

# Why do we have so many different types of sampling plans ?

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# Product testing

Outbreak: new microbiological criteria:

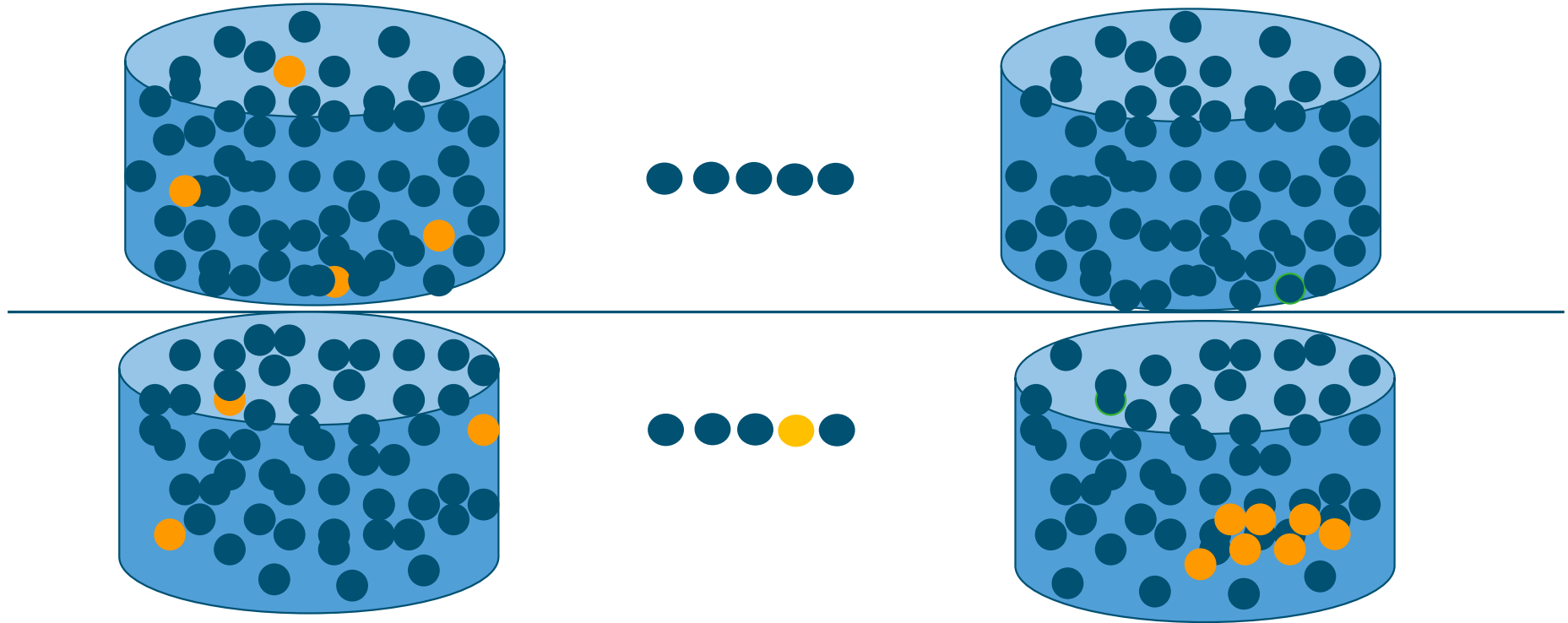
close the well after the calf has drowned

(shutting the stable door after the horse has bolted)

Testing is not very effective in detecting contaminants

- lottery effect
- local contaminations
- methods not perfect

# End product testing useful or lottery ?



*If the tested sample units are negative, this does not mean the batch is free of the pathogen*

# Only a very minor proportion of product is sampled

*Salmonella* in poultry in the EC: 50 samples per slaughterhouse in 10 weeks: 0.0022% of the carcasses !

*Cronobacter* in PIF 30 samples of 10g per batch = 0.3 kg / 20,000 kg = 0.0014%

Sampling and testing for pathogens in food: finding the needle in a haystack and the impact of the food microbiome. Heidi MW den Besten, Johanna Mentani and Marcel H Zwietering.

<https://doi.org/10.1016/j.cofs.2025.101332>

Actual distribution of *Cronobacter* spp. in industrial batches of powdered infant formula and consequences for performance of sampling strategies. I. Jongenburger, M.W. Reij, E.P.J. Boer, L.G.M. Gorris, M.H. Zwietering. <https://doi:10.1016/j.ijfoodmicro.2011.08.003>

# Testing is not the basis of food safety



Verification  
by MicroCrit

Monitor Critical Limits

Validated CCPs

HACCP

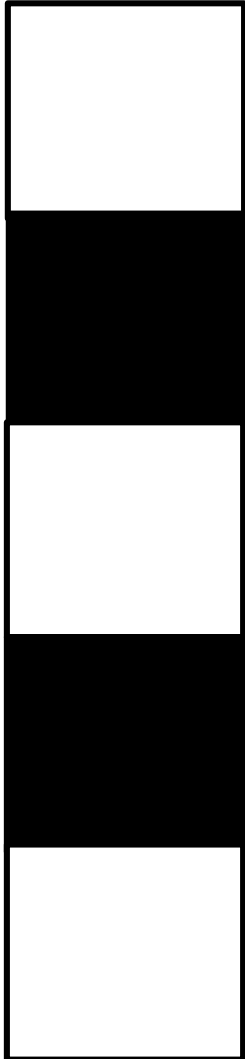
PRP (GMP, GHP, ....)

# Only testing is not solid

verification  
by MicroCrit



# Why different types: it is not black and white



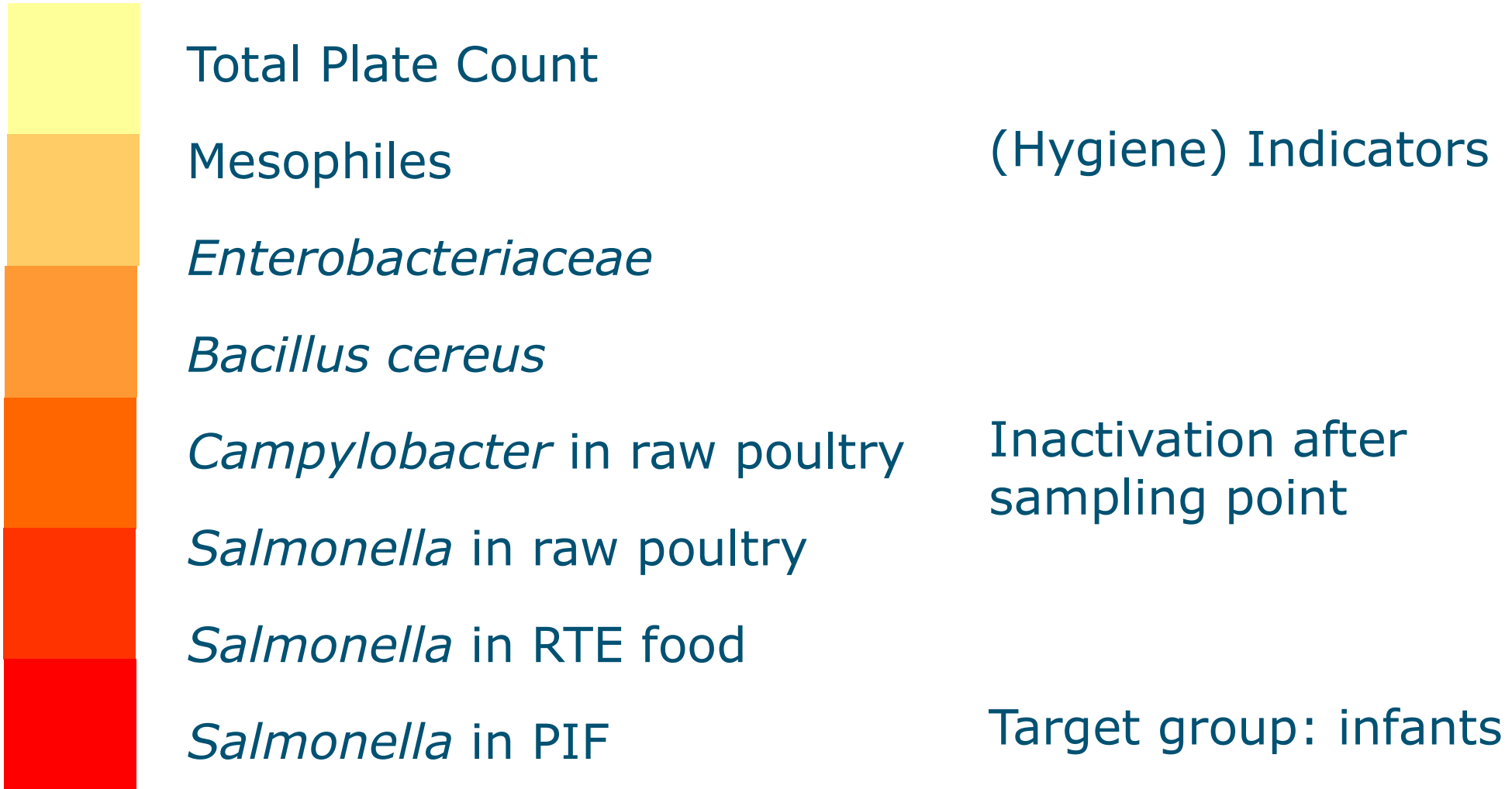
indicators / hygiene indicators

toxigenic organisms / infective organisms

target group: general population, infants, medicinal food

potential after sampling point (inactivation, stable, growth)

# 50 shades of red



RTE= Ready to Eat    PIF = Powdered Infant Formula

# ICMSF Table of 15 cases



	Likely change before consumption		
Category	Reduce	No Change	Increase
Utility	Case 1: $n=5, c=3$	Case 2: $n=5, c=2$	Case 3: $n=5, c=1$
Indicator	Case 4: $n=5, c=3$	Case 5: $n=5, c=2$	Case 6: $n=5, c=1$
Moderate	Case 7: $n=5, c=2$	Case 8: $n=5, c=1$	Case 9: $n=10, c=1$
Serious	Case 10: $n=5, c=0$	Case 11: $n=10, c=0$	Case 12: $n=20, c=0$
Severe	Case 13: $n=15, c=0$	Case 14: $n=30, c=0$	Case 15: $n=60, c=0$

3 Class sampling plan

2 Class sampling plan

# Types of sampling plans

Qualitative  
2-class

Food Safety Criteria

Quantitative  
3-class

Process Hygiene Criteria

Qualitative: +/-: 0/25g

Quantitative:  $\leq 100$  cfu/g or  $>100$  cfu/g

2-class: +/- or  $x \leq 100$  cfu/g ;  $x > 100$  cfu/g

3-class:  $x < 500$  /g;  $500 < x \leq 5000$ ;  $x > 5000$ /g

# Types of sampling plans

Qual/Quant	Qual	Quant	Quant
Class	2	2	3
Example	<i>Salmonella</i> in PIF	<i>Listeria</i> in no growth RTE	Mesophiles in PIF

# Sampling plan: Food Safety Criterion

Food category: powdered infant formulae (PIF)

Microorganism	Sampling plan		Sample weight (g)	Analytical method
	$n$	$c$		
<i>Salmonella</i>	60	0	25	ISO 6579

CODEX Code of hygienic practice for powdered formulae for infants and young children CAC/RCP 66-2008

Qualitative, 2-class,  $c=0$

Is there one or more *Salmonella* (detected) in my 25 g

# Sampling plan: Process Hygiene Criterion

Food category: powdered infant formulae (PIF)

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Enterobacteriaceae</i>	10	2	0/10 g	-	ISO 21528-1/21528-2

CODEX Code of hygienic practice for powdered formulae for infants and young children CAC/RCP 66-2008

Qualitative, 2-class,  $c \neq 0$

Is there one or more enteros (detected) in my 10 g

## Sampling plan: Food Safety Criterion

Ready-to-eat foods, not supporting growth, from end of manufacture or port of entry, to the point of sale

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Listeria monocytogenes</i>	5	0	100 cfu/g	-	ISO 11290-2

CODEX Guidelines on the application of general principles of food hygiene to the control of *Listeria monocytogenes* in foods. CAC/GL 61 - 2007

Quantitative, 2-class,  $c=0$

>100 cfu/g of *Listeria* in my sample ?

# Sampling plan: Process Hygiene Criterion

## *Campylobacter* on broilers

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Campylobacter</i> spp.	50	10*	1000 cfu/g	-	ISO 10272-2

\* c-value increased stringency: 2018:  $c=20$ ; 2020:  $c=15$ ; 2025:  $c=10$   
EC regulation 2073/2005

Quantitative, 2-class,  $c \neq 0$   
are there  $>1000$  cfu/g of *Campylobacter* in my sample

# Sampling plan: Process Hygiene Criterion

Food category: powdered infant formulae (PIF)

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
Mesophiles	5	2	500/g	5000/g	ISO 4833

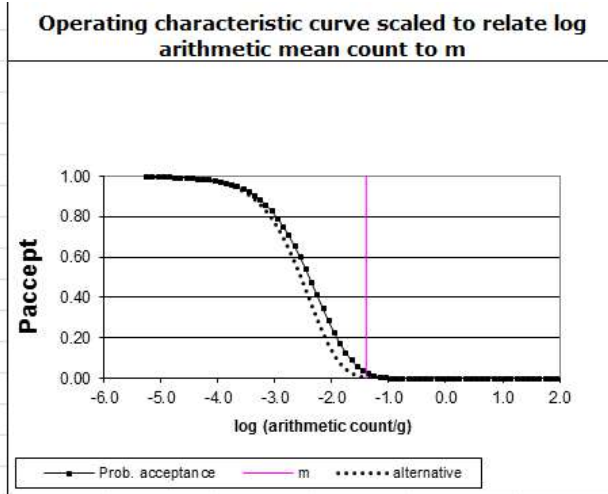
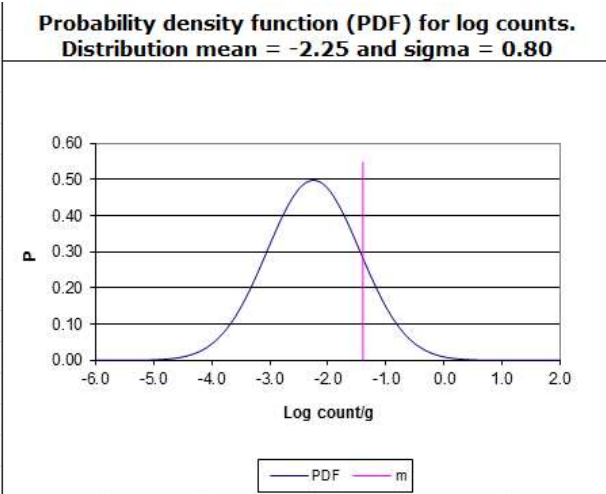
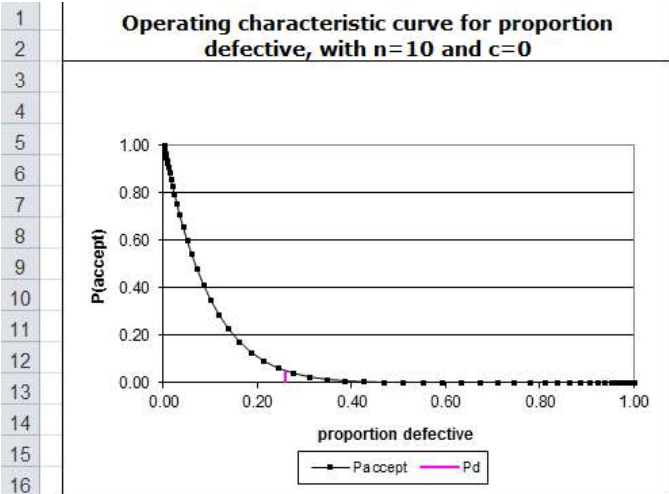
CODEX Code of hygienic practice for powdered formulae for infants and young children CAC/RCP 66-2008

## Sampling plan: Food Safety Criterion

Potential criterion for *Listeria monocytogenes* in RTE food\*

Micro-organism	Sampling plan		$m$	$M$	Analytical method
	$n$	$c$			
<i>Listeria monocytogenes</i>	5	1	0/25 g	100 cfu/g	ISO 11290-1 ISO 11290-2

3-class,  $c \neq 0$ , qualitative and a quantitative limit



Batch acceptance for Pd		
Pd	20 %	P(accept) 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)

## Three statistical phenomena are relevant:

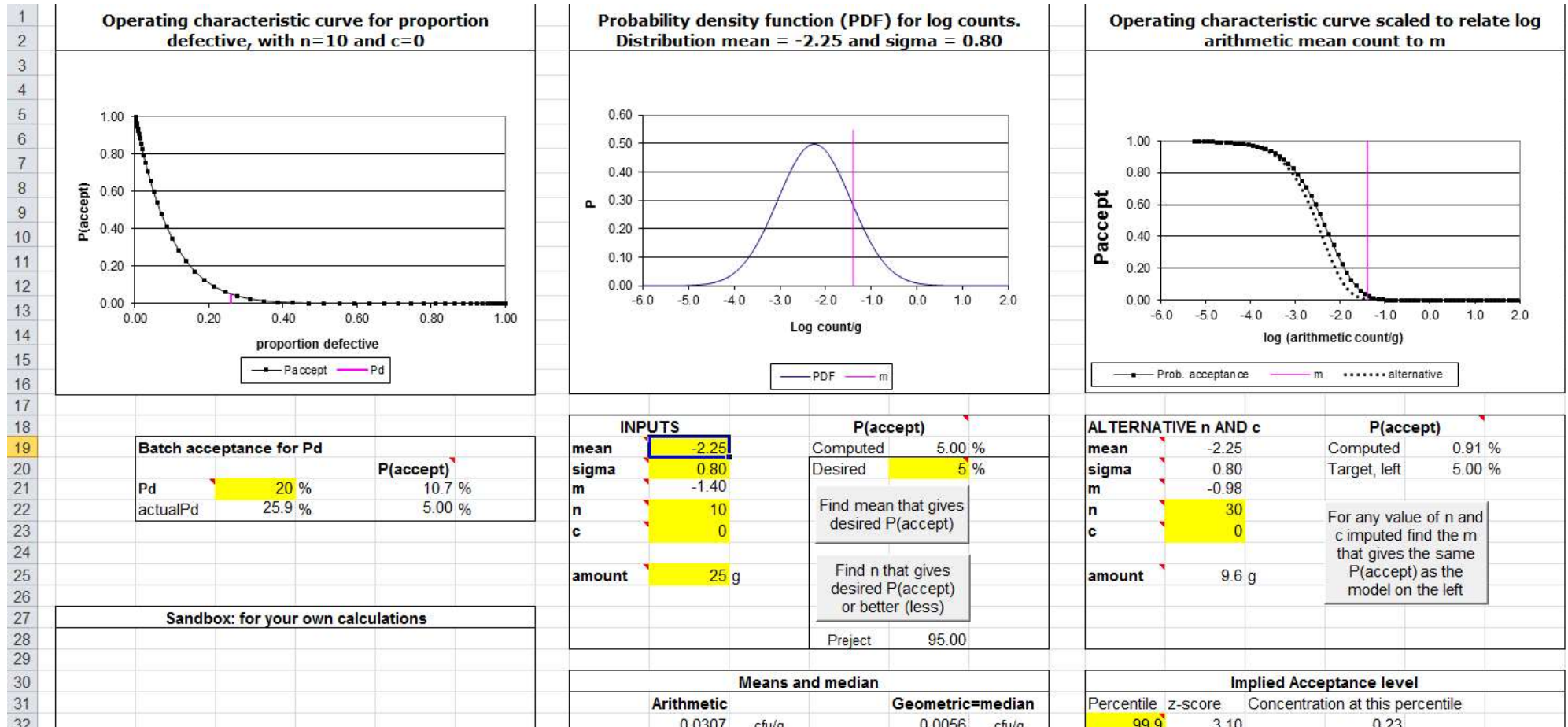
1. the actual spatial distribution of microorganism in the food batch
2. the statistical process of taking a sample unit and it being defective  $P_{defective}$
3. the acceptance of the plan based on  $n$  sample units, of which  $c$  are accepted to be positive and  $P_{defective}$

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 plan based on  $P_{defective}$ ,  $n$  sample units, and  $c$  is a binomial process

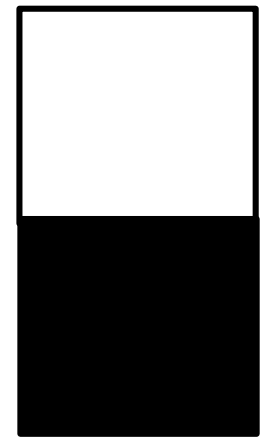
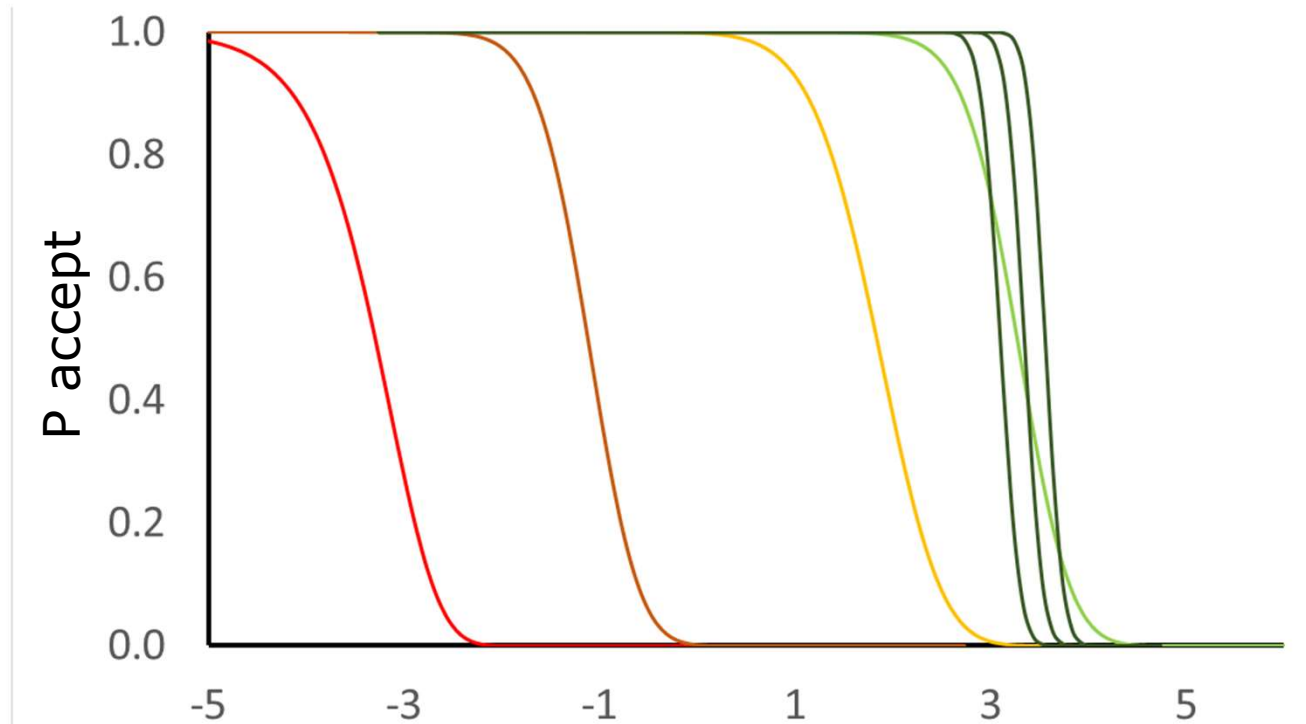
$P_{accept}$  is then a Binomial(Poisson(LogNormal)) distribution !

# <http://www.icmsf.org>



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 g giving detection of the organism)

# Performance (concentration detected with 95% P)



*Salmonella*

$n=60$   $c=0$  0/25g

cfu/g  
0.0027

*Enterobacteriaceae*

$n=10$   $c=2$  0/10g

0.34

*Listeria*

$n=5$   $c=0$   $m=100$  cfu/g

434

*Campylobacter*

$n=50$   $c=20$   $m=1000$  cfu/g

6155

Mesophiles

$n=5$   $c=2$   $m=500$  cfu/g  $M=5000$  cfu/g

8952

# If life would be easy: what sampling plan to use

- Safety / Hygiene / Spoilage ?
- Pathogen or indicator ?
- qualitative/quantitative ?
- 2-class/3-class ?

It depends .....



# If life would be easy: what sampling plan to use

- Safety / Hygiene / Spoilage
- Pathogen or indicator: both (safety and hygiene)
- qualitative: for very infective organisms
- quantitative: only higher levels result in disease
- 3-class: if certain prevalence or levels are acceptable



# Conclusions

- Many different sampling plans exist
- Sampling can have different objectives
- Safety / Hygiene / Spoilage
- Focus at different places (ingredients, environment, end product)
- Sampling is no control
- Information for producers / governments
- Different types (2/3-class; qual/quant)
- Combination especially within a FSM systems gives confidence

