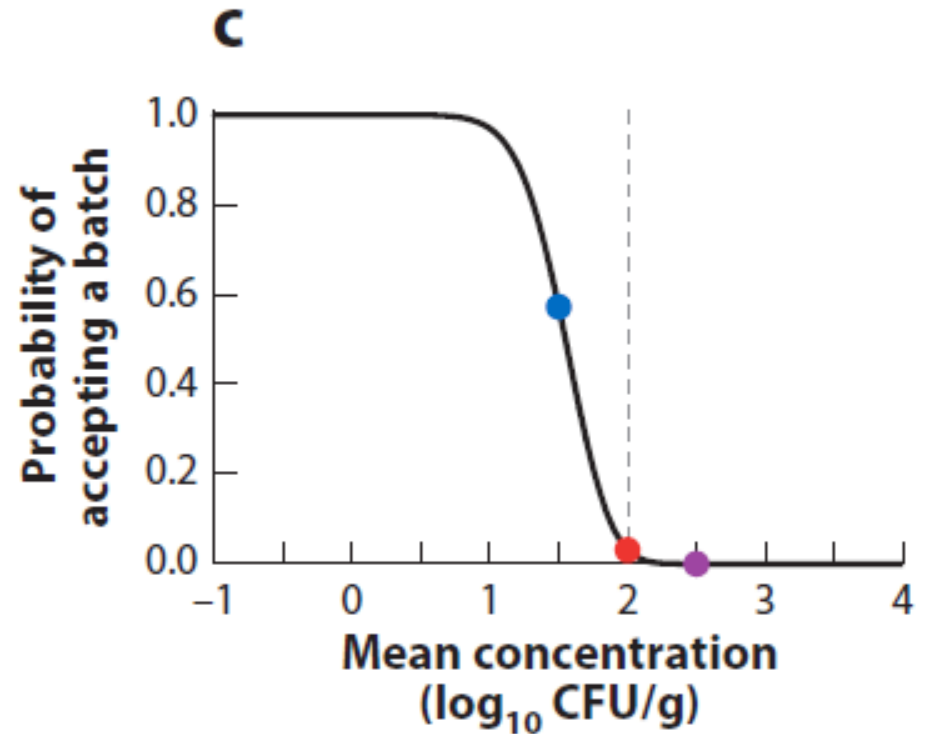
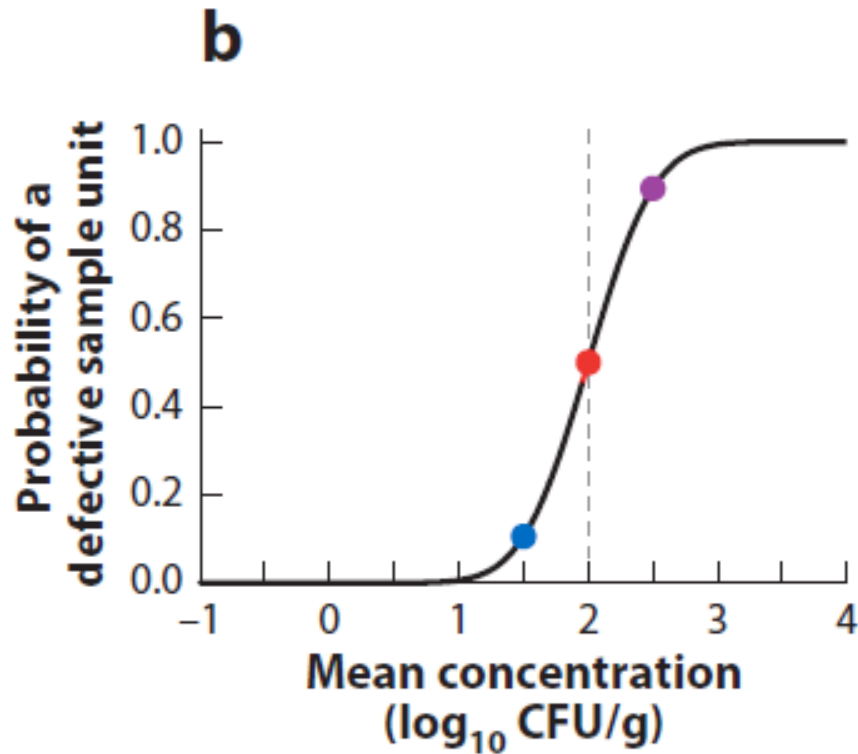
MISCONCEPTION

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



$$\begin{aligned}
 P_{\text{defective}} &= P_{\text{normal}}(\log_{10} C > m, \mu_{\log C}, \sigma_{\log C}) \\
 &= 1 - P_{\text{normal}}(\log_{10} C \leq m, \mu_{\log C}, \sigma_{\log C}),
 \end{aligned}$$

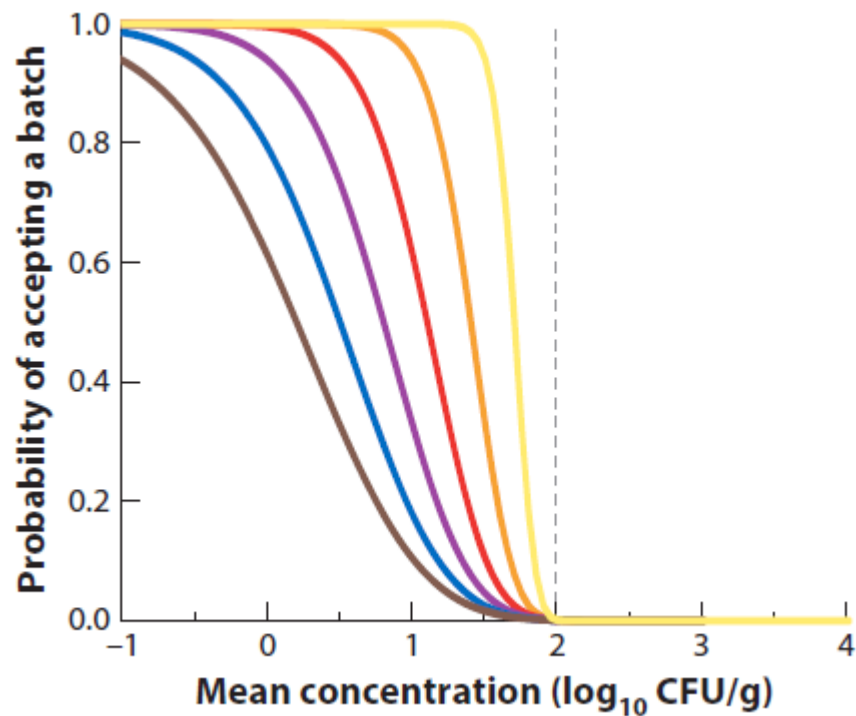
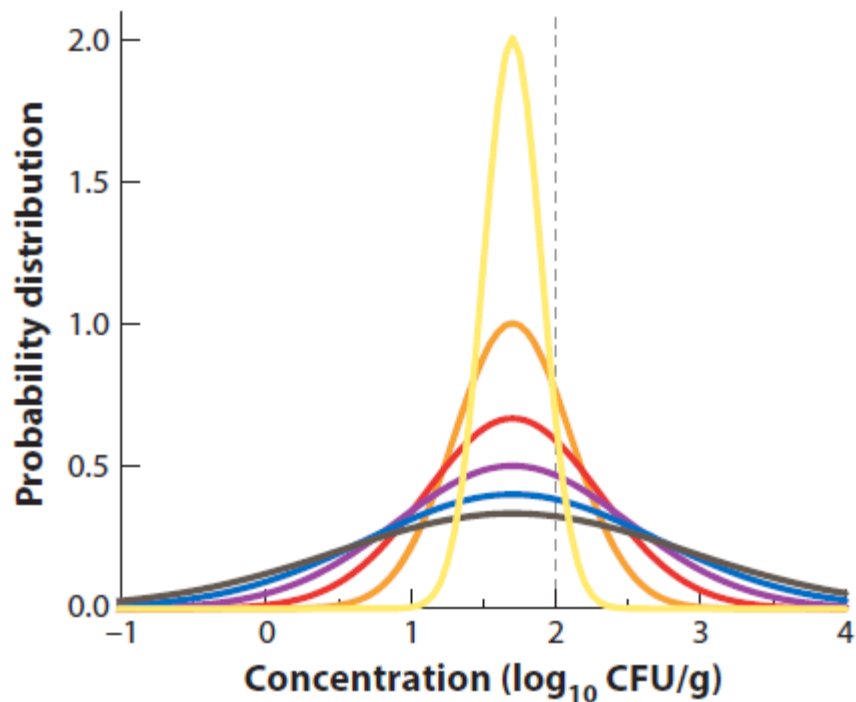
OC curve: Operating Characteristic



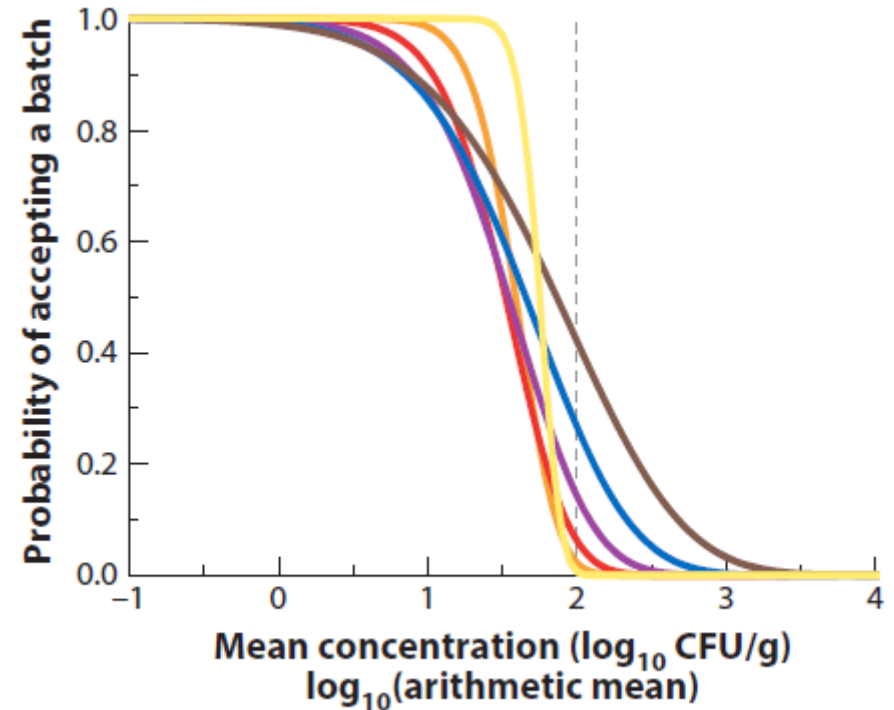
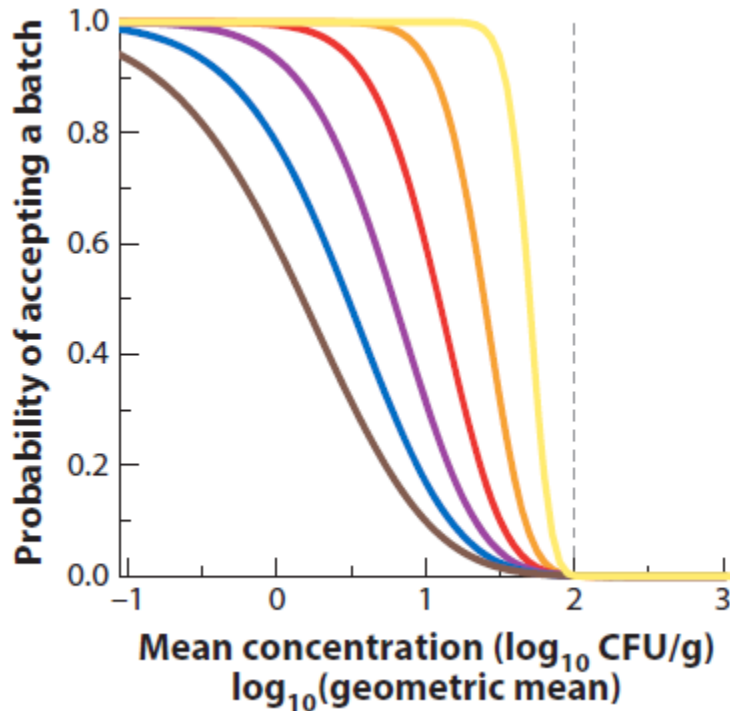
$$P_{accept}(c, n, P_{defective}) = \text{binomial}(k \leq c, n = n, P = P_{defective})$$

$n=5$

$n=10$; $\sigma = 1.2$ (brown), 1.0 (blue), 0.8 (purple), 0.6 (red), 0.4 (orange), and 0.2 (yellow) \log_{10} CFU/g.

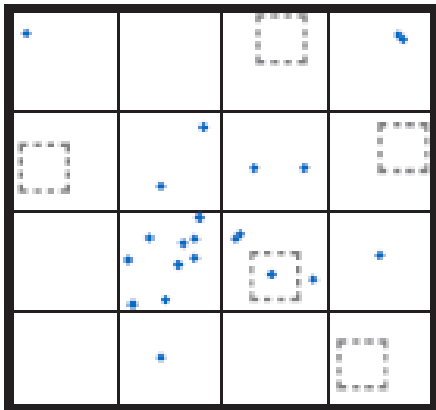


$n=10$; $\sigma = 1.2$ (brown), 1.0 (blue), 0.8 (purple), 0.6 (red), 0.4 (orange), and 0.2 (yellow) \log_{10} CFU/g.



$$\log_{10}(\bar{C}) = \overline{\log_{10} C} + 0.5 \cdot \ln 10 \cdot \sigma_{\log_{10} C}^2$$

C



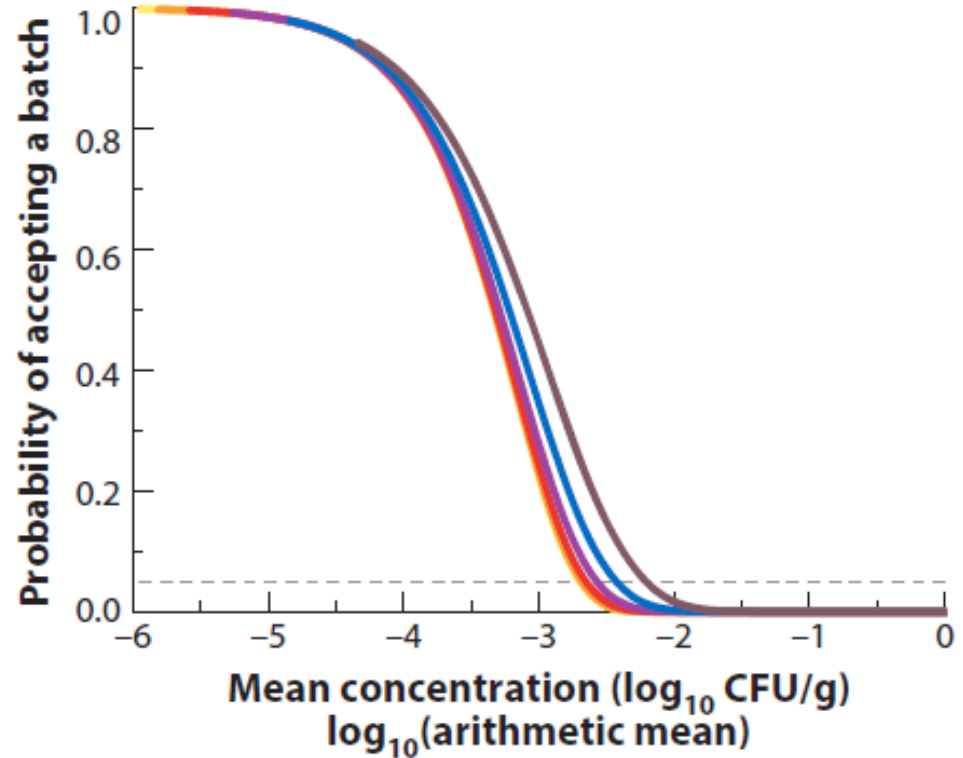
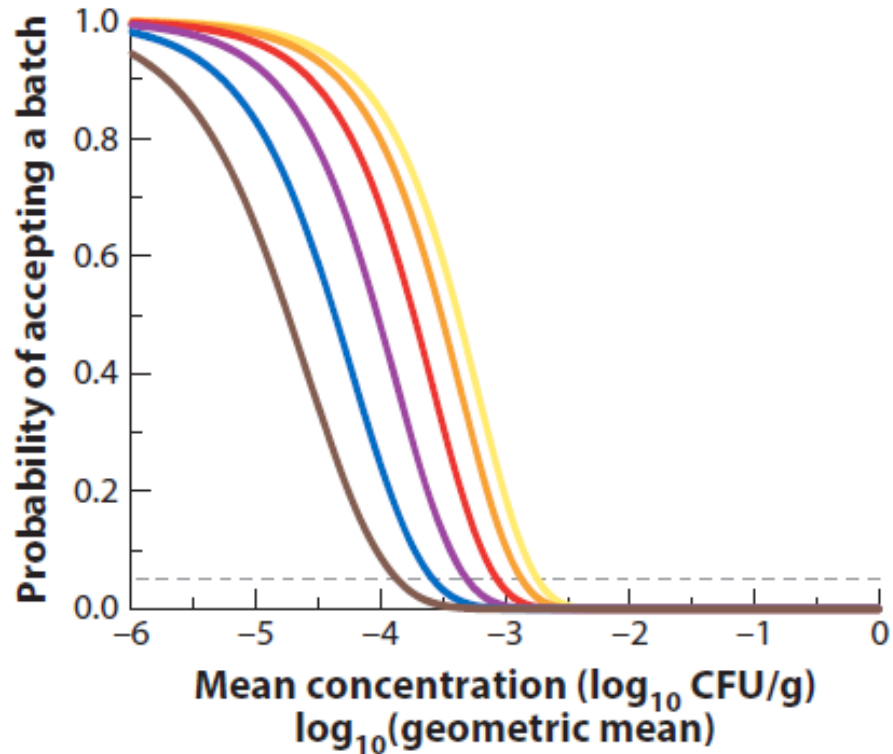
Heterogeneous
low-level
contamination

$$P_{detect} = 1 - Poisson(0, \hat{n}_{cells})$$

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

$$= \int_{-\infty}^{\infty} [P_{normal}(\log C, \mu_{\log C}, \sigma_{\log C}) \cdot (1 - Poisson(0, \hat{n}_{cells}))] d \log C$$

$n=60$; $\sigma = 1.2$ (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 $P_{defective}$

For example

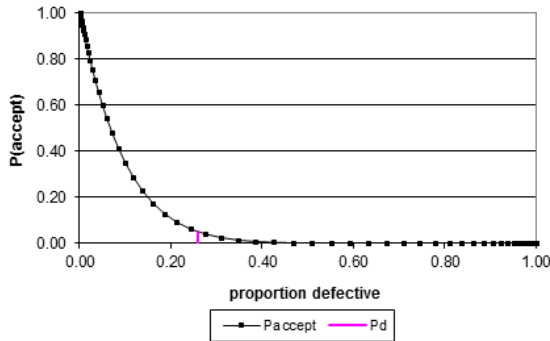
1. organism lognormally distributed in product
2. taking one sample is a Poisson process

$P_{defective}$ is a Poisson-lognormal distribution of contaminant in the sample unit

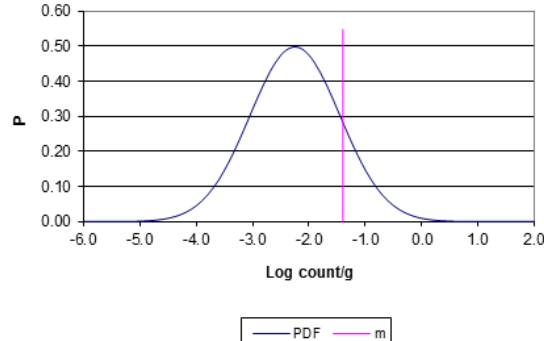
3. P_{accept} of a lot based on $P_{defective}$, n sample units, and c is a binomial process

P_{accept} is then a Binomial(Poisson(LogNormal)) distribution !

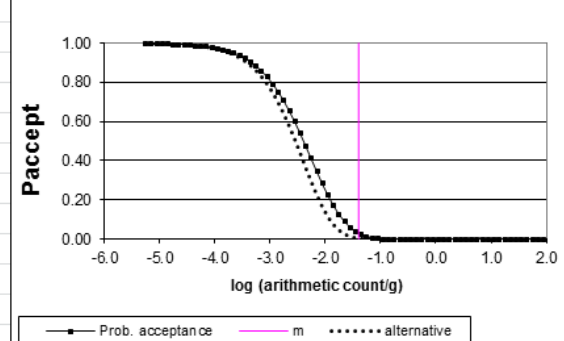
Operating characteristic curve for proportion defective, with $n=10$ and $c=0$



Probability density function (PDF) for log counts. Distribution mean = -2.25 and sigma = 0.80



Operating characteristic curve scaled to relate log arithmetic mean count to m



Batch acceptance for Pd		P(accept)
Pd	20 %	10.7 %
actualPd	25.9 %	5.00 %

INPUTS		P(accept)	
mean	-2.25	Computed	5.00 %
sigma	0.80	Desired	5 %
m	-1.40	Find mean that gives desired P(accept)	
n	10	Find n that gives desired P(accept) or better (less)	
c	0		
amount	25 g	Preject	95.00

ALTERNATIVE n AND c		P(accept)	
mean	-2.25	Computed	0.91 %
sigma	0.80	Target, left	5.00 %
m	-0.98	For any value of n and c imputed find the m that gives the same P(accept) as the model on the left	
n	30		
c	0		
amount	9.6 g		

Sandbox: for your own calculations

Means and median			
Arithmetic		Geometric=median	
0.0307	cfu/g	0.0056	cfu/g
one cfu in	32.6 grams	one cfu in	177.7 grams
	-1.51 log cfu/g		-2.25 log cfu/g

Implied Acceptance level		
Percentile	z-score	Concentration at this percentile
99.9	3.10	0.23

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 32.6 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 extent 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>